POLICY ISSUE
NOTATION VOTE

April 24, 2001 SECY-01-0069

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STATUS OF POTASSIUM IODIDE ACTIVITIES

PURPOSE:

To provide to the Commission revised draft NUREG-1633 (Attachment 1), "Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action During Severe Reactor Accidents" for approval for public comment as directed in Staff Requirements - Affirmation Session, 10:15 A.M. Friday, December 22, 2000, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance) (Attachment 2). To provide information on the status of program development to implement KI funding for States. To provide the status of the revision to the Federal KI Policy.

BACKGROUND:

On December 22, 2000, the Commission approved a final rule amending 10 CFR 50.47(b)(10) to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a protective measure for the general public in the plume exposure pathway. The final rule was published in the *Federal Register* on January 19, 2001 (66 FR 5427) with an effective date of April 19, 2001. Staff Requirements Memorandum (SRM), dated December 22, 2000, states that the Commission will fund State stockpiles of KI and work with the Federal Emergency Management Agency (FEMA) for the effective implementation of the distribution of KI. The Commission directed the staff to recommend consideration by FEMA of revisions to the Federal Policy on KI and keep the Commission informed of FEMA's progress in producing the final draft. Additionally, the Commission directed that NUREG-1633 be revised pursuant to the Commission's decisions on KI and the final rule, and pursuant to Food and Drug Administration (FDA) draft revised guidance, and, when revised, be submitted to the Commission for approval prior to publication for a 60-day comment period.

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DISCUSSION:

There are three principal activities associated with implementing the Commission's decision on KI. They are (1) preparation of revised draft NUREG-1633, "Assessment of the Use of Potassium Iodide as a Supplemental Public Protective Action During a Severe Reactor Accident"; (2) development and implementation of a KI tablet/funding program; and (3) publication of revised federal policy on the use of KI. The status of each of these activities is discussed below.

1. NUREG-1633 "Assessment of the Use of Potassium Iodide as a Supplemental Public Protective Action During a Severe Reactor Accident"

In SRM, COMSECY-98-016, issued on September 30, 1998, the Commission directed the staff to withdraw the existing draft version of NUREG-1633, and to reissue a substantially revised document taking public comments into account and making the following changes:

> "The reissued document should include an improved discussion of how the practical problems in KI stockpiling, distribution, and use are handled in States which already use KI as a supplement and in the numerous nations which use KI as a supplement. A discussion, in some detail, of the various guidance documents of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA), as well as the U.S. Food and Drug Administration (FDA), would be very useful to state and local decision makers. The guidance document should be consistent with the policy adopted by the Commission in response to the petition for rulemaking and should fairly discuss the factors that need to be weighed in the state and local decisions. The revised document should be submitted to the Commission as a SECY information paper."

The revised draft NUREG forwarded with this paper for Commission approval to be published for public comment, presents information that State and local decision makers could use to (1) decide whether KI should be incorporated into their current offsite emergency response plans; and (2) determine the best method to distribute KI to members of the public living within the 10-mile emergency planning zone (EPZ) of nuclear power plants. To this end, the staff considered the public comments and the comments of the 'KI Core Group', as well as the direction provided in COMSECY-98-016 and SRM dated December 22, 2000, in preparing the revised draft NUREG-1633. The revised draft discusses various aspects of the use of KI during nuclear power plant emergencies. The revised draft also contains direct input from those States that have KI as a supplemental protective action (Alabama, Tennessee, Arizona and New Hampshire). These States detailed the experiences they have had in the implementation as well as KI distribution phases of their programs. The international community also provided input on the programs that they have in place.

The revised draft FDA guidance is also included in its entirety as a chapter within revised NUREG-1633. The comment period on the draft FDA guidance ends on April 27, 2001. Revised NUREG-1633 relies heavily upon findings as presented in the draft FDA guidance. Should the

FDA guidance change as a result of the public comments received, then the appropriate changes would also be made in NUREG-1633. The WHO recommendations are included in an appendix to provide an international perspective on the use of KI. The IAEA guidance document has not been published in final form and therefore was not included in the NUREG.

2. Development and Implementation of a KI program

The NRC/FEMA Steering Committee co-chairs met on January 29, 2001 to discuss the expectations of the Commission on the implementation of a KI program as outlined in SRM dated December 22, 2000. At this meeting, it was determined that a KI subcommittee would be appointed, under the auspices of the NRC/FEMA Steering Committee, with staff from NRC and FEMA participating. Office of Nuclear Reactor Regulation (NRR) staff met with the Office of the General Counsel (OGC) on February 14, 2001 to request that an appropriately worded disclaimer, per the SRM and the Statements of Consideration (SOC) Issue H, be developed. OGC has drafted a proposed disclaimer which is attached (Attachment 3). FEMA will use a similar disclaimer.

A teleconference with the KI subcommittee was held on February 16, 2001, to discuss the SRM, proposed federal policy on KI, as well as the final rule SOC. The subcommittee met on February 27, 2001 to develop a charter and task list and discuss an implementation plan (Attachment 4). The charter and task list were presented to the NRC/FEMA Steering Committee at their March 1, 2001, meeting for approval. As an action item from the Steering Committee, the subcommittee met on March 14, and drafted a letter (Attachment 5) that was sent from both agencies steering committee co-chairs, to inform their regional offices about the rulemaking and program development.

NRC/FEMA staff roles and responsibilities for the KI program and a milestone schedule for program implementation are under development by the KI subcommittee and will be finalized pending the completion of FEMA staff's brief of their new Director. The subcommittee has developed three proposed application processes as well as three distribution options. These options are provided for information and are discussed below. The subcommittee decided that, while local governments may be designated by the States to request KI, all requests for KI should come through the appropriate State or Tribal government. An application form detailing the State's request for KI will be developed. The options are presented in the current order of preference of the KI subcommittee. The options detailing the application process assume NRC management of funds.

A. Application Process

Option 1. States apply to designated NRC HQ office. The requests are date-stamped and forwarded to FEMA HQ. FEMA HQ would then forward the application to the appropriate FEMA region for review and approval. The approved applications will then be forwarded, via FEMA HQ, to the NRC for release of KI tablets or funds. This process is similar to the process by which NRC and FEMA interact to coordinate the resolution of off-site Emergency Preparedness (EP) issues, such as allegations.

Option 2. States apply to FEMA HQ office. The requests are date-stamped and forwarded to FEMA region for review and approval. The approved forms would be forwarded from FEMA HQ to NRC for release of KI tablets or funds.

Option 3. States apply directly to FEMA regional offices for review and approval. The approved applications are then forwarded to FEMA HQ and in turn to NRC for release of KI tablets or funds.

B. Distribution Process

Option 1. NRC would purchase KI tablets in bulk and arrange direct shipment of KI tablets to States after approval of application by appropriate FEMA office. This option is preferred by the KI subcommittee because it enables bulk purchase of tablets for the lowest cost and ensures that the appropriated funding will be used only for the purchase of KI tablets. This option places minimal burden on FEMA and maintains NRC control of the program and expenditure of funds. The FDA guidance must be final prior to a statement of work and contract for bulk purchase of KI tablets to insure that the correct dosages and numbers of tablets are purchased.

Option 2. NRC would transfer funds to FEMA. FEMA would distribute either funds or tablets to the States after approval of the State's application. The program implementation for KI use in offsite EP would rest with FEMA, who is primarily responsible for offsite EP per NRC/FEMA Memorandum of Understanding. However, this option would reduce NRC control over the actual spending of the limited funds available for KI as well as increase the burden on FEMA.

Option 3. NRC would transfer funds directly to States for purchase of KI tablets by the States after completing the approval process. This may be the quickest option to get funding to the States. The disadvantages of this option are: 1) smaller orders for KI may result in higher costs for tablets; and 2) more NRC staff effort would be required to ensure that funds are used only for KI tablets and not funding of any State program costs.

These options will be presented to the NRC/FEMA Steering Committee for their consideration and recommendations.

The staff is developing a KI website to keep interested parties informed of the program development and subsequent implementation (Attachment 6). This will be updated regularly as the program development and implementation moves forward.

The staff met with the Office of Administration (ADM) contract specialist on March 9, 2001, to discuss various purchase options for KI, including bulk purchase of KI tablets, with direct shipment to the requesting states. The staff will continue to work with ADM to evaluate cost-effective options for purchase of KI tablets.

The staff has briefed the Office of Public Affairs (OPA) and the staff is working with OPA on answers to likely questions from the interested parties about the rulemaking, KI, and the implementation program. The Office of State and Tribal Programs (STP) was briefed during their regional counterpart meeting with State Liaison Officers. Representatives of NRR attended and made a presentation on KI, as well as participated in a panel on KI with FEMA and FDA, at the National Radiological Emergency Preparedness Conference held in Nashville, TN on April 2-5, 2001. Additionally, the staff regularly provides updates for the Chairman's Tasking Memorandum milestone schedule.

The next meeting of the KI subcommittee is scheduled for April 18, 2001 to continue development and implementation of the KI program. The NRC/FEMA Steering Committee will be briefed and provided the application and distribution options and the milestone schedule for their consideration and recommendations at their next meeting in June 2001.

3. Draft Federal KI Policy

The staff presented the Commission's recommended revision of the KI Federal Policy to the Federal Radiological Preparedness Coordinating Committee (FRPCC) for review and comment on January 17, 2001. FRPCC member agencies were requested to review the draft and provide comments to FEMA by February 16, 2001. As of the due date, FEMA had received comments from only two agencies. The staff participated in an FRPCC retreat held on March 7-8, 2001. At this retreat, the NRC staff requested a commitment from the FRPCC on timely approval of the Federal KI Policy. The FRPCC Chair committed to conduct a vote on approval of the draft Federal KI Policy at the next FRPCC meeting scheduled for May 8, 2001. However, the policy is still under review by FEMA. When FEMA sends its formal comments to the NRC, the staff will forward them to the Commission for its review and approval. FEMA has recognized that a special meeting of the FRPCC may need to be convened if the May 8 vote cannot be realized due to a delay in forwarding the comments to the NRC.

CONCLUSION:

The staff has followed the Commission's direction provided in COMSECY-98-016 and SRM dated December 22, 2000, in preparing the revised draft NUREG-1633 forwarded with this paper for Commission approval for publication for public comment. The issuance of NUREG-1633 as a

final document and the implementation of the KI program is dependent upon the issuance of FDA's final guidance on the use of KI. The comment period on the draft FDA

guidance was extended from February 4, 2001 until April 27, 2001. It is unknown at this time, when the final guidance will be issued. The FDA's final guidance may impact draft NUREG-1633, which would need to be revised prior to publication, to accommodate any FDA guidance changes. The staff intends to develop a program structure to enable timely implementation of the program when the final FDA guidance is released.

RECOMMENDATION:

That the Commission approve the staff recommendation to publish draft NUREG-1633 for a 60-day public comment period.

COORDINATION:

The Office of the General Counsel has reviewed this paper, as well as draft NUREG-1633, and has no legal objection.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. NUREG-1633, Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action During Severe Reactor Accidents
2. Staff Requirements Memorandum, dated December 22, 2000, M001222
3. Draft Disclaimer
4. NRC/FEMA KI Subcommittee charter and task list
5. NRC and FEMA letters to Regional Directors on KI rulemaking
6. KI Website

NUREG-1633

Assessment of the Use of Potassium Iodide (KI) As a Supplemental Public Protective Action During Severe Reactor Accidents

April 11, 2001

(DRAFT FOR COMMENT)

Prepared by:
P.A. Milligan/NRR

ABSTRACT

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

CONTENTS

APPENDICES

ABBREVIATIONS

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

WHO	World Health Organization

PREFACE

This document presents information to assist State officials in determining whether the prophylactic use of KI for their population is appropriate in the unlikely event that a severe reactor accident occurs within their state. The Commission finds that the use of KI is a reasonable, prudent, and an inexpensive supplement to evacuation and sheltering. The Commission also finds that KI would help prevent thryoid cancers in the unlikely event of a major release of radioactive iodine. Therefore, the Commission has amended its emergency planning regulations to require that off-site authorities consider KI as a protective measure for the general public that would supplement evacuation and sheltering.

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

EXECUTIVE SUMMARY

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

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

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

This guidance document discusses the various factors that need to be weighed in State and local decisions on the use of KI. This document presents information from which State and local officials can draw conclusions pertinent to their specific conditions related to the use of KI by the general public. This guidance begins with a brief discussion of the basis for emergency planning, reactor accidents and associated consequences, and an overview of severe reactor accident source terms. Next, thyroid and whole body doses, their associated risk assessments, and their relationship to severe reactor accident source terms are discussed. This guidance document contains a discussion of how the practical problems in KI stockpiling, distribution, and

use are handled in the States which already use KI as a supplement and in the several nations which use KI as a supplement. The staff has also included guidance documents of the World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA), which should be useful to State decision makers.

ACKNOWLEDGMENTS

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

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

The following NRC staff is thanked for their assistance: Robert Bores, RGN-1; Frank Congel, IRO; Kathy Halvey Gibson, NRR; Vincent Holahan, RES; Mike Jamgochian, NRR; Falk Kantor, NRR; Steve LaVie, NRR; Stephen McGuire, IRO; Aby Mohseni, NMSS; Marjorie Rothschild, OGC; and Glenn Tracy, NRR.

CHAPTER 1
BASIS FOR EMERGENCY PLANNING

1.1 Introduction

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

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

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

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

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

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

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

1.2 Accident Classification and Source Term History

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

1.2.1 Design-Basis Accidents

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

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

1.2.2 Severe Accidents

Accidents that are considered to be so low in probability as not to require specific additional provisions in the design of a reactor facility are known as severe accidents accompanied by core melt. Such accidents would involve sequences of successive failures more severe than

those postulated for the purpose of establishing the design basis for protective systems and engineered safety features. The consequences of severe accidents are those leading to a gross fuel clad failure or partial melt with independent failures of the containment boundary and total core melt and consequent degradation of the containment boundary.

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

1.3 Reactor Accidents and Source Terms

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

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

1.3.1 The Accident at Three Mile Island

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

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

The TMI accident did not cause deaths, injuries or over-exposures to radiation**.** The maximum dose to a member of the public was about 0.85 mSv (85 mrem), the equivalent of the dose the average person receives from natural sources every 3 months. The TMI accident had a major impact on the US nuclear power program, including a major increase in regulatory requirements. TMI also showed the need for improved emergency preparedness, both on-site as well as off-site. Additionally, this accident also cast serious doubt on the emphasis that had been placed on the importance of the radioiodines in a U.S. nuclear accident. At TMI-2, a major core melt occurred, millions of curies of noble gases were released to the environment but the iodine release was limited to approximately 15 curies. These doubts led to the development of a revised source term.

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

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

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

- the choice of moderators is different, in the U.S., water is used, whereas the Chernobyl type reactors (RBMK-1000) use graphite;
- because of the core characteristics, the RMBK is less stable and more difficult to control, unlike U.S. designs, and power excursions present a greater risk;
- a graphite moderator, unlike water, is flammable;
- "defense-in-depth" barriers provided to ensure that nuclear fuel and fission products cannot escape from the core. Both the RMBK-1000 and U.S. LWRs use uranium oxide (UO_2) fuel pellets surrounded by zirconium cladding, however,

the RMBK-1000 reactors use more than 1600 individual pressure tubes to contain the fuel elements and the light-water coolant that flows past these elements. The pressure tube walls are about 4 mm (0.16 in) thick, whereas, the U.S. LWRs use a pressure vessel with walls that are about 187 mm (7.5 in) thick, (NUREG-1250);

- "full containment" concept (NUREG-1250).

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

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

1.4 Meteorology

The atmospheric release of radioactive material is the most significant release mode for off-site consequences. Therefore, meteorology is important because it determines: (1) where the offsite release (also known as the plume) goes, and (2) the concentration of the radionuclides to which the public is exposed at some point downwind. Meteorological information includes wind speed, wind direction, wind persistence, wind variability, and vertical dispersion. These factors describe the stability of the atmosphere or how fast and far radionuclides are transported in air. Atmospheric stability is very important in determining how the radioactive effluents will be dispersed. Atmospheric stability is described by Pasquill-Gifford stability classes. This model breaks down stability into six classes, ranging from very unstable (A) to very stable (F). Under very stable atmospheric conditions, there is not much dispersion of the plume and the radionuclide concentration in the air, or plume, is much greater than under very unstable atmospheric conditions. Stable conditions (unfavorable meteorology[2]) are usually chosen when performing DBA calculations. Most often, the prevailing meteorological conditions are not the conditions under which the DBA analysis are performed. In other words, the more unfavorable conditions chosen for the DBA analysis are not typically the predominant meteorological conditions.

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

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

1.5 Dose and Health Effects

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

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

The possible adverse health effects from exposure to radiation are categorized as either "stochastic" or "non-stochastic." Stochastic effects are those effects for which the probability of the effect directly relates to dose, while non-stochastic effects are those for which the magnitude of the effect directly relates to dose.

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

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

effects require relatively large doses, and emergency response programs are designed to move people away from the source of radiation before they receive such large doses.

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

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

1.6 Reactor Accident Exposure Pathways

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

The thyroid can also be exposed internally from the intake of radioiodines by the consumption of contaminated milk or leafy vegetables, commonly known as the ingestion pathway. The milk pathway is particularly important because radioiodines deposited on pasture grass are effectively transferred to the milk of grazing animals (particularly, cows, goats, and reindeer). It

takes a day or two before the radioiodines first appear in milk. To reduce any internal exposure from the ingestion pathway, including thyroid exposure, officials should recommend that dairy animals be given stored feed and/or recommend the interdiction of local milk supplies and leafy vegetables within 80 km (50 miles) (FDA 1982). This distance can be altered when actual plume pathways are established.

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

CHAPTER 2.
BASIS FOR IODINE PROPHYLAXIS

2.1 Physiology of the Thyroid Gland

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

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

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

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

Subsequently, when stable iodine was added to most table salt (about half of a teaspoonful of salt provides the minimum daily requirement of 150 μg of iodine), colloid goiter essentially disappeared from the U.S. In recent decades, stable iodine has also become an important additive to bread and fast foods. It is estimated that the average American takes in over 600 micrograms of stable iodine daily (Combs 1998). The fast food diet in the United States contributes approximately 30 times the minimum daily requirement of iodine. As a result, thyroid glands in the United States are already partially saturated (Brucer 1990). The primary significance of dietary iodide levels is that for a common exposure to radioiodide (inhalation or ingestion), individuals with a lower dietary intake of stable iodide will have a higher thyroid uptake of radioiodide, resulting in a proportionately higher thyroid exposure. Daily intake levels of stable iodide may also influence adverse reactions to stable iodide when administered in doses that greatly exceed dietary levels. However, daily dietary intake of iodine is not a factor in the consideration of the use of iodine prophylaxis.

2.2 Thyroid Pathologies

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

2.2.1 Hormonal Imbalance

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

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

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

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

2.2.2 Thyroid Enlargement

A thyroid goiter is a substantial enlargement of the thyroid gland. The thyroid can become very large so that it can easily be seen as a mass in the neck. There are a number of factors that may cause the thyroid to become enlarged. A diet deficient in iodine can cause a goiter, but this is rarely the cause in the United States because iodine is readily available in the diets of Americans. Typically, in America a goiter is caused by an increase in thyroid-stimulating hormone (TSH) in response to a defect in normal hormone synthesis within the thyroid gland. Most small to moderate-sized goiters can be treated by prescribing thyroid hormone in the form of a pill. By supplying thyroid hormone in this manner, the pituitary will make less TSH which should result in stabilization in size of the gland. This technique often will not cause the size of the goiter to decrease but will usually keep it from growing any larger.

2.2.3 Thyroid Nodules

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

2.2.4 Thyroid Cancer

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

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

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

2.3 Radiation Induced Thyroid Diseases

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

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

Follicular thyroid cancers (about 10% of the radiation induced thyroid cancers) tend to metastasize early by way of the blood stream to lung and bones. The tumors are TSH responsive and tend to pick up and metabolize iodide and to form the thyroid hormone. They

are not a common type of thyroid cancer. This type of cancer has a lower survival rate than papillary carcinomas, typically a 10-year survival rate of 50 percent (ACS).

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

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

2.3.1. Chernobyl

The accident at Chernobyl has produced more recent data on the effects of I-131 on the thyroid. In Belarus, Russia and the Ukraine, about 4 years after the accident, there was an increase in the number of detectable thyroid cancers and abnormalities. This increase, which is seen both close to the plant and in areas more than 240 km (150 miles) from the site, continues to this day (OECD 1995) and primarily affects children who were 0-14 years old at the time of the accident. The incidence of thyroid cancer in children born after the accident drops to the levels found before the accident. Moreover, most of the cases are concentrated in areas thought to have been contaminated by radioiodine as a result of the accident. In some areas, direct thyroid measurements as well as survey data indicate that the dose from ingestion, with the largest contribution to the thyroid dose from consumption of fresh cows' milk, was responsible for most of the thyroid dose (UNSCEAR 2000, FDA 2000). There are considerable uncertainties in the estimates of individual thyroid doses, primarily due to the lack of thyroid measurements and survey data (UNSCEAR 2000). However it is thought that many of the children that have developed thyroid cancer were exposed to an estimated dose as low as 50 to 100 mGy (5 rem to 10 rem), (although the authors of this study are self-critical of the methodology to determine the estimated doses) (Astakhova 1998, UNSCEAR 2000).

While several studies (WHO 1999, FDA 2000) have suggested a strong relationship between the increases of thyroid cancers and releases from the Chernobyl accident, UNSCEAR 2000 reports that, "other factors that might influence radiation risks have been identified. Many of the regions around Chernobyl are iodine-deficient and iodide dietary supplementation had been terminated before the accident. Although large amounts of stable iodine were distributed to the population living near the plant as prophylaxis shortly after the accident, the distribution was incomplete and is thought not to have been effective. Genetic susceptibility to radiation-associated thyroid cancer also has been suggested as a potential modifier of risk. Finally, other potential environmental contaminants need to be investigated." (UNSCEAR 2000)

However, with the Chernobyl plant located close to the border of Belarus, it is known that this region was heavily impacted by the accident. This impact was heightened by the fact that protective actions were not implemented in Belarus during the first 6 days after the accident.

Belarus residents continued their normal activities; there was no sheltering, evacuation, or food interdiction. Several authors have stated that KI was distributed to the population in Belarus during the first week following the accident. However, there is no confirmed published data on the dosage, coverage, or other details concerning the implementation of the thyroid blocking in Belarus. There were no restrictions implemented by the authorities blocking the consumption of contaminated milk or food for the first 10 days following the accident.

Since 1990, a rapid increase has been observed in the incidence of thyroid cancer among Belarus children who were 0 - 14 years old at the time of the accident. Before the accident, the rate of thyroid cancer among this group was about 0.3 per 1 million; by 1994, this rate was reported to have risen to 30.6 per 1 million (OECD 1995). The total number of excess cancers among this group is currently about 750, and is estimated to reach a maximum of more than 3500 over the lifetime of this group (OECD 1995). The majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site. The increase in the rate of thyroid cancers in Belarus is concentrated among those who were youngest at the time of the accident. To date, three of the Belarus children diagnosed with thyroid cancer have died as a result of that disease (OECD 1995).

2.3.2 Poland and the Chernobyl Accident

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

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

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

- Feeding of cows on pastures or with fresh fodder was banned countrywide until May 15, 1986.
- Fresh milk with radioactivity above 1,000 Bq/L was banned for consumption by children and pregnant or lactating women.
- All children under the age of 4 were given powdered milk through numerous distribution centers.
- Children and pregnant or lactating women were advised to eat a minimum of fresh leafy vegetables (until May 16, 1986).

The distribution of KI was initiated on April 29 and was completed by May 2. This included the distribution of KI to more than 90 percent of the children under the age of 16 and about a quarter of the adults. A total of 10.5 million doses of KI were given to children and 7 million

doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases. In addition, about 6 percent of the prophylaxis resulted from self-administered tincture of iodine before the KI program was initiated (Wolff 1995). Because of diminishing air contamination, the KI prophylaxis was not repeated. In the second phase of the response, powdered milk was made available to all children less than 4 years of age.

It is estimated that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions. (OECD Stockholm Workshop). Due to the relatively low iodine concentrations in Poland, it is not likely that epidemiological studies could detect excess cancers resulting from intake of radioiodine (WHO 1995). However, the Polish experience supports the use of KI as safe and effective when administered to large populations.

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CHAPTER 3
POTASSIUM IODIDE AS A THYROID BLOCKING AGENT

3.1 What is KI?

KI is potassium iodide. It is a salt, similar to table salt and, in fact, KI is the ingredient that is routinely added to table salt to make it "iodized". KI will be taken up by the thyroid gland and, if taken in large enough quantities, will effectively saturate the thyroid gland. This saturation of the thyroid gland can prevent the uptake of radioactive iodine that may be released in the unlikely event of a severe nuclear reactor accident. KI offers additional protection for one radiation-sensitive organ, the thyroid, under conditions of inhalation or ingestion of radioactive iodine.

3.2 FDA Guidance

The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, "FDA concludes in the final recommendations that risk from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem". That notice also provides recommended dosages for adults and children. New FDA guidance was published in the Federal Register for public comment on January 4, 2001 (66 FR 801). In this draft guidance, the FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland under certain specified conditions for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency where there is a release of radioactive iodine. The new FDA guidance is presented in this chapter in its entirety.

CHAPTER 4
EMERGENCY PREPAREDNESS AND THE ROLE OF KI

4.1 Emergency Preparedness and Nuclear Power Plants

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

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

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

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

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

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

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

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

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

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

4.2 Consideration of the Use of KI

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

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

4.3 Funding of KI

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

The Commission intends to fund initial supplies for one to two doses per individual for those within the 10-mile EPZ provided in NRC and FEMA regulations. The Commission also only intends to fund purchases consistent with the anticipated revision of the FDA recommendations on KI doses. The funding available for KI is not intended to fund any ancillary costs, including costs associated with storing stockpiles or distributing KI in the event of an emergency. States are encouraged to begin their process for considering KI as early as possible, recognizing that the NRC's resources for this purpose are limited.

4.4 The Role of Evacuation and Sheltering in Emergency Preparedness

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

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

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

4.5 The Role of KI in Emergency Preparedness

The Commission has found that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The use of KI for public protection is a special kind of protective measure in that it offers very specialized protection. KI can provide protection against internal doses to the thyroid from radioiodines. Depending on the specific circumstances around an NPP and the type of accident, a State may find the availability of KI to be an added benefit.

The Food and Drug Administration (FDA) has approved the use of KI as a radioprotective drug for use during radiological emergencies. KI, when taken in a timely manner, can significantly reduce thyroid exposure from an intake of radioiodines and is, therefore, an effective prophylactic. KI is readily available and does not require a prescription for purchase. The FDA has determined that KI is safe and effective for short-term use if administered in proper dosage with proper medical advice to those patients who are not also taking certain medications, have an allergy to iodine or do not have certain medical conditions. The FDA guidance concludes that the studies following the Chernobyl accident supports the causative role of relatively low doses of radioiodines in the increase in cancers found among children who were between the ages of 0 to 14 years of age at the time of the accident. The FDA further concludes that the Polish experience of widespread distribution of KI supports the use of KI as a safe and effective means by which to protect against thyroid cancer caused by inhalation of radioactive iodine or ingestion of foodstuffs contaminated with radioactive iodine when exposure cannot be prevented by evacuation, sheltering, or food and milk control. The use of KI will reduce the radiation exposure to the thyroid gland only from inhalation or ingestion of radioiodines. KI will not protect the thyroid gland from external exposures to radiation, nor will it protect the thyroid gland from exposure to any other inhaled or ingested radionuclides. For optimum benefit, KI should be administered just prior to, concurrent with or within 6 hours after the release. The FDA concluded that prevention of thyroid uptake of ingested radioiodines, once the plume has passed and radiation protection measures (including KI) are in place, is best accomplished by food control measures and not by repeated administration of KI.

Currently, KI is considered for administration to NPP plant workers and emergency workers. Thyroid blocking for emergency workers was recommended because (1) these individuals have more emergency response responsibility that may not permit them to evacuate, (2) the number of individuals involved at any site is relatively small and requires a limited supply of KI that can be readily distributed, (3) the storage, distribution, and administration of KI can be readily controlled, (4) the known sensitivity to iodide of this limited number of individuals can be reviewed, and (5) these individuals can be readily monitored for adverse side effects by medical personnel. In certain situations, KI may also be appropriate for institutionalized individuals for similar reasons.

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

4.6 Distribution of KI

Once a State has decided to incorporate KI into its emergency plans, decisions regarding distribution of the tablets to the public need to be resolved. At least three States have added KI as a supplemental protective action for the general public. Their experiences in implementing KI as a supplemental protective action for the general public are presented in Chapter 5. Chapter 6 details the international experiences with KI prophylaxis distribution.

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

The information in this appendix is reflected as submitted by the respective States. These States have either implemented a KI program, are in the process of implementation, or are considering whether to add KI to their emergency planning. Each State submitted a description of its KI program as well as discussion reflecting the State's experiences with the public and the distribution of KI, as well as any lessons learned.

5.1. Tennessee

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

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

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

KI was distributed in the same manner in 1988 and 1992. In 1993 distribution was extended to include the 0 to 5 mile area around Watts Bar in anticipation of that plant coming on line. The only difference in the 1993 distribution was that in some offices, clerks were allowed to distribute the KI after they had received training. Distribution was repeated around both plants in 1996. By this time, the response to the distribution of KI around Sequoyah had dropped to such a small percentage of the population that the decision was made to discontinue the

extensive media campaign. One local press release was sent out only in the Sequoyah area. Notification of the public that the KI was available to be picked up, was made through the information calendar that is distributed to all residents within 16 km (10 miles) of either plant each year. Fewer than 15 percent of the population responded to this offer within 8 km (5 miles) of the two plants. One county had no one come by to get the drug.

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

5.2 Alabama

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

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

The climate in Alabama is such that the roadways are seldom impassable due to weather conditions, nor is serious traffic congestion anticipated near either of the nuclear power plants in Alabama. Provisions would be made for distributing KI to evacuees when they arrive at the reception centers if exposure to radioiodine received before or during the evacuation corresponded to a child's thyroid dose in excess of 0.1 Gy (10 rad). The drug would be ordered for arriving evacuees according to evacuation sectors. The evacuees would be issued "informed consent" forms and upon signature, evacuees would be given a 3-day supply of KI tablets for each member of the family.

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

- KI was packed only in bottles containing 14 tablets. Therefore, each member of the family would not have an individual supply.
- Potassium iodide has a 3-year expiration date and must be replaced.

- Administration of KI is not appropriate if radioactive iodines are not being released. Some persons may take the KI and assume that they are "safe" when, in fact, they should be evacuated.

- It is possible that many families would misplace or lose their KI before they needed it.

- There was no way to have advanced distribution of the medication to such groups as transients and other visitors.

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

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

If needed, additional KI for evacuees from the Farley EPZ would be brought in from elsewhere in the State. At Farley, on the Alabama side of the river, there are 34 people who live within the 3.2-km (2-mile) EPZ, 2200 people in the 3.2-km to 8-km (2-mile to 5-mile) EPZ, and 8,431 people in the 8-km to 16-km (5-mile to 10-mile) EPZ for a total of 10,665 people within the 16km (10 mile) EPZ. The evacuation times are 45 minutes for the 3.2-km (2-mile) EPZ, 2 hours for the 3.2-km to 8-km (2-mile to 5-mile) EPZ, and 6 hours for the 8-km to 16-km (5-mile to 10-mile) EPZ.

The intervention level for the health order to make KI available to emergency workers and evacuees in Alabama is a projected dose of 0.25 Sv (25 rem) to the thyroid. The dose to the thyroid would be calculated by using RASCAL or MIDAS computer programs.

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

Since Alabama has chosen to store KI at selected local health departments until such time as it might be needed at pre-determined distribution centers, there are no identifiable costs associated with public education, staffing/training, management, follow-up, maintenance, and distribution. Any costs involved with these areas of interest would be covered as part of the standard REP training. The drug is stored under the control of the nursing director in the affected local health departments.

5.3. Arizona

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

Evacuation is the preferred protective action. In the event a member of the public could not evacuate in time to avoid inhaling of radioactive iodine, the State has enough KI available to give to the public on an *ad hoc* basis. For a limited number of individuals, this can be done within 3 to 6 hours of exposure. The available supply of KI is sufficient to meet the needs of approximately 4,000 people.

5.4. Pennsylvania

The Radiological Preparedness Advisory Committee (REPAC) of the Pennsylvania State Emergency Management Council formed a working group comprised of representatives from the medical, health physics, public health, emergency response, and emergency management communities. The charter of the work group is to make recommendations about to whether or not KI should be used in conjunction with a nuclear power plant accident. If the group affirms the use of KI, it would then recommend the populations, the dosage, the precautions of KI usage. In addition, the group would also make recommendations about how the distribution would be made, including procurement, distribution methods, warehousing, replacement, and redundant supply.

The working group has completed a draft report and is about to publish it for review and comment. In addition, the work group will sponsor three public informational meetings for those individuals and groups who wish to provide comment in person. The work group anticipates completing the review of the written and oral comments, revising the draft report, as appropriate and providing a final report to the REPAC in the second half of 2001.

5.5. New Hampshire

The New Hampshire KI Policy Study Group implemented the following:

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

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

- The State of New Hampshire obtained an agreement with manufacturers of KI to make it available for over-the-counter purchase by members of the public. The

State encouraged retail pharmaceutical outlets in New Hampshire to maintain supplies of KI for purchase by members of the public.

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

The policy recommended by the New Hampshire study group recognized that attempting to distribute KI to the public would be an inappropriate and ineffective use of State and municipal emergency response resources. In the event of a radiological emergency, those resources would be required to implement the primary, preferred and most effective protective action which is evacuation of the public at risk. To the extent, and under the narrow set of circumstances for which KI may be used effectively, KI should be available to any person who would benefit from its use.

New Hampshire's current policy is to provide KI for emergency workers and people in institutions. The New Hampshire study group finds that this current policy has a sound basis.

The following issues were involved in implementing the recommended New Hampshire KI policy:

- Obtaining a written commitment from KI manufacturers to make KI easily available for over-the-counter purchase (Carter-Wallace Laboratories, Inc. of Cranberry, New Jersey and Anbex Inc. of Palmdale, Florida). Obtaining agreements from local pharmaceutical outlets to stock it for sale to the public.

- Encouraging appropriate groups to assist people who cannot afford to purchase KI on their own to acquire it if they decide they want it.

- Encouraging physicians to educate themselves on the radioprotective properties of KI so can advise their patients of its potential benefits or detriments for them and their families and on its proper use.

New Hampshire emergency preparedness officials will monitor developments at the Federal and international levels and in other States. The policy study group is particularly interested in KI policy developments in Massachusetts and Vermont with which New Hampshire shares EPZs. The group wants to ensure that actions taken by New Hampshire and its neighboring States do not cause confusion, and do not conflict with or disrupt each other's emergency response plans.

The New Hampshire KI Policy Group will be reconvened if necessary to review other issues that may be raised with respect to KI.

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

6.1 Canada

6.1.1 New Brunswick

Executive authorities in New Brunswick have no official KI policy, but public health officials have decided to distribute KI to the approximately 3,000 residents in a 20km (12.5-mile) zone surrounding the province's one nuclear plant. All area residents are currently listed in a demographic database that is updated annually. KI is distributed to residents as part of the door-to-door survey conducted every summer to update the database. This mechanism ensures that new residents have the chance to obtain KI within one year of moving to the area, and it also gives health officials the chance to replace expired stocks of KI tablets. Compliance with the survey is excellent. Only one resident has refused to participate to date.

Residents who receive KI are also given cards explaining its usage. However, the annual survey has discovered that only two-thirds of those who had received the KI could find it one year later. For this reason, in the event of a NPP accident, public health officials also plan to distribute KI at roadblocks set up on the way out of the evacuation zone.

New Brunswick officials see KI as a supplement to evacuation, and do not rely on sheltering. KI use is currently recommended at radiation doses to the thyroid of 0.5 Sv (50 rem) or above. This is likely to be revised downwards to 0.1 Sv (10 rem) in the future.

6.1.2 Ontario

The Province of Ontario has a policy that requires municipalities to make KI available to members of the public who may be exposed to plumes containing radioiodines. Local government, in particular the local medical officer for health, determine how this is best done. Currently, all affected local governments are relying on stockpiles that can be distributed at reception centers in the event of an emergency. KI has also been distributed to schools (parental permission slips are kept on file), hospitals, and nursing homes. No municipalities have distributed KI to residences.

Ontario Hydro is the licensee for nuclear power plants in the province. The 10-km (6.25-mile) EPZ surrounding the Pickering plant contains between 400,000 and 500,000 residents of the Toronto metropolitan area, and that surrounding the Darlington plant includes 100,000 residents. The third plant is in a less urbanized area, with approximately 20,000 residents in the EPZ. The EPZ for the Fermi- 2 plant in Michigan also crosses into Ontario, potentially affecting up to 10,000 people. Finally, there is a research reactor at the Chalk River site north of Ottawa. The EPZ for this site contains between 9,000 and 10,000 people, mostly Chalk River employees and their families.

KI stockpiles are kept at the three Ontario Hydro plants, and plant employees are responsible for bringing it to reception centers if the local medical officer of health determines that distribution is warranted. Distribution is called for at projected radiation doses to the thyroid of 0.10 Sv (10 rem) . Standard 130-mg tablets are available for adults; and the problems associated with dividing tablets for children and infants are currently under discussion.

The “polluter pays” principle is applied to KI in Ontario, so the power plants are responsible for paying for this program. The financial specifics are worked out in negotiations with the province. Availability of KI at reception centers is mentioned in the standard public information brochures distributed to EPZ residents.

6.2 United Kingdom (UK)

Offsite emergency plans for dealing with incidents involving the release of radioactive iodine include procedures for distributing KI tables. These plans were developed by the local health authorities on a site-specific basis. The requirements addressed the following important issue:

- The need for rapid distribution of KI tablets to people residing within the detailed emergency planning zone (DEPZ) (1-km to 3.5-km for NPPs or its equivalent), since the effectiveness of stable iodine for thyroid blocking depends on administration shortly before or as soon as possible after ingestion or inhalation to radioiodine.

The best means of distributing KI tables, including advance distribution where appropriate, bearing in mind local circumstances and possible accident scenarios pertaining to their respective areas, is left to the authority of local officials. The details of these arrangements depend on the local geography, demography and available manpower. The agreed-upon arrangements will be capable of immediate activation.

Advance distribution of KI is considered for (1) less accessible households or communities, and (2) evacuation reception centers, police stations, hospitals, pharmacies, schools and other strategic locations (so as to minimize delays in administration)

Site operators and consignors of mobile sources of radioactive iodine are responsible for providing and maintaining the bulk stocks of KI tablets. At reception centers and locations under their own control, health authorities and local authorities should take responsibility for storing and distributing the tablets.

Even in areas in which the prime planned countermeasure is evacuation coupled with KI tablets, plans contain procedures for distributing the tablets to a sheltering population if such a scenario is deemed plausible by the local offsite planning body.

When tablets are issued, they must be accompanied by guidance covering indications, contraindications, and dosage.

In the highly unlikely event that distribution of KI tablets might be indicated following an incident other than at a major nuclear site, or with effects extending beyond the DEPZ , plans address (in outline) how this might be accomplished so that arrangements can be quickly developed if the need arises.

6.3 Sweden

In 1982, the Swedish Parliament decided that stable iodine tablets should be distributed to all households within the 12-km to 15-km (7 to 10 miles) area around the four Swedish NPP sites. Approximately 50,000 households have received 20 tablets containing 65 mg KI. The distribution is repeated every 5 years through a mailing organized by the regional authorities. The mailing contains information on basic facts about radiation, the related risks, and what to do in case of a nuclear accident.

In addition to the already distributed tablets, there are two central storage sites, one in Malmo, close to the Barseback NPP and one in Stockholm. These two storage sites contain about 350,000 packages of 10 tablets each to be used if needed as a complement to the already distributed tablets in the vicinity of an accident.

The Swedish Radiation Protection Institute (SSI) is funded by the government to purchase the tablets. However, the nuclear power industry ultimately funds this program.

6.4 Germany

On the basis of the World Health Organization (WHO) recommendations made in 1989, German authorities decided to reduce the intervention level and adopt a new philosophy concerning thyroid-blocking in response to NPP accidents. This philosophy was implemented in the summer of 1998. According to this new philosophy, people over 45 years of age should not take iodine tables because the drug could cause a greater health risk than the radioactive iodine averted by KI.

In addition, Germany states that KI tablets should be stored in such a way that they can be easily distributed when needed. On the basis of accident analysis, the German government has proposed the following distribution strategy:

- Within a radius of 5 km (3 miles) of the plants, the tablets should be distributed in advance to households.

- Within a radius of 5 km to 10 km (3 miles to 6 miles) of the plants, the tablets should be stored at locations allowing distribution within 2 to 4 hours (e.g. town halls, schools, hospitals, factories, etc) or distributed in advance.

- Within a radius of 10 km to 25 km (6 to 15 miles) of the plants, the tablets should be stored in suitable buildings and distributed in advance only in exceptional cases, where people cannot be readily evacuated.

For areas beyond 25 km, iodine tablets will be stored at one or two central places for children up to 12 years of age and pregnant women. The tablets will be stored in such a way that they can be distributed within 12 hours after the decision is made to distribute KI. In addition, every inhabitant is able purchase iodine tablets in pharmacies without a prescription.

Packages distributed to homes will contain 10 tablets of 130-mg KI. Packages will have a clearly readable inscription and an instruction leaflet containing understandable information concerning thyroid blocking, as well as a warning concerning misuse and overdose.

6.5 Switzerland

Iodine prophylaxis tablets have been purchased for the entire population in Switzerland (10 tablets for each person, totaling 70 million tablets). The tablets are distributed as follows in the area surrounding the NPPs:

- Within EPZ 1 (about 5 km), the tablets are distributed in advance to households.
- Within EPZ 2 (about 20 km), the tablets are stored at the community offices, thereby allowing rapid distribution.
- The remainder of the tablets are stored at the state level.

In the event of an accident, the National Emergency Operation Center is responsible for making recommendations concerning protective actions. The plans call for the following provisions:

- At the Warning Level (similar to a US site area emergency) the communities activate their own KI distribution system.
- At the General Emergency Level (similar to a US General Emergency) the people within EPZ 1 are advised to go to the shelter and to take a first dose of KI; the people in EPZ 2 are advised to go to the community distribution center, where they will obtain the tablets and shelter.

There are special “fall out” shelters for virtually everyone in Switzerland.

6.6 Finland

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

- preventive evacuation within 5 km (before the release)
- elsewhere in Finland, sheltering (preferably inside one’s own home) and stable iodine to be taken as a prophylaxis

In principle, every person has iodine tablets available. In 1993, the Ministry of the Interior decided that all workplaces with 25 employees or more, schools, and similar organizations should have a reserve of iodine tablets (2 per person). In addition, block houses having 4 or more flats should have KI tablets available for all residents.

Within 5 km of a NPP, the plant has to distribute iodine tablets in advance to people staying in all permanent and vacation houses (independent of the number of households), as well as to all workplaces. All people living in single family houses outside the 5 km zone must buy tablets from pharmacies (freely sold and inexpensive). Many cities provide the tablets to all of their citizens without any cost.

In addition, all towns and municipalities have central storage locations for iodine tablets, and each is responsible for reserving tablets for 25 percent of the population staying in the area. Visitors and tourists will obtain their tablets from these central storage locations.

Instructions on the use of KI and dosage come with the tablets. Instructions were also mailed out in 1993, and are printed in telephone books.

6.7 France

The Prime Minister issued the following instructions in April 1997:

- Within the 5-km (3-mile) zone surrounding a NPP (or more depending on the local demographic and other conditions), iodine prophylaxis tablet stocks will be available at schools, day nurseries, hospitals, and other public buildings. The total number of affected persons is about 600,000.

- Within the 5-km to 10-km zone, stocks will be available for the local population. Tablets will not be predistributed but the local people can obtain the tablets in advance.

Within France, there are stocks (mainly in hospitals) of about 4 million additional tablets. In addition, anyone can get stable iodine tablets free of charge from a pharmacy without a prescription.

CHAPTER 7
CONCLUSION

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

The use of KI in Poland, during the Chernobyl accident, supports the use of KI as safe and effective when administered to large populations. Both the FDA as well as the WHO endorse the use of KI as a thyroid prophylaxis during severe reactor accidents involving the release of radioactive iodines. The FDA and the WHO further conclude that KI is a safe and effective means by which to block uptake of radioiodines by the thyroid gland in a radiation emergency under certain specified conditions of use (FDA 2000, WHO 1999).

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

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

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APPENDIX A
WORLD HEALTH ORGANIZATION RECOMMENDATIONS

APPENDIX B
THE FINAL RULE

APPENDIX C
GLOSSARY OF TERMS

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

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

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

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

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

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

Goiter: An enlargement of the thyroid gland.

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

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

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

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

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

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

IN RESPONSE, PLEASE
REFER TO: M001222

December 22, 2000

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /RA/

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 10:15 A.M., FRIDAY, DECEMBER 22, 2000, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)[1]

I. SECY-00-0037 - Status of Potassium Iodide Activities
- and -
SECY-00-0040 - Final Amendments to 10 CFR 50.47; Thereby Granting in Part Two Petitions for Rulemaking (50-63 and 50-63A); Relating to a Reevaluation of Policy on the use of Potassium Iodide (KI) for the General Public after a Severe Accident at a Nuclear Power Plant

The Commission approved a final rule amending 10 CFR 50.47 to grant one petition in part and grant the amended petition for rulemaking related to NRC policy and regulations concerning the consideration and use of potassium iodide as one of the elements in offsite emergency planning in the event of a severe reactor accident. The final rule amends 10 CFR 50.47(b)(10) to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone (EPZ) that would serve as a supplement to sheltering and evacuation.

The revised Federal Register notice (Attachment 1) should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.
(EDO) (SECY Suspense: 1/26/01)

The Commission has decided to fund State stockpiles of potassium iodide (KI) and work with the Federal Emergency Management Agency (FEMA) for the effective implementation of the distribution of KI.[2] The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchases of KI for use by that State during a radiological

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[1] Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Chairman Meserve and Commissioners Dicus and McGaffigan were present in the Conference Room. Commissioners Diaz and Merrifield participated in the meeting via speakerphone.

[2] In limited circumstances, the Commission will provide funding for local stockpiles as discussed below.

emergency would make a direct contribution to fulfilling NRC's regulatory mission. This decision is consistent with the decisions of the Commission on June 30, 1997, and June 26, 1998, and reverses the April 22, 1999, decision to establish and fund regional stockpiles of KI. The Commission has also disapproved the staff's recommendation to pursue inclusion of KI in the National Pharmaceutical Stockpile (NPS) at NRC expense. However, the Commission does not discourage the inclusion of KI in the NPS if the Centers for Disease Control and Prevention, or any other government entity, deem it appropriate. To expedite the work with FEMA, which has the lead for drafting the Federal Policy on Potassium Iodide (Draft Policy), the NRC staff should recommend consideration by FEMA of the attached revisions in the Draft Policy reflecting the Commission's decisions in this SRM. The staff should ascertain FEMA's plans for finalizing the Draft Policy and keep the Commission informed of FEMA's progress in producing its final draft.

FEMA's Draft Policy currently provides that "[a]ny State, or in some cases, local government, that selects the use of KI as a supplemental protection measure for the general public may so notify the FEMA Regional Director from the FEMA Region in which the State is located, and may request funding for the purpose of purchasing a supply." Because the policy contemplates that requests for funding for stockpiles will be directed to FEMA, but will also provide that the Commission will be responsible for funding States' requests for KI supplies, the staff should work closely with FEMA to carry out the Commission's decision on funding. Accordingly, the staff should inform FEMA that in offering to fund State or in some cases local government stockpiles, the Commission intends only to fund supplies for one to two doses per individual for those within the 10-mile Emergency Planning Zone (EPZ) provided in NRC and FEMA Regulations. The Commission also only intends to fund purchases consistent with the anticipated revision of the Food and Drug Administration (FDA) recommendations on potassium iodide doses. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. The Commission also does not intend to fund any ancillary costs, including costs associated with storing stockpiles or distributing KI in the event of an emergency.

The Commission is anxious to work cooperatively with FEMA and other members of the Federal Radiological Preparedness Coordinating Committee (FRPCC) to bring this important issue to a conclusion. The Commission's expectation is that FEMA will only provide funding in response to requests by States, by local governments that have been designated by the State to request such funding and by federally recognized Tribal governments. The Commission believes that the funding scheme should be consistent with, and supportive of, the Commission's long-standing working relationships with Agreement States, non-Agreement States, and Tribal governments.

The staff should coordinate with FEMA the most efficient and cost-effective way to fund the stockpiles. The Commission expects a cost per dose of about 20 cents or less. Further, the staff and FEMA should consider purchasing KI in bulk to take advantage of volume acquisition at low cost, and therefore, effectively cap the amount the NRC will pay per recommended dose. The staff should inform FEMA that the Commission has budgeted $400,000 in FY 2001 for KI funding and will be requesting similar funding in FY 2002. The staff and FEMA should work out a fair policy for allocating the authorized funding to meet funding requests. Therefore, the States are encouraged to begin their process for considering KI as early as possible, recognizing that the NRC's resources for this purpose will be limited. The staff should accompany any funding for KI with the appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting,

storing, distributing, administering, using, or determining the proper doses of KI for adults or children.

The Commission believes that substantial additional changes may be needed in the revised draft NUREG-1633 pursuant to the Commission's decisions on this paper and the final rule, and pursuant to FDA's draft revised guidance. The revised draft NUREG-1633, when it is available, should be submitted to the Commission for approval to be published for a 60-day public comment period.

(EDO) (SECY-Suspense: 90 days after FDA issues the draft revised guidance for public comment)

Attached are the Commission's revisions to the Statements of Consideration on the final rule and FEMA's Draft Policy.

Attachment 1: Revised Federal Register for Final Rule in SECY-00-0040
Attachment 2: Revised draft FEMA Federal Register Notice

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance

DISCLAIMER

(DFH 3/27/01 DRAFT VERSION)

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ATTACHMENT 4

NRC/FEMA KI Subcommittee charter and task list

NRC/FEMA KI Implementation Plan

Charter and Tasks

NRC/FEMA Steering Committee KI Subcommittee

1. Charter: To develop a schedule, program and procedures for implementation of NRC Final Rule "Consideration of Potassium Iodide in Emergency Plans" and related Commission decisions on KI.

2. References: Title 10, Code of Federal Regulations (CFR), Part 50, NRC Staff Requirements Memorandum M-001222, and NUREG-0654.

3. Tasks:

   a. determine NRC/FEMA roles and responsibilities;

   b. develop schedule and milestones for program implementation;

   c. develop guidelines for State* "consideration" of KI;

   d develop application guidelines/procedures for States* to obtain funding or KI tablets;

   e. develop guidelines for program eligibility: States* and states with existing KI programs;

   f. develop communications plan/public information brochure/website;

   g. develop procedures for approval of applications;

   h. determine most equitable and cost-efficient way to distribute either KI or funding;

   i. develop criteria for contracts for KI procurement;

   j. develop audit procedure for KI tablet/funding distribution.

State* refers to States, and in some cases local governments, and Tribal governments.

NRC/FEMA KI Implementation Plan

I. Preparation

A. Charter and Task List

B. Milestones and Schedule

C. Communication Plan

II Consideration

A. Who

1. States with NPPs within their borders and States with populations within the 10 mile EPZ

2. In some cases local governments

3. Tribal governments

4. Includes those that have previously considered

5. Includes those with current KI programs

B. What

1. NRC SRM, Final Rule and SOC

2. NUREG-1633

3. FDA Guidelines

4. EPA PAGs

5. Public Information Brochure

C. When

1. Rule effective (4/19/01)

2. Final guidance published (TBD)

3. First annual review after guidance available

4. Exercise frequency

5. Rule does not articulate any implementation date

D. How

1. Review rule and guidance

2. Make a determination

3. States notify FEMA and NRC of results of consideration

    a) mail

    b) e-mail

    c) web

4. Licensees obligated to confirm offsite authorities have considered use of KI

III. Application

A. From

1. States

2. Local governments via State

3. Tribal Government

B. To

1. FEMA Regional Director

2. FEMA HQ

3. NRC HQ

C. How

1. mail

2. e-mail

3. web (both e-mail and web will require verification)

D. Form

1. Name of government entity

2. Name of responsible person or contact

3. Address (office location and shipping/mailing)

4. Name and address of NPPs

5. Number of persons (i.e. population within 10 mile EPZ, including transients)

6. Quantity of KI (units/tablets/??) requested

7. Basis for number of persons and quantity of KI requested, including age distribution

IV Approval

A. Who

1. FEMA Region

2. FEMA HQ

B. Criteria

1. State Offsite Response Organization

2. Reasonableness check:

a) total population based on ETE

b) school population

c) transient population

C. FEMA Notify NRC

1. Who at NRC

2. How

a) mail

b) e-mail

c) web

V. Distribution

A. Fair and Equitable

1. First come, first serve

2. Other criteria?

B. Process for cutting check, mailing, verification of receipt and use and/or electronic funds transfer

C. KI

1. Locate vendors (bulk purchase)

2. Contracting Process

3. Arrangements for drop shipping, verification of receipt

VI. Process Feedback

A. Stakeholders

1. States, local governments, tribal governments

2. FEMA

3. NRC

4. Public

5. Licensee

B. Effectiveness and Efficiency

C. Public Confidence

D. Regulatory Burden

VII. Evaluation

A. FEMA

1. Who
   a) State
   b) Local
   c) Tribal

2. What?

3. How?

B. NRC

1. Who
   a) Licensees

2. What

a) Have responsible offsite authorities considered KI?

3. How

a) Inspection

b) Rule does not articulate inspection criteria

Federal Emergency Management Agency

Washington, D.C. 20472

MAR 26 2001

PT-CR

MEMORANDUM FOR: Acting FEMA Regional Directors
(Regions I-X)

FROM: Robert Shea
Director
Chemical and Radiological Preparedness Division

SUBJECT: Status of Activities Related to NRC Potassium Iodide (KI) Rulemaking

The purpose of this memorandum is to advise you that the Nuclear Regulatory Commission (NRC) has revised a section of its emergency preparedness regulations to require that States consider including potassium iodide (KI) as a protective measure for the general public to supplement sheltering and evacuation in the event of a severe nuclear power plant accident.[1] The NRC published the rule change in the *Federal Register* (Volume 66, Number 13, page 5427) on January 19, 2001. The change becomes effective April 19, 2001.

Concomitant with this action, the NRC has agreed to provide funding for a supply of KI for a State, or Tribe, that chooses to incorporate KI for the general public in their emergency plans. In some cases, if designated by the State, local governments may also request the funding. After funding the initial purchases of KI ($400,000 in FY 2001 and a similar amount requested in FY 2002), the Commission may consider extending the program to fund replenishment supplies, but has made no commitments in this regard.

NRC and FEMA staff have been working on a program to implement this new rule. In conjunction with this action, we are awaiting the issuance of the Food and Drug Administration (FDA) final guidance on KI. This issuance will address recommended doses for different risk groups (age groups) and protective action recommendations as to when the population should ingest KI to protect the thyroid from the uptake of radioactive iodine.

The NRC has revised draft NUREG-1633 which provides guidance on the use of KI. The draft NUREG-1633 will be sent to the NRC Commissioners in April 2001. After review by the Commission, the NUREG will be issued for a 60-day comment period.

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[1] If taken in time, Potassium Iodide blocks the thyroid gland's uptake of radioactive iodine and thus would prevent thyroid cancers and other diseases that might otherwise be caused by exposure to radioactive iodine that could be dispersed in a severe nuclear accident.

States are encouraged to begin their process for considering KI as early as possible, recognizing that the NRC's resources for this purpose will be limited. However, the consideration process by State, Tribal, and in some cases, local government is not expected to have been completed until the final FDA guidance and NUREG-1633 has been issued and the application process established.

Please advise the States and Tribes within your Regional jurisdiction of this new rulemaking and its implementation status. We will keep you informed of further developments. If you have any questions regarding this matter, please contact Vanessa E. Quinn, Chief, Radiological Emergency Preparedness Branch, FEMA at (202) 646-3664. For the NRC, contact Kathy Halvey Gibson, Chief, Emergency Preparedness and Health Physics Section at (301) 415-1086.

cc: Glenn Tracy, NRC
PT&E Division Chiefs

The Consideration of Potassium Iodide(KI) in Emergency Plans

[Consideration of KI in Emergency Plans|Nuclear Reactors|NRC Home Page]

The Nuclear Regulatory Commission has revised a section of its emergency preparedness regulations. The revised rule requires that States with population within the 10-mile emergency planning zone of commercial nuclear power plants consider including potassium iodide (KI) as a protective measure for the general public to supplement sheltering and evacuation in the unlikely event of a severe nuclear power plant accident.

Potassium iodide is a salt, similar to table salt. Its chemical symbol is KI. It is routinely added to table salt to make it "iodized." Potassium iodide, if taken in time and at the appropriate dosage, blocks the thyroid gland's uptake of radioactive iodine and thus would prevent thyroid cancers and other diseases that might otherwise be caused by exposure to radioactive iodine that could be dispersed in a severe nuclear accident.

The final rule amends 10 CFR 50.47 (b) (10). The NRC published the rule change in the *Federal Register* (Volume 66, Number 13, page 5427) on January 19, 2001. The change becomes effective April 19, 2001.

Concomitant with this action, the NRC will provide funding for a supply of KI for a State, or Tribe, that chooses to incorporate KI for the general public in their emergency plans. In some cases, if designated by the State, local governments may also request the funding. After funding the initial purchases of KI, the Commission may consider extending the program to fund replenishment supplies, but has made no commitments in this regard.

- **Background**
  Federal Register Notice

- **Who is eligible to obtain KI funding?**
  This rule applies to States and Tribal governments with Nuclear Power Plants (NPPs) within their borders, with populations within the 10-mile EPZ, and local governments designated by States to request KI funding.

  The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matter. By requiring consideration of the use of KI, the Commission recognizes the important role of States and local governments in matters of emergency planning.

- **The process to obtain KI**
  NRC and FEMA staff are working on a program to implement this new rule.

- **Current Status**
  The Nuclear Regulatory Commission (NRC) and Federal Emergency Management Agency (FEMA) are the two Federal agencies responsible for oversight of emergency preparedness at and around nuclear power plants (NPP). NRC and FEMA staff are working on a program to implement this new rule. In conjunction with this action, we are awaiting the issuance of the Food and Drug Administration (FDA) final guidance on KI. This issuance will address recommended doses for different risk groups (age groups) and protective action recommendations as to when the population should ingest KI to protect the thyroid from the uptake of radioactive iodine.

  The NRC has revised draft NUREG-1633 which provides guidance on the use of KI. The draft NUREG-1633 will be sent to the NRC Commissioners in April 2001. After review by the Commission, the NUREG will be issued for a 60-day public comment period.

  The status of NRC and FEMA activities to implement the KI rule will be periodically updated.

- **Frequently Asked Questions**
  This section is under development. FAQs will be posted here as soon as they are available.

- **Licensees**

  The Commission notes that this rule will introduce another element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. While this ultimate responsibility could have practical implications, with some associated burdens, the extent is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements. The rule does not articulate any implementation date or inspection criteria.

- **Related Regulations and Guidance**

  NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action during Severe Reactor Accidents," is in draft form.

  FDA draft guidance is available for public comment. The public comment period ends on April 27, 2001.

- **Schedule**

  NUREG-1633 will be sent to the NRC Commission in April 2001 for review and comment.

  The final rule will be effective on April 19, 2001.

  The comment period for the FDA proposed guidance ends on April 27, 2001.

  The publication date of FDA's guidance is unknown at this time.