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NUREG-1633

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

Draft Report for Comment

U.S. Nuclear Regulatory Commission

Office for Analysis and Evaluation of Operational Data

Office of Nuclear Reactor Regulation

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ABSTRACT

The use of potassium iodide as a supplemental protective action within the plume pathway emergency planning zone during severe reactor accidents is evaluated. A brief history of reactor accidents is given, leading to an overview of severe reactor accident source terms. Thyroid and whole body dosimetry, their associated risk assessment, and their relationship to severe accident source terms are discussed. The offsite doses for several accident scenarios with and without KI are estimated. The Chernobyl accident and its consequences are discussed. The European practices, along with the World Health Organization's and the International Atomic Energy Agency's recommendations within the plume pathway emergency planning zone, are reviewed.

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EXECUTIVE SUMMARY

Each nuclear power plant (NPP) in the United States has two emergency planning zones (EPZ): the plume EPZ and the ingestion EPZ. The plume EPZ is that area requiring immediate action to reduce risk to the public and is approximately 10 miles in 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 plans exist for protecting the public from the consumption of contaminated food and for which there is considerable time for action to reduce risk. The ingestion EPZ is approximately 50 miles in radius, which also includes the 10 mile radius plume EPZ.

In NPP licensing, the U.S. Nuclear Regulatory Commission (NRC) subscribes to the defense-in-depth safety strategy. The elements of that strategy include: accident prevention, redundant safety systems, containment, accident management, siting, and emergency planning. Following the Three Mile Island Unit 2 (TMI) accident, 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 extensive training and are evaluated by periodic drills.

The NRC and the Federal Emergency Management Agency (FEMA) are the two Federal agencies tasked to evaluate emergency preparedness at and around NPPs. The NRC will not issue an operating license for a nuclear power reactor unless a finding is made by the NRC 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 as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented and on the NRC assessment as to whether the utility's onsite emergency plans are adequate and whether there is reasonable assurance that they can be implemented.

One of the emergency planning elements that FEMA evaluates 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 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. In general, when core damage is projected, persons within 2-3 miles around the plant are evacuated and persons in the remainder of the plume EPZ are directed to remain indoors and await further instructions.

The use of potassium iodide (KI) as a supplemental protective action for the general public is the subject of this technical paper. Specifically, this technical assessment documents the basis that the NRC staff used to evaluate options related to the use of KI by the general public within the 10-mile EPZ. To ensure an informed decision, this assessment begins with a brief history of reactor accidents, leading to an overview of severe reactor accident source terms. Next, thyroid and whole body dosimetry, their associated risk assessments, and their relationship to severe reactor accident source terms are discussed. In addition, this assessment summarizes the medical aspects of KI use, and includes a glossary of medical terms, as well as a comprehensive list of references.

To assess the effectiveness of KI in reducing the radiological impact on populations close to NPPs, the staff estimated offsite doses for several accident scenarios, with and without the timely distribution of KI. The staff then related these findings and insights to the Chernobyl accident and the resulting emergency responses of the Ukraine, Belarus, and Poland. To complete the picture, the staff then summarized the KI guidance and policies of the United Kingdom, Sweden, Switzerland, Finland, France, the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA).

The staff's approach to assessing the effectiveness of KI involved calculating whole body and internal organ doses, including thyroid, to populations within the 10-mile EPZ. The staff performed these calculations for several severe reactor accident scenarios using the source terms for the Surry NPP, as specified by NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," dated 1990. For each accident scenario, the staff performed two identical calculations, except that one calculation assumed that KI was administered to every person within the 10-mile EPZ just before any exposure to radioactive releases.

Examination of the resulting data indicates that timely administration of KI reduces thyroid doses by about a factor of 10 for all scenarios and distances. If the doses are in the stochastic range (up to several thousand rads), thyroid blocking could reduce the risk of thyroid cancer by about a factor of about 5. Other cancer risks are not affected by the use of KI, and this reduction in the risk of thyroid cancer obviously does not apply if the thyroid is ablated (dose greater than about 25,000 rads). The effects of whole body doses greater than 25 rem can be seen as changes in blood chemistry, and doses above about 100 rad cause serious physiological damage. About 50 percent of individuals receiving acute doses greater than about 400 rad die within about 90 days. For the two most severe accident scenarios considered, reductions in thyroid doses are dwarfed by the physiological effects of the accompanying acute whole body doses. Early death or very serious effects would occur to all individuals exposed out to nearly 10 miles.

The third accident yields whole body doses that are substantial, but probably not fatal. Timely administration of KI offers some thyroid dose saving, but the major population impact (e.g., leukemia, lymphoma, and other radiogenic cancers) results from stochastic effects associated with the large whole body doses. The fourth accident scenario which yields the least impacting source term would cause insignificant doses for both the thyroid and the whole body.

This technical assessment yielded the following insights and conclusions:

Reactor Accident Frequencies and Protective Actions

- Although there have been no evacuations in the United States from NPP emergencies since the TMI-2 accident, in theory, there could be numerous evacuations without an associated release of radioactive material. The calculated frequency of core damage is generally decades higher (e.g., about 40 times higher for Surry) than the calculated frequency of core damage accompanied by a significant release. Current practice, as described in references published by the NRC and the U.S. Environmental Protection Agency (EPA), requires 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. Similarly, if KI were used as a routine protective measure, theoretically, it could be administered to a general public numerous times without any associated exposure to radioiodines.

- Evacuation of the public during non-nuclear emergencies or disasters is relatively common in the United States. A study ("Identification and Analysis of Factors Affecting Emergency Evacuation," NUMARC, 1989) indicated that there are on the average about 31 major evacuations a year in the US involving more than a 1000 people. By contrast, the administration of a drug to the general public, including pregnant women and children, during an emergency in the United States without direct medical supervision is a significant departure from the norm in emergency response.

- After the onset of core damage, the probability of a relatively insignificant release of the key radioisotopes is about the same as the probability of a major release. Consequently, because the potential exists that severe health effects may result any time core damage occurs, evacuation is the principal effective action used to protect the general public.

Chernobyl Experience

- Following the Chernobyl accident, excess thyroid cancer among the children in Belarus, the Ukraine, and Russia has been detected. Essentially all the affected children lived more than 10 miles from the reactor and are believed to have been irradiated as a result of consuming contaminated foodstuffs. Above all, this experience underscores the importance of early action to prevent ingestion of contaminated foodstuffs by the general public, especially children. The United States provisions for the interdiction of contaminated food and water would have prevented this unfortunate occurrence. Thus, given the significant alternative food supplies in the United States, KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs.

KI Benefits and Challenges

- KI is relatively safe for short-term use if administered in proper dosage with proper medical advice to those patients who are not under certain medication or do not have certain medical conditions. The U.S. Pharmacopeia (USP) Drug Information monograph states that KI is contraindicated in several situations. For example, use of KI with other medications (such as anti-thyroid agents, diuretics (potassium sparing), and lithium) could lead to problems of major clinical significance. A high degree of caution would have to be exercised before recommending its administration on a mass basis, including to pregnant women and children. Logistics and liability are significant issues probably best handled by the States.

- Use of KI for the general public is not an alternative to evacuation. The benefits of KI can be fully realized only if it is administered just before the inhalation of radioiodines[1]. The use of KI in conjunction with evacuation could potentially delay evacuation. The States and local officials are responsible for implementing protective actions. KI distribution could present considerable logistical concerns. The officials must make sure that the public self-administers the correct amount of medication and is cognizant of potential contraindications when used with other medication. Realistically, the State and local officials are in the best

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[1] KI protects the thyroid from interal exposure to radioiodines. KI does not protect against internal exposure to other radioisotopes and does not protect against external irradiation.

position to deal with these issues, and determine how best to allocate State's resources following a severe accident.

- The existing emergency response capability for each NPP site is principally based on moving people rapidly out of potential harm's way. Introducing a process that requires critical timing in distribution/administration of a drug could slow evacuation and thereby reduce effectiveness of a process that protects the population from all radionuclides and pathways.

- National stockpiles of KI have been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis.

International Practices

- Other countries and major international organizations, including the IAEA and WHO, endorse the use of KI. The international policies, in some cases, are significantly different from the U.S. policies. The principal example is the recommendation by the WHO to administer KI to pregnant women and children, whereas U.S. references specifically warn against administering KI to that same group. Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on general drug use.

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ABBREVIATIONS

CCI	Corium and concrete interaction
CEDE	Committed effective dose equivalent
DEPZ	Detailed emergency planning zone
DPH	Department of Public Health
EPA	U.S. Environmental Protection Agency
EPZ	Emergency Planning Zone
FDA	U.S. Food and Drug Administration
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
KI	Potassium Iodide
LB-LOCA	Large break loss-of-coolant accident
NAZ	National Emergency Operation Center
NCRP	National Council on Radiation Protection and Measurements
NPP	Nuclear power plant
NRC	U.S. Nuclear Regulatory Commission
PAG	Protective action guide
SSI	Swedish Radiation Protection Institute
TEDE	Total effective dose equivalent
TMI	Three Mile Island
USP	U.S. Pharmacopeia
WHO	World Health Organization

I. INTRODUCTION

Since the United States undertook its first nuclear programs, the industry has recognized that a severe accident could impose radiological risks to members of the public. In the early years, remote siting was the principal protective measure. In 1948, containment was introduced as a "consequence-mitigating" feature to permit the siting of a Naval prototype reactor near West Milton, New York. Subsequently, the "defense-in-depth" approach to reactor safety was developed, through which attention to detail made even minor accidents unlikely and major accidents highly improbable. In particular, the defense-in-depth approach implemented a variety of consequence-mitigating measures that would protect the public even if a serious accident were to occur. In addition, it required "emergency preparedness" measures that would protect the public even if the consequence-mitigating provisions failed. Over the years, these emergency plans and requirements have been the subject of assessment and fine tuning. The present study represents yet another example of this ongoing assessment.

A severe accident could result in the release of radioactive materials including radioiodines. The Windscale accident in the United Kingdom in 1957 called special attention to radioiodines because they dominated the resulting offsite contamination and because radioiodine-contaminated milk was interdicted as a public health measure after the accident. By 1961, radioiodines became the principal radiological focus of the reactor licensing program in the United States. Because radioiodines can occur in elemental, organic, and/or particulate form(s) and because they have the potential to produce a high calculated dose in a specific organ (the thyroid), radioiodines have traditionally been considered an effective surrogate for all of the radionuclides, other than the noble gases, that could be released as a result of a severe reactor accident. The use of this surrogate has worked well because credit was given only for protective measures (containment, air cleaning systems, etc.) that would also be effective against the other radionuclides. This attention to radioiodines, however, has led to misunderstandings about their radiological significance.

The primary objective of actions to protect the public from radiological risks is to prevent or minimize the potential for early health effects (deterministic effects). Given that objective, it has been determined that prompt evacuation offers the best protection. The second objective of protective actions is to reasonably reduce the likelihood of delayed health effects (stochastic effects), such as cancer. This objective is achieved by implementing the Protective Action Guides (PAGs) developed by the EPA and the U.S. Food and Drug Administration (FDA).

Over the years, criteria and intervention levels have been developed to aid decision-makers in determining the most appropriate protective actions. These are contained in draft Supplement 3 to NUREG-0654 and in the EPA's "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." These documents recognize that prompt evacuation is the most effective protection for the general public in close proximity to a NPP during a severe reactor accident. Timely evacuation can provide almost complete protection — certainly a higher level of protection than any other alternative. Sheltering is also worth considering under certain circumstances, but primarily as a prelude to evacuation. Of course, sheltering can provide significant protection if the shelter is a large building with ventilation control; however, sheltering is of little value in a single-family home, and fallout shelters are rare.

Evacuation is relatively commonplace in the United States. People evacuate because of severe weather conditions, floods, chemical spills, fires, and similar emergencies. The American situation is particularly well suited to evacuation because people largely have their own means of transportation, travel routes are generally well suited to the movement of large numbers of people, and people have places to go. Consequently, when hazard levels reach unacceptable proportions, Americans evacuate.

In a 1989 study by NUMARC entitled "Identification and Analysis of Factors Affecting Emergency Evacuations," it is stated that the average annual number of major evacuations in the U.S. between 1980 and 1987 was 31. A major evacuation is defined as that which involves more than 1000 evacuees. Of the 250 major evacuations between 1980 and 1987, 168 (67 percent) resulted from technological hazards and the remaining 33 percent resulted from natural hazards. The technological hazards included chemical plants, hazardous waste sites, industrial facilities, and railroad accidents.

On several occasions, the staff of the NRC and other Federal agencies have considered using stable iodine, in the form of KI or other compounds, as a means of protecting the public from radiological doses to the thyroid. Such action has never been required, however, except for emergency workers and other limited populations. For the most part, this is because KI protects only one organ from one element via one pathway and the use presents logistical problems because the potential benefits can be realized only if the compound is administered just before the inhalation or ingestion of radioiodines. Also, unlike evacuation, administration of a drug like KI to the general public has no precedence in the United States. Thus, it is not known how the public (or public officials) would react to a recommendation to administer KI, especially when school officials are asked to administer KI to children.

Assessment of the use of KI as a means of protecting the public in the event of a severe reactor accident is not a new undertaking. The technical justifications for this reassessment include experience gained from the Chernobyl accident, insights from severe accident studies and advances in internal dosimetry. This paper does not address the cost-benefit analysis of the use of KI, which was the subject of a previous study documented in NUREG/CR-630. In addition, this paper does not address the psychological and legal factors associated with the use (or non-use) of KI.

II. SEVERE ACCIDENTS

The discussion in this section is limited to U.S. experience in commercial NPP design. When the nuclear power program first began, the dominant concerns centered around nuclear accidents that developed very quickly, as in a power transient. However, the accident at TMI and detailed studies of severe accidents (as documented in WASH-1400 and NUREG-1150) have refocused attention to more protracted accidents. Even in a postulated large break loss-of-coolant accident (LB-LOCA), a significant delay is now believed to occur before there is a large release of radioactive material into the containment.

Moreover, one insight from severe accident studies is that serious damage to the reactor core, which in turn causes a major release of radioactive material into the containment, may not necessarily result in a large release into the environment. If containment integrity can be maintained for 24 hours or more, the offsite risk is limited because of decay and in-containment removal processes. Thus, to be considered severe in the present context, an accident must involve both a large release of radioactive material from the core and an early containment failure or bypass. Without both occurrences, there is no need for any protective actions, including evacuation or administration of KI. Protective actions are generally taken when core damage is deemed probable (well before the release occurs), in order to protect the health and safety of the public to the greatest possible degree.

For most core damage accident scenarios, instruments provide warnings of abnormal conditions in time for operators to implement accident management protocols to keep the accident from progressing to the severe level. However, operator error or additional failures could permit an accident to reach the severe level.

From an emergency response perspective, one particularly important aspect of severe accidents is the composition of the radioactive materials released from the core. To provide a better understanding of the "source term" issue, fission product release experiments have been conducted since 1942. By the 1958 Geneva Conference, these experiments had contributed to the following principles:

- Essentially all of the noble gases will (eventually) escape if the cladding is damaged, even at operating temperatures corresponding to normal plant operation.

- Halogens also readily escape, but the rate of release is affected by environmental conditions such as temperature, rate of temperature change, and the presence of water or steam.

- Certain other nuclides of "intermediate volatility" (Cs and Te) also readily escape at slightly higher temperatures than those assumed.

- Other nuclides (Ru, Tc, and Mo) are volatile only under oxidizing conditions.

- Nuclides in the "low-volatility" group (Sr, Ba & Sb) resist escape until temperatures reached a high level.

- Still other nuclides, particularly the refractory group (Sm, Zr, Nd, etc.), show little propensity to escape.

In light of these principles, an important conclusion of this laboratory work was that core release would strongly depend on local conditions, such as the degree of burnup before the accident, the rates of heatup and cooldown, and the conditions under which the fuel damage occurred. Thus, the source term for a real accident is subject to large variability.

Early risk assessments, such as WASH-740, made gross assumptions such as 100-percent release of all radioactive material (except the nuclear fuel itself), or release of the volatile fission products (noble gases, halogens, tellurium and cesium). Various other model mixes were proposed until 1962, when the licensing model source term (i.e., the instantaneous release of 100 percent of the noble gases, 50 percent of the halogens with half plating out, and 1 percent of all others) was established in TID-14844. On the basis of licensing experience, the NRC subsequently changed the licensing source terms in 1970, with the publication of Safety Guides 3 and 4. (Specifically, the changes amounted to dropping the "1 percent of all others" and partitioning the radioiodine by chemical form.) Recently, with the publication of NUREG-1465, the NRC again changed the model source term. (The release is now modeled as gradual rather than instantaneous, but still predominantly comprises noble gases, radioiodine, cesium, and tellurium, with a very small fraction of other nuclides.) These were representative source terms and not worst case or bounding.

By contrast, the fission product release experiments clearly show that very different source terms are possible. For example, under oxidizing conditions, the bulk of the ruthenium could be released, and very high temperatures could cause the release of a substantial fraction of the solids. Thus, the composition of the source term may be subject to large uncertainties; in fact, even a few hours after the release, the composition can be determined only by analyzing the coolant or containment atmosphere air samples.

Operational experience and design requirements indicate that, for most situations, the operators will be aware of a sequence with the potential to core damage well before there is a substantial release of radioactive material into containment. However, the operators *will not know* whether core damage will subsequently occur, what the magnitude or composition of the release will be, or whether the containment will hold. Consequently, emergency preparedness must accommodate considerable uncertainty.

III. HEALTH EFFECTS

In discussing the possible adverse health effects of radiation, it has become customary to categorize these effects as "stochastic" or "deterministic." Stochastic effects are those effects for which the *likelihood* of the effect directly relates to dose, while deterministic effects are those for which the *magnitude* of the effect directly relates to dose.

The principal stochastic effects are carcinogenesis and genetic damage. Such effects can result from low doses to the whole body. For example, among the survivors of the atomic bombs at Hiroshima and Nagasaki, of those who received doses between 10 and 20 rem, about 9.3 percent died of cancer by 1990, while of those who received between 100 and 200 rem, 13 percent died of cancer in the same period. A similar pattern is assumed for genetic effects, but such effects are too small to be detected in human populations. It is postulated that the risk of stochastic effects increases in proportion to the dose even for very small doses, although, in human populations, stochastic effects are not discernable from doses of 10 rems or less.

Deterministic effects range from reddening of the skin to dermatitis to narcosis of the skin. Other effects include 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 400 rad to the whole body can cause death in about 50 percent of exposed individuals within about 90 days. Large doses to the thyroid also cause deterministic effects, including ablation from doses in the range of 20,000 rads. Deterministic effects require relatively large doses, and emergency response programs are generally designed to get people away from the source of the radiation before such large doses are received.

In a reactor accident, there are three principal ways for radioactive materials to deliver doses to people: (1) external exposure to the passing plume with 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 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 occurs in what is commonly called the "plume phase" immediately after the accident. During the plume phase of a reactor accident release, the thyroid may be exposed one of two ways: (1) externally from the passing plume (from gamma radiation of any gamma-emitting isotope, or (2) externally and internally, if inhalation is also a pathway (if radioiodines are present and are inhaled). It is in the plume phase and in the plume EPZ when and where the potential for large doses to whole body and to the thyroid exist.

The thyroid can also be exposed internally from the intake of radioiodine by the consumption of contaminated milk or leafy vegetables, commonly known as the ingestion pathway. By contrast, the ingestion pathway is a protracted low-level exposure, which can be addressed with less urgency than the "plume phase" exposure. In this context, the "milk pathway" is particularly important because radioiodine is effectively deposited on pasture grass and transferred to the milk of grazing animals (particularly cows, goats, and reindeer). To reduce any internal exposure from the ingestion pathway, including thyroid exposure, officials recommend that dairy animals be placed on stored feed and/or recommend the interdiction of local milk supplies or leafy vegetables within 50 miles. (This distance can be altered when actual plume pathways are established.)

The FDA is responsible for developing the ingestion pathway protective action guides (PAGs) and protective actions for the associated ingestion phase. In particular, the FDA recommends interdiction and removal from commerce and consumption of any foodstuff containing radioactive contaminants in levels that could exceed the PAGs. Dilution by adulteration of contaminated foodstuff (including milk) or continued consumption of contaminated food with simultaneous administration of KI were not deemed acceptable.

A. Thyroid and Whole Body Doses as Functions of Distance Downwind

Theoretically, after a major release under poor atmospheric dispersion conditions (mild inversion), the whole body doses from noble gases alone could be lethal in an area extending more than 6 miles downwind. If 25 percent of the halogens also are released, the distance within which whole body doses could be lethal increases to about 9 miles. Whole body doses above about 50 rad[2] are immediately harmful, especially to the vulnerable members of society.

If the noble gases are accompanied by radioiodines as in the NRC's model source terms, the thyroid doses would be (numerically) much higher than the whole body doses. However, the adverse health effects of the thyroid doses would be much less severe than those of the whole body doses. For example, a person who receives a very a high thyroid dose might experience serious thyroid damage (ablation) but would also likely receive a lethal whole body dose.

B. Doses

1. Whole Body Doses

Generally, the whole body dose is the primary concern with regard to adverse health effects. Traditionally, the whole body dose was calculated from sources outside the human body, as well as sources inside the body that did not concentrate in a single organ (such as cesium and tritium). More recently, internal doses to the various organs are calculated, multiplied by a prescribed weighting factor, and summed to give a committed effective dose equivalent (CEDE). However, the CEDE is valid only for estimating radiation-related carcinogenesis; it is not applicable where concern relates to deterministic effects. Thus, the use of CEDE (or total

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[2] Higher doses are expressed in rad rather than rem to indicate that no quality factors are used. Quality factors are valid only for stochastic effects.

effective dose equivalent, TEDE) would apply in the stochastic range. For example, an acute dose of 1,000 rad to the whole body is lethal, whereas 20,000 rad to the thyroid (1,000 rem CEDE) is a dose commonly given in therapy and is clearly *not* lethal.

From a public health perspective, the primary concern in a severe nuclear accident is the whole body dose that is delivered in a short period of time (acute dose). Generally, if the whole body dose is kept below about 25 to 50 rad, there will be no short-term adverse health effects from radiation. By contrast, acute whole body doses above this level may have a variety of adverse health effects, depending on the dose. These effects range from temporary sterility to radiation sickness to death within 90 days or less. Where the dose is to an embryo or fetus, high whole body doses can impair development and have severe adverse effects, including death.

Radiation-related carcinogenesis is the primary (and perhaps only) concern for lower doses. Clearly, the survivors of the atomic bombs at Hiroshima and Nagasaki 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 where the doses are kept below about 10 rem, but the possibility of radiogenic cancer from lower doses cannot be ruled out. The radiation-related carcinogenesis that has been observed to date is predominantly attributable to irradiation of the whole body. Where radiation-related carcinogenesis has been determined to result from the irradiation of individual organs, the doses have been quite large. For example, bone cancer from ingesting radium was caused by doses of over 1,000 rad, and a few other instances of radiogenic cancer have been attributed to internal emitters.

In an effort to relate the significance of individual organ doses to CEDE doses, the International Commission on Radiological Protection (ICRP)[3] developed a set of "tissue weighting factors." For example, a thyroid dose is said to be only 5 percent as effective as a whole body dose of the same magnitude. That is, 20 rem to the thyroid is equivalent to 1 rem to the whole body. Even a dose to more radiosensitive tissue such as the lung is considered less biologically significant (by a factor of eight) than a dose to the whole body. Consequently, control of the whole body dose is the primary consideration in protecting people from radiation-related carcinogenesis.

2. Thyroid Doses

Large doses to the thyroid can have deterministic effects. Hypothyroidism is believed to be a possible consequence of I-131 doses to the thyroid of as little as 1,000 rad, and virtually certain from doses of 60,000 rad or more. Doses in the range of 25,000 rad are used to ablate thyroids as part of a therapeutic procedure. Such thyroid doses are possible during severe accidents. However, in such instances, the associated whole body doses would be more significant and would necessitate evacuation even if one could entirely rely on KI to protect the thyroid. Consequently, in the range of interest, carcinogenesis is the primary concern.

Thyroid cancer can be radiogenic, as demonstrated in several studies. The thyroid is a tiny organ, weighing only about 30 grams, yet it is quite effective in collecting iodine. As a result, the calculated thyroid dose tends to be higher than the internal doses to other organs when

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[3] NRC regulations are based on ICRP-26. However, ICRP-60 was used in this assessment because it provides a tissue weighting factor of 5 percent instead of 3 percent, as used in ICRP-26, thereby providing a higher risk value for the thyroid.

considerable radioiodine is released in a reactor accident. Thus, controlling the thyroid dose is an effective surrogate for controlling all internal doses, if we continue to use generally effective control measures that reduce exposure from *all* radionuclides.

The probability of radiogenic thyroid cancer is generally assumed to be proportional to the dose to the thyroid. It has been observed that an internal dose to the thyroid from I-131 may be less effective than an external dose to the thyroid[4], which is the kind of radiation that has caused most of the known thyroid damage. The best estimates concerning the risk of thyroid cancer are derived from a series of studies including the data from external doses to the survivors of the atomic bombs in Japan and the children living near Rochester, New York, who were irradiated with doses ranging from about 5 to 110 rem as a treatment for thymus problems. (These studies are deemed "best" because many of the studies of people with high doses to their thyroids show no excess thyroid cancer.) The Marshall Islanders who were irradiated by heavy fallout from a weapons test were a special case in that the internal doses from I-131 and other radioiodines seem to have made major contributions to the thyroid doses; even here, however, the external doses were significant. Thus, the National Council on Radiation Protection and Measurements (NCRP) started its discussion of the development of a model for estimating the risks from thyroid irradiation with the statement "Because I-131 has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from I-131 with that from x-ray exposure is difficult."[5] Nevertheless, NCRP did conclude that, on the basis of animal data, the relative effectiveness for inducing thyroid cancer per unit dose from internal I-131 radiation is one-third that of external gamma radiation.

C. Thyroid Blocking Effectiveness

Figure 1 illustrates the blocking effect of stable iodine (130 mg of KI) as a function of time of administration before and after an intake of I-131. In this paper, a 95-percent blocking is assumed. The reader should note that this assumption is optimistic, since the logistical exigencies of such access to KI by the general public during severe reactor accidents are difficult to meet.

D. Thyroid Uptake and Thyroid Dose

The thyroid dose from internal sources is basically proportional to the thyroid uptake of radioiodines. Perfect internal blockage of the thyroid significantly reduces the internal exposure of the thyroid but has no impact on the external radiation dose to the thyroid (as would evacuation). Moreover, perfect blocking is not possible; up to 95-percent blockage of the thyroid uptake may be possible by saturating the thyroid gland with stable iodine. The effectiveness of thyroid blocking depends primarily on three factors: the isotopes involved, the timing of the intakes of the radioactive iodine and stable iodine, and the condition of the "normal" (unblocked) thyroid.

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[4] However, preliminary epidemiological studies associated with the Chernobyl accident indicate that internal and external dose may be equally effective in producing thyroid cancer (Chernobyl Section Reference #12).

[5] NCRP-80, "Induction of Thyroid Cancer by Ionizing Radiation," National Council on Radiation Protection and Measurements, Bethesda, MD, 1985.

Thyroid blocking is most effective in reducing doses to the thyroid from the intake of I-131 because of its relatively long half life (about 8 days). The shorter-lived nuclides deliver a smaller fraction of their doses to the thyroid. When the thyroid gland is saturated with stable iodine (i.e., KI), its uptake of inhaled radioiodines is significantly reduced. Of the various radioiodines present in a reactor source term, it is the thyroid exposure to I-131 that is most effectively blocked by the saturation of the thyroid with stable iodine (KI).

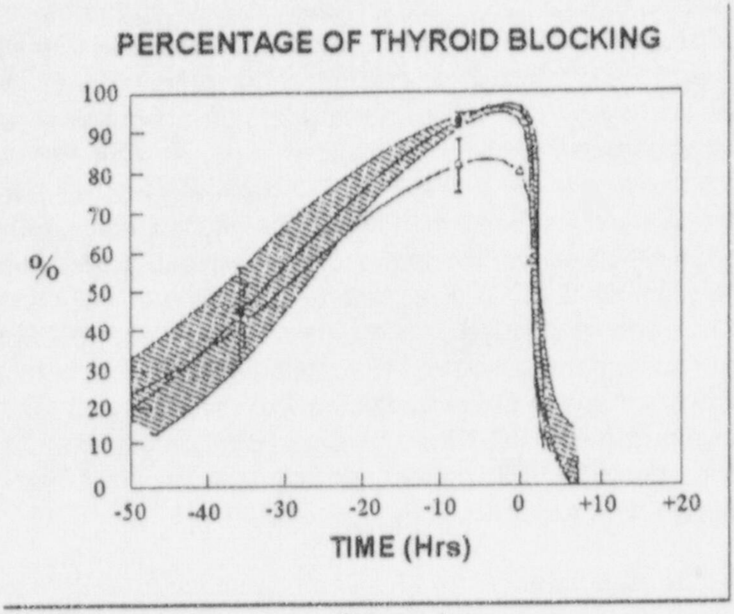

Figure 1

[NUREG/CR-6310, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident"]

With the ICRP model, at best, KI blockage could effectively reduce thyroid doses from all inhaled radioiodine nuclides, essentially by a factor of 20 from I-131 and moderately less from other radioiodines. For thyroid uptake, the ICRP model uses 30 percent as the fraction of total inhaled iodine absorbed by the thyroid. This value is consistent with American nuclear medicine experience from 1960 and earlier. However, in 1824, 1907, and 1920, it was established that the lack of stable iodine in the diet led to colloid goiter, while an excess of stable iodine led to nodular goiter. Subsequently, stable iodine was added to most table salt (about half a teaspoonful of salt provides the minimum daily requirement of 150 micrograms) and colloidal goiter essentially disappeared from the United States. In recent decades, stable iodine has also become an important additive to bread and fast foods (especially hamburgers). In 1975, *Consumer Reports* noted that fast foods contain more than 30 times the minimum daily requirement of iodine. Of course, the high level of stable iodine in Americans' diets leads to a high level of thyroiditis and toxic nodular goiter; however, for present purposes, the important fact is that the ICRP model is not representative of Americans because American thyroids are already partially blocked. (1)

For instances where exposure to radioiodine is prolonged, it is important that the blocking action of KI be persistent. In fact, this is the basis for the recommended dose of 130 mg; 30 mg would be adequate for a short time, but the higher dosage is expected to extend the high level of blocking for up to 9 hours. The important characteristic is that KI is of relatively little value if taken more than a few hours after the radioiodine is inhaled; the NCRP suggests that the I-131 thyroid dose may be reduced by a factor of two if the KI is taken within 3 to 4 hours of exposure (2).

The thyroid dose increases as a function of thyroid uptake of the radioiodines. The ICRP-30 model generally ignores the dose contributions of radioiodine not taken up by the thyroid. In order to assess doses after the administration of KI for thyroid blocking, the staff looked more carefully into the iodine dosimetry, taking into account nuclear medicine experience.

E. Risk as a Function of Thyroid Uptake

The thyroid dose from internal sources basically is proportional to the thyroid's uptake of radioiodines; however, the relationship between risk and uptake is more complex, as illustrated by experience. While experience is limited with regard to accidental exposure to high levels of radioiodine, there is extensive experience with exposure to radioiodine in medicine. The experience in Sweden with I-131 therapy for hyperthyroidism may be considered typical. In this case, 10,552 hyperthyroid patients were treated with I-131 between 1950 and 1975; doses were about 7,000 rad to the thyroid, 25 rem to the stomach wall, and 10 rem or less to other organs. The patients were followed for an average of 15 years, and as expected in studies where there is no discernible effect, in some groups (defined by age and dose) cancer rates seemed higher than expected; in other groups, the cancer rates were lower than expected. The elevated cancer rates were observed as stomach cancer in the people followed for more than 15 years, and thyroid cancer in those with the highest doses (3). Overall, there was no detectable increase in mortality or cancer (3).

Other representative groups studied to determine a relationship between thyroid doses and thyroid cancers include 16,042 patients with Graves disease (exophthalmic goiter) without palpable nodules, and a group of 273 children with Graves disease, who received thyroid doses averaging about 9,000 rad. Other groups studied for excess thyroid cancer included patients who received I-131 doses in diagnosis, such as 10,133 patients who received thyroid doses of about 60 rad, and a smaller group of 494 younger people for whom the doses averaged about 160 rad. These studies led the NCRP to state that "Because I-131 has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from I-131 with that from x-ray exposure is difficult." Nevertheless, the NCRP noted that the effectiveness ratio is between 0 and ½, and recommended using a value of ⅓ (4).

Radiogenic thyroid cancer from external sources has primarily been established through studies of groups such as the *tinea capitis* patients (who received 10 rem) and the enlarged thymus patients (who received 140 rad). Even with external sources, however, the risk is difficult to assess for several reasons. First, the less-reliable incidence data must be used because thyroid cancer is only infrequently fatal. Even this factor is further complicated by the tendency of papillary cancer to recur in a more aplastic form some 10 to 20 years later. Further, bias in detection is a potential problem because there are many more "occult" thyroid cancers than clinically significant ones. Another complication is the apparent sensitivity of certain groups, such as people with *ataxia telangiectasia* or neuroblastoma. Finally, the risk of radiogenic thyroid cancer is decidedly non-linear, being a strong function of age, sex, time since exposure, and dose rate (5).

It follows that any risk estimate is fraught with uncertainty. The ICRP risk estimates are believed to be conservative and the best presently available. These estimates have changed over the years as new information became available; however, the changes have not been dramatic (only a factor of 2) since the publication of ICRP-2 in 1959, through ICRP-26, ICRP-60, and the current (still unpublished) values used here (6, 7, 8, 9).

As used in this assessment, the effects of thyroid blocking are estimated on the basis of experience in nuclear medicine, where uses of KI and I-131 are not uncommon. The staff has primarily relied on the data summarized in ICRP-53 (10) as modified by more recent biokinetic models (9). KI is most effective for reduction of thyroid dose from inhaled radioiodines; here, the dose might be reduced by a factor of 20.

In a severe accident release, the thyroid is also irradiated from external sources. When such sources are taken into account, the use of KI reduces the thyroid doses by a factor of 10. Finally, using the factor of ⅓ for I-131 internal dose effectiveness as recommended by the NCRP, the overall reduction in thyroid cancer risk from thyroid blocking drops to about a factor of 5. Moreover, the reader should note that this reduction in thyroid cancer risk can only be realized if the thyroid doses were in the stochastic range. Of course, people who received high doses could suffer the same acute (deterministic) effects whether or not the thyroid is blocked.

Of course, an actual severe accident might result in a substantially different release, as demonstrated by numerous fission product release experiments (11, 12, 13). Cesium and tellurium are relatively volatile and might well be released in substantial quantities. Under oxidizing conditions, ruthenium forms an oxide that is so highly volatile that, in certain fission product release experiments, the ruthenium releases have exceeded the noble gas releases. Other experiments have shown that, if the fuel temperature were higher than expected, other nuclides including the strontiums and bariums would be released in substantial quantities. A substantial release of these "other" nuclides would essentially increase the risk of deterministic and stochastic health effects for which KI is ineffective.

F. Medical Aspects of Potassium Iodide

The staff performed a limited literature search to find more information on the use of KI in the medical field. According to the USP Drug Information monograph, KI is available in different strengths and in different forms. USP states that KI is a prescription drug except when used as a radiation protectant (100-150 mg taken orally for adults, and 65 mg taken orally for infants). USP also states that the KI strengths commercially available are prescription strengths and do not include the strength recommended for radiation protection; however, KI tablets are available to government and public health organizations for use in radiation emergencies.

The staff contacted several local pharmacies and confirmed that KI in tablet form or otherwise was not available in the radiation protectant strength. The pharmacists contacted all stated that their suppliers' inventory lists did not have KI in that strength and therefore orders could not be placed. All pharmacies contacted carried KI in prescription strength but none had it in tablet form. KI is a constituent of several medications, cough syrups and expectorants intended to liquefy tenacious bronchial secretions. Given the amount of these medications sold and the reported number of adverse effects, the NCRP estimated that the risk of an adverse health effect from a 130 mg dose of KI as 5×10^{-7}. Notably, the NCRP made this apparently accepted estimate despite the following FDA warning:

> Accumulated case reports cannot be used to calculate incidence or estimates of drug risk. They must be carefully interpreted as reporting rates and not occurrences or incidence rates. Comparison of drug safety cannot be made from these data.

The NCRP risk estimate is somewhat different from the reported experience in Poland following the Chernobyl accident (Section V. C). As discussed in Section V-C, it is reported that about 18 million doses of KI were administered, with about 0.2 percent (36,000) "medically significant" and 2 "serious" reactions. Considerations of conditions in Poland at the time, however, gives rise to questions such as: What actually was delivered? What fraction of the material delivered actually was taken? What portion of the adverse reactions were reported? What fraction of the reported adverse reactions were forwarded to the central authorities? The implications of this experience are far from clear; however, to the extent that we believe the report, it seems to suggest a serious difference in outcomes when KI is given to a population rather than prescribed individually.

The staff's review of the *Physicians' Desk Reference* (45th Edition, published by E.R. Barnhart, 1991) suggested that the safety of KI is far from absolute, especially if the drug is taken without medical supervision. The various reports concerning the medications containing KI are as diverse as the companies that produce the medications; however, these reports consistently state that the products are contraindicated for various groups of people (principally pregnant women; nursing mothers; and people with hyperthyroidism, enlarged thyroids, or sensitivity to iodine).

In addition to the consistent contraindications, the reports include a variety of other warnings:

- "Potassium iodide can cause fetal harm, abnormal thyroid function and goiter when administered to a pregnant woman. Because of the possible development of fetal goiter, if the drug is used during pregnancy or if the patient becomes pregnant during therapy, apprise the patient of the potential hazard."

- "A few neonatal deaths resulting from tracheal obstruction due to congenital goiters have been reported."

- "Children with cystic fibrosis appear to have an exaggerated susceptibility to the goitrogenic effects of iodides."

- "Concurrent use with lithium and other antithyroid drugs may potentiate the hypothyroid and goitrogenic effect of these medications. Concurrent use with potassium-containing medications and potassium-sparing diuretics may result in hyperkalemia and cardiac arrhythmia or cardiac arrest."

Of course, a wide range of adverse health effects have been reported, but there is no verification that these effects were caused by the KI, and no solid evidence exists that other effects occurred without being reported.

The USP *Drug Information for the Health Care Professional*, 17th Edition, 1997, also identifies major clinical significance with regard to KI interactions with anti-thyroid agents, diuretics (potassium-sparing), and lithium. The listed side and adverse effects include allergic reactions, especially swelling of the arms, face, legs, lips, tongue, and/or throat, as well as joint pain and hives. This is of sufficient significance that one would have to exercise caution before recommending KI on a mass basis.

IV. EMERGENCY PREPAREDNESS

The purpose of nuclear emergency preparedness is to protect people from the effects of radiation exposure after a severe accident at a NPP. The highest priority is to prevent short-term (deterministic) effects such as epilation, radiation dermatitis, teratogenic effects, radiation sickness, and death. The second priority is to reduce risk of delayed (stochastic) health effects, primarily radiogenic cancer. To do so, it is essential to get the people in greatest jeopardy out of harm's way as quickly as possible.

To achieve these objectives, the area around each plant is divided into two planning zones. The zone within 10 miles of the plant is considered the plume EPZ and the region within 50 miles from the plant is considered the ingestion EPZ. Current analyses indicate that direct exposure to the plume will dominate doses near the plant, with people being 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, the doses delivered in a short period of time may be high enough to produce deterministic effects. Further from the plant, the dominant doses are expected to be from radioactive materials taken into the body, primarily by the consumption of contaminated foodstuffs. Logically, the planned protective measures differ in the two zones. Of course, there is flexibility and the protective measures will be adapted to the circumstances at the time of the accident.

The nuclear 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 occur (10 CFR 50.47 and Appendix E, and NUREG-0654, Supp. 3). Specifically, the licensee is required to notify the NRC and the State and local officials when an unsafe condition develops, and to recommend evacuation to those officials if conditions reach a point where core damage appears probable.

The State and local officials are ultimately responsible for protecting the health and safety of the public, making sound protective action decisions, and implementing protective measures. The default plan is to evacuate the general public within 2 miles of the plant and from the downwind sectors within 5 miles. Other people in the plume exposure pathway EPZ (i.e. within 10 miles of the plant) will be directed to go indoors and listen to Emergency Alert Stations while the situation is further assessed. Thus, the people most at risk will be removed first and the remaining members of the public will be positioned to receive, and respond to, additional instructions.

Travel conditions that would present an extreme hazard may prompt the responsible officials to initially shelter (rather than evacuate) the nearby population until conditions improve. Shelter may also be the appropriate initial protective action for transit-dependant persons, who should be advised to remain indoors until transportation arrives. In addition, shelter 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.

Plant and offsite officials would continue assessing the accident on the basis of additional plant information, dose projections, and field monitoring results. 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 to locate 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 accidents, protective actions may be required beyond the plume EPZ.

When people are evacuated, they will be directed to reception centers where they may be monitored, decontaminated if needed, and directed to shelters. Of course, if evacuation is completed before a significant release occurs, there is no need for monitoring or decontamination.

Some State and local decision-makers have also considered distributing KI to members of the public as an adjunct to the existing emergency preparedness program. The principal questions raised by the decision-makers concern distribution procedures and legal liabilities. In addition, there is concern that KI distribution procedures could slow evacuation and thereby diminish the most effective dose-reducing process available. Secondary concerns include procedures necessary for school officials to administer drugs to children. Hazardous travel conditions also received special consideration. The most probable conditions to jeopardize travelers are storms; however, the attendant unstable meteorology and high winds would more effectively disperse radioactive materials and thereby reduce the overall radiological hazard. In addition, seismic events or traffic accidents could block some evacuation routes. Distribution of KI is especially challenging under these circumstances. For maximum protection, officials need to direct efforts to clearing obstacles and finding alternative routes as opposed to distributing KI. Even under conditions of heavy ice, emergency actions should be directed toward getting people out. If the potential exists for a release of radioactive material, it may be worthwhile to distribute KI to immobilized people, but the limited effectiveness of the drug should be considered in making this decision. KI cannot be used as an alternative to evacuation, even under adverse conditions, but could provide limited benefits in certain unusual circumstances.

Some State and local decision-makers have also considered distributing KI at reception centers, which are located at sufficient distance from the plant to ensure minimal risk of exposure to radioactive releases. If people reaching the center have not yet been exposed, there is no need for any protective measures. If people have been exposed and/or contaminated, there are decontamination procedures to be implemented, followed by medical evaluations. As part of a broader medical consideration, KI is available to the medical community.

V. EXPERIENCE RELATED TO THE CHERNOBYL ACCIDENT

The Chernobyl reactor (a RBMK-1000 design) is located in the Ukraine close to Belarus. The well-known accident involving this reactor occurred at 01:23 on Saturday, 26 April 1986, when explosions destroyed the core and reactor building of Unit 4 of the reactor. The explosions sent debris from the core flying into the air and exposed the reactor core to the atmosphere. The heavier debris from the plume was deposited close to the site. In general, the initial release is thought to have risen to over 1 km in altitude, thereby resulting in much lower doses close to the site than those expected from a ground-level release. The major release lasted 10 days, over which most of the noble gas and more than 40 percent of the iodines are estimated to have been released (14). The varying meteorological conditions, release rates, and release heights resulted in very complex dose and ground deposition patterns. This is illustrated by Figures 2 and 3, which show the cesium deposition patterns resulting from the accident. If cesium and iodine deposited in the same ratio as released from the core, the areas with Cs-137 deposition

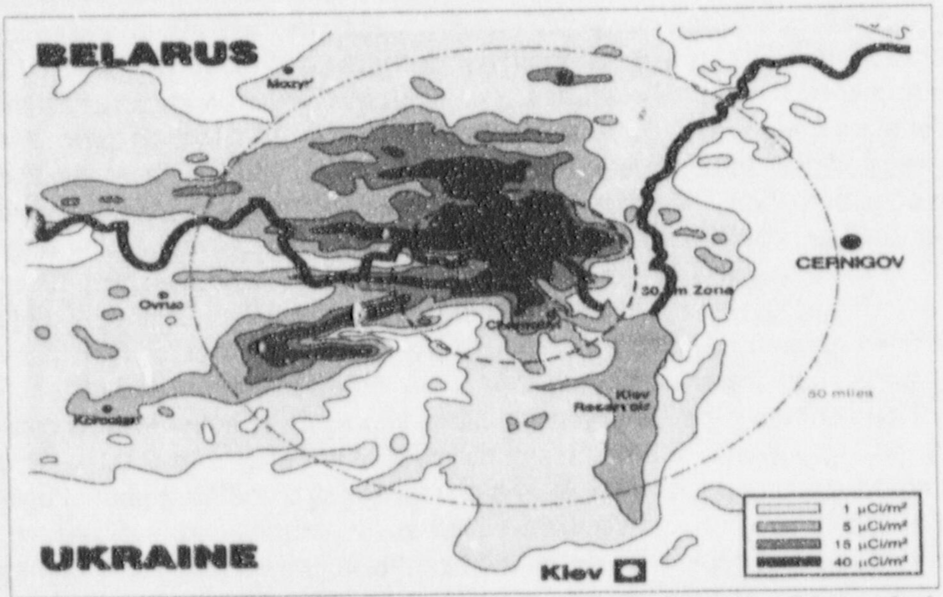

Figure 2: Local Cs Contamination Level Following the Chernobyl Accident

levels of 1 μCi/m² would equate to approximately 10 times the FDA emergency derived response levels (15) for I-131. Under FDA guidance, action should be taken at this level to isolate milk produced by cows grazing in those areas. This derived response level corresponds to a thyroid dose to an infant by the grass-cow-milk pathway of 15 rem. These figures illustrate the large area of concern and the difficulties in predicting the areas that will be impacted during the course of the accident. These figures may provide an indication of the general distribution of thyroid dose. However, no studies showing a relationship between Cs-137 deposition and thyroid dose were found in the literature. Iodine and cesium were deposited at considerably different rates during the Chernobyl release.

It is often assumed that ingestion was the major source of thyroid dose early in the accident. However, the contribution of inhalation cannot be assessed because air sampling was not effectively conducted early in the accident. Nonetheless, inhalation most likely was a major source of the dose received in some areas near the plant.

In response to the accident, KI was administered to some of the operating staff on site during the first day; however, there are no data concerning the effectiveness of this application (1). The first protective action for the public was the evacuation of Pripyat, located within 1 to 2 km of the site. This evacuation began at 14:00 on April 27, a day and a half after the start of the release, and the people in Pripyat were allowed to act normally before the evacuation (1). On

May 2, day 7 following the accident, protective actions were started for the public within the 30-km zone as discussed below.

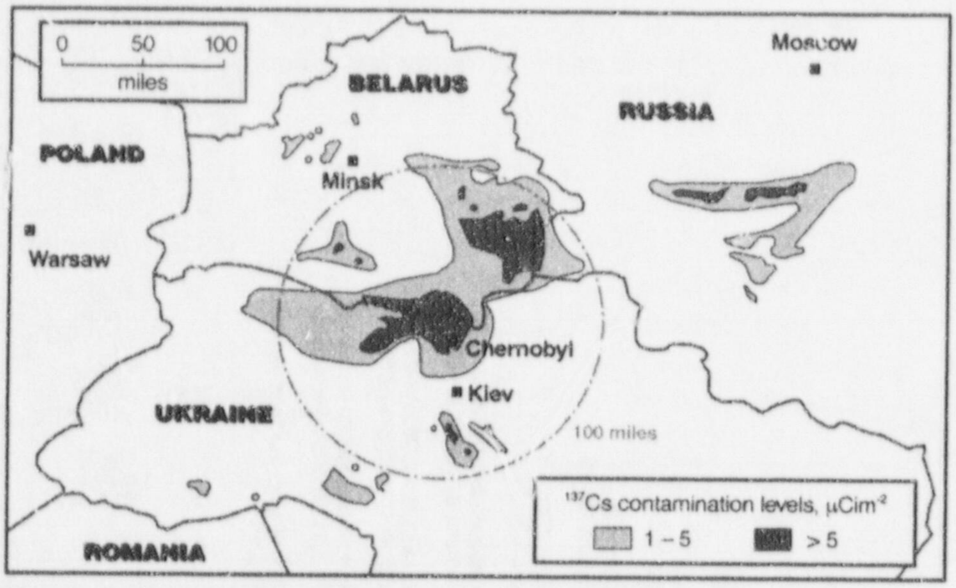

Figure 3: Regional Cs Contamination Level Following the Chernobyl Accident (16)

Four years after the accident, an increase in the number of thyroid cancers was detected in Belarus, Russia, and Ukraine, as shown in Figure 4. Notably, this increase, seen in areas more than 150 miles (300 km) from the site, continues to this day (17) 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. This temporal and geographical distribution of cancers clearly indicates a relationship between the increases and releases from the Chernobyl accident. The increased screening of children does not seem to have been the reason for the increased rates of diagnosed thyroid cancers (17). It has also been suggested that genetic predisposition may have contributed to the increased rate of thyroid cancer; however, while these and other contributory factors can not be excluded, it appears unlikely that they have played a major role (17). Nonetheless, the possibility that iodine deficiency played a role *cannot* be excluded. As of 1996, except for thyroid cancer, there has been no confirmed increase in the rates of other cancers, including leukemia, among the first responders, liquidators,[6] or the public, that have been attributed to releases from the accident. In addition, there is no evidence of any excess hereditary diseases in children born after the accident (17).

A. Belarus Experience

With the Chernobyl plant located only 4 miles (7 km) away, Belarus was heavily impacted by the accident. This impact was heightened by the fact that protective actions were not implemented in Belarus during the first six days after the accident. Several authors have stated that KI was

[6] Liquidators are a large number (about 200,000) of workers and military personnel who performed cleanup, construction of the sarcophagus, and other operations in the contaminated zones following the accident.

distributed to the population in Belarus during the first week following the accident (18). However, there is no confirmed published data on the dosage, coverage, or other details concerning the implementation of the thyroid blocking (19) in Belarus. In addition, cows typically grazed in Belarus at the time of year when the accident occurred, and yet no efforts were taken to restrict the consumption of contaminated milk for the first 10 days following the accident.

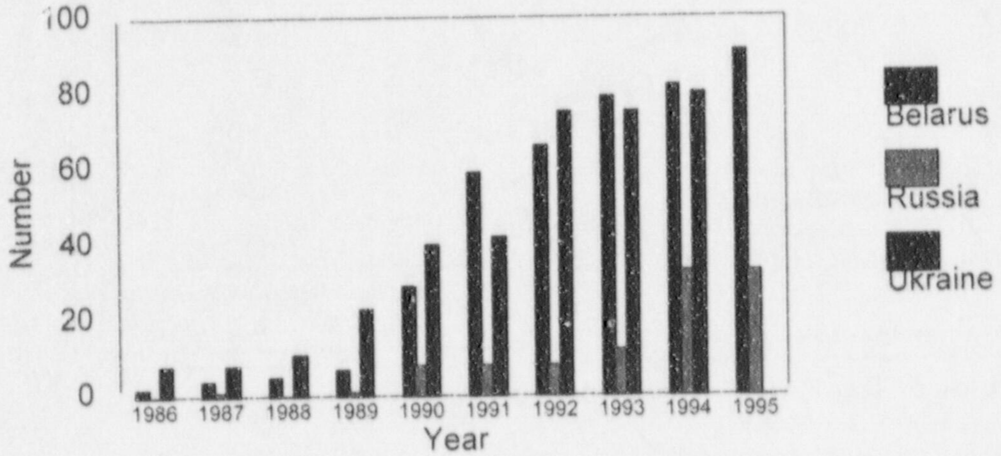

Figure 4: Annual Number of Thyroid Cancers Among Children (0–14 Years Old)

On May 2 (day 7 following the accident) the decision was made to evacuate the areas of Belarus and Ukraine within 18 miles (30 km) of the plant (30 km zone). The evacuation was completed on May 5, 1986.

Since 1990, a rapid increase has been observed in the incidence in thyroid cancer among Belarus children who were 0 to 14 years old at the time of the accident (Figure 4). Before the accident, the rate of thyroid cancer among this cohort was about 0.4 per 100,000; by 1996, this rate had risen to 3.9 per 100,000 (20, 21). This included approximately 3,000 children, 0 to 18 years old, that were evacuated from the 30-km zone within Belarus. Among this group, four thyroid cancer cases have been detected since the accident. All of these cases were registered after the end of the latent period for radiation-induced thyroid cancer. Taking into account the spontaneous rate of this disease in this age group and the number of evacuated persons, all of these cases are considered accident-induced (19).

Figure 5 illustrates the incidence of excess thyroid cancers in Belarus children as a function of distance from Chernobyl. 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 cohort (18, 19, 21). Figure 5 shows that the vast majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site. The distribution of thyroid dose and incidence of excess thyroid cancers among those under 6 years old[7] at the time of the

[7] The age distribution of the "children" cohort is different among the various published studies.

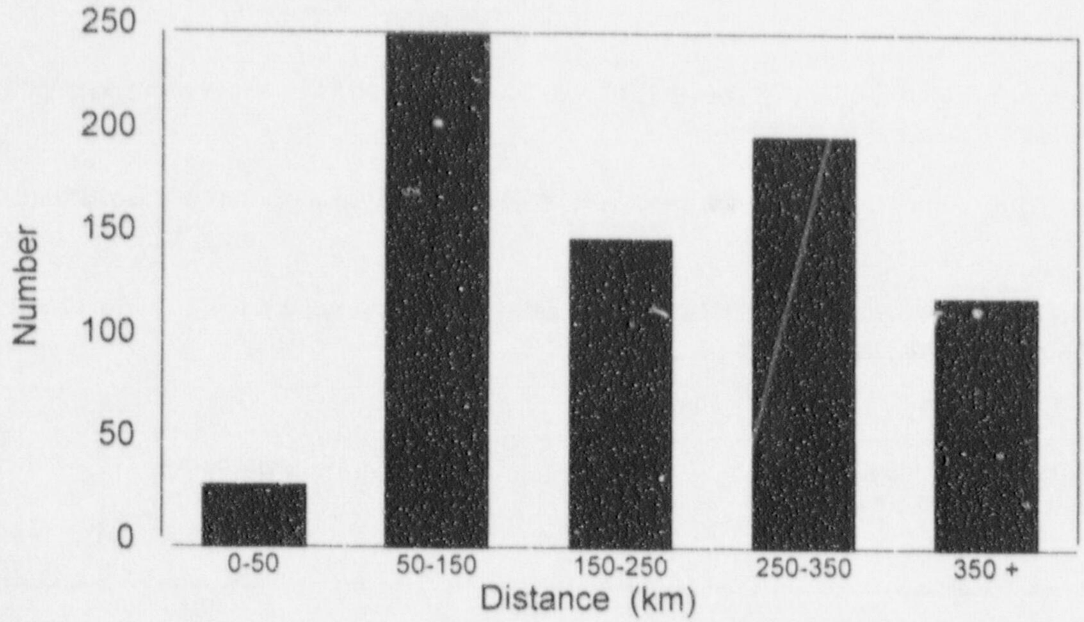

Figure 5: Total Number of Thyroid Cancers in Belarus Among Those 0 -18 Years Old At the Time of the Chernobyl Accident.

accident is shown in Table 1 (21). Data showing thyroid dose in Belarus as a function of distance from Chernobyl could not be found in the literature.

The increase in the rate of thyroid cancers in Belarus is concentrated among those who were youngest at the time of the accident. Figure 6 shows distribution of excess cancer cases through 1995 as a function of age at the time of the accident (17). Fortunately, these cancers respond favorably to early treatment; to date, two or three of the Belarus children diagnosed with thyroid cancer have died as a result of that disease (17, 22).

B. Poland Experience

Poland detected increased levels of airborne radioactive contamination on the night of April 27, 1986 (day 2). 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 (day 3), the country 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 (day 4) (23).

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 (23).

The commission then instituted the following additional protective measures (23):

- 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).

Dose Range (rem)	Number of Settlements	Population	Estimated Average Dose (rem)	Estimated Person-Year-rem	Number of Thyroid Cancer Cases
<10	14	294,664	6.1	12,593,300	84
10 - 49	21	169,602	34.9	41,487,900	214
50 - 99	9	19,722	71.5	9,871,500	29
≥100	6	16,359	158	18,121,300	52
TOTAL	50	500,347	23	82,074,000	379
Estimated Background					**9**
Excess cases due to accident					**370**

Table 1: Thyroid Cancer in Belarus Children under 6 Years of Age at the Time of the Chernobyl Accident

The distribution of KI was initiated on April 29 (day 4) and was virtually completed by May 2 (day 7). 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 (23). 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. This program effectively started on May 3 (day 8).

It is estimated (24) that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions in the 11 provinces treated (24). Had the Russian authorities given prompt warning, the 24- or 48-hour gain in time might have improved effectiveness.

There were no reported serious adverse reactions except for two adults with known iodide sensitivity (23, 24). There were also about 36,000 medically significant reactions reported.

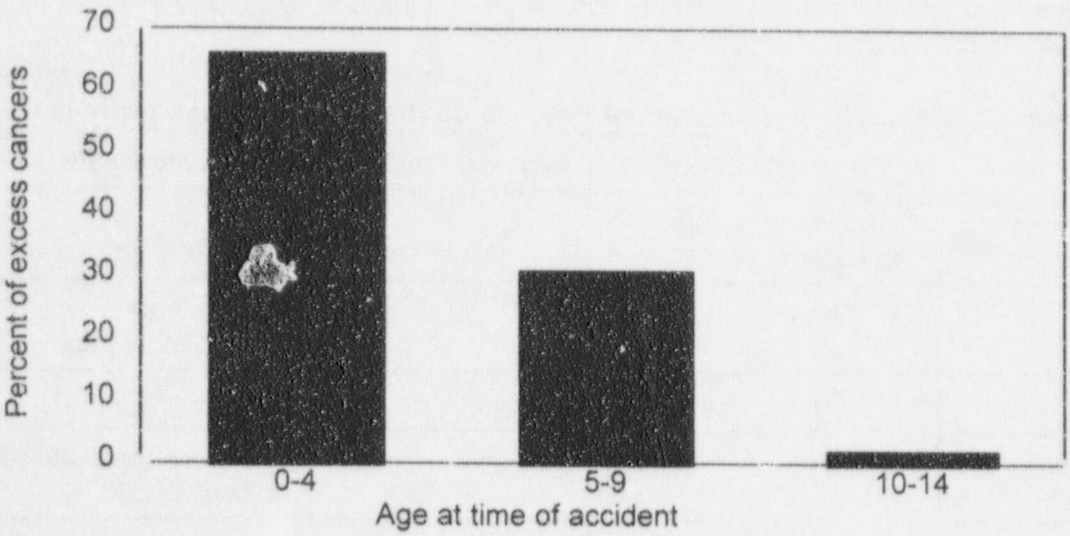

Figure 6: Distribution of Excess Thyroid Cancer as a Function of Age at the Time of the Chernobyl Accident

Because of the low iodine concentrations in Poland it is doubtful that epidemiological studies could detect excess cancers resulting from intake of radioiodine (25).

VI. INTERNATIONAL PRACTICE REGARDING THE USE OF IODINE PROPHYLAXIS

During this assessment, the NRC staff examined the current policies and practices regarding the use of thyroid blocking during NPP accidents for a number of countries. The staff primarily accomplished this task through personal communication with colleagues in each country. The results are summarized in Table 2, and Appendix 1 provides additional detail. In general, the countries either are following or intend to implement systems that are consistent with the guidance promulgated by the WHO. Specifically, the WHO recommends predistribution of stable iodine close to the site and stockpiles further from the site (26, 27). These stocks should be strategically stored at points such as schools, hospitals, pharmacies, fire stations, or police stations, thereby allowing prompt distribution. A further description of the WHO guidance is provided below, followed by a discussion of the guidance promulgated by IAEA, and a comparison between U.S. and international practice.

A. World Health Organization (WHO) Guidance

The main points of the WHO Guidelines (26, 27) regarding the use of stable iodine are as follows:

- Near field: Stable iodine should be available for immediate distribution to all groups if the predicted thyroid dose is likely to exceed national reference levels. Close to nuclear installations iodine tablets should be stored or pre-distributed to facilitate prompt utilization.

- Far field: Stable iodine should be available for distribution to pregnant women, neonates, infants, and children if the predicted dose is likely to exceed reference levels. Stable iodine should not be distributed on wide scale to juveniles or adults. Arrangements should be made for distribution of stable iodine to special groups through storage at emergency centers, produce centers, hospitals, etc.

Table 2: Summary of International Practice on the Use of Iodine Prophylaxis

Country	Pre-distribution (a)	Regional Stocks (b)	National Stocks
United Kingdom	Provisions for rapid distribution within 1-3.5 km		
Sweden	0 to 12-15 km		Two central stocks of 350,000 doses each
Germany (c)	0 to 5 km	5-25 km	Proposed (d)
Switzerland	0 to 5 km	5-20 km	For entire population (~70 million doses)
Finland	0 to 5 km		All citizens advised to buy tablets; towns have tables for 25% of population
France (c)	0 to 5 km	5-10 km	About 4 million doses (d)

a. In households
b. At locations allowing prompt distribution (e.g., schools, pharmacies, fire stations)
c. Not yet fully implemented
d. Public can purchase KI without prescription

The following extracts are from the WHO *Manual on Public Health Actions in Radiation Emergencies* (27):

- Deterministic effects from doses of the order of several Gy (i.e., >200 rem) in the thyroid are only likely to occur near the source of the accident where the route of exposure is primarily by inhalation. If this is considered to be possible, then iodine prophylaxis should be given to all population groups.

- As the time of implementation of prophylaxis is critical, prompt availability of the tablets to individuals has to be ensured. One important option could be their pre-distribution to households with provision for storage in places that can be controlled by responsible people. Clear instructions should be issued with the tablet and individuals should be kept aware of the procedures on a regular basis.

- At greater distances from the accident site there is likely to be more time for decision-making. If pre-distribution is not considered feasible, greater control over administration is needed. Stocks of iodine should be stored strategically at points that could include schools, hospitals, pharmacies, fire stations, police stations, and civil defense centers. National authorities should consider the need for these storage points to be widespread, with overlapping distribution areas to minimize delays. The designated authority should plan for issuing, controlling, and reviewing such stocks. It might be useful to deposit stocks at places or institutions where stock controls are normal procedure.

- In regions where only stochastic effects are the cause for concern, the present WHO guidelines recommend that iodine prophylaxis be used only if exposure by inhalation is possible or if potential exposure to radioactive isotopes of iodine by the ingestion route cannot be prevented by food and milk bans. Special groups for concern are children, pregnant women, and lactating women.

- Evidence of a marked excess of thyroid cancer in young children in the population affected by fallout from the Chernobyl accident has now been established. It is overwhelmingly probable that the excess of thyroid cancer resulted from exposure to the radioactive isotopes of iodine from the Chernobyl accident. Therefore this indicates that stable iodine prophylaxis would be beneficial, especially for young children, after nuclear accidents involving releases of radioactive iodine to the environment. Moreover, the experience in Poland following the Chernobyl accident shows that the risks of serious side effects from a single dose of stable iodine are very low (less than 1 in 10,000,000) in this age group.

- Current evidence reinforces the benefits of stable iodine prophylaxis. The risks of side effects are now believed to be minimal. The WHO now advises national authorities that they should consider the benefits of allowing voluntary purchase by the general public within the framework of their plans for nuclear emergencies if it is not the practice already.

B. International Atomic Energy Agency (IAEA) Guidance

Together with other international organizations, IAEA publishes international standards (28) stating that iodine prophylaxis should be taken to avert 100 mGy (10 rem) to the thyroid. In addition, in July and August of 1997, IAEA published two technical documents (29, 30) providing guidance regarding the appropriate response to radiological and nuclear accidents. IAEA plans to revise these documents and republish them in 1999 as part of their Safety Series.

In the event of a severe accident (general emergency), these documents recommend that the population with 3 to 5 km of the plant promptly evacuate or take substantial shelter and take KI. The population within 40 km should shelter and take KI. This guidance indicates that distribution of thyroid blocking must not delay evacuation or sheltering.

C. Comparison Between U.S. and International Practice

The differences between practices in the United states and Europe might be attributed to several key aspects embedded in history, geography, and cultural/political conditions, as follows:

1. Emergency planning in the United States and Europe has evolved differently over the years. In the United States, the TMI accident in 1979 was the defining moment, whereas in Europe, the turning point was the Chernobyl accident in the former Soviet Union in 1986. The TMI accident led to a major change in the U.S. outlook regarding accident phenomenonolgy; severe accidents were deemed more probable and emergency planning was redefined to improve the assurance of the capability to deal with such unlikely accidents. After the Chernobyl accident, U.S. officials conducted a study to determine what lessons, if any, could be learned that would apply to U.S. nuclear plants and accidents. Among other things, the study concluded that there were sufficient differences in the reactor design, operation, and safety culture in the two countries that no major change in emergency planning was warranted as a result of Chernobyl.

The Europeans, on the other hand, had a different experience with Chernobyl. They experienced the consequences of a transboundary accident over which they had no control or warning. The realization that a NPP in a country with a different design and safety culture could have such a large impact on its neighbors served as a wake-up call for European countries. This experience had far reaching implications for the development of emergency planning in Europe (and justifiably so).

As a result, the Europeans developed a greater reliance on KI. The Chernobyl accident largely shaped their views on emergency planning, and some of the key reasons for the European system, are as follows:

- likely transboundary events
- less robust reactor designs, operations, and safety culture
- an unreliable, untimely transboundary notification system
- different political and decision-making systems in neighboring countries
- the degree of public trust in authorities of a different country
- the continued consumption of contaminated food and milk after the Chernobyl accident

The United States was minimally impacted by the Chernobyl accident. As a result of Chernobyl, there have been international exercises between neighboring countries to improve emergency response coordination. The United States and Canada have developed a Joint Agreement in this regard to ensure prompt notification and mutual aid in the event of a major radiological accident.

2. There are certain cultural and political differences between Europe and US that might account for the difference in response during a major crisis. The public's trust of their elected officials at different levels of government influences how and to whom they turn to in the event of a major disaster. The U.S. political structure differs from that of most European countries. Public involvement in the development of public policy is more accepted in the U.S. than in many European countries. For example, in the U.S. local school districts may not have the authority to administer a drug to school children even when the local health officer so recommends.

3. The tort system in the U.S. is also quite unique and different from other European countries. In the US, the implementation of a protective action may entail litigation and liability for long after the accident. The TMI accident is a case in point. One can expect that administration of KI on a mass basis would certainly entail litigation in this country, whereas the government of Poland, which administered KI on a mass-basis, did not appear to be faced with such litigation. In fact, we are not even aware of any pending lawsuits against the former Soviet Union government or plans by the government to compensate people of other countries for the pain and suffering they might have experienced as a result of Chernobyl.

VII. SAMPLE CALCULATIONS

A great variety of accident conditions are possible and there is no way to foretell just what conditions will prevail in an actual severe accident. Still, estimates are needed for planning purposes so, using a variety of assumptions, analyses of possible severe accidents and their offsite consequences have been performed. Generally, the assumed conditions emphasize the release of the radioiodines. Had a higher fuel temperature been assumed, there would have been a larger release of particulates, so the iodines would be relatively less important. Had conditions been oxidizing (i.e., air in the core), the release of ruthenium oxide (RuO_4) would have been a major factor. Had the containment sprays been effective, the radioiodine release would have been greatly reduced. Thus, the following discussion deals with what may be considered a "best case" for illustrating the possible benefits of administering KI to the public.

To determine the potential effectiveness of using KI as a means to protect the health and safety of the general public, sample calculations are performed using insights from NUREG-1150. These sample calculations are limited to the 10-mile EPZ, which is the planning zone for the plume phase of an accident at a U.S. NPP. The plume phase of a severe accident has the potential to yield doses to the public large enough to result in early health effects (deterministic effects). However, the analytical tools and methods used in the 10-mile EPZ (such as the straight-line Gaussian model) and the uncertainties associated with input values (i.e., meteorological parameters), do not lend themselves to simple extrapolation to distances beyond the EPZ. For example, the Chernobyl release produced a pattern that was extremely difficult, if not impossible, to project.

Moreover, the uncertainties associated with dose projection increase with distance. In fact, the uncertainties become so large and the area of impact so vast that analytical assessment would have to be coupled with field and laboratory data for any meaningful assessment. Because the potential for large doses is limited to the 10-mile EPZ, emergency responders and planners have time for a more thorough assessment of areas beyond 10 miles. The preparations made in the 10-mile EPZ allow public officials to expand their protective actions beyond 10 miles if needed on a case-by-case basis.

For the current assessment, the staff used the core inventory at the end of a power cycle for the Surry NPP (a pressurized water reactor) with thermal power of 3,050 MW. To calculate thyroid exposures and health effects, the staff identified four representative source terms. These four categories represented the accidents postulated in NUREG-1150 for the Surry NPP, which not only lead to core damage, but also result in the release of significant quantities of radioactive material, including (in particular) radioiodines.

Tables 3 and 4 depict the characteristics of the four accident categories, labeled RSUR-1 through 4 (31, 32). For the first three categories, the initiating event of the accidents is the loss of offsite power, while for the other category (RSUR-4) the initiating event is containment bypass resulting from a large break in a system interfacing with the primary reactor cooling system. The highest release of iodine is associated with release category RSUR-1, in which the containment rupture coincides with the breach of the reactor pressure vessel indicated by steam explosions. For category RSUR-2, the containment failure involves a leak and follows the occurrence of corium and concrete interaction (CCI). For RSUR-3, the containment functions as intended, but a release occurs through a leak that is within the design limits of the containment. The RSUR-3 source term is further mitigated by the operation of a containment spray system, which is not available for the other three categories. For RSUR-4, no containment failure occurs, but two plumes are released by bypassing the containment. For all four accident categories, CCI occurs, and the reactor coolant system is at low pressure (<200 psia) at the breach of the reactor pressure vessel. The above source terms cover a range of release timing into the environment (early to delayed release), and reflect a variation in containment performance, including failure, and the impact of sprays on release mitigation.

Among the five plants studied in NUREG-1150, it was concluded that for the iodine, cesium, and strontium groups, the mean distribution exceedance curves decrease only slightly over the range of release fractions 10^{-5} to 10^{-1} and then fall rapidly from 0.1 to 1. As a result of the flatness of the exceedance curves, the frequency of accidents with source terms that are marginally capable of resulting in early fatalities is only slightly less than the frequency of accidents covering a very broad spectrum of health consequences up to the occurrence of fatalities. This was a very significant insight into the range of consequences of severe accidents for a given frequency.

If RSUR-3 were ignored because of its minimal offsite consequence, the combined annual frequency of RSUR-1, RSUR-2, and RSUR-4 represents the annual probability of a large offsite release of radioactive material, estimated to be about 4×10^{-6}. The annual frequency of accidents leading to core damage from both internal and external events at Surry NPP is estimated to be 1.7×10^{-4}. This implies that, on the average, 1 in every 40 core damage accidents would result in a significant offsite release of radioactive material. Furthermore, the annual frequency of events with a potential for progressing to core damage is still order(s) of magnitude higher. Because offsite protective actions are contingent on recognition of events that *could* lead to core damage (rather than the actual occurrence of a release), actions to protect the public must be initiated and carried out many more times than the accident release frequencies.

For RSUR-1 through 4, the staff calculated the centerline doses using the NRC's emergency dose projection code, RASCAL. All calculations were performed for a wind speed of 4 mph, stability class D, with no precipitation. The dose coefficients for normal thyroid uptake and 95-percent blocked thyroid were taken from ICRP-60. The thyroid dose components, the CEDE dose components, the acute whole body dose, and the TEDE were calculated for normal thyroid uptake and for 95 percent thyroid blockage. Table 5 depicts the comparison of the doses for normal and 95-percent blocked thyroid.

As shown in Table 5, if KI is used with a 95-percent uptake blockage, the thyroid doses drop by an order of magnitude within the EPZ. The use of KI does not affect the acute whole body dose from inhalation. Acute whole body doses of this magnitude would cause serious early health effects with or without the use of KI. The impact of severe accidents is strongly dependent on the effectiveness of the implementation of protective actions (in this case, timely public access to KI). A more realistic evaluation of the effectiveness of KI would show a smaller risk reduction.

Table 3: Plant Damage States for Surry Nuclear Plant (Ref. 1 and 2)

Release category	plant damage state	Accident Progression Characteristics						
		containment failure time	containment failure size	Core concrete Interaction (CCI)	amount CCI	RCS pressure (PSIA)	Vessel Breach mode	Sprays
RSUR-1	LOSP	CF at VB	rupture	prompt dry	medium	<200	alpha	no
RSUR-2	LOSP	CF at CCI	leak	prompt dry	large	<200	pour	no
RSUR-3	LOSP	no CF	no CF	prompt dry	large	<200	pour	late & very late
RSUR-4	BYPASS (V)	bypass/ no CF	bypass/ no CF	prompt dry	large	<200	pour	no

Table 4: Source Terms Derived for Severe Accidents at Surry (Ref. 1 and 2)

source term	frequency (per yr)	elevation (m)	energy (MW)	release time (h)	release duration	fraction of core inventory released								
						NG	I	Cs	Te	Sr	Ru	La	Ce	Ba
RSUR-1	0	1010	2828	66.06	200s 2h	10	0.25 0.1	0.18 0.13	0.08 0.1	0.02 0.04	0.005 0.001	0.001 0.005	0.005 0.005	0.02 0.04
RSUR-2	0	0	0	12	3h	1	0.06	0.03	0.09	0.003	0.001	0	0	0.003
RSUR-3	0	0	0	616	10h 10h	2.5E-3 2.5E-3	1.5E-5 1.5E-5	1.2E-8 1.2E-8	7.5E-9 7.5E-9	2.5E-9 2.5E-9	2E-10 2E-10	3E-10 3E-10	4E-10 4E-10	2.5E-9 2.5E-9
RSUR-4	0	1010	2828	11.5	30m 2h	10	0.075 0.04	0.06 0.06	0.02 0.05	0.005 0.02	0	3.00e-40	0.001 0.003	0.005 0.02

Alpha: Steam explosion induced failure
Pour: Pouring of corium
CCI: Corium concrete interaction
CF: Containment failure
LOSP: Loss of offsite power
Prompt Dry: CCI takes place promptly following vessel breach; there is no overlying water pool to scrub the release
V: Large break in a system interfacing the high pressure coolant system
VB: Vessel breach

Table 5: Comparison of Doses (Rem) for Normal and 95% Blocked Thyroid Uptake

	THY (Normal)	THY (Blocked)	ACUTE
RSUR-1			
1 MILE	8.6×10^{5}	9.2×10^{4}	6.3×10^{3}
5 MILES	6.2×10^{4}	6.7×10^{3}	5.1×10^{2}
10 MILES	1.9×10^{4}	2.0×10^{3}	1.6×10^{2}
RSUR-2			
1 MILE	1.4×10^{4}	1.3×10^{3}	9.8×10^{1}
5 MILES	3.5×10^{3}	3.2×10^{2}	2.8×10^{1}
10 MILES	1.5×10^{3}	1.4×10^{2}	1.1×10^{1}
RSUR-3			
1 MILE	2.9×10^{0}	2.6×10^{-1}	7.1×10^{-2}
5 MILES	7.5×10^{-1}	6.0×10^{-2}	2.0×10^{-2}
10 MILES	3.2×10^{-1}	2.9×10^{-2}	8.6×10^{-3}
RSUR-4			
1 MILE	3.8×10^{4}	3.4×10^{3}	7.4×10^{2}
5 MILES	9.8×10^{3}	8.8×10^{2}	2.0×10^{2}
10 MILES	4.2×10^{3}	3.8×10^{2}	8.4×10^{1}

VIII. INSIGHTS AND CONCLUSIONS

As a result of the re-examination of the Federal KI Policy, the staff performed an updated study on the use of KI as a protective measure for the general public. Insights from of the Chernobyl experience and new radioiodine dosimetry parameters were coupled with model source terms for severe reactor accidents as used in NUREG-1150. The following insights and conclusions are presented:

Reactor Accident Frequencies and Protective Actions

- Although there have been no evacuations in the United States from NPP emergencies since the TMI-2 accident, in theory, there could be numerous evacuations without an associated release of radioactive material. The calculated frequency of core damage is generally decades higher (e.g., about 40 times higher for Surry) than the calculated frequency of core damage accompanied by a significant release. Current practice, as described in references published by the NRC and the U.S. Environmental Protection Agency (EPA), requires 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. Similarly, if KI were used as a routine protective measure, theoretically, it could be administered to a general public numerous times without any associated exposure to radioiodines.

- Evacuation of the public during non-nuclear emergencies or disasters is relatively common in the United States. A study ("Identification and Analysis of Factors Affecting Emergency Evacuation," NUMARC, 1989) indicated that there are on the average about 31 major evacuations a year in the US involving more than a 1000 people. By contrast, the administration of a drug to the general public, including pregnant women and children, during an emergency in the United States without direct medical supervision is a significant departure from the norm in emergency response.

- After the onset of core damage, the probability of a relatively insignificant release of the key radioisotopes is about the same as the probability of a major release. Consequently, because the potential exists that severe health effects may result any time core damage occurs, evacuation is the principal effective action used to protect the general public.

Chernobyl Experience

- Following the Chernobyl accident, excess thyroid cancer among the children in Belarus, the Ukraine, and Russia has been detected. Essentially all the affected children lived more than 10 miles from the reactor and are believed to have been irradiated as a result of consuming contaminated foodstuffs. Above all, this experience underscores the importance of early action to prevent ingestion of contaminated foodstuffs by the general public, especially children. The United States provisions for the interdiction of contaminated food and water would have prevented this unfortunate occurrence. Thus, given the significant alternative food supplies in the United States, KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs.

KI Benefits and Challenges

- KI is relatively safe for short-term use if administered in proper dosage with proper medical advice to those patients who are not under certain medication or do not have certain medical conditions. The U.S. Pharmacopeia (USP) Drug Information monograph states that KI is contraindicated in several situations. For example, use of KI with other medications (such as anti-thyroid agents, diuretics (potassium sparing), and lithium) could lead to problems of major clinical significance. A high degree of caution would have to be exercised before recommending its administration on a mass basis, including to pregnant women and children. Logistics and liability are significant issues probably best handled by the States.

- Use of KI for the general public is not an alternative to evacuation. The benefits of KI can be fully realized only if it is administered just before the inhalation of radioiodines[8]. The use of KI in conjunction with evacuation could potentially delay evacuation. The States and local officials are responsible for implementing protective actions. KI distribution could present considerable logistical concerns. The officials must make sure that the public self-administers the correct amount of medication and is cognizant of potential contraindications when used with other medication. Realistically, the State and local officials are in the best position to deal with these issues, and determine how best to allocate State's resources following a severe accident.

- The existing emergency response capability for each NPP site is principally based on moving people rapidly out of potential harm's way. Introducing a process that requires critical timing in distribution/administration of a drug could slow evacuation and thereby reduce effectiveness of a process that protects the population from all radionuclides and pathways.

- National stockpiles of KI have been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis.

International Practices

- Other countries and major international organizations, including the IAEA and WHO, endorse the use of KI. The international policies, in some cases, are significantly different from the U.S. policies. The principal example is the recommendation by the WHO to administer KI to pregnant women and children, whereas U.S. references specifically warn against administering KI to that same group. Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on general drug use.

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[8] KI protects the thyroid from interal exposure to radioiodines. KI does not protect against internal exposure to other radioisotopes and does not protect against external irradiation.

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APPENDIX 1

INTERNATIONAL PRACTICE ON THE USE OF IODINE PROPHYLAXIS

United Kingdom (UK) (33)

Offsite emergency plans for dealing with incidents involving the release of radioactive iodine should include procedures for distributing KI tablets. These plans are to be developed by the local health authorities on a site-specific basis. The requirements (34) state the following major points:

- Detailed plans should be drawn up for the rapid distribution of KI tablets to people residing within the detailed emergency planning zone (DEPZ) (1 to 3.5 km for NPPs (26)) or its equivalent.

- The aim ***must*** be to rapidly distribute the tablets distributed since the effectiveness of stable iodine for thyroid blocking depends on administration shortly before or as soon as possible after exposure to radioiodine.

- Local emergency planners will need to collectively discuss the best means of distributing KI tablets, including predistribution where appropriate, bearing in mind local circumstances and possible accident scenarios pertaining to their respective areas. The details of these arrangements need to be agreed upon within the framework locally established for planning the response to radiological incidents involving the release of radioactive iodine, since decisions will critically depend on the local geography, demography, and available manpower. The agreed-upon arrangements should be capable of immediate activation.

- Two recipients might be considered for predistribution:

  — less accessible households or communities

  — evacuation reception centers, police stations, hospitals, pharmacies, schools, and other strategic locations (so as to minimize delays in administration)

  Predistribution of KI tablets to less accessible households or communities may be undertaken, provided that the DPH has explicitly agreed to this policy.

- 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 should include 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 should address (in outline) how this might be accomplished so that arrangements can be quickly developed if the need arises.

Sweden (35)

In 1982, the Swedish Parliament decided that stable iodine tablets should be predistributed to all households within the 12 to 15 km around the four Swedish NPP sites. Approximately 50,000 households have received 20 tablets containing 65 mg potassium iodine. The predistribution is repeated every 5 years through a mailing organized by the regional authorities. The mailing includes information regarding basic facts about radiation, the related risks, and what to do in case of an accident.

In addition to the predistributed tablets, there are two central storage sites, one in Malmö, close to the Barsebäck 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 predistributed 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.

Germany (36)

On the basis of the 1989 WHO recommendations, Germany decided to reduce the intervention level and adopt a new philosophy concerning thyroid blocking in response to NPP accidents. This new philosophy will be implemented in spring/summer 1998. According to this new philosophy, persons over 45 years of age should not take iodine tablets because the drug could cause a greater health risk than the radioactive iodine averted by KI.

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

- Within a radius of 0 to 5 km of the plants, the tablets should be predistributed to households.

- Within a radius of 5 to 10 km 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 predistributed.

- Within a radius of 10 to 25 km of the plants, the tablets should be stored suitable buildings, and predistributed only in exceptional cases.

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. Storage will be in such a way that the tablets can be distributed within 12 hours after the decision is made. In addition, every inhabitant can 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.

Plant operators and/or the energy industry may be required to pay for the tablets, but this is still under discussion.

Switzerland (37)

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

- Within EPZ 1 (about 5 km), the tablets are predistributed 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 (NAZ) is responsible for making recommendations concerning protective actions. The plans call for the following provisions:

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

It is important to note that there are special "fallout" shelters for virtually everyone in Switzerland,

Finland (7)

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 with iodine taken as 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 predistribute iodine tablets to persons staying in all permanent and vacation houses (independent of the number of households), as well as to all workplaces.

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 are provided with the tablets. Instructions were also mailed out in 1993, and are provided in telephone books.

France (39)

France has decided to follow the Swiss model for the use of KI. The Prime Minister issued the following instructions in April 1997:

- Within the 5-km zone surrounding a NPP (or more depending on the local demographic and other conditions), iodine prophylaxis tablets will be predistributed to families. In addition, 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 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 (this is new).

APPENDIX 2

GLOSSARY (40)

Acute Radiation Thyroiditis: Inflammation and necrosis of thyroid tissue as a result of radiation doses greater than 20,000 rem to the thyroid (D_{50}= about 120,000 rem.); symptoms are usually mild and abate in a few weeks, but can lead to a dangerous release of stored thyroid hormones (thyroid storm).

Adenocarcinoma: A cancer of the glandular epithelium.

- Follicular: About 10 percent of radiogenic thyroid cancers.
- Papillary: About 80 percent of all thyroid cancers and about 90 percent of radiogenic thyroid cancers; alveoli of the adenoma are filled with fluid.

Aplastic: Having deficient or arrested development.

Ataxia Telangiectasia: A hereditary progressive disease complex characterized by cerebellar ataxia (defective muscular coordination), recurrent sinopulmonary infections, and variable immunological defects.

Goiter: An enlargement of the thyroid gland.

- Colloidal: Goiter in which there is a great increase in follicular contents.
- Exophthalmic: Goiter with bulging eyeballs (exophthalmos), generally enlarged thyroid, tremor of fingers and hands, increased metabolism, vomiting, diarrhea, skin eruptions, anemia, hyperglycemia, and emaciation (Graves disease, hyperthyroidism, thyrotoxicosis).
- Follicular: Goiter characterized by multiplication of cells lining the follicles, usually with a reduction in colloid (parenchymatous).
- Nodular: Goiter characterized by an enlarged thyroid that contains nodules.
- Toxic: Exophthalmic goiter, or goiter in which in which there is an excessive production of thyroid hormone.

Hyperkalemia: Excessive amount of potassium in the blood.

Hyperthyroidism: A condition caused by excessive secretion of the thyroid gland (such as exophthalmic goiter).

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

Iodine Tincture: Disinfectant and germicide; 50 percent alcohol, 2 percent iodine, about 45 percent water; 3 drops in a quart of water kills amebas and bacteria in 30 minutes; a 4 oz. bottle contains enough iodine to block 22 thyroids.

Neuroblastoma: A malignant hemorrhagic tumor principally composed of cells resembling neuroblasts that give rise to cells of the sympathetic system; frequently in the retroperitoneal region.

Occult: Obscure or concealed (as a hemorrhage).

Palpable: Perceptible, especially by touch.

Potassium iodide (KI): 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 require lifelong therapy with thyroid hormone.

Tinea Capitis: Ringworm of the scalp; actually, *tinea* means any fungal skin disease and *capitis* refers to the scalp.

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The use of potassium iodide (KI) as a supplemental protective action for the general public during severe reactor accidents is evaluated. A brief history of reactor accidents leading to an overview of severe reactor accident source terms is presented. Next, thyroid and whole-body dosimetry, their associated risk assessments, and their relationship to severe reactor accident source terms are discussed. The medical aspects of KI use are discussed. An estimation of offsite doses for several accident scenarios, with and without KI, is made. These findings are then related to the Chernobyl accident. A summary of international guidance and practices is provided.

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