U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-03-01

To: NRC Management Directives Custodians

Subject: Transmittal of Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation"

Purpose: Directive and Handbook 10.131 are being reissued to implement the following changes—

- The policy statement has been revised to include guidance on the use of potassium iodide (KI) by NRC employees during incidents involving radiological releases.
- The requirement for a periodic peer review of radiation safety program procedures was replaced with a new requirement for offices to conduct an annual internal audit.
- Provisions were added to distribute the employee exposure database and establish local databases in offices with a radiation safety officer (RSO).
- The NRR RSO shall be notified of any packages containing radioactive material at NRC Headquarters.

Office and Division of Origin: Office of Nuclear Material Safety and Safeguards

Contact: Anita Turner, 415-5508

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Availability: Rules and Directives Branch
Office of Administration
Michael T. Lesar, (301) 415-7163
Christy Moore, (301) 415-7086

Protection of NRC Employees Against Ionizing Radiation

Directive 10.131

Contents

Protection of NRC Employees Against Ionizing Radiation Directive 10.131

Policy
(10.131-01)

It is the policy of the U.S. Nuclear Regulatory Commission to maintain occupational radiation doses to NRC employees below the limits established in this directive and as low as reasonably achievable (ALARA). NRC shall provide dosimeters to employees in accordance with the provisions of this directive. NRC shall also provide potassium iodide (KI) and other protective equipment (as appropriate) to employees involved in emergency response activities. Otherwise, when an approved radiation safety program exists at a site, NRC shall rely on the program to protect NRC employees assigned to the site (i.e., resident inspectors) or visiting the site. This requirement applies to normal operations and emergency response activities. NRC employees shall comply with the requirements established by the site radiation safety program.

Objectives
(10.131-02)

To establish procedures and standards for protecting NRC employees from ionizing radiation hazards associated with activities conducted by the NRC. These procedures and standards must be—

Objectives

(10.131-02) (continued)

- Consistent with the regulations of the Occupational Safety and Health Administration (OSHA), Department of Labor, as required by Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees." (021)

- Consistent with the radiation protection guidance to Federal agencies prepared by the former Federal Radiation Council or by the Environmental Protection Agency. (022)

- Consistent with guidance of the Food and Drug Administration (FDA), U.S. Department of Health and Human Services, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001 (see Exhibit 3; available at http://www.fda.gov/cder/guidance/4825fnl.pdf). (023)

- Consistent with "Questions and Answers on Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," July 3, 2002 (see Exhibit 4). (024)

- Consistent with the standards adopted by NRC for application to NRC-licensed operations. (025)

Organizational Responsibilities and Delegations of Authority

(10.131-03)

Executive Director for Operations (EDO)

(031)

- Establishes and oversees activities that create and implement standards for protection against radiation for NRC operations. (a)

Organizational Responsibilities and Delegations of Authority
(10.131-03) (continued)

Executive Director for Operations (EDO)
(031) (continued)

- Delegates to the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) responsibility for establishing radiation protection standards and providing technical oversight of the radiation safety programs for NRC employees. (b)

- Delegates to the Director of the Office of Human Resources (HR) authority to act as the Designated Agency Safety and Health Official (DASHO) for the NRC responsible for the management and administration of nonradiological safety and health programs for NRC employees, and administrative support of the radiation safety program with regard to interaction with OSHA. (c)

Director, Office of Nuclear Regulatory Research (RES)
(032)

Develops and maintains the employee exposure database system (EEDS) and provides guidance on its use. EEDS is the central database maintained by the EEDS contractor. Local databases will be maintained by each regional office, NMSS, and the Office of Nuclear Reactor Regulation (NRR). Validated quarterly data from the local databases will be transmitted to the EEDS contractor for entry into the central database.

Organizational Responsibilities and Delegations of Authority

(10.131-03) (continued)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)

(033)

- Maintains this management directive and reviews and approves, or disapproves, any proposed routine deviation (other than emergency actions) from the provisions of this directive dealing with radiation safety standards for NRC employees. (a)

- Provides the project officer and other technical support for the contract that provides personnel monitoring equipment for NRC employees. (b)

- Renders interpretations of the provisions of this management directive in consultation with the Office of the General Counsel. (c)

- Ensures that NRC headquarters and regional offices implement and maintain the standards for protection against radiation under the provisions established by this management directive by initiating a peer review of internal audit results each year by all of the NRC radiation safety officers (RSOs). These reviews should include any deviations authorized under item (033)(a) of this directive. (d)

- Provides quality assurance and implementation guidance as necessary to ensure consistency of radiation safety programs. (e)

- Initiates an annual counterparts meeting for all NRC RSOs, providing a written agenda to discuss NRC radiation safety

Organizational Responsibilities and Delegations of Authority
(10.131-03) (continued)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(033) (continued)

program matters and to resolve problems. Provides minutes reflecting the results of the meeting to the EDO, program office directors, and regional administrators as an annual report on the NRC radiation safety program. (f)

Director, Office of Human Resources (HR)
(034)

- Reviews and approves, or disapproves, any proposed deviation from the nonradiological requirements dealing with employee occupational safety and health. (a)

- Ensures that new employees complete an NRC Form 4, "Lifetime Occupational Exposure History," or an equivalent form, when they enter on duty and forwards this form to RES for entry in the EEDS. (b)

- Ensures that the provisions of this directive are consistent with the safety and health regulations issued by OSHA and acts as the NRC representative with OSHA. (c)

- Establishes and offers training courses to support the training requirements of this directive. (d)

- Maintains records of NRC employees who have successfully completed radiation safety training (including Site Access Training and NMSS Radiation Worker Training) within the last 12 months and provides reports to NRC RSOs upon request. (e)

Organizational Responsibilities and Delegations of Authority

(10.131-03) (continued)

Director, Office of Human Resources (HR)

(034) (continued)

- Maintains records of NRC employees and provides electronic data files to RES quarterly to update the personnel table in the EEDS. (f)

Director, Office of Administration (ADM)

(035)

- Develops procedures for the distribution of personnel radiation monitoring equipment to headquarters employees. (a)

- Executes the contract(s) necessary to provide personnel radiation monitoring services and provides administrative support with regard to contract-related activities for NRC headquarters, regional, and field offices. (b)

Office Directors and Regional Administrators

(036)

- Ensure that employees under their jurisdiction are informed of the provisions of this management directive and that they comply with these provisions. (a)

- Ensure that any employee under their jurisdiction is notified immediately if the employee has been exposed to any radiation (single or cumulative exposure) that exceeds the limits specified in this management directive (see Table II-1 in the handbook). (b)

- Each regional administrator and the Directors of NRR and NMSS shall appoint an RSO and an alternate RSO, and

Organizational Responsibilities and Delegations of Authority
(10.131-03) (continued)

Office Directors and Regional Administrators
(036) (continued)

establish a radiation safety program for using dosimeters and maintaining occupational doses below the limits established in this directive and ALARA. All other NRC office directors shall obtain their radiation safety support from the NRR RSO. The minimum qualification for an RSO is a working knowledge of basic health physics and radiological controls gained from 3 to 5 years of training and experience. (c)

- Each regional administrator and the Directors of NRR and NMSS shall ensure that an internal audit of the radiation safety program for the office is conducted annually. Individuals performing the audit will have technical expertise in radiation safety but no direct responsibility for the program. (d)

- Each regional administrator and the Directors of NRR and NMSS shall ensure that a local database is maintained, including loading and validating data as well as transmitting validated data to the central database maintained by the EEDS contractor. (e)

- Decide and act when immediate decisions and actions are required and immediately inform the Director of NMSS of any action that results in an exception to this directive. (f)

- Each regional administrator shall ensure that provisions for personnel radiation monitoring devices are adequate to support regional emergency response duties. (g)

- Each regional administrator shall maintain a supply of potassium iodide (KI) for site teams dispatched during an emergency. (h)

Organizational Responsibilities and Delegations of Authority
(10.131-03) (continued)

Office Directors and Regional Administrators
(036) (continued)

- Establish procedures to ensure the appropriate technical training of employees who may receive occupational exposures to radiation. (i)

- Each regional administrator shall develop and implement a written radiation safety program for possession and use of radioactive materials, and radiation-producing devices, in the regional office. (j)

Applicability
(10.131-04)

The policy and guidance in this directive and handbook apply to all NRC employees.

- This management directive applies to occupational exposures received by NRC employees during official duties at any location. However, requirements concerning the control of radioactive material apply to facilities controlled by NRC only. (041)

- This management directive does not apply to non-NRC employees (e.g., contractors), and it does not apply to exposures from background radiation, medical exposures, exposures to individuals administered radioactive materials and released under 10 CFR Part 35, nor exposures from voluntary participation in medical research programs. (042)

Handbook
(10.131-05)

Handbook 10.131 contains guidelines, procedures, and standards for protection of NRC employees against ionizing radiation to be applied in conformance with the requirements of this management directive.

Definitions
(10.131-06)

The terms used in this directive and handbook are as defined in 10 CFR Part 20, "Standards for Protection Against Radiation."

References
(10.131-07)

Code of Federal Regulations

"Notices, Instructions, and Reports to Workers: Inspection and Investigations," 10 CFR Part 19.

"Standards for Protection Against Radiation," 10 CFR Part 20.

"Occupational Safety and Health Standards," 29 CFR Part 1910.

"Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters," 29 CFR Part 1960.

Environmental Protection Agency "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA 400-R-92-001, May 1992.

Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees" (45 FR 12769), February 26, 1980.

References

(10.131-07) (continued)

NRC Management Directives—

3.53, "NRC Records Management Program."

10.130, "Safety and Health Program Under the Occupational Safety and Health Act."

NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," June 1999.

NUREG-0910, "NRC Comprehensive Records Disposition Schedule," Revision 3, February 1998.

NUREG/CR-4214, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," Revision 1, Part II, Addendum 1, August 1991.

Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

Privacy Act of 1974, as amended (5 U.S.C. 552a).

"Radiation Protection Guidance to Federal Agencies for Occupational Exposure; Approval of Environmental Protection Agency Recommendations," Administrative Order (52 FR 2822) January 27, 1987.

Protection of NRC Employees Against Ionizing Radiation

Handbook 10.131

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Part I
General Provisions

Purpose (A)

The purpose of the guidelines and procedures in this handbook is to control the possession, use, and transfer of sources of radiation by NRC personnel in such a manner that the dose to an individual does not exceed the standards of radiation protection prescribed herein and is maintained as low as reasonably achievable (ALARA). This handbook also provides standards to protect NRC employees from radiation hazards during licensing, inspection, enforcement, and other regulatory activities, including visits to nuclear facilities in other countries.

Training (B)

Each program office and region shall establish provisions for radiation safety training commensurate with the duties of its employees. In general, the training frequency should be at least once every 2 years. Employees requesting power reactor and certain fuel cycle facilities to accept NRC site access training in place of their own training for unescorted access will need training every 12 months. In addition, each office should provide discretionary training to ancillary personnel commensurate with their duties.

Responsibilities of the Radiation Safety Officers (RSOs) (C)

RSOs shall—

- Ensure that headquarters or regional office procedures implement the provisions of this directive. (1)

Responsibilities of the Radiation Safety Officers (RSOs) (C) (continued)

- Review radiation exposure information on monitored employees in their headquarters or regional offices for overexposures and anomalies and distribute information to managers, as appropriate, to allow them to maintain the doses to their staff ALARA. The release of employee exposure information must be conducted with due regard for employee rights under the Privacy Act. (2)

- Maintain a local employee exposure database, including loading electronic files, validating records, and transmitting validated records to the central employee exposure database. (3)

- Furnish radiation exposure information, upon request, to office directors or regional administrators who have a need to know. (4)

- Furnish radiation exposure data to current and former employees as required by this management directive. (5)

- Maintain prior dose records in accordance with Part II(B)(1) of this handbook and prepare records for each planned special exposure in accordance with 10 CFR 20.2105(a). (6)

- Ensure that an annual written internal audit of the radiation safety program is conducted. Internal audits shall be performance based and focused on verification that accurate exposure records are being developed and maintained for each NRC employee in the office or region. Each audit shall include an evaluation of radiological risks in the office or region and verification that the program, as implemented, addresses these risks. Peer reviews of written audit results shall be

Responsibilities of the Radiation Safety Officers (RSOs) (C) (continued)

performed during the annual RSO counterpart meeting. Individuals performing the audit will have technical expertise in radiation safety but no direct responsibility for that program. (7)

- Furnish reports of overexposures to the appropriate office director or regional administrator. (8)

- Participate in the annual RSO counterpart meeting, providing copies of procedures and records, as requested, and performing peer reviews of written and implemented radiation safety programs. (9)

- Determine, in consultation with an employee's immediate supervisor, when it is necessary or desirable to furnish bioassay services to an employee and assist the employee with obtaining bioassay services, as appropriate. (10)

- Determine and assign appropriate radiation dose to employees who have incomplete dose records as a result of loss of or damage to their dosimeters. (11)

Responsibilities of Employees (D)

Employees shall—

- Comply with the standards and procedures established by the NRC that are applicable to their own actions and conduct. (1)

- Make every reasonable effort to maintain the sum of internal and external radiation exposure and the release of radioactive materials in effluents to unrestricted areas ALARA. (2)

Responsibilities of Employees (D) (continued)

- Use safety and personal protective equipment and other devices or means necessary for their protection that the employee is provided or instructed to use by the NRC or the radiation protection staff at the licensed site. (3)

- Use correct, safe practices in all official activities and follow the licensee radiation safety procedures during site visits and inspections. (4)

- Report any observed radiation hazards to a supervisor as soon as reasonably possible. (5)

- Inform their RSO of any occupational exposure history in accordance with this management directive and applicable office procedures. (6)

- Make every effort to exchange dosimeters and report lost or damaged dosimeters in a timely manner. (7)

- If female, at their discretion, voluntarily declare in writing to their immediate supervisor that they are pregnant. Supervisors will inform the RSO of all declared pregnancies. Regulatory Guide 8.13 contains a sample letter for declaring pregnancy[1] and information that can help pregnant employees and others make decisions regarding exposure during pregnancy. These employees should discuss any questions regarding the information contained in Regulatory Guide 8.13 with their RSOs or immediate supervisors. (8)

[1]This sample letter is designed for use by employees of NRC licensees. It has been revised for use by NRC employees and is attached to this handbook as Exhibit 1.

Part II
Permissible Doses, Levels, and Concentrations

Occupational Dose Limits for Adults (A)

The occupational dose to individual adult employees shall be limited to the following doses:

Table II-1 Occupational Dose Limits for Adults

Dose	Routine Rem/Year	Planned Special Rem/Year	Planned Special Rem/Lifetime
LDE	15	15	75
SDE, WB	50	50	250
SDE, ME	50	50	250
TEDE	5	5	25
TODE	50	50	250

LDE — Lens (eye) dose equivalent measured at a dose depth of 300 mg/cm^2.

SDE, WB — Shallow dose equivalent to the skin of the whole body measured at a dose depth of 7 mg/cm^2 averaged over 1 cm^2.

SDE, ME — Shallow dose equivalent to the skin of the maximally exposed extremity measured at a dose depth of 7 mg/cm^2 averaged over 1 cm^2.

TEDE — Total effective dose equivalent defined as the sum of the deep dose equivalent and the committed effective dose equivalent.

Occupational Dose Limits

for Adults (A) (continued)

TODE — Total organ dose equivalent defined as the sum of the deep dose equivalent and the committed dose equivalent (from internally deposited sources) to the maximally exposed organ other than the lens of the eye.

Determination of Prior Dose (B)

Before authorizing official duties likely to cause an employee to receive an occupational dose requiring monitoring pursuant to Part III of this handbook, the responsible headquarters office director or regional administrator shall ensure that—(1)

- The occupational radiation dose received by the employee during the current year has been determined. (a)

- An attempt has been made to determine the occupational dose that the employee has received over his or her lifetime. (b)

The NRC shall maintain records of prior dose for 75 years from the date of the creation of the record (see NUREG-0910, Schedule 2-22.4.a). (2)

Before allowing an individual to participate in a planned special exposure, the responsible region or headquarters program office shall obtain—(3)

- The individual's signed certificate, NRC Form 4, "Lifetime Occupational Exposure History," showing each period the individual was monitored for occupational exposure to radiation and the results of that monitoring. (a)

Determination of Prior Dose (B) (continued)

- A letter authorizing the planned special exposure signed by the individual and the individual's immediate supervisor, with organizational concurrence through the level of office director or regional administrator. (b)

In preparing the NRC Form 4, or a clear and legible record containing all the information required in NRC Form 4, NRC shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose or a printout from the Radiation Exposure Information Reporting System (REIRS) database. The NRC's Privacy Act System of Records, NRC-27, "REIRS Files," contains additional information regarding records on individuals that are maintained in the system. For each period for which these reports are obtained, the dose shown in the report must be used in preparing NRC Form 4. The provisions of 10 CFR 20.2104(e) shall be observed if records are unavailable. The NRC shall retain and preserve records used in preparing NRC Form 4 and database records for 75 years from the date of the creation of the record or report (see NUREG-0910, Schedule 2-22.4.a and b). (4)

Exposure of Individuals to Radioactive Materials in the Air (C)

It is assumed that an individual inhales radioactivity at the airborne concentration in which he or she is present unless respiratory protective equipment is used. To ascertain if the sum of external and internal dose is as low as reasonably achievable (ALARA), concentrations of radioactive materials in the air will be measured to detect and assess airborne radioactivity in restricted areas and, as appropriate, radioactivity in the body, excreted from the body, or any combination thereof will be measured to detect and assess individual intakes of radioactivity by exposed individuals. (1)

To limit concentrations of radioactive materials in the air, process or other engineering controls will be used at NRC facilities, to the

Exposure of Individuals to Radioactive Materials in the Air (C) (continued)

extent practicable. When it is impractical to apply engineering controls (e.g., fume hoods) to limit concentrations of radioactive material in the air, other precautionary procedures, such as increased surveillance, limitation of working times, or the use of respiratory protection equipment, will be used to maintain the sum of internal and external exposures ALARA. The use of respiratory protection equipment shall be consistent with the provisions in 10 CFR 20.1703. (2)

Planned Special Exposures (D)

The need for a planned special exposure is not anticipated, but, if necessary, an office director or a regional administrator may authorize an adult employee to receive a planned special exposure, provided that the conditions specified in 10 CFR 20.1206 are satisfied.

Occupational Dose Limits for Minors (E)

No individual under 18 shall receive an annual dose in excess of 10 percent of the limits of exposure to sources of radiation or radioactive material under the control of NRC (see Section (A) of this part for limits). Minors may not participate in planned special exposures.

Dose Limits for Members of the Public (F)

No member of the public shall receive a dose in excess of 0.1 rem total effective annual dose equivalent from the sum of external and internal exposures from sources of radiation or radioactive

Dose Limits for Members of the Public (F) (continued)

material under the control of NRC. This restriction excludes the dose contribution from any disposal of radioactive material into sanitary sewerage pursuant to Part IV of this handbook. Also, a dose from external sources in unrestricted areas must be less than 2 millirem in any one hour.

Dose to an Embryo or a Fetus (G)

The dose to the embryo or fetus during the entire pregnancy of a woman who has voluntarily declared in writing to her immediate supervisor that she is pregnant must not exceed 0.5 rem from the sum of exposure to sources external to the mother, intakes of radioactive material deposited in the mother, and intakes of radioactive material deposited in the embryo or fetus. If the dose to the declared pregnant employee has already exceeded 0.45 rem at the time of the declaration, the dose for the remainder of the pregnancy must be limited to 0.05 rem. Every effort should be made to avoid substantial variation above a uniform monthly exposure rate (i.e., about 55 millirem per month). All of the occupational dose limits in Section (A) of this part continue to apply to the declared pregnant employee as long as the limits in this section are not exceeded.

Compliance With Dose Limits for Members of the Public (H)

NRC offices possessing radioactive material shall measure, as appropriate, radiation levels in unrestricted areas to demonstrate compliance with the dose limits for members of the public mentioned in Section (F) above. Compliance shall be demonstrated using methods consistent with those specified in 10 CFR 20.1302.

Furnishing of Bioassay Services (I)

When the cognizant radiation safety officer, in consultation with an employee's immediate supervisor, determines that bioassay services are necessary or desirable, appropriate bioassay services shall be made available to the employee to aid in determining the extent of the employee's exposure to concentrations of radioactive material. Each office or region shall make provisions for obtaining bioassay services if the need arises.

Part III
Precautionary Procedures

Surveys (A)

Surveys shall be made at NRC facilities as necessary to comply with the provisions of this handbook and to determine the extent of any radiation hazard that may be present. (1)

Instruments and equipment used for quantitative radiation measurements by NRC employees and/or at NRC facilities (e.g., dose rate measurements and effluent monitoring) shall be calibrated periodically for the radiation measured. It is recommended that instruments be calibrated at least annually. (2)

Personnel Monitoring (B)

NRC licensees are legally responsible for limiting workers' exposures to radioactive material in their possession in accordance with 10 CFR Part 20. This responsibility includes visitors and other individuals, as well as the licensee's employees. (1)

When NRC issues a dosimeter, it will be the primary dosimeter of record unless there is reason to believe that another dose measurement or estimate is more accurate; in which case, the more accurate dose shall be recorded. NRC office directors and regional administrators shall ensure that personnel monitoring equipment, supplied by NRC or the licensee, is issued to NRC employees and used during visits to facilities at which radioactive material is stored or used if any of the following criteria are met: (2)

- An employee is likely to exceed 10 percent of any of the limits listed in Part II (A) of this handbook. (a)

Personnel Monitoring (B) (continued)

- Any employee under 18 years of age is likely to exceed the conditions listed in 10 CFR 20.1502 for minors. (b)

- A declared pregnant employee is likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem.[1] (c)

- An employee is entering a high or a very high radiation area. (d)

All NRC personnel dosimeters used to demonstrate compliance with the dose limits in this handbook shall comply with the provisions in 10 CFR 20.1501, including the use of an accredited dosimetry processor. Supplemental dosimeters, such as pocket ionization chambers and electronic dosimeters, may be used also. (3)

If monitoring is required and licensee monitoring programs are used instead of NRC monitoring programs, the monitoring results should be obtained from the licensee using NRC Form 525, "Request for and Authorization of Release of Dosimetry Records" (see Exhibit 2 of this handbook), (or an equivalent procedure), and provided to the appropriate RSO for review. If the results are acceptable, the RSO shall enter them into the local employee exposure database. (4)

The NRC is not required to make independent radiation measurements or duplicate radiation safety programs at facilities that are not under its direct control. NRC employees who visit facilities at which they may be exposed to radioactive materials may accept the measurements made by the facility personnel and rely on the radiation safety programs established at the facility. (5)

[1]All of the occupational doses in Part II(A) of this handbook continue to apply to the declared pregnant employee as long as the embryo/fetus dose limit in Part II(G) is not exceeded.

Caution Signs, Labels, Signals, and Controls (C)

Unless a deviation is authorized by the Director of the Office of Nuclear Material Safety and Safeguards, caution signs, labels, signals, and controls will be used as specified in 10 CFR 20.1901, 20.1902, 20.1903, 20.1904, and 20.1905. (1)

A current copy of this handbook and any operating procedures applicable to work involving radiation or radioactive material will be conspicuously posted in appropriate locations of NRC facilities to ensure that employees who have the potential to receive an occupational exposure from NRC-controlled radiation sources shall observe these documents. If posting these documents is not practicable, a notice shall be posted that describes the documents and explains where they may be examined. The office director or a designated representative shall keep these documents available for examination upon request. (2)

Picking Up, Receiving, and Opening Packages (D)

Each region shall maintain and follow procedures consistent with the requirements specified in 10 CFR 20.1906 for safely picking up, receiving, and opening packages in which radioactive material is contained. Due consideration shall be given to special instructions for the type of package being opened. The ADM mail room staff shall notify the NRR RSO if they receive any packages that are labeled indicating that they contain radioactive material. The NRR RSO shall assist with the proper handling of the package.

Instructions to Employees (E)

All employees who have the potential for receiving an occupational dose shall be advised and instructed—(1)

Instructions to Employees (E) (continued)

- About the storage, transfer, and use of radioactive materials and about radiation levels associated with their assigned duties. (a)

- About the health protection problems associated with exposure to radioactive materials and radiation, precautions and procedures to minimize exposure, and the purposes and functions of protective devices employed. (b)

- To observe to the extent within the worker's control the applicable provisions of this handbook for the protection of personnel from exposure to radiation or radioactive materials associated with their assigned duties. (c)

- About their responsibility to promptly report any condition that may lead to or cause a violation of the provisions of this handbook or unnecessary exposure to radiation or to radioactive material. (d)

- About the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material. (e)

- About the results of monitoring for exposure to radiation or radioactive material on an annual basis. (f)

The extent of these instructions will be commensurate with the potential radiological health risk. (2)

Each individual shall receive appropriate training before being issued a dosimeter, unless the individual will be escorted by someone with equivalent training. (3)

Storage and Control of Radioactive Materials in Unrestricted Areas (F)

Radioactive materials stored by NRC staff in an unrestricted area shall be secured to prevent unauthorized removal from the place of storage. (1)

NRC staff shall control and maintain constant surveillance of radioactive material that is in an unrestricted area and not in storage. (2)

Part IV
Waste Disposal

General Requirement (A)

No NRC facility shall dispose of radioactive material except under any of the following conditions:

- By transfer to an authorized recipient as defined by 10 CFR 20.2001(a)(1). (1)
- As provided in Sections (B) and (C) of this part or by release in effluents within the limits in Part II(A) of this handbook. (2)
- As otherwise provided in NRC regulations for licensees. (3)

Disposal of Radioactive Material by Release Into Sanitary Sewerage Systems (B)

Radioactive material may be discharged into a sanitary sewer system if the conditions specified in 10 CFR 20.2003 are satisfied. Care should be taken to comply with local and State regulatory requirements concerning the nonradioactive properties of materials discharged into a sanitary sewer system.

Disposal of Specific Wastes (C)

NRC facilities may dispose of wastes specified in 10 CFR 20.2005 as if they are not radioactive.

Mixed Waste (D)

The generation of mixed radiological and hazardous waste at NRC facilities will be avoided if at all possible. Any mixed waste generated will be managed and disposed of in accordance with all applicable Federal and State regulations.

Records (E)

Records of any waste disposal made pursuant to this part will be maintained in accordance with Part V of this handbook.

Part V
Records, Reports, and Notifications

Records of Surveys, Radiation Monitoring, and Disposal (A)

General Provisions (1)

The records required by this handbook will contain the units curie, rad, and rem, including multiples and subdivisions, and the units will be clearly indicated. Units of roentgen and disintegrations per minute (dpm) are acceptable on records of radiation and contamination surveys. The quantities in the records also will be clearly indicated as the total effective dose equivalent, the shallow dose equivalent, the deep dose equivalent, the eye dose equivalent, and the committed effective dose equivalent. The shallow dose equivalent pertains to both the maximum extremity and the skin of the whole body. (a)

The retention requirements of this directive and handbook are not intended to limit or reduce any other NRC record retention requirements. (b)

Records of the NRC Radiation Protection Program (2)

Historical records of the provisions specified in this directive and handbook, including any interpretations or deviations, shall be maintained by the Office of Nuclear Material Safety and Safeguards (NMSS) for 75 years in accordance with NUREG-0910, Schedule 1-2.2.b. (a)

Audits and other reviews of program content and implementation will be maintained in accordance with standard NRC record retention requirements. (b)

Records of Surveys, Radiation Monitoring, and Disposal (A) (continued)

Records of Surveys (3)

Records showing the results of surveys and calibrations required by Part III(A) of this handbook will be retained for 75 years in accordance with the National Archives and Records Administration (NARA) approved records schedule N1-431-00-13, Item 16. (a)

The following records, when applicable to an individual, will be retained for 75 years from the date of the creation of the record (see NUREG-0910, Schedule 2-22.4.a). (b)

- Records of the results of surveys to determine the dose from external sources and used in the absence of or in combination with individual monitoring data in the assessment of individual dose equivalents. (i)

- Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. (ii)

- Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. These records will be retained for 75 years in accordance with the NARA approved records schedule N1-431-00-13, Item 16. (iii)

- Records of pregnant employee declarations. (iv)

- Records of abnormal dose investigation results. (v)

- Records of respiratory protection medical examinations. (vi)

Records of Surveys, Radiation Monitoring, and Disposal (A) (continued)

Records of Prior Dose (4)

Records of prior dose will be prepared pursuant to Part II(B) of this handbook. (a)

Records of prior dose will be maintained for 75 years from the date of the creation of the record (see NUREG-0910, Schedule 2-22.4.a). (b)

Records of Planned Special Exposures (5)

For each planned special exposure of an NRC employee, the radiation safety officer for that employee shall ensure that the records specified in 10 CFR 20.2105(a) are prepared. (a)

Records of planned special exposures will be maintained for 75 years from the date of the creation of the record (see NUREG-0910, Schedule 2-22.4.a). (b)

Records of Individual Monitoring Results (6)

NRC shall maintain records of doses received by NRC employees for whom monitoring was required and records of doses received during planned special exposures, accidents, and emergency conditions. These records will include the same information required by 10 CFR 20.2106(a). These records will be stored under the NRC's Privacy Act System of Records (NRC-27, "Radiation Exposure Information Reporting System [REIRS] Files"). NRC shall ensure that personnel data, such as social security numbers of individuals, provided to contractors for dosimetry processing are protected from public disclosure pursuant to the Privacy Act of 1974, as amended. (a)

Records of Surveys, Radiation Monitoring, and Disposal (A) (continued)

Records of Individual Monitoring Results (6) (continued)

Entries on the records specified in paragraph (a) above will cover periods not exceeding 1 calendar year. (b)

The records required by this section will be in a format similar to that of NRC Form 5, "Occupational Exposure Record for a Monitoring Period." (c)

The records required under this section shall be protected from public disclosure pursuant to the Privacy Act of 1974, as amended. (d)

NRC shall maintain records of dose to an embryo or a fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy also will be kept on file but may be maintained separately from the dose records. Both records will be stored under the NRC's Privacy Act System of Records, NRC-27, "REIRS Files." (e)

Records of individual monitoring results will be maintained for 75 years from the date of the creation of the record (see NUREG-0910, Schedule 2-22.4.a). (f)

Dosimeter and film badge processing reports will be maintained for 75 years from the date of the report (see NUREG-0910, Schedule 2-22.4.a). (g)

Records of Dose to Individual Members of the Public (7)

Each headquarters and regional office possessing radioactive material, other than quantities that are exempt from NRC regulations, shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (a)

Records of Surveys, Radiation Monitoring, and Disposal (A) (continued)

Records of Dose to Individual Members of the Public (7) (continued)

The records required by paragraph (a) above will be retained for 75 years in accordance with NARA approved records schedule N1-431-00-13, Item 16. (b)

Records of Waste Disposal (8)

Records of waste disposal made pursuant to Part IV of this handbook will be retained for 75 years in accordance with NARA approved records schedule N1-431-00-13, Item 16.

Record Requirements (9)

Each record required by this part shall be accumulated in locations formally designated as "official file stations" and retained in accordance with the applicable NARA approved records disposition schedules contained in NUREG-0910, "NRC Comprehensive Records Disposition Schedule." The file custodian of these records shall maintain an updated "Files Maintenance and Disposition Plan" (NRC Form 306, which is available on InForms) for each respective official file station in accordance with Management Directive 3.53, "NRC Records Management Program," that includes the records schedule number and approved disposition for each record series maintained. These records are to be transferred to the Office of the Chief Information Officer (OCIO) for storage when they become inactive or when they are 2 to 3 years old, whichever comes first. Any changes in the media used to store these records shall be coordinated with the NRC Records Officer (i.e., Chief of the Records Management Branch, OCIO) to ensure that the records are properly scheduled and that the records are retained accordingly.

Reports of Theft or Loss of Radioactive Material (B)

Headquarters and regional offices shall report by telephone to the NRC Operations Center under either of the following circumstances: (1)

- Immediately after discovering that any radioactive material in a quantity greater than 1000 times the quantity specified in 10 CFR 20.1001-2402, Appendix C, is lost, stolen, or missing under circumstances in which an exposure could result to persons in unrestricted areas. (a)

- Within 30 days after discovering that any lost, stolen, or missing radioactive material in a quantity greater than 10 times the quantity specified in 10 CFR 20.1001-2402, Appendix C, is still missing. (b)

Within 30 days of reporting the lost, stolen, or missing radioactive material, the reporting office shall submit to the Director of NMSS and the appropriate Deputy Executive Director for Operations a written report containing the following information: (2)

- A description of the radioactive material involved, including kind, quantity, chemical form, and physical form. (a)

- A description of the circumstances under which the loss or theft occurred. (b)

- A statement of disposition or probable disposition of the radioactive material involved. (c)

- Radiation exposures to individuals, circumstances under which the exposures occurred, and the possible total effective dose equivalent (TEDE) to persons in unrestricted areas. (d)

Reports of Theft or Loss of Radioactive Material (B) (continued)

- Actions that were taken or will be taken to recover the material. (e)

- Procedures or measures that were adopted or will be adopted to prevent a recurrence of the loss or theft of radioactive material. (f)

Subsequent to filing the written report, the reporting office also shall report to the Director of NMSS and the appropriate Deputy Executive Director for Operations any substantive additional information on the loss or theft that becomes available within 30 days of learning this information. (3)

Notification of Incidents (C)

Immediate Notification (1)

Headquarters and regional offices shall immediately notify the NRC Operations Center in person or by telephone after discovering any incident involving radioactive material under NRC control that may have caused—

- An individual to receive any of the following: (a)
  - A TEDE of 25 rem or more (i)
  - An eye dose equivalent of 75 rem or more (ii)
  - A shallow dose equivalent to the skin or extremities of 250 rads or more (iii)

- The release of radioactive material inside or outside a restricted area that could cause an individual present for 24 hours to receive an intake five times the annual limit on

Notification of Incidents (C) (continued)

Immediate Notification (1) (continued)

intake. **Note:** The provisions of this paragraph do not apply to locations in which personnel are not normally stationed during routine operations, such as hotcells or process enclosures. (b)

Twenty-four Hour Notification (2)

Headquarters and regional offices shall notify the NRC Operations Center in person or by telephone within 24 hours of discovering any of the following events involving radioactive material under NRC control:

- An event that may have caused an individual to receive any of the following in a period of 24 hours: (a)
  - A TEDE of 5 rem or more (i)
  - An eye dose equivalent of 15 rem or more (ii)
  - A shallow dose equivalent to the skin or extremities of 50 rem or more (iii)
- An event that may have caused a release of radioactive material inside or outside a restricted area that could cause an individual present for 24 hours to receive an intake in excess of one annual limit on intake (ALI). **Note:** The provisions of this paragraph do not apply to locations in which personnel are not normally stationed during routine operations, such as hotcells or process enclosures. (b)
- An unplanned contamination event that requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or prohibiting entry into the area. (c)

Notification of Incidents (C) (continued)

Twenty-four Hour Notification (2) (continued)

- An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body. (d)

- An unplanned fire or explosion that damages radioactive material, or any device, container, or equipment containing radioactive material when—(e)

  – The quantity of material involved is greater than five times the lowest ALI specified for the material in 10 CFR 20.1001-2402, Appendix B (i)

  – The damage affects the integrity of the radioactive material or its container (ii)

Reports of Overexposures and Excessive Levels and Concentrations of Radioactivity (D)

In addition to any notification required by Section (C) of this part, headquarters and regional offices shall submit a written report to the Director of NMSS and the appropriate Deputy Executive Director for Operations within 30 days of discovering any of the following events: (1)

- Each exposure of an individual to radiation or radioactive material in excess of the applicable limits specified in Part II of this handbook (a)

- Any incident for which notification is required by Section (C) of this part (b)

Reports of Overexposures and Excessive Levels and Concentrations of Radioactivity (D) (continued)

- Levels of radiation or concentrations of radioactive material in—(c)
  - A restricted area in excess of any applicable limit specified in 10 CFR Part 20 (i)
  - An unrestricted area in excess of 10 times any applicable limit specified in 10 CFR Part 20, whether or not these levels cause an overexposure (ii)

Each written report required by this section must describe the extent of exposure of individuals to radiation or to radioactive material, including, as appropriate—(2)

- Estimates of each individual's dose (a)
- The levels of radiation and concentrations of radioactive material involved (b)
- The cause of the event (c)
- The corrective steps taken or planned (d)

Each written report required by this section shall include, in a separate and detachable part, the name, social security number, and date of birth for each individual exposed. If an embryo or a fetus is involved, the identifiers should be those of the declared pregnant woman. (3)

Reports of Planned Special Exposures (E)

Headquarters and regional offices shall submit a written report to the Director of NMSS and the appropriate Deputy Executive Director for Operations within 30 days of any planned special exposure informing them that a planned special exposure was conducted, indicating the date the planned special exposure occurred, and providing the information required by Section (A)(5)(a) of this part.

Notifications and Reports to Individuals (F)

Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual will be reported to the individual on at least an annual basis or as otherwise specified in this part. The information reported will include data and results obtained pursuant to the provisions of this handbook. Each notification and report will be in writing and will include appropriate identifying data, such as the name of the individual, the individual's social security number, and the individual's exposure information: (1)

NRC management shall inform the employee that (a) the report is furnished under the provisions of NRC Management Directive 10.131 and (b) the report should be preserved for further reference.

At the employee's request, the NRC shall advise the employee of any exposure to radiation or radioactive material as shown in records maintained pursuant to this handbook. (2)

At the request of an individual formerly engaged in activities involving exposure to radiation while employed by the NRC, the

Notifications and Reports to Individuals (F) (continued)

individual will be furnished a report of exposure to radiation or radioactive material. This report—(3)

- Will be furnished within 30 days from the time the request is made or within 30 days after the exposure has been determined, whichever is later (a)

- Will cover, for the period of time specified in the request, each year in which the individual's activities involved exposure to radiation or radioactive material associated with NRC activities (b)

- Will include the dates and office assignments for the individual who participated during this period (c)

When a report of an overexposure to radiation or radioactive material is required under Section (D) of this part, the individual shall be notified. The NRC shall transmit this notice before or at the same time as the report. (4)

At the request of an individual who is terminating NRC employment that involved exposure to radiation or radioactive materials, the NRC shall provide, at termination, a written report regarding the radiation dose received by that individual during his or her employment with the NRC. If the most recent individual monitoring results are not available at that time, a written estimate will be provided, together with a clear indication that it is an estimate. (5)

Part VI
Guidance for Emergency Exposure Control During Rescue and Recovery Activities

Purpose (A)

The emergency action guidance contained in this part provides instructions and background information for use by NRC employees in determining appropriate actions for the rescue and recovery of persons and the protection of health and property during an emergency.

General Considerations (B)

Rescue and recovery operations should always be performed so as to minimize the risk of injury to those persons involved in such operations, to limit radiation exposures consistent with the saving of human life and the recovery of deceased victims, and to protect the health of the public and preserve property. Performing rescue and recovery operations requires the prompt assessment of hazards that may be involved with these operations and the determination of alternate methods of accomplishing them. Sound judgment, flexible plans, and adequate and versatile resources are crucial to the success of rescue and recovery operations. (1)

To avoid undue restrictions on actions that may be necessary during rescue and recovery operations, these instructions include flexibility in the establishment of exposure limits by responsible officials. The determination of exposures appropriate to rescue and recovery operations is the responsibility of the official in charge of these operations. (2)

General Considerations (B) (continued)

The official in charge of the rescue or recovery activity shall determine the suitability of any proposed action involving radiation exposure by weighing the risks of radiation exposure, actual or potential, against the benefits to be gained by the proposed action. The magnitude of the expected individual and collective doses and the biological consequences related to these doses are the essential elements to be evaluated in making a risk determination. (3)

The following tables list some of the biological effects associated with various radiation doses. (4)

Table VI-1 Health Effects Associated With Whole-Body Absorbed Doses Received Within a Few Hours*

Whole-Body Absorbed Dose (rads)	Early Fatalities (percent)	Whole-Body Absorbed Dose (rads)	Prodromal Effects** (percent affected)
140	5	50	2
200	15	100	15
300	50	150	50
400	85	200	85
460	95	250	98

*EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," May 1992.
**Warning symptoms (e.g., nausea, fatigue, and so on) of more serious health effects associated with large doses of radiation.

General Considerations (B) (continued)

Table VI-2 Approximate Cancer Risk to Average Individuals From 25 Rem Effective Dose Equivalent Delivered Promptly*

Age at Exposure (years)	Approximate Risk of Premature Death (deaths per 1,000 persons exposed)	Average Years of Life Lost If Premature Death Occurs (years)
20 to 30	9.1	24
30 to 40	7.2	19
40 to 50	5.3	15
50 to 60	3.5	11

*EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," May 1992.

In these instructions, the criteria for accident situations that involve saving lives and valuable property and protecting the health of the public differ from the criteria for recovering deceased victims. In the latter instance, the amount of expected dose received by individual participants should be limited to occupational exposure limits. (5)

The use of potassium iodide will be considered to minimize thyroid doses. Potassium iodide shall be issued (1) in accordance with applicable medical guidelines, including the Food and Drug Administration Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" (see Exhibit 3; available at http://www.fda.gov/cder/guidance/4825fnl.pdf) and (2) in accordance with Commission guidance, including the "Questions and Answers on Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," July 3, 2002 (see Exhibit 4). This process includes questioning individuals about possible allergic reactions. (6)

Emergency Situations (C)

Specific dose criteria and judgment factors are specified for three categories of actions: saving human life, recovering deceased victims, and protecting health and property. When emergency actions are likely to affect an employee or a facility of an NRC licensee, emergency actions will be coordinated with those specified in the licensee's emergency plans or other existing plans to avoid any appreciable differences between dose criteria and judgment factors used by the NRC and the licensee. These actions will not be limited to the rescue of NRC employees and NRC contractors alone but will also apply to employees of licensees, contractors, and visitors. Guidance on dose limits for workers performing emergency services extracted from the Environmental Protection Agency (EPA) "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" is provided in Table VI-3 of this part.

Saving Human Life (1)

When a reasonable expectation exists that an individual is alive within the affected areas during an emergency and is in need of rescue or medical treatment, the course of action to be pursued should be determined by the official on site having responsibility for emergency actions. (a)

The official on site having responsibility for emergency action shall determine the amount of exposure suitable for this type of action. The dose expected in performing the action must be weighed in terms of the effects of acute external whole-body exposure and the entry of radioactive material into the body. In accordance with EPA's protective action guide, the official may permit volunteers to receive a dose up to 25 rem total effective dose equivalent (TEDE) without informed consent for emergency lifesaving activities. Any lifesaving action that may involve a dose greater than 25 rem TEDE, or other substantial personal risk, must be performed by volunteers advised of the known or estimated risk

Emergency Situations (C) (continued)

Saving Human Life (1) (continued)

before participation. Preference will be given to volunteers who meet the following criteria: (b)

- Over 45 years of age (i)
- Physically fit and in good physical condition as determined by a recent physical examination, for example, no adverse heart condition (ii)

In establishing exposure limits for the rescue operation, the official shall keep in mind that the accuracy of the prediction of radiation injury cannot be any better than the accuracy of the dose estimate. Therefore, consideration will be given to limits of error associated with the specific instruments and techniques used to estimate the dose. This process is especially crucial when the estimated doses are greater than 25 rem. The possibility of reducing estimated doses through appropriate mechanisms, such as the use of protective equipment, remote manipulation equipment, the use of potassium iodide, or similar means, will be considered. (c)

When making a decision to perform the action, the risk to rescue personnel will be weighed against the probability of the success of the rescue action. (d)

Protecting Health and Property (2)

When the risk (probability and severity) of the radiation hazard either bears significantly on the state of health of people or may result in undue loss of property and requires immediate remedial action, the following criteria apply:

- When the official in charge of emergency action on site deems it essential to reduce a potential hazard or to prevent a

Emergency Situations (C) (continued)

Protecting Health and Property (2) (continued)

substantial loss of property and determines that occupational dose limits applicable to routine operations may be exceeded, an emergency exposure consistent with guidance on dose limits specified in Table VI-3 may be authorized. However, planned special exposures are encouraged if there is time (see Part II of this handbook). (a)

- When the potential risk of radiation hazard following a nuclear incident jeopardizes life or poses severe adverse effects on the public health, the criteria specified in Section (C)(1) of this part for the saving of human life apply. (b)

Recovering Deceased Victims (3)

Accidents that involve recovering deceased victims require criteria different from those for saving lives. Because the element of time is no longer a critical factor, more time may be allowed for the planning of the recovery operation. The amount of radiation exposure received by persons engaged in these recovery operations should be within existing occupational exposure limits. (See Part II of this handbook.) (a)

When bodies are located in areas that are inaccessible because of high radiation fields and the recovery mission would result in exposure in excess of occupational exposure limits, remote recovery devices will be used to the extent practical to retrieve the bodies. (b)

In special circumstances, such as the entry of emergency workers into high radiation fields to recover bodies, the individual in charge of the recovery mission may determine that it is necessary to exceed the occupational exposure limits applicable to routine operations. In this case, a planned special exposure may be

Emergency Situations (C) (continued)

Recovering Deceased Victims (3) (continued)

authorized for participating individuals. (See Part II of this handbook.) (c)

Table VI-3 Guidance on Dose Limits for Workers Performing Emergency Services*

Dose Limit (rem)	Activity	Condition
5	All	None
10	Protecting valuable property	Lower dose not practicable
25	Lifesaving or protecting large populations	Lower dose not practicable
>25	Lifesaving or protecting large populations	Only on a voluntary basis to persons fully aware of the risks

*EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," May 1992.
NOTE: "Dose limit" refers to the sum of external effective dose equivalent and committed effective dose equivalent to nonpregnant adults from exposure and intake during an emergency situation. Workers performing services during emergencies should limit the dose to the lens of the eye to three times the listed value and doses to any other organ, including skin and body extremities, to 10 times the listed values.

Dose limits for Planned Special Exposures are specified in 10 CFR 20.1206.

Implementation (D)

Each regional office must establish a plan to implement this guidance for emergency response during rescue and recovery activities. This plan will—

- Designate an individual by position or title who has authority to authorize emergency workers to receive doses in excess of limits specified in this handbook. The regional administrator in each region should be designated as the lead person in charge of emergency action for the region. (1)

- Provide for periodic training, including written examinations, to all appropriate regional personnel on the emergency exposure procedures to be followed during rescue and recovery activities. (2)

Exhibit 1
FORM LETTER FOR DECLARING PREGNANCY[1]

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter or you may write your own letter.

DECLARATION OF PREGNANCY

To: _____

In accordance with the NRC's Management Directive 10.131,"Protection of NRC Employees Against Ionizing Radiation,"[2] I am declaring that I am pregnant. I believe I became pregnant in _____ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that my Radiation Safety Officer will be notified of my pregnancy in order to ensure that the lower dose limit is met, and I understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____
(Your Signature)

_____
(Your Name Printed)

_____
(Date)

---

[1]This form letter is taken from NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," June 1999. It has been adapted for use by NRC employees.

[2]Applying to NRC employees the same dose limits that are applicable to employees of NRC licensees under 10 CFR 20.1208, "Dose Equivalent to an Embryo/Fetus."

Exhibit 2
NRC Form 525, "Request for and Authorization of Release of Dosimetry Records"

NRC FORM 525 (11-91) — U.S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR AND AUTHORIZATION OF RELEASE OF DOSIMETRY RECORDS

REQUEST TO

NAME OF ORGANIZATION	NAME OF FACILITY

ADDRESS

REQUEST FROM

NAME OF NRC EMPLOYEE	SOCIAL SECURITY NUMBER

EXPOSURE RECORD PERIOD

BEGINNING		ENDING	

I request, pursuant to 10 CFR 19.13, that a copy of my exposure records required by 10 CFR 20.401(a) and (c) for the period listed here be provided to:

RADIATION SAFETY OFFICER
MAIL STOP _____
U. S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

SIGNATURE - NRC EMPLOYEE	DATE

NRC FORM 525 (11-91)

Exhibit 2 (continued)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by Section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 525. This information is maintained in a system of records designated as NRC-11 and described at 55 Federal Register 33975 (August 20, 1990).

1. **AUTHORITY:** 42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, and 2201(o) (1988). The authority for soliciting the social security number is Executive Order 9397, dated November 22, 1943.

2. **PRINCIPAL PURPOSE(S):** The information is used by the NRC in its evaluation of the risk of radiation exposure associated with NRC activities and in exercising its statutory responsibility to monitor and regulate the safety and health practices of its employees. The data permits maintaining a complete record of radiation exposure received while performing NRC business. Data on your exposure to radiation is available to you upon your request.

3. **ROUTINE USES:** The information may be used to provide data to other Federal and State agencies involved in monitoring and/or evaluating radiation exposure received by NRC employees employed as radiation workers on a permanent or temporary basis and exposure received by monitored visitors. This information may also be disclosed to an appropriate Federal, State, or local agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** It is voluntary that you furnish the requested information, including social security number; however, the licensee must provide radiation exposure data upon your request as required under 10 CFR 19.13 and in accordance with the requirements imposed under 10 CFR 20.401 to keep records of radiation exposure of all individuals entering a restricted area. Failure to provide the social security number to the licensee may result in the licensee being unable to accurately identify the individual requesting radiation exposure information. The social security number is used to ensure that NRC and the licensee have an accurate identifier not subject to the coincidence of similar names or birthdates among the large number of persons on whom data is maintained.

5. **SYSTEM MANAGER(S) AND ADDRESS:**

   DIRECTOR
   OFFICE OF PERSONNEL
   U. S. NUCLEAR REGULATORY COMMISSION
   WASHINGTON DC 20555

Exhibit 3
Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

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

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

December 2001
Procedural

Exhibit 3 (Continued)

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Exhibit 3 (Continued)

Guidance
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

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

I. INTRODUCTION

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

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

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

II. BACKGROUND

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

1

Exhibit 3 (Continued)

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

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

III. DATA SOURCES

A. Reliance on Data from Chernobyl

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

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

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

Exhibit 3 (Continued)

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

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

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

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

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

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

Exhibit 3 (Continued)

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

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

B. Thyroid Cancers in the Aftermath of Chernobyl

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

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

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

Exhibit 3 (Continued)

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

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

IV. CONCLUSIONS AND RECOMMENDATIONS

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

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

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

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

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

Exhibit 3 (Continued)

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

B. KI Use in Radiation Emergencies: Treatment Recommendations

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

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

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

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

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

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

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

Exhibit 3 (Continued)

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

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

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

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

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Exhibit 3 (Continued)

V. ADDITIONAL CONSIDERATIONS IN PROPHYLAXIS AGAINST THYROID RADIOIODINE EXPOSURE

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

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

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

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

VI. SUMMARY

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

Exhibit 3 (Continued)

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

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

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BIBLIOGRAPHY

Astakhova LN, Anspaugh LR, Beebe GW, Bouville A, Drozdovitch VV, Garber V, Gavrilin YI, Khrouch VT, Kuvshinnikov AV, Kuzmenkov YN, Minenko VP, Moschik KV, Nalivko AS, Robbins J, Shemiakina EV, Shinkarev S, Tochitskaya VI, Waclawiw MA. "Chernobyl-Related Thyroid Cancer in Children in Belarus: A Case-Control Study." *Radiat Res* 1998; 150:349-356.

Baverstock K, Egloff B, Pinchera A, Ruchti C, Dillwyn W. "Thyroid Cancer After Chernobyl" (letter to the editor). *Nature* 1992; 359:21-22.

Becker DV, Robbins J, Beebe GW, Bouville AC, Wachholz BW. "Childhood Thyroid Cancer Following the Chernobyl Accident: A Status Report." *Endocrinol Metab Clin North Am* 1996; 25(1): 197-211.

Bongers-Schokking JJ, Koot HM, Wiersma D, Verkerk PH, de Muinck Keizer-Schrama SMPF. "Influence of timing and dose of thyroid hormone replacement on development in infants with congenital hypothyroidism." *J Pediatrics* 2000; 136(3): 292-297.

Calaciura F, Mendoria G, Distefano M, Castorina S, Fazio T, Motta RM, Sava L, Delange F, Vigneri R. "Childhood IQ Measurements in Infants With Transient Congenital Hypothyroidism." *Clin Endocrinol* 1995;43:473-477.

Davis S, Kopecky KJ, Hamilton T, Amundson B, Myers PA. *Summary Final Report of the Hanford Thyroid Disease Study*. Seattle: Fred Hutchinson Cancer Research Center,1999.

Fisher DA. "The importance of early management in optimizing IQ in infants with congenital hypothyroidism." *J Pediatrics* 2000; 136(3): 273-274.

Gavrilin YI, Khrouch VT, Shinkarev SM, Krysenko NA, Skryabin AM, Bouville A, Anspaugh LR. "Chernobyl Accident: Reconstruction of Thyroid Dose for Inhabitants of the Republic of Belarus." *Health Phys* 1999; 76(2):105-119.

Gilbert ES, Tarone R, Bouville A, Ron E. "Thyroid Cancer Rates and ^{131}I Doses From Nevada Atmospheric Nuclear Bomb Tests." *J Natl Cancer Inst* 1998; 90(21): 1654-60.

Harrison JR, Paile W, Baverstock K. Public Health Implications of Iodine Prophylaxis in Radiological Emergencies. In: "Thomas G, Karaoglou A, Williams ED.", eds. *Radiation and Thyroid Cancer*. Singapore: World Scientific, 1999; 455-463.

IARC- International Agency for Research on Cancer. IARC Monographs non the evaluation of carcinogenic risk to humans. Volume 78- Ionizing radiation, Part 2: Some internally deposited radionuclides. IARC Press, Lyon, France; 2001.

Exhibit 3 (Continued)

Il'in LA, Arkhangel'skaya GV, Konstantinov YO, Likhtarev IA. *Radioactive Iodine in the Problem of Radiation Safety.* Moscow, Atomizdat 1972; 208-229.

Ivanov VK, Gorski AI, Pitkevitch VA, Tsyb AF, Cardis E, Storm H. "Risk of Radiogenic Thyroid Cancer in Russia Following the Chernobyl Accident." In: Thomas G, Karaoglou A, Williams ED., eds. *Radiation and Thyroid Cancer.* Singapore: World Scientific, 1999; 89-96.

Jacob P, Goulko G, Heidenreich WF, Likhtarev I, Kairo I, Tronko ND, Bogdanova TI, Kenigsberg J, Buglova E, Drozdovitch V, Goloneva A, Demidchik EP, Balonov M, Zvonova I, Beral V., "Thyroid Cancer Risk to Children Calculated." *Nature* 1998; 392:31-32.

Kazakov VS, Demidchik EP, Astakhova LN. "Thyroid Cancer After Chernobyl" (letter to the editor). *Nature* 1992; 359:21.

Likhtarev, IA, Shandala NK, Gulko GM, Kairo IA, Chepurny NI, "Ukranian Thyroid Doses After The Chernobyl Accident." *Health Physics* 1993; 64(6):594-599.

Likhtarev IA, Sobolev BG, Kairo IA, Tronko ND, Bogdanova TI, Oleinic VA, Epshtein EV, Beral V. "Thyroid Cancer in the Ukraine." *Nature* 1995; 375:365.

Mettler FH, Becker DV, Walchholz BW, Bouville AC., "Chernobyl: 10 Years Later." *J Nucl Med* 1996; 37:24N-27N.

Nauman J, Wolff J. " Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks." *Am J Med* 1993; 94: 524-532.

Robbins J, Adams WH. "Radiation Effects in the Marshall Islands." In: Nagataki S, ed. *Radiation and the Thyroid. Proceedings of the 27th Annual Meeting of the Japanese Nuclear Medicine Society.* Amsterdam, Excerpta Medica, 1989; 11-24.

Robbins J, Schneider AB. "Thyroid Cancer following Exposure to Radioactive Iodine." *Reviews in Endocrine and Metabolic Disorders* 2000; 1:197-203.

Rubery ED. "Practical Aspects of Prophylactic Stable Iodine Usage." In: Rubery E, Smales E., 416 eds. *Iodine Prophylaxis Following Nuclear Accidents: Proceedings of a Joint WHO/CEC Workshop.* Oxford, Pergamon Press, 1990; 141-150.

Souchkevitch GN, Tsyb AL, eds. *Health Consequences of the Chernobyl Accident: ScientificReport.* World Health Organization, Geneva, 1996; 248-250.

Stepanenko V, Tsyb A, Skvortsov V, Kondrashov A, ShakhtarinV, Hoshi M, Ohtaki M, Matsuura M, Takada J, Endo S. "New Results of Thyroid Retrospective Dosimetry in Russia Following the Chernobyl Accident." In: Thomas G, Karaoglou A, Williams ED., eds. *Radiation and Thyroid Cancer. Singapore: World Scientific,* 1999; 333-339.

Exhibit 3 (Continued)

Stsjazhko VA, Tsyb AF, Tronko ND, Souchkevitch G, Baverstock K. "Childhood Thyroid Cancer Since Accident at Chernobyl." *BMJ* 1995; 310:801.

UNSCEAR. United Nations Scientific Committee on the Effects of Atomic Radiation. Sources, effects and risks of ionizing radiation 2000 Report to the General Assembly, with annexes, New York, N.Y., United Nations; 2000.

Williams ED, Becker D, Dimidchik EP, Nagataki S, Pinchera A, Tronko ND. "Effects on the Thyroid in Populations Exposed to Radiation as a Result of the Chernobyl Accident." In: *One Decade After Chernobyl: Summing up the Consequence of the Accident.* Vienna, International Atomic Energy Agency, 1996; 207-230.

World Health Organization, Geneva, *Guidelines for Iodine Prophylaxis following Nuclear Accidents: Update 1999.*

"Report on the Joint WHO/CEC Workshop on Iodine Prophylaxis following Nuclear Accidents: Rationale for Stable Iodine Prophylaxis." In: Rubery E, Smales E., eds. *Iodine Prophylaxis following Nuclear Accidents: Proceedings of a joint WHO/CEC Workshop.*

Zvonova IA and Balonov MI. "Radioiodine Dosimetry and Prediction of Consequences of Thyroid Exposure of the Russian Population Following the Chernobyl Accident." Pages 71-125 in : The Chernobyl Papers. Doses to the Soviet Population and Early Health Effects Studies. Volume I (S.E. Mervin and M.I. Balonov, eds.). Research Enterprises Inc., Richland, Washington, 1993.

Exhibit 4
Questions and Answers on Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Why would I be offered KI?

As a resident inspector, a regional inspector, or a site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest.

When is KI use recommended?

The U.S. Food and Drug Administration (FDA) is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Predicted Thyroid Radiation Exposures at Which KI Prophylaxis Is Recommended and Recommended Daily Doses of KI[1]

	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	≥ 500	130	1	2
Adults 18-40 yrs	≥ 10			
Pregnant or lactating women[2]	≥ 5			

[1]FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001, which is available at www.fda.gov/cder/guidance/4825fnl.pdf. (See Exhibit 3 of Management Directive (MD) 10.131, "Protection of NRC Employees Against Ionizing Radiation.")

[2]MD 10.131 specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

Exhibit 4 (continued)

In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function ($\geq$ 500 cGy[3]).

FDA recommends that pregnant women be given KI to protect themselves and their fetuses; however, repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

NRC will provide KI to each resident inspector office. In addition, each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who at NRC determines when KI is recommended?

The NRC Regional Administrator, in consultation with the Headquarters Executive Team, will determine when to recommend KI to resident inspectors and site team members. In

[3]1 cGy = 1 rad.

Exhibit 4 (continued)

determining whether to recommend KI, managers will utilize the best available information from licensees and other response organizations to assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a recommendation to use KI, employee requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions, and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation.

You should decline the KI if any of the following statements apply to you:

Exhibit 4 (continued)

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine [for example, you have experienced an adverse reaction after eating seafood, shellfish, or iodized salt; after applying topical iodine (e.g., tincture of iodine, povidone-iodine, betadine, and iodophore solutions) to a cut or injury; or after a medical diagnostic procedure involving the use of iodinated contrast material that you were told was likely a reaction to iodine].
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]

You should use caution in taking KI if you have any of the following conditions, especially if dosing extends beyond a few days:

1. You have multinodular goiter.
2. You have Graves' disease.
3. You have autoimmune thyroiditis.

[4]Extremely rare conditions associated with an increased risk of iodine hypersensitivity.