FDA RADIOLOGICAL EMERGENCY RESPONSE PLAN SUMMARY

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U.S. FOOD AND DRUG ADMINISTRATION
RADIOLOGICAL EMERGENCY RESPONSE PLAN

I. INTRODUCTION

Unexpected emergencies involving radiation or radioactive materials have the potential to cause adverse health effects for large segments of the population and animals, either through direct exposure or indirectly through consumption of or contact with radiation sources or radioactively contaminated products. To mitigate the consequences of such exposure, the Food and Drug Administration (FDA) must prepare to respond to these emergencies and provide the necessary resources to address the myriad of health issues that could arise.

I.A MISSION

The mission of the FDA is to—

- Protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- Advance the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable.
- Help the public get accurate, science-based information needed to use medicines and foods to improve health.

I.B PURPOSE

The purpose of the *FDA Radiological Emergency Response Plan* is to provide a coordinated response to radiological emergencies involving FDA-regulated products. To accomplish this, the plan—

- Describes the essential steps to take in response to any emergency related to radiation (i.e., accidental, deliberate, or threat of such occurrence).
- Defines procedures for the use of FDA resources to augment and support local and state governments and other federal agencies.
- Describes specific actions FDA components and personnel take when responding to radiological emergencies.
- Enhances the Agency's emergency preparedness and response capabilities.

I.C SCOPE

This plan applies to radiological events, both accidental and intentional (terrorism), for which the FDA provides assistance under Emergency Support Function (ESF) #8 of the Federal Response Plan (FRP), the Federal Radiological Emergency Response Plan (FRERP), or under its own authority under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended. This plan does not address long-term response or recovery.

For the purpose of this plan, radiological events include acts of terrorism and sabotage, accidental or intentional acts affecting fixed nuclear facilities (e.g., nuclear power plants, nuclear fuel cycle facilities, and research facilities), emergencies at medical and/or industrial facilities, international events with worldwide impact (e.g., Chernobyl), nuclear-powered satellite re-entry, and transportation of radioactive materials (e.g., military shipments). This plan also addresses accidents resulting from radiation-emitting medical and electronic devices.

The *FDA Radiological Emergency Response Plan* guides FDA personnel and provides top government officials outside the FDA with a comprehensive resource explaining FDA emergency responsibilities and procedures during a potential or actual radiological emergency. Subsequent to a suspected or confirmed radiological threat or emergency, the FDA Headquarters and Regional/District staff follow these response procedures.

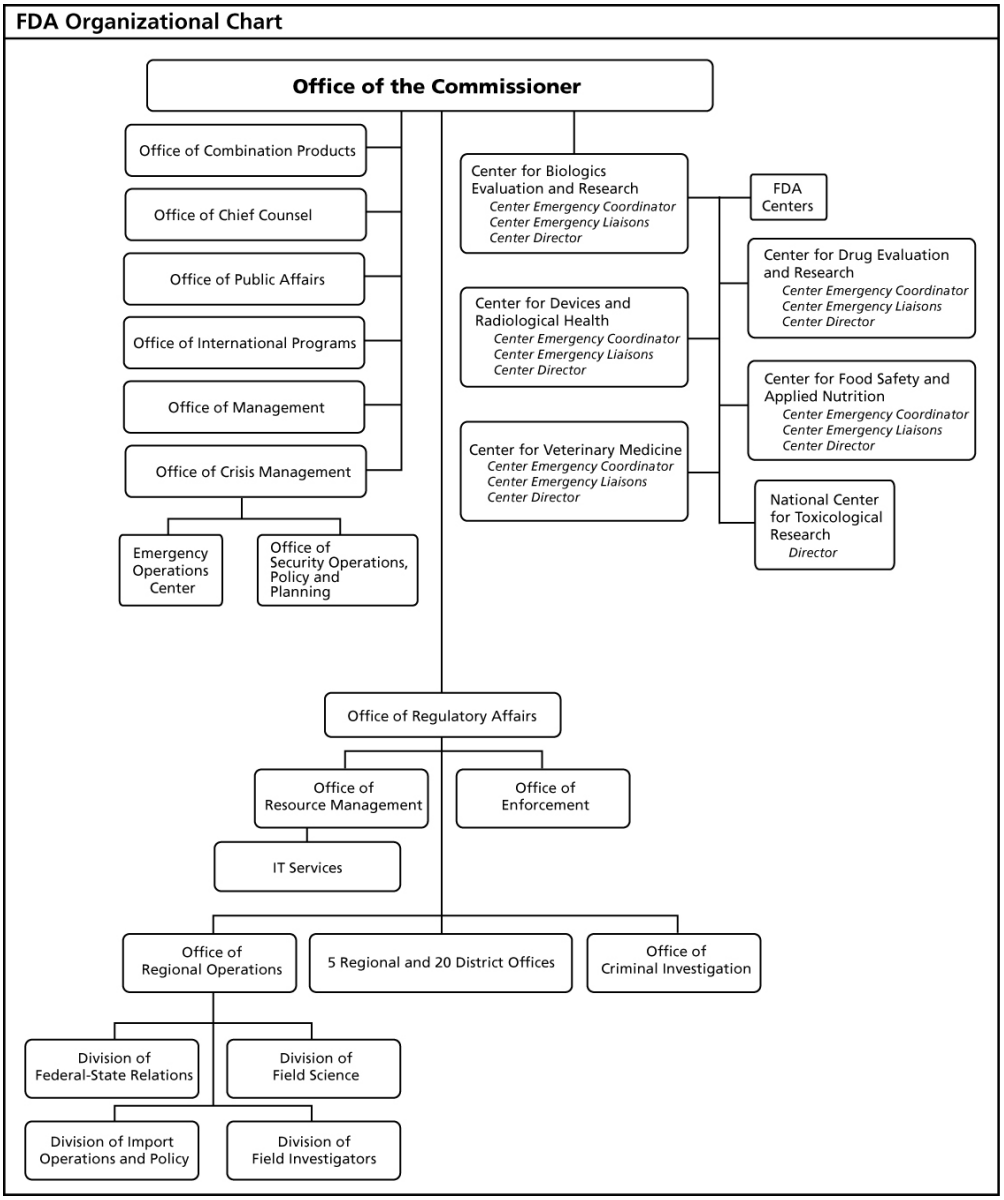
II. PLANNING ASSUMPTIONS

- A radiological emergency may overwhelm the capabilities of a state and its local governments, requiring the FDA and other federal agencies to assist the state in meeting the needs of the emergency situation. Local resources perform the urgent emergency response for the first 24 to 48 hours with requested federal help arriving thereafter. FDA assets supplement the local response, as needed, when the emergency involves an FDA-regulated product or requires the use of medical countermeasures involving FDA-approved products or investigational products (investigational new drug [IND], investigational new animal drug [INAD], or investigational device exemption [IDE]).
- Radiological emergencies involving FDA-regulated products require an immediate response by the FDA. Protection of the affected or potentially affected population is the highest priority during response operations.
- Contamination of critical facilities and large geographic areas may result. The release may affect other countries requiring extensive coordination with local, state, and foreign governments, in conjunction with other federal agencies.
- Unannounced and unrecognized releases of radiological material will be more severe than announced releases that allow the population to prepare. In addition, contaminants transmitted via FDA-regulated products may show wide dispersal affecting both humans and animals.

III. RESPONSIBILITIES AND ORGANIZATION

Section III identifies the roles and responsibilities of FDA Centers and Offices responding to a radiological emergency. FDA Centers and Offices work closely with the Office of the Commissioner and with industry and government partners to ensure the safety and efficacy of products for human use that prevent, diagnose, and treat the public health effects of a radiological emergency in the United States or worldwide using novel and expeditious approaches to product regulation for optimized availability and use in all populations. Note that in many emergencies, issues might arise that involve more than one Center or Office. A brief description of each Center or Office listed in Figure III-1 follows.

Figure III-1. FDA Organizational Chart



III.A OFFICE OF THE COMMISSIONER

A number of the Office of the Commissioner (OC) offices play a significant role in supporting the response to a radiological emergency, such as the Office of Crisis Management, the Office of International Programs, and the Office of Public Affairs. In addition, other OC offices, such as the Office of Combination Products, the Office of Chief Counsel, and the Office of Management/Office of Shared Services, can provide valuable assistance during the FDA's response to a radiological emergency.

III.A.1 Office of Combination Products

The Office of Combination Products (OCP) assigns an FDA Center to have primary jurisdiction for review of combination products (drug-device, drug-biologic, and device-biologic products). OCP works with FDA Centers to develop guidance to clarify the regulation of combination products and serves as a focal point for combination product issues, within and outside the FDA. If a radiological emergency involves a combination product, OCP can assist in coordinating emergency responses from each Center with jurisdiction of a given combination product.

III.A.2 Office of Chief Counsel

The Office of Chief Counsel (OCC) provides legal services involving the Agency's regulatory activities. FDA lawyers support the Agency's public health and consumer protection missions in two primary ways: handling litigation and providing counseling advice.

III.A.3 Office of Public Affairs

The Office of Public Affairs (OPA) serves as the FDA's primary liaison with the news media and develops much of the material the FDA uses to communicate its public health and consumer protection messages to the public. OPA issues press releases, talk papers, and other public statements; responds to media requests; and arranges and supports media interviews. For example, OPA can coordinate with FDA Centers to rapidly provide consumer education materials explaining steps consumers can take to protect themselves after a radiological emergency.

III.A.4 Office of International Programs

The Office of International Programs (OIP) is responsible for communicating appropriate emergency-related information with foreign governments and organizations, such as the World Health Organization (WHO). OIP also receives information and requests for information from foreign governments.

III.A.5 Office of Management/Office of Shared Services

The Office of Management (OM)/Office of Shared Services (OSS) has the capability to provide information technology (IT) support to the FDA Centers and Offices during a radiological emergency.

III.A.6 Office of Crisis Management

The Office of Crisis Management (OCM) consists of the OCM Director (and staff); FDA EOC staff; and Office of Security Operations, Policy, and Planning (OSOPP) staff. OCM is responsible for developing crisis management policies and managing Agency emergencies when they occur. OCM's responsibilities include coordination of FDA participation in internal and external counter-terrorism (CT) and emergency exercises; planning, developing, and directing all activities relating to the Agency's physical and personnel security program; coordinating Agency evaluation of radiological emergencies to determine response actions; and coordinating intra-agency and interagency preparedness and response activities.

III.A.6.a Emergency Operations Center

The FDA Emergency Operations Center (EOC), a branch of the OCM, is the single point of coordination for the FDA's response to any radiological emergency. The FDA EOC is the physical facility that serves as the central point for the Agency's response activity. During a radiological emergency, the FDA EOC will coordinate and report on all response activity and interagency communication. The FDA EOC monitors accidental and intentional radiological emergencies; triages complaints and alerts; issues assignments to the field; coordinates responses; and communicates with other federal, state, and local agencies as they request technical and material support from the FDA.

The FDA EOC maintains contact with the Department of Health and Human Services (HHS) Secretary's Command Center (SCC), Centers for Disease Control and Prevention (CDC) EOC, United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) Office of Food Security and Emergency Preparedness, and other EOCs, as appropriate. The FDA EOC will continue to direct and monitor all FDA response activities throughout the life cycle of an emergency.

III.A.6.b Office of Security Operations, Policy, and Planning

The Office of Security Operations, Policy, and Planning (OSOPP) will enhance the FDA’s emergency response to a radiological emergency. OSOPP may, for example, verify security clearances for FDA liaisons responding to EOCs at other government agencies, at the FDA EOC, or at the Joint Operations Center (JOC) located near the site of a radiological emergency, as OSOPP maintains a list of all cleared FDA personnel and processes security clearances. OSOPP can also assist with providing guidance on the proper handling, marking, processing, and storage of classified materials.

III.B OFFICE OF REGULATORY AFFAIRS

The Office of Regulatory Affairs (ORA), which the Associate Commissioner for Regulatory Affairs (ACRA) leads, serves as the focal point for all FDA Field Offices and four Headquarters offices: Office of Regional Operations, Office of Criminal Investigation, Office of Resource Management, and Office of Enforcement, as well as five Regional and 20 District Offices. In addition, ORA maintains a database of FDA-regulated establishments. The database enables the FDA to rapidly identify affected establishments.

III.B.1 Office of Resource Management

Within the Office of Resource Management (ORM), the Division of Planning, Evaluation, and Management (DPEM) generates a field workforce work plan every fiscal year. The field workforce work plan adjusts as required in the event that emergencies arise. The field workforce, via the ACRA, is able to divert resources in response to an emergency. DPEM is also responsible for generating after action reports (AAR) pertaining to resources used in emergency response. NOTE: Evaluation of resources used to respond to any emergency is possible via the FDA Field Accomplishments and Compliance Tracking System (FACTS). Predefined Program Assignment Codes exist in the reporting system that enable DPEM to track accomplishments and resources expended during a brief or extended response period.

III.B.2 Office of Enforcement

The Office of Enforcement (OE) handles enforcement actions against individuals and companies that violate the FFDCA. When appropriate, OE monitors the extent of product removal. OE notifies the Department of Defense (DoD) Defense Supply Center of any food contamination situation.

III.B.3 Office of Regional Operations

The Office of Regional Operations (ORO) Headquarters consists of four divisions:

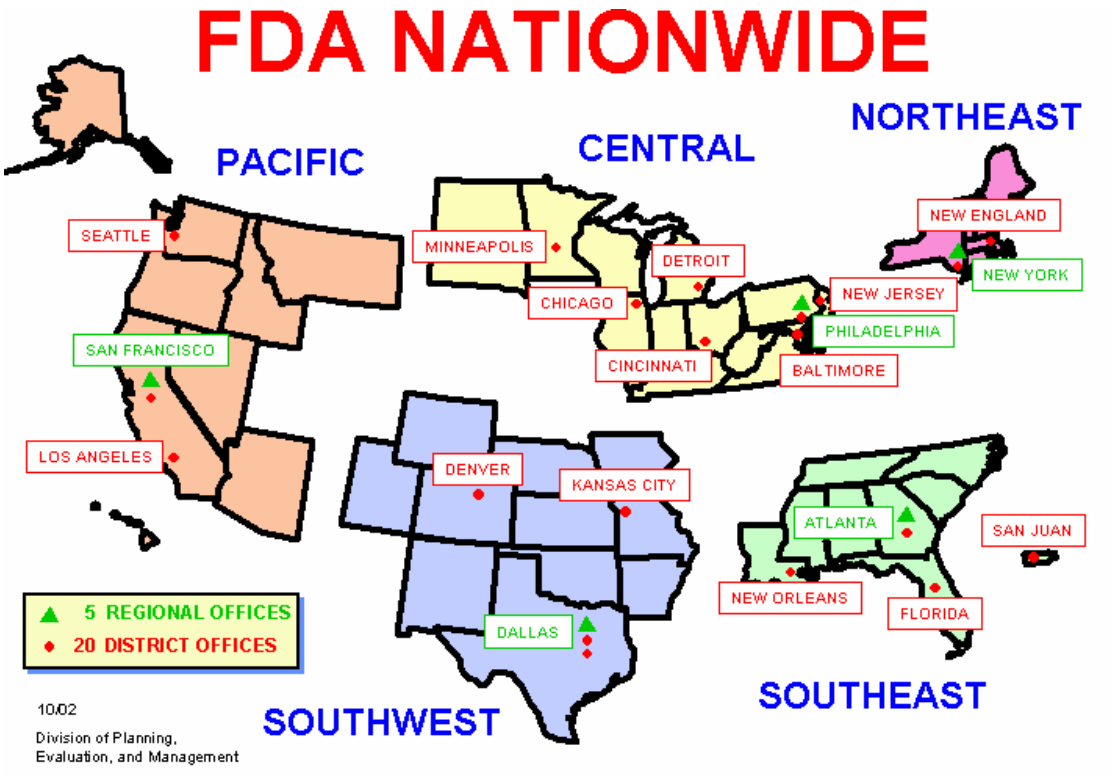
- The Division of Federal-State Relations (DFSR) maintains the FDA's rapid communication system to state governments, major municipalities, and poison control centers during an emergency.
- The Division of Field Science (DFS) prepares the ORA laboratory response and monitors surveillance databases.
- The Division of Import Operations and Policy (DIOP) monitors and controls import and export activity associated with implicated product, countries, foreign manufacturers and shippers, filers, importers, and/or consignees. DIOP can also coordinate targeted surveillance of imported products with the U.S. Bureau of Customs and Border Protection (CBP).
- The Division of Field Investigations (DFI) provides guidance and assistance in coordinating emergency field investigations.

Working together with the field, these divisions handle the FDA's day-to-day field operations at 5 regional offices, 20 district offices, and more than 165 resident posts.

III.B.4 Regional and District Offices

The 5 Regional and 20 District Offices develop and maintain cooperative relationships with state, local, and other federal agencies in support of coordinated emergency response activities. The Regional and District Offices work with these other agencies to verify product information and secure the suspect product. They obtain additional information by reviewing records and examining products to focus follow-up actions. Field investigators may collect samples for laboratory analysis; detain, seize, and/or embargo product in support of public health protection and state and local government; request state officials to hold suspect product; issue requests for voluntary holds or suspension of operations of industry; request and monitor industry recalls; conduct necessary inspections, detentions, and sampling of domestic and imported products; and conduct traceback investigation work. Figure III-2 illustrates the FDA across the nation.

Figure III-2. FDA Nationwide



III.B.5 Office of Criminal Investigation

The Office of Criminal Investigation (OCI) has special agents at Headquarters and in offices nationwide. OCI is responsible for the criminal casework of the FDA, including serving as the FDA partner and liaison to law enforcement and intelligence agencies. OCI works closely with the Federal Bureau of Investigation (FBI) during the investigative process. Any deliberate contamination of an FDA-regulated product is a criminal act under Title 18 of the United States Code (USC), Section 1365 (tampering with consumer product). OCI derives the authority to investigate violations of 18 USC 1365 from Title 18.

III.C FOOD AND DRUG ADMINISTRATION CENTERS

The FDA product centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should a radiological emergency occur. The National Center for Toxicological Research (NCTR) primarily conducts regulatory and applied research based on agency needs.

Centers are responsible for scientific evaluations and policy decisions (in cooperation with the FDA EOC and the ACRA) in their respective program areas. FDA product centers participate in an emergency response when the response includes, or may include, regulatory activities or products under their jurisdiction.

III.C.1 Center for Biologics Evaluation and Research

The Center for Biologics Evaluation and Research (CBER) ensures the safety, efficacy, and quality of biological products potentially threatened by a radiological or nuclear emergency. The Center's product countermeasure activities include the following:

- Providing sponsors and other stakeholders with guidance on the development of biologic products as medical countermeasures.
- Ensuring the safety of the blood and tissue supplies, including donor suitability, processing of blood and blood products, and other tissue and donor issues.
- Assessing the availability and production capacity of blood and tissue providers for products used as countermeasures in radiological health medicine.
- Collaborating with HHS and CDC regarding product stockpile issues, including labeling of product for appropriate usage and other evolving issues.
- Providing information regarding manufacturers' compliance with good manufacturing practices (GMP) and other relevant product quality issues, including guidance on stability protocols to evaluate whether a manufacturer can extend an expiration date.

- Assisting in the assessment of biological products potentially contaminated by a radiological or nuclear emergency.

III.C.2 Center for Drug Evaluation and Research

The Center for Drug Evaluation and Research (CDER) ensures the safety, efficacy, and quality of drugs and biological therapeutics with use as countermeasures in response to a radiological emergency. Drugs with potential for use in this area currently include radioprotectants (e.g., agents such as free radical scavengers), radiation mitigators (e.g., agents such as cytokines and stem cell factors), radionuclide eliminators (e.g., Prussian Blue, Calcium and Zinc Diethylenetriamine Pentaacetic Acid [DTPA]), and radiation blocking agents (e.g., Potassium Iodide [KI]). CDER's product countermeasure activities include the following:

- Providing sponsors and other stakeholders with guidance on the development of drug and therapeutic biologic agents as medical countermeasures.
- Collaborating with public health agencies (e.g., CDC and HHS) regarding product stockpile issues, including labeling, appropriate usage, product performance, monitoring and use in special populations, and other evolving issues.
- Providing regulatory guidance on the use of medical countermeasures when either the drug product or proposed indication is not an FDA-approved product or indication.
- Providing information regarding manufacturers' compliance with GMP and other relevant product quality issues, including shelf life extension guidance.
- Providing advice in the assessment of drug and therapeutic biologic product involving a radiological contaminant.
- Assessing the availability, production capacity, and surge capacity of drug and therapeutic biologic products used as countermeasures in radiological health medicine, and providing information on alternative sources of critical medical countermeasures in shortage situations.
- Collaborating with other government agencies (e.g., Armed Forces Radiobiology Research Institute [AFRRI] and the National Cancer Institute [NCI]) to develop animal models in determining the efficacy of radiation countermeasures (e.g., animal efficacy rule).

III.C.3 Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) ensures the safety, efficacy, and quality of medical devices and the safety and quality of radiological products potentially threatened by, or employed during, a radiological emergency. CDRH also collaborates with other federal agencies, states, industry, and trade organizations in the planning, preparedness, and response to radiological emergencies. To accomplish this, the Center:

- Regulates radiation-emitting products and medical devices.
- Evaluates the capabilities of instruments for diagnostic radiology and security screening using machine-produced radiation.
- Collaborates with federal agencies and the states on radiation policies, standards, and test methods (e.g., Conference of Radiation Control Program Directors, Inc. [CRCPD] committees and Interagency Steering Committee on Radiation Standards [ISCORS]).
- Coordinates with regulated industry and trade associations to facilitate the availability of medical devices in the event of shortages during an emergency.
- Provides technical liaisons to other federal and international agencies with radiation responsibilities through participation in working groups and committees.
- Provides representation on the Federal Radiological Preparedness Coordinating Committee (FRPCC) as an alternate to the CDC for HHS.
- Participates in FRPCC training, exercises, and response planning for radiological accidents and participates in actual emergencies as they occur.
- Provides health physics support to other FDA centers, the FDA EOC, the Regional Radiological Health Representatives (RRHR), and external agencies for emergencies involving radiological contamination of Agency-regulated products.
- Coordinates the Radiation Emergency Preparedness Compliance Program for field participation (through RRHRs) in state exercises and training.
- Participates in investigations of specific cases of over-exposure to radiation (e.g., with the Nuclear Regulatory Commission [NRC] on radiation therapy misadministrations).

III.C.4 Center for Food Safety and Applied Nutrition

The Center for Food Safety and Applied Nutrition (CFSAN), in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and labeled properly. CFSAN has the authority to regulate food producers and distributors involved in interstate commerce and to issue recommendations and guidelines on acceptable levels of radioactive contamination in food. CFSAN also determines whether data collected by another agency or organization (e.g., Federal Radiological Monitoring and Assessment Center [FRMAC]) are adequate for FDA decisions in an emergency.

III.C.5 Center for Veterinary Medicine

The Center for Veterinary Medicine (CVM) ensures the safety, efficacy, and quality of drugs used in animals, including food-producing and companion animals, animal food and feed, and medical devices used on animals potentially threatened by a radiological emergency. The Center's product countermeasure activities include the following:

- Providing sponsors and other stakeholders with guidance on the development of animal drugs with potential as medical countermeasures.
- Collaborating with public health agencies (e.g., CDC, HHS, and USDA) regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry involving radiological contamination.
- Providing information regarding manufacturers' compliance with GMP and other relevant animal drug product quality issues.
- Providing advice in the assessment of animal drug or feed product involving radiological contamination.
- Providing an assessment on the diversion of radiologically contaminated human food for animal feed use.
- Providing advice to pet owners regarding animal safety measures.

III.C.6 National Center for Toxicological Research

The National Center for Toxicological Research (NCTR) conducts scientific research to support and anticipate the FDA's current and future regulatory needs. This research includes fundamental and applied research on biological mechanisms of action underlying the toxicity of regulated products that could have utility in responding to radiological emergencies. Center activities with potential for use in CT include the ability to respond with innovative techniques in identifying agents and providing consultative expertise and information.

IV. OPERATING PROCEDURES

IV.A OPERATING PROCEDURE—NOTIFICATION

IV.A.1 Information Flow into the FDA EOC

The FDA EOC may receive notification of a radiological emergency through a variety of means, including from FDA Headquarters, CDC, FBI, USDA, FDA District Offices, FDA Centers, other federal and state agencies, consumers, and other sources outside the FDA, such as through monitoring of the media.

The FDA EOC expects immediate notification of any actual or potential radiological emergency via phone (primary notification method) with a secondary notification by fax or e-mail referencing the initial notification. An FDA EOC Emergency Coordinator will record all information about the initial call and subsequent follow-up information.

Report any actual or potential radiological incident promptly by phone to the FDA EOC with follow-up by fax or e-mail referencing the initial notification. Figure IV-1 lists FDA EOC contact information.

Figure IV-1. Contacting the FDA EOC

FDA Emergency Operations
5600 Fishers Lane
Room 12A-55, HFA-615
Rockville, MD 20857
301-443-1240 (24-hour line)
301-827-3333 (Main fax)

The FDA's EOC serves as the Agency's focal point for all emergency response activities 7 days a week, 24 hours a day. After regular duty hours (8:00 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays), and when the FDA EOC is not operating, an answering service refers all emergency calls via pager to the EOC Late Duty Officer. The Late Duty Officer follows guidelines set forth in the *EOC Procedures Manual*, including notification procedures.

If the FDA EOC receives information regarding a radiological emergency or threat, the FDA EOC transmits such information to the HHS SCC, appropriate FDA Centers, District Office(s) involved, and the FDA OCI. OCI notifies the FBI and/or local law enforcement officials, if required. Notification of state officials occurs at the direction of the FDA EOC or OCI via the DFSR.

Table IV-1. Notification Listing For a Radiological Emergency

Office	Personnel/Designate
Office of the Commissioner	Associate Deputy Commissioner
Office of Regional Operations	Deputy Director/Director
Office of Regulatory Affairs	Associate Commissioner
HHS SCC	Duty Officer
Centers for Disease Control and Prevention	EOC
Office of Criminal Investigation	Deputy Director/Director
U.S. Bureau of Customs and Border Protection	Other Government Agency Liaison
Department of Defense	VSA Deputy Director
Center for Food Safety and Applied Nutrition	Director, Emergency Response and Coordination Staff
Center for Devices and Radiological Health	Center Emergency Coordinator
Center for Drug Evaluation and Research	Center Emergency Coordinator
Center for Biologics Evaluation and Research	Center Emergency Coordinator
Center for Veterinary Medicine	Center Emergency Coordinator
Office of Enforcement	Deputy Director
Office of Public Affairs	Associate Commissioner
Appropriate Field Offices	
Division of Federal-State Relations	Director, DFSR
Division of Import Operations and Policy	Director, DIOP
Division of Field Science	Director, DFS
Division of Field Investigations	Director, DFI
Office of Chief Counsel	Chief Counsel
Office of International Programs	Director, International Relations Staff
Office of Legislative Affairs	Associate Commissioner
USDA/Animal Plant Health and Inspection Service	EOC
USDA/Food Safety and Inspection Service	Office of Public Health and Science
Trade and Industry Associations	Contacted by respective Centers

IV.A.2 Risk Assessment/Situation Analysis

The FDA supports the Lead Federal Agency (LFA) and/or FBI in performing a risk assessment/situational analysis for radiological emergency impact on FDA-regulated products. The LFA (e.g., NRC, Environmental Protection Agency [EPA], or DoD) is usually the agency that owns or regulates the source of radiation. For a terrorist emergency, the Department of Homeland Security (DHS) coordinates an independent criminal investigation and the FBI conducts the investigation. Working with DHS, FBI, and other involved agencies, the FDA helps determine the nature of a threat, the risk posed by the threat, and the appropriate actions and response measures to eliminate or mitigate the threat.

The following situation requires the FDA to support risk analysis and situational assessment for a radiological threat:

- Receipt of intelligence indicating that an FDA-regulated product is the target of a radiological threat, or a radiological threat affected by an FDA-regulated product. The FDA supports the FBI threat credibility assessment by helping determine the technical feasibility of the threat and operational viability of the threat. Determination of a credible threat may result in the activation of the FDA EOC. The FDA also supports analysis of measures to prevent or mitigate the threat.

After a radiological emergency occurs, state and local agencies normally provide the first on-scene responders to the emergency site. State and local agencies assess the severity of the emergency and determine necessary resources to support emergency operations. When the emergency exceeds available state resources, a state can request supplemental resources from the federal government to augment state resources.

The LFA in Washington, DC, directs federal activities to support affected states through an EOC (the LFA EOC) and may decide to deploy a response team and/or lead official in proximity to the site of a radiological emergency, based on its assessment of the developing situation. The LFA may request supporting federal agencies, such as HHS, to send liaisons to the LFA EOC or to support the LFA near the emergency site.

The following situations require the FDA to support risk analysis and situational assessment for radiological emergencies:

- The occurrence of deliberate or accidental contamination of an FDA-regulated product (presumptive emergency). The FDA supports efforts to confirm the occurrence of contamination, determine the impact of the suspected contamination, and identify appropriate response measures to mitigate the impacts of the contamination. A presumptive emergency may result in the activation of the FDA EOC.
- The confirmation of deliberate or accidental contamination of an FDA-regulated product. The FDA assists in determining the impact of the contamination and

identifies appropriate response measures to mitigate that impact. A confirmed emergency may result in the activation of the FDA EOC.

The LFA normally requests the FRMAC and the Advisory Team for Environment, Food, and Health (A-Team). The FRMAC provides state, local, and federal agencies with radiological measurement data for their use in analyzing the situation and conducting risk assessments. The FRMAC generates plume and ground dispersion maps from land- and air-based radiological measurements, coupled with meteorological data. Modeling provides preliminary information for decision-making until measurement results are available. The FDA may provide analytical assistance to the FRMAC, as required. The A-Team encompasses liaisons from the EPA, USDA, CDC, FDA, and other federal agencies. The A-Team continuously assesses the situation and provides advice, such as protective action recommendations (PAR) for states, local governments, and the LFA.

In addition to its support role for the LFA, the FDA conducts risk assessments and independently verifies whether food is safe outside potentially contaminated areas. FDA threat analysis also consists of assessments of impact of potential radiological contamination on manufacturers or producers of blood, blood products, tissues, animal feed, human and animal biologics and drugs, and devices. The FDA has analytical facilities and maintains the radiological component of the Food Emergency Response Network (FERN) through its Winchester Engineering and Analytical Center (WEAC). The FDA coordinates sample collection and analysis efforts with those of the FRMAC.

IV.B OPERATING PROCEDURE—ACTIVATION

IV.B.1 Activation of the FDA EOC

The FDA EOC Director and/or the FDA EOC team leaders receive briefings on reports of an alert or emergency, such as the following: national emergency; natural disaster; manmade disaster; injury and illness complaints, including reports of tampering; epidemiological investigations; and emergency preparedness exercises involving radiological emergencies. The FDA EOC's response to this notification may include partial or full activation of the FDA EOC. The authority to activate the FDA EOC resides with the FDA EOC Director. The OCM Director may also order the activation of the EOC. The ACRA, the Commissioner, and/or the Secretary of HHS may also request the activation of the FDA EOC.

In addition, the FDA EOC may activate when one or more of the following occurs:

- DHS announces Red, "severe threat level," for a potential terrorist attack.
- DHS announces Orange, "high threat level," based on intelligence that an attack may target the food and agriculture sector.
- The FDA receives intelligence information that an FDA-regulated product is the target of a credible threat or actual radiological emergency.

- An illness or injury emergency covers a large geographic or population area (more than one state), requiring the coordination of multiple districts, Centers, and/or agencies.
- Deliberate or accidental contamination of an FDA-regulated product causes illness, injury, or death to consumers.
- The President, or his designee, activates the FRP and FDA resources are requested. NOTE: The Initial National Response Plan (INRP) is still a living document in draft form. Once finalized, this document will fully replace the FRP.

Activation requires the FDA EOC Director to formally announce the activation of the FDA EOC and notify appropriate Centers/Offices and the HHS SCC. This activation announcement may include a status report explaining the decision to activate and a description of operating hours and staffing level (see Figure IV-2 below). In determining operating hours and staffing levels for the FDA EOC, the FDA EOC Director will follow these general guidelines to respond to an actual/potential national emergency, disaster, or exercise (NOTE: Centers/Offices should develop additional specific guidance for their staff on appropriate staffing levels as required):

- Category 4:
  - There is a need for FDA-wide coordination that may require FDA EOC staffing of 12- or 24-hours a day, 7 days a week (or until resolution of the emergency).
  - There are mass casualties/fatalities, or there is the potential for such.
  - Examples include acts of terrorism, natural emergencies, nuclear attacks, or terrorism exercises.
- Category 3:
  - There may be a need for FDA-wide coordination that requires full day coverage (7:00 a.m.–11:00 p.m.) with limited night coverage (11:00 p.m.–7:00 a.m.) in the FDA EOC.
  - The emergency is life threatening with the potential for additional population exposure.
  - The emergency involves a large sector of the population and/or multiple FDA-regulated products.
  - Examples include tampering, some natural emergencies, or emergencies with the potential for adverse event recurrence.
- Category 2:
  - There may be a need for limited Center and Office participation that requires regular working day coverage in the FDA EOC.

- The emergency is moderate to high risk and involves a limited number of patients or FDA-regulated products.
- An example includes the potential for deaths or serious injuries, possibly resulting from a product malfunction or multi-state foodborne illness outbreak.

- Category 1:
  - There may be a need for coordination with only a single FDA Office or Center for regular working day coverage in the FDA EOC.
  - The emergency is negligible to low risk.
  - The emergency involves an isolated or very contained incident, single manufacturer, or limited manufacturing lot or date.
  - Examples include contaminated alcohol prep swabs or mouthwash.

Figure IV-2. Activation/Deactivation Checklist

Activation

- Determine operating level and shifts needed:
  - Category 4 Category 3 Category 2 Category 1
- Prepare notice of activation (Example: The FDA EOC activated on [date] beginning at [time]. This activation is due to [emergency].).
- Issue notice of activation.
- Notify EOC staff to report to the EOC.
- Notify ORA IT for necessary support.

Deactivation

- Prepare notice of deactivation (Example: The FDA EOC is returning to normal operations effective on [date and time]. Please provide Lessons Learned Report Input to the Planning Section no later than [date and time].)
- Issue notice of deactivation.
- Collect documents applicable to the emergency response and submit them to the Planning Section for archiving, as required.

After the activation procedures commence, the FDA EOC requests additional resources necessary to support the FDA EOC. The FDA EOC requests a technical support representative from ORA IT to work in the FDA EOC during the initial FDA EOC activation and to remain on call for the duration of the FDA EOC activation if operating on a 24-hour shift. The FDA EOC also alerts ORM of the potential need for additional administrative support personnel, such as secretaries.

When activation occurs and 24-hour operations commence, the FDA staffs the EOC for either two or three shifts. NOTE: The FDA EOC maintains a reserve roster of the FDA staff from Headquarters Offices with pre-training to work in the FDA EOC for additional staffing support during 24/7 FDA EOC operations.

IV.B.2 Additional Notifications

The FDA EOC, working with the appropriate Center Emergency Coordinators (CEC), coordinates the response to a radiological emergency affecting an FDA-regulated product. The FDA EOC has primary responsibility for coordinating with other FDA entities (Centers and ORA) to ensure necessary investigations and actions are occurring in response to a radiological emergency. The FDA EOC prepares periodic updates or status reports on investigations and actions for the participating districts, FDA Headquarters units, and other agencies as appropriate. The FDA EOC coordinates information concerning emergencies with Headquarters offices of other federal agencies.

The FDA EOC notifies OIP of the following:

- Radiological emergencies originating from foreign sources.
- Radiological emergencies originating in the United States with the potential to impact other countries.

The FDA EOC notifies OPA of the following:

- All radiological emergencies so that OPA can monitor ongoing or imminent press coverage and begin to prepare public educational materials for FDA statements to respond to inquiries.

The FDA EOC provides DFSR with the following:

- Copies of any press releases issued.

The FDA EOC notifies DIOP of the following:

- Radiological emergencies originating from foreign sources. The FDA EOC also provides DIOP with any traceback information derived from the FDA EOC Emergency Coordinator or Late Duty Officer's initial report.

IV.B.3 Mobilization and Deployment of FDA Resources

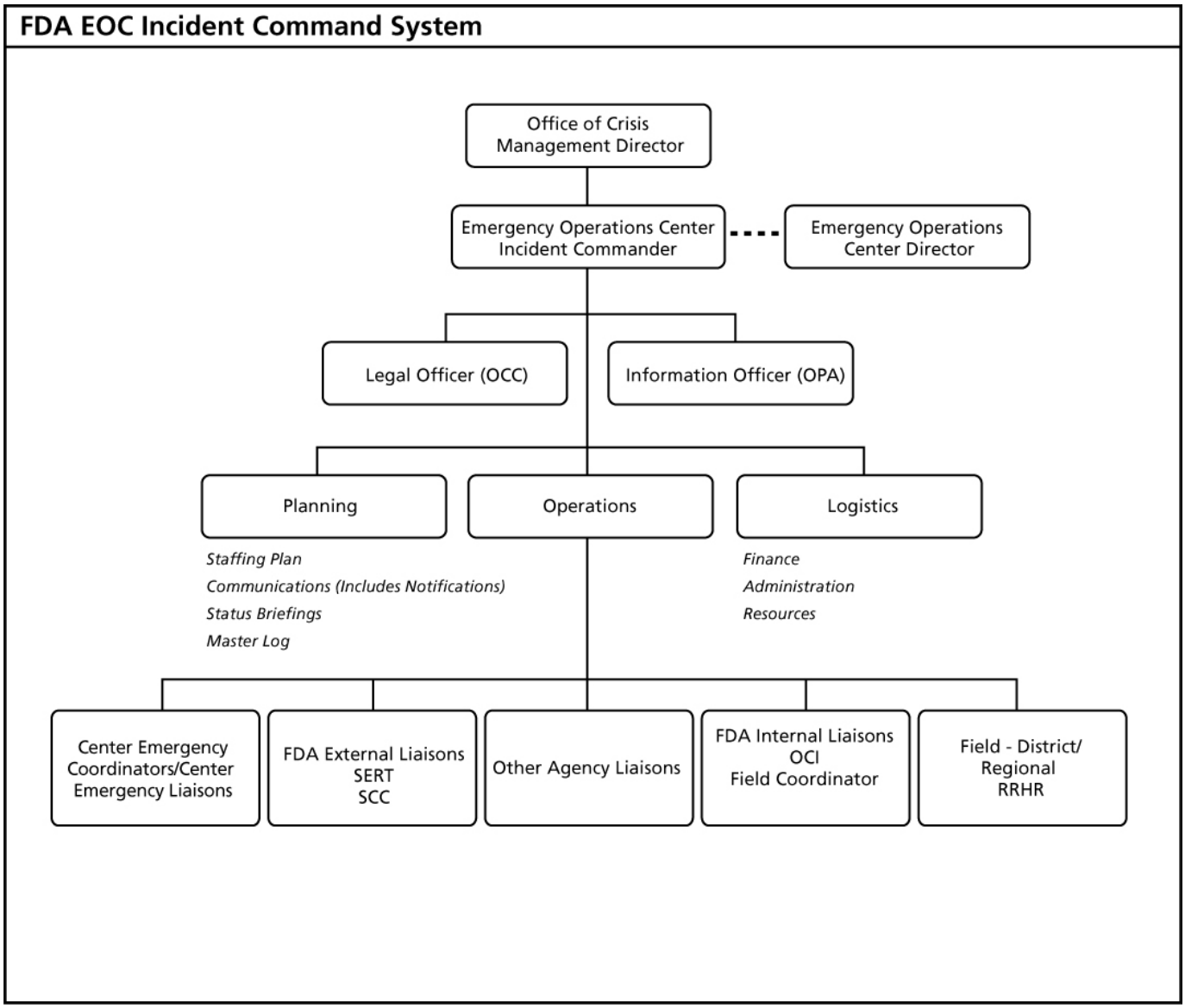
The FDA EOC assesses resource requirements on an ongoing basis during a radiological emergency. The FDA EOC works with HHS and/or the HHS Secretary's Emergency Response Team (SERT) to coordinate the provision of required resources. The FDA EOC distributes mobilization and deployment timelines. If requested, HHS and/or the HHS SERT support the FDA in fulfilling or meeting its deployment requirements.

IV.C OPERATING PROCEDURE—RESPONSE OPERATIONS

IV.C.1 Introduction

The FDA conducts response operations under the Incident Command System (ICS). The command function and subordinate functions of planning, operations, and logistics act as the foundation of the ICS (finance and administrative functions fall under logistics in the FDA EOC ICS structure). The design of the system enables the rapid expansion of support to emergency operations. The FDA EOC follows the ICS, illustrated in Figure IV-3.

Figure IV-3. FDA EOC Incident Command System



IV.C.2 Overview of ICS Positions

IV.C.2.a Office of Crisis Management Director

The OCM Director provides strategic leadership and guidance for the FDA EOC's response to a radiological emergency. The OCM Director coordinates with the FDA EOC Director to ensure the FDA EOC is fulfilling its role in the response. The OCM Director is the FDA EOC's point of contact for communicating with the FDA OC.

IV.C.2.b FDA EOC Incident Commander

During the response to an emergency, the Incident Commander (IC) for the FDA EOC for that response serves as the leader for the FDA EOC. The FDA EOC IC coordinates the dissemination of information to the FDA EOC staff responding to the radiological emergency. The FDA EOC IC ensures information review for appropriate action, including referral to the field for any necessary follow-up. In addition, the FDA EOC IC is the coordination point for consultation regarding command and operations decisions involving appropriate agency, departmental, and interagency issues. The OCM Director may select the FDA EOC IC for each particular emergency from an appropriate Center or Office senior manager and may consult with Center and Office Directors in making that decision.

IV.C.2.c FDA EOC Director

The FDA EOC Director directs the daily functions for the FDA EOC. The FDA EOC Director may also serve as the FDA EOC IC. When the FDA EOC Directors serves as the IC, then responsibility for daily EOC functions transfers to an FDA EOC Team Leader.

IV.C.2.d Legal Officer

OCC provides a Legal Officer to work as a member of the FDA EOC, as required. The Legal Officer provides legal advice to the FDA EOC IC and responds to requests for information and assistance from Centers and Offices regarding legal issues.

IV.C.2.e Information Officer

OPA provides an Information Officer to work as a member of the FDA EOC. The Information Officer handles all media inquiries and coordinates the release of information to the media with other agencies' public affairs officers.

IV.C.2.f Planning Section

The Planning Section's function includes the collection, evaluation, dissemination, and utilization of information regarding the development of the emergency and the status of resources. This section's responsibilities can also include creation of the Incident Action Plan (IAP), which defines the emergency response activities and resource utilization for a specified time period during the FDA EOC's response to an emergency.

IV.C.2.g Operations Section

The Operations Section is responsible for carrying out the response activities described in the IAP. The Operations Section Chief coordinates the activities of the Operations Section and has primary responsibility for receiving and implementing the IAP. The Operations Section Chief reports to the FDA EOC IC and determines the required resources and organizational structure needed within the Operations Section.

IV.C.2.h Logistics Section

The Logistics Section is responsible for coordinating support for facilities, services, and materials. This section takes on a greater role in long-term or extended operations. In addition to logistics, this section is responsible for financial and administrative issues that are critical for tracking emergency costs and reimbursement accounting.

IV.C.2.i Center Emergency Coordinators

Each FDA Center has a designated CEC who serves as the conduit of emergency information between his/her Center and the FDA EOC. Throughout the emergency, CECs are proactive and keep direct contact with the FDA EOC to facilitate efficient communication of relevant emergency updates. CECs maintain a current knowledge of the evolving situation and ongoing FDA EOC activities and ensure the appropriate relay of information to and from their Centers.

IV.C.2.j Center Emergency Liaisons

Each FDA Center has a designated CEL who deploys, as requested, to the FDA EOC during the response to emergencies requiring the activation of the FDA EOC. CELs maintain a current knowledge of the evolving situation and ongoing FDA EOC activities and communicate such activity to and from their CECs. CELs operate a Center desk within the FDA EOC and act as a member of the FDA EOC staff while present.

IV.C.2.k FDA External Liaisons

FDA external liaisons report to external agencies' EOCs and represent the FDA during an emergency. These outside agencies might include the HHS, USDA, FBI, FRPCC, and Department of State (DOS). These liaisons not only serve as direct links between the FDA EOC IC and their assigned agencies, but also work as members of the external agencies' EOCs. FDA External Liaisons maintain an awareness of the situation and external agency activities and communicate these activities to the FDA EOC. Further, FDA External Liaisons inform the external agencies' EOCs of activities, concerns, and information requests from the FDA.

IV.C.2.l Other Agency Liaisons

During a radiological emergency, other agencies (USDA, FBI, and others) may send a representative to the FDA EOC. These agency liaisons provide assistance to the FDA EOC IC regarding decisions involving their respective outside agencies. Other Agency

Liaisons maintain communication between the other agencies and the FDA EOC and work as members of the FDA EOC team. Further, Other Agency Liaisons inform the FDA EOC of activities, concerns, and information requests from their own agencies.

IV.C.2.m Field—District/Regional

FDA Districts will be the lead response organization when an emergency occurs within their district boundaries. The FDA EOC maintains contact with the Districts and Regions to ensure that they are aware of any events that would necessitate their involvement in the response.

Each Regional and District Office maintains a means by which headquarters can communicate emergency situations 24 hours a day, 7 days a week. Each region/district will establish and maintain procedures for internal communications and provide for appropriate liaison and notification systems to city, county, and state governments, and local offices of federal agencies.

All reports of a radiological emergency, a radiological alert, or actual adverse effects associated with FDA-regulated products require immediate investigation and immediate reporting to the EOC by phone, e-mail, or fax (see Figure IV-1, Contacting the FDA EOC). Report the nature and effect of the emergency, including the following information:

- Probable or actual distribution pattern, if known, for suspect product(s).
- Steps taken to coordinate FDA actions with state, local, and other federal officials, and any independent actions the state and/or local officials take.
- Actions firms take, corrective actions, recalls, etc.

The district in which the emergency is occurring will assume the lead investigative role in determining the cause of the emergency and obtaining necessary information for the Agency to confirm the health hazard. If it becomes apparent during the course of the investigation that a firm in another district is responsible for the product involved in the emergency, the “lead district” designation transfers to the home district of the responsible firm. Any change in the designation of "lead district" should occur in concurrence with the FDA EOC. In certain widespread emergencies involving more than one responsible firm, the FDA EOC may assume the lead role without designation of a “lead district.”

The "lead district" will identify an ad hoc emergency management team headed by the District Director or a designated district person and a coordinator. The district will determine the exact number and mix of persons on the team. Districts should direct any recommendations for reallocation of field staff between or among districts during emergencies to ORO.

The district should promptly name a senior staff employee as coordinator of the emergency response activities. Generally, this person’s location is at the lead district

office in order to facilitate communication and record review. In a widespread emergency, the involved districts may name additional coordinators, as necessary. The coordinator is responsible for advising management of necessary follow-up actions and channeling all necessary communications. This includes any or all of the following steps:

- Investigation/analysis:
  - Issuing assignments to district personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation.
  - Monitoring assignments to assure timely completion.
  - Arranging for continuing contact with investigators for flow of information.
  - Seeking technical guidance through the FDA EOC relating to the investigation, samples needed, etc.
  - Determining, in consultation with DFS and FDA EOC, the appropriate laboratory to which to submit samples and alerting that laboratory as soon as possible to allow for necessary preparations.
- Maintaining communications:
  - Keeping appropriate center, district, and regional officials informed of investigational and analytical progress.
  - Preparing daily status reports.
  - Contacting appropriate state and local authorities involved with the investigation.
  - Serving as the local FDA press contact concerning the emergency. The coordinator or other designated official will work with headquarters in preparing statements to the press.
  - FDA field and headquarters employees may receive requests to respond to media inquiries about ongoing investigations when not in a position to first seek guidance from OPA. Personnel should refer all media inquiries on emergency-related subject matter to OPA. This ensures the issuance of only accurate, complete, timely, authorized, and coordinated information, allowing for a full perspective of the situation.
    - Notify OPA, either directly or through the FDA EOC, as soon as possible after such media contacts.
    - Report significant press coverage of the emergency as soon as possible to the FDA EOC so that OPA, DFSR, and other offices stay informed.
    - Obtain copies of state, company, or other press releases and fax them to the FDA EOC in a timely manner.

The FDA lead district office (or a large resident post) facility should generally serve as the FDA's field command post because of the available communications equipment. If the emergency is in a state without a well-equipped FDA office, the FDA's field command post may co-locate with the cooperating lead state agency.

IV.D OPERATING PROCEDURE—RESPONSE DEACTIVATION

The FDA discontinues emergency response operations under the U.S. Government Domestic Terrorism Concept of Operations Plan (CONPLAN) or other applicable directives, when advised that the FBI or LFA no longer requires its assistance, or upon fulfillment of its statutory responsibilities. The INRP has significant guidelines directing the termination of consequence management assistance.

Actions the FDA EOC takes upon deactivation include the following:

- Notification of all FDA Centers/Offices.
- Notification of supporting agencies/personnel.
- Notification of staff on other EOC shifts.
- Compilation of records detailing personnel and resources used to support response operations.
- Confirmation that all FDA personnel returned from deployments in support of emergency operations.
- Verification of LFA and HHS final report/lessons learned requirements.
- Development of FDA internal lessons learned report.

IV.E OPERATING PROCEDURE—RECOVERY

The FDA EOC IC continually assesses the emergency and coordinates with the LFA to determine whether to continue crisis management or terminate the FDA's response operations. This decision includes determining whether the FDA achieved its objectives for protecting public health. In making this decision, the FDA EOC IC coordinates with and seeks input from appropriate experts and stakeholders. The FDA participates in consequence management activity, as required and as directed by the LFA. The FDA EOC may resume operating during normal business hours during the recovery stage. The FDA EOC IC determines when the FDA EOC should return to normal operating procedures in coordination with the OCM Director, and he/she issues a corresponding Agencywide announcement.

Recovery activities may begin before the response phase is complete. Primary recovery activities include—

- Working with HHS to issue press releases clarifying the safety of affected products.

- Completing investigational findings, laboratory analysis, and reports.
- Initiating compliance actions and/or recommendations.
- Completing all emergency communications.
- Destroying or storing sample reserve.
- Implementing appropriate security measures.
- Developing a follow-up monitoring program to determine the safety of unrestricted products.
- Obtaining input from stakeholders on the effectiveness of the FDA's emergency response.

During the recovery period, the FDA EOC Planning Section works with stakeholders to conduct a lessons learned analysis that identifies the following:

- Improvements to emergency response plans and procedures.
- Interventions to better protect public health.
- Improvements for communications.
- Recommendations to modify regulatory policy, laboratory and field operations, and research activities.
- Improvements for preparedness.

A final lessons learned report draws conclusions from data collected and relevant parties within the FDA receive the report. All FDA Centers and Offices should submit their input to the FDA EOC Director no later than 2 weeks following the emergency.

V. AUTHORITIES

The FDA conducts activities pursuant to the following authorities:

- Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended (USC Title 21)
  (http://www.access.gpo.gov/uscode/title21/chapter9_.html).
- The Public Health Service Act (USC Title 42)
  (http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm).
- Radiological Emergency Planning and Preparedness, Final Regulations (44 CFR Part 351)
  (http://www.access.gpo.gov/nara/cfr/waisidx_99/44cfr351_99.html).
- The Federal Anti-Tampering Act (USC Title 18, Section 1356)
  (http://www.fda.gov/opacom/laws/fedatact.htm).
- Other sections of USC Title 18 related to threats, terrorist acts, or incidents involving radiological agents
  (http://www.access.gpo.gov/uscode/title18/title18.html).
- Relevant U.S. Government operating plans
  (See specific agencies' web sites).
- Federal Response Plan, January 2003
  (http://www.fema.gov/pdf/rrr/frp/frp2003.pdf).
- Federal Radiological Emergency Response Plan, May 1996
  (http://www.fas.org/nuke/guide/usa/doctrine/national/frerp.htm#_1_3).
- U.S. Department of Health and Human Services Counter-Terrorism Concept of Operations Plan (Version IXb).

VI. ANNEXES

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ANNEX A—ACRONYMS

AAR	After Action Report
ACPA	Assistant Commissioner for Public Affairs
ACRA	Associate Commissioner for Regulatory Affairs
ACS	Automated Commercial System
AERS	Adverse Event Reporting System
AFRRI	Armed Forces Radiobiology Research Institute
AMU	Atomic Mass Unit
ARS	Acute Radiation Syndrome
ASPHEP	Assistant Secretary for Public Health Emergency Preparedness
ASTHO	Association of State and Territorial Health Officials
A-Team	Advisory Team for Environment, Food, and Health
ATSDR	Agency for Toxic Substance and Disease Registry
BEIR	Biological Effects of Ionizing Radiation
BIA	Bureau of Indian Affairs
Bq/kg	Becquerel per Kilogram
CAERS	CFSAN Adverse Event Reporting System
CBER	Center for Biologics Evaluation and Research
CBP	U.S. Bureau of Customs and Border Protection
CCC	Corporate Coordination Center
CCRF	Commissioned Corps Readiness Force
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEC	Center Emergency Coordinator
CEL	Center Emergency Liaison
CERP	CFSAN Emergency Response Plan
CFO	Chief of Field Operations
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CNC	Communication Network Coordinator
CONPLAN	Concept of Operations Plan
CRCPD	Conference of Radiation Control Program Directors, Inc.
CT	Counter-Terrorism
CVM	Center for Veterinary Medicine
DEST	Domestic Emergency Support Team
DFI	Division of Field Investigations
DFO	District Field Office
DFS	Division of Field Science
DFSR	Division of Federal-State Relations
DHS	Department of Homeland Security
DIL	Derived Intervention Levels
DIOP	Division of Import Operations and Policy
DMAT	Disaster Medical Assistance Team

DMORT	Disaster Mortuary Operational Response Team
DoD	Department of Defense
DOE	Department of Energy
DOS	Department of State
DOT	Department of Transportation
DPEM	Division of Planning, Evaluation, and Management
DTPA	Diethylenetriamine Pentaacetic Acid
EC	Emergency Coordinator
ECRS	Emergency Coordination and Response Staff
ECT	Emergency Coordination Team
eLEXNET	Electronic Laboratory Exchange Network
EO	Emergency Operations (former name of the FDA's Emergency Operations Center)
EOC	Emergency Operations Center
EP&R	Emergency Preparedness and Response Directorate
EPA	Environmental Protection Agency
Epi-X	Epidemic Information Exchange
ERT	Emergency Response Team
ESF	Emergency Support Function
FACTS	Field Accomplishments and Compliance Tracking System
FBI	Federal Bureau of Investigation
FCO	Federal Coordinating Officer
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug and Cosmetic Act of 1938
FGR	Federal Guidance Report
FOIA	Freedom of Information Act
FRC	Federal Radiation Council
FRC	Federal Region Center
FRERP	Federal Radiological Emergency Response Plan
FRMAC	Federal Radiological Monitoring and Assessment Center
FRP	Federal Response Plan
FRPCC	Federal Radiological Preparedness Coordinating Committee
FSIS	Food Safety and Inspection Service
FT4	Free Thyroxine
GETS	Government Emergency Telecommunications Service
GI	Gastrointestinal
GIS	Geographical Information System
GMP	Good Manufacturing Practices
HAN	Health Alert Network
HazMat	Hazardous Materials
HHS	Health and Human Services
HRSA	Health Resources and Services Administration

HSPD	Homeland Security Presidential Directive
IAEA	International Atomic Energy Association
IAP	Incident Action Plan
IATA	International Air Transport Association
IC	Incident Commander
ICS	Incident Command System
IDE	Investigational Device Exemption
IHS	Indian Health Service
INAD	Investigational New Animal Drug
IND	Improvised Nuclear Device
IND	Investigational New Drug
INRP	Initial National Response Plan
IOM	Investigations Operations Manual
ISCORS	Interagency Steering Committee on Radiation Standards
IT	Information Technology
JIC	Joint Information Center
JOC	Joint Operations Center
KI	Potassium Iodide
LFA	Lead Federal Agency
LRN	Laboratory Response Network
MOU	Memorandum of Understanding
MST	Management Support Team
NASA	National Aeronautics and Space Administration
NCI	National Cancer Institute
NCS	National Communications System
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NDMS	National Disaster Medical System
NEDSS	National Electronic Disease Surveillance System
NIH	National Institutes of Health
NIMS	National Incident Management System
NLM	National Library of Medicine
NRC	Nuclear Regulatory Commission
NRP	National Response Plan
NSC	National Security Council
OASIS	Operational and Administrative System for Input Support
OC	Office of the Commissioner
OCC	Office of the Chief Counsel
OCD-ODE	Office of the Center Director – Office of Drug Evaluation
OCI	Office of Criminal Investigation
OCM	Office of Crisis Management
OCP	Office of Combination Products

ODP	Office for Domestic Preparedness
OE	Office of Enforcement
OEO	Office of Emergency Operations (former name of the FDA's Emergency Operations Center)
OER	Office of Emergency Response
OIP	Office of International Programs
OLAP	On-Line Analytical Processing
OM	Office of Management
OPA	Office of Public Affairs
OPDIV	Operational Division
ORA	Office of Regulatory Affairs
ORM	Office of Resource Management
ORO	Office of Regional Operations
OSHA	Occupational Safety and Health Administration
OSC	On-Scene Coordinator
OSOPP	Officer of Security Operations, Policy, and Planning
OSS	Office of Shared Services
OTC	Over-the-Counter
PAG	Protective Action Guides
PAR	Protective Action Recommendations
PC	Personal Computer
PHS	Public Health Service
POC	Point of Contact
PPE	Personal Protective Equipment
RAD	Radiation Absorbed Dose
RCE	Radiological Contamination Event
RDD	Radiological Dispersal Device
REOC	Regional Emergency Operations Center
RFA	Request for Assistance
RFI	Request for Information
RHA	Regional Health Administrator
RPM	Regulatory Procedures Manual
RRHR	Regional Radiological Health Representative
SCC	Secretary's Command Center
SERT	Secretary's Emergency Response Team
SOP	Standard Operating Procedures
SNS	Strategic National Stockpile
TEDE	Total Effective Dose Equivalent
TLD	Thermoluminescent Dosimeter
TNT	2,4,6-Trinitrotoluene
TSH	Thyroid Stimulating Hormone
UCS	Unified Command System
USAMRIID	U.S. Army Medical Research Institute of Infectious Disease

USC	United States Code
USCG	United States Coast Guard
USDA	United States Department of Agriculture
USTR	U.S. Trade Representative
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VMAT	Veterinary Medical Assistance Team
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WMD	Weapons of Mass Destruction

ANNEX B—DEFINITIONS

Tab 1 General Definitions

Alert: Information received without support. An alert occurs upon receipt of the following types of information:

- Unconfirmed report of product-related illness/injury or unanticipated adverse reaction.
- Unconfirmed report of the presence of a toxic (chemical, radioactive, or microbial) substance.
- A report of a manmade disaster or a natural disaster.

A-Team: Interagency team consisting of EPA, HHS, USDA, and other federal agencies as necessary, that advises the LFA and state officials on environment, food, and health issues during a radiological emergency. If requested, the A-Team can deploy close to the emergency scene and collocate with the FRMAC.

Disaster Medical Assistance Teams (DMAT): A group of healthcare practitioners and providers that provide emergency medical care during a disaster or other unusual event. They may provide primary healthcare and/or augment overloaded local healthcare staff. The design of DMATs allows a rapid-response element to supplement local medical care until the mobilization of other federal or contract resources or the resolution of the situation. DMATs fall under the overarching National Disaster Medical System, and as such, receive the medical authority, training, and standards to practice throughout the nation from HHS. However, in the event of an emergency requiring activation of the FRP, the NDMS and all the assets it encompasses fall under the ultimate jurisdiction of DHS. Once finalization of the NRP is complete, this may change.

Derived Intervention Level: Concentration of a radionuclide (in Bq/kg) in food or water, which if consumed for a certain period of time following an emergency without any intervention, delivers a dose equal to a Protective Action Guide (PAG).

Disaster Field Office (DFO): The office established in or near the disaster area to support federal and state response and recovery operations. The Disaster Field Office houses the Federal Coordinating Officer (FCO), the Emergency Response Team, and, where possible, the State Coordinating Officer and support staff.

Emergency: An unforeseen combination of circumstances or the resulting state that calls for immediate action.

Emergency Response Team (ERT): A team composed of federal program and support personnel, which FEMA activates and deploys into an area affected by a major disaster or emergency. This team assists the FCO in carrying out his/her responsibilities under the Stafford Act, an emergency declaration, applicable laws, regulations, and the FEMA-State agreement. The team is an interagency team, consisting of the lead representative from each federal department or agency assigned

primary responsibility for an Emergency Support Function (ESF) and key members of the FCO's staff, formed to assist the FCO in carrying out his/her responsibilities. The team provides a forum for coordinating the overall federal consequence management response requirements.

Federal Coordinating Officer: Federal official who represents the President and coordinates overall response and recovery activities. The FCO represents the President as provided by Section 303 of the Stafford Act for the purpose of coordinating the administration of federal relief activities in the designated area.

Federal Response Plan: Plan for federal disaster assistance under the Stafford Act.

Federal Radiological Emergency Response Plan: Plan for federal response to a radiological emergency initiated independently of a Stafford Act FRP declaration. The FRERP becomes an annex to the FRP when the President, or his designee, activates the FRP.

Federal Radiological Monitoring and Assessment Center: The on-scene organization that directs and coordinates federal monitoring and assessment activities. During a radiological emergency, the FRMAC becomes a deployable asset of DHS.

Federal Radiological Preparedness Coordinating Committee: An interagency committee that coordinates federal radiological planning and training.

Incident: An alert or presumptive or confirmed report that potentially involves an FDA-regulated product or a physical FDA office.

Incident Action Plan: The written or oral plan that defines the emergency response activities for a specified time period during a response. It contains objectives reflecting the overall incident strategy, goals to accomplish, resources needed and obtained, and specific actions and supporting information for the next operational period.

Incident Command System: A model for the command, control, and coordination of resources at the scene of an emergency and at emergency operations centers.

Lead Federal Agency: The federal agency responsible for leading and coordinating all aspects of the federal response. Criteria to select the LFA include the type of emergency and the agency's authority over the radiological activity causing the emergency. The LFA is typically the agency with regulatory authority over the radiation source (NRC, EPA, or DOE), or the agency in possession of the source (DoD or National Aeronautics and Space Administration [NASA]).

National Defense Area: Area on non-federal land at scene of a radiological emergency, established as temporary federal property for the purpose of safeguarding DoD classified information or equipment.

National Disaster Medical System: An asset sharing partnership designed to provide emergency medical assistance to states following a catastrophic disaster or other major

emergency. The design of the system enables it to care for victims of any emergency that exceeds the medical care capability of the affected local and state resources. The NDMS receives the medical authority, training, and standards to practice throughout the nation from HHS. However, in the event of an emergency requiring activation of the FRP, the NDMS and all the assets it encompasses fall under the ultimate jurisdiction of DHS. Once the finalization of the NRP is complete, this may change.

The NDMS has three primary objectives:

- Provide health, medical, and related social service response to a disaster area in the form of medical response units or teams and medical supplies and equipment.
- Evacuate patients who cannot receive care in the affected area to designated locations elsewhere in the nation.
- Provide hospitalization in federal hospitals and a voluntary network of non-federal acute care hospitals that agree to accept patients during a national emergency.

National Security Area: Area on non-federal land at the scene of radiological emergency, established as temporary federal property for purpose of safeguarding DOE or NASA classified information or equipment.

Protective Action Guide: A projected committed effective dose equivalent or committed dose equivalent to an individual organ or tissue that warrants protective action following a release of radioactive materials into the environment and/or food.

Protective Action Recommendation: Recommendation on actions to take to avoid or reduce exposure and contamination from radioactive material.

Public Information Officer: Headquarters or field official responsible for preparing and disseminating public information in cooperation with responding federal, state, and local agencies. Under the FDA EOC Incident Command System during an emergency response, the Information Officer performs this role within the FDA EOC.

Radiological Incidents Classification: For a nuclear power plant, the NRC provides guidelines for classifying incidents based on their potential severity, ranging from "notification of unusual event" (no emergency-plan activation needed) to "alert," "site area emergency," and "general emergency."

- A **notification of unusual event**, the lowest classification, is the occurrence of a minor event, but with no expectation of a radiation leak. Notification occurs to local and state officials, but there are no ramifications for the public.
- An **alert** is the occurrence of a minor problem within the plant resulting in the notification of officials. Again, there is no effect on the public.
- A **site area emergency** suggests a more serious problem. If necessary, local and state officials become involved and activate their EOCs.

- A **general emergency** is the most serious event. In this instance, radiation may leak outside the plant and beyond the plant boundary. Appropriate personnel may implement emergency response procedures.

Regional Emergency Operations Center: Temporary facility, established at the FEMA Regional Office or FEMA Regional Center, for coordination of federal response until the DFO becomes operational.

Senior FEMA Official: Official appointed by the FEMA Director to direct initial FEMA response on-scene and as a team leader for the advance element of the ERT.

State Coordinating Officer: Official designated by the governor of the affected state to work with the on-scene coordinator (OSC) and FCO in coordinating response efforts.

Surveillance of Radiological Contamination or Radiation Sickness: The continuing scrutiny of all aspects of occurrence and spread of radiological contamination that is pertinent to effective control. Included in this scrutiny are the systematic collection and evaluation of data from initial investigations by local, state, and other agencies; identification of radionuclides involved; and systematic collection and analyses of samples (if necessary) by the FDA, with evaluation of data from those collections.

Suspect Versus Implicated Product: In the outset of an investigation, preliminary evidence may suggest contamination of an FDA-regulated medical or veterinary product or device, a food or foods, or animal feed by a radionuclide or radionuclides. The FDA considers these suspect products (unconfirmed radiological contamination event [RCE]). When substantive evidence becomes available showing an association between the product and the illness, this implicates the product (confirmed RCE) as the cause of the illness. Initial on-site monitoring data (e.g., verified handheld or other portable radiation monitor) results and laboratory (local, state, the FDA, or other agency) results of the suspected product that are positive for the radionuclide are examples of substantive evidence that elevate the product from being suspect to implicated. In some instances in which the suspect product is unavailable, a valid epidemiologic cohort or case control study may be sufficient to implicate the suspect product vehicle.

Traceback Investigation: The method used to identify the sources of the products implicated in an RCE. The purpose is to determine and document the distribution and production chain for a product back to its source.

Traceforward Investigation: The method used to identify the distribution of the product downstream from its source. The purpose is to determine and document the distribution and production chain and identify additional persons at risk for exposure to a product implicated during an RCE.

Tab 2 Radiological-Specific Definitions

(Adapted from http://www.bt.cdc.gov/radiation/glossary.asp)

Absolute Risk: The proportion of a population expected to get a disease over a specified time period. See also Risk, Relative Risk.

Absorbed Dose: The amount of energy deposited by ionizing radiation in a unit mass of tissue. Units of joule per kilogram (J/kg), called grays (Gy), express it.

Activity (Radioactivity): The rate of decay of radioactive material expressed as the number of atoms disintegrating per unit time measured in units called Becquerels (Bq) or curies (Ci).

Acute Exposure: An exposure to radiation occurring in a relatively short period of time, i.e., seconds, minutes, or hours. See also Chronic Exposure, Exposure, Fractionated Exposure.

Acute Radiation Syndrome: A collection of symptoms caused by receiving a relatively high dose of radiation (greater than 50 rads) to the body in a short time (usually minutes). The earliest symptoms are blood cell changes, nausea, fatigue, vomiting, and diarrhea. Hair loss, bleeding, swelling of the mouth and throat, and general loss of energy may follow. If the exposure is roughly 1,000 rads or more, death may occur within 2 to 4 weeks. For more information, see CDC's fact sheet "Acute Radiation Syndrome" at http://www.bt.cdc.gov/radiation/ars.asp.

Air Burst: A nuclear weapon explosion that is high enough in the air to keep the fireball from touching the ground. Because the fireball does not reach the ground and does not pick up any surface material, the radioactivity in the fallout from an air burst is relatively insignificant compared with a surface burst. For more information, see Chapter 2 of CDC's Fallout Report at http://www.cdc.gov/nceh/radiation/fallout/falloutreport.pdf.

Alpha Particle: The nucleus of a helium atom composed of two neutrons and two protons with a charge of +2. Certain radioactive nuclei emit alpha particles. Alpha particles generally carry more energy than gamma or beta particles and deposit that energy over very short distances while passing through tissue. A thin layer of light material, such as a sheet of paper, can stop alpha particles. Alpha particles cannot penetrate the outer, dead layer of skin; therefore, they do not damage living tissue when outside the body. However, alpha-emitting atoms are especially damaging when inhaled or swallowed because they transfer relatively large amounts of ionizing energy to living cells. See also Beta Particle, Gamma Ray, Neutron, X-ray.

Ambient Air: The air that surrounds us.

Americium (Am): A silvery metal; it is a manmade element whose isotopes Am-237 through Am-246 are all radioactive. Am-241 forms spontaneously by the beta decay of plutonium-241. Smoke detectors and neutron sources in neutron moisture gauges utilize americium.

Atom: The smallest particle of an element that can enter into a chemical reaction.

Atomic Number: The number of protons in the nucleus of an atom.

Atomic Mass Unit (amu): 1 amu is equal to one-twelfth of the mass of a carbon-12 atom.

Atomic Mass Number: The total number of protons and neutrons in the nucleus of an atom.

Atomic Weight: The mass of an atom, expressed in atomic mass units. For example, the atomic number of Helium-4 is 2, the atomic mass is 4, and the atomic weight is 4.00026.

Background Radiation: Ionizing radiation from natural sources, such as terrestrial radiation attributed to radionuclides in the soil or cosmic radiation originating in outer space.

Becquerel (Bq): A unit of radioactivity equivalent to one decay (disintegration) per second.

Beta Particles: Electrons ejected from the nucleus of a decaying atom. Although a thin sheet of aluminum can stop them, beta particles can penetrate the dead skin layer, potentially causing damage to tissue, thus posing a direct, external radiation hazard. They can also pose an internal radiation hazard if ingested or inhaled. See also Alpha Particle, Gamma Ray, Neutron, X-ray.

Bioassay: An assessment of radioactive materials that may be present inside a person's body through analysis of the person's blood, urine, feces, or sweat.

Biological Effects of Ionizing Radiation Reports: Reports of the National Research Council's committee on the Biological Effects of Ionizing Radiation (BEIR). For more information, see http://www.nap.edu/books/0309039959/html.

Biological Half-Life: The time required to eliminate one-half of the amount of a substance, such as a radionuclide, from the body by natural metabolic processes, not including counting radioactive decay, once someone takes it in through inhalation, ingestion, or absorption. See also Radioactive Half-Life, Effective Half-Life.

Carcinogen: A cancer-causing substance.

Chain Reaction: A process that initiates its own repetition. In a fission chain reaction, a fissile nucleus absorbs a neutron and fissions (splits) spontaneously, releasing additional neutrons. Other fissile nuclei can absorb these neutrons, releasing still more neutrons. A fission chain reaction is self-sustaining when the number of neutrons released in a given time equals or exceeds the number of neutrons lost by absorption in non-fissile material or by escape from the system.

Chronic Exposure: Exposure to a substance over a protracted period of time (e.g., weeks, months, or years), possibly resulting in adverse health effects. See also Acute Exposure, Fractionated Exposure.

Cobalt (Co): Gray, hard, magnetic, and somewhat malleable metal. Cobalt is relatively rare and generally obtained as a byproduct of other metals, such as copper. Radiography and medical applications utilize its most common radioisotope, cobalt-60 (Co-60). Cobalt-60 emits beta particles and gamma rays during radioactive decay.

Collective Dose: The estimated cumulative dose to a population.

Committed Dose: The cumulative dose to an individual's whole body or a specific organ resulting from continuous exposure to radioactive materials deposited inside the body, projected to either 50 or 70 years for an occupational worker or member of the general public, respectively.

Concentration: The ratio of the amount of a specific substance in a given volume or mass of solution to the mass or volume of solvent.

Conference of Radiation Control Program Directors, Inc.: An organization whose members represent state radiation protection programs. For more information, see the CRCPD Web site at http://www.crcpd.org.

Contamination (Radioactive): The unexpected or undesired presence of radioactive material in or on the surfaces of structures, areas, objects, or people. See also Decontamination.

Cosmic Radiation: Radiation produced in outer space from the interactions of heavy, charged particles with matter (nuclei of all known natural elements) that bombard the earth. See also Background Radiation, Terrestrial Radiation.

Criticality: A fission process where the neutron production rate equals the neutron loss rate to absorption or leakage. A nuclear reactor is "critical" when it is operating.

Critical Mass: The minimum amount of fissile material that can achieve a self-sustaining nuclear chain reaction.

Cumulative Dose: The total dose resulting from repeated or continuous exposures of the same portion of the body, or of the whole body, to ionizing radiation.

Curie: The traditional measure of radioactivity based on the observed decay rate of 1 gram of radium. One curie of radioactive material will have 37 billion disintegrations in 1 second.

Cutaneous Radiation Syndrome (CRS): The complex syndrome resulting from radiation exposure of more than 200 rads to the skin. The immediate effects can be reddening and swelling of the exposed area (such as with a severe sunburn), blisters, ulcers on the skin, hair loss, and severe pain. Very large doses can result in permanent

hair loss, scarring, altered skin color, deterioration of the affected body part, and death of the affected tissue (requiring surgery). For more information, see CDC's fact sheet "Acute Radiation Syndrome" at http://www.bt.cdc.gov/radiation/ars.asp.

Decay Chain (Decay Series): The series of decays that certain radioisotopes undergo before reaching a stable form. For example, the decay chain that begins with uranium-238 (U-238) ends in lead-206 (Pb-206) after forming isotopes, such as uranium-234 (U-234), thorium-230 (Th-230), radium-226 (Ra-226), and radon-222 (Rn-222).

Decay Constant: The fraction of a number of atoms of a radioactive nuclide that disintegrates in a unit of time. The decay constant is inversely proportional to the radioactive half-life.

Decay Products (Daughter Products): The isotopes formed during radioactive decay. Also known as "decay chain products" or "progeny." A decay product may be either radioactive or stable.

Decay (Radioactive): Disintegration of the nucleus of an unstable atom by the release of radiation.

Decontamination: The reduction or removal of radioactive contamination from a structure, object, or person.

Depleted Uranium: Uranium containing less than 0.7 percent uranium-235, the amount found in natural uranium. Common uses include as a shielding material and in specialized weaponry due to its very high density. See also Enriched Uranium.

Deposition Density: The activity of a radionuclide per unit area of soil. Reported as Becquerels per square meter or curies per square meter.

Deterministic Effects: Effects related directly to the radiation dose received. The severity increases as the dose increases. A deterministic effect typically has a threshold below which the effect will not occur. See also Stochastic Effect, Non-Stochastic Effect.

Deuterium: A non-radioactive isotope of the hydrogen atom that contains a neutron in its nucleus in addition to the one proton normally seen in hydrogen. A deuterium atom is twice as heavy as normal hydrogen. See also Tritium.

Dirty Bomb: A device designed to spread radioactive material by conventional explosives when the bomb explodes. A dirty bomb kills or injures people through the initial blast of the conventional explosive and spreads radioactive contamination over possibly a large area—hence the term "dirty." Such bombs could be miniature devices or large truck bombs. See also Radiological Dispersal Device.

Dose Coefficient: A factor used to convert radionuclide intake or content to radiation dose. One usually expresses it as dose per unit intake (e.g., sieverts per becquerel).

Dose Equivalent: A quantity used in radiation protection to place all radiation on a common scale for calculating tissue damage. Dose equivalent is the absorbed dose in grays times a quality factor. The quality factor accounts for differences in radiation effects caused by different types of ionizing radiation. Some radiation, including alpha particles, causes a greater amount of damage per unit of absorbed dose than other radiation. The sievert is the unit that measures dose equivalent.

Dose Rate: The radiation dose delivered per unit of time.

Dose Reconstruction: A scientific study that estimates doses to people from releases of radioactivity or other pollutants. The amount of material released, the way people came in contact with it, and the amount they absorbed determine dose reconstruction.

Dosimeter: A small portable instrument (e.g., a film badge, thermoluminescent dosimeter [TLD], or pocket dosimeter) for measuring and recording the total accumulated dose of ionizing radiation a person receives.

Dosimetry: Assessment (by measurement or calculation) of radiation dose.

Effective Dose: A dosimetric quantity useful for comparing the overall health effects of irradiation of the whole body. It takes into account the absorbed doses received by various organs and tissues and weighs them according to present knowledge of the sensitivity of each organ to radiation. It also accounts for the type of radiation and the potential for each type to inflict biologic damage. Use the effective dose, for example, to compare the overall health detriments of different radionuclides in a given mix. The unit of effective dose is the sievert (Sv); 1 Sv = 1 J/kg.

Effective Half-Life: The time required for the amount of a radionuclide deposited in a living organism to reduce by 50 percent as a result of the combined radioactive decay and biological elimination. See also Biological Half-Life, Decay Constant, Radioactive Half-Life.

Electron: An elementary particle with a negative electrical charge and a mass 1/1837 that of the proton. Electrons surround the nucleus of an atom because of the attraction between their negative charge and the positive charge of the nucleus. A stable atom will have as many electrons as it has protons. The number of electrons that orbit an atom determines its chemical properties. See also Neutron.

Electron Volt (eV): A unit of energy equivalent to the amount of energy gained by an electron when it passes from a point of low potential to a point 1 volt higher in potential.

Element: 1) All isotopes of an atom that contain the same number of protons. For example, the element uranium has 92 protons, and the different isotopes of this element may contain 134 to 148 neutrons. 2) In a reactor, a fuel element is a metal rod containing the fissile material.

Enriched Uranium: Uranium with an increased proportion of the isotope uranium-235, due to chemical removal of uranium-238. See also Depleted Uranium.

Epidemiology: The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.

Exposure (Radiation): A measure of ionization in air caused by x-rays or gamma rays only. The unit of exposure most often used is the Roentgen (R).

Exposure Pathway: A route by which a radionuclide or other toxic material can enter the body. The main exposure routes are inhalation, ingestion, absorption through the skin, and entry through a cut or wound in the skin.

Exposure Rate: A measure of the ionization produced in air by x-rays or gamma rays per unit of time (frequently expressed in Roentgens per hour).

External Exposure: Exposure to radiation outside the body.

Fallout (Nuclear): Minute particles of radioactive debris that descend slowly from the atmosphere after a nuclear explosion. For more information, see Chapter 2 of CDC's Fallout Report at http://www.cdc.gov/nceh/radiation/fallout/falloutreport.pdf.

Fissile Material: Any material in which neutrons can cause a fission reaction. The three primary fissile materials are uranium-233, uranium-235, and plutonium-239.

Fission (Fissioning): The splitting of a nucleus into at least two other nuclei that releases a large amount of energy. Two or three neutrons usually release during this transformation. See also Fusion.

Fractionated Exposure: Exposure to radiation that occurs in several small acute exposures, rather than continuously as in a chronic exposure.

Fusion: A reaction in which two lighter, less stable nuclei produce at least one heavier, more stable nucleus. Reactions of this type are responsible for the release of energy in stars or in thermonuclear weapons.

Gamma Rays: High-energy electromagnetic radiation emitted by certain radionuclides when their nuclei transition from a higher to a lower energy state. These rays have high energy and a short wave length. All gamma rays emitted from a given isotope have the same energy, a characteristic that enables scientists to identify which gamma emitters are present in a sample. Gamma rays penetrate tissue to a greater extent than beta or alpha particles, but leave a lower concentration of ions in their path that could potentially cause cell damage. Gamma rays and x-rays are similar types of radiation, but differ in their origin within the radioactive atom. See also Neutron.

Geiger Counter: A radiation detection and measuring instrument consisting of a gas-filled tube containing electrodes, between which an electrical voltage but no current flows. When ionizing radiation passes through the tube, a short, intense pulse of current passes from the negative electrode to the positive electrode and for measuring or counting. The number of pulses per second measures the intensity of the radiation

field. The most commonly used portable radiation detection instruments are Geiger counters.

Genetic Effects: Hereditary effects (mutations) that can pass on through reproduction because of changes in sperm or ova. See also Teratogenic Effects, Somatic Effects.

Gray (Gy): A unit of measurement for absorbed dose. It measures the amount of energy absorbed in a material. The unit Gy is proper for any type of radiation, but it does not describe the biological effects of the different radiations.

Half-Life: The time it takes for radioactive material to decay by half of its original amount. See also Biological Half-Life, Decay Constant, Effective Half-Life, Radioactive Half-Life.

Health Physics: A scientific field that focuses on protection of humans and the environment from radiation. Health physics uses physics, biology, chemistry, statistics, and electronic instrumentation to help protect individuals from the damaging effects of radiation. For more information, see the Health Physics Society Web site http://www.hps.org/.

High-Level Radioactive Waste: The radioactive material resulting from spent nuclear fuel reprocessing. This can include liquid waste directly produced in reprocessing or any solid material derived from the liquid wastes having a sufficient concentration of fission products. Other radioactive materials can be high-level waste, if they require permanent isolation. The NRC makes this determination on the basis of criteria established in U.S. law. See also Low-Level Waste, Transuranic Waste.

Hot Spot: A locus of radioactive contamination.

Ingestion: 1) The act of swallowing. 2) In the case of radionuclides or chemicals, swallowing radionuclides or chemicals by eating or drinking.

Inhalation: 1) The act of breathing in. 2) In the case of radionuclides or chemicals, breathing in radionuclides or chemicals.

Internal Exposure: Exposure to radioactive material taken into the body.

Iodine: A non-metallic solid element. There are both radioactive and non-radioactive isotopes of iodine. Medical applications widely use radioactive isotopes of iodine. Radioactive iodine is a fission product and is the largest contributor to people's radiation dose after an accident at a nuclear reactor.

Ion: An atom that has fewer or more electrons than it has protons, causing it to have an electrical charge and, therefore, be chemically reactive.

Ionization: The process of adding one or more electrons to, or removing one or more electrons from, atoms or molecules, thereby creating ions. High temperatures, electrical discharges, or nuclear radiation can cause ionization.

Ionizing Radiation: Any radiation capable of displacing electrons from atoms, thereby producing ions. High doses of ionizing radiation may produce severe skin or tissue damage. See also Alpha Particle, Beta Particle, Gamma Ray, Neutron, X-ray.

Irradiation: Exposure to radiation.

Isotope: Nuclide of an element having the same number of protons but a different number of neutrons.

Kiloton (Kt): The energy of an explosion that is equivalent to the detonation of 1,000 tons of 2,4,6-Trinitrotoluene (TNT). One kiloton equals 1 trillion (1012) calories. See also Megaton.

Latent Period: The time between exposure to a toxic material and the appearance of a resultant health effect.

Lead (Pb): A heavy metal. Several isotopes of lead, such as the beta emitter Pb-210, are in the uranium decay chain. Common lead uses include as a shielding material in its stable form, due to its high density.

Lead Federal Agency: The federal agency that leads and coordinates the emergency response activities of other federal agencies during a nuclear emergency. Following a nuclear emergency, the FRERP, available at http://www.fas.org/nuke/guide/usa/doctrine/national/frerp.htm, determines which federal agency will be the LFA.

Local Radiation Injury: Acute radiation exposure (more than 1,000 rads) to a small, localized part of the body. Most local radiation injuries do not cause death. However, if the exposure is from penetrating radiation (neutrons, x-rays, or gamma rays), it may cause damage to internal organs, and some symptoms of acute radiation syndrome (ARS), including death, may occur. Local radiation injury invariably involves skin damage, possibly requiring a skin graft or other surgery. See also CDC's fact sheet "Acute Radiation Syndrome" at http://www.bt.cdc.gov/radiation/ars.asp.

Low-Level Waste: Radioactively contaminated industrial or research waste such as paper, rags, plastic bags, medical waste, and water-treatment residues. It is waste that does not meet the criteria for any of three other categories of radioactive waste: spent nuclear fuel and high-level radioactive waste; transuranic radioactive waste; or uranium mill tailings. Its categorization does not depend on the level of radioactivity it contains.

Megaton (Mt): The energy of an explosion that is equivalent to the detonation of 1 million tons of TNT. One megaton is equal to a quintillion (1018) calories. See also Kiloton.

Molecule: A combination of two or more atoms bonded together chemically. A molecule is the smallest unit of a compound that can exist by itself and retain all of its chemical properties.

Neoplastic: Pertaining to the pathologic process resulting in the formation and growth of an abnormal mass of tissue.

Neutron: A small atomic particle possessing no electrical charge, typically found within an atom's nucleus. Neutrons are, as the name implies, neutral in their charge—that is, they have neither a positive nor a negative charge. A neutron has about the same mass as a proton. See also Alpha Particle, Beta Particle, Gamma Ray, Nucleon, X-ray.

Non-Ionizing Radiation: Radiation that has lower energy levels and longer wavelengths than ionizing radiation. It is not strong enough to affect the structure of atoms it contacts, but is strong enough to heat tissue and can cause harmful biological effects. Examples include lasers, radio waves, microwaves, visible light, and infrared from a heat lamp.

Non-Stochastic Effects: Effects related directly to the radiation dose received. The severity of the effect increases with dose. There is typically a threshold, below which the effect will not occur. These are sometimes called deterministic effects. For example, a skin burn from radiation is a non-stochastic effect that worsens as the radiation dose increases. See also Stochastic Effects.

Nuclear Energy: The heat energy produced by the process of nuclear fission within a nuclear reactor or by radioactive decay.

Nuclear Fuel Cycle: The steps involved in supplying fuel for nuclear power plants. It can include mining, milling, isotopic enrichment, fabrication of fuel elements, use in reactors, chemical reprocessing to recover the fissile material remaining in the spent fuel, re-enrichment of the fuel material refabrication into new fuel elements, and waste disposal.

Nuclear Tracers: Radioisotopes that enable doctors to "look" inside the body and observe soft tissues and organs in a way similar to that in which x-rays provide images of bones. A radioactive tracer is chemically attached to a compound that will concentrate naturally in an organ or tissue to allow the taking of an image.

Nucleon: A proton or a neutron; a constituent of the nucleus of an atom.

Nucleus: The central part of an atom that contains protons and neutrons. The nucleus is the heaviest part of the atom.

Nuclide: A general term applicable to all atomic forms of an element. The number of protons and neutrons in the nucleus and the amount of energy contained within the atom characterize nuclides.

Pathways: The routes by which people receive exposure to radiation or other contaminants. The three basic pathways are inhalation, ingestion, and direct external exposure. See also Exposure Pathway.

Penetrating Radiation: Radiation that can penetrate the skin and reach internal organs and tissues. Photons (gamma rays and x-rays), high-energy beta particles, neutrons, and protons are penetrating radiations. Alpha particles are not penetrating radiation.

Photon: A photon is a discrete "packet" of pure electromagnetic energy. Photons have no mass and travel at the speed of light. The term "photon" describes energy when it acts like a particle (causing interactions at the molecular or atomic level), rather than a wave. Gamma rays and x-rays are photons.

Pitchblende: A brown to black mineral that has a distinctive luster. It consists mainly of urananite (UO2), but also contains radium. It is the main source of uranium ore.

Plume: The material spreading from a particular source and traveling through environmental media, such as air or ground water. For example, a plume could describe the dispersal of particles, gases, vapors, and aerosols in the atmosphere, or the movement of contamination through an aquifer (e.g., dilution, mixing, or adsorption onto soil).

Plutonium (Pu): A heavy, manmade, radioactive metallic element. The most important isotope is Pu-239, which has a half-life of 24,000 years. Reactor fuel uses Pu-239, and it is the primary isotope in weapons. One kilogram is equivalent to about 22 million kilowatt-hours of heat energy. The complete detonation of a kilogram of plutonium produces an explosion equal to about 20,000 tons of chemical explosive. The bones readily absorb all isotopes of plutonium; it can be lethal depending on the dose and exposure time.

Polonium (Po): A radioactive chemical element and a product of radium decay. Polonium exists in uranium ores.

Prenatal Radiation Exposure: Radiation exposure to an embryo or fetus while it is still in its mother's womb. The effects of prenatal exposure to radiation vary with the stage of pregnancy and can range from no effect to potential birth defects to prenatal death. The threshold for prenatal effects is at least 10 rads, but could be higher. For more information, see CDC's fact sheet, "Possible Health Effects of Radiation Exposure on Unborn Babies," at http://www.bt.cdc.gov/radiation/prenatal.asp.

Proton: A subatomic particle, typically found within an atom's nucleus that possesses a positive electrical charge. Protons and neutrons are about 2,000 times heavier than electrons. The number of protons is unique for each chemical element. See also Nucleon.

Quality Factor (Q): The factor by which one multiplies the absorbed dose (rad or gray) to obtain a quantity that expresses the potential biological damage to an exposed person (the rem). It is useful because some types of radiation, such as alpha particles, are more biologically damaging internally than other types.

Radiation Absorbed Dose (Rad): A basic unit of absorbed radiation dose. It is a measure of the amount of energy absorbed by the body. The rad is the traditional unit of absorbed dose. The gray, which is equivalent to 100 rad, is now replacing it. One rad equals 100 ergs of energy per gram of material.

Radiation: Energy moving in the form of particles or waves. Familiar radiations are heat, light, radio waves, and microwaves. Ionizing radiation is a very high-energy form of electromagnetic radiation.

Radiation Sickness: See Acute Radiation Syndrome (ARS) or the CDC fact sheet "Acute Radiation Syndrome," at http://www.bt.cdc.gov/radiation/ars.asp.

Radiation Warning Symbol: A symbol consisting of a magenta or black trefoil on a yellow background. Areas where certain quantities of radioactive materials are present or where one could receive certain doses of radiation must display it.

Radioactive Contamination: The deposition of unwanted radioactive material on the surfaces of structures, areas, objects, or people. It can be airborne, external, or internal. See also Contamination, Decontamination.

Radioactive Decay: The spontaneous disintegration of the nucleus of an atom.

Radioactive Half-Life: The time required for a quantity of a radioisotope to decay by half. For example, because the half-life of iodine-131 (I-131) is 8 days, a sample of I-131 that has 10 mCi of activity on January 1, will have 5 mCi of activity 8 days later, on January 9. See also Biological Half-Life, Decay Constant, Effective Half-Life.

Radioactive Material: Material that contains unstable (radioactive) atoms which emit energy in the form of radiation as they decay.

Radioactivity: The process of spontaneous transformation of the nucleus, generally with the emission of alpha or beta particles often accompanied by gamma rays. This process is the decay or disintegration of an atom.

Radioassay: A test to determine the amounts of radioactive materials through the detection of ionizing radiation. Radioassays will detect transuranic nuclides, uranium, fission and activation products, naturally occurring radioactive material, and medical isotopes.

Radiogenic: Health effects caused by exposure to ionizing radiation.

Radiography: 1) Medical—the use of radiant energy (such as x-rays and gamma rays) to image body systems. 2) Industrial—the use of radioactive sources to photograph internal structures, such as turbine blades in jet engines. A sealed radiation source, usually iridium-192 (Ir-192) or cobalt-60 (Co-60), emits high-energy gamma rays at the object. Gamma rays passing through flaws in the metal or incomplete welds strike special photographic film (radiographic film) on the opposite side.

Radioisotope (Radioactive Isotope): Isotopes of an element that have an unstable nucleus. Science, industry, and medicine commonly use radioactive isotopes. The nucleus eventually reaches a stable number of protons and neutrons through one or more radioactive decays. Roughly 3,700 natural and artificial radioisotopes have been identified.

Radiological (Radiologic): Related to radioactive materials or radiation. The radiological sciences focus on the measurement and effects of radiation.

Radiological Dispersal Device: A device that disperses radioactive material by conventional explosive or other mechanical means, such as a spray. See also Dirty Bomb.

Radionuclide: An unstable and therefore radioactive form of a nuclide.

Radium (Ra): A naturally occurring radioactive metal. Radium is a radionuclide formed by the decay of uranium and thorium in the environment. It occurs at low levels in virtually all rock, soil, water, plants, and animals. Radon is a decay product of radium.

Radon (Rn): A naturally occurring radioactive gas found in soils, rock, and water throughout the United States. Radon may have a part in causing lung cancer and can be a potential to health hazard if it collects in homes at high concentrations. Radon is the largest source of exposure to people from naturally occurring radiation.

Relative Risk: The ratio between the risk for disease in an irradiated population to the risk in an unexposed population. A relative risk of 1.1 indicates a 10 percent increase in the risk of cancer from radiation, compared with the "normal" incidence. See also Risk, Absolute Risk.

Roentgen Equivalent Man (Rem): A unit of equivalent dose. Not all radiation has the same biological effect, even for the same amount of absorbed dose. Rem relates the absorbed dose in human tissue to the effective biological damage of the radiation. One determines rem by multiplying the number of rads by a quality factor, a number reflecting the potential damage caused by the particular type of radiation. The rem is the traditional unit of equivalent dose, but the sievert, which is equal to 100 rem, is replacing it.

Risk: The probability of injury, disease, or death under specific circumstances and time periods. Risk expression can be a value that ranges from 0 percent (no injury or harm will occur) to 100 percent (harm or injury will definitely occur). Risk influences are from many factors, including exposure, personal behavior or lifestyle, environmental exposure to other material, or inborn or inherited characteristic known from scientific evidence to associate with a health effect. Because many risk factors are not measurable, risk estimates are uncertain. See also Absolute Risk, Relative Risk.

Risk Assessment: An evaluation of the risk to human health or the environment by hazards. Risk assessments can look at either existing hazards or potential hazards.

Roentgen (R): A unit of exposure to x-rays or gamma rays. One roentgen is the amount of gamma or x-rays needed to produce ions carrying 1 electrostatic unit of electrical charge in 1 cubic centimeter of dry air under standard conditions.

Sensitivity: The ability of an analytical method to detect small concentrations of radioactive material.

Shielding: The use of material placed between a radiation source and an individual to reduce exposure.

Sievert (Sv): A unit of dose equivalent. This relates the absorbed dose in human tissue to the effective biological damage of the radiation. Not all radiation has the same biological effect, even for the same amount of absorbed dose. Dose equivalent is often expressed as millionths of a sievert, or micro-sieverts (µSv). One sievert is equivalent to 100 rem.

SI units: The Systeme Internationale (or International System) of units and measurements. Nearly all countries of the world adopted this system of units, which officially came into being in October 1960.

Somatic Effects: Effects of radiation limited to the exposed person, as distinguished from genetic effects, which may affect subsequent generations. See also Teratogenic Effects.

Stable Nucleus: The nucleus of an atom with balanced forces among its particles. See also Unstable Nucleus.

Stochastic Effect: A biological effect in which the probability of occurrence increase with the dose. There is no threshold for the occurrence of these effects. If it occurs, the severity of a stochastic effect is independent of the dose received. Cancer is a stochastic effect. See also Non-Stochastic Effect, Deterministic Effect.

Strontium (Sr): A silvery, soft metal that rapidly turns yellow in air. Sr-90 is one of the radioactive fission materials created within a nuclear reactor during its operation. Sr-90 emits beta particles during radioactive decay.

Surface Burst: A nuclear weapon explosion that is close enough to the ground for the radius of the fireball to vaporize surface material. Fallout from a surface burst contains very high levels of radioactivity. See also Air Burst. For more information, see Chapter 2 of CDC's Fallout Report at http://www.cdc.gov/nceh/radiation/fallout/falloutreport.pdf.

Tailings: Waste rock from mining operations that contains concentrations of mineral ore that are too low to make typical extraction methods economical.

Thermonuclear Device: A "hydrogen bomb." A device with explosive energy that comes from not only fusion of small nuclei, but also fission.

Teratogenic Effect: Birth defects not passed on to future generations, and caused by exposure to a toxin as a fetus. See also Genetic Effects, Somatic Effects.

Terrestrial Radiation: Radiation emitted by naturally occurring radioactive materials in the Earth's soil, such as uranium, thorium, and radon.

Thorium (Th): A naturally occurring radioactive metal found in small amounts in soil, rocks, water, plants, and animals. The most common isotopes of thorium are thorium-232 (Th-232), thorium-230 (Th-230), and thorium-238 (Th-238).

Transuranic: Pertaining to elements with atomic numbers higher than uranium (92). For example, plutonium (Pu) and americium (Am) are transuranics.

Tritium (H-3): A radioactive isotope of the element hydrogen (H). See also Deuterium.

Unstable Nucleus: A nucleus that contains an unbalanced number of protons and neutrons and seeks to reach equilibrium between them through radioactive decay (e.g., the nucleus of a radioactive atom). See also Stable Nucleus.

Uranium (U): A naturally occurring radioactive element whose principal isotopes are uranium-238 (U-238) and uranium-235 (U-235). Natural uranium is a hard, silvery-white, shiny metallic ore that contains a minute amount of uranium-234 (U-234).

Uranium Mill Tailings: Naturally radioactive residue from the processing of uranium ore. Although the milling process recovers about 95 percent of the uranium, the residues, or tailings, contain several isotopes of naturally occurring radioactive material, including uranium, thorium, radium, polonium, and radon.

Whole Body Count: The measure and analysis of the radiation emitted from a person's entire body, detected by a counter external to the body.

Whole Body Exposure: An exposure of the entire body, as opposed to an isolated part, to an external radiation source.

X-Ray: Electromagnetic radiation caused by deflection of electrons from their original paths, or inner orbital electrons that change their orbital levels around the atomic nucleus. X-rays, like gamma rays can travel long distances through air and most other materials. Like gamma rays, x-rays require more shielding to reduce their intensity than do beta or alpha particles. X-rays and gamma rays differ primarily in their origin: x-rays originate in the electronic shell; gamma rays originate in the nucleus. See also Neutron.

ANNEX C—FDA'S RESPONSIBILITIES UNDER THE FEDERAL RADIOLOGICAL EMERGENCY RESPONSE PLAN

In the event of a peacetime radiological emergency, the FRERP activates to establish and organize an integrated capability of timely coordinated response by federal agencies. State and local governments have primary responsibility for response to an event and implementing measures to protect the populace. Should the emergency overwhelm state and local governments, they can request federal assistance through the annotated LFA, based on the type of emergency, as listed in Table C-1.

Table C-1. FRERP Identification of LFAs

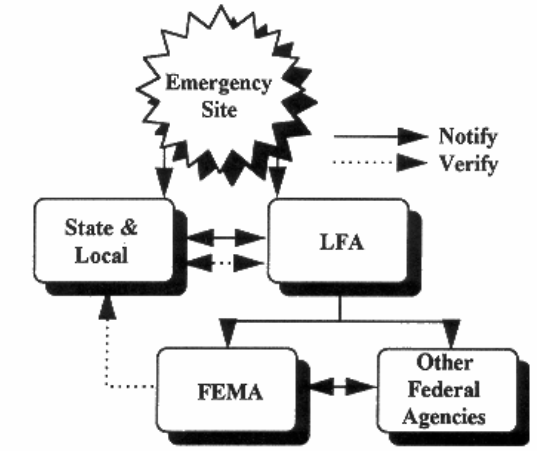
Type of Emergency	LFA
1. Nuclear facility	
a. Licensed by NRC or an agreement state	NRC
b. Owned or operated by DoD or DOE	DoD or DOE
c. Not licensed, owned, or operated by a federal agency or an agreement state	EPA
2. Transportation of radioactive materials	
a. Shipment of materials licensed by NRD or an NRC agreement state	NRC
b. Materials shipped by or for DoD or DOE	DoD or DOE
c. Shipment of materials not licensed or owned by a federal agency or an agreement state	EPA
3. Satellites containing radioactive materials	NASA or DoD
4. Impact from foreign or unknown source	EPA
5. Other types of emergencies	LFAs confer

Source: Federal Radiological Emergency Response Plan, May 1996; Table II-1, p. 7

Should the LFA deem a federal assistance request appropriate, Figure C-1 shows the request flow.

The LFA contacts various federal agencies to provide assistance within their realm. CDC is the lead agency for HHS when the FRERP calls upon the Department. However, through a memorandum of understanding (MOU), the FDA is the alternate lead agency. Consequently, the FDA prepares to act as such, leading the coordination of the support that HHS must provide.

Figure C-1. Notification Process



Source: Federal Radiological Emergency Response Plan, May 1996; p. 19

Under the FRERP, HHS (CDC or the FDA) is responsible for providing a variety of functions, including—

- Ensuring the availability of health and medical care and other human services (especially for the age, poor, infirm, blind, and others most in need).
- Assisting in providing crisis counseling to victims in affected geographic areas.
- Providing guidance to state and local health officials on disease control measures and epidemiological surveillance and study of exposed populations.
- Providing advice on proper medical treatment of personnel with radioactive material exposure or contamination.
- Providing advice and guidance in assessing the impact of the effects of radiological emergencies on the health of persons in the affected area.
- Providing representatives to the A-Team to advise the LFA on environment, food, and health matters.
- In conjunction with USDA, inspecting production, processing storage, and distribution facilities for human and animal feed, used in interstate commerce, to ensure protection of the public health.
- Collecting and analyzing samples of agricultural products to monitor and assess the extent of contamination as a basis for recommending or implementing protective actions.

To specifically accomplish HHS objectives, under the MOU with CDC, the FDA is responsible for providing technical assistance to CDC and carrying out the following activities:

- Developing guidance on the development and use of drugs and biologicals, including blood and blood products, as well as cellular- and tissue-based products, for prophylaxis and treatment of exposure to radiation.
- Protection of that portion of the food supply that it regulates.
- Protection of drugs, biologicals, tissues, and the blood supply.
- Protection of medical devices and radiation-producing devices.