FDA CHEMICAL AND BIOLOGICAL EMERGENCY RESPONSE PLAN SUMMARY

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U.S. FOOD AND DRUG ADMINISTRATION
CHEMICAL AND BIOLOGICAL EMERGENCY RESPONSE PLAN

I. INTRODUCTION

Chemical/biological (C/B) emergencies, whether accidental or intentional, 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 these C/B agents or 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 Chemical and Biological Emergency Response Plan* is to provide a coordinated response to C/B emergencies involving FDA-regulated products. To accomplish this, the plan—

- Describes the essential steps to take in response to any C/B emergency (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, including medical countermeasures, FDA components and personnel take when responding to C/B emergencies.
- Enhances the Agency's emergency preparedness and response capabilities.

I.C SCOPE

This plan applies to C/B emergencies, both accidental and intentional (terrorism), for which the FDA provides assistance under Emergency Support Function (ESF) #8 of the Federal Response Plan (FRP) 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.

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

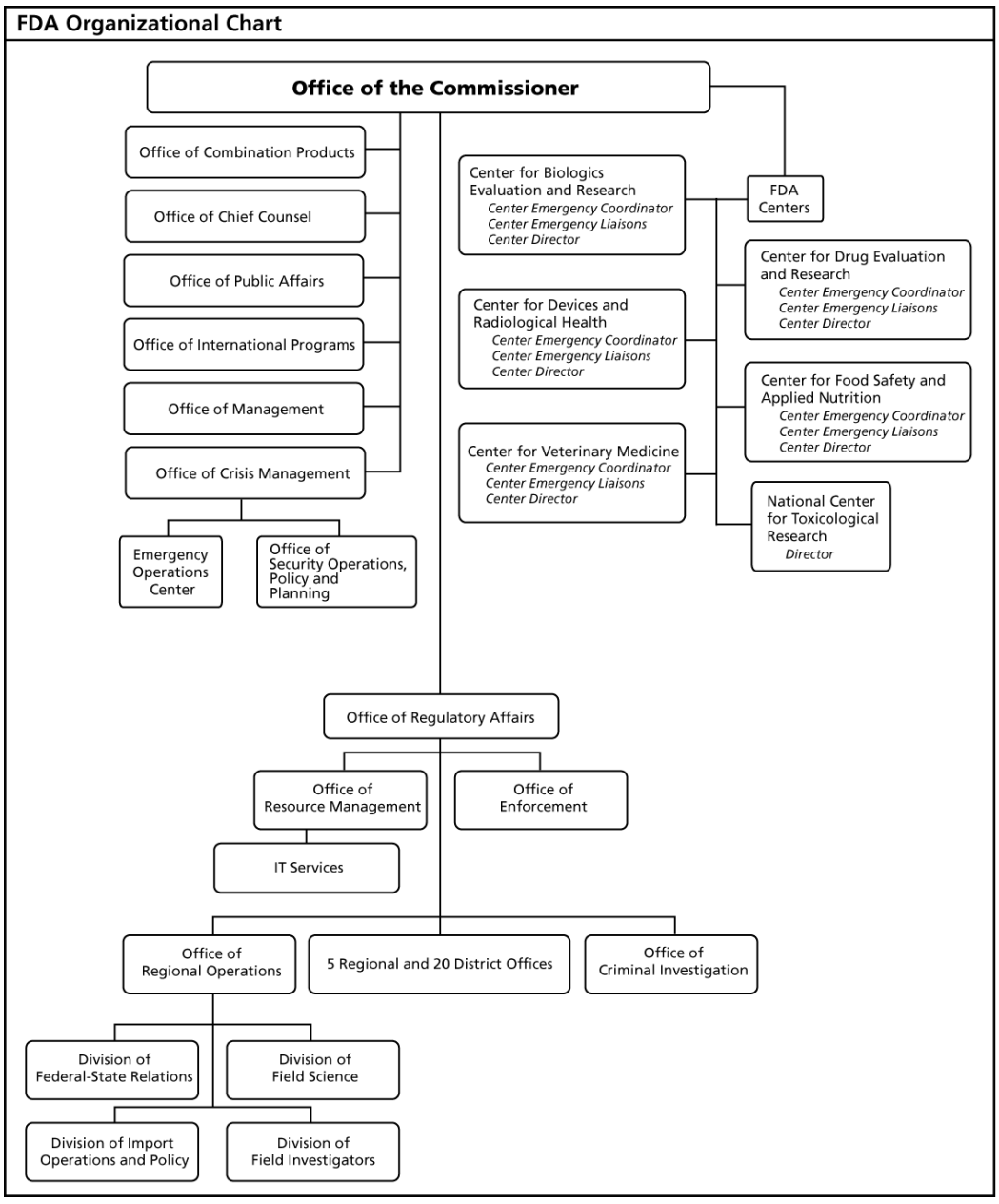
II. PLANNING ASSUMPTIONS

- A C/B 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 FDA-regulated products 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]).
- C/B 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 C/B agents 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 C/B 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 C/B emergency in the United States or worldwide. They accomplish this 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 C/B 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 C/B 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 C/B 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 C/B 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 an 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 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 C/B emergencies to determine response actions; and coordinating intra-agency and interagency emergency 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 C/B emergency. The FDA EOC is the physical facility that serves as the central point for the Agency's response activity. During a C/B emergency, the FDA EOC will coordinate and report on all response activity and interagency communication. The FDA EOC monitors accidental and intentional C/B 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) can provide support during the FDA's response to a C/B emergency in several ways. For example, in the event of a requirement to 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 C/B emergency, 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 lead office for all regulatory activities of the FDA. ORA consists of 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 can enable 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:

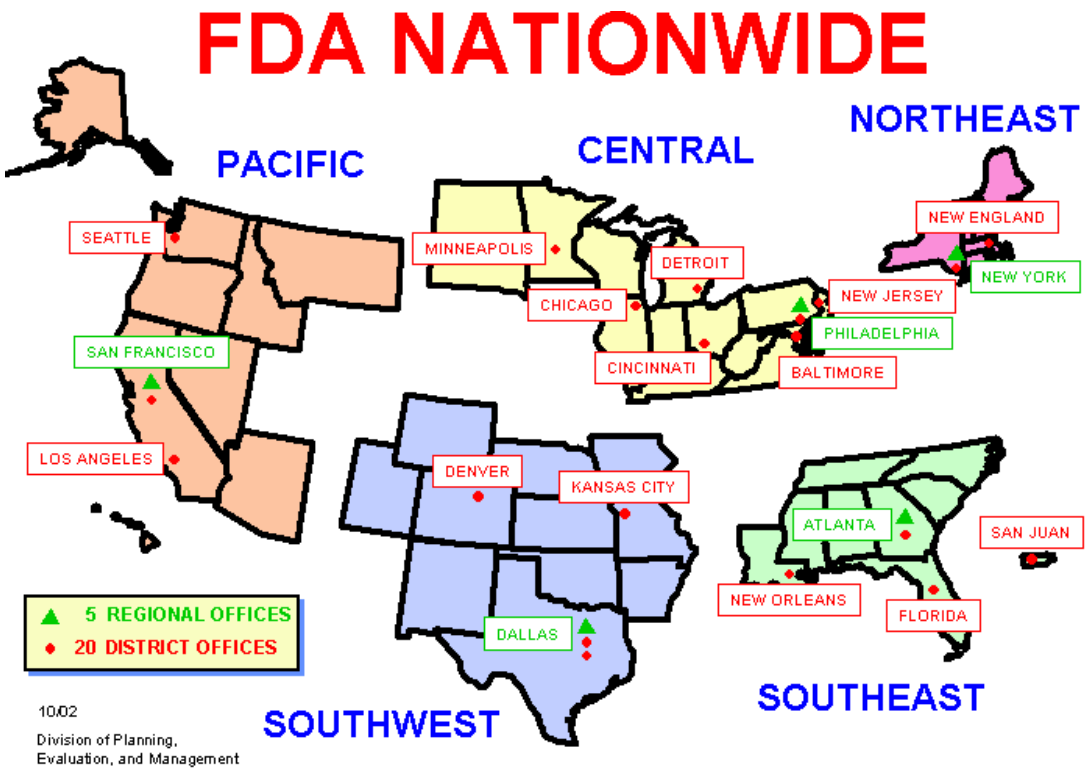
- The Division of Federal-State Relations (DFSR) maintains the FDA's rapid communication system to state governments, major municipalities, and poison control centers during an emergency.
- The Division of Field Science (DFS) prepares the ORA laboratory response and monitors surveillance databases.
- 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 C/B 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 used as countermeasures in response to threats or outbreaks of biologic or chemical threat agents. 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 and efficacy of biological products, such as blood and blood products, cellular- and tissue-based therapies, vaccines, and related devices.
- Facilitating the development of safe and effective vaccines, cellular- and tissue-based therapies, biological devices, and other biological products used as countermeasures in a biologic or chemical threat scenario.
- Collaborating with public health agencies (e.g., CDC and other HHS units) regarding product stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, and other evolving issues.
- Providing regulatory guidance on the use of medical countermeasures when there is not FDA approval for either the product or proposed indication.

- Providing information regarding manufacturers' compliance with current 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 during a C/B emergency.
- Assessing the availability, production capacity, and surge capacity of biologic products used as medical countermeasures and providing information on alternative sources of critical medical countermeasures in shortage situations.
- Managing CBER laboratory capabilities and providing this information to the FDA EOC.

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 therapeutic biologic agents with use as countermeasures or antidotes in response to outbreaks of biologic threat agents or chemical exposure. Products with potential for use in this area currently include antibiotics, antifungals, antivirals, antidotes that are chemical threat agent-specific, dermal or mucosal protectants, and monoclonal antibodies and other agents with utility against biologic or chemical threats. CDER's product countermeasure activities include the following:

- Providing sponsors and other stakeholders with guidance on the development of drug and therapeutic biologic products 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 quality and purity of drug and therapeutic biologic products involving a biologic or chemical contaminant.
- Assessing the availability, production capacity, and surge capacity of drug and therapeutic biologic products used as countermeasures, and providing information on alternative sources of critical medical countermeasures in shortage situations.
- Managing CDER laboratory capabilities and providing this information to the FDA EOC.

III.C.3 Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) ensures the safety, effectiveness, and quality of medical and diagnostic devices, and the safety and quality of radiological products potentially used as countermeasures in response to outbreaks of biologic threat agents or chemical exposure. CDRH's countermeasure activities include:

- Regulating radiological-emitting products and medical devices and diagnostic devices, including those that may be essential in responding to chemical, biological, or radiological threats.
- Collaborating with federal and international agencies on standards, policies, and test methods.
- Collaborating with regulated industry and trade associations to facilitate the availability of critical diagnostic and medical devices in the event of public health need during emergencies.
- Evaluates the capabilities of instruments for diagnostic radiology and security screening using machine-produced radiation.
- Providing technical liaisons to other federal and international agencies through participation in working groups and committees.
- Preparing for collaboration with state and federal agencies in regards to aerosolizing in times of "dirty bomb" exposure from a radiological health physics and diagnostic devices perspective.
- Providing health physics and agent specific diagnostic information to the FDA EOC and external agencies during emergencies, exercises, and training involving C/B agent exposure and/or radiological contamination, as in a dirty bomb scenario.
- Monitoring and investigating adverse events due to diagnostic or medical devices used during a suspected or actual C/B emergency.
- Participating in investigations of specific cases of exposure related to a dirty bomb emergency.

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 have honest labeling, and that cosmetic products are safe and have proper labeling. CFSAN also determines whether data collected by another agency or organization 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 C/B 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.
- 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 a biologic or chemical contaminant.
- Providing an assessment on the diversion of contaminated human food for animal feed use.
- Assessing the availability, production capacity, and surge capacity of animal drugs, and providing information on alternative sources of critical products in shortage situations.
- Managing CVM laboratory capabilities and providing this information to the FDA EOC.

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 C/B 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 C/B 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 C/B emergency 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 C/B 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 C/B 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
U.S. Bureau of Customs and Border Protection	Other Government Agency Liaison (Contacted by DIOP)
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
Office of Criminal Investigation	
ORA/IT	
Department of State	Contacted by OIP

IV.A.2 Risk Assessment/Situational Analysis

The FDA performs a risk assessment analysis for C/B emergency impact on FDA-regulated products.

Figure IV-2. Risk Assessment and Situational Analysis

The following situations require the FDA to support risk assessment and situational analysis for a C/B—

- **Threat:**
  - Receipt of information or intelligence indicating that an FDA-regulated product is the target of or affected by a C/B threat. 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.
- **Emergency:**
  - 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.

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 the threat, the risk posed by the threat, and the appropriate actions and response measures to eliminate or mitigate the threat.

After a C/B 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.

In summary, 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 C/B contamination on manufacturers or producers of blood, blood products, tissues, animal feed, human and animal biologics and drugs, and devices.

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 C/B 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 C/B 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 requests for FDA resources occur. 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-3). Circumstances, including an actual/potential national emergency, disaster, or exercise, will dictate operating hours and staffing levels for the FDA EOC.

Figure IV-3. Activation/Deactivation Checklist

Activation

- ❑ Determine operating level and shifts needed:

  _____

- ❑ 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 will request 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 C/B 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 C/B 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 will coordinate information concerning emergencies with Headquarters offices of other federal agencies.

The FDA EOC notifies OIP of the following:

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

The FDA EOC notifies OPA of the following:

- All C/B emergencies so that OPA can monitor ongoing or imminent press coverage and begin to prepare public educational materials or 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:

- C/B 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

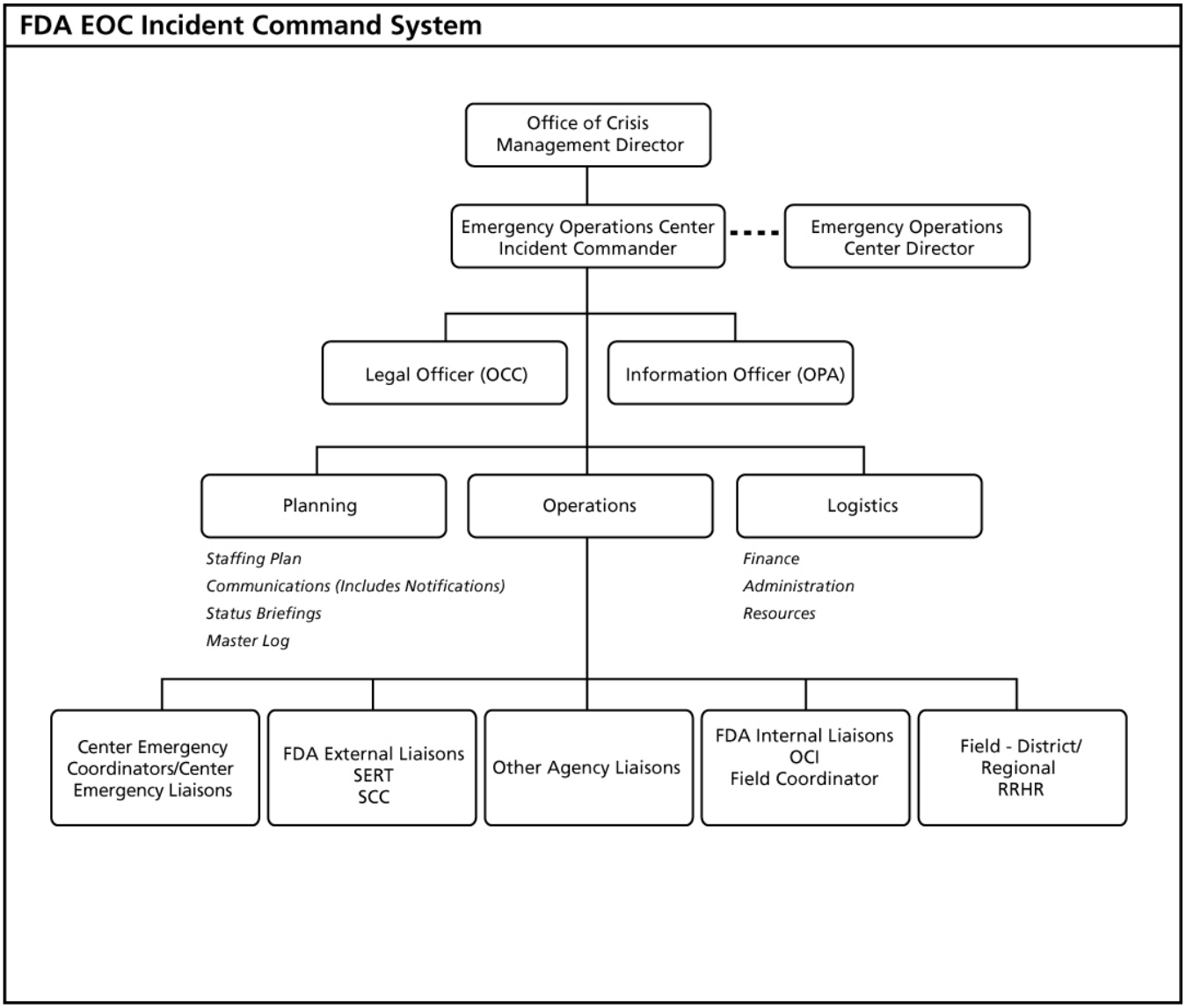
The FDA EOC assesses resource requirements on an ongoing basis during a C/B emergency. The FDA EOC works with HHS and/or the HHS Secretary's Emergency Response Team (SERT) to coordinate the provision of required resources. The FDA EOC distributes mobilization and deployment timelines. If requested, HHS 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-4.

Figure IV-4. 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 C/B 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

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 C/B 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 HHS, USDA, FBI, 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 C/B 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 C/B emergency, a C/B 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 no longer requires its assistance, or upon fulfillment of its statutory responsibilities. The INRP contains 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 any deployments in support of emergency operations.
- Development of FDA internal lessons learned report.

IV.E OPERATING PROCEDURE—RECOVERY

The FDA EOC IC will continually assess the emergency and determine whether to continue operating the FDA EOC or modify or terminate the FDA EOC'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 will participate in recovery activity, as required. 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, disposing, and reconditioning of products.
- Implementing appropriate security measures.
- Assessing similar products for potential contamination.
- 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 using the Lessons Learned Report input form.

V. AUTHORITIES

The FDA conducts activities pursuant to the following authorities:

- DHHS and Medical Services Support Plan for the Federal Response to Acts of Chemical/Biological Terrorism (June 1996).
- Executive Order #12656, National Security Emergency Preparedness (November 18, 1988). (http://www.fas.org/irp/offdocs/EO12656.htm).
- Executive Orders (as issued).
- The Federal Anti-Tampering Act (USC Title 18, Section 1356) (http://www.fda.gov/opacom/laws/fedatact.htm).
- Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended (USC Title 21). (http://www.access.gpo.gov/uscode/title21/chapter9_.html).
- Homeland Security Presidential Directive 5; HSPD-5 (February 2003). (http://www.whitehouse.gov/news/releases/2003/02/20030228-9.html).
- PDD 62, "Combating Terrorism" (May 22, 1998). (http://www.fas.org/irp/offdocs/pdd-62.htm).
- Public Health Service Act, as amended, 42 USC, Section 319 & 311. (http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm).
- Public Law 93-288, As Amended "The Robert T. Stafford Disaster Relief and Emergency Assistance Act." (http://www.fema.gov/library/stafact.shtm).
- Public Law No: 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (http://tis.eh.doe.gov/biosafety/library/PL107-188.pdf).
- The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, Title VI, 42 USC 5195 et seq. (http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm).
- U.S. Department of Health and Human Services Counter-Terrorism Concept of Operations Plan (Version IXb).
- U.S. Government Interagency Domestic Terrorism Concept of Operations Plan (CONPLAN). (http://www.fema.gov/pdf/rrr/conplan/conplan.pdf).
- U.S. Policy on Counter-terrorism, PDD 39 (June 21, 1995). (http://www.fas.org/irp/offdocs/pdd39.htm).

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
APHIS	Animal and Plant Health Inspection Service
ASPHEP	Assistant Secretary for Public Health Emergency Preparedness
ASTM	American Standard Testing Methods
ATP	Adenosine Triphosphate
ATSDR	Agency for Toxic Substance and Disease Registry
BIA	Bureau of Indian Affairs
CAERS	CFSAN Adverse Event Reporting System
CAM	Chemical Agent Monitor
CAS	Chemical Abstract Service
C/B	Chemical/Biological
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
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
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
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DIOP	Division of Import Operations and Policy
DIS	Defense Investigative Service
DMAT	Disaster Medical Assistance Team
DMORT	Disaster Mortuary Operational Response Team

DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOE	Department of Energy
DOS	Department of State
DOT	Department of Transportation
DPEM	Division of Planning, Evaluation, and Management
ECRS	Emergency Coordination and Response Staff
eLEXNET	Electronic Laboratory Exchange Network
EOC	Emergency Operations Center
EP&R	Emergency Preparedness and Response
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
FOIA	Freedom of Information Act
FRP	Federal Response Plan
FSIS	Food Safety and Inspection Service
GETS	Government Emergency Telecommunications Service
GIS	Geographical Information System
GMP	Good Manufacturing Practices
HAN	Health Alert Network
HazMat	Hazardous Materials
HHS	Health and Human Services
Hg	Hectogram
HSPD	Homeland Security Presidential Directive
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	Investigational New Drug
IOM	Investigations Operations Manual

IT	Information Technology
IUPAC	International Union of Pure and Applied Chemistry
JIC	Joint Information Center
JOC	Joint Operations Center
LD	Lethal Dose
LRN	Laboratory Response Network
MEK	Methyl Ethyl Ketone
MOU	Memorandum of Understanding
MSDS	Material Safety Data Sheet
MST	Management Support Team
NCS	National Communications System
NCTR	National Center for Toxicological Research
NDMS	National Disaster Medical System
NEDS	National Electronic Disease Surveillance System
NIH	National Institutes of Health
NIMS	National Incident Management System
NLM	National Library of Medicine
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
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
OIT	Office of Information Technology
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
OSC	On-Scene Coordinator

OSOPP	Office of Security Operations, Policy, and Planning
OSS	Office of Shared Services
PCR	Polymerase Chain Reaction
pH	Potential of Hydrogen
PHS	Public Health Service
POC	Point of Contact
PPE	Personal Protective Equipment
REOC	Regional Emergency Operations Center
RFA	Request for Assistance
RFI	Request for Information
RHA	Regional Health Administrator
RPM	Regulatory Procedures Manual
SCC	Secretary's Command Center
SERT	Secretary's Emergency Response Team
SOP	Standard Operating Procedures
SNS	Strategic National Stockpile
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
VVND	Newcastle Disease Virus
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WMD	Weapons of Mass Destruction

ANNEX B—DEFINITIONS

Items in this section are as follows:

Tab 1 General Definitions
Tab 2 C/B-Specific 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.

Code of Federal Regulations: A collection of regulations promulgated under United States Law. For example, 29 CFR 1910.120 applies to Hazardous Waste Operations and Emergency Response (HAZWOPER).

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.

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.

Food Safety: The protection of food and cosmetic products from reasonably foreseeable chemical, biological, or physical hazards. Food safety serves as the foundation for food security efforts and pertains to unintentional contamination.

Food Security: Measures taken to prevent or deter the intentional contamination of food or cosmetic products.

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

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.

Presumptive: Information (analytical, inspectional, investigational, etc.) strongly suggests that a problem exists. Presumptive describe situations that include the following:

- Epidemiological data providing a significant association between the illness, injury, or unanticipated adverse reactions and the product.
- An original analysis by a reliable laboratory revealing a significant level of a toxic chemical or microbial substance in a regulated product, but confirmation is not complete.

Presumptive Positive: A sample that causes a positive reaction in a screening test, but requires confirmation through other biochemical or serological methods.

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.

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.

Suspect Versus Implicated Product: In the outset of an investigation, preliminary evidence may suggest association of a product or products with the illness. The FDA considers these suspect products. When substantive evidence becomes available showing an association between the product and the illness, it implicates the product (e.g., a food) as the cause of the illness. Epidemiological data (e.g., statistically valid cohort study), laboratory results of the suspected product that are positive for the pathogen causing the illness, and/or a product preparation review identifying the vehicle and the contributing factors that lead to the illness are examples of the substantive evidence that elevate the product from suspect to implicated.

Tampering: Interfering with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, with reckless disregard for the risk of placing another person in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tainting any consumer product or rendering materially false or misleading the labeling of, or container for, a consumer product if such consumer product affects interstate or foreign commerce; and/or knowingly communicating false information of a tainted consumer product, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, would create a risk of death or bodily injury to another person.

Terrorism: 28 CFR, Section 0.85 defines terrorism as "…the unlawful use of force and violence against persons or property to intimidate or coerce a government, the civilian population, or any segment thereof, in furtherance of political or social objectives."

Traceback Investigation: The method used to identify the sources of the products implicated in a foodborne outbreak. 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 epidemiological investigation of foodborne illness.

Tab 2 C/B-Specific Definitions

(Adapted from *Hazardous Waste Site Worker Manager/Supervisor Instructor Guide*, Aberdeen Proving Ground Technical Escort Unit, All American Environmental Services, Inc.)

Absorption: Use of a sorbent, which pulls the product inside the sorbent. Examples include application of clay or organic fiber (fiber pearl, peat sorb, drum mats, Spill pillows, Drum Collars, etc.) absorbent to a hazardous material spill.

Acid: Substances with a pH less than or equal to 2 ($pH \leq 2$) categorize an acid as corrosive by the Environmental Protection Agency (EPA). Some organic acids, such as acetic and butyric, can have a pH around 3 or 4.

Acidic: Substances with a pH less than 7 ($pH < 7$).

Acute Effect: Adverse effect on a human or animal that has severe symptoms developing rapidly and coming quickly to a crisis.

Acute Toxicity: Acute effects resulting from a single dose of or exposure to a substance. Ordinarily used to denote effects in experimental animals.

Acutely Hazardous Waste: A waste material that exhibits the following criteria: (1) fatal in low doses in humans, and (2) contributes to an increase in a serious irreversible or incapacitating reversible illness. In the absence of data on human toxicity, studies indicate to have an oral LD_{50} toxicity (rat) of less than 50 milligrams per kilogram, or an inhalation LC_{50} toxicity (rat) of less than 2 milligrams per liter, or a dermal LD_{50} toxicity (rabbit) of less than 200 milligrams per kilogram.

Airborne Exposure Limit: An arbitrary limit established for personnel exposed to a particular material. Usually expressed in milligrams (of material) per meter cubed of air.

Base: A substance that (1) liberates hydroxide (OH) ions when dissolved in water, (2) receives hydrogen ions from a strong acid to form a weaker acid, and (3) neutralizes an acid. Bases react with acids to form salts and water. Bases have pH greater than 7 and turn litmus paper blue. Substances with a pH greater than or equal to 12.5 ($pH \geq 12.5$) categorize a basic as corrosive by the EPA. Bases often have secondary characteristics. Organic bases have a pH greater than 7 ($pH > 7$) and always contain nitrogen. Cyanide, a poison, has a pH near or above 12.

Biological Agent: Any microorganism, virus, infectious substance, or biological product engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, capable of causing (1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (2) deterioration of food, water, equipment, supplies, or material of any kind; or (3) deleterious alteration of the environment.

Biological Terrorism: Offensive and deliberate use of biological agent(s) with the intent to cause harm to human, animals, plants, and/or materials to advance a political, religious, or other purpose.

Biological Toxin: The toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including (1) any poisonous substance or biological product engineered as a result of biotechnology produced by a living organism; or (2) any poisonous isomer or biological product, homolog, or derivative of such a substance.

Blister Agents: Chemical agents designed to blister the skin or mucous membranes upon contact.

Blood Agents: Chemical agents designed to interfere with the normal functioning of blood.

Blood Borne Pathogens: Usually associated with 29 CFR 1910.1030 ruling on the protection required for workers contaminated with blood or other media that possibly contains blood borne pathogens. First aid providers must be familiar with the protection and the Toxic Exposure Plan due to the chance of exposure to blood borne pathogens as a part of the requirements of their job.

Boiling Point: The temperature at which a product's vapor pressure equals atmospheric pressure. At this temperature, the liquid will rapidly become a vapor.

Breakthrough: When a substance permeates a barrier (such as the barrier fabric of chemical protective clothing or an Air Purifying Respirator), breakthrough occurs at the detection of the substance on the inside of the barrier.

Chemical Abstract Service (CAS) Number: A number assigned to a chemical by the American Chemical Society.

Caustic: Any strong alkaline substance that has a corrosive or irritating effect on living tissue. A substance that is chemically similar to sodium hydroxide (NaOH).

Ceiling Limit: The maximum allowable human exposure limit for an airborne substance that one should not exceed even momentarily.

Characterization: The classification and identification of the material from a drum, container, or sample that identifies the hazards, packaging criteria, handling criteria, and other information that an emergency responder or hazardous material handler should know prior to handling/packaging/shipping any material.

Chemical: An element (e.g. chlorine) or a compound (e.g., sodium bicarbonate) produced by a chemical reaction.

Chemical Asphyxiates: Materials which prevent or slow down the absorption of oxygen by the blood, causing illness or death due to the lack of oxygen to the body despite sufficient available oxygen in the atmosphere.

Chemical Degradation: The decomposition of any material through the action of a chemical that causes this decomposition through a reaction with the surface of the material affected.

Chemical Family: A group of single elements or compounds with a common general name. Example: acetone, methyl ethyl ketone (MEK), and methyl isobutyl ketone (MIBK) are of the "Ketone" family; acrolein, furfural, and acetaldehyde are of the "aldehyde" family.

Chemical Formula: The elements and chemical structure as specified by the American Chemical Society.

Chemical Name: The name given to a chemical in the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the CAS. The scientific designation of a chemical or a name that clearly identifies the chemical for hazard evaluation. Most common military agents have CAS numbers that are available in FM 3-9 and/or in Section One of their particular Material Safety Data Sheet (MSDS).

Chemical Sub Class: The American Standard Testing Methods (ASTM) F1186 defines chemical sub classes. This information is critical when selecting personal protective equipment.

Chemical Terrorism: Offensive and deliberate use of chemical agent(s) with the intent to cause harm to humans, animals, plants, and/or materials to advance a political, religious, or other purpose.

Chlorine: Cl is a halogenated elemental material.

Choking Agents: Chemical agents that cause membranes to swell in the nose, throat, and lungs which causes a choking sensation. In extreme cases, the lungs fill with fluid and cause the death of the individual through suffocation (referred to as a dry land drowning).

Chronic Toxicity: Adverse (chronic) effects resulting from repeated doses of or exposures to a substance over a relatively prolonged period of time. Ordinarily used to denote effects in experimental animals.

Combustible Liquid: Any liquid having a flashpoint at or above 100 F (37.8 C), but below 200 F (93.3 C), except any mixture having components with flashpoints of 200 F (93.3 C) or higher, the total volume of which makes up ninety-nine (99) percent or more of the total volume of the mixture.

Common Name: Any means used to identify a chemical other than its chemical name (e.g., code name, code number, trade name, brand name, or generic name). See also Generic.

Concentration: The relative amount of a substance when combined or mixed with other substances.

Confirmed: Confirmation of a problem through laboratory analyses, field investigations, analysis of epidemiological data, or a combination of these. Information received from another governmental agency or other source known to be reliable.

Containment: Holding the product within a damaged container, by use of plugging, patching, or other techniques.

Control: Any action or technique used to lessen the effects of a hazardous materials emergency, including containment and confinement.

Corrosive: By 49 CFR definition, a corrosive material is a liquid or solid that causes visible destruction or irreversible alterations in human skin tissue at the site of contact, or, in the case of leakage from its packaging, a liquid that causes a corrosion rate to mild steel greater than 1/4 inch per year. According to the EPA, substances with a pH less than or equal to 2 ($pH < 2$) categorize acid corrosives, and substances with a pH greater than or equal to 12.5 ($pH > 12.5$) categorize basic corrosives.

Cryogenics: Gases requiring cooling to a very low temperature to bring about a change from gas to liquid states. Stored at temperatures less than -150 F (-101. 9 C).

Decomposition: Breakdown of a material or substance (by heat, chemical reaction, electrolysis, decay, or other processes) into parts, elements, or simpler compounds.

Decontamination: Standard function required at hazardous materials incidents involving selection of decontamination tactics, establishment of decontamination facilities, and decontamination of contaminated victims and properly protected response personnel who are leaving the Hot Zone.

Degradation: The act of a chemical physically and visibly changing a piece of barrier fabric. Degradation observations include charring, a color change, a loss or gain in the weight of the barrier fabric, shrinking, swelling, or brittleness of the barrier fabric or other component of Personal Protective Equipment.

Diking: Use of natural and manmade barriers to retain or prevent the passage of spilled hazardous materials to an uncontaminated or critical area.

Dilution: The use of a solvent, such as water, to lessen the concentration of a contaminant.

Emergency Decontamination: Removal of contaminants from contaminated persons and/or persons injured at the time of release or during operations.

Etiologic: Biological hazards, primarily from disease causing organisms or the toxins they produce.

Evaporate: The change of a substance from a liquid to form a vapor in which the substance has the same chemical structure it had in the liquid state.

Exposure or Exposed: State of being open and vulnerable to a hazardous chemical by inhalation, ingestion, skin contact, absorption, or any other course; includes potential (accidental or possible) exposure.

Extremely Flammable: A flash point less than 30 F to 140 F.

Extremely Hazardous Substance: Chemicals determined by the EPA to be extremely hazardous to a community during an emergency spill or release as a result of their toxicity and physical/chemical properties (EPA).

Flammable Liquid: A liquid with a flashpoint not more than 141 F (60.5 C) or any material in a liquid phase with a flashpoint at or above 100 F (37.8 C) intentionally heated and offered for transportation or transported at or above its flashpoint in bulk packaging, with the following exceptions: Liquids meeting the definition of another hazard class or any mixture having one or more components with a flashpoint of 141 F (60.5 C) or higher, that makes up at least 99% of the total volume and the liquid is not for transportation or transported at or above its flashpoint.

Flashpoint: The lowest temperature at which a liquid produces enough vapors to momentarily support a fire on the surface of a liquid when an ignition source is near. The fire will not sustain.

Gas Chromatography: A process of detection in which a long thin tube (called a column), which contains a medium by way of a carrier gas (usually helium), draws in an unknown sample. The contaminant absorbs to the medium with different strength bonds and subsequently flows out the other end of the column into a detector.

Generic Name: A designation or identification used to identify a chemical by other than its chemical name (e.g., code name, code number, trade name, and brand name).

Halogen: An element in group seven of the Periodic Table. Listed in the order of their decreasing activity, halogens include fluorine, chlorine, bromine, iodine, and astatine. Fluorine is the most active of all chemical elements.

Hazard Class 3: Hazard Class 3 includes both flammable (having a high flammability hazard) and combustible (having a moderate flammability hazard) liquids.

Hazard Class 4: This Hazard Class includes flammable solids, spontaneously combustible materials (liquids or solids), and materials that are dangerous when wet (solids or liquids which are water reactive).

Hazardous Chemical: Any chemical whose presence or use is a physical hazard or a health hazard.

Health Hazard: A chemical for which there is significant evidence, based on at least one study conducted in accordance with established principles, that acute or chronic health effects may occur in exposed employees. The term “health hazard” includes chemicals that are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents that act on the hematopoietic system, and agents that damage the lungs, skin, eyes, or mucous membranes.

Hepatotoxins: Chemicals that produce liver damage.

Hydraulic: Physical properties of fluids.

Impervious: A material that does not allow another substance to pass through or penetrate it.

Incompatible: Materials that could cause dangerous reactions by direct contact with one another or other materials.

Inhalation: Breathing in of a substance in the form of a gas, vapor, fume, mist, or dust.

Insoluble: Incapable of dissolving in a liquid.

Irritant: A chemical, which is not corrosive, that causes a reversible inflammatory effect on living tissue by chemical action at the site of contact.

Isolation/Disposal: Isolation provides a temporary method of decontamination by containing contaminated items for either later decontamination or disposal. Disposal is the final step in the decontamination process; any material that cannot undergo effective decontamination must undergo safe and legal disposal.

Lethal Concentration: The concentration at which a substance will kill.

Lethal Concentration, Low: Lowest concentration of a gas or vapor capable of killing a specified species over a specified time.

Lower Explosive Limit: The minimum concentration of gas or vapor in air below which it is not possible to ignite the vapors.

Medical Countermeasures: Drugs, including vaccines and other biological products, and medical devices for individuals potentially exposed to a chemical or biological agent.

Medical Monitoring: The measurement of the body’s vital signs to determine current physical health. This type of monitoring is not a legal requirement, but assists greatly in

ensuring worker safety while involved in hazardous materials emergency response operations.

Medical Surveillance: A systematic program of medical examinations sequenced to detect and monitor the impact of workplace chemical exposures. 29 CFR 1910.120(f) requires Medical Surveillance.

MERCK Index: A reference manual that provides hazard information on a wide range of chemicals, drugs, and biological substances. It provides cross-references by CAS Number, Names, and Chemical Formula.

Material Safety Data Sheet: A brief written description of a material that is more complete than provided on a label. It contains information to aid in understanding the associated hazards of the material.

Nephrotoxins: Chemicals that produce kidney damage.

Nerve Agents: Chemical agents (usually organophosphorous cholinesterase inhibitors) that produce rapid effects to incapacitate or kill an exposed individual through effects on the central nervous system. Inhibition of the three cholinesterase enzymes affects the process by causing them to be unable to hydrolyze the acetylcholine. The acetylcholine accumulates at the site and continues to stimulate the organ or muscle.

Neurotoxins: Chemicals that produce their primary toxic effects on the nervous system.

Neutralization: Process by which one adjusts pH closer to neutral.

Neutralize: To eliminate potential hazards by inactivating strong acids, caustics, and oxidizers.

Non-Metals: The elements in the upper right side of the Periodic Table that are not metals.

Odor: A description of the smell of the substance.

Oral Toxicity: Adverse effects resulting from taking a substance into the body by mouth. Ordinarily used to denote effects in experimental animals.

Organic: Compounds based on carbon-hydrogen compounds that result from living organisms.

Overexposure: Exposure to a hazardous material beyond the allowable exposure limits.

Oxidizer: A chemical other than a blasting agent that initiates or promotes combustion in other materials. Oxidizers increase the flammability of materials and can cause fire when in contact with combustibles.

Oxidizing Agent: A chemical or substance that brings about an oxidation reaction. The agent may (1) provide the oxygen to the substance being oxidized, or (2) receive electrons being transferred from the substance undergoing oxidation.

Penetration: The act of a chemical passing through a piece of barrier fabric at an opening, such as zippers, tears, or holes in the garment.

Permeation: The act of a chemical passing through barrier fabric on a molecular level.

pH: The negative logarithm of the hydrogen ion concentration of a solution. The pH of a material can only be between 0 and 14. A pH of 7 is neutral and is the natural pH of water. As the number decreases below 7, the material is more acidic. As the number increases above 7, the material is more basic. Normally, materials are not dangerous to humans until the pH reaches 2 on the acidic side or 12.5 on the basic side.

Placards and Labels: Symbols, provided by the Department of Transportation (DOT), for identifying hazardous materials.

Reaction: A chemical transformation or change; the interaction of two or more substances to form new substances.

Solidification: The use of a chemical agent to solidify the contaminant for removal.

Solvent: A substance, usually a liquid, which dissolves other substances. The most common solvent is water.

Specific Chemical Identity: The chemical name, CAS Registry Number, or any precise chemical designation of a substance.

Stability: The ability of a material to remain unchanged. For MSDS purposes, a material is stable if it remains in the same form under expected and reasonable conditions of storage or use.

Toxic Concentration, Low: The lowest concentration of a gas or vapor capable of producing a defined toxic effect in a specified test species over a specified time.

Toxic Dose, Low: The lowest administered dose of a material capable of producing a defined toxic effect in specified test species.

Tear Agents: Chemical agents that have the ability to cause tearing of the eyes and mucous membranes up exposure to unprotected individuals.

Threshold Limit Value: A term used to express the airborne concentration of material to which nearly all persons can receive exposure day after day without adverse effects.

Toxic Chemical Agents: Chemical agents that will produce a toxic effect in exposed individuals.

Toxic Substance: Any substance that can cause acute or chronic injury to the human body, or may cause diseases or injury under some conditions.

Toxicity: The sum of adverse effects resulting from exposure to a material, generally by the mouth, skin, or respiratory tract.

Upper Explosive Limit: The maximum concentration of gas or vapor in air at which it is no longer possible to ignite the vapors.

Unstable: Tending toward decomposition or other unwanted chemical change during normal handling or storage.

Vapor Density: The weight of a vapor or gas compared to the weight of an equal volume of air is an expression of the density of the vapor or gas. Materials lighter than air have vapor densities less than 1.0; materials heavier than air have vapor densities greater than 1.0.

Vapor Emissions: The physical displacement of saturated vapors can produce short-term, relatively high vapor concentrations.

Vapor Pressure: The pressure of vapor molecules pushing against their container; identifies how fast the liquid will convert to a vapor. The higher the vapor pressure, the faster the released liquid will become a vapor. Products with vapor pressures greater than 14.7 psi or 760 mm Hg are normally found in the gaseous state.

Vapor: The gaseous form of a solid or liquid substance as it evaporates.

Volatility: A measure of how quickly a material evaporates.

Vomiting Agents: Chemical agents that will cause exposed subjects to vomit.

Water Reactivity: A material that will decompose or react when exposed to moisture or water.

Water Solubility: The relative amount of something that will dissolve in water.