

DOE Order 151.1C and Guidance for Biosafety Facilities

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Agenda

- **DOE Order 151.1C**
 - General
 - Screening Process
 - Operational Emergency
 - Protective Action Criterion (PAC)
 - Hazardous Materials Program [including Emergency Planning Hazards Assessment (EPHA)]

Agenda

- **Guidance for 151.1C**
 - General Approach
 - Technical Planning Basis
 - Programmatic Elements
 - Response Elements

Order 151.1C

GENERAL

- Biological hazardous materials used/stored for research in DOE/NNSA facilities

NOT

- Materials that may be brought onto DOE/NNSA sites and employed in malevolent events by terrorists

Order 151.1C

GENERAL

- **Order foundation:**
 - **10 CFR 851** Biological Safety
 - *Select Agent Rule(s)* biosafety concepts from Biosafety in Microbiological and Biomedical Laboratories (*BMBL*) and incident planning
 - Fundamental concepts of DOE Emergency Management System

Order 151.1C

GENERAL

- **10 CFR 851**

- Requires a biological safety program that establishes an *Institutional Biosafety Committee* (IBC) to review:
 - ✘ Work with biological *etiologic* agents for compliance with regulations and other guidelines and assesses containment level, facilities, procedures, practices, and training and expertise of personnel
 - ✘ Reviews site *emergency management* plans and procedures to ensure that they adequately consider work involving biological *etiologic* agents

Order 151.1C

GENERAL

- **10 CFR 851**

- Biological safety program:

- ✘ Maintains an inventory and status of biological etiologic agents
 - ✘ Confirms that emergency management programs address biological *etiologic* agents, with particular emphasis on biological *Select Agents*

Order 151.1C

GENERAL

- **SELECT AGENT RULE(S)**

- “Commensurate with hazards” as reflected in the BMBL Biosafety Levels (BSL)
- Minimum quantity subject to regulations
 - ✗ AGENTS – No minimums specified
 - ✗ TOXINS – Minimum threshold quantities given for *Select Agent Rule(s)* applicability

Order 151.1C

GENERAL

■ SELECT AGENT RULES

- Notifications/communications to Centers for Disease Control (CDC)/Animal and Plant Health Inspection Service (APHIS)
 - ✘ No measure of severity – *any release* from primary containment
 - ✘ *Incident Response* includes Protective Actions (PAs)

Order 151.1C

GENERAL

- **DOE EMERGENCY MANAGEMENT**
 - Planning and preparedness for emergency response are “*commensurate with hazards*”
 - Emergency response is the “*last line of defense*”
 - “*Prompt recognition*” is vital to effective and commensurate response

Order 151.1C

SCREENING PROCESS

- ***Identify*** Hazardous Biological Materials:
 - *Select Agents and Toxins* regulated by 42 CFR Part 73 and/or 7 CFR Part 331 or 9 CFR 121
 - Regulated *implies* quantities of toxins exceed minimums specified in Rule(s)
- ***IF*** a facility uses or stores **Select Agents and Toxins, *THEN***:
 - Subject to DOE O 151.1C
 - Required to perform an **EPHA**
 - Requires a **Hazardous Materials Program**

Order 151.1C

OPERATIONAL EMERGENCY

- Operational Emergency (OE) - *ANY* actual or potential release of a hazardous biological agent/toxin outside of the *secondary* barriers of the biocontainment area
 - *Categorized*, but *NOT* classified
 - *Notifications* to CDC/APHIS, DOE/NNSA HQ and Cognizant Field Elements, and Local and State Response/Public Health Agencies (by prior agreement)

Order 151.1C

PROTECTIVE ACTION CRITERION

- For *Select Agents/Toxins*:
 - Protective action criterion is considered exceeded and immediate protective actions are required for *any biological Operational Emergency*
 - Long term protective action criteria are specified by State or local public health officials

Order 151.1C

HAZARDOUS MATERIALS PROGRAM

- *Select Agents/Toxins* in a DOE/NNSA facility
 - *Hazardous Materials Program* required:
 - ✘ Technical Planning Bases
 - ✓ Hazards Survey
 - ✓ EPHA
 - ✘ Programmatic Elements
 - ✘ Response Elements

Guidance

GENERAL APPROACH

- Focus/emphasis on *integration* with site emergency management program
- *Analyze* emergency events (*qualitative; semi-quantitative; quantitative*)
- **Response** is *scenario-* and *agent/toxin-specific*
- *All guidance related to biosafety facilities is contained in Vol. V of the Emergency Management Guide (EMG)*



Guidance

TECHNICAL PLANNING BASIS

- Hazards Survey
- Emergency Planning Hazards Assessment (EPHA)

Guidance

HAZARDS SURVEY

- *All DOE/NNSA facilities* are required to develop a Hazards Survey
- Biosafety facility Hazards Surveys . . . same level of detail as other facilities
- If the screening process identifies Select Agents or Toxins, an EPHA and Hazardous Materials Program is required

Guidance

EMERGENCY PLANNING HAZARDS ASSESSMENT (EPA)

- Generally, the same methodology for *airborne biological releases* as applied to other hazardous materials
- Exceptions:
 - No full consequence calculations unless an applicable model can be identified
 - Currently, no Protective Action Criteria (PACs)
 - Geographic area for protective actions may be based on *professional judgment* making use of available indicators and MET parameters

Guidance

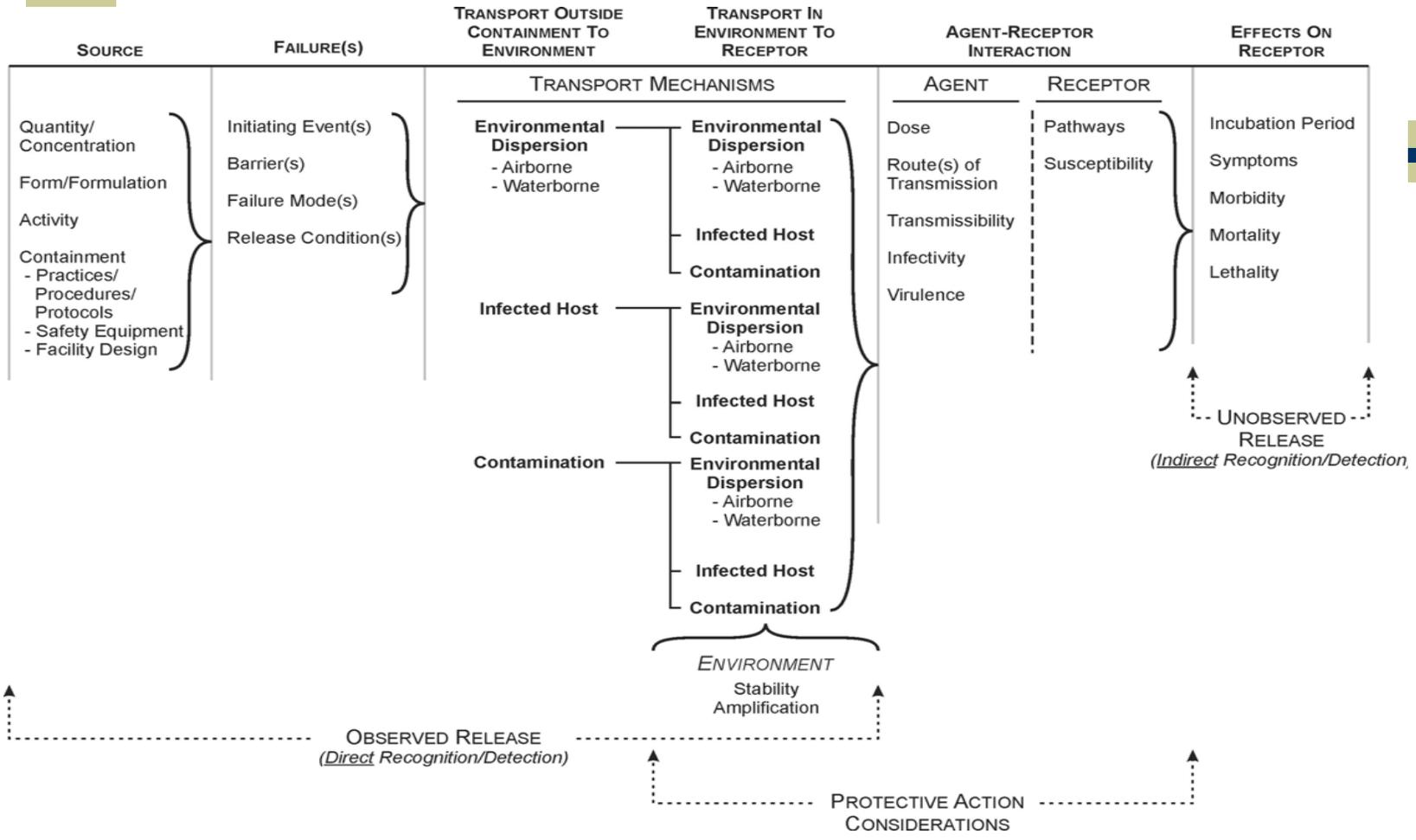
EMERGENCY PLANNING HAZARDS ASSESSMENT (EPA)

- Other plausible *transport mechanisms* addressed
- *Observed* and *unobserved* releases should be considered/analyzed
- Plausible release scenarios and associated *recognition factors* for *direct* (observed) and *indirect* (unobserved) detection
- *Initial protective actions* determined for both *observed* and *unobserved* releases

Guidance

EMERGENCY PLANNING HAZARDS ASSESSMENT (EPA)

- No detailed quantitative methodology provided in the guidance
- A structured approach for “analysis” is suggested
 - A (simplified) *schematic representation of a release scenario*
 - Includes agent, activity, and facility characteristics that impact recognition, potential consequences, and selection of protective actions





Guidance

PROGRAMMATIC ELEMENTS

- Program Administration
- Training and Drills
- Exercises
- Readiness Assurance

Guidance

PROGRAM ADMINISTRATION

- The *Responsible Official (RO)* has overall responsibility for implementing and maintaining the emergency management program as the **emergency management program administrator**:
 - Responsible for the development of an integrated emergency plan based on Order 151.1C and the Select Agent Rule(s)
 - Ensures that training, drills, and exercises for biological response are coordinated and integrated with existing site programs

Guidance

TRAINING AND DRILLS

- *Integration* of DOE O 151.1C and Select Agent Rule(s) training needs and requirements
- Routine surveillance of experience and skill levels of biosafety facility personnel in *at-risk positions*
- *Symptom-specific awareness training* should be provided for all personnel directly involved with biosafety facility activities
- *Onsite medical personnel* should be involved in emergency and hazard-specific training and drills

Guidance

TRAINING AND DRILLS

- Training and drills should address both *observed* and *unobserved* releases
- *Offsite* personnel/organizations expected to respond to onsite emergencies (e.g., public health officials, community medical personnel) should be invited to participate in *hazard-specific (within security constraints) training and drills*, periodically

Guidance

EXERCISES

- The Select Agent Rule(s) requires that drills or exercises be conducted at least annually to *test and evaluate* the effectiveness of the emergency plan
- DOE O 151.1C requires that a *facility-level exercise* must be conducted annually
- *Biosafety facility* should be the *basis for a site exercise*, in its turn, as part of the *rotation among facilities*

Guidance

EXERCISES

- The *integration* of hazardous biological release response with the site-wide emergency program should be tested and demonstrated
- The biological exercise program should be hazard specific and address *observed* and *unobserved* releases
- *Offsite response organizations* should be invited to participate in exercises at least *every three years*, and more frequently if possible

Guidance

READINESS ASSURANCE

- As part of a site-wide *readiness assurance program*, biosafety facilities should implement a structured program of evaluations, improvements, and ERAPs
- Mutual sharing of *lessons learned* among similar DOE/NNSA laboratories, as well as, academic institutions and private industry should be an integral part of the improvement program

Guidance

RESPONSE ELEMENTS

- **Emergency Response Organization (ERO)**
- **Offsite Response Interfaces**
- **Emergency Facilities and Equipment**
- **Emergency Categorization and Classification**
- **Notifications and Communications**
- **Consequence Assessment**
- **Protective Actions and Reentry**
- **Emergency Medical Support**
- **Emergency Public Information**
- **Termination and Recovery**

Guidance

EMERGENCY RESPONSE ORGANIZATION (ERO)

- The biosafety *facility-level* ERO should be structured to respond to a biological release as required
- Personnel from the biological health and safety program and laboratory personnel (e.g., microbiologists and toxicologists) should be assigned to the ERO along with an expanded role for the site medical staff.

Guidance

OFFSITE RESPONSE INTERFACES

- Offsite organizations and professionals that may be primary responders in biological OEs:
 - HHS/CDC and/or the USDA/APHIS
 - State and local Public Health Departments
 - Local Medical and Academic Community
 - Veterinarians

Guidance

OFFSITE RESPONSE INTERFACES

- DOE/NNSA biosafety personnel should interface with local and State public health organizations to:
 - Provide guidance for *identifying symptoms* associated with agents/toxins from the facility
 - Establish *mutual understanding* of response measures to be implemented onsite in anticipation of their involvement
- Local medical and academic community may provide *backup capability* for responding to an outbreak

Guidance

EMERGENCY FACILITIES AND EQUIPMENT

- The command center onsite should be fully prepared to respond to a hazardous biological release (A command center dedicated solely to biological OEs is *not* necessary)
- Equipment should be available, operational and maintained to support actions to *contain the hazards associated with the facility-specific agents or toxins*. Lists of emergency equipment, and their locations should be included in the emergency plan

Guidance

EMERGENCY CATEGORIZATION AND CLASSIFICATION

- *Any* actual or potential release of a hazardous biological agent or toxin outside of the secondary barriers of the biocontainment area should be *categorized* as an OE
- OEs do not require classification
- Establish *criteria* or *indicators* for determining quickly if an event is a biological release OE

Guidance

EMERGENCY CATEGORIZATION AND CLASSIFICATION

- *Biosafety programs* should be monitored (i.e., routine surveillance activities) with an *active* focus on *recognition indicators*
- *Discretionary* criteria for declaring a biological OE should be available to the categorization authority
- Criteria for recognizing an *outbreak* related to facility-specific agents/toxins should be provided to the local medical/public health community for *prompt recognition* and *categorization* of an unobserved release

Guidance

NOTIFICATIONS AND COMMUNICATIONS

- Immediate notification of CDC or APHIS upon discovery of a release causing *occupational exposure* or a release outside of the *primary barriers* of the biocontainment area
- The *initial* notification format for a biological release OE can incorporate both DOE and CDC/APHIS requirements

Guidance

CONSEQUENCE ASSESSMENT

- *Confirmation* that a release to the environment has occurred
- Dose contours (e.g., ID₁₀, ID₅₀) may provide sufficient information for making safety determinations (**if *applicable model is available***), since there is no PAC for biological agents
- For *unobserved* releases, discovery will depend on indirect methods of detection and assessment (e.g., epidemiological modeling, medical expertise)

Guidance

PROTECTIVE ACTIONS AND REENTRY

- *Initial protective actions* for *OE*s will be a combination of general protective actions and agent/release-specific measures focused on *collocated workers* and the *public*
- *Predetermined* conservative initial onsite Protective Actions (PAs) and offsite Protective Action Recommendations (PARs) associated with the categorization of *OE*s
- *Onsite* protective actions should be implemented for an *unobserved* release, once the release is discovered

Guidance

PROTECTIVE ACTIONS AND REENTRY

- Specific protective actions depend on agent/disease characteristics (e.g., stability in the environment, transmissibility, infectivity)
 - If calculations are unavailable, area of implementation may be based on professional judgment using some meteorological parameters (e.g., wind direction)
- The planning and development of initial protective actions requires a coordinated effort between DOE/NNSA onsite *medical personnel* and offsite *public health agencies*

Guidance

EMERGENCY MEDICAL SUPPORT

- Provide *symptom-specific awareness training* and coordinate a central reporting and tracking process for ongoing onsite medical surveillance
- Medical personnel may be the *primary responders* and provide assistance in release detection/confirmation, consequence assessment, and protective actions
- Sources and means for obtaining *vaccines, antibiotics, or other specialized medicines* and *supplies* should be detailed in the *Emergency Plan*

Guidance

EMERGENCY PUBLIC INFORMATION

- *Medical and biosafety* personnel should be involved in the *development* of materials to be used in news releases
- In situations involving classified or unclassified controlled information, *sufficient releasable information should be made available to the public and the workers to explain the emergency and ensure their health and safety*

Guidance

TERMINATION AND RECOVERY

- *Termination* criteria for biological material release OEs will be similar to OEs that require classification
- *Recovery* from a biological release OE can involve significant coordination with local and State public health organizations, and possibly with CDC/APHIS

Order and Guidance

SUMMARY

- The scope of the Order may eventually be broadened to include biological *etiologic* agents, if appropriate
- Admittedly, detailed guidance is missing or vague in some areas of the current written guidance
- More detailed guidance will be developed as biosafety facilities begin to develop emergency management programs and experience is gained in the implementation of the Order and application (and evolution) of the guidance
- It is anticipated that the next version of the Emergency Management Guide (EMG) will *integrate* guidance for biological, radioactive, and chemical materials