



WMD Subcommittee Consultation with EPA-SAB-HSAC on BA-TAD

(Environmental Response Technical Assistance Document for *Bacillus anthracis*
Intentional Releases)

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BA-TAD Purpose

- Mitigate threats to public health and environment from intentional (actual or suspected terrorist) releases of *B. anthracis*.
- Provide Federal On-Scene Coordinators (FOSCs) with technical resources needed for their leadership role in Consequence Management phase (i.e., site characterization, decontamination, disposal, and clearance) of response
- Not intended for use in response to naturally occurring *B. anthracis* in agricultural or occupational settings.





BA-TAD Scope

- Designed specifically for the National Response Team (NRT) Federal On Scene Coordinators (FOSCs), whose agencies are part of the NRT, to support their role in these responses
- Content may also be helpful to first responders, facility managers and owners, and local, state, tribal, and territorial government agencies
- Not intended as detailed guidance for forensic investigations, public health (e.g., medical countermeasures), public affairs (e.g., instructions to the public), or recovery operations (e.g., rebuilding or relocation).





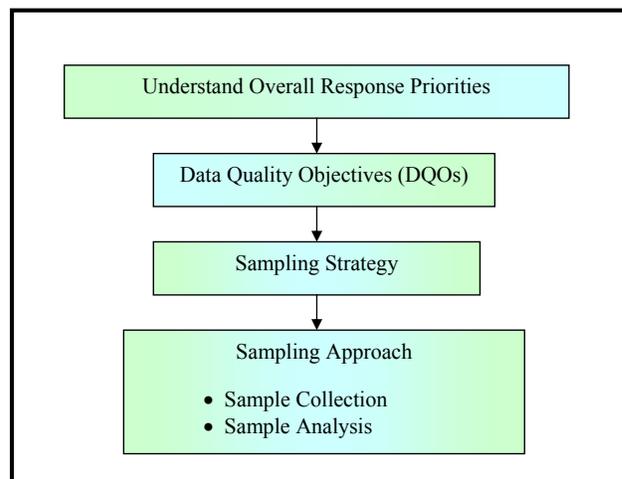
Basics of A Response

- Crisis Management - notification/first response
- Consequence Management
 - Site Characterization
 - Decontamination
 - Disposal
 - Clearance
- Recovery



Preparing to Sample: Overview

- Determine response priorities
- Develop DQOs
- Questions to answer
 - Where is contamination?
 - How much is there?
 - Is it alive?
 - Is it clean?
 - Confidence of results?





Preparing to Sample: Classification

- Divide area(s) into Classification Zones based on level of contamination or expected contamination:
 - Zone 1: Contaminated
 - Zone 2: Contamination Highly Likely
 - Zone 3: Contamination Not Likely
 - Zone 4: Contamination Very Unlikely





To Sample or Not to Sample?

- It may be more cost effective to immediately proceed to decontaminate an area or simply dispose of items w/out EXTENSIVE sampling and study based on site intelligence or visual clues.





Classification Zone 1: Contaminated

- Contamination is confirmed
- Will be decontaminated
- Judgmental sampling is recommended
- Confirm what we know and think





Classification Zone 2: Contamination Highly Likely

- Contamination is highly likely
- Not sure if decontamination is necessary
- Judgment and probabilistic
 - Use existing info to determine sampling locations
 - Use probabilistic sampling
 - Confidence Statements (e.g., 95% sure 99% area clean)
 - If < than Selected Release Criterion: Clear area
 - If > than Selected Release Criterion: Reclassify area Zone 1





Classification Zone 3: Contamination Not Likely

- Decontamination not likely
- Probabilistic or;
- Combination of Judgmental and Probabilistic
 - Use existing info to determine sampling locations
 - Use probabilistic sampling
 - Confidence statements (95% sure 99% area clean)
 - If < than Selected Release Criterion: Clear area
 - If > than Selected Release Criterion: Reclassify as Zone 1





Classification Zone 4: Contamination Very Unlikely

- No plausible pathway
- Decontamination not necessary
- No sampling necessary



Preparing to Sample: Sampling Plan (SP) Recommendations

- SPs should specify number, type, method and location (spatial and temporal) of sampling.
- SPs should provide an explanation and justification for the number and type of samples.





Preparing to Sample: Strategies

- Judgmental sampling
 - Based on observations, screening information and knowledge of event
- Statistical sampling
 - Probability-based
 - Provides confidence in results
- Composite





Sampling Strategy Selection

- Depends on Decision to be made:
 - Results must demonstrate release criterion has been met within predetermined confidence levels.
 - Sampling area has been evaluated sufficiently to develop a technically defensible decontamination or cleanup approach.
 - Verification of cleanup is possible





Sampling Strategy: Judgmental

- Professional judgment sample locations
- Source of contamination is known
- Physical/chemical characteristics are known
- Event-specific information is known
- Indirect evidence is available





Sampling Strategy: Probability-based

- Little or nothing is known where release occurred
- Applies statistical approach to sampling plan design
- Random sampling location selection
- Statistical inferences drawn about the data set
- Appropriate for quantitative comparisons with risk-based exposure levels



Types of Probability-based Samples Mentioned

- What it is and When used
 - Simple Random Sampling
 - Stratified Sampling
 - Systematic Sampling
 - Adaptive Cluster Sampling



Recommended Sampling Strategies

- Composite Sampling
 - Discrete samples are combined & homogenized into a single representative sample for analysis.
 - Averaging the analytical results of a few composites can produce an estimated mean that is as precise as one based on many more individual sample results thereby substantially reducing sampling costs.
 - Downside: Data from these samples cannot be applied to statistical tests.





Sampling: Collection

- Surface – Primary focus
 - Determines extent of contamination
- Air - Secondary focus
 - Provides additional relevant risk assessment info



Surface Sample Recommendations

- Porous Surface
 - High efficiency particulate air (HEPA)-vacuum filter socks.
- Non-Porous Surface
 - Swab or wipe samples are preferred
 - HEPA-vacuum sampling is also applicable



Air Sampling Recommendations

- Further characterize the agent
- PPE for Worker H&S
- Verification of containment of “Hot Zone” during cleanup operations
- Post decontamination confirmatory sampling





Analysis: Recommended Methods

- Laboratory Response Network (LRN) (future ELRN) methods or;
- Method(s) agreed upon by Response SMEs
 - Culture / PCR – Pros and Cons
 - Others?
 - Limit of detection





Cleanup Decision-Making Framework

- “Optimization Process;” flexible process that balances a variety of site-specific factors;
 - Stakeholder Concerns & Feasibility Issues
 - Populations of concern,
 - economic interests,
 - decontamination efficacy,
 - extent of contamination, etc.
 - Population dynamics and exposure estimates are combined with agent-specific information
 - pathogenicity,
 - preparation characteristics, etc.



Cleanup Decision-Making Framework

-site-specific factors (Continued)
 - Results of scientific vetting of decontamination options
 - Verification of clearance criteria – evaluation of criteria to define successful decontamination
 - Practicability of orderly reuse/re-occupancy that includes post-re-occupancy monitoring
- Clearance decisions then based on;
 - technical input,
 - interpretation of scientific data,
 - economic realities
 - as well as other factors





Decontamination: Overview

- Guidance will be provided for:
 - Developing a decontamination plan for an intentional (terrorist) release event
 - Options and technologies rather than prescriptive since the strategy chosen in an incident will be event-specific
 - The reality that our current approach may not be feasible for a large or wide-area release scenario



Decontamination: Overview

- Pros and cons of various decontamination technologies will be provided
- Considerations for use of a technology
- Off-site decontamination
- Criteria for confirming decontamination effectiveness





Decontamination: Wide-Area Issues

- BA-TAD may not fully address Wide-Area Issues; Information is sparse or not well vetted
- Expecting to finalize BA-TAD with best information at time of publication – more/better coming soon (2010)
- Anticipating updating when more definitive and broadly accepted information and approaches are available (e.g., IBRD* program currently addressing)

* IBRD = Department of Homeland Security and Defense Threat Reduction Agency are co-sponsoring the Interagency Biological Restoration Demonstration (IBRD) program. The IBRD program is a multi-year effort (ends in 2010) aimed at determining the best response and contamination mitigation methods for a wide-area, multiple-release bioterrorism event in an urban area.





Waste: Expected Types

- Personal Protective Equipment (PPE)
- Material & Equipment (e.g., metals, tools, piping, drywall, carpeting, conduit, furniture and dispersible bulk materials such as trash, rubble, roofing materials, and sludges)
- Wastewaters from decontamination and fumigant scrubbers





Waste: Waste Management

- Recommendations:
 - Notify waste & recycling providers early-on for agreement on packaging, labeling, storage, shipment, etc.
 - Using waste decision support tools (software)
 - Arrange for on-site treatment
 - If necessary, arrange for off-site treatment and certification of inactivation (e.g., radiation, autoclaving)



Waste: Pertinent Regulations

- Transportation – local, state, & federal
 - Packaging
 - Labeling
 - Shipping documents
- Disposal: size, packaging, and labeling considerations
 - Incineration – local, state and federal regulations regarding exhaust and ash disposal
 - Traditional incinerator
 - Hazardous or medical waste incinerator
 - Air curtain destructors
 - Landfill – local acceptance regulations





Waste Disposal Conclusions

- State and local regulatory agencies must be contacted early
- Approved disposal plans should be in place well before attempting any disposal activity



Releasing Wastewater to Publicly Owned Treatment Works

- Guidance will be provided for:
 - Handling of wastewater
 - Coordinating with local authorities on wastewater acceptance criteria
 - Chlorine concentrations and exposure times for acidified-bleach (white vinegar-household bleach-wastewater) solutions for containerized wastewater
 - Sampling and analysis (laboratory coordination) for determining effectiveness of disinfection within containers
- Recent research findings on inactivation of *B. anthracis* spores with aqueous chlorine will be included.



BA-TAD Status and Plans

- Draft 3 (Expect \approx 10 drafts to finalize)
- EPA-SAB-HSAC Consult in April 2009
- Use EPA-SAB-HSAC input to develop Internal Agency Review (IAR) BA-TAD
- IAR Draft BA-TAD – Summer 09
- Public Review Draft and EPA-SAB-HSAC Review Fall/Winter 2010
- Final Spring – Summer 2010





Charge Question 1 & 2

Given the intent that the BA-TAD will serve as a technical assistance versus technical methodology or resource document, what tools and strategies should be addressed in preparing the Federal On-Scene Coordinator (FOSC) to successfully manage and oversee the components of a response (i.e., characterization, decontamination, disposal, and clearance) to an intentional **INDOOR and WIDE AREA OUTDOOR** release of *B. anthracis* in industrial, commercial and residential buildings?





Charge Question 3

Are there worker health and safety issues, particular to *B. anthracis*, the BA-TAD should address?





Charge Question 4

For critical infrastructures or wide-area locations, a “Zero-Culturable-Spore” (ZCS) decontamination goal may not be achievable.

- What are possible cleanup strategies for minimizing risk to facilitate re-occupancy in industrial, commercial and residential buildings where a “ZCS” decontamination goal was not achieved?





Charge Question 5

The FOSC would, in a *B. anthracis* event, be functioning within an Incident Command System which typically includes a centralized communication structure with specific roles and responsibilities. The BA-TAD will address the key issues pertinent to the cleanup of environmental contamination with *B. anthracis*.

- What recommendations does the HSAC have for scientifically-sound communications to be included in the BA-TAD?
- More specifically, for the purposes of the BA-TAD, what recommendations does the HSAC have for the content of these communications?



Questions

