

TABLE OF CONTENTS

14		
15	1.0 Introduction	9
16	1.1 Purpose	9
17	1.2 Audience	9
18	1.3 Scope	9
19	1.4 Organization	10
20	2.0 Background on Biological Agents	12
21	2.1 Types of Biological Agents	12
22	2.1.1 Pathogens	12
23	2.1.2 Bacteria	12
24	2.1.3 Viruses	12
25	2.1.4 Biotoxins	12
26	2.2 Characteristics of Biological Agents	13
27	2.2.1 Infectivity	13
28	2.2.2 Viability of Pathogens and Activity of Biotoxins	14
29	2.2.3 Transmission	15
30	2.2.4 Routes of Exposure and Infection	15
31	2.2.5 Method of Dissemination	16
32	2.2.6 Availability and Effectiveness of Prophylaxis and Treatment	16
33	2.2.7 Availability	17
34	2.2.8 Environmental Persistence	17
35	2.2.9 Zoonotic Potential and Environmental Reservoirs	17
36	2.2.10 Resistance to Decontamination	17
37	2.2.11 Biotoxins	18
38	2.3 Biological Agents of Concern	18
39	2.3.1 Anthrax (<i>Bacillus anthracis</i>)	22
40	2.3.2 Plague (<i>Yersinia pestis</i>)	23
41	2.3.3 Smallpox (<i>Variola major</i>)	24
42	2.3.4 Tularemia (<i>Francisella tularensis</i>)	26
43	2.3.5 Glanders (<i>Burkholderia mallei</i>)	27
44	2.3.6 Botulinum Toxin	28
45	2.3.7 Botulinum Ricin	29
46	2.4 References	31
47	3.0 Overview of a Response to a Biological Incident	36
48	3.1 Overview	36
49	3.2 Biological Agent Incident-Response Decision Process	37
50	3.3 Reference	43
51	4.0 EPA Policy	44
52	4.1 Introduction	44
53	4.2 Response Authorities	44
54	4.3 Clean-up Timeline	46
55	4.4 Infection Control	47
56	4.5 Sampling: Extensive, Limited, or None?	48
57	4.6 Decontamination: Fumigation versus Surface Treatment Methods	49
58	4.6.1 Naturally Occurring <i>B. anthracis</i> Contamination	49
59	4.6.2 Intentional <i>B. anthracis</i> Contamination	50

60	4.7 Clearance Goals and Authority	51
61	4.8 Development of Self-Remediation Guidance	51
62	4.9 Response to Privately-Owned Monitoring Systems and “False-Positive” Incidents	52
63	4.10 Reference	53
64	5.0 Notification and First Response	54
65	5.1 Notification	54
66	5.2 First Response	54
67	5.3 Site Containment	55
68	5.4 References	55
69	6.0 Understanding Risk to Develop a Clearance Goal	Error! Bookmark not defined.
70	6.1 What’s the Risk?	Error! Bookmark not defined.
71	6.2 Assessing Risks of Biothreat Agents	Error! Bookmark not defined.
72	6.3 Site-Specific Risk Assessment for Bioterrorism	Error! Bookmark not defined.
73	6.3.1 Problem Formulation	Error! Bookmark not defined.
74	6.3.2 Data Collection and Analysis	Error! Bookmark not defined.
75	6.4 Derivation of a Clean-up Goal for <i>Bacillus anthracis</i>	Error! Bookmark not defined.
76	6.5 Summary	Error! Bookmark not defined.
77	6.6 References	Error! Bookmark not defined.
78	7.0 Worker Health and Safety	57
79	7.1 Introduction	57
80	7.2 Background and Regulatory Basis	57
81	7.3 Requirements and Training	57
82	7.3.1 40-hour HAZWOPER	Error! Bookmark not defined.
83	7.3.2 Medical Monitoring with Biological Clearance	57
84	7.3.3 Biological Awareness	58
85	7.4 Overview of Biological Agents	Error! Bookmark not defined.
86	7.4.1 CDC Classification of Biological Agents A, B, C	58
87	7.4.2 BioWatch	Error! Bookmark not defined.
88	7.5 Elements of Health and Safety	59
89	7.5.1 Medical Monitoring and Surveillance	59
90	7.5.2 Health and Safety Plan	59
91	7.5.3 Training	Error! Bookmark not defined.
92	7.5.4 Prophylaxis	59
93	7.5.5 Personal Protective Equipment (PPE)	60
94	7.5.6 Decontamination	61
95	7.6 References	61
96	8.0 Characterization Environmental Sampling and Analysis	62
97	8.1 Introduction	62
98	8.2 EPA Policy	62
99	8.3 Environmental Sampling Team	Error! Bookmark not defined.
100	8.4 Documentation	62
101	8.4.1 Written Documentation	63
102	8.4.2 Photographic and Video Documentation	63
103	8.4.3 Evidence Documentation	64
104	8.5 Data Management	64
105	8.6 Sampling Design	64

106	8.6.1 Define Overall Response Priorities	65
107	8.6.2 Develop Sampling Objectives	65
108	8.6.3 Specifying a Hypothesis	66
109	8.6.4 Developing a Sampling Plan	66
110	8.6.5 Sampling Approaches	67
111	8.6.6 Pre-Incident Data	67
112	8.6.7 Identifying Sampling Locations	68
113	8.7 Sampling Objectives	69
114	8.7.1 Immediate Assessment of Potential Contamination	69
115	8.7.2 Identification of Bulk Materials	69
116	8.7.3 Determine Exposure Pathway	69
117	8.7.4 Determine Contamination of an Article	69
118	8.7.5 Initial Agent Identification and Viability	70
119	8.7.6 Extent and Location of Contamination (Characterization Sampling)	70
120	8.7.7 Exposure Monitoring	70
121	8.7.8 Effectiveness of Decontamination (Remediation Sampling)	71
122	8.7.9 Post-Decontamination Verification (Clearance and Transitional Sampling)	71
123	8.8 Sampling Approaches	71
124	8.8.1 Judgmental Sampling	74
125	8.8.2 Probabilistic Sampling	76
126	8.8.3 Combined Judgmental and Probabilistic Sampling Approach	78
127	8.8.4 Advantages and Disadvantages of the Sampling Approaches	79
128	8.8.5 Composite Sampling	80
129	8.9 Sampling Methods	82
130	8.9.1 Types of Sampling	82
131	8.9.2 Sampling Collection Quality Assurance and Quality Control	97
132	8.9.3 Sample Preservation, Handling, and Storage	98
133	8.10 Sample Decontamination, Packaging, and Transport	98
134	8.10.1 Sample Decontamination	98
135	8.10.2 Sample Packaging	99
136	8.10.3 Sample Transport	99
137	8.11 Standard Operating Procedures	99
138	8.11.1 Sampling	99
139	8.11.2 Sample Documentation	100
140	8.12 References	102
141	9.0 Data Management	104
142	9.1 Introduction	104
143	9.2 Sample Documentation	104
144	9.2.1 Sample Collection Form	105
145	9.2.2 Sample Analysis Submission Form	105
146	9.2.3 Chain of Custody	Error! Bookmark not defined.
147	9.3 Data Management Plan	106
148	9.3.1 Managing Large Amounts of Data	106
149	9.3.2 Electronic Data Format	Error! Bookmark not defined.
150	9.4 Decision Support Tools	107
151	9.5 References	107

152	10.0 Analytical Methods	108
153	10.1 Introduction	Error! Bookmark not defined.
154	10.2 Complexity of Biodetection from Environmental Samples	108
155	10.3 Analytical methods	108
156	10.3.1 Analytical Methods for Site Characterization Samples	110
157	10.3.2 Analytical Methods for Post-Decontamination Samples	110
158	10.4 Protocol for Detection of <i>Bacillus anthracis</i> in Environmental Samples During the	
159	Remediation Phase of an Anthrax Event	116
160	10.5 Method Validation	117
161	10.6 Sample Storage	117
162	10.7 Important Laboratory Considerations	Error! Bookmark not defined.
163	10.8 Compositing the Samples for Analyses in a Laboratory	Error! Bookmark not defined.
164	defined.	
165	10.8.1 Questions	Error! Bookmark not defined.
166	10.8.2 Advantages	Error! Bookmark not defined.
167	10.8.3 Disadvantages	Error! Bookmark not defined.
168	10.9 Biological Select Agents	118
169	10.10 References	118
170	11.0 Clearance Strategy	120
171	11.1 Clearance Goals	120
172	11.2 EPA's Position on Clearance Goals and Authority	120
173	11.3 Interim Clearance Strategy for Environments Contaminated with <i>Bacillus anthracis</i> -	
174	DRAFT	121
175	11.3.1 Purpose	121
176	11.3.2 Overview of EPA Clearance Strategy	121
177	11.3.3 Indoor Clearance Guidance	122
178	11.3.4 Outdoor Clearance Guidance	123
179	11.3.5 Annex A - Clearance Strategy	123
180	11.4 Clearance Environmental Sampling and Analysis	125
181	11.5 Clearance Decision	126
182	11.6 References	127
183	12.0 Decontamination	128
184	12.1 Remediation/Decontamination Strategy	128
185	12.1.1 Decontamination Approach	129
186	12.1.2 Decontamination	130
187	12.1.3 Disposal	131
188	12.1.4 Cost	132
189	12.1.5 Plans	132
190	12.1.6 Remediation Action Plan	133
191	12.2 EPA's Position	134
192	12.3 Technical Decontamination Considerations	134
193	12.3.1 Background	136
194	12.3.2 Systems Approach to Remediation	137
195	12.3.3 Decontamination Options Support Tool	151
196	12.4 References	154
197	13.0 Technical Waste Management Considerations	157

198	13.1 Waste Management within an Integrated National Response Strategy	157
199	13.1.1 Overall Waste Management Approach for a Biological Agent Release	158
200	13.2 Key Statutory Authorities	159
201	13.2.1 Federal	159
202	13.2.2 Summary of the Proposed NY DEC Regulation for Regulating Biohazard Waste	
203	Management Facilities	161
204	13.2.3 Off-Site Rule [CFR 300.440]	Error! Bookmark not defined.
205	13.3 Waste Management	161
206	13.3.1 Applying Waste Management Strategies in Response to a Biological Incident	161
207	13.3.2 Evaluation of Waste Management Facilities for Supporting a Biological Incident	
208		163
209	13.3.3 State of the Science of Treatment/Disposal of Biological Agent-Containing Waste	
210		164
211	13.4 Key Policy Guidance	165
212	13.5 Characterization of Waste	166
213	13.6 Ownership of Waste	166
214	13.7 Types of Waste	166
215	13.8 Waste Management Options	167
216	13.8.1 Disposal	167
217	13.8.2 Treatment	167
218	13.8.3 Government Assets	168
219	13.8.4 Private Sector Assets	168
220	13.8.5 Interface Between ESF10 and ESF3	168
221	13.8.6 Waste Characterization and Identification	168
222	13.8.7 Waste Segregation, Storage, and Transportation	170
223	13.8.8 Waste Reduction and Minimization	171
224	13.8.9 Waste Acceptance by Receiving Waste Management Facilities	172
225	13.8.10 Waste Sampling and Analysis	172
226	13.8.11 Data Needs for Integrated Response	172
227	13.8.12 Waste Generation	173
228	13.8.13 Decision Trees and Flow Charts	175
229	13.8.14 Useful Tools for Responders	181
230	13.8.15 Community Outreach/Communications Plan	182
231	13.9 References	183
232	Appendices – All are located at http://epaossc.org/bioguide	184
233	A-1 Preparedness Strategy	184
234	A-2 Special Events Planning	184
235	A-3 Bio Technical Working Group	184
236	A-4 Training SOPs	184
237	A-5 Self Remediation	184
238	A-6 Risk Communication	184
239	A-7 Approved Decontaminants	184
240	A-8 Equipment	184
241	A-9 Sample Remediation Action Plan (RAP)	184
242	A-10 Transportation Facilities Decontamination	184
243	A-11 Water Systems Decontamination	184

244	A-12 Vehicle Decon Guide	184
245	A-13 Personnel Decon SOPs	184
246	A-14 CDC-EPA Interim Clearance Strategy for Environments Contaminated with <i>Bacillus anthracis</i>	184
247		
248	A-15 Subcommittee on Decontamination Standards and Technology of the White House	
249	National Science and Technology Council's Committee on Homeland and National Security	
250	(SDST) (2012), <i>Draft Planning Guidance for Recovery Following Biological Incidents</i> .	
251		184
252	A-16 EPA (2011), Wide-Area Anthrax Response Guidance.	184
253	A-17 DHS (2009), Draft Interim Consequence Management Guidance for a Wide-Area	
254	Biological Attack"	184
255	A-18 Sampling Appendices	184
256	A-18A – Sampling Checklists	184
257	A-18B – Example Forms	184
258	A-18C – List of Supplies	184
259		
260		
261	Table of Figures	
262	Figure 1. Basic phases of response to a biological incident	37
263	Figure 2. Biological-agent incident response decision process (1 of 5)	38
264	Figure 3. Biological-agent incident response decision process (2 of 5)	39
265	Figure 4. Biological-agent incident response decision process (3 of 5)	40
266	Figure 5. Biological-agent incident response decision process (4 of 5)	41
267	Figure 6. Biological-agent incident response decision process (5 of 5)	42
268	Figure 7. Diagram of NRC Risk Assessment/Risk Management Paradigm	Error! Bookmark
269	not defined.	
270	Figure 8. Site-Specific Risk Assessment Framework for Bioterrorism Events	Error!
271	Bookmark not defined.	
272	Figure 9. Bioterrorism Disease Triangle	Error! Bookmark not defined.
273	Figure 10. Exposure Pathway Analysis	Error! Bookmark not defined.
274	Figure 11. Basic Road Map for a Sampling Strategy	64
275	Figure 12. An example of a 1 hp leaf blower	95
276	Figure 13. Overall Schematic Diagram of Sample Analyses	109
277	Figure 14. Analytical Methods for the Remediation Phase Samples	111
278	Figure 15. An Example of Hand-Held Immunoassays	112
279	Figure 16. Principle of an Electrochemiluminescence Reaction	Error! Bookmark not
280	defined.	
281	Figure 17. Principle of TaqMan® Real-time PCR	Error! Bookmark not defined.
282	Figure 18. Examples of Commonly Used Real-time PCR Thermal Cyclers (Biosensors)	Error!
283	Bookmark not defined.	
284	Figure 19. Comparison of the RV-PCR and Culture-based Method for Sample Analysis	115
285	Figure 20. Explanation of the RV-PCR Results Algorithm	Error! Bookmark not defined.
286	Figure 21. The Clearance Process	124
287	Figure 22. Remediation Strategy	130
288	Figure 23. Schematic of Interdependencies of Homeland Security Response (Remediation)	
289	Activities	135