

**BIOTERRORISM DECONTAMINATION
A CRITICAL
REVIEW OF THE LITERATURE
May 4, 2009**

Prepared by the
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Abstract

Purpose: This report is an evaluation of the utility of *published* research and practices to facilities decontamination after a bioterrorism event. The primary intent was to establish the underpinning of the knowledge base to policy formulation.

Approach: Appropriate search engines were employed using pre-selected terms and phrases to identify relevant publications. Selected publications were subjected to a critical appraisal based upon established review criteria designed to assess the literature's quality, strength of evidence, and relevance to medical and health policy, guidelines or standards. The criteria were validated for consistency and used in the evaluations of the sampled literature. Both environmental and surface decontamination were addressed. Most weapon grade bio-agents are delivered into the environment in the form of respirable particles or droplets, and surface contamination is a secondary phenomenon. A pre-publication draft of this report was reviewed and commented on by a panel of experts. Monitoring, measuring or other sampling methods of surfaces or the environment are not addressed in this report.

Conclusions: Multiple combinations of search terms in two scientific databases yielded few relevant articles. We conclude that literature and scientific evidence regarding decontamination of biologic agents is sparse. This may be due, in part, to security concerns. No dedicated central government website or database for bioterrorism decontamination was identified. There is need for decontamination guidelines and specific recommendations to which facility managers and businesses can refer in the aftermath of a biologic event. Efforts by federal agencies to compile relevant literature into a single database would facilitate both experimental and translational research efforts.

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Purpose

The purpose of this paper is to address the adequacy and utility of published literature describing decontamination practices and standards for critical facilities after an intentional exposure to a biological agent (bioterrorism). We also assessed the adequacy of this information to policy development.

Definitions

Biological agents (bio-agent, bioterrorism agent) are viruses, bacteria, or other microorganisms and biological toxins used to cause illness or death in people, animals, or plants¹. These agents are divided into 3 categories (A, B, and C) by the Centers for Disease Control and Prevention (CDC). Category A agents are considered to present the highest risk to the public and to national security, while Category C agents include emerging pathogens which, if weaponized, could present a real public danger in the future.

Decontamination:

1. *Environmental decontamination* denotes removal of biological agents from the air.
2. *Surface decontamination* involves the disinfection or sanitization of surfaces contaminated with biological agents, such as carpet, ceiling materials, electronic equipment and furniture. Surface decontamination is considered by some experts to be a subset of environmental decontamination. Bio-agents resting on a surface may re-contaminate the environment if they become airborne.

Critical facilities: Are the assets or systems “so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, public health or safety, or any combination thereof.”²

Key Resources: Publicly or privately controlled resources essential to the minimal operations of the economy and government.

¹ Centers for Disease Control and Prevention. Emergency Preparedness and Response. “Bioterrorism Overview.” Available online: <http://www.bt.cdc.gov/bioterrorism/overview.asp>. Last accessed: April 14, 2009.

² Department of Homeland Security. “Critical Infrastructure and Key Resources.” Available online: http://www.dhs.gov/xprevprot/programs/gc_1189168948944.shtm. Last accessed: April 27, 2009.

Introduction

In 2001, the United States experienced its first, and so far only, bioterrorist event using weapons-grade *Bacillus anthracis* delivered by the postal service. Government facilities, private sector and individual property were contaminated as the result of this attack. Two Congressional office buildings were contaminated along with 26 other facilities processing and receiving contaminated mail, including the Library of Congress³. Clean-up costs for the Capitol Hill buildings are estimated at \$26 million⁴. In contrast, decontaminating the Brentwood and Trenton (New Jersey) mail distribution centers cost \$268.8 million⁵. Following the anthrax attacks, the Postal Service spent over an estimated \$1 billion in decontamination, equipment upgrades and emergency preparedness⁶. Both the Brentwood post office and a news building remained closed for over 18 months following the incident⁷.

While experts have identified bio-agents most likely to be used as weapons, information on environmental decontamination protocols and guidelines remains sparse. Clean-up of facilities affected during the 2001 anthrax attacks in some cases required repeated dosing of decontaminants due to insufficient knowledge of facility-appropriate needs⁸. Additionally, some experts have suggested that natural decay would render chemical decontamination unnecessary⁹; however, there is a paucity of scientific literature supporting this claim, as will be discussed.

In 2005 the National Academies published a report addressing the reoccupation of facilities after intentional contamination by a bioagent. The George Mason University (GMU) literature review has, in part, been undertaken to evaluate the progress in the scientific decontamination knowledge base three years following the publication of the National Academies report. The GMU evaluation attempts to add to the National Academies report by analyzing the literature for adequacy to decontamination policy and standard development.

This paper is a critical review of the *published* body of knowledge on bioterrorism decontamination through a standardized and systematic analysis. This analysis draws from the CDC category classification system for potential bioterrorism agents. The CDC system is used to identify and target microorganisms and viruses for analysis. Refer to Table A-1 below. An

³ United States General Accounting Office. Report to the Chairman, Committee on Finance, U.S. Senate. "Capitol Hill Anthrax Incident. EPA's Cleanup Was Successful; Opportunities Exist to Enhance Contract Oversight." Available online: <http://www.gao.gov/new.items/d03686.pdf>. Last accessed: April 14, 2009.

⁴ United States General Accounting Office. Report to the Chairman, Committee on Finance, U.S. Senate. "Capitol Hill Anthrax Incident. EPA's Cleanup Was Successful; Opportunities Exist to Enhance Contract Oversight." Available online: <http://www.gao.gov/new.items/d03686.pdf>. Last accessed: April 14, 2009.

⁵ Masci JR, Bass, ER (2004). *Bioterrorism: A Guide for Hospital Preparedness*. CRC Press.

⁶ Ibid.

⁷ United States General Accounting Office. Report to the Chairman, Committee on Finance, U.S. Senate. "Capitol Hill Anthrax Incident. EPA's Cleanup Was Successful; Opportunities Exist to Enhance Contract Oversight." Available online: <http://www.gao.gov/new.items/d03686.pdf>. Last accessed: April 14, 2009.

⁸ Cords, BR. "Biological Agents and Factors Effecting Decontamination." Available from Institute of Food Technologists. Accessed online: <http://members.ift.org/NR/rdonlyres/82C70B13-3D78-49C0-AC37-80523B8E20B0/0/Cords.ppt>. Last accessed: April 14, 2009.

⁹ Stuart A, Wilkening D (2005). "Degradation of Biological Weapons Agents in the Environment: Implications for Terrorism Response." *Environmental Science & Technology* 39(8), pages 2736-2743.

adequate, evidence-based, body of knowledge is necessary for the formulation of appropriate decontamination policies, guidelines and standards of practice.

Table A-1: CDC Bioterrorism Diseases/Agents by Category

Category A	
	Anthrax (<i>Bacillus anthracis</i>)
	Botulism (<i>Clostridium botulinum</i> toxin)
	Plague (<i>Yersinia pestis</i>)
	Smallpox (<i>Variola major</i>)
	Tularemia (<i>Francisella tularensis</i>)
	Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])
Category B	
	Brucellosis (<i>Brucella</i> species)
	Epsilon toxin of <i>Clostridium perfringens</i>
	Food safety threats (e.g., <i>Salmonella</i> species, <i>Escherichia coli</i> O157:H7, <i>Shigella</i>)
	Glanders (<i>Burkholderia mallei</i>)
	Melioidosis (<i>Burkholderia pseudomallei</i>)
	Psittacosis (<i>Chlamydia psittaci</i>)
	Q fever (<i>Coxiella burnetii</i>)
	Ricin toxin from <i>Ricinus communis</i> (castor beans)
	Staphylococcal enterotoxin B
	Typhus fever (<i>Rickettsia prowazekii</i>)
	Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
	Water safety threats (e.g., <i>Vibrio cholerae</i> , <i>Cryptosporidium parvum</i>)
Category C	
	Emerging infectious diseases such as Nipah virus and hantavirus

From: Centers for Disease Control and Prevention. "Emergency Preparedness and Response. Bioterrorism Disease/Agent by Category." Accessed online: January 8, 2008. Online: <http://www.bt.cdc.gov/agent/agentlist-category.asp>.

For background informational purposes, the websites of key stakeholders in bioterrorism decontamination were visited to assess role and adequacy of information provided.

National Academies

The National Academies perform a unique public service by bringing together experts in the sciences and technologies. These experts provide advice to the federal government and the public on issues of interest.

A 2005 National Academies Report was a two-year analytical project aimed at determining “how clean is safe?” and to address criteria that must be satisfied to reopen a biologically contaminated facility¹⁰. Specifically the report addresses the following questions:

What are the best ways to assess the presence of the agent? What are the best tests and how should they be applied? How much and what type of sampling is enough? How sensitive do the tests need to be? How many organisms constitute an “infectious” dose? What tests are necessary to declare an area safe? Risk analysis constitutes a major component of this study¹¹.

The report did not specifically analyze literature with the aim of determining the best evidence for decontamination technologies or agents; however, it does discuss decision-making issues surrounding the selection of certain decontamination methods and agents. It must be noted that most disinfectants commonly used for decontamination pose a distinct hazard to human health¹².

The National Academies Study Group concluded:

What has become clear is that there are three levels of consideration in the approach to decontamination: The first is the fact that decontamination within a ‘reasonable’ period is necessary and must proceed in a manner that is consistent with available knowledge and current regulations. The social aspect of decontamination and safe reoccupation—for example, stakeholder and occupant concerns—is another consideration. The third involves the recognition that there

¹⁰ National Research Council of the National Academies (2005). *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework*. The National Academies Press: Washington D.C.

¹¹ National Research Council of the National Academies (2005). *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework*. The National Academies Press: Washington D.C., page VIII.

¹² U.S. Environmental Protection Agency. “Anthrax spore decontamination using Chlorine Dioxide.” Accessed online: <http://www.epa.gov/pesticides/factsheets/chemicals/chlorinedioxidefactsheet.htm> . Last accessed: October 27, 2008. U.S. Department of Labor. Office of Occupational Safety and Health Administration. “Occupational safety and Health Guideline for Chlorine Dioxide.” Accessed online: <http://www.osha.gov/SLTC/healthguidelines/chlorinedioxide/recognition.html>. Last accessed: October 27, 2008. U.S. Environmental Protection Agency. “Anthrax spore decontamination using ethylene oxide.” Accessed online: <http://www.epa.gov/pesticides/factsheets/chemicals/etofactsheet.htm>. Last accessed: October 27, 2008.

is a lack of information that could influence both the effectiveness and the cost of decontamination, a state of affairs that should be remedied.¹³

National Response Team

The U.S. National Response Team (NRT) is responsible for coordinating federal planning, preparedness, and response actions related to releases of hazardous substances. NRT comprises 16 federal agencies each of which have responsibilities in the areas of public health, emergency response and environmental protection. The NRT composed a detailed report discussing *Bacillus anthracis* decontamination procedures, governmental resources, issues and processes¹⁴. The document was developed as a technical resource specifically for response to an actual or suspected terrorist release of anthrax. Fact sheets, provided for certain decontamination agents, indicate mechanism of action, application methods and sites, as well as previous decontamination use *in situ*.

Environmental Protection Agency

The Environmental Protection Agency's (EPA) mission is to protect human health and the environment. Following the terrorist attacks of September 11, 2001, and the subsequent mailing of anthrax-tainted letters, EPA's role with respect to homeland security was expanded¹⁵. Presidential Directives identify the EPA as the primary federal agency responsible for public water supplies and remediation following an attack on indoor or outdoor areas. EPA is the lead federal agency in charge of preparing the water sector for terrorist attacks and the lead agency for decontaminating indoor and outdoor areas following an attack. These areas include buildings, large public spaces such as airports, and wide outdoor areas such as stadiums. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. The National Homeland Security Research Center (NHSRC), within the EPA, is directed with the task of research in the area of indoor and outdoor decontamination. NHSRC research targets three areas: detection, containment and mitigation and remediation¹⁶.

The Office of Pesticide Programs within the EPA has oversight into registering and regulating chemicals and formulations as decontamination agents. As such, the EPA has produced "Topical and Chemical Fact Sheets" on the primary chemicals that have been given exemptions allowing them to be used as decontamination agents in previous events¹⁷. However, no references or

¹³ National Research Council of the National Academies (2005). *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework*. The National Academies Press: Washington D.C.

¹⁴ National Response Team. "Technical Assistance for Anthrax Response- Interim-Final Draft." Updated July 2005. Available online: [http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllAttachmentsByTitle/A-47AnthraxTAD/\\$File/Anthrax_TAD_72905.pdf?OpenElement](http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllAttachmentsByTitle/A-47AnthraxTAD/$File/Anthrax_TAD_72905.pdf?OpenElement). Last accessed: November 17, 2008.

¹⁵ U.S. Environmental Protection Agency. Homeland Security Research. "Basic Information." Available online: <http://www.epa.gov/nhsrc/basicinfo.html>. Last accessed: March 4, 2009.

¹⁶ U.S. Environmental Protection Agency. Homeland Security Research. "Indoor and outdoor decontamination research: Research focus." Available online: <http://www.epa.gov/nhsrc/aboutdecon.html>. Last accessed: March 4, 2009.

¹⁷ Environmental Protection Agency. "Pesticides: Topical and Chemical Fact Sheets." Available online: http://www.epa.gov/pesticides/factsheets/chemical_fs.htm. Last accessed: November 17, 2008.

evaluation methods are cited nor recommendations made regarding the practical uses of each in remediation efforts.

Additionally, the EPA Environmental Technology Validation (ETV) Building Decontamination Technology (BDT) Center is charged with validating the effectiveness of certain new technologies used for biologic decontamination. Reports were found on biologic decontamination technology validation, utilizing chlorine dioxide gas, hydrogen peroxide gas, formaldehyde gas (paraformaldehyde) and Ultra-violet light.

The Office of Research and Development, within the EPA, conducted workshops annually from 2005-2007 on decontamination and clean-up of sites contaminated with CBR (Chemical, Radiological and Biological) materials. The findings and conclusions of these workshops are presented in a later section of this report.

The research presented in this report evaluated and incorporated all obtainable relevant information available the general public in the published literature and on the EPA National Homeland Security Research Center website.

Methodology

The “critical appraisal” of the bioterrorism decontamination literature is aimed at calibrating “strength of evidence”¹⁸ and is intended to provide greater consistency in:

- Surveying and evaluating the knowledge base which underpins the analysis and formulation of policies and standards
- Facilitating the development of practice guidelines
- Providing information to improve the relevance for planning future research

The three focal questions used to assess the critical appraisal are:

1. What is the *quality* of the study’s (or article’s) design and methods?
2. What is the *strength* or level of evidence presented?
3. What is the *utility* and *relevance* of the study findings to the formulation of a policy, guideline or standard?

The main electronic search resource used was the National Center for Biotechnology Information (NCBI) of the U.S. National Library of Medicine. The primary search engine was PubMed, an NCBI service. PubMed is an integrated, text-based search and retrieval system that includes over 16 million citations from MEDLINE and other life science journals for biomedical articles dating back to the 1950s. PubMed also provides links to select full text articles and other related resources. (You may want to add the website for PubMed in the text.)

¹⁸ “Level” is used interchangeably with “Strength.”

Additional tools used for literature searches and citation analysis included:

- *Web of Science*: provides access to current and retrospective multidisciplinary information from approximately 8,700 of the most prestigious research journals in the world. It also provides a search method featuring cited reference searching. It is possible to navigate forward, backward, and through the literature, searching all disciplines and time spans.
- Specialty textbooks, abstracts, presentations at scientific meetings and other resources as appropriate.

Neither specific detection devices nor other means for environmental/surface sampling and monitoring were addressed in this report and are considered beyond the scope of the current review. The literature evaluation methodology addresses both environmental and surface (including electronic equipment) clean up and disinfection protocol, standards and policies. This assessment is based on the *strength, quality and relevance* of published research and/or operational experience.

Evidence Selection

The literature searches addressed primarily *surface or environmental decontamination of biologic agents*. All literature searches were updated in spring 2009. Relevant supporting information derived from agricultural and device-testing research was incorporated into the review process. The four steps used in the search and identification of the literature consisted of:

1. Identification of key words or phrases

Both Web of Science and PubMed searches incorporated the same search terms. Broad terms such as “biologic decontamination” and “bioterrorism decontamination” were used. Additionally, narrower search terms using the common disease name and the scientific disease name coupled with decontamination, such as “smallpox decontamination” and “variola major decontamination” were used. Two searches were performed for each disease. As appropriate, International Statistical Classification of Diseases and Related Health Problems (ICD) 10 categories were used in the search of articles. Searches were done for all Centers for Disease Control and Prevention Category A, B, and C diseases.

2. Selection of the Most Relevant Publications

The primary searches identified the relevant bioterrorism surface and environmental decontamination literature. They included:

- Identification of comprehensive review articles,
- Identification of the most relevant original research from the selected review articles and from database searches,

- Acquisition of the full text of the original research articles (a criteria for inclusion into the database). (How many articles did this eliminate? Were authors contacted to get copies of papers that couldn't be obtained electronically? Good research is sometimes inaccessible.)

3. *Literature Categorization Process*

Published, obtainable English-language materials (Is there any reason to suspect the language restriction removed essential articles?) and EPA reports listed on the National Homeland Security Research Center website were categorized and entered into the electronic citation database.

Data Extraction and Quality Assessment

1. *Guiding Questions*

A set of generic questions was formulated to ensure that an objective and descriptive evaluation was performed on each study included in the database. The descriptive evaluation aims to reduce evaluation bias. This set of questions provided the framework for establishing the *strength*, *quality* and *relevance* of each publication. These questions were intended as a guide for the evaluators in the evaluation process and to provide supplemental information for the purposes of this report. They do not constitute the sole means of evaluation of the publications. Presented in Appendix A is the evaluation worksheet as used for this analysis.

Evaluating Strength

1. Does the publication address environmental and/or surface decontamination?
2. Is the focus of the publication on environmental and/or surface decontamination?
3. How effective was the decontamination/cleaning in eradicating/killing the organism?

Evaluating Quality

4. Does the decontamination procedure require relocation of personnel?
5. Is personal protection available for the organism studied other than decontamination (i.e. vaccine)?
6. Does the procedure involve multiple treatments or agents (is it complex)?
7. Was the procedure a lab test or field test?
8. Was the procedure/agents used compared to other procedures or agents?

Evaluating Relevance

9. Is there sufficient evidence to change or support current policy or standards?
10. Is a policy for environmental and/ or surface decontamination proposed by the author?

2. *Establishing the Level of Evidence*

The adopted “level of evidence” benchmarks were derived from the Scottish Intercollegiate Guidelines Network (SIGN) classification system¹⁹. The SIGN classification was slightly modified to ensure consistency of interpretation of research. The *strength of evidence* was based on the research methodology described in the published literature. *Table 1-3* presents the modified SIGN ‘level of evidence’ system as used in this literature review.

¹⁹ “Chapter 6: Forming guideline recommendations.” *In SIGN 50: a guideline developers' handbook*. 2001 (updated May 2004). Edinburgh: Scottish Intercollegiate Guidelines Network. Available at <http://www.sign.ac.uk/guidelines/fulltext/50/section6.html>. Accessed 30 August 2007.

Table 1-3: Classification of Evidence and Adopted Level of Strength

Levels of evidence	
1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias. <i>Meta-analysis</i> that includes <i>randomized controlled trials (RCT)</i> , with a very low risk of bias. <i>Directly applicable to environmental decontamination.</i>
1+	Well-conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias and <i>directly applicable to environmental decontamination.</i> <i>Small (n) studies</i> that include well-defined research questions with appropriate outcome measures, study designs customized for alternative methods of statistical analysis, sample characteristics and methods of data collection, and evaluates the consistency and robustness of the results, with very low risk of bias.
1 -	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias and <i>directly applicable to environmental decontamination.</i>
<hr/>	
2++	High quality systematic reviews of non-randomized or case studies. High quality non-randomized or case studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal. Review of original research studies with statistical analysis demonstrating causal relationship with a <i>low risk of bias.</i> <i>Other RCT studies not directly applicable to environmental decontamination.</i>
2+	Well-conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal. Original Research with low <i>bias</i> and high probability of causal relationship.
2 -	Non-randomized or case studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal. Non-RCT, small (n) original research with statistical analysis and a potential for bias. A <i>small (n) original study</i> (non-RCT) that includes: well-defined research questions, careful description of all sample characteristics, and corroborative statistical analyses to evaluate the consistency and robustness of the results, with a potential for bias.
<hr/>	
3	Non-analytic studies, e.g. case reports, case series. Case Reports with no statistical analysis. <i>Reports with bias</i> such as <i>general specialty reviews</i> , <i>extrapolations</i> from existing data collected for other purposes, or <i>editorial.</i>
<hr/>	
4	Expert opinion. Accepted standard of practice, internet reports and presentations or expert opinions. <i>Common practice</i> , <i>web sites</i> or <i>expert opinions.</i>

Adapted from: Scottish Intercollegiate Guidelines Network (SIGN). *SIGN 50: a guideline developers' handbook*. Edinburgh, Scottish Intercollegiate Guidelines Network, 2001 (updated May 2004) (Chapter 6: forming guideline recommendations; <http://www.sign.ac.uk/guidelines/fulltext/50/section6.html>). Accessed 3 December 2007.

3. Assessing the Quality

This assessment focuses on the *quality* of the design of a study or article, its execution, and outcomes. *It is important to note that assigning a Level to a study has to be defined in the context of the final rating: for example a Level 1 study can be excellent or poor, and a Level 4 study could be excellent or poor.* Both the SIGN grading system and the Excellent to Unsatisfactory system were used in this review. Criteria for this evaluation appear in *Tables 1-4* and *1-5* below.

Table 1-4: Criteria Used to Evaluate the Quality of the Publications

Component of Study and Rating	Excellent	Good	Fair	Poor	Unsatisfactory
Design	Highly appropriate sample or model, randomized, proper controls	More than adequate design; minimally biased	Adequate design, but possibly biased	Small or clearly biased population or model	Anecdotal, off-target end-points
Methods	Outstanding accuracy, precision, and data collection in its class	More than adequate in its class	Adequate under the circumstances	Weakly defensible in its class, limited data or measures	Not defensible in its class, insufficient data or measures

Table 1-5: SIGN Grades of Recommendation

A	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

From: Scottish Intercollegiate Guidelines Network (SIGN). *SIGN 50: a guideline developers' handbook*. Edinburgh, Scottish Intercollegiate Guidelines Network, 2001 (updated May 2004) (Chapter 6: forming guideline recommendations). Accessed online: <http://www.sign.ac.uk/guidelines/fulltext/50/section6.html>. Last accessed: 3 December 2007.

4. Determining the Relevance

The final analytical procedure evaluated the relevance of the selected publications either addressing existing policy or proposing new policy in the area of environmental and/or surface decontamination. This was accomplished by subjectively evaluating the 3 scores discussed above combined with the descriptive evaluation of the generic questions. Heavier weight was given to “Excellent” or “Good” 1-, 1+, or 1++ studies, as these most likely provide the strongest scientific basis for policy formulation. Additionally, the “SIGN” Grades of Recommendation appeared to correlate strongly with the Level of Strength categories. The studies selected for inclusion in this paper were judged to be the most relevant to policy formulation process.

Limitation of the Research Methodology

The process for selecting relevant publications and subjectiveness of parts of the evaluation process might have introduced bias in the formulation of findings and conclusions. Certain articles may have not been selected using the above process. The incorporation of multiple evaluation steps was intended to limit potential bias.

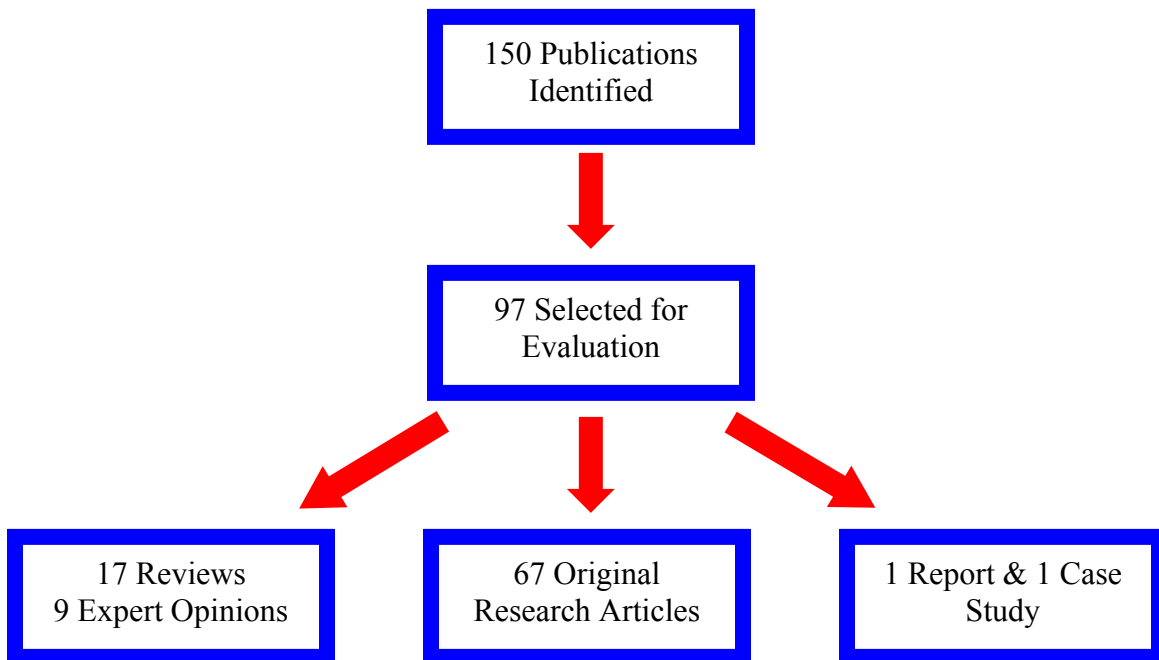
Findings

The findings presented below are separated into published literature and publications obtained from the EPA web-site.

Published Literature

From a total of 150 publications, the 97 obtainable publications analyzed consisted of 67 original research articles and 1 short report, 1 case study, 17 review articles, and 9 references or expert opinions, with one considered upon review to be irrelevant. See *Figure 1*. All evaluated publications are listed in Appendix B. Reports identified on the EPA web-site were evaluated separately and the results are presented separately. Of the evaluated articles, 6 discussed environmental decontamination and all others focused on various surface decontamination issues and methods. The overall distribution in strength, quality and SIGN Grades of Recommendation is shown in Table 2-1.

Figure 1: Evidence Selection Flow



A second literature search was conducted in spring 2009, approximately 15 months after the original searches were conducted, in order to up-date the database. A total of 140 different search term combinations, including those discussed above, were used in this search utilizing only the ISI Web of Science database. Searches were done for all Centers for Disease Control and Prevention Category A, B, and C diseases. This search identified 180 articles relevant to surface decontamination. This database includes studies evaluating decontamination of food surfaces; it does not include decontamination of food or meat surfaces. Food surface decontamination publications include all of the *Clostridium* and *Escherichia coli* O157:H7 decontamination publications. Removal of these publications, which have only limited relevance to facilities decontamination, results in a total of 115 articles. Further, it was noted that *Cryptosporidium parvum*, a water-borne disease, was the focus of 8 articles; removal of these articles leaves a total of 106 publications most directly relevant to facilities decontamination.

Of the articles identified in this search, 54 were published in the 15 month period between searches. Of note, 69 articles identified in the original searches were not found in the second search despite the use of an expanded list of search terms. This is likely due to the sole use of the ISI Web of Science database rather than PubMed. The general search terms of ‘bioterrorism decontamination’ and ‘bioterrorism remediation’ accounted for 18 articles.

Table 2-A: Distribution of Decontamination Literature by Agent and Category

Bioterrorist Agent	CDC Category	Number of Publications
<i>Bacillus anthracis</i>	A	75
<i>Clostridium botulinum</i>	A	19
<i>Francisella tularensis</i> (Tularemia)	A	3
<i>Variola major</i> (Smallpox)	A	3
<i>Yersinia pestis</i> (Plague)	A	2
<i>Burkholderia mallei</i> (Glanders)	B	1
<i>Cryptosporidium parvum</i>	B	8
<i>Escherichia coli</i> O157:H7	B	46
<i>Vibrio cholerae</i>	B	2
<i>Brucella</i> species	B	1
<i>Hantavirus</i>	C	1

As seen in Table 2-A above, the focus of the large majority of the published literature identified in the second search was on *Bacillus anthracis*, *Clostridium botulinum*, and *Escherichia coli* O157:H7. Little research has been conducted on any of the other CDC-identified bioterrorist agents, as found in this study. The distribution of the publications, by first author country is shown in Table 2-B. Only countries with two or more publications are shown. The United States was the source of the large majority of the publications.

Table 2-B: Distribution of Decontamination Literature by First Author Country

Country	Number of Publications
United States	115
England	7
Spain	5
Australia	4
France	4
Belgium	3
Ireland	3
Japan	3
Turkey	3
Brazil	2
China	2
Germany	2
South Korea	2
Sweden	2
The Czech Republic	2
The Netherlands	2

Table 2-C below presents the most published first authors, as found in both literature searches conducted for this report. Only first authors with 3 or more publications are shown.

Table 2-C: First Authors with 3 or More Publications

First Author	Number of Publications
Rogers JV	6
Sapers GM	5
Bialka KL	5
Dorsa WJ	4
Inglesby TV	3
Sagripanti J	3
Kuo SP	3

Initial evaluation of the decontamination literature included 97 original publications identified in the initial literature search. Each publication was evaluated on its Quality and Strength and assigned a Grade based on study type. The distribution of the literature is presented in Table 2-1 below.

Table 2-1: Distribution of Decontamination Literature

Total	Strength	Quality	Grade
8	1++	Excellent	A
4	1++	Good	A
1	1+	Excellent	A
6	1+	Good	A
1	1+	Fair	A
1	1+	Excellent	B
1	1+	Fair	B
1	1+	Good	B
5	1-	Fair	B
2	2++	Good	B
1	2++	Good	C
1	2++	Fair	C
1	2+	Excellent	C
5	2+	Fair	C
1	2-	Good	C
1	1-	Fair	C
1	2-	Unsatisfactory	D
11	3+	Fair	D
6	3+	Poor	D
1	3	Excellent	D
1	3	Good	D
8	4	Fair	D
11	2-	Poor	D
12	2-	Fair	D
3	2-	Good	D

The results presented below are separated into Environment and Surface decontamination.

Environmental Decontamination

The findings from the environmental literature are summarized in Tables 3-1, 3-2 and 3-3. Table 3-1 is a summary of the evaluations of individual papers using the guiding questions. Table 3-2 is a synthesis of the ratings for the *Strength of Evidence*, *Quality of the Experimental Design*, and *Methodology*. Table 3-3 presents the Disease, Method, and Surface studied, as well as *Relevance and Utility* to decontamination policy or standard formulation for each publication subject to a critical appraisal.

Table 3-1: Summary of the Environmental Decontamination Literature

Authors	1- Decontamination Addressed	2- Focus Decontamination	3- Effectiveness of treatment	4- Relocation	5- PPE available	6- Complex	7- Lab/ Field	8- Comparison
Inglesby, T; O'Toole, T; Henderson, D; Bartlett, J; et al (2002)	Yes	No	ND*	Yes	Vaccine	No	ND*	No
Inglesby, T; Henderson, D; Bartlett, J; Ascher, M; et al (1999)	Yes	No	ND*	Yes	Vaccine	No	ND*	No
Henderson, D; Inglesby, T; Bartlett, J; Ascher, M; et al (1999)	Yes	No	ND*	ND*	Vaccine	ND*	ND*	No
Dennis, D; Inglesby, T; Henderson, D; Bartlett, J; et al (2001)	Yes	No	ND*	ND*	Vaccine	ND*	ND*	No
Borio, L; Inglesby, T; Peters, CJ; Schmaljohn, A; et al (2002)	Yes	No	ND*	No	PPE	ND*	ND*	No
Inglesby, T; Dennis, D; Henderson, D; Bartlett, J. (2000)	Yes	No	ND*	Yes	No	ND*	ND*	No
Stuart, A; Wilkening, D (2005)	Yes	Yes	Much variability	ND*	ND*	ND*	Modeling	No

* ND indicates No Discussion in the publication.

Table 3-2: Overall Assessment of the Environmental Decontamination Literature

Author	Quality	SIGN Grade	Classification
Inglesby, T; O'Toole, T; Henderson, D; Bartlett, J; et al (2002)	4	Fair	D
Inglesby, T; Henderson, D; Bartlett, J; Ascher, M; et al (1999)	4	Fair	D
Henderson, D; Inglesby, T; Bartlett, J; Ascher, M; et al (1999)	4	Fair	D
Dennis, D; Inglesby, T; Henderson, D; Bartlett, J; et al (2001)	4	Fair	D
Borio, L; Inglesby, T; Peters, CJ; Schmaljohn, A; et al (2002)	4	Fair	D
Inglesby, T; Dennis, D; Henderson, D; Bartlett, J (2000)	4	Fair	D
Stuart, A; Wilkening, D (2005)	2-	Fair	D

Table 3-3: Focus and Relevance of the Environmental Decontamination Literature

Authors	Organism	Method/Compound	Surface	CDC Category	Relevance to Policy
Inglesby, T; O'Toole, T; Henderson, D; Bartlett, J; et al (2002)	<i>Bacillus anthracis</i>	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Inglesby, T; Henderson, D; Bartlett, J; Ascher, M; et al (1999)	<i>Bacillus anthracis</i>	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Henderson, D; Inglesby, T; Bartlett, J; Ascher, M; et al (1999)	<i>Variola major</i>	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Dennis, D; Inglesby, T; Henderson, D; Bartlett, J; et al (2001)	<i>Francisella tularensis</i>	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Borio, L; Inglesby, T; Peters, CJ; Schmaljohn, A; et al (2002)	Hemorrhagic fever viruses	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Inglesby, T; Dennis, D; Henderson, D; Bartlett, J (2000)	<i>Yersenia pestis</i>	General review of agent with some discussion of decontamination	Environment	A	Consensus statement. Few references cited. Unable to reliably inform policy.
Stuart, A; Wilkening, D (2005)	Various	Environmental Degradation.	Environment	A	Modeling of degradation of agents in environment. No lab or field testing. Very limited use in policy making.

The summaries of the findings of the surface decontamination literature review are presented below. The analysis of both environmental and surface decontamination is addressed in a subsequent section.

Surface Decontamination

The findings from the environmental literature evaluation are summarized in Tables 4-1, 4-2 and 4-3. *Table 4-1* is a summary of the evaluations of individual papers using the guiding questions. *Table 4-2* is a synthesis of the ratings for the *Strength of Evidence, Quality of the Experimental Design, and Methodology*. *Table 4-3* presents the Disease, Method, and Surface studied, as well as *Relevance and Utility* to decontamination policy or standard formulation for each publication subject to a critical appraisal. For each of the following tables, *only those studies rated “Excellent” or “Good” 1-, 1+, or 1++ are shown.*

Table 4-1: Summary of the Surface Decontamination Literature

Authors	1- Decontamination Addressed	2- Decontamination of treatment	3- Effectiveness of treatment	4- Relocation	5- PPE available	6- Complex	7- Lab/Field	8- Comparison
Kuo, S; Tarasenko, O; Popovic, S; Levon, K (2006)	Yes	Yes	85%	No	Biocabinet	No	Lab	No
Patterson, G Morley, P; Blehm, K Lee, D; Dunowska, M (2005)	Yes	Yes	99-90%	Yes	ND*	No	Field	No
Kenar, I; Ortatagli, M; Yaren, H; Karayilanoglu, T; Aydogan, H (2007)	Yes	Yes	Many 100%	Some yes	ND	Yes, for some	Lab	Yes
Wu, V; Kim, B. (2007)	Yes	Yes	up to 100%	No	ND	No	Lab	No
Lemieux, P; Sieber, R; Osborne, A; Woodard, A (2006)	Yes	Yes	100%	Requires sending items to facility	ND	Equipment required	Field	No
Wei, H; Wolf, G; Hammes, W. (2006)	Yes	Yes	.7-2 log	No	ND	No	Lab	No
Rogers, JV; Sabourin, CLK; Choi, YW; Richter, WR; Rudnicki, DC; Riggs, KB; et al (2005)	Yes	Yes	99%	Yes	PPE	8 hour contact time in controlled environment	Lab	No
Curry, R; Unklesbay, K; Unklesbay, N; Clevenger, T; et al (2000)	Yes	Yes	99%	ND*	ND	Equipment required; Long exposure time	Lab	No
Raber, E; McGuire, R (2002)	Yes	Yes	100% in Lab tests; 99% in field tests	No	ND	No	Lab and Field	No
Rose, L; Donlan, R; Banerjee, S; Arduino, M (2003)	Yes	Yes	100% after 48 hours, except on paper	Yes	Used Biosafety Level 3	No	Lab	No

Authors	1- Decontamination Addressed	2- Focus Decontamination	3-Effectiveness of treatment	4- Relocation	5- PPE available	6- Complex	7-Lab/Field	8-Comparison
Deza, MA; Araujo, M; Garrido, MJ (2003)	Yes	Yes	> 5 log	ND*	ND*	Equipment required	Lab	No
O'Connor, L; Harper, B; Larsen, L. (2001)	Yes	Yes	Varied by compound	Yes	ND	ND*	Lab	Yes
Weber, G; O'Brien, J; Bender, F (2004)	Yes	Yes	100%	ND	ND	No	Lab	Yes
Klapes, NA; Vesley, D (1990)	Yes	Yes	86-100%	No	ND	Equipment required	Lab	No
Blatchley III, E; Meeusen, A; Aronson, A; Brewster, L. (2005)	Yes	Yes	5+log reduction after 5 minutes	ND	ND	Source of radiation required	Lab	Yes
Rutala, WA; Stiegel, MM; Sarubbi Jr, FA (1982)	Yes	Yes	100% after 45 minutes above 220 degrees	No	ND	Equipment	Lab	No
Jones Jr., LA; Hoffman, RK; Phillips, CR (1968)	Yes	Yes	minutes to hours	ND	ND	No	Lab	No
Ozanne, G; Huot, R; Montpetit, C (1993)	Yes	Yes	70 minutes	No	ND	Equipment-autoclave	Field	No
Sagranti, J; Bonifacio, A (1999)	Yes	Yes	3-20 minutes	ND	ND	Long contact time for some	Lab	Yes
Monro, K, Lanser, J; Flower, R (1999)	Yes	Yes	24hours	ND	ND	Exhaust fans, long contact time, heater used	Lab	No

* ND indicates No Discussion in the publication.

Table 4-2: Overall Assessment of the Surface Decontamination Literature

Authors	Strength	Quality	Grade
Kuo, S; Tarasenko, O; Popovic, S.; Levon, K (2006)	1++	Good	A
Patterson, G; Morley, P; Blehm, K; Lee, D; Dunowska, M (2005)	1++	Good	A
Kenar, L; Ortatati, M; Yaren, H; Karayilanoglu, T; Aydogan, H (2007)	1++	Excellent	A
Wu, V; Kim, B (2007)	1++	Excellent	A
Lemieux, P; Sieber, R; Osborne, A; Woodard, A (2006)	1++	Excellent	A
Wei, H; Wolf, G; Hammes, W (2006)	1++	Excellent	A
Rogers, JV; Sabourin, CLK; Choi, YW; Richter, WR; Rudnicki, DC; Riggs, KB; et al (2005)	1+	Good	A
Curry, R; Unklesbay, K; Unklesbay, N; Clevenger, T; et al (2000)	1+	Good	A
Raber, E; McGuire, R (2002)	1++	Excellent	A
Rose, L; Donlan, R; Banerjee, S; Arduino, M (2003)	1+	Good	A
Deza, MA; Araujo, M; Garrido, MJ (2003)	1+	Good	A
O'Connor, L; Harper, B; Larsen, L (2001)	1+	Excellent	A
Weber, G; O'Brien, J; Bender, F (2004)	1++	Excellent	A
Klapes, NA; Vesley, D (1990)	1++	Excellent	A
Blatchley III, E; Meeusen, A. Aronson, A; Brewster, L (2005)	1++	Excellent	A
Rutala, WA; Stiegel, MM; Sarubbi Jr, FA (1982)	1++	Good	A
Jones Jr., LA; Hoffman, RK; Phillips, CR (1968)	1+	Fair	A
Ozanne, G; Huot, R; Montpetit, C (1993)	1+	Good	A
Sagripanti, J; Bonifacino, A (1999)	1+	Good	A
Monro, K; Lanser, J; Flower, R (1999)	1++	Good	A

Table 4-3: Focus and Relevance of the Surface Decontamination Literature

Authors	Disease	Method/Compound	Surface	CDC Category	Relevance to Policy
Kuo, S; Tarasenko, O; Popovic, S; Levon, K (2006)	<i>Bacillus cereus</i>	Microwave Torch	Paper	Surrogate	Device unstable during testing
Patterson, G; Morley, P; Blehm, K; Lee, D; Dunowska, M (2005)	<i>Staph aureus</i> , <i>Salmonella enterica</i>	4% Peroxy-monosulfate	Polyester transparencies	B	Effective
Kenar, L; Ortatatli, M; Yaren, H; Karayilanoglu, T; Aydogan, H (2007)	<i>Bacillus atrophaeus</i>	Sodium Hypochlorite (3 dilutions), UV radiation, boiling, autoclaving, Glutaraldehyde, Hydrogen peroxide (3%), Free chlorine	Metal, plastic, clothing, glass, tile, soil, water, paper, wood	Surrogate	Very effective methods as specified; least effective boiling and UV radiation
Wu, V; Kim, B (2007)	<i>Listeria monocytogenes</i> , <i>Pseudomonas aeruginosa</i> , <i>Staph typhimurium</i> , <i>S aureus</i> , <i>Yersenia enterocolitica</i>	Chlorine dioxide	Blueberries	A	Efficacy dependant on organism; <i>Listeria</i> and <i>pseudomonas</i> best efficacy
Lemieux, P; Sieber, R; Osborne, A; Woodard, A (2006)	<i>Geobacillus stearothermophilus</i>	Autoclave	Wallboard, ceiling tiles, carpet, upholstered furniture	Surrogate	Effective device
Wei, H; Wolf, G; Hammes, W (2006)	<i>Salmonella typhimurium</i> , <i>Listeria innocua</i>	Hydrogen peroxide and warm water	Field salad	B	Very limited efficacy
Rogers, JV; Sabourin, CLK; Choi, YW; Richter, WR; Rudnicki, DC; Riggs, KB; et al (2005)	<i>Bacillus anthracis</i> , <i>Bacillus subtilis</i> , <i>Geobacillus stearothermophilus</i>	Hydrogen peroxide gas	Various room surfaces	A	Very effective, though potential small n; more research beneficial
Curry, R; Unklesbay, K; Unklesbay, N; Clevenger, T; et al (2000)	<i>E Coli</i> 0157:H7	High-dose-rate x-rays	Ground Beef	B	Effective device
Raber, E; McGuire, R (2002)	<i>Bacillus subtilis</i> , <i>Yersenia pestis</i> , <i>Botulinum toxin</i>	L-gel	Various Surfaces	Surrogate, A	Effective compound, can be used on many surfaces, short contact time

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Rose, L; Donlan, R; Banerjee, S; Arduino, M (2003)	<i>Yersenia pestis</i>	Natural decay	Various surfaces	A	Effective after 48 hours except on paper which required 120 hours
Deza, MA; Araujo, M; Garrido, MJ (2003)	<i>E Coli</i> 0157:H7, <i>Salmonella enteritidis</i> , <i>Listeria monocytogenes</i>	Neutral electrolyzed water	Tomato surfaces	A, B	Potential small n, effective method, more research helpful
O'Connor, L; Harper, B; Larsen, L (2001)	<i>Bacillus globigii</i>	Diligen II; nano-particles; L-gel; nano-emulsion; aqueous foam; hypochlorite; GD-5	Ceiling tile, carpet, fabric-covered panels; wall board, concrete, painted metal	Surrogate	Small n; nano-emulsion effective on ceiling tile, cement; panels, painted metal; aqueous foam effective for wallboard and panels; L-gel effective on carpet
Weber, G; O'Brien, J; Bender, F (2004)	<i>E Coli</i> 0157:H7	Sodium Metasilicate	Suspensions	B	Effective treatment in suspension
Klapes, NA; Vesley, D (1990)	<i>Bacillus globigii</i> , <i>Bacillus stearothermophilus</i>	Hydrogen peroxide gas	Stainless steel coupons	Surrogate	Efficacy dependent on location in machine, duration and organism; more research required
Blatchley III, E; Meeusen, A; Aronson, A; Brewster, L (2005)	<i>Bacillus cereus</i> spores, <i>Bacillus subtilis</i> spores, <i>Bacillus anthracis</i> spores	Gamma radiation	Plastic, Paper, Aluminum foil, Suspensions, Painted Paper, cellulose membrane	A	Good effect after approximately 10 mminutes at 80mj/cm ³ ; <i>Bacillus anthracis</i> more resistant than other spp to irradiation but <i>subtilis</i> had similar kill pattern; suggests <i>B subtilis</i> be used in radiation studies as surrogate for <i>B anthracis</i>
Rutala, WA; Stiegel, MM; Sarubbi Jr, FA (1982)	<i>Bacillus Stearothermophilus</i>	Steam Autoclave	Petri dishes inside Plastic bags and Stainless Steel containers	Surrogate	Effective device: best effect with 5-10lb plastic bags; temp above 220 degrees; 30-90 minute cycles
Jones Jr., LA; Hoffman, RK; Phillips, CR (1968)	<i>Bacillus subtilis</i>	Sodium hypochlorite (Clorox)	Suspensions	Surrogate	Effective treatment in suspension: effective at varied cold temperatures though pH 7.2 recommended, longer contact time required for colder temperatures

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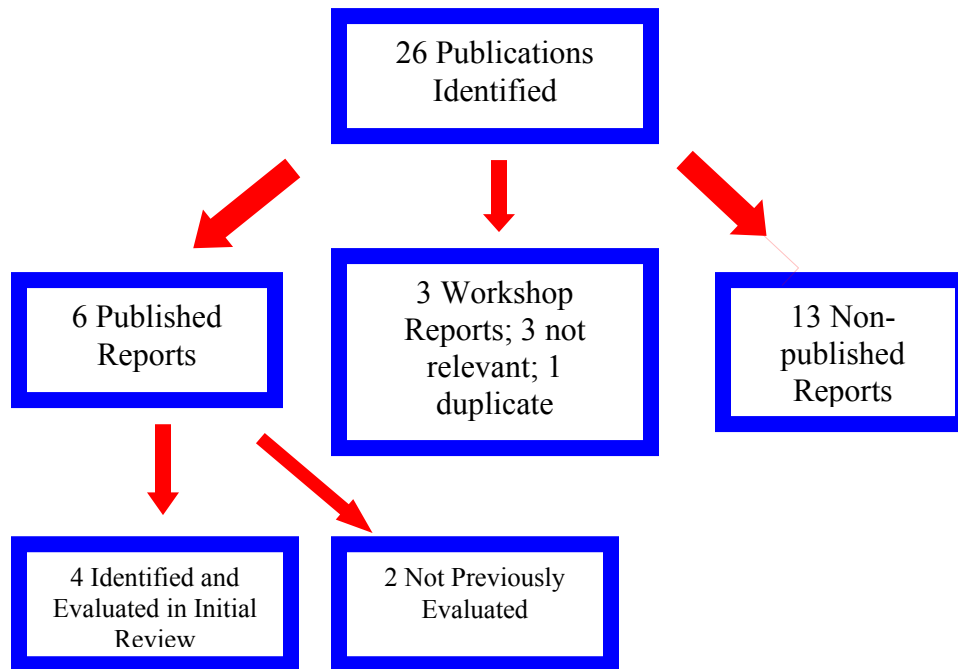
Ozanne, G; Huot, R; Montpetit, C (1993)	<i>Bacillus cereus</i> , <i>Bacillus</i> <i>stearothermophilus</i> , <i>Listeria</i> <i>monocytogenes</i>	Steam Autoclave	Biomedical waste in polypropylene bags	Surrogate	Effective device: recommends 121 degrees C for 70 minute cycle with closed 1/2 full bags
Sagripanti, J; Bonifacino, A (1999)	<i>Bacillus subtilis</i>	Renalin, Clorox, cavicide, lysol, cidex plus, ExSpor, Wavicide, cupric ascorbate	Stainless steel machine screws, dental burrlactics, silicone rubber tubing	Surrogate	Some effective treatments: Renalin after 11 hours; ExSpor 3- 20 minutes; Wavicide 10 hours. All tests resulted in corrosion of corrodible steel. Renalin exhibited short shelf life.
Monro, K; Lanser, J; Flower, R (1999)	<i>Bacillus subtilis</i> , <i>Bacillus</i> <i>stearothermophilus</i>	Formaldehyde gas	Metal strips	Surrogate	Limited effectiveness: 24 hour contact time with 45% humidity, 22 degrees C and .25-.65% paraformaldehyde killed about 67% of organisms

The findings of the EPA literature are summarized below.

EPA Literature

Reports relevant to bioterrorism decontamination were identified from the EPA National Homeland Security Research Center web-site. The distribution of the reports is presented in *Figure 2*.

Figure 2: Distribution of Reports, by typology



Of the 26 publications identified as relevant to bioterrorism or decontamination, only six were published in peer-reviewed journals; of these, four were evaluated in the initial evaluations presented separately. One study was not obtainable. The remaining 19 were evaluated using methods previously described. The list of the 19 EPA reports evaluated is presented in Appendix C. Distribution of the reports by agent of focus is presented in Table 4-5. Only bio-agents used in the reports are cited. *CDC Category A, B and C Bioterrorist Agents not listed below were not evaluated in the identified EPA literature.*

Table 4-5: Distribution of EPA Reports by Agent and Category

Bioterrorist Agent	CDC Category	Number of Publications Using Bio-agent	Number of Publications Using Surrogate
<i>Bacillus anthracis</i>	A	6	9
<i>Clostridium botulinum</i>	A	1	0
<i>Francisella tularensis</i> (Tularemia)	A	2	0
<i>Variola major</i> (Smallpox)	A	0	1
<i>Yersinia pestis</i> (Plague)	A	2	0
<i>Burkholderia mallei</i> (Glanders)	B	2	0
Ricin toxin from <i>Ricinus communis</i>	B	1	0
<i>Brucella</i> species	B	1	0

As shown in Table 4-5, the majority of the EPA reports identified focused on *Bacillus anthracis* decontamination. Some reports discussed more than one bio-agent. Table 4-6 presents the distribution of the identified EPA literature with regard to publication focus.

Table 4-6: Distribution of EPA Reports by Focus

Type	Total Number of Publications	Environment Decontamination	Surface Decontamination	Drinking System Decontamination
Evaluation of Technology	8	3	4	1
Evaluation of Decontaminant	3	0	1	2
Persistence of Bio-agents	2	0	2	0
Review/Article/Case Report	6	1	5	0

As seen in Table 4-6, the majority of publications evaluated focused on evaluation of decontamination technology, followed by reviews and case reports. Also of note, the majority of the studies focused on surface decontamination. Approximately 25% of the above publications focused on incineration of indoor materials.

Table 4-7 shows the distribution of the EPA literature by year. Of note, the largest volume of reports was in 2008. Additionally, the date of four reports was not cited within the publication and therefore was not available.

Table 4-7: Distribution of EPA Reports by Year

Year	Number of Publications
2003	2
2004	1
2005	3
2006	2
2007	1
2008	6
Not Available	4

The nineteen publications were evaluated on Quality and Strength and assigned a Grade based on study type using the methodology described previously. The distribution of the literature is presented in Table 4-8 below.

Table 4-8: Distribution of Decontamination Literature

Author	Quality	Grade	Strength
Martin GB (2003)	Unsatisfactory	D	4
Rose LJ, Rice EW, Jensen B, Murga R et al (2005)	Good	A	1+
Science Applications International Corporation (2005)	Fair	D	4
Lemieux P (2005)	Fair	D	4
Dun S, Wood J (2005)	Unsatisfactory	D	4
Rogers JV, Richter WR, Choi YW, Fleming EJ et al (2006)	Fair	B	4
Stone HJ, Rogers JV, Fleming EJ, Choi YW et al (2006)	Excellent	A	4
Wood JP, Lemieux P, Lee C-W (2004)	Poor	D	4
Canter DA (2003)	Unsatisfactory	D	4
Lee C-W, Wood JP, Betancourt DA et al*	Good	A	4
Dennis-Hoover WJ, Wade MM, Li Y et al*	Fair	B	4
Bartram PW, Lynn JT, Reiff LP et al (2008)	Excellent	B	4
Wood JP, Lemieux P, Betancourt D, Griffin N et al*	Fair	B	4
Shaw Environmental, Inc. (2008)	Fair	B	4
Wood JP, Lemieux P, Betancourt D, et al. (2008)	Good	A	1++
Kogan V, Harto C, Hesse DJ, Hofacre KC (2008)	Fair	B	4
Wang A, Hofacre KC (2008)	Good	B	4
Hofacre KC, Hecker RT, Wang A, Shell MC et al (2008)	Good	B	4
Rose LJ, Rice EW, Hodges L, Peterson A, Arduino MJ (2007)	Poor	D	2-
RTI International*	Poor	D	4

* Date not available

Only 2 of the EPA publications rated 1+ or better and are considered to be of most use to policy formulation.

Strength and Quality

Environmental Decontamination

Of the five published articles obtained focusing on environmental decontamination, only one was a research article. Another five were consensus statements about the disease agent and addressed environmental decontamination. The consensus statements all indicated that degradation of the agent in the environment would be the likely method of addressing environmental

decontamination. The research article (Stuart A, Wilkening D, 2005) examined the effectiveness of degradation of agents in the environment through computer modeling. This article found that agents should be expected to decay in the environment, depending on agent, in a period of 4 hours to days. However, none of the articles were based on field or lab tests. The consensus statements contained no statistical assessments. The authors posit that a surface cannot be considered disinfected unless the surrounding environment is also disinfected.

An evaluation of the EPA literature identified 4 reports focused on environmental decontamination. One of the articles was a critical analysis of current environmental decontamination technology. The other 3 evaluated the efficacy of certain technologies for deactivation of bio-agents in aerosol. None of the articles was suitable for policy formulation.

Surface Decontamination

The majority of the published articles did both address and focus on decontamination. However, few discussed employee concerns, such as relocation requirements of the treatment and personal protection. These issues are important in choosing a decontamination method due to the cost burden incurred by companies in neutralizing decontamination agents or for an extended facility closing. Comparison of different methods or agents would provide some strength or credence to the results of the study; few of the publications incorporated this. Also limiting the usefulness of these studies was the lack of statistical analysis of the results. Several studies reported results in percentages killed, while others reported log reductions in bacterial counts. There was little consistency in reporting methods from one study to the next. One had serious inconsistency in results, while the short report and the Tarasenko et al. (2006) article had no numerical reporting of results. Only a small number of these publications used statistical analysis to show significance in bacterial population reduction. Only one review article discussed specific decontamination agents. None of the reviews was a meta-analysis.

The EPA articles were split between review and original research articles. None of the reviews was a meta-analysis. Three research articles focused on water decontamination and evaluated bio-agents other than *Bacillus spp.* The remaining surface-focused decontamination articles evaluated only *Bacillus spp.* While two articles evaluated persistence of other bio-agents on indoor surfaces and in landfill waste leachates. None of the surface decontamination articles used field tests. Comparison of different methods or agents would provide some strength or credence to the results of the study; few of the publications incorporated this. Also limiting the usefulness of these studies was the lack of statistical analysis of the results. Of those rated to be of utility to policy formulation, one evaluated efficacy of thermal destruction of *Bacillus spp.* in carpet using a kiln and the other assessed the efficacy of chlorine in decontaminating water spiked with *Bacillus anthracis*, *Yersenis pestis*, *Brucella spp.*, *Burkholderia spp.* and *Francella tularensis*.

Relevance

Environmental Decontamination

Most of the consensus statements contained neither direct evidence from experimental studies nor other statistical analysis of efficacy of degradation. It is felt they did not contribute significantly to the environmental decontamination policy development process. Similarly, the published research article had no corroborating evidence from either field or lab testing. This renders the information provided to be less than ideal for policy formulation.

The EPA literature contained one critical analysis of environmental technologies; however, it did not evaluate decontamination efficacy. Two EPA reports assessed efficacy of technologies at decontaminating aerosol contaminated with *Bacillus spp.* The other EPA report did not use a bio-agent in testing. None were field tests, sample sizes were unclear, and no statistics were presented. This renders the information provided to be less than ideal for policy formulation.

Surface Decontamination

Of the published *Bacillus anthracis* (anthrax) studies, less than one half used the *anthracis* species; non-virulent *Bacillus spp.* were used as a surrogate in the other studies. This is of concern as it has been noted in the literature that certain *Bacillus spp.* surrogates may not exhibit the hardiness of the *Bacillus anthracis* species²⁰. The surfaces studied varied widely, from fruit to paper to solutions. Additionally, the method used for decontamination varied widely from a microwave torch to various disinfectants, aqueous ozone, a plasma torch and chlorine foam. Further, of those studies that evaluated decontamination effectiveness on different surfaces, it was frequently noted that the efficacy of the method varied by surface. Most of the articles indicate the usefulness of the particular application studied to decontamination. None provide surface decontamination policy recommendations, which is significant considering surfaces interact with many bacterial species and can either facilitate or inhibit growth. For example, copper surfaces have been found to exhibit bactericidal properties towards certain bacteria, specifically *E. coli*²¹.

Of the published studies addressing *Yersenia pestis* (plague), none discussed surface decontamination for this particular organism. Plague decontamination was briefly discussed by one review article; however efficacy of the treatment was not presented. This rendered the information not useful to policy formulation.

²⁰ Blatchley III, E; Meeusen, A; Aronson, A; Brewster, L (2005). "Inactivation of *Bacillus* spores by ultraviolet or gamma radiation." *Journal of Environmental Engineering* 131 (9), pages 1245-1252. Accessed online: <https://engineering.purdue.edu/CE/Academics/Groups/Environmental/Details/FacultyInfo/EBlatchley/EBlatchley/Links/InactivationBacillusSpores.pdf>. Last accessed: March 4, 2009.

²¹ Hoshino N, Kimura T, Hayakawa F, Yamaji, A, Ando T (2001). "Bactericidal activity of catechin-copper (II) complexes against *Staphylococcus aureus* compared with *Escherichia coli*." *Letters in Applied Microbiology* 31 (3), 213-217.

The EPA reports largely studied decontamination of *Bacillus anthracis* surrogates. The surfaces studied were more consistent than noted in the published literature, with many using carpet and ceiling tiles. However, field testing was lacking in all of the EPA articles reviewed. Further, statistical analysis was rare and generalizability was often limited due to specific technologies used or the manner in which the testing occurred. None of the EPA reports made any recommendations regarding decontamination.

Utility to Policy Formulation

The above analysis documents the identification of levels of evidence, relevance and quality of the 97 published studies and 19 EPA reports evaluated. Determining the utility of these studies to policy formulation requires a further step which is presented here. Linking clinical/scientific studies to policy formulation directly can lead to inaccuracies due to subjective bias. Therefore, a final rating scale was determined to be the most appropriate method of tying the scientific studies with the policy formulation process. Higher rating was given to those publications that utilized field versus lab studies. This scale was adopted from the Agency for Healthcare Research and Quality. See *Table 5-1*.

Table 5-1: Utility to Policy Formulation

Explanation	Quality of Evidence
Support policy or standard with benefits outweighing any potential harm	Well designed studies with consistent findings and incorporating field studies (Excellent)
Support policy or standard which could improve decontamination and outweigh potential harm or health risks	Well designed studies with mostly consistent findings in specific diseases or appropriate surrogates and incorporating field studies (Good)
Supports policy or standard in select situations but cannot be generalized	Evidence is sufficient to determine effects on decontamination, but the strength of the evidence is limited but the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the decontamination process and including those studies only conducted in the laboratory setting (Fair)
Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Evidence is sufficient to determine effects on decontamination, but the strength of the evidence is limited by the number, quality or consistency of the individual studies, generalizability to routine practice or the indirect nature of the evidence on decontamination and including those studies only conducted in the laboratory setting (Good)
Insufficient evidence to formulate a policy or standard	Evidence is insufficient to assess the effects on decontamination because of the limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important outcomes (Poor)

This scale was used to determine the utility of the studies presented above. *Table 5-2* presents the rating for each of the studies under discussion.

Table 5-2: Assessment of Utility to Policy Formulation

Authors	Organism	Utility	Rationale
Kuo, S; Tarasenko, O; Popovic, S; Levon, K (2006) *lab test*	<i>Bacillus cereus</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Unstable device; effectiveness 85%
Patterson, G; Morley, P; Blehm, K; Lee, D; Dunowska, M (2005) *field test*	<i>Salmomella enterica</i>	Support policy or standard which could improve decontamination and outweigh potential harm or health risks	Relocation of personnel during decontamination required; may be used with care
Kenar, Lt; Ortatatli, M; Yaren, H; Karayilanoglu, T; Aydogan, H (2007) *lab test*	<i>Bacillus atrophaeus</i>	Supports policy or standard in select situations but cannot be generalized	Efficacy dependent on surface and decontamination compound/process; may require relocation of personnel during decontamination
Wu, V; Kim, B (2006) *lab test*	<i>Listeria monocytogenes, Yersenia enterocolitica</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Limited efficacy on <i>Yersenia enterocolitica</i>
Lemieux, P; Sieber, R; Osborne, A; Woodard, A (2006) *field test*	<i>Geobacillus stearothermophilus</i>	Support policy or standard which could improve decontamination and outweigh potential harm or health risks	Equipment required, may require mailing affected items to processing facility
Wei, H; Wolf, G; Hammes, W (2005) *lab test*	<i>Salmonella typhimurium, Listeria innocua</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Ineffective decontamination process
Rogers, JV; Sabourin, CLK; Choi, YW; Richter, WR; Rudnicki, DC; Riggs, KB; et al (2000) *lab test*	<i>Bacillus anthracis, Bacillus subtilis, Geobacillus stearothermophilus</i>	Supports policy or standard in select situations but cannot be generalized	Relocation of personnel during decontamination required; may be used with care; lab test only in controlled environment

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Curry, R; Unklesbay, K; Unklesbay, N; Clevenger, T; et al (2002) *lab test*	<i>E Coli</i> 0157:H7	Supports policy or standard in select situations but cannot be generalized	Equipment required; long-exposure time; requires employee PPE or relocation
Raber, E; McGuire, R (2003) *lab and field tests*	<i>Bacillus subtilis</i> , <i>Yersenia pestis</i> , <i>Botulinum</i> toxin	Support policy or standard with benefits outweighing any potential harm	<i>Yersenia pestis</i> , Botulinum toxin studied; both lab and field tests done
Rose, L; Donlan, R; Banerjee, S; Arduino, M (2003) *lab test*	<i>Yersenia pestis</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Requires personnel relocation up to 120 hours; efficacy dependent on surface and exposure time
Deza, MA; Araujo, M; Garrido, MJ (2001) *lab test*	<i>E Coli</i> 0157:H7, <i>Salmonella enteritidis</i> , <i>Listeria monocytogenes</i>	Support policy or standard which could improve decontamination and outweigh potential harm or health risks	Equipment required
O'Connor, L; Harper, B; Larsen, L (2004) *lab test*	<i>Bacillus globigii</i>	Insufficient evidence to formulate a policy or standard	Specifics of decontamination process not specified
Weber, G; O'Brien, J; Bender, F (1990) *lab test*	<i>E Coli</i> 0157:H7	Supports policy or standard in select situations but cannot be generalized	Effective as specified on bacteria in suspension
Klapes, NA; Vesley, D (2005) *lab test*	<i>Bacillus globigii</i> , <i>Bacillus stearothermophilus</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Equipment required; effectiveness dependent on location in device
Inglesby, T; O'Toole, T; Henderson, D; Bartlett, J; et al (2002)	<i>Environmental Bacillus anthracis</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement
Inglesby, T; Henderson, D; Bartlett, J; Ascher, M; et al (1999)	<i>Environmental Bacillus anthracis</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement

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Henderson, D; Inglesby, T; Bartlett, J; Ascher, M; et al (1999)	<i>Environmental Variola major</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement
Dennis, D; Inglesby, T; Henderson, D; Bartlett, J; et al (2001)	<i>Environmental Francisella tularensis</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement
Borio, L; Inglesby, T; Peters, CJ; Schmaljohn, A; et al (2002)	<i>Environmental Hemorrhagic fever viruses</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement
Inglesby, T; Dennis, D; Henderson, D; Bartlett, J. (2000)	<i>Environmental Yersenia pestis</i>	Insufficient evidence to formulate a policy or standard	General review; no statistics; consensus statement
Stuart, A; Wilkening, D. (2005)	<i>Environmental Various</i>	Insufficient evidence to formulate a policy or standard	Modeling. No lab or field testing. Needs further supportive analysis.
Rose, LJ; Rice, EW; Jensen, B; Murga, R et al. (2005) * EPA *lab test*	<i>Water Decontamination Bacillus anthracis, Yersenia pestis, Brucella spp., Burkholderia spp., Francella tularensis</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Sample size not specified; multiple organisms tested; good controls; compared to previous data and current drinking water treatment levels; statistics used
Wood, JP; Lemieux, P ; Betancourt, D et al. (2008) * EPA *lab test*	<i>Surface Decontamination Geobacillus Stearothermophilus</i>	Fair evidence that implementing policy or standard will be ineffective or that harms outweigh benefits	Decontaminate <i>B stearothermophilus</i> on strips in pilot-kiln on 3 surfaces; log reductions and statistics used; good sample; good discussion; survivability shown on ceiling tiles after 35 minutes

As presented above, of the 28 studies only 1 was determined to rate “Excellent” in Utility to Policy formulation (Raber & McGuire, 2002); this was due in large part to Raber & McGuire conducting both lab and field tests and using CDC classified potential bioterrorist agents rather than surrogates. Results presented ranged from a justification for unstable decontamination devices to a comparative study with closed methodology in which specifics of the decontamination process were not disclosed. Additionally, a lower weight was given to laboratory research and limited operational application due to the lack of a demonstrated field test. Field testing is considered, for the purposes of this report, to have the best and most reliable applicability to real-life decontamination situations.

Table 5-3 below presents a summary of the distribution of publications appropriate for use in policy formulation, by agent.

Table 5-3: Distribution of Articles of Use in Policy Formulation, by Bio-Agent

Bio-Agent or Surrogate	CDC Category	Number of Publications
<i>Bacillus anthracis</i> or surrogate	A	8
Salmonella sp.	B	3
<i>E.coli</i>	B	3
<i>Yersenia pestis</i> or surrogate	A	4
<i>Clostridium botulinum</i>	A	1
<i>Brucella spp.</i>	B	1
<i>Burkholderia spp.</i>	B	1
<i>Francella tularensis</i>	A	1

As seen in Table 5-3, the majority of publications appropriate for use in policy formulation focus on anthrax. Slightly more than 50% focus on Category A agents.

Table 5-4 below, presents the distribution of evaluated articles appropriate for use in policy formulation, by lab or field test.

Table 5-4: Distribution of Articles of Use in Policy Formulation, by Lab or Field Test

Bio-Agent or Surrogate	Lab Test	Field Test
<i>Bacillus anthracis</i> or surrogate	6	2
Salmonella sp.	2	1
<i>E.coli</i>	3	0
<i>Yersenia pestis</i> or surrogate	4	1
<i>Clostridium botulinum</i>	1	1
<i>Brucella spp.</i>	1	0
<i>Burkholderia spp.</i>	1	0
<i>Francella tularensis</i>	1	0

** Some publications may have used both lab and field testing.

As presented above, the majority of policy-relevant studies have used lab testing versus field testing. The following section discusses the findings from the evaluation process, the GMU forum and select other functions.

Discussion

Of the evaluation worksheet questions, question 5 (“Is personal protection available for the organism studied other than decontamination (i.e. vaccine?)”) was the least answered and least addressed in any of the articles analyzed. While this information would be useful for policy

determination and personnel safety it is infrequently mentioned in the literature. Therefore, this might represent a gap in knowledge and require a more in-depth discussion in a future forum.

More research is required on other potential decontamination protocols for biological weapons. Various internet sites were visited in the course of this review, including the Environmental Protection Agency, the Centers for Disease Control and Prevention, the World Health Organization, the American Red Cross and the Department of Health and Human Services. Bioterrorism decontamination is discussed at a select number of these internet sites. However, the data analysis presented in this paper suggests that the information upon which they base their recommendations and standards is limited. *Bacillus* species have been the subject of many studies, in contrast to most other potential bioterrorist weapons, such as botulism, plague, smallpox, tularemia and viral hemorrhagic fevers, all of which are listed Category A. Additionally, few studies were found on diseases in either Category B or C.

As mentioned above, field studies are also limited. Most likely this is due to the increased difficulty of conducting these studies; however, this would greatly increase knowledge regarding limitations of decontaminants as well as identifying proper use of such in real-life situations.

Finally, an excellent recent survey by the CDC²² addressed the readiness of health care facilities for handling a Chemical Biological Radiological Nuclear Explosive (CBRNE) event. While the decontamination of personnel was addressed (showers, protective ensembles, etc.), facility decontamination was not part of this survey and should be addressed in future surveys conducted by the CDC.

This report and the above issues were presented to a group of experts at a forum held on the George Mason University campus on November 3, 2008. The forum also addressed the following issues:

1. The efficacy of the decontamination process and “acceptable levels” of cleanup before reoccupation of facilities. For example, standard vacuum protocol for ventilation systems or simple replacement of the Air Conditioning components and filters might not be enough to reduce the threat to employees.
2. At what point should a decision be made to condemn a facility (-ies). This is especially important for small- to medium-sized businesses which might not be able to survive financially protracted closure and clean-up of their premises.
3. Identify reliable indicators for projected economic impacts from such events:
 - a. Cost of decontamination;
 - b. Proper modeling of impacts and policies;
 - c. Cost of handling the resettlement of “healthy” workers;
 - d. Cost to insurers (if any);
 - e. Size of the financial “rescue package” and the availability of emergency and disaster loans.

²² Niska RW, Burt CW. (2007). Emergency Response Planning in Hospitals, United States, 2003-2004. Advance data from vital and health statistics: Number 391. Hyattsville, MD: National Center for Health Statistics.

Findings from the November 3, 2008 forum:

1. Literature and scientific evidence regarding decontamination of biologic agents is difficult to locate due to lack of sufficient and effective inter-agency and governmental-private sector communication and sharing.
2. There is a need for decontamination guidelines and specific recommendations, perhaps in scenario format, to which facilities and businesses can refer in the aftermath of a biologic event.
3. There is need for greater involvement in disaster preparedness efforts by the private sector, which might be improved with emphasis on the economic cost-benefit to businesses of such planning.
4. Environmental studies by NASA should be shared with the private sector as these may be a source of information on decontamination of biologic agents.
5. There is similarity between decontamination of *Bacillus anthracis* and *Clostridium difficile* which could be explored further.
6. There is need for governmental and private sector emphasis on risk communication during biologic events.

Remaining Knowledge Gaps Based on the National Academies Report

The National Academies study group identified four gaps in knowledge related to decontamination practices and agents. In relation to these four National Academies recommendations, the George Mason team has found:

National Academies Recommendation 2005	George Mason Team Findings 2008
<p>The committee recommends that the National Cancer Institute lead an interagency task force to reevaluate the possible carcinogenic effects of paraformaldehyde.</p>	<p>No reports were found evaluating the possible carcinogenic effects of paraformaldehyde.</p>
<p>For now, and given its successful application after the 2001 attacks, ClO₂ should be considered the standard for decontaminating buildings—pending further guidance and information from federal agencies. Research leading to the development of new methods and processes should be expected to demonstrate that any new methods have the potential to be at least as effective, safe, and cost-effective as ClO₂ for decontamination.</p>	<ol style="list-style-type: none"> 1. Few comparison studies have been done evaluating decontamination agents. 2. Chlorine dioxide may negatively impact health and can be explosive²³. 3. Several studies were identified evaluating new modes of decontamination and new decontamination technologies [10, 16, 44, 45, 46, 47, 49, 66, 67] 4. It is not known if research in this area has been adequately funded.
<p>EPA and the CDC should establish standards for remediation and validation of contaminated buildings and for the training of remediation teams.</p>	<p>No standards have been established.</p>
<p>Current and emerging decontamination techniques should be thoroughly evaluated to ascertain the achievable efficiencies of kill.</p>	<p>Decontamination techniques are evaluated to ascertain achievable efficiencies of kill. However, there appears to be little consensus on a standard kill-rate which should be achieved. Also, kill-rate measures vary from test to test.</p>

²³ U.S. Department of Labor. Office of Occupational Safety and Health Administration. "Occupational safety and Health Guideline for Chlorine Dioxide." Accessed online: <http://www.osha.gov/SLTC/healthguidelines/chlorinedioxide/recognition.html>. Last accessed: April 27, 2009.

Remaining Knowledge Gaps Based on EPA Workshops

The Office of Research and Development within the EPA conducted 3 workshops annually from 2005-2007. The conclusions identified by the participants are presented below.

2005 ²⁴ and 2006 ²⁵	2007 ^{26,*}	GMU Findings ^{***}
There is a need for better information sharing and perhaps a data repository.	Additional information is needed to fully understand bio-agent interactions with water-system pipes and biofilms.	There is no central data repository and limited information sharing. An EPA report on water system interactions was placed online in 2008.
There is a need for a decontamination response database linking threat agents with appropriate decontamination methods and site conditions.	There is a need for further research on efficacy of incineration and bio-agent residues.	There is no database linking threat agents with decontamination methods by site conditions. Incineration has been a focus of 5 recent EPA reports (25% of those identified).
There is a need for more field testing and real-life scenario research.	Do/can bio-agents survive on building materials?	There is limited field testing- none of the EPA articles were field tests. No study was found addressing bio-agent survivability on building materials.
There is a need for research on threat agents other than <i>B. anthracis</i> .	Guidelines need to be established regarding personal protective equipment use, reuse and disposal for emergency responders and other personnel.	There has been limited research on agents other than <i>B. anthracis</i> or <i>E. coli</i> . This may be due to funding issues. No guidelines regarding personal protective equipment were found.
There is a need to identify bio-agent surrogates and the situations in which they can be used to most appropriately mimic the true agent.	Standards and guidelines are needed regarding sampling techniques, decontamination methods, clean-up and disposal by scenario and agent.	One study was identified discussing bio-agent surrogate use (<i>B. anthracis</i> surrogate). No standards or guidelines were found regarding sampling techniques, decontamination methods, clean-up and disposal by scenario and agent.
There is a need to determine appropriateness and accuracy of testing strips, coupons and other testing methods.	Translational research is needed.	No studies were found assessing the appropriate use and accuracy of testing strips, coupons and other testing methods. No translational research was found.
There is a need to determine whether biological indicators and spore strips are comparable to environmental samples and to what	Direct interagency communication during bio-agent events is essential.	No studies were identified focusing on whether biological indicators and spore strips are comparable to environmental samples. No

²⁴ Dun S (2005). "Workshop on decontamination, cleanup and associated issues for sites contaminated with chemical, biological or radiological materials." EPA/600/R-05/083. Accessed online: <http://www.epa.gov/nhsrc/pubs/600r05083.pdf>. Last accessed: April 28, 2009.

²⁵ Dun S (2006). "Report on the 2006 Workshop on Decontamination, Cleanup, and Associated Issues for Sites Contaminated with Chemical, Biological, or Radiological Materials." EPA/600/R-06/121. Accessed online: <http://www.epa.gov/nhsrc/pubs/600r06121.pdf>. Last accessed: April 28, 2009.

²⁶ Dun S (2007). "Report on the 2007 Workshop on Decontamination, Cleanup, and Associated Issues for Sites Contaminated with Chemical, Biological, or Radiological Materials." EPA/600/R-08/059. Accessed online: <http://www.epa.gov/nhsrc/pubs/600r08059.pdf>. Last accessed: April 28, 2009.

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degree.		guidelines were found regarding recommendations for interagency communications during bioterrorist events.
There is a need for additional research into material compatibility with decontamination technologies.	Chlorine dioxide interaction with equipment needs to be assessed.	Some studies have been conducted on interaction of decontamination agents with materials. Chlorine dioxide interaction with equipment research was not found.
There is a need for research to determine “How clean is clean?” and standardization development.	NA**	There is no established definition/standard of “How clean is clean?”
There is a need for research to determine the impact of background materials (dust, dirt etc.) on decontamination.	NA**	A report was indentified focusing on interaction of background material with environmental decontamination.
There is a need to develop a standard end-date or culture period for bio-agent cultures as biological indicators report positive results on different days.	NA**	Research addressing a standard end-date or culture period for bio-agent cultures was not found.
There is a need to identify knowledge gaps and areas of redundancy in current research.	NA**	There is perhaps an over-abundance of research on <i>B. anthracis</i> and <i>E. coli</i> and a large knowledge gap regarding other bio-agents of concern.

*The format of reporting the workshop changed from 2005-2006 and 2007. Recommendations, findings and knowledge gaps from the 2005 and 2006 workshops were provided by workshop participants. The 2007 format changed so that research needs were provided by panel experts only.

** No further comments or recommendations were provided.

*** GMU findings address findings from 2005, 2006, 2007.

Of note, the 2007 discussions seemed to focus on areas of current research within the EPA and thus expert recommendations were narrowly focused to those topics. A broader range of recommendations was noted for both the 2005 and 2006 workshops.

This critical review identified the following knowledge gaps:

- a. Very few studies addressed the National Academies recommendations.
- b. Field tests to evaluate decontamination methods are scarce. Laboratory testing cannot replicate the issues and scenarios which would be found in an actual biologic event. Additionally, use of *Bacillus anthracis* in decontamination testing is limited. There is no standard on use or appropriateness of surrogate organisms in testing. Surfaces studied vary and few studies examined more than one surface. Comparisons between alternate methods were limited. Exact sample sizes, *n*, were not specified in several studies, leading to some question regarding bias.

- c. Statistical analysis of the significance of microbe decontamination is lacking. Results reporting vary, with use of log reduction and percentages reduced, making comparison of results between studies difficult.
- d. Of the CDC Bioterrorism Categories of potential bioterrorist weapons, only *Bacillus anthracis* (or *Bacillus* species), Salmonella and E. coli have been studied fairly extensively. Little data on other A, B, or C agents was identified in this review.

Conclusions

It is anticipated that most weaponized biological agents will be delivered into the environment in the form of powder or droplets. ***Cleaning surfaces alone will be inefficient without environmental decontamination since continued deposition and re-aerosolization²⁷ of weaponized grade bio-agents will persist.*** Secondary dissemination within facilities (buildings) will occur primarily through the ventilation system and to some degree by the occupants of those facilities.

The following are potential policy gaps derived from the cumulative literature analysis, expert forum and external reader inputs:

1. Increased emphasis should be placed on facilities, furniture and equipment testing (field testing). There is over-use of coupon testing²⁸ in the decontamination literature.
2. Standardization of methods and reporting would facilitate comparison of study results and translation to policy.
3. A clear definition of ‘effectiveness’ of decontamination needs to be established, whether this be sterilization or a degree of log-reduction.
4. Clear identification of appropriate surrogate organisms and standards/guidelines regarding their use needs to be determined.
5. The accuracy of surface sampling techniques to assess environmental decontamination should to be established.
6. Lack of consistency between database search results suggests that a single repository or database should be maintained with all relevant articles for ease of access.

²⁷ Hadler JL (2003). Testimony to Subcommittee on National Security, Emerging Threats, International Relations. “Stamping out anthrax in USPS facilities: technologies and protocols for bio-agent detection.” Testimony to the Congressional Committee on Government Reform, Subcommittee on National Security, Emerging Threats and International Relations, Chaired by Representative Christopher Shays of Connecticut. May 19, 2003. Accessed online: <http://www.cdc.gov/niosh/nas/RDRP/appendices/chapter6/a6-71.pdf>. Last accessed: April 28, 2009.

²⁸ Coupon testing refers to the use of smaller-than-normal-sized material, which is spiked with a bio-agent or its surrogate, for testing purposes.

7. There is an extreme paucity of published literature and EPA reports on Category A and B agents other than *Bacillus anthracis* and *E.coli*. There is a need to improve the decontamination knowledge base on all high-risk potential bio-agents in order to be adequately prepared in event of a bio-terrorist attack.
8. As identified by EPA and other governmental experts, there is limited and insufficient inter-governmental coordination regarding exchange of information and priority setting. Improved communication would reduce redundancy in research efforts, streamline dissemination of information, and perhaps lend itself to inter-agency decontamination standards and policy development.
9. Governmental agencies often focus on real-time data acquisition which is not always published in a timely fashion. This renders data difficult to access and perhaps more targeted to individual agency goals and funding than addressing knowledge gaps as evidenced by the perhaps over-emphasis on anthrax decontamination and incineration methods. Neither governmental reports nor published literature recommends policy for decontamination and translational research in facilities decontamination is notably absent from the literature. Increased focus on development of decontamination policy is required, particularly for hospitals, governmental buildings and other large, high-risk facilities.

Better coordination between different government and academic facilities is required to address the knowledge gaps. Clear and concise practice guidelines for decontamination should be developed through appropriately funded research. Decontamination guidelines, together with the appropriate training procedures, should be made available to managers of critical facilities. Guidelines for condemning contaminated property and disposal should be developed as soon as possible and communicated to the responsible organizations such as first responders and boards of health.

The George Mason University team will continue to monitor the literature pertaining to facilities bio-decontamination. GMU will host another forum in the future on this topic.

Appendix A: Evaluation Work Sheet: Biological Decontamination

Article Control Number: _____

Authors: _____

Title: _____

Journal: _____

Date Reviewed: _____

Article Type: _____

Number of References cited: _____

Times Cited (ISI): _____

Organism/Disease: _____

Decontamination method/compound: _____

Surfaces Studied: _____

Classification:

Rating: Excellent _____ Good _____ Fair _____ Poor _____ Unsatisfactory _____

Number of Subjects: _____

Justification: _____

Strength of Evidence and Justification:

Level (SIGN): -1 _____ 0 _____ 1 _____ 2 _____ 3 _____ 4 _____

Justification: _____

Reviewer Evaluation of the Publication:

1. Does the study address decontamination?

2. Is the focus of the publication on decontamination?

-
3. How effective was the decontamination/cleaning in eradicating/killing the organism?

 4. Does the decontamination procedure require relocation of personnel?

 5. Is personal protection available for the organism studied other than decontamination (i.e. vaccine)?

 6. Does the procedure involve multiple treatments or agents (is it complex)?

 7. Was the procedure a lab test or field test? (indicate which, if neither please indicate)

 8. Was the procedure/agents used compared to other procedures or agents?

 9. Is there sufficient evidence to change or support current policy or standards?

 10. Is a policy for environmental and/ or surface decontamination proposed by the author?

Appendix B: Reviewed Article List

1. Ackland, NR; Hinton, MR; Denmeade, KR (1980). "Controlled Formaldehyde Fumigation System." *Applied and Environmental Microbiology* 39(3), pages 480-487.
2. Ahmadi, B; Velthuis, A; Hogeveen, H; Huirne, R (2006). "Simulating *Escherichia coli* 0157:H7 transmission to assess effectiveness of interventions in Dutch dairy-beef slaughterhouses." *Preventive Veterinary Medicine* 77, 15-30.
3. Anonymous. "Norton & Davis Hold Hearing On DC Main Post Office." Accessed online: <http://groups.msn.com/AAEA/anthrax.msnw>. Last accessed: December 7, 2007.
4. Ammor, S; Chevallier, I; Laguet, A; Labadie, J; et al. (2004). "Investigation of the selective bactericidal effect of several decontaminating solutions on bacterial biofilms including useful, spoilage and/or pathogenic bacteria." *Food Microbiology* 21, 11-17.
5. Arnon, S; Schechter, R; Inglesby, T; Henderson, D; et al. (2001). "Botulinum toxin as a biological weapon: medical and public health management." *JAMA* 285(8), pages 1059-2081.
6. Bagamboula, CF; Uyttendaele, M; Debevere, J (2003). "Inhibitory effect of thyme and basil essential oils, carvacrol, thymol, estragol, linalool, and p-cymene towards *Shigella sonnei* and *S flexneri*." *Food Microbiology* 21, 33-42.
7. Bhalla, D; Warheit, D (2004). "Biological agents with potential for misuse: A historical perspective and defensive measures." *Toxicology and Applied Pharmacology* 199, 71-84.
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Appendix C: EPA Reports

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