NBAF
NATIONAL BIO AND AGRO-DEFENSE FACILITY

Diagnostics • Vaccines • Training

Updated Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment

February 2012
Final Report

Volume I

Homeland Security
Science and Technology Directorate

Defending America Against Foreign Animal Diseases

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Glossary of Acronyms and Terms

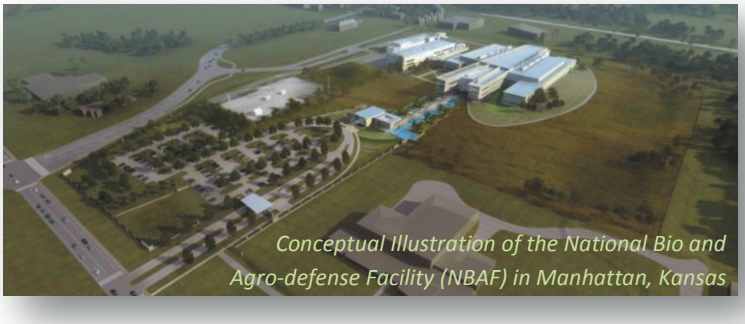
AAALAC	Association for Assessment and Accreditation for Laboratory Animal Care
AAHL	Australian Animal Health Laboratory
ABSL	Animal Biosafety Level
APHIS	Animal and Plant Health Inspection Service
APHIS-VS	Animal and Plant Health Inspection Service – Veterinary Services
ARF	Aerosol Release Fraction
ARS	Agricultural Research Service
AUSVETPLAN	Australian Veterinary Emergency Plan
ACVP	American College of Veterinary Pathologists
BDM	Biotechnology Development Module
BEA	Bureau of Economic Analysis
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BRI	Biosecurity Research Institute
BSAT	Biological Select Agents and Toxins
BSC	Biological Safety Cabinet
BSL	Biosafety Level
CAFO	Concentrated animal feeding operation
CDC	Center for Disease Control (aka CDCP)
CDCP	Center for Disease Control and Prevention (aka CDC)
CEAH	Centers for Epidemiology and Animal Health
CFSPH	The Center for Food Security and Public Health
cGMP	current Good Manufacturing Practices
CSCHAH	Canadian Science Centre for Human and Animal Health
CSIRO	Commonwealth Scientific and Industrial Research Organization
CUP	Central Utility Plant
cwt	Hundredweight
D&B	Dunn and Bradstreet
DADS	Davis Animal Disease Simulation
DEFRA	United Kingdom, Department of Environment, Food and Rural Affairs
DHS	Department of Homeland Security
DoD	Department of Defense
DOT	Department of Transportation
DSAT	Division of Select Agent and Toxins
DTRA	Defense Threat Reduction Agency
DVM	Doctor of Veterinary Medicine
EDS	Effluent Decontamination System
EIS	Environmental Impact Statement

EOPs	Emergency Operations Plans
EPA	Environmental Protection Agency
EPCRA	Emergency Planning Community Right-to-Know Act
ERA	European Centre for Medium-Range Weather Forecasts Re-Analysis
ERA-Interim	European Centre for Medium-Range Weather Forecasts Interim Re-Analysis
ERP	Emergency Response Plan
ERS	Economic Research Service
EU	European Union
FAD	Foreign Animal Disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
FADRU	Foreign Animal Disease Research Unit
FAZD Center	National Center for Foreign Animal and Zoonotic Disease Defense
FEMA	Federal Emergency Management Agency
FMD	Foot and Mouth Disease
FMDv	Foot and Mouth Disease virus
GAO	Government Accountability Office [of US Congress]
GMP	Good Manufacturing Practices
GNL	Galveston National Laboratory
GSF	Gross Square Feet
HEPA	High Efficiency Particulate Air
HeV	Hendra virus
HHS	Health and Human Services
HPAC	Hazard Prediction and Assessment Capability
HSPD	Homeland Security Presidential Directive
HVAC	Heating, Ventilation and Air Conditioning
IAH	Institute of Animal Health
IATA	International Air Transport Association
ICC	International Code Council
ID	Infectious Dose
IMPLAN	Impact Analysis for Planning
ISC	Interagency Security Commission
ISO	International Standards Organization
JEM	Joint Effects Model
K-State	Kansas State University
LAI	Laboratory Acquired Infection
LEPCs	Local Emergency Planning Committees
LMIC	Livestock Marketing Information Center
MAR	Material available for release
MESA	Multiscale Epidemiological/Economic Simulation and Analysis

MFD	Manhattan Fire Department
MHK	Manhattan Regional Airport
MID	Minimum Infectious Dose
MOU	Memorandum of Understanding
MPH	Master of Public Health
MPH	Miles per hour
MPPS	Most Penetrating Particle Size
MRHC	Mercy Regional Health Clinic
MTV	Minute Tidal Volume
NAADSM	North American Animal Disease Spread Model
NAHLN	National Animal Health Laboratory Network
NAS	National Academy of Sciences
NASS	National Agricultural Statistics Service
NBACC	National Biodefense Analysis and Countermeasures Center
NBAF	National Bio and Agro-Defense Facility
NCAH	National Centers for Animal Health
NCAR	National Center for Atmospheric Research
NCEP	National Center for Environmental Prediction
NDP	NBAF Design Partnership
NEHRP	National Earthquake Hazards Reduction Program
NIH	National Institute of Health
NIMS	National Incident Management System
NiV	Nipah virus
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
NRC	Nuclear Regulatory Commission
NSF	Net Square Feet
NVSL	National Veterinary Services Laboratories
O&M	Operation and Maintenance
OHS	Occupation Health Services
OIE	World Organisation for Animal Health
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy (White House)
PFU	plaque-forming units
PIADC	Plum Island Animal Disease Center
PMP	Probable Maximum Precipitation
PPE	Personal protective equipment
PReP	Preparedness and Response Plan
R&D	Research and Development
RCEM	Riley County Emergency Management

RIMS	Regional Input/Output Modeling System
RVF	Rift Valley Fever
RVFv	Rift Valley Fever virus
S&T	Science and Technology
SARA	Superfund Amendments and Reauthorization Act
SCIPUFF	Second-order Closure Integrated PUFF (model)
SME	Subject Matter Expert
SOMs	Self Organizing Maps
SOP	Standard Operating Procedure
SPC	Storm Prediction Center
SSO	Sanitary Sewer Overflow
SSRA	Site-Specific Risk Assessment
STAR	Science and Technology in Atmospheric Research (Institute)
TAD	Targeted Advanced Development
TCID	Tissue Culture Infectious Dose
U.S.	United States
UFC	Unified Facilities Criteria (Department of Defense)
UK	United Kingdom
USDA	United States Department of Agriculture
USDHHS	United States Department of Health and Human Services
USGS	U.S. Geological Survey
V.M.O.	Veterinary Medical Officer
WHO	World Health Organization
WWTP	Wastewater Treatment Plant

Executive Summary


Conceptual Illustration of the National Bio and Agro-defense Facility (NBAF) in Manhattan, Kansas

The National Bio and Agro-defense Facility (NBAF) in Manhattan, Kansas, will be used by U.S. Department of Homeland Security (DHS), U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) Foreign Animal Disease Diagnostic Laboratory (FADDL), and the USDA Agricultural Research Service (ARS) Foreign Animal Disease Research Unit (FADRU) for critical U.S. research, diagnostic, and training needs. An Updated Site-Specific Risk Assessment (Updated SSRA) for the NBAF, based on the 65% Design documents, was performed for DHS. The quantitative results from modeling potential infection-causing accidental releases of viable Foot and Mouth Disease virus (FMDv) from the NBAF and risks associated with research on large animals within the highest containment level (Biosafety Level 4, or BSL-4) were determined and assessed to inform DHS on potential facility design modifications that will be considered prior to finalizing the construction documents. In addition, recommendations on the continuing development of operational and accident response strategies were provided to facilitate the evolution of the safest and most effective protocols and procedures during the culmination of the design period and while construction is underway. ***This Updated SSRA assessment indicates that the NBAF 65% Design is sound and has no evident fundamental flaws or design features that would prohibit the implementation of the best and safest practices used in animal and zoonotic pathogen research facilities.***

The Updated SSRA was performed as part of the DHS commitment to NBAF safety and to satisfy the Congressional requirements stipulated in Public Law 112–10, §1647. As required by Congress, cumulative (NBAF project lifetime) calculations on the probability of an FMD outbreak caused by an accidental release of the virus from the NBAF were also performed. The calculations performed in this Updated SSRA indicate that ***the estimated expected probability that an accidental release of viable FMDv from the NBAF will occur and result in a subsequent outbreak during the NBAF's nominal 50-year operating lifetime is less than 0.11% (including catastrophic events such as tornados and earthquakes) and less than 0.008% when catastrophic events are excluded.***

NBAF Background

The research infrastructure that will be provided by the NBAF is necessary for continuing protection of the U.S. food and agriculture industry. This highly integrated, global, and complex industry is inherently vulnerable to foreign animal, emerging, and zoonotic disease outbreaks that could threaten the stability of the economy, food security, and the Nation's public health. DHS has the responsibility and the

national stewardship mandate to detect, prevent, protect against, and respond to terrorist attacks within the U.S. (Homeland Security Act of 2002, 6 U.S.C 182). DHS shares these responsibilities, as they apply to the defense of animal agriculture, with the U.S. Department of Agriculture (USDA); hence, a coordinated agricultural research strategy (as called for in the Homeland Security Act of 2002 and Homeland Security Presidential Directive 9 (HSPD-9), "Defense of U.S. Agriculture and Food," January 30, 2004) has been developed. HSPD-9 also specifically identified the need for "safe, secure, and state-of-the-art agriculture biocontainment laboratories that support research and develop diagnostic capabilities for foreign animal and zoonotic diseases." The NBAF will provide the infrastructure needed to satisfy the need for these modern biocontainment laboratories.

The White House Office of Science and Technology Policy (OSTP) organized a Blue Ribbon Panel in 2003 to examine research and development requirements to support efforts to mitigate the potential threat of bioterrorism directed against agricultural livestock. This panel presented a series of recommendations, including a prioritization of pathogens requiring study [Kelly, 2003]. Subsequently, DHS and USDA partnered on the development of the list of high-consequence diseases that threaten the U.S. and will be researched in the NBAF: Foot-and-Mouth Disease, African Swine Fever, Classical Swine Fever, Japanese Encephalitis, Rift Valley Fever, and Contagious Bovine Pleuropneumonia. These diseases were identified for study based on the threats and consequences of their introduction into the U.S. In addition, the NBAF will be the first facility of its kind in the U.S. to conduct critical studies on Nipah and Hendra and other emerging zoonotic viruses in large animal models (*e.g.,* cattle and swine) in the highest containment level.

Foreign animal diseases (FADs) affect livestock, poultry, and wildlife and are not indigenous to the U.S. For the past 50 years, much of the Nation's FAD research has been conducted off the coast of Long Island, New York, at the Plum Island Animal Disease Center (PIADC). Because the food and agriculture industries are significant contributors to U.S. economic prosperity, any disruptions from a deliberate or natural FAD introduction that caused a significant loss in the agro business chain would have significant economic consequences. In addition, FADs that also result in zoonoses (transmission from animals to humans) may cause a human health crisis. The NBAF will replace the PIADC and expand the research that is currently available. Facilities at the PIADC have limited laboratory space, antiquated infrastructure, and do not include Biosafety Level 4 (BSL-4) laboratories, which are required to safely conduct research on emerging and high-threat exotic pathogens such as the Nipah and Hendra viruses.

When operational, the NBAF will enable DHS and USDA to conduct comprehensive research of high-threat foreign animal and zoonotic diseases within the U.S. and will therefore serve to protect the Nation's animal agriculture and public health against numerous foreign animal and emerging diseases. Specifically, the NBAF will provide:

- Capabilities to perform basic and advanced research;
- Enhanced means to perform laboratory diagnostic detection and response;

- Expanded capabilities for development of new vaccines against high-threat foreign animal diseases; and
- Facilities for training veterinarians in preparedness and response to high-consequence foreign animal disease outbreaks.

Safety and security are of paramount importance in the planning, design, construction, and operations of the NBAF. From selection of the site to the design of the facility and, finally, the operation of the NBAF, DHS is committed to understanding the associated safety and security risks and mitigating those risks through the necessary design, engineering, operational protocols, and response planning efforts. To date, DHS has completed an Environmental Impact Statement (EIS), including a Health and Safety Chapter [DHS, 2008], a Threat and Risk Assessment (December 2008), a Site-Specific Threat and Risk Assessment (intentional acts) [Sandia, 2010], and a Site-Specific Risk Assessment (SSRA) [DHS, 2010].

Since the 15% Design phase and completion of the 2010 SSRA, DHS has incorporated recommendations to include additional mitigation measures for carcass disposal systems, liquid waste treatment and management, fully redundant dual-HEPA exhaust systems, and tornado hardening. In addition, DHS has continued to advance operations and response plans that also reduce risks. ***The relatively low risk observed across the various potential release events evaluated in this Updated SSRA are the result of the design, operational plans, and response practices that have been adopted or improved upon since the 15% Design.***

Risk Assessment Process Summary

The Updated SSRA is part of the overall DHS risk management effort for the NBAF and is based on the 65% Design. This update satisfies Congressional requirements (Public Law 112–10, §1647), addresses feedback provided by the NAS SSRA Committee, incorporates additional data collected on the selected site (Manhattan, Kansas), uses the most up-to date modeling tools, and integrates updated design, operations, and accident response strategies into the assessment. DHS has completed the 50% and 65% Designs, thus satisfying the requirements of §1647(b)(1). The Updated SSRA satisfies the Congressional requirements for demonstrating how calculated risks have been significantly reduced by incorporating mitigations into the risk assessment and addressing shortcomings identified by the NAS SSRA Committee (§1647(b)(2), §1647(c)(1)) through the application of the following enhancements, and others, to the risk assessment process:

- Providing a more systematic approach to the assessment of potential accident events including the use of fault tree and event tree analyses;
- Characterizing uncertainties in calculated results based on standard deviations, unknowns, assumptions, and stochastic variability associated with inputs that are modeled in the assessment;
- Incorporating the use of a published tornado return period methodology;

- Providing additional knowledge and data collected for the NBAF location (e.g., susceptible populations, outbreak control measure resources, etc.) that were used in the predictive epidemiological modeling; and
- Developing and using a methodology to estimate the cumulative risk of an FMD infection that would result from an accidental release from the laboratory over the anticipated operating lifetime of the facility.

Other enhanced risk assessment methodologies used in the Updated SSRA comprise the use of updated epidemiological modeling and sensitivity analyses, higher-fidelity meteorological modeling, and advanced economic modeling of potential outbreaks.

In addition, this Updated SSRA satisfies §§1647(c)(2) and (3) by assessing the impact of surveillance, response, and mitigation plans, and providing an assessment of the overall risks associated with research involving large animal models in BSL-4 containment to assist the government in evaluation of the effectiveness of control measures and inform stakeholders on the feasibility of implementation.

Conclusions

The quantitative modeling of infrequent FMD outbreaks caused by unintentional pathogen release from the NBAF (excluding catastrophic earthquake and tornado events) indicated that human error and the associated transfer of virus from the laboratory by human vectors or fomites are the most likely causes of an accident that would result in an outbreak. The potential for the release of pathogenic material (viable FMDv) from the NBAF was assessed by modeling each accident event by the mechanism of virus transfer or pathway. The four transport pathways used to characterize all accident events were aerosol, solid waste, liquid waste, and transference (which includes human vectors and fomites). Among all non-catastrophic FMDv events, the transference pathway occupied approximately 75.3% of the overall risk (the product of frequency and consequences) space, as illustrated in Figure ES-1. The assessed risks for the aerosol, solid waste, and liquid waste pathways represent approximately 16.2%, 0.1%, and 8.4% of the risk space, respectively.

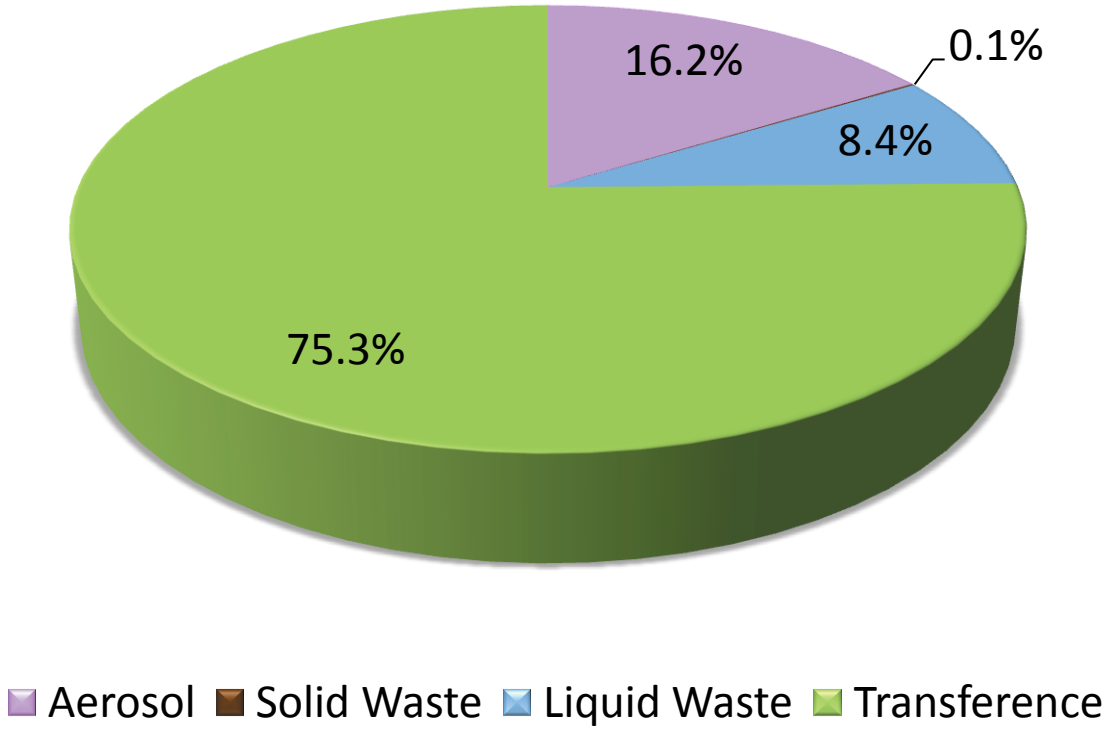


Figure ES-1: Proportion of Risk Space by Pathway for FMD

The catastrophic events, earthquakes and tornados, potentially involve multiple transport pathways. The most current NBAF design provides for maintaining laboratory containment even in tornado events with winds up to ~228 mph. However, the catastrophic events comprise approximately 81% of the total risk space when included in the calculations with the accident events. More than 99% of this 81% is attributed to the modeled risk from an earthquake (catastrophic tornado events comprise the remaining risk space). The large contribution to risk presented by earthquakes is a function of the modeled values for the frequency of an earthquake that could potentially compromise the containment integrity of the NBAF and possibly lead to an infection event. These frequencies are likely overestimated because the containment area modifications incorporated in the latest NBAF design that address the high wind and tornado risks will also provide benefit to the containment performance characteristics during an earthquake event, but these benefits have not yet been characterized. The detailed dynamic structural modeling that will characterize the present earthquake performance characteristics is currently being performed. When catastrophic events are included, the aerosol, solid waste, liquid waste, and transference events represent approximately 3.1%, 0.02%, 1.6%, and 14.3% of the risk, respectively. As modeled, the expected return period for the catastrophic earthquake is 2,500 years and for a catastrophic tornado the expected return frequency is 14.2 million years.

As required, cumulative risk estimates associated with the release and subsequent infection of susceptible species with FMD were estimated for the projected 50-year lifecycle of the NBAF. The risks assessed in the Updated SSRA were based on the projected research activities that are scheduled to begin around 2020. The uncertainties, assumptions, and unknowns associated with modeled research activities increase with time. For example, it is reasonable to assume that FMD research will still be a high priority in 2020, but it is more difficult to make the same assertion for 2070. The practice of numerically estimating risk over such a long period is not recommended (but required by Public Law 112–10, §1647), and care should be taken to avoid over-interpreting the cumulative risk estimates developed in the Updated SSRA. Also, the uncertainty associated with the estimates comprising the cumulative risk values are, in many cases, large relative to the estimated risks.

With these caveats, the estimated probability that a release of viable FMDv from the NBAF will occur and cause an infection was calculated for a single year (the first year) of NBAF operation and across the 50-year operating lifetime of the facility. For a single year of NBAF operation, when all events are considered (including catastrophic), the expected probability of at least one release resulting in an infection in a given year is 2.16×10^{-5} and the estimated range is approximately 3.07×10^{-11} to 4.23×10^{-4}. When catastrophic events are excluded, the probability of at least one release resulting in an infection in a given year is estimated to be between 3.07×10^{-11} and 2.33×10^{-5} with an expected value of 1.52×10^{-6}. The risk over all events for one year was $0.70M when all events were included and $0.13M when the catastrophic events were excluded.

The 50-year cumulative probability estimate for an FMD event is 1.08×10^{-3} (ranging from 1.54×10^{-9} to 2.35×10^{-2}) when all events were included and 7.61×10^{-5} (ranging from 1.54×10^{-9} to 1.17×10^{-3}) when catastrophic events were excluded. In other words, when all events (all causes) are considered, the probability of at least one release resulting in an FMD infection over the 50-year NBAF operating lifetime is estimated to be less than 0.11%, as illustrated in Figure ES-2. (The upper bound (95th percentile) and lower bound (5th percentile) are also illustrated in this figure. When catastrophic events are excluded, the probability of at least one release resulting in an infection over the 50-year NBAF operating lifetime is estimated to be less than 0.008%. The cumulative risk over the 50-year operating lifetime of the NBAF was $35M when all events were included and $7M when the catastrophic events were omitted. The uncertainty (standard deviation) in the 50-year cumulative risk was found to be approximately $15B, regardless of whether catastrophic events are included.

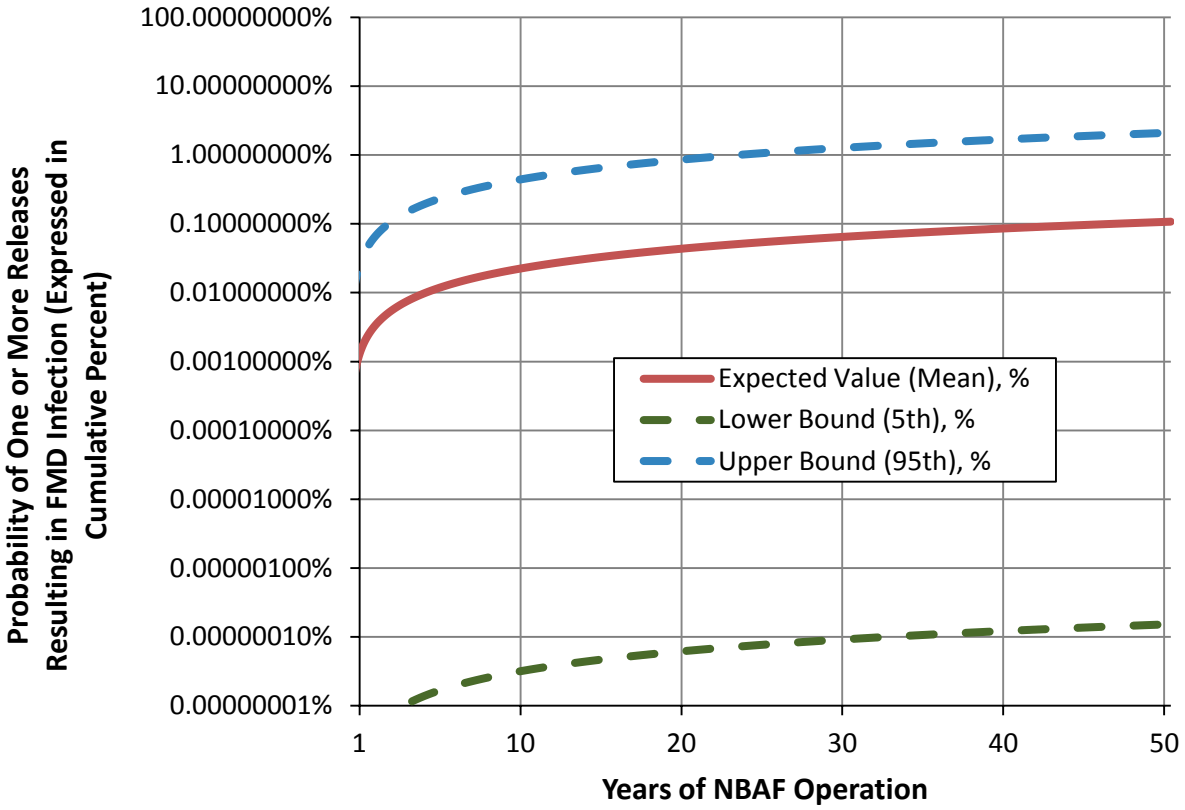


Figure ES-2: Cumulative Probability of FMD Infection over the 50-Year Operating Lifetime of the NBAF

The estimated probability (with the stipulated caveats) that an accidental release of viable FMDv from the NBAF will occur and result in a subsequent outbreak during the NBAF's nominal 50-year operating lifetime is less than 0.11%.

The Updated SSRA concludes that the NBAF 65% Design incorporates the most current validated biocontainment techniques and meets or exceeds required and recommended design and construction standards, and human factors (errors) again dominate the risk space, as was determined in the 2010 SSRA. Architectural features and engineered systems included in the design support the application of best operational biosafety and biocontainment practices, but sufficient personnel training will be required, as planned, to minimize the potential for an accidental pathogen release. Facility features and systems that were identified as being associated with elevated risks in the 2010 SSRA were addressed in the most current design by adding or changing appropriate facility features and systems. Compared to the 2010 SSRA, fewer recommendations that have risk-mitigating potential were made as a result of the Updated SSRA because of the addition of several mitigation measures in the maturing design and response strategies.

Large Animal BSL-4 Assessment

This Updated SSRA also provides an assessment of the risks associated with research on high-consequence zoonotic pathogens (Nipah and Hendra) with large animal models in BSL-4 laboratories.

Again, the risks were defined as the product of event frequency and consequences but the consequences were modeled with less fidelity since there is a lack of applicable and validated modeling tools for these pathogens. This assessment used the same transport pathways as the FMD assessment but the modeled events differed. The transference pathway for the BSL-4 events also dominated the risk space—more than 99.999% of the risk space was attributed to transference events for both Nipah and Hendra viruses. The recommendations derived from this assessment were aggregated with recommendations from the FMD assessment and are summarized below.

Recommendations

The recommendations for consideration by DHS, USDA, and other stakeholders presented in Table ES-1 are intended to inform NBAF planning processes on design features, operations-related concepts, and response strategies that may help further reduce risks associated with animal and zoonotic pathogen research. Recommendations have been derived from the quantitative assessment of FMD-related research in BSL-3Ag and BSL-3E facilities (including the Special Procedure areas) and the assessment of zoonotic pathogen research in the large animal BSL-4 facilities. Also considered in this assessment and the development of recommendations are the most current risk mitigation and planning efforts of DHS and USDA and all design modifications that have been implemented since the performance of the 2010 SSRA. As the design nears completion, DHS will intensify the operational and response planning efforts. Specifically, DHS has initiated or continued the following activities to further advance operational and response planning:

- Continued to engage the Plum Island Animal Disease Center (PIADC) to leverage 60 years of operating experience, knowledge, and planning documents;
- Leveraged and applied information from a highly successful CDC/USDA inspection of the National Biodefense and Countermeasures Center (NBACC) laboratory to support planning efforts;
- Engaged local and regional emergency responders to initiate Memorandums of Understanding (MOUs) for needed response capabilities;
- Established the Research and Transition Working Group to begin formulating training requirements;
- Continued stakeholder engagements to ensure full understanding by local and regional community of the NBAF mission; and
- Established appropriate baseline biosafety guidelines for incorporation into design basis and standard operating procedures.

DHS has also started the development of the initial operating capability (IOC) of the NBAF in preparation for the migration of personnel, equipment, and operations from the PIADC facility. In collaboration with USDA, DHS is in the beginning stages of developing the NBAF Emergency Response Plan (ERP). The NBAF ERP will provide guidance and direction to assure an integrated and coordinated response to emergency situations at the NBAF. The ERP will include the delineated steps and actions needed for mitigation, preparedness, response, and recovery and will provide guidance and direction to assure an integrated and coordinated response to emergencies at the NBAF.

While DHS has started the development of operational and response plans, it has been purposefully slow to publish protocols, practices, and strategies. With laboratory commissioning and operations still several (7-8) years away, there is adequate time to develop, review, and inculcate scientific users, personnel, and response stakeholders without the risk of prematurely developing plans that many not be relevant when the facility is finally constructed. As research priorities and technology advance, it is important to have practices and procedures that represent the best available at the time of commissioning and operation. In addition, there may be some concerns about the enhancement of strategic risks related to public disclosure of sensitive information on U.S. countermeasure programs. However, as described above, the collaborative process is underway.

In summary, new recommendations for the NBAF program are presented (Table ES-1) as part of the continuing effort to make the NBAF among the safest containment laboratories in the world, while providing infrastructure and facilities necessary to minimize the risks to U.S. agriculture.

Table ES 1: Updated SSRA Recommendations Summary

No.	Description	Status
1	Add permanent disinfection fixtures to the design in shower (water) areas between containment levels.	**Accepted**
2	Incorporate time-interlocked doors in shower area between the BSL-3E containment area and non-containment.	**Accepted**
3	Assess the enhanced earthquake performance that may be derived from the structural hardening and containment penetration specifications added for the high-wind and tornado design mitigations for the benefit of future risk assessments.	**Accepted**
4	Perform additional analyses, as needed, prior to incorporating beneficial reuse into designs and plans.	**Accepted**
5	Continue to include outside emergency and incident response stakeholders in the operational planning cycle and distribute plans (upon completion) for review and additional contributions.	**Accepted**
6	Begin periodic training on newly developed and evolving NBAF SOPs, plans, and practices.	**Accepted**

Table ES 1: Updated SSRA Recommendations Summary		
No.	Description	Status
7	Develop practices and procedures that reduce handling of and exposure to potentially infectious packages outside of containment.	**Accepted**
8	Accelerate response planning efforts while including emergency and incident response stakeholders (Recommendation 5) and appropriate interested entities.	**Accepted**
9	To the extent possible, make vaccination response plans publicly available**.**	**Accepted**
10	Publish a high-level description of the cooperative arrangements and roles of public and veterinary health providers.	**Accepted**
11	Develop and implement a producer education program for livestock producers in the NBAF region.	**Accepted**

1. Introduction

Homeland Security Presidential Directive 9 (HSPD-9), "Defense of U.S. Agriculture and Food" (January 30, 2004), revealed a capability gap with respect to the development of new countermeasures against the introduction or natural occurrence of foreign animal diseases (FADs) and zoonotic diseases. HSPD-9 recommended that this gap be filled by an integrated research, development, testing, training, and infrastructure evaluation for combating agricultural and public health threats posed by FADs. HSPD-9 also specifically identified the need for safe, secure, and state-of-the-art agriculture biocontainment laboratories that facilitate research and development of diagnostic capabilities for foreign animal and zoonotic diseases. To address the capability gap and need for modern biocontainment facilities, the U.S. Department of Homeland Security (DHS) is building the National Bio and Agro-Defense Facility (NBAF) to provide a facility for advanced research, diagnostic testing, and testing of biologic countermeasures for high-threat FADs affecting livestock. Additionally, in accordance with the Homeland Security Act of 2002, DHS, United States Department of Agriculture (USDA) Agricultural Research Service (ARS), and USDA Animal and Plant Health Inspection Service –Veterinary Services (APHIS-VS) are collaborating on the coordinated agricultural research strategy that will be implemented at the NBAF.

The U.S. food and agriculture industry is a highly integrated, global, and complex system that relies on a large agricultural infrastructure. These characteristics make the food and agriculture industry efficient but vulnerable to emerging and zoonotic FAD outbreaks that would threaten the stability of the economy and the nation's public health. Foreign animal diseases (FADs) affect livestock, poultry, and wildlife and are not indigenous to the U.S. As the food and agriculture industries are significant contributors to U.S. economic prosperity, any deliberate or natural disruptions from an introduction of an FAD to this agricultural infrastructure would cause a significant loss in a food market and would have significant adverse economic consequences. FADs that result in zoonoses (i.e., transmission from animals to humans) may also result in a human health crisis. DHS has the responsibility and the national stewardship mandate to detect, prevent, protect against, and respond to terrorist attacks within the U.S. (Homeland Security Act of 2002, 6 U.S.C 182). DHS shares these responsibilities, as they apply to the defense of animal agriculture, with USDA.

This document, the Updated Site-Specific Risk Assessment (Updated SSRA), is an update of the 2010 Site-Specific Risk Assessment (SSRA) [DHS, 2010] developed by DHS for the Manhattan, Kansas, location of the NBAF. The 2010 SSRA was based on an assessment of the 15% NBAF (schematic) Design. The Updated SSRA, based on the 65% NBAF Design, is intended to address feedback provided by the National Academy of Sciences (NAS) SSRA Committee, incorporate additional data collected on the selected site, and integrate updated design, operations, and accident response strategies into the assessment.

1.1 National Bio and Agro-Defense Facility (NBAF) Project Background

The NBAF will provide a modern laboratory resource for two federal departments (DHS and USDA) engaged in integrated research efforts. The scope and complexity of the anticipated research programs require a specialized and unique containment facility with the most current engineering and safety systems available. The purpose and benefits of the NBAF are identified in Section 1.1.1. The partnership between DHS and USDA is described in Section 1.1.2. An overview of the planning basis for research, diagnostics, and teaching is presented in Section 1.1.3. A description of the selected location and a summary of the design basis are presented in Section 1.1.4 and 1.1.5, respectively. The project timeline is provided in Section 1.1.6 and operational planning is summarized in Section 1.1.7.

1.1.1 NBAF Purpose and Benefits

In December 2003, the White House Office of Science and Technology Policy (OSTP) organized a Blue Ribbon Panel to examine research and development requirements to support efforts to mitigate the potential threat of bioterrorism directed against agricultural livestock. This panel presented a series of recommendations including a prioritization of pathogens to be studied [Kelly et al., 2003]. DHS and USDA have since partnered to identify the following high-consequence FADs that threaten the U.S. animal industry (through intentional, unintentional, natural, or anthropogenic activities) for study at the NBAF: Foot-and-Mouth Disease (FMD); African Swine Fever; Classical Swine Fever; Japanese Encephalitis; Rift Valley Fever; and Contagious Bovine Pleuropneumonia. These diseases were identified for study based on the threats and consequences of their introduction into the U.S. In addition, the NBAF will be the first laboratory of its kind in the U.S. to conduct critical studies on emerging and high-threat exotic pathogens, such as the Nipah and Hendra viruses, that affect large livestock (e.g., cattle and swine).

For the past 50 years, much of the nation's FAD research has been conducted off the coast of Long Island, New York, at the Plum Island Animal Disease Center (PIADC). Since June 2003, PIADC has been operated by DHS with two tenant USDA entities: the Foreign Animal Disease Diagnostic Laboratory (FADDL), which is a part of APHIS-VS, and the ARS Foreign Animal Disease Research Unit (FADRU). The NBAF will replace and expand PIADC capabilities and broaden the research and diagnostic capabilities of the country. PIADC has limited laboratory space, with infrastructure that is nearing the end of its lifecycle and that does not include biosafety level 4 (BSL-4) laboratories. BSL-4 laboratories are necessary to safely conduct research on emerging and high-threat exotic pathogens in livestock (e.g., Nipah and Hendra viruses). Importantly, PIADC continues to operate and is staffed with outstanding management, scientists, and support personnel that have been critically important to the NBAF design effort. These same individuals will be instrumental in preparing plans and documentation for the transition to and operation of the new facility. Meanwhile, DHS continues to invest resources in PIADC to ensure that its infrastructure can support immediate research and training needs in a safe laboratory facility.

When operational (estimated operational date is 2020), the NBAF will enable DHS and USDA to conduct comprehensive research activities and provide diagnostic capabilities for emerging and zoonotic diseases and will therefore serve to protect the nation against these threats. Specifically, the NBAF will provide:

- A modern facility to perform basic and advanced research;
- Enhanced ability to perform laboratory diagnostic detection and response;
- Expanded and dedicated space for the development of new vaccines and other countermeasures; and
- Training space for animal health specialists to collaborate and improve the nation's capability to respond to high-consequence foreign animal diseases.

1.1.2 DHS and USDA Strategic Partnership

To safeguard the U.S. against the impacts of naturally occurring and intentional animal disease outbreaks, USDA engages in animal disease research, including research and diagnostics of highly contagious animal pathogens and animal diseases not endemic to the U.S. These research and diagnostics activities historically have been conducted at PIADC. The Homeland Security Act of 2002 (6 U.S.C. 182) authorizes the Undersecretary for Science and Technology (DHS S&T) to collaborate with USDA to mitigate the threat of biological terrorism to U.S. livestock. The resulting interdependencies of DHS and USDA missions require development of a coordinated strategy to adequately protect the nation against biological threats to agriculture. In general, USDA focuses on basic science research, FAD diagnostics and detection, and training, while DHS develops and translates the results of basic science research into applications for FAD countermeasures.

The first step in the strategic partnership between USDA and DHS was the transfer of PIADC from USDA to DHS. DHS now owns and operates PIADC, which houses two USDA tenants (ARS and APHIS-VS). PIADC currently hosts several FAD research and diagnostic programs, including:

- Early detection of the introduction of FADs and associated training (APHIS FADDL);
- Basic research related to the prevention, detection, control, and eradication of FADs (ARS FADRU); and
- Development, testing and evaluation of new FAD countermeasures (e.g., vaccines and diagnostics) (DHS S&T Targeted Advanced Development (TAD)).

1.1.3 Planning Basis for Research and Teaching

APHIS FADDL, ARS FADRU and DHS S&T TAD have specific requirements that necessitate the expansion of existing research capabilities. APHIS FADDL needs to expand veterinary training, proficiency testing, diagnostic reagents, and reference materials programs for the National Animal Health Laboratory Network (NAHLN) and National Veterinary Services Laboratories (NVSL) to include emerging, vector-borne, and zoonotic agents (e.g., Nipah and Hendra viruses). The ARS FADRU scientific mission, which

currently focuses on Foot and Mouth Disease, Vesicular Stomatitis, and Classical Swine Fever, also needs to expand to include diseases such as Rift Valley Fever, Contagious Bovine Pleuropneumonia, and African Swine Fever, as well as vector-borne and zoonotic diseases. Finally, the DHS S&T TAD program is currently constrained in its efforts to expand veterinary countermeasure development by an insufficient number of large biocontainment animal rooms, as well as insufficient space that meets good manufacturing practices (GMP) regulatory requirements. These types of suites and laboratories are essential to attract industry partners that further the development of next-generation biotechnology products. Together, the interagency scientific programs require:

- The ability to conduct research on emerging and high-threat pathogens in a BSL-4 environment that can accommodate large animal study models;
- Appropriate facilities and skilled personnel ready to perform the diagnostic mission;
- Enhanced infrastructure for the development of new countermeasure technologies;
- Inclusion of additional FADs addressed by countermeasure development;
- A biotechnology development capability that will allow for the development (not large-scale production) of vaccines, therapeutics, and diagnostics that are ready for transition to industry (for production at a different location); and
- Facilities that meet or exceed the requirements for International Standards Organization (ISO) 17025 "General requirements for the competence of testing and calibration laboratories" accreditation, the Biosafety in Microbiological and Biomedical Laboratories (BMBL, Fifth Edition), and ARS Facilities Design Standards (242.1-ARS).

Ultimately, the research agenda for the NBAF may change based on contemporaneous threat assessments and is therefore subject to change as threats to US agriculture evolve. However, the current research agenda for the NBAF requires specific design and operational planning for advanced, specialized, high-containment facilities. The use of large animals at the NBAF further underscores the need for very specialized infrastructure and controls. These requirements include biosafety level 3 enhanced (BSL-3E), BSL-3E Special Procedure[1] rooms, biosafety level 3 agriculture (BSL-3Ag), and large animal BSL-4 (ABSL-4) laboratories as described in BMBL [USDHHS/CDCP, 2007].

The NBAF campus provides approximately 715,000 gross square feet (GSF) to accommodate DHS and USDA program requirements and supporting infrastructure [NDP, 2011]. A considerable fraction of the NBAF main laboratory building is dedicated to the bio-containment zone, including BSL-3E, BSL-3E Special Procedure, BSL-3Ag, BSL-4, and large animal BSL-4 (ABSL-4) laboratories and supporting spaces.

The NBAF will be the first laboratory in the U.S. to provide BSL-4 containment suitable for large animal research, including ABSL-4 large animal holding and ABSL-4 large animal necropsy facilities; critical

[1] A BSL-3E "Special Procedure" laboratory differs from BSL-3E in that it contains redundant double HEPA filtration of exhaust air (as opposed to single HEPA filtration). BSL-3E "Special Procedure" laboratories will be utilized at the NBAF for procedures generating greater than typical volumes, concentrations, or aerosolization of viable pathogens.

infrastructure that the nation currently lacks. According to the 65% Design documents, the NBAF will provide approximately 13,376 net square feet (NSF) of BSL-4 space (including standard BSL-4 and ABSL-4 laboratories) [NDP, 2011]. Figure 1.1.3-1 shows the relative position of the containment areas on the first floor of the NBAF Main Laboratory Building.

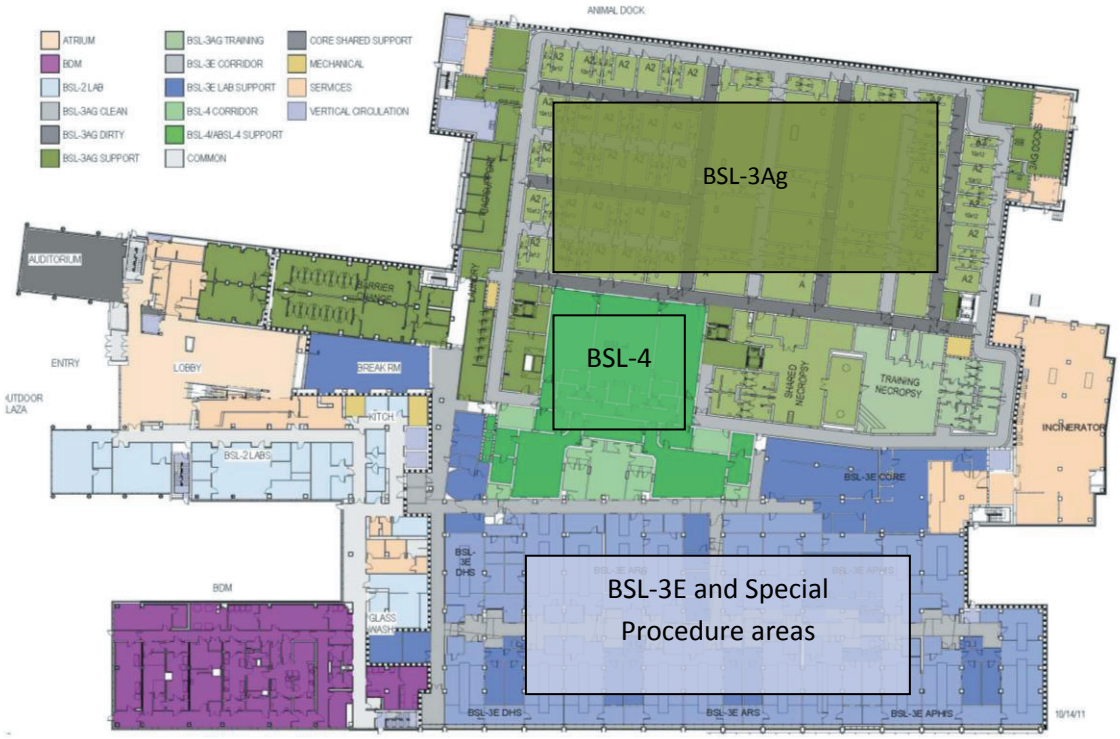


Figure 1.1.3-1: NBAF Program Areas (First Floor of Main Laboratory Building)

1.1.4 NBAF Site in Manhattan, Kansas

Following an extensive and competitive process that evaluated multiple domestic sites, DHS issued a record of decision (74 Fed Reg 3065-3080) on 19 January 2009 announcing the selection of Manhattan, Kansas, as the site for the NBAF. The selection of Manhattan, Kansas, was based on the need for space to support a laboratory building, a transshipping facility, surface parking, and ancillary support facilities. The 45.6-acre NBAF site offers sufficient buildable area. It is located on the Kansas State University (K-State) North Campus, near the College of Veterinary Medicine. The site is adjacent to the Westar facility (electrical substation) to the northwest and Pat Roberts

DHS selected the NBAF Design Partnership (NDP) Associates of Atlanta, Georgia, to design the NBAF. The NBAF Design Partnership is comprised of the following architect-engineering firms:

- Perkins + Will
- Flad & Associates
- Weidlinger Associates, Inc.
- Haynes Whaley Associates
- Affiliated Engineering, Inc.
- CCRD Partners
- Travis Pruitt & Associates
- Kroll
- Merrick & Company

Each of these firms has significant experience in designing high-containment facilities such as: USDA Ames Modernization Project; Pfizer Animal Health Building; Ohio University Ag Facility, Arthropod-Borne Animal Disease Research Laboratory, Laramie, Wyoming; CDC Building

Hall, home to the Biosecurity Research Institute (BRI), to the southwest. The site has significant frontage and setback from two roads that can support the additional traffic circulation anticipated by NBAF Design Partnership. The Manhattan, Kansas, site was selected over other options through a competitive process by a panel of experts using the following criteria developed by DHS and USDA:

- Proximity to other animal research capabilities;
- Proximity to a specialized workforce and workforce training capabilities;
- Acquisition, construction, and operations requirements; and
- Community acceptance.

1.1.5 Design Basis

The NBAF has been designed with a main laboratory building and several outbuildings that support the NBAF operations. These outbuildings include a Central Utility Plant (CUP), Transshipping Facility (TF), Visitor Center (VC), Entry Control Points (ECPs), and other miscellaneous support structures. Figure 1.1.5-1 provides a conceptual design (aerial view) of the NBAF site.

Figure 1.1.5-1: NBAF Campus Concept

DHS and USDA program representatives and the design team began the site-specific design process in June 2009. The project team is working together to create a design that maximizes the safety and security aspects of the facility. The NBAF is designed and constructed to meet modern biocontainment design principles and standards and, as mentioned above, complies with recommendations and requirements from the following codes and standards (as well as additional codes/standards that are not listed here):

- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition;
- USDA Agricultural Research Service (ARS) Facilities Design Standards, Manual 242.1;

- International Building Codes (IBC), 2009 Edition, International Code Council (ICC);
- Federal Occupational Safety and Health Act (OSHA) of 1970;
- U.S. Environmental Protection Agency (EPA) Regulations;
- Department of Defense Unified Facilities Criteria (UFC); and
- Integrated Security Committee (ISC) Security Design Criteria.

The design team began by benchmarking other high-containment animal laboratory facilities. Benchmarking trips included both facility tours and personnel interviews to determine facility design and operational best practices. The team toured the National Centers for Animal Health (NCAH) in Ames, Iowa; the National Biodefense Analysis and Countermeasures Center (NBACC) in Frederick, Maryland; and the St. Jude current Good Manufacturing Practices (cGMP) facility in Memphis, Tennessee. The project team also considered lessons learned from previous tours of the Canadian Science Centre for Human and Animal Health (CSCHAH) in Winnipeg, Canada. The design team incorporated design features and the best practices from these facilities to enhance the NBAF design.

In January 2010, expert biocontainment and research scientists from premier research institutes participated in a review of the NBAF design. This review panel included representatives from the Australian Animal Health Laboratory (Geelong, Australia), the Institute for Animal Health (Pirbright, United Kingdom), the CSCHAH, and the Lovelace Respiratory Research Institute (Albuquerque, New Mexico). The panel provided advice for ensuring relevant standards and regulations are met, explored the practicality of the design from the laboratory workers' points of view to ensure their safety and ease of use, and presented an international perspective based on lessons learned from other containment laboratory facilities. Recommendations from this review session were incorporated into the NBAF design.

In June 2010, DHS completed the 15% Design stage, which is commonly referred to as the "schematic design." The schematic design included a completion of a program review, a layout of the NBAF components, primary program layouts, and documentation on the basis of design. The results from the 2010 SSRA were based on the schematic design. Following the publication of the 2010 SSRA, the risk assessment team worked directly with the design team to minimize risk and incorporate risk mitigation recommendations described in the SSRA. The 35% Design stage, commonly referred to as "design development" was completed in July 2011 and included the design recommendations from the SSRA, as well as design recommendations from the NAS SSRA Committee's evaluation. A government review of the design development documents was completed to validate incorporation of the recommendations. In August 2011, the 50% Design stage was completed and used as the preliminary basis for the development of the events in this Updated SSRA. After the 65% Design was completed in October 2011, the Updated SSRA models were adjusted to incorporate differences between the 50% and 65% Designs. The Updated SSRA team also worked with the design team to review all events and potential pathogen release pathways and to ensure incorporation of the most current design (65%) in the event

descriptions. Additionally, all design changes were assessed in a review process, which incorporated input from the Updated SSRA team and other experts, scientific users, and administrators. DHS has implemented this process to ensure that future design enhancements do not adversely affect the risks assessed in the Updated SSRA. Additionally, all design changes must be approved by the Chief of Construction and Chief of Operations following consultation with the respective biosafety officers. The 65% Design documents were provided to the NAS SSRA Committee for review.

1.1.6 Integrated Project Timeline

Figure 1.1.6-1 depicts the integrated project timeline beginning with the construction process and ending when the NBAF begins full research and development (R&D) operations in 2020.

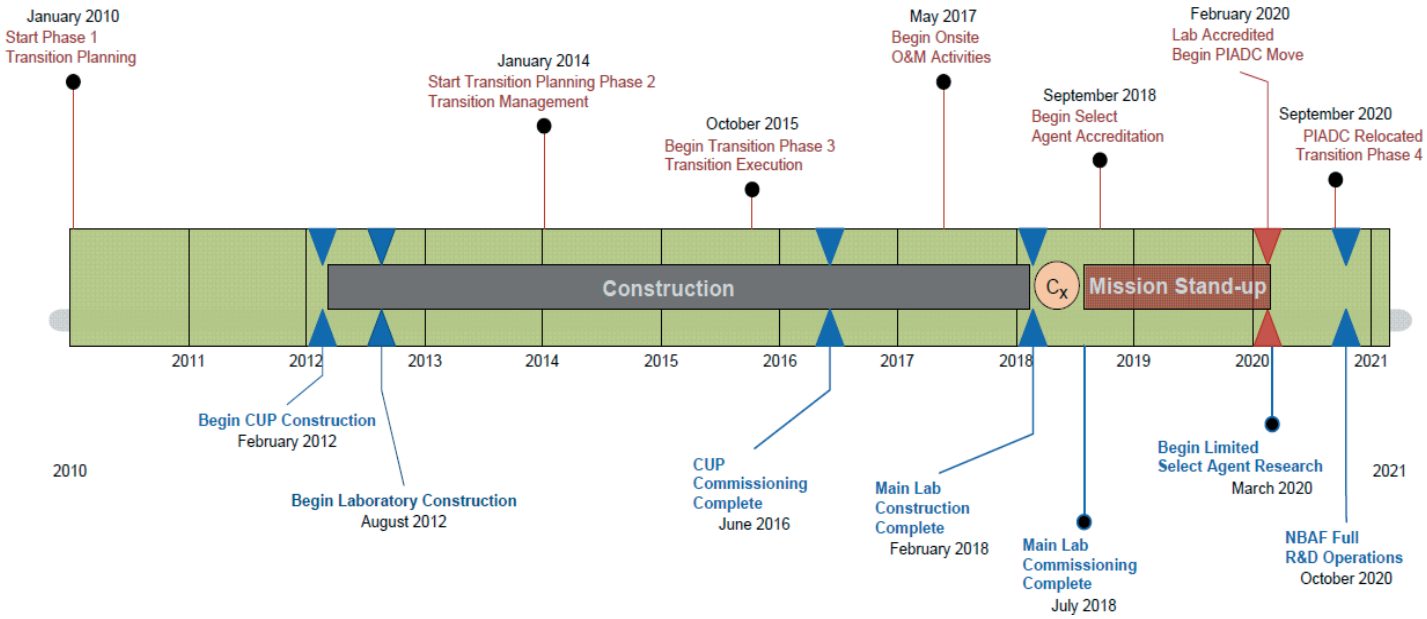


Figure 1.1.6-1: Integrated Project Timeline

1.1.7 Operational Planning

Prior to beginning routine operations, the NBAF will be challenged in a series of critical commissioning activities. In addition, it is necessary to establish the initial operating capability (IOC) in preparation for the migration of personnel, equipment, and operations from PIADC. Operational planning is comprised of two major activities and their various sub-activity elements: 1) NBAF Operations and Maintenance (O&M) Establishment and 2) NBAF Science Program.

NBAF will be operated as a Government Owned/Government Operated (GOGO) facility. The current planning approach is to utilize the PIADC operating model, which is a GOGO facility with O&M contractor support. The science and administrative core comprises Federal employees that provide direction to the contractor for the support and O&M of the facility. This governance model offers the opportunity to draw upon private sector experience while Federal employees provide long-term,

mission-enabling benefits by maintaining essential government capability and inherently governmental functions.

Once operational, the NBAF will employ approximately 350 people. In addition to the scientific and administrative staff, the NBAF will require maintenance technicians, building engineers, security personnel, and veterinary and animal care staff. All laboratory staff will receive thorough pre-operational training, as well as ongoing training required for the handling of hazardous infectious agents, understanding biocontainment functions related to standard and special practices for each biosafety level, understanding biocontainment equipment, and the specialized engineering and maintenance required for the NBAF research to be performed. The NBAF Responsible Official (RO) and the facility Biosafety Officer will lead the development of the laboratory safety policies, plans and procedures, and ensure compliance with all applicable regulations, permits, and licenses. The NBAF safety staff, biosafety staff, and senior NBAF management will review and approve proposed protocols and standard operating procedures (SOPs) for the laboratory prior to use. Under the auspices of the RO and the NBAF Laboratory Director and in collaboration with the NBAF Biosafety Office, an Institutional Biosafety Committee, a Health and Safety Committee, and the Institutional Animal Care and Use Committee (IACUC) will be established at the NBAF.

DHS and USDA are fully committed to accident prevention and risk mitigation. Risk mitigation approaches fall into three major categories: 1) administrative controls, which are based on procedures and staff training; 2) the use of safety equipment (primary barriers such as biological safety cabinets); and 3) facility design (which incorporates HEPA filtration, liquid effluent decontamination, clean vs. dirty corridors, air pressure resistant (APR) doors, etc.). The concept of organizing risk mitigation into these three broad categories is well established in the safety field and is a cornerstone of the BMBL [USDHHS/CDCP, 2007] approach to safety. Administrative controls must be incorporated in operational plans that ultimately drive the development of SOPs, training plans, and emergency response plans for the NBAF. When the NBAF completes commissioning and all physical controls are deemed fully operational, a trained and reliable workforce will be available for the safe, secure operation of the NBAF.

DHS S&T Directorate (through the Office of National Laboratories) has the primary responsibility for leading the development of the NBAF Emergency Response Plan (ERP). Ultimately implemented by NBAF staff, the NBAF ERP will provide guidance and direction to assure an integrated and coordinated response to emergency situations at the NBAF (e.g., accidental or intentional release of FMDv or other hazardous pathogen from the facility, hazardous chemical spill, weather-related events, etc.). The NBAF ERP will be the framework for coordinating efforts among city, regional, state, and federal officials and agencies. DHS will develop and implement the ERP (i.e., delineated steps and actions needed for mitigation, preparedness, response, and recovery) in collaboration with USDA prior to commencing operations at the NBAF. A kickoff meeting to review DHS planning for the NBAF ERP and to obtain feedback from local emergency management officials (K-State, BRI, City of Manhattan, Riley County, and FBI-Kansas City) was held at the BRI in Manhattan, Kansas, on 25 May 2010. This and additional meetings will facilitate further refinement of the ERP and incorporation of input from first responders

and emergency management officials from Ft. Riley, surrounding counties, the state of Kansas, the region, and others as appropriate.

1.1.7.1 Operations and Maintenance Standup

The first critical component of transitioning operational activities once construction has been completed is to "stand up" basic facility operations and maintenance (O&M) programs and activities. This includes ensuring the completed facility operates within the design specifications, establishing the service contracts necessary to operate and maintain the facility, developing operating procedures and plans, securing the appropriate licenses and permits, and defining the roles and responsibilities of facility maintenance staff. The O&M timeline is presented in Figure 1.1.7-1. Operational planning will ensure management, operations, and protection of government-owned facilities and infrastructure has been established prior to R&D program commencement.

The following elements are critical to O&M standup:

1. Develop NBAF O&M staffing plan based on mission requirements. All staff will require appropriate clearances. Research personnel that will be working with biological select agents and toxins (BSAT) will require a security risk assessment. Staffing schedule and timing must include allowances for recruitment and required training.
2. Develop and implement a comprehensive, approved physical security plan. The security plan with its policies and procedures shall provide a disciplined, integrated security approach, and address all Federal and state security requirements.
3. Develop facility management practices, policies, and procedures such as:
    a. Emergency Management Program and Emergency Response Plan (ERP);
    b. Continuity of Operations Plan;
    c. Employee Health and Safety Program; and
    d. Regulatory Compliance Plan.
4. Develop cooperative agreements and Memoranda of Understanding (MOUs) with other organizations and local support entities.
5. Develop and implement a comprehensive training program for laboratory and facility personnel.
6. Obtain all required regulatory and operating permits and inspections.

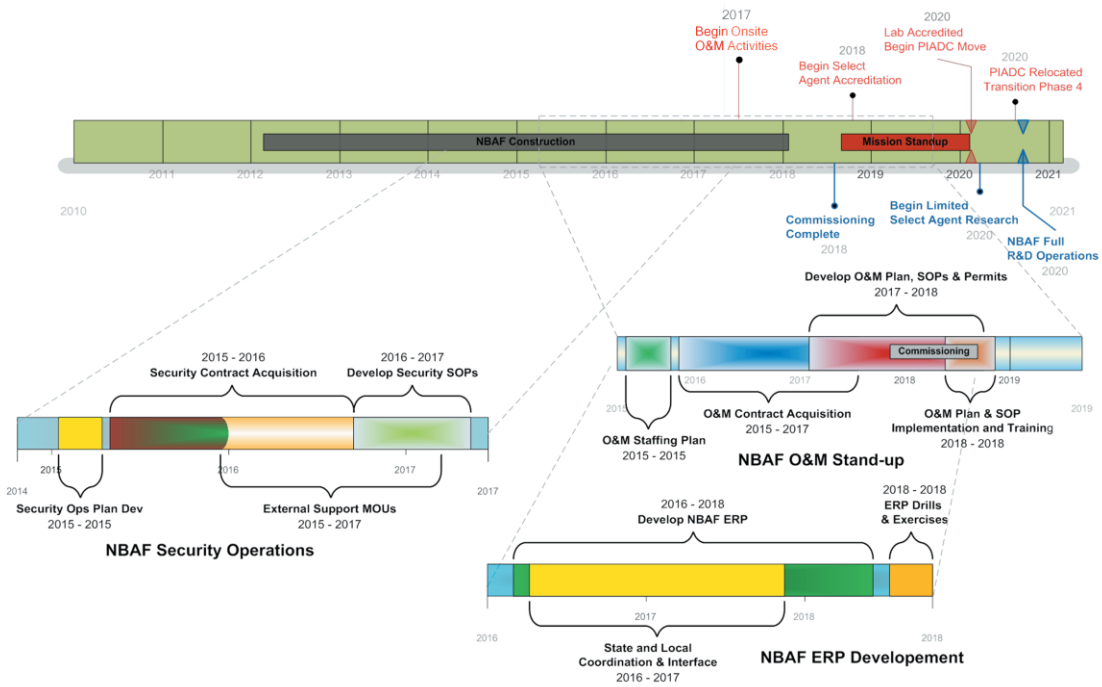


Figure 1.1.7-1: NBAF Program Timelines

1.1.7.2 Laboratory Operations Standup

The activities required to "stand up" operations at the NBAF will be accomplished over an approximately 4½ year period, beginning in November 2015 and ending in March 2020. Figure 1.1.7-2 illustrates the timeline for developing the program for laboratory operations in direct support of mission requirements. The certifications, registrations, licenses, and permits required to perform biocontainment-related research will not transfer from PIADC to the new location. This critical compliance and accreditation documentation must be applied for and acquired in advance of the operational mission commencing at the NBAF. Advanced planning for laboratory operations will ensure that all research program activities and all laboratory operations (including procedures, facilities, security, and personnel) are in accordance with current and appropriate rules, regulations, guidelines, and policies as they pertain to laboratory operations for use of BSAT, controlled substances, animal use, other relevant laboratory biosecurity regulatory requirements (e.g., BMBL 5th Edition; USDHHS/CDC, 2007; and USDA regulations), and DHS directives.

The following activities are critical to laboratory operations standup:

1. Ensure registration of BSAT with USDA APHIS agricultural select agent program and the CDC Division of Select Agent and Toxins (DSAT) program will comply with 42 CFR 73, 7 CFR 331, and 9 CFR 121.
2. Develop a biosafety program, manual, and training regimen that identifies the hazards that will or may be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards.

3. Develop a biosurety program that promotes an ethical, security-conscious culture. The biosurety program shall include personnel reliability, biosafety, biosecurity, agent security and agent accountability, as well as address the following elements (at a minimum):
   a) Laboratory work practices and SOPs that ensure biosurety;
   b) Environment, Health and Safety (EHS) Plan;
   c) Incident Response Plan(s) to include contingency, emergency preparedness, operations and response procedures, medical monitoring, and surveillance program per 42 CFR 73.14, 7 CFR 331.14, and 9 CFR 121.14;
   d) Institutional Biosafety Committee, Health and Safety Committee, and Institutional Animal Care and Use Committee (IACUC) charters;
   e) Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC) certification;
   f) BSAT registration and permitting; and
   g) ISO accreditations for diagnostic testing and reagent production.

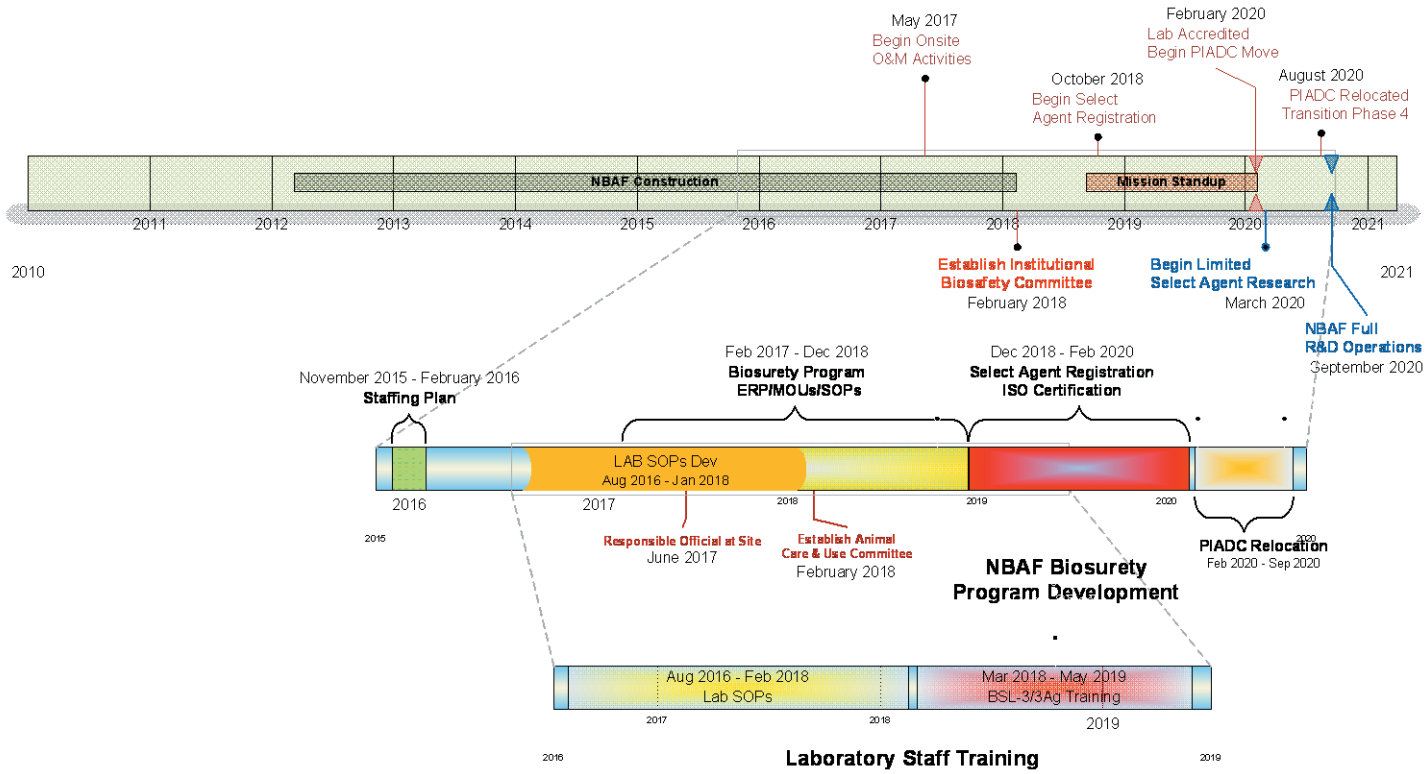


Figure 1.1.7-2: Laboratory Operations Standup

1.2 Updated SSRA Purpose and Objectives

The Updated SSRA provides a current assessment of the risks associated with the operation of the NBAF at the selected Manhattan, Kansas, location based on the latest design documents. The Updated SSRA is intended to address recommendations and observations from the NAS SSRA Committee, provide an updated quantitative assessment on the risks associated with FMD research, provide an assessment of

risk associated with large-animal BSL-4 operations, and present additional risk mitigation strategies, if any, for the NBAF.

The Updated SSRA will specifically comply with Congressional requirement § 1647.(a) Section 560 of Public Law 111–83, which states that:
(b) No funding provided in this division shall be used for construction of the National Bio- and Agro-defense Facility until the Department of Homeland Security has, pursuant to the schedule submitted by the Department of Homeland Security on March 31, 2011, to the Committees on Appropriations of the Senate and House of Representatives—

(1) completed 50 percent of design planning for the National Bio- and Agro-defense Facility, and

(2) submitted to the Committees on Appropriations of the Senate and the House of Representatives a revised site-specific biosafety and biosecurity mitigation risk assessment that describes how to significantly reduce risks of conducting essential research and diagnostic testing at the National Bio and Agro-defense Facility and addresses shortcomings identified in the National Academy of Sciences' evaluation of the initial site-specific biosafety and biosecurity mitigation risk assessment.

(c) The revised site-specific biosafety and biosecurity mitigation risk assessment required by subsection (b) shall—

(1) include a quantitative risk assessment for foot-and-mouth disease virus, in particular epidemiological and economic impact modeling to determine the overall risk of operating the facility for its expected 50-year life span, taking into account strategies to mitigate risk of foot-and-mouth disease virus release from the laboratory and ensure safe operations at the approved National Bio- and Agro-defense Facility site;

(2) address the impact of surveillance, response, and mitigation plans (developed in consultation with local, State, and Federal authorities and appropriate stakeholders) if a release occurs, to detect and control the spread of disease; and

(3) include overall risks of the most dangerous pathogens the Department of Homeland Security expects to hold in the National Bio- and Agro-defense Facility's biosafety level 4 facility, and effectiveness of mitigation strategies to reduce those risks.

(d) The Department of Homeland Security shall enter into a contract with the National Academy of Sciences to evaluate the adequacy and validity of the risk assessment required by subsection (b). The National Academy of Sciences shall submit a report on such evaluation within four months after the date the Department of Homeland Security concludes its risk assessment.

The Updated SSRA will meet the Congressional requirements through advancement of the strategic risk assessment methodology for the NBAF Program utilizing the current design drawings (65% Design). The Updated SSRA will incorporate newly developed methodology for determining the cumulative probability and overall risk of performing FMD research over the projected life span of the NBAF. Finally, the risk assessment methodology will encompasses updated epidemiological modeling that includes sensitivity analysis and other evaluations to; determine effectiveness of control measures and inform the feasibility of their implementation.

1.2.1 Address NAS SSRA Recommendations

The Updated SSRA has been revised to comply with the 2011 Congressional Mandate, to incorporate the current 65% Design elements, and to specifically address the NAS SSRA Committee recommendations. The most significant changes in the Updated SSRA include:

- A more systematic approach to the assessment of potential accident events to include fault trees and consideration of known periodic activities such as animal room washdowns;
- Characterization of the uncertainties in results that are developed as a function of uncertainty in inputs or unknowns that are modeled in the assessment;
- Incorporation of a published tornado return period calculation model;
- Additional data (susceptible populations, outbreak control measure resources, etc.) collected for the NBAF location and used in the predictive epidemiological modeling; and
- An assessment of cumulative risk of an FMD release over the predicted lifetime of the NBAF.

Appendix B1 provides the detailed comments received from the NAS SSRA Committee and references the section(s) where each comment is specifically addressed in the Updated SSRA.

1.2.2 Quantitative Risk Assessment for Foot-and-Mouth Disease Virus

The Updated SSRA includes an updated quantitative risk assessment related to the risk of a release of Foot-and-Mouth Disease virus (FMDv) with subsequent infections. Epidemiological modeling was used to identify the release pathways of greatest risk and to ascertain the relative importance of outbreak control and mitigation measures to reduce the risk of working with high-consequence livestock and zoonotic pathogens at the NBAF. The epidemiological modeling informed economic impact analysis that was ultimately used to determine the overall risk of performing FMDv research within the facility over its expected 50-year life span. The following advancements to the modeling approach were included in the Updated SSRA:

- The 65% Design engineering controls were employed to ensure safe operations at the NBAF site;
- A team of NAADSM (a computer program designed to simulate the spread and control of foreign animal diseases in a population of susceptible livestock herds) developers collaborated with the Updated SSRA team to identify validated parameters for use in the modeling;
- The Updated SSRA team prepared an updated and detailed data set of the susceptible populations, transportation hubs, and building infrastructure in the Manhattan, Kansas, and surrounding areas to support quantitative epidemiological modeling of the pathogen release scenarios;
- An evaluation of each state's culling capacity was determined through a series of interviews with state veterinarians, emergency coordinators, and health commissioners on resources

available at the state level to inform the culling capacity parameter. The directors of the National Veterinary Stockpile and National Animal Health Emergency Response Corps (NAHERC) were consulted on the availability of federal resources. These capacities were expressed in the epidemiological modeling assumptions;

- Modeling data included a thorough treatment of uncertainty, including both aleatory and epistemic, to provide a reasonable range of possible outbreak risks;
- Various state-of-the-practice outbreak response strategies were integrated into the epidemiological assumptions used to minimize the impact of an FMD outbreak; and
- Thorough uncertainty analysis was performed to better understand the value of risk mitigation measures and their relative effect on risk.

The modeling approach used to perform the quantitative risk assessment for FMDv was comprised of multiple interrelated tasks, each with specific goals and objectives as described below.

1.2.2.1 Susceptible Population Data Collection

The Updated SSRA team prepared an updated and detailed data set of the susceptible populations, transportation hubs, and building infrastructure in the Manhattan, Kansas, and surrounding areas to support quantitative epidemiological modeling of the pathogen release scenarios. The level of detail collected on the number, type, and location of susceptible animal species, including farms, feed lots, sales barns, small private holders, and animal transportation hubs in Kansas and the surrounding states (NE, OK, CO, IA, MO and TX), is extremely thorough and represents a level of fidelity never previously compiled or modeled for this region.

1.2.2.2 Event and Source Term Descriptions

The risks were further characterized by modeling potential accident events in this Updated SSRA. A systematic approach to evaluating each event was performed through fault analyses that make use of conceptual models of the originating locations within the NBAF (BSL-3Ag, BSL-3E, and BSL-3E "Special Procedure" laboratories, as well as non-containment areas); the four release transport pathways (aerosol, solid waste, liquid waste, and transference); published virus and disease characteristics; forecasted research activity; the NBAF 65% Design; presumptive procedures; and operational plans based on best practices and existing DHS directives. The resulting detailed loss-of-containment events depict the series of potential actions, errors, or containment system or process failures that could lead to a loss of FMDv containment. In addition, the frequency at which the events occur and the resulting quantities and distribution of FMDv material involved in a potential release event are evaluated and calculated. The Updated SSRA event source terms represent a range of potential values of FMDv material expected to be handled at the NBAF and span 5th, 50th, and 95th percentile values to account for uncertainty in the pathogen estimation assumptions, whereas the SSRA used a single-point estimate.

1.2.2.3 Fate and Transport Modeling

In the unlikely event that an infectious quantity of pathogen escapes biocontainment and is released to the outside environment, the pathogen would travel from the NBAF by one or more of the four transport pathways. The fate and transport of pathogenic material released due to any of the accident events developed were modeled to determine the quantity of viable pathogen delivered to susceptible premises. The probability of infection was then applied to determine the extent and numbers of resultant infected animals and premises for the modeled event. The outputs from the fate and transport modeling were used as the input to the epidemiological modeling.

1.2.2.4 Quantitative Epidemiological Modeling

The primary purpose of performing epidemiological modeling on the spread and subsequent control of FMD from an event at the NBAF was used to identify the release pathways of greatest risk and to ascertain the relative importance of outbreak control and mitigation measures to reduce the impact. Epidemiological modeling served to test various hypotheses on the relative value of various risk mitigation measures and enabled the Updated SSRA team to quantify risk and evaluate the efficacy of various risk mitigation strategies. The output of these models served as input for the economic consequence modeling discussed below.

1.2.2.5 Economic Consequence Assessments

The objective of the economic consequence assessments was to determine the effect of FMD release on the susceptible populations and to project costs and disruptions to public and private trade activities (such as animal commodity flow, and collateral industry and workforce populations). The economic consequence assessment serves to provide cost-benefit analyses of proposed countermeasures and mitigation strategies (e.g., containment, clean-up, and animal stop movement zones) that factor into the overall risk. These economic impacts, by event, were used in the calculation of risk.

1.2.2.6 Risk Calculation

Following all modeling, risk calculations were performed for each event. The risks and associated uncertainties were first computed for each individual outcome; then risks and uncertainties were aggregated over all outcomes by origin and pathway. Cumulative risks summed over all events across time were also calculated and presented for a single year and summed over the fifty-year operating lifetime of the NBAF. These resulting risk values were used to drive associated conclusions and risk mitigation recommendations for the NBAF.

1.2.3 Large Animal BSL-4 (ABSL-4) Assessment

During development of the Qualitative Risk Assessment (QRA), which was part of the SSRA published by DHS in January 2010, the QRA panel members identified two elements of risk that will be unique to the NBAF: 1) the research and handling of FMDv in a high-containment laboratory environment in the contiguous mainland United States (Manhattan, Kansas); and 2) the potential for research work with emerging and/or incompletely characterized zoonotic and non-zoonotic agents in livestock within BSL-4 containment. The risk of handling FMDv at the NBAF was thoroughly evaluated through the quantitative

risk assessment effort. The second element of risk, namely emerging or incompletely characterized pathogen research in large animals, was the focus of the NBAF Large Animal BSL-4 (ABSL-4) Assessment.

The primary objective of the ABSL-4 Assessment was to identify and categorize the unique risks associated with working with livestock exposed to pathogens studied in BSL-4 containment. Understanding the sequence of events that may lead to a release from ABSL-4 containment informs current NBAF plans and identifies alternate design, operations, and response strategies that may be leveraged for use at the NBAF. A sub-objective of this effort was to revise pathogen characteristics that were presented in the 2010 QRA for Nipah and Hendra viruses based on recent research results and data related to pathogen etiology, host range, epidemiology, immune response, laboratory requirements, and anticipated research needs. These updates may support future quantitative modeling efforts of these pathogens as new data continue to become available.

Similar to the approach described for the FMDv risk assessment, the ABSL-4 Assessment developed a set of credible events that represent hazards and/or accidents associated with working with large livestock inside BSL-4 containment through elicitation of expert opinions from within the BSL-4 and large animal handling communities. Each of the four potential release transport mechanisms (i.e., aerosol, solid waste, liquid waste, and transference) was considered. The probability and the number of opportunities per year for each event evaluated were also estimated and used to prioritize the potential mitigation strategies, design considerations, and/or operational changes.

As the probability or frequency of a release does not fully convey risk, the ABSL-4 Assessment also evaluated the probability of an infection from a release or laboratory exposure, and the potential consequences from an infection. In contrast to the probability and frequency of FMDv-related events, for which quantitative estimates were possible and appropriate, lack of available data on NBAF BSL-4 pathogens (Nipah and Hendra viruses) hindered the ability to perform epidemiological or economic impact modeling to quantify the consequences of subsequent infection(s). Rather, the ABSL-4 Assessment estimated the resulting impact of a release of these agents based on documented outbreaks of Nipah (e.g., Bangladesh, India, Malaysia, and Singapore) and Hendra (e.g., Australia). The probability of events in ABSL-4 containment and the associated impact of their occurrence were combined to estimate the relative risk of working with these pathogens within ABSL-4 containment.

2. Facilities Description

The NBAF is designed to provide a safe and modern research facility for high-consequence, biological threats including potentially zoonotic and foreign animal diseases. It will enable continued research; diagnostics development, testing, and validation; advanced countermeasure development (e.g., vaccines, biotherapeutics, diagnostic assays, therapies, and vector control); and training for high-consequence livestock diseases. The NBAF will integrate aspects of public and animal health research that have been determined to be central to national security and will incorporate the latest, most secure design practices in order to operate safely and securely.

2.1 Site Description

The NBAF site is on the Kansas State University (K-State) campus in Manhattan, Kansas, in Riley County. The site is approximately 105 miles west of Kansas City, Missouri (Figure 2.1-1). Manhattan's population is 52,281 according to the 2010 U.S. Census, approximately a 16.6 percent increase from the 2000 census count of 44,831. These figures include both the student population from K-State as well as Fort Riley soldiers and their families residing in Manhattan [City of Manhattan, 2011]. The K-State Registrar's Office reports an enrollment of 23,863 for the 2011 fall semester [K-State, 2011]. The 45.6-acre site is located in the North Campus Zone of K-State (Figure 2.1-2) near the southeast corner of the intersection of Kimball and Denison Avenues, as shown in Figure 2.1-3, and is adjacent to the Biosecurity Research Institute (BRI).

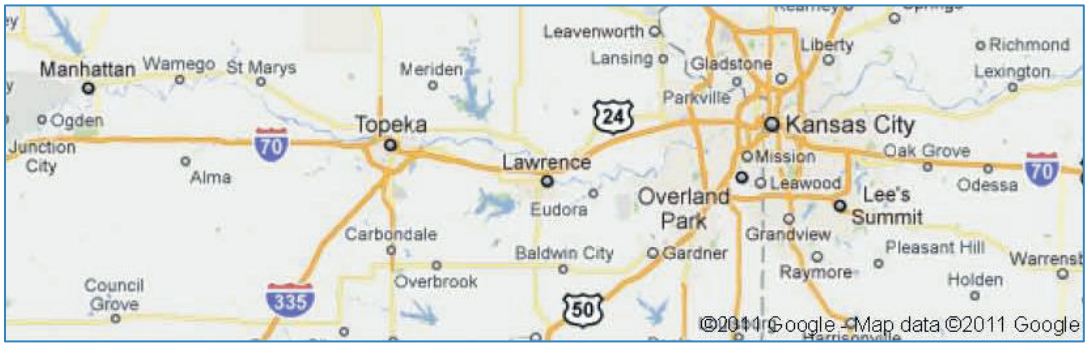


Figure 2.1-1: Manhattan, Kansas Relative to Kansas City, MO

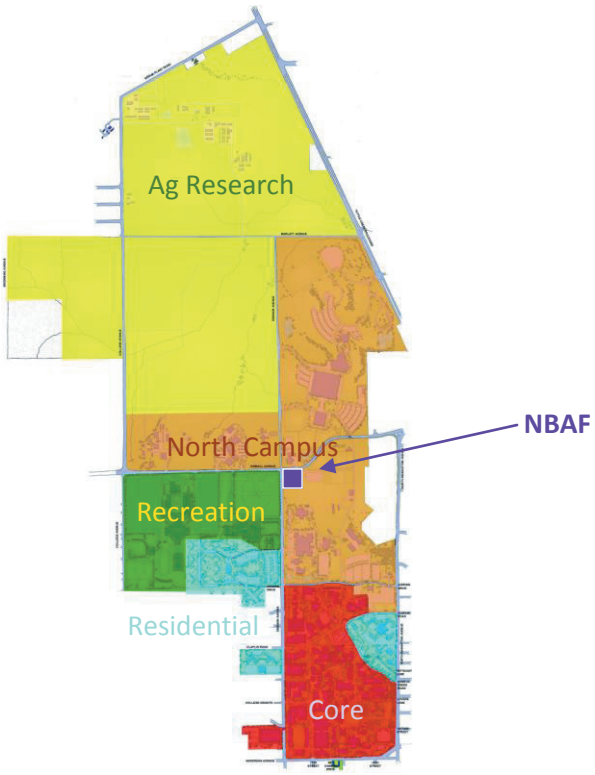


Figure 2.1-2: K-State Campus Zones and NBAF Location

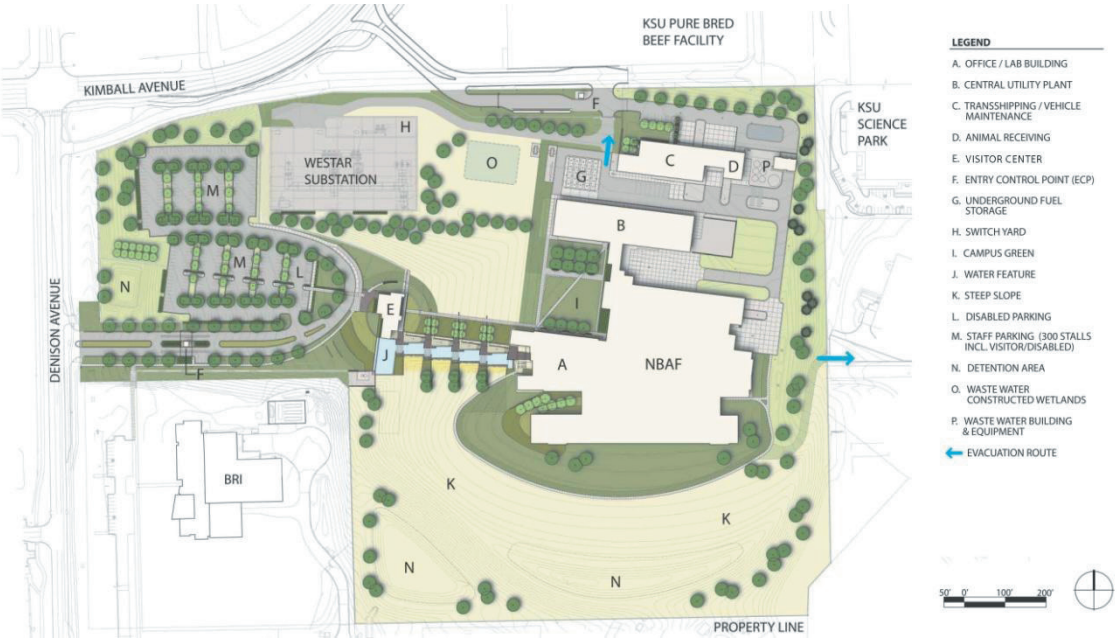


Figure 2.1-3: NBAF Location near Kimball and Denison Avenues

2.1.1 Topography and Geology

The site includes an approximately 50' change in grade from end to end. According to best practices and ARS Facilities Design Standards 242.1 guidelines, new facilities should be situated on a site to maximize the integration of their development with existing topographical contours [USDA, 2002]. The orientation and design of the NBAF incorporate such considerations and minimize the use of the steepest slopes on the site. Site slopes are indicated in Figure 2.1.1-1 [NDP, 2011].

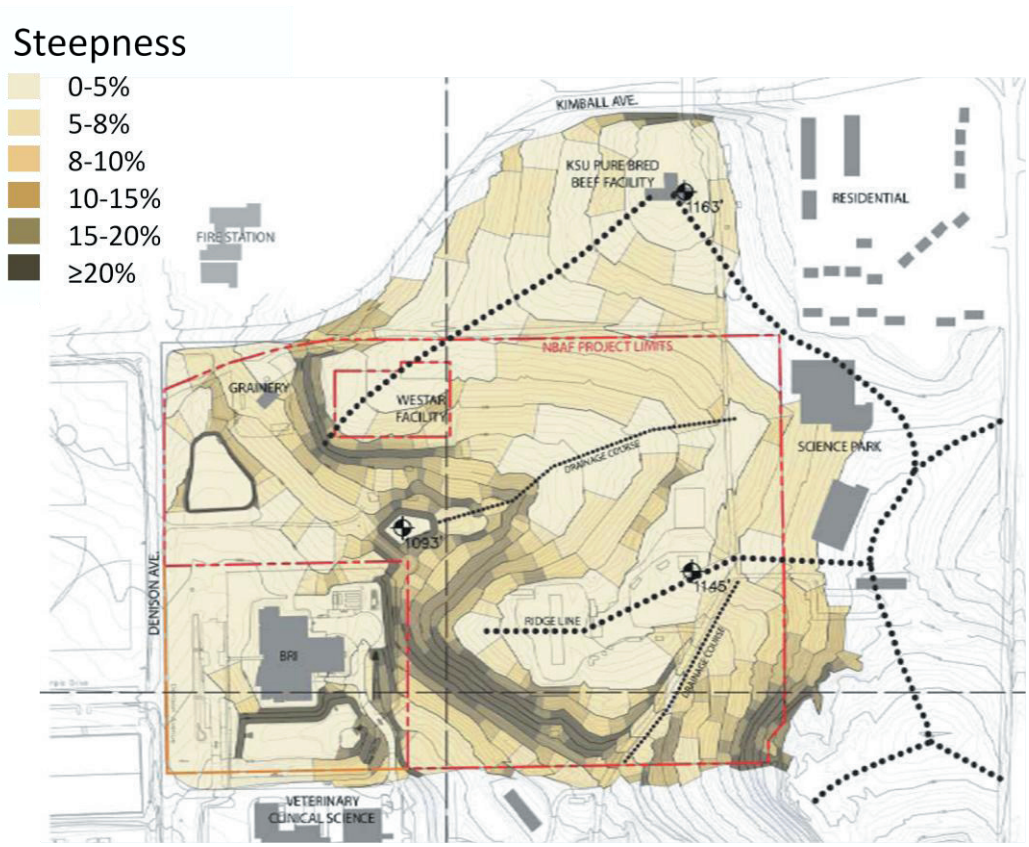


Figure 2.1.1-1: Site Grading

An assessment of the existing stormwater drainage patterns for the site was also incorporated in the site planning and facility orientation to identify potential areas of stormwater influence on the laboratory and support buildings. This assessment was used to develop grading and elevation plans to mitigate stormwater intrusion. An assessment of soil types, boundaries, and depths was used to determine the required design features and construction techniques, and to estimate the potential for liquefaction and earthquake response. Soil boring information on the site indicates the presence of bedrock ranging in depth from 11’ to 34’ beneath the surface [NDP, 2011].

2.1.2 Climate

Prevailing winds at the site are southerly in the summer and northerly in the winter [NDP, 2011]. The NBAF Design Partnership considered the prevailing wind direction in siting considerations and for air intake and exhaust system designs. The average annual precipitation in the area is 32" to 34" with mean monthly precipitation that ranges from 0.8" (approximately 20 mm) in January to 5.8" (approximately 147 mm) in June. The average annual mean high and mean low temperatures are 66.3° F (19.1° C) and 43.8° F (6.6° C), respectively, with a mean monthly average high temperature of 91.4° F (33° C) in July and an average low of 17.2° F (-8.2° C) in January.

2.2 Layout and Buildings

The NBAF campus comprises the Main (Laboratory) Building, the Transshipping Building, the On-Site Wastewater Pretreatment Facility, and several support buildings (refer to Figure 2.1-3).

2.2.1 Office/Lab (Main)

The Office/Lab (Main) Building incorporates approximately 581,000 gross square feet on four levels; the square footage of each level is presented in Table 2.2.1-1. The first floor of the Main Building houses offices, common areas, public spaces, support areas, laboratories, and containment areas, as illustrated in Figure 2.2.1-1. The containment "block" includes BSL-3 containment or higher (BSL-3E, BSL-3E "Special Procedure," BSL-3Ag, and BSL-4) laboratories.

Table 2.2.1 1: Main Building Size [NDP, 2011]

Level (Floor)	Base Gross Square Footage
Office 2 Penthouse	130,590
Office 1 Interstitial	169,056
First Floor/Entry Laboratory	175,668
Basement	105,435
Total	580,749

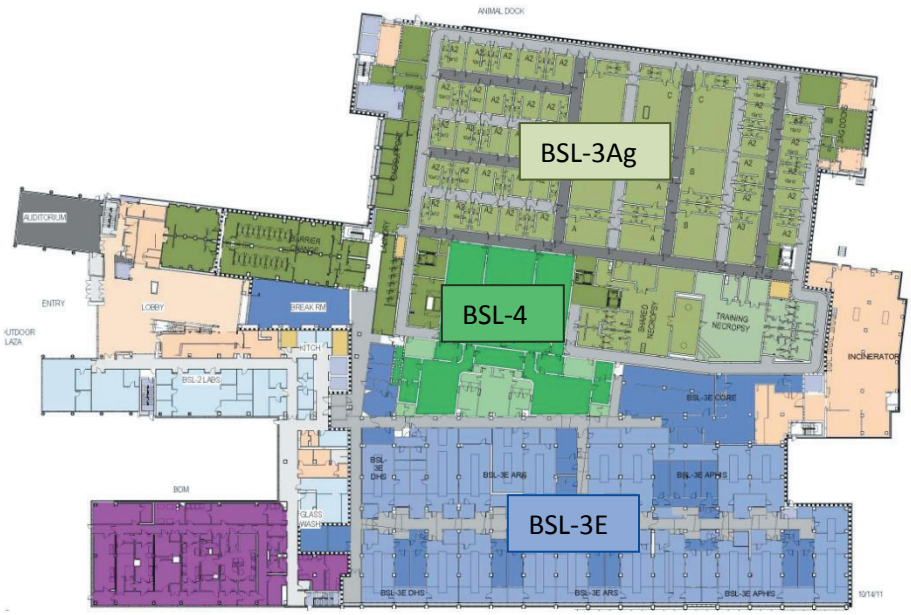


Figure 2.2.1-1 Main Building First Floor Plan [NDP, 2011]

2.2.1.1 Non-Containment Area

The entry to the Main Building is on the first floor and opens to an atrium that serves as the NBAF lobby, reception, and café seating area. The first floor also includes an auditorium, break room, kitchen, and restrooms. Access to some mechanical rooms and the other levels (floors) is provided by stairs and elevators in the non-containment areas. The central barrier change room connects the containment areas (BSL-3E, BSL-3Ag, and BSL-4) to the lobby. All research and work associated with the handling and manipulation of viable FMDv is performed in the containment areas. Other laboratory areas on the first floor include BSL-2 spaces and the cGMP Biotechnology Development Module (BDM). Service areas and the incinerator staging area are also on the first floor, but are not directly accessible from the non-containment area.

2.2.1.2 Containment Area

Delineation of the containment zone begins in the barrier change area. “Clean” and “dirty” clothes changing areas are provided for both genders and are separated by shower facilities. Inside the containment zone, the BSL-3E and BSL-3Ag are separated and buffered from each other by “clean” corridors. The BSL-4 is in the middle of the containment zone, between the BSL-3Ag and BSL-3E. The net space dedicated to each level of containment and support areas is provided in Table 2.2.1-2.

Table 2.2.1 2: Net Space [NDP, 2011]

Area	Base Gross Square Footage
BSL 3E	37,578
BSL 3Ag	43,596
BSL 3E/BSL 3Ag Support	10,233
BSL 4	13,376

The major functional components of the BSL-3Ag area include the Animal Holding Rooms (AHRs), necropsy rooms, and support services. The 46 AHRs are designed to house a variety of species for numerous study group sizes. Two necropsy areas (one supporting research programs and one normally supporting training programs) serve the BSL-3Ag while providing redundancy for both programs. It is not anticipated that the BSL-4 area will be used for FMDv research.

2.2.2 Transshipping Facility

The Transshipping Facility (TF), Figure 2.2.2-1, is the principal shipping and receiving location for the NBAF. All incoming material, equipment, and supplies will be required to go through the TF before being transferred to the Main Building. All solid waste also will be processed through the TF. Delivery and pickup vehicles (and occupants) will have to be cleared for access to the TF by the North Entry Control Point. The TF provides part of the perimeter barrier surrounding the Main Building and other parts of the NBAF campus. The TF also includes a Diagnostic Samples Storage Vault with a secure cold storage unit that provides short-term storage of incoming samples and controlled agents that cannot be immediately delivered to an approved chain-of-custody representative in the Main Building [NDP, 2011]. A more complete description of the TF is provided in the Design.

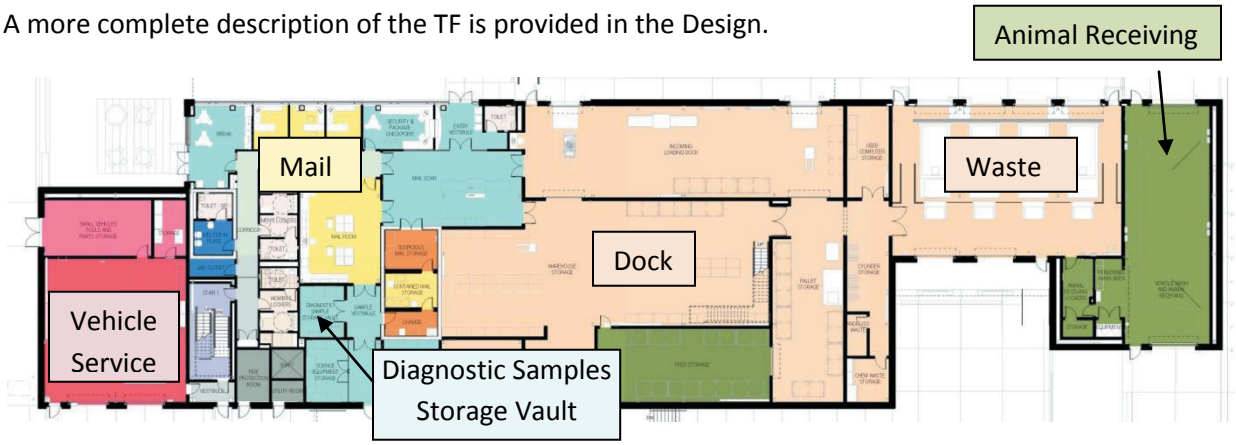


Figure 2.2.2-1: Transshipping Facility

2.2.3 On-Site Wastewater Pretreatment Facility

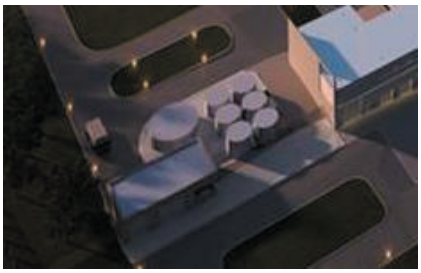


Figure 2.2.3-1: On-Site Wastewater Pretreatment Facility

The NBAF Design Partnership was notified on 26 May 2010 that pretreatment of the liquid effluent waste stream from the NBAF facility is required to satisfy local discharge requirements. Therefore, an on-site Wastewater Pretreatment Facility (Section 2.4.2) was added to the NBAF design and is located near the northeast corner of the site. A rendering of this facility is provided in Figure 2.2.3-1. A plan of the facility is provided as Figure 2.2.3-2. The flow processing requirements were developed by assessing waste stream characteristics from other similar facilities and estimating needs for NBAF-planned operations. The waste stream is a blend of all wastewater generated at the NBAF, which includes flows from domestic sewage, laboratory sinks and drains, equipment, facility washdown (including significant solid manure loads), and tissue autoclave

decant. Cooling tower blowdown, boiler water, and a small stream of domestic wastewater generated from some outbuildings will bypass the wastewater pretreatment facility and be pumped from the NBAF lift station directly to the municipal sanitary sewer. It is important to note that all liquid effluent from laboratory operations and containment are treated prior to being processed by the wastewater pretreatment facility (see Section 2.3.3 for details).

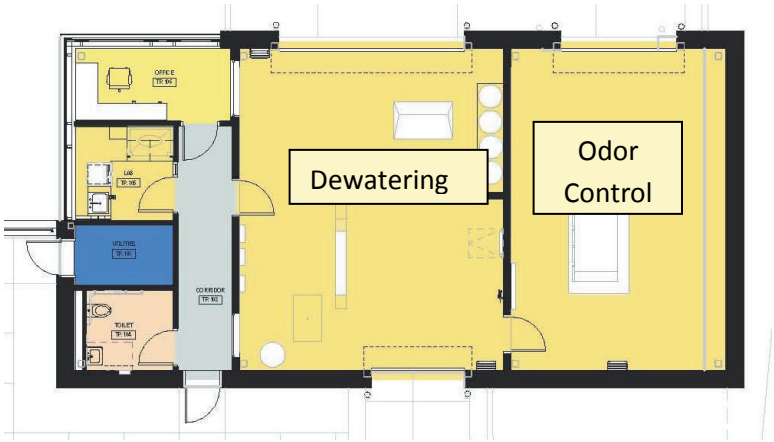


Figure 2.2.3-2: On-Site Wastewater Pretreatment Facility First Floor Plan

The mass loading of biochemical oxygen demand, total suspended solids, total nitrogen, and total phosphorus were driving factors in the wastewater pretreatment system design. The complete development of requirements for the pretreatment facility is documented in the Design.

2.2.4 Other Features and Structures

The NBAF campus includes other features and structures that are included in assumptions and considerations in the Updated SSRA. The Entry Control Point, Visitors Center, Central Utility Plant, and underground fuel storage locations can be identified in Figure 2.2.4-1.

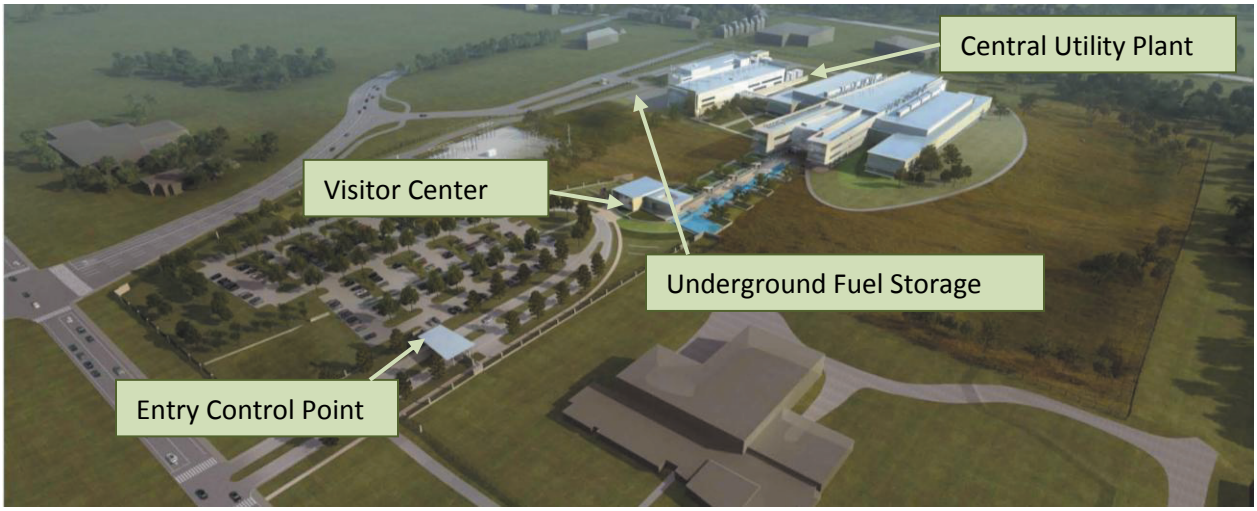


Figure 2.2.4-1: Other NBAF Site Features and Structures

2.3 Containment Systems

In all modern containment facilities, containment is maintained by providing redundant systems and processes that decontaminate and/or sterilize everything that leaves a containment area. During a review of the 2010 SSRA, the NAS SSRA Committee suggested that risk assessments should be performed by considering the potential loss of pathogen materials from four transport pathways. The four pathways, or transport mechanisms, by which infectious materials might leave the containment block are:

- As an **aerosol**;
- As **solid** waste through the NBAF solids waste management system for the containment areas;
- As a **liquid** through the NBAF liquid effluent treatment system; and/or
- Via a **fomite** or **vector** (human or other animal).The term **transference** is used to capture all mechanisms in this pathway.

Pathogen release risks from aerosols, including laboratory aerosols, animal expiratory aerosols, and aerosols generated by other activities such as animal room washdowns, will be mitigated by the use of engineering controls (e.g., biosafety cabinets) and facility design features (e.g., in series/double high-volume HEPA filtration systems). Each of these containment systems/practices is described in more detail below. Solids (i.e., all materials exiting containment by autoclave, dunk tank, wipedown, or vapor decontamination) are sequentially decontaminated. For example, materials leaving the BSL-4 area are processed through a pass-through autoclave into the BSL-3 area. These same materials are steam sterilized a second time in a pass-through batch autoclave before leaving containment to be incinerated on-site. Liquids (i.e., all materials discharged into the NBAF liquid effluent treatment system) from laboratories are disinfected, by protocol, prior to being collected and processed by the liquid Effluent Decontamination System (EDS). Fomites are controlled by access restrictions, procedural requirements for the decontamination and/or sterilization of everything prior to removal from a containment area, and protective garments/garment changes and shower-out requirements (including a chemical shower required on exit from BSL-4). Vectors are controlled by layered confinement systems and strict adherence to vector control procedures. Human vectors are managed by access restrictions, contact restrictions from susceptible species, appropriate personal protective equipment, and personal hygiene practices.

2.3.1 Aerosol Containment Systems and Practices

Like all high-containment facilities, the NBAF design and operational strategies depend on sound laboratory practices and layered engineering solutions. Specifically with regard to air handling/filtration systems, good laboratory practices are used to minimize the creation of aerosols. Layered engineering solutions include the use of biosafety cabinets (BSCs), negative pressure/directional airflow, in-laboratory flow patterns, air exchange rates, HEPA filtration, single-pass circulation, biocontainment dampers, and other manual and automated safety systems. In BSL-3Ag and BSL-4 animal holding rooms,

the rooms themselves (for large animals) become the primary containment barrier; thus, effective air handling and filtration systems are critical to successful biocontainment.

In areas inside the containment block that do not house large animals, BSCs will be used as the primary engineering control for aerosols. There are three classes of BSCs available (Class I, II, and III). Properly maintained Class I and II BSCs, when used in conjunction with good microbiological techniques, provide an effective containment system for safe manipulation of moderate and high-risk microorganisms, including BSL-2 and BSL-3. Most, but not all, Class II BSCs also protect the research material through HEPA filtration of the air flow across the work surface. Class III BSCs offer the maximum protection to laboratory personnel as all hazardous materials are contained in a fully enclosed, gas-tight cabinet.

The BSL-3 supply air is provided by four 100% outside-air handling units (AHUs) connected to a common supply manifold. The BSL-3 supply air AHUs are sized to provide N+1 redundancy. Conditioned supply air is delivered from high pressure ductwork to the HEPA caissons (single HEPA in these lower risk areas), which serve as a final filter of laboratory supply air.

The BSL-3Ag supply air system, which also services the BSL-3E spaces and the BSL-3Ag areas, is also provided with outside air from four 100% outside-air AHUs. For BSL-3Ag, conditioned supply air is provided by high pressure ductworks to spaces through multiple AHUs to maximize reliability and minimize supply air disruption that may otherwise result from single unit failures. All intake air is filtered numerous times— the last through a HEPA filter. The specific air distribution design provides individual air terminal units and HEPA filter caissons for each space served, allowing for individual room control of temperature and humidity in the AHRs. The BSL-3Ag spaces have redundant (2N) HEPA caissons in parallel per BMBL recommendations. Larger AHRs (Types C and D) have multiple supply air assemblies and provide N+1 redundancy.

The BSL-3E is serviced by a dedicated central exhaust air system that removes the room air and exhaust air from the BSCs, point source ventilation, and hoods. Each BSL-3E room is exhausted through a HEPA filter caisson with bubble-tight dampers. BSL-3E Special Procedure laboratories are served by a dedicated central exhaust system with N+1 redundancy on fans. The Special Procedure laboratories will be exhausted through double HEPA filters (in series) with bubble-tight dampers.

The BSL-3Ag exhaust air system is distributed so that each AHR has dedicated terminal units that provide redundant dual HEPA filtration. Smaller AHRs have full 2N redundancy and larger AHRs (Types C and D) have N+1 redundancy. This configuration is consistent with BMBL guidance and exceeds the filtration capability of other existing large animal holding rooms. A rendering of a redundant double-HEPA caisson like those used in the NBAF is provided Figure 2.3.1-1, and a drawing of a similar caisson is presented in Figure 2.3.1-2. A summary of the supply and exhaust HEPA configuration is provided in Table 2.3.1-1.

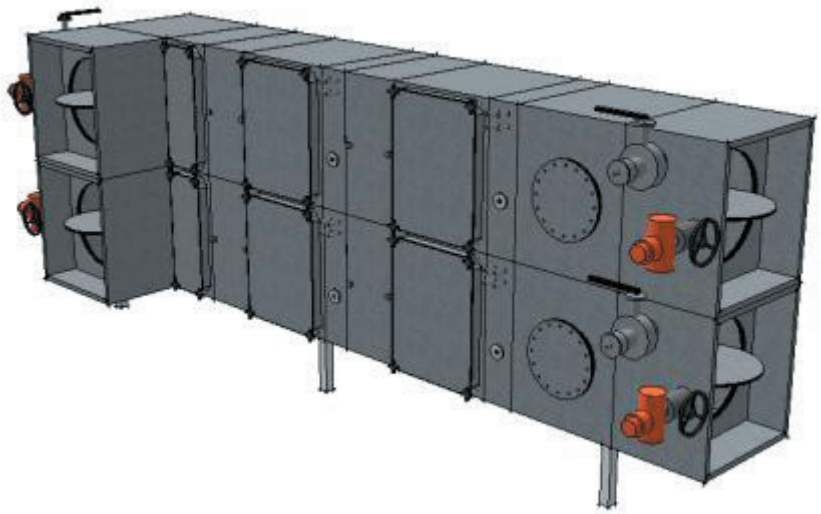


Figure 2.3.1-1: Parallel Dual-HEPA Caisson Rendering

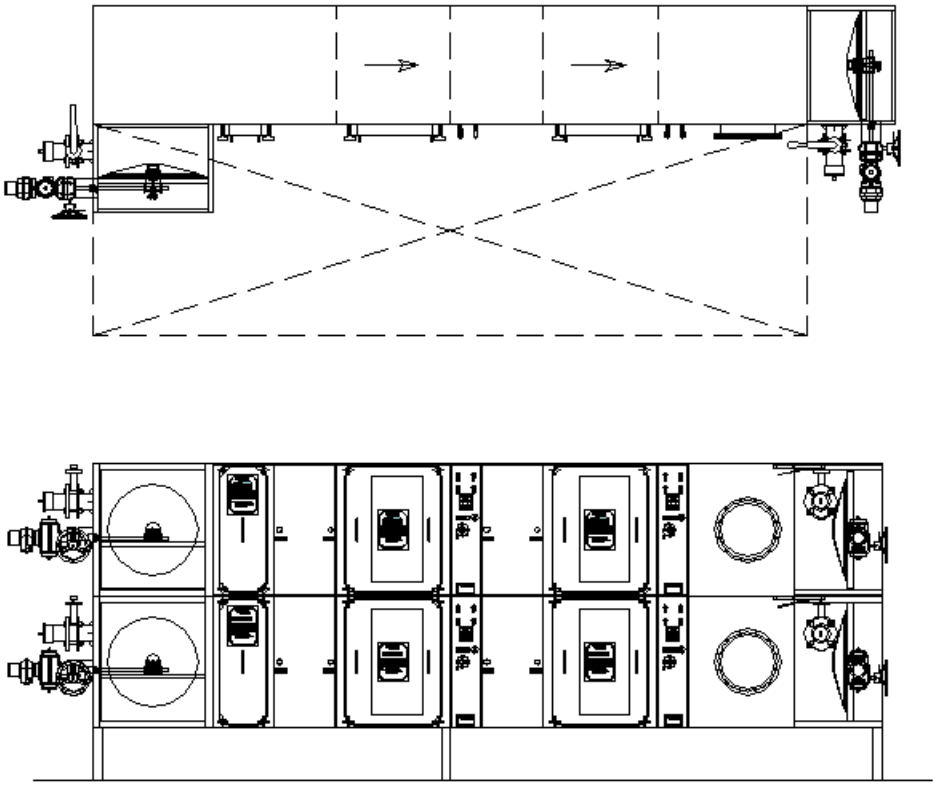


Figure 2.3.1-2: Parallel Dual-HEPA Caisson Drawing

Table 2.3.1 1: HEPA Configurations		
Biosafety Level	**Intake**	**Exhaust**
BSL 3E	Redundant Single HEPA	Redundant Single HEPA
BSL 3E Special Procedure Rooms	Redundant Single HEPA	Redundant Double HEPA
BSL 3Ag	Redundant Single HEPA	Redundant Double HEPA
BSL 4	Redundant Single HEPA	Redundant Double HEPA

2.3.2 Solid Waste Management

The solid waste decontamination systems will include carcass disposal systems, autoclaves, dunk tanks, gaseous decontamination chambers, and laundry systems. All solid materials that are removed from a containment area must be sterilized by one or more of these methods (or another acceptable method such as multiple wipedowns with an agent-appropriate disinfectant) prior to being removed from the BSL-3Ag, BSL-3E "Special Procedure," or BSL-4. These materials are then processed a second time to be removed from the BSL-3E area. Solid waste flow diagrams for all of the containment areas are documented in the Design.

2.3.2.1 Carcass Disposal Systems

The current 65% NBAF Design includes two large tissue autoclaves for the BSL-3 (including BSL-3Ag and BSL-3E) areas with the capacity to process either six 500-pound carcasses per cycle or a single 1,200 pound carcass (up to 42" in diameter) per cycle. Two additional tissue autoclaves of the same capacity are provided for the BSL-4 area. The tissue autoclaves will be mounted in the basement directly beneath the containment areas with penetrations for the primary vessel into each appropriate location. The systems are capable of heating the waste to 300° F (149° C) and the maximum total cycle time is estimated to be 10 hours. The cycle comprises approximately two hours of heat up, three hours of temperature hold, four hours of dehydrations, and one hour of product removal. The final product is containerized, moved, and held at the incinerator staging area until incineration. All vents and safety pressure relief components are HEPA filtered.

2.3.2.2 Autoclaves

Pass-through autoclaves are used to sterilize materials before removal from a containment area. Non-waste items may also be autoclaved out of containment, depending on compatibility of the item and other sterilization methods available for treatment before removal. The NBAF design and operational strategy for BSL-3/BSL-4 autoclave wastes provides complete redundancy. Any materials to be removed by the autoclave process are first autoclaved upon removal from the containment area (BSL-3Ag, BSL-3E, BSL-3E Special Procedure rooms or BSL-4) and are then re-autoclaved at the NBAF biocontainment barrier. Sterilized solid waste residuals are staged for on-site incineration. Reusable garments from AHRs are autoclaved (from BSL-3Ag to BSL-3E) and then laundered prior to reuse. At the end of the garment

service life, the item will be autoclaved twice (from BSL-3Ag to BSL-3E and from BSL-3E to the waste staging area) and then incinerated.

2.3.2.3 Other Solid Waste Treatment Systems

For materials and equipment (and other solids) that are removed from containment, the most appropriate disinfection methods will be used. For some items this may include the use of disinfectant solutions applied in dunk tanks or another acceptable method such as multiple wipedowns with an agent-appropriate disinfectant. Other items may be subjected to gaseous decontamination (using chemical disinfectants such as vaporous hydrogen peroxide, formaldehyde gas, or chlorine dioxide gas). The NBAF has incorporated pass-through chambers, including dunk tanks and decontamination chambers, for all of these methods.

2.3.3 Liquid Waste Management

The NBAF liquid EDS provides treatment for all liquid wastes produced in the BSL-3 containment areas (BSL-3Ag, BSL-3E, and BSL-3E "Special Procedure") and in the BSL-4 area. Liquid waste streams from these areas (BSL-3 and BSL-4) are not mixed prior to treatment, but share an alternative redundancy tank, as depicted in Figure 2.3.3-1. There is one decontamination system for BSL-3 and a separate system, which has a built-in 2N redundancy, for BSL-4; the alternative redundancy tank is available for BSL-3 or BSL-4 liquid waste as necessary. Operationally, liquid waste effluents may be chemically treated with a disinfectant (the specific disinfectant, concentration, and protocols depend on the research pathogen) or other sterilization/disinfection methods prior to or during discharge into the EDS. For example, in animal handling rooms and necropsy suites, and in BSL-3Ag "dirty" hallways, etc., chemical pretreatment may be applied by priming drain traps (one or two times daily during experiments) with disinfectant in accordance with protocols. Animal watering systems will have an auto-flush capability. No other auto-priming traps or automated systems for the addition of disinfectant to the tanks are included in the facility design. All traps will accommodate the maximum room static pressure differential with a minimum of an additional 2-inch (water column) seal depth.

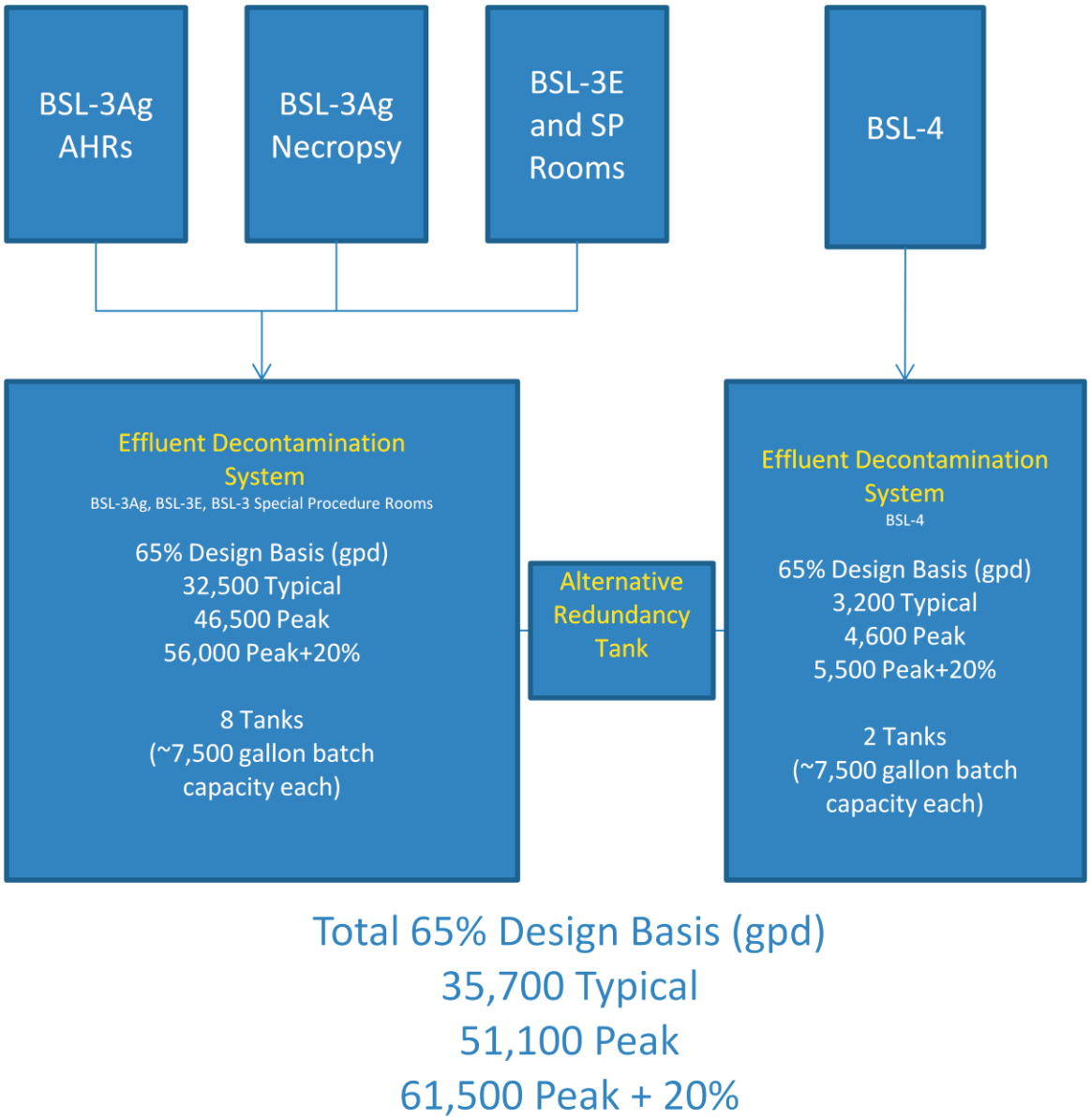


Figure 2.3.3-1: NBAF Effluent Decontamination Systems

The EDS is located in the basement underneath the containment areas and the gravity-fed effluent passes through a trap, which also serves as a seal. Drains that are not in continuous or routine use are blocked to prevent loss of seal by dry traps. BSL-3 (BSL-3Ag AHRs and showers, BSL-3E Special Procedure rooms and showers, BSL-3E laboratories, the central shower facility, and laundry) effluent flows into a series of eight sequentially-filled treatment tanks; BSL-4 effluent flows into a separate set of two sequentially-filled tanks. The tanks hold the waste until a batch (~7,500 gallons) is treated using a high-temperature, high-pressure batch treatment process referred to as “cooking.” Specific operating protocols and temperature and pressure profiles will be determined at a later date and in consultation with the Biosafety Officer, Responsible Official, the Biosafety Committee, and other informed sources. Utilities (air, steam, and water) will be provided by the CUP (with appropriate backflow prevention),

with redundant valves used at each critical point. The cook cycle will be monitored and controlled by automated systems that will maintain the prescribed pressure and temperature for the specified period of time. Agitation and mixing of the effluent being treated will be achieved by use of an internal mechanical agitation system. After "cooking," the decontaminated effluent is cooled through heat exchangers and mixed with other disinfected containment and non-containment liquid effluent (e.g., office and domestic sewage) before being discharged from the Main Building. The cooled and combined liquid effluent is then pumped to the On-Site Wastewater Pretreatment Facility.

The design requirements for liquid effluent treatment were developed from analyses that included comparisons to other similar facilities [NDP, 2011]. All EDS tanks (11 total) have an 11-hour cycle time, but the number of tanks that can simultaneously heat the effluent is limited to three. (The heating sequence will typically be five to six hours.)

The NBAF Design Partnership flow analysis indicates that the "typical" effluent flow (gpd) is calculated as 70% of the "peak" flow; peak flow assumes 100% utilization. An "absolute peak" flow was estimated by adding a 20% margin to the peak flow. Data from the Canadian Science Center was used to calculate a liquid effluent flow rate on a square-foot-containment-area basis. The NBAF Design Partnership used this value (0.33 gpd/ft^2) to calculate a "comparative" flow for the NBAF. The resulting design-basis values are presented in Table 2.3.3-1.

Table 2.3.3 1: Liquid Waste Effluent Requirements (NDP)

Area	Liquid Effluent Flow (gpd)			
Rate	Typical	Peak	Absolute Peak	Comparative
BSL 3	32,500	46,500	56,000	37,300
BSL 4	3,200	4,600	5,500	4,600
Total	**35,700**	**51,100**	**61,500**	**41,900**

Section 17.1 of the 65% Design develops processing schedules that illustrate the need for eight tanks to provide continuous processing of the peak flow from the combined BSL-3 sources. Thus, the alternative redundant tank serves as the N+1 redundancy for the peak BSL-3 combined liquid waste. The BSL-4 liquid waste can be processed by one tank per day since the peak BSL-4 liquid waste system (2 tanks) has a built-in 2N redundancy, plus the alternative redundancy tank.

The tanks are not pressurized during effluent collection. However, these tanks may be pressurized to test for tank and valve integrity prior to the receipt of liquid effluent. All tanks are equipped with double-HEPA filtered ventilation and pressure release valves. During the heating cycle, positive pressure develops in the tanks and pressure is used to assist with drainage when the tanks are being emptied. The EDS is designed to accommodate large animal waste solids and other solids such as unused feed or pieces of necropsy waste tissues. SOPs will provide direction on the collection and disposal of other solid wastes that need to be removed from the containment areas without being processed by the EDS. In all

laboratory areas, except for the animal holding/handling areas, floor drains will be capped and sealed unless needed for washdown. The BSL-3E areas will not have floor drains.

After pretreatment, gravity flow sewer lines carry the remaining liquid fraction to the NBAF-dedicated lift station just west of the NBAF and north of the BRI (on NBAF property). The lift station and its integral sump and pumps move the effluent, via a force main, in a northerly direction to the top of the hill on the north side of Kimball Avenue. There, the NBAF force main terminates and the effluent empties into a City of Manhattan gravity drain system where it will be eventually processed by the publicly-owned treatment works (POTW). Section 5 provides a more detailed description of the municipal system.

2.3.4 Flow and Transference Management

Fomites (i.e., inanimate objects that may transfer infectious materials) have been linked to the spread of viral pathogens, including FMDv, in past events. Early consideration of risk mitigation for fomites associated with research on robust and hardy pathogens, like FMDv, is critical to the NBAF design. Thus, the transference of infectious materials by fomites and human vectors or animal vectors is considered separately from infectious materials inadvertently released from containment via the aerosol, solid, or liquid waste streams.

Non-waste fomites include, but are not limited to: clothing; footwear; personal items (glasses, prosthetics, jewelry, writing instruments, etc.); office supplies; service equipment; tires; containers; printed materials/paper; animal handling equipment; emergency response equipment; PPE; and many other ordinary items. Ultimately, in addition to design considerations, containment of fomites in the NBAF (and other similar facilities) requires following diligent process and procedural requirements. Basic strategies for fomite containment include the use of good laboratory practices, PPE, centralized ingress/egress pathways, and access limitations. Implementation of these strategies must be carefully considered in the design and operating of a laboratory in order to prevent transference of infectious materials.

In the context of this assessment, vectors are living organisms that transport pathogens from an infected animal (or their excretions, etc.) to a susceptible species (or their immediate environs). Common vectors for FMDv include susceptible species that suffer from the pathogen (e.g., infected cattle), as well as infected species that do not ever develop symptoms, and human vectors. Human vectors are persons that unwittingly transport the virus without being infected. It has been reported that humans, independent of personally-carried fomites, can carry and subsequently infect susceptible species with FMDv [Sellers, 1970].

The NBAF Design Partnership has developed containment level relationship diagrams and flow diagrams for animals, personnel (including shower and change room), samples, consumables, and materials for the BSL-3E, BSL-3E Special Procedure, and BSL-3Ag AHRs in the 65% Design [NDP, 2011]. This part of the design process also includes consideration of methods used to introduce animals in the midst of a study and adding feed and/or other supplies during a period of infectivity in an AHR.

The NBAF animal flow diagrams show the conceptual pathways for the movement of incoming animals. All animals will be received at the BSL-3Ag dock by a site-restricted vehicle. (The transfer of animals from commercial/private carriers to the site-restricted vehicle will occur at the TF.) For the introduction of animals into the laboratory, the site-restricted vehicle will be backed into a docking bay and the outside door will be closed before the animal unloading begins. Once unloaded, all animals will be confined to a holding area while the site-restricted vehicle leaves the docking bay. An air lock system will be used between the docking bay and the BSL-3Ag area. New, uninfected animals will be moved down "clean" corridors of the BSL-3Ag area to reach the assigned AHR. The concept of "clean" corridors and "dirty" corridors is a critically important element of fomite/vector control. Infected animals, wastes, and materials, and persons working with such infected materials, will use only the "dirty" corridors. The current NBAF design (65% Design) allows "clean" or "dirty" access to each AHR.

2.4 Design Enhancements

The SSRA [DHS, 2010] used the 15% Design to provide the site-specific assessment of risk and developed the risks on a relative basis to help inform DHS on investment and design-modification decisions. As a result of these recommendations, and other input including observations from the design team, government reviewers, and the NAS, several critical enhancements to the NBAF design were incorporated into the 35%, 50%, and 65% Design. Of particular value to the Updated SSRA are the modifications to the plans for carcass disposal systems, management of wastewater effluent, potable water supplies, redundant dual-HEPA room exhaust systems, and tornado hardening.

2.4.1 Carcass Disposal

The SSRA recommended that DHS identify a different carcass disposal technology to potentially replace the carcass incineration method (SSRA Recommendation #2). After considerable study and deliberation, DHS and the NBAF Design Partnership Design Team selected another proven carcass disposal technology that addresses the concerns noted in the SSRA. The selected technology (large tissue autoclave) is capable of processing and dehydrating carcasses and other waste materials without some of the integration complications inherent to carcass incinerators. Solid residuals from the large tissue autoclaves are incinerated on site. The identification and incorporation of this technology satisfies SSRA Recommendation #2.

2.4.2 Sewage Retention and On-Site Wastewater Pretreatment

The SSRA recommended that DHS consider adding an on-site sanitary sewage waste retention system to accommodate the accumulation of sewage during a denial of service without causing undue risk to the experiments or the environment (SSRA Recommendation #7). Subsequent developments (e.g., upcoming regulatory requirements and the selection of a different carcass disposal technology) drove the NBAF Design Partnership and DHS to add an on-site wastewater pretreatment facility as described above. Additional storage capacity for disinfected liquid effluent and the addition of this new On-Site Wastewater Pretreatment Facility satisfies SSRA Recommendation #7.

2.4.3 Potable Water

The SSRA recommended that the NBAF have access to emergency potable water supplies to accommodate safe laboratory and containment operations in the event of temporary denial of routine service (SSRA Recommendation #11). DHS and the NBAF Design Partnership have added 60,000 gallons of storage capacity (see rendering in Figure 2.4.3-1), and agreements with the municipality will provide for a 12-hour reserve of potable water.

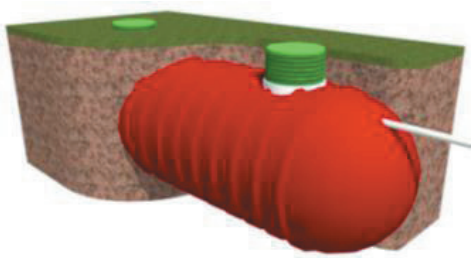


Figure 2.4.3-1. On-site Potable Water Backup Storage

2.4.4 Redundant HEPA Caissons and Autoscan Capability

The NAS Committee that reviewed the SSRA was particularly concerned about the lack of complete redundancy for the dual-HEPA filtration capacity of room exhaust from areas with an elevated risk for pathogen aerosols—specifically the BSL-3Ag AHRs. The NBAF Design Partnership and DHS have addressed this issue by providing full redundancy for animal holding rooms (2N for smaller AHRs and N+1 for larger AHRs), BSL-3E "Special Procedure" rooms, and BSL-4. The addition of a built-in HEPA autoscan capability (Figure 2.4.4-1) will also enhance the safety and reliability of the HEPA filtration systems.

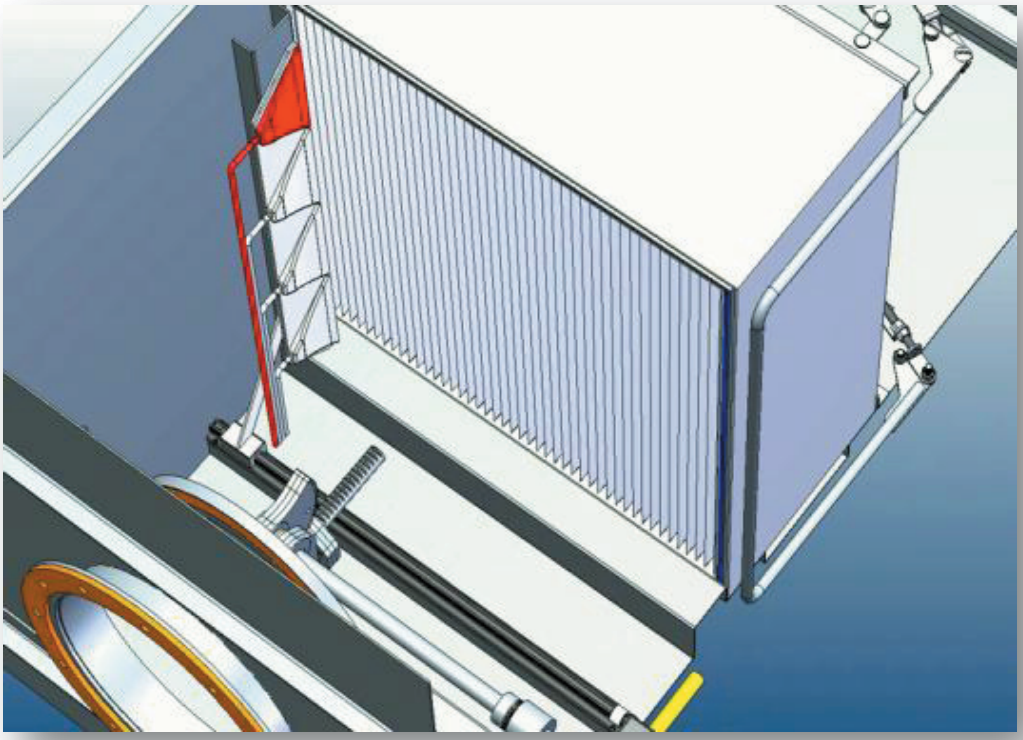


Figure 2.4.4-1: HEPA Autoscan Capability

2.4.5 Tornado Hardening

The SSRA presented two recommendations (SSRA Recommendations #5 and #6) related to enhancing the NBAF's ability to survive a direct strike by a tornado without the loss of pathogens. DHS and the NBAF Design Partnership developed a plan that provides an equivalent level of protection to that required by the Nuclear Regulatory Commission (NRC) for U.S. nuclear power plants, because there are no prevailing standards for biocontainment laboratories. Current design standards for biocontainment facilities, such as the BMBL, do not identify specific requirements for facility hardening for high-wind events. DHS, however, directed the NBAF Design Partnership to establish appropriate design criteria to provide confidence that the facility will maintain containment during and after a credible high-wind event. The NBAF comprises a tornado-hardened zone (Figure 2.4.5-1) that would protect the BSL-3E, BSL-3Ag, and BSL-4 laboratories from loss of containment resulting from a tornado strike. Section 8 of the 65% Design provides full details on the analysis used to establish the new design requirements. Section 5 provides an assessment of credible high-wind events and the potential loss of pathogenic materials resulting from such events.

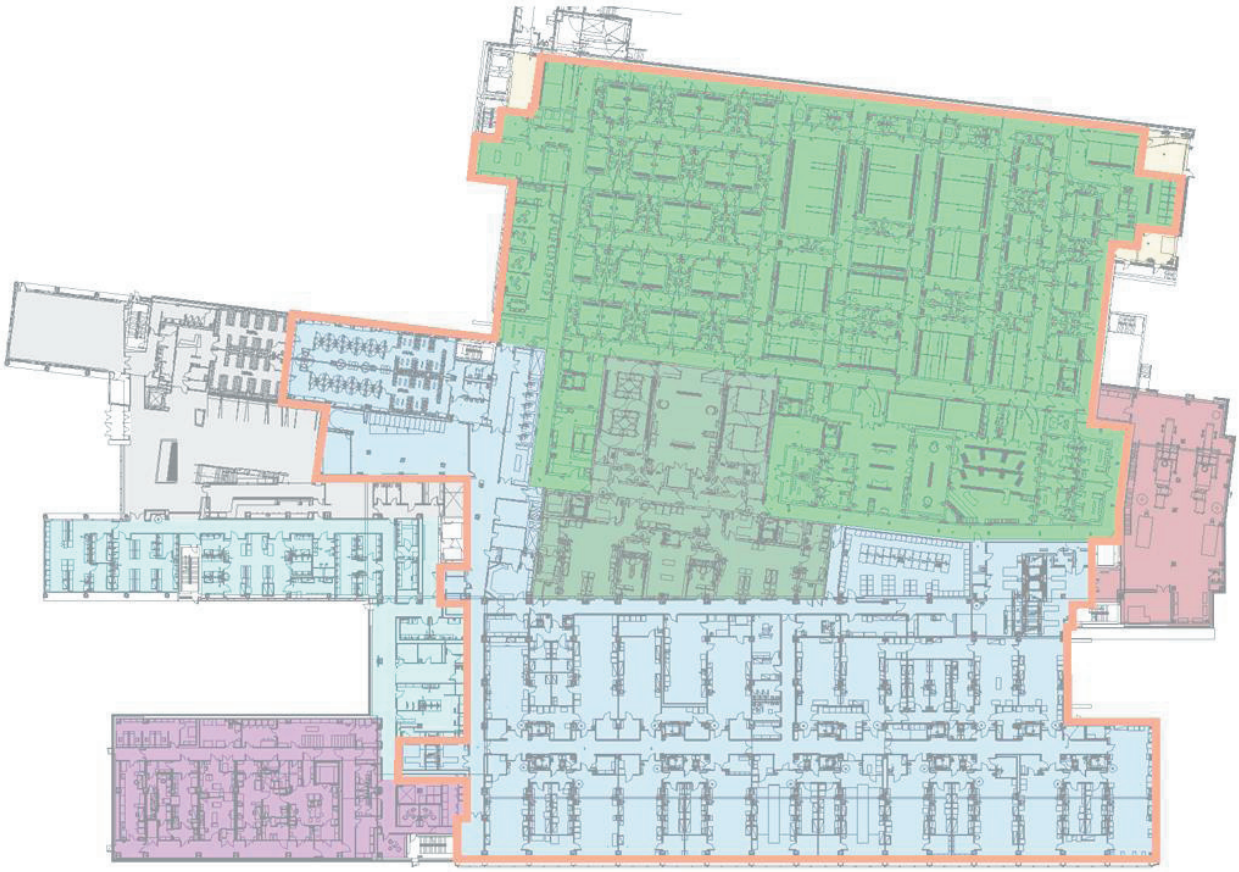


Figure 2.4.5-1: Tornado-Hardened Zone

The current NBAF 65% Design will provide protection against the failure of penetrations and cracking of surfaces for wind speeds up to 228 mph. Integrity of the containment area, delineated with a solid red

line in the section drawing presented as Figure 2.4.5-2, includes protection for airborne missiles (e.g., projectiles and debris) that may accompany high winds. Structural integrity will be provided for the penthouse, interstitial, and basement areas as indicated by the dashed line in this same figure.

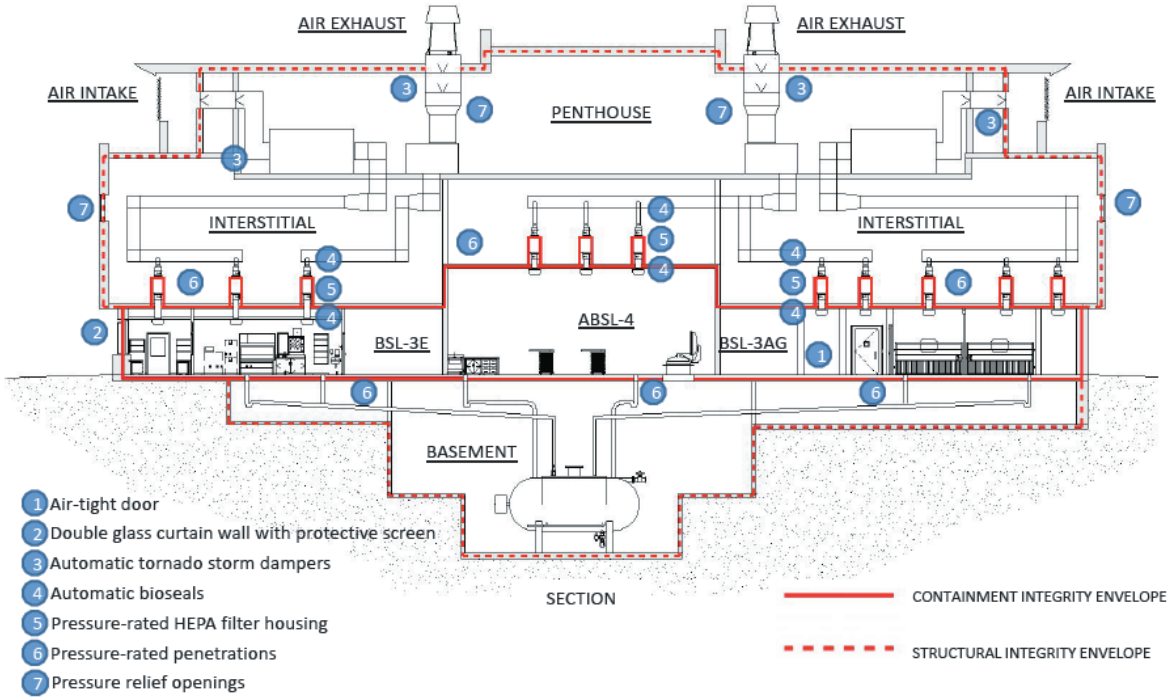


Figure 2.4.5-2: Tornado-Hardened Section

3. Best Practices for Design, Operations, and Response Planning

DHS has demonstrated an interest in developing collaborative relationships with experts and organizations that represent the different professions, disciplines, and specialties needed to design and build safe facilities; safely operate containment laboratories; and develop mitigation and response planning infrastructure for the NBAF. Prominent national and international experts in animal, zoonotic, and human pathogen research have been involved in the facility design process and are being identified to assist with operational and response planning. Furthermore, representatives from the international biocontainment community continue to be consulted during critical phases of facility design. Lessons learned from historical successes and failures in biocontainment have been and will be used in the NBAF development process to help ensure that the necessary research and education conducted in the laboratory are performed in a safe facility using the best available practices.

The objective of DHS is to design, build, commission, operate, maintain, and provide emergency response plans (ERPs) that meet or exceed recommendations and standards such as the Biosafety in Microbiological and Biomedical Laboratories (BMBL, Fifth Edition) [USDHHS/CDCP, 2007], USDA ARS Facilities Design Standards (242.1-ARS) [USDA, 2002], and other relevant international standards. The NBAF 65% Design has been completed and submitted to DHS for review. Reviewers submitted comments on the 65% Design in December 2011. This latest design incorporates recommendations made in the SSRA and additional risk mitigation measures that were specified by DHS. A description of the current design status is presented in Section 2. Since the NBAF will not be operational until 2020, formal operational procedures and final response plans have not been completed. The presumptive baseline operations and response strategies for the NBAF that are being used in the Updated SSRA modeling were developed from reviews of current practices from local, state, federal, and international operational strategies and response plans employed by other high-containment research facilities in the U.S. and abroad.

Meanwhile, the DHS Office of National Laboratories (ONL) is in the process of developing the plans required for the transition of the research, diagnostic, and agricultural countermeasures programs from PIADC to the NBAF. These plans will include details on the schedule and sequence of events that are needed to successfully move equipment, staff, vaccines, and Select Agents (and other biological materials) to the NBAF. The transition will be a complicated process that will require significant detail and proactive management on the part of both DHS and USDA (ARS and APHIS). Laboratory commissioning should begin in 2018 (after laboratory construction is complete) and will precede Select Agent accreditation and mission start-up. Limited Select Agent research is not anticipated to begin until 2020 and full operational capability is not expected until later that same year, or in early 2021.

Section 3.1 describes some of the domestic and international facilities that are involved in research similar to the proposed NBAF research, and provides an overview of lessons learned and best practices from these laboratories. Section 3.2 summarizes future endeavors for the development of operational plans and for the development of the emergency response strategies. These planning needs are currently being addressed by DHS and USDA.

3.1 Lessons Learned and Best Practices

Animal and zoonotic diseases have been researched for many years. Interestingly, a description of an FMD epidemic in Italy was recorded by a monk in 1546 and FMDv was the first virus of vertebrates to be discovered [Mahy, 2005]. As science evolves and globally integrated research efforts advance, many scientists and laboratories throughout the world have engaged in the study of infectious animal and zoonotic diseases. The benefits of such research may be best illustrated by the recent change of status in an animal disease that has been problematic for many years. In May 2011, the World Organisation for Animal Health (OIE) declared that Rinderpest, or "cattle plague," had been eradicated and no longer plagued susceptible species. The Food and Agriculture Organization (FAO) of the United Nations declared global freedom from Rinderpest in June 2011 and noted that this contributor to human famines had been successfully eliminated. Such success is the direct result of animal disease research and a clear indication of its value.

FMD outbreaks are still relatively frequent events in many parts of the world. During the first half of 2011, the OIE reports that more than 39 countries have clinical FMD in domestic species. It is apparent that continued FMD research is required to help prevent its re-introduction to the United States and other countries that are currently free of the disease. Existing facilities (and new facilities) that are able to accommodate FMDv studies will have to continue research to provide solutions to pressing problems from many diseases, including FMD. Because of successful biocontainment, very few FMD outbreaks have been attributed to laboratory accidents. However, as discussed in Section 3.1.1, research facility accidents have provided valuable lessons in engineering, operations, and response practices that are important to the success of the NBAF. The most recent FMD outbreak that was attributed to a laboratory facility occurred in Surrey, United Kingdom, in 2007.

As a result of this incident, it was necessary to cull 2,160 animals on less than ten farms. In contrast, a 2001 non-laboratory origin outbreak resulted in the destruction of approximately six million animals in the United Kingdom [IAH, 2008]. A review of the 2007 incident and other documented FMDv laboratory accidents is provided in Section 3.1.1. During the performance of the SSRA and the Updated SSRA, the Pirbright containment facility in Surrey, United Kingdom, and other containment facilities were visited to collect information on best biocontainment engineering, practices, and response that DHS and USDA may apply to the NBAF. A high-level summary of the relevant best practices data from these visits is presented in Section 3.1.2. FMD-related best practices gleaned from these visits and interviews are summarized in Section 3.1.3. Section 3.1.4 presents best practice information associated with emergency response and contingency planning.

3.1.1 Laboratory Accidents

3.1.1.1 Surrey, United Kingdom

The 2007 FMD outbreak in Surrey, United Kingdom, was assessed by the United Kingdom Health and Safety Executive (HSE) and it was determined that it is "highly likely" that the virus strain originated from Pirbright (a multi-occupant facility including an FMDv vaccine production laboratory) [HSE, 2007]. Small differences in the sequenced nucleotides from the three tenants of Pirbright and the strains involved in the outbreak made it unlikely that the exact origin of the virus could be determined. In its report, the HSE assessed the possible routes for virus to escape containment, including solid waste disposal, aerosols, liquid waste disposal, and human movements (transference)—the same mechanisms studied in the Updated SSRA. No evidence of a solid waste failure or airborne release was identified by HSE during the investigation.

Two of the Pirbright tenants, the Institute of Animal Health (IAH) and Stabilitech Ltd., work with only small amounts of viable FMDv. The laboratory liquid waste from these sources is subject to a chemical inactivation process (performed at the point of discharge) that is followed by a final treatment (performed in a different building) before the effluent is discharged into the public sewer. Since the chemical inactivation is not complete and small quantities of viable material (including liquid effluent from personnel showers in the changing areas) may have been released from the primary laboratory locations, it was determined that small quantities of live virus from these sources may have entered the on-site drainage system that collected partially-treated liquid effluent for the final treatment system.

The third Pirbright tenant, Merial Animal Health Ltd., was involved in large-scale (volumes up to five liters in the laboratory facility and 6,000 liters in the production facility) FMD vaccine production during the time period preceding the index cases of the outbreak [HSE, 2007]. HSE determined that live FMDv (Type O1 BFS) was flushed into the Merial effluent sump and then passed to the on-site drainage system—part of the same system used by IAH and Stabilitech.

The on-site drainage system was an old underground system that provided liquid effluent conveyance between the laboratories and the final treatment system. Indications of long-term damage and leakage from the on-site system were found and included cracked pipes, unsealed manholes, and root infiltrations. The damaged on-site drainage system, exacerbated by significant precipitation events, was potentially a contributing factor to on-site surface soil contamination.

Human movements (and the movement of fomites) were also likely components of the outbreak. Reportedly, vehicles involved in construction at the site repeatedly drove over segments of the underground on-site drainage system. HSE reports that mud containing viable FMDv might have contaminated the tires and undercarriages of these vehicles. It was established that some of the vehicles drove on a road that passed by the first infected (index) farm. However, the final method of transfer and infection (contamination from the vehicles to the susceptible animals) is not known.

It is the intent of the Updated SSRA to identify the potential causes of such containment losses and ensure that the NBAF design incorporates "lessons learned" from these experiences. The new facilities at Pirbright incorporate many lessons learned in its modern biocontainment design and the staff is well-

trained and cognizant of risk mitigation techniques incorporated in protocols and procedures. At the NBAF, no large-scale production with viable FMDv will be performed, and all liquid effluent disinfection processes will be performed within the laboratory building. Also, personnel shower drainage is collected and treated in the NBAF EDS so that partially-contaminated waste is not conveyed outside of containment. Vehicular traffic is limited to NBAF-owned vehicles that are restricted to on-site movements. NBAF site grading and stormwater runoff are also intended to minimize the potential of pooling and flooding events. NBAF SOPs will include predictive and routine maintenance practices that will minimize the likelihood of liquid effluent system failures. Thus, best practices gleaned from the 2007 outbreak in Surrey, United Kingdom, are inculcated in the NBAF 65% Design.

3.1.1.2 Plum Island, New York

At the PIADC in 1978, cattle in two pens (in Building 62) were unexpectedly infected with FMDv (Type O1) from another building (Building 101). A USDA Safety Investigation Committee reviewed the incident to determine how virus from the laboratory building infected cattle in the separate building [Plum Island Safety Committee, 1979]. The Safety Investigation Committee concluded that the sources of containment loss from Building 101 were:

1) Faulty air balance of the incinerator area:

Airflow reversals from the incinerator corridor to another corridor were reported by the Committee as “a problem”. Contemporaneous smoke tests revealed that unfiltered air was escaping from the incinerator area to outside the building on a nearly continuous basis [Plum Island Safety Committee, 1979]. The Committee also determined that a safety interlock was improperly installed resulting in frequent over-pressurization of the incinerator charging room.

2) Leakage through inadequately maintained air filter and ventilation systems:

It was noted by the Committee that the exhaust air filtration systems in Building 101 “were of acceptable design at the time of construction…but would not be considered acceptable…using today’s standards.” The air filters and gaskets had deteriorated and were reportedly not effective. The maintenance program did not include gasket replacement requirements and routine maintenance was not performed as intended.

3) Seepage of water under or through a construction barrier at the west end of the incinerator corridor:

The Committee identified construction activities that may have contributed to the incident. A “temporary plywood partition had been built across the west end of the incinerator corridor so, after appropriate decontamination, the masonry wall at the end of the corridor could be removed” [Plum Island Safety Committee, 1979]. The report indicates that there was no evidence that contaminated air flowed past the partition to the environment but that “water was able to seep under the barrier to the inside and presumably out again.”

The Committee cited “mismanagement of Engineering and Plant Management operations” that resulted in the above-mentioned circumstances leading to the escape of virus from containment. Cited examples

of mismanagement were related to failures in preventative maintenance programs, communications (including failure to notify the Safety Office of conditions that might affect agent containment), training, and standard operating procedures. The Committee also concluded that the most probable means for transport of the virus from the Building 101 area to Building 62 was by contaminated personnel. This contamination most likely occurred during "delivery of animals directly to the airlocks at the laboratory Building 101." The Committee indicated that no virus was detected in over 200 samples taken during the incident investigation from areas in and around Building 101, including samples from exhaust filters and sewage treatment lagoons. The Committee also concluded that the pattern of disease observed in the infected animals was not consistent with aerosol contamination. After this incident, protocols were changed, and animals are no longer held outside PIADC.

The 65% NBAF Design and planned practices incorporate biocontainment practices derived from the lessons learned. For example, the NBAF incorporates incineration technology for solid waste disposal, but the incinerators do not connect a containment area to a non-containment area. Additionally, advanced building automation systems and numerous redundancies, coupled with thorough testing during commissioning (and during operations), minimize the potential of airflow reversals. Contemporary HEPA filtration media and advanced gasket materials have a longer life (than older generations of gaskets) and are combined with periodic testing and redundant continuous monitoring to minimize the risks associated with loss of FMDv through air filtration systems. The NBAF design and planned practices dictate that no personnel will be exposed to viable FMDv without 1) being in a designated containment area and 2) following appropriate decontamination procedures. Furthermore, any construction or remodeling of containment spaces after commissioning will require careful planning and conformance to well defined SOPs to reduce the opportunity for accidental releases associated with disrupted procedures, traffic patterns and personnel movements associated with any construction project.

Other FMDv-related incidents that have transpired at PIADC are summarized in Table 3.1.1-1 [GAO, 2008]. These incidents did not result in infections outside of PIADC. Information from causality assessments contributes to the field of biocontainment knowledge and has been incorporated into the NBAF design and planned practices.

Date	Incident	Assigned Cause	PIADC and NBAF Mitigations
September 1971	Unexpected infection of two steers.	Leaking door gasket.	Improved door seals, directional airflow, flow reversal prevention design.
April 1974	Unexpected infection of two steers.	Wall leaks or power failure causing flow reversal.	High-performance wall coatings make walls leakproof. Designed penetrations sealed and tested regularly. Uninterruptable power supplies and redundant monitoring and air handling equipment minimize the

Table 3.1.1 1: Other PIADC Incidents			
Date	**Incident**	**Assigned Cause**	**PIADC and NBAF Mitigations**
			potential for flow reversals.
August 1980	18 steers had antibodies for Type O and Type C but were not vaccinated with Type O.	None assigned.	Quality assurance, SOPs, and advanced diagnostics and analytical capabilities will minimize such accidents.
February 1981	Four steers vaccinated with Type O but infected with Type A.	None assigned.	Quality assurance, SOPs, and advanced diagnostics and analytical capabilities will minimize such accidents.
May 1987	One heifer infected with Type O with no known exposure. Type O used in two nearby rooms.	Carcass fluids or aerosolized virus from movement of infected carcasses along hallway.	Animals euthanized in necropsy. Improved door seals and air management systems.
June July 2004	Two cattle infected with Type O with no known exposure. Four pigs also infected with a different strain of Type O with no intentional exposure.	No specific cause assigned.	New protocols and training, in addition to enhanced PPE and hygiene practices for workers.

3.1.1.3 Winnipeg, Manitoba, Canada

The Public Health Agency of Canada (PHAC) and the National Centre for Foreign Animal Diseases (NCFAD) Canadian Science Centre for Human and Animal Health (CSCHAH) in Winnipeg, Manitoba, provide outstanding examples of public outreach and cooperation for biocontainment facilities. The best practices developed and implemented by the agency were motivated by public reaction to an event that occurred during commissioning in 1999. A significant quantity of untreated effluent from the laboratory's wastewater system was accidentally emptied into a blending tank. The effluent was then released into the city's sanitary sewer system. In the Winnipeg facility, effluent from the laboratories is normally treated in one of three isolated 5,000-liter containment tanks prior to discharge from the facility. The accidental release occurred when a staff member mistakenly opened a valve that bypassed treatment systems. Subsequent engineering and protocol changes were implemented to prevent a recurrence of this event. While it was determined that no infectious disease resulted from the release (note: FMDv was not involved), the lessons learned from this incident have provided benefit to containment laboratories (including the NBAF). At the NBAF, unused drains are blocked and unblocked drains can only flow into the effluent decontamination system. The NBAF valving controls incorporate redundancies, monitoring systems, interlocks, and alarms that minimize the potential for a release of untreated liquid waste. One of the most significant lessons learned, however, is from the public outreach and communications strategies developed and implemented after this incident. DHS has planned similar communication and outreach practices for the NBAF.

3.1.2 Collection of Other Operational Best Practices Information

Suggestions and recommendations for design, construction, operation, and response have been developed and incorporated into the NBAF plans after site visits and discussions with staff from the following facilities, all of which perform FAD research on large animals:

- CSCHAH, Winnipeg, Manitoba, Canada;
- Institute of Animal Health (IAH), Pirbright, Surrey, United Kingdom;
- PIADC, Plum Island, New York, U.S.;
- BRI, Manhattan, Kansas, U.S.; and
- The National Veterinary Institute of the Technical University of Denmark (DTU Vet), Copenhagen, Denmark.

Similar information was collected from the Australian Animal Health Laboratory (AAHL), Geelong, Victoria, Australia, but no site visit was made. The AAHL and the CSCHAH have additional BSL-4 capacity for FAD and zoonotic research programs and provided key information regarding establishment of a BSL-4 large animal laboratory facility, including construction, design and operational philosophies (see Section 9). At each domestic or international site visit (or interview), the following details were discussed:

- Research programs and priorities;
- Air handling and waste treatment processes;
    - Air handling
    - Liquid waste treatment
    - Solid waste treatment
    - Carcass disposal
- Space allocation;
    - Flexibility
    - Ratio of containment to non-containment laboratory areas
- Physical security;
- Construction;
    - Pre-operational plans
        - Commissioning process
        - “Cold” period to test systems and processes
        - Computational fluid dynamics modeling
    - Renovation and repair issues
- Personnel;
    - Training programs
    - Occupational health programs

  - Personnel reliability and clearance programs
  - Recruitment and retention of qualified staff

- Utilities supply;
- Operational budgets;
- Development of facility-specific SOPs;
- Biosafety and biosecurity programs;
- Community education and outreach;
- Occupational health;
  - Immunization program
  - Serological testing
  - Local medical capacity/capability
  - Identification cards
- Diagnostic laboratories for the detection of animal diseases; and
- Training programs for veterinarians and scientists to detect animal diseases.

The facilities visited were located in various climates and encompassed both urban and rural settings. All of the facilities had large animal research capabilities with at least BSL-3 containment space. Of the sites visited, only the CSCHAH had BSL-4 facilities (<4% of the laboratory space is BSL-4); however, other international laboratories do have this capability (e.g., AAHL in Geelong, Victoria, Australia). A comparison of the facilities visited is summarized in Table 3.1.2-1.

As indicated in Table 3.1.2-1, the overall mission and containment measures of the NBAF are very similar to facilities operating elsewhere across the globe with a few notable exceptions, and these exceptions reflect new or expanded capabilities to be included in the NBAF. The NBAF is significantly larger than the other laboratory facilities because it is designed with an animal holding capacity sufficient for performing vaccine studies with livestock. These types of studies, if they are to be conducted with meaningful statistical rigor, must use sufficiently large study groups (i.e., animal count). Therefore, the facility must accommodate multiple study group configurations and many animals to provide flexibility and to optimize testing of new vaccines and other countermeasures.

Table 3.1.2 1: Facility/Design Comparison (2010/11)					
Site	**Canadian Science Centre for Human and Animal Health (CSCHAH), Winnipeg, Manitoba, Canada**	**Institute for Animal Health (IAH), Pirbright, Surrey, United Kingdom**	**Plum Island Animal Disease Center (PIADC), Plum Island, New York, U.S.**	**Biosecurity Research Institute (BRI), Manhattan, Kansas, U.S.**	**National Bio and Agro Defense Facility (NBAF), Manhattan, Kansas, U.S.**
Operational Start Date	1999	1924	1954	2008	Expected in 2020
Facility Location	Urban	Suburban/Rural	Island	Suburban/Rural	Suburban/Rural
Number of employees	400-500	380-400	250-300	50-100	> 300
Research Programs	Foreign Animal Diseases	Foreign Animal Diseases	Foreign Animal Diseases	Foreign Animal Diseases	Planned Foreign Animal Diseases
	FMDv	FMDv	FMDv	No FMDv	Planned FMDv
	Zoonotic diseases	No zoonotic diseases	No high-consequence zoonotic diseases	Zoonotic diseases (approval pending)	Planned zoonotic diseases
Animal Exclusion Zone	No	No	FMD susceptible wildlife rare on the island	No	No
Sentinel Animals	None	None	None	None	None Planned
Proximity of Livestock or Wildlife	Urban environment with no susceptible animals immediately adjacent to facility	Suburban/Rural facility with both susceptible livestock and wildlife near the facility	Susceptible wildlife rarely immediately near the facility	Suburban/rural environment with susceptible university research animals near the facility	Suburban/rural environment with susceptible university research animals near the facility
Education Programs and Foreign Animal Disease Training	Foreign Animal Disease Training	Foreign Animal Disease Training	Foreign Animal Disease Training	Biosafety and Laboratory Training	Foreign Animal Disease Training
Sewage Treatment	Batch system with cookers within the facility with release to public system	Batch system in an adjacent facility with release to public system	Semi-continuous system in adjacent treatment facility	Batch system with cookers within the facility with release to public system	Batch system with cookers within the facility and on-site wastewater pretreatment (and emergency storage) prior to release to public system

Table 3.1.2 1: Facility/Design Comparison (2010/11)					
Site	**Canadian Science Centre for Human and Animal Health (CSCHAH), Winnipeg, Manitoba, Canada**	**Institute for Animal Health (IAH), Pirbright, Surrey, United Kingdom**	**Plum Island Animal Disease Center (PIADC), Plum Island, New York, U.S.**	**Biosecurity Research Institute (BRI), Manhattan, Kansas, U.S.**	**National Bio and Agro Defense Facility (NBAF), Manhattan, Kansas, U.S.**
Air Handling	Single high efficiency particulate air (HEPA) supply and double HEPA exhaust	Single HEPA supply and double HEPA exhaust	Single HEPA supply and HEPA exhaust in older labs. Double HEPA exhaust in newer labs.	Single HEPA supply and double HEPA exhaust	Redundant single HEPA supply and redundant double HEPA exhaust for BSL-3 Ag, BSL-3E Special Procedure, and BSL-4 labs; Single HEPA supply and single HEPA exhaust for general BSL-3E.
Carcass Disposal	Renderer: Carcasses have to be cut into 50 lb. sections	Incinerator	Incinerator	Digester: Solid bone material to landfill and liquid waste treated as liquid effluent	Tissue autoclaves with agitation and optional caustic additives. Solid residuals incinerated.
Solid Waste	Double autoclave out	Double autoclave out, then incinerated offsite with point-to-point transfer	Double autoclave out, then incinerated offsite with point-to-point transfer	Autoclave out	Double autoclave out and on-site incinerator
Prohibitions on animal contact after leaving lab	5 day exclusion period; employees cannot keep susceptible animals at home	5 day exclusion period; employees cannot keep susceptible animals at home	5 day exclusion period; employees cannot keep susceptible animals at home	5-day exclusion period; employees cannot own susceptible animals	Presumptively, a 5-day exclusion period; employees cannot own susceptible animals
Community Outreach Programs	Extensive programs with Community Liaison Committee, media engagement, and education programs that are the model for the other facilities	Community outreach is growing due to new construction projects and community interest	Community outreach is increasing, but isolation makes site visits difficult	Strong community outreach program including facility tours	Community outreach implemented during 3-year site selection and EIS development, continuing with design/construction and into operations.

Table 3.1.2 1: Facility/Design Comparison (2010/11)					
Site	**Canadian Science Centre for Human and Animal Health (CSCHAH), Winnipeg, Manitoba, Canada**	**Institute for Animal Health (IAH), Pirbright, Surrey, United Kingdom**	**Plum Island Animal Disease Center (PIADC), Plum Island, New York, U.S.**	**Biosecurity Research Institute (BRI), Manhattan, Kansas, U.S.**	**National Bio and Agro Defense Facility (NBAF), Manhattan, Kansas, U.S.**
Break/Dining Room in Containment	Yes	Yes, but in separate building within the multi-building "containment zone" (existing facility)	Yes	No	Yes
Annual Operational Budget in U.S. Dollars	$9.5 million	$6 million	$35 million	$5 million	To be determined
Facility Associated External Release	No	Yes, FMDv in 2007 and 1960	Yes, FMDv in 1978, but limited to laboratory campus	No	Not applicable
Natural Disaster Threats	Cold weather extremes, winds	Inclement weather	Hurricanes, inclement weather	Tornados, Inclement weather	Tornados, inclement weather

With regard to space utilization at the NBAF and other similar facilities, only a fraction of the total space is dedicated to high-containment laboratories (BSL-3 and above). It is typical for the amount of space dedicated to research to be less than one-third of the total facility due to the space requirements for the mechanical and electrical systems, laboratory support, and common areas. For example, the air handling and liquid effluent treatment systems are usually located on the floor above and below the containment area, respectively.

The allotment of high-containment space for the NBAF is approximately the same as that observed in other facilities. The NBAF also includes a Biotechnology Development Module (BDM) that can operate under cGMP to produce animal vaccine seed stocks. However, no pathogenic FMDv will be produced in the BDM at the NBAF.

All high-containment laboratory facilities use air handling systems to develop directional airflow. The NBAF design fully incorporates recommendations for redundant double HEPA filtration of room exhaust air in containment areas with a higher risk of infectious aerosols, as described in the BMBL 5th Edition [USDHHS/CDCP, 2007]. These systems limit the accidental release of pathogens by providing pressure gradients between areas with different levels of expected aerosol loading. All exhaust air from the NBAF containment areas passes through at least one HEPA filter, and many areas (BSL-3E "Special Procedure," BSL-3Ag, and BSL-4—see Section 2) incorporate redundant double HEPA filtration as mentioned above. The NBAF (and other biocontainment facilities) also use HEPA filtration on supply air. Each facility uses a slightly different design to control and filter air supplies, but the overall concepts are the same—negative pressure cascades with HEPA-filtration of supply and exhaust air.

The liquid waste handling systems are comparable between the various biocontainment facilities. The NBAF will use a similar batch-processing system with redundant liquid effluent cookers—a widely used and accepted practice within high-containment laboratories. The NBAF will also have an on-site wastewater pretreatment system to de-water the waste and manage odors.

The carcass disposal systems used at biocontainment facilities vary, but all of the observed system technologies have demonstrated success in high-containment laboratories and are able to inactivate a wide range of pathogens (including bacteria, bacterial endospores, viruses, and fungi). The three major carcass disposal systems observed included incineration, alkaline digestion, and rendering. Incineration systems use a staged burning process to inactivate infectious material using direct heat. Alkaline digestion is a chemical process performed at a high pH, under heat, and pressure that degrades animal material, including the pathogens, into amino acids and other degraded components [NABC, 2004]. Effluent from an alkaline digestion system usually requires downstream processing to neutralize the high pH before it can be released into a public wastewater system. Rendering uses high heat to degrade animal products, including infectious materials, into solids, fat, and water [NABC, 2004]. Each method provides different benefits and drawbacks, so facilities use the system best suited for their applications and local and federal regulations (e.g., some locations are under strict air quality rules that limit the use of incineration systems). NBAF will use tissue autoclaves, as described in Section 2, which treat the

waste with high temperature and high pressure. In addition, after being autoclaved and removed from containment, the autoclaved tissue waste will be incinerated on site.

The AAHL in Geelong, Australia enforces an animal exclusion zone to restrict the presence of certain susceptible animals within a defined perimeter around the laboratory. However, none of the facilities visited enforced animal exclusion zones, and few other labs take such rigid measures. Both the BRI and the IAH have susceptible animals in the vicinity. The NBAF will not have an animal exclusion zone.

All of the facilities use some form of personnel reliability programs and screen potential employees before allowing workers to access containment areas. Other security measures include cameras to monitor Select Agent storage areas and/or central key locations, and the use of keycards or personal identification number codes to restrict access to certain areas of the laboratory and to track employee movements. Another method reported is the development of a modern pathogen inventory tracking system to monitor the location and use of certain pathogens. Systems are also in place to allow staff to report unusual or high-risk activities to management. The NBAF will incorporate similar programs and practices.

All facilities use biosafety, biosecurity, and operations training programs that include required periodic refresher training. Employees at most facilities are also encouraged to report “near misses,” in which an accident or incident, if not averted, would have led to bodily harm or the loss of containment. These incidents and resulting mitigation strategies are incorporated into facility training programs to highlight risk and reduce the likelihood of future occurrences. The NBAF will have similar biosafety, biosecurity, and operations training programs and reporting practices. In addition, the NBAF will have areas designed specifically to better accommodate the Foreign Animal Disease Diagnostician (FADD) training mission that also can be shared to maximize space utilization.

A topic of great interest discussed during site visits and interviews was the use of respiratory protection by staff while working with FMDv-infected animals. While the virus does not readily infect humans and is not considered zoonotic, there is concern that infectious material may be physically transported in the nasal passages or the upper respiratory tract of a human, thus providing a potential source of infection (via “transference” or human vector) if the individual comes into contact with a susceptible animal after leaving the facility. During laboratory site visits, biosafety staff members were asked to elaborate on how the facility addresses this issue. The general response from those interviewed was that the increased risks of donning respiratory protection outweigh the risk of spreading the disease (e.g., FMD), in that the respiratory protection device potentially limits the user’s field of vision and ability to communicate effectively, and causes other physical hindrances that could increase the risk of bodily harm to staff while handling large animals. When assessing this response, it should be noted that the “risk” identified by the interviewed individuals is relative to worker health and safety and does not include an assessment of the risk presented by an outbreak caused by a laboratory worker.

One study has indicated that after investigators (involved in the study experiment) worked with FMDv-inoculated pigs for approximately 40 minutes; no FMDv was detected in their nasal swabs that were periodically collected up to 85.43 hours after interaction with the infected animals [Amass et al., 2004]. Nonetheless, NBAF current plans include a respiratory protection strategy that requires personnel to use respiratory protection when potentially exposed to FMDv aerosols.

Beyond design, construction, and operational issues, two other topics that were strongly emphasized during the site visits were: 1) the hiring and retention of a skilled workforce, and 2) the importance of dynamic community engagement and outreach programs. Several site visit sources suggested that the key to a properly functioning facility is the staff that operates it, emphasizing that personnel represent the first line in protecting the facility and maintaining containment. As a result, it was recommended that great attention and consideration be given to the staffing plan. At the facilities visited, the key engineering and biosafety personnel were hired during the construction phase to encourage the development of an intimate level of knowledge on key systems of the facility. It was recommended by several sources to develop a system that engages and encourages a responsible and reliable staff. All of this information will be considered when recruiting and hiring staff at the NBAF.

DHS has recognized the need to engage in an active stakeholder outreach effort and has developed a plan (with USDA) to reach out to the community. For community outreach, the CSCHAH in Winnipeg, Manitoba, has developed an extensive community outreach and engagement

Suggested FMD Best Practices

- Staff will undergo a background investigation for reliability and security.
- Animal handlers will have a specified minimum level of education, training, and experience as requirements for the position.
- Staff will receive periodic, routine medical examinations to ensure their ability to work with large animals safely.
- All staff working with or near FMDv or infected animals will receive ongoing training on operations, relevant SOPs, and biosafety. This training must be periodically reviewed and updated as new procedures are developed or modified.
- Animal holding areas will be limited to staff that have access requirements.
- Staff must change into dedicated clothing before entering animal holding or containment laboratories.
- Staff must shower and change back into clean clothes after leaving animal holding or containment areas, and blow their nose before showering.
- Loading dock staff must don dedicated clothing and thoroughly clean the area after every animal shipment.
- Staff and visitors will avoid contact with susceptible animal species for at least five days after leaving the containment area. Staff will be restricted from owning susceptible animals.
- All materials leaving the high containment area will be appropriately inactivated using validated procedures or removed according to prescribed SOPs and properly packaged.
- All infectious samples will be opened and manipulated only in a biological safety cabinet.
- Animal area cleaning will flow from cleanest to dirtiest areas.
- Animal handler staff rotations will be developed that limit entry into uninfected animal areas after working in areas with ongoing FMD research.

program that others have used as a model (e.g., Galveston National Laboratory (GNL), Galveston, Texas). The core strength of the CSCHAH program is active participation and collaborative input from the community. For example, the CSCHAH and the GNL have Community Liaison Committees comprised of local stakeholders. CSCHAH also hosted multiple open houses and tours before the facility was fully operational. These open house events were targeted at special stakeholder populations, including the media, and were used to attract and recruit potential employees. Similarly, the director at the BRI in Manhattan, Kansas, has developed strong community relations by providing tours of the BRI (to both its supporters and opponents) to demonstrate laboratory operations and the control measures used to protect the staff, the community, and the environment. PIADC has also been active in its community by hosting community forums, family days, and public meetings. The NBAF, while still in the design stage, has hired a local (Manhattan, Kansas-area) contractor with experience in community engagement and outreach. It is clear that a policy of active engagement of concerned groups and citizens is critical to success, and DHS and USDA have committed to such efforts for the NBAF.

A lack of understanding of risk within a community can damage community trust. It was recommended by multiple sources that any communication strategy developed for the NBAF should provide a level of understanding of the risk, even if the actual risk is low. In the rare cases where incidents do happen, the CSCHAH has developed an incident reporting system composed of a tiered communication strategy that reports incidents to various stakeholders based upon a risk analysis. The more serious the incident and the potential risk, the more high-level official positions outside the facility and media are contacted. Similar community outreach and communication strategies will be implemented at the NBAF.

3.1.3 FMD-Related Operational Best Practices

Several FMD-specific precautions and practices were generally recommended by all facility staff interviewed that work with FMDv. These practices include personnel management, training, and SOPs. Safety and security precautions are only reliable if all staff know and understand the associated risks when working with the virus.

The current standard precautions of showering after leaving infected animal rooms, and restricting susceptible animal interactions for employees, contractors, and visitors after leaving the facility, limit the overall risk considerably. Ultimately, NBAF operational planning will advise the operation(s) and protocols for handling FMD-infected animals, and develop tailored solutions that protect the animal care workers, the animals themselves, and the outside environment.

A summary of the best practices associated with working with FMDv as compiled from the various interviews and literature review conducted as part of the SSRA and Updated SSRA is included in this section. DHS has indicated that these best practices will be incorporated into the NBAF facility operating plans and procedures.

3.1.4 Collection of Emergency Response Best Practices Information

Information regarding existing Emergency and Contingency Plans was collected either through personal interviews or telephone discussions with representatives from state/county/local agencies (including medical facilities), K-State, local and national USDA-APHIS officials, state animal health officials, the Kansas Livestock Association, and federal resources. The purpose of this data collection was to:

- Identify and evaluate current animal or human health plans and response capability at the state, local, and regional/national levels;
- Determine what additional steps or actions may be required for the inclusion of the NBAF operations in those plans; and
- Provide recommendations to address those additional steps or actions as part of the ongoing NBAF planning process.

Also documented were any concerns or issues the participants voiced regarding either the construction of the BRI or its presence in the community. In addition, the documents listed in Table 3.1.4-1 were reviewed and considered while completing this assessment.

Table 3.1.4 1: Additional Resources Reviewed During Assessment

NUREG 0654, FEMA Rep 1 Rev 1 Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants	United Kingdom, Department of Environment, Food and Rural Affairs (DEFRA), Contingency Plan for Exotic Diseases of Animals, Version 4, 2009
Animal Stop Movement Order Functional and Full Scale Exercise Report, October 2009; After Action Report and Improvement Plan, December 2009	State of Kansas - Nuclear Facilities Incidents Response Plan (to ESF #10 of the Kansas Response Plan)
Kansas Department of Health and Environment Crisis/Emergency Risk Communications Plan (draft, 2008)	APHIS – Foot and Mouth Disease (FMD) Preparedness and Response Plan (PReP) (Now the USDA APHIS FAD PReP FMD Response Plan: The Red Book (draft September 2011))
Germs, Viruses and Secrets: Government Plans to Move Exotic Disease Research to the Mainland U.S. (Congressional Hearing compilation prepared by the Naval Postgraduate School Center for Homeland Defense and Security)	APHIS PReP Appendix B3 – Surveillance (draft, 2008) (Now the USDA APHIS FAD PReP FMD Surveillance SOP (draft, August 2011)).
Kansas Animal Health Department County Foreign Animal Disease Standard Operating Guidelines	APHIS PReP Appendix B4 - Diagnostic Sample Testing, Surge Capacity and Testing (draft, October 2008)
Kansas County Foreign Animal Disease Annex for County Emergency Operations Plans (EOPs)	APHIS PReP Appendix B10 - Quarantine and Movement Control: Continuity of Business Planning and in Control Zones (draft, October 2008)

Table 3.1.4 1: Additional Resources Reviewed During Assessment	
Foot and Mouth Review 2007 Summary and Recommendations The Story of the Outbreak	APHIS PReP Appendix B11 - Depopulation and Euthanasia (draft, October 2008)
Kansas Incident Specific Plan for Foreign Animal Disease, 2008	APHIS PReP Appendix B12 – Disposal (draft, October 2008)
Australian Veterinary Emergency Plan (AUSVETPLAN)	APHIS PReP Appendix B14 - Vaccination (draft, October 2008)
Kansas Animal Health Department Foreign Animal Disease Annex	APHIS PReP Appendix B15 - Wildlife Management (draft, October 2008)
Kansas Hazard Mitigation Plan, 2007 Agricultural Infestation Plan	APHIS PReP Appendix B19 - EMRS and Information Management (draft, October 2008)
Homeland Security Act of 2002	Federal, State and Local Actions, Timelines and Responsibilities for Responding to FMD Outbreaks (draft, October 2008)
Animal Health Protection Act	National Response Framework

Note

The most current FMD response planning information developed by APHIS and state and industry partners can be found on the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) website (https://fadprep.lmi.org/default.aspx). First time users need to request access as instructed on the page. Within the FAD PReP site, the following pages are most applicable:

https://fadprep.lmi.org/Design/docstructure.aspx

https://fadprep.lmi.org/Design/diseaseresplans.aspx

https://fadprep.lmi.org/Design/FMD.aspx

Review of the Australian Veterinary Emergency Plan (AUSVETPLAN) [AUSVETPLAN, 2006] and the United Kingdom Contingency Plan for Exotic Diseases of Animals [DEFRA, 2009] provided particularly valuable guidance on methods used to identify an FMD outbreak and strategies to reduce the spread and impact, including depopulation with reduced social, psychological, and environmental effects. Although not a planning document, information on the release associated with the IAH laboratory in Pirbright, United Kingdom, discussed in the Foot and Mouth Review 2007 [Anderson, 2008] provided valuable insight into factors contributing to a release; from this insight potential planning concepts were incorporated into the SSRA and the Updated SSRA recommendations.

Interviews indicated that the state and local emergency management agencies in Kansas have significant emergency preparedness strengths, as well as identified gaps, in their ability to maintain an appropriate capability to respond to or recover from an accidental release from the NBAF. In addition to considering local and regional planning, DHS has prepared the “Draft Plan for Preparing the NBAF Emergency

Response Plan" (see Appendix A3), which describes the steps necessary to implement a robust response in the event of an incident.

There are many interdependencies which will require considerable preparedness integration throughout the lifetime of the NBAF. The state and local NBAF-specific planning is currently limited because the NBAF will not be operational until 2020, but the appropriate local jurisdictions and organizations appear to have a long history of cooperation and effective communication in developing and revising response plans. This strong collaborative emergency management practice will enable efficient completion of the off-site NBAF emergency preparedness planning task once the detailed NBAF information required for its completion has been generated and communicated. The state and local emergency planning community also considers K-State to be a strong partner that is highly regarded for its integrated planning efforts involving the BRI, a BSL-3 and BSL-3Ag animal research facility situated on its Manhattan, Kansas, campus. The consolidation of law enforcement functions and local public safety organizations of the city and county jurisdictions around K-State and the NBAF site (e.g., Riley County Police Department) further enhances local emergency response capability.

The State of Kansas has participated in several FAD emergency planning exercises. The state's current and past emergency planning efforts will serve as a strong foundation for what will be required for the NBAF. Kansas frequently exercises its ERPs and associated procedures. One example of the type of training Kansas participates in includes a table-top exercise (TTX) hosted May 18-19, 2010, by the National Agriculture Biosecurity Center (NABC) at K-State, called May Day II. This TTX focused on National Animal Health Laboratory Network (NAHLN) involvement in an FMD outbreak. Participants included staff from the Kansas State Veterinary Diagnostic Laboratory (KSVDL), Kansas Animal Health Department, Iowa State University Veterinary Diagnostic Laboratory (ISU VDL), Iowa Department of Agriculture and Land Stewardship, NAHLN program office, USDA-APHIS-VS National Surveillance Unit, and National Pork Board.

The objectives of this TTX were to examine early, middle, and late-response activities regarding the decision-making process for NAHLN activation and de-activation, testing capacity at KSVDL and ISU VDL in light of a theoretical FMD outbreak and surveillance sample collection protocols, testing algorithms after an FMD outbreak has been confirmed and for proving freedom from disease, and communication and coordination processes. The exercise involved a simulated disease outbreak that began with a Foreign Animal Disease Diagnostician conducting a vesicular disease investigation on a cow-calf farm in northeast Kansas. The exercise progressed through confirmation of FMD, spread of the disease into the cattle-dense area of southwest Kansas, and then to swine in southwest Iowa. It concluded with a discussion of the outbreak recovery and the implication on NAHLN testing for disease freedom. This type of exercise, and others performed in conjunction with the Multi-State Partnership for Security in Agriculture, will facilitate the NBAF exercise planning process.

In addition to the FAD planning, Kansas has extensive experience in off-site radiological emergency preparedness that has been developed for the Wolf Creek Nuclear Operating Corporation's power plant and the Cooper Nuclear Station that is owned and operated by the Nebraska Public Power District. The

state has maintained the Annual Letter of Certification for their preparedness efforts. These efforts include working within an Emergency Planning Zone (EPZ) for the Wolf Creek facility, as well as the 50-mile radius ingestion pathway zones for both facilities. The Nuclear Regulatory Commission (NRC) requires an ongoing and structured inter-governmental exercise regimen that has enhanced state and local preparedness as well as strengthened agency partnerships. It appears that this collective competency and experience is also a foundation for response capability, as well as being helpful to the preparation of NBAF emergency response planning. K-State also houses a TRIGA Mark II research reactor which provides training for nuclear reactor operators, indicating university-level expertise in similar response protocols.

The Superfund Amendments and Reauthorization Act (SARA) of 1986 created the Emergency Planning Community Right-to-Know Act (also known as EPCRA or SARA Title III). EPCRA requires local communities throughout the U.S. to establish Local Emergency Planning Committees (LEPCs) and empowers these LEPCs to serve a pivotal role in local emergency planning efforts. Additionally, each county in Kansas is required to have an emergency management agency. Accordingly, a strong emergency management organizational design exists in Kansas that will be beneficial to the future success of the NBAF off-site emergency preparedness, planning, and response efforts. Also of key importance is the Kansas Commission on Emergency Planning and Response. This Commission has extensive membership requirements, as well as advisory responsibility, for emergency management matters within the state; therefore, this Commission could also serve as a solid foundation for successful emergency response planning at the NBAF.

Various state agencies agreed to provide all or key portions of existing ERPs to DHS to demonstrate their preparedness activities and to leverage these published resources during the development of future NBAF plans. Each of these documents, which were evaluated during this assessment, provided specific response planning perspectives and, in total, outlined a structure that will allow state agencies to:

- Develop effective inter-agency emergency notifications;
- Establish an effective emergency operations center; and
- Link with local jurisdictions to initiate emergency response and communication functions.

Both Riley and Pottawatomie Counties have all-hazard emergency plans with access to the County Foreign Animal Disease Standard Operating Guidelines (planning template) developed by the Kansas Animal Health Department.

Current medical readiness in the Manhattan, Kansas, area was also evaluated. Should an incident involving human cases occur in the Manhattan, Kansas, community, it is critical that the region have the medical capacity and staff to respond in an effective manner. Unlike the current PIADC, the NBAF staff will be working with high-consequence zoonotic agents. The NBAF will develop occupational health programs to monitor not only physical injuries but also potential human and zoonotic pathogen exposures or laboratory-acquired infections (LAIs). A major medical provider and resource in the Manhattan, Kansas, area is the Mercy Regional Health Center (MRHC), part of the larger Via Christi Health System in Wichita, Kansas.

The MRHC Occupational Health Services (OHS) is already working closely with the BRI (BSL-3Ag containment lab which will study zoonotic agents) at K-State on its occupational health program for BRI employees. MRHC OHS currently provides a variety of services to the BRI including respirator fit testing, baseline serology assays for Select Agent work, and occupational therapy. The BRI staff has identification cards that can be presented to hospital staff or local physicians that identify their place of employment and potential exposure risks. MRHC is coordinating with the BRI to receive periodic updates on the pathogens being studied in order to disseminate relevant information to OHS and hospital staff. The BRI and OHS have drafted a 24-hour response plan for sick/injured BRI employees. This level of MRHC interaction has already been discussed at DHS for the NBAF. Alternatively, the NBAF may develop relationships with other health care providers, such as the University of Kansas Hospital or the Ft. Riley Hospital.

Mercy Regional Health Center (MRHC) Capabilities

- Hospital licensed for 150 beds (but the current daily census is usually 75-100)
- Nine isolation rooms with HEPA filtration and negative pressure:
  - Two in the Emergency Room area
  - Two in the Intensive Care Unit
  - Remaining five spread throughout the other wards
- All medical specialties are represented with the exception of neurosurgery. The hospital is a self-sufficient medical system that can treat almost all medical emergencies on-site without the need for transport out of the area
- A heli-pad for helicopter access to/from the hospital
- An infectious disease physician on staff that is currently working closely on Occupational Health issues with the BRI at K-State
- The Emergency Medical Service (EMS) is managed by the hospital and is not a separate entity. EMS has already performed drills at the BRI and determined that the VHF-based radios had issues due to the wall thickness in the lab; however, they are considering internal repeaters to boost performance
- Two decontamination units
  - One is located in the hospital with hot and cold water
  - One is a deployable field system with cold water only
- Unified command system in use for communication and response
- Ability to tap into the Via Christi Health System in Wichita, Kansas for additional surge resources (both materials and staff)

MRHC clearly has many capabilities in this area and is willing to support the NBAF. To be most effective, DHS may engage MRHC or other parts of the healthcare community by the following means:

- Pre-coordination with the NBAF concerning agents with active research programs or any new agents introduced to the primary research agenda;
- Providing potential opportunities to assist with the development of a medical education program;
- Potentially supporting the development of a communication system to push information to private physicians in the area;
- Providing access to occupationally-related human vaccines in Manhattan, Kansas;
- Provision of emergency contacts at the NBAF in case of an unusual infectious disease case that might be somehow related to the facility;
- Provision of direct contact between medical staff and CDC experts for streamlined communications regarding vaccine consults, disease information, and potential therapies in case of an LAI; and
- Collaboration between all medical and response groups and the federal government to identify any NBAF-related needs, and the provision to address those needs cooperatively.

Other emergency support operations may be provided by the Manhattan, Kansas, Fire Department (MFD) which was found to be ready and willing to develop and practice NBAF-specific response plans as the facility nears completion. The MFD is located approximately one block away from the proposed NBAF site and houses uniformed officers and Hazardous Materials-trained officers. The MFD Level A suits are tested twice per year, but are reportedly getting old and may need to be replaced. The MFD has interacted with the BRI and discussed facility response plans, and as such, MFD staff is already familiar with some aspects of high-containment laboratories. The current protocol for a medical emergency response at the BRI dictates that the MFD wait until injured individual(s) are removed from containment before providing medical assistance. Discussions continue, however, regarding whether to provide medical assistance to a severely injured person (i.e., in a life or death situation) prior to removal from a containment laboratory.

The Riley County Emergency Management (RCEM) team is also prepared to work with DHS and the NBAF to clearly define the roles and responsibilities of each party. The RCEM team has a working relationship with nearby Ft. Riley, with whom they participate in periodic joint exercises (e.g., establishing a mobile field hospital in Manhattan, Kansas). The RCEM office also communicated interest in developing pre-packaged community engagement and outreach plans for a variety of potential threats in order to streamline communications after an incident, and increase message unity among first responders, local leaders and federal stakeholders.

3.2 Future Plans

The NBAF design continues to mature while incorporating recommended design changes that enhance the engineered safety features and enable procedurally-driven mitigation strategies. The NBAF Design Partnership has significant biocontainment expertise (large animal facilities) and has added expertise, as needed, to address site-specific concerns that include tornado hardening and wastewater treatment systems. DHS has adopted a sophisticated design review process that elicits comments on design milestones from experts in all relevant disciplines. Domestic and international partners continue to be informed on design topics and queried on best engineering practices.

While design and construction are in progress, DHS and USDA have the opportunity to continue the development of best practices in the form of operational documentation (SOPs, training programs, policies and procedures, security, information technology, etc.), operational production (facility service provider contracts, supply chain development, etc.), and response planning (memorandums of understanding, surveillance systems, diagnostics systems, industry collaboration, community organization, health care alignment, etc.). The design and construction period also provides DHS and USDA with an opportunity to begin staff training well in advance of any laboratory activities. It is recommended that the training be developed around an integrated “one health” paradigm. Animal disease researchers and human (and zoonotic) disease researchers work in very similar environments, use similar lexicons, and apply many of the same basic biosafety practices, however practical differences in procedures and operations (especially considering the difference in research models) do exist . Early, integrated, and periodic training will leverage the consistencies in practice and help mitigate risks that may arise from potential operational differences.

DHS will be leveraging existing response plan networks in Kansas while developing NBAF-specific documentation. DHS has met with local emergency responders and reviewed existing capabilities. While the facility remains in its design stages, the emergency response planning has started but with the NBAF operations not beginning until 2020, the ERP effort will not accelerate until 2015 (about midway through the construction phase). During the interviews and meetings conducted for this assessment, state and local representatives did request additional information from DHS regarding emergency preparedness requirements and expectations for local, state, and tribal governments, and for university organizations. The representatives interviewed stated that for the emergency preparedness process to begin, the state, local and tribal governments must receive detailed and specific information from federal partners (i.e., DHS and USDA) on the NBAF configuration and the potential risks. The State of Kansas, local jurisdictions, K-State, and American Indian Tribes are waiting to begin their planning process. The NBAF ERP will be developed starting in 2016; however, DHS has begun its coordination and planning efforts through the development of the NBAF Plan for the Emergency Response Plan (Appendix A3).

4. Event Descriptions

The use of best practices and experience-based knowledge compiled from the design, construction, and operation of animal and human pathogen facilities greatly reduces the NBAF-related risk to U.S. citizens and agricultural infrastructure. Since it is impossible to eliminate all of the risk associated with high-consequence pathogen research and laboratory activities, it is important to use accident event modeling to inform decision-makers and designers on risk mitigation strategies. The principal objective of the Updated Site-Specific Risk Assessment (Updated SSRA) is to assess the residual risks associated with the current NBAF design (65% Design) that incorporate changes made since the 15% Design used as the basis for the SSRA. The assessment of these residual risks will be used to inform DHS such that additional changes can be made, if necessary, to the facility design, operational planning, and response mitigation strategies. This analysis is an update of the 2010 SSRA that used a scenario-based assessment of risk. The SSRA leveraged previous NBAF-related efforts by drawing on the Hazard and Accident Analysis performed for the EIS [DHS, 2008], the Threat and Risk Assessment [DHS, 2010], and the Design Basis Threat [Sandia, 2009].

During an interim review of the SSRA, the National Academy of Sciences Review Committee (NAS SSRA Committee) suggested that it would be useful to organize the analyses of NBAF containment release accident events by the mechanism of pathogen transport. Specifically, the recommendations included organizing the events by aerosol, liquid effluent, solid waste, and fomites/vectors/carriers (i.e., transference) pathways. The SSRA was adjusted to characterize the events into these release pathways. In this Updated SSRA, the risks are again characterized by modeling potential accident events and the associated economic consequences. However, the Updated SSRA incorporates a more systematic consideration of the pathways and the potential originating locations of an accident event. With the assistance of DHS and the NBAF Design Partnership (NDP), the Updated SSRA team enhanced the fidelity of data used in the assessment of risk by incorporating information from the 65% Design and collecting additional information on planned containment practices, historical containment accidents, systems performance, response capabilities/plans, and susceptible species. This updated assessment is ultimately intended to develop policies and procedures that will allow DHS to build and safely operate a model containment laboratory facility.

In this Updated SSRA, emphasis has been applied to identifying more refined values for parameters used to model the potential accident events and to characterize the uncertainty of these values. The values and ranges selected for the modeled parameters are representative of actual anticipated values – not the worst case circumstances. The uncertainty associated with the selected values is, where possible, propagated through the analysis and captured in the final risk rankings and absolute event frequency and consequence estimates. Another difference between the SSRA and Updated SSRA is in terminology. During a preliminary meeting with the NAS SSRA Committee, it was suggested that terminology in the Updated SSRA be consistent with terminology provided in ISO 31000, prepared by the International

Organization for Standardization [ISO, 2009]. This recommendation from the NAS SSRA Committee is incorporated into the Updated SSRA along with other terminology guidance from the DHS Risk Lexicon [DHS, 2010]. Of particular significance is the use of the term "event" in the Updated SSRA. An event is an accident (loss of containment) that may or may not result in an infection outside of containment (the undesirable outcome), which is consistent with ISO 31000 and DHS Risk Lexicon. In the 2010 SSRA, the term "case" was used for this purpose.

The events that are modeled in the Updated SSRA make use of conceptual models of the potential originating locations, transport pathways, published virus and disease characteristics, forecasted research activity, NBAF laboratory plans (65% Design), presumptive processes or procedures, and response plans based on best practices and existing DHS directives. Section 4.1 provides a description of the four originating locations – describing the specific NBAF components that are represented by each conceptual location. Section 4.2 presents the pathogen pathways and the corresponding models of the proposed NBAF mitigation systems and practices. A high level description of the circumstances leading to the accident events modeled is presented in Section 4.3. The modeled quantities of FMDv material and the distribution of pathogens for the pathways that may be involved in an event are described in Section 4.4. The modeled FMDv facility utilization and operational tempo are also described in Section 4.4. In Section 4.5, the locations, pathways, fault trees, and tempo are used to develop the collection of accident events. Section 4.6 describes the catastrophic events that are modeled in this assessment and finally, Section 4.7 provides a summary of all Updated SSRA events.

4.1 Originating Locations

The NBAF comprises laboratory spaces that are designed and operated as BSL-2, BSL-3 Enhanced (BSL-3E), BSL-3E "Special Procedure" laboratories, BSL-3Ag, and BSL-4 levels [NDP, 2011]. In the U.S., research on viable FMDv can be performed only if the laboratory facilities are engineered and operated at a BSL-3 or higher level; furthermore, a permit to research FMD must be issued to the laboratory by the USDA. The Plum Island Animal Disease Center (PIADC) is the only U.S. facility that is currently permitted to perform research and activities on live FMDv. When the NBAF becomes a permitted FMD facility, research on viable FMD will be performed in the BSL-3Ag, BSL-3E, and BSL-3E "Special Procedure" laboratories. Section 9 of this Updated SSRA incorporates a non-quantitative assessment of risk associated with pathogen research on large animals (FMDv and other pathogens) in a BSL-4 facility. The Biotechnology Development Module (BDM) is not modeled because it will not be working with viable FMDv. The modeled components of the BSL-3Ag areas include animal holding rooms (AHRs) and necropsy suites – areas that have different types of activities and are thus modeled separately in the Updated SSRA. In addition to the BSL-3Ag areas, the BSL-3E laboratories and BSL-3E "Special Procedure" laboratories are modeled in the Updated SSRA. A non-containment area is also modeled to incorporate the ability to assess the frequency and consequences of events that originate at the NBAF but occur prior to the pathogenic material being properly received in a containment area or after accidentally introducing contamination to an area outside of containment — such as from leaking pipes. Figure 4.1-1 identifies the NBAF containment areas that are modeled in the Updated SSRA while Figure 4.1-2 lists

these modeled areas. Underneath each originating location is a list of the anticipated dominant sources of FMDv for that area. These lists are not intended to be exhaustive nor are they rank-ordered by prevalence – they are only intended to illustrate the likely sources of virus for each type of room. A brief overview of the four originating locations is presented below. The protection and mitigation systems for each release pathway are described in Section 4.2.

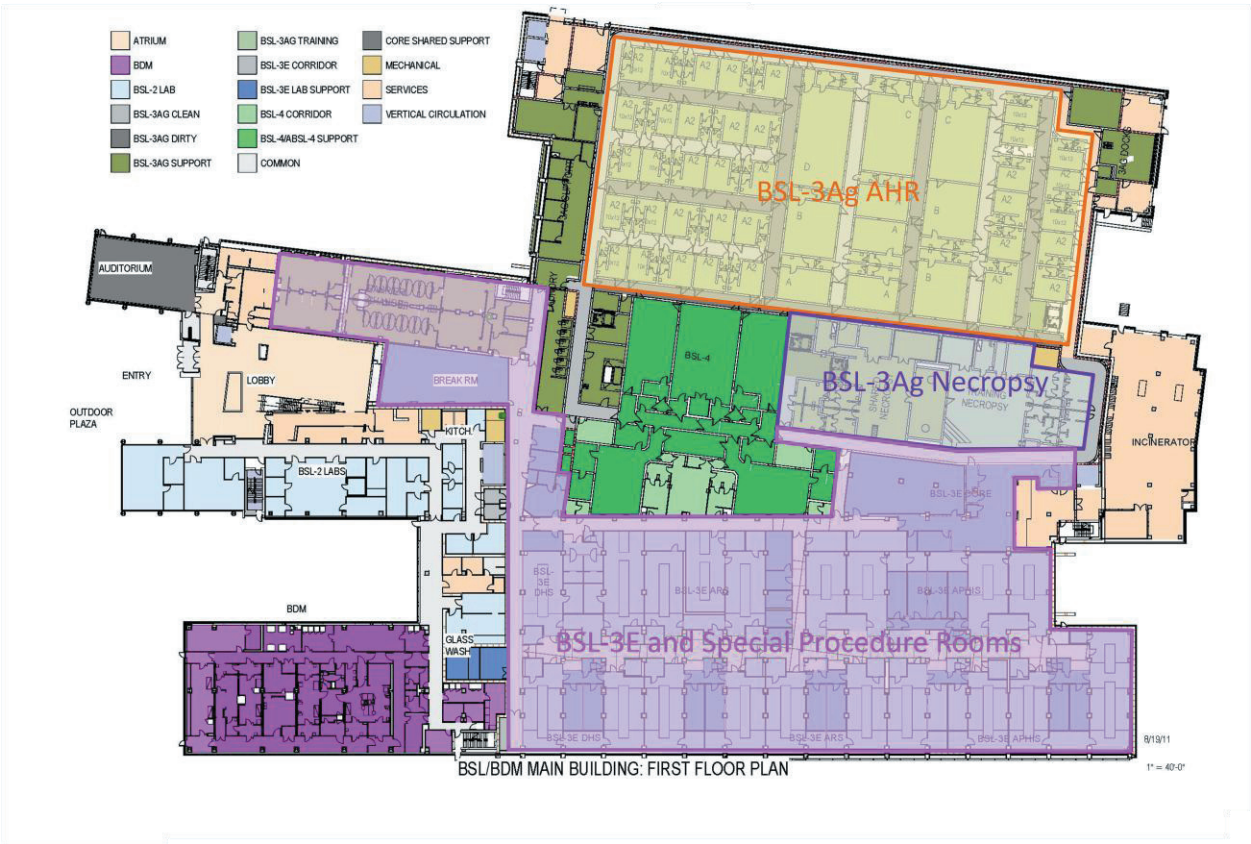


Figure 4.1-1: NBAF Containment Areas

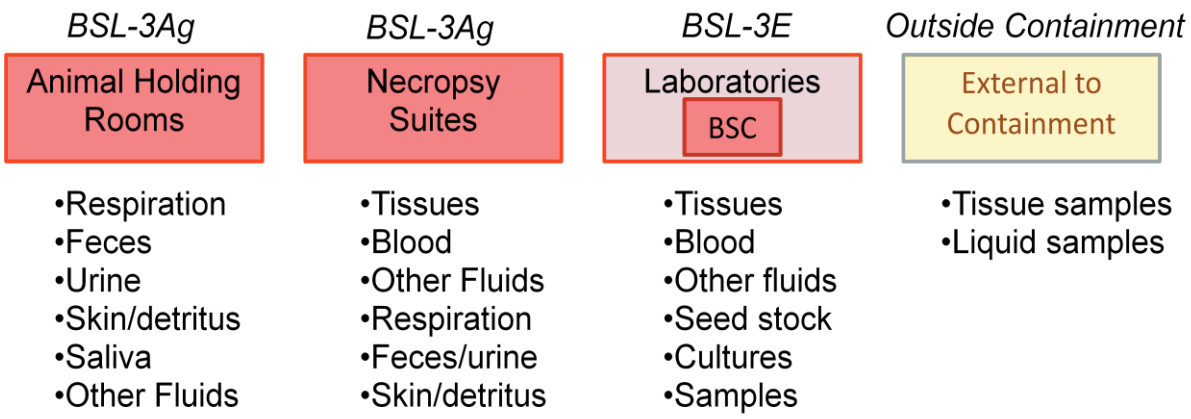


Figure 4.1-2: Originating Locations of FMDv Events

4.1.1 BSL-3Ag Animal Holding Rooms

The BSL-3Ag containment area of the NBAF includes animal holding rooms (AHRs), "clean" corridors, "dirty" corridors, necropsy suites (Section 4.1.2), and other support spaces. The NBAF comprises 46 AHRs of seven different types, as listed in Table 4.1.1-1. In general, the different types of AHRs incorporate the same engineering controls and will be operated with similar protocols and procedures. All AHRs are accessed through a BSL-3Ag "clean" corridor or a BSL-3Ag "dirty" corridor.

Table 4.1.1 1: Animal Holding Room Types

Animal Holding Room Type	Number of Rooms
A	4
A2 12'x12	20
A2 10'x12	15
A3	1
B	3
C	2
D	1

Prior to an experiment, animals are moved along the clean corridors from the animal receiving area into an AHR through a series of doors and species-appropriate gating as described in the 65% Design. After an experiment begins, personnel enter and exit the AHR through the clean anteroom, shower, or dirty anteroom with prescribed garment change, personal protective equipment (PPE) use, shower, and hygiene protocols. The BSL-3Ag dirty corridors are accessed through the AHRs. The BSL-3Ag AHRs are considered a "primary barrier" because once the research animals are infected, shedding, etc.; the room containment systems are the first barrier to environmental contamination in the containment strategy. Typical room configurations for each type of AHR are presented in Figures 4.1.1-1 through 4.1.1-7 (not to scale). The penning is arranged as appropriate for the species and research needs. A detailed description of the modeled efficiencies of the AHR containment systems (for aerosols, solids, liquids, and transferred fomites) is provided in Section 4.2. However, a brief description of the engineered and procedural containment systems for the AHRs is included in this section.

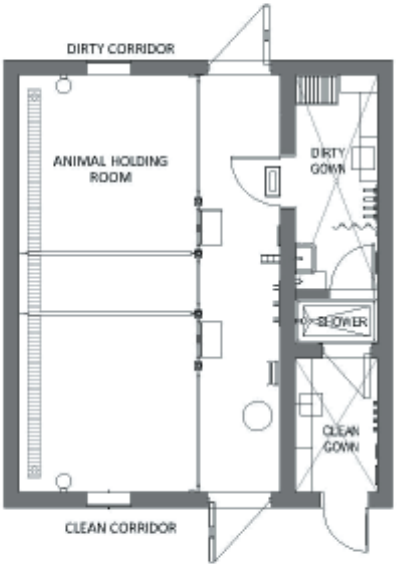


Figure 4.1.1-1: Animal Holding Room Type A

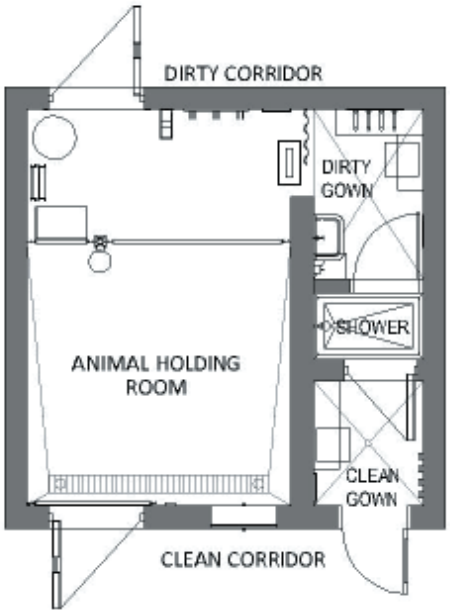


Figure 4.1.1-2: Animal Holding Room Type A2 12’ × 12’

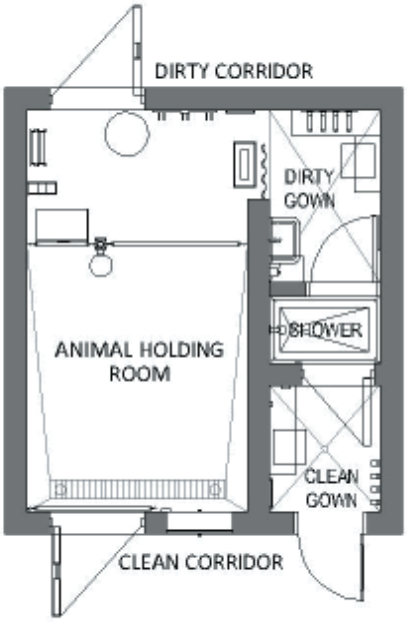


Figure 4.1.1-3: Animal Holding Room Type A2 10’ × 12’

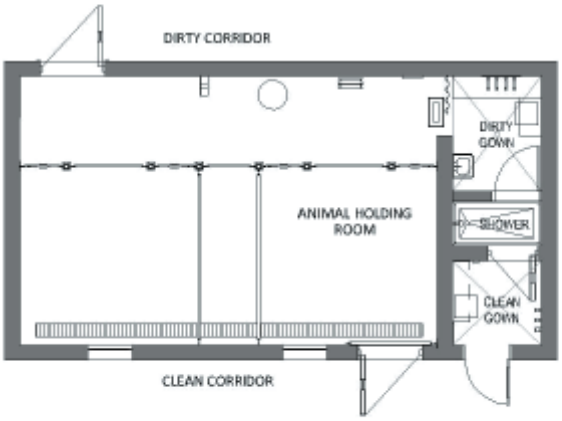


Figure 4.1.1-4: Animal Holding Room Type A3

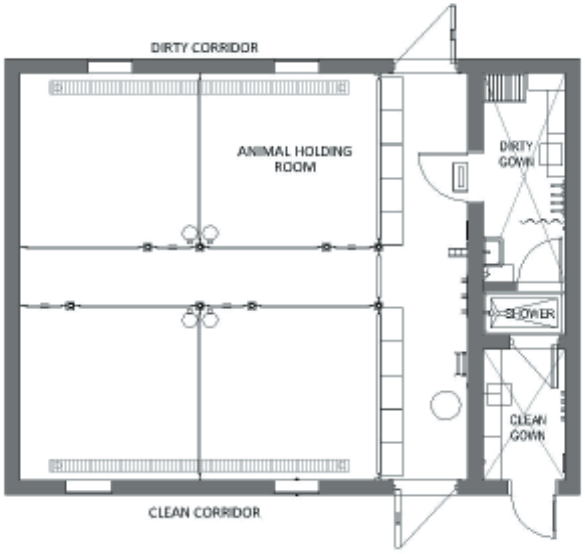


Figure 4.1.1-5: Animal Holding Room Type B

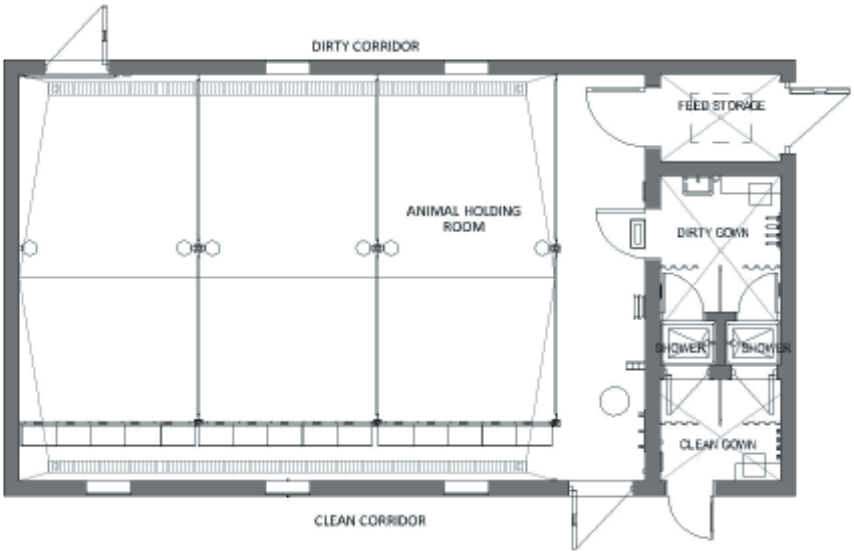


Figure 4.1.1-6: Animal Holding Room Type C

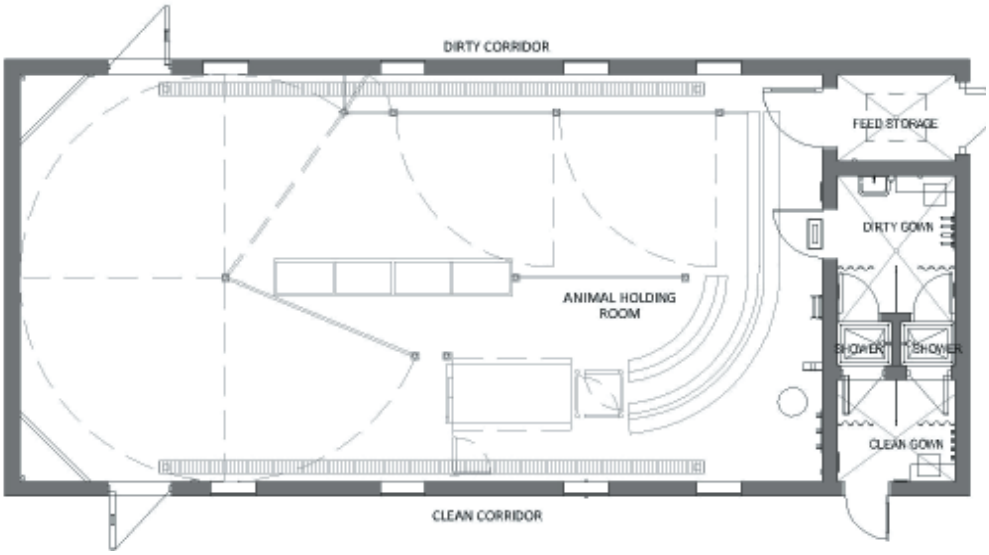


Figure 4.1.1-7: Animal Holding Room Type D

The combination of the number of rooms and room sizes provides the flexibility to accommodate varying research needs and is amenable to a "hoteling" concept. Each room provides flexible penning options and will accommodate all species, current and anticipated, used in FMD research. As can be seen from the AHR configurations, each type of room has two doors that are capable of accessing the AHR from the clean corridor and a single door that provides access to the dirty corridor. The door from the clean corridor that opens directly from the AHR is not typically used during an experiment – it may be used between experiments and is used to bring the animals into the AHR prior to the beginning of experiments. During an experiment, access from the clean corridor to the AHR is through the clean gowning/anteroom. Each area (anterooms and shower) has its own room exhaust ventilation and directional airflow (into the AHR) is maintained by a pressure gradient. Personnel will disrobe, go through the shower, and don "clean" attire stored in the dirty gown room. The relative arrangement of the AHRs (all seven types: A, A2 10' × 12', A2 12' × 12', A3, B, C, and D) and the clean/dirty corridors are presented in Figure 4.1.1-8.

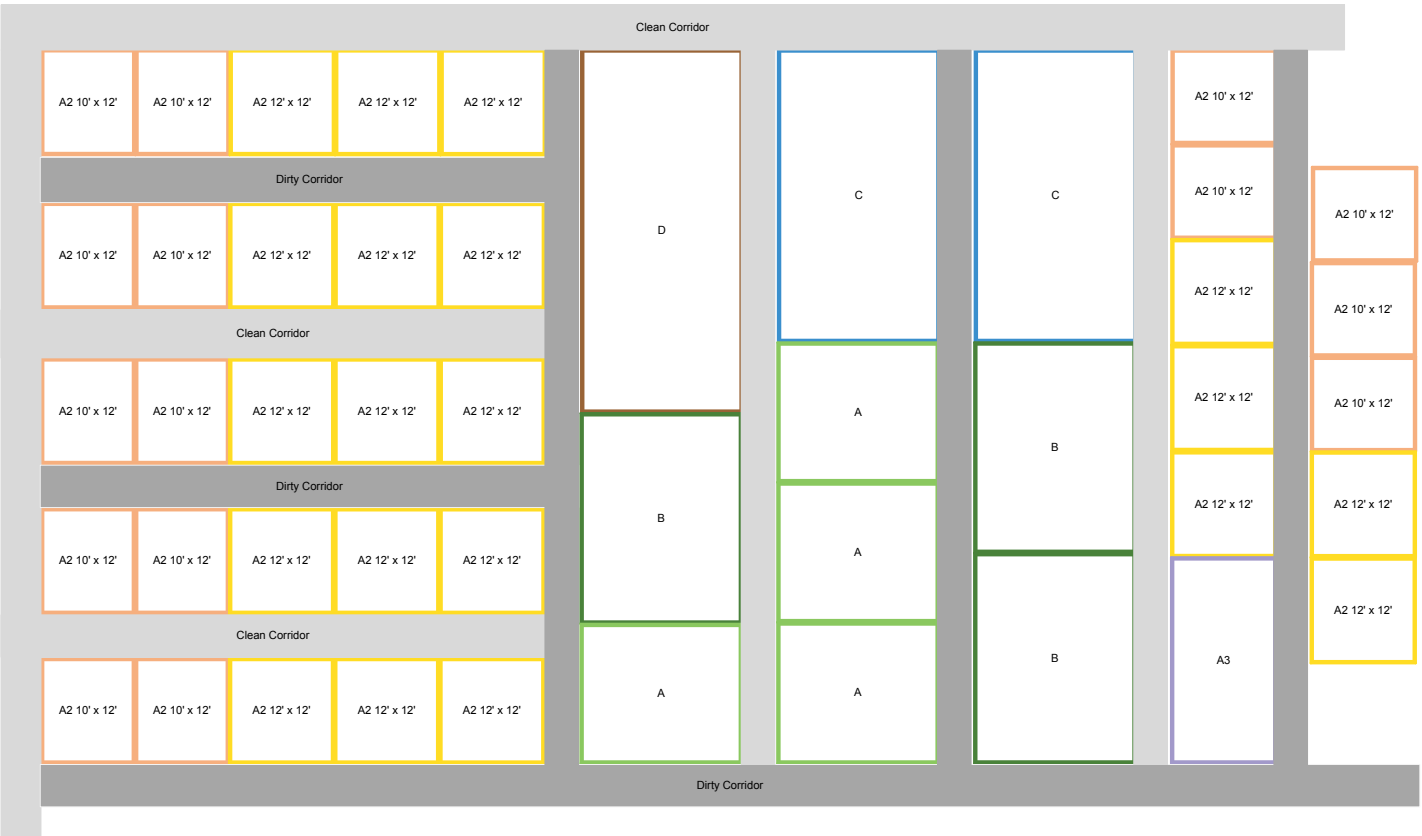


Figure 4.1.1-8: Relative Arrangement of AHR and Clean/Dirty Corridors in BSL-3Ag

All AHRs are designed to handle solid waste and the movement of contaminated equipment in similar ways. Bagged waste is carried from the AHR into the dirty corridor. From the BSL-3Ag dirty corridors, the solid waste and contaminated equipment is decontaminated or sterilized as it is moved to the BSL-3E area. The decontamination is accomplished by pass-through autoclaves, dunk tanks, and/or gaseous decontamination chambers. Samples to be removed from the AHR must be appropriately packaged inside the AHR and then removed in the possession of the researcher or other responsible personnel. The external container of the sample is decontaminated by submersion in a disinfecting solution and/or disinfectant wipedown.

All AHRs in the BSL-3Ag area use gravity floor drains for liquid waste and the solid fraction of animal waste. By anticipated procedure, the floor drains are primed with disinfectant on a daily basis. During animal occupancy, the AHRs are subjected to a daily (or twice daily) washdown. The washdowns may be limited and serve to remove animal waste from the room. Laboratory personnel will push animal waste to the grated floor drains and then use prescribed washdown techniques to remove animal waste from the walls and floors – the rinse water going down the drain. The liquid effluent from all AHRs is collected in cook tanks that are part of the Effluent Decontamination System (EDS). The EDS provides batch sterilization of the liquid waste from the containment side of the NBAF before it is diluted with sanitary

waste from other parts of the building (e.g., the administrative side) and eventually discharged to the onsite wastewater pretreatment system.

4.1.2 BSL-3Ag Necropsy

The NBAF BSL-3Ag research facilities include two necropsy suites. The primary "shared" necropsy suite and the "training" necropsy suite incorporate the same containment concepts employed in the AHRs; however, the room configurations and anticipated procedures and utilization frequencies are different. The tissue autoclaves (i.e., carcass disposal systems) are accessed through the necropsy areas. All animals that are used in BSL-3Ag research activities are euthanized at the culmination of the experiment and carcasses are disposed of through the tissue autoclaves. Euthanasia occurs in a special vestibule that connects a "dirty" corridor to the necropsy suites. Figures 4.1.1-9 and 4.1.1-10 illustrate the shared necropsy suite and training necropsy suite configurations, respectively.

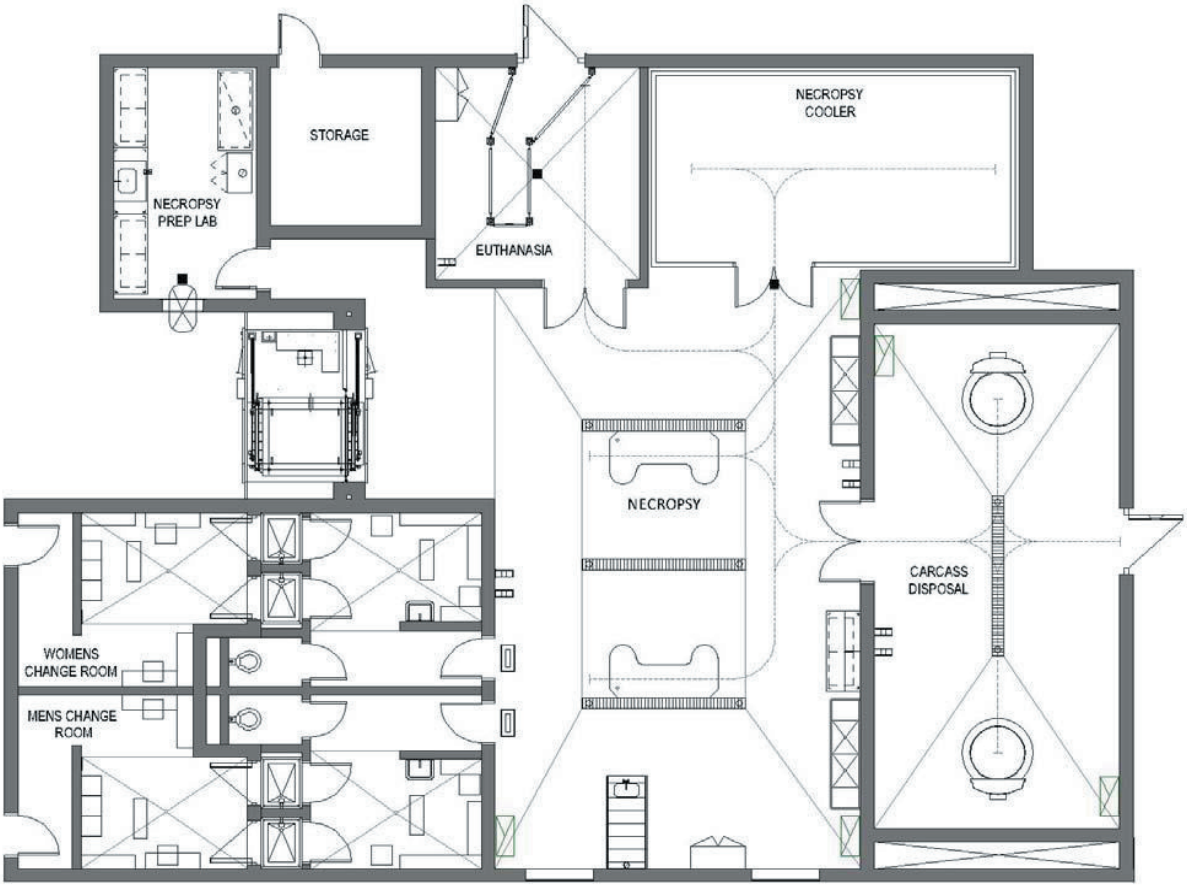


Figure 4.1.2-1: Shared Necropsy Suite Configuration

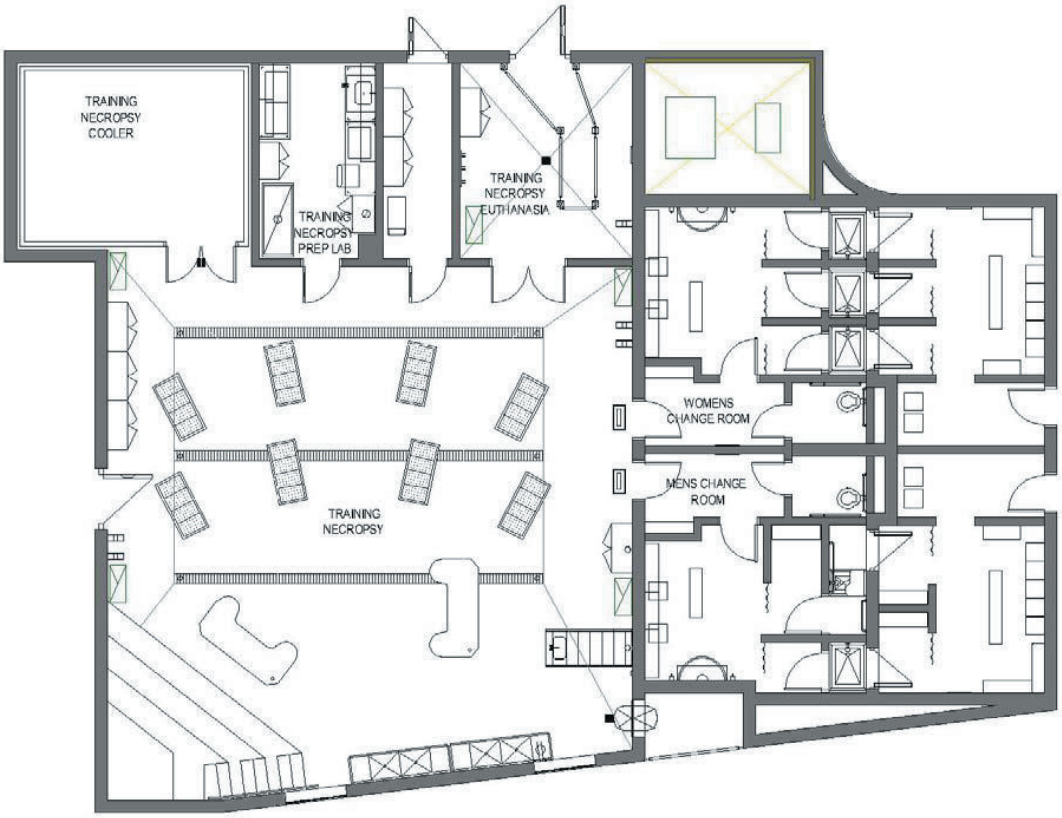


Figure 4.1.2-2: Training Necropsy Suite Configuration

The necropsy suites incorporate specialized systems for the accommodation of anticipated procedures in these areas. These special features include the euthanasia area, the overhead hoist railing (for carcass movement), hydraulic necropsy tables with down draft air curtains/filtering and liquid collection, carcass storage areas (cooled), and access to the tissue autoclaves. The room exhaust air handling system is very similar to the systems used for the AHRs. The management of solid waste is similar to the AHRs but decontamination systems are directly integrated into the necropsy suites. Liquid waste is processed in the same EDS as the AHRs.

4.1.3 BSL-3E and BSL-3E "Special Procedure" Laboratories

The BSL-3E laboratories in the NBAF provide bench top research capacity and laboratory support capabilities for the researchers without requiring them to ingress/egress the BSL-3E "containment barrier" several times each day. FMDv laboratory research activities will take place in the BSL-3E or BSL-3E "Special Procedure" laboratories. The BSL-3E laboratories include biosafety cabinets (BSCs) that are used to provide primary containment of any FMDv research activity. The BSL-3E laboratories will use both Class II Type A2 BSCs and Class II Type B2 BSCs, depending on the location and anticipated activities within the specific BSL-3E module. The Type A2 BSC is not ducted to the building exhaust and uses integral HEPA filtration to recirculate air from the cabinet into the workspace. The Type B2 BSC facilitates working with low volumes of volatile organics as well as particulates. The Type B2 BSC is totally exhausted through a dedicated exhaust plenum connected to the laboratory exhaust system.

Figure 4.1.3-1 depicts a typical BSL-3E suite that includes two laboratories that will operate at the BSL-3E level and two laboratories that have the potential to operate as BSL-3E "Special Procedure" laboratories. Note that the BSL-3E labs (on the left and right in Figure 4.1.3-1 and labeled as the "DHS Assay Development Lab" and "DHS Molecular Biology Lab") directly access the BSL-3E corridor system. If the BSL-3E "Special Procedure" laboratory (labeled as "BSL-3EE Support Lab") is not being used for a high-risk research activity, these laboratories have easy access to the BSL-3E corridor system through the BSL-3E labs. However, when the BSL-3E "Special Procedure" laboratories are being used for a high-risk research activity, both ends of the "BSL-3EE" corridor (see Figure 4.1.3-1) are sealed to the BSL-3E laboratories and access to the BSL-3E "Special Procedure" areas is provided through the clean anteroom ("clean change"), shower, and dirty anteroom ("dirty change"). Note that the reference to "BSL-3EE" support labs and corridor should actually state BSL-3E "Special Procedure" support labs and corridor.

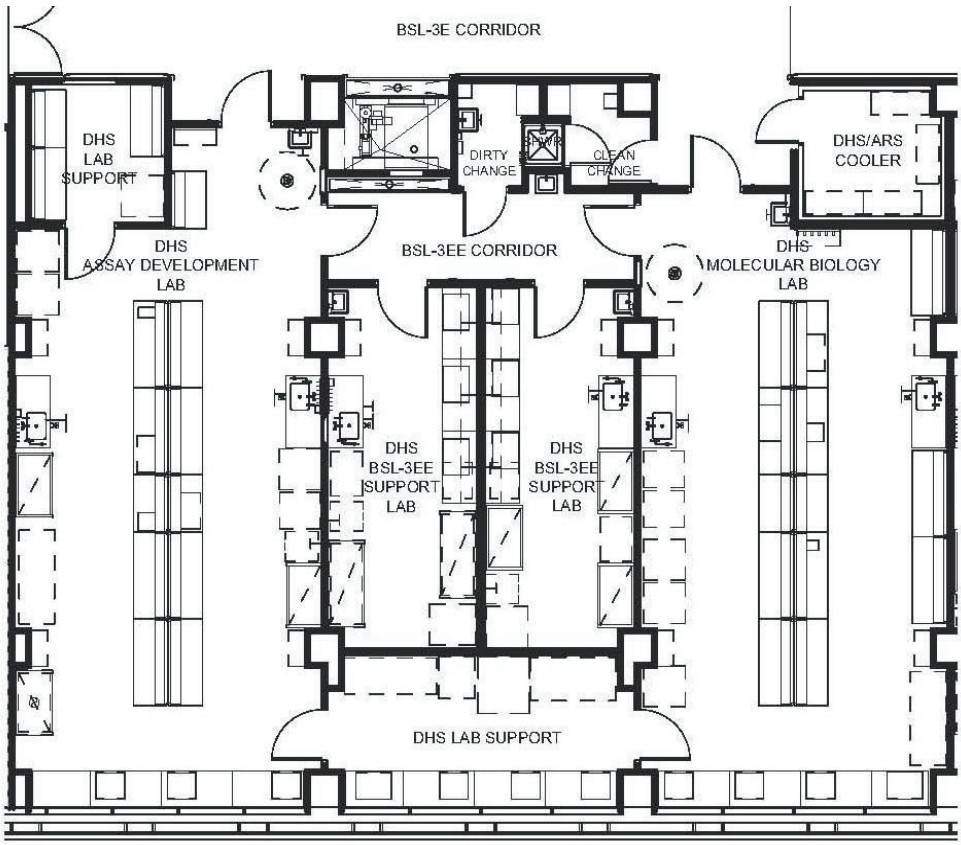


Figure 4.1.3-1: Typical BSL-3E and BSL-3E "Special Procedure" Room Suite

(The DHS Assay Development Lab and DHS Molecular Biology Lab are BSL-3E laboratories.)

Solid waste management is accomplished through pass-through autoclaves and single-door autoclaves. Liquid waste is similarly processed through the autoclaves, and no liquid waste should be disposed of through the drains in the BSL-3E laboratories. However, if protocols are not followed, the liquid waste is accommodated by the EDS.

4.1.4 Non-Containment Areas

The BSL-3E containment zone includes the BSL-3Ag and BSL-4 areas. Areas outside of these zones are considered a non-containment area (with the exception of the BSL-2) and include administrative offices, laboratory infrastructure, and support laboratories. In the Updated SSRA, an event that originates from a non-containment area must have been contaminated with infectious material from one of the modeled containment areas (BSL-3Ag AHRs, necropsy suites, or BSL-3E/BSL-3E "Special Procedure" laboratories) due to a protocol failure or engineering failure; or the contamination was due to infectious materials received at the NBAF prior to being transferred to the containment area. As previously stated, the number and types of accident events that can be hypothesized for the non-containment areas are virtually limitless. For modeling purposes, the specific non-containment locations that are considered are certain maintenance areas (e.g., inspection of a leak in a drain pipe outside of containment) or between the Transshipping Facility (TF) and the containment areas of the laboratory building. In these scenarios, the precipitating events include a failed drain or the receipt of a sample containing infectious FMDv from an outside source. The few drain pipes located outside of containment have double-walled piping and a containment box surrounding the trap. All deliveries are received at the TF, and special handling procedures for identified incoming samples are being developed. However, after receipt and sorting, it is anticipated that deliveries will be directed to the appropriate locations on the NBAF campus including the laboratory building. The outdoor accident event sequences comprise the receipt at the TF and the mishandling of the package during transport to the laboratory building.

4.2 Pathways and Conceptual Models

Pathogen containment is maintained by providing redundant systems and processes that are designed to decontaminate and/or sterilize biological materials that leave containment. There are four pathways, or transport mechanisms (consistent with NAS SSRA Committee recommendations), by which infectious materials might escape the containment areas:

1. In certain modeled accident events, FMDv, in a viable condition, may escape containment as an **aerosol**. **Aerosols**, including procedure-generated aerosols, animal respiration, and other sources are generally controlled by the use of biosafety cabinets (BSCs), special air flow control devices, and high-volume HEPA filtration systems.
2. FMDv could theoretically escape containment in **solid waste**. **Solid wastes** are sequentially decontaminated when leaving containment through autoclaves (or alternative processes) and incineration. Generally, all such materials are subjected to two or three inactivation and/or decontamination processes.
3. Other accident sequences can be developed where FMDv could escape containment as a **liquid waste**. **Liquids** (i.e., all materials discharged into the NBAF liquid effluent treatment system) in containment areas are disinfected by anticipated processes (either with disinfectant in the drain traps or neutralization prior to discharge) prior to being collected and processed by the liquid Effluent Decontamination System (EDS).

4. The potentially most elusive mode of containment loss is the **transference** pathway. **Transference** includes fomites and human vector accidents. Since FMDv is not generally considered to be a zoonotic pathogen, laboratory-acquired infections are not considered in the quantitative portion of this Updated SSRA. However, the human vector events – events where viable FMDv leaves the containment area in the nasal and upper respiratory tracts of laboratory personnel are modeled. **Fomites** and other solid (non-waste) materials are controlled by access restrictions and procedural requirements for the decontamination and/or sterilization of all materials prior to removal from a containment area and by PPE, garment changes, and showering requirements. Decontamination protocols include chemical disinfections (e.g., dunk tanks, wipedowns), gamma irradiation, vapor decontamination, and showers.

Thus, for any of the originating locations, as provided in Figure 4.1-2, the conceptual pathways of the pathogen release are illustrated in Figure 4.2-1.

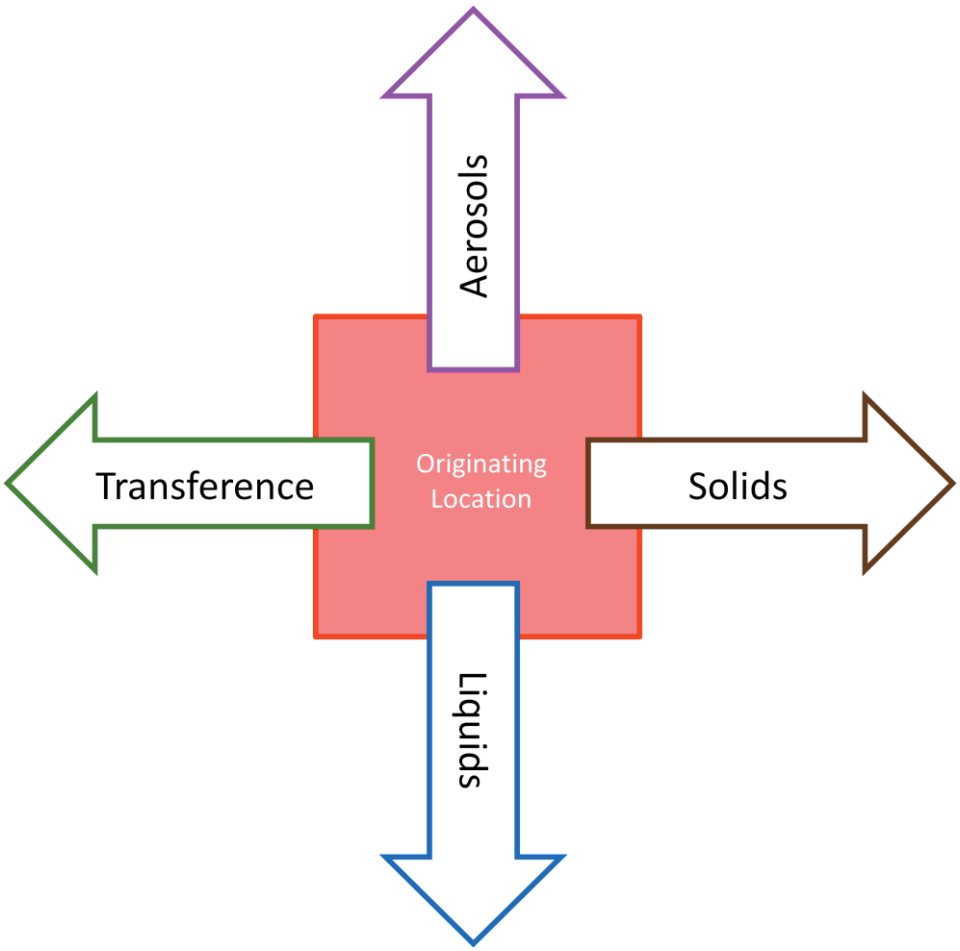


Figure 4.2-1: Pathways for Loss of Containment

In the following subsections, the modeled engineering and anticipated procedural mitigations for the loss of pathogenic material by each of the four pathways is discussed for each of the four originating locations. These discussions include an illustration of the modeled mitigation techniques derived from the 65% Design and presumptive NBAF procedures.

4.2.1 Aerosols

As with all high-containment facilities, the NBAF design and operational strategies depend on sound laboratory practices and layered engineering solutions. Specifically with regard to aerosols, good laboratory practices are used to minimize the creation of aerosols and high-efficiency air handling filtration systems are used to minimize the potential for accidental releases. Layered engineering solutions include the use of BSCs, negative pressure and directional airflow, in-laboratory airflow patterns by design including placement of room supply and exhaust, air exchange rates, HEPA filtration, single-pass circulation, well-maintained equipment-level aerosol mitigation systems (e.g., autoclaves, centrifuges, pipette systems, necropsy tables, etc.), biocontainment dampers, and other manual and automated safety systems. In BSL-3Ag and BSL-4 AHRs, the rooms are designed and constructed to provide the primary containment and effective building air handling and filtration systems that are critical to successful biocontainment.

Aerosol physics and associated modeling techniques are capable of providing very detailed aerosol flow and dispersion patterns as well as an accurate representation of aerosol surface interactions and losses. Such high-fidelity aerosol modeling is resource-intensive and will best serve DHS as the NBAF design is near finalization and additional detail is available on the placement of room fixtures. As in the SSRA, this Updated SSRA makes some simplifying assumptions about the aerosols being modeled. For example, it is assumed that the aerosols are uniformly distributed in the room under consideration. Also, since the Updated SSRA is being performed on the 65% Design, no attempt is made to model aerosol losses from specific room surface interactions or along specific ductwork pathways. However, as is reported in Section 5, transport and fate modeling mechanisms for the aerosols incorporate parameters such as relative humidity and temperature to increase fidelity of the modeling process.

4.2.1.1 BSL-3Ag Animal Holding Rooms

BSL-3Ag rooms will use HEPA-filtered supply air and double-HEPA exhaust filtration (with redundancy) to protect against and reduce the probability of a release of a biological agent under study (e.g., FMDv). The smaller animal holding rooms (AHRs) (Type A, Type A2 12’ × 12’, Type A2 10’ × 10’, Type A3, and Type B) have a single room exhaust penetration. In accordance with recommendations from the CDC and NIH publication on Biosafety in Microbiological and Biomedical Laboratories (BMBL-5th Edition) [2007], the room exhaust air is filtered by two HEPA filters in series. The NBAF design, as depicted in the conceptual model provided in Figure 4.2.1-1, incorporates two filtration caissons (each with two HEPA filters in series).The BMBL-suggested redundancy is accomplished by having each caisson capable of providing full room exhaust filtration. In this figure and subsequent conceptual model figures, the controls and fault/event tree nodes are illustrated in the same arrangement that is used to calculate failure rates in the fault analyses and event description section (Section 4.5).

Under nominal conditions, the AHR exhaust air is first filtered by a rough-filter, which is accessible from the AHR, to remove larger airborne particulates (e.g., detritus, dust, hair, etc.) that could potentially accelerate degradation of HEPA filter performance or damage a filter surface. Because there is a lack of published data on the fraction of viable virus material that may be removed by this rough-filter, no loss

of virus is attributed to this element. The room air is divided in a plenum to flow through both caissons to achieve the HEPA series filtration. Flow balance is accomplished with a control valve at the exhaust plenum. Each of the caissons also has an independent set of bubble-tight bio-seal dampers that can be used to isolate the flow paths and the animal holding room. Each caisson also includes a pre-filter section (different from the rough-filter inside the AHR) that is intended to remove large airborne particulate and aerosols. However, like the rough-filters, no removal of virus is attributed to the pre-filters. Test and scan areas are incorporated before and after each HEPA filter. The entire room exhaust flow can be diverted to either one of the parallel caissons in the event that service is needed on one caisson or an anomalous pressure indication is reported by the control system. This configuration provides a 2N redundancy.

The larger AHRs (Types C and D) have four room exhaust penetrations, as indicated in Figure 4.2.1-2. (Note that the fault tree nodes indicated in this figure and subsequent figures correspond to modeled nodes to determine the probability of each aerosol release event in Section 4.5, and that the nodes that are gray are not used in the Updated SSRA model.) The four exhaust room penetrations, each with its own caisson, provide N+1 redundancy for the room exhaust system. Each penetration has a rough-filter like that described above. Under normal circumstances, exhaust air is removed and filtered by all four HEPA caissons. In the event that one of the caissons is in need of service or if there is an anomalous pressure indication, a caisson can be shut down and isolated while the three remaining systems provide the full requirement for room exhaust air movement.

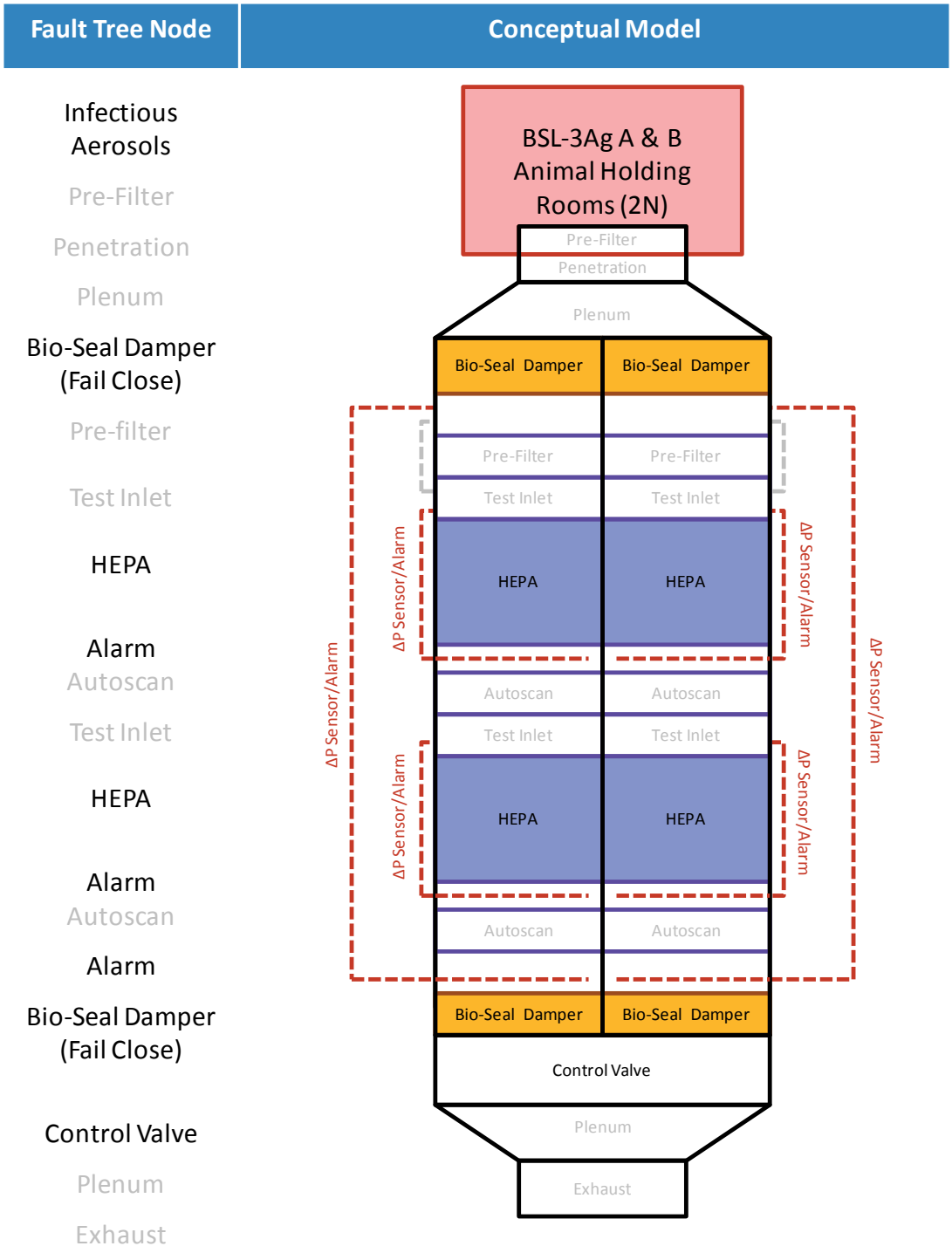


Figure 4.2.1-1: Conceptual Model of BSL-3Ag Room Exhaust System for A and B Rooms

Figure 4.2.1-2: Conceptual Model of BSL-3Ag Room Exhaust System for C, D, and Necropsy Rooms

HEPA Efficiency

DHS has specified that there will be 100% acceptance testing for every new installation and every replacement filter – ensuring that the filtration efficiency of each filter meets or exceeds HEPA specifications and DHS requirements. The HEPA specification is based on the filtration efficiency of the Most Penetrating Particle Size (MPPS), which is specified as 0.3 µm (300 nm). HEPA filters must arrest 99.97% of the MPPS particles – inferring that the filtration efficiency for smaller and larger particulate and aerosols will be greater than 99.97%; however, the DHS specification requires 99.99% of the MPPS to be arrested. (Many references indicate, however, that the MPPS for production HEPA filters is

actually in the 170-200 nm range, but this difference is not critical for the analysis performed in this Updated SSRA.) It is also important to note that typical HEPA efficiency versus particle size curves are for illustrative purposes only. Modern HEPA filters use multi-fiber (multiple fiber diameters) designs to control impaction, interception, and diffusion to optimize filtration efficiency, and the specific performance of HEPA filters will vary by manufacturer.

Gloster reported that FMDv aerosols are distributed almost equally across three particle size ranges (< 3 µm, 3-6 µm, and > 6 µm) and log-normally distributed between particle sizes of 0.015–20.0 µm [2007]. Therefore, the use of the HEPA specification (for the MPPS) provides a conservative (low) estimate of the filtration efficiency. The use of this filtration efficiency corresponds to a pass-through factor of 3×10^{-4}. However, the DHS specification for the NBAF HEPA filters exceeds the standard HEPA definition and requires 99.99% of the MPPS to be arrested. Per the 65% Design, the filters shall be individually scan tested, certified, and labeled to have an efficiency of not less than 99.99% (for BSL-3E, BSL-3Ag, and BSL-4 supply and exhaust filters). This requirement corresponds to a pass-through factor of 1×10^{-4}.

Kowalski indicates that generally smaller and larger airborne microorganisms are removed more efficiently by HEPA filters [1999], consistent with the concept of MPPS. FMDv, a member of the Picornaviridae family, is non-enveloped, icosahedrally-shaped, and about 25-30 nm in diameter [Mahy, 2005]. Kowalski's published work on virus filtration from Picornaviridae such as rhinoviruses and Coxsackieviruses – both similar in size to FMDv – indicate the filtration efficiency of HEPA filters exceeds the required efficiency. The specific penetration rates for rhinoviruses and Coxsackieviruses are not provided by Kowalski, but they are indicated to be less than 30 HEPA penetrations per million (less than 3×10^{-5}).

Wang tested 300 HEPA filters to determine statistically-significant testing times (in accordance with IEST RP-CC007.1) and efficiencies for HEPA filters [2004]. The measured efficiency of the filters exceeded 99.997% at the 95% confidence interval. This efficiency corresponds to a 3.0×10^{-5} pass-through factor – the same value derived from Kowalski's work.

Arunkumar published data on the performance of HEPA filters under a variety of conditions including those that result in compromised performance of the filters [2004]. Baseline studies were conducted to determine the correlation between differential pressures and filtering efficiency. The filtering efficiency of new filters exceeded HEPA specifications and efficiencies rapidly increased with filter loading. Specifically, for a potassium chloride (KCl) aerosol with 130 nm count mean diameter (CMD) and a geometric standard deviation (GSD) of 2.0, initial filter efficiency was approximately 99.9985%, corresponding to a pass-through factor of 1.5×10^{-5}. As the filter is loaded with mass and the pressure differential increases by 20%, the filter efficiency exceeds 99.9998%, corresponding to a pass-through factor of 2×10^{-6}.

For modeling purposes, consideration was given to the selection of a nominal pass-through factor derived from specifications (3×10^{-4} and 1×10^{-4}) and the published references described above. A summary of the specifications and findings is provided in Table 4.2.1-1. The pass-through factors from Kowalski, Wang, and Arunkumar are based on empirical data and are the basis for the selection of the modeled pass-through factor of 1×10^{-5}.

Table 4.2.1 1: HEPA Filter Pass Through Factors

Source	Pass Through Factor
HEPA Definition	3.0×10^{-4}
DHS Specification	1.0×10^{-4}
Kowalski	3.0×10^{-5}
Wang	3.0×10^{-5}
Arunkumar (new filter)	1.5×10^{-5}
Arunkumar (loaded)	2.0×10^{-6}

In many HEPA filtration installations, there is some potential for "pinhole" leaks in the filter, or leaks at the filter frame or housing seals (either resulting from manufacturing defects or human errors) that could reduce the efficiency of the filter. The NBAF design incorporates systems to monitor the pressure differential across each HEPA filter and across the entire HEPA caisson as well as to investigate and resolve pressure deviations. The pressure monitoring components and requirements have not yet been specified (in the 65% Design). It is possible that small pressure drops across a pinhole or seal leak will be undetectable by the pressure monitoring system. However, having two HEPA filters in series helps mitigate the risk from these small pressure drops across pinhole or seal leaks but the reduced efficiency of the HEPA filters from such leaks is modeled.

4.2.1.2 BSL-3Ag Necropsy

The necropsy rooms are primarily designed for large animals. Infected animals will be moved through a dirty corridor into a euthanasia vestibule and then into the shared necropsy spaces. A gating system is used to hold the animal during euthanasia and then the overhead-rail hoist system will be used to move the carcass to the desired location in the necropsy suite. Downdraft workstations are used in the necropsy area to assist with the management and removal of procedurally-generated aerosols. The downdraft workstations incorporate an independent HEPA filter housing and the filtered downdraft is ducted to the laboratory room exhaust system. The downdraft workstations will be used when procedures are performed that may generate large aerosol loads or if potentially hazardous chemicals (e.g., fixing reagents) are used. Otherwise, the general room exhaust air handling systems are the same as described for the AHRs except that the necropsy area has an N+2 redundancy.

4.2.1.3 BSL-3E and BSL-3E "Special Procedure" Laboratories

BSL-3 laboratories are designed with different room exhaust air handling requirements. Specifically, the BSL-3E areas include HEPA filtration of the supply air (as do the BSL-3Ag areas) and the room air is exhausted through single HEPA caissons, as depicted in Figure 4.2.1-3. By practice, the BSL-3E areas will

have lower concentrations of aerosolized FMDv than the AHRs or the necropsy suites. Activities that may generate high levels of aerosolized viable biological agents (FMDv) will be conducted in the BSL-3E "Special Procedure" laboratories.

For *in vitro* research activities in the BSL-3E and "Special Procedure" Rooms, BSCs are used as part of the primary engineering controls for aerosols. There are three designs of Class II BSCs: Type A1; Type A2; and Type B2; that are common to the industry. Class II Type A2 and Type B2 BSCs will be used at the NBAF. Properly maintained BSCs, when used in conjunction with good microbiological techniques, provide an effective containment system for safe manipulation of moderate and high-risk microorganisms. Class II Type A2 and Class II Type B2 BSCs will be installed at various locations within BSL-3E laboratories. The NBAF Biosafety Officer, in consultation with senior scientists, will be responsible for the selection of the appropriate type of BSC and the protocols for its use for each experiment or research activity.

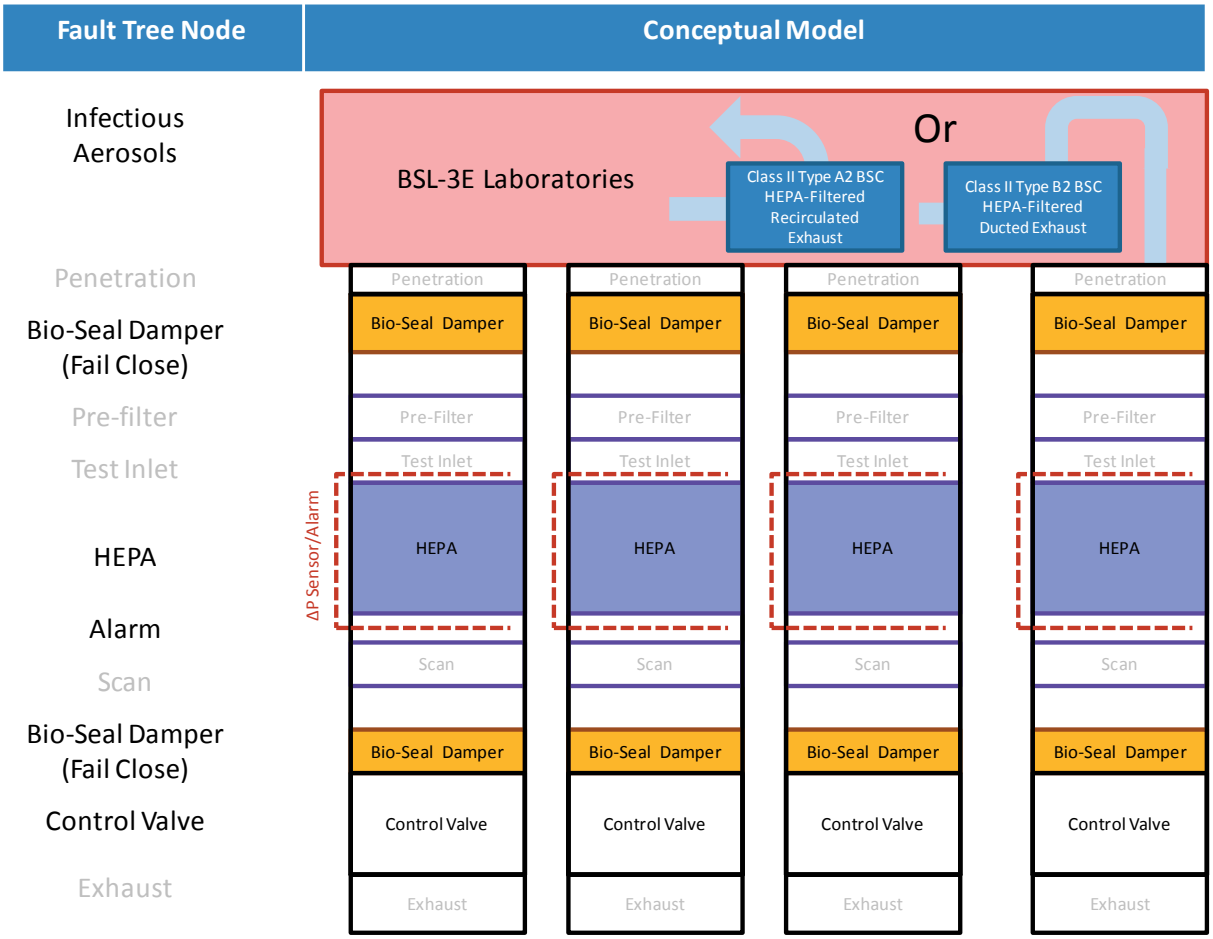


Figure 4.2.1-3: Conceptual Model of BSL-3E Room Exhaust Systems

The BSL-3E "Special Procedure" rooms have ventilation systems similar to those systems used in the BSL-3Ag areas. The "Special Procedure" laboratories are intended to be used for research activities that

are more likely to generate high-risk aerosols and/or large production volumes. The diagram for the room exhaust for the BSL-3E "Special Procedure" laboratories is presented in Figure 4.2.1-4.

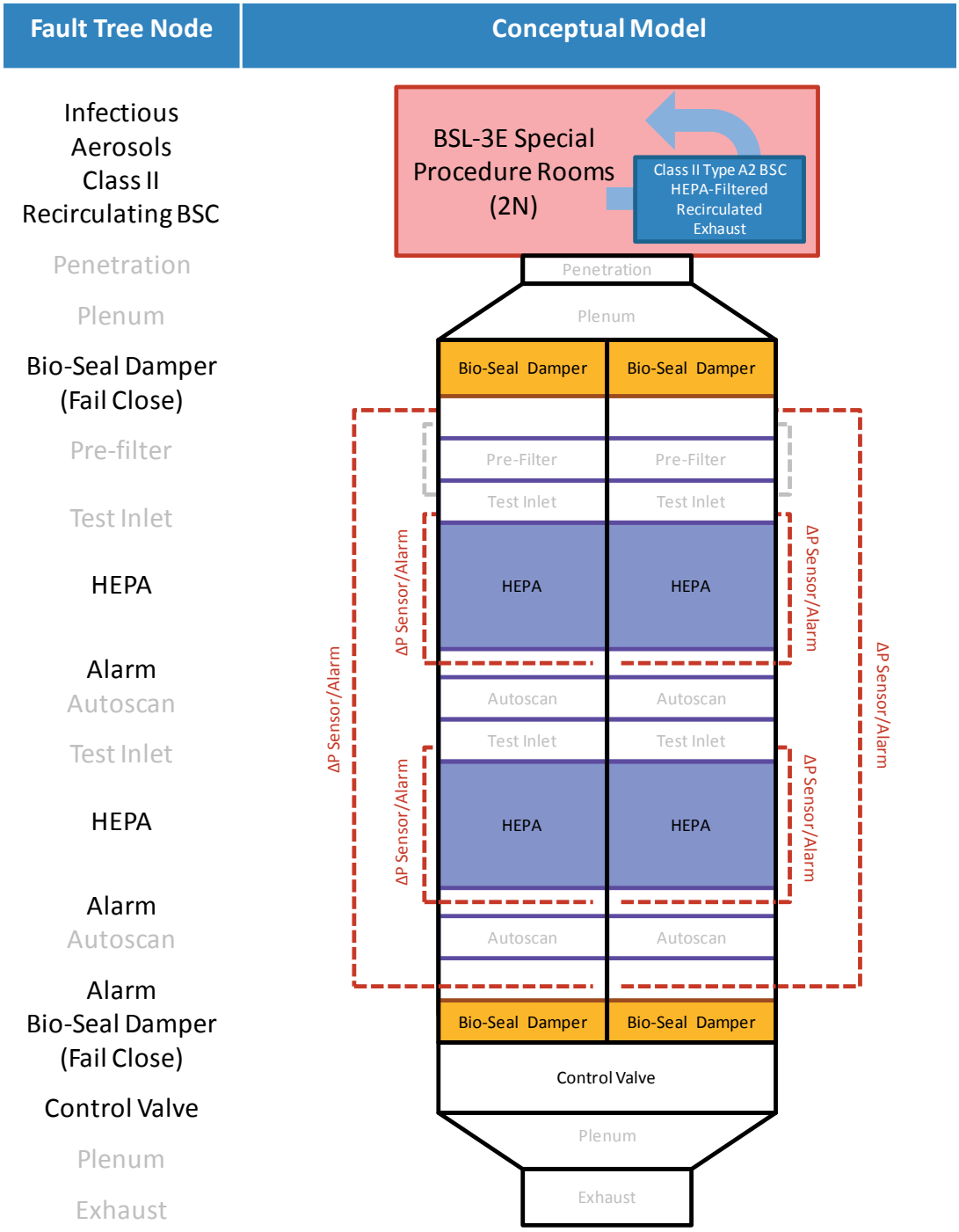


Figure 4.2.1-4: Conceptual Model of BSL-3E "Special Procedure" Room Exhaust Systems

Every HEPA filter in an exhaust process is modeled as having the same efficiency. In all figures presented in this section, the conceptual model is labeled with fault tree nodes to correlate to the calculation of failure rates and source term reduction, as presented in Section 4.5.

4.2.1.4 Non-Containment Areas

The conceptual non-containment areas have no provisions for aerosol controls. If a sample is dropped and all of its layered containers fail, an aerosol fraction of the sample may be released. This aerosol fraction is not controlled by any NBAF system or standard practices and will be modeled with the aerosol fate and transport modeling system.

4.2.2 Solid Waste

During the performance of an experiment, solid waste will be generated and articles will become contaminated. At the NBAF, the safe removal of waste from the containment areas is accomplished by engineered systems and practices that have been validated in many facilities and have been successfully employed for several years. Pass-through autoclaves are used to sterilize compatible materials before removal from containment areas at the NBAF. By design, all solid waste materials leaving containment will be autoclaved twice and then incinerated. (The double-autoclaving procedure is a logistical-driven activity based on facility design; waste materials can only be removed from containment by passing through two autoclaves.) Reusable laundry is autoclaved once before being laundered (within the BSL-3E area) and the laundry water is discharged to the EDS. Non-waste materials, such as equipment, samples, and personal effects are disinfected by other mechanisms that include disinfectant wipedowns, dunk tanks, water and soap showers, gaseous decontamination, and/or gamma irradiation, as appropriate, and these are discussed in the transference section (Section 4.2.4). The solid waste pathway is discussed for each originating location in the following subsections. As a majority of these techniques are used in all originating locations, the descriptions of the modeled mitigation (design and operational) are discussed as related to the first type of originating location – the BSL-3Ag AHRs.

4.2.2.1 BSL-3Ag Animal Holding Rooms

The (non-animal) solid waste generated in the BSL-3Ag AHRs is collected and containerized in the AHR. The modeled conceptual illustration of solid waste and contaminated materials handling for the BSL-3Ag AHRs is presented in Figure 4.2.2-1. In accordance with anticipated procedures, the waste container is moved out of the AHR via the door to the dirty corridor and is transported to the end of the corridor where there is a pass-through autoclave. The pass-through autoclaves from the BSL-3Ag areas terminate in BSL-3E containment spaces. (It is important to note that the solid fraction of animal waste is disposed of by the liquid EDS.) Dirty laundry is collected in a dirty hamper and then moved along the dirty corridor to a pass-through autoclave where it is processed into the BSL-3E space for laundering.

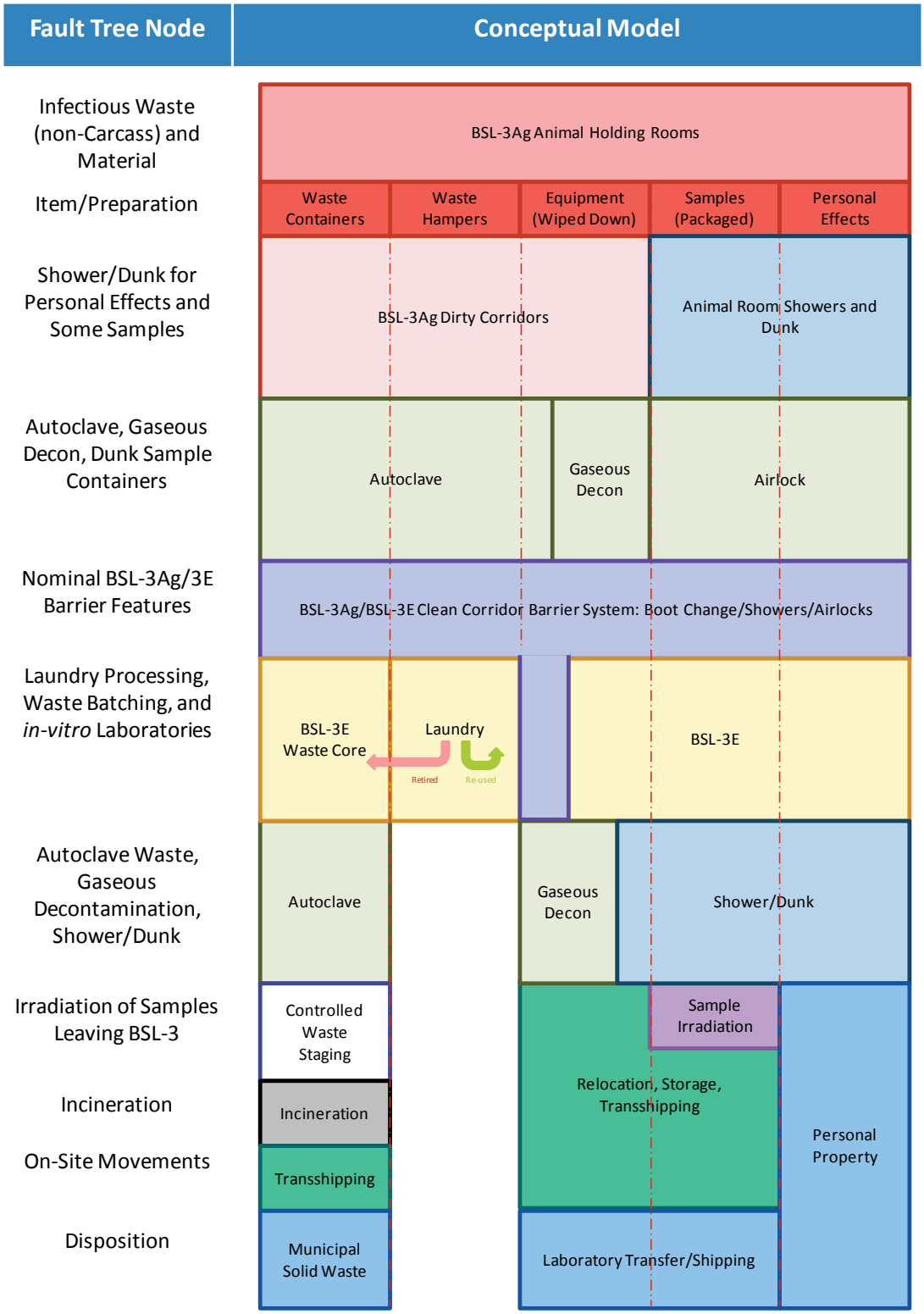


Figure 4.2.2-1: Conceptual Diagram for Solid Waste and Removal of Other Items from BSL-3Ag AHRs

Efficiency of Autoclaves

Steam and high pressure have been used to sterilize materials for many years. Modern autoclaves are capable of accommodating many different sizes and shapes of materials while providing effective sterilization when used correctly. With appropriate pressure, temperature, steam, and exposure time, practically any virus material can be neutralized in an autoclave. The NBAF 65% Design provides preliminary procurement specifications for the autoclaves that will be used at the NBAF [GMP-3, 2011]. NBAF autoclaves will incorporate biological seals, door interlocks, and other safety features to ensure effective sterilization. Periodic testing of the system helps to ensure that the instrument is calibrated and operating in accordance with specifications. Autoclaves will be routinely validated against microbial spore challenges, and additional testing will be performed by OEM or OEM-authorized technicians. Small, medium-sized, and bulk pass-through autoclaves are used at the NBAF to satisfy many of the sterilization needs. Specific protocol development and methods validation must be performed to determine the efficiency of the installed NBAF autoclaves based on the types of materials used and sterility objectives. Walker et al. evaluated high temperature/high pressure sterilization methods against FMDv in infected milk [1984]. Walker et al. demonstrated that while FMDv is heat resistant in this matrix (and other matrices), a time and temperature curve could be established to neutralize the virus. However, the efficiency demonstration of virus neutralization is limited by the initial titer. The initial FMDv titer levels were only 6.3×10^{6} PFU/mL (plaque forming units per mL). In other research, Lewis developed logarithmic reduction constants (D-values) to model the neutralization of microbial activity at fixed temperature and pressure conditions [2002]. Other references provide similar results and limitations on the efficacy of the autoclave but there is limited data on the efficiency with high initial titers. Thus, the Updated SSRA uses the most representative value of autoclave efficiency of 99.9999%, which results in a reduction factor of 10^{-6}.

Efficiency of Incineration

NBAF waste management incorporates the use of redundant self-contained medical waste incineration systems that are capable of processing up to 400 pounds/hour. Each incinerator will have at least two combustion chambers: the primary chamber shall be capable of maintaining a set point of 1600 °F and the secondary chamber must be capable of maintaining 1800 °F. The ash removal system is automated and facilitates continuous operations, if needed. Per the 65% Design, the projected load for an average week (approximately 9,000 pounds consisting of approximately 2,400 pounds of dried bone meal and 6,600 pounds of biohazardous red bag waste) can be processed in less than four 8-hour shifts. The Environmental Protection Agency (EPA) tested the reduction of endospore counts (*B. anthracis*) and reported a five log reduction in viable spore counts after incineration [Wood et al., 2004]. However, this research included some experimental limitations that were noted in the report. Biological testing of a laboratory pathological waste incinerator at the Australian Animal Health Laboratory in Australia produced extraordinary results [Le Blanc Smith et al., 2002]. Using another biological indicator (*Escherichia coli* K12), a reduction of $10^{8.39}$ PFU of bacteriophage was measured from the processes in the primary and secondary chamber and an additional $10^{7.65}$ reduction was determined to occur in the stack. The total reduction factor was $10^{16.04}$ PFU. The reduction factors calculated by Le Blanc Smith are

very useful, but may not be representative of the lethality (i.e., removal factor) of incineration for FMDv. In Le Blanc Smith's research, the indicator was sprayed in the primary chamber – a form of pathogen introduction most conducive to high kill rates. Given the large range of incineration efficiencies gleaned from the literature, a representative reduction factor of 10^{-9} is used in the Updated SSRA.

4.2.2.2 BSL-3Ag Necropsy

The solid waste generated in the BSL-3Ag necropsy is similarly collected and containerized within the suite. The modeled conceptual illustration of solid waste and contaminated materials handling for the BSL-3Ag necropsies is presented in Figure 4.2.2-2. All of the mitigation design and practices for the solid waste and equipment pathway are similar to those discussed for the AHRs. However, the necropsy has an additional solid waste removal mechanism – the tissue autoclave. The two (N+1 redundancy) tissue autoclaves comprise a processing vessel that can accommodate up to six 500-pound carcasses (3,000 pounds total) per cycle. Alternatively, a vessel can receive and process a single 1,200-pound whole animal carcass. Larger carcasses, if any, will have to be sectioned. The systems are capable of heating the contents to 302 °F (~150 °C) and macerating the contents during the decontamination cycle. After the decontamination cycle, excess liquids will be boiled off, vapors cooled to 140 °F (~60 °C), collected, and discharged to the EDS and vented via a double HEPA filtration system, leaving behind a semi-solid that is containerized and incinerated on-site. The principals of pathogen neutralization used in the tissue autoclave are the same as those of more traditional autoclaves: high temperature, high pressure, liquid content, and long exposure times combined with mechanical agitation of the contents. Thus, the modeled reduction factor of pathogen destruction for the tissue autoclave is also 10^{-6}.

In addition to the dual pressure and dual temperature transmitters built-into the NBAF tissue autoclave system, the performance of each tissue autoclave run will be verified using a redundant, orthogonal indicator, such as a biological indicator or independent temperature/pressure indictor (the specific indicator type is to be determined) prior to release of the contents to the incinerator or the EDS. The tissue autoclave system outlined in the 65% Design includes a biotest drywell with removable rod and adjustable basket assembly that will accommodate a biological test or other performance indicator. If the performance of the tissue autoclave is not verified, the contents will be subject to another round of tissue autoclave decontamination and verification. This redundant tissue autoclave system verification provides an additional layer of fault protection with a systems failure rate of 1×10^{-5}.

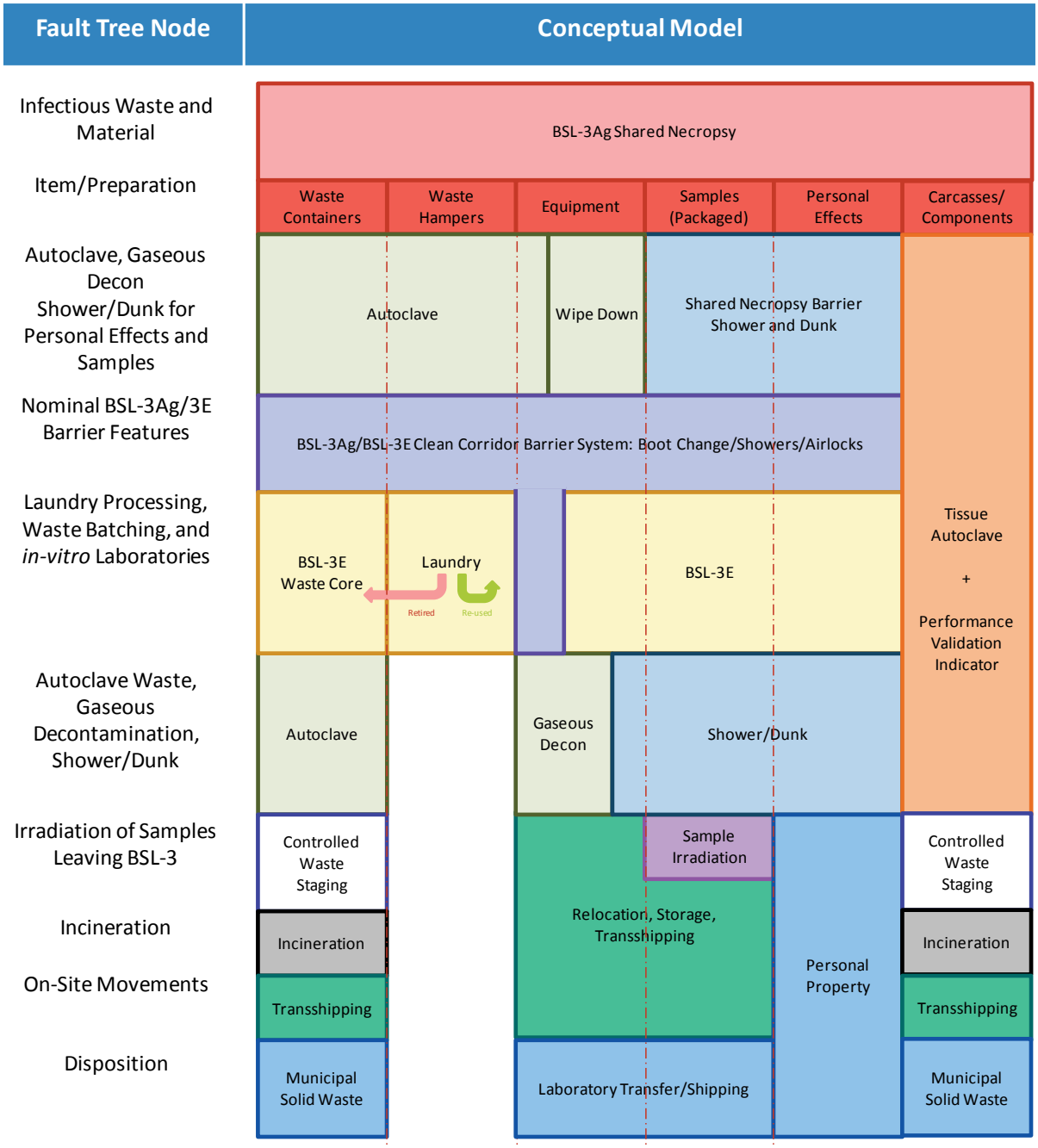


Figure 4.2.2-2: Conceptual Diagram for Solid Waste and Removal of Other Items from BSL-3Ag Necropsy

4.2.2.3 BSL-3E and BSL-3E "Special Procedure" Laboratories

The conceptual models for the solid waste removal pathways for the BSL-3E and BSL-3E "Special Procedure" laboratories are depicted in Figures 4.2.2-3 and 4.2.2-4, respectively. The BSL-3E laboratories and BSL-3E "Special Procedure" laboratories use the same mitigation strategies for the treatment of solid waste and potentially contaminated equipment.

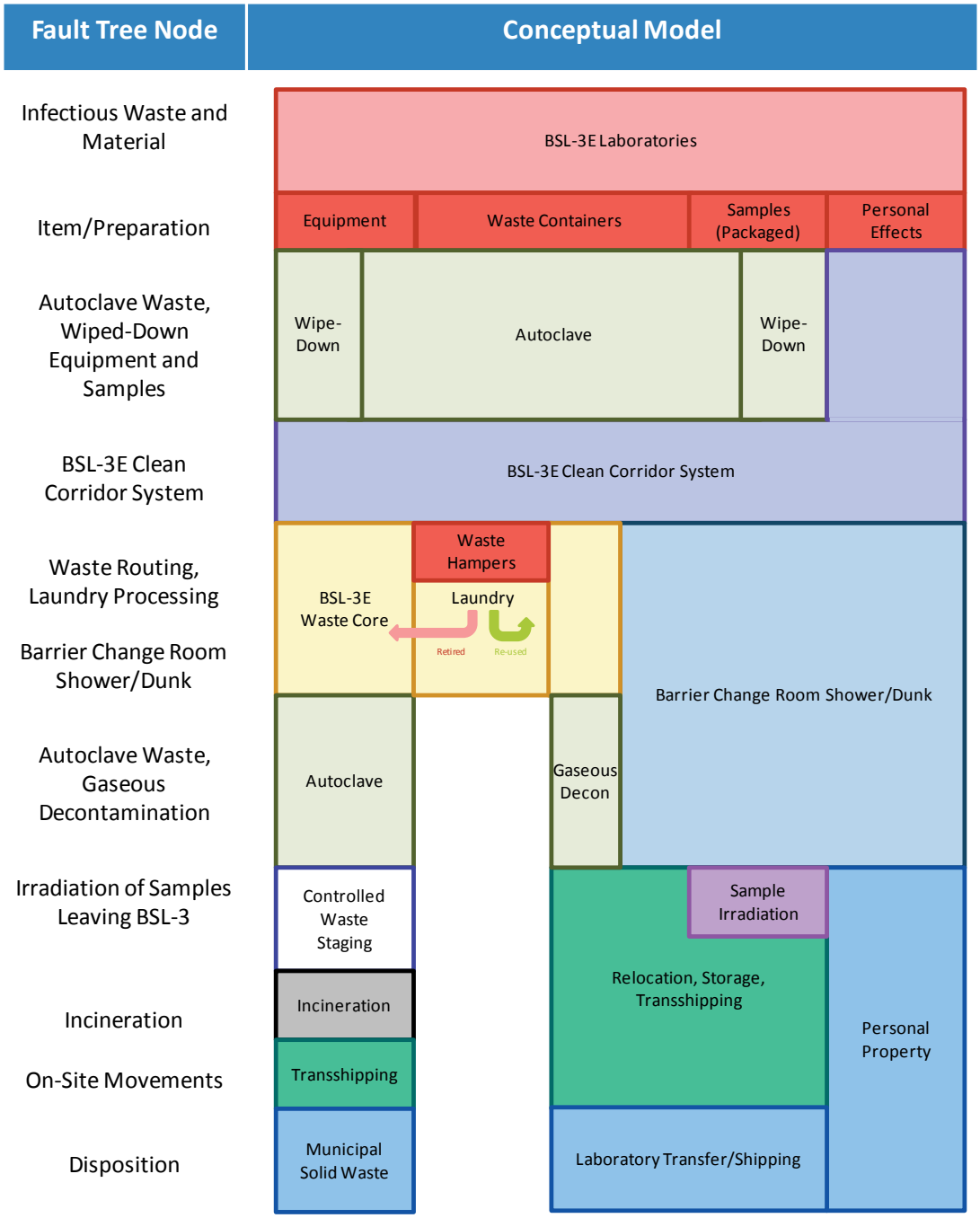


Figure 4.2.2-3: Conceptual Diagram for Solid Waste and Removal of Other Items from BSL-3E

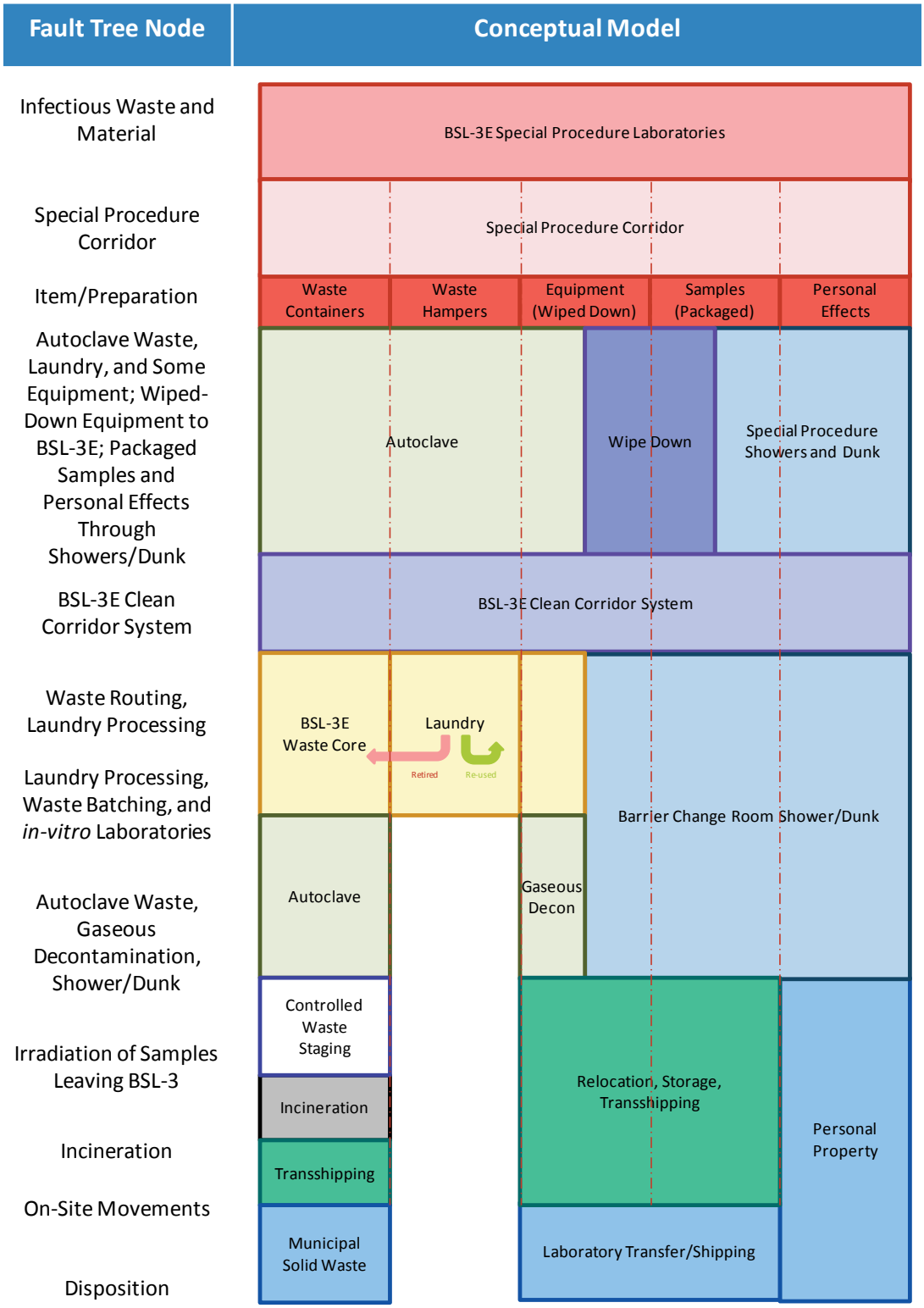


Figure 4.2.2-4: Conceptual Diagram for Solid Waste and Removal of Other Items from BSL-3E "Special Procedure" Laboratories

4.2.3 Liquid Waste

The NBAF's operational practices will require that liquids disposed through the drains within the containment laboratories be decontaminated by a validated method before being discharged and released from the NBAF. The EDS provides gravity-based drainage from each of the originating locations – the drainage piping is sized appropriately for the anticipated waste streams and components. The mode of initial disinfection depends on the originating location – it is different for the AHRs, the necropsy suite, and the BSL-3E laboratories. The EDS comprises eleven cook tanks – eight cook tanks for the BSL-3Ag/3E areas and three for the BSL-4 areas (N+1). The redundant tank for the BSL-4 area can be used to provide redundant capacity for the BSL-3Ag/E areas if an anomalous condition requires its use. However, BSL-3E/Ag and BSL-4 liquid effluents will not be combined in a cook tank. Each cook tank has a minimum capacity of 7,500 gallons and is capable of heating (under pressure) the liquid effluent up to 270 °F (~132 °C). The contents of the cook tanks are continuously agitated. Tanks should be greater than 50% full during the treatment process. Multiple process alarms provide indications to the control system and operators if any system failure or anomaly is detected during the process. The NBAF 65% Design provides for a readily-accessible pipe inspection area in the basement level beneath all of the containment areas that feed the EDS [NDP, 2011]. The pipe inspection areas facilitate periodic visual inspections and incorporate automated leak detection systems that are used to alert staff if a leak in the piping is detected.

The conceptualized and modeled liquid waste flow for the originating locations in the containment areas is provided in Figure 4.2.3-1. All liquid effluent, including shower drainage, from the containment areas is processed through the EDS. The barrier change room (showers and restrooms), laundry, and other restrooms in the containment area are all serviced by the decontamination system. The potential introduction of FMDv from containment restroom sinks, barrier showers, BSL-3Ag showers, and laundry facilities is mitigated by some form of disinfection at the source and is also treated with other potentially infectious waste in the EDS. Thus, the Updated SSRA uses the same originating locations as those used in the SSRA, modeling the potential FMDv contributions from major sources in these locations: BSL-3Ag AHRs, BSL-3Ag necropsy, and the BSL-3E and BSL-3E "Special Procedure" laboratories.

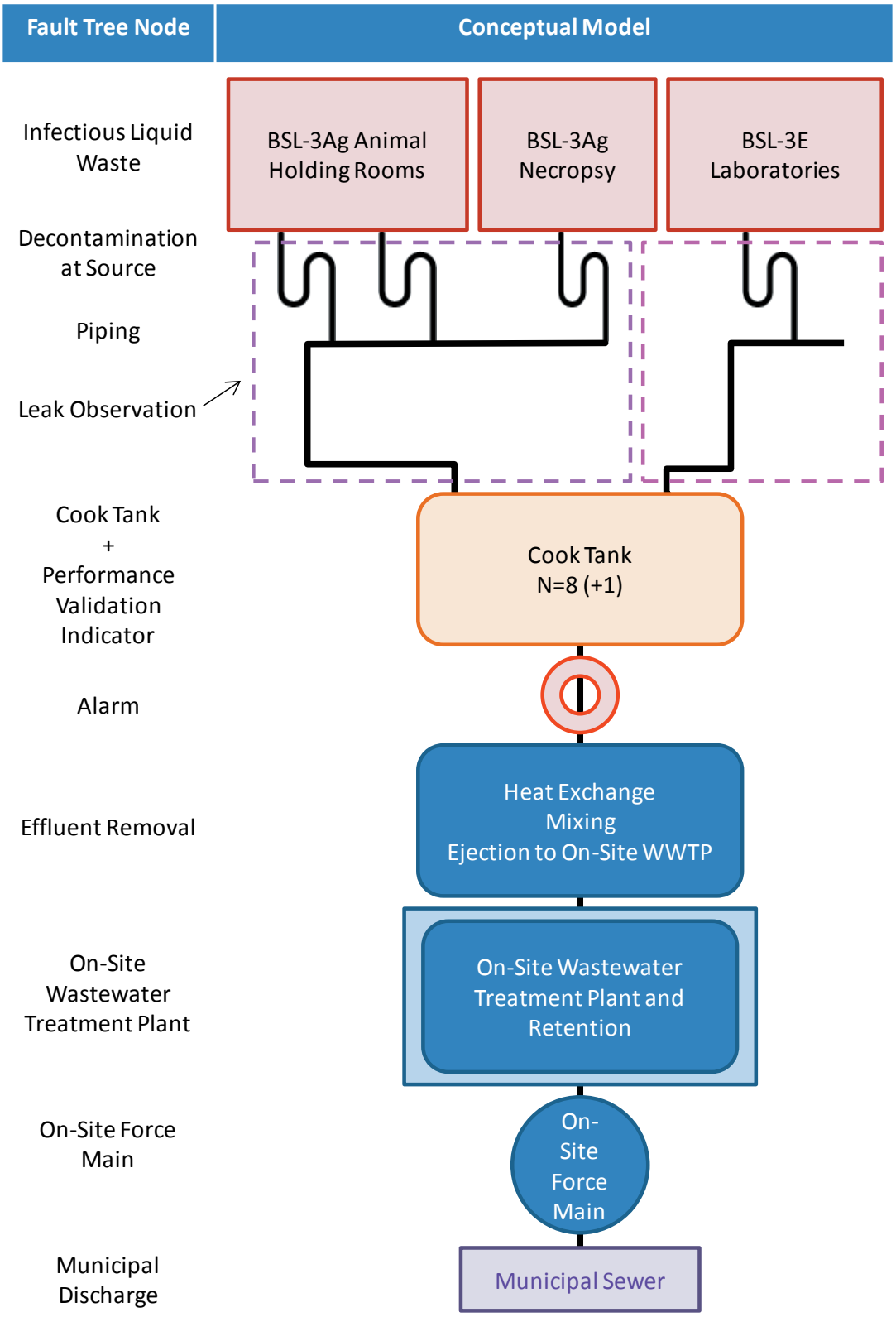


Figure 4.2.3-1: Conceptual Diagram for Liquid Effluent Collection and Treatment for All Originating Locations in Containment

4.2.3.1 BSL-3Ag Animal Holding Rooms

The AHR floors are equipped with grated drains for animal waste and other liquid wastes. The NBAF Biosafety Officer, in consultation with the facility animal manager and attending veterinarian, will determine the most appropriate practices for the addition of disinfectants (selection of chemical disinfectant, concentration/quantity, and frequency of addition) to the animal room floor drains, prior to the liquid waste being drained to the EDS cook tanks. When disinfectant is added to the drains, it will act on both portions of the floor drain and on the trapped liquid effluent. However, as additional animal waste and other liquid wastes are added to the drain, the disinfectant in the trap is diluted (as the trap drains) but residual disinfectant action may continue. As the trap drains, the liquid waste effluent along with any remaining active disinfectant is discharged to a designated cook tank where it is mixed with liquid effluent from other AHRs, the necropsy suite, and the BSL-3E and "Special Procedure" laboratories.

The NBAF Biosafety Officer in conjunction with the facility animal manager and attending veterinarian will also determine the procedures and frequencies for AHR washdowns. The purpose of the washdowns is to remove animal waste products from the walls, floors, and animals in order to: 1) provide a hygienic environment for the research animals and researchers; and 2) satisfy research objectives. AHR washdowns may occur twice per day (modeled as occurring approximately every 12 hours), but the timing and extent of the washdowns will change based on the needs of the animals, researchers, and regulatory requirements. Specific procedures will be developed that will accomplish the washdown objectives while minimizing (to the extent possible) the creation of additional aerosols. Low-volume and low-pressure systems will be used as much as possible. The washdown may be preceded by priming the floor drains with disinfectant. Based on the timing of these events, the Biosafety Officer may elect to prime the traps, perform the AHR washdowns, and then re-prime the traps for maximum disinfectant benefit. While not always part of the protocol, it is possible some experiments will require the spray application of a disinfectant to the walls and floors prior to a water washdown. All other drains (including showers) in the BSL-3Ag AHR areas drain into the cook tanks as well.

The upper end of the range of disinfectant efficiency is bounded by the maximum efficiency (99.9999%) or the modeled nominal value of 99.999% (see Section 4.2.4 for chemical disinfection efficiencies). If it is assumed that each deep seal P-trap (estimated volume 1-2 L) is primed with a high concentration of disinfectant, the liquid fraction of animal manure (depending on species, number of animals, and room type) will likely dilute the trap volume – no data is available on the decontamination efficiency for diluted disinfectant volumes and its ability to work on mixed waste in the trap. In addition, residual disinfection of aggregated AHR effluent in the cook tank should be considered. Empirical data will eventually need to be collected to accurately characterize the efficiency of disinfectants used for NBAF-specific conditions. For the purpose of modeling, a representative efficiency of 90% was used. In terms of the disinfectant reduction factor, these modeling assumptions equate to 1×10^{-1}.

4.2.3.2 BSL-3Ag Necropsy

The BSL-3Ag necropsy areas only produce a fraction of the animal waste products that are generated in the AHRs. Animals are euthanized on entry to the necropsy area and relatively small amounts of animal waste products are generated during this process. However, the floor drain in the necropsy areas will drain significant quantities of infected blood, blood products, and other contaminated animal fluids and tissue fragments. The necropsy tables are equipped with sinks and drain pans that collect most of the liquids and excised tissue that are not collected for disposal in the tissue digesters. Based on activity levels and research objectives, washdowns will also be performed in the necropsy area with all liquid waste being discharged to the EDS. In general, the liquid waste effluent in the necropsy area is scheduled or at least more predictable than effluent generated in the AHRs. Thus, the practice of priming the drain traps is likely to be much more effective. It will still be necessary to characterize the effectiveness of disinfection practices with the collection of empirical data, but it can be assumed that the source disinfection rates in the necropsy area are between one and two orders of magnitude more efficient. Thus, the modeled efficiency of the disinfection rates is 99.9%, corresponding to a reduction factor of 1×10^{-3}.

4.2.3.3 BSL-3E and "Special Procedure" Laboratories

The BSL-3E and BSL-3E "Special Procedure" laboratories use significantly less water than the BSL-3Ag areas. Infectious materials will typically be decontaminated through the solid waste pathway (i.e., autoclaves). Other decontamination methods may include chemical and/or physical techniques intended to neutralize or sterilize the virus before it is discharged. In the BSL-3E or BSL-3E "Special Procedure" laboratories, the drain pipes are designed to be plugged and thus are not primed with disinfectant. In the event that liquids are disposed of through the drains in the BSL-3E or BSL-3E "Special Procedure" laboratories (violating protocol), by operational practice, the liquids would have been decontaminated by a validated method. The cook tanks and on-site wastewater treatment facility are modeled as protection systems to decontaminate any infectious material that may be disposed of through these drains prior to any liquids being discharged from the NBAF.

EDS Cook Tank Efficiency

Specifications from the vendor provided in the 65% Design indicate a kill efficiency of 99.9999% (reduction factor of 1×10^{-6}). Given that the mode of treatment and action is similar to that of an autoclave, the modeling in the Updated SSRA uses the same reduction factor of 10^{-6} for a successful effluent decontamination batch. Within the cook tank system designed for the NBAF, temperature and pressure are continually monitored while the cook tank is in heat mode. As a redundant check of the cook tank system, an orthogonal temperature and pressure or biological indicator (the specific type is to be determined) will be included in each cook tank batch. The temperature/pressure or biological indicator performance will be verified after each batch prior to release of its contents to the onsite wastewater pretreatment plant. If the performance is not verified, the contents will be subject to another round of cook tank decontamination and verification. This redundant cook tank system verification provides an additional layer of fault protection with a systems failure rate of 1×10^{-5}.

After decontamination and preliminary cooling, the cook tank(s) are drained to a common header where the treated effluent from multiple tanks may be mixed and sanitary sewer effluent from the non-containment portions of the laboratory is added. It is important to note that all liquid waste from the containment areas is completely treated prior to its discharge from the laboratory building. (The 2007 FMDv release at Pirbright has been attributed to the loss of containment of partially-treated liquid effluent in a transfer pipeline between two buildings [Health and Safety Executive, 2007].) From the laboratory building, the combined liquid waste (treated containment effluent and sanitary sewer waste from non-containment) is pumped to the on-site pretreatment facility.

On-Site Wastewater Pre-Treatment Efficiency and Dilution

When the NBAF is ready for commissioning and operations, wastewater discharged to the municipal sanitary wastewater collection system must satisfy certain City of Manhattan regulations – driven by discharge requirements anticipated with a new National Pollutant Discharge Elimination System (NPDES) permit expected by the city in 2014. Specifically, the pH, temperature, biochemical oxygen demand, total suspended solids, total nitrogen, and phosphorus levels must be within the specifications provided in Table 4.2.3-1.

Table 4.2.3 1: City of Manhattan Sanitary Wastewater Collection System Requirements

Parameter	Acceptable Range
pH	5.5 – 10.5
Temperature	< 104 °F
Biochemical Oxygen Demand	< 300 mg/L
Total Suspended Solids	< 350 mg/L
Total Nitrogen	< 60 mg/L
Phosphorus	< 12 mg/L

Schijven et al. previously examined the (illegal) discharge of FMD-contaminated milk into surface waters and sanitary sewers in the Netherlands [2005]. This report summarized data collected from research on the inactivation rate of FMDv in aqueous matrices. Relying heavily upon the research of Donaldson and Sellers [Donaldson, 1997; Sellers, 1971], Schijven reported that in an aqueous matrix, initial inactivation of FMDv is rapid, but the inactivation rate slows after some period. Schijven concluded that the average inactivation rate of FMDv in liquid manure (39-62 °F) is 4-5 × 10^{-2} log per day. However, given the relatively short duration of the on-site wastewater treatment process and conveyance to the municipal wastewater treatment plant, the natural decay rate (not influenced by the on-site wastewater treatment process) is not likely to be a significant factor in the risk calculations.

Schijven also stated that data on FMDv inactivation by sewage treatment has not been published. In the absence of such data, Schijven used measured decontamination results on enteroviruses from two large sewage treatment plants in the Netherlands which indicated that the concentration of enterovirus is reduced by two orders of magnitude (10^{-2}). Schijven suggested this same removal efficiency could be

applied to FMDv [Hoogenboezem et al., 2001]. A 2005 report indicated reductions between raw sewage and treated sewage of 1-2 orders of magnitude for noroviruses, rotaviruses, reoviruses, and enteroviruses [Lodder and de Roda Husman, 2005]. Irving calculated enterovirus reduction of 93% by wastewater treatment – a reduction of approximately 1 order of magnitude [Irving and Smith, 1981]. Thus, for the purposes of risk modeling in the Updated SSRA, the wastewater treatment process is assumed to provide a 1 order of magnitude reduction factor (10^{-1}).

In addition to potentially providing some virus reduction, the on-site wastewater treatment plant is also the dilution point for the laboratory-generated waste effluent. The *Re-Baseline On-Site Wastewater Analysis* [NDP, 2010] describes how wastewater discharged from the laboratory building, after going through the complete pathogen neutralization process, becomes the influent for the on-site treatment system. From the laboratory building, the average total daily flow and average maximum daily flow are 37,099 gpd and 54,220 gpd, respectively [NDP, 2011]. It is estimated that 10% of this volume is from non-containment contributions. Effluent from the Central Utility Plant, the TF, and the Water Treatment office space contribute an estimated additional 10% to the treatment system influent.

The on-site wastewater pre-treatment facility incorporates a waste holding tank that permits continuing laboratory operations even if there is a temporary interruption of services at the municipal sewer discharge point. After pretreatment, the remaining liquid fraction of the waste stream is drained (gravity) to an on-site lift station that also collects sanitary sewer effluent from other (non-containment) NBAF locations. The NBAF lift station ejects the aggregated NBAF effluent to the City of Manhattan sewer system. From the above, it is estimated that 85% of the discharge into the Manhattan sanitary sewer system originated from containment sources.

4.2.4 Transference

The NAS SSRA Committee suggested the use of four pathways in the risk assessment process: 1) aerosols; 2) solid waste; 3) liquid waste and sanitary wastewater; and 4) fomites or hosts including workers, equipment, vectors, and dead or living animals [NRC, 2010]. The fourth pathway is referred to as “transference” in the Updated SSRA. As concluded in the SSRA and confirmed in Finding 9 of the NAS SSRA Committee, human error is the most likely cause of an accidental pathogen release. However, it is important to note that not all human error considerations are factored into the modeled transference events. The failure probabilities and estimates used in modeling the events from other pathways include contributions from human error and mechanical/material failures. The transference events are intended to model the transfer of viable FMDv from the NBAF to a susceptible animal by mechanisms other than those modeled for the aerosol, solid waste, and liquid waste pathways.

A conceptual model of the transference events with containment staff (up to the “loss of containment”) is depicted in Figure 4.2.4-1. The conceptual model of transference events with fomites (e.g., non-waste materials and equipment) is shown in Figure 4.2.2-1.

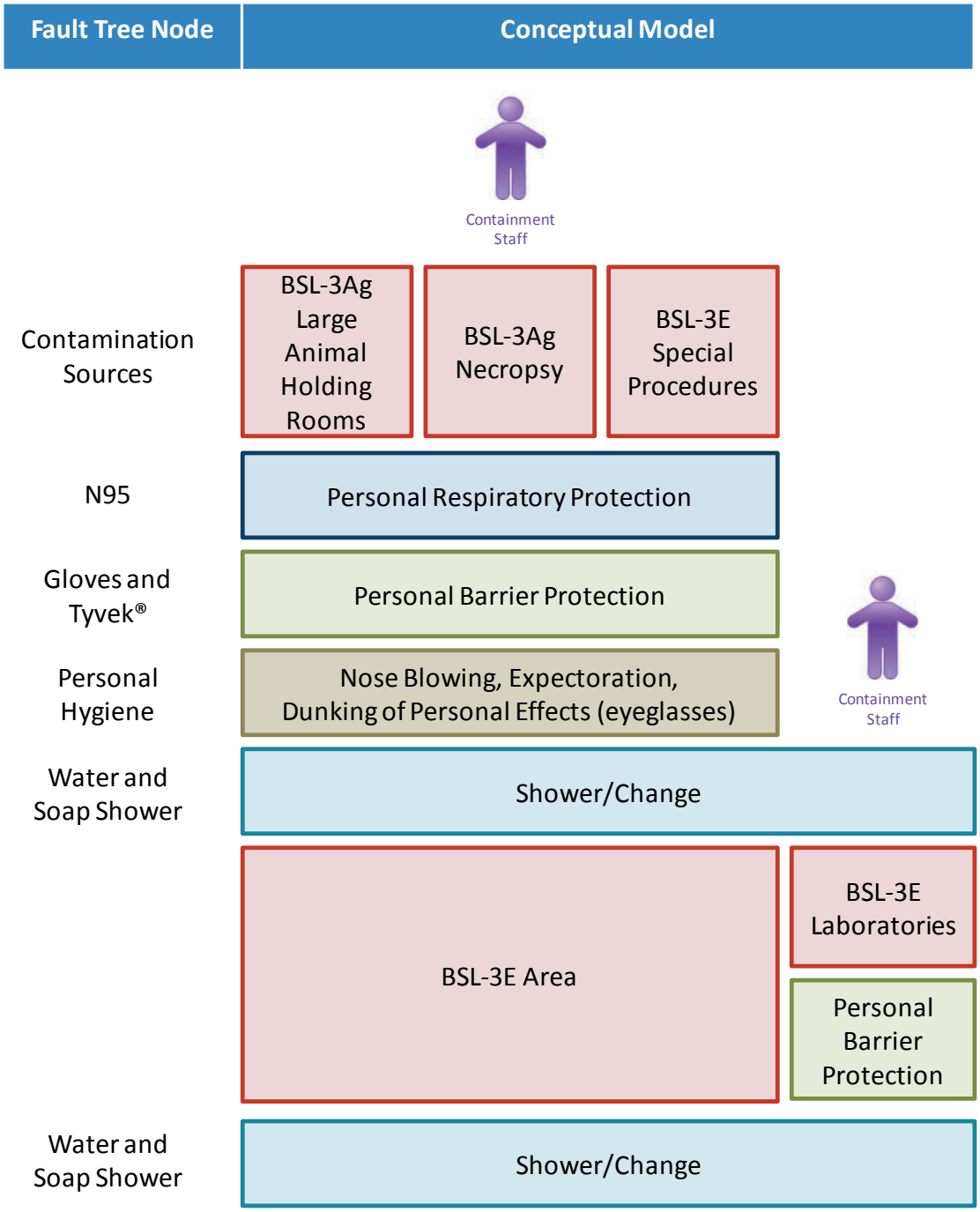


Figure 4.2.4-1: Conceptual Model of Transference Pathway

There are a virtually unlimited number of accident event sequences that could be theorized and modeled to represent the risk of containment loss via the transference pathway. However, large uncertainties and other practical limitations make it necessary to identify a manageable number of modeled transference events that are most representative of credible accident sequences. The set of modeled transference events should incorporate site-specific data related to the laboratory's proximity to Kansas State University (K-State), the city of Manhattan, other animal research facilities, veterinary

facilities, and rural agricultural livestock areas. Additional discussion on the fate and transport associated with these events is provided in Section 5. The NAS SSRA Committee specifically commented on the proximity of the K-State University football stadium and the potential for FMDv being carried as fomites on vehicle tires, etc., as well as zoonotic pathogens. Brief discussions on the significance of the stadium's proximity to the assessed risk are included in Section 5 and Section 6.

Two modes of transference were modeled: respiratory and contact. The contact events involve both contact between infectious material and fomites as well as infectious material and workers of the NBAF. Respiratory transference events are mitigated by the use of respiratory protection and nose blows. Contact events between infectious material and the workers are mitigated by the use of PPE and body showers. Fomites (e.g., equipment and other materials) are decontaminated as appropriate. If autoclaving is not an option, the equipment or material will be wiped down with a chemical disinfectant and may be processed in a gaseous decontamination chamber. The gaseous decontamination chamber also terminates in the BSL-3E area (see Figure 4.2.2-1 for the conceptual model). Samples and personal effects are retained by the personnel exiting the AHR through the dirty anteroom. Surface disinfection of these items is accomplished by immersion in a disinfection solution or wipedown.

Respiratory Transference

To model the average amount of FMDv that could be inhaled into the upper respiratory tract of a researcher exposed to aerosolized FMDv, data from Sellers et al. was used to calculate the percent FMDv transferred to human nasal passages [Sellers and Parker, 1969; Sellers et al., 1970]. Sellers et al. measured the airborne excretion of FMDv from cattle, pigs, and sheep in addition to measuring the amount of viable FMDv in the nostrils of the animal handlers [Sellers et al., 1970]. In this study, a total of six experiments were performed in which two FMDv strains were used and three animal species were tested (cattle, sheep, and pigs). For each of these six experiments, the ID_{50} (infectious dose for infections in 50% of the animals) of FMD virus from air samples (samples collected for 60 minutes at 1,000 L/min) was measured and for the same time periods as the ID_{50} of FMDv measured in nasal swabs of the animal handlers. The mean FMDv levels in the air samplers was 4.4 ± 1.4 (log ID_{50}) and the mean FMDv levels in the nasal swabs was 2.9 ± 1.2 (log ID_{50}). The data from this work is presented in Table 4.2.4-1. In terms of percent ratio of FMDv measured in the nasal swabs to FMDv in the air samples, the mean was 5.7 ± 7.2%. This transfer percentage of 5.7% was used to calculate the amount of FMDv available for fate and transport modeling in the transference events. It should be noted, as discussed in more detail in Section 5 on Fate and Transport, that Sellers et al. also reported that virus titers in the nasal passages decreased by 1.3–3 logs within five hours after exposure [1970].

Table 4.2.4 1: FMD virus levels in air surrounding infected animals and in nasal passages of animal handlers.

(Data from Sellers et al. 1970.)

Species	Number of Animals	Strain	Hours Post Infection	FMDv (log ID_{50})		FMDv (ID_{50})		Percent FMDv in Nasal Swabs (%)
				Air	Nasal	Air	Nasal	
Bovine	2	O1 Swiss	70	6.3	4.1	2.00×10^6	1.26×10^4	0.63
Bovine	2	A5	46	5.6	3.7	3.98×10^5	5.01×10^3	1.26
Ovine	8	O2	22	3.0	1.6	1.00×10^3	3.98×10^1	3.98
Ovine	8	C Noville	22	4.6	3.9	3.98×10^4	7.94×10^3	19.95
Porcine	8	A5	46	3.0	1.5	1.00×10^3	3.16×10^1	3.16
Porcine	8	C Noville	70	3.6	2.3	3.98×10^3	2.00×10^2	5.01
							Average	**5.7**
							Std. Dev.	7.2

While a mean transference of 5.7% was measured by Sellers et al., Wright et al. also calculated the frequency of nasal swab samples in researchers and animal technicians which were positive for infectious FMDv [Wright et al., 2010]. For any nasal swab sample that was positive for viral RNA by RT-PCR, these samples were subsequently analyzed by virus isolation. For the animal technicians who were exposed to the animals intermittently over eight hours, all 11 samples were positive for viral RNA, but only one of these 11 samples was positive for viable FMDv. The frequency of positive infectious FMDv was 9.1% for animal technicians. For the researchers in the same experiment, 12/17 nasal swab samples were positive for viral RNA (70.6%) but only 2 out of 17 samples were positive for infectious FMDv (11.8%). These results indicate that approximately 10.7% of individuals handling infected animals (pigs, sheep, and cattle) become human vectors for viable FMDv. However, as the amount of viable material in the air was not quantified in this study, as a conservative estimate, the 5.7% transfer efficiency of aerosolized FMDv is used in this assessment.

Contact Transference

Upon physical contact between a surface, spill, or material contaminated with viable FMDv, a certain percentage will be transferred to the recipient surface or material. The contaminated fomite or individual might act as a vehicle to transfer viable FMDv to animals outside of the NBAF if not appropriately decontaminated. To model such contact transference pathways, a single transfer percentage was determined. The transfer efficiency in a contact event varies greatly depending on the conditions and parameters of the contact including: the physical state of the donor material (wet or dry); contact duration; contact pressure; friction applied during contact; and the time between deposition and contact. Ansari et al. measured transfer efficiencies of approximately 16% for human rotavirus for a dry, 10-second contact between a stainless steel disc and fingerpad [1988]. Mbithi et al. calculated similar transfer efficiencies for hepatitis A virus (22%) between a steel disc and a fingerpad under dry conditions [1992]. In a more recent study, Knobben et al. evaluated transfer efficiencies of bacteria under dry and moist conditions between fomites and a glove and obtained an average

efficiency of 42% for moist conditions without friction applied [2007]. Similarly, Julian et al. studied virus transfers for MS2 and bacteriophages for a dry, 10-second contact, and determined 21% to 39% of the deposited material was transferred [Julian et al., 2010]. Cohen et al. characterized residue transfer using a fluorescent tracer under a variety of contact conditions and determined that higher transfer efficiencies were obtained with greater pressure and with moist conditions, with efficiencies ranging from 3% to 14% under all conditions [2005]. In earlier work, Reed also determined that transfer efficiencies of rhinovirus were greater with damp material, ranging from 0.6% to 49% (average of 22%) [1975]. Based on these data, for the transference events that will typically involve contact with liquid spills or moist, contaminated material, a conservative transfer efficiency of 40% is used in the Updated SSRA.

For the data presented in the above studies, the contact area between the donor and recipient surfaces encompassed the complete mass of the deposited material. However, in the event of a spill, the hand touching the spill will only be in contact with a fraction of the spill surface area. In order to account for the difference in surface areas of the donor surface (e.g., a spill) and the recipient surface (e.g., a researcher's palm), the transfer efficiencies were applied to the ratio of the contact surface area to donor surface area. For example, a 100 cm^2 donor surface has a total contamination of 1,000 PFU (i.e., 10 PFU/cm^2) and a finger touches the surface with a contact surface area of 2.5 cm^2. If the transfer efficiency is 40%, then the amount of material transferred from the surface to the hand would be equal to 10 PFU, for a net transfer efficiency of 1% (40% × 2.5 cm^2 / 100 cm^2). To calculate the amount transferred, a spill of a known volume was modeled as a thin film (thickness of 1 mm) to obtain a volume and surface area. Using the average concentration of FMDv in the transference scenarios based on the originating location and source terms, the total amount of material in the spill was calculated. The transfer was presumed to yield a thin film of the same thickness on the donor surface, to allow for a ratio of surface areas to be used in the calculation. (The shape of the donor and recipient surfaces was not accounted for in these calculations.) For cases in which the recipient surface area is less than the donor surface area, the formulas used for the transference events are listed in Eq. 4.2.4-1 and Eq. 4.2.4-2:

$$\text{Amount Transferred} = \text{Transfer Efficiency} \times \frac{\text{Recipient Surface Area (cm}^2\text{)}}{\text{Donor Surface Area (cm}^2\text{)}} \times \text{Deposited Amount (PFU)}$$

Equation 4.2.4-1

where

$$\text{Deposited Amount} = \text{Average Concentration (PFU/mL)} \times [\text{Donor Surface Area (cm}^2) \times \text{Film Thickness (cm)}$$ Equation 4.2.4-2

For cases in which the donor surface area is less than the recipient surface area, Eq. 4.2.4-3 is used instead of 4.2.4-1, as all infectious material is assumed to be in contact between the donor and the recipient.

$$\text{Amount Transferred} = \text{Transfer Efficiency} \times \text{Deposited Amount (PFU)}$$ Equation 4.2.4-3

The donor surfaces included a complete hand, the palm including fingers, a complete foot, a fraction of the body surface, and a fomite. An average hand (437 cm^2) and foot surface area (557 cm^2) was calculated using the average heights and weights of a U.S. male and female and the equations presented by Yu et al. [Yu et al., 2008, 2010; Yu and Tu, 2009]. Palm surface areas including the fingers were calculated by taking 45% of the total hand surface area. The values for male and female were averaged together and then used as the recipient surface areas. For a fraction of the body, a 20 cm × 20 cm region (400 cm^2) was used in the contact transference modeling calculations.

4.2.4.1 BSL-3Ag Animal Holding Rooms

BSL-3Ag AHRs are primary containment vessels. During periods of animal infection, people and objects are potentially exposed to FMDv in aerosols, solid waste, and liquid waste when they are in the AHRs. The AHRs are used as the representative originating location for transference events involving human respiratory contamination and fomites. The mitigation measures that will be used to mitigate respiratory and contact contamination include respiratory protection, PPE barriers (e.g., gloves and Tyvek® suits), room-specific footwear/boots, clothing changes, blowing of the nose, body showers from the AHR to BSL-3E, and the body shower/change upon exiting the BSL-3E. Mitigation measures for fomites include a disinfection procedure (dunk, wipedown, autoclave, or gaseous decontamination) between the BSL-3Ag area and BSL-3E, and a second disinfection procedure on exit from BSL-3E.

Efficiency of Respiratory Protection

In an application of new precautionary measures, DHS has determined that respiratory protection will be used by NBAF personnel (and other persons) that are potentially exposed to research animals that have been inoculated with FMDv, are clinically symptomatic, or are reasonably expected to be infected with FMDv. The specific timing of respiratory protection requirements during an experiment and the type of respiratory protection will be determined by the NBAF Biosafety Officer in conjunction with occupational health and safety, the principal investigator, and the animal facility manager. It is perceived by many of the scientific users of the NBAF that powered air purifying respirators (PAPRs) are too cumbersome and logistically challenging (power requirements, weight, possibility of animal tearing or damaging the breathing tube and causing harm to the animal caretakers or researchers, etc.) to use during activities associated with the research and care of contained large animals. Thus, it is assumed

that the prescribed respiratory protection will be compliant with filtering face pieces (e.g., masks with edge seals) that satisfy NIOSH N95 standards.

In 2006, the Edgewood Chemical Biological Center (ECBC) published an extensive study on respiratory protection efficiency against particulate and biological aerosols [ECBC (CR-085), 2006]. This research studied the effects of high work rates and cyclic flow conditions (breathing) and included cartridge-based products and filtering face pieces such as the MSA Affinity Plus and the Gerson 1730. The most penetrating particle size was determined to be 0.05-0.10 µm for the N95s. NIOSH certification requires testing at a constant flow rate of 85 L/min but during periods of physical exertion and stress, peak inhalation flow rates can increase significantly, especially when considering cyclic respiration. ECBC characterized the range of human (adult) minute tidal volumes to be from 40 L/min to 135 L/min and challenged the protective face pieces with both constant flows and cyclic flows equivalent to the target total rates. No "practical differences" were noted between the filter efficiency of "wet" and "dry" aerosolization methods.

In MS2 phage aerosol challenges (MS2 "wet" aerosols are very near the most penetrating particle size), ECBC reported that both N95 face pieces exceeded NIOSH performance specifications for N95 under constant and cyclic flow conditions, as summarized in Table 4.2.4-2.

Table 4.2.4 2: N95 Penetration Data

Filtering Face Piece	Penetration % from Cyclic Flow Testing Minute Tidal Volume (L/min), mean ± σ			
	85 (Wet)	85 (Dry)	135 (Wet)	135 (Dry)
MSA N95	0.93 ± 0.60	0.022 ± 0.009	1.1 ± 0.61	0.082 ± 0.030
Gerson N95	0.48 ± 0.07	0.60	0.89 ± 0.43	0.075 ± 0.034

For the Updated SSRA, it is assumed that the cyclic flow testing is more representative of the respiration process so the constant flow data were not used. For the cyclic flow, a statistical assessment of these data (both manufacturers, both aerosols, and both minute volumes) yield a median penetration value of 0.5% with the 5th-percentile and 95th-percentile being 0.02% and 1.3% respectively. These values are summarized in Table 4.2.4-3.

Table 4.2.4 3: N95 Penetration Model

Value	Penetration Percentage	Probability of Penetration
Median	0.5%	5.0×10^{-3}
5th Percentile	0.02%	2.0×10^{-4}
95th Percentile	1.3%	1.3×10^{-2}

The corresponding nominal filtration efficiency, used for Updated SSRA modeling purposes, is 99.5%. However, the filtering face pieces also have a relatively high rate of improper fitting which is considered in the probability of failure calculations (Section 4.5).

Efficiency of Nose Blows

Early experiments by Sellers et al. demonstrated that FMDv can be conveyed by human subjects in the nose, throat, and mouth [1970]. Nasal swabs from these individuals contained as many as 10^4 infectious units. After one nose blow, 31.4 ± 11.0% of virus in the nasal cavity remained; 68.6% of the virus was removed by a single blow. After 10 blows, 15.8 ± 14.7% of the virus remained [Sellers et al., 1970]. Anticipated NBAF protocols will require a single blow. Thus, the retention of 31.4% is modeled in the Updated SSRA.

Efficiency of Disinfectants for Wipedown and Dunk Tanks

The effective use of disinfectants is critical to the safe operation of any biocontainment laboratory. The specific disinfectant(s), concentration, and immersion time will be determined based on pathogen and susceptibility study data required by the Biosafety Officer in consultation with senior scientists. These factors include suitability for the pathogen, concentration, application method, contact time, stability, and special procedures or safety precautions [Dvorak, 2008]. The Biosafety Officer will also specify the protocols for the appropriate use of the disinfectant and include instructions on the removal of organic load, temperature, materials, etc. Several commercially-available disinfectants have demonstrated efficacy against FMDv. Virkon®S is a blend of peroxygen compounds and a surfactant that is representative of the types of modern disinfectants that are effective on FMDv. The manufacturer claims Virkon®S kills 99.9999% of FMDv (10^{-6} reduction) and other viruses when used as directed. The CDC publishes guidelines for disinfection and sterilization in healthcare facilities that provide some insight into the effectiveness of various disinfectants on different types of viruses [Rutala, 2008]. Reduction factors are reported in the 10^{-4} to 10^{-5} range for commercially-available decontamination solutions such as glutaraldehyde and chlorine dioxide commonly used in BSL-3 laboratories. However, some disinfectants were noted to completely inactivate viruses like SARS. A list of the efficacies and reduction factors for chlorine dioxide against a variety of biological agents is shown in Table 4.2.4-4 [Taylor and Butler, 1982; Chen and Vaughn, 1990; Zoni et al., 2007].

Table 4.2.4 4: Efficacy of Chlorine Dioxide Disinfectant

Conc.	Organism	Time (min)	pH	Efficacy (%)	Reduction Factor	Reference
6 µM	coliphage f2	2.0	9	0.999998	2.00×10^{-6}	Taylor and Butler, 1982
0.5 mg/L	SA-11	2.0	6	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990
0.3 mg/L	SA-11	5.0	6	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990
0.2 mg/L	HRV	2.0	6	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990
0.6 mg/L	SA-11	0.5	7	0.999980	2.00×10^{-5}	Chen and Vaughn, 1990
0.2 mg/L	HRV	3.0	7	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990
0.05 mg/L	SA-11	0.3	8	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990

Table 4.2.4 4: Efficacy of Chlorine Dioxide Disinfectant						
Conc.	Organism	Time (min)	pH	Efficacy (%)	Reduction Factor	Reference
0.05 mg/L	HRV	0.3	8	0.999990	1.00×10^{-5}	Chen and Vaughn, 1990
1.0 mg/L	Staphylococcus aureus	1.0	7	0.999990	1.00×10^{-5}	Zoni et al., 2007
0.25 mg/L	Escherichia coli	1.0	7	0.999995	5.00×10^{-6}	Zoni et al., 2007
1.0 mg/L	Streptococcus	0.3	7	0.999995	5.00×10^{-6}	Zoni et al., 2007
1.0 mg/L	Lactobacillus brevis	5.0	7	0.999995	5.00×10^{-6}	Zoni et al., 2007
1.0 mg/L	Pseudomonas aeuruginosa	1.0	7	0.999995	5.00×10^{-6}	Zoni et al., 2007
0.6 mg/L	Coxsackie Virus B5	4.5	7	0.999990	1.00×10^{-5}	Zoni et al., 2007
0.6 mg/L	HAV	2.5	7	0.999990	1.00×10^{-5}	Zoni et al., 2007
			Average	**0.999991**	**8.80×10^{6}**	
			Std. Dev.	0.000004	4.02×10^{6}	

As the specific chemical used for disinfection at the NBAF has not yet been selected, for the purposes of modeling in the Updated SSRA, the representative value of reduction by a disinfectant is 10^{-5}. NBAF protocols on use of dunk tanks and chemical disinfection wipedowns, when followed properly, should result in a 99.999% efficiency of decontamination of materials introduced**,** corresponding to a reduction factor of 10^{-5}.

Efficiency of Gaseous Decontamination

Vapor-phase hydrogen peroxide (VHP) is used by many containment laboratories for the gaseous decontamination of equipment, materials, and inanimate materials potentially contaminated with exotic animal viruses [Heckert et al., 1997]. The use of VHP is only one option for gaseous decontamination but is widely considered to be a choice consistent with best practices and is likely to be one of the agents available for use at the NBAF. The NBAF 65% Design specifications for the gaseous decontamination systems are compatible with the use of VHP. Heckert et al. evaluated the effectiveness of VHP against viruses from eight virus families of avian and mammalian species, including Picornaviridae (in the FMDv family) [1997]. In this study, viruses from multiple matrices (standard growth medium, allantoic fluid, or porcine blood) were used in suspension (100 µL) and dried on different types of equipment (laptop computer, wristwatch, pipette aid, electronic timer, etc.) and surfaces (glass and steel) to challenge the decontamination process. The initial titer of the representative Picornaviridae virus (Swine Vesicular Disease virus, SVDv) was $10^{8.1}$ $TCID_{50}$/mL. The measured titer of the virus on the control samples ranged from $10^{7.7}$ to $10^{8.2}$ $TCID_{50}$/mL. In all experiments except one, there was no detected virus from the test samples after the VHP decontamination process. One post decontamination test sample (glass surface) indicated a residual virus concentration of 8 x 10^{0} $TCID_{50}$/mL, but no replicates were able to duplicate this result. Effectively, this study indicated that the efficiency of VHP for virus removal (including

Picornaviridae) is nearly 100%. Since the initial titer (10^8 $TCID_{50}$/mL) and volume (100 µL) only provided the opportunity to demonstrate a 10^{-7} reduction in $TCID_{50}$, this is the value used for modeling in the Updated SSRA.

Efficiency of Gamma Irradiation

The inactivation of infectious materials is often achieved by exposing a sample to gamma radiation. The specific device and procedures that will be used at the NBAF have not yet been determined (65% Design). Dekker recommends that gamma irradiation delivering more than 40 kGy will provide sufficient decontamination results [1998]. Many irradiation devices use sources (e.g., ^{60}Co, ^{137}Cs) with higher activities to deliver higher doses, in the same time duration, that are necessary to inactivate NBAF samples. There is research and literature available on the dose-response relationship of FMDv survival in various matrices that will be used by NBAF officials, researchers, and safety experts to plan the appropriate protocols and procedures. House uses experimental data to develop a first-order model for the reduction of log titer values in samples as a function of gamma exposure [House, 1990]. This research specifically included FMDv in serum from an infected steer. Sullivan developed similar dose-reduction models for numerous viruses but indicated that frozen or very cold fractions of the matrix may require a higher dose [Sullivan, 1971]. Infection control specialists use a Sterility Assurance Level (SAL) to define a set of procedures and conditions that demonstrate the reduction of pathogen from specific levels. Initial titers of 10^6 are common for this purpose. The conditions that demonstrate a complete kill for the 10^6 titer are extended to ensure that additional kill is accomplished in processed matrices. Additional pathogen reduction research is not difficult to perform, but the initial titers should be representative of the anticipated titers in the processed matrix. NBAF procedures will have to be developed that apply the appropriate exposure times and irradiation levels that are specific to the needs of the facility. Some evidence of SALs of 10^{-7} have been documented but NBAF-specific circumstances will need to be validated while simultaneously studying the potential deleterious effects on the matrix and containers.

4.2.4.2 BSL-3Ag Necropsy

At the conclusion of a research project, all animals involved in the research are euthanized – infected or not. The euthanasia typically occurs as an animal is brought into the necropsy area. Following euthanasia, the carcass is stored, necropsied, or prepared for the tissue autoclave. During these activities, there is a relatively high likelihood for a researcher or other staff to come into contact with infectious blood and other pieces of animal tissue. For this reason, the BSL-3Ag necropsy area is one of the modeled originating locations for contact transference events. Normal precautionary measures used to mitigate the potential for an accidental loss of containment include the use of PPE (barriers) such as nitrile gloves and Tyvek®. Additional mitigation includes the shower/change from the necropsy area to BSL-3E and the shower/change upon exit from the BSL-3E. The efficiencies of all these mitigation techniques are presented below.

Efficiency of Gloves

NBAF protocols will require the use of some barrier glove protection when researchers and technicians are involved in an activity with potential FMDv contact exposure. The specific type of glove and gloving arrangements has not yet been determined. Gloves of practically any material have the potential to develop small perforations during use which will reduce their effectiveness. In a study of healthcare workers, Olsen found that 86 of 135 gloves cultured after use had evidence of contamination [1993]. The health care workers used in this study were performing activities not unlike those that may be performed in BSL-3Ag AHRs. In 11 of these 86 (12.8%) events in which contamination was noted, the hands of the worker were found to be contaminated after glove removal. These observations likely include contamination which can occur when gloves or other PPE are removed. Quantitative culture results of these 11 hand contamination events demonstrated that the colony-forming units recovered from the surface of the gloves ranged from 6.5×10^2 cfu/mL to 2.0×10^2 cfu/mL, whereas the quantities found on the hands were typically reduced by 2 to 4 orders of magnitude. In a study of surgeons, Dodds identified a 4% rate of hand contamination when gloves remained intact and a 6% rate when gloves were perforated [1988].

Several other studies have been performed examining the penetration rate of viruses through medical examination and surgical gloves [Klein et al., 1990; Korniewicz et al., 1990, 2004; Nelson et al., 1999; Rego and Roley, 1999; O'Connell et al., 2004]. In these experiments, gloves were either tested prior to use or after being challenged after stress, use, and/or puncture. Failure rates (i.e., percent of gloves in which virus was measured to have penetrated the barrier) of the gloves ranged from 0% to 13% depending upon the stress conditions. Higher penetration rates, between 52% and 92%, were measured for punctured gloves. The failure rates of gloves are enumerated in Table 4.2.4-5.

Table 4.2.4 5: Failure Rate of Gloves

Latex Gloves		Nitrile Gloves		Unspecified Gloves		
Percent Failure	n[a]	Percent Failure	n[a]	Percent Failure	n[a]	Reference
33.3%	6	7.5%	120	---	---	Korniewicz et al., 2004
20.0%	30	10.1%	248	---	---	Korniewicz et al., 2004
20.0%	5	6.5%	46	---	---	Korniewicz et al., 2004
50.0%	4	5.9%	85	---	---	Korniewicz et al., 2004
12.5%	8	5.3%	38	---	---	Korniewicz et al., 2004
8.3%	12	6.8%	382	---	---	Korniewicz et al., 2004
18.2%	22	7.8%	153	---	---	Korniewicz et al., 2004
0.0%	12	7.9%	165	---	---	Korniewicz et al., 2004
0.0%	4	5.3%	283	---	---	Korniewicz et al., 2004
1.9%	54	2.8%	433	---	---	Korniewicz et al., 2004
10.0%	10	11.5%	26	---	---	Korniewicz et al., 2004
0.0%	24	2.3%	86	---	---	Korniewicz et al., 2004
4.2%	24	3.0%	297	---	---	Korniewicz et al., 2004
---	---	3.9%	153	---	---	Korniewicz et al., 2004
---	---	3.8%	132	---	---	Korniewicz et al., 2004

Table 4.2.4 5: Failure Rate of Gloves						
Latex Gloves		Nitrile Gloves		Unspecified Gloves		Reference
Percent Failure	n[a]	Percent Failure	n[a]	Percent Failure	n[a]	
---	---	---	---	12.8%	582	Dodds et al., 1988
---	---	---	---	31.6%	98	Olsen et al., 1993
---	---	---	---	6.3%	16	Olsen et al., 1993
---	---	---	---	0.0%	17	Olsen et al., 1993
Percent Failure (Weighted Average)						7.67%

[a]Number of gloves tested.

Based on the data presented in this table, the average failure rate of latex gloves and nitrile gloves (as well as unspecified gloves) is 7.67%. Broyles et al. further examined the viral titers of bacteriophage on the outside and inside of punctured gloves to determine the efficacy of the glove barrier in the event of the glove failing [2002]. For the powdered and non-powdered latex gloves, the ratios of bacteriophage penetration were 0.0059 and 0.0075, respectively. On average, for punctured latex gloves only 0.67% of the virus penetrated the glove.

On the basis of these data, the Updated SSRA models the pathogen reduction factor of gloves as 0.0067 (6.7×10^{-3}). For intact gloves, no viral penetrations were observed [Korniewicz et al., 1990]; thus a reduction factor of 1×10^{-5} is used in the Updated SSRA.

Efficiency of Protective Apparel

PPE will be used at the NBAF to help reduce the opportunity for contamination of skin and clothing by infectious materials and to help reduce transmission of these materials to non-contaminated areas. Several commercially-available products, like Tyvek® and Tychem® help provide a barrier against this contamination by protecting the wearer from splash, aerosol, and contact hazards. However, the protection provided by this apparel is not 100% efficient. Seams, closures, “pinholes”, and other small holes from wear or snag reduce the effectiveness of the barrier seal. No independent data on FMDv penetration rate for Tyvek-like garments were identified. The Biosafety Officer may require the use of Tychem® garments and aprons that will add an additional barrier for the highest levels of exposure. Furthermore, Tyvek® provides excellent protection against liquids with water penetration rates of less than 0.2% (the detection limit), suggesting that the actual penetration is lower than 0.2% [DuPont, 2007]. In the Updated SSRA, the effectiveness of the protection apparel is modeled as 99.98% for liquid exposures. This is equivalent to a reduction factor of 2×10^{-4}, corresponding to an order of magnitude below the detection limit of the assay used to evaluate the Tyvek® suits. No data was identified detailing the protection efficiency of Tyvek® suits that fail; as a conservative estimate, a reduction value of 0.15 for failed Tyvek® suits was used in the modeling.

Efficiency of Showers

At the NBAF, personnel will be required to go through two body showers consisting of soap and water to exit the BSL-3Ag or BSL-3E/SP labs. While the use of PPE and the complete removal of apparel exposed to an FMDv-laden environment provide a valuable barrier layer to the contamination of skin, microorganisms on the skin surface can be effectively removed when water and a cleansing agent/surfactant such as a soap or detergent are used simultaneously [Ayliffe et al., 1990]. The soap or detergents help emulsify water-soluble and fat-soluble materials on the skin. Once emulsified, the mechanical action of the shower spray and showering process effectively removes the solution. Any procedure involving showering of an individual will result in significant removal of contamination from the skins surface [Amlôt et al., 2010]. Amlôt et al. also showed, with a fluorescent tracer contaminant, that the use of a washcloth can enhance the removal of a skin contamination by approximately 20%. Unfortunately, this study did not quantify the overall removal efficiency of the contamination. However, data on the efficiency of removal of bacteria by shower indicate that 84% to 98% of contamination is removed by a single washing with unmediated liquid soap [Ojajärvi, 1981]. For hand washing, it has been demonstrated that the mean percentages of virus removal with liquid soap and water alone are 86.9% and 83.6%, respectively [Ansari, 1989]. A 2004 review by Kampf and Kramer reports data from Bellamy [1993] on the removal of rotavirus from hands when washing with plain soap and water or water alone [Kampf and Kramer, 2004]. A range of 1.17-1.19 log $TCID_{50}$ of virus (6.8% to 7.6%) remained. Other studies by Ansari and Mbithi performed similar experiments with rotavirus, HAV, and poliovirus, and found a removal rate of 81.44 to 98.39%, indicating that 1.61% to 18.56% remained [Ansari et al., 1989; Mbithi et al., 1993]. Without data specific on water showers and FMDv removal, these data were used to model the rate of virus removal by decontamination showers as a beta distribution with a mean of 89.9% removal; a reduction factor of 0.101 was used in all modeling calculations.

4.2.4.3 BSL-3E and BSL-3E "Special Procedure" Laboratories

In vitro experiments and research on FMD are performed in BSL-3E laboratories or BSL-3E "Special Procedure" laboratories, as determined by Biosafety Officer in consultation with senior scientists and based on the anticipated level of risk from the quantities and titers of the research specimens. Sample handling and manipulation is performed in a BSC. However, the potential of a spill, drop/breakage, or other accident that necessitates a cleanup activity is the representative transference event that is based in the BSL-3E area; such events are modeled with the spill occurring outside of the BSC. Prevention measures, largely based on training and laboratory materials/equipment, help minimize the potential for such accidents. However, the most important mitigation system is the BSC. For accidents that occur outside of the BSC, the researcher and/or other staff will be involved in the cleanup. The contact/splash risks are also mitigated by gloves and Tyvek® suits. Additional risk mitigation measures (from a BSL-3E laboratory room) include the shower/change upon exit from the BSL-3E.

4.2.4.4 Non-Containment Areas

The potential for accidental losses of infectious materials from the containment areas cannot be eliminated, however small. Transference events modeled from the non-containment areas of the NBAF campus include an event that is intended to represent the contamination of a maintenance technician or facility engineer that is unknowingly contaminated during pipe inspection, filter testing, or other scheduled, preventive, or responsive maintenance. (It is assumed that if a trained staff member is cognizant of potential exposure/contamination, the response will include a special decontamination procedure that is modeled as part of the normal containment risks.) This event is also representative of other facility staff and visitors including emergency responders, who may be unwitting of the potential exposure/contamination – package handling, waste removal, administration, etc. Without awareness and the recognition of a potential exposure/contamination, the modeled event includes no special mitigation procedures.

4.3 Event Circumstances

Based on the FMDv-related activities and experiments to be performed at the NBAF, a total of 24 different circumstances were modeled that can result in a release of infectious material via the four pathways and from the four originating locations. Further, critical feedback from subject matter experts was used to develop and refine these situations based on their concerns. These 24 circumstances are detailed in Table 4.3.1-1 and include five originating from the AHRs, seven originating from activities in the necropsy suite, six from the BSL-3E/SP, and six originating outside of containment.

Each event is assigned a unique Event Identifier (Event ID). The Event Identifier begins with a letter that represents the originating location: A for BSL-3Ag animal holding rooms (AHRs), N for BSL-3Ag necropsy suites, E for BSL-3E and BSL-3E “Special Procedure” laboratories, and O for non-containment areas. The modeled pathway (or pathways) is indicated by the second letter in the Event Identifier: A for aerosol, S for solid waste, L for liquid waste, and T for transference. For each originating location/pathway, the events are then sequentially numbered, as presented in Section 4.5.

Table 4.3.1 1: BSL 3Ag AHR, BSL 3Ag Necropsy, BSL 3E/ BSL 3E SP, and Non Containment Event Circumstances Summary			
Label	**Originating Location**	**Pathway**	**Circumstances Leading to a Release of Infectious Material**
AA	AHR	Aerosol	Continuous or nearly-continuous animal respiration, animal room washdowns, animal/researcher movements causing resuspension, shedding, detritus, and other aerosol-creating activities in the AHRs when animals are infected with FMDv.
AL	AHR	Liquid Waste	Continuous or nearly-continuous flow of potentially liquid and solid wastes generated in AHRs when animals are infected with FMDv.
AS	AHR	Solid Waste	Periodic disposal of potentially infectious solid biohazardous waste generated from AHRs when animals are infected with FMDv.
ATR	AHR	Transference (Respiratory)	Transfer of aerosolized infectious material into the nasal passages of a researcher when researchers are in an AHR with animals infected with FMDv.
ATF	AHR	Transference (Fomite)	Transfer of infected liquid waste, suspended solid wastes, or small fractions of solid wastes onto a fomite from an AHR when animals are infected with FMDv.
NA	Necropsy	Aerosol	Aerosolized infectious material from animal respiration (short periods), euthanasia, and other necropsy procedures released into the necropsy room while working with FMDv infected animals.
NL	Necropsy	Liquid Waste	Disposal of liquid waste generated in necropsy room while working with FMDv infected animals.
NSW	Necropsy	Solid Waste (Biohazardous Red Bag)	Disposal of solid biohazardous waste generated in necropsy room while working with FMDv infected animals.
NST	Necropsy	Solid Waste (Tissue/Carcasses)	Disposal of animal tissue and carcasses generated in necropsy room while working with FMDv infected animals.
NTH1-6	Necropsy	Transference (Contact, Hand)	During necropsy procedures, infectious material is transferred to the palm region of a researcher when working with FMDv infected animals.
NTH7-12	Necropsy	Transference (Contact, Hand)	During necropsy procedures, infectious material is transferred to the glove of a researcher and the researcher improperly removes the glove resulting in the transfer of infectious FMDv to their palm.
NTB	Necropsy	Transference (Contact, Body)	Transfer of infectious material during necropsy procedures to the body of a researcher.
EA	BSL-3E/SP	Aerosol	Spill of infectious FMDv outside of the BSC resulting in an aerosolized fraction.
EL	BSL-3E/SP	Liquid Waste	Infectious liquid discharge from a BSL-3E/SP area resulting from a failure to follow protocol resulting in untreated FMDv being put down the drains in the BSL-3E/SP.
ES	BSL-3E/SP	Solid Waste	Disposal of infectious solid biohazardous waste generated in BSL-3E/SP.

Table 4.3.1 1: BSL 3Ag AHR, BSL 3Ag Necropsy, BSL 3E/ BSL 3E SP, and Non Containment Event Circumstances Summary			
Label	**Originating Location**	**Pathway**	**Circumstances Leading to a Release of Infectious Material**
ETP1-6	BSL-3E/SP	Transference (Contact, Palm)	During the clean-up of a spill of infectious FMDv outside of the BSC, infectious material is transferred to the palm of a researcher.
ETP7-12	BSL-3E/SP	Transference (Contact, Palm)	Infectious material is transferred to the glove of a researcher and the researcher improperly removes the glove resulting in the transfer of infectious FMDv to their palm.
ETB	BSL-3E/SP	Transference (Contact, Body)	Spill of infectious FMDv outside of the BSC results in a fraction splashing onto the body region of a researcher.
OA	Non-containment	Aerosol	Spill of a shipment of infectious FMDv results in aerosolized fraction which is released.
OTP	Non-containment	Transference (Contact, Palm)	During the clean-up of a spill of a shipment of infectious FMDv, infectious material is transferred to the palm region of an individual.
OTF	Non-containment	Transference (Contact, Foot)	During the clean-up of a spill of a shipment of infectious FMDv, infectious material is transferred to the foot region of an individual.
OTB	Non-containment	Transference (Contact, Body)	Spill of a shipment of infectious FMDv results in a fraction splashing onto the body region of an individual.
OTFom	Non-containment	Transference (Fomite)	A technician working on a leak in a drain pipe in the AHR has infectious FMDv transferred to a wrench.
OTPalm	Non-containment	Transference (Contact, Palm)	A technician working on a leak in a drain pipe in the AHR has infectious FMDv transferred to their palm region.

4.4 FMD Virus Source Terms

To determine the risk of working with FMDv, the typical amounts of FMDv involved in related research activities were determined. These amounts, specifically concentrations and distributions, used in experiments, activities and procedures involving susceptible species in the BSL-3Ag AHRs and necropsy suites, as well as activities in the BSL-3E and BSL-3E "Special Procedure" laboratories, were used to model the accident events. In order to estimate the amount of material available for release (MAR), the concentration distribution (i.e., source terms) was determined by searching open source literature for experiments involving FMDv as well as viral shedding levels of FMDv-infected animals. The MAR is the total amount of FMDv available for release generated from a particular room type or event and is a function of the species of animal (e.g., bovine) and the matrix which contributes the virions (e.g., urine). Species of interest for the Updated SSRA include cattle, pigs, and sheep; the associated potentially infected matrices include air, urine, feces, blood, tissues, and culture materials.

To accurately characterize the distribution of the viral source terms, individual contributions from all animals (infected and non-infected) in a study were included in the statistical analysis; e.g., measurements of 0 PFU in tissues of an individual animal in an experiment were included to account for animals which may have been inoculated but did become diseased or infected. In addition, only studies which had measurements of infectious virus were included in the source term distributions; no attempts were made to convert relative viral RNA levels to infectious concentrations (i.e., $TCID_{50}$ or PFU). All infectious concentrations or amounts were converted to PFU. The modeled quantities of FMDv used in the Updated SSRA characterize the uncertainties involved. As the SSRA was intended to provide a relative assessment of risks, maximum point estimates were used to model each scenario. The modeled values used in the SSRA were derived from various studies and commentary on prior hazard assessments. In the Updated SSRA, virus concentration distributions (e.g., 5th, 50th, and 95th percentiles or qualitatively as low, medium, or high) have been developed for use in accident event modeling.

Values reported in the literature were assessed for representativeness, completeness, and quality. Although many articles were reviewed, the data from a subset of articles were compiled and used to calculate MARs. Because the bovine thyroid cell (BTY) assay is the most sensitive assay for determining the concentration of FMDv, studies that used this assay were selected over others that used alternate, less sensitive assays [Snowden, 1966], provided that data derived from the BTY assay were found. If BTY data were not available for a given species and matrix combination, the most representative data available were used. The statistical distribution of each data set was examined to assess whether the data appear to be consistent with a normal distribution or a log-normal distribution, and an estimate of the mean and standard deviation were calculated (using either the raw or log-transformed data). The data set which appeared more normally distributed, based on assessing histograms, was used to determine the average and standard deviation of that data set.

The use and frequency of each originating location (i.e., AHRs, necropsy suites, and BSL-3E/BSL-3E SP laboratories) and pathway (i.e., aerosol, liquid waste, solid waste, and transference) were estimated from the 65% Design, from expected activities in these BSL-3 originating locations at the NBAF derived

from interviews with PIADC management and research staff and other scientific contributors, and from known activities at similar laboratories. The use and frequency values were used in conjunction with the source terms to calculate the MAR for each set of circumstances as defined in Section 4.6. For each set of circumstances, there are mitigating nodes (see Section 4.2) that reduce the MAR to its *Q* value (or quantity of infectious material released at that stage of the accident sequence), and these *Q* values are presented in Section 4.6.

4.4.1 BSL-3Ag Animal Holding Rooms

The BSL-3Ag AHRs are used by NBAF researchers for studies and experiments that involve multiple species and varied objectives. The flexible configuration of the AHRs makes it possible to incorporate several separate rooms in a single study or to conduct multiple simultaneous studies that involve the use of different pathogens. The development of modeling estimates on the frequency of AHR use associated with FMDv is presented in Section 4.4.1.1. The modeling estimates for the MAR values for the AHRs are presented in Section 4.4.1.2.

4.4.1.1 Use and Frequency

Probability of BSL-3Ag Animal Holding Room Occupancy

The NBAF BSL-3Ag facility is comprised of 46 AHRs of seven different sizes and types that can accommodate different species and numbers of animals. The AHRs are a shared resource of the NBAF tenants including USDA/ARS, USDA/APHIS, and DHS. Typical experiments will involve the use of one or more AHRs, based on the research objectives of a particular experiment. Input compiled for the 65% Design indicates that most USDA/ARS BSL-3Ag studies will involve a small number (2-4) of research animals but some studies may involve larger study groups of 16-20 or 30-40 animals. Much of the USDA/APHIS research will not require BSL-3Ag AHRs. (BSL-3E and BSL-3E "Special Procedure" rooms will be used to accommodate diagnostics and isolate characterization needs for much of the APHIS activities.) However, the Foreign Animal Disease Diagnostician (FADD) course, conducted up to six times per year, will require BSL-3Ag AHRs to accommodate small numbers (1, 2-6) of animals for relatively short time periods. DHS research activities will generally require larger study groups. For these larger studies, up to 15 cattle or swine may be housed in separate rooms to form study groups of 30-40 total animals. The number and size of each of the seven types of AHRs is provided in Table 4.4.1-1 [NDP, 2011].

Table 4.4.1 1: BLS 3Ag Animal Holding Rooms

Room Type	Number of Rooms	Size (ft^2) per Room
A	4	288
A2 (large)	20	144
A2 (small)	15	120
A3	1	288
B	3	576
C	2	864
D	1	1,000

The 65% Design illustrates the AHR utilization estimates for each individual room. The overall planned occupancy rate and occupancy duration for each type of room derived from the 65% Design is presented in Table 4.4.1-2. The occupancy percentages presented generally include one week for decontamination, cleaning, and unscheduled maintenance on an "as-needed" basis. Thus, the term occupancy does not necessarily mean that the room is occupied by animals, but rather that the room is reserved for an experiment.

Table 4.4.1 2: Mean General Use Occupancy Rates and Durations for AHRs

Room Type	% Occupancy	Occupancy Duration (Days)
A	76%	53.1
A2 (large)	71%	40.9
A2 (small)	71%	32.0
A3	93%	49.0
B	77%	53.4
C	73%	52.1
D	93%	50.0
All	**73%**	

Probability of FMDv-Related Occupancy of BSL-3Ag Animal Holding Rooms

FMDv is not the only pathogen that will be studied in the BSL-3Ag (and BSL-3E/ BSL-3E SP) facilities. DHS has identified a total of eight "Research Pathogens" including two pathogens that will be studied in the BSL-4 facility. Thus, in addition to FMDv, there are five pathogens (African Swine Fever virus, Classical Swine Fever virus, Japanese Encephalitis virus, Rift Valley Fever virus, and Contagious Bovine Pleuropneumonia (*Mycoplasma mycoides*)) that may be studied in the NBAF BSL-3Ag AHRs. PIADC executive staff and scientific users have projected 6-7 FMDv-related experiments will be conducted in the BSL-3Ag AHRs every year, similar to the number of studies per year at PIADC [Barrett, L., personal communication, 27 September 2011]. The duration of experiments is estimated to be 5-8 weeks. It is also estimated that one-third of the AHR occupancies will be for FMD research. These estimates were used to calculate the corresponding mean probability of AHR use for FMD-related activities for each room type. This data is presented in Table 4.4.1-3.

Table 4.4.1 3: Probability of FMD Related Occupancy by Room Type

Room Type	P (mean)
A	0.25
A2 (large)	0.24
A2 (small)	0.24
A3	0.31
B	0.26
C	0.24
D	0.31
All	**0.24**

Probability of Species Specific FMDv-Related Occupancy of BSL-3Ag Animal Holding Rooms

Research objectives and experimental design will determine the number and type of rooms that will be used in the experiments. There is not a direct correlation between the NBAF AHR types and the existing FMD research facility at PIADC. Therefore, a Monte Carlo analysis was performed to simulate the occupancy and species utilization for each AHR type (described below). The annual animal inventory as provided by the 65% Design and the maximum animal capacity for the three species for each type of AHR is used to model the relative proportion of AHR occupancy by species [NDP, 2011]. Since FMD-related research is performed on susceptible species, animal inventory data from the 65% Design for non-susceptible species was not included; only data for cattle, swine, and sheep were used. As described in the 65% Design, 491 swine, 519 bovine, and 4 goats are expected to occupy the NBAF per year (1,014 animals total); the goat data was used as an estimate for sheep. On a percentage basis, over the course of a year, 51.2% of the animals in FMDv studies are expected to be bovine, 48.4% porcine, and 0.4% ovine.

Probability of Infectious Material During BSL-3Ag Animal Holding Room Occupancy (FMDv)

When a BSL-3Ag AHR is occupied for FMD-related research, the animals involved in the experiment will not be FMDv-infected or viremic for the entire occupancy period. For all experiments, animals introduced to an AHR will be acclimated for a one week period prior to the initiation of FMD research or studies. This time period is included in the average occupancy periods for the reserved rooms (Table 4.4.1-2). Vaccine challenge studies will typically begin with the animals being vaccinated on Day 8 of the study – immediately after the acclimation period. After vaccination, the animals will be held in the AHR(s) for two weeks (14 days) before a challenge inoculation or exposure event. For vaccine studies, this results in a minimum three-week period during which no animal-generated virus would be shed in the occupied AHRs. If the challenge is successful (i.e., the animal(s) become infected as a result of the inoculation challenge), there will be low levels of virus shed during the first post-challenge day. It is difficult to predict the challenge success rate for future vaccine testing – as vaccines improve, the rate of successful challenges are likely to decline. Vaccine challenges may continue for up to three weeks (21 days) post challenge inoculation/exposure. However, many studies are terminated between three and five days after challenge/exposure – based on the experiment objectives and animal welfare concerns. After the study, the room will be cleaned and decontaminated, requiring one week (7 days).

For animals that become viremic, peak virus shedding will occur around day-four post-challenge, and virus shedding, while declining, may persist through the end of the experiment. The virus shedding levels used in this assessment were based on data gathered during peak virus-shedding periods and, for this analysis, were applied to the entire post-inoculation/exposure period. Thus, vaccine challenge studies were modeled as seven-week (49-day) events – four of these weeks (28 days) were modeled as a “no-shedding” period which includes the one-week acclimation period, two-week period between vaccination and challenge, and the one-week cleaning. Three weeks (21 days) were modeled as a “shedding” period with a statistical mean and standard deviation for the quantity of virus shed derived from data collected during the peak virus-shedding periods. Each of the three representative large animal models (bovine, porcine, and ovine) was considered separately. The modeled probability of

infectious materials generated by the animals (aerosols, solids, liquids, fomites) for vaccine studies is 42.9% (21 days of expected shedding divided by 49 days of room occupancy).

Monte Carlo Simulations

A Monte Carlo analysis was performed to determine, for each room type, the expected values and the uncertainties associated with the number of days per year during which FMDv-infected animals will be present and the breakdown by species (cattle, pigs, and sheep). The Monte Carlo analysis was performed using input parameters that were derived from the literature reviews and interviews summarized above. For each BSL-3Ag AHR type, the usage statistics incorporated into the Monte Carlo analysis are summarized in Table 4.4.1-4. In addition, the following rates were assumed:

- The expected proportion of experiments performed in a given year in a BSL-3Ag AHR that involves FMDv (regardless of room type) was 33% [White, W., personal communication, 27 September 2011].
- The expected proportion of days during an FMDv experiment that the animals are infected with FMDv was 42.9%.
- For all rooms except the D Room, the proportion of AHRs that involve cattle was 76.3%, pigs 23.6%, and sheep 0.2%. For the D Room, all experiments were assumed to involve cattle only.

Table 4.4.1 4: BSL 3Ag Animal Holding Room Usage Statistics and Capacities

Room Type	Number of Rooms	Room Occupancy Rate		Experiment Duration (Days)		Animal Capacities		
		Average	Std. Dev.	Average	Std. Dev.	Bovine[a]	Porcine	Ovine
A	4	76.0%	12.2%	53.1	23.5	4	14	16
A2 (large)	20	70.9%	10.4%	40.9	37.5	2	7	10
A2 (small)	15	70.7%	7.2%	32.0	21.8	2	6	8
A3	1	93.0%	7.4%	49.0	14.0	8	28	32
B	3	76.7%	5.9%	53.4	12.6	8	28	32
C	2	73.0%	1.4%	52.1	14.9	12	42	48
D	1	93.0%	7.4%	50.0	8.5	22	0	0
Weighted Average		**72.7%**		**40.7**				

[a]Capacity determined based on bovine weighing 440-770 lbs.

Based on the usage statistics and proportions summarized above, the following Monte Carlo analysis was run:

- 1,000 runs were performed, where each run represents a year.
- For each run (year), a set of experiments was simulated for each of the 46 rooms.
- For each run/room, the experiments for that run/room were simulated as follows:

1. Based on the average and standard deviation of the occupancy rate and assuming a normal distribution, the number of days per year that the room was occupied was randomly determined.
2. Based on the average and standard deviation of the duration of experiments (which were assumed to be normally distributed), the number of experiments and duration of each experiment was randomly determined (with the constraint that the total number of days equaled the number of days determined in Step 1 above).
3. For each experiment determined in Step 2 above, the following random determinations were made:
   a) Was the experiment in that AHR a bovine, porcine, or ovine experiment? This was determined based on a single draw from a multinomial distribution with probabilities equal to 76.3%, 23.6%, and 0.2% corresponding to bovine, porcine, and ovine, respectively. (This breakdown was computed from the capacity of each room by species, as shown in Table 4.4.1-4, to achieve a final percentage breakdown of 51.2% bovine, 48.4% porcine, and 0.4% ovine, as described above.)
   b) Was the experiment an FMDv experiment? This was determined based on a single observation from a Bernoulli trial (i.e., a binomial distribution with one "draw"), assuming a 33% probability that the experiment was an FMDv experiment.
   c) If the experiment was an FMDv experiment, for how many days were the animals infected? This was determined based on a single observation from a binomial distribution with the number of "draws" equal to the duration of the experiment (determined in Step 2 above), and the expected proportion of infected days was set to 42.9%.

The outcome of these simulations created a random distribution of the total number of days in which an FMDv-infected animal was present in each of the 46 BSL-3Ag rooms, and a breakdown of the days by animal type. Table 4.4.1-5 presents a summary of the number of FMDv-infected days per room type.

Table 4.4.1 5: Monte Carlo Output. Number of FMDv Infected Days per Year by Room Type

Room Type	5th Percentile[a]	50th Percentile[a] (Median)	95th Percentile[a]
A	75	154	249
A2 (large)	538	720	934
A2 (small)	420	558	695
A3	0	47	94
B	52	120	193
C	22	74	133
D	2	47	93
All Rooms	**1474**	**1735**	**2012**

[a]Total infected days across all occupied rooms of the same types.

4.4.1.2 Pathogen Contribution

As the distributions of the potential MARs vary by species and as each BSL-3Ag AHR may contain different species of animals for varying durations throughout the course of a year, a Monte Carlo analysis was performed to characterize the distribution of the potential MAR values on any given day that a BSL-3Ag AHR is used for an FMDv experiment. The output from the Monte Carlo simulations summarized in Section 4.4.1.1 (which resulted in an estimated distribution of the total number of days in which an FMDv-infected animal was present in each of the 46 BSL-3Ag rooms, along with a breakdown of days by species) was used as the starting point for each MAR Monte Carlo analysis.

The following additional parameters and assumptions were used as input into the MAR Monte Carlo analysis:

- For a given pathway (e.g., aerosol release), for each species (bovine, porcine, ovine), the statistical distribution and the mean and standard deviation of the MAR values were required. This information was derived from the literature review.
- It was assumed that when a room is in use for a given animal type, the room is at full capacity. The capacity values shown in Table 4.4.1-4 were used.

For a given pathway, the Monte Carlo simulation was performed as follows:

- Data from the Monte Carlo simulation summarized in Section 4.4.1 was compiled and used as the starting point for this simulation. Each of the 1000 runs in the previous Monte Carlo simulation represents a year. For each run and for each of the 46 rooms, the simulation generated the number of days that FMDv-infected cattle, pigs, and sheep are present in the room (days present by species).
- Using that data set, for each run, room, and animal type, the following steps were performed:
    1. MAR values (in log-transformed units if appropriate) were randomly generated from a normal distribution with mean and standard deviation equal to those derived based on the literature review for the given species/pathway. The number of values generated was equal to the number of FMDv-infected days for the given run, room, and animal type.
    2. The randomly generated values were converted to the appropriate units (e.g., PFU so that consistent source terms were applied for subsequent modeling) and multiplied by the capacity of the room (using the values shown in Table 4.4.1-4).
- For each room type, the output from the simulations above was compiled to obtain the distribution of all possible MARs for each room type (appropriately weighted by the different animal types).
- The output from the simulations was also compiled across all rooms to obtain the overall distribution of possible MARs from BSL-3Ag rooms (appropriately weighted by animal types and room types).

Contributions to Aerosol Pathway – BSL-3Ag Animal Holding Rooms

Data were compiled from the literature for air samples collected from holding rooms during experiments involving bovine, porcine, and ovine species infected with FMDv [Alexandersen et al., 2002; Gloster et al., 2008]. Because of the nature of these samples, any contributions from skin, semen, splashing from urination, washdown-induced aerosolization, etc. were accounted for in the collected data. For all species, the air sample data compiled reported FMDv shed per 24 hours per animal.

For FMDv levels in air from pig enclosures, the log transformed data set was used to calculate the average and standard deviation. For the FMDv levels in air from cattle and sheep, few data points were available (two or three data points). Therefore, the average values for these two species were calculated in the same way as the porcine data: using the log-transformed results. The standard deviations for the bovine and ovine data sets were calculated by determining the relative standard deviation of the porcine data. Based on these reviews, the following species-specific MAR distributions listed in Table 4.4.1-6 based on literature review were used as input into the Monte Carlo analysis.

Table 4.4.1 6: Mean Aerosol FMDv Levels per Day by Species

	Bovine[a]	Porcine[b]	Ovine[a]
log $TCID_{50}$ per day per animal	4.30 ± 1.80	3.84 ± 1.62	4.24 ± 1.79
log PFU per day per animal	4.14 ± 1.64	3.68 ± 1.46	2.26 ± 1.63

[a]Data from Gloster et al., 2008. [b] Data from Alexandersen et al., 2002.

The results of the Monte Carlo simulations to obtain the overall MARs for each room type (across species) are presented in Table 4.4.1-7. Figure 4.4.1-1 graphically summarizes the overall distribution of MARs across all room types.

Table 4.4.1 7: Monte Carlo Output Distribution of Aerosol Pathway MARs for BSL 3Ag Animal Holding Rooms by Type and Combined (PFU/Day)

Room Type	5th Percentile	50th Percentile (Median)	95th Percentile
A	7.04×10^1	5.84×10^4	4.73×10^7
A2 (large)	3.55×10^1	2.91×10^4	2.31×10^7
A2 (small)	3.41×10^1	2.77×10^4	2.25×10^7
A3	1.39×10^2	1.19×10^5	9.33×10^7
B	1.43×10^2	1.18×10^5	9.27×10^7
C	2.22×10^2	1.75×10^5	1.42×10^8
D	3.27×10^2	3.08×10^5	2.70×10^8
Average per Room	**4.56×10^1**	**4.01×10^4**	**3.55×10^7**
Total per Day	**2.17×10^2**	**1.91×10^5**	**1.69×10^8**

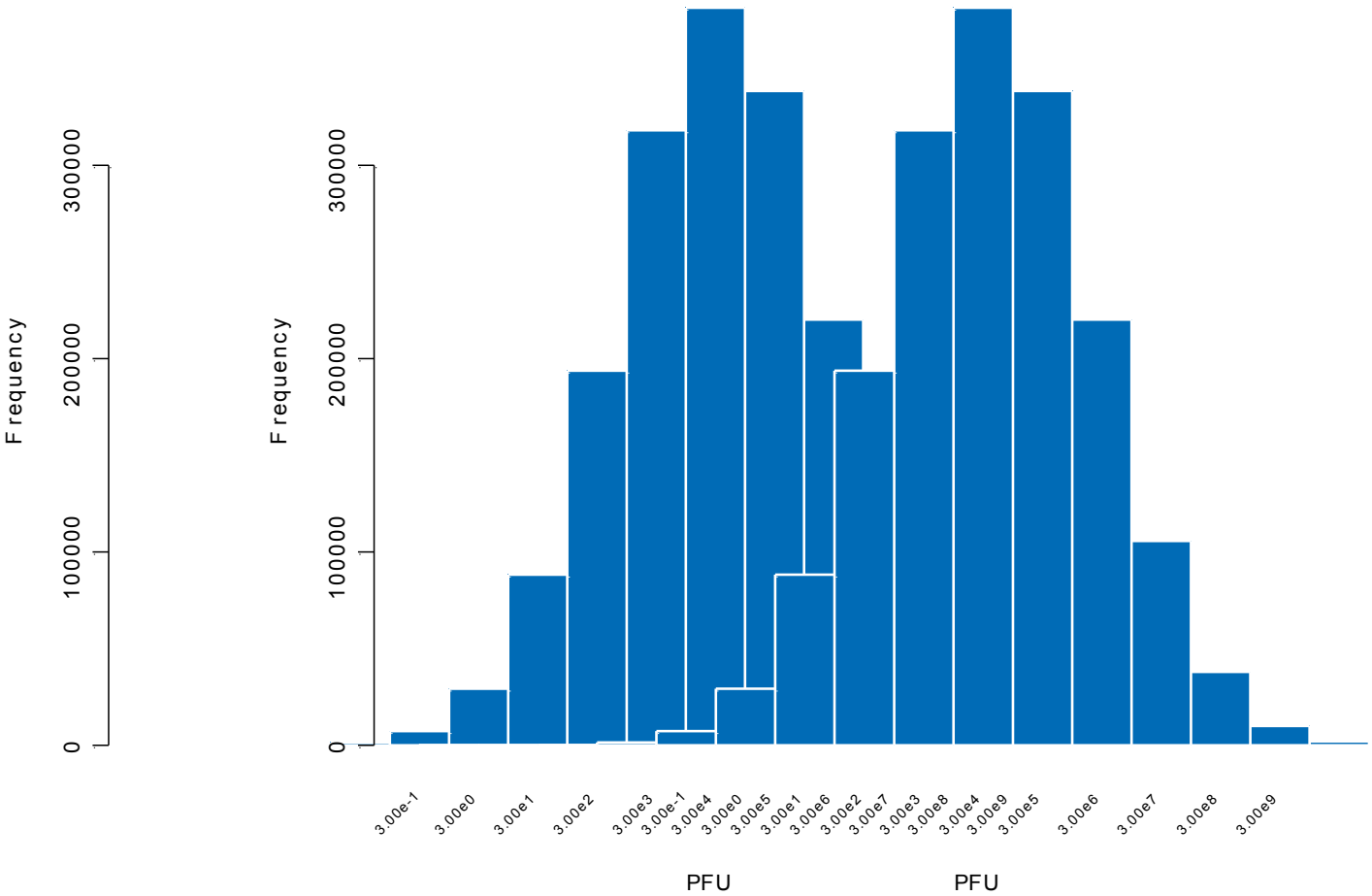


Figure 4.4.1-1: Monte Carlo Output. Distribution of Aerosol Pathway MARs Across all BSL-3Ag Rooms (PFU/Day)

Contributions to Liquid Waste Pathway – BSL-3Ag Animal Holding Rooms

For the liquid waste pathway, the primary contributions of FMDv from the BSL-3Ag AHRs are expected to be from urine and fecal excretions of the animals. The concentrations of FMDv in these excretions at various time points after the animals were infected were compiled from the literature search. In addition, the average masses of urine and feces produced per day for each species were compiled and are shown in Table 4.4.1-8 [American Society of Agricultural Engineers, 2005].

Table 4.4.1 8: Urine and Feces Mass per Day by Species and Matrix

Species	Urine (L/day)		Feces (kg/day)	
	Mean	Std. Dev.	Mean	Std. Dev.
Bovine	4.95	1.16	11.00	4.81
Ovine	0.35	0.08	0.58	0.27
Porcine	1.76	0.22	2.03	1.10
Total	**7.06**		**13.61**	

Histograms of urine and feces virus concentrations were assembled and assessed for both the log transformed and non-transformed data for each species. Log transformed data were used to calculate averages and standard deviations for the FMDv concentrations in ovine feces [Sharma and Murty, 1981], bovine urine [Alexandersen et al., 2003], and bovine feces [Alexandersen et al., 2003] data sets while non-transformed data were used for the porcine feces [Parker, 1971] and ovine urine [Sharma and Murty, 1981]. No data was found for porcine urine, which is consistent with the literature [Schijven et al., 2005]. For porcine urine, the distribution of virus concentrations was assumed to be equal to that for porcine feces. The species-specific MAR distributions (based on published data) were used as input to the Monte Carlo analysis and are depicted in Table 4.4.1-9 below.

Table 4.4.1 9: Assumed Distribution of Urine and Feces Virus Concentrations by Species and Matrix

Species	Urine	Feces
Bovine	0.66 ± 0.71 log PFU/mL	1.00 ± 1.56 log PFU/g
Porcine	68.1 ± 161 PFU/mL[a]	68.1 ± 161 PFU/mL
Ovine	11.5 ± 47.7 PFU/mL	0.11 ± 0.50 log PFU/mL

[a]No literature values were available for porcine urine. Values for porcine feces were used for all porcine calculations.

A Monte Carlo simulation was performed as described above for the aerosol pathway, except that an additional step was incorporated for the liquid pathway. For each day and animal in each simulation run, the specific mass of urine and feces produced was randomly selected (based on the means and standard deviations shown in Table 4.4.1-9 above). These random values were multiplied by the randomly selected virus concentrations (which were converted to PFU/mL or PFU/gram as appropriate) to obtain the distribution of MAR values in units of PFU/day. Overall MARs for each room type (species combined) are presented in Table 4.4.1-10. Figure 4.4.1-2 graphically summarizes the overall distribution of MARs across all room types. Note that these liquid waste MAR estimates were not reduced by the fraction of liquid waste that was assumed to be lost to the solid waste pathway (see section below), and therefore may be a slightly elevated estimate. (When examined, the reduction to solid waste was negligible for the low and medium values, and impacted the 95th percentile value by approximately ½ log.) The total amount of FMDv produced per day by the AHRs is 4.75 times the per room output, as on average, 4.75 of the 46 rooms are in use per day (see Table 4.4.1-5) for FMD research.

Table 4.4.1 10: Monte Carlo Output Distribution of Liquid Pathway MARs by Animal Handling Room Type (PFU/Day)

Room Type	5th Percentile	50th Percentile (Median)	95th Percentile
A	1.2×10^{0}	1.0×10^{6}	1.6×10^{8}
A2 (large)	1.5×10^{1}	5.0×10^{5}	8.0×10^{7}
A2 (small)	4.0×10^{1}	4.8×10^{5}	8.1×10^{7}
A3	1.3×10^{3}	2.0×10^{6}	3.2×10^{8}

Table 4.4.1 10: Monte Carlo Output Distribution of Liquid Pathway MARs by Animal Handling Room Type (PFU/Day)			
Room Type	**5th Percentile**	**50th Percentile (Median)**	**95th Percentile**
B	6.0×10^{1}	2.0×10^{6}	3.2×10^{8}
C	1.5×10^{3}	3.0×10^{6}	4.9×10^{8}
D	1.3×10^{5}	5.3×10^{6}	1.6×10^{9}
Average Per Room	**2.5×10^{1}**	**6.9×10^{5}**	**1.3×10^{8}**
Total in AHRs	**1.19×10^{2}**	**3.28×10^{6}**	**6.18×10^{8}**

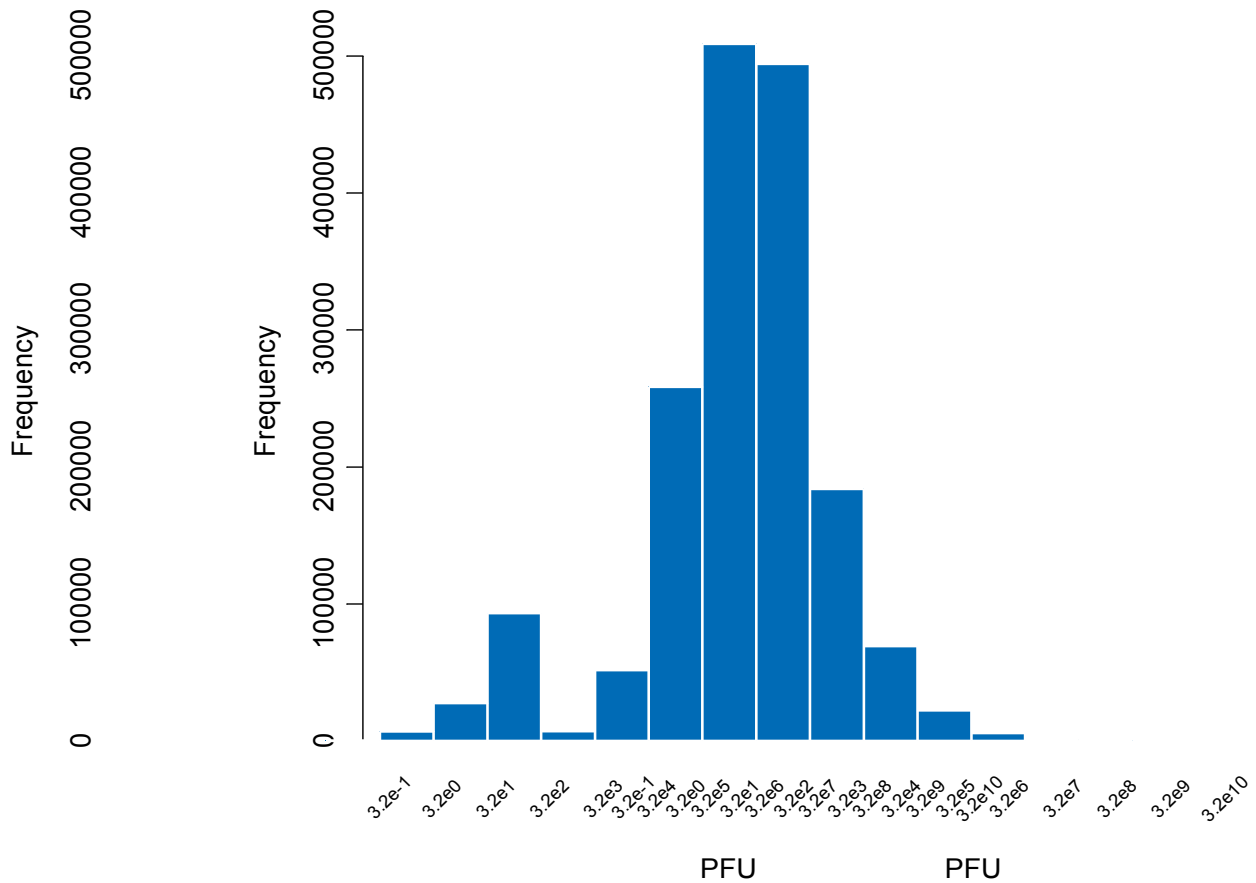


Figure 4.4.1-2: Monte Carlo Output – Distribution of Liquid Pathway MARs Across all BSL-3Ag Rooms (PFU/Day)

Contributions to Solid Waste Pathway – BSL-3Ag Animal Holding Rooms

Based on the capacity of and research activities within the BSL-3Ag AHRs, the NBAF Design Partnership team has estimated that the equivalent of 10 biohazard bags (10-15 lbs each) of solid waste materials will be generated per working day [Kronser, C., personal communication, 26 October 2011]; these bags will pass through the BSL-3Ag bulk autoclave. The solid wastes that comprise the bulk of the material to be autoclaved from the BSL-3Ag AHRs include towels that have come into contact with the urine and feces animal waste generated in the area, disposable PPE (Tyvek™, gloves, etc.) that have come into contact with these same wastes, and unconsumed animal feed. No animal bedding is expected to be

used at the NBAF [DHS, 2010] and animal solid fecal material enters the liquid waste stream directly along with the urine output. Therefore, the fecal material does not directly contribute to the solid waste pathway FMDv load [NDP, 2011].

The FMDv present in the urine and feces (versus the air) within the AHR represents the greatest contact potential for items entering the solid waste stream. The amount of FMDv generated in the urine and feces per day within the AHRs at the NBAF includes a range of 1.2×10^2 PFU/day, 3.3×10^6 PFU/day and 6.2×10^8 PFU/day for the low, median, and high estimated values respectively (see Table 4.4.1-10). The amount of aerosolized FMDv within the room (due to respiring infected animals, washdowns, aerosolized fractions of urine and feces contributions, etc.) is approximately an order of magnitude less at the median and high percentiles (2.2×10^2 PFU/day, 1.9×10^5 PFU/day and 1.7×10^8 PFU/day – see Table 4.4.1-8). Although some amount of the aerosolized FMDv in the room will contribute to the contact exposure of the biohazardous waste – due to the absorptive nature of the towels used and the direct contact of boots, gloves, and Tyvek™ suits to liquid and solid slurry of wastes during animal handling, animal examination and waste management activities – the amount of aerosolized FMDv contributing to the biohazardous waste solids within the AHR is considered a minor fraction and was not included in the MAR for the AHRs.

The percentage of FMDv that is transferred to the towels, PPE and other materials disposed of in biohazardous waste from the AHRs is estimated at 20% of the total FMDv amount present in the liquid waste (urine/feces). (After significant review of published literature and interviews with biosafety and medical waste specialists, no data were revealed that indicated the quantity of infectious material that is expected in biohazardous waste from either AHRs or clinical or microbiological laboratories. As these specific data were not available, an average estimate of 20% transfer was chosen. This amount is within the range reported for contact transfer studies reviewed which suggested a transfer rate between 0.1% to 40% depending on the physical state of the matrix (dry/wet), contact duration, contact pressure, time between deposition and contact, and friction applied during contact [Ansari et al., 1988, 1991; Cohen Hubal et al., 2007; Julian et al., 2010; Knobben et al., 2007; Lingaas and Fagernes, 2009; Mbithi et al., 1992].)

Using a 20% estimate for the fraction of FMDv from infected urine and feces, the total FMDv contribution to the solid waste pathway per day from the BSL-3Ag AHRs was determined to be 2.38×10^1, 6.56×10^5 and 1.24×10^8 PFU/day for the low, medium, and high levels, respectively.

Per the 65% Design, the equivalent of ten biohazard bags will be generated from the BSL-3Ag AHRs on any given day and a single bulk autoclave run will be performed daily, processing all solid waste [NDP, 2011]. The total daily MAR and MAR per biohazard bag equivalent are presented in Table 4.4.1-11.

Table 4.4.1 11: BSL 3Ag Animal Holding Room Solid Waste MAR			
	All Rooms (PFU/Day)	PFU/Bag (10 bags/day)	PFU/Bulk Autoclave Run (1 run per day)
Low	2.38×10^{1}	2.38×10^{0}	**2.38×10^{1}**
Medium	6.56×10^{5}	6.56×10^{4}	**6.56×10^{5}**
High	1.24×10^{8}	1.24×10^{7}	**1.24×10^{8}**

Contributions to Transference Pathway – BSL-3Ag Animal Holding Rooms

The source of FMDv involved in the transference pathway via respiratory exposure is the amount of aerosolized FMDv in the BSL-3Ag AHRs at any given time such that a worker may potentially inhale and carry FMDv in their nasal passages and upper respiratory tract (for potential subsequent transfer). The FMDv load within the urine and feces prior to its ultimate delivery to the liquid effluent system provides a source of contact hazard for the animal handlers. Lastly, the FMDv soiled solid waste materials (soiled towels, soiled PPE) provides a contact hazard for BSL-3Ag AHR staff. The transference pathway FMDv contributions are thus based on the amount of FMDv described for the aerosol, solid and liquid waste pathways as they are the primary source of FMDv within the BSL-3Ag AHRs.

Specifically, for the BSL-3Ag AHRs, two transference events were modeled: 1) respiratory contamination; and 2) fomite contamination, which was modeled as a contact event between the fomite and liquid waste. For the respiratory contamination, the source terms for aerosolized FMDv at the low, medium, and high levels were used to calculate the FMDv levels in nasal passages and upper respiratory tracts of researchers working in the AHRs. As described in Section 4.2.4, Sellers et al. measured the FMDv amounts in nasal passages of animal handlers as well as FMDv levels in the air surrounding the infected animals. Approximately 5.7% (±7.2%) of the aerosolized FMDv was measured in the handlers' nasal passages [Sellers et al., 1970]. Using this transfer percentage and assuming that all aerosolized FMDv produced on a daily basis in the BSL3-Ag AHRs is available for transfer, the low, medium, and high levels available for further transfer outside of the NBAF are presented in Table 4.4.1-12.

Table 4.4.1 12: Viable FMDv Particles Available for Transfer via Respiratory Tract in BSL 3Ag Animal Holding Rooms			
	Aerosolized PFU/Day		
	Low	Medium	High
BSL3 Ag AHR	4.56×10^{1}	4.01×10^{4}	3.55×10^{7}
Researchers Nasal Passages without Respiratory Protection	2.60×10^{0}	2.29×10^{3}	2.02×10^{6}

In the fomite contamination circumstances, liquid waste (i.e., urine and/or feces of an infected animal) comes into contact with an inanimate object that subsequently leaves the BSL-3Ag AHR. In such a contact transfer event, no protective measures were modeled to reduce the quantity transferred to the

fomite in the AHR. As described above and in Section 4.2.4, a contact transfer efficiency of 40% was assumed, i.e., 40% of the viable FMDv in contact between the donor and recipient surfaces is transferred. A spill with a total surface area of 900 cm^2 and volume of 90 mL was modeled (30 cm × 30 cm, spill thickness of 1 mm) with low, medium, and high concentration values obtained from the Monte Carlo simulations. The recipient donor surface was modeled as having a surface area of 50 cm^2. Using the methodology as described in Section 4.2.4, 2.2% of the viable FMDv was modeled as being transferred in this fomite transference event (50 cm^2 / 900 cm^2 × 40% = net 2.2% material transferred). The Monte Carlo simulations for the liquid waste pathway also provided the 5th, 50th, and 95th percentiles of FMDv per mL. Using these values, the low, medium, and high FMDv amounts transferred to a fomite are detailed in Table 4.4.1-13.

Table 4.4.1 13: FMDv Amounts Transferred in Fomite Contact Event in BSL 3Ag AHRs

Distribution	PFU/day (Liquid Waste MAR)	Amount of FMDv in Spill and on Fomite	
		90 mL Spill	Transferred to Fomite
Low	7.42×10^{-5}	6.68×10^{-3}	1.48×10^{-4}
Medium	3.89×10^{1}	3.50×10^{3}	7.78×10^{1}
High	4.06×10^{3}	3.65×10^{5}	8.12×10^{3}

4.4.2 BSL-3Ag Necropsy

4.4.2.1 Use and Frequency

At the NBAF, every animal that enters a containment area, regardless of its state of infection, is ultimately euthanized. A necropsy may or may not be performed at the end of the experiment but the Updated SSRA models necropsies for all of the animals. The NBAF BSL-3Ag necropsy suite contains two necropsy tables, each with a 2000 lb load capacity per table [NDP, 2011]. Based on staff (considering worker fatigue) and resource capacity (number of necropsy tables), it is assumed that up to 8 necropsies of bovine, porcine or ovine species can be performed in the BSL-3Ag necropsy suite, within any given work day [DHS, 2010]. This figure was confirmed by a scientific end-user focus group meeting conducted for the non-quantitative assessment presented in Section 9. Based on the number of AHRs, the capacity of each room by animal type, and the projected percent FMDv research occupancy presented in Section 4.4.1.1, the total number of FMDv infected animals to be researched at the NBAF per year was calculated to be 338. As it was estimated that one-third of the animal studies at the NBAF would be on FMD, the number of FMDv infected animals corresponds to one-third the yearly capacity of susceptible animals species of 1014 [NDP, 2011].

Since all infected animals will ultimately be euthanized, it was assumed that all 338 FMDv experimental animals expected at the NBAF per year will eventually be moved from the BSL-3Ag AHR, euthanized, and introduced into the necropsy suite, for a total number of 338 bovine, porcine or ovine necropsies per year (assuming all animals are necropsied, as stated above). With the NBAF capacity of 8 large animal

necropsies per day, this represents a total of 42 work days per year during which necropsies would be performed.

4.4.2.2 Pathogen Contribution

Contributions to Aerosol Pathway – BSL-3Ag Necropsy

During necropsy, workers may be exposed to droplets of infected blood, other fluids, or tissues that may pose a risk for inhalation and mucous membrane exposure, especially when performing procedures using power tools [Green and Yoshida, 1990]. During necropsy of FMDv infected animals at the NBAF, it is assumed that approximately 50% of the blood volume will drain from the animal into the liquid EDS (see *Contributions to the Liquid Waste Pathway* below for detail regarding amount of FMDv present in the blood matrix). During the draining of blood or the cutting of bone and tissues, some fraction of the blood volume will be aerosolized. Green and Yoshida reported an average 500 particles/mL measured in the breathing zone due to operating a bone saw during human autopsy experiments [1990]. When converted to a 15 L/min human respiration rate, the unprotected worker could inhale 22.5×10^6 bone dust particles during a three minute bone saw procedure. These results indicate that aerosols are generated during standard autopsy procedures but it did not attempt to quantify the number of infectious particles within the dust.

As no other specific data were found that detailed the amount of infectious FMDv material aerosolized during necropsy procedures, the aerosolized release fraction of tissue due to cutting of the carcasses was set to ten times the aerosolized release fraction (ARF) employed for liquid spills in the SSRA (1×10^{-4}) or 1×10^{-3}. The low, medium, and high concentrations of FMDv in the tissue of the animals derived from Monte Carlo simulations, along with the maximum number of animals that can be processed per day in the necropsy room, were used to calculate the aerosolized tissue levels of FMDv (see *Contributions to the Solid Waste Pathway* below for details on this distribution). One percent of the tissue was estimated to be exposed to cutting and thus available to be aerosolized. For the blood, the contribution to the aerosol pathway was determined by using the aerosolized release portion (1×10^{-4}) of 50% of the blood volume of the animals, as it was estimated that 50% of the blood volume would be lost to the liquid effluent drain [Scientific End-User group for the NBAF, SSRA 2010]. (Although this ARF for the blood does not account for velocity changes due to blood spray or splatter, because the majority of the blood lost to the liquid EDS during necropsy is expected to be gravity driven, this ARF was used.) The low, medium, and high concentrations of FMDv in the blood of the animals derived from Monte Carlo simulations, along with the maximum number of animals that can be processed per day in the necropsy room, were used to calculate the aerosolized tissue levels of FMDv (see *Contributions to the Liquid Waste Pathway* below for details on this distribution). As described in the Use and Frequency of the necropsy suite, a maximum of eight animals can be processed per day; this value was used to calculate the aerosolized tissue and aerosolized blood contributions, which were summed to calculate the total aerosol MAR for the necropsy suite, as detailed in the following equations and Table 4.4.2-1.

$$\text{Aerosolized Blood} = ARF \times 50\% \text{ Blood Volume} \times (\text{FMDv Conc. in Blood/Animal}) \times \#\text{Animals}$$

Equation 4.2.2-1

$$\text{Aerosolized Tissue} = 10 \times ARF \times 1\%\text{Tissue} \times (\text{FMDv Conc. in Tissue/Animal}) \times \#\text{Animals}$$

Equation 4.4.2-2

$$\text{Aerosolized MAR} = \text{Aerosolized Blood} + \text{Aerosolized Tissue}$$

Equation 4.2.2-3

Table 4.4.2 1: BSL 3Ag Necropsy Aerosol Pathway MAR

	Tissue PFU/Animal	Aerosolized Tissue (PFU/day)	Blood PFU/animal	Aerosolized Blood (PFU/day)	Aerosolized FMDv (PFU/day)[a]
Low	9.62×10^{-4}	7.70×10^{-8}	2.13×10^{3}	8.63×10^{-1}	**6.65×10^{0}**
Medium	7.24×10^{4}	5.79×10^{0}	4.34×10^{6}	1.74×10^{3}	**1.74×10^{3}**
High	1.73×10^{11}	1.39×10^{7}	5.76×10^{9}	2.30×10^{6}	**1.39×10^{7}**

[a]Values obtained using the distributions of the aerosolized tissue and aerosolized blood contributions.

Contributions to Liquid Waste Pathway – BSL-3Ag Necropsy

Within the NBAF BSL-3Ag necropsy suites the primary source of FMDv material that will enter the Effluent Decontamination System (EDS or liquid waste pathway) are the fluids from infected animals that are lost during post-mortem analysis, namely the blood, that are not apportioned to the aerosolized release fraction, and animal excrement from the euthanasia vestibule.

A literature review was performed to determine a distribution of the concentration of FMDv in the blood of infected animals. All measurements were converted to PFU/mL and then multiplied by the average blood volume of each species to calculate the mean concentration of FMDv in each animal (presented in log scale). The distribution of the concentration of FMDv in bovine [Blackwell et al., 1982], porcine [Lee et al., 2009], and ovine [Burrows, 1968] is presented in Table 4.4.2-2. These mean values were used as inputs for a Monte Carlo simulation.

Table 4.4.2 2: Distribution of Blood Virus Concentrations by Species

Species	PFU/mL		Blood Volume (L)	log PFU/animal	
	Mean	Std. Dev.		Mean	Std. Dev.
Bovine	1.39×10^{4}	3.62×10^{4}	30.0	5.92	1.89
Porcine	2.91×10^{5}	5.03×10^{5}	2.5	7.34	1.73
Ovine	6.52×10^{3}	2.03×10^{4}	1.5	3.43	3.16

A Monte Carlo simulation was performed to obtain the overall distribution of MAR values across animals. This was performed by simulating 1,000,000 observed concentration values. (511,830 of these corresponded to bovine observations, 485,210 to porcine observations, and 2,906 to ovine observations.) In each case, a normal distribution with the means and standard deviations for the virus

concentration (in units of PFU/animal and PFU/mL), as listed in Table 4.4.2-3, was assumed. The data were combined across species to obtain the overall distribution of virus concentration per animal. The 5th, 50th, and 95th percentiles associated with this combined distribution are provided in Table 4.4.2-3.

Table 4.4.2 3: Monte Carlo Output Distribution of Blood MAR

Distribution	Blood MAR (PFU/mL)	Blood MAR (PFU/Animal)
5th Percentile	9.57×10^{-2}	2.16×10^{3}
Median (50th Percentile)	5.08×10^{2}	4.34×10^{6}
95th Percentile	1.57×10^{6}	5.76×10^{9}

Per the Scientific End-User group for the NBAF, approximately 50% of the blood is allowed to drain off the necropsy table and flow into the liquid waste pathway [DHS, 2010]. The remaining portion of the blood is modeled as entering the solid waste pathway through the carcasses and tissue.

To calculate the corresponding low, medium, and high BSL-3Ag necropsy liquid waste pathway FMDv MAR per work day values, the low, medium, and high amount of FMDv (PFU/animal) in the blood matrix derived from the Monte Carlo simulation (from Table 4.4.2-6) was multiplied by: the total number of animals necropsied per work day (8) and the fraction of FMDv loss to the liquid effluent drain (50%), and the result was then combined with the low, medium, and high distribution of the urine and feces waste of animals being euthanized. These calculations are detailed in Table 4.4.2-4 along with the final FMDv MAR values for the BSL-3Ag necropsy liquid waste pathway.

Table 4.4.2 4: BSL 3Ag Necropsy Liquid Pathway MAR

	Blood PFU/Animal	Blood PFU/Day	Excrement PFU/Animal[a]	Excrement PFU/Day	FMDv Liquid Waste MAR (PFU/day)[b]
Low	2.16×10^{3}	8.63×10^{3}	4.51×10^{0}	3.61×10^{1}	**1.00×10^{6}**
Medium	4.34×10^{6}	1.74×10^{7}	1.24×10^{5}	9.95×10^{5}	**1.84×10^{7}**
High	5.76×10^{9}	2.30×10^{10}	2.34×10^{7}	1.87×10^{8}	**2.31×10^{10}**

[a]Determined from the daily liquid waste produced in the AHRs divided by 26.38 animals that occupy the AHRs per day, as determined through the Monte Carlo simulations.
[b]Values obtained using the distributions of the tissue and excrement contributions.

Contributions to Solid Waste Pathway – BSL-3Ag Necropsy

The primary contributor of FMDv to the solid waste pathway in the BSL-3Ag necropsy suite is the FMDv infected animals themselves, specifically the remaining carcasses containing infected tissues, hides, and a portion of the blood. While the animals are euthanized in the necropsy suite, no solid waste contributions from animal excrement were included in the modeling as all animal excrement (i.e., urine and feces) is expected to be disposed of through the EDS. (Animal excrement is included in the liquid waste pathway for the BSL-3Ag necropsy suite as detailed in the following section.)

The concentrations of FMDv in various tissues and organs in infected bovine, porcine, and ovine were compiled from the literature search; the average concentration values and the distribution used for

Monte Carlo simulations are listed in Table 4.4.2-5. For the purposes of modeling, cattle were modeled with a mass of 605 lbs (~274,000 g), sheep 50 lbs (~22,700 g), and pigs 100 lbs (~45,400 g).

Table 4.4.2 5: Assumed Distribution of Tissue Virus Concentrations by Species

Species	log PFU/g	log PFU/animal	Reference
Bovine	2.44 ± 1.58	7.16 ± 3.06	[Gailiunas and Cottral, 1966]
Porcine	0.91 ± 2.08	1.81 ± 3.81	[Lee et al., 2009]
Ovine	1.69 ± 1.61	4.21 ± 3.67	[Sharma and Murty, 1981]

Using the data in Table 4.4.2-5 as the inputs, a Monte Carlo simulation was performed to obtain the overall distribution of MAR values across animals. This was performed by simulating 1,000,000 observed concentration values. (511,830 of these corresponded to bovine observations, 485,210 to porcine observations, and 2,906 to ovine observations.) In each case, a log normal distribution with the means and standard deviations listed in Table 4.4.2-5 was assumed. Units were converted to PFU/animal after the random generation was performed, and the data were combined across species to obtain the overall distribution of virus concentration per animal. The 5th, 50th, and 95th percentiles associated with this combined distribution are listed below in Table 4.4.2-6 both on a per gram and per animal basis.

Table 4.4.2 6: Monte Carlo Output Distribution of Tissue MAR

Statistic	Tissue MAR (PFU/g)	Tissue MAR (PFU/Animal)
5th Percentile	1.74×10^{-2}	9.62×10^{-4}
Median (50th Percentile)	6.34×10^{1}	7.24×10^{4}
95th Percentile	6.30×10^{4}	1.73×10^{11}

In the estimation of total of FMDv/animal in PFU, no reduction was taken for the expected loss of organs/tissues during necropsy (e.g., those that will be contained and taken to the BSL-3E corridor for research) or the fraction of animal products that are not expected to be infected, or infected to a lesser extent than the tissues typically studied (and thus reported) in the literature (e.g., bone less the bone marrow). Therefore, it is likely that this estimation may be artificially high. However, 50% of the animal blood (see Table 4.4.2-3) was included in the solid waste contributions.

The amount of FMDv expected within each carcass following necropsy was used to estimate the total amount of FMDv expected to enter the solid waste pathway from the necropsy suite for any given day (or any unit of time). According to the NBAF Design Partnership [Update to Proposed Tissue Disposal System Report 18, June 2010], the BSL-3Ag necropsy suite solid waste pathway will be serviced by two tissue autoclaves (followed by incineration), with a tissue autoclave system capacity to process up to 42 500 lb animals or 21,000 lbs of tissue per week, with an average weekly load of 5,000 lbs. As freezer space is available to accommodate the storage of 42 animals, during large studies where several specimens are disposed, it is assumed that the disposal of these specimens will occur over the period of

one week, and not all in one day. With the maximum capacity considered, up to 4,200 lbs, or roughly eight 500 lb animals may be processed on any given work day. The resulting total FMDv MAR to the solid waste pathway from the necropsy suite are represented in Table 4.4.2-7, using the maximum load capacity of eight animals. It is assumed that 80% of the total solid waste produced in the necropsy suite goes through a tissue autoclave and incineration (i.e., the tissue/carcass pathway), while remaining 20% is transferred to disposable materials (e.g., PPE, absorbent towels, etc.) which will be disposed in biohazard bags through two autoclaves prior to incineration.

Table 4.4.2-7: BSL-3Ag Necropsy Solid Waste MAR

	Tissue PFU/Animal	Blood PFU/Animal	Tissue PFU (8 Animals)	50% Blood (8 Animals)	Total Solid Waste MAR (PFU)	Biohazard Bag Waste (20%) (PFU)	Tissue/Carcass Solid Waste (80%) (PFU)
Low	9.62×10^{-4}	2.16×10^{3}	7.70×10^{-3}	8.63×10^{3}	8.63×10^{3}	$\mathbf{1.73 \times 10^{3}}$	$\mathbf{6.91 \times 10^{3}}$
Medium	7.24×10^{4}	4.34×10^{6}	5.79×10^{5}	1.74×10^{7}	1.79×10^{7}	$\mathbf{3.59 \times 10^{6}}$	$\mathbf{1.44 \times 10^{7}}$
High	1.73×10^{11}	5.76×10^{9}	1.39×10^{12}	2.30×10^{10}	1.41×10^{12}	$\mathbf{2.82 \times 10^{11}}$	$\mathbf{1.13 \times 10^{12}}$

Contributions to Transference Pathway – BSL-3Ag Necropsy

For the BSL-3Ag necropsy room, one transference event was modeled: bodily contamination, which was modeled as a contact event between the contaminated animal blood and either the hand or the body. In such a contact transfer event, protective measures such as gloves and Tyvek® suits were modeled with their known protective efficiencies and failure rates; these reduced MAR (*Q* values) are listed in Section 4.6. As described above and in Section 4.2.4, a contact transfer efficiency of 40% was assumed between the donor and recipient surfaces. A spill with a total surface area of 900 cm^2 and volume of 90 mL was modeled (30 cm × 30 cm, spill thickness of 1 mm) with low, medium, and high concentrations (determined across all animals) obtained from the Monte Carlo simulations. The recipient donor surfaces of the hand, and body were modeled as having surface areas of 437 cm^2 and 400 cm^2 respectively (see Section 4.2.4 for details on these surface area determinations). An additional event was also included in which the researcher improperly removes the contaminated gloves resulting in a secondary transfer of infectious material from the glove to the unprotected hand. For this event, the second transfer efficiency was also set to 40%. The amounts transferred are detailed in Table 4.4.2-8.

Table 4.4.2-8: BSL-3Ag Necropsy - FMDv Transferred via Bodily Contact Event

	Viable FMDv		
	Low	Medium	High
Concentration of Blood (PFU/mL)	9.57×10^{-2}	5.08×10^{2}	1.57×10^{6}
Amount of FMDv in 90 mL Blood (PFU)	8.61×10^{0}	4.58×10^{4}	1.41×10^{8}
Amount of FMDv Transferred to Hand Region (PFU)	1.67×10^{0}	8.89×10^{3}	2.74×10^{7}
Amount of FMDv Transferred from Glove to Hand (PFU)	6.69×10^{-1}	3.55×10^{3}	1.10×10^{7}
Amount of FMDv Transferred to Body Region (PFU)	1.53×10^{0}	8.13×10^{0}	2.51×10^{0}

4.4.3 BSL-3E and BSL-3E "Special Procedure" Rooms

4.4.3.1 Use and Frequency

The BSL-3E and BSL-3E "Special Procedure" rooms at the NBAF are designed to accommodate *in vitro* research and development work and other laboratory activities with FMDv. This work is expected to range from preparation of materials for administering and testing vaccinations, preparation of FMDv materials for animal experimentation, diagnostic analysis of necropsy or incoming samples, research and development of new diagnostic assays, genetic sequencing, protein biochemistry, and other FMDv research initiatives. The frequency of which these laboratories are expected to be occupied with FMDv related activities (i.e., experiments or handling of infectious FMDv material and samples) is related to the number of work days per year (250), the expected research capacity (70% per the 65% Design), the FMDv research occupancy rate (33%), the fraction of the day (8 hours) dedicated to lab research (33%), and the number of BSL-3E corridor modules or labs (20). This calculation indicates approximately 381 FMDv-related experimental (24-hour) days per year at the NBAF – or essentially daily FMDv research activity within the BSL-3E corridor.

4.4.3.2 Pathogen Contribution

More than 20 references of peer-reviewed and published laboratory *in vitro* research on FMDv were evaluated to estimate the range of FMDv viral titers and volumes expected to be manipulated in the BSL-3E and/or BSL-3E "Special Procedure" laboratory suites where *in vitro* and diagnostic FMDv work will be conducted at the NBAF [Richard A., 1960; Cunliffe, 1962; Cottral et al., 1966; Polatnick, 1967; Campbell, 1969; Fellowes and Sutmoller, 1970; Martinsen, 1970; Vande Woude et al., 1970; Graves et al., 1971; Sutmoller and McVicar, 1972; McVicar et al., 1974; Hyde et al., 1975; Polatnick and Bachrach, 1978; Knudsen et al., 1979; House and Yedloutschnig, 1982; McVicar and Eisner, 1983; Knudsen et al., 1986; Grubman et al., 1987; Twomey et al., 1995; Baxt and Mason, 1995; O'Donnell et al., 2001, 2005; Carrillo et al., 2007]. The total FMDv (PFU) used in each study was calculated by multiplying the concentration by the volume used in the noted experimentation. Only studies that explicitly detailed the concentration and volume (of the 25 reviewed) were used to calculate these statistics (n = 12). The log of the total PFU handled was calculated and the average and standard deviation of the log (PFU) values determined. To represent the range of potentialities, three MAR values were derived from these published data to represent the 5th, 50th, and 95th percentile values (based on a normal distribution using the mean and standard deviation) for total FMDv in PFU present in any given experiment. Note that in this context an "experiment" is defined as any research activity within a BSL-3E/ BSL-3E "Special Procedure" laboratory unit that requires the use or physical manipulation of the 5th, 50th, or 95th percentile values of FMDv as depicted in Table 4.4.3-1.

Table 4.4.3 1: BSL 3E/BSL 3E Special Procedure" MDv MAR Per Experiment		
Statistic	**Log PFU/Experiment**	**PFU/Experiment**
Mean	4.54	3.46×10^4
Std. Dev	2.76	n/a
5th Percentile	0.00696	1.02×10^0
50th Percentile (Median)	4.54	3.46×10^4
95th Percentile	9.07	1.18×10^9

The presented range of total number of FMDv PFU per experiment spans 9 orders of magnitude and is assumed to represent the majority of potential FMDv *in vitro* or diagnostic research activities that could occur in the BSL-3E laboratory corridor. For reference, the high PFU MAR value could represent handling a liter or more of FMDv-infected blood from a cow at the height of viremia or 1 mL of stock culture at 10^9 PFU/mL. The median and low values could represent the amount of FMDv expected in performing experimentation on diagnostic tissue samples, preparing vaccines and/or inocula for study delivery and/or preparing dilution series for quantitative analyses.

Contrary to the BSL-3Ag AHR and BSL-3 necropsy MAR calculations, no Monte Carlos simulations were performed in the preparation of the 5th, 50th, and 95th percentile values presented in Table 4.4.3-1 above as these data did not require weighting to adjust for varying occupancy rates and animal sizes, or collapsing of values across animal species.

The total amount of FMDv potentially present in the BSL-3E or BSL-3E "Special Procedure" laboratories on any given work day can be estimated by multiplying the amount of FMDv manipulated in any given experiment (at the 5th, 50th and 95th percentile values) by the average number of FMDv experiments (i.e., handling activities with viable FMDv) conducted in the BSL-3E and/or BSL-3E "Special Procedure" laboratories on any given day. The average number of experiments conducted within the BSL-3E and BSL-3E "Special Procedure" laboratories on any given day at the NBAF is a function of the capacity of the laboratory. The 65% Design has provided the capacity for a total of 180 scientists to be working within the BSL-3E corridor [NDP, personal communication, October 2011] – with approximately nine scientists working within a single laboratory module. Within the BSL-3E corridor, there are 20 BSL-3E modules. Assuming 70% capacity and that each scientist is conducting one experiment per day, this results in a total of 180 experiments or activities per work day. Assuming that one-third of the experiments are FMDv-related, approximately 42 FMDv-related activities are expected to be conducted in the BSL-3E corridor per day and approximately 2 FMDv-related activities per BSL-3E module. With these assumptions, the resulting BSL-3E/ BSL-3E "Special Procedure" FMDv MAR are presented in Table 4.4.3-2.

Table 4.4.3 2: BSL 3E Corridor FMDv MAR Per Work Day			
	FMDv per Experiment (PFU/experiment)	MAR PFU/Work Day (Single BSL 3E/SP Unit)	MAR PFU/Work Day (Entire BSL 3E Corridor 20 Units)
Low	1.02×10^{0}	2.14×10^{0}	4.28×10^{1}
Medium	3.46×10^{4}	7.27×10^{4}	1.45×10^{6}
High	1.18×10^{9}	2.48×10^{9}	4.96×10^{10}

Contributions to Aerosol Pathway – BSL-3E & BSL-3E "Special Procedure"

The amount of FMDv that is aerosolized within the BSL-3E and BSL-3E "Special Procedure" laboratories should be negligible (relative to other pathways in the room) when protocols are followed and design features/engineering controls are functioning as expected. The FMDv contributions to the aerosol release pathway due to an accident at the NBAF are therefore event specific, such that the amount of aerosolized FMDv in the BSL-3E or BSL-3E "Special Procedure" laboratory units for any given event could include: the amount involved in a single experiment; the amount generated within a single BSL-3E or BSL-3E "Special Procedure" room for an entire work days' worth of experiments; or the amount generated within the entire BSL-3E corridor (20 units) over a standard work day (or some other periodicity). The amount available as an aerosol in the BSL-3E corridor is the aerosol release fraction (ARF= 1×10^{-4}) of the FMDv MAR of the BSL-3E area (previously presented in Table 4.4.3-2 and corresponding text). This results in the following aerosolized BSL-3E area MAR (see Table 4.4.3-3). Note that the specific event modeled includes the FMDv ARF portion of a single experiment – whereby the researcher drops an experimental vial outside of the biosafety cabinet resulting in a fraction of the contents of that vial available for release through the aerosol pathway (first column of Table 4.4.3-3). For completeness, the aerosolized amount generated within a single BSL-3E or BSL-3E "Special Procedure" laboratory for an entire work days' worth of experiments (middle column) and the aerosolized amount generated within the entire BSL-3E corridor over a standard work day (last column) are also presented in Table 4.4.3-3.

Table 4.4.3 3: BSL 3E Area Aerosol FMDv MAR (Aerosolized Release Fraction in PFU)			
	MAR PFU/Sample	MAR PFU per BSL 3E/SP Unit	MAR PFU per BSL 3E Corridor
Low	**1.02×10^{-4}**	3.06×10^{-4}	6.11×10^{-3}
Medium	**3.46×10^{0}**	1.04×10^{1}	2.07×10^{2}
High	**1.18×10^{5}**	3.54×10^{5}	7.07×10^{6}

Contributions to Solid Waste Pathway – BSL-3E & BSL-3E "Special Procedure"

Based on the capacity of and research activities within the BSL-3E corridor, it is estimated that 40 biohazard bags (10-15 lb ea), or the equivalent, of solid waste materials will be generated per working day. This assumes 2 bags per day per BSL-3E corridor module, all sterilized within a single (1) medium

autoclave cycle per day [Kronser, C., personal communication, 26 October 2011]. These items will pass through the BSL-3E autoclave, followed by a second bulk final autoclave cycle prior to on-site incineration.

The solid wastes that are expected to be generated within the BSL-3E laboratories include: spent consumables that have contacted infectious materials (pipette tips, t-flasks, tubes); disposable PPE; spent media; portions of cultures; samples or stocks no longer required for future experimentation; and/or any other material exiting the BSL-3E corridor modules that is amendable to steam sterilization. The amount of FMDv expected within these biohazardous waste materials is the fraction of the total FMDv utilized during *in vitro* research activities that is not retained or consumed through experimental procedures. The total amount of FMDv (PFU) expected to be in use at the NBAF within the BSL-3E corridor per day is presented in Table 4.4.3-2 above. Of that amount, it is assumed that the majority of the material will be retained for experimentation on any given day; however, to be conservative and to allow for days where disposal of stock cultures may occur (such as the end of an experimental phase), this retention value was placed at 80%. With an FMDv material retention percentage of 80%, the amount of FMDv expected within the solid biohazard waste for any given work day is 20% of the total FMDv MAR per work day within the BSL-3 corridor. Given the estimated number of biohazardous waste bags per unit (2), per day (40) and per daily autoclave cycle (40) at the NBAF, the following MARs were calculated (Table 4.4.3-4).

Table 4.4.3 4: BSL 3E Corridor Solid Waste MAR

	Total MAR (PFU/BSL 3E Corridor)	Solid Waste MAR (PFU/Bag)	Solid Waste MAR (PFU/Module)	Solid Waste MAR (PFU/Autoclave Run)
Low	4.28×10^{1}	2.14×10^{-1}	4.28×10^{-1}	$\mathbf{8.57 \times 10^{0}}$
Medium	1.45×10^{6}	7.27×10^{3}	1.45×10^{4}	$\mathbf{2.91 \times 10^{5}}$
High	4.96×10^{10}	2.48×10^{8}	4.96×10^{8}	$\mathbf{9.91 \times 10^{9}}$

Contributions to Liquid Waste Pathway – BSL-3E & BSL-3E "Special Procedure"

Within the BSL-3E and BSL-3E "Special Procedure" laboratories, FMDv infectious wastes are not expected to enter the liquid waste pathway unless an incident occurs such as a researcher fails to follow protocol and pours infectious FMDv waste down the drain. Per the 65% Design minor spills in BSL-3E containment will be decontaminated via wipe down and gross contamination will be decontaminated using an appropriate gas/vapor method such as a portable chlorine dioxide or vaporized hydrogen peroxide (VHP) unit. Such events are expected to occur at a frequency of 1-2 annual occurrences and thus no material contributes to the liquid waste pathway. The vast majority of other infectious wastes generated within the BSL-3E corridor enter the solid waste pathway (via the autoclaves as presented above, or via dunk tanks). Although an unlikely event with trained staff, it is possible that a researcher could dispose of FMDv infectious waste improperly by pouring materials down the sink or floor drain (e.g., failing to properly dispose of the material through the autoclave-autoclave-incinerator solid waste pathway per the 65% Design). (The probability of failing to follow protocol and performing an improper protocol was set to 10^{-4}.) The potential MAR to the liquid pathway given such an event is assumed to be

equivalent to the amount of FMDv estimated for any given sample as presented in Table 4.4.3-5 (see text surrounding Table 4.4.3-1 and 4.4.3-2 above for detail regarding how these estimates were derived). For completeness, the corresponding values if all of the FMDv material used throughout a single work day in a single lab or across all 20 labs is improperly released to the liquid waste pathway is also presented (although these two MAR are not specifically modeled as these are not considered credible events due to the extremely low frequency of occurrence).

Table 4.4.3 5: BSL 3E Liquid Pathway FMDv MAR (Following Failure to Follow Protocol and Disposing of a Sample Down the Drain)

	MAR PFU/Sample	MAR PFU per BSL 3E/SP Unit	MAR PFU per BSL 3E Corridor
Low	**1.02×10^{0}**	2.14×10^{0}	4.28×10^{1}
Medium	**3.46×10^{4}**	7.27×10^{4}	1.45×10^{6}
High	**1.18×10^{9}**	2.48×10^{9}	4.96×10^{10}

Contributions to Transference Pathway – BSL-3E & BSL-3E "Special Procedure"

For the BSL-3E corridor, one transference event was modeled: bodily contamination from a liquid spill. This was modeled as a contact event between a solution of viable FMDv and either the palm and fingers or the body. In such a contact transfer event, protective measures such as gloves and Tyvek suits® were modeled with their known protective efficiencies and failure rates as detailed in the master event table in Section 4.6. As described above and Section 4.2.4, a contact transfer efficiency of 40% between the donor and recipient surfaces, and a spill of 900 cm^2 total surface area assumed. The low (5th-percentile), medium (50th-percentile, median), and high (95th-percentile) amounts of viable FMDv used for transference were the same as those determined for a given experiment (1.02×10^{0}, 3.46×10^{4} and 1.18×10^{9}, respectively and as shown in Table 4.4.3-1).

The recipient donor surfaces of the palm and body were modeled as having surface areas of 197 cm^2 and 400 cm^2 respectively (see Section 4.2.4 for details on these surface area determinations). An additional event was also included in which the researcher improperly removes the contaminated gloves resulting in a secondary transfer of infectious material from the glove to the unprotected hand. For this event, a 40% transfer efficiency was used. The amounts transferred are detailed in Table 4.4.3-6.

Table 4.4.3 6: Viable FMDv Particles Transferred in Bodily Contact Event in BSL 3E Laboratory

	Viable FMDv (PFU)		
	Low	Medium	High
Amount of FMDv in Spill	1.02×10^{0}	3.46×10^{4}	1.18×10^{9}
Amount of FMDv Transferred to Palm Area	8.92×10^{-2}	3.03×10^{3}	1.03×10^{8}
Amount of FMDv Transferred from Glove to Palm	3.57×10^{-2}	1.21×10^{3}	4.12×10^{7}
Amount of FMDv Transferred to Body Area	1.81×10^{-1}	6.15×10^{3}	2.10×10^{8}

4.4.4 Outside of Containment

4.4.4.1 Use and Frequency

While very rare, spills and leaks of infectious materials can occur during shipment and receipt of packages. The packaging and shipping of infectious materials require the use of specific packaging constructed to meet defined tolerances and the personnel responsible for preparing such packages must be trained and certified in order to ship packages by land (DOT Regulations) or air (IATA Regulations). Select agent infectious materials packaging and handling requirements are covered by *Select Agent Regulations for Possession, Use, and Transfer of Select Agents and Toxins*, published by HHS (42 CFR part 73) and by USDA (9 CFR part 121 and 7 CFR part 331) [USDHHS/USDA, 2007]. These regulations provide many requirements, including:

- Required permits (e.g., granted by the U.S. Public Health Service, USDA, DOT, U.S. Department of Commerce, and IATA) shall be obtained before select agents are prepared for transport. Standard operating procedures should be in place for import and export activities;
- Packaging, labeling, and transporting select agents must be performed in conformance with all applicable local, federal, and international transportation and shipping regulations;
- Personnel who package, handle, and ship these agents should be subject to all applicable training. Hazardous materials shipping training and certification is required for shippers; and
- Recommendations for facilities are to avoid hand-carrying select agents when transferring them to other external facilities and to develop and follow protocols for intra-facility transfers.

The opportunities for these shipping events could occur on or outside of the NBAF grounds, as with any infectious materials package shipped to any Select Agent registered facility. For the purpose of this Updated SSRA however, the location is assumed to be between the Transshipping Facility (TF) and the BSL-3E or BSL-3E "Special Procedure" laboratories at the NBAF.

For this originating location, the total number of opportunities per year was determined by estimating (with assistance from the Scientific End-Users Group) the number of employees that may be handling incoming packages every day (20), the number of opportunities each employee has to handle such materials each day (3), the fraction of incoming materials expected to contain FMDv versus other infectious materials (33%) and the number of work days in one year (250).The resulting opportunity frequency (Opportunities/Year) was = $20 \times 3 \times 0.33 \times 250 = 5.0 \times 10^3$.

4.4.4.2 Pathogen Contribution

The FMDv related samples received at the NBAF may include diagnostic samples, *in vitro* research materials and/or reference materials from other facilities. These FMDv related samples will be opened, manipulated and stored as needed in the BSL-3E or BSL-3E "Special Procedure" suites where *in vitro* and diagnostic analyses will be performed at the NBAF. The amount of pathogen present in these samples may vary significantly, and is assumed to be representative of the amount of pathogen estimated per sample or experimental manipulation as previously defined for the BSL-3E/BSL-3E "Special Procedure" laboratory *in vitro* and diagnostic research activities. These MAR are re-iterated here in Table 4.4.4-1 for

ease of reference (see BSL-3E/BSL-3E "Special Procedure" Pathogen Contribution Section 4.4.3.2 for details as to how these values were derived).

Table 4.4.4 1: Outside Containment Transshipping FMDv MAR

	MAR (PFU/Sample)
Low	1.02×10^{0}
Medium	3.46×10^{4}
High	1.18×10^{9}

Contributions to Aerosol Pathway – Outside Containment

The contributions to the aerosol pathway are identical to those previously defined for the BSL-3E/BSL-3E "Special Procedure" rooms, as the initiating source of material (per experiment/sample) with the exception that the aerosolized release fraction is applied (1×10^{-4}) to represent the fraction of these (presumably liquid sample materials that are dropped) that are aerosolized upon initiation of an event. The MAR presented in the following table represents the low, medium, and high MAR presented in Table 4.4.4-1 above times the aerosolized release fraction (1×10^{-4}). The MAR for this outside containment event assumes that only a single sample is involved in the error. The resulting MAR within the aerosol pathway are presented in Table 4.4.4-2.

Table 4.4.4 2: Outside Containment Transshipping FMDv Aerosol Pathway MAR

	MAR (PFU/Sample)
Low	1.02×10^{-4}
Medium	3.46×10^{0}
High	1.18×10^{5}

Contributions to Solid Waste Pathway – Outside Containment

As this is an outside of containment event, no event specific contribution to the solid waste pathway MAR was developed. It is assumed that if a transshipping sample is dropped outside of containment, the spill will be decontaminated and the materials used in the clean-up will be disposed of within the BSL-3E containment corridor. The MAR contribution from these spill clean-up related materials is already represented in the total FMDv assumed for the BSL-3E corridor laboratory solid waste pathway.

Contributions to Liquid Waste Pathway – Outside Containment

As this is an outside of containment event, the spilled/dropped package material is not likely to enter any liquid effluent drains at the NBAF and therefore no contribution to the liquid waste pathway was considered. As stated previously, the materials used to clean up and decontaminate the spill will enter the BSL-3E corridor solid waste pathway and have been assumed within those MAR estimations.

Contributions to Transference Pathway – Outside Containment

For the non-containment originating location, five transference sets of circumstances were modeled: the first three involve NBAF transshipping worker events and the second two involve maintenance worker events.

The first three events involve NBAF staff handling incoming samples (such as described in the transshipping event above) containing FMDv infected liquids. In these events, during a spill/leak of the FMDv containing sample, NBAF staff experience bodily contamination. This bodily contamination associated with a spill was modeled as a contact event between 50 mL solution of FMDv infected sample and either the palm and fingers, the foot, or the body (note that this assumed the spill occurred outside of containment in the transshipping area). For this bodily contact event, protective measures such as gloves and Tyvek® suits were modeled with their known protective efficiencies and failure rates. As described above and in Section 4.2.4, a contact transfer efficiency of 40% was assumed between the donor and recipient surfaces. A spill with a total surface area of 500 cm^2 (50 mL) was assumed with low, medium, and high amounts of FMDv identical to those determined for BSL-3E experiments (Table 4.4.4-1). The recipient donor surfaces of the palm, foot, and body were modeled as having surface areas of 197 cm^2, 557 cm^2, and 400 cm^2, respectively. The amounts transferred in this bodily contact event are detailed in Table 4.4.4-3.

Table 4.4.4 3: Non Containment FMDv Transferred via Bodily Contact with FMDv Sample

	Viable FMDv (PFU)		
	Low	Medium	High
Amount of FMDv in 50 mL Sample	1.02×10^{0}	3.46×10^{4}	1.18×10^{9}
Amount of FMDv Transferred to Palm Region	1.61×10^{-1}	5.45×10^{3}	1.86×10^{8}
Amount of FMDv Transferred to Foot Region	4.55×10^{-1}	1.54×10^{4}	5.26×10^{8}
Amount of FMDv Transferred to Body Region	3.26×10^{-1}	1.11×10^{4}	3.78×10^{8}

The last two outside containment transference events occur during inspection and maintenance of the liquid effluent system pipeline. In these events, a maintenance worker services a drain trap from the BSL-3Ag AHR that experienced a minor leak whereby 5 mL of liquid waste (the 5th, 50th and 95th percentile value of the average FMDv/mL generated from urine and feces from FMDv infected animals) was assumed to have slowly leaked from the joint and remained on the pipe. In this event it is assumed that the laboratory staff followed the proper drain trap priming protocol and that a 10^{-1} reduction of the FMDv MAR due to the decontamination solution in the trap was achieved. The maintenance worker's hand is assumed to have come into contact with the 5 mL leak of FMDv liquid waste generated from the BSL-3Ag AHR (when infected FMDv animals were present). As described above and in Section 4.2.4, a contact transfer efficiency of 40% was assumed between the donor and recipient surfaces and the contact event covers the entire surface area of the spill (assumed to be smaller than the palm or surface of the wrench/tool). The worker is assumed to be wearing gloves for inspection/maintenance of pipes within the containable NBAF areas, as per standard practice in containment facilities where

maintenance of systems potentially containing or contaminated with infectious materials occurs. As stated in Section 4.2.4, the gloves offer a 10^{-5} reduction in MAR. The amounts transferred in this palm contact event are detailed in Table 4.4.4-4.

Table 4.4.4 4: Non Containment FMDv Transferred via Palm Contact with FMDv Contaminated Pipe

	Viable FMDv (PFU)		
	Low	Medium	High
Amount of FMDv in 5 mL Waste (post trap decontamination of 10 [1])	3.71×10^{-5}	1.95×10^{1}	2.03×10^{3}
Amount of FMDv Transferred to Glove	1.48×10^{-5}	7.78×10^{0}	8.12×10^{2}
Amount of FMDv Transferred to Palm through Glove (with full glove protection)	1.48×10^{-10}	7.78×10^{-5}	8.12×10^{-3}

In the final transference event, a maintenance worker's tool (e.g., a wrench) comes into contact with the FMDv material on the pipe. In this instance the same 40% transfer efficiency is applied as was for the maintenance worker's palm. The tool used in the repair is also assumed to have been properly decontaminated following the repair via a wipedown or dunk with suitable decontamination solution to provide a further 10^{-5} reduction of MAR. The FMDv transferred to the fomite from contact with the contaminated pipe are detailed in Table 4.4.4-5.

Table 4.4.4 5: Non Containment FMDv Transferred via Fomite (Wrench) Contact with FMDv Contaminated Pipe

	Viable FMDv (PFU)		
	Low	Medium	High
Amount of FMDv in 5 mL Waste (post trap decontamination of 10 [1])	3.71×10^{-5}	1.95×10^{1}	2.03×10^{3}
Amount of FMDv Transferred to Wrench (no wipedown)	1.48×10^{-5}	7.78×10^{0}	8.12×10^{2}
Amount of FMDv Remaining on Wrench (following wipedown)	1.48×10^{-10}	7.78×10^{-5}	8.12×10^{-3}

4.5 Fault Analyses and Event Descriptions

The originating locations, potential pathogen release pathways and the conceptual models for the systems and procedures used for containment in each of the originating locations is presented in Sections 4.1 and 4.2. Section 4.4 develops the quantities of materials that are modeled for each of the originating locations and pathways. In this section, failure rates and probabilities for the modeled components and procedures are presented in conjunction with the development of accident sequences that culminate in an event. Fault trees used for the events modeled in the Updated SSRA are presented throughout this section. A generic fault tree (like the type provided) is presented in Figure 4.5-1. This example is provided to illustrate the features of the fault trees. Each fault tree has a corresponding fault table. The fault tables complement the fault trees by providing the associated probabilities and

reductions of the MAR at each node. A generic fault table is presented in Table 4.5-1. The fault trees begin with an opportunity for failure. The rate of this failure opportunity is independent of the probabilities associated with the modeled nodes in the fault tree.

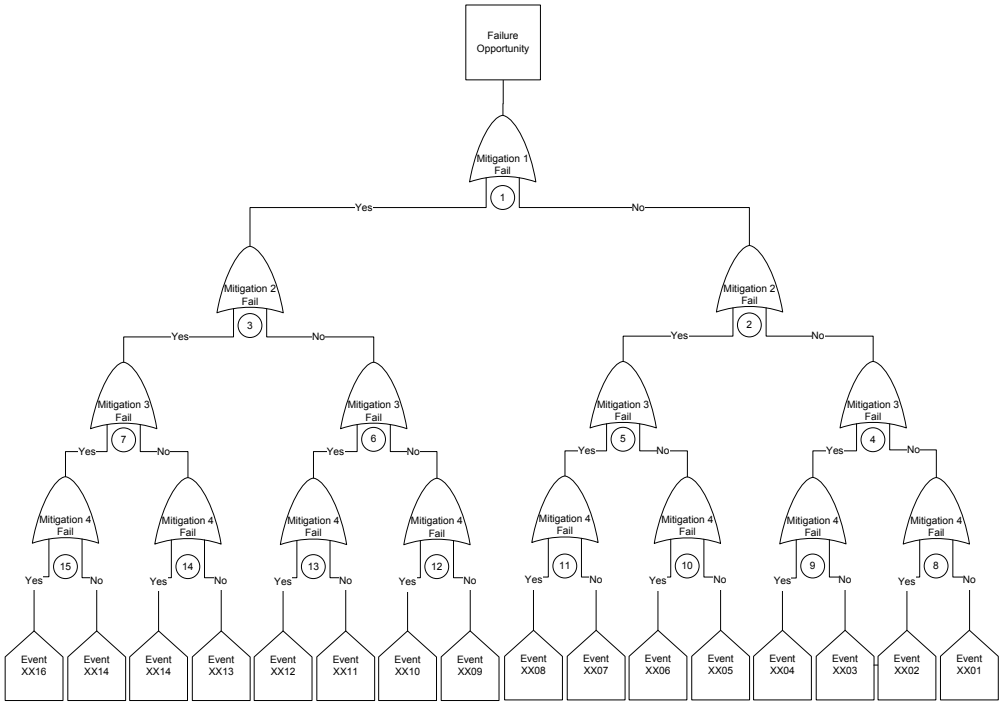


Figure 4.5-1: Generic Fault Tree

For each fault tree, a table is presented for the set of circumstances leading to the release of material, indicating which nodes or mitigating systems are functional or had failed. For each circumstance, each event node or mitigating (i.e., protection) system is included, along with their modeled probability of failure, reduction factor of the viral quantity when the mitigating system or node is functional, and the reduction factor when the mitigating system or node fails. The opportunity rate (i.e., how often such circumstances could occur based on the use and frequency of the AHRs and necropsy room per year, R_o) is also presented for each circumstance. Each unique detailed accident sequence creates an event under the circumstances and the probability for these specific loss-of-containment events occurring (P_{Loss}), the overall reduction factor along with the Q value (quantity released at this point in the event), and the frequency of the loss-of-containment event (F_{Loss}) are presented. The probability of loss-of-containment is the product of the probabilities of each node's state (i.e., success/functional or failure) and the overall reduction is similarly the product of the reduction factors for each node based on its state. The frequency of loss-of-containment (F_{Loss}) (number of times per year) is the product of the opportunity rate (R_o) and the probability (P_{Loss}).

$$F_{Loss} = P_{loss} R_o \qquad \text{Equation 4.5-1}$$

Based on the FMDv-related activities and experiments to be performed at the NBAF, a total of 24 circumstances were modeled that can result in a release of infectious material via the four pathways

and from the four originating locations. Further, critical feedback from subject matter experts was used to develop and refine these circumstances based on their concerns. These 24 circumstances are detailed in Table 4.3.1-1 and include five originating from the AHRs, seven originating from activities in the necropsy suite, six from the BSL-3E/BSL-3E "Special Procedure" laboratories, and six originating outside of containment.

A summary of all of the nodes, the probability of failure, the reduction factor when the mitigating system is functional, and the reduction factor upon failure is listed in Table 4.5-1. The probability of human error for most nodes was set to 5×10^{-3} based on human reliability assessments for highly reliable and trained workers such as those to be employed at the NBAF [Spurgin, 2009]. This failure rate was used for any mitigating systems or event nodes that were dependent upon a worker performing the action. Where other data were not available, system failure rates were set to 1×10^{-5} [DHS, 2010]. Additional assumptions to the failure rates and transfer percentages are noted in Table 4.5-1 and for each set of event circumstances in the following sections.

Table 4.5 1: Summary of Mitigating Systems and Nodes Reduction Factors and Probabilities						
Pathway(s)	Originating Location(s)	Node/Mitigation System	Probability of Failure	Reduction Factor (Success)	Reduction Factor (Failure)	Notes
Aerosol	AHR, Necropsy, 3E	HEPA filter degraded	1.00E-02	1.00E-05	2.60E-04	See following sections
Aerosol	AHR, Necropsy, 3E	HEPA filter blow-out	1.00E-06	1.00E-05	1.00E+00	See following sections
Liquid	AHR	Source decontamination at (10) drain pipes (AHR)	4.89E-02	1.00E-01	1.92E-01	10 drains ≈ 4.75 AHRs in use, 2 trench drains per AHR
Liquid	AHR, Necropsy, 3E	Cook tank	1.00E-05	1.00E-06	1.00E+00	Systems failure rate
Liquid	AHR, Necropsy, 3E	Cook tank performance indicator	1.00E-05	n/a	n/a	Systems failure rate
Liquid	AHR, Necropsy, 3E	On-site wastewater treatment	1.00E-05	1.00E-01	1.00E+00	Systems failure rate
Liquid	Necropsy	Source decontamination at (2) drain pipes	9.975E-03	1.00E-03	5.02E-01	2 sink drains
Liquid	3E	Not pouring a sample down the drain	1.00E-04	0.00E+00	1.00E+00	Disregard of protocol failure rate
Solid	AHR, Necropsy, 3E	Autoclave	1.00E-05	1.00E-06	1.00E+00	Systems failure rate
Solid	Necropsy	Tissue autoclave	1.00E-05	1.00E-06	1.00E+00	Systems failure rate
Solid	Necropsy	Tissue autoclave performance indicator	1.00E-05	n/a	n/a	Systems failure rate
Solid	AHR, Necropsy, 3E	Incinerator	1.00E-10	1.00E-09	1.00E+00	Systems failure rate for incinerator multiplied by systems failure rate for built-in redundant and orthogonal performance indicator
Transference	Necropsy, 3E, Non-containment	Body shower	5.00E-03	1.01E-01	1.00E+00	Human error rate (5×10^{-3})
Transference	Necropsy, 3E, Non-containment	Chemical spot treatment	5.00E-03	1.00E-05	1.00E+00	Human error rate (5×10^{-3})
Transference	Necropsy, 3E, Non-containment	Chemical disinfection (dunk-tank or wipedown)	5.00E-03	1.00E-05	1.00E+00	Human error rate (5×10^{-3})
Transference	AHR	Nose blow	5.00E-03	3.14E-01	1.00E+00	Human error rate (5×10^{-3})
Transference	AHR	N95 Mask	2.50E-02	5.00E-03	1.00E+00	Human error rate (5×10^{-3})
Transference	Necropsy, 3E, Non-containment	Gloves	7.67E-02	1.00E-05	6.70E-03	See Section 4.2
Transference	Non-containment	Primary and secondary container (when shipper packages correctly)	1.00E-06	0.00E+00	1.00E+00	Container failure rate (primary) times container failure rate (secondary)
Transference	Non-containment	Tertiary container	1.00E-03	9.00E-01	1.00E+00	Container failure rate

Table 4.5 1: Summary of Mitigating Systems and Nodes Reduction Factors and Probabilities						
Pathway(s)	Originating Location(s)	Node/Mitigation System	Probability of Failure	Reduction Factor (Success)	Reduction Factor (Failure)	Notes
Transference	3E	Container spill/drop	2.00E-03	0.00E+00	1.00E+00	Two times very highly skilled workers error rate
Transference	Non-containment	Shipper fails to package sample correctly	1.00E-02	n/a	n/a	Two times skilled human error rate
Transference	AHR, Necropsy, 3E	Gamma irradiation	5.00E-03	1.00E-06	1.00E+00	Human error rate (5×10^{-3})
Transference	Necropsy, 3E, Non-containment	Tyvek Suit	1.00E-02	2.00E-04	1.50E-01	Estimates on failure rate and reduction factor for failed suit

4.5.1 BSL-3Ag Animal Handling Room Events

As with all NBAF containment areas, the engineered mitigation solutions and anticipated protocols provide multiple layers of containment protection and redundancy. The NBAF AHRs have been designed to meet or exceed the suggested requirements for containment integrity provided by the BMBL.

4.5.1.1 AHR – Aerosol (AA)

All NBAF AHR exhaust systems provide double-HEPA (in series) filtration, multiple failure detection points, and built-in redundancies. During periods when infected animals are shedding virus, the AHR exhaust system provides essential containment protection as room air is exhausted. The filtration and discharge of large volumes of filtered air is provided by dedicated HEPA caissons that provide efficiency (by running in parallel in nominal conditions) and accommodate full room exhaust capacity even when one caisson is out of service. The smaller AHRs (Type A, A2 (large), A2 (small), A3, and B) provide a full 2N redundancy (complete room air exhaust volume can be accommodated by either HEPA caisson) and the larger AHRs (Types C and D) provide N+1 redundancy (complete room air exhaust volume can be accommodated with any three of the four caissons).

In all AHRs, the room exhaust is filtered by a pre-filter prior to discharge from the room. In the evaluation of the SSRA, the NAS SSRA Committee expressed concern about the life span of HEPA filters being shortened by airborne animal hair and food residue. Data from the Australian Animal Health Laboratory (AAHL) in Geelong, Australia, as reported in the Journal of the American Biological Safety Association, indicate that HEPA filter replacement rates for room exhaust filters from animal rooms and other laboratory rooms are similar based on 13 years of collected data [Abraham et al., 1999]. The Geelong data show that appropriate pre-filtration (as designed for the NBAF) will mitigate the potential for accelerated HEPA degradation in the AHR HEPA filtration systems. The data from the AAHL also indicate that HEPA filters have been “exceptionally reliable” with “little deterioration in performance over 13 years of service.” Similar comments on the longevity and reliability of HEPA systems (after installation and acceptance testing) were made by facility engineers and managers during a data collection visit to the Canadian Science Centre for Human and Animal Health in 2010.

The NBAF design and protocols will provide continuous performance (pressure) monitoring with periodic (more than once per year) filter testing. The purpose of the continuous monitoring and periodic testing is to ensure that the filter media, seals, housing, and pressure differentials are operating within specifications. Continuous monitoring of the pressure drop across each HEPA filter, and redundant pressure drop monitoring for each caisson, provides real-time feedback and alarm indications for anomalous conditions. Routine filter testing is facilitated by the incorporated autoscanning capabilities and will identify performance data that can be used in the assessment and preventive and predictive maintenance of the filtration systems.

A summary of the HEPA filter replacement rates at the AAHL is presented in Table 4.5.1-1. These data indicate, as a percent of installations, that supply filters were the most frequently replaced filters when

comparing supply, exhaust, and vents/local HEPA filters. Room exhaust filters had the lowest replacement frequency.

Table 4.5.1 1: Filter Replacements at AAHL over 13 Year Period

Number of Installations	Cause for Replacement				Total Replaced	Percent of Installed
	Media	Gasket/Seal	Blockage	Damage		
Supply Air (317)	16	14	90	1	121	38.1%
Exhaust Air (511)	54	9	27	35	125	24.4%
Vents/Local (141)	14	24	---	18	56	37.7%
Total (969)	84	47	117	54	302	31.2%

The mean annual exhaust air HEPA filter "replacement" rate of the room exhaust air filters at the AAHL is approximately 1.9% (125/6643). Importantly, this is the replacement rate for filters with degraded performance (media, gaskets/seal, blockage, or other damage); no filters have ever failed catastrophically at AAHL [Abraham et al., 1999]. As mentioned above, facility engineers and managers of the Canadian Science Centre for Human and Animal health indicated similar reliability of HEPA systems. Published data on Department of Energy systems [Carbaugh, 1992] indicated much higher rates of HEPA filter replacement in nuclear facilities but it was noted that the filters most often replaced in these facilities service areas contained elevated concentrations of hydrofluoric acid. It is not anticipated that hydrofluoric acid will be used in NBAF AHRs. While the use of disinfectants in the AHRs will cause some chemical exposure to the HEPA filters, AAHL data (where disinfectants are also used) do not indicate accelerated filter degradation from AHRs due to exposure from disinfectants or ammonia.

A National Technical Information Service (NTIS) publication [Cadwallader, 1998] on component failure rate data indicates that the estimated rate of HEPA failures (for all failure modes) is 1×10^{-8} per hour – which equates to 8.76×10^{-5} per year for a filter in continuous operation for an entire year. Thus, the probability of a HEPA filter operating normally could be modeled as 0.999912. However, Cadwallader cites two sources (one for "all failure modes" and one for "leakage and plugging") that estimate the failure rate for "leakage and plugging" to be between 3×10^{-6} per hour and 3×10^{-5} per hour with a mean value of 1.65×10^{-6} per hour. Using these data, the probability of leakage and plugging rate (assuming continuous operation) is approximately 1.5%. These data are not consistent with the inferred probability of normal performance cited by NTIS but are consistent with AAHL data as described below.

The AAHL data were used to determine the probability of any HEPA filter being replaced because of abnormal performance or observation. Over a thirteen year period, 98 room exhaust HEPA filters were replaced for reasons other than blockage. The number of replacement opportunities, 6,643, is calculated as the product of the number of filter installations (511) and the number of years (13). The probability of a HEPA filter being replaced (for pass-through degradation causes) is given by 98 divided by 6,642 or 1.48×10^{-2}. Thus, the estimated probability of degraded HEPA filter performance, P_{DEG}, is 1.50×10^{-2}. The NBAF design incorporates pressure transducers (and redundant monitoring systems)

that provide continuous ΔP data across each HEPA filter and across each caisson (a redundancy). While the ΔP associated with degraded performance may be non-detectable, an actual filter failure would trigger the flow path redundancy and all room exhaust air would be directed through the parallel caisson. The conceptual models for the HEPA room exhaust systems were presented in Figures 4.2.1-1 through 4.2.1-4 of this report. All of these systems normally operate with room exhaust air in balanced flow through the parallel caissons.

AAHL has never had a HEPA room exhaust HEPA failure (blowout) and it is not possible to calculate a failure rate from the AAHL data. However, the AAHL data are the most comprehensive and representative data set (for the NBAF) that has been located. Thus, a maximum individual filter failure rate was estimated based on the lack of failure events over the data collection period. The number of filter-years (6,643) is again given by the product of the number of filter installation (511) and the number of years (13). If there had been one failure during this data collection interval, the probability of failure, P_{FAIL}, would be 1 divided by 6643 or 1.5×10^{-4}. Since no failure has occurred, P_{FAIL} must be less than 1.5×10^{-4} and this value is used for the model. If a filter fails at the NBAF, the redundant pressure alarms (each modeled with a 10^{-3} demand failure rate) will initiate the room exhaust redundancy. For one parallel caisson to exhaust unfiltered room air, there would have to be two filter failures, two primary alarm failures, and a redundant alarm failure. The probability of this event is given by $(P_{FAIL} \times P_{ALARM} \times P_{FAIL} \times P_{ALARM} \times P_{ALARM})^2 = 5.06 \times 10^{-34}$. The probability of normal operating conditions is the difference between 1 and the modeled failure modes, as provided in Table 4.5.1-2.

Table 4.5.1 2: HEPA Filter Probabilities

Mode	Probability
Degraded Performance	1.500×10^{-2}
Fail	1.000×10^{-4}
Normal	9.849×10^{-1}

The probabilities associated with the condition of each filter are used to determine the probabilities and frequency of each modeled HEPA event. The operating/failure modes of the redundant parallel caissons are illustrated in Figure 4.5.1-1. The HEPA filters (indicated by each individual box) can have a status (for modeling purposes) of normal or fully functional (green), degraded performance (yellow), or failed (pink). The modeled event numbers are listed on the bottom with the reduction factors and probability of each event on the top. Modeled event AA1 represents the normal operation of all four HEPA filters in two parallel caissons (two filters each). AA2 and AA3 model undetected degraded performance of one and two HEPA filters, respectively, in one of the caissons. AA4 models one degraded performance in both caissons. AA5 models 3 degraded performance filters and AA6 models all four HEPA filters as being degraded. Events AA7 through AA9 model the shutdown of one caisson with combinations of nominal and degraded performance for the remaining caisson. Event AA10 models the complete failure of all filters and alarm systems. AA11 represents the successful shutdown of the filtration system.

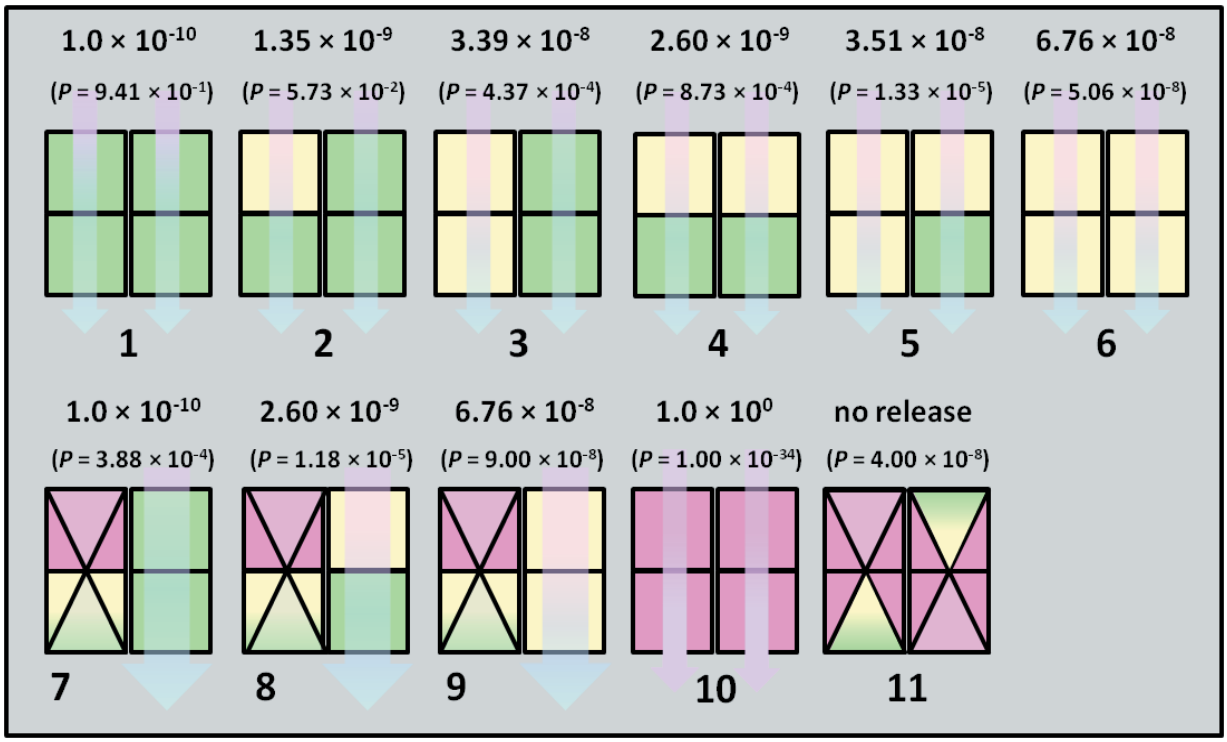


Figure 4.5.1-1: HEPA Caisson Failure Models and BSL-3Ag Aerosol Events

The probability of each event is:

$$P_{AA1} = (P_{NORM})^4 \qquad \text{Equation 4.5.1-1}$$

$$P_{AA2} = 4 \times (P_{NORM})^3 \times P_{DEG} \qquad \text{Equation 4.5.1-2}$$

$$P_{AA3} = 2 \times (P_{NORM})^2 \times {P_{DEG}}^2 \qquad \text{Equation 4.5.1-3}$$

$$P_{AA4} = 4 \times (P_{NORM})^2 \times {P_{DEG}}^2 \qquad \text{Equation 4.5.1-4}$$

$$P_{AA5} = 2 \times P_{NORM} \times {P_{DEG}}^3 \qquad \text{Equation 4.5.1-5}$$

$$P_{AA6} = {P_{DEG}}^4 \qquad \text{Equation 4.5.1-6}$$

$$P_{AA7} = 2 \times ([2 \times P_{FAIL} \times (1 - P_{FAIL}) \times (2 \times (1 - P_{ALARMFAIL}) - (1 - P_{ALARMFAIL})^2] + [P_{FAIL}^2 \times ((1 - (P_{ALARMFAIL})^3)]) \times P_{NORM}^2 \qquad \text{Equation 4.5.1-7}$$

$$P_{AA8} = 2 \times ([2 \times P_{FAIL} \times (1 - P_{FAIL}) \times (2 \times (1 - P_{ALARMFAIL}) - (1 - P_{ALARMFAIL})^2] + [P_{FAIL}^2 \times ((1 - (P_{ALARMFAIL})^3)]) \times (2 \times P_{NORM} \times P_{DEG}) \qquad \text{Equation 4.5.1-8}$$

$$P_{AA9} = 2 \times ([2 \times P_{FAIL} \times (1 - P_{FAIL}) \times (2 \times (1 - P_{ALARMFAIL}) - (1 - P_{ALARMFAIL})^2] + [P_{FAIL}^2 \times ((1 - (P_{ALARMFAIL})^3)]) \times P_{DEG}^2 \qquad \text{Equation 4.5.1-9}$$

$$P_{AA10} = P_{FAIL}^4 * P_{ALARMFAIL}^6 \qquad \text{Equation 4.5.1-10}$$

$$P_{AA11} = ([2 \times P_{FAIL} \times (1 - P_{FAIL}) \times (2 \times (1 - P_{ALARMFAIL}) - (1 - P_{ALARMFAIL})^2)] + [P_{FAIL}^2 \times ((1 - (P_{ALARMFAIL})^3)])^2$$ Equation 4.5.1-11

where

$$P_{NORM} = 9.849 \times 10^{-1}$$ Equation 4.5.1-12

$$P_{DEG} = 1.5 \times 10^{-2}$$ Equation 4.5.1-13

$$P_{FAIL} = 1.0^{-4}$$ Equation 4.5.1-14

The opportunity rate for the failures, R_{AA} = 1,735 opportunities/year, is from the number of infected animal room-days from Table 4.4.1-5. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.1-3. The fault tree is shown in Figure 4.5.1-2. The MAR for the aerosol events in the AHRs is the aerosols respired from shedding FMDv-infected animals in a single AHR.

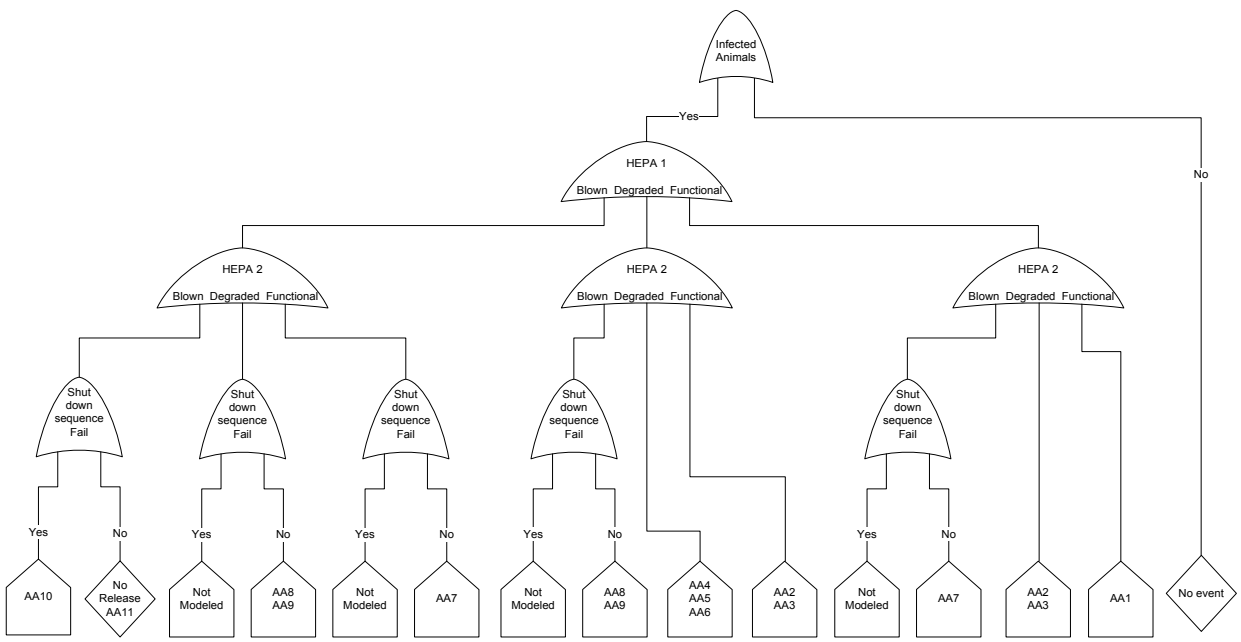


Figure 4.5.1-2: Fault Tree for Aerosol Release in AHRs (AA)

Table 4.5.1-3: Animal Holding Room – Aerosol (AA)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor	AA1	AA2	AA3	AA4	AA5	AA6	AA7	AA8	AA9	AA10	AA11
HEPA Specific Failure Probabilities	n/a	n/a	n/a	9.410E-01	5.732E-02	4.365E-04	8.730E-04	1.330E-05	5.063E-08	3.880E-04	1.182E-05	9.000E-08	1.000E-34	4.000E-08
HEPA Specific Reduction Factors	n/a	n/a	n/a	1.000E-10	1.350E-09	3.385E-08	2.598E-09	3.509E-08	6.761E-08	1.000E-10	2.598E-09	6.761E-08	1.000E+00	0.000E+00
			Overall Reduction Factor	**1.000E-10**	**1.350E-09**	**3.385E-08**	**2.598E-09**	**3.509E-08**	**6.761E-08**	**1.000E-10**	**2.598E-09**	**6.761E-08**	**1.000E+00**	**0.000E+00**
			Q_{Low} (PFU)	4.560E-09	6.158E-08	1.544E-06	1.185E-07	1.600E-06	3.083E-06	4.560E-09	1.185E-07	3.083E-06	4.560E+01	0.000E+00
			Q_{Medium} (PFU)	4.010E-06	5.415E-05	1.358E-03	1.042E-04	1.407E-03	2.711E-03	4.010E-06	1.042E-04	2.711E-03	4.010E+04	0.000E+00
			Q_{High} (PFU)	3.550E-03	4.794E-02	1.202E+00	9.221E-02	1.246E+00	2.400E+00	3.550E-03	9.221E-02	2.400E+00	3.550E+07	0.000E+00
			Probability (P_{Loss})	**9.410E-01**	**5.732E-02**	**4.365E-04**	**8.730E-04**	**1.330E-05**	**5.063E-08**	**3.880E-04**	**1.182E-05**	**9.000E-08**	**1.000E-34**	**4.000E-08**
			Frequency (F_{Loss}) (yr^{-1})	**1.63E+03**	**9.95E+01**	**7.57E-01**	**1.51E+00**	**2.31E-02**	**8.78E-05**	**6.73E-01**	**2.05E-02**	**1.56E-04**	**1.74E-31**	**6.94E-05**

MAR Low = 4.56×10^{1} PFU
MAR Medium = 4.01×10^{4} PFU
MAR High = 3.55×10^{7} PFU
Opportunity Rate = 1,735 yr^{-1}

4.5.1.2 AHR – Solid Waste (AS)

The solid waste generated in the AHRs is sterilized by two autoclaves, the first to remove the material from the BSL-3Ag into the BSL-3E and the second to remove the material into non-containment for subsequent incineration. The failure rate of each autoclave was set to the systems failure rate of 1×10^{5}, while the failure rate of the incinerator was set to 1×10^{-10} as it has a built-in orthogonal performance validation indicator [DHS, 2010]. The MAR is 20% of the liquid waste generated in the AHRs and transferred to disposable solid materials (e.g., PPE, towels). As there are an average of 6.5 FMDv experiments conducted per year, with an average duration of 40.7 days of which 42.9% are days in which the animals are shedding, the number of infectious days in the AHRs per year is 113.5. The opportunity rate for this set of circumstances is 113.5 yr^{-1}, corresponding to the number of infectious FMDv days in the AHRs. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.1-4. The fault tree is shown in Figure 4.5.1-3.

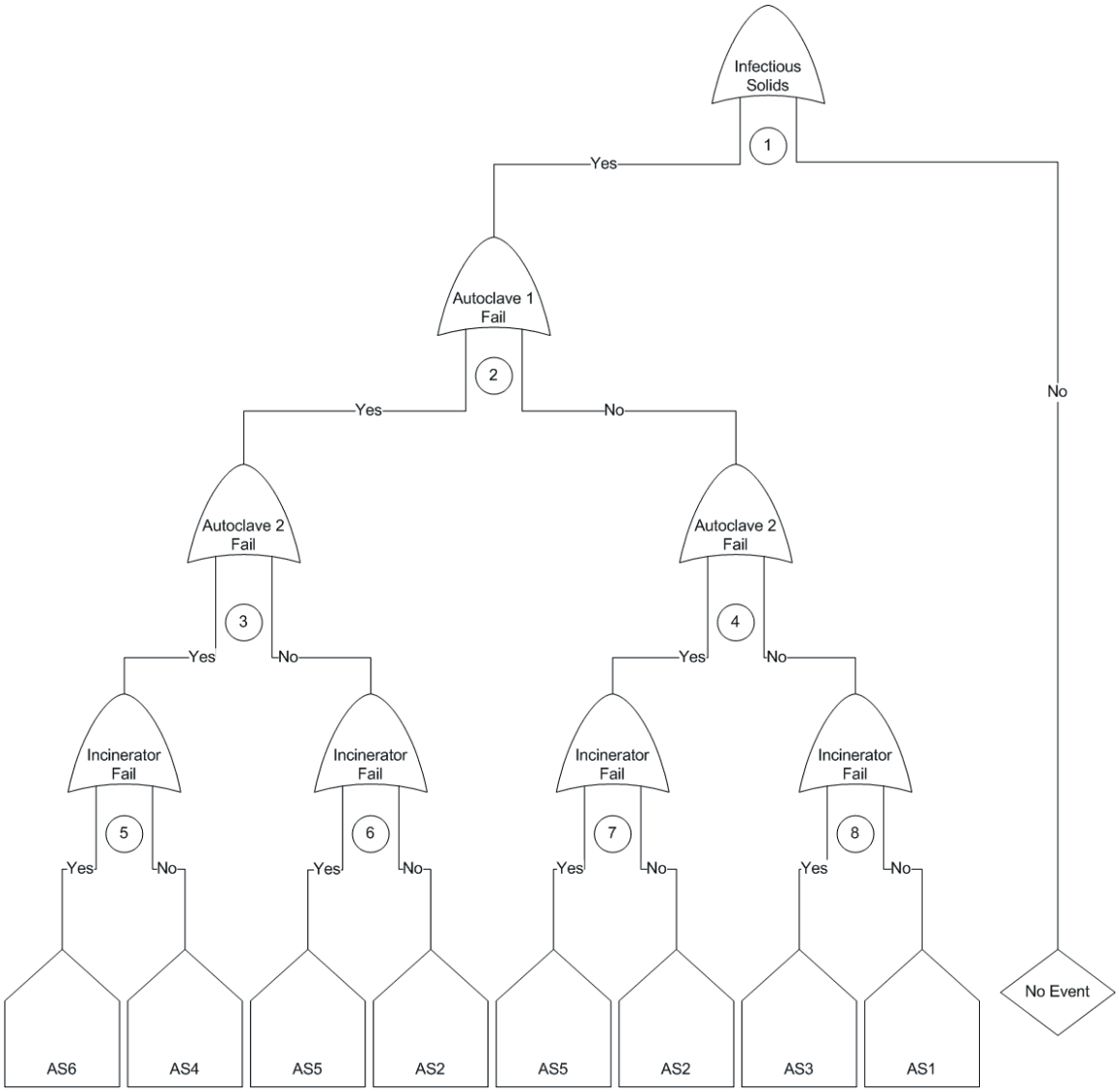


Figure 4.5.1-3: Fault Tree for Solid Waste Release in AHRs (AS)

Table 4.5.1 4: Animal Holding Rooms Solid Waste (AS)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	AS1	AS2[a]	AS3	AS4	AS5[b]	AS6
Autoclave #1	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	WORK	WORK	FAIL	WORK	FAIL
Autoclave #2	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	FAIL	WORK	FAIL	FAIL	FAIL
Incinerator	1.00E-10	1.0000E+00	1.00E-09	1.00E+00	WORK	WORK	FAIL	WORK	FAIL	FAIL
Overall Reduction Factor					1.000E 21	1.000E 15	1.000E 12	1.000E 09	1.000E 06	1.000E+00
	Q_{Low} (PFU)				2.380E-20	2.380E-14	2.380E-11	2.380E-08	2.380E-05	2.380E+01
	Q_{Medium} (PFU)				6.560E-16	6.560E-10	6.560E-07	6.560E-04	6.560E-01	6.560E+05
	Q_{High} (PFU)				1.240E-13	1.240E-07	1.240E-04	1.240E-01	1.240E+02	1.240E+08
Probability (P_{Loss})					9.9998E 01	2.0000E 05	9.9998E 11	1.0000E 10	2.0000E 15	1.0000E 20
Frequency (F_{Loss}) (yr^{1})					1.13E+02	2.27E 03	1.13E 08	1.13E 08	2.27E 13	1.13E 18

[a]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator works.

[b]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator fails.

MAR Low = 2.38×10^{1} PFU

MAR Medium = 6.56×10^{5} PFU

MAR High = 1.24×10^{8} PFU

Opportunity Rate = 113.5 yr^{-1}

4.5.1.3 AHR – Liquid Waste (AL)

The liquid waste generated in the AHRs is decontaminated by the EDS. The urine and feces excreted from the animals are sent through drain pipes which are primed with a chemical disinfectant. The liquid waste is then combined with other liquid waste streams and heated in a cook tank, and then further disinfected in the on-site wastewater treatment plant. The four mitigating nodes are the priming of the drain pipes, the cook tank, the redundant and orthogonal cook tank performance indicator, and the wastewater treatment plant. The failure rates of the cook tank and the on-site wastewater treatment plant were modeled with the systems failure rate of 1×10^{-5}.

As there are an average of 4.75 AHRs with animals for FMD-experiments, with two drains per room, a total of approximately 10 drains need to be primed in the AHRs. As each drain has an independent failure rate of 5×10^{-3} (human error rate), an overall probability of failing to prime the drains was calculated. Failure to prime the drains was defined as failing to prime any number (1 – 10) of drains (P_{PRIME}) by the following equations:

$$P_{PRIME} = \sum_{i=1}^{n_d} \left[\binom{n_d}{i} (P_{TRAP})^i (1 - P_{TRAP})^{n_d - i} \right] \qquad \text{Equation 4.5.1-15}$$

where

$$P_{TRAP} = \text{Probability of failing to prime a single trap} = 5 \times 10^{-3} \qquad \text{Equation 4.5.1-16}$$

$$n_d = \text{number of drains in AHRs with infected animals} = 10 \qquad \text{Equation 4.5.1-17}$$

A weighted reduction factor for failing to prime any number of drains was also calculated by using the following equations:

$$\text{eighted Reduction Factor} = \frac{\sum_{i=1}^{n_d} \varphi}{P_{PRIME}} \qquad \text{Equation 4.5.1-18}$$

where

$$\varphi = \frac{[\delta_{SUCCESS} \times (n_d - i) + \delta_{FAIL} \times (i)]}{n_d} \times \left[\binom{n_d}{i} (P_{TRAP})^i (1 - P_{TRAP})^{n_d - i} \right] \qquad \text{Equation 4.5.1-19}$$

where

$$\delta_{SUCCESS} = \text{Reduction Factor Successful Priming of All Traps} \qquad \text{Equation 4.5.1-20}$$

$$\delta_{FAIL} = \text{Reduction Factor Failure to Prime at east 1 Trap} \qquad \text{Equation 4.5.1-21}$$

The MAR is the viral levels present in the urine and feces generated in the AHR on a daily basis. The opportunity rate for this set of circumstances is 113.5 yr^{-1}, corresponding to the number of infectious days in the AHRs (see Section 4.5.1.2 for details). The probabilities (P_{Loss}), reduction factors, *Q* values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.1-5. The fault tree is shown in Figure 4.5.1-4.

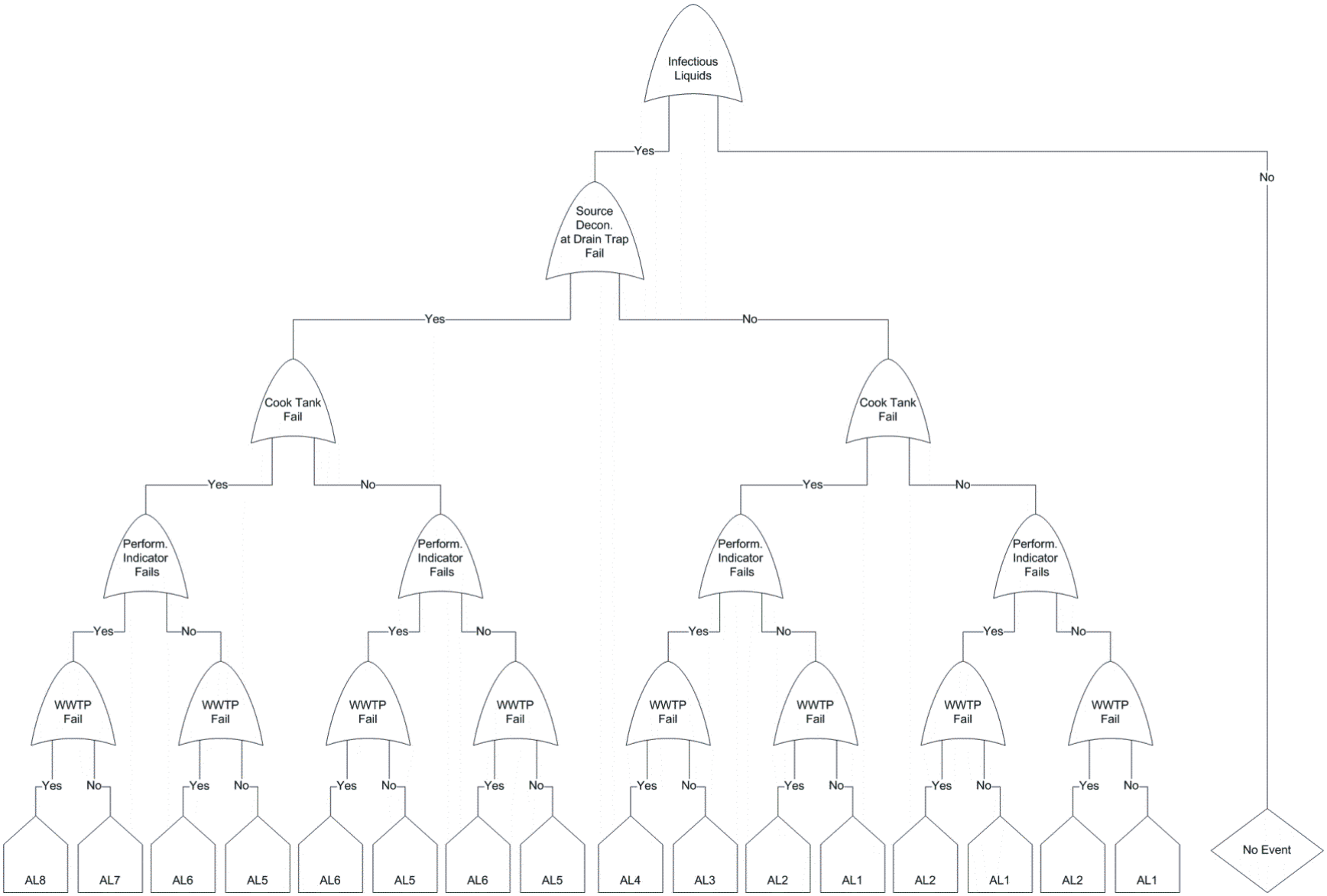


Figure 4.5.1-4: Fault Tree for Liquid Waste Release in AHRs (AL)

Table 4.5.1-5: Animal Holding Rooms – Liquid Waste (AL)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	AL1	AL2	AL3	AL4	AL5	AL6	AL7	AL8
Source Decontamination at Drain Pipes (10)	4.89E-02	9.5111E-01	1.00E-01	1.92E-01	WORK	WORK	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Cook Tank	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK or	WORK or	FAIL	FAIL	WORK or	WORK or	FAIL	FAIL
Cook Tank Performance Indicator	1.00E-05	9.9999E-01	n/a	n/a	WORK	WORK	FAIL	FAIL	WORK	WORK	FAIL	FAIL
On-Site Wastewater Treatment	1.00E-05	9.9999E-01	1.00E-01	1.00E+00	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL
Overall Reduction Factor					**1.000E-08**	**1.000E-07**	**1.000E-02**	**1.000E-01**	**1.920E-08**	**1.920E-07**	**1.920E-02**	**1.920E-01**
	Q_{Low} (PFU)				1.190E-06	1.190E-05	1.190E+00	1.190E+01	2.285E-06	2.285E-05	2.285E+00	2.285E+01
	Q_{Medium} (PFU)				3.280E-02	3.280E-01	3.280E+04	3.280E+05	6.299E-02	6.299E-01	6.299E+04	6.299E+05
	Q_{High} (PFU)				6.180E+00	6.180E+01	6.180E+06	6.180E+07	1.187E+01	1.187E+02	1.187E+07	1.187E+08
Probability (P_{Loss})					**9.511E-01**	**9.511E-06**	**9.511E-11**	**9.511E-16**	**4.889E-02**	**4.889E-07**	**4.889E-12**	**4.889E-17**
Frequency (F_{Loss}) (yr^{-1})					**1.08E+02**	**1.08E-03**	**1.08E-08**	**1.08E-13**	**5.55E+00**	**5.55E-05**	**5.55E-10**	**5.55E-15**

MAR Low = 1.19×10^{2} PFU
MAR Medium = 3.28×10^{6} PFU
MAR High = 6.18×10^{8} PFU
Opportunity Rate = 113.5 yr^{-1}

4.5.1.4 AHR – Transference (Respiratory) (ATR)

The animal holding room transference respiratory event is shown conceptually in Figure 4.5.1-5. Respiratory contamination, while a potential hazard in any area, is modeled as occurring in the BSL-3Ag AHRs. The AHRs are expected to have relatively high levels of airborne FMDv and aerosols as a result of infected animal respiration, detritus, and re-aerosolization by animal room washdown and animal/staff movements. The protection systems in place to reduce the amount of material which can be transferred to the nasal or oral passages of researchers and workers are N95 masks and the blowing of the nose prior to leaving containment. The failure rate for the N95 masks was set to 2.5%, one order of magnitude lower than the rate of improper fits on N95 masks in the absence of fitting [Cummings et al., 2007]. In this study, the authors note that without fitting of masks, approximately 75% of the non-fitted masks will provide full protection, i.e., approximately 25% of the non-fitted do not provide full protection. The failure rate of the N95 masks was set to an order of magnitude lower as fitting of masks is expected to be a procedure at the NBAF. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.1-6. The fault tree is shown in Figure 4.5.1-6. The MAR for the respiratory transference events is the amount of aerosolized FMDv from shedding animals on a single day in a single AHR which is transferred to the nasal passages of a worker. The opportunity rate for these events is the number of FMDv-infectious days in the AHRs (113.5 yr^{-1}) multiplied by the number of workers which enter and leave the AHRs. It is expected that two animal handlers will enter the AHRs in the morning, two handlers in the evening, and one researcher during the day for a total of five workers. The opportunity rate for respiratory transference was set to 567.5 yr^{-1}.

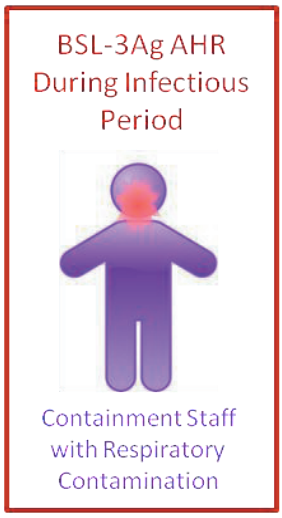


Figure 4.5.1-5. Conceptual Respiratory Transference

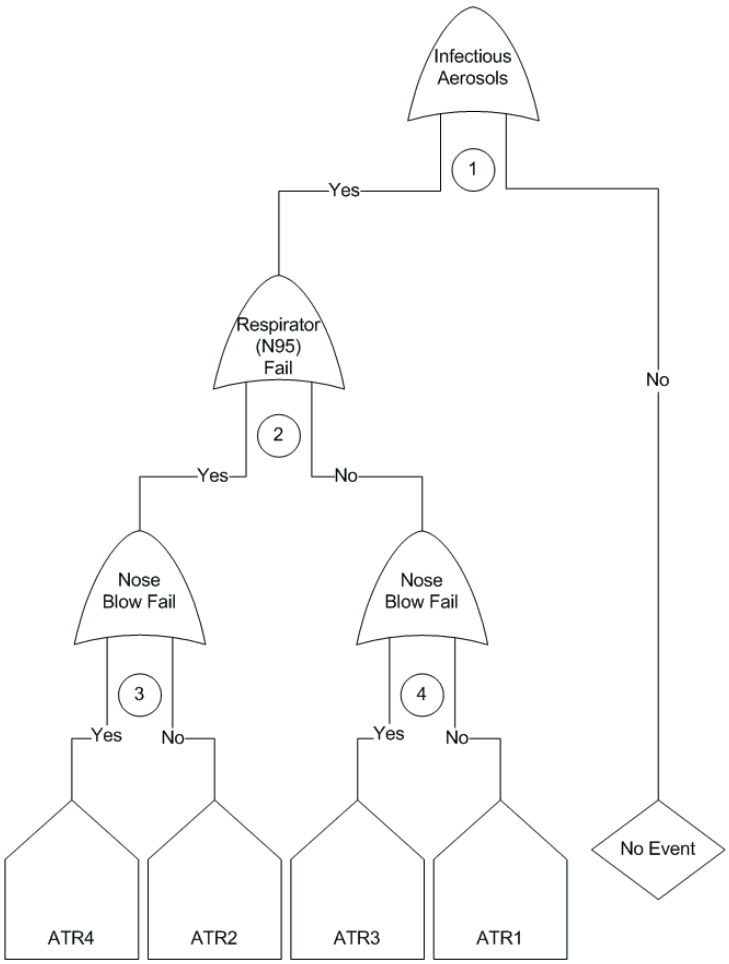


Figure 4.5.1-6: Fault Tree for Transference through Respiratory Tract in AHRs (ATR)

Table 4.5.1 6: Animal Holding Rooms Transference Respiratory (ATR)								
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	ATR1	ATR2	ATR3	ATR4
Transfer Percentage	0.00E+00	1.0000E+00	5.70E-02	n/a	n/a	n/a	n/a	n/a
N95 Mask	2.50E-02	9.7500E-01	5.00E-03	1.00E+00	WORK	FAIL	WORK	FAIL
Nose Blow	5.00E-03	9.9500E-01	3.14E-01	1.00E+00	WORK	WORK	FAIL	FAIL
				Overall Reduction Factor	8.9490E 05	1.7898E 02	2.8500E 04	5.7000E 02
				Q_{Low} (PFU)	4.081E-03	8.161E-01	1.300E-02	2.599E+00
				Q_{Medium} (PFU)	3.589E+00	7.177E+02	1.143E+01	2.286E+03
				Q_{High} (PFU)	3.177E+03	6.354E+05	1.012E+04	2.024E+06
				Probability (P_{Loss})	9.7013E 01	2.4875E 02	4.8750E 03	1.2500E 04
				Frequency (F_{Loss}) (yr^{1})	5.51E+02	1.41E+01	2.77E+00	7.09E 02

MAR Low = 4.56×10^{1} PFU
MAR Medium = 4.01×10^{4} PFU
MAR High = 3.55×10^{7} PFU
Opportunity Rate = 567.5 yr^{-1}

4.5.1.5 AHR – Transference (Contact, Fomite) (ATF)

Fomite contact transference events are also modeled in the BSL-3Ag AHRs. The removal of fomites (such as jewelry, eyeglasses, writing instruments, etc.) is modeled as originating in the AHRs; however, there are likely to be procedures at the NBAF to prevent such items from entering the AHRs. The protection systems to reduce the amount of infectious material prior to fomites leaving containment are two chemical disinfections (e.g., dunk tanks or wipedowns), each with human error failure rates. The conceptual diagram for the fomite transference events is shown in Figure 4.5.1-7. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.1-7. The fault tree is shown in Figure 4.5.1-8. The MAR for these set of events is the amount of infectious FMDv in 90 mL of liquid waste, consisting of the urine and feces of infectious animals, transferred to a fomite.

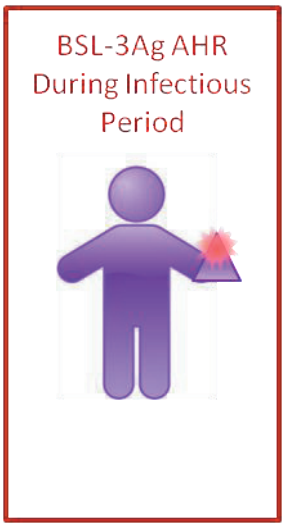


Figure 4.5.1-7. Conceptual Fomite Contact Transference

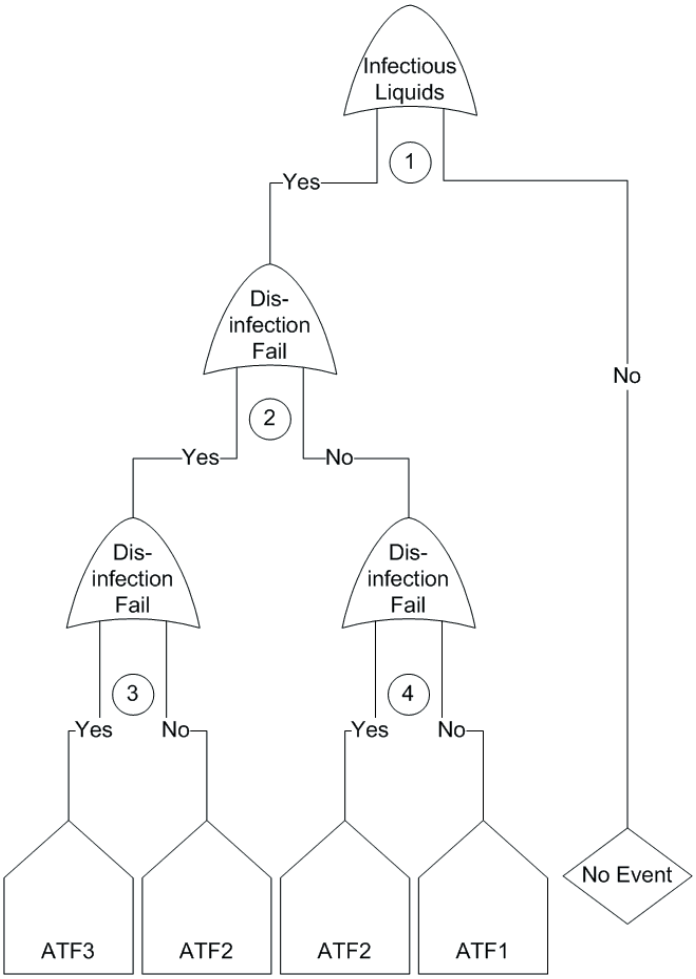


Figure 4.5.1-8: Fault Tree for Transference through Contact with a Fomite in AHRs (ATF)

Table 4.5.1 7: Animal Holding Rooms Transference Contact with Fomite (ATF)							
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	ATF1	ATF2	ATF3
Area Ratio	0.00E+00	1.0000E+00	5.56E-02	n/a	n/a	n/a	n/a
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	n/a	n/a	n/a
Disinfection #1	5.00E-03	9.9500E-01	1.00E-05	1.00E+00	WORK	WORK	FAIL
Disinfection #2	5.00E-03	9.9500E-01	1.00E-05	1.00E+00	WORK	FAIL	FAIL
				Overall Reduction Factor	2.2222E 12	2.2222E 07	2.2222E 02
				Q_{Low} (PFU)	1.484E-14	1.484E-09	1.484E-04
				Q_{Medium} (PFU)	7.780E-09	7.780E-04	7.780E+01
				Q_{High} (PFU)	8.120E-07	8.120E-02	8.120E+03
				Probability (P_{Loss})	9.9003E 01	9.9500E 03	2.5000E 05
				Frequency (F_{Loss}) (yr^{1})	5.62E+02	5.65E+00	1.42E 02

MAR Low = 6.68×10^{-3} PFU
MAR Medium = 3.50×10^{3} PFU
MAR High = 3.65×10^{5} PFU
Opportunity Rate = 567.5 yr^{-1}

4.5.2 BSL-3Ag Necropsy Events

The BSL-Ag necropsy suite includes engineered mitigation systems similar to those used for the BSL-3Ag AHRs. Because of the types of procedures and potential hazards, the necropsy suite incorporates special mitigation systems such as down-draft necropsy tables. Additional PPE may also be required to protect researchers from gross contamination.

4.5.2.1 Necropsy – Aerosol (NA)

The NBAF BSL-3Ag necropsy suite exhaust air systems provide double-HEPA (in series) filtration, multiple failure detection points, and built-in redundancies. During operational periods the necropsy exhaust air system provides essential containment protection as room air is exhausted. The filtration and discharge of large volumes of filtered air is provided by dedicated HEPA caissons that provide efficiency (by running in parallel during nominal conditions) and accommodate full suite exhaust capacity even when one caisson is out of service. The development of the failure probabilities for the necropsy area HEPA systems are identical to those presented for the BSL-3Ag AHRs. However, the failure opportunity rate is different and is calculated as the number of days per year during which a necropsy on an FMDv-infected animal is be performed. The number of necropsy days per year was determined by assuming necropsies would be performed at the end of each study and that eight animal necropsies would be performed on any given necropsy day. Per the 65% Design, 1014 FMDv-susceptible animals will be used for animal studies in a given year. Of these animals, it was modeled that 33% would be devoted to FMDv research or 338 animals. Assuming eight necropsies per day, there would be 42.25 necropsy days per year (338/8). The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-1. The fault tree is shown in Figure 4.5.2-1. The MAR for the necropsy aerosol events is aerosolized tissue from bone cutting and the aerosolized release fraction from 50% of the blood.

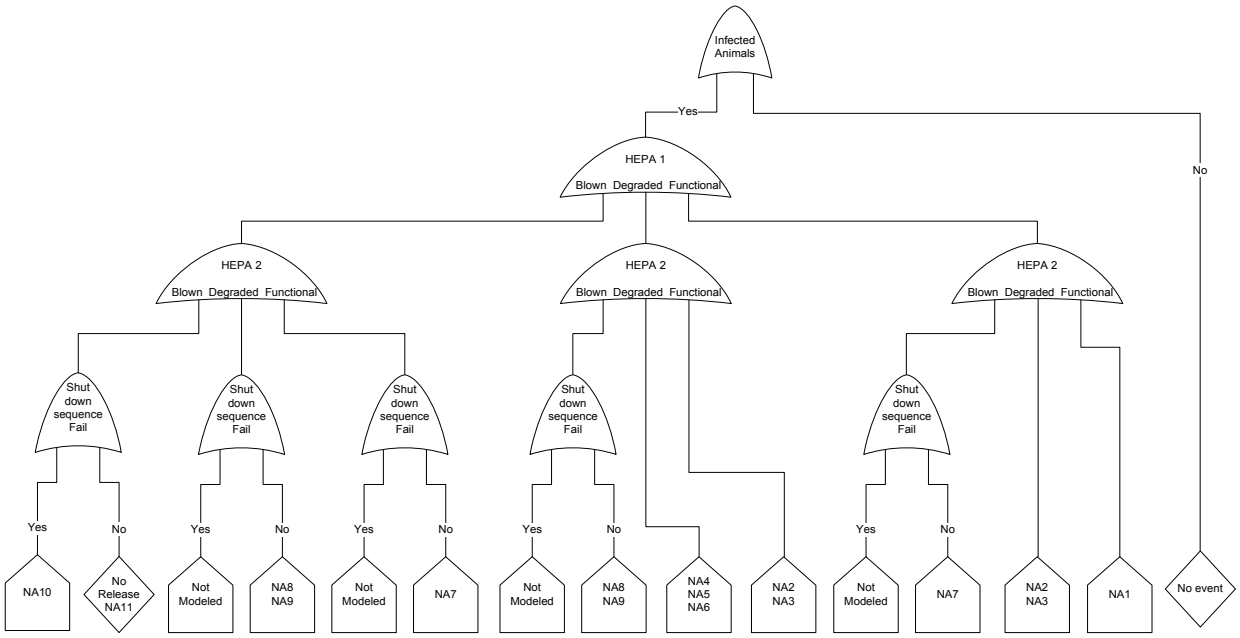


Figure 4.5.2-1: Fault Tree for Aerosol Release via Aerosolized Tissue and Blood from Necropsy (NA)

Table 4.5.2-1: Necropsy – Aerosol (NA)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor	NA1	NA2	NA3	NA4	NA5	NA6	NA7	NA8	NA9	NA10	NA11
HEPA Specific Failure Probabilities	n/a	n/a	n/a	9.410E-01	5.732E-02	4.365E-04	8.730E-04	1.330E-05	5.063E-08	3.880E-04	1.182E-05	9.000E-08	1.000E-34	4.000E-08
HEPA Specific Reduction Factors	n/a	n/a	n/a	1.000E-10	1.350E-09	3.385E-08	2.598E-09	3.509E-08	6.761E-08	1.000E-10	2.598E-09	6.761E-08	1.000E+00	0.000E+00
			Overall Reduction Factor	**1.000E-10**	**1.350E-09**	**3.385E-08**	**2.598E-09**	**3.509E-08**	**6.761E-08**	**1.000E-10**	**2.598E-09**	**6.761E-08**	**1.000E+00**	**0.000E+00**
			Q_{Low} (PFU)	6.653E-10	8.983E-09	2.252E-07	1.728E-08	2.335E-07	4.498E-07	6.653E-10	1.728E-08	4.498E-07	6.653E+00	0.000E+00
			Q_{Medium} (PFU)	1.743E-07	2.353E-06	5.900E-05	4.527E-06	6.116E-05	1.178E-04	1.743E-07	4.527E-06	1.178E-04	1.743E+03	0.000E+00
			Q_{High} (PFU)	1.387E-03	1.873E-02	4.695E-01	3.603E-02	4.867E-01	9.377E-01	1.387E-03	3.603E-02	9.377E-01	1.387E+07	0.000E+00
			Probability (P_{Loss})	**9.410E-01**	**5.732E-02**	**4.365E-04**	**8.730E-04**	**1.330E-05**	**5.063E-08**	**3.880E-04**	**1.182E-05**	**9.000E-08**	**1.000E-34**	**4.000E-08**
			Frequency (F_{Loss}) (yr^{-1})	**3.98E+01**	**2.42E+00**	**1.84E-02**	**3.69E-02**	**5.62E-04**	**2.14E-06**	**1.64E-02**	**4.99E-04**	**3.80E-06**	**4.23E-33**	**1.69E-06**

MAR Low = 6.65×10^{0} PFU
MAR Medium = 1.74×10^{3} PFU
MAR High = 1.39×10^{7} PFU
Opportunity Rate = 42.25 yr^{-1}

4.5.2.2 Necropsy – Solid Waste (Tissue/Carcasses) (NST)

The tissue and carcasses of infected animals is sterilized by a tissue autoclave and then incinerated. The MAR is 80% of the overall solid waste MAR in BSL-3Ag necropsy suite corresponding to the tissue and 50% of the blood of the infected animals (i.e., the carcasses). The opportunity rate for this set of circumstances is 42.25 yr^{-1}, corresponding to the number of necropsy days per year. The tissue autoclave was modeled with a failure rate of a system, 1×10^{-5}; the performance indicator for the tissue autoclave was also modeled with a failure rate of a system, 1×10^{-5}. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-2. The fault tree is shown in Figure 4.5.2-2.

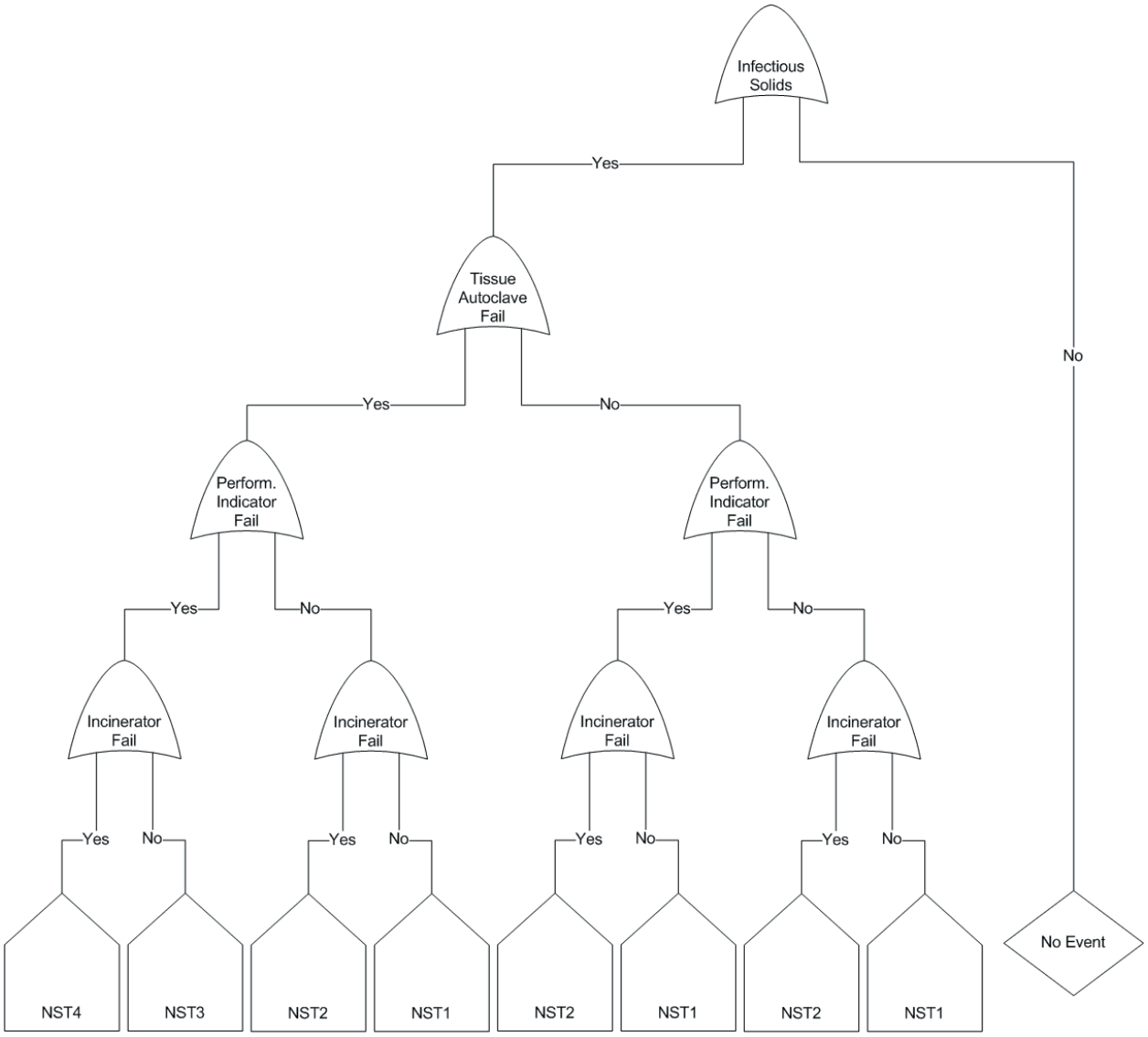


Figure 4.5.2-2: Fault Tree for Solid Waste Release of Infectious Tissue/Carcasses in Necropsy (NST)

Table 4.5.2 2: Necropsy Solid Waste from Tissue and Carcasses (NST)								
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NST1	NST2	NST3	NST4
Tissue Autoclave	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	WORK	FAIL	FAIL
Tissue Autoclave Performance Indicator	1.00E-05	9.9999E-01	1.00E+00	1.00E+00	or WORK	or WORK	FAIL	FAIL
Incinerator	1.00E-10	1.000E+00	1.00E-09	1.00E+00	WORK	FAIL	WORK	FAIL
				Overall Reduction Factor	1.0000E 15	1.0000E 06	1.0000E 09	1.0000E+00
				Q_{Low} (PFU)	6.906E-12	6.906E-03	6.906E-06	6.906E+03
				Q_{Medium} (PFU)	1.436E-08	1.436E+01	1.436E-02	1.436E+07
				Q_{High} (PFU)	1.128E-03	1.128E+06	1.128E+03	1.128E+12
				Probability (P_{Loss})	1.0000E+00	1.0000E 10	1.0000E 10	1.0000E 20
				Frequency (F_{Loss}) (yr^{1})	4.22E+01	4.22E 09	4.22E 09	4.23E 19

MAR Low = 6.91×10^{3} PFU
MAR Medium = 1.44×10^{7} PFU
MAR High = 1.13×10^{12} PFU
Opportunity Rate = 42.25 yr^{-1}

4.5.2.3 Necropsy – Solid Waste (Biohazard Bags) (NSW)

The solid waste generated in the necropsy room which is transferred to disposable materials (e.g., PPE, towels) is sterilized by two autoclaves (one from the BSL-3Ag to the BSL-3E and the second in the BSL-3E to non-containment) and then incinerated. The MAR is 20% of the overall solid waste MAR from the necropsy room which corresponds to the FMDv quantities in the tissue and 50% of the blood (i.e., FMDv-infected animal carcasses). The opportunity rate for this set of circumstances is 42.25 yr^{-1}, corresponding to the number of necropsy days. For each day of necropsy, all solid biohazardous (e.g., red bag) waste will be sterilized (i.e., one autoclave run per necropsy day). The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-3. The fault tree is shown in Figure 4.5.2-3.

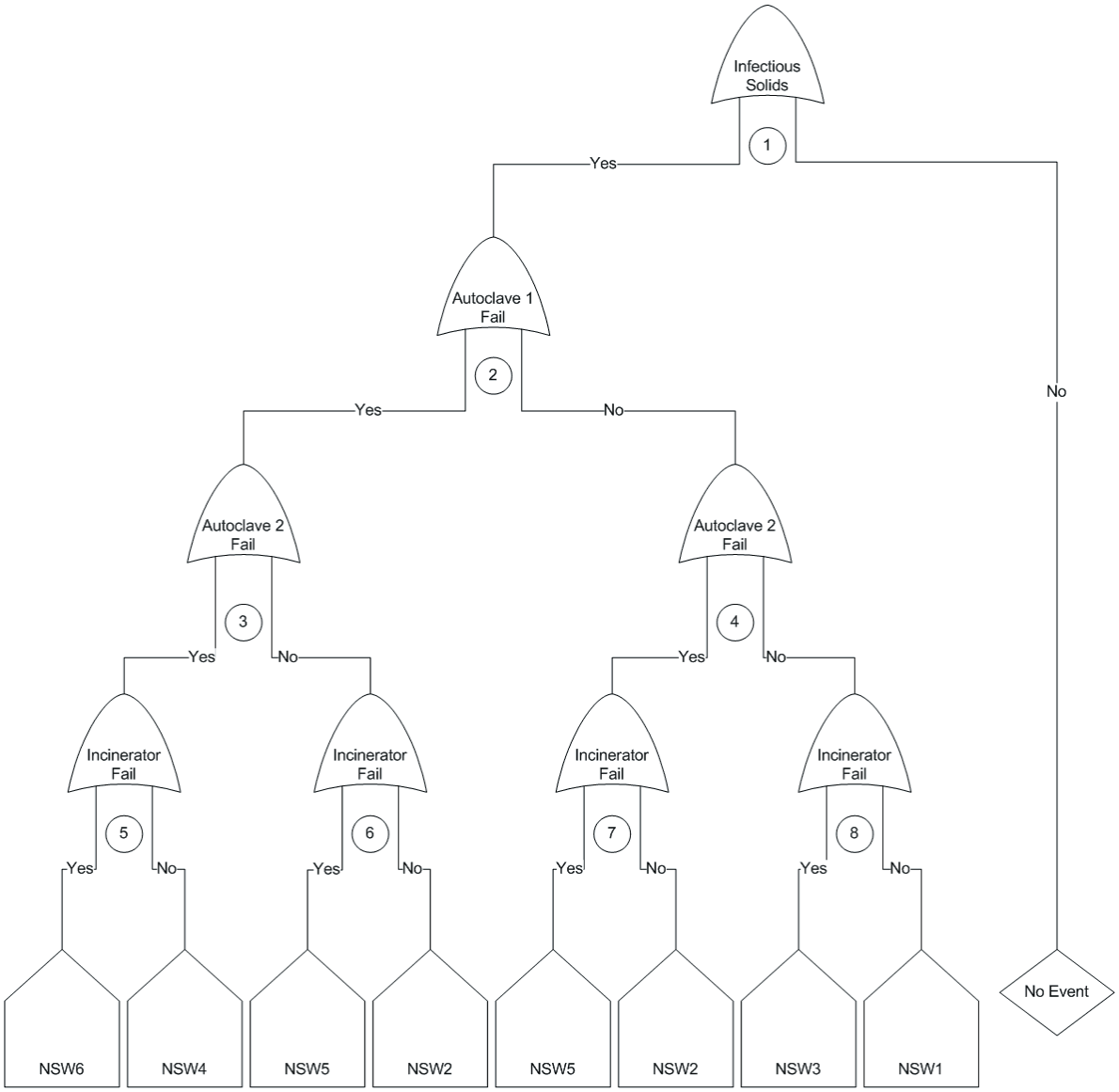


Figure 4.5.2-3: Fault Tree for Solid Waste Release of Infectious Biohazard Bags in Necropsy (NSW)

Table 4.5.2 3: Necropsy Solid Waste of Biohazardous Bags (NSW)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NSW1	NSW2[a]	NSW3	NSW4	NSW5[b]	NSW6
Autoclave #1	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	WORK	WORK	FAIL	WORK	FAIL
Autoclave #2	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	FAIL	WORK	FAIL	FAIL	FAIL
Incinerator	1.00E-10	1.0000E+00	1.00E-09	1.00E+00	WORK	WORK	FAIL	WORK	FAIL	FAIL
				Overall Reduction Factor	**1.0000E 21**	**1.0000E 15**	**1.0000E 12**	**1.0000E 09**	**1.0000E 06**	**1.0000E+00**
				Q_{Low} (PFU)	1.727E-18	1.727E-12	1.727E-09	1.727E-06	1.727E-03	1.727E+03
				Q_{Medium} (PFU)	3.590E-15	3.590E-09	3.590E-06	3.590E-03	3.590E+00	3.590E+06
				Q_{High} (PFU)	2.820E-10	2.820E-04	2.820E-01	2.820E+02	2.820E+05	2.820E+11
				Probability (P_{Loss})	**9.9998E 01**	**2.0000E 05**	**9.9998E 11**	**1.0000E 10**	**2.0000E 15**	**1.0000E 20**
				Frequency (F_{Loss}) (yr^{1})	**4.22E+01**	**8.45E 04**	**4.22E 09**	**4.22E 09**	**8.45E 14**	**4.23E 19**

[a]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator works.
[b]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator fails.

MAR Low = 1.73×10^{3} PFU
MAR Medium = 3.59×10^{6} PFU
MAR High = 2.82×10^{11} PFU
Opportunity Rate = 42.25 yr^{-1}

4.5.2.4 Necropsy – Liquid Waste (NL)

The liquid waste generated in the necropsy room is also decontaminated by the EDS. During necropsy, a fraction of the liquid waste (e.g., blood) is drained through pipes which are primed with a chemical disinfectant. The liquid waste is then combined with other liquid waste streams and decontaminated in a cook tank and the cook tank performance verified prior to the contents being released and subjected to the on-site wastewater treatment. The four mitigating nodes are the priming of the drain pipes, the cook tank, the redundant and orthogonal cook tank performance indicator, and the wastewater treatment plant.

As there are three total drains which need to be primed in the AHRs each with an independent failure rate of 5×10^{-3} (human error rate), an overall probability of failing to prime the drains was calculated. Failure to prime the drains was defined as failing to prime any number (1 – 3) of drains (P_{PRIME}) by the following equations:

$$P_{PRIME} = \sum_{i=1}^{n_d} \left[\binom{n_d}{i} (P_{TRAP})^i (1 - P_{TRAP})^{n_d - i} \right] \qquad \text{Equation 4.5.2-1}$$

where

$$P_{TRAP} = \text{Probability of failing to prime a single trap} = 5 \times 10^{-3} \qquad \text{Equation 4.5.2-2}$$

$$n_d = \text{number of drains in AHRs with infected animals} = 3 \qquad \text{Equation 4.5.2-3}$$

A weighted reduction factor for failing to prime any number of drains was also calculated by using the following equations:

$$\text{eighted Reduction Factor} = \frac{\sum_{i=1}^{n_d} \varphi}{P_{PRIME}} \qquad \text{Equation 4.5.2-4}$$

where

$$\varphi = \frac{[\delta_{SUCCESS} \times (n_d - i) + \delta_{FAIL} \times (i)]}{n_d} \times \left[\binom{n_d}{i} (P_{TRAP})^i (1 - P_{TRAP})^{n_d - i} \right] \qquad \text{Equation 4.5.2-5}$$

where

$$\delta_{SUCCESS} = \text{Reduction Factor Successful Priming of All Traps} \qquad \text{Equation 4.5.2-6}$$

$$\delta_{FAIL} = \text{Reduction Factor Failure to Prime at east 1 Trap} \qquad \text{Equation 4.5.2-7}$$

The MAR is the viral levels present in 50% of the blood of the necropsied animals as well as the daily urine and fecal excrement from the animals euthanized in the necropsy suite. The opportunity rate for this set of circumstances is 42.25 yr^{-1}, corresponding to the average number of necropsy days in a year. The probabilities (P_{Loss}), reduction factors, *Q* values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-4. The fault tree is shown in Figure 4.5.2-4.

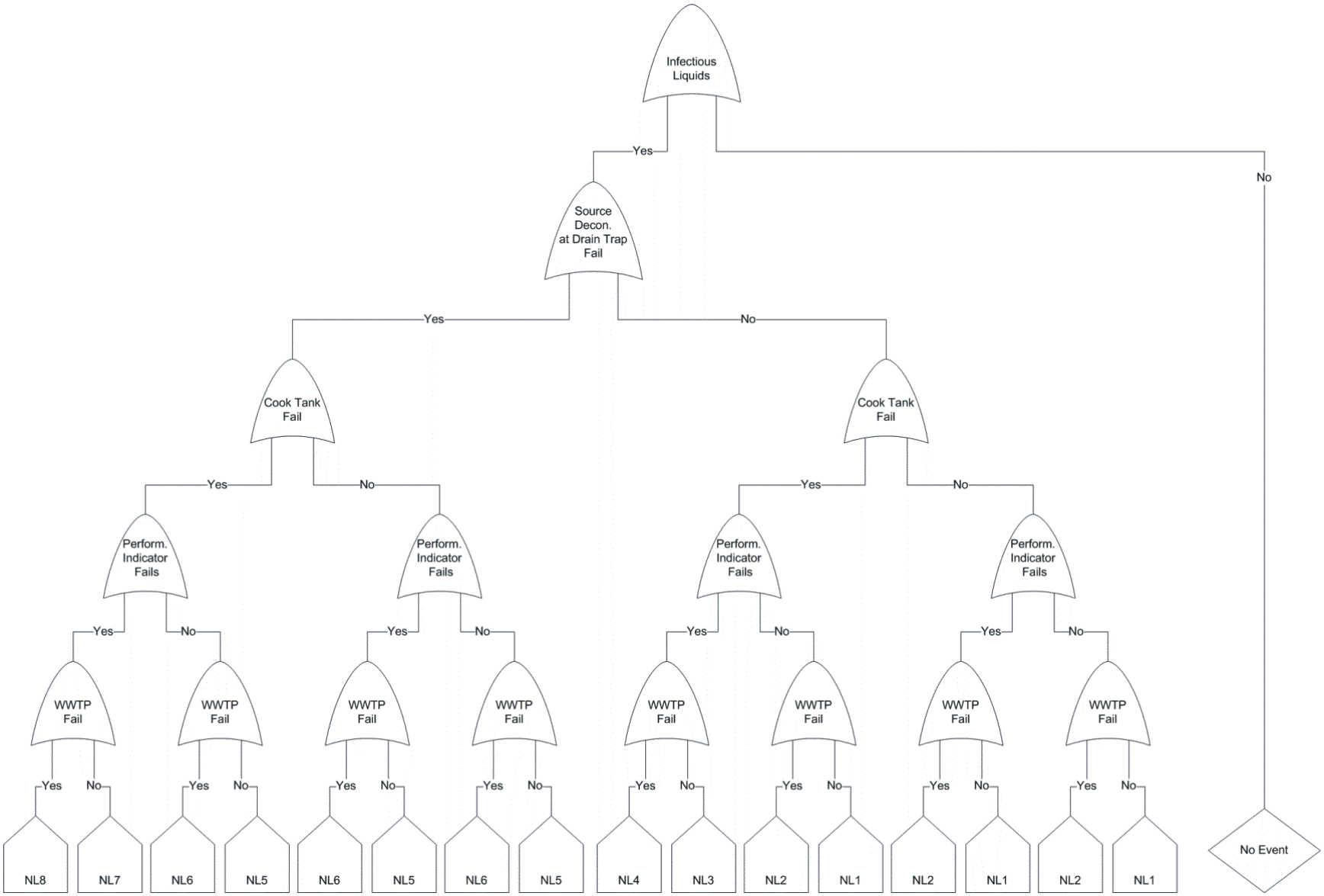


Figure 4.5.2-4: Fault Tree for Liquid Waste Release in Necropsy (NL)

Table 4.5.2-4: Necropsy – Liquid Waste (NL)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NL1	NL2	NL3	NL4	NL5	NL6	NL7	NL8
Source Decontamination at Drain Pipes (3)	9.98E-03	9.9003E-01	1.00E-03	5.02E-01	WORK	WORK	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Cook Tank	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK or	WORK or	FAIL	FAIL	WORK or	WORK or	FAIL	FAIL
Cook Tank Performance Indicator	1.00E-05	9.9999E-01	n/a	n/a	WORK	WORK	FAIL	FAIL	WORK	WORK	FAIL	FAIL
On-Site Wastewater Treatment	1.00E-05	9.9999E-01	1.00E-01	1.00E+00	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL
Overall Reduction Factor					**1.000E-10**	**1.000E-09**	**1.000E-04**	**1.000E-03**	**5.018E-08**	**5.018E-07**	**5.018E-02**	**5.018E-01**
	Q_{Low} (PFU)				1.003E-04	1.003E-03	1.003E+02	1.003E+03	5.034E-02	5.034E-01	5.034E+04	5.034E+05
	Q_{Medium} (PFU)				1.836E-03	1.836E-02	1.836E+03	1.836E+04	9.214E-01	9.214E+00	9.214E+05	9.214E+06
	Q_{High} (PFU)				2.305E+00	2.305E+01	2.305E+06	2.305E+07	1.157E+03	1.157E+04	1.157E+09	1.157E+10
Probability (P_{Loss})					**9.900E-01**	**9.900E-06**	**9.900E-11**	**9.900E-16**	**9.975E-03**	**9.975E-08**	**9.975E-13**	**9.975E-18**
Frequency (F_{Loss}) (yr^{-1})					**4.18E+01**	**4.18E-04**	**4.18E-09**	**4.18E-14**	**4.21E-01**	**4.21E-06**	**4.21E-11**	**4.21E-16**

MAR Low = 1.00×10^{6} PFU
MAR Medium = 1.84×10^{7} PFU
MAR High = 2.31×10^{10} PFU
Opportunity Rate = 42.25 yr^{-1}

4.5.2.5 Necropsy – Transference (Contact, Hand) (NTH1-6)

Figure 4.5.2-5. Conceptual Contact Transference

Given the activities performed in the necropsy suite, it is expected that infectious FMDv will come in contact with these workers (e.g., blood spill or splatter, touching infectious tissue and organs, etc.). The first six transference contact events with the hand are modeled as infectious material coming into contact with gloved hands. The conceptual model is shown in Figure 4.5.2-5. The protection systems are the gloves and two body showers which are required to leave containment. The gloves have a failure rate of 7.67×10^{-2} as detailed in Section 4.2.4, while the body showers have a failure rate of human error (5×10^{-3}). As the activities in the necropsy suite will also involve physically handling the animal carcasses, contact with the entire surface area of the hand (front and back) was modeled. The opportunity rate for these transference events was the number of necropsy days per year multiplied by the number of workers in the necropsy suite, which was estimated at four. The opportunity rate modeled was 169 yr^{-1}. The MAR for these set of events is the FMDv levels in 90 mL of infectious blood. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-5. The fault tree is shown in Figure 4.5.2-6.

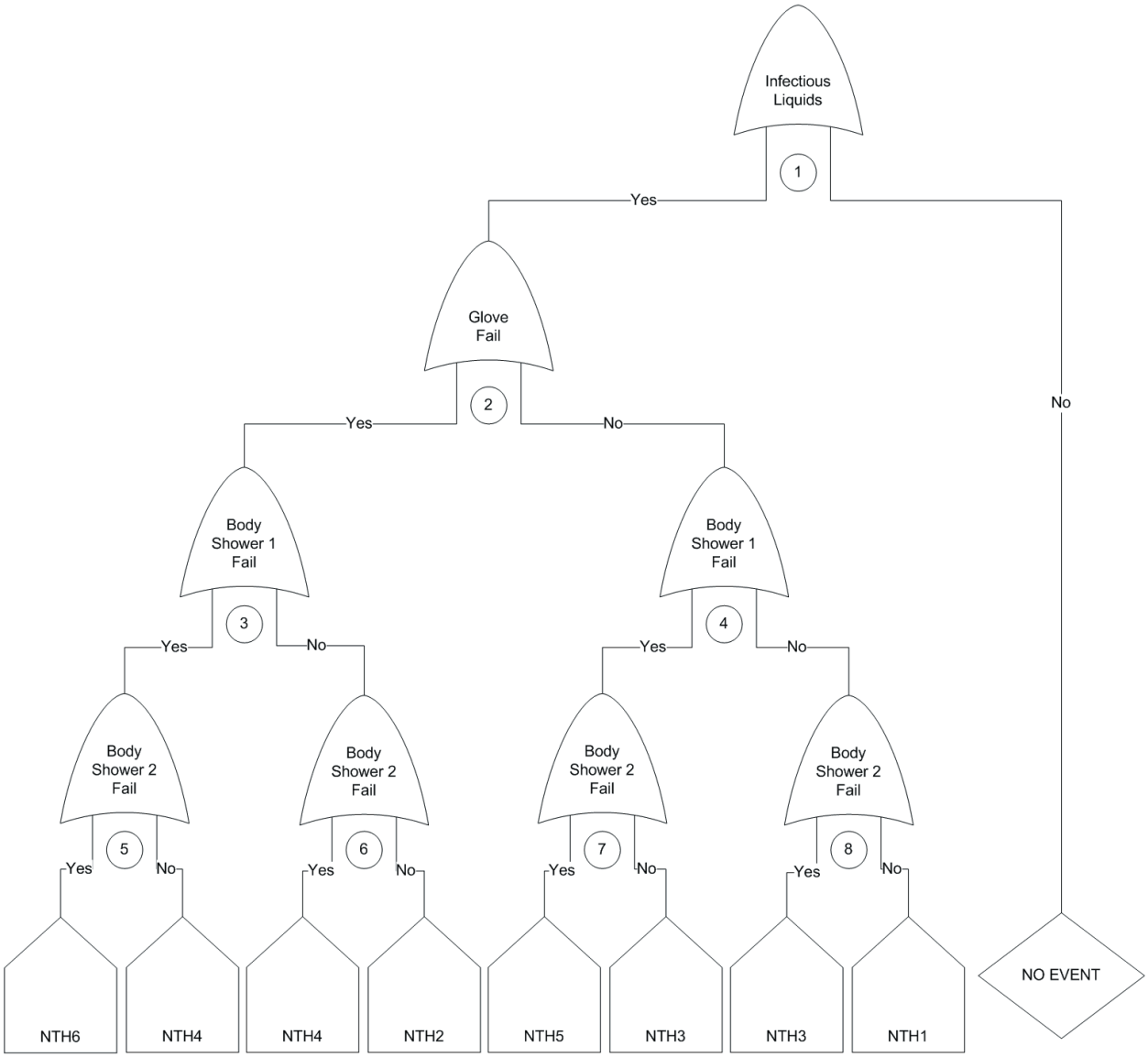


Figure 4.5.2-6: Fault Tree for Transference Contact Events with Hand in Necropsy (NTH1-6)

Table 4.5.2 5: Necropsy Transference Contact with Hand (NTH1 6)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NTH1	NTH2	NTH3	NTH4	NTH5	NTH6
Area Ratio	0.00E+00	1.000E+00	4.86E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Gloves	7.67E-02	9.233E-01	1.00E-05	6.70E-03	WORK	FAIL	WORK	FAIL	WORK	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	WORK	WORK	WORK	FAIL	FAIL
				Overall Reduction Factor	1.9813E 08	1.3274E 05	1.9616E 07	1.3143E 04	1.9422E 06	1.3013E 03
				Q_{Low} (PFU)	1.706E-07	1.143E-04	1.689E-06	1.132E-03	1.672E-05	1.120E-02
				Q_{Medium} (PFU)	9.064E-04	6.073E-01	8.975E-03	6.013E+00	8.886E-02	5.953E+01
				Q_{High} (PFU)	2.792E+00	1.871E+03	2.764E+01	1.852E+04	2.737E+02	1.834E+05
				Probability (P_{Loss})	9.141E 01	7.593E 02	9.187E 03	7.632E 04	2.308E 05	1.918E 06
				Frequency (F_{Loss}) (yr ^{1})	1.54E+02	1.28E+01	1.55E+00	1.29E 01	3.90E 03	3.24E 04

MAR Low = 8.61×10^{0} PFU
MAR Medium = 4.58×10^{4} PFU
MAR High = 1.41×10^{8} PFU
Opportunity Rate = 169 yr^{-1}

4.5.2.6 Necropsy – Transference (Contact, Glove to Hand) (NTH7-12)

The second set of six transference contact events with the hand involve the improper removal of gloves and the transfer of infectious material on contaminated gloves being transferred to bare hands. For these events, there are two transfer nodes – from the carcasses of the infected animals to the gloves, and from the gloves to the researcher's hands. (For the second transfer event, it was assumed that all material transferred to the glove would be in contact with the bare skin.) The protection systems are a spot decontamination performed by the researcher on the site of contact upon recognizing the laboratory exposure to infectious materials and two body showers which are required to leave containment. The spot chemical decontamination and the two body showers each have a failure rate of human error (5×10^{-3}). As the activities in the necropsy suite will also involve physically handling the animal carcasses, contact with the entire surface area of the hand (front and back) was modeled. The opportunity rate for these transference events was the number of necropsy days per year multiplied by the number of workers in the necropsy suite, which was estimated at four. The opportunity rate modeled was 169 yr^{-1}. The MAR for these set of events is the FMDv levels in 90 mL of infectious blood. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-6. The fault tree is shown in Figure 4.5.2-7.

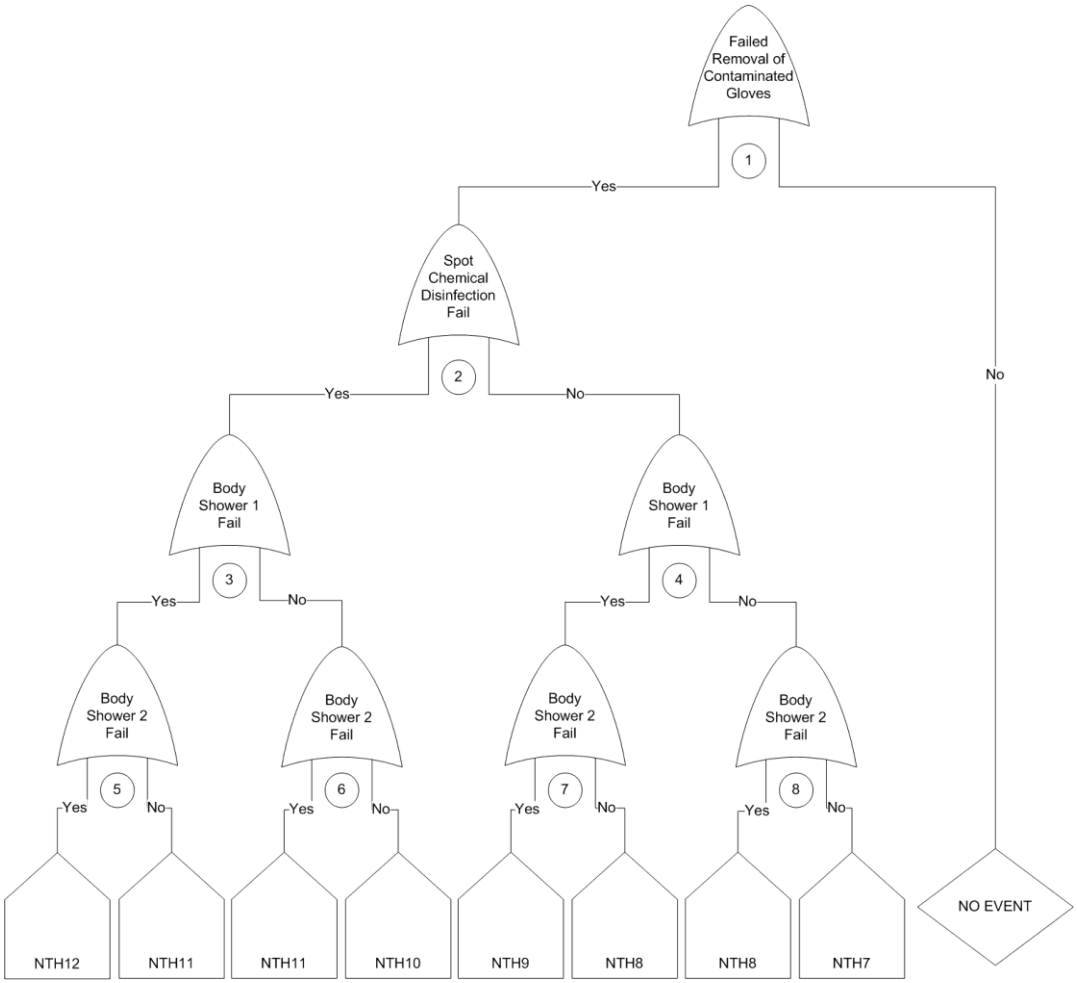


Figure 4.5.2-7: Fault Tree for Transference Contact Events with Hand from Contaminated Glove in Necropsy (NTH7-12)

Table 4.5.2 6: Necropsy Transference Contact with Hand from Contaminated Glove (NTH7 12)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NTH7	NTH8	NTH9	NTH10	NTH11	NTH12
Failed Removal of Gloves	5.00E-03	9.950E-01	0.00E+00	4.00E-01	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
Area Ratio	0.00E+00	1.000E+00	4.86E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Spot Chemical Disinfection	5.00E-03	9.950E-01	1.00E-05	1.00E+00	WORK	WORK	WORK	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	FAIL	FAIL	WORK	FAIL	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	WORK	FAIL	WORK	WORK	FAIL
				Overall Reduction Factor	7.9250E 09	7.8466E 08	7.7689E 07	7.9250E 04	7.8466E 03	7.7689E 02
				Q_{Low} (PFU)	6.824E-08	6.756E-07	6.689E-06	6.824E-03	6.756E-02	6.689E-01
				Q_{Medium} (PFU)	3.626E-04	3.590E-03	3.554E-02	3.626E+01	3.590E+02	3.554E+03
				Q_{High} (PFU)	1.117E+00	1.106E+01	1.095E+02	1.117E+05	1.106E+06	1.095E+07
				Probability (P_{Loss})	4.925E 03	4.950E 05	1.244E 07	2.475E 05	2.488E 07	6.250E 10
				Frequency (F_{Loss}) (yr^{1})	8.32E 01	8.37E 03	2.10E 05	4.18E 03	4.20E 05	1.06E 07

MAR Low = 8.61×10^{0} PFU
MAR Medium = 4.58×10^{4} PFU
MAR High = 1.41×10^{8} PFU
Opportunity Rate = 169 yr^{-1}

4.5.2.7 Necropsy – Transference (Contact, Body) (NTB)

Given the activities performed in the necropsy suite, it is expected that infectious FMDv will come in contact with the body region of the workers (e.g., blood spill or splatter, touching infectious tissue and organs, etc.). The body transference contact events are modeled as infectious material coming into contact with a Tyvek suit. The conceptual model is shown in Figure 4.5.2-5. The protection systems are the Tyvek suit and two body showers which are required to leave containment. No data was obtained on the failure rate of Tyvek suits so a conservative estimate of 1.0×10^{-2} was used. The body showers have a failure rate of human error (5×10^{-3}). The opportunity rate for these transference events was the number of necropsy days per year multiplied by the number of workers in the necropsy suite, which was estimated at four. The opportunity rate modeled was 169 yr^{-1}. The MAR for these set of events is the FMDv levels in 90 mL of infectious blood. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.2-7. The fault tree is shown in Figure 4.5.2-8.

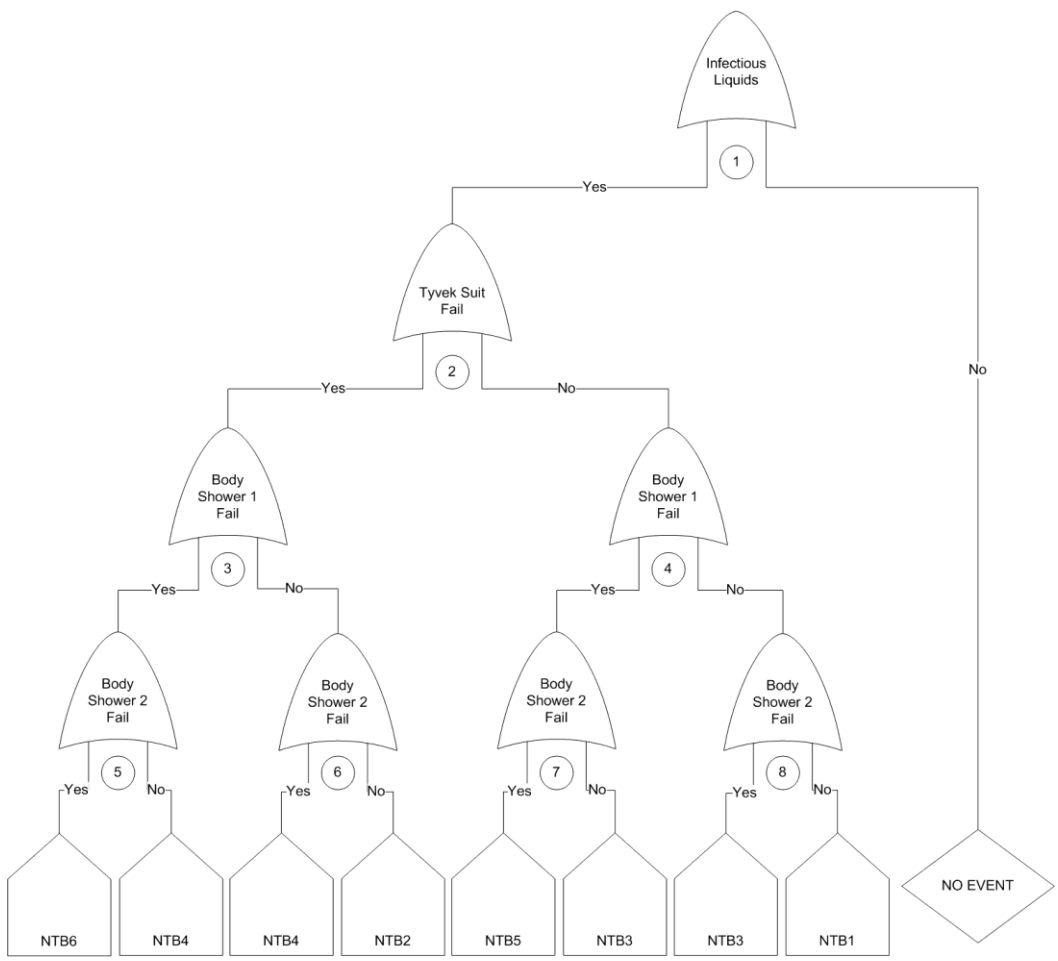


Figure 4.5.2-8: Fault Tree for Transference Contact Events with Body in Necropsy (NTB)

Table 4.5.2 7: Necropsy Transference Contact with Body (NTB)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	NTB1	NTB2	NTB3	NTB4	NTB5	NTB6
Area Ratio	0.00E+00	1.0000E+00	4.44E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Tyvek Suit	1.00E-02	9.9000E-01	2.00E-04	1.50E-01	WORK	FAIL	WORK	FAIL	WORK	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	WORK	WORK	WORK	WORK	FAIL	FAIL
				Overall Reduction Factor	3.6270E 07	2.7203E 04	3.5911E 06	2.6933E 03	3.5556E 05	2.6667E 02
				Q_{Low} (PFU)	3.123E-06	2.342E-03	3.092E-05	2.319E-02	3.061E-04	2.296E-01
				Q_{Medium} (PFU)	1.659E-02	1.245E+01	1.643E-01	1.232E+02	1.627E+00	1.220E+03
				Q_{High} (PFU)	5.111E+01	3.833E+04	5.061E+02	3.795E+05	5.010E+03	3.758E+06
				Probability (P_{Loss})	9.801E 01	9.900E 03	9.851E 03	9.950E 05	2.475E 05	2.500E 07
				Frequency (F_{Loss}) (yr ^{1})	1.66E+02	1.67E+00	1.66E+00	1.68E 02	4.18E 03	4.23E 05

MAR Low = 8.61×10^{0} PFU
MAR Medium = 4.58×10^{4} PFU
MAR High = 1.41×10^{8} PFU
Opportunity Rate = 169 yr^{-1}

4.5.3 BSL-3E Laboratories and BSL-3E "Special Procedure" Room Events

4.5.3.1 BSL-3E/ BSL-3E SP – Aerosol (EA)

For these set of events, a researcher or worker spills a sample of infectious FMDv outside of the biosafety cabinet (BSC) resulting in the release of aerosolized material. The MAR for this event is the quantity of FMDv in a typical sample or solution, of which only 1×10^{-4} of the material is aerosolized (the aerosolized release fraction). The probability of a researcher spilling a solution was set to 2×10^{-4}, a low number for human error rates as workers at the NBAF will be highly skilled (25 times lower than the human error of skilled workers, 5×10^{-3}). The protection systems are the HEPA filters with the same reduction factors and probabilities of failures as those modeled in the AHR and necropsy aerosol events. The opportunity rate for these set of events is set to 52,500 yr^{-1}, corresponding to the product of the maximum number of workers in a BSL-3E/SP unit (9), the number of BSL-3E/SP units (20), 70% occupancy of the NBAF, one-third of research and activities devoted to FMD, 250 work days per year, and five opportunities to drop a sample per day per worker.

$$\text{Opportunity Rate}_{BSL-3E/SP\ Aerosol} = 9\frac{\text{workers}}{\text{unit}} \times 20 \text{ units } \times 70\% \text{ occupancy} \times \frac{1}{3}\text{FMD research} \times 250\ \frac{\text{work days}}{\text{year}} \times 5\ \frac{\text{drop opportunities per worker}}{\text{day}}$$

Equation 4.5.3-1

The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-1. The fault tree is shown in Figure 4.5.3-1.

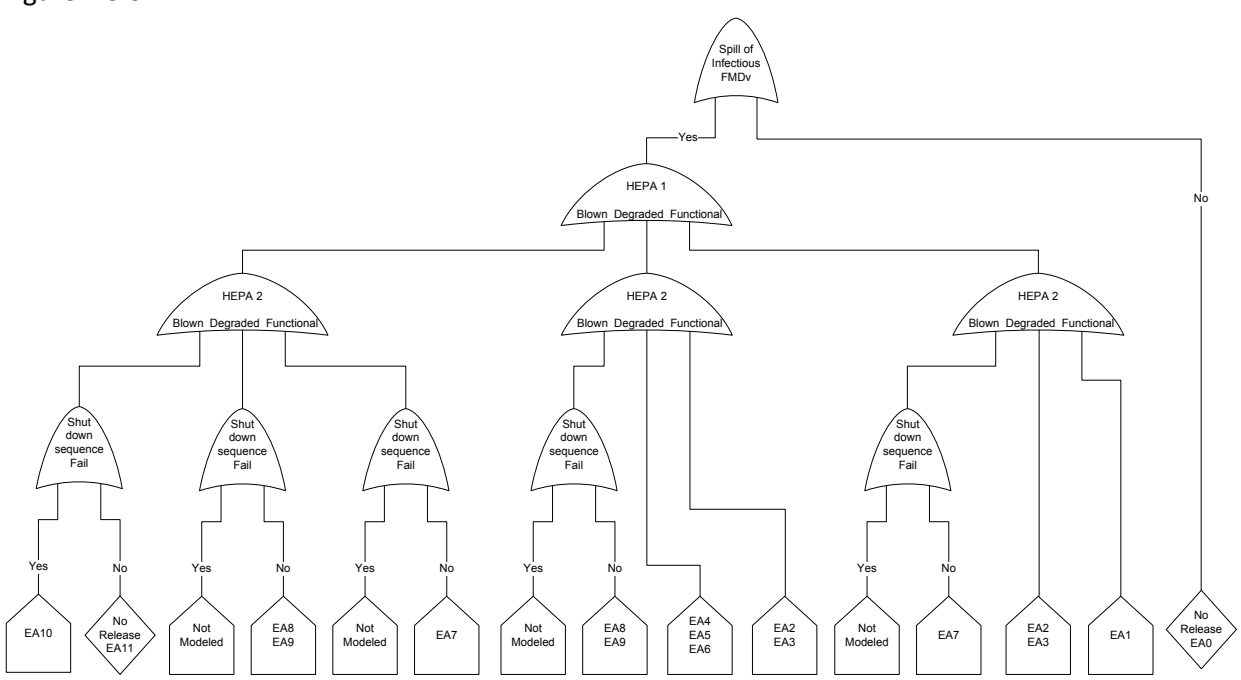


Figure 4.5.3-1: Fault Tree for Aerosol Release via Dropped FMDv Sample in BSL-3E/BSL-3E SP (EA)

Table 4.5.3-1: BSL-3E/BSL-3E SP – Aerosol (EA)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor	EA0	EA1	EA2	EA3	EA4	EA5	EA6	EA7	EA8	EA9	EA10	EA11
Spill (aerosolized release fraction = reduction factor)	2.00E-03	9.98E-01	1.00E-04	WORK	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
HEPA Specific Failure Probabilities	n/a	n/a	n/a	n/a	9.410E-01	5.732E-02	4.365E-04	8.730E-04	1.330E-05	5.063E-08	3.880E-04	1.182E-05	9.000E-08	1.000E-34	4.000E-08
HEPA Specific Reduction Factors	n/a	n/a	n/a	n/a	1.000E-10	1.350E-09	3.385E-08	2.598E-09	3.509E-08	6.761E-08	1.000E-10	2.598E-09	6.761E-08	1.000E+00	0.000E+00
Overall Reduction Factor				**0.00E+00**	**1.000E-14**	**1.350E-13**	**3.385E-12**	**2.598E-13**	**3.509E-12**	**6.761E-12**	**1.000E-14**	**2.598E-13**	**6.761E-12**	**1.000E-04**	**0.000E+00**
	Q_{Low} (PFU)			0.000E+00	1.020E-14	1.377E-13	3.453E-12	2.650E-13	3.580E-12	6.896E-12	1.020E-14	2.650E-13	6.896E-12	1.020E-04	0.000E+00
	Q_{Medium} (PFU)			0.000E+00	3.460E-10	4.672E-09	1.171E-07	8.988E-09	1.214E-07	2.339E-07	3.460E-10	8.988E-09	2.339E-07	3.460E+00	0.000E+00
	Q_{High} (PFU)			0.000E+00	1.180E-05	1.593E-04	3.995E-03	3.065E-04	4.141E-03	7.978E-03	1.180E-05	3.065E-04	7.978E-03	1.180E+05	0.000E+00
Probability (P_{Loss})				**9.980E-01**	**1.882E-03**	**1.146E-04**	**8.730E-07**	**1.746E-06**	**2.659E-08**	**1.013E-10**	**7.760E-07**	**2.364E-08**	**1.800E-10**	**2.000E-37**	**7.999E-11**
Frequency (F_{Loss}) (yr^{-1})				**5.24E+04**	**9.88E+01**	**6.02E+00**	**4.58E-02**	**9.17E-02**	**1.40E-03**	**5.32E-06**	**4.07E-02**	**1.24E-03**	**9.45E-06**	**1.05E-32**	**4.20E-06**

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 52,500 yr^{-1}

4.5.3.2 BSL-3E/ BSL-3E SP – Liquid Waste (EL)

Within the BSL-3E and BSL-3E "Special Procedure" rooms, FMDv infectious wastes are not expected to enter the liquid waste pathway unless an incident occurs such as a researcher fails to follow protocol and pours infectious FMDv waste down the drain. Per the 65% Design [NDP, 2011], minor spills in BSL-3E containment will be decontaminated via wipe down and gross contamination will be decontaminated using a portable chlorine dioxide or vaporized hydrogen peroxide (VHP) unit (at a frequency of 1-2 annual occurrences) and thus no material contributes to the liquid waste pathway. The vast majority of other infectious wastes generated within the BSL-3E corridor enter the solid waste pathway (via the autoclaves as presented above, or via dunk tanks). Although an unlikely event with trained staff, it is possible that a researcher could dispose of FMDv infectious waste improperly by pouring materials down the sink or floor drain. If such an event occurs, the only protection systems are the cook tank, the redundant and orthogonal cook tank performance indicator, and the on-site wastewater treatment plant. The failure rate of skilled staff violating protocols and disposing of infectious FMDv down the drain in the BSL-3E/SP was set to 1×10^{-4}. The MAR for this set of events is the quantity of FMDv in a typical sample. The opportunity rate for this set of events was se to 52,500 yr^{-1}, the same as used for the BSL-3E/SP aerosol events as it was modeled that there would be five opportunities per worker per day to violate protocol and dispose of a sample down the drain. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-2. The fault tree is shown in Figure 4.5.3-2.

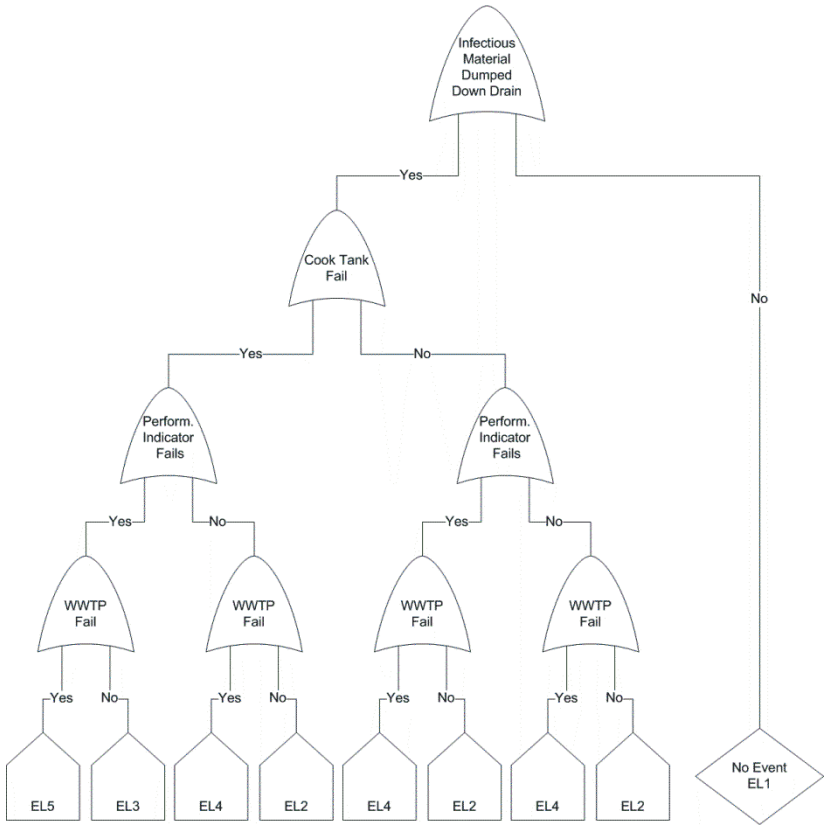


Figure 4.5.3-2: Fault Tree for Liquid Waste Release via Improper Disposal of a Sample Down the Drain in BSL-3E/BSL-3E SP (EL)

Table 4.5.3 2: BSL 3E/BSL 3E SP Liquid Waste (EL)									
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	EL1	EL2	EL3	EL4	EL5
Follows protocol and sample is not dumped down the drain	1.00E-04	9.9990E-01	0.00E+00	1.00E+00	WORK	FAIL	FAIL	FAIL	FAIL
Cook Tank	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	n/a	WORK or	FAIL	WORK or	FAIL
Cook Tank Performance Indicator	1.00E-05	9.9999E-01	n/a	n/a	n/a	WORK	FAIL	WORK	FAIL
On Site Wastewater Treatment	1.00E-05	9.9999E-01	1.00E-01	1.00E+00	n/a	WORK	WORK	FAIL	FAIL
				Overall Reduction Factor	0.0000E+00	1.0000E 07	1.0000E 01	1.0000E 06	1.0000E+00
				Q_{Low} (PFU)	0.000E+00	1.020E-07	1.020E-01	1.020E-06	1.020E+00
				Q_{Medium} (PFU)	0.000E+00	3.460E-03	3.460E+03	3.460E-02	3.460E+04
				Q_{High} (PFU)	0.000E+00	1.180E+02	1.180E+08	1.180E+03	1.180E+09
				Probability (P_{Loss})	9.9990E 01	9.9999E 05	9.9999E 15	1.0000E 09	1.0000E 19
				Frequency (F_{Loss}) (yr^{-1})	5.25E+04	5.25E+00	5.25E 10	5.25E 05	5.25E 15

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 52,500 yr^{-1}

4.5.3.3 BSL-3E/BSL-3E SP – Solid Waste (ES)

During a typical work day, some fraction of the FMDv samples will be disposed of through the solid waste pathway. It is assumed that the majority of the material will be retained for experimentation on later days. To be conservative and to allow for days where disposal of stock cultures may occur (such as the end of an experimental phase), this retention value was placed at 80%. The remaining 20% of the FMDv material was modeled to be disposed through the solid waste pathway which includes two autoclaves and an incineration process. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-3. The fault tree is shown in Figure 4.5.3-3.

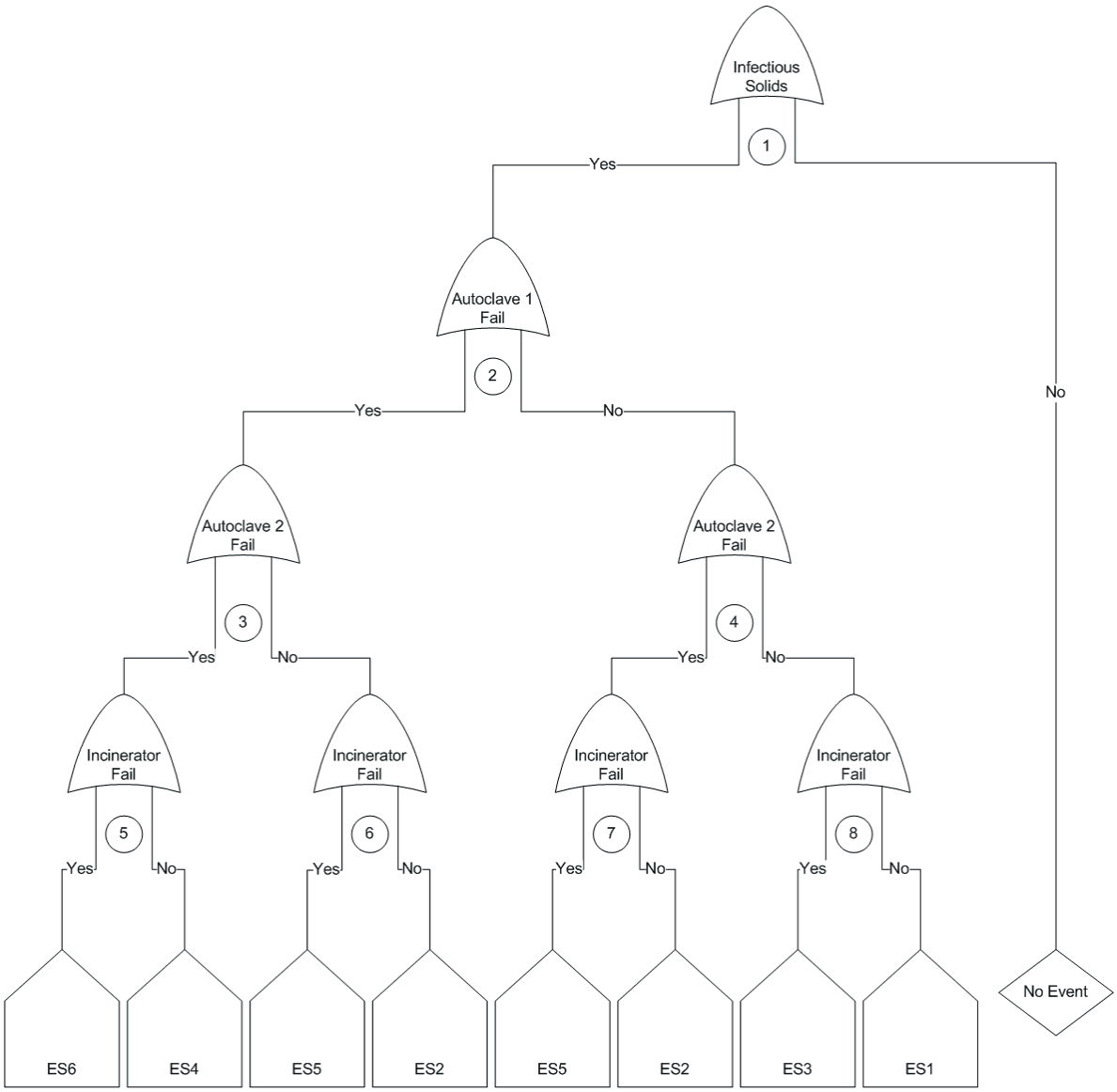


Figure 4.5.3-3: Fault Tree for Solid Waste Release in BSL-3E/BSL-3E SP (ES)

Table 4.5.3 3: BSL 3E/BSL 3E SP Solid Waste (ES)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	ES1	ES2[a]	ES3	ES4	ES5[b]	ES6
Autoclave #1	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	WORK	WORK	FAIL	WORK	FAIL
Autoclave #2	1.00E-05	9.9999E-01	1.00E-06	1.00E+00	WORK	FAIL	WORK	FAIL	FAIL	FAIL
Incinerator	1.00E-10	1.0000E+00	1.00E-09	1.00E+00	WORK	WORK	FAIL	WORK	FAIL	FAIL
				Overall Reduction Factor	**1.000E 21**	**1.000E 15**	**1.000E 12**	**1.000E 09**	**1.000E 06**	**1.000E+00**
				Q_{Low} (PFU)	8.568E-21	8.568E-15	8.568E-12	8.568E-09	8.568E-06	8.568E+00
				Q_{Medium} (PFU)	2.906E-16	2.906E-10	2.906E-07	2.906E-04	2.906E-01	2.906E+05
				Q_{High} (PFU)	9.912E-12	9.912E-06	9.912E-03	9.912E+00	9.912E+03	9.912E+09
				Probability (P_{Loss})	**9.9998E 01**	**2.0000E 05**	**9.9998E 11**	**1.0000E 10**	**2.0000E 15**	**1.0000E 20**
				Frequency (F_{Loss}) (yr^{1})	**2.50E+02**	**5.00E 03**	**2.50E 08**	**2.50E 08**	**5.00E 13**	**2.50E 18**

[a]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator works.
[b]Probability is the sum of all events in which one of the two autoclaves fails and the incinerator fails.

MAR Low = 8.57×10^{0} PFU
MAR Medium = 2.91×10^{5} PFU
MAR High = 9.91×10^{9} PFU
Opportunity Rate = 250 yr^{-1}

4.5.3.4 BSL-3E/BSL-3E SP – Transference (Contact, Palm) (ETP1-6)

For the first set of six events involving contact transference with the palm, a researcher or worker spills a sample of infectious FMDv and a fraction of the material is transferred to the palm region of the gloved hands of a worker (e.g., during the clean-up). (In contrast to the necropsy suite in which the whole hand is likely to be exposed to infectious material, particularly during the handling of organs and animal carcasses, only one side of the hand, e.g., the palm, is modeled as potentially being exposed to infectious FMDv in the BSL-3E/SP.) The conceptual model is shown in Figure 4.5.2-5. The protection systems are the gloves and two body showers which are required to leave containment. The gloves have a failure rate of 7.67×10^{-2} as detailed in Section 4.2.4, while the body showers have a failure rate of human error (5×10^{-3}). The opportunity rate for these set of events is set to 21,000 yr^{-1}, corresponding to the product of the maximum number of workers in a BSL-3E/SP unit (9), the number of BSL-3E/SP units (20), 70% occupancy of the NBAF, one-third of research and activities devoted to FMD, 250 work days per year, and two times during the day in which a worker would leave containment.

$$\text{Opportunity Rate}_{BSL-3E/SP\ Contact\ Transference} = 9\frac{\text{workers}}{\text{unit}} \times 20\ \text{units} \times 70\%\ \text{occupancy} \times \frac{1}{3}\text{FMD research} \times 250\ \frac{\text{work days}}{\text{year}} \times 2\ \frac{\text{times leaving containment}}{\text{day}}$$

Equation 4.5.3-2

The MAR for these set of events is the FMDv levels in 90 mL of a typical sample prior to transfer. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-4. The fault tree is shown in Figure 4.5.3-4.

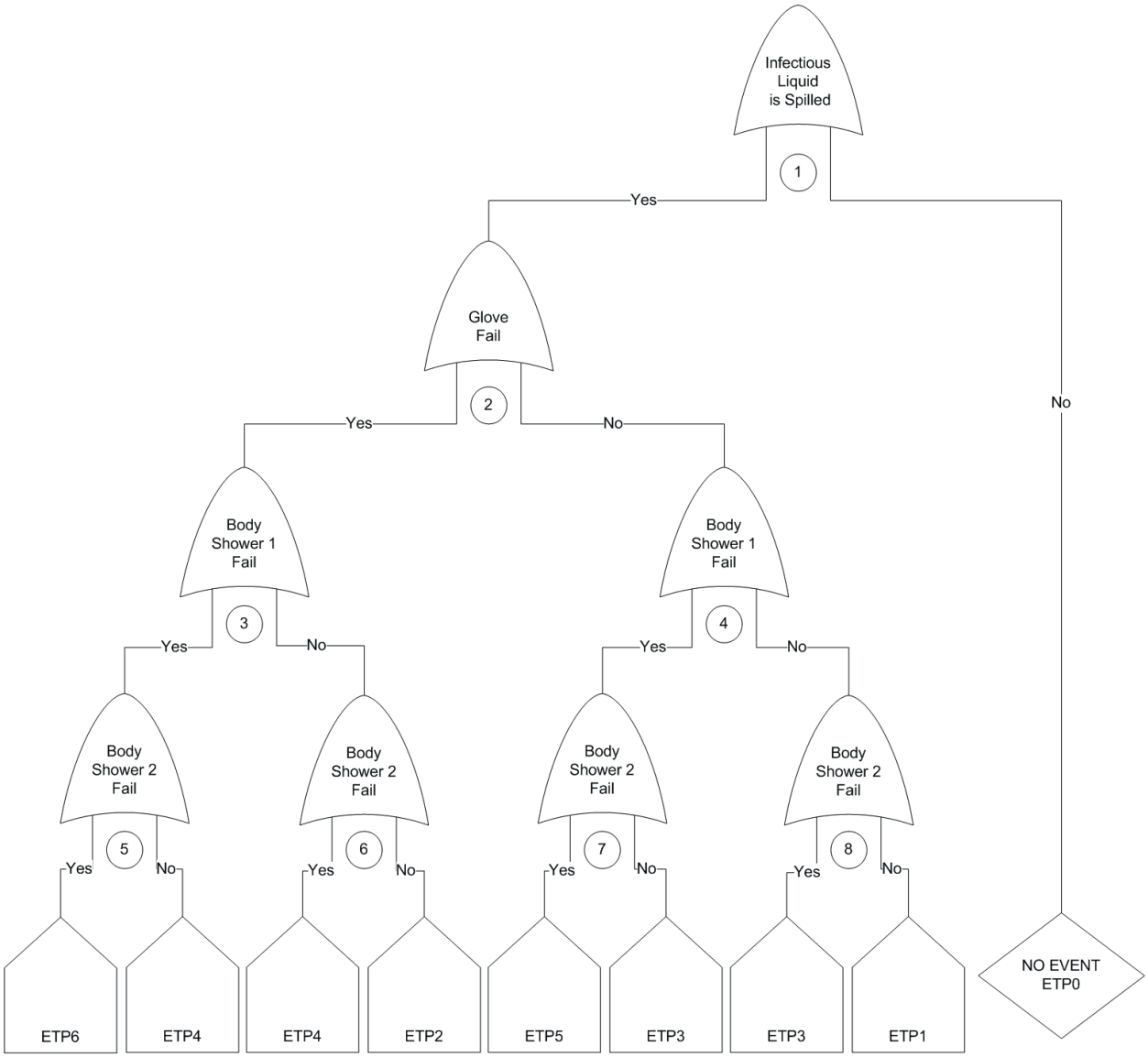


Figure 4.5.3-4: Fault Tree for Transference Contact Events with Palm in BSL-3E/BSL-3E SP (ETP1-6)

Table 4.5.3 4: BSL 3E/BSL 3E SP Transference Contact with Hand (ETP1 6)											
Node/Mitigation System	**Probability of Failure**	**Probability of Success**	**Reduction Factor (Success)**	**Reduction Factor (Failure)**	**ETP0**	**ETP1**	**ETP2**	**ETP3**	**ETP4**	**ETP5**	**ETP6**
Sample is not dropped or spilled	2.00E-03	9.9800E-01	0.00E+00	1.00E+00	WORK	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
Area Ratio	0.00E+00	1.0000E+00	2.19E-01	n/a	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Gloves	7.67E-02	9.2330E-01	1.00E-05	6.70E-03	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	n/a	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	n/a	WORK	WORK	WORK	WORK	FAIL	FAIL
Overall Reduction Factor					**0.0000E+00**	**8.9315E 09**	**5.9841E 06**	**8.8431E 08**	**5.9249E 05**	**8.7556E 07**	**5.8662E 04**
	Q_{Low} (PFU)				0.000E+00	9.110E-09	6.104E-06	9.020E-08	6.043E-05	8.931E-07	5.984E-04
	Q_{Medium} (PFU)				0.000E+00	3.090E-04	2.071E-01	3.060E-03	2.050E+00	3.029E-02	2.030E+01
	Q_{High} (PFU)				0.000E+00	1.054E+01	7.061E+03	1.043E+02	6.991E+04	1.033E+03	6.922E+05
Probability (P_{Loss})					**9.980E 01**	**1.828E 03**	**1.519E 04**	**1.837E 05**	**1.526E 06**	**4.617E 08**	**3.835E 09**
Frequency (F_{Loss}) (yr^{1})					**2.10E+04**	**3.84E+01**	**3.19E+00**	**3.86E 01**	**3.21E 02**	**9.69E 04**	**8.05E 05**

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 21,000 yr^{-1}

4.5.3.5 BSL-3E/BSL-3E SP – Transference (Contact, Glove to Palm) (ETP7-12)

The second set of six transference contact events with the palm involve the improper removal of gloves and the transfer of infectious material on contaminated gloves being transferred to bare skin. For these events, there are two transfer nodes – from a sample to the glove, and from the gloves to the researcher's hands. (For the second transfer event, it was assumed that all material transferred to the glove would be in contact with the bare skin.) The protection systems are a spot decontamination performed by the researcher on the site of contact upon recognizing the laboratory exposure to infectious materials and two body showers which are required to leave containment. The spot chemical decontamination and the two body showers each have a failure rate of human error (5×10^{-3}). The opportunity rate for these transference events was the same as presented for the first set of transference events with the palm in the BSL-3E/BSL-3E SP (Section 4.5.3.4), 21,000 yr^{-1}. The MAR for these set of events is the FMDv levels in 90 mL of a typical sample prior to transfer. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-5. The fault tree is shown in Figure 4.5.3-5.

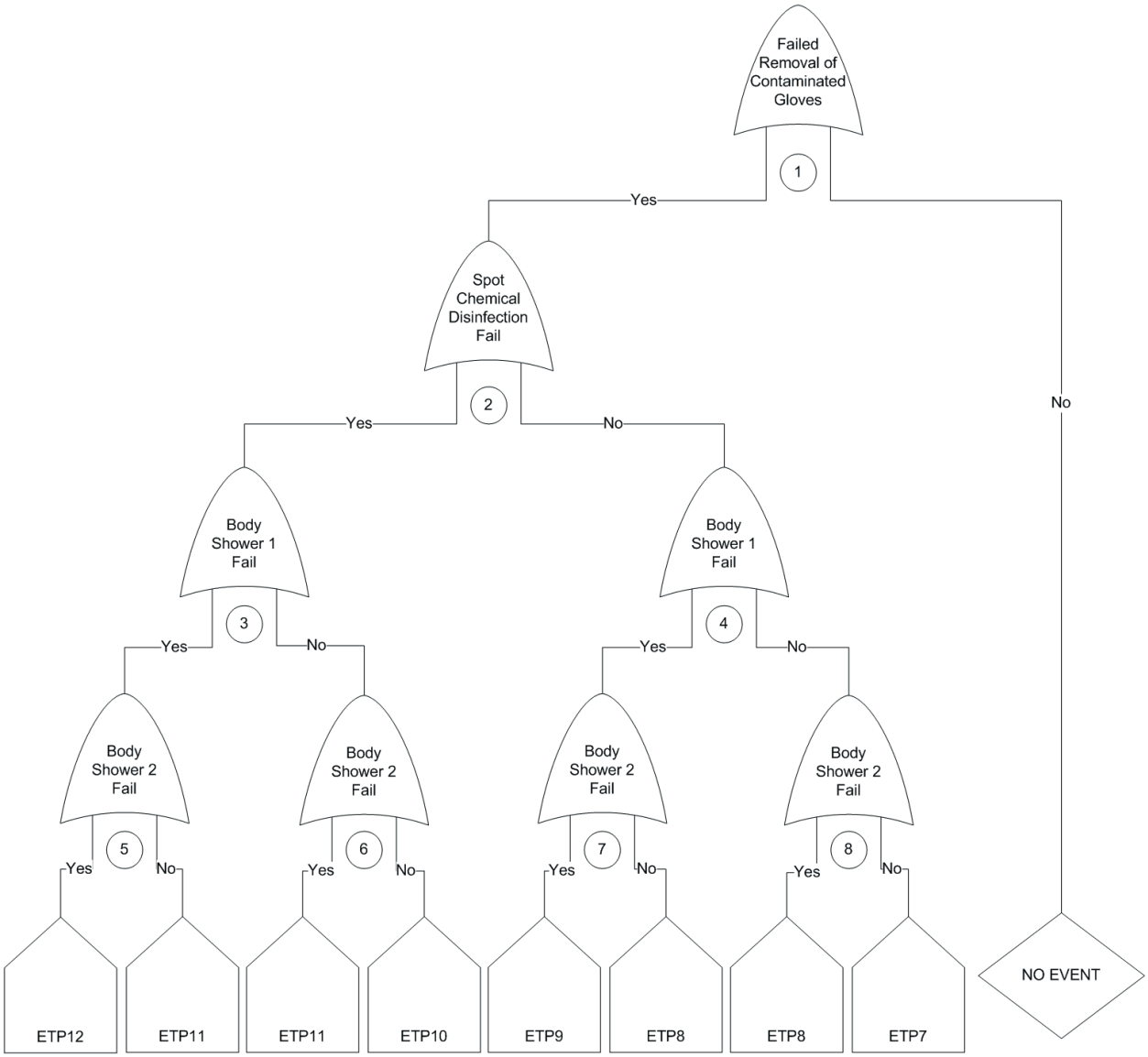


Figure 4.5.3-5: Fault Tree for Transference Contact Events with Palm from Contaminated Glove in BSL-3E/BSL-3E SP (ETP7-12)

Table 4.5.3 5: BSL 3E/BSL 3E SP Transference Contact with Hand from Contaminated Glove (ETP7 12)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	ETP7	ETP8	ETP9	ETP10	ETP11	ETP12
Failed Removal of Gloves	5.00E-03	9.950E-01	0.00E+00	4.00E-01	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
Area Ratio	0.00E+00	1.000E+00	2.19E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Spot Chemical Disinfection	5.00E-03	9.950E-01	1.00E-05	1.00E+00	WORK	WORK	WORK	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	FAIL	FAIL	WORK	FAIL	FAIL
Body Shower	5.00E-03	9.950E-01	1.01E-01	1.00E+00	WORK	WORK	FAIL	WORK	WORK	FAIL
				Overall Reduction Factor	7.9250E 09	7.8466E 08	7.7689E 07	7.9250E 04	7.8466E 03	7.7689E 02
				Q_{Low} (PFU)	6.824E-08	6.756E-07	6.689E-06	6.824E-03	6.756E-02	6.689E-01
				Q_{Medium} (PFU)	3.626E-04	3.590E-03	3.554E-02	3.626E+01	3.590E+02	3.554E+03
				Q_{High} (PFU)	1.117E+00	1.106E+01	1.095E+02	1.117E+05	1.106E+06	1.095E+07
				Probability (P_{Loss})	4.925E 03	4.950E 05	1.244E 07	2.475E 05	2.488E 07	6.250E 10
				Frequency (F_{Loss}) (yr^{1})	1.03E+02	1.04E+00	2.61E 03	5.20E 01	5.22E 03	1.31E 05

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 21,000 yr^{-1}

4.5.3.6 BSL-3E/BSL-3E SP – Transference (Body) (ETB)

For the contact transference events with the body, a researcher or worker spills a sample of infectious FMDv and a fraction of the material is transferred to the body region of a worker wearing a Tyvek® suit. The conceptual model is shown in Figure 4.5.2-5. The protection systems are the Tyvek® suit and two body showers which are required to leave containment. No data was obtained on the failure rate of Tyvek® suits so a conservative estimate of 1.0×10^{-2} was used. The body showers have a failure rate of human error (5×10^{-3}). The MAR is the amount of infectious FMDv in a typical sample prior to transfer. The same opportunity rate as the BSL-3E/BSL-3E SP palm transference events (Sections 4.5.3.4 and 4.5.3.5) were used (21,000 yr^{-1}). The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Table 4.5.3-6. The fault tree is shown in Figure 4.5.3-6.

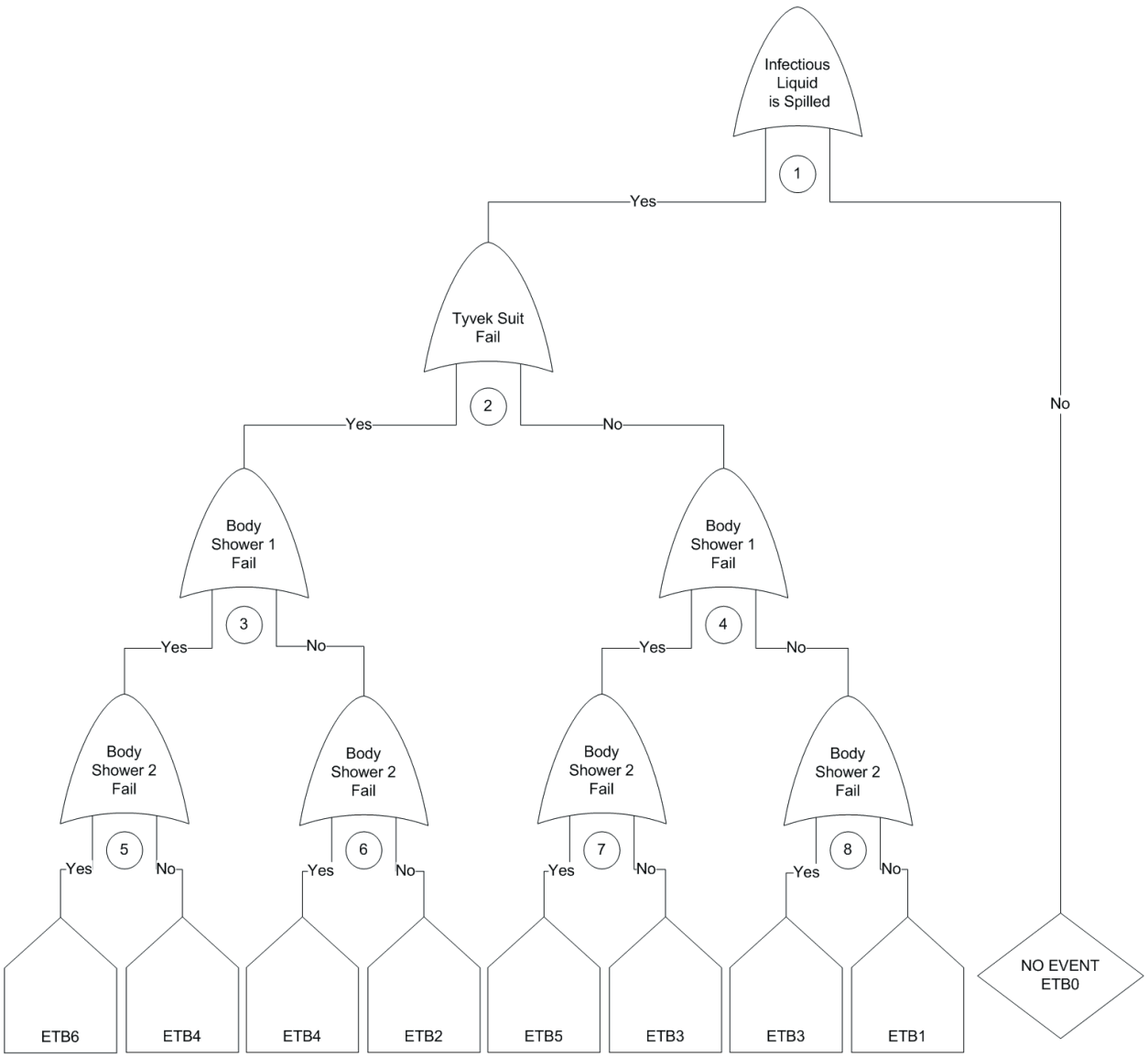


Figure 4.5.3-6: Fault Tree for Transference Contact Events with Body in BSL-3E/BSL-3E SP (ETB)

Table 4.5.3 6: BSL 3E/BSL 3E SP Transference Contact with Body (ETB)											
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	ETB0	ETB1	ETB2	ETB3	ETB4	ETB5	ETB6
Sample is not dropped or spilled	2.00E-03	9.9800E-01	0.00E+00	1.00E+00	WORK	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
Area Ratio	0.00E+00	1.0000E+00	4.44E-01	n/a	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	n/a	WORK	WORK	WORK	WORK	WORK	WORK
Tyvek® Suit	1.00E-02	9.9000E-01	2.00E-04	1.50E-01	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	n/a	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Body Shower	5.00E-03	9.9500E-01	1.01E-01	1.00E+00	n/a	WORK	WORK	WORK	WORK	FAIL	FAIL
				Overall Reduction Factor	0.0000E+00	3.6270E 07	2.7203E 04	3.5911E 06	2.6933E 03	3.5556E 05	2.6667E 02
				Q_{Low} (PFU)	0.000E+00	3.700E-07	2.775E-04	3.663E-06	2.747E-03	3.627E-05	2.720E-02
				Q_{Medium} (PFU)	0.000E+00	1.255E-02	9.412E+00	1.243E-01	9.319E+01	1.230E+00	9.227E+02
				Q_{High} (PFU)	0.000E+00	4.280E+02	3.210E+05	4.238E+03	3.178E+06	4.196E+04	3.147E+07
				Probability (P_{Loss})	9.980E 01	1.960E 03	1.980E 05	1.970E 05	1.990E 07	4.950E 08	5.000E 10
				Frequency (F_{Loss}) (yr^{-1})	2.10E+04	4.12E+01	4.16E 01	4.14E 01	4.18E 03	1.04E 03	1.05E 05

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 21,000 yr^{-1}

4.5.4 Non-Containment Events

Two sets of circumstances were modeled for the non-containment events: 1) failure of packages shipped with an infectious FMDv sample; and 2) maintenance of a leaking drain pipe in the AHRs. For the package failure events, it was assumed that the sample would be appropriately packaged with a primary, secondary, and tertiary (e.g., outside box) containers. For there to be a release of infectious FMDv, both the primary and the secondary containers must fail. The tertiary container was modeled as only "blocking" (e.g., through absorption) 10% of the material (i.e., a reduction factor of 0.9). For the shipping events, two sets of probabilities for failure of the primary and secondary containers were used: 1) if the shipper failed to appropriately package the sample, the probability for failure of both the primary and secondary container was modeled as 1×10^{-4} (corresponding to $1 \times 10^{-2} \times 1 \times 10^{-2}$); and 2) if the shipper correctly packaged the sample, the probability of failure of both the primary and the secondary containers was set to 1×10^{-6} (corresponding to $1 \times 10^{-3} \times 1 \times 10^{-3}$). The probability of the tertiary container was set to 1×10^{-3}.

For the events in which contact exposure to the infectious FMDv (from the failed containers) was modeled, an additional node was included: recognition of potential contact exposure by handling a package that may contain infectious material. If the individual recognizes that they may be handling a package that has pathogenic material, they will take precautionary measures when dealing with the failed package, e.g., wear gloves or Tyvek® suit, remove footwear and leave footwear in containment, and take a body shower. Each of these subsequent protection nodes (PPE use, body shower) were not modeled as nodes: if the recognition of potential exposure was a success, the protection measures were a success; if the individual failed to recognize potential exposure, no protection measures were modeled to reduce the quantity of infectious FMDv.

The opportunity rate for these set of shipping and failed packing events is 500 yr^{-1}. This value corresponds to a very conservative estimate of 20 shipments of samples per work day, one-third of the shipments being FMDv samples, and 10% of these FMDv shipments being positive for viable FMDv, three handling events in which the shipment could be dropped, jostled, etc. leading to failure of the primary and secondary containers, and 250 work days per year.

4.5.4.1 Non-Containment – Aerosol (OA)

The non-containment aerosol events are modeled based on the failed containers of a shipment of a viable FMDv sample. As described above, if both the primary and secondary containers, a fraction of the sample will be aerosolized and released in a non-containment area. The MAR for this set of events is the typical amount of FMDv in a sample, as determined from the BSL-3E/BSL-3E SP source terms, prior to aerosolization. The opportunity rate was set to 500 yr^{-1}, as noted above. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Tables 4.5.4-1 and 4.5.4-2. The fault tree is shown in Figure 4.5.4-1.

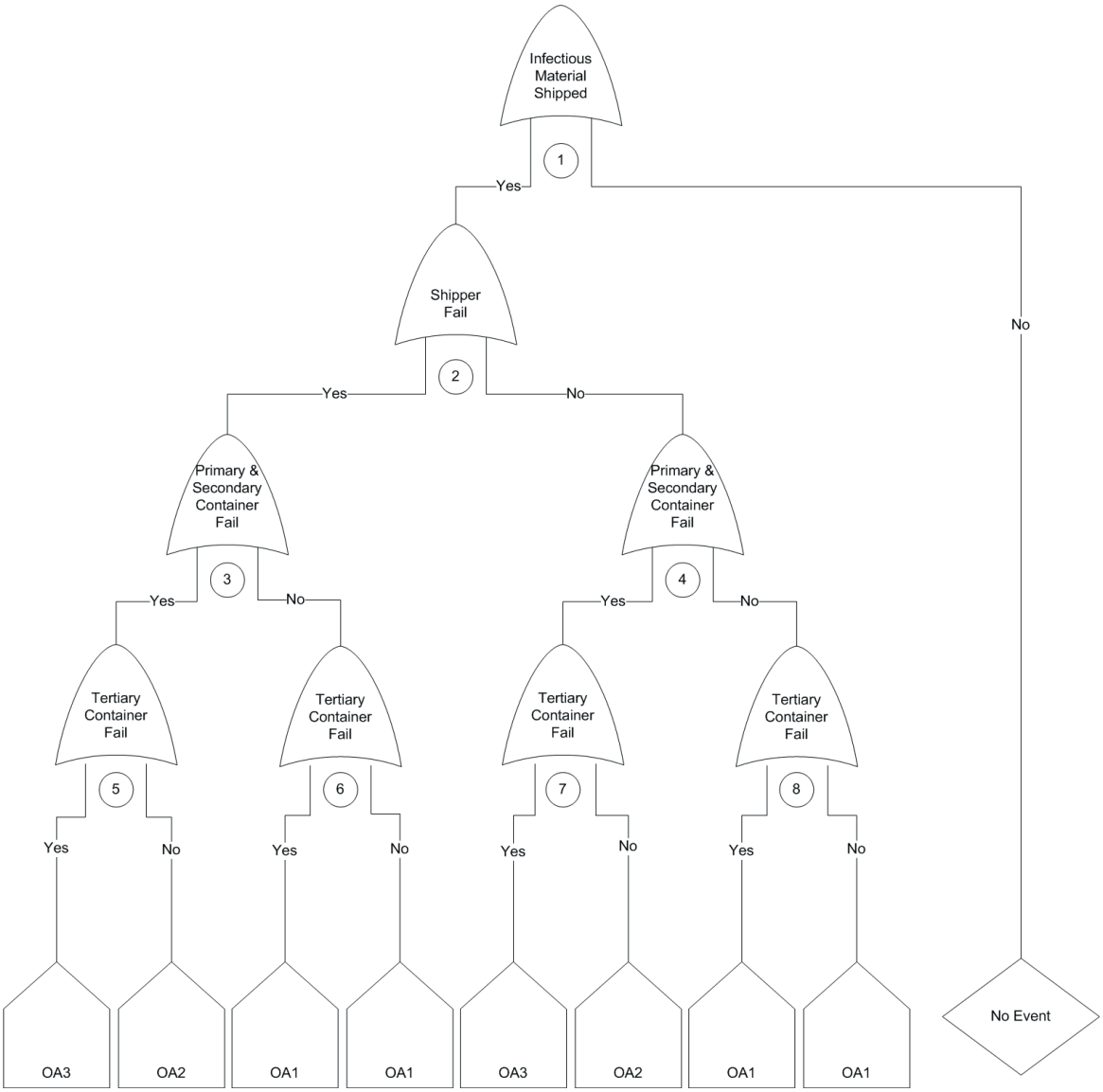


Figure 4.5.4-1: Fault Tree for Aerosol Release via Dropped Shipment of Infectious FMDv (OA)

Table 4.5.4 1: Non Containment Aerosol (OA) (Detailed)										
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OA1.1	OA1.2	OA2.1	OA2.2	OA3.1	OA3.2
Shipper fails to properly package sample	1.00E-02	9.9000E-01	n/a	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL
Primary and secondary containers work (packaged correctly) (reduction factor failure aerosolized release fraction)	1.00E-06	1.0000E+00	0.00E+00	1.00E-04	WORK	n/a	FAIL	n/a	FAIL	n/a
Primary and secondary containers work (packaged incorrectly) (reduction factor failure aerosolized release fraction)	1.00E-04	9.9990E-01	0.00E+00	1.00E-04	n/a	WORK	n/a	FAIL	n/a	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	n/a	WORK	WORK	FAIL	FAIL
Overall Reduction Factor					0.000E+00	0.000E+00	9.000E 05	9.000E 05	1.000E 04	1.000E 04
Probability (P_{Loss})					9.9000E 01	9.9990E 03	9.8901E 07	9.9900E 07	9.9000E 10	1.0000E 09
Frequency (F_{Loss}) (yr ^{1})					4.95E+02	5.00E+00	4.95E 04	5.00E 04	4.95E 07	5.00E 07

Table 4.5.4 2: Non Containment Aerosol (OA) (Summary)							
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OA1	OA2	OA3
Primary and secondary containers work	---	---	0.00E+00	1.00E-04	WORK	FAIL	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	WORK	FAIL
				Overall Reduction Factor	0.000E+00	9.000E 05	1.000E 04
				Q_{Low} (PFU)	0.000E+00	9.180E-05	1.020E-04
				Q_{Medium} (PFU)	0.000E+00	3.114E+00	3.460E+00
				Q_{High} (PFU)	0.000E+00	1.062E+05	1.180E+05
				Probability (P_{Loss})	9.99998E 01	1.9880E 06	1.9900E 09
				Frequency (F_{Loss}) (yr ^{1})	5.00E+02	9.94E 04	9.95E 07

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.46×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 500 yr^{-1}

4.5.4.2 Non-Containment – Transference (Contact, Palm) (OTP)

The transference contact events with the palm in the non-containment areas are similarly modeled based on the failed containers of a shipment of a viable FMDv sample. As described above, if both the primary and secondary containers fail, a fraction of the sample was modeled as coming into contact with any individual handling the package. If the individual handling the clean-up of a failed shipment of viable FMDv recognizes the risks of contact exposure, proper mitigating systems will be used. For these set of events, the mitigating systems are working gloves and a body shower. The MAR for this set of events is the typical amount of FMDv in a sample, as determined from the BSL-3E/BSL-3E SP source terms. The opportunity rate was set to 500 yr^{-1}, as noted above. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Tables 4.5.4-3 and 4.5.4-4. The fault tree is shown in Figure 4.5.4-2.

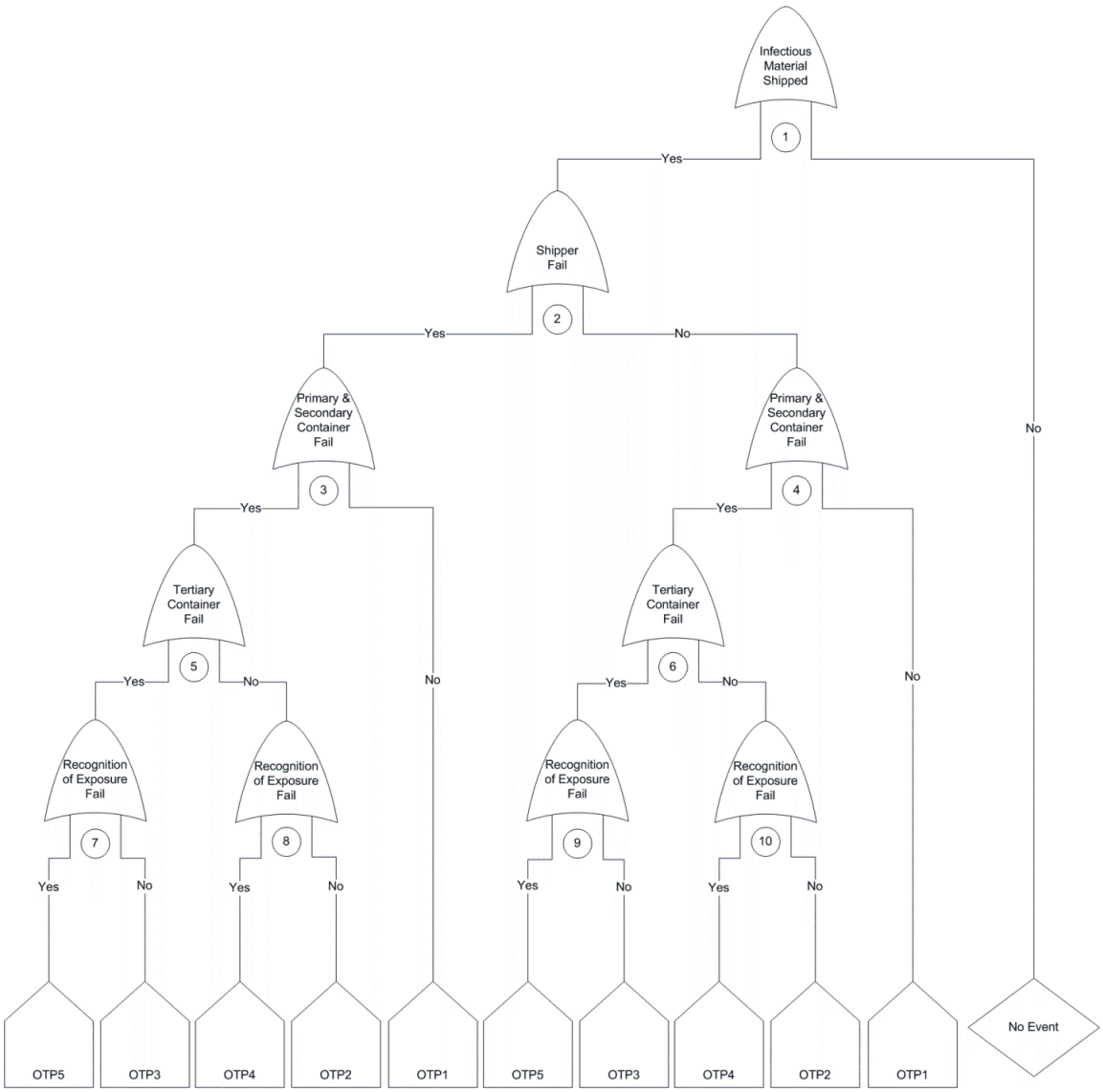


Figure 4.5.4-2: Fault Tree for Transference Contact Events with Palm from Failed Packaging of a Shipment of Infectious FMDv (OTP)

Table 4.5.4-3: Non-Containment – Transference Contact with Palm (OTP) (Detailed)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTP1.1	OTP1.2	OTP2.1	OTP2.2	OTP3.1	OTP3.2	OTP4.1	OTP4.2	OTP5.1	OTP5.2
Shipper fails to properly package sample	1.00E-02	9.9000E-01	n/a	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL
Primary and secondary containers work (when shipped packages correctly)	1.00E-06	1.0000E+00	0.00E+00	1.00E+00	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a
Primary and secondary containers work (when shipped packages incorrectly)	1.00E-04	9.9990E-01	0.00E+00	1.00E+00	n/a	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	n/a	WORK	WORK	FAIL	FAIL	WORK	WORK	FAIL	FAIL
Area Ratio	0.00E+00	1.0000E+00	3.94E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Recognition of potential exposure (gloves and body shower)	5.00E-03	9.9500E-01	1.01E-06	1.00E+00	n/a	n/a	WORK	WORK	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Overall Reduction Factor					**0.000E+00**	**0.000E+00**	**1.433E-07**	**1.433E-07**	**1.592E-07**	**1.592E-07**	**1.418E-01**	**1.418E-01**	**1.576E-01**	**1.576E-01**
Probability (P_{Loss})					**9.900E-01**	**9.999E-03**	**9.841E-07**	**9.940E-07**	**9.851E-10**	**9.950E-10**	**4.945E-09**	**4.995E-09**	**4.950E-12**	**5.000E-12**
Frequency (F_{Loss}) (yr^{-1})					**4.95E+02**	**5.00E+00**	**4.92E-04**	**4.97E-04**	**4.93E-07**	**4.98E-07**	**2.47E-06**	**2.50E-06**	**2.48E-09**	**2.50E-09**

Table 4.5.4-4: Non-Containment – Transference Contact with Palm (OTP) (Summary)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTP1	OTP2	OTP3	OTP4	OTP5
Primary and secondary containers work	---	---	0.00E+00	1.00E+00	WORK	FAIL	FAIL	FAIL	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	WORK	FAIL	WORK	FAIL
Recognition of potential exposure (gloves and body shower)	5.00E-03	9.9500E-01	1.01E-06	1.00E+00	n/a	WORK	WORK	FAIL	FAIL
Overall Reduction Factor					**0.000E+00**	**1.433E-07**	**1.592E-07**	**1.418E-01**	**1.576E-01**
	Q_{Low} (PFU)				0.000E+00	1.461E-07	1.624E-07	1.447E-01	1.608E-01
	Q_{Medium} (PFU)				0.000E+00	4.957E-03	5.507E-03	4.908E+03	5.453E+03
	Q_{High} (PFU)				0.000E+00	1.690E+02	1.878E+02	1.674E+08	1.860E+08
Probability (P_{Loss})					**9.99998E-01**	**1.9781E-06**	**1.9801E-09**	**9.9401E-09**	**9.9500E-12**
Frequency (F_{Loss}) (yr^{-1})					**5.00E+02**	**9.89E-04**	**9.90E-07**	**4.97E-06**	**4.98E-09**

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.48×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 500 yr^{-1}

4.5.4.3 Non-Containment – Transference (Contact, Foot) (OTF)

The transference contact events with the foot in the non-containment areas are similarly modeled based on the failed containers of a shipment of a viable FMDv sample. As described above, if both the primary and secondary containers fail, a fraction of the sample was modeled as coming into contact with any individual handling the package, and such contact could occur with the shoe, boot, or foot region of the individual. If the individual handling the clean-up of a failed shipment of viable FMDv recognizes the risks of contact exposure, proper mitigating systems will be used. For these set of events, the mitigating systems are removal and containment of the exposed footwear; when the contaminated footwear is contained, no material was modeled as being released. The MAR for this set of events is the typical amount of FMDv in a sample, as determined from the BSL-3E/BSL-3E SP source terms. The opportunity rate was set to 500 yr^{-1}, as noted above. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Tables 4.5.4-5 and 4.5.4-6. The fault tree is shown in Figure 4.5.4-3.

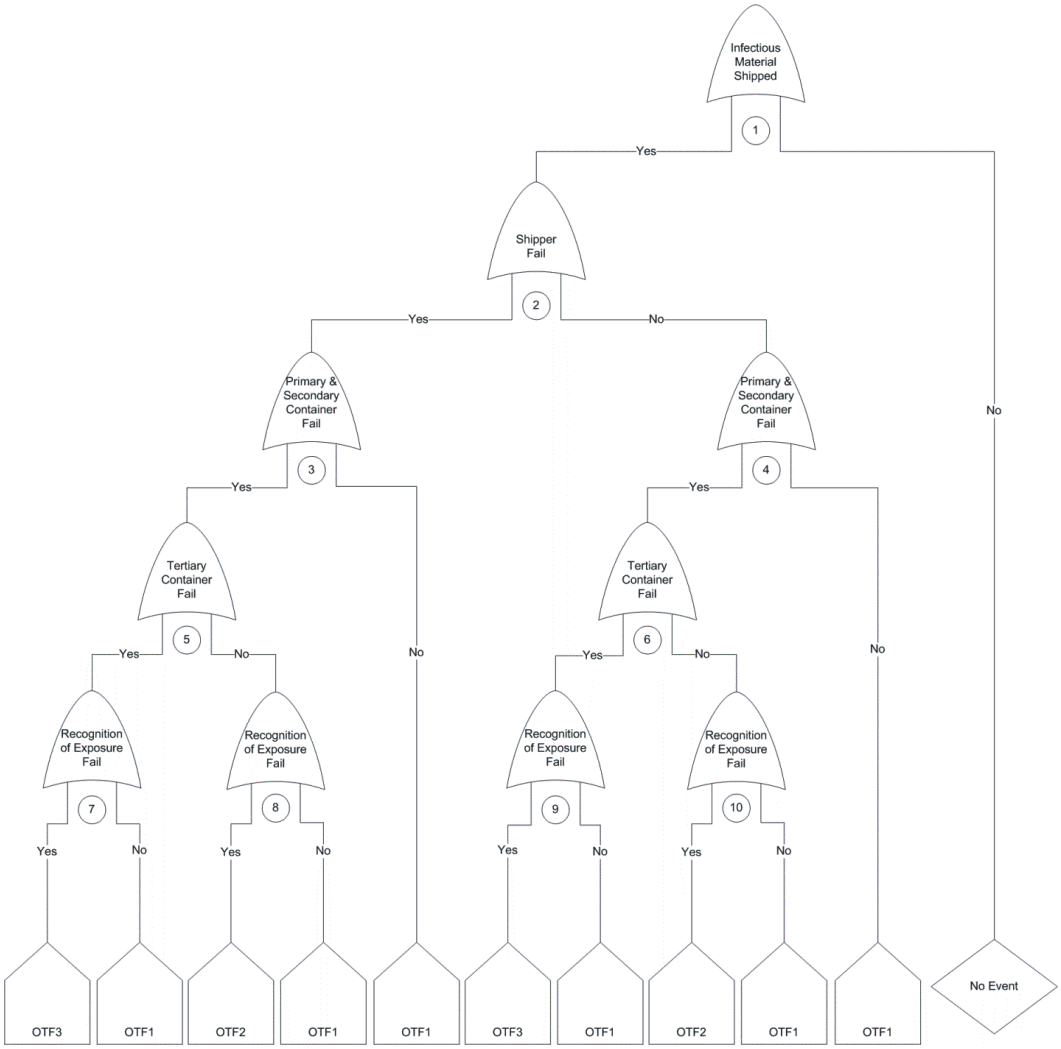


Figure 4.5.4-3: Fault Tree for Transference Contact Events with Foot Region from Failed Packaging of a Shipment of Infectious FMDv (OTF)

Table 4.5.4-5: Non-Containment – Transference Contact with Foot (OTF) (Detailed)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTF1.1	OTF1.2	OTF2.1	OTF2.2	OTF2.3	OTF2.4	OTF2.5	OTF2.52	OTF3.1	OTF3.2
Shipper fails to properly package sample	1.00E-02	9.9000E-01	n/a	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL
Primary and secondary containers work (when shipped packages correctly)	1.00E-06	1.0000E+00	0.00E+00	1.00E+00	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a
Primary and secondary containers work (when shipped packages incorrectly)	1.00E-04	9.9990E-01	0.00E+00	1.00E+00	n/a	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	n/a	WORK	WORK	FAIL	FAIL	WORK	WORK	FAIL	FAIL
Area Ratio	0.00E+00	1.0000E+00	1.00E+00	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Recognition of potential exposure (shoes kept in containment)	5.00E-03	9.9500E-01	0.00E+00	n/a	n/a	n/a	WORK	WORK	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Overall Reduction Factor					**0.000E+00**	**0.000E+00**	**0.000E+00**	**0.000E+00**	**0.000E+00**	**0.000E+00**	**3.600E-01**	**3.600E-01**	**4.000E-01**	**4.000E-01**
Probability (P_{Loss})					**9.9000E-01**	**9.9990E-03**	**9.8406E-07**	**9.9401E-07**	**9.8505E-10**	**9.9500E-10**	**4.9451E-09**	**4.9950E-09**	**4.9500E-12**	**5.0000E-12**
Frequency (F_{Loss}) (yr^{-1})					**4.95E+02**	**5.00E+00**	**4.92E-04**	**4.97E-04**	**4.93E-07**	**4.98E-07**	**2.47E-06**	**2.50E-06**	**2.48E-09**	**2.50E-09**

Table 4.5.4-6: Non-Containment – Transference Contact with Foot (OTF) (Summary)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTF1	OTF2	OTF3
Primary and secondary containers work or recognition of potential exposure	---	---	0.00E+00	1.00E+00	WORK	FAIL	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	WORK	WORK
Overall Reduction Factor					**0.000E+00**	**3.600E-01**	**4.000E-01**
Q_{Low} (PFU)					0.000E+00	3.672E-01	4.080E-01
Q_{Medium} (PFU)					0.000E+00	1.246E+04	1.384E+04
Q_{High} (PFU)					0.000E+00	4.248E+08	4.720E+08
Probability (P_{Loss})					**1.00000E+00**	**9.9401E-09**	**9.9500E-12**
Frequency (F_{Loss}) (yr^{-1})					**5.00E+02**	**4.97E-06**	**4.98E-09**

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.48×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 500 yr^{-1}

4.5.4.4 Non-Containment – Transference (Contact, Body) (OTB)

The transference contact events with the palm in the non-containment areas are similarly modeled based on the failed containers of a shipment of a viable FMDv sample. As described above, if both the primary and secondary containers fail, a fraction of the sample was modeled as coming into contact with the body of an individual handling the package. If the individual handling the clean-up of a failed shipment of viable FMDv recognizes the risks of contact exposure, proper mitigating systems will be used. For these set of events, the mitigating systems are a working Tyvek® suit and a body shower. The MAR for this set of events is the typical amount of FMDv in a sample, as determined from the BSL-3E/BSL-3E SP source terms. The opportunity rate was set to 500 yr^{-1}, as noted above. The probabilities (P_{Loss}), reduction factors, Q values, and frequencies of loss-of-containment (F_{Loss}) for the events included in this set of circumstances are detailed in Tables 4.5.4-7 and 4.5.4-8. The fault tree is shown in Figure 4.5.4-4.

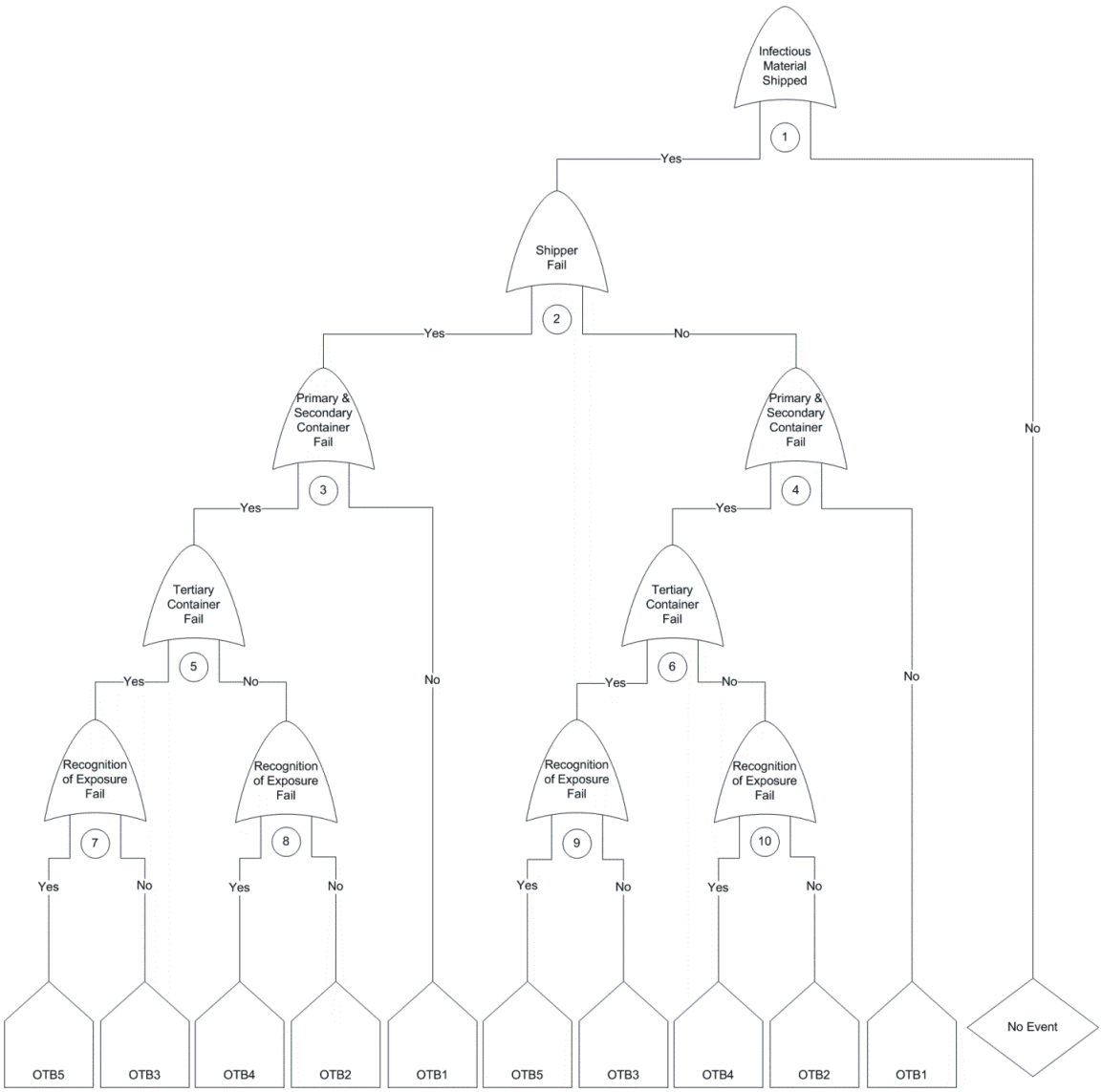


Figure 4.5.4-4: Fault Tree for Transference Contact Events with Body from Failed Packaging of a Shipment of Infectious FMDv (OTB)

Table 4.5.4-7: Non-Containment – Transference Contact with Body (OTB) (Detailed)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTB1.1	OTB1.2	OTB2.1	OTB2.2	OTB3.1	OTB3.2	OTB4.1	OTB4.2	OTB5.1	OTB5.2
Shipper fails to properly package sample	1.00E-02	9.9000E-01	n/a	n/a	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL	WORK	FAIL
Primary and secondary containers work (when shipped packages correctly)	1.00E-06	1.0000E+00	0.00E+00	1.00E+00	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a
Primary and secondary containers work (when shipped packages incorrectly)	1.00E-04	9.9990E-01	0.00E+00	1.00E+00	n/a	WORK	n/a	FAIL	n/a	FAIL	n/a	FAIL	n/a	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	n/a	WORK	WORK	FAIL	FAIL	WORK	WORK	FAIL	FAIL
Area Ratio	0.00E+00	1.0000E+00	8.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Transfer Percentage	0.00E+00	1.0000E+00	4.00E-01	n/a	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK	WORK
Recognition of potential exposure (Tyvek® suit and body shower)	5.00E-03	9.9500E-01	2.02E-05	1.00E+00	n/a	n/a	WORK	WORK	WORK	WORK	FAIL	FAIL	FAIL	FAIL
Overall Reduction Factor					**0.000E+00**	**0.000E+00**	**5.818E-06**	**5.818E-06**	**6.464E-06**	**6.464E-06**	**2.880E-01**	**2.880E-01**	**3.200E-01**	**3.200E-01**
Probability (P_{Loss})					**9.9000E-01**	**9.9990E-03**	**9.8406E-07**	**9.9401E-07**	**9.8505E-10**	**9.9500E-10**	**4.9451E-09**	**4.9950E-09**	**4.9500E-12**	**5.0000E-12**
Frequency (F_{Loss}) (yr^{-1})					**4.95E+02**	**5.00E+00**	**4.92E-04**	**4.97E-04**	**4.93E-07**	**4.98E-07**	**2.47E-06**	**2.50E-06**	**2.48E-09**	**2.50E-09**

Table 4.5.4-8: Non-Containment – Transference Contact with Body (OTB) (Summary)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTB1	OTB2	OTB3	OTB4	OTB5
Primary and secondary containers work	1.00E-06	1.0000E+00	0.00E+00	1.00E+00	WORK	FAIL	FAIL	FAIL	FAIL
Tertiary container works	1.00E-03	9.9900E-01	9.00E-01	1.00E+00	n/a	WORK	FAIL	WORK	FAIL
Recognition of potential exposure (Tyvek® suit and body shower)	5.00E-03	9.9500E-01	1.01E-06	1.00E+00	n/a	WORK	WORK	FAIL	FAIL
Overall Reduction Factor					**0.000E+00**	**5.818E-06**	**6.464E-06**	**2.880E-01**	**3.200E-01**
	Q_{Low} (PFU)				0.000E+00	5.934E-06	6.593E-06	2.938E-01	3.264E-01
	Q_{Medium} (PFU)				0.000E+00	2.013E-01	2.237E-01	9.965E+03	1.107E+04
	Q_{High} (PFU)				0.000E+00	6.865E+03	7.628E+03	3.398E+08	3.776E+08
Probability (P_{Loss})					**9.99998E-01**	**1.9781E-06**	**1.9801E-09**	**9.9401E-09**	**9.9500E-12**
Frequency (F_{Loss}) (yr^{-1})					**5.00E+02**	**9.89E-04**	**9.90E-07**	**4.97E-06**	**4.98E-09**

MAR Low = 1.02×10^{0} PFU
MAR Medium = 3.48×10^{4} PFU
MAR High = 1.18×10^{9} PFU
Opportunity Rate = 500 yr^{-1}

4.5.4.5 Non-Containment – Transference (Contact, Palm and Fomite from Drain Pipe Leak) (OTPalm, OTFom)

For the last two non-containment transference events, the circumstances of the release of infectious material was modeled as originating from a leak in a drain pipe in the AHRs. Maintenance of the leak was modeled as resulting in the transfer of material to the gloved hand of the maintenance worker or to fomite (e.g., wrench) in contact with the leaking drain pipe. The gloves were assumed to be working and thus reducing the amount of material which would penetrate the gloves to the bare skin of the maintenance worker. For the fomite event, the wrench was assumed to be chemically disinfected through a dunk tank or a wipedown. It was also assumed that the drain pipe would have been primed with disinfectant, thus reducing the amount of viable FMDv available for transfer. (Modeling of these events without gloves, without the chemical disinfection, or without the priming of the drain pipes with disinfectant was not performed.) In addition, the contact exposure was modeled as involving the entire surface area of the donor (i.e., the drain pipe). The frequency of the drain trap leak associated with these transfer events assumed one (1) drain trap leak occurs per year, and that infectious material is present in the drain pipe every day (due to the persistence and robustness of FMDv; thus the opportunity rate for such contact events is 1 per year. The associated probability that the transfer occurs given that FMDv material is present on the pipe is set to 1 as it assumes the worker's palm and the wrench make full contact with the small contaminated region of the pipe. The MAR for these two events is 5 mL of infectious liquid waste (urine and feces) from the AHRs. The tables detailing the overall reduction factors and quantity of material are shown below (Tables 4.5.4-9 and 4.5.4-10).

Table 4.5.4 9: Non Containment Transference Contact with Palm from Drain Pipe Leak (OTPalm)

Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTPalm1
Drain Pipe Disinfection	0.00E+00	1.00E+00	1.00E-01	1.00E+00	WORK
Transfer Percentage	0.00E+00	1.00E+00	4.00E-01	n/a	WORK
Gloves	0.00E+00	1.00E+00	1.00E-05	6.70E-03	WORK
				Overall Reduction Factor	**4.000E 07**
				Q_{Low} (PFU)	1.484E-10
				Q_{Medium} (PFU)	7.780E-05
				Q_{High} (PFU)	8.120E-03
				Probability (P_{Loss})	**1.00E+00**
				Frequency (F_{Loss}) (yr ^{1})	**1.00E+00**

MAR Low = 3.71×10^{-4} PFU
MAR Medium = 1.95×10^{2} PFU
MAR High = 2.03×10^{4} PFU
Opportunity Rate = 1.00 yr^{-1}

Table 4.5.4 10: Non Containment Transference Contact with Fomite from Drain Pipe Leak (OTFom)					
Node/Mitigation System	Probability of Failure	Probability of Success	Reduction Factor (Success)	Reduction Factor (Failure)	OTFom1
Drain Pipe Disinfection	0.00E+00	1.00E+00	1.00E-01	1.00E+00	WORK
Transfer Percentage	0.00E+00	1.00E+00	4.00E-01	n/a	WORK
Chemical Disinfection (Wipedown/Dunk)	0.00E+00	1.00E+00	1.00E-05	1.00E+00	WORK
				Overall Reduction Factor	4.000E 07
				Q_{Low} (PFU)	1.484E-10
				Q_{Medium} (PFU)	7.780E-05
				Q_{High} (PFU)	8.120E-03
				Probability (P_{Loss})	1.00E+00
				Frequency (F_{Loss}) (yr ^{1})	1.00E+00

MAR Low = 3.71×10^{-4} PFU
MAR Medium = 1.95×10^{2} PFU
MAR High = 2.03×10^{4} PFU
Opportunity Rate = 1.00 yr^{-1}

4.6 Catastrophic Events

Catastrophic events are characterized by the potential loss of containment from multiple originating locations and through multiple pathways. In prior iterations of the assessment of the NBAF risks, DHS has assessed natural hazards including tornadoes, hurricanes, floods, earthquakes, and high winds. In the 2010 SSRA, particular fidelity was applied to the assessment of tornadoes (SSRA Scenario 11) because of the NBAF's location within "tornado alley". Hurricanes and flooding are discussed below (Sections 4.6.1 and 4.6.2), but are not modeled as catastrophic events. A catastrophic tornado event (Section 4.6.3) is reconsidered in the Updated SSRA to model the effect of significant NBAF design changes and incorporate the comments from the NAS SSRA Committee. The catastrophic earthquake event is discussed in Section 4.6.4.

4.6.1 Hurricanes

The risk to the NBAF (Manhattan, Kansas) from hurricanes is low, as depicted in Figure 4.6.1-1. This figure delineates the portion of the United States where 20-40 hurricanes may be expected during a 100-year period. The dark blue and red areas are expected to have more frequent hurricanes. With the NBAF location in the center of the US, it can be inferred that it is very unlikely that its location will suffer the direct effects of a hurricane. Any hurricane impact to the NBAF will take the form of high winds or a tornado. Thus, the hurricane was not directly considered in the Updated SSRA analysis. Although some high-wind conditions may be associated with tropical weather patterns, these wind events are included in the meteorological data set used for event modeling and will have no impact on the loss of containment risk for the NBAF.

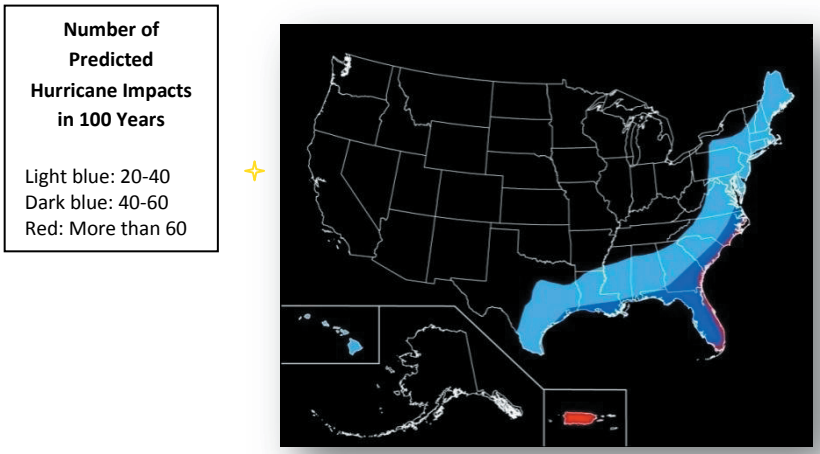


Figure 4.6.1-1: Hurricane Return Period (National Atlas and the USGS)

4.6.2 Flooding

FEMA flood data for the NBAF area classify the location as "Zone X" – indicating there is less that a 0.2% likelihood of flooding in any given year. Inspection of topographic contours (Figure 4.6.2-1) of the area indicates that the NBAF location is near the top of a hillside and away from any terrain that appears to be subject to flooding or fast-moving high water.

As can be seen in Figure 4.6.2-1, the nearest significant surface water is the Big Blue River, approximately 1.75 miles from the NBAF at its closest point. Tuttle Creek Dam is on the Big Blue River about 9 miles upstream of the confluence of the Big Blue River and the Kansas River. The dam is 3.7 to 4.0 miles (depending on which part of the dam the distance is measured from) from the NBAF location. Tuttle Creek Reservoir is behind (on the north side of) the dam. At normal "multipurpose pool" levels, the surface water elevation of the reservoir behind the dam is 1,075′ (msl) The crest of the spillway is at 1,116′ (msl)

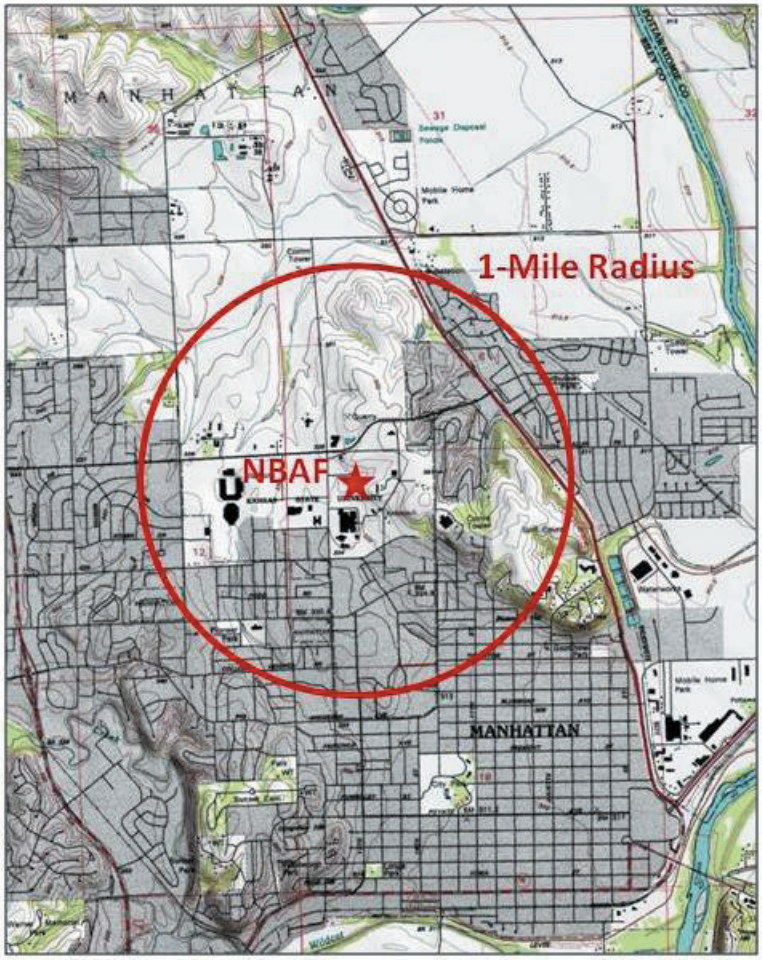


Figure 4.6.2-1. Topographic Map of the NBAF Area

and the top of the crest gates 1,136′ (msl) [USACE, 2004]. The elevation of the terrain surrounding the NBAF varies from 1,104 to 1,240 ft (msl) [NDP, 2011]. The reservoir and dam are pictured in Figures 4.6.2-2 and 4.6.2-3.

Figure 4.6.2-2: Tuttle Creek Dam and Reservoir (aerial)

Figure 4.6.2-3: Tuttle Creek Reservoir and Tuttle Creek Dam (in distance)

Modeling of potential major flooding of Tuttle Creek Lake has been performed by developing a theoretical storm known as the Probable Maximum Precipitation (PMP) event. The PMP modeled for the Tuttle Creek watershed was positioned to result in the maximum runoff into the reservoir. This storm modeled approximately 23.6″ of rain in a three-day period and is believed to be the worst storm that could ever occur in the area. Standard computer models were used to simulate the drainage running into the reservoir, flowing through the lake, and out the emergency spillway in accordance with the lake operating manual. Under these modeled circumstances, it estimated that flow through the spillway will be approximately ten times larger than the flow during the 1993 flood. However, the studies indicate that the reservoir would not be expected to rise above the top of the dam during the flood if all of the gates are working properly. If two or more gates fail the dam could be overtopped. The studies also indicated that wind-driven waves could splash over the dam.

The University of Kansas (Jude Kastens, Ph.D.) developed an evacuation and inundation zones map based on a failure event of the Tuttle Lake Dam. The inundation models were developed by the Kansas Applied Remote Sensing Program at the University of Kansas. This assessment used a nominal set of starting conditions and indicated that most areas west of Turtle Creek Boulevard (including the NBAF location) would not be inundated with floodwater, as illustrated in Figure 4.6.2-4.

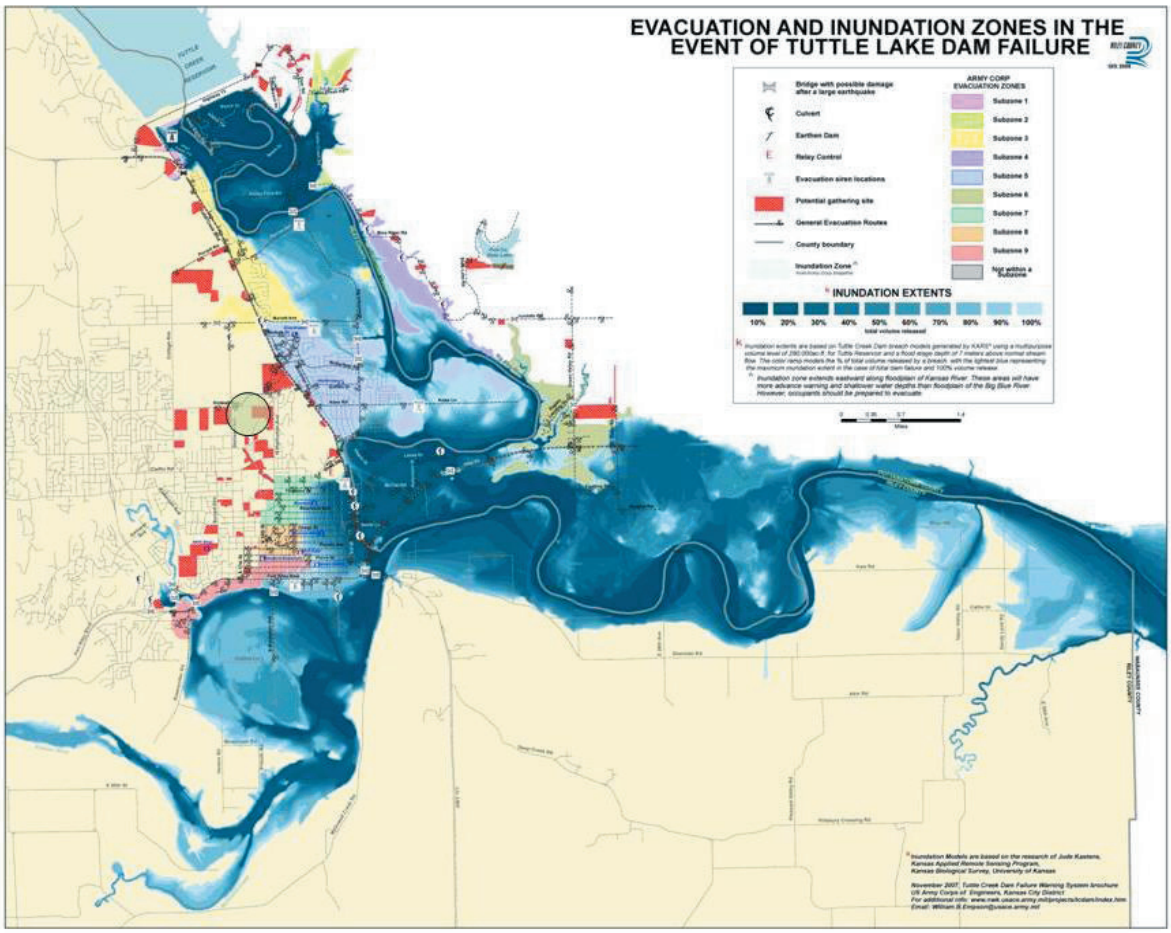


Figure 4.6.2-4: Flood Evacuation and Inundation Zones

Dr. Kastens [personal communication, 14 March 2011] described the modeling as "quasi-dynamic" in that a bolus of floodwater is modeled as it moves downstream and the extents of inundation represent the extents of floodwater intrusion, but not as a function of time. The NBAF site drawings [NDP, 2011] indicate the facility elevation will be in excess of 1,104 feet (msl). Given that the spillway crest is 1,116 (msl), it is improbable that the release of water from the dam during a flood event would cause the site to flood.

Instantaneous complete catastrophic failure of the dam is difficult to characterize as a credible potential event. However, Dr. Mustafa Altinakar (Director at the National Center for Computational Hydroscience and Engineering at the University of Mississippi) has reviewed the topographic and hydrographic data and reached the conclusion that dynamic inundation (waves) from a catastrophic failure of the dam [personal communication, October 2011] is not a plausible outcome.

A 2001 Tuttle Creek Dam Fact Sheet on Earthquake Effects on the Dam [US Army Corps of Engineers, 2001] described two maximum credible earthquake events (MCEs). The first earthquake event was a magnitude 6.6 quake occurring 12 miles from the dam (at the Humboldt Fault) at a depth of 6 miles. USACE concluded that the probability of occurrence (return period) was on the order of 10,000 years for the magnitude 6.6 event. Prior to the completion of some recent dam improvements, this event would have caused some liquefaction and made the dam sink – but not below the level of the water. However, a slow failure could have resulted over time. The second event was a magnitude 5.6 quake occurring almost directly under the dam (less than one mile from the dam at a depth of 6 miles.) This event was not considered to be a threat because the duration (approximately two seconds) is too short to affect the dam [USACE, 2001]. A dam improvement project was completed since the USACE assessment and now it is highly unlikely that the dam is threatened by either MCE. As a result, flooding and inundation are not included in the catastrophic events modeled in the Updated SSRA.

4.6.3 Tornadoes

DHS has incorporated a high level of tornado protection into the current 65% Design of the NBAF. With regard to the containment areas, the objective is to maintain containment during a design-basis tornado event. Specifically, maintaining containment, or "containment integrity," includes preventing cracks exceeding 0.01" in width in the containment structure, preserving the integrity of all containment penetration seals, and protecting HEPA filter caissons from dislocation during the event. The exterior walls of the containment area, laboratory floor, and containment floor (laboratory ceiling) are designed to satisfy these criteria. A projectile barrier system protects the exterior of the tornado protection zone from airborne missiles generated during a tornado event. All openings and penetrations into the containment area are protected with high-pressure-resistant materials. The adjusted design basis tornado, since the SSRA, is now an F3 storm (EF3-EF4), which requires the NBAF to be resistant to maximum wind speeds of 200 mph. A comparison of this baseline event to the Nuclear Regulatory Commission design-basis tornado is presented in Table 4.6.3-1. DHS elected to pursue a design-basis tornado with 200 mph (maximum EF4) wind speed and a 1.3 load factor that brings the effective service load to 228 mph (EF5 storm) – comparable to the requirements that would be generated using the NRC

storm that includes a 230 mph maximum wind speed [NRC (1.76), 2007]. The 65% Design provides detailed modeling data on internal pressures and transient pressures that will develop inside the NBAF containment areas [NDP, 2011]. The NBAF design basis includes a 30" pressure drop tolerance with a 1.6 load factor to surpass the NRC requirements of 33".

Table 4.6.3 1: Comparison of Design Basis Tornado Event

Fujita Scale (F)	Enhanced Fujita Scale (EF)	Maximum Velocity, V_{max} (mph)	Rotational Velocity, V_r (mph)	Translational Velocity, V_t (mph)	Tornado Diameter (m)	Minimum Pressure (inches H_2O)	Max ΔP per second (inches H_2O/s)
3	4	158-206 (F) 166-200 (EF)	195	5	500	-28	1.8
NRC		230 (EF5)	184	46	91	33	14.0

4.6.3.1 Tornado Frequency

For the 2010 SSRA, a tornado frequency analysis was performed to estimate the mean return periods for tornados of a given intensity based on the original Fujita Scale (Table 4.6.3-2) for a 9° by 7° region encompassing the proposed NBAF site (Figure 4.6.3-1). The analysis utilized tornado records from the National Oceanic and Atmospheric Administration (NOAA) Storm Prediction Center (SPC), covering the period from January 1, 1950 to December 31, 2009, that had been adjusted using the spatial bias correction technique of Ray, Bieringer et al. [2003]. Tornado tracks for all of the confirmed tornados from 1950-2010 are shown in Figure 4.6.3-1 for F/EF0-F/EF1 (Black), F/EF2-F/EF3 (Blue), and F/EF4-F/EF5 (Red) intensity tornados. The proposed NBAF location is denoted by the red dot in northeastern Kansas.

Table 4.6.3 2: Fujita Damage Classification Scale (F Scale)

F Scale	Highest 1/4 mile Wind Speed (mph)	Three Second Gust (mph)	Damage Description
F0	40-72	45-78	Minor damage
F1	73-112	79-11	Moderate damage
F2	113-157	118-161	Considerable damage
F3	158-207	162-209	Critical damage
F4	208-260	210-261	Severe damage
F5	261-318	262-317	Devastating damage

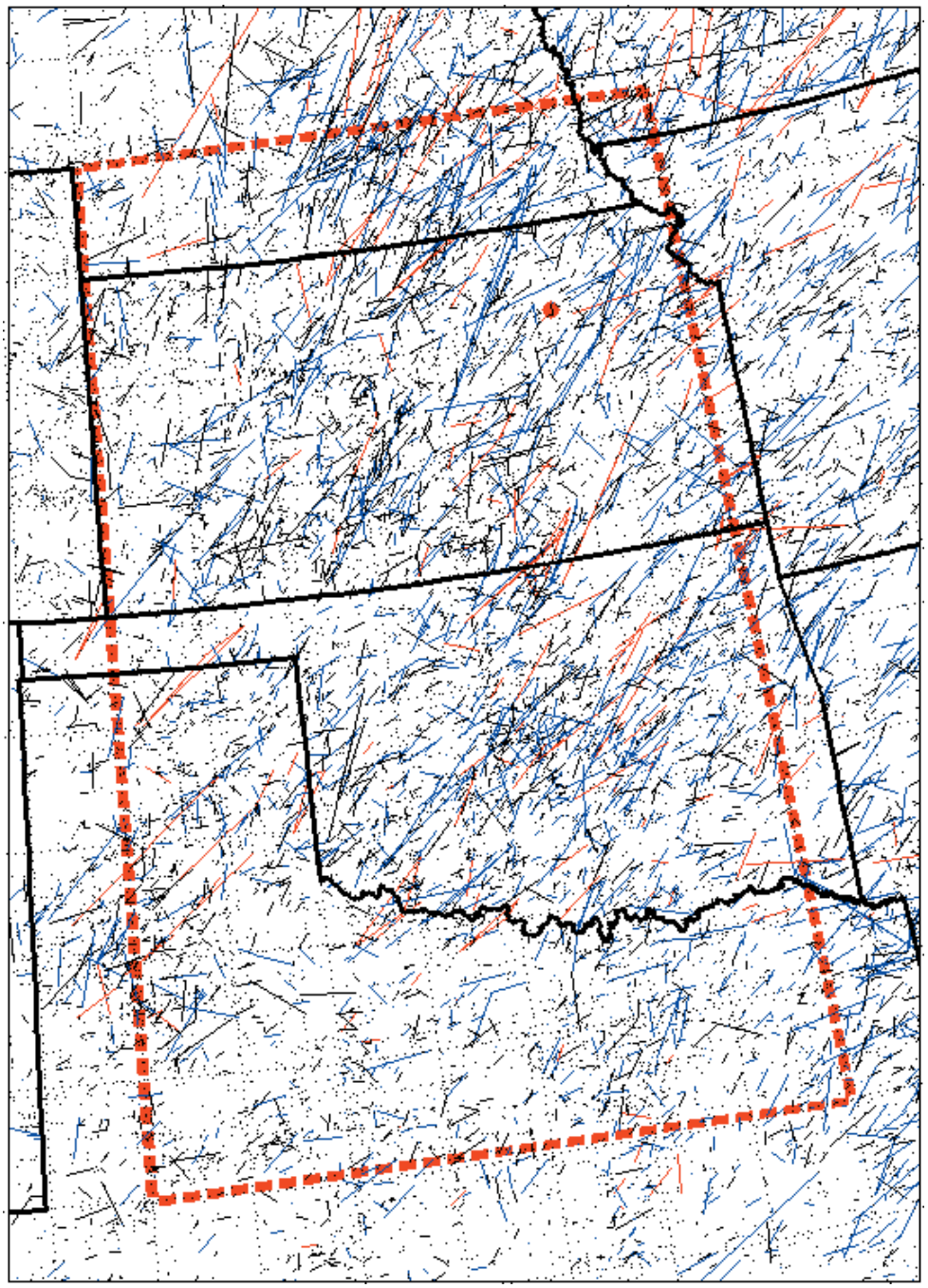


Figure 4.6.3-1: 9° by 7° Region (Red Dashed Box) Used in the 2010 SSRA

For the Updated SSRA, the analysis results have been extended and refined by leveraging methods developed by the Pacific Northwest National Laboratory (PNNL) [Ramsdell, 2007]. These methods include recent tornado events, account for the change from the Fujita (F-Scale) to the Enhanced Fujita Scale (EF-Scale) classification system (Table 4.6.3-3), account for the size of the NBAF facility when determining the probability of a tornado strike, account for the documented variation of wind speeds across a tornado's damage area when determining the probability of exceeding a specified wind speed at the NBAF, use these probabilities to develop continuous probabilities of exceedance curves for a

range of wind speeds, and use these curves to estimate the return period for specific wind speeds. Additional details on the tornado model are presented in Section 5.

Table 4.6.3 3: Enhanced Fujita Damage Classification Scale (EF Scale)

EF Scale	Three Second Gust (mph)	Damage Description
EF0	65-85	Minor damage
EF1	86-110	Moderate damage
EF2	111-135	Considerable damage
EF3	136-165	Critical damage
EF4	166-200	Severe damage
EF5	>200	Devastating damage

A characteristic building dimension of 380′ was used to estimate the probabilities associated with the finite size structure of the NBAF. This dimension was based on the 65% Design, which includes a hardened tornado zone with a rectangular area of approximately 320′ (in the east/west direction) by 380′ (in the north/south direction). The tornado strike probabilities, illustrated in Figure 4.6.3-2, were used in the Updated SSRA to determine the probability of exceedance as a function of threshold wind speed and the associated return periods, as presented in Table 4.6.3-4. However, the modeling methodology starts to break down at wind speeds in excess of 260 mph.

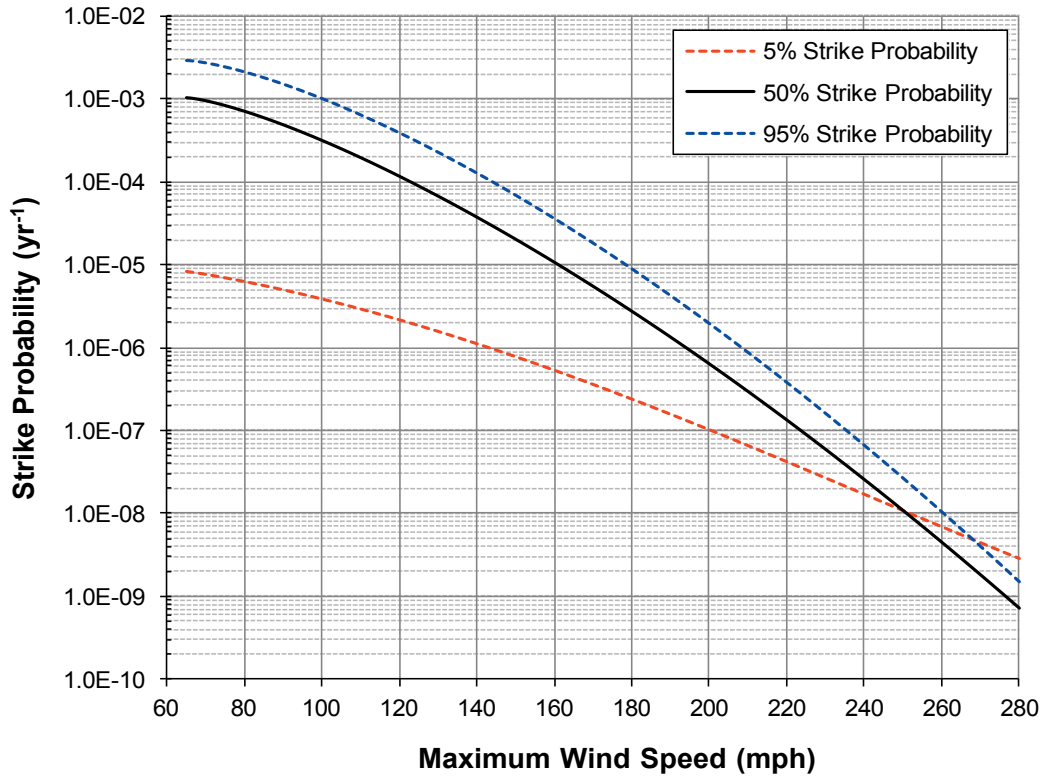


Figure 4.6.3-2. Tornado Strike Probability at NBAF vs. Maximum Wind Speed

Table 4.6.3 4: Probability of Exceedance and Return Period of High Wind Events at NBAF

Wind Speed Threshold (mph)	Probability of Exceedance (yr^{-1})			Return Period (years)		
	5% Limit	Expected Value	95% Limit	5% Limit	Expected Value	95% Limit
228	2.98×10^{-8}	7.06×10^{-8}	1.89×10^{-7}	3.4×10^{7}	1.4×10^{7}	5.3×10^{6}
254	9.20×10^{-9}	7.72×10^{-9}	1.81×10^{-8}	1.1×10^{8}	1.3×10^{8}	5.6×10^{7}

4.6.3.2 Pathogen Contributions to Tornado Events

As long as crack widths are less than 0.01”, the elasticity of the interior coating and sealing systems maintain integrity with such minimal crack sizes. Additionally, the systems that seal all penetrations are designed for this same loading. While significant damage to the outside of the facility should be expected if the laboratory is struck by a design basis tornado (or more intense event), the containment integrity and structural enclosure of the containment areas is designed to not fail. Figure 4.6.3-3 indicates the tornado containment integrity envelope (solid red line) and structural integrity envelope (dashed red line) incorporated in the current design.

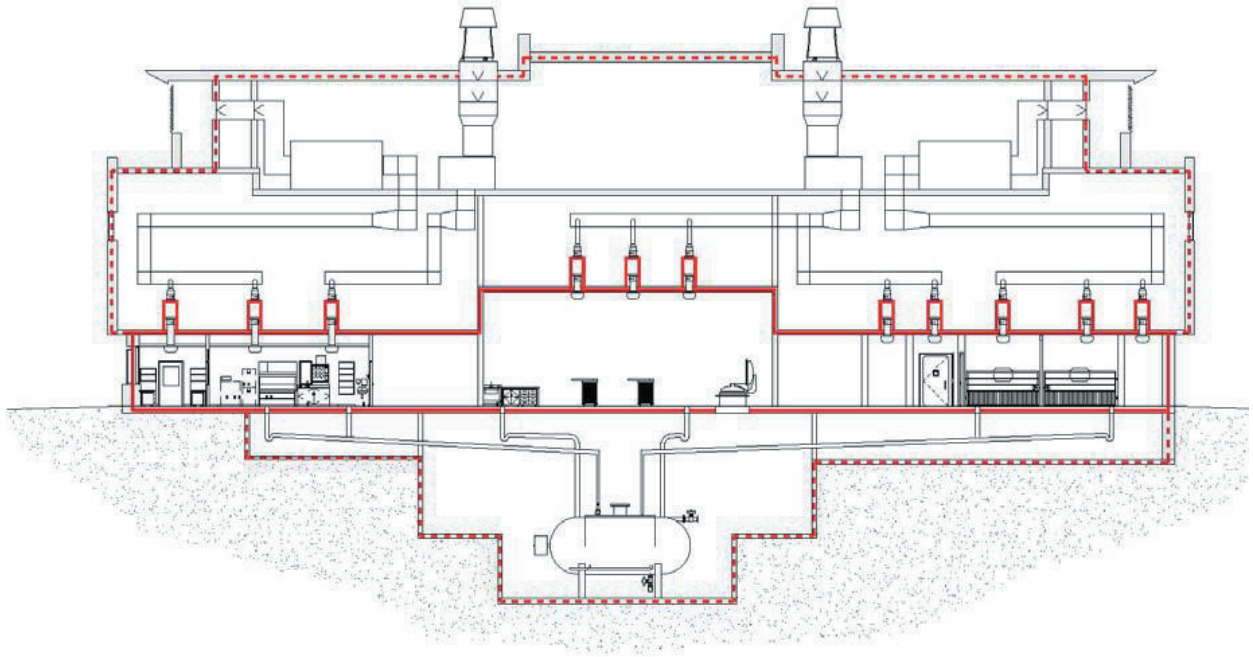


Figure 4.6.3-3: NBAF Containment Integrity Envelope and Structural Integrity Envelope

In the Updated SSRA modeling, if the NBAF is struck by a tornado, the amount of infectious material that may potentially be released, $MAR_{tornado}$, is used to determine the amount of material that is modeled as being released. One hour of the daily aerosolized FMDv released in the BSL-3Ag AHRs is multiplied by the average number of occupied rooms for FMD research (4.75) and the product is used as one of the contributions to the $MAR_{tornado}$. This contribution is used because the model assumes the steady-state aerosol condition will be lost and that the infected animals could continue to breathe for one hour after the tornado strike. Liquid waste is continuously processed during the day in all of the originating locations. Because of the low atmospheric pressure and high wind conditions that would be sustained in the containment areas during the catastrophic failure process, 50% of the daily liquid waste contribution from the AHRs is included in the source term. As the solid waste contributions from the AHRs is derived from transfer of the liquid waste to solid materials (see Section 4.4.1), no solid waste contribution from the AHRs is used for the $MAR_{tornado}$. Infected animal and carcass parts from the BSL-3Ag AHRs are not included in the tornado events as FMDv will be contained within the animals and few, if any, animals are expected to be physically displaced from the NBAF. As there are 338 animals which will be euthanized in the necropsy suite per year, on average over the course of a year, 0.92 animals will be in the necropsy suite per day. The 5th, 50th, and 95th percentiles of the blood FMDv quantities per animal were multiplied by the average number of animals in the necropsy suite per day (weighted across an entire year). No contribution from the necropsy tissue to the $MAR_{tornado}$ was modeled. The contributions to the $MAR_{tornado}$ also include all of the infectious FMDv materials (stocks, etc.) on hand in the BSL-3E and "Special Procedure" laboratories. A summary of the build-up of the total value of $MAR_{tornado}$ is presented in Table 4.6.3-5. The $MAR_{tornado}$ was determined by modeling a distribution from the distributions of

these five contributors (AHR Aerosol, AHR liquid waste, animal blood, animal tissue, and BSL-3E/BSL-3E SP infectious material).

Table 4.6.3 5: Contributions to MAR for Tornado Event

Originating Location	Material Source	Notes	Low (PFU)	Medium (PFU)	High (PFU)
AHR	Aerosol	4.75 rooms occupied per day 1 h of daily aerosol released	4.29×10^{1}	3.78×10^{4}	3.34×10^{7}
AHR	Liquid Waste (urine and feces)	50% of daily waste	5.95×10^{1}	1.64×10^{6}	3.09×10^{8}
Necropsy	Carcasses (blood)	0.92 animals in necropsy/day	2.00×10^{3}	4.02×10^{6}	5.34×10^{9}
BSL-3E/ BSL-3E SP	Stocks, samples, solutions	---	4.28×10^{1}	1.45×10^{6}	4.96×10^{10}
			5th (PFU)	**50th (PFU)**	**95th (PFU)**
		Total $MAR_{tornado}$	**3.13×10^{6}**	**7.15×10^{6}**	**4.96×10^{10}**

If the NBAF is struck by a design-basis storm (or more intense storm) cracking may start to exceed the tolerance of the ductile interior coatings and begin to compromise the containment volume. It is also possible that penetration seals and portals will start to fail as a result of such storms. In order to model the loss of pathogen during the failure of the containment area, it is assumed that no pathogen (in excess of nominal losses) is lost at the maximum end of the design basis wind speed of 228 mph. Likewise, it is assumed that 100% of the $MAR_{tornado}$ will be released if the wind speed reaches 260-280 mph, which is the estimated catastrophic failure wind speed range [NDP, personal communications, December 2011]. Since a detailed catastrophic failure model of the most current NBAF design has not been developed (and is beyond the scope of this effort), the fraction of $MAR_{tornado}$ released from the facility between the design-basis wind (228) and the 260-280 mph wind is modeled as a cumulative distribution function (incorporating the $MAR_{tornado}$ provided in Table 4.6.3-5) as presented in Figure 4.6.3-4.

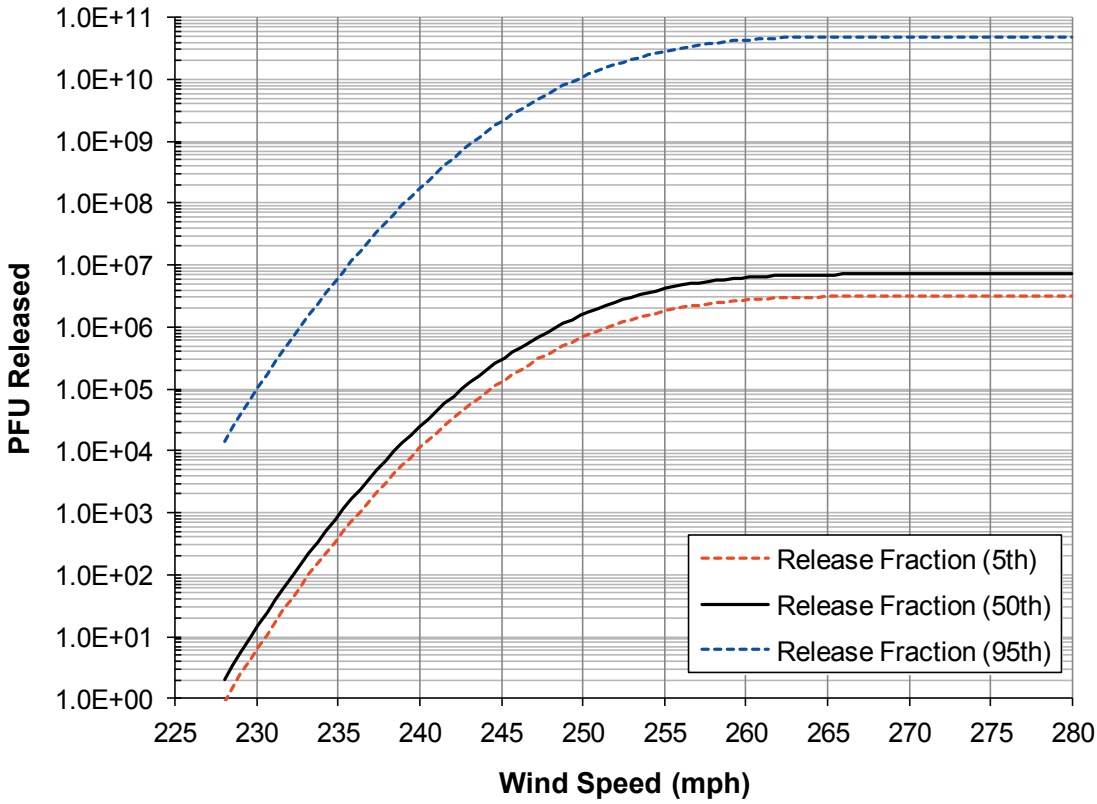


Figure 4.6.3-4: Cumulative Distribution of $MAR_{tornado}$ During Containment Failure

For the Updated SSRA, a single tornado event with a wind speed of at least 228 mph was modeled using the release fraction corresponding to a wind speed of 254 mph, at which speed 50% of material is released. The modeled tornado event is summarized in Table 4.6.3-6.

Table 4.6.3 6: Probability of Exceedance and Return Period of High Wind Events at NBAF

Wind Speed Threshold (mph)	Probability of Exceedance, Expected Value (yr ^{1})	Release Fraction	*Q* Values (PFU)		
			Low	Medium	High
>228	7.06×10^{-8}	5.00×10^{-1}	1.57×10^{6}	3.58×10^{6}	2.48×10^{10}

4.6.4 Earthquakes

An earthquake is the result of a sudden release of energy in the Earth's crust that creates seismic waves and is commonly measured in terms of the Richter magnitude scale. The magnitude of an earthquake is determined from the logarithm of the amplitude. On the Richter scale, magnitude is expressed in whole numbers and decimal fractions. For example, a magnitude 5.3 might be computed for a moderate earthquake, and a strong earthquake might be rated as magnitude 6.3. Because of the logarithmic basis of the scale, each whole number increase in magnitude represents a tenfold increase in measured amplitude. The potential consequences of a significant earthquake at the NBAF result from the

generation of spills, primary container failures, large-scale engineering failures, and emergency facility evacuations. If the NBAF containment areas maintain structural and containment integrity, the opportunity for containment loss is from elevated source terms and associated aerosols inside of containment – challenging the HEPA exhaust filtration. If the NBAF containment areas lose structural and/or containment integrity and/or the HEPA systems become non-functional as the result of an earthquake, the release may include the loss of pathogens in larger aerosolized quantities. From the building and systems perspective, however, the ground motion, usually expressed as accelerations, at the site is more important than the magnitude of the earthquake.

4.6.4.1 Earthquake Frequency

Different metrics are used to characterize earthquakes for building and laboratory design practices. Mapped spectral accelerations for short periods, often 0.1 or 0.2 seconds, (S_s) and 1-second (S_1) are specified for design practices and engineering consideration. The United States Geological Survey (USGS) collects and publishes data on the probability of exceedance of such accelerations for all locations in the United States. Figure 4.6.4-1 shows the spectral accelerations for which there is a 2% probability of exceedance over a 50-year exposure period. For the short spectral accelerations, S_s, the Manhattan, Kansas NBAF location is in an area characterized by 0.12 - 0.16 × g, where g is the acceleration of gravity. Thus, there is a 2% probability that the location will see an event of greater than 0.12 - 0.16 × g with a short spectral acceleration (0.2 seconds) in a 50-year period. From Figure 4.6.4-2, it can be estimated that there is a 2% probability of exceedance over a 50-year exposure period for 1-second accelerations, S_1, at the NBAF location of accelerations of approximately 0.04 – 0.06 × g.

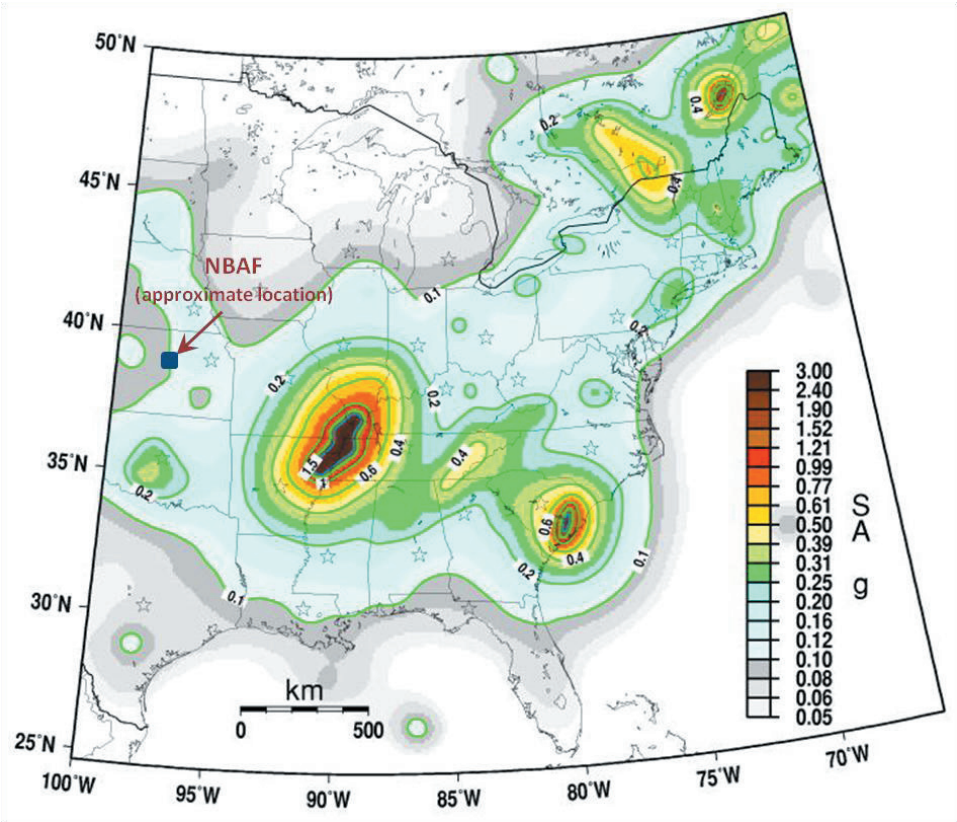


Figure 4.6.4-1: Spectral Accelerations over 0.2 seconds with Probability of 2% Exceedance over 50 Years

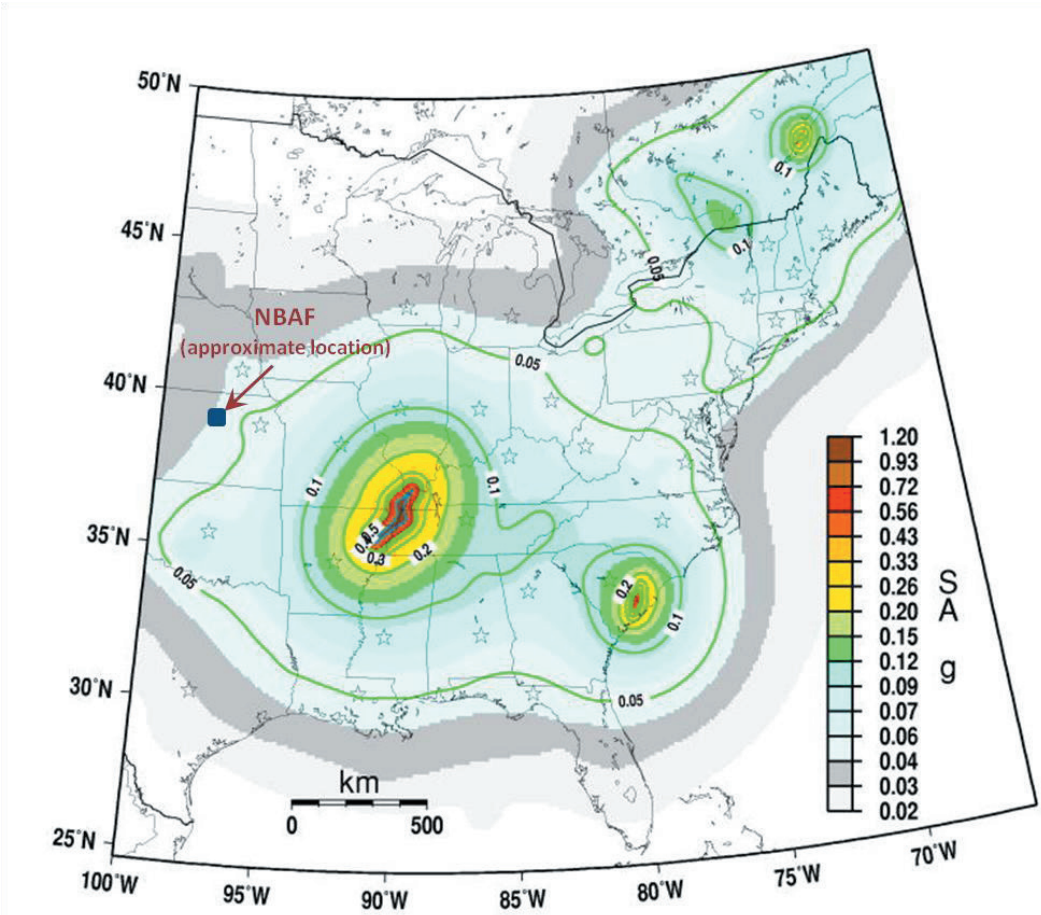


Figure 4.6.4-2: Spectral Accelerations over 1.0 Second with Probability of 2% Exceedance over 50 Years

The USGS "DesignMaps" application (available at https://geohazards.usgs.gov/) provides an on-line tool for calculating the ground motion values for a specific location. The 65% Design also describes the NBAF site classification as "C" which indicates very dense soil and soft rock. The specific values determined for the NBAF (approximate latitude and longitude of 39.202396, -96.581075) using the 2008 USGS Hazard data are:

$$S_S = 0.155\ g \qquad \text{Equation 4.6.4-1}$$

$$S_1 = 0.057\ g \qquad \text{Equation 4.6.4-2}$$

The USGS develops site coefficients for the short period accelerations and the 1-second accelerations that are referred to as F_a and F_v, respectively. These site coefficients incorporate the site soil conditions into the design parameters. The values for these parameters, F_a and F_v, as determined by the DesignMaps application and confirmed by the 65% Design, are 1.2 and 1.7, respectively. The Maximum Considered Earthquake ($S_{M,S}$ and $S_{M,1}$) accelerations are then designated as:

$$S_{M,S} = F_a \times S_S = 1.2 \times 0.155\ g = 0.186\ g \qquad \text{Equation 4.6.4-3}$$

$$S_{M,1} = F_v \times S_a = 1.7 \times 0.057\ g = 0.096\ g$$ Equation 4.6.4-4

The calculated (USGS) design spectral acceleration parameters for the short (0.2 second) and 1 second accelerations, $S_{D,S}$ and $S_{D,1}$, are then given by:

$$S_{D,S} = {}^{2}/_{3} \times S_{M,S} = 0.124\ g$$ Equation 4.6.4-5

$$S_{D,1} = {}^{2}/_{3} \times S_{M,1} = 0.064\ g$$ Equation 4.6.4-6

The 65% Design states that design earthquake load specifications for the NBAF are:

$$S_{S,NBAF} = 0.207\ g$$ Equation 4.6.4-7

$$S_{1,NBAF} = 0.053\ g$$ Equation 4.6.4-8

As $S_{D,1}$ is greater than $S_{1,NBAF}$, the 1-second acceleration from the NBAF design load specification ($S_{1,NBAF}$) will be used to determine the frequency and return period of the earthquake event. The limiting (1-second) acceleration was used to calculate the corresponding frequency of exceedance using the USGS Probabilistic Hazard Curves. These values are plotted in Figure 4.6.4-3 as a function of ground motion at the NBAF location.

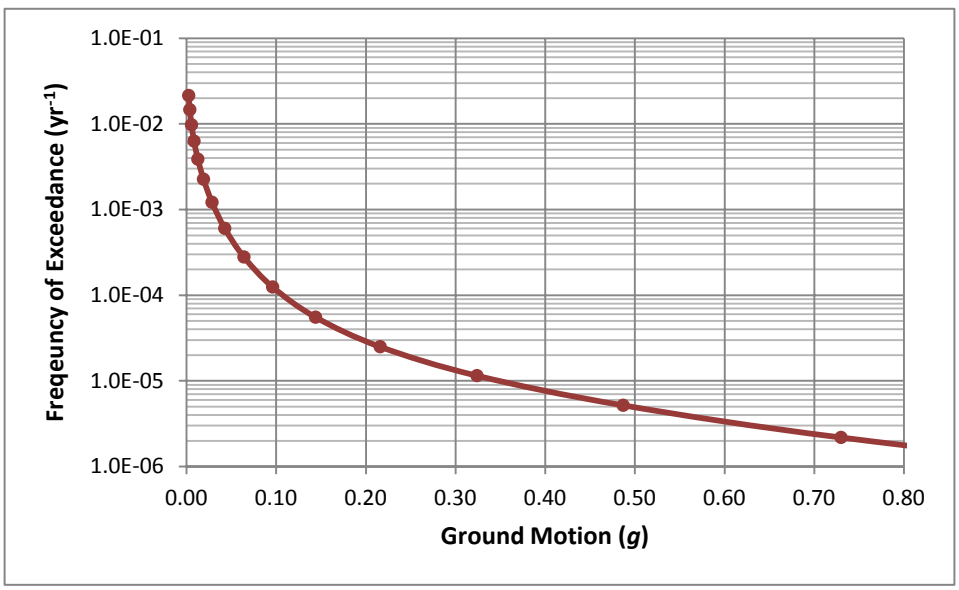


Figure 4.6.4-3: Frequency of Exceedance vs. round Motion at 39° 12' 31.97", -96° 35' 12.90" (Data from USGS Probabilistic Hazard Curves)

The frequency of exceedance over one year (P_{1Y}) for a 1-second ground acceleration of 0.053 *g* is 3.998×10^{-4}. The corresponding frequency of exceedance over the 50-year expected lifetime of the NBAF (P_{50Y}) is calculated using the following formula:

$$P_{1Y} = 3.998 \times 10^{-4}\ \mathrm{yr}^{-1}$$ Equation 4.6.4-9

$$P_{50Y} = 1 - (1 - P_{1Y})^{50} = 1.98 \times 10^{-2}\ \mathrm{yr}^{-1}$$ Equation 4.6.4-10

For the purposes of modeling, the 1 year frequency of exceedance of 3.998×10^{-4} yr^{-1} is used.

It is important to note that the NBAF 65% Design incorporates significant structural design modifications intended to "harden" the containment areas against containment failure and catastrophic failure from a tornado strike or high-wind event. These hardening measures will also have an effect on the ability of the facility to withstand the earthquake acceleration design specifications but the enhanced earthquake protection has not been fully modeled. Structural engineers with the NBAF Design Partnership have estimated that the containment integrity envelope, specified for the tornado hardening, will withstand structural forces that are twice the forces that would be developed for the design-basis earthquake accelerations. However, converting the additional strength provided by the tornado hardening into an additional ground accelerations tolerance will require detailed modeling and validation. Where possible, consideration of the additional strength will be incorporated in the modeling assumptions.

The National Earthquake Hazards Reduction Program (NEHRP) uses a factor that is called the Seismic Occupancy Importance Factor, or I. For the NBAF design, I as been set to 1.5 – the highest value [NDP, 2011]. The higher value of this factor has influenced the ductility demands incorporated during NBAF design and will also result in less damage to the facility from an earthquake that produces the design basis accelerations. When combined with more stringent drift limits (e.g., lateral deflections), the result is improved earthquake performance for the facility [American Society of Civil Engineers 7-10, 2010].

If there is an earthquake that causes anomalous internal events at the NBAF (such as toppled flasks, spills, breakages, etc.) while the HEPA filtration systems remains functional, the potential for an airborne containment loss is mitigated by the pathogen reduction provided by the HEPA filtration. Source terms for the earthquake include aerosol and liquid contributions from the containment areas. The event would likely cause numerous simultaneous "spills" in the BSL-3E/BSL-3E SP laboratories but the aerosolized fraction of spilled quantities, assuming the air handling systems, HEPA filtration, and containment penetrations remain intact, would be accommodated by the BSCs and room exhaust filtration systems. In addition, most of the infectious *in vitro* materials in these areas are not being handled at any given time. Scientific users report that 99% of the infectious materials are stored in freezers, refrigerators, incubators, etc. or would not be handled or manipulated during operating hours [DHS, 2010]. The *in vivo* materials will not be "spilled" by an event but the static, or steady-state, aerosol load in the AHRs could be released and the animals enclosed in damaged rooms may continue to breathe for an hour before being relocated or euthanized. Since the earthquake is self-announcing, special NBAF response protocols and procedures (to be developed) would be used to mitigate potential losses from solid waste and liquid waste streams. Additional measures that will mitigate the potential of enhanced transference are also likely to be applied. Thus, the uncontrolled potential aerosol losses (including the AHRs and a fraction of the liquid and solid waste) are considered as the modeling source term.

If the earthquake causes damage to HEPA systems (and infectious aerosols were generated in the containment areas, as described above), the potential quantities of released pathogen would increase (because of the lack of HEPA filtration). However, if power is lost, the normally-closed bioseal dampers should isolate the containment spaces. In addition, if there is no power for the HVAC systems, the loss of airborne infectious material would only be from leakage and not from unfiltered containment exhaust being ejected from the ventilation stacks.

Table 4.6.4 1: Contributions to MAR for Earthquake Event

Originating Location	Material Source	Notes	Low (PFU)	Medium (PFU)	High (PFU)
AHR	Aerosol	4.75 rooms occupied per day times; 1 hour of daily release	4.29×10^{1}	3.78×10^{4}	3.34×10^{7}
AHR	Liquid Waste (urine and feces)	1×10^{-4} (aerosolized release fraction)	5.95×10^{-3}	1.64×10^{2}	3.09×10^{4}
Necropsy	Carcasses (blood)	0.92 animals in necropsy per day; 1×10^{-4} (aerosolized release fraction)	2.00×10^{-1}	4.02×10^{2}	5.34×10^{5}
BSL-3E/SP	Stocks, samples, solutions	1%	4.28×10^{-1}	1.45×10^{4}	4.96×10^{8}
			5th (PFU)	50th (PFU)	95th (PFU)
		Total $MAR_{Earthquake}$	1.51×10^{4}	5.29×10^{4}	4.96×10^{8}

For the purposes of the modeling, the contributions to the earthquake MAR include only 1 hour of daily aerosol release in the occupied AHRs, the aerosolized release fraction of the liquid waste produced per day in the AHRs, the aerosolized release fraction of the average number of animals being processed in the necropsy suite per day, and 1% of the stocks, samples, and solutions in the BSL-3E and BSL-3E "Special Procedure" laboratories. These contributions and the total earthquake MAR are presented in Table 4.6.4-1. As a very conservative estimate, no reduction factor was applied to these MAR values (i.e., the *Q* values are equivalent to the MAR) for the earthquake event.

4.7 Events Summary

The 142 events (140 accidental and two catastrophic) used in the modeling for the Updated SSRA are summarized in the following tables and figures. A description of the originating locations is provided in Section 4.1. The pathways and conceptual models, including the development of mitigation factors and terms is presented in Section 4.2. The infectious materials that are potential involved in events are described in Section 4.4. Section 4.5 presents background information on the development of accident event frequencies. Catastrophic events are described in Section 4.6.

The complete summary of events including the event description, MAR, reduction factor and *Q* values (reduced MAR), event probabilities, opportunity rates (per year), and event frequencies (per year) are listed in the summary table, Table 4.7-1.

Table 4.7-1: Master Summary of Loss-of-Containment Events including Descriptions, MAR, Reduction Factors, Q Terms, Probabilities, Opportunity Rate, and Frequencies

Event ID	Originating Location	Pathway	Description	MAR (PFU)			Reduction Factor	*Q* Values (PFU)			Probability (P_{Loss})	Opportunity Rate (yr^{-1}) (R_o)	Frequency (yr^{-1}) (F_{Loss})
				Low	Medium	High		Low	Medium	High			
AA1	BSL-3Ag AHR	Aerosol	All 4 filters are normal	4.56E+01	4.01E+04	3.55E+07	1.00E-10	4.56E-09	4.01E-06	3.55E-03	9.4095E-01	1,735	1.63E+03
AA2	BSL-3Ag AHR	Aerosol	Three filters are normal, 1 filter is degraded	4.56E+01	4.01E+04	3.55E+07	1.35E-09	6.16E-08	5.41E-05	4.79E-02	5.7323E-02	1,735	9.95E+01
AA3	BSL-3Ag AHR	Aerosol	Both filters in one column are normal while both filters in the other column are degraded	4.56E+01	4.01E+04	3.55E+07	3.39E-08	1.54E-06	1.36E-03	1.20E+00	4.3651E-04	1,735	7.57E-01
AA4	BSL-3Ag AHR	Aerosol	One filter in each column is normal, one filter in each column is degraded	4.56E+01	4.01E+04	3.55E+07	2.60E-09	1.18E-07	1.04E-04	9.22E-02	8.7303E-04	1,735	1.51E+00
AA5	BSL-3Ag AHR	Aerosol	Three filters are degraded, 1 filter is normal	4.56E+01	4.01E+04	3.55E+07	3.51E-08	1.60E-06	1.41E-03	1.25E+00	1.3296E-05	1,735	2.31E-02
AA6	BSL-3Ag AHR	Aerosol	All 4 filters are degraded	4.56E+01	4.01E+04	3.55E+07	6.76E-08	3.08E-06	2.71E-03	2.40E+00	5.0625E-08	1,735	8.78E-05
AA7	BSL-3Ag AHR	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are normal	4.56E+01	4.01E+04	3.55E+07	1.00E-10	4.56E-09	4.01E-06	3.55E-03	3.8799E-04	1,735	6.73E-01
AA8	BSL-3Ag AHR	Aerosol	One column fails (but at least one alarm works) while in the other column one filter is normal and one filter is degraded	4.56E+01	4.01E+04	3.55E+07	2.60E-09	1.18E-07	1.04E-04	9.22E-02	1.1818E-05	1,735	2.05E-02
AA9	BSL-3Ag AHR	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are degraded	4.56E+01	4.01E+04	3.55E+07	6.76E-08	3.08E-06	2.71E-03	2.40E+00	8.9995E-08	1,735	1.56E-04
AA10	BSL-3Ag AHR	Aerosol	Total HEPA failure	4.56E+01	4.01E+04	3.55E+07	1.00E+00	4.56E+01	4.01E+04	3.55E+07	1.0000E-34	1,735	1.74E-31
AA11	BSL-3Ag AHR	Aerosol	Both columns fail (but at least one alarm works on each column). HEPA is closed off	4.56E+01	4.01E+04	3.55E+07	0.00E+00	0.00E+00	0.00E+00	0.00E+00	3.9996E-08	1,735	6.94E-05
AS1	BSL-3Ag AHR	Solid Waste	Solid waste bulk batch processed normally	2.38E+01	6.56E+05	1.24E+08	1.00E-21	2.38E-20	6.56E-16	1.24E-13	9.9998E-01	113.5	1.13E+02
AS2	BSL-3Ag AHR	Solid Waste	Single autoclave failure	2.38E+01	6.56E+05	1.24E+08	1.00E-15	2.38E-14	6.56E-10	1.24E-07	2.0000E-05	113.5	2.27E-03
AS3	BSL-3Ag AHR	Solid Waste	Incinerator failure	2.38E+01	6.56E+05	1.24E+08	1.00E-12	2.38E-11	6.56E-07	1.24E-04	9.9998E-11	113.5	1.13E-08
AS4	BSL-3Ag AHR	Solid Waste	Both autoclaves fail	2.38E+01	6.56E+05	1.24E+08	1.00E-09	2.38E-08	6.56E-04	1.24E-01	1.0000E-10	113.5	1.13E-08
AS5	BSL-3Ag AHR	Solid Waste	Single autoclave failure and incinerator failure	2.38E+01	6.56E+05	1.24E+08	1.00E-06	2.38E-05	6.56E-01	1.24E+02	2.0000E-15	113.5	2.27E-13
AS6	BSL-3Ag AHR	Solid Waste	Failure of all systems	2.38E+01	6.56E+05	1.24E+08	1.00E+00	2.38E+01	6.56E+05	1.24E+08	1.0000E-20	113.5	1.13E-18
AL1	BSL-3Ag AHR	Liquid Waste	Nominal Liquid Waste Disposal	1.19E+02	3.28E+06	6.18E+08	1.00E-08	1.19E-06	3.28E-02	6.18E+00	9.5110E-01	113.5	1.08E+02
AL2	BSL-3Ag AHR	Liquid Waste	Decon works, cook tank works, and wastewater fails	1.19E+02	3.28E+06	6.18E+08	1.00E-07	1.19E-05	3.28E-01	6.18E+01	9.5111E-06	113.5	1.08E-03
AL3	BSL-3Ag AHR	Liquid Waste	Decon works cook tank fails and performance indicator fails, and wastewater works	1.19E+02	3.28E+06	6.18E+08	1.00E-02	1.19E+00	3.28E+04	6.18E+06	9.5110E-11	113.5	1.08E-08
AL4	BSL-3Ag AHR	Liquid Waste	Decon works, cook tank fails and performance indicator fails, and wastewater fails	1.19E+02	3.28E+06	6.18E+08	1.00E-01	1.19E+01	3.28E+05	6.18E+07	9.5111E-16	113.5	1.08E-13
AL5	BSL-3Ag AHR	Liquid Waste	Decon fails, cook tank works, and wastewater works	1.19E+02	3.28E+06	6.18E+08	1.92E-08	2.29E-06	6.30E-02	1.19E+01	4.8889E-02	113.5	5.55E+00
AL6	BSL-3Ag AHR	Liquid Waste	Decon fails, cook tank works, and wastewater fails	1.19E+02	3.28E+06	6.18E+08	1.92E-07	2.29E-05	6.30E-01	1.19E+02	4.8890E-07	113.5	5.55E-05
AL7	BSL-3Ag AHR	Liquid Waste	Decon fails cook tank fails and performance indicator fails, and wastewater works	1.19E+02	3.28E+06	6.18E+08	1.92E-02	2.29E+00	6.30E+04	1.19E+07	4.8889E-12	113.5	5.55E-10
AL8	BSL-3Ag AHR	Liquid Waste	Decon fails, cook tank fails and performance indicator fails, and wastewater fails	1.19E+02	3.28E+06	6.18E+08	1.92E-01	2.29E+01	6.30E+05	1.19E+08	4.8890E-17	113.5	5.55E-15
ATR1	BSL-3Ag AHR	Transference (Respiratory)	Transference to nasal passages. N95 mask is used properly and nose blow.	4.56E+01	4.01E+04	3.55E+07	8.95E-05	4.08E-03	3.59E+00	3.18E+03	9.7013E-01	567.5	5.51E+02
ATR2	BSL-3Ag AHR	Transference (Respiratory)	Transference to nasal passages. N95 mask is not used properly and nose blow.	4.56E+01	4.01E+04	3.55E+07	1.79E-02	8.16E-01	7.18E+02	6.35E+05	2.4875E-02	567.5	1.41E+01
ATR3	BSL-3Ag AHR	Transference (Respiratory)	Transference to nasal passages. N95 mask is used properly and no nose blow.	4.56E+01	4.01E+04	3.55E+07	2.85E-04	1.30E-02	1.14E+01	1.01E+04	4.8750E-03	567.5	2.77E+00
ATR4	BSL-3Ag AHR	Transference (Respiratory)	Transference to nasal passages. N95 mask is not used properly and no nose blow.	4.56E+01	4.01E+04	3.55E+07	5.70E-02	2.60E+00	2.29E+03	2.02E+06	1.2500E-04	567.5	7.09E-02
ATF1	BSL-3Ag AHR	Transference (Fomite)	Transference to fomite and 2 disinfections (dunks or wipedowns)	6.68E-03	3.50E+03	3.65E+05	2.22E-12	1.48E-14	7.78E-09	8.12E-07	9.9003E-01	567.5	5.62E+02
ATF2	BSL-3Ag AHR	Transference (Fomite)	Transference to fomite and 1 disinfection (dunk or wipedown)	6.68E-03	3.50E+03	3.65E+05	2.22E-07	1.48E-09	7.78E-04	8.12E-02	9.9500E-03	567.5	5.65E+00
ATF3	BSL-3Ag AHR	Transference (Fomite)	Transference to fomite and 0 disinfections (dunks or wipedowns)	6.68E-03	3.50E+03	3.65E+05	2.22E-02	1.48E-04	7.78E+01	8.12E+03	2.5000E-05	567.5	1.42E-02
NA1	BSL-3Ag Necropsy	Aerosol	All 4 filters are normal	6.65E+00	1.74E+03	1.39E+07	1.00E-10	6.65E-10	1.74E-07	1.39E-03	9.4095E-01	42.3	3.98E+01
NA2	BSL-3Ag Necropsy	Aerosol	Three filters are normal, 1 filter is degraded	6.65E+00	1.74E+03	1.39E+07	1.35E-09	8.98E-09	2.35E-06	1.87E-02	5.7323E-02	42.3	2.42E+00
NA3	BSL-3Ag Necropsy	Aerosol	Both filters in one column are normal while both filters in the other column are degraded	6.65E+00	1.74E+03	1.39E+07	3.39E-08	2.25E-07	5.90E-05	4.70E-01	4.3651E-04	42.3	1.84E-02

Table 4.7-1: Master Summary of Loss-of-Containment Events including Descriptions, MAR, Reduction Factors, Q Terms, Probabilities, Opportunity Rate, and Frequencies

Event ID	Originating Location	Pathway	Description	MAR (PFU)			Reduction Factor	*Q* Values (PFU)			Probability (P_{Loss})	Opportunity Rate (yr^{-1}) (R_o)	Frequency (yr^{-1}) (F_{Loss})
				Low	Medium	High		Low	Medium	High			
NA4	BSL-3Ag Necropsy	Aerosol	One filter in each column is normal, one filter in each column is degraded	6.65E+00	1.74E+03	1.39E+07	2.60E-09	1.73E-08	4.53E-06	3.60E-02	8.7303E-04	42.3	3.69E-02
NA5	BSL-3Ag Necropsy	Aerosol	Three filters are degraded, 1 filter is normal	6.65E+00	1.74E+03	1.39E+07	3.51E-08	2.33E-07	6.12E-05	4.87E-01	1.3296E-05	42.3	5.62E-04
NA6	BSL-3Ag Necropsy	Aerosol	All 4 filters are degraded	6.65E+00	1.74E+03	1.39E+07	6.76E-08	4.50E-07	1.18E-04	9.38E-01	5.0625E-08	42.3	2.14E-06
NA7	BSL-3Ag Necropsy	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are normal	6.65E+00	1.74E+03	1.39E+07	1.00E-10	6.65E-10	1.74E-07	1.39E-03	3.8799E-04	42.3	1.64E-02
NA8	BSL-3Ag Necropsy	Aerosol	One column fails (but at least one alarm works) while in the other column one filter is normal and one filter is degraded	6.65E+00	1.74E+03	1.39E+07	2.60E-09	1.73E-08	4.53E-06	3.60E-02	1.1818E-05	42.3	4.99E-04
NA9	BSL-3Ag Necropsy	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are degraded	6.65E+00	1.74E+03	1.39E+07	6.76E-08	4.50E-07	1.18E-04	9.38E-01	8.9995E-08	42.3	3.80E-06
NA10	BSL-3Ag Necropsy	Aerosol	Total HEPA failure	6.65E+00	1.74E+03	1.39E+07	1.00E+00	6.65E+00	1.74E+03	1.39E+07	1.0000E-34	42.3	4.23E-33
NA11	BSL-3Ag Necropsy	Aerosol	Both columns fail (but at least one alarm works on each column). HEPA is closed off	6.65E+00	1.74E+03	1.39E+07	0.00E+00	0.00E+00	0.00E+00	0.00E+00	3.9996E-08	42.3	1.69E-06
NSW1	BSL-3Ag Necropsy	Solid Waste	Solid waste bulk batch processed normally	1.73E+03	3.59E+06	2.82E+11	1.00E-21	1.73E-18	3.59E-15	2.82E-10	9.9998E-01	42.3	4.22E+01
NSW2	BSL-3Ag Necropsy	Solid Waste	Single autoclave failure	1.73E+03	3.59E+06	2.82E+11	1.00E-15	1.73E-12	3.59E-09	2.82E-04	2.0000E-05	42.3	8.45E-04
NSW3	BSL-3Ag Necropsy	Solid Waste	Incinerator failure	1.73E+03	3.59E+06	2.82E+11	1.00E-12	1.73E-09	3.59E-06	2.82E-01	9.9998E-11	42.3	4.22E-09
NSW4	BSL-3Ag Necropsy	Solid Waste	Both autoclaves fail	1.73E+03	3.59E+06	2.82E+11	1.00E-09	1.73E-06	3.59E-03	2.82E+02	1.0000E-10	42.3	4.22E-09
NSW5	BSL-3Ag Necropsy	Solid Waste	Single autoclave failure and incinerator failure	1.73E+03	3.59E+06	2.82E+11	1.00E-06	1.73E-03	3.59E+00	2.82E+05	2.0000E-15	42.3	8.45E-14
NSW6	BSL-3Ag Necropsy	Solid Waste	Failure of all systems	1.73E+03	3.59E+06	2.82E+11	1.00E+00	1.73E+03	3.59E+06	2.82E+11	1.0000E-20	42.3	4.23E-19
NST1	BSL-3Ag Necropsy	Solid Waste (Carcasses/Tissue)	Nominal (Tissue Autoclave or performance indicator, and incinerator working)	6.91E+03	1.44E+07	1.13E+12	1.00E-15	6.91E-12	1.44E-08	1.13E-03	1.0000E+00	42.3	4.22E+01
NST2	BSL-3Ag Necropsy	Solid Waste (Carcasses/Tissue)	Tissue autoclave or performance indicator works, incinerator fails	6.91E+03	1.44E+07	1.13E+12	1.00E-06	6.91E-03	1.44E+01	1.13E+06	1.0000E-10	42.3	4.22E-09
NST3	BSL-3Ag Necropsy	Solid Waste (Carcasses/Tissue)	Tissue Autoclave Fails and performance indicator fails, incinerator works	6.91E+03	1.44E+07	1.13E+12	1.00E-09	6.91E-06	1.44E-02	1.13E+03	1.0000E-10	42.3	4.22E-09
NST4	BSL-3Ag Necropsy	Solid Waste (Carcasses/Tissue)	Tissue Autoclave fails and performance indicator fails, incinerator fails	6.91E+03	1.44E+07	1.13E+12	1.00E+00	6.91E+03	1.44E+07	1.13E+12	1.0000E-20	42.3	4.23E-19
NL1	BSL-3Ag Necropsy	Liquid Waste	Nominal case	1.00E+06	1.84E+07	2.31E+10	1.00E-10	1.00E-04	1.84E-03	2.31E+00	9.9002E-01	42.3	4.18E+01
NL2	BSL-3Ag Necropsy	Liquid Waste	Decon works, cook tank works, and wastewater fails	1.00E+06	1.84E+07	2.31E+10	1.00E-09	1.00E-03	1.84E-02	2.31E+01	9.9002E-06	42.3	4.18E-04
NL3	BSL-3Ag Necropsy	Liquid Waste	Decon works cook tank fails and performance indicator fails, and wastewater works	1.00E+06	1.84E+07	2.31E+10	1.00E-04	1.00E+02	1.84E+03	2.31E+06	9.9002E-11	42.3	4.18E-09
NL4	BSL-3Ag Necropsy	Liquid Waste	Decon works, cook tank fails and performance indicator fails, and wastewater fails	1.00E+06	1.84E+07	2.31E+10	1.00E-03	1.00E+03	1.84E+04	2.31E+07	9.9003E-16	42.3	4.18E-14
NL5	BSL-3Ag Necropsy	Liquid Waste	Decon fails, cook tank works, and wastewater works	1.00E+06	1.84E+07	2.31E+10	5.02E-08	5.03E-02	9.21E-01	1.16E+03	9.9749E-03	42.3	4.21E-01
NL6	BSL-3Ag Necropsy	Liquid Waste	Decon fails, cook tank works, and wastewater fails	1.00E+06	1.84E+07	2.31E+10	5.02E-07	5.03E-01	9.21E+00	1.16E+04	9.9750E-08	42.3	4.21E-06
NL7	BSL-3Ag Necropsy	Liquid Waste	Decon fails cook tank fails and performance indicator fails, and wastewater works	1.00E+06	1.84E+07	2.31E+10	5.02E-02	5.03E+04	9.21E+05	1.16E+09	9.9749E-13	42.3	4.21E-11
NL8	BSL-3Ag Necropsy	Liquid Waste	Decon fails, cook tank fails and performance indicator fails, and wastewater fails	1.00E+06	1.84E+07	2.31E+10	5.02E-01	5.03E+05	9.21E+06	1.16E+10	9.9750E-18	42.3	4.21E-16
NTH1	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves work and 2 body showers.	8.61E+00	4.58E+04	1.41E+08	1.98E-08	1.71E-07	9.06E-04	2.79E+00	9.1409E-01	169.0	1.54E+02
NTH2	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves fail and 2 body showers	8.61E+00	4.58E+04	1.41E+08	1.33E-05	1.14E-04	6.07E-01	1.87E+03	7.5935E-02	169.0	1.28E+01
NTH3	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves work and 1 body shower.	8.61E+00	4.58E+04	1.41E+08	1.96E-07	1.69E-06	8.97E-03	2.76E+01	9.1868E-03	169.0	1.55E+00
NTH4	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves fail and 1 body shower.	8.61E+00	4.58E+04	1.41E+08	1.31E-04	1.13E-03	6.01E+00	1.85E+04	7.6317E-04	169.0	1.29E-01
NTH5	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves work and 0 body showers.	8.61E+00	4.58E+04	1.41E+08	1.94E-06	1.67E-05	8.89E-02	2.74E+02	2.3083E-05	169.0	3.90E-03
NTH6	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Gloves fail and 0 body showers.	8.61E+00	4.58E+04	1.41E+08	1.30E-03	1.12E-02	5.95E+01	1.83E+05	1.9175E-06	169.0	3.24E-04
NTH7	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 2 body showers.	8.61E+00	4.58E+04	1.41E+08	7.93E-09	6.82E-08	3.63E-04	1.12E+00	4.9254E-03	169.0	8.32E-01
NTH8	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 1 body showers.	8.61E+00	4.58E+04	1.41E+08	7.85E-08	6.76E-07	3.59E-03	1.11E+01	4.9501E-05	169.0	8.37E-03
NTH9	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 0 body showers.	8.61E+00	4.58E+04	1.41E+08	7.77E-07	6.69E-06	3.55E-02	1.09E+02	1.2438E-07	169.0	2.10E-05
NTH10	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 2 body showers.	8.61E+00	4.58E+04	1.41E+08	7.93E-04	6.82E-03	3.63E+01	1.12E+05	2.4751E-05	169.0	4.18E-03

Table 4.7-1: Master Summary of Loss-of-Containment Events including Descriptions, MAR, Reduction Factors, Q Terms, Probabilities, Opportunity Rate, and Frequencies

Event ID	Originating Location	Pathway	Description	MAR (PFU)			Reduction Factor	*Q* Values (PFU)			Probability (P_{Loss})	Opportunity Rate (yr^{-1}) (R_o)	Frequency (yr^{-1}) (F_{Loss})
				Low	Medium	High		Low	Medium	High			
NTH11	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 1 body showers.	8.61E+00	4.58E+04	1.41E+08	7.85E-03	6.76E-02	3.59E+02	1.11E+06	2.4875E-07	169.0	4.20E-05
NTH12	BSL-3Ag Necropsy	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 0 body showers.	8.61E+00	4.58E+04	1.41E+08	7.77E-02	6.69E-01	3.55E+03	1.09E+07	6.2500E-10	169.0	1.06E-07
NTB1	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit works and 2 body showers.	8.61E+00	4.58E+04	1.41E+08	3.63E-07	3.12E-06	1.66E-02	5.11E+01	9.8012E-01	169.0	1.66E+02
NTB2	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit fail and 2 body showers	8.61E+00	4.58E+04	1.41E+08	2.72E-04	2.34E-03	1.24E+01	3.83E+04	9.9003E-03	169.0	1.67E+00
NTB3	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit works and 1 body shower.	8.61E+00	4.58E+04	1.41E+08	3.59E-06	3.09E-05	1.64E-01	5.06E+02	9.8505E-03	169.0	1.66E+00
NTB4	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit fail and 1 body shower.	8.61E+00	4.58E+04	1.41E+08	2.69E-03	2.32E-02	1.23E+02	3.80E+05	9.9500E-05	169.0	1.68E-02
NTB5	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit works and 0 body showers.	8.61E+00	4.58E+04	1.41E+08	3.56E-05	3.06E-04	1.63E+00	5.01E+03	2.4750E-05	169.0	4.18E-03
NTB6	BSL-3Ag Necropsy	Transference (Body)	Transference to body. Tyvek® suit fails and 0 body showers.	8.61E+00	4.58E+04	1.41E+08	2.67E-02	2.30E-01	1.22E+03	3.76E+06	2.5000E-07	169.0	4.23E-05
EA0	BSL-3E and SP	Aerosol	Nominal BSL-3E	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.9800E-01	52,500	5.24E+04
EA1	BSL-3E and SP	Aerosol	All 4 filters are normal and spill	1.02E+00	3.46E+04	1.18E+09	1.00E-14	1.02E-14	3.46E-10	1.18E-05	1.8819E-03	52,500	9.88E+01
EA2	BSL-3E and SP	Aerosol	Three filters are normal, 1 filter is degraded	1.02E+00	3.46E+04	1.18E+09	1.35E-13	1.38E-13	4.67E-09	1.59E-04	1.1465E-04	52,500	6.02E+00
EA3	BSL-3E and SP	Aerosol	Both filters in one column are normal while both filters in the other column are degraded	1.02E+00	3.46E+04	1.18E+09	3.39E-12	3.45E-12	1.17E-07	3.99E-03	8.7303E-07	52,500	4.58E-02
EA4	BSL-3E and SP	Aerosol	One filter in each column is normal, one filter in each column is degraded	1.02E+00	3.46E+04	1.18E+09	2.60E-13	2.65E-13	8.99E-09	3.07E-04	1.7461E-06	52,500	9.17E-02
EA5	BSL-3E and SP	Aerosol	Three filters are degraded, 1 filter is normal	1.02E+00	3.46E+04	1.18E+09	3.51E-12	3.58E-12	1.21E-07	4.14E-03	2.6592E-08	52,500	1.40E-03
EA6	BSL-3E and SP	Aerosol	All 4 filters are degraded	1.02E+00	3.46E+04	1.18E+09	6.76E-12	6.90E-12	2.34E-07	7.98E-03	1.0125E-10	52,500	5.32E-06
EA7	BSL-3E and SP	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are normal	1.02E+00	3.46E+04	1.18E+09	1.00E-14	1.02E-14	3.46E-10	1.18E-05	7.7598E-07	52,500	4.07E-02
EA8	BSL-3E and SP	Aerosol	One column fails (but at least one alarm works) while in the other column one filter is normal and one filter is degraded	1.02E+00	3.46E+04	1.18E+09	2.60E-13	2.65E-13	8.99E-09	3.07E-04	2.3636E-08	52,500	1.24E-03
EA9	BSL-3E and SP	Aerosol	One column fails (but at least one alarm works) while both filters in the other column are degraded	1.02E+00	3.46E+04	1.18E+09	6.76E-12	6.90E-12	2.34E-07	7.98E-03	1.7999E-10	52,500	9.45E-06
EA10	BSL-3E and SP	Aerosol	Total HEPA failure	1.02E+00	3.46E+04	1.18E+09	1.00E-04	1.02E-04	3.46E+00	1.18E+05	2.0000E-37	52,500	1.05E-32
EA11	BSL-3E and SP	Aerosol	Both columns fail (but at least one alarm works on each column). HEPA is closed off	1.02E+00	3.46E+04	1.18E+09	0.00E+00	0.00E+00	0.00E+00	0.00E+00	7.9992E-11	52,500	4.20E-06
ES1	BSL-3E and SP	Solid Waste	Solid waste bulk batch processed normally	8.57E+00	2.91E+05	9.91E+09	1.00E-21	8.57E-21	2.91E-16	9.91E-12	9.9998E-01	250	2.50E+02
ES2	BSL-3E and SP	Solid Waste	Single autoclave failure	8.57E+00	2.91E+05	9.91E+09	1.00E-15	8.57E-15	2.91E-10	9.91E-06	2.0000E-05	250	5.00E-03
ES3	BSL-3E and SP	Solid Waste	Incinerator failure	8.57E+00	2.91E+05	9.91E+09	1.00E-12	8.57E-12	2.91E-07	9.91E-03	9.9998E-11	250	2.50E-08
ES4	BSL-3E and SP	Solid Waste	Both autoclaves fail	8.57E+00	2.91E+05	9.91E+09	1.00E-09	8.57E-09	2.91E-04	9.91E+00	1.0000E-10	250	2.50E-08
ES5	BSL-3E and SP	Solid Waste	Single autoclave failure and incinerator failure	8.57E+00	2.91E+05	9.91E+09	1.00E-06	8.57E-06	2.91E-01	9.91E+03	2.0000E-15	250	5.00E-13
ES6	BSL-3E and SP	Solid Waste	Failure of all systems	8.57E+00	2.91E+05	9.91E+09	1.00E+00	8.57E+00	2.91E+05	9.91E+09	1.0000E-20	250	2.50E-18
EL1	BSL-3E and SP	Liquid Waste	Nominal case; follows protocol	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.9990E-01	52,500	5.25E+04
EL2	BSL-3E and SP	Liquid Waste	Failure to follow protocol and pouring down drain; cook tank and wastewater work	1.02E+00	3.46E+04	1.18E+09	1.00E-07	1.02E-07	3.46E-03	1.18E+02	9.9999E-05	52,500	5.25E+00
EL3	BSL-3E and SP	Liquid Waste	Failure to follow protocol, cook tank fails and performance indicator fails, wastewater works	1.02E+00	3.46E+04	1.18E+09	1.00E-01	1.02E-01	3.46E+03	1.18E+08	9.9999E-15	52,500	5.25E-10
EL4	BSL-3E and SP	Liquid Waste	Failure to follow protocol, cook tank works, wastewater fails	1.02E+00	3.46E+04	1.18E+09	1.00E-06	1.02E-06	3.46E-02	1.18E+03	1.0000E-09	52,500	5.25E-05
EL5	BSL-3E and SP	Liquid Waste	Failure to follow protocol, cook tank fails and performance indicator fails, wastewater fails	1.02E+00	3.46E+04	1.18E+09	1.00E+00	1.02E+00	3.46E+04	1.18E+09	1.0000E-19	52,500	5.25E-15
ETP0	BSL-3E and SP	Transference (Hand)	Nominal case - no spill and no transference to hand.	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.9800E-01	21,000	2.10E+04
ETP1	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves work and 2 body showers.	1.02E+00	3.46E+04	1.18E+09	8.93E-09	9.11E-09	3.09E-04	1.05E+01	1.8282E-03	21,000	3.84E+01
ETP2	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves fail and 2 body showers	1.02E+00	3.46E+04	1.18E+09	5.98E-06	6.10E-06	2.07E-01	7.06E+03	1.5187E-04	21,000	3.19E+00
ETP3	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves work and 1 body shower.	1.02E+00	3.46E+04	1.18E+09	8.84E-08	9.02E-08	3.06E-03	1.04E+02	1.8374E-05	21,000	3.86E-01
ETP4	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves fail and 1 body shower.	1.02E+00	3.46E+04	1.18E+09	5.92E-05	6.04E-05	2.05E+00	6.99E+04	1.5263E-06	21,000	3.21E-02
ETP5	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves work and 0 body showers.	1.02E+00	3.46E+04	1.18E+09	8.76E-07	8.93E-07	3.03E-02	1.03E+03	4.6165E-08	21,000	9.69E-04
ETP6	BSL-3E and SP	Transference (Hand)	Spill and transference to hand. Gloves fail and 0 body showers.	1.02E+00	3.46E+04	1.18E+09	5.87E-04	5.98E-04	2.03E+01	6.92E+05	3.8350E-09	21,000	8.05E-05

Table 4.7-1: Master Summary of Loss-of-Containment Events including Descriptions, MAR, Reduction Factors, Q Terms, Probabilities, Opportunity Rate, and Frequencies

Event ID	Originating Location	Pathway	Description	MAR (PFU)			Reduction Factor	*Q* Values (PFU)			Probability (P_{Loss})	Opportunity Rate (yr^{-1}) (R_o)	Frequency (yr^{-1}) (F_{Loss})
				Low	Medium	High		Low	Medium	High			
ETP7	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 2 body showers.	1.02E+00	3.46E+04	1.18E+09	3.57E-09	3.64E-09	1.24E-04	4.22E+00	4.9254E-03	21,000	1.03E+02
ETP8	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 1 body shower.	1.02E+00	3.46E+04	1.18E+09	3.54E-08	3.61E-08	1.22E-03	4.17E+01	4.9501E-05	21,000	1.04E+00
ETP9	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. Spot decon & 0 body showers.	1.02E+00	3.46E+04	1.18E+09	3.50E-07	3.57E-07	1.21E-02	4.13E+02	1.2438E-07	21,000	2.61E-03
ETP10	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 2 body showers.	1.02E+00	3.46E+04	1.18E+09	3.57E-04	3.64E-04	1.24E+01	4.22E+05	2.4751E-05	21,000	5.20E-01
ETP11	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 1 body shower.	1.02E+00	3.46E+04	1.18E+09	3.54E-03	3.61E-03	1.22E+02	4.17E+06	2.4875E-07	21,000	5.22E-03
ETP12	BSL-3E and SP	Transference (Hand)	Transference to hand. Failed removal of gloves and transfer to hands. No spot decon & 0 body showers.	1.02E+00	3.46E+04	1.18E+09	3.50E-02	3.57E-02	1.21E+03	4.13E+07	6.2500E-10	21,000	1.31E-05
ETB0	BSL-3E and SP	Transference (Body)	Nominal case - no spill and no transference to hand.	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.9800E-01	21,000	2.10E+04
ETB1	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit works and 2 body showers.	1.02E+00	3.46E+04	1.18E+09	3.63E-07	3.70E-07	1.25E-02	4.28E+02	1.9602E-03	21,000	4.12E+01
ETB2	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit fails and 2 body showers	1.02E+00	3.46E+04	1.18E+09	2.72E-04	2.77E-04	9.41E+00	3.21E+05	1.9801E-05	21,000	4.16E-01
ETB3	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit works and 1 body shower.	1.02E+00	3.46E+04	1.18E+09	3.59E-06	3.66E-06	1.24E-01	4.24E+03	1.9701E-05	21,000	4.14E-01
ETB4	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit fails and 1 body shower.	1.02E+00	3.46E+04	1.18E+09	2.69E-03	2.75E-03	9.32E+01	3.18E+06	1.9900E-07	21,000	4.18E-03
ETB5	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit works and 0 body showers.	1.02E+00	3.46E+04	1.18E+09	3.56E-05	3.63E-05	1.23E+00	4.20E+04	4.9500E-08	21,000	1.04E-03
ETB6	BSL-3E and SP	Transference (Body)	Spill and transference to body. Tyvek® suit fails and 0 body showers.	1.02E+00	3.46E+04	1.18E+09	2.67E-02	2.72E-02	9.23E+02	3.15E+07	5.0000E-10	21,000	1.05E-05
OA1	Non-containment	Aerosol	Shipment of viable FMDv, primary and secondary containers work	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.99998E-01	500	5.00E+02
OA2	Non-containment	Aerosol	Primary and secondary fail, tertiary works	1.02E+00	3.46E+04	1.18E+09	9.00E-05	9.18E-05	3.11E+00	1.06E+05	1.98801E-06	500	9.94E-04
OA3	Non-containment	Aerosol	Primary and secondary fail, tertiary fails	1.02E+00	3.46E+04	1.18E+09	1.00E-04	1.02E-04	3.46E+00	1.18E+05	1.99000E-09	500	9.95E-07
OTP1	Non-containment	Transference (Hand)	Shipment of viable FMDv, primary and secondary containers work	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.99998E-01	500	5.00E+02
OTP2	Non-containment	Transference (Hand)	Primary and secondary fail, tertiary works; gloves work and body shower (recognition of potential exposure)	1.02E+00	3.46E+04	1.18E+09	1.43E-07	1.46E-07	4.96E-03	1.69E+02	1.97807E-06	500	9.89E-04
OTP3	Non-containment	Transference (Hand)	Primary and secondary fail, tertiary fails; gloves work and body shower (recognition of potential contamination)	1.02E+00	3.46E+04	1.18E+09	1.59E-07	1.62E-07	5.51E-03	1.88E+02	1.98005E-09	500	9.90E-07
OTP4	Non-containment	Transference (Hand)	Primary and secondary fail, tertiary works; no gloves and no body shower	1.02E+00	3.46E+04	1.18E+09	1.42E-01	1.45E-01	4.91E+03	1.67E+08	9.94005E-09	500	4.97E-06
OTP5	Non-containment	Transference (Hand)	Primary and secondary fail, tertiary fails; no gloves and no body shower	1.02E+00	3.46E+04	1.18E+09	1.58E-01	1.61E-01	5.45E+03	1.86E+08	9.95000E-12	500	4.98E-09
OTF1	Non-containment	Transference (Foot)	Shipment of viable FMDv, primary and secondary containers work or recognition of potential contamination upon spill	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	1.00000E+00	500	5.00E+02
OTF2	Non-containment	Transference (Foot)	Primary and secondary fail, tertiary works; failed recognition of potential contamination	1.02E+00	3.46E+04	1.18E+09	3.60E-01	3.67E-01	1.25E+04	4.25E+08	9.94005E-09	500	4.97E-06
OTF3	Non-containment	Transference (Foot)	Primary and secondary fail, tertiary fails; failed recognition of potential contamination	1.02E+00	3.46E+04	1.18E+09	4.00E-01	4.08E-01	1.38E+04	4.72E+08	9.95000E-12	500	4.98E-09
OTB1	Non-containment	Transference (Body)	Shipment of viable FMDv, primary and secondary containers work	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.99998E-01	500	5.00E+02
OTB2	Non-containment	Transference (Body)	Primary and secondary fail, tertiary works; Tyvek® suit work and body shower (recognition of potential exposure)	1.02E+00	3.46E+04	1.18E+09	5.82E-06	5.93E-06	2.01E-01	6.86E+03	1.97807E-06	500	9.89E-04
OTB3	Non-containment	Transference (Body)	Primary and secondary fail, tertiary fails; Tyvek® suit work and body shower (recognition of potential exposure)	1.02E+00	3.46E+04	1.18E+09	6.46E-06	6.59E-06	2.24E-01	7.63E+03	1.98005E-09	500	9.90E-07
OTB4	Non-containment	Transference (Body)	Primary and secondary fail, tertiary works; no Tyvek® suit and no body shower	1.02E+00	3.46E+04	1.18E+09	2.88E-01	2.94E-01	9.96E+03	3.40E+08	9.94005E-09	500	4.97E-06
OTB5	Non-containment	Transference (Body)	Primary and secondary fail, tertiary fails; no Tyvek® suit and no body shower	1.02E+00	3.46E+04	1.18E+09	3.20E-01	3.26E-01	1.11E+04	3.78E+08	9.95000E-12	500	4.98E-09
OTFom1	Non-containment	Transference (Fomite)	Nominal transference to fomite	3.71E-04	1.95E+02	2.03E+04	4.00E-07	1.48E-10	7.78E-05	8.12E-03	1.0000E+00	1.0	1.00E+00
OTPalm1	Non-containment	Transference (Hand)	Nominal transference to hand. Reduction by gloves and body shower.	3.71E-04	1.95E+02	2.03E+04	4.00E-07	1.48E-10	7.78E-05	8.12E-03	1.0000E+00	1.0	1.00E+00
Tornado	NBAF	Catastrophic	Tornado, >228 mph	3.13E+06	7.15E+06	4.96E+10	5.00E-01	1.57E+06	3.58E+06	2.48E+10	7.0576E-08	1	7.06E-08
Earthquake	NBAF	Catastrophic	Earthquake	1.51E+04	5.29E+04	4.96E+08	1.00E+00	1.51E+04	5.29E+04	4.96E+08	3.9984E-04	1	4.00E-04

5. Fate and Transport Modeling

In the unlikely event that an infectious quantity of pathogen escapes biocontainment and is released to the outside environment, the pathogen would travel from the NBAF by one or more of the four transport pathways: aerosol, solid waste, liquid effluent, or transference. An index case for epidemiological modeling will occur if a sufficient quantity of viable pathogenic material reaches susceptible premises and infects at least one animal. The fate and transport of pathogenic material from the accident events developed in Section 4 were modeled to determine the quantity of viable pathogen delivered to susceptible premises. The probability of infection was then applied to determine the extent and numbers of infected animals and premises for the modeled event. The fate and transport models for each transport pathway are discussed in the following sections.

5.1 Aerosol Fate and Transport (Plume) Modeling

Aerosol fate and transport simulations were performed for the Updated SSRA to model the potential for FMD outbreaks resulting from an aerosol release and to provide initial conditions for epidemiological modeling and agricultural economic assessments. Aerosol source characteristics were derived for each event (Section 4) and served as input conditions to the aerosol transport model, which was then executed over a representative range of meteorological conditions. Estimates of pathogen concentrations (and the uncertainties associated with these concentrations) were combined with documented locations of susceptible animal populations (cattle, swine, sheep, and goats) to estimate inhalation/ingestion exposure levels and subsequently determine resulting index infections. These index infections then serve as input conditions to the epidemiological model to further estimate the subsequent disease spread, as illustrated in Figure 5.1-1.

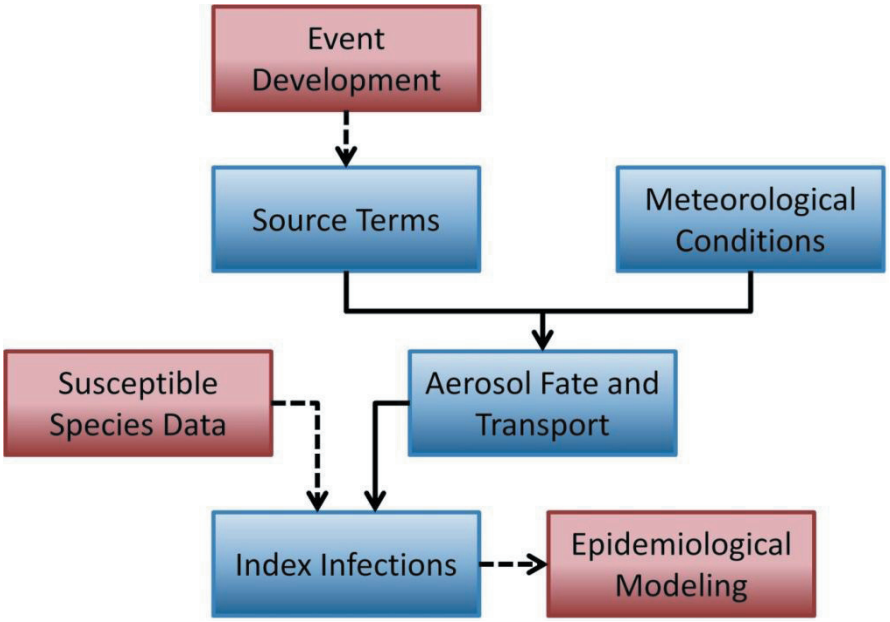


Figure 5.1-1: Aerosol Fate and Transport Work Flow

For the Updated SSRA, the above approach was further modified to address several recommendations from the NAS SSRA Committee, particularly the need to better quantify the impacts of parameter uncertainties on the final predicted infection index cases, and the need to better validate the representativeness of the meteorological dataset used to drive the aerosol transport calculations. In order to quantify the impact of parameter uncertainties, particularly the uncertainties associated with the quantity of released aerosolized pathogen, a range of source amounts were defined for each defined release event, which represented the likely distribution of release amounts. This set of aerosol source terms was subsequently used to define a set of corresponding input conditions to the aerosol transport simulations and the corresponding set of resulting infections determined. To account for uncertainties associated with the estimation of infection likelihood for a given aerosolized pathogen exposure level, three different infection methodologies were examined based on species type and herd size. Finally, to better account for uncertainties associated with the driving meteorological conditions, the set of representative meteorological conditions was greatly expanded from the 200 used in the original SSRA to 600 representative events in the Updated SSRA, based on additional data from the Manhattan Regional Airport and an assessment of the underlying meteorological dataset. As a result of these modifications, a much improved estimate of the final distribution of possible infections, for each release event defined in Section 4, was developed and subsequently used to define the distribution of starting conditions for the epidemiological modeling calculations. A separate sensitivity study was performed to explore the sensitivity of the aerosol model results to a small representative set of model parameters, as detailed in Section 5.1.10.

The remaining aerosol fate and transport sections are organized as follows: A description of the general climatological conditions for Kansas and the NBAF region is provided in Section 5.1.1, including a detailed assessment of the NBAF site-specific surface characteristics. Sections 5.1.2 - 5.1.5 provide details on the site-specific meteorological data set selected for the Updated SSRA, the subsequent data classification and frequency analysis, and the validation of the dataset. The aerosol transport model, model configuration, and representative output are described in Sections 5.1.6, 5.1.7, and 5.1.8, respectively. Section 5.1.9 summarizes the results of the aerosol transport calculations, for each aerosol release event. And as described above, the results of the aerosol transport model sensitivity analysis are included in Section 5.1.10.

5.1.1 Kansas Climate

According to the Köppen climate classification system, the state of Kansas is situated at the intersection of three major climatic zones: cold (Dfa) in the northeast, arid (Bsk) in the west, and temperate (Cfa) in the southeast [Peel, Finlayson et al., 2007] (Figure 5.1.1-1). Evidence of this range of climatic zones can be found in the spatial distribution of both mean annual temperatures and annual average precipitation patterns across the state, which range from approximately 58 °F and 42 inches in the southeast to 52 °F and 20 inches in the westernmost portions of the state. Winds are predominately out of the south, throughout most of the state, with annual average wind speeds of approximately 12 mph (5 m/s) [National Climatic Data Center, 2001].

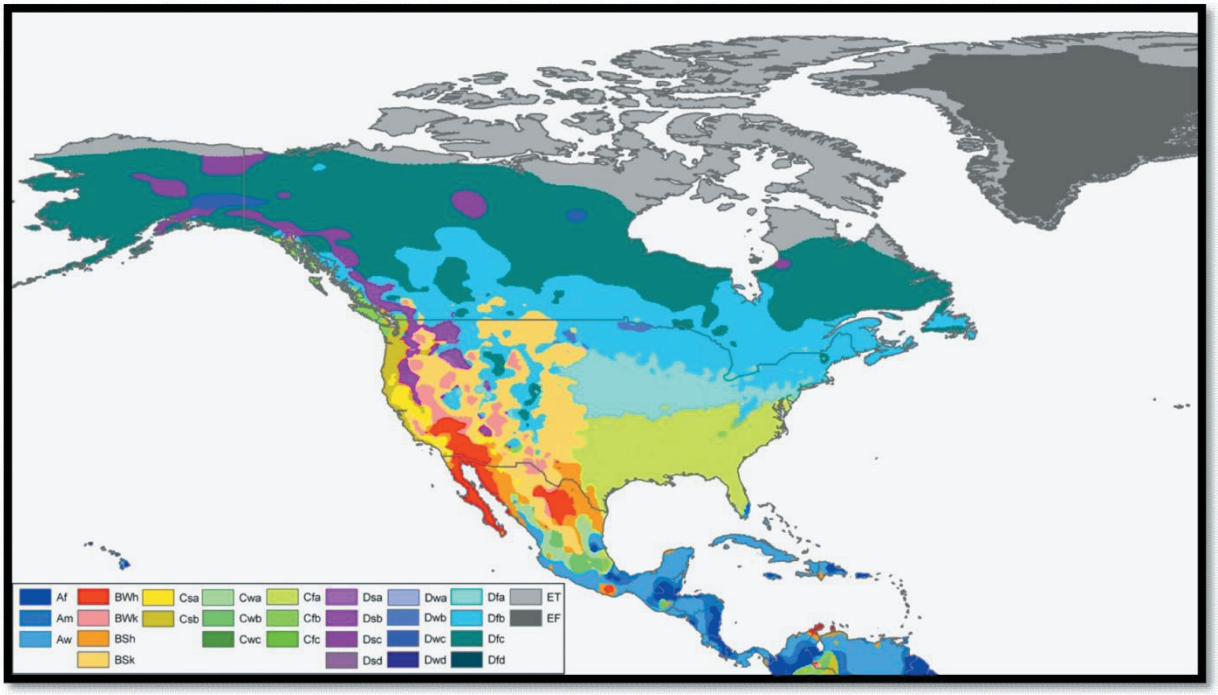


Figure 5.1.1-1: Köppen-Geiger Climate Map of North America [Peel, Finlayson et al., 2007]

The Manhattan, Kansas, area is situated within the cold climate (hot summer without dry season) subzone, Köppen climate classification Dfa, which is characterized by temperatures ranging from less than or equal to 0 °C (32 °F) to greater than 10 °C (50 °F), without a defined dry season, and with temperatures in the hottest month exceeding 22 °C (72 °F) [Peel, Finlayson et al., 2007]. As noted in Table 5.1.1-1 [National Climatic Data Center, 2010], Topeka, Kansas, (approximately 50 miles east of Manhattan), experiences average annual temperatures of approximately 12 °C (54 °F), with normal daily max/min temperatures of 18.3/6.1 °C (65/43 °F). Wind speeds are on average 10 mph (4 m/s), with maximums of 55 mph (25 m/s), and a prevailing wind direction of 180°. The area stays relatively humid year round, ranging from a monthly afternoon minimum of 62% in October and morning maximum of 86% in August.

Table 5.1.1 1: Climate Norms for Topeka, Kansas

Parameter	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	Annual
AVERAGE WIND SPEED (MPH)	9.7	10	11.4	11.6	10	9.3	8.2	7.8	8.3	8.8	9.6	9.5	9.5
MAXIMUM WIND SPEED (MPH)	39	37	55	51	47	54	44	44	43	39	45	37	55
MAXIMUM WIND SPEED DIRECTION (DEG)	310	320	180	80	340	360	340	240	320	230	310	300	180
AVERAGE MORNING RH (%)	77	77	76	78	82	85	84	85	86	81	79	78	81
AVERAGE AFTERNOON RH (%)	67	66	62	61	65	66	66	66	65	62	66	69	66
NORMAL DAILY MEAN TEMP (°F)	27.2	33.4	44.2	54.5	64.4	73.9	78.4	76.7	68.1	56.6	42.6	31.4	54.3
NORMAL DAILY MAX TEMP (°F)	37.2	43.8	55.5	66.1	75.3	84.5	89.1	87.9	80.3	68.9	53.1	40.9	65.2
NORMAL DAILY MIN TEMP (°F)	17.2	23	32.9	42.9	53.4	63.2	67.7	65.4	55.9	44.3	32.1	21.8	43.3

Table 5.1.1 1: Climate Norms for Topeka, Kansas

Parameter	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	Annual
NORMAL PRECIPITATION (INCHES)	0.95	1.18	2.56	3.14	4.86	4.88	3.83	3.81	3.71	2.99	2.31	1.42	35.64
NORMAL SNOWFALL (INCLUDING ICE PELLETS) (INCHES)	5.4	4.8	3.4	0.5	T	T	T	T	T	0.2	1.4	5	20.7
HIGHEST TEMPERATURE OF RECORD (°F)	74	84	89	95	97	107	110	110	109	96	85	73	110
LOWEST TEMPERATURE OF RECORD (°F)	-20	-23	-7	10	26	43	43	41	29	19	2	-26	-26

Based on these observations, a general set of predictions can be made regarding the expected behavior of aerosolized pathogens released from the NBAF. First, the most likely directions of transport will generally be to the north and south of the facility. Second, transport distances could reach approximately 200 miles 24 hours after release, not accounting for gravitational settling and pathogen decay effects. And third, aerosolized pathogens with decay that is particularly sensitive to ambient relative humidity levels will either decay rapidly (decay rate is directly proportional to humidity level) or remain relatively stable (decay rate is inversely proportional to humidity level) during transport. For example, aerosolized FMDv released in this region will likely remain relatively stable during transport due to stabilizing effects of higher relative humidities. Although useful for providing general guidelines, or rules of thumb, regarding the expected behavior of aerosolized pathogens, these climatic characteristics do not provide the level of detail and site specificity needed to accurately model the fate and impact of aerosols released from the NBAF. Therefore, a more detailed and site specific analysis of meteorological conditions, representative of the NBAF region, was performed and is further described in the following sections.

5.1.2 Site-Specific Meteorological Data

In order to effectively characterize the expected range of meteorological conditions, which would directly impact the atmospheric fate/transport of materials (gases, aerosols) released into the environment from the NBAF site, it is necessary to use meteorological data which best represents the driving atmospheric turbulent transport processes. In particular, as noted in the latest regulatory guidance from the Environmental Protection Agency (EPA), "...data representativeness should be viewed in terms of the appropriateness of the data for constructing realistic boundary layer profiles and three dimensional meteorological fields." More specifically, when choosing a meteorological data set that best represents the site specific meteorological conditions, EPA provides the following guidelines: First, the historical period of record should be long enough to ensure worst case meteorological conditions (in terms of atmospheric transport and dispersion) are represented and ensure a stable distribution of conditions is obtained. For example, initial investigations by Landsberg and Jacobs [1951], which examined distributions of atmospheric conditions over different time periods, found that periods in excess of ten years may be required to obtain stable distributions. Burton, Stoeckenius et al. [1983] also examined the impact of observation record stability on atmospheric dispersion simulations but recommended a minimum period of only 5 years. Consequently, the latest EPA guidance [EPA, 2005] also recommends the use of at least 5 years of representative data, preferably from the most recent 5 years, although 1 year of data may be acceptable under certain circumstances. Second, the data should

minimally include estimates of hourly averaged wind velocities (10 meters above ground level (AGL)), air temperature (2 meters AGL), and other information necessary to estimate vertical and lateral dispersion properties. Ideally, estimates of total incoming solar radiation at the surface, and vertical profiles of temperature, wind velocities, and wind velocity fluctuations (turbulence) should be included when available. Third, the data should be used from either the nearest National Weather Service (NWS) observing site, a locally-sited observation platform, or from a meteorological model, depending on the underlying surface characteristics of the region and the maximum downwind ranges of concern. When analyzing dispersion over regions with generally uniform surface characteristics (terrain elevation and land use) and for short downwind ranges, EPA recommends the use of observational data (NWS or locally obtained). Conversely, over regions with non-uniform surface conditions and when calculating dispersion for long downwind ranges, 3-dimensional model-generated data is generally recommended.

As illustrated in Figure 5.1.2-1 and Figure 5.1.2-3, the underlying surface characteristics of the NBAF and the surrounding region are relatively non uniform, representing a range of terrain elevations (~1,000 to 1,400 feet) and land use categories (developed, partly developed, dry cropland/pasture, and cropland/grassland). With regard to transport distances relevant for the Updated SSRA, studies by Sorenson [2003] have suggested that long range atmospheric transport of infectious doses of FMDv can occur over distances of several hundred kilometers, highlighting the need to consider long range transport effects for this assessment. Based on these considerations and the EPA recommendations, it was determined that a dataset derived from a 4-dimensional meteorological model would provide the most representative conditions for the Updated SSRA aerosol transport calculations. The dataset chosen for this analysis was originally developed by the National Center for Atmospheric Research (NCAR) to support aerosol transport modeling for the Department of Defense (DoD) Joint Effects Model (JEM) system and the Defense Threat Reduction Agency (DTRA) Hazard Prediction and Assessment Capability (HPAC) [National Center for Atmospheric Research, 2010]. This dataset contains hourly, three-dimensional analyses of all standard meteorological variables over a 21-year period (1985–2005) on a global 40-km horizontal grid that extends from the surface up to a height of approximately 60,000 feet [Rife, Pinto et al., 2010]. Other datasets that were initially considered for this analysis, but not chosen, included the NCAR/NCEP Reanalysis [Kalnay, Kanamitsu et al., 1996] and the European Centre for Medium-Range Weather Forecasts Interim Re-Analysis (ERA-Interim). These were not used because of the lower spatial (250 km and 75 km for NCAR/NCEP and ERA, respectively) and temporal (6-hourly for both NCAR/NCEP and ERA) resolutions, as compared to the NCAR dataset (40 km and hourly), which allowed for higher-fidelity spatial scale features to be included and ensured that the effects of the diurnal cycle were fully resolved.

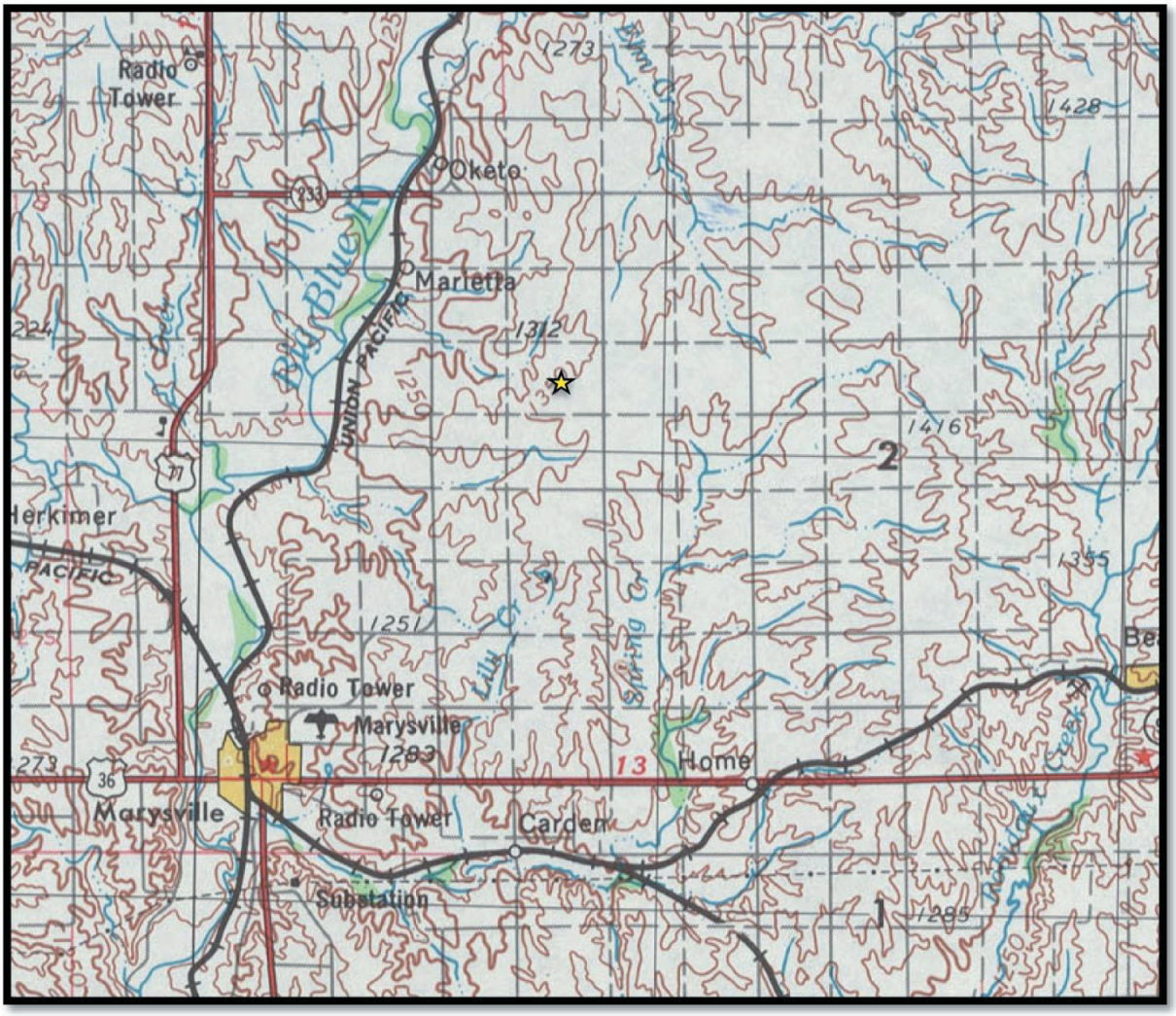


Figure 5.1.2-1: Kansas Topographic Map (Scale 1:250,000), Zoomed over Manhattan, Kansas

The yellow star denotes the approximate location of the NBAF. The original map image is courtesy of the University of Texas Libraries.

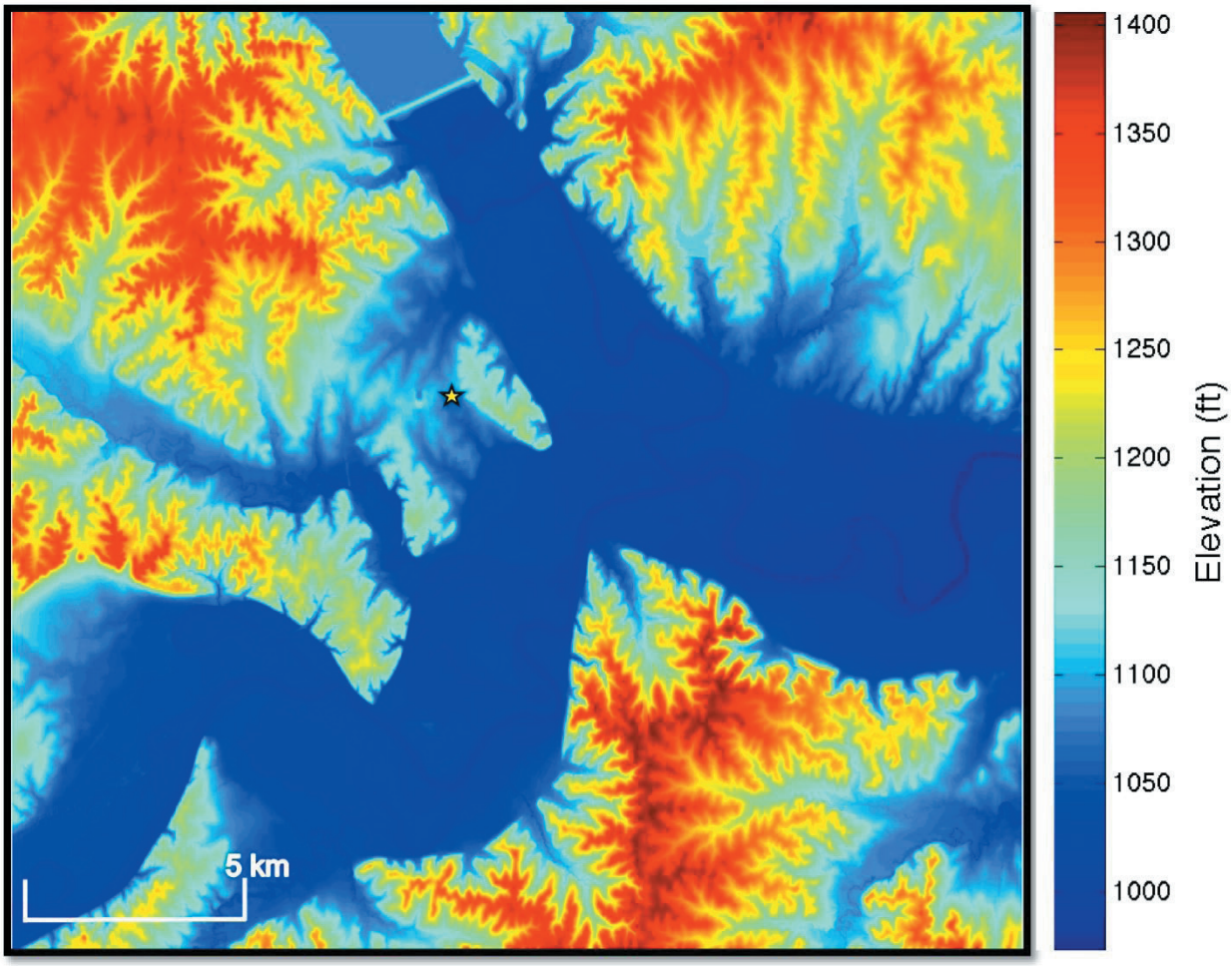


Figure 5.1.2-2: Digital Elevation Map (1/3 arc second) of the Manhattan, KS, Region

The yellow start denotes the approximate location of the NBAF. The Digital Map was extracted from the USGS National Elevation Dataset [Gesch, Oimoen et al., 2002].

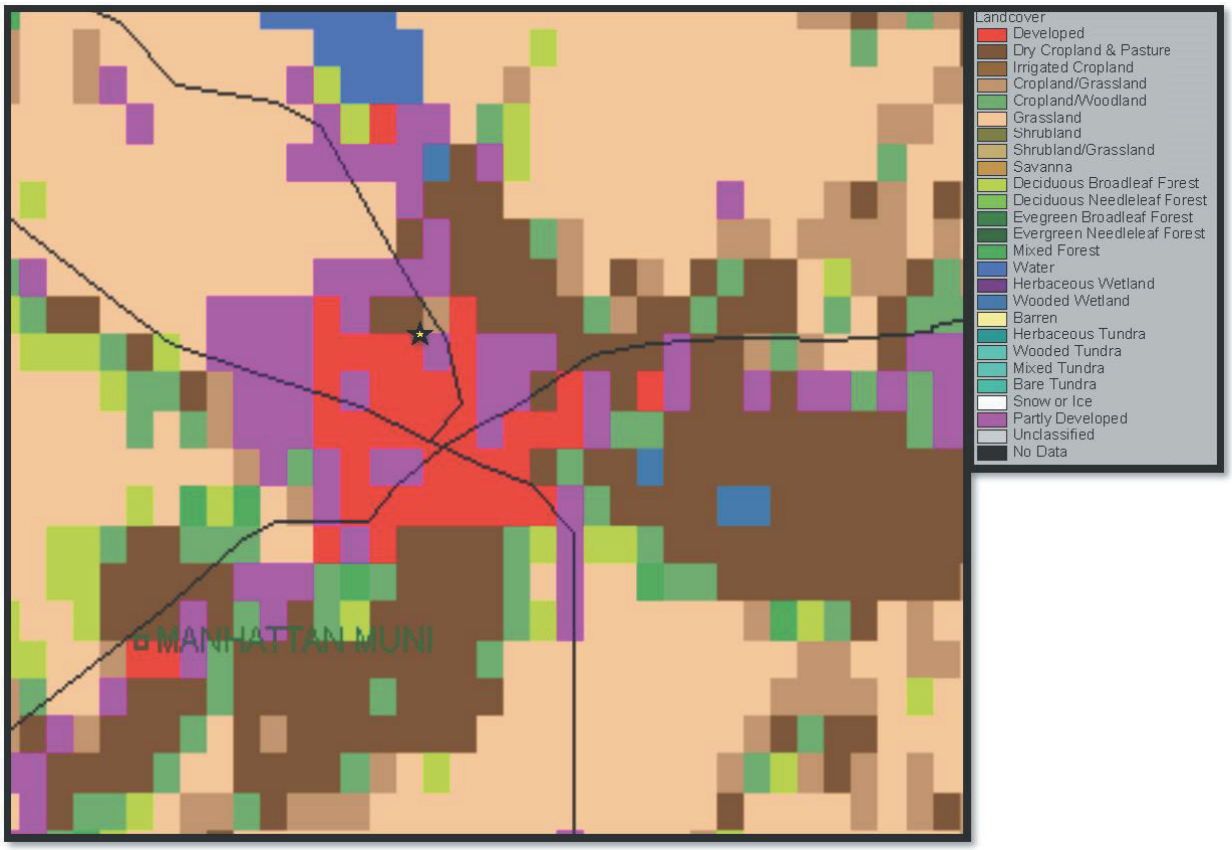


Figure 5.1.2-3: Zoomed in View of Land Cover in the Manhattan, Kansas, Region

The selected NCAR reanalysis has been validated against observations from the National Oceanic and Atmospheric Administration (NOAA) Profiler Network (NPN), located in the central United States, to evaluate its ability to recreate the observed characteristics of the Great Plains Nocturnal Low Level Jet (NLLJ) [Rife, Pinto et al., 2010] and verified by Monaghan, Rife et al. [2010] on its ability to replicate the observed spatial patterns of rainfall. Additionally, an NBAF-specific validation was performed against observations obtained from the Manhattan Regional Airport (KMHK), located approximately 7 miles (11 km) southwest of the NBAF site. In particular, wind velocity statistics (wind roses) extracted from KMHK [National Climatic Data Center, 2010] were compared to coincident statistics from the NCAR reanalysis (Figure 5.1.2-4). As shown, although not exactly alike, the NCAR-derived wind rose compares favorably to that derived from KMHK. Both illustrate a generally bimodal wind direction distribution, with the most frequently occurring wind direction out of the south (consistent with statewide climate characteristics) and a generally similar distribution of wind speeds. Although minor differences do exist, these differences are to be expected, and are likely due to issues associated with comparing a single point observation location (KMHK) to a model reanalysis that represents the average value in that model grid cell.

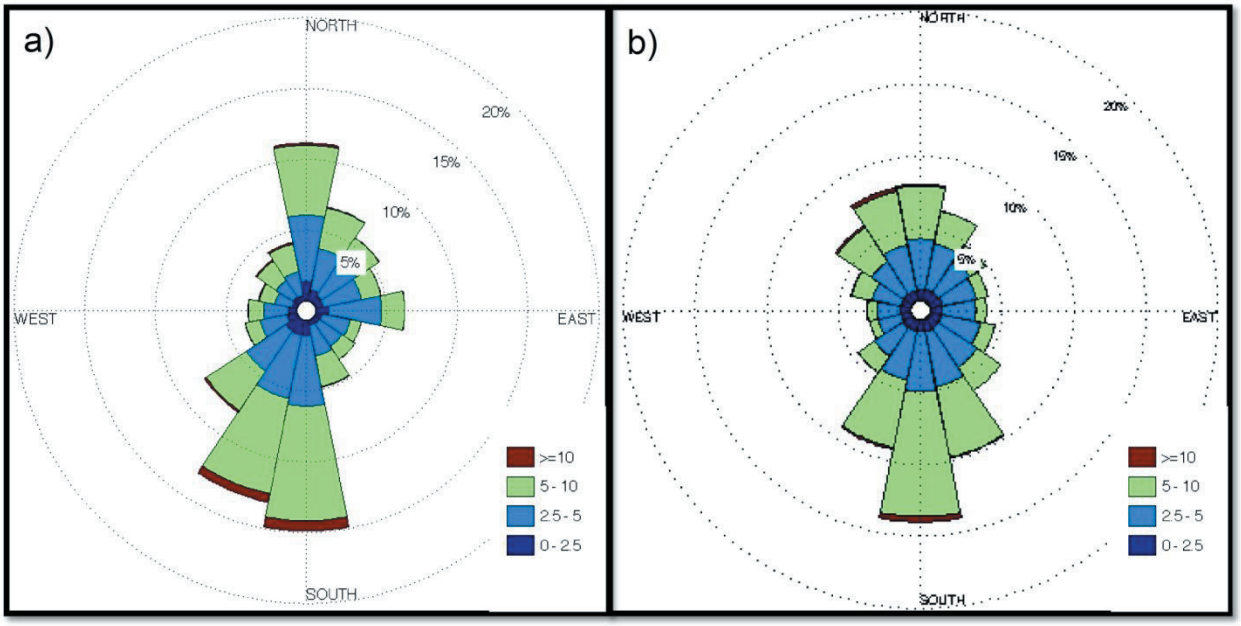


Figure 5.1.2-4: Wind roses for a) Manhattan Regional Airport (KMHK) and b) the NCAR Gridded Historical Database

Wind speeds are presented in m/s.

5.1.3 Meteorological Data Reduction and Frequency Analysis

In order to comprehensively account for the effects of any and all possible meteorological conditions on the resulting aerosol transport, simulations would ideally be executed for every hour in the full 21-year database. However, this would result in over 180,000 simulations required per release event and source term. Based on the EPA guidance discussed previously, the period of record can be effectively reduced to the most recent 5 years, resulting in approximately 43,000 required simulations per event/source. For the Updated SSRA analysis, aerosol calculations were required for over 30 separate release event and source amounts, raising the total number of required simulations to over 130,000. To reduce the computational burden to a manageable level, the original 21-year hourly database was decomposed into a smaller set of representative meteorological conditions using a feature extraction and pattern classification technique known as the Self Organizing Map (SOM) [Kohonen, 1982].

The SOM is an artificial neural network technique that uses an unsupervised iterative learning method to group large amounts of data into a smaller set of clusters, or “nodes,” with similar characteristics. These nodes are then organized into the final map or SOM. The SOM technique has been widely used in a variety of scientific disciplines [Joutsiniemi, Kaski et al., 1995; Palakal, Murthy et al., 1995; Chen and Gasteiger, 1997; Kaski, Kangas et al., 1998] and more recently has been used within the atmospheric science community [Hewitson and Crane, 2002; Cassano, Uotila et al., 2006; Schuenemann, Cassano et al., 2009]. In particular, SOMs were used by Cassano, Uotila et al. [2006] to characterize arctic circulation patterns from an ensemble of global circulation model predictions, while Schuenemann, Cassano et al. [2009] used the SOM technique to identify Sea Level Pressure (SLP) patterns over Greenland from the 40-year European Centre for Medium-Range Weather Forecasts (ECMWF) Re-Analysis (ERA-40

database). Liu, Weisberg et al. [2006] performed an extensive evaluation of the SOM technique's ability to extract features from known patterns and provided a list of recommended SOM configurations.

For the Updated SSRA, the SOM analysis was performed using the freely available SOM-PAK software package [Kohonen et al., 1996], version 3.1, and configured as detailed in Table 5.1.3-1.

Table 5.1.3 1: NBAF Updated SSRA SOM Configuration

SOM Configuration Option	NBAF Updated SSRA SOM Configuration Choice
Map Lattice Structure	Hexagonal (10 × 20)
Number of Map Nodes	200
Initialization Method	Evenly distributed random values
Neighborhood Function	Bubble
Neighborhood Radius (1st and 2nd Stages)	10 and 3
Training Weight (1st and 2nd Stages)	0.5 and 0.03
Training Iterations (1st and 2nd Stages)	1,000 and 10,000

A 10 × 20 hexagonal lattice of nodes was used to construct the NBAF-specific SOM and was chosen over a rectangular lattice structure for several reasons. First, it provides more neighbors within a given radius of a node, which can potentially strengthen the relationship between adjoining nodes. Second, the overall shape of the mapping helps to ensure the stability of the learning process [Kohonen, 2001]. For the 2010 SSRA, a map size of 200 nodes was chosen to generate a manageable number of meteorological scenarios, while also attempting to sufficiently sample the number of expected meteorological patterns. As will be described later in this section, the original 200 nodes were effectively expanded to better represent the full range of meteorological conditions.

Several methods were available to initialize the SOM nodes. These included: a) randomly selecting data vectors from the entire data set; b) selecting random values that were evenly distributed through the input data set, and; c) using a more mathematically rigorous method, which ensured that the nodes spanned the sub-space defined by the two main eigenvectors of the input data set. Of these, the second initialization method (b) was chosen because it is more computationally efficient than the eigenvector method and because the final result tends to be insensitive to the choice of initialization method [Kohonen, 2001].

Thus, each SOM node was initialized randomly from a sample in the training data, which consisted of 21 years of 24-hour periods of output for a 1000 × 1000 km domain (Figure 5.1.3-1) centered over Manhattan, Kansas. The choice of domain size was based on initial estimates of the maximum plausible downwind distance for delivery of an infective dose of FMDv based on the work of Sorensen [2003], and some conservative idealized dispersion calculations (not shown). Additionally, this domain size ensured meteorological patterns could be effectively characterized based on the 40 km spatial resolution of the reanalysis dataset.

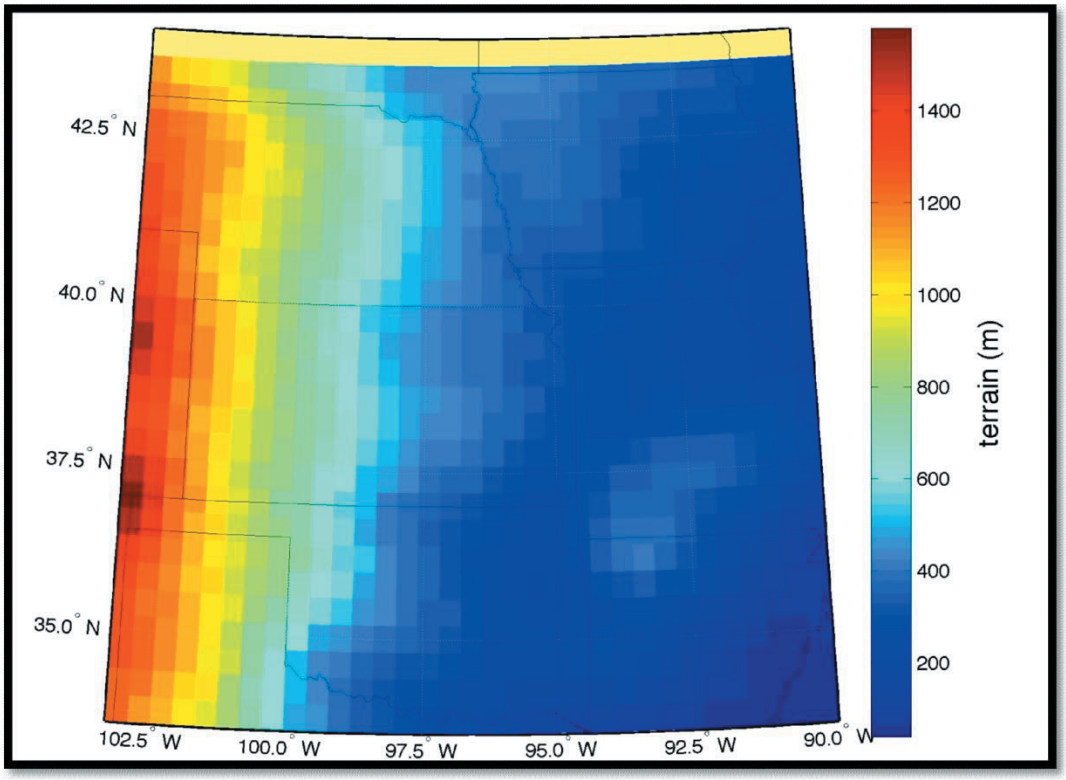


Figure 5.1.3-1: NCAR Climatological Database Spatial Domain (1000 km x 1000 km) Used in the NBAF Updated SSRA SOM Analysis

Also shown is the NCAR database terrain elevation for the specified domain (color filled contours).

The data vectors used to initialize and train the SOM were composed of 2-dimensional arrays of the meteorological variables that most strongly impact the aerosol transport, dispersion, and decay of FMDv, as indicated in Table 5.1.3-2. The variables chosen included boundary layer winds (U_{10m}, V_{10m}, U_{850mb}, V_{850mb}), relative humidity (RH_{2m}), and surface sensible heat flux ($SH_{surface}$).

Table 5.1.3 2: NCAR Database Meteorological Variables Used to Initialize the NBAF Updated SSRA SOM

SOM Meteorological Variable ID	SOM Meteorological Variable Description
U_{10m}	U component of the wind at 10 meters AGL
V_{10m}	V component of the wind at 10 meters AGL
U_{850mb}	U component of the wind at 850 millibar (mb) pressure level
V_{850mb}	V component of the wind at 850 millibar (mb) pressure level
RH_{2m}	Relative Humidity at 2 meters AGL
$SH_{surface}$	Sensible Heat Flux at the surface

In order to maintain equal weighting during the training of the SOM, these meteorological variables were each normalized to have zero mean and unit standard deviation. The SOM was trained by taking each 24-hour period of data from the training data set and finding the SOM node it best matched. Each

input vector was presented to the SOM and the Best Matching Unit (BMU) was determined by finding the smallest Euclidian distance between the input vector and each map node. The BMU and its neighboring nodes were adjusted by the weighted difference between the node and the input vector. For this study, a "bubble" neighborhood function was used, which weights all neighboring nodes within the neighborhood radius equally [Kohonen, 2001].

This training process was repeated for each input vector in the data set. After cycling through the data set, the neighborhood radius and training weight were recomputed and the process repeated. For the Updated SSRA SOM analysis, the training was conducted in two stages. The first stage was a coarse training of the SOM for 1000 iterations using an initial neighborhood radius of 10 units and an initial training weight of 0.5. The second refining stage of SOM training was for 10,000 iterations using an initial neighborhood radius of 3 units and an initial training weight of 0.03.

After the SOM was successfully trained, the original meteorological input data were presented to the map a final time to determine node membership for each meteorological input vector and subsequently used to determine the frequency of occurrence of each SOM node. In the original 2010 SSRA, the best match between the training samples and the SOM node pattern was used to define a typical 24-hour period for each pattern, which was defined as the input vector with the closest Euclidian distance to the SOM node vector. It was this typical 24-hour period that was then used to drive the resulting aerosol transport simulations associated with each SOM pattern. For the Updated SSRA, this technique was extended to include additional members per SOM node to better incorporate the full range of meteorological events observed in the NBAF region of interest. In addition to choosing the best matching member, two additional members were chosen from each SOM node, which represented the median and maximum Euclidian distances respectively. The associated frequency of occurrences for each of the three SOM node members were calculated by weighting the total SOM node frequency based on the Euclidian distance of each member from the node vector as shown below:

$$\boldsymbol{w_i} = \frac{\dfrac{\mathbf{max}\,(\boldsymbol{q_1}, \boldsymbol{q_2}, \boldsymbol{q_3})}{\boldsymbol{q_i}}}{\sum_{\boldsymbol{i=1}}^{\mathbf{3}} \dfrac{\mathbf{max}\,(\boldsymbol{q_1}, \boldsymbol{q_2}, \boldsymbol{q_3})}{\boldsymbol{q_i}}} \qquad \text{Eq. 5.1.3-1}$$

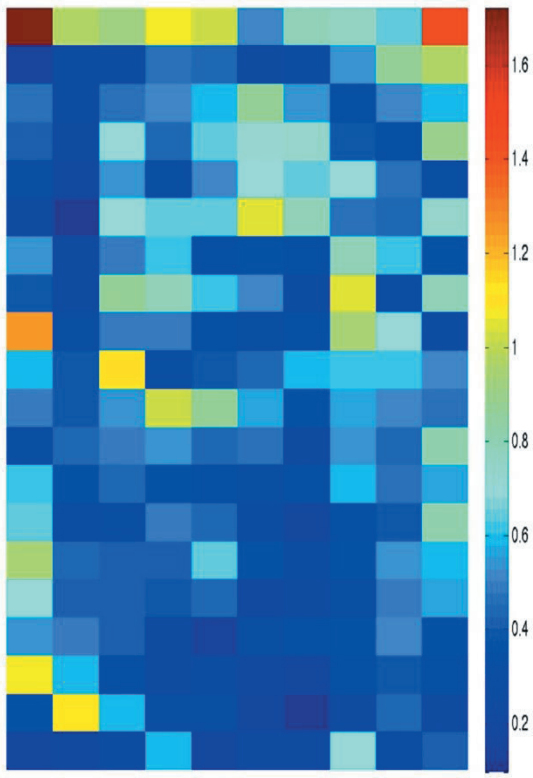
and

$$\boldsymbol{p_i} = \boldsymbol{p_t w_i} \qquad \text{Eq. 5.1.3-2}$$

where w_i represents the SOM node membership weights for the three members with the minimum, median, and maximum Euclidian distances (q_1, q_2, and q_3, respectively). These weights were then applied to the total SOM node frequency of occurrence, p_t, to derive the associated frequency of occurrence of each of the three members (p_i). Results from the NBAF Updated SSRA SOM analysis are summarized in the figures below. The 10 × 20 SOM node identifiers and the total SOM node associated frequency of occurrence (p_t), are highlighted in Figure 5.1.3-2 and Figure 5.1.3-3.

0	1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18	19
20	21	22	23	24	25	26	27	28	29
30	31	32	33	34	35	36	37	38	39
40	41	42	43	44	45	46	47	48	49
50	51	52	53	54	55	56	57	58	59
60	61	62	63	64	65	66	67	68	69
70	71	72	73	74	75	76	77	78	79
80	81	82	83	84	85	86	87	88	89
90	91	92	93	94	95	96	97	98	99
100	101	102	103	104	105	106	107	108	109
110	111	112	113	114	115	116	117	118	119
120	121	122	123	124	125	126	127	128	129
130	131	132	133	134	135	136	137	138	139
140	141	142	143	144	145	146	147	148	149
150	151	152	153	154	155	156	157	158	159
160	161	162	163	164	165	166	167	168	169
170	171	172	173	174	175	176	177	178	179
180	181	182	183	184	185	186	187	188	189
190	191	192	193	194	195	196	197	198	199

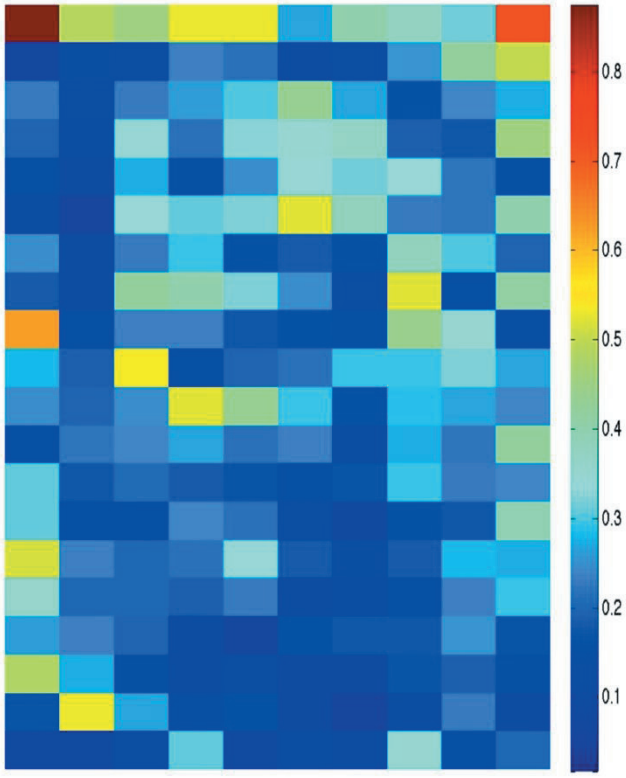
Figure 5.1.3-2: SOM Node Identifiers



1.72%	0.96%	0.93%	1.06%	1.03%	0.52%	0.79%	0.77%	0.64%	1.42%
0.14%	0.27%	0.26%	0.47%	0.44%	0.23%	0.27%	0.55%	0.86%	0.97%
0.46%	0.26%	0.46%	0.51%	0.59%	0.88%	0.55%	0.34%	0.52%	0.58%
0.41%	0.23%	0.69%	0.45%	0.65%	0.71%	0.74%	0.38%	0.34%	0.90%
0.30%	0.21%	0.55%	0.31%	0.52%	0.68%	0.65%	0.69%	0.45%	0.30%
0.25%	0.12%	0.70%	0.63%	0.64%	1.05%	0.78%	0.46%	0.43%	0.75%
0.54%	0.23%	0.48%	0.61%	0.33%	0.37%	0.33%	0.79%	0.61%	0.36%
0.39%	0.24%	0.86%	0.79%	0.62%	0.52%	0.26%	1.05%	0.29%	0.78%
1.26%	0.32%	0.49%	0.48%	0.34%	0.32%	0.34%	0.94%	0.68%	0.27%
0.59%	0.39%	1.09%	0.30%	0.38%	0.44%	0.60%	0.61%	0.61%	0.52%
0.50%	0.40%	0.54%	1.03%	0.87%	0.58%	0.35%	0.56%	0.53%	0.47%
0.32%	0.44%	0.49%	0.54%	0.44%	0.48%	0.24%	0.54%	0.45%	0.83%
0.63%	0.36%	0.43%	0.37%	0.33%	0.31%	0.34%	0.59%	0.46%	0.56%
0.63%	0.30%	0.31%	0.48%	0.43%	0.26%	0.18%	0.34%	0.38%	0.83%
0.95%	0.44%	0.41%	0.42%	0.64%	0.36%	0.27%	0.37%	0.54%	0.58%
0.70%	0.42%	0.41%	0.39%	0.44%	0.22%	0.24%	0.30%	0.48%	0.57%
0.55%	0.50%	0.42%	0.24%	0.13%	0.31%	0.34%	0.37%	0.52%	0.35%
1.08%	0.60%	0.34%	0.22%	0.26%	0.20%	0.20%	0.33%	0.39%	0.34%
0.37%	1.12%	0.58%	0.30%	0.32%	0.19%	0.10%	0.24%	0.45%	0.23%
0.19%	0.20%	0.27%	0.60%	0.18%	0.23%	0.23%	0.70%	0.29%	0.40%

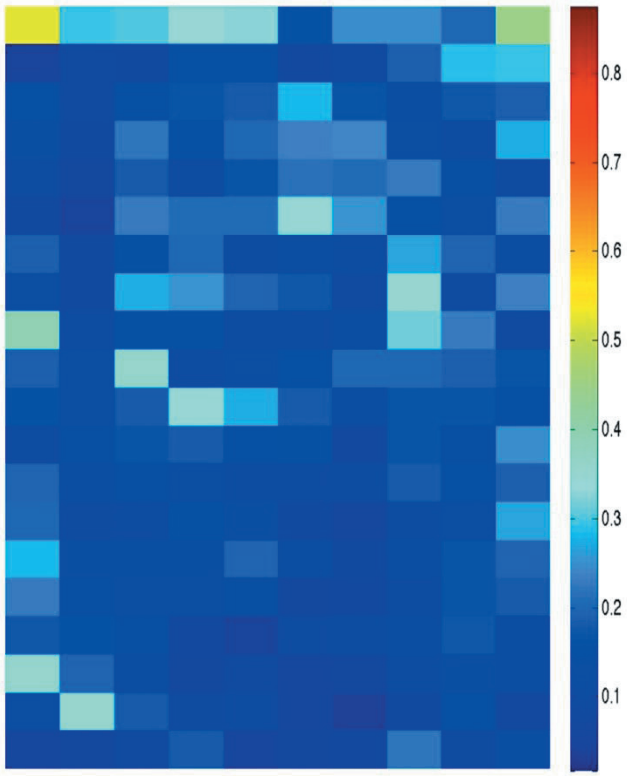
Figure 5.1.3-3: SOM Node Total (p_t) Frequencies of Occurrence (%)

As mentioned earlier, this original SOM was further extended by extracting an additional 2 members per node and calculating each member's associated frequency of occurrence. This new expanded SOM and their associated frequencies of occurrence are summarized in Figures 5.1.3-4, 5.1.3-5, and 5.1.3-6.



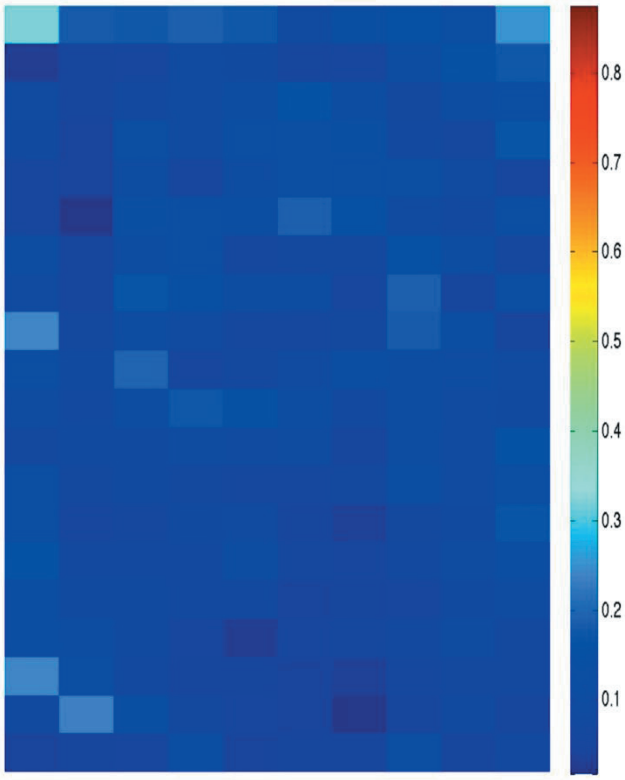
0.87%	0.49%	0.45%	0.53%	0.53%	0.27%	0.40%	0.38%	0.31%	0.71%
0.07%	0.14%	0.13%	0.24%	0.22%	0.11%	0.12%	0.26%	0.42%	0.50%
0.23%	0.12%	0.23%	0.26%	0.30%	0.43%	0.27%	0.16%	0.24%	0.28%
0.19%	0.12%	0.34%	0.22%	0.33%	0.35%	0.37%	0.19%	0.17%	0.45%
0.15%	0.10%	0.27%	0.15%	0.25%	0.34%	0.32%	0.34%	0.22%	0.16%
0.11%	0.06%	0.34%	0.31%	0.32%	0.52%	0.38%	0.23%	0.22%	0.40%
0.25%	0.10%	0.22%	0.29%	0.16%	0.18%	0.15%	0.39%	0.30%	0.19%
0.18%	0.11%	0.42%	0.40%	0.32%	0.24%	0.12%	0.52%	0.15%	0.42%
0.62%	0.15%	0.24%	0.24%	0.17%	0.16%	0.16%	0.44%	0.35%	0.14%
0.28%	0.18%	0.54%	0.15%	0.19%	0.21%	0.29%	0.30%	0.32%	0.26%
0.25%	0.20%	0.25%	0.52%	0.44%	0.29%	0.16%	0.29%	0.27%	0.24%
0.15%	0.22%	0.24%	0.27%	0.22%	0.23%	0.11%	0.28%	0.22%	0.42%
0.31%	0.17%	0.21%	0.18%	0.17%	0.15%	0.16%	0.29%	0.23%	0.24%
0.31%	0.15%	0.15%	0.24%	0.21%	0.13%	0.08%	0.16%	0.18%	0.39%
0.51%	0.23%	0.20%	0.21%	0.34%	0.18%	0.13%	0.18%	0.28%	0.28%
0.36%	0.20%	0.20%	0.19%	0.23%	0.11%	0.12%	0.15%	0.24%	0.30%
0.26%	0.23%	0.20%	0.11%	0.06%	0.16%	0.17%	0.18%	0.26%	0.17%
0.48%	0.27%	0.15%	0.11%	0.12%	0.10%	0.10%	0.17%	0.19%	0.15%
0.17%	0.53%	0.27%	0.14%	0.16%	0.09%	0.05%	0.12%	0.23%	0.11%
0.09%	0.09%	0.12%	0.31%	0.09%	0.11%	0.11%	0.35%	0.15%	0.20%

Figure 5.1.3-4: SOM Node Frequencies of Occurrence (%) for the Member with the *Minimum* Euclidian Distance to the Node Centroid (p_1)



0.53%	0.30%	0.30%	0.34%	0.33%	0.16%	0.25%	0.25%	0.20%	0.45%
0.04%	0.09%	0.08%	0.15%	0.14%	0.07%	0.09%	0.19%	0.29%	0.30%
0.15%	0.09%	0.15%	0.16%	0.18%	0.28%	0.17%	0.11%	0.17%	0.19%
0.14%	0.08%	0.22%	0.14%	0.20%	0.23%	0.24%	0.12%	0.10%	0.27%
0.10%	0.07%	0.18%	0.10%	0.17%	0.22%	0.21%	0.23%	0.14%	0.09%
0.08%	0.04%	0.23%	0.21%	0.21%	0.34%	0.25%	0.15%	0.13%	0.23%
0.18%	0.08%	0.16%	0.20%	0.11%	0.12%	0.11%	0.27%	0.19%	0.11%
0.13%	0.08%	0.27%	0.25%	0.19%	0.17%	0.09%	0.35%	0.10%	0.24%
0.39%	0.10%	0.16%	0.15%	0.10%	0.10%	0.11%	0.32%	0.22%	0.09%
0.19%	0.13%	0.36%	0.10%	0.12%	0.15%	0.20%	0.20%	0.19%	0.16%
0.16%	0.13%	0.18%	0.34%	0.28%	0.18%	0.12%	0.17%	0.17%	0.15%
0.10%	0.14%	0.16%	0.18%	0.15%	0.15%	0.08%	0.17%	0.14%	0.25%
0.19%	0.11%	0.14%	0.12%	0.10%	0.10%	0.11%	0.18%	0.15%	0.19%
0.20%	0.10%	0.10%	0.15%	0.14%	0.08%	0.06%	0.11%	0.13%	0.27%
0.28%	0.14%	0.13%	0.13%	0.19%	0.11%	0.08%	0.12%	0.17%	0.19%
0.23%	0.14%	0.13%	0.13%	0.14%	0.07%	0.07%	0.10%	0.17%	0.18%
0.17%	0.16%	0.14%	0.08%	0.04%	0.10%	0.11%	0.11%	0.18%	0.11%
0.36%	0.19%	0.11%	0.07%	0.08%	0.06%	0.06%	0.11%	0.13%	0.12%
0.12%	0.35%	0.18%	0.10%	0.10%	0.06%	0.03%	0.08%	0.15%	0.07%
0.06%	0.06%	0.08%	0.18%	0.05%	0.07%	0.07%	0.22%	0.09%	0.13%

Figure 5.1.3-5: SOM Node Frequencies of Occurrence (%) for the Member with the *Median* Euclidian Distance to the Node Centroid (p_2)



0.32%	0.18%	0.17%	0.19%	0.18%	0.09%	0.13%	0.15%	0.12%	0.26%
0.03%	0.05%	0.05%	0.09%	0.08%	0.05%	0.05%	0.11%	0.15%	0.17%
0.09%	0.05%	0.08%	0.09%	0.11%	0.16%	0.11%	0.07%	0.11%	0.12%
0.08%	0.04%	0.13%	0.09%	0.12%	0.13%	0.13%	0.07%	0.06%	0.17%
0.06%	0.04%	0.10%	0.06%	0.10%	0.13%	0.12%	0.13%	0.09%	0.05%
0.05%	0.02%	0.13%	0.12%	0.11%	0.19%	0.15%	0.09%	0.07%	0.12%
0.11%	0.05%	0.10%	0.12%	0.06%	0.07%	0.06%	0.14%	0.11%	0.06%
0.09%	0.05%	0.17%	0.14%	0.11%	0.10%	0.05%	0.19%	0.05%	0.13%
0.24%	0.07%	0.10%	0.09%	0.06%	0.06%	0.07%	0.18%	0.11%	0.04%
0.12%	0.08%	0.19%	0.05%	0.07%	0.08%	0.11%	0.11%	0.10%	0.09%
0.09%	0.07%	0.11%	0.17%	0.15%	0.11%	0.07%	0.10%	0.09%	0.08%
0.06%	0.08%	0.08%	0.09%	0.08%	0.09%	0.05%	0.10%	0.09%	0.16%
0.12%	0.07%	0.08%	0.07%	0.06%	0.06%	0.06%	0.11%	0.09%	0.13%
0.12%	0.05%	0.06%	0.08%	0.09%	0.05%	0.04%	0.07%	0.08%	0.17%
0.16%	0.07%	0.07%	0.07%	0.11%	0.06%	0.05%	0.07%	0.09%	0.11%
0.11%	0.08%	0.08%	0.07%	0.07%	0.04%	0.05%	0.06%	0.08%	0.10%
0.11%	0.10%	0.08%	0.05%	0.03%	0.06%	0.06%	0.08%	0.09%	0.07%
0.24%	0.13%	0.07%	0.05%	0.05%	0.04%	0.04%	0.06%	0.07%	0.07%
0.08%	0.24%	0.13%	0.06%	0.06%	0.04%	0.02%	0.05%	0.08%	0.05%
0.04%	0.05%	0.06%	0.11%	0.04%	0.05%	0.05%	0.13%	0.05%	0.07%

Figure 5.1.3-6: SOM Node Frequencies of Occurrence (%) for the Member with the *Maximum* Euclidian Distance to the Node Centroid (p_3)

The meteorological conditions associated with this newly expanded SOM are illustrated below for the meteorological variables that most strongly impact the aerosol fate and transport (e.g., 10-meter winds (transport direction and speed), 2-meter relative humidity (decay amplitude), surface sensible heat flux (decay and dispersion amplitude), and planetary boundary layer height (dispersion amplitude)). While the details in any one SOM node are difficult to discern, the images illustrate the main characteristics of the SOM technique—particularly the grouping of similar spatial patterns and overall magnitudes of variables into specific regions of the map and the ability to characterize a wide range of patterns and magnitudes. For example, the 10-meter wind speed patterns, illustrated in Figure 5.1.3-7a, are generally clustered into five main groupings located in the upper left, upper right, lower right, lower left, and center of the map. Wind speeds in the upper left cluster tend to increase from the southeast to the northwest corner of the domain, ranging from < 1 m/s up to approximately 8 m/s throughout the domain. The upper right cluster contains a similar range of wind speeds, but generally contains a southwest to northeast-oriented wind maxima oriented in the center of the region, with lighter winds in the northwestern region of the domain. Maximum speeds characterized in the bottom right and left corners are generally higher (9 – 11 m/s), while maximum speeds in the center grouping are generally lighter (< 5 m/s). Lastly, the overall speed magnitudes suggest that, on average, the winds over this region are between 3 and 5 m/s, which are consistent with climatological observations for this area.

As previously described, the original 200 meteorological patterns (illustrated in Figure 5.1.3-7a, below) were expanded to a total of 600 patterns to better reflect the expected range of meteorological

phenomenon, particularly the more extreme low frequency events. When referring to surface-based wind speeds, these low frequency events tend to correspond with large-scale high wind speed situations as illustrated in Figure 5.1.3-7b and 5.1.3-7c. In general, moving from left to right in Figure 5.1.3-7, the wind speed magnitudes steadily increase, peaking at > 15 m/s, in many of the SOM nodes representing the lowest frequency (< 0.32%) events (Figure 5.1.3-7c). As in Figure 5.1.3-7a, clusters of similar patterns again emerge in the corners and center of the maps (Figure 5.1.3-7b and Figure 5.1.3-7c), with patterns representing the transition between cluster groups located in the remaining regions of the map.

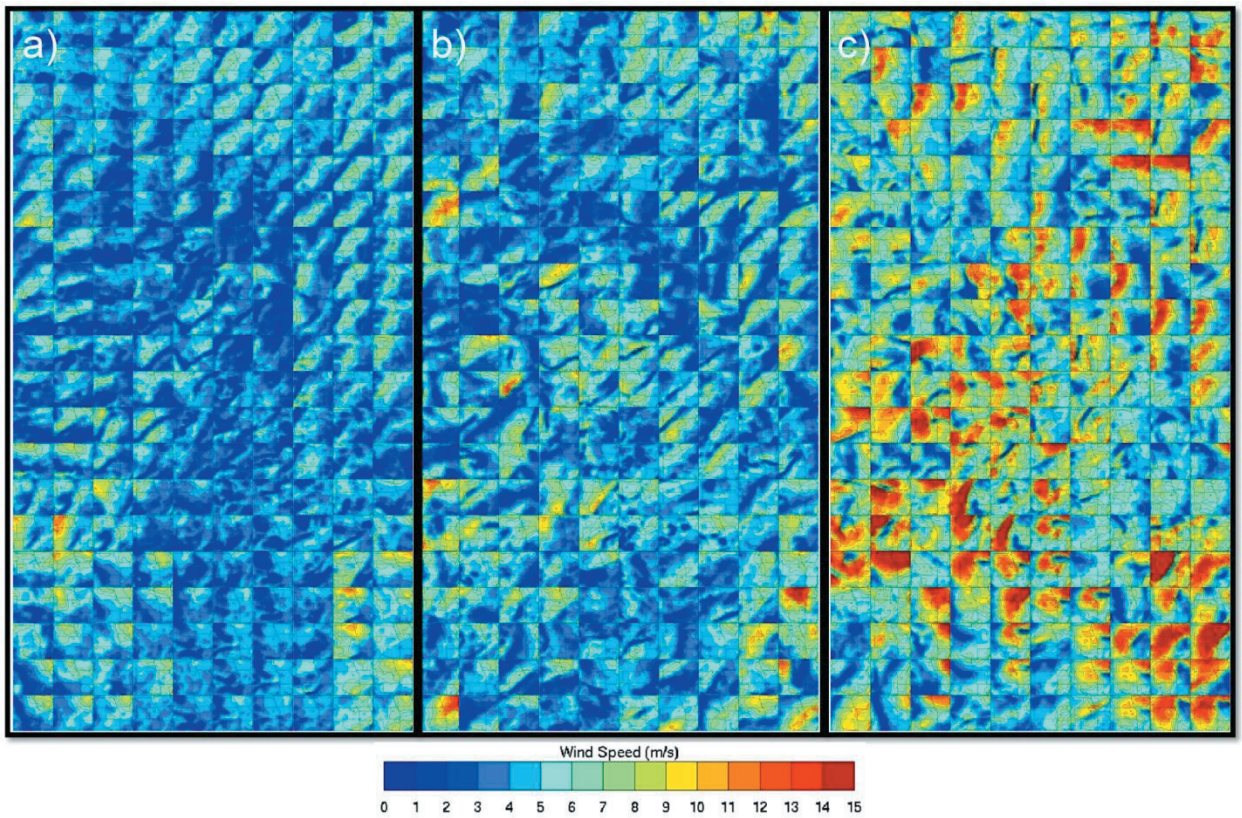


Figure 5.1.3-7: 10-Meter Wind Speed (m/s) for the 1st Hour of SOM Node Members with the a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

As illustrated in Figure 5.1.3-8a, relative humidity patterns appear to group into four major clusters with generally moist conditions in the upper left and lower right quadrants (RH > 85%) and drier conditions in the upper right and lower left quadrants (RH < 60%). Also, the more rare events (Figure 5.1.3-8b and Figure 5.1.3-8c) correspond with much drier conditions, some with humidities lower than 5%. Similarly, the surface sensible heat and planetary boundary layer heights (Figure 5.1.3-9 and Figure 5.1.3-10) also group in these same quadrants, with near zero sensible heating (low boundary layer heights) corresponding with higher humidities and positive surface heating (high boundary layer heights) corresponding to lower humidities as one would ultimately expect.

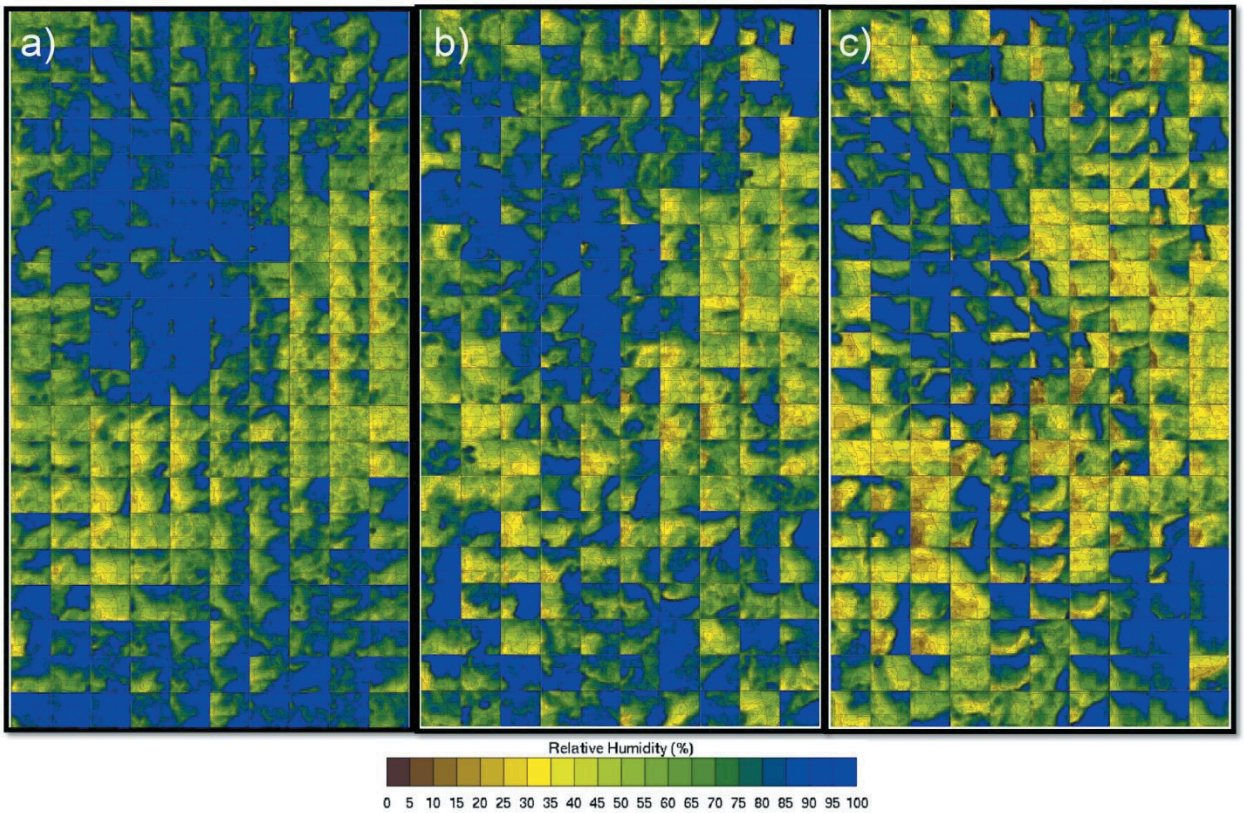


Figure 5.1.3-8: 2-meter Relative Humidity (%) for the 1st Hour of SOM Node Members with the a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

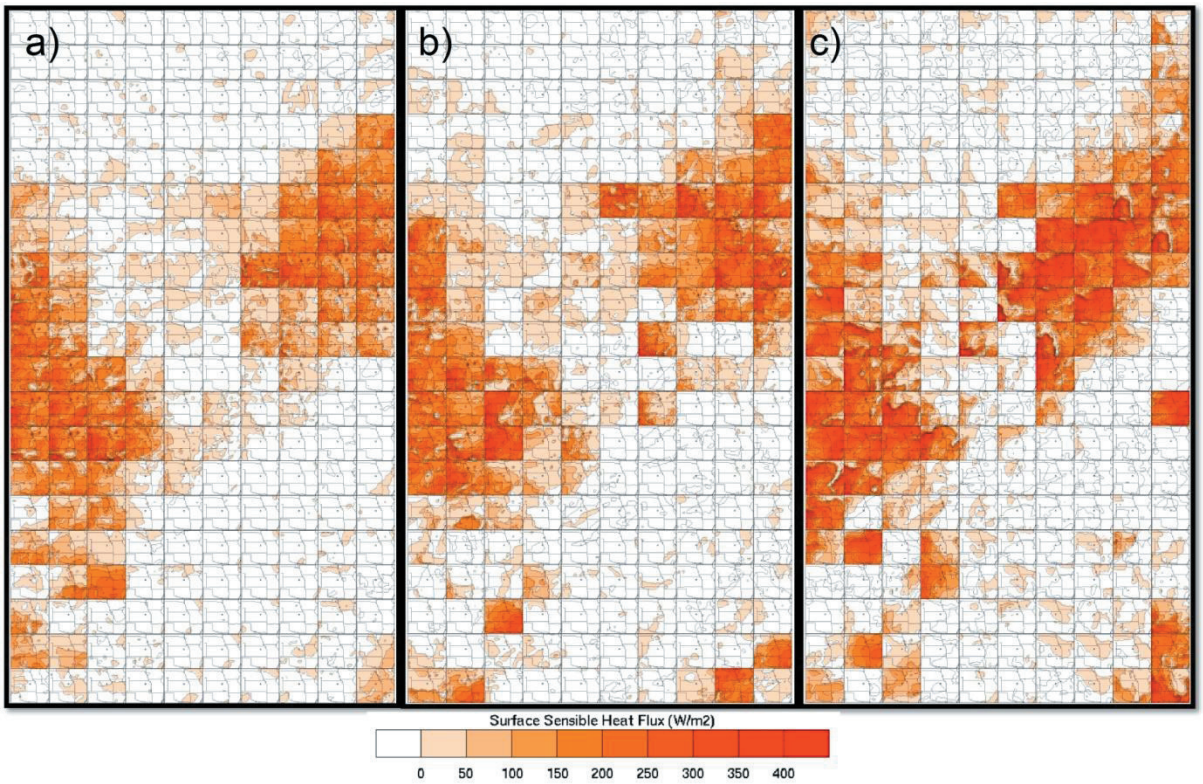


Figure 5.1.3-9: Surface Sensible Heat Flux (W/m²) for the 1st Hour of SOM Node Members with the a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

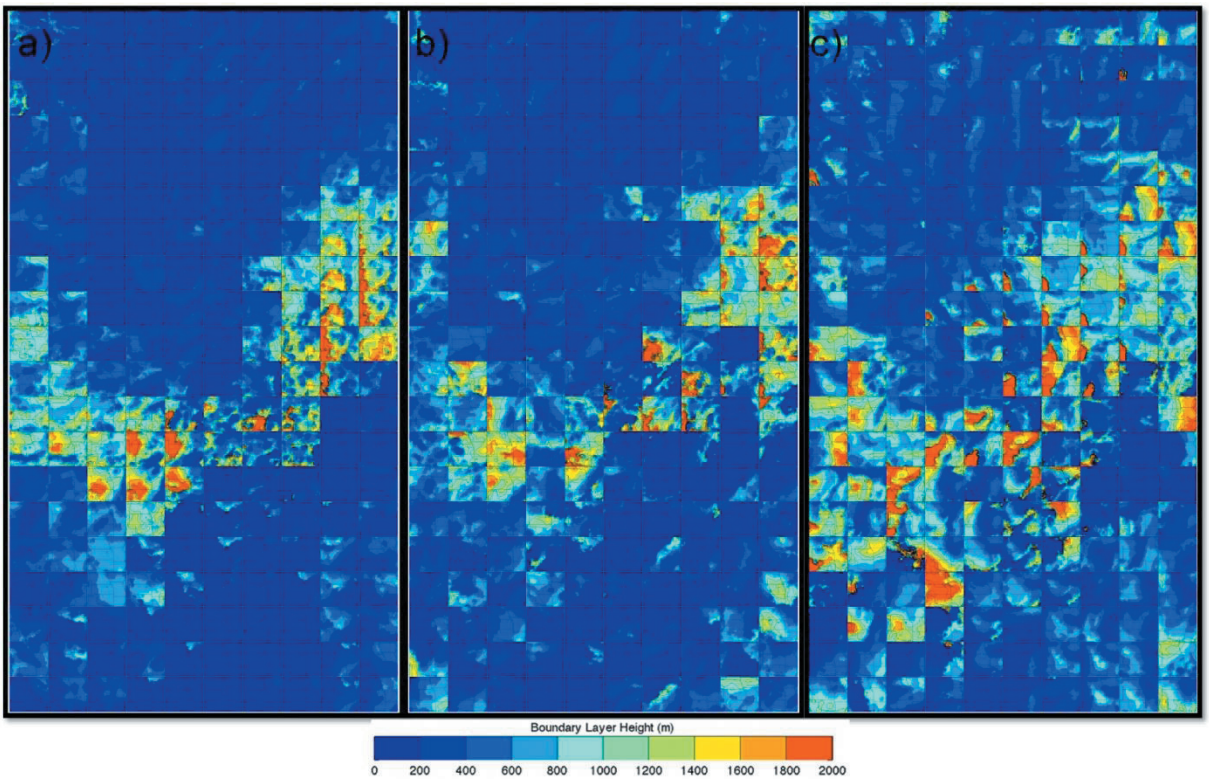


Figure 5.1.3-10: Planetary Boundary Layer Height (m) for the 1st Hour of SOM Node Members with the a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

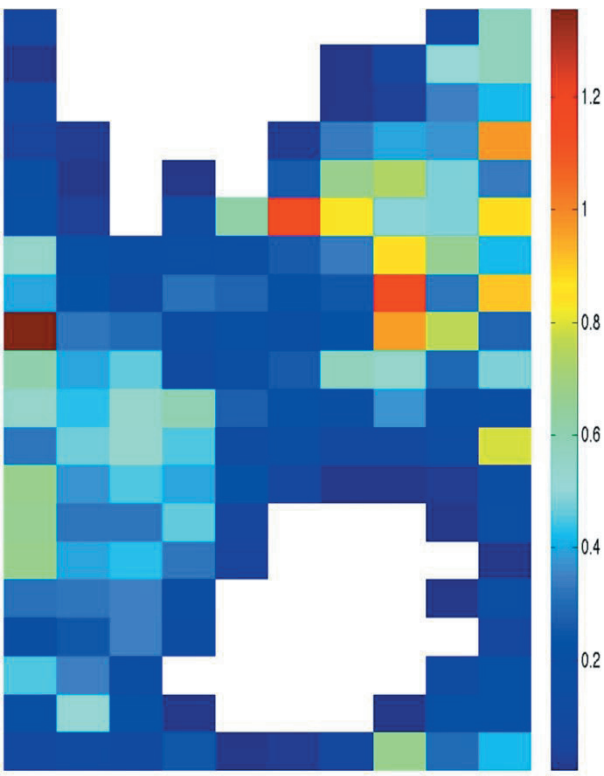
5.1.4 Event-Specific Climate Data Classification

For release events which could occur anytime over a 24-hour period, all 600 meteorological patterns illustrated previously were used to simulate the resulting aerosol fate and transport. For releases that could only occur during a specified portion of the day (e.g., laboratory spill during working hours) or due to a rare natural event (e.g., tornado), these patterns were further reduced to better characterize the likely meteorological conditions. Therefore, release events were classified as occurring during the NBAF regular operating hours (0700-1800 Central), occurring anytime over a 24-hour period, or occurring due to a tornado impact on the facility (Table 5.1.4-1). Subsequently, these classifiers were used to generate two additional meteorological condition matrices representing conditions prevalent during regular working hours (451 unique patterns) and those representative of tornadic conditions (435 patterns), as detailed in the sections below.

Table 5.1.4 1: Meteorological Condition Matrix Criteria

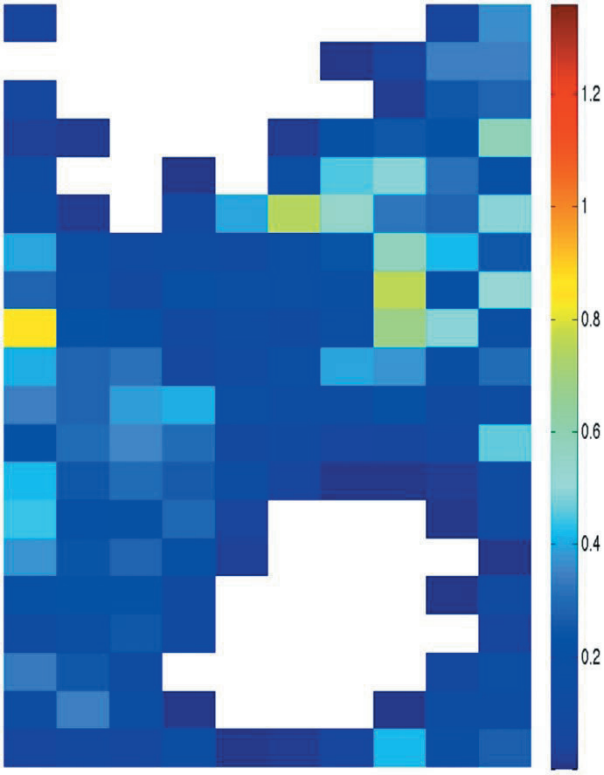
Time of Release	Tornado	Met Matrix ID	Met Patterns
Anytime	NA	allHours	600
0700 1800	NA	workHours	451
Anytime	Tornado Occurred	tornado	435

Meteorological patterns with starting hours contained within the defined operating hours of the NBAF (0700-1800 Central) were extracted from the full membership of each SOM node and subsequently used to update each SOM node's total frequency of occurrence (p_t) and calculate frequencies of occurrence (p_1, p_2, and p_3) for the three representative members of each node (Figure 5.1.4-1, Figure 5.1.4-2, and Figure 5.1.4-3). An interesting outcome of this process is how certain node groupings are removed from the final map, based on the working hour criteria (upper middle, upper left, and lower middle). The 10-meter wind speed for the corresponding minimum, median, and maximum Euclidian distances from the Node Centroid are shown in Figure 5.1.4-4. This result makes intuitive sense when re-examining those groupings within the original SOM maps, particularly the relative humidity, surface sensible heat flux, and height fields (Figure 5.1.4-5, Figure 5.1.4-6, and Figure 5.1.4-7). As shown, it is apparent that these groupings generally correspond with relatively high humidities, zero sensible surface heat fluxes, and small boundary layer heights, all of which are indicative of nighttime conditions. Conversely, the groupings corresponding to the NBAF operating hours (workHours), generally correspond to lower humidities, nonzero surface heat fluxes, and large boundary layer heights (Figure 5.1.3-8, Figure 5.1.3-9, and Figure 5.1.3-10), indicative of daytime conditions.



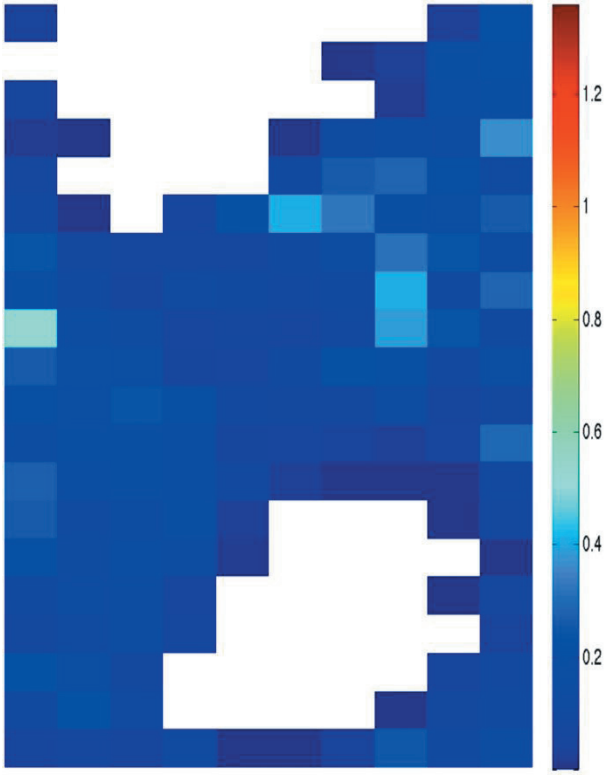
0.0732%	NaN	NaN	NaN	NaN	NaN	NaN	NaN	0.0682%	0.5787%
0.0012%	NaN	NaN	NaN	NaN	NaN	0.0025%	0.0441%	0.5040%	0.5803%
0.0931%	NaN	NaN	NaN	NaN	NaN	0.0012%	0.0283%	0.3505%	0.4198%
0.0396%	0.0126%	NaN	NaN	NaN	0.0189%	0.3350%	0.3940%	0.3777%	0.9742%
0.1825%	0.0012%	NaN	0.0014%	NaN	0.2619%	0.6741%	0.7342%	0.4863%	0.3393%
0.1937%	0.0247%	NaN	0.1234%	0.6187%	1.1386%	0.8350%	0.4958%	0.4875%	0.8782%
0.5440%	0.1970%	0.1549%	0.1702%	0.1738%	0.2612%	0.3318%	0.8401%	0.6630%	0.4175%
0.3935%	0.2314%	0.1122%	0.3145%	0.2853%	0.2236%	0.2479%	1.1360%	0.3250%	0.9125%
1.3579%	0.3217%	0.3071%	0.1494%	0.1960%	0.1508%	0.2248%	0.9559%	0.7560%	0.2849%
0.6084%	0.4025%	0.4577%	0.1169%	0.1772%	0.2567%	0.5802%	0.5458%	0.2899%	0.4799%
0.5422%	0.4298%	0.5444%	0.6038%	0.2749%	0.2029%	0.1825%	0.3746%	0.1506%	0.1882%
0.3291%	0.4771%	0.5312%	0.4534%	0.1195%	0.1522%	0.0803%	0.0767%	0.1316%	0.7873%
0.6768%	0.3762%	0.4473%	0.3944%	0.2305%	0.0652%	0.0012%	0.0107%	0.0182%	0.1599%
0.6667%	0.3220%	0.3199%	0.4643%	0.0456%	NaN	NaN	NaN	0.0031%	0.1706%
0.6725%	0.3997%	0.4296%	0.3291%	0.0381%	NaN	NaN	NaN	NaN	0.0086%
0.3183%	0.3247%	0.3485%	0.1568%	NaN	NaN	NaN	NaN	0.0016%	0.1664%
0.1847%	0.2537%	0.3443%	0.1451%	NaN	NaN	NaN	NaN	NaN	0.0704%
0.4559%	0.3469%	0.1544%	NaN	NaN	NaN	NaN	NaN	0.1196%	0.2090%
0.1984%	0.5114%	0.2186%	0.0012%	NaN	NaN	NaN	0.0045%	0.2076%	0.2115%
0.0939%	0.1115%	0.1048%	0.2523%	0.0048%	0.0137%	0.0810%	0.6702%	0.3018%	0.4224%

Figure 5.1.4-1: *workHours* SOM Node Frequencies of Occurrence (%) for the Member with the *Minimum* Euclidian Distance to the Node Centroid (p_1)



0.0540%	NaN	NaN	NaN	NaN	NaN	NaN	NaN	0.0495%	0.3621%
NaN	NaN	NaN	NaN	NaN	NaN	0.0024%	0.0361%	0.3417%	0.3474%
0.0726%	NaN	NaN	NaN	NaN	NaN	NaN	0.0205%	0.2504%	0.2828%
0.0295%	0.0118%	NaN	NaN	NaN	0.0145%	0.2208%	0.2494%	0.2240%	0.5903%
0.1245%	NaN	NaN	0.0010%	NaN	0.1731%	0.4476%	0.4914%	0.3139%	0.2057%
0.1413%	0.0187%	NaN	0.0905%	0.3961%	0.7481%	0.5509%	0.3252%	0.2826%	0.4935%
0.4031%	0.1498%	0.1144%	0.1232%	0.1170%	0.1701%	0.2379%	0.5784%	0.4237%	0.2453%
0.2801%	0.1719%	0.0798%	0.2017%	0.1716%	0.1627%	0.1823%	0.7558%	0.2101%	0.5166%
0.8579%	0.2252%	0.2078%	0.0953%	0.1187%	0.0968%	0.1646%	0.6796%	0.4896%	0.1814%
0.4130%	0.2826%	0.3189%	0.0750%	0.1122%	0.1739%	0.3958%	0.3732%	0.1821%	0.3071%
0.3466%	0.2813%	0.3926%	0.4054%	0.1713%	0.1306%	0.1346%	0.2215%	0.0975%	0.1333%
0.2241%	0.3075%	0.3585%	0.3078%	0.0846%	0.1019%	0.0615%	0.0457%	0.0913%	0.4583%
0.4249%	0.2484%	0.3044%	0.2639%	0.1489%	0.0505%	0.0012%	0.0085%	0.0128%	0.1240%
0.4405%	0.2113%	0.2149%	0.2885%	0.0353%	NaN	NaN	NaN	0.0030%	0.1219%
0.3802%	0.2395%	0.2854%	0.2066%	0.0290%	NaN	NaN	NaN	NaN	0.0072%
0.2122%	0.2273%	0.2253%	0.1047%	NaN	NaN	NaN	NaN	0.0016%	0.1154%
0.1188%	0.1736%	0.2507%	0.1029%	NaN	NaN	NaN	NaN	NaN	0.0501%
0.3398%	0.2480%	0.1226%	NaN	NaN	NaN	NaN	NaN	0.0841%	0.1693%
0.1435%	0.3409%	0.1511%	0.0011%	NaN	NaN	NaN	0.0035%	0.1457%	0.1438%
0.0631%	0.0852%	0.0709%	0.1599%	0.0041%	0.0116%	0.0578%	0.4233%	0.1873%	0.2736%

Figure 5.1.4-2: *workHours* SOM Node Frequencies of Occurrence (%) for the Member with the *Median* Euclidian Distance to the Node Centroid (p_2)



0.0400%	NaN	NaN	NaN	NaN	NaN	NaN	NaN	0.0317%	0.2078%
NaN	NaN	NaN	NaN	NaN	NaN	0.0022%	0.0241%	0.1868%	0.2008%
0.0525%	NaN	NaN	NaN	NaN	NaN	NaN	0.0141%	0.1531%	0.1840%
0.0198%	0.0064%	NaN	NaN	NaN	0.0116%	0.1211%	0.1485%	0.1321%	0.3617%
0.0723%	NaN	NaN	NaN	NaN	0.1032%	0.2605%	0.2775%	0.1921%	0.1176%
0.0953%	0.0100%	NaN	0.0624%	0.2181%	0.4059%	0.3199%	0.1913%	0.1629%	0.2642%
0.2360%	0.0847%	0.0745%	0.0741%	0.0696%	0.1033%	0.1404%	0.3157%	0.2375%	0.1302%
0.1870%	0.1017%	0.0522%	0.1109%	0.0979%	0.0926%	0.1044%	0.4055%	0.1062%	0.2803%
0.5285%	0.1489%	0.1277%	0.0564%	0.0706%	0.0547%	0.0955%	0.3857%	0.2421%	0.1051%
0.2612%	0.1720%	0.1647%	0.0451%	0.0627%	0.1064%	0.2225%	0.1976%	0.0887%	0.1614%
0.1982%	0.1613%	0.2413%	0.1999%	0.0956%	0.0813%	0.0847%	0.1365%	0.0518%	0.0792%
0.1402%	0.1827%	0.1818%	0.1552%	0.0472%	0.0637%	0.0384%	0.0305%	0.0568%	0.2967%
0.2698%	0.1507%	0.1824%	0.1537%	0.0913%	0.0313%	0.0011%	0.0069%	0.0093%	0.0872%
0.2619%	0.1128%	0.1373%	0.1909%	0.0246%	NaN	NaN	NaN	0.0022%	0.0845%
0.2085%	0.1266%	0.1562%	0.1341%	0.0206%	NaN	NaN	NaN	NaN	0.0056%
0.1001%	0.1331%	0.1445%	0.0645%	NaN	NaN	NaN	NaN	0.0016%	0.0702%
0.0783%	0.1144%	0.1447%	0.0709%	NaN	NaN	NaN	NaN	NaN	0.0360%
0.2333%	0.1639%	0.0810%	NaN	NaN	NaN	NaN	NaN	0.0488%	0.0958%
0.1026%	0.2288%	0.1117%	NaN	NaN	NaN	NaN	0.0027%	0.0782%	0.0975%
0.0445%	0.0665%	0.0496%	0.1083%	0.0030%	0.0090%	0.0414%	0.2519%	0.1000%	0.1480%

Figure 5.1.4-3: *workHours* SOM Node Frequencies of Occurrence (%) for the Member with the *Maximum* Euclidian Distance to the Node Centroid (p_3)

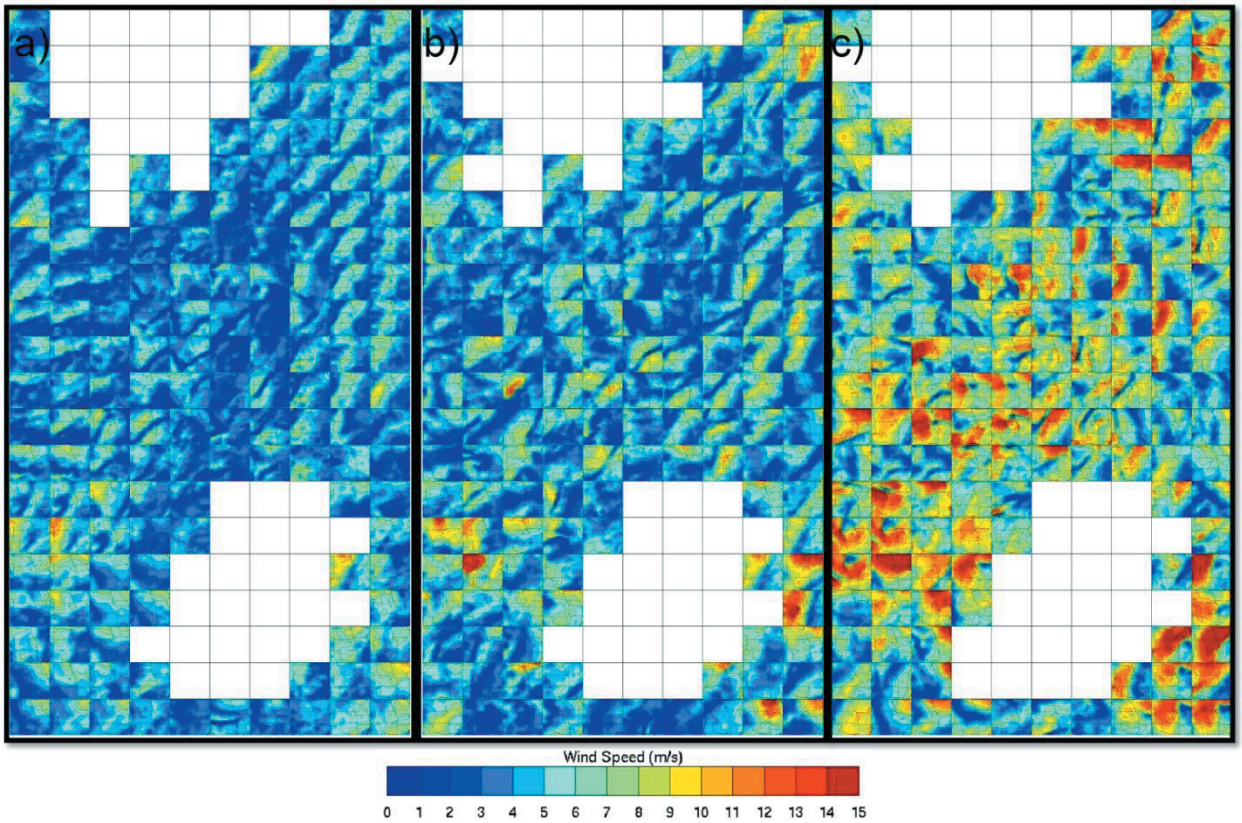


Figure 5.1.4-4: 10-meter Wind Speed (m/s) for workHours SOM Node Members with a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

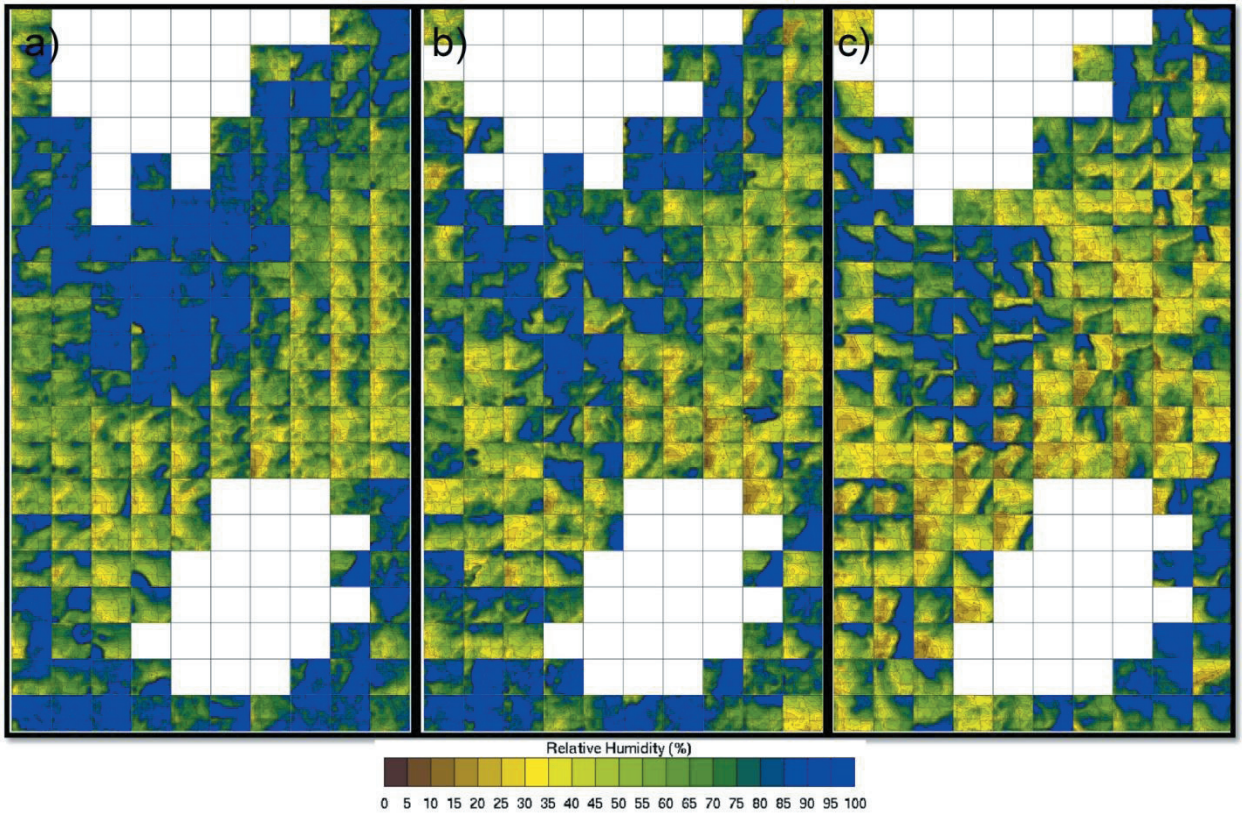


Figure 5.1.4-5: 2-meter Relative Humidity (%) for workHours SOM Node Members with a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

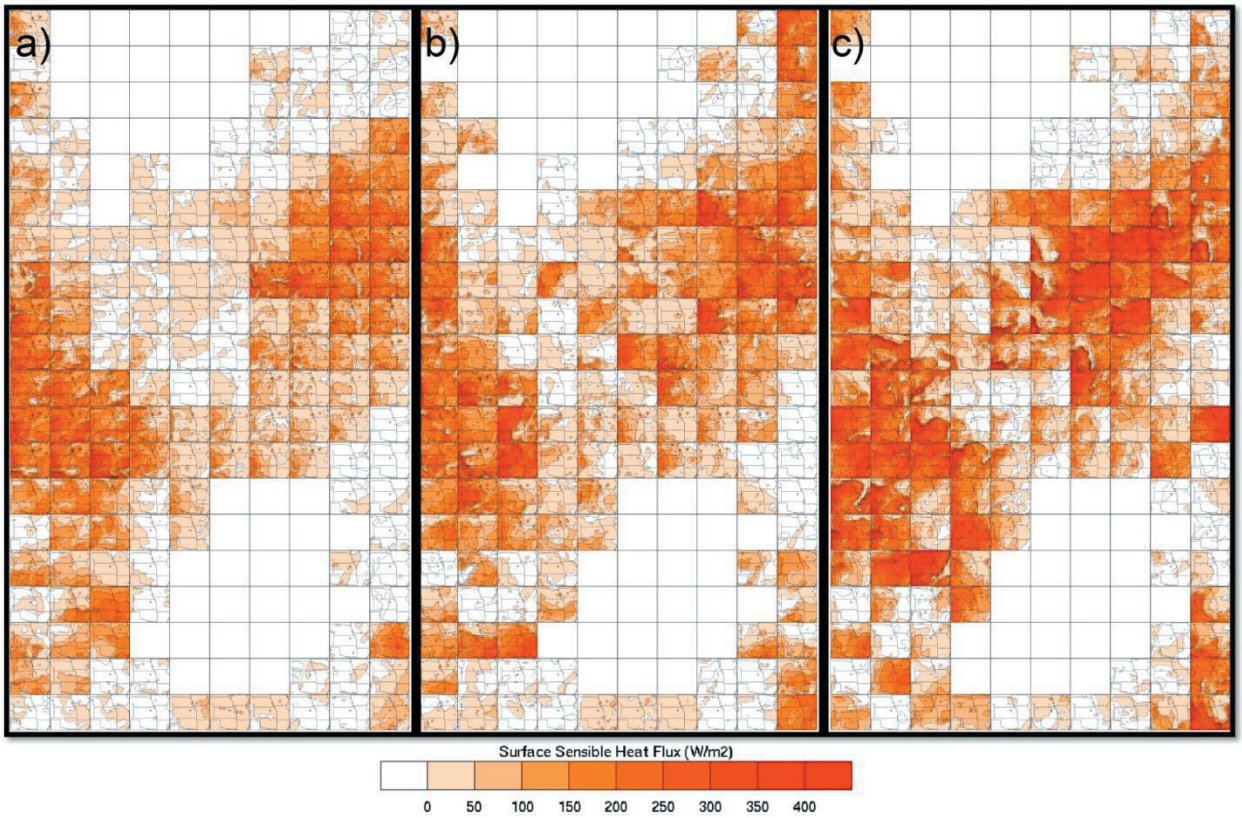


Figure 5.1.4-6: Surface Sensible Heat Flux (W/m²) for workHours SOM Node Members with a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

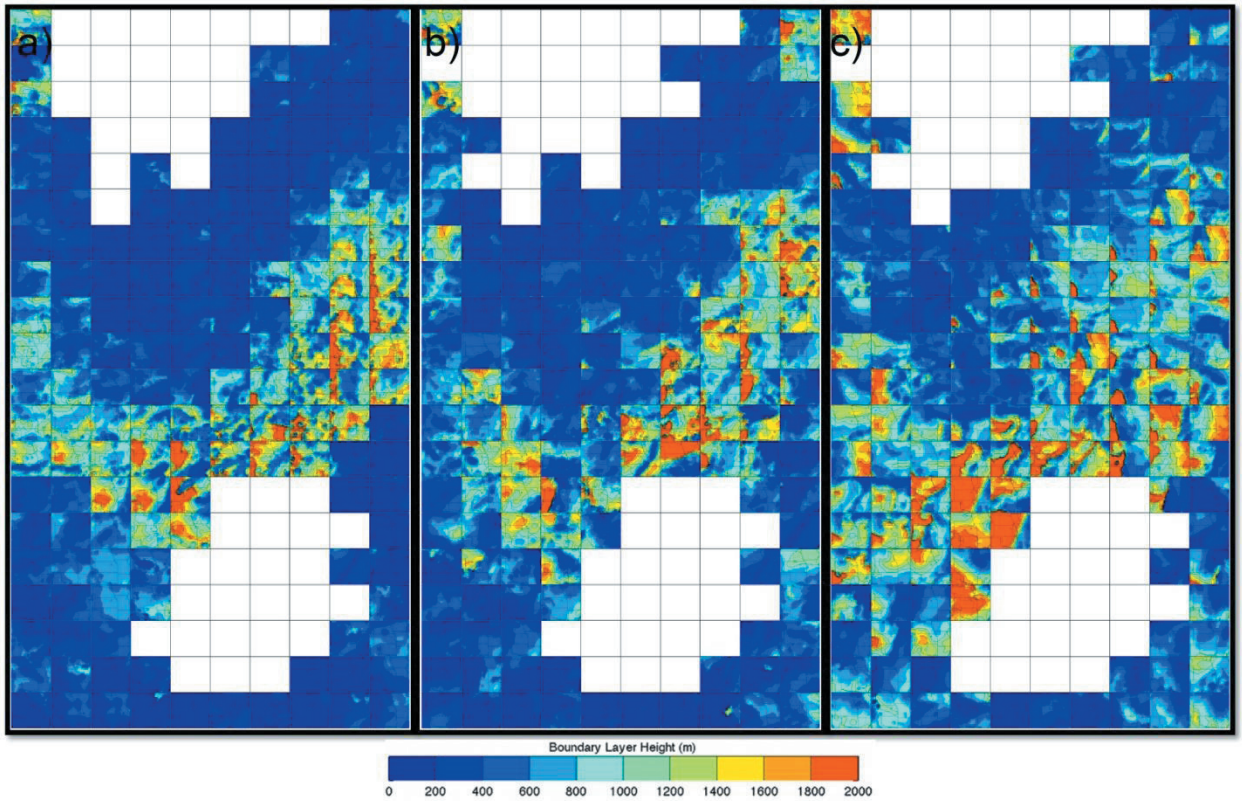


Figure 5.1.4-7: Planetary Boundary Layer Height (m) for workHours SOM Node Members with a) Minimum, b) Median, and c) Maximum Euclidean Distances from the Node Centroid

Each square panel represents the 1000 × 1000 km spatial domain depicted in Figure 5.1.3-1.

As in the 2010 SSRA, and similar to the operating hours classification methodology discussed above, meteorological dates/times from each SOM node were correlated with documented tornado events and used to update each SOM node's total frequency of occurrence, resulting in 72 unique patterns. For this Updated SSRA, a more traditional, non-SOM based approach was utilized to better capture a wider range of atmospheric conditions that are conducive to tornado development. Based on an analysis of historical tornado events (1950–2010), detailed in Appendix A-5, 435 distinct tornadic events were identified within approximately 100 nautical miles of the NBAF site. Subsequently, the dates and times of these events were used to extract the corresponding larger scale meteorological conditions from the full NCAR climatological database, resulting in 435 distinct meteorological patterns, each assigned with an equivalent probability of occurrence (1/435 = 0.0023 = 0.23 %). This expanded set of meteorological conditions was then used to simulate the aerosol fate and transport associated with a tornado impacting the NBAF.

5.1.5 Climate Data Reduction Validation

Before utilizing this reduced climate data set to perform the aerosol fate and transport calculations, it is important to verify that the reduced data set effectively captures the statistical distribution of conditions represented in the original data; particularly those meteorological variables that have the greatest impact on aerosol transport (e.g., wind velocities). Therefore, similar to the raw database

validation exercise described earlier, wind velocity statistics extracted from the full 21-year climatological database were compared to statistics derived from the reduced set of meteorological conditions, from both the 2010 SSRA and the Updated SSRA (Figure 5.1.5-1 and Figure 5.1.5-2). As illustrated in Figure 5.1.5-1b, the original 2010 SSRA reduced dataset did not fully replicate the original distribution of wind velocities as shown in Figure 5.1.5-1a, particularly the higher wind speed (≥ 10 m/s), lower frequency events. It was this discovery that subsequently led to the expansion of the original SOM from 200 to 600 meteorological events for the Updated SSRA. As illustrated in Figure 5.1.5-2, the expanded SOM more accurately replicates most aspects of the original distribution, including the less frequent, high wind events, which are important to include in the final aerosol fate and transport analysis.

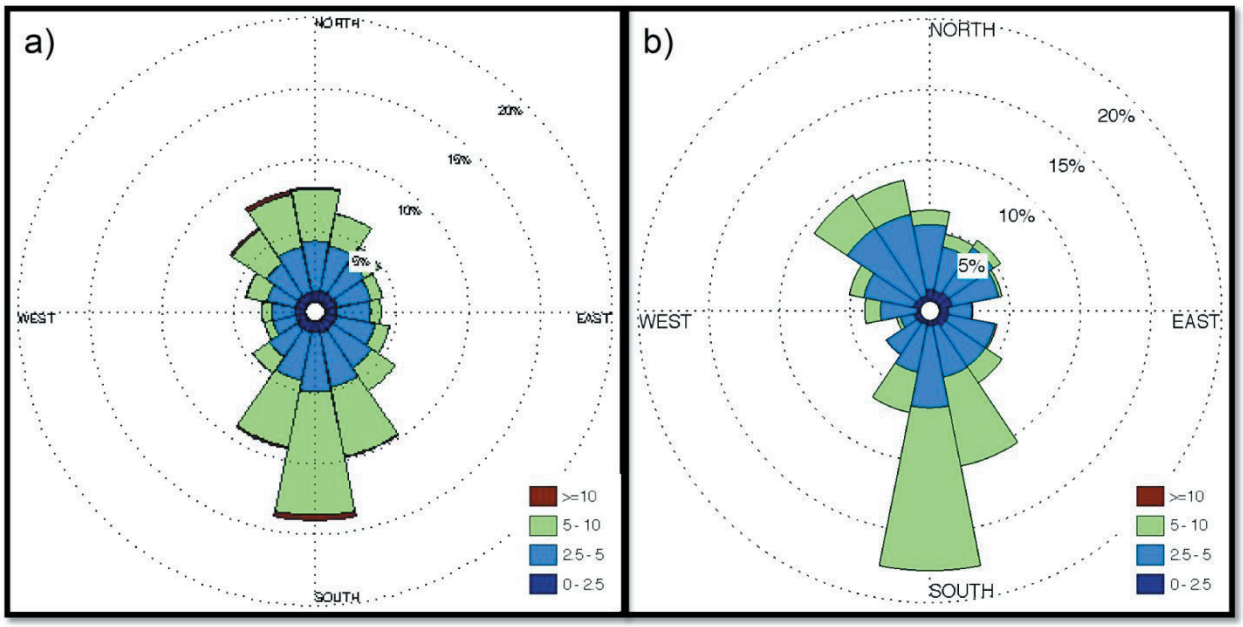


Figure 5.1.5-1: Wind Roses Derived from the a) Full 21-year Climate Database and b) Original 2010 SSRA SOM Reduced Dataset (200 Node Map)

Wind speeds are presented in m/s

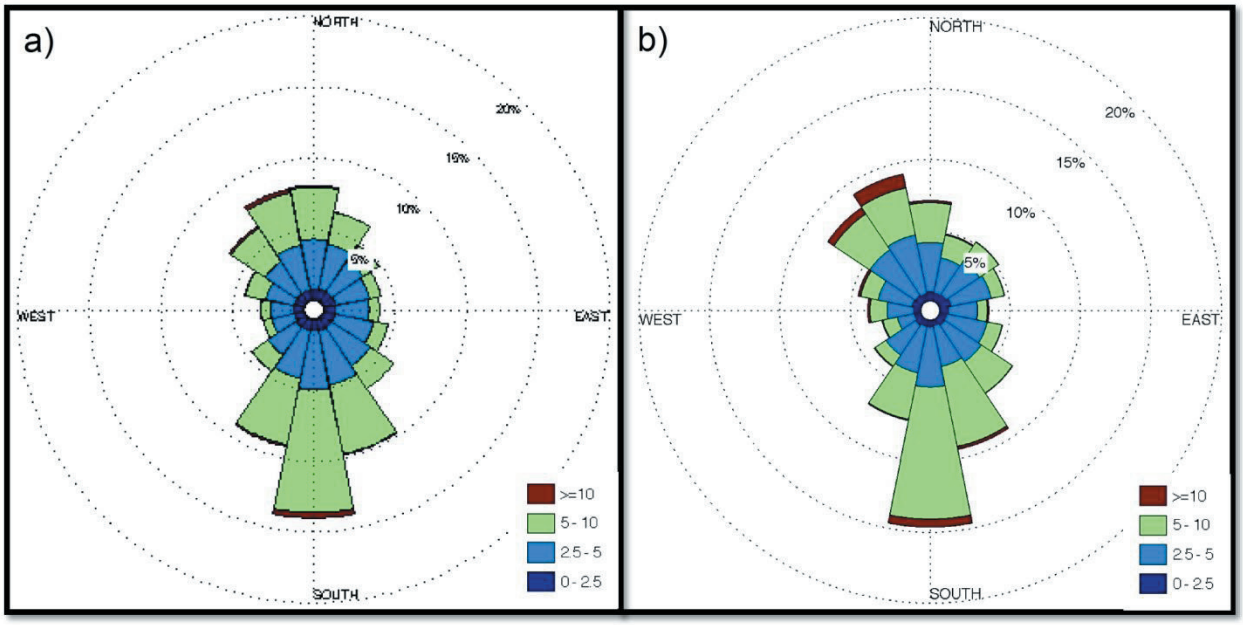


Figure 5.1.5-2: Wind Roses Derived from the a) Full 21-year Climate Database and b) Updated SSRA SOM Reduced Dataset (600 Node Map)

Wind speeds are presented in m/s

5.1.6 SCIPUFF Aerosol Fate and Transport Model

As in the original 2010 SSRA, the Second-order Closure Integrated PUFF model (SCIPUFF), Version 2.4, as described by Sykes, Parker et al. [2008] and recommended as an alternative model by the EPA for air quality regulatory applications, was chosen to perform the aerosol transport calculations. SCIPUFF is a Lagrangian puff model, which uses a collection of three-dimensional Gaussian puffs to represent an arbitrary time varying concentration field. Turbulent diffusion is parameterized using the second-order turbulence closure techniques devised by Donaldson [1973] and Lewellen [1977], which utilize available velocity statistics to predict the associated dispersion rates. SCIPUFF supports the modeling of various material types, including gases, particles, and liquid droplets and their associated size distributions. Particle and droplet dynamic effects are included, particularly dry/wet deposition and material decay. Additionally, a large variety of meteorological inputs are supported.

5.1.7 SCIPUFF Model Configuration

Tables 5.1.7-1 through 5.1.7-3 summarize the SCIPUFF model configuration used for the Updated SSRA. As shown, the aerosol transport computational domain extended approximately 50 km north, south, east, and west of the NBAF and approximately 2.5 km vertically from the ground surface. All aerosol releases were assumed to occur near the center of the proposed facility location at a latitude of 39° 12' 7.9914" N (4342.007 km Northing, UTM Zone 14) and longitude of 96° 34' 50.016" W (708.9186 km Easting, UTM Zone 14). It was assumed that most of the releases occurred through the facility HVAC exhaust stacks located on top of the facility at a planned height of 85 feet (25.908 m), while the non-containment releases were assumed to occur at ground level. Aerosol transport was simulated over a 24

hour period to properly capture the effects of the diurnal cycle. The initial release geometry was based on the designed diameter of the exhaust stacks of 21" (0.5334m) and the planned exhaust exit velocity of 6.34 m/s, by assuming that 99.7% of the horizontal Gaussian puff (3-sigma) was contained within the exhaust stack diameter and that 99.7% (3-sigma) of the vertical puff was exhausted in 1 second from the stack.

Table 5.1.7 1: Updated SSRA SCIPUFF Simulation Configuration

Parameter	Value
Spatial Domain XMIN, XMAX (UTM Zone 14, km)	659.8656, 757.4983
Spatial Domain YMIN, YMAX (UTM Zone 14, km)	4,293.606, 4,390.489
Spatial Domain ZMAX (m)	2,521.336
Simulation Length (hrs)	24
Maximum Time Step (s)	900
Release X Location (UTM Zone 14, km)	708.9186
Release Y Location (UTM Zone 14, km)	4,342.007
Release Z Location (m)	25.908 (HVAC Releases), 0 (Non-containment Release)
Gaussian Puff Initial Dimensions (m), σ_x, σ_y, σ_z	8.89E-02, 8.89E-02, 1.0567
Conditional Averaging Time (s)	0
Terrain/Land Use Effects	On

Table 5.1.7 2: Updated SSRA SCIPUFF FMDv Properties

Parameter	Value
Particle Type	Wet
Mass Units	PFU
Dry Density (kg/m^3)	500
Slurry Fraction	2.0526636 x10^{-2} (lab sample), 0.1468837 (respired aerosol)
Laboratory Sample PSD	Lognormal PSD, MMD = 14.79, σ_g = 2.0 µm
AHR Aerosol PSD	28 Discrete Bins

Table 5.1.7 3: Respired FMDv Aerosol PSD		
Upper (µm)	Lower (µm)	Mass Fraction
0.009	0.01	0.000000743
0.01	0.02	0.0000206
0.02	0.03	0.000032
0.03	0.04	0.0000431
0.04	0.05	0.0000576
0.05	0.06	0.0000591
0.06	0.07	0.0000359
0.07	0.08	0.0000582
0.08	0.09	0.0000454
0.09	0.1	0.0000197
0.1	0.2	0.000149
0.2	0.3	0.000293
0.3	0.4	0.000552
0.4	0.5	0.000716
0.5	0.6	0.000819
0.6	0.7	0.001058
0.7	0.8	0.001205
0.8	0.9	0.00157
0.9	1	0.001335
1	2	0.036599
2	3	0.090498
3	4	0.174425
4	5	0.144776
5	6	0.115365
6	7	0.125527
7	8	0.114297
8	9	0.08911
9	10	0.030855
10	20	0.070478

In order to properly account for dynamic aerosol effects such as gravitational settling and surface deposition, particle size distributions were derived based on the release origin and mechanism. The distribution of aerosol sizes resulting from the spillage of a laboratory sample was modeled as a lognormal distribution with a Mean Mass Diameter (MMD) of 14.79 µm and σg of 2.0 µm [Kenny and Sabel, 1968]. Aerosols generated from animal respiration and animal holding room activities were modeled as a discrete set of size bins (28), ranging in size from 0.009 µm up to 20 µm [Gloster, Williams et al., 2007]. Aerosol particles were modeled within SCIPUFF as a wet particle, which assumes the aerosol is composed of a water droplet spray containing solid particulates. Gravitational settling and deposition rates are based on the size of the water droplets, which shrink or grow based on the ambient relative humidity [Sykes, Parker et al., 2008]. FMDv aerosol modeling uses a dry virus density of 500 kg/m^3 (based on the dry virus density of the smallpox virus), and assuming a slurry fraction (mass

fraction of dry material to water) of 2.0526636×10^{-2} for laboratory samples and 0.1468837 for animal-respired aerosols.

FMDv decay was modeled as a two stage (primary and secondary) decay process, the secondary decay based on time after release and dependent on ambient values of relative humidity and ultraviolet exposure. Primary decay was assumed to occur during transit from the release originating site, within the laboratory, to the facility HVAC exhaust stack, over a 5 minute period (e.g. before the material was released into the open atmosphere), effectively reducing the quantity of material used as input to the SCIPUFF transport model. Secondary decay was then directly calculated within SCIPUFF during aerosol transport, using decay rates derived from ambient levels of relative humidity and ultraviolet exposure (incoming solar radiation).

In order to better account for the local terrain induced effects on the surface layer winds, the 40 km resolution meteorological fields, described in Section 5.1.3, were downscaled to a 1 km horizontal resolution grid by using SCIPUFF's internal mass-consistent model (MC-SCIPUFF). MC-SCIPUFF uses a simplified three dimensional mass-consistent scheme to adjust the interpolated wind fields, ensuring mass conservation (e.g., minimizing the three-dimensional divergence field) using either an iterative Fast Fourier Transform (FFT) solver or point relaxation scheme, depending on the effective terrain gradient magnitude [Sykes, Parker et al. 2008]. The underlying 30 arc-second resolution Digital Terrain Elevation Data (DTED Level 0) used to perform the mass-consistent adjustment was developed by the National Geospatial-Intelligence Agency (NGA) and is illustrated in Figure 5.1.7-1 for the 100 km × 100 km computational domain.

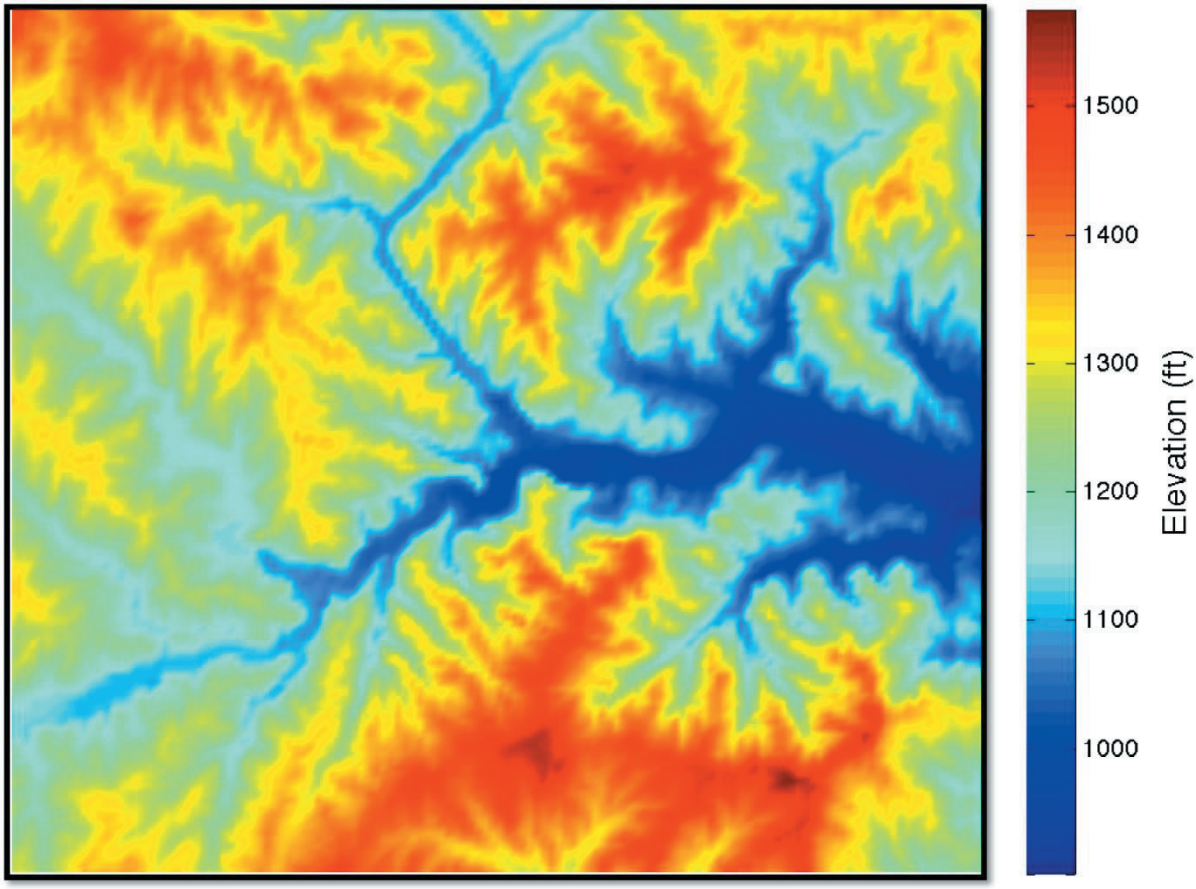


Figure 5.1.7-1: NGA Digital Terrain Elevation Data (DTED) Level 0 (30 arc second resolution) for the 100 × 100 km SCIPUFF Domain and Used in the MC-SCIPUFF Mass-Consistent Adjustment Calculations

The impact of land use on the surface layer wind fields were modeled using a 30 arc-second resolution Land Use/Land Cover (LU/LC) database, developed by Oak Ridge National Laboratory (ORNL) and based on ORNL's Landscan 2006 product. The database contains 24 LU/LC categories, as shown in Table 5.1.7-4. For each category, seasonally varying (winter, spring, summer, and fall) surface properties are defined; including surface roughness, canopy height, canopy flow parameter, albedo, and Bowen ratio (Table 5.1.7-4, for the spring)). Figure 5.1.7-2 illustrates the distribution of LU/LC over the 100 x 100 km SCIPUFF domain.

Table 5.1.7 4: SCIPUFF LU/LC Categories and Associated Surface Parameters (summer, fall, and winter values not shown)

	Roughness (m)	Canopy Height (m)	Velocity Parameter Alpha	Albedo	Bowen Ratio (Dry)	Bowen Ratio (Normal)	Bowen Ratio (Wet)
Developed	2.00E+00	2.00E+01	2.00E+00	1.60E-01	2.00E+00	1.00E+00	5.00E-01
Dry Cropland & Pasture	1.00E-02	1.00E-01	3.00E+00	1.80E-01	2.00E+00	1.00E+00	5.00E-01
Irrigated Cropland	2.00E-02	2.00E-01	2.00E+00	1.80E-01	7.00E-01	5.00E-01	5.00E-01
Missing	5.00E-02	5.00E-01	2.00E+00	1.80E-01	1.00E+00	5.00E-01	3.00E-01
Cropland/Grassland	2.00E-02	2.00E-01	2.50E+00	1.80E-01	1.00E+00	5.00E-01	2.00E-01
Cropland/Woodland	3.00E-01	3.00E+00	1.00E+00	1.50E-01	1.00E+00	5.00E-01	2.00E-01
Grassland	5.00E-02	5.00E-01	2.00E+00	1.80E-01	1.00E+00	5.00E-01	3.00E-01
Shrubland	2.00E-01	2.00E+00	1.00E+00	1.40E-01	1.00E+00	5.00E-01	3.00E-01
Shrubland/Grassland	1.00E-01	1.00E+00	1.50E+00	1.60E-01	1.00E+00	5.00E-01	3.00E-01
Savanna	1.00E-01	1.00E+00	2.00E+00	1.80E-01	1.00E+00	5.00E-01	3.00E-01
Deciduous Broadleaf Forest	1.50E+00	2.00E+01	2.00E+00	1.20E-01	1.50E+00	8.00E-01	3.00E-01
Deciduous Needleleaf Forest	1.50E+00	2.00E+01	2.00E+00	1.20E-01	1.50E+00	8.00E-01	3.00E-01
Evergreen Broadleaf Forest	2.00E+00	2.00E+01	4.00E+00	1.20E-01	1.50E+00	8.00E-01	3.00E-01
Evergreen Needleleaf Forest	2.00E+00	2.00E+01	4.00E+00	1.20E-01	1.50E+00	8.00E-01	3.00E-01
Mixed Forest	1.80E+00	2.00E+01	3.00E+00	1.20E-01	1.50E+00	8.00E-01	3.00E-01
Water	1.00E-04	0.00E+00	0.00E+00	1.20E-01	1.00E-01	1.00E-01	1.00E-01
Herbaceous Wetland	1.00E-01	1.00E+00	1.50E+00	1.20E-01	2.00E-01	1.00E-01	1.00E-01
Wooded Wetland	1.00E+00	1.00E+01	2.00E+00	1.20E-01	4.00E-01	2.00E-01	2.00E-01
Barren	1.00E-03	0.00E+00	0.00E+00	3.00E-01	5.00E+00	3.00E+00	1.00E+00
Herbaceous Tundra	1.00E-02	1.00E-01	2.00E+00	1.80E-01	6.00E-01	3.00E-01	2.00E-01
Wooded Tundra	3.00E-01	3.00E+00	1.00E+00	1.20E-01	8.00E-01	4.00E-01	3.00E-01
Mixed Tundra	1.00E-01	2.00E+00	1.50E+00	1.50E-01	7.00E-01	4.00E-01	3.00E-01
Bare Tundra	1.00E-03	0.00E+00	0.00E+00	3.00E-01	2.00E+00	3.00E+00	1.00E+00
Snow or Ice	1.00E-04	0.00E+00	0.00E+00	6.00E-01	2.00E+00	1.00E+00	5.00E-01
Partly Developed	1.00E+00	1.00E+01	1.00E+00	1.60E-01	2.00E+00	1.00E+00	5.00E-01

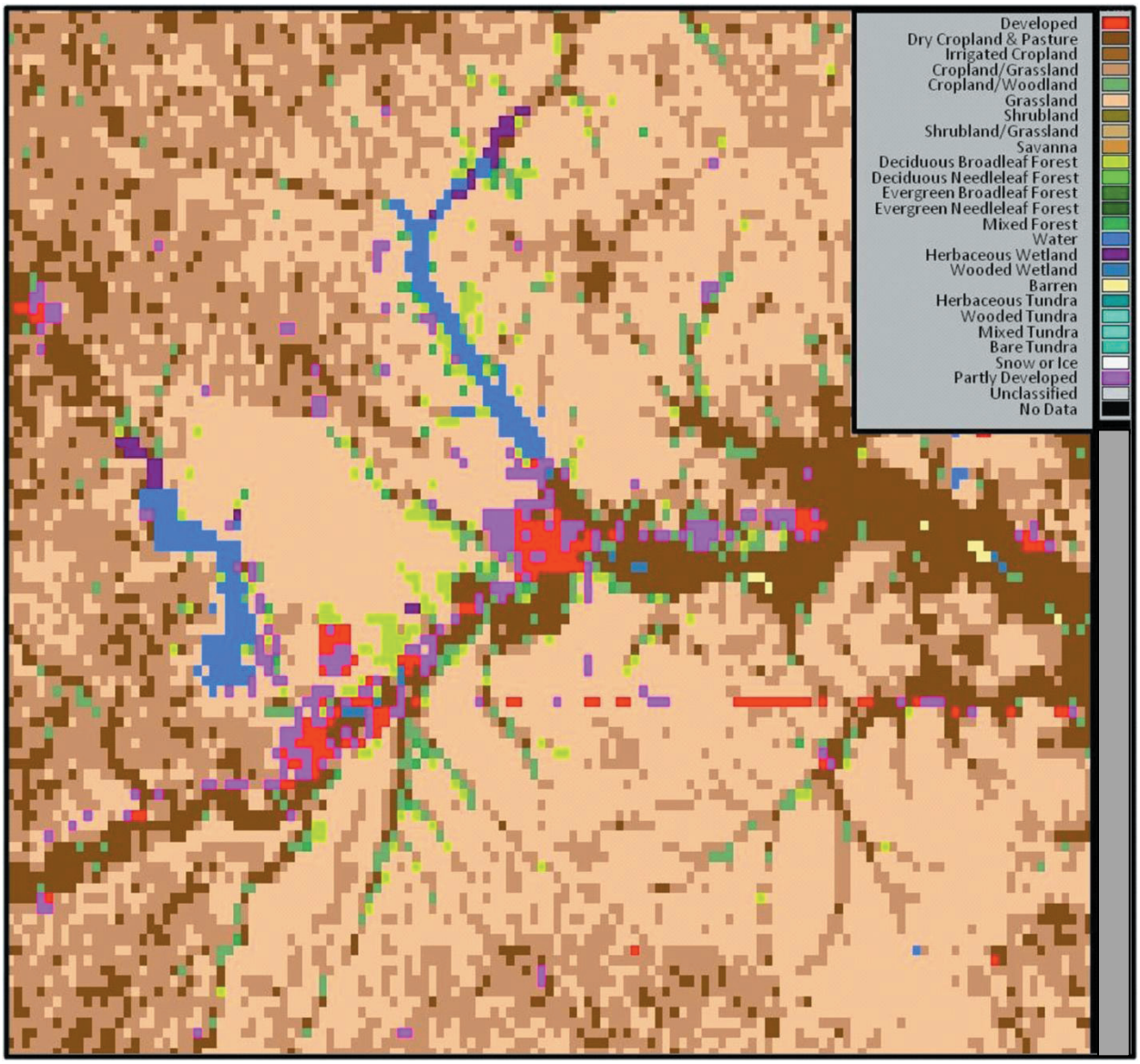


Figure 5.1.7-2: Land Use/Land Cover within the 100 × 100 km SCIPUFF domain

5.1.8 SCIPUFF Model Output and Post Processing

The raw output from the SCIPUFF simulations included instantaneous airborne FMDv aerosol concentration (pfu/m^3), time-integrated airborne concentration (pfu-sec/m^3), and a frequency of occurrence associated with the specific meteorological condition used to drive the simulation as shown, conceptually, in Figure 5.1.8-1 and Figure 5.1.8-2.

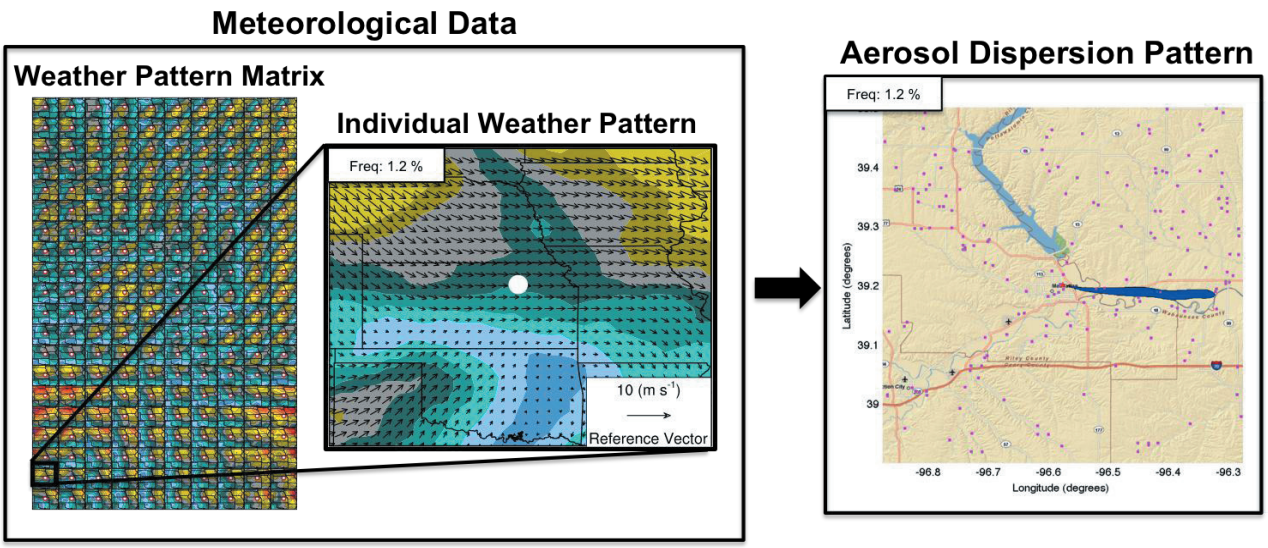


Figure 5.1.8-1: Conceptual Diagram of Aerosol Transport Inputs/Outputs

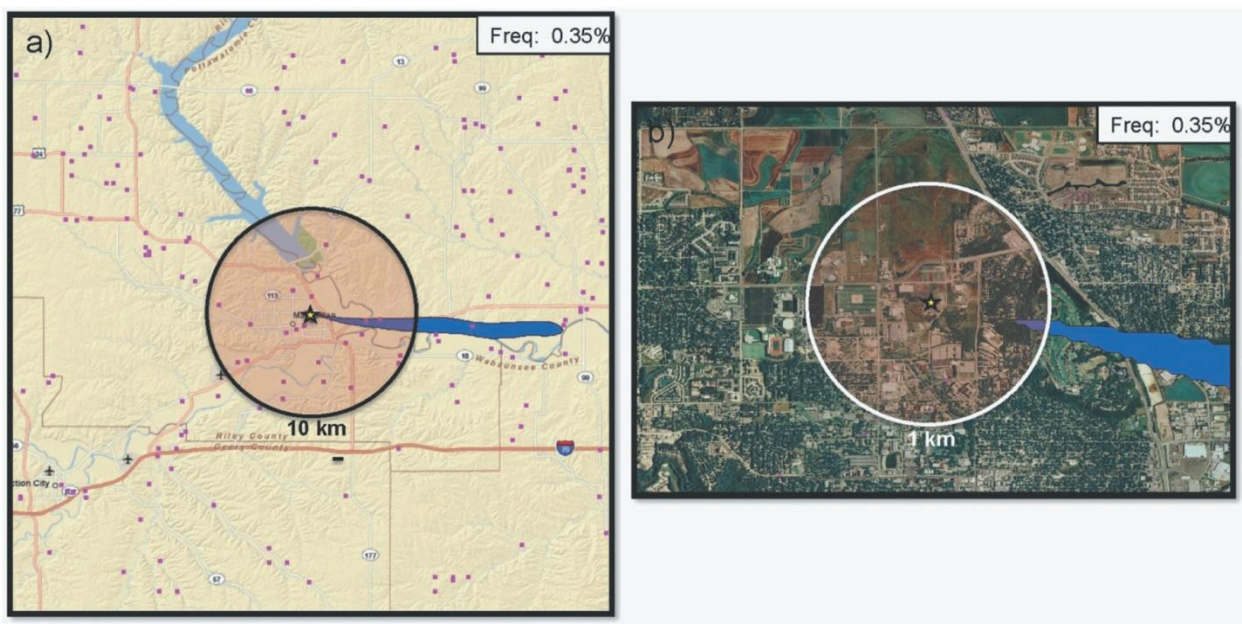


Figure 5.1.8-2: Time-Integrated Airborne Aerosol Concentration Over the a) 100 x 100 km SCIPUFF Domain and b) Area Immediately Surrounding the NBAF

The colored contour represents concentration values greater than or equal to 48.41 pfu-sec/m3. The light purple squares designate susceptible species population locations.

These model outputs were subsequently used to derive inhalation exposure levels for each susceptible species type, including cattle, sheep, swine, and goats. Inhalation exposure, which represents the accumulated quantity of pathogen inhaled over a specified time period, is the product of the time-

integrated concentration and the Minute Tidal Volume (MTV) of the species of interest as shown in the equation below.

$$E = MTV \int c(x, y, z, t)dt \qquad \text{Eq. 5.1.8-1}$$

where, E is inhalation exposure (pfu), MTV is the minute tidal volume (m^3/s), $c(x, y, z, t)$ is the 4-dimensional aerosol concentration field (pfu/m^3) and $\int c(x, y, z, t)dt$ represents the time integrated concentration ($pfu\text{-}s/m^3$) for a specific three dimensional location. As illustrated in Table 5.1.8-1, the average MTV, which represents the volume of air exchanged during respiration in one minute, was estimated for each susceptible species. As indicated, cattle, due to their generally larger size, exchange approximately ten times more air per minute than smaller species. Sheep, swine, and goats all have roughly equivalent respiratory air exchange capacities. A direct consequence of this is that cattle, when exposed to an equivalent time integrated concentration of aerosolized virus, will inhale approximately ten times more virus than the smaller species, as illustrated in Figures 5.1.8-3 and 5.1.8-4.

Table 5.1.8 1: Susceptible Species MTV

Species	MTV (L/min)	MTV (m^3/sec)
Cattle (beef)	123.95	2.1×10^{-3}
Swine	18.28	3.0×10^{-4}
Sheep	12.77	2.1×10^{-4}
Goats	12.77	2.1×10^{-4}

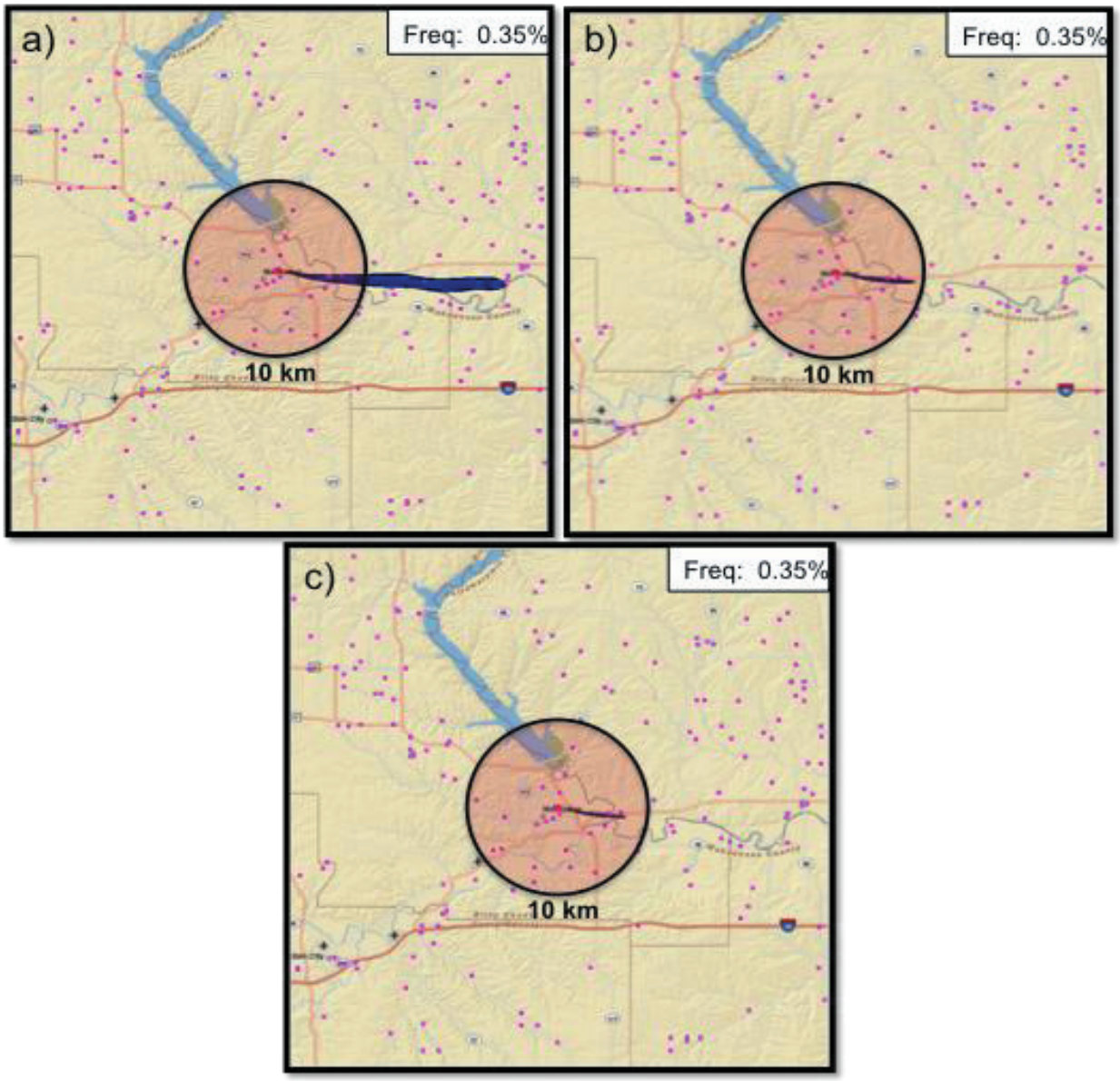


Figure 5.1.8-3: Inhalation Exposure at the Surface for a) Cattle, b) Swine, and c) Sheep from a Hypothetical Release of FMDv

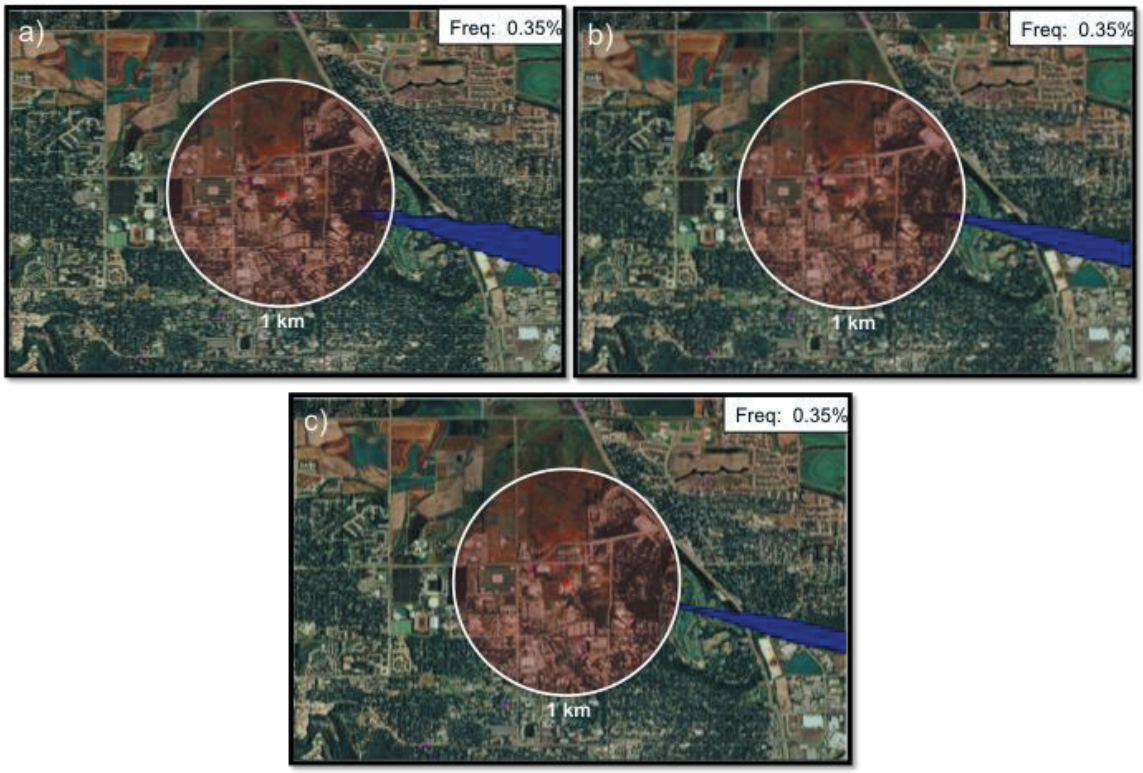


Figure 5.1.8-4: Magnification of Areas shown in Figure 5.1.8-3

In order to determine whether the modeled aerosol release was likely to cause downwind infections, the latest inventory of all farming operations within the state of Kansas was obtained, which included farm location (latitude, longitude), animal species housed on that property (cattle, swine, sheep, or goats), and the corresponding number of animals (Figure 5.1.8-5). These locations were correlated with the inhalation exposure patterns illustrated, as illustrated in Figure 5.1.8-3 and Figure 5.1.8-4, to calculate the inhalation exposure at each location. Infection at each location was initiated when the location specific inhalation exposure exceeded a specified exposure threshold. For the 2010 SSRA, an exposure threshold of 0.1 PFU was used to trigger infection. Based on recommendations by the NAS SSRA Committee, the exposure threshold value is now calculated based on the animal species and the size of the herd at a particular location, using three different approaches. The first approach uses experimental data that relates aerosol exposure to the probability of infection to identify premises that have a 50% or greater chance of having at least one infection. This approach first determines the probability that an individual animal would become infected, given an exposure dose, then, based on the herd size, calculates what individual probability of infection is required to exceed a 50% probability of at least one infection in the herd (Figure 5.1.8-6). The second approach assumes infection occurs if at least one animal in the herd inhales at least 1 PFU. For this approach, the herd is considered a single unit, with a MTV equal to the herd size (number of animals) multiplied by the MTV for one animal. Using this herd MTV, inhalation exposure is then calculated for the entire herd. An infection occurs if the consolidated herd inhalation exposure exceeds 1 PFU (Figure 5.1.8-7). The third approach uses the same methodology but employs published minimum infectious dose (MID) inhalation values (9 PFU for cattle,

7 PFU for sheep, and 150 PFU for swine) to trigger an infection (Figure 5.1.8-8). These methods were subsequently combined to represent three levels of infection risk (high, medium, and low) as a function of herd size for each species, as illustrated in Figures 5.1.8-9 through 5.1.8-11.

The medium and low thresholds were used for the final analysis based on a preliminary assessment of the three methods. The medium (method 2) and low (method 3) thresholds are believed to be the most realistic. The details of this assessment and the associated justification for this decision can be found in Section 6. Using these methods, two location-specific risk threshold values were calculated for each farming operation contained in the Kansas inventory and subsequently correlated with the inhalation exposure at each location to determine whether an infection was triggered. The locations of these infected premises were then used in epidemiological modeling to estimate the subsequent disease spread.

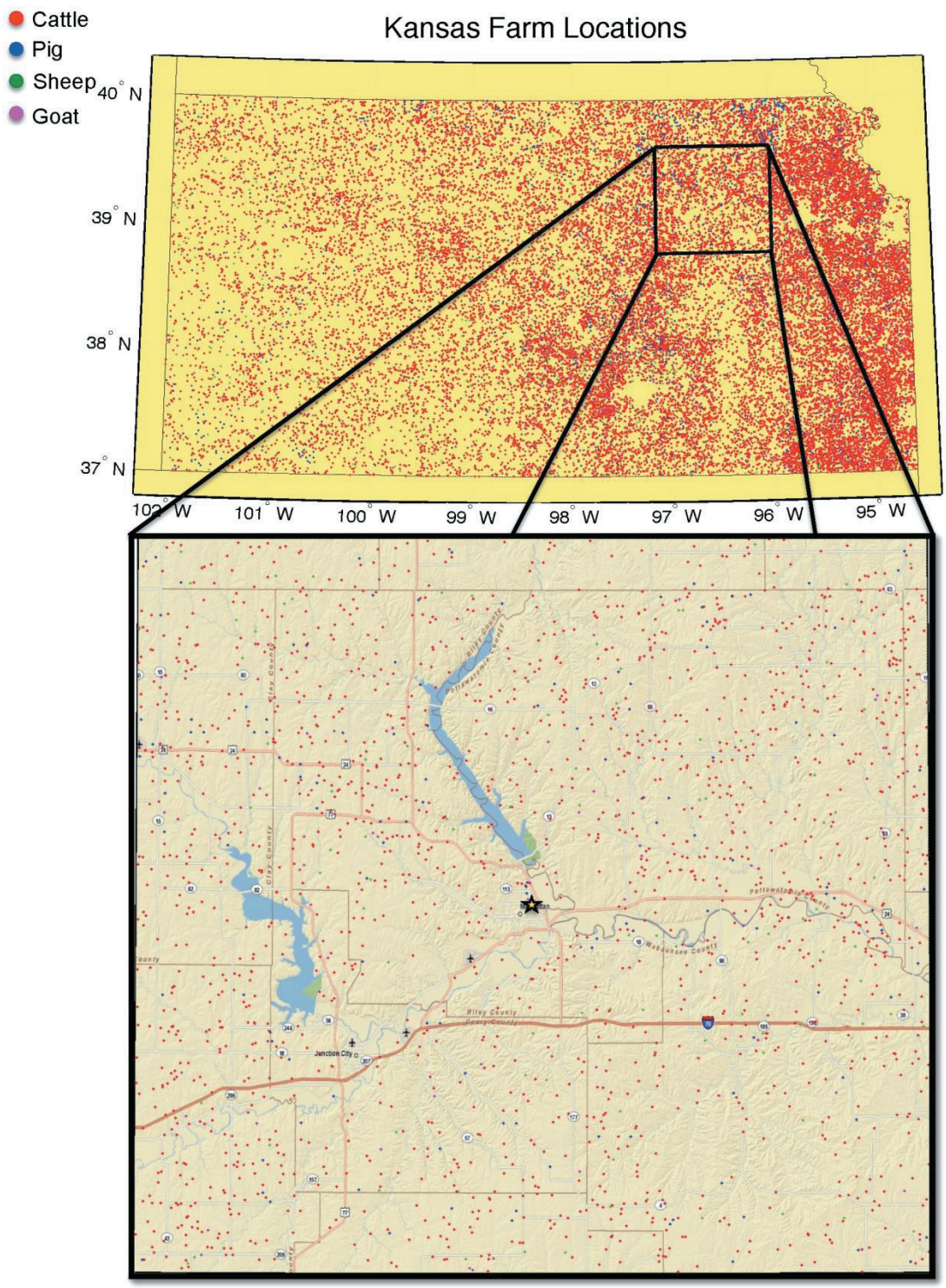


Figure 5.1.8-5: Kansas Farming Operations Statewide (top) and within the 100 x 100 km SCIPUFF Computational Domain (bottom)

The red, blue, green, and magenta dots represent locations of cattle, pig, sheep, and goat operations. The yellow star denotes the approximate location of the NBAF.

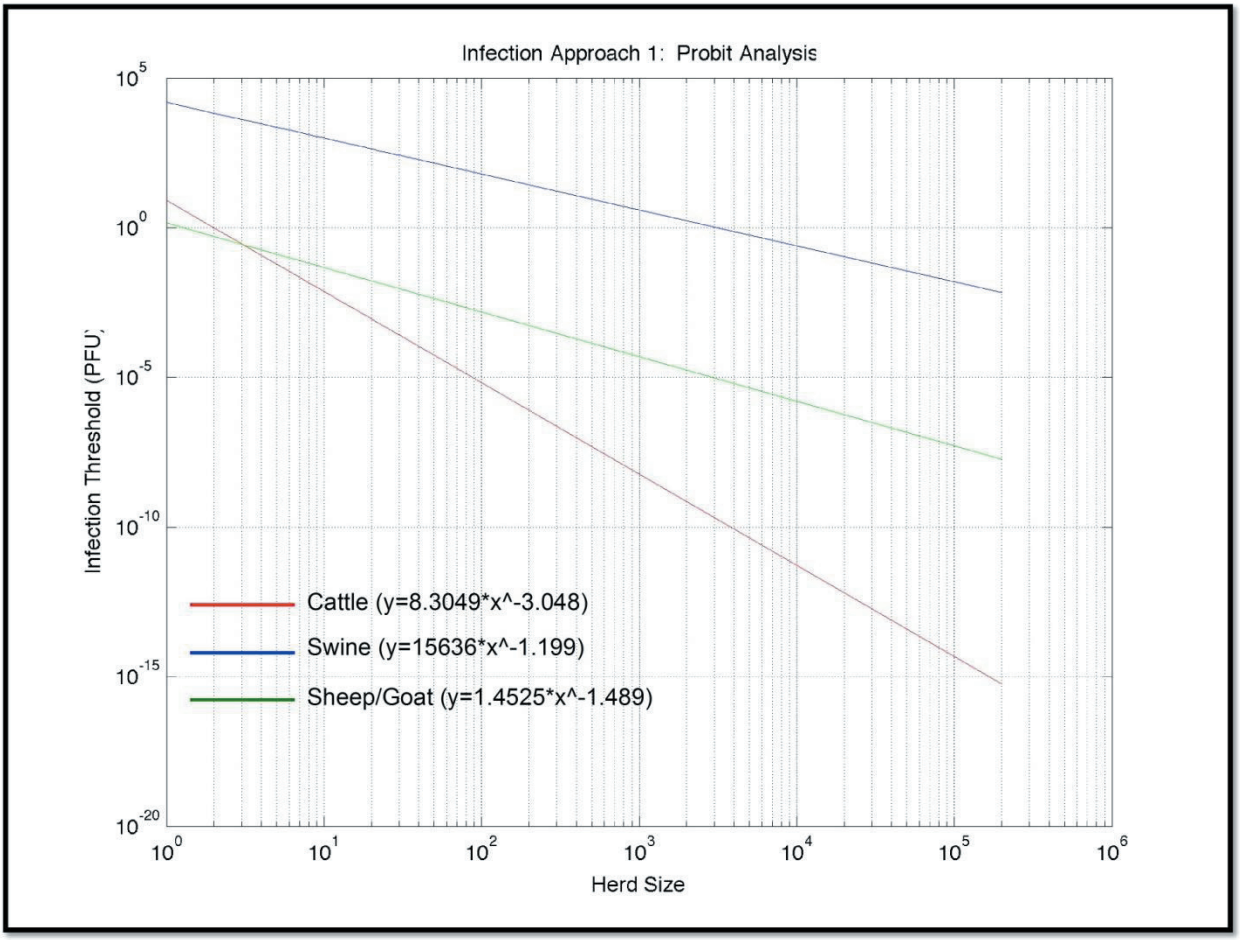


Figure 5.1.8-6: Inhalation Exposure Thresholds for Infection Utilizing Approach 1 (Probit Analysis)

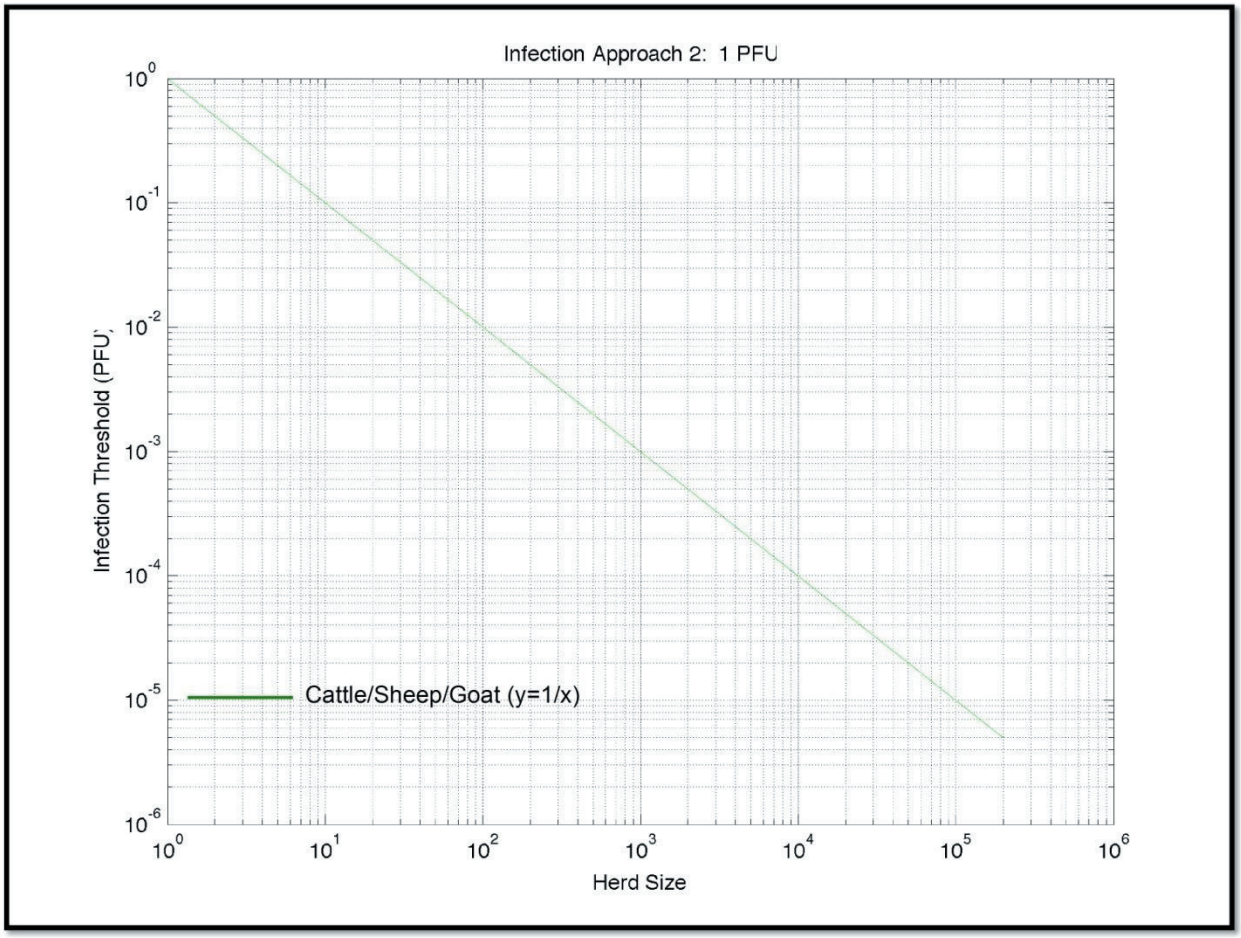


Figure 5.1.8-7: Inhalation Exposure Thresholds for Infection Utilizing Approach 2 (1 PFU)

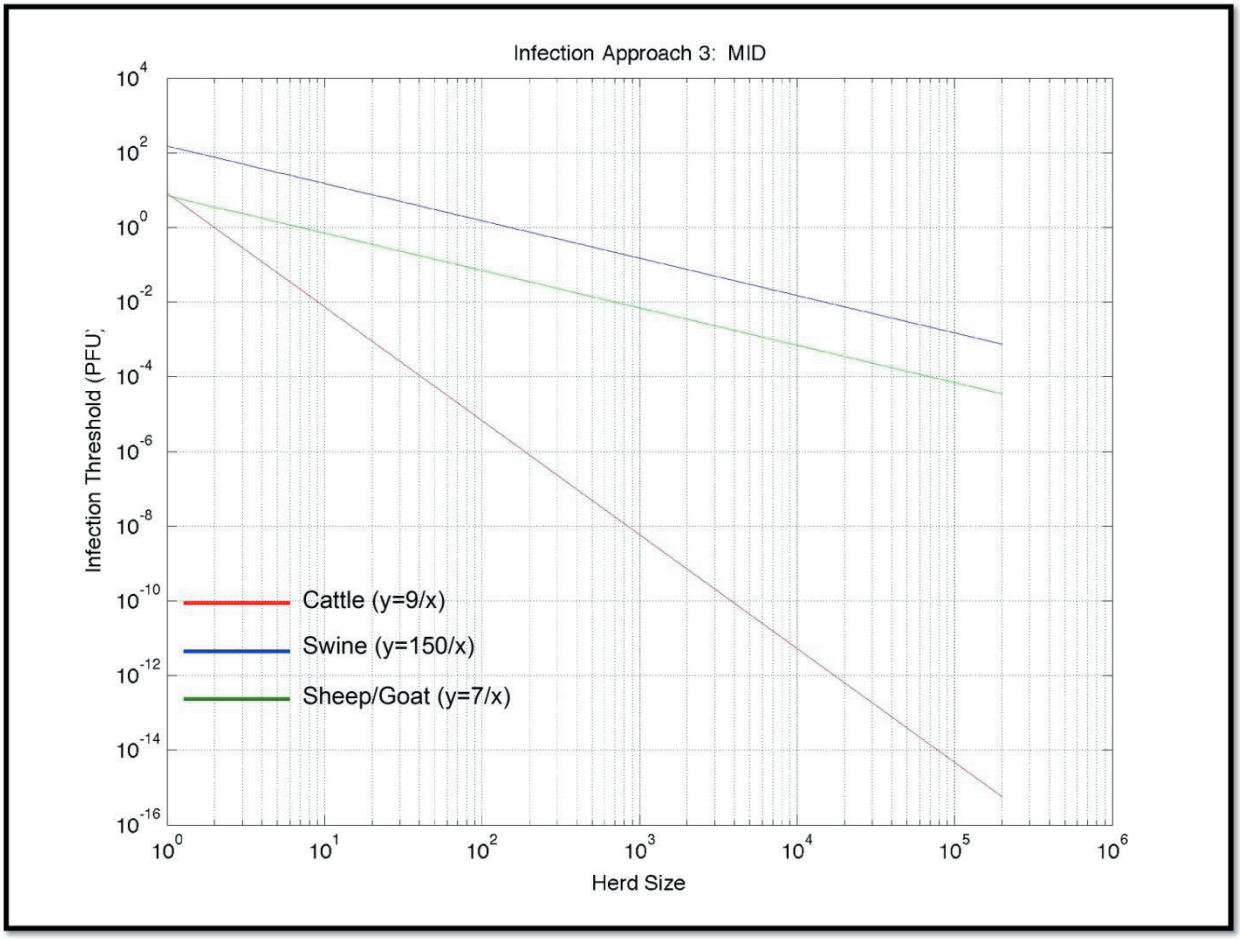


Figure 5.1.8-8: Inhalation Exposure Thresholds for Infection Utilizing Approach 3 (MID)

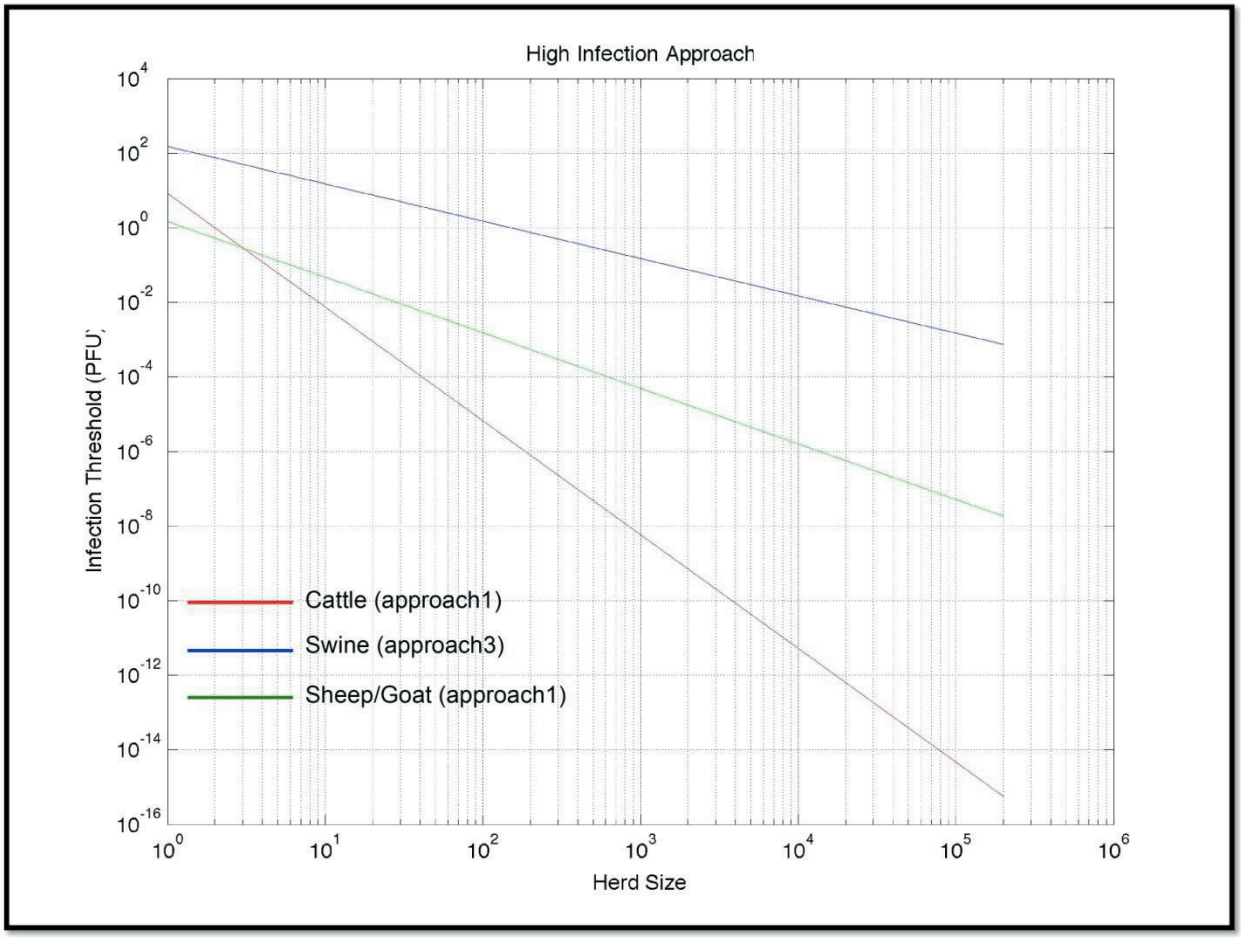


Figure 5.1.8-9: Inhalation Exposure Thresholds for Infection Representing a High Risk of Infection

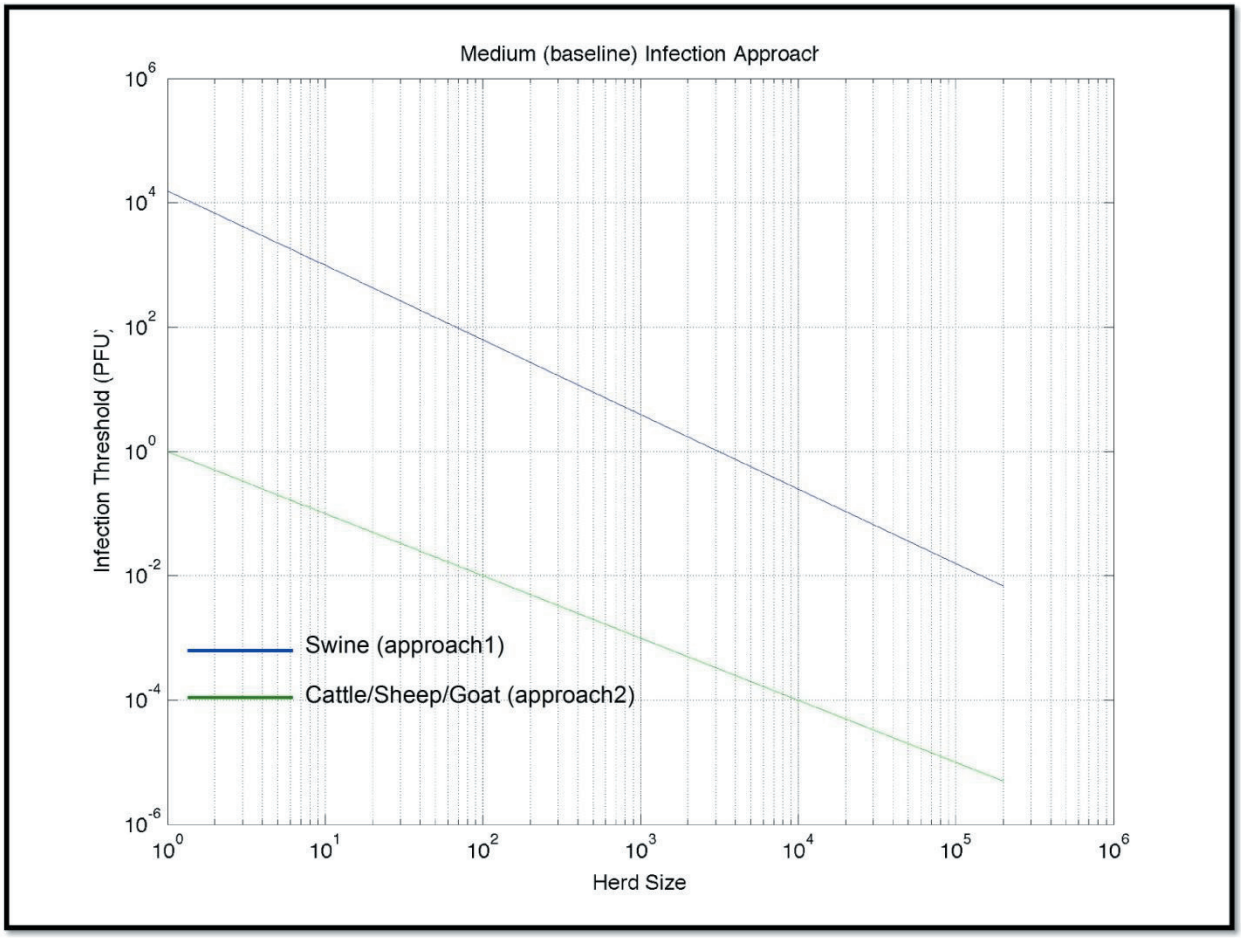


Figure 5.1.8-10: Inhalation Exposure Thresholds for Infection Representing a Medium Risk of Infection

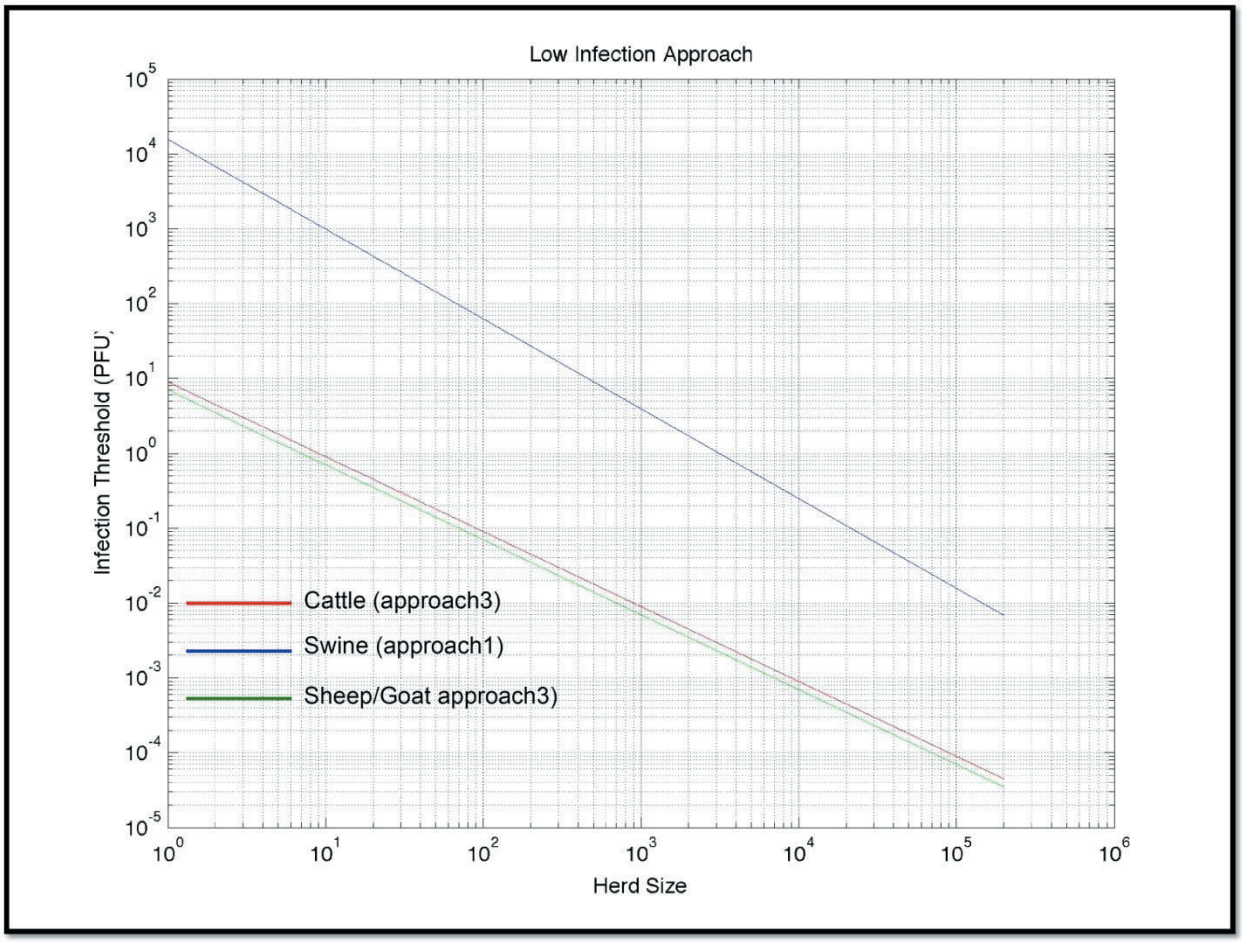


Figure 5.1.8-11: Inhalation Exposure Thresholds for Infection Representing a Low Risk of Infection

5.1.9 Updated SSRA Aerosol Fate and Transport Results

For the Updated SSRA, FMDv aerosol transport simulations were performed for a wide range of release events, representing releases originating from specific areas both inside and outside of the laboratory. As described in Section 4, aerosol releases were assumed to originate from one of three areas within the facility (BSL-3Ag Animal Holding Rooms (AHRs), BSL-3Ag Necropsy, and BSL-3E and BSL-3E "Special Procedure" laboratories) and one location outside of the facility (non-containment area). For each originating location, source term values were estimated, representing low (5th percentile), medium (50th percentile), and high (95th percentile) material amounts. The subsequent amount of material released into the environment was estimated and provided as the initial source amount for the aerosol transport simulations, as summarized in Table 5.1.9-1. As indicated, most of the failure modes for many of the release events resulted in less than 1 PFU being released into the environment. Generally speaking, only release events with failure modes associated with a total failure of the HEPA system, non-containment spills, or catastrophic events (tornado, earthquake) resulted in appreciable quantities of virus being released (greater than 1 PFU). Consequently, aerosol transport simulations were only executed for these events (e.g., releases larger than 1 PFU) to determine whether that particular event/failure mode

resulted in any downwind infections, with the assumption that other accidents (releasing < 1 PFU from containment) would result in no infections. Only a small number of release events/failure modes resulted in subsequent infections, as indicated by the red cells in Table 5.1.9-1. In particular, for the releases which originated from locations inside the NBAF (BSL-3E, BSL-3Ag Necropsy, BSL-3Ag AHR), only those involving a total HEPA system failure (EA10, NA10, AA10) and with the highest source terms (95th percentile) resulted in downwind infections. The release of agent associated with shipping container failure modes occurring outside containment (OA2 and OA3) also produced infections, but once again only for the highest source terms (95th percentile). The catastrophic release events, associated with natural disasters such as tornadoes and earthquakes, also caused downwind infections, but only for the medium and high source strengths (50th percentile and 95th percentile, respectively). It should be noted that the release event associated with a design basis tornado striking the facility did not result in infections for any of the release amount strengths because the modeled release fraction is very low at the design basis wind speed but increases with higher wind speed events. A more detailed analysis of each major release event and its associated consequences is provided in the following sections.

Table 5.1.9 1: Summary of FMDv Aerosol Transport Simulations

Event ID	Originating Location	Release Opportunities	*Q* Values (PFU)			PSD Type
			Low	Medium	High	
AA1	AHR	All	4.56E-09*	4.01E-06*	3.55E-03*	Respired
AA2	AHR	All	6.16E-08*	5.41E-05*	4.79E-02*	Respired
AA3	AHR	All	1.54E-06*	1.36E-03*	1.20E+00*	Respired
AA4	AHR	All	1.18E-07*	1.04E-04*	9.22E-02*	Respired
AA5	AHR	All	1.60E-06*	1.41E-03*	1.25E+00*	Respired
AA6	AHR	All	3.08E-06*	2.71E-03*	2.40E+00*	Respired
AA7	AHR	All	4.56E-09*	4.01E-06*	3.55E-03*	Respired
AA8	AHR	All	1.18E-07*	1.04E-04*	9.22E-02*	Respired
AA9	AHR	All	3.08E-06*	2.71E-03*	2.40E+00*	Respired
AA10	AHR	All	4.56E+01*	4.01E+04*	3.55E+07*	Respired
AA11	AHR	All	0.00E+00	0.00E+00	0.00E+00	Respired
NA1	Necropsy	Working Hours	6.65E-10*	1.74E-07*	1.39E-03*	Laboratory
NA2	Necropsy	Working Hours	8.98E-09*	2.35E-06*	1.87E-02*	Laboratory
NA3	Necropsy	Working Hours	2.25E-07*	5.90E-05*	4.70E-01*	Laboratory
NA4	Necropsy	Working Hours	1.73E-08*	4.53E-06*	3.60E-02*	Laboratory
NA5	Necropsy	Working Hours	2.33E-07*	6.12E-05*	4.87E-01*	Laboratory
NA6	Necropsy	Working Hours	4.50E-07*	1.18E-04*	9.38E-01*	Laboratory
NA7	Necropsy	Working Hours	6.65E-10*	1.74E-07*	1.39E-03*	Laboratory
NA8	Necropsy	Working Hours	1.73E-08*	4.53E-06*	3.60E-02*	Laboratory
NA9	Necropsy	Working Hours	4.50E-07*	1.18E-04*	9.38E-01*	Laboratory
NA10	Necropsy	Working Hours	6.65E+00*	1.74E+03*	1.39E+07*	Laboratory
NA11	Necropsy	Working Hours	0.00E+00	0.00E+00	0.00E+00	Laboratory
EA0	BSL-3E/BSL-3E SP	Working Hours	0.00E+00	0.00E+00	0.00E+00	Laboratory
EA1	BSL-3E/BSL-3E SP	Working Hours	1.02E-14	3.46E-10	1.18E-05	Laboratory
EA2	BSL-3E/BSL-3E SP	Working Hours	1.38E-13	4.67E-09	1.59E-04	Laboratory

Table 5.1.9 1: Summary of FMDv Aerosol Transport Simulations

Event ID	Originating Location	Release Opportunities	*Q* Values (PFU)			PSD Type
			Low	Medium	High	
EA3	BSL-3E/BSL-3E SP	Working Hours	3.45E-12	1.17E-07	3.99E-03	Laboratory
EA4	BSL-3E/BSL-3E SP	Working Hours	2.65E-13	8.99E-09	3.07E-04	Laboratory
EA5	BSL-3E/BSL-3E SP	Working Hours	3.58E-12	1.21E-07	4.14E-03	Laboratory
EA6	BSL-3E/BSL-3E SP	Working Hours	6.90E-12	2.34E-07	7.98E-03	Laboratory
EA7	BSL-3E/BSL-3E SP	Working Hours	1.02E-14	3.46E-10	1.18E-05	Laboratory
EA8	BSL-3E/BSL-3E SP	Working Hours	2.65E-13	8.99E-09	3.07E-04	Laboratory
EA9	BSL-3E/BSL-3E SP	Working Hours	6.90E-12	2.34E-07	7.98E-03	Laboratory
EA10	BSL-3E/BSL-3E SP	Working Hours	1.02E-04	3.46E+00	1.18E+05	Laboratory
EA11	BSL-3E/BSL-3E SP	Working Hours	0.00E+00	0.00E+00	0.00E+00	Laboratory
OA1	Non-containment	Working Hours	0.00E+00	0.00E+00	0.00E+00	Laboratory
OA2	Non-containment	Working Hours	9.18E-05	3.11E+00	1.06E+05	Laboratory
OA3	Non-containment	Working Hours	1.02E-04	3.46E+00	1.18E+05	Laboratory
Tornado	NBAF	All	1.57E+06*	3.58E+06*	2.48E+10*	Respired
Earthquake	NBAF	All	1.51E+04*	5.29E+04*	4.96E+08*	Respired

Red cells indicate that at least one infection resulted from the loss of containment.
*Modeled value is different from *Q* value in Table 4.7-1 but of the same order of magnitude.

5.1.9.1 BSL-3Ag Animal Holding Rooms

A detailed summary of infections resulting from all BSL-3Ag AHR originating aerosol releases is provided in Table 5.1.9-2. Downwind infections occurred only during total failure of the HEPA filtration system (AA10), and only with the highest (95th percentile) source term of approximately 10^7 PFU. The number of infected locations is presented for each method used to calculate the infection risk and the maximum number of infections for each event is provided. All other non-catastrophic aerosol-associated events resulted in no premises becoming infected over the range of modeled source terms and meteorological conditions. A more detailed analysis of the AA10 event with the high source term simulation results is provided below.

Table 5.1.9 2: BSL 3Ag AHR Aerosol Release Results									
Event ID	*Q* Value Range	Maximum Number of Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
AA1	High	0	0	0	0	0	0	0	0
AA1	Medium	0	0	0	0	0	0	0	0
AA1	Low	0	0	0	0	0	0	0	0
AA2	High	0	0	0	0	0	0	0	0
AA2	Medium	0	0	0	0	0	0	0	0
AA2	Low	0	0	0	0	0	0	0	0
AA3	High	0	0	0	0	0	0	0	0
AA3	Medium	0	0	0	0	0	0	0	0
AA3	Low	0	0	0	0	0	0	0	0
AA4	High	0	0	0	0	0	0	0	0
AA4	Medium	0	0	0	0	0	0	0	0
AA4	Low	0	0	0	0	0	0	0	0
AA5	High	0	0	0	0	0	0	0	0
AA5	Medium	0	0	0	0	0	0	0	0
AA5	Low	0	0	0	0	0	0	0	0
AA6	High	0	0	0	0	0	0	0	0
AA6	Medium	0	0	0	0	0	0	0	0
AA6	Low	0	0	0	0	0	0	0	0
AA7	High	0	0	0	0	0	0	0	0
AA7	Medium	0	0	0	0	0	0	0	0
AA7	Low	0	0	0	0	0	0	0	0
AA8	High	0	0	0	0	0	0	0	0
AA8	Medium	0	0	0	0	0	0	0	0
AA8	Low	0	0	0	0	0	0	0	0
AA9	High	0	0	0	0	0	0	0	0
AA9	Medium	0	0	0	0	0	0	0	0
AA9	Low	0	0	0	0	0	0	0	0
AA10	High	121	25	0	0	0	0	36	4
AA10	Medium	0	0	0	0	0	0	0	0
AA10	Low	0	0	0	0	0	0	0	0
AA11	High	0	0	0	0	0	0	0	0
AA11	Medium	0	0	0	0	0	0	0	0
AA11	High	0	0	0	0	0	0	0	0

AA10 (High *Q* Value)

Due to the possibility that aerosol releases could originate from the BSL-3Ag AHRs at any time over the course of a 24-hour period, all 600 meteorological conditions were used in the aerosol transport modeling to generate the inhalation exposure patterns illustrated in Figure 5.1.9-1. It should be noted that in order to illustrate the general exposure pattern behavior for each meteorological condition, only cattle inhalation exposure patterns are shown. Pig, sheep, and goat exposure patterns are similar in shape, but smaller in magnitude. As evident in Figure 5.1.9-1, similar exposure patterns tend to group in certain areas of the SOM; comparable results were observed in the SOM node groupings of meteorological conditions as discussed in Section 5.1.2.3. In particular, relatively narrow patterns extending north of the facility generally group in the upper right quadrant of the map, while similarly narrow patterns extending south of the facility generally cluster in the lower right. As might be expected, these patterns correspond to relatively strong surface wind speeds (Figure 5.1.3-7) and greater atmospheric stability as denoted by low planetary boundary layer heights (Figure 5.1.3-10) and surface sensible heat flux (Figure 5.1.3-9). A mixture of eastern and western oriented patterns, with varying widths, populate the remaining quadrants of the map corresponding with relatively less stable atmospheric conditions (higher boundary layer heights and surface heat flux).

The patterns observed for this event are similar to those that are presented for events NA10 and EA10, events also corresponding to complete HEPA failure: generally northerly and southerly oriented exposure areas, but with a larger variety of plume directions and shapes (some quite complex), and maximum inhalation exposure levels. When these patterns are combined with their associated frequency of occurrence, probability maps of exceeding a defined exposure level can be developed, illustrating which areas surrounding the NBAF have a higher risk of being exposed to levels exceeding these thresholds. The probability of exceedance distributions for this event (Figure 5.1.9-2) also illustrate higher exposure risk areas north and south of the facility, but with maximum probabilities of approximately 40%. Utilization of the medium (baseline) and low infection risk threshold methodologies resulted in a maximum of 121 and 25 infected farms, respectively, for any one meteorological condition. Fifty percent of the meteorological conditions resulted in 0 farm infections for both infection risk thresholds, with only 5% of the conditions resulting in more than 36 infected premises for the medium risk threshold and four infected premises for the low risk threshold methodology (Figure 5.1.9-3).

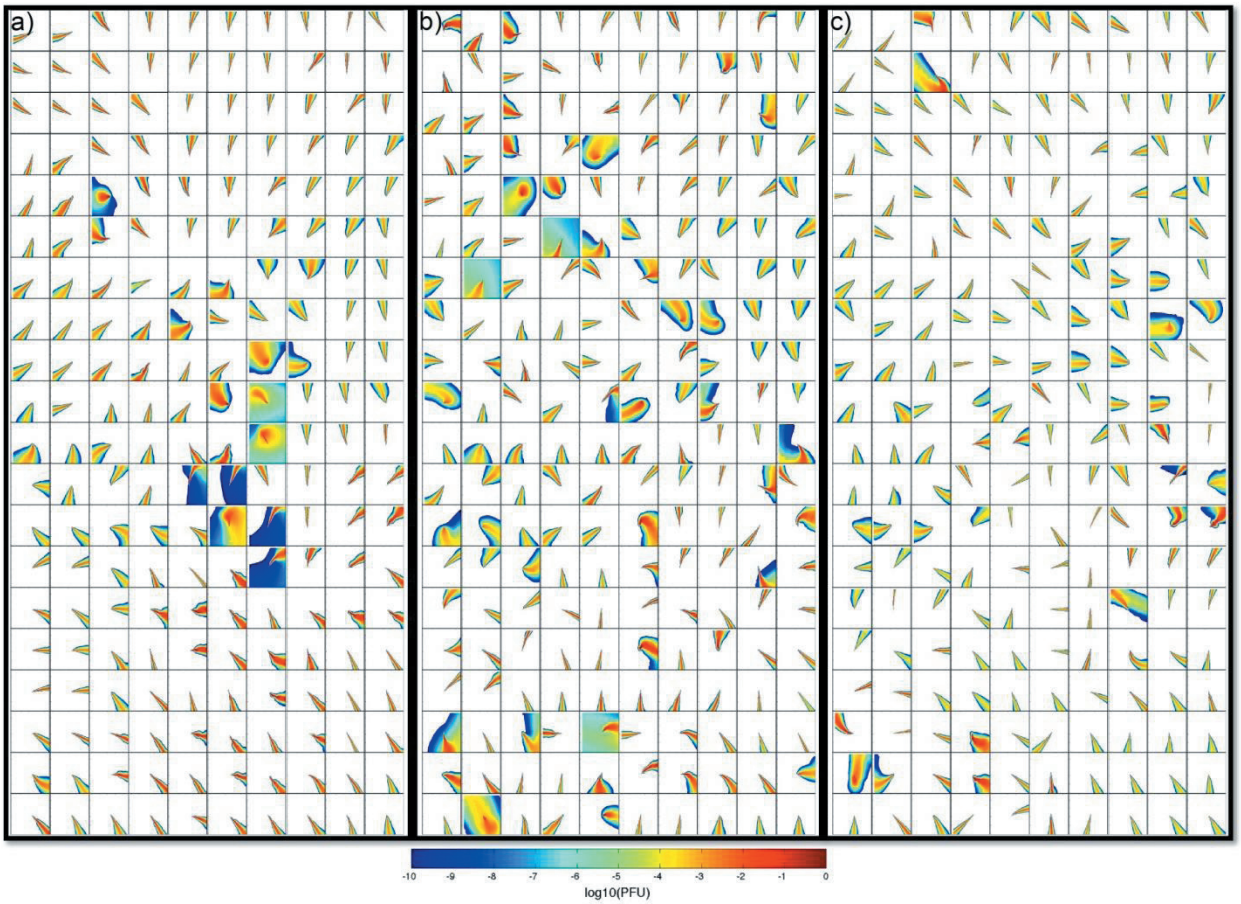


Figure 5.1.9-1: Cattle Inhalation Exposure Maps Corresponding to Meteorological Conditions Contained in the "All Hours" SOM Matrix (Event AA10, High *Q* Value)

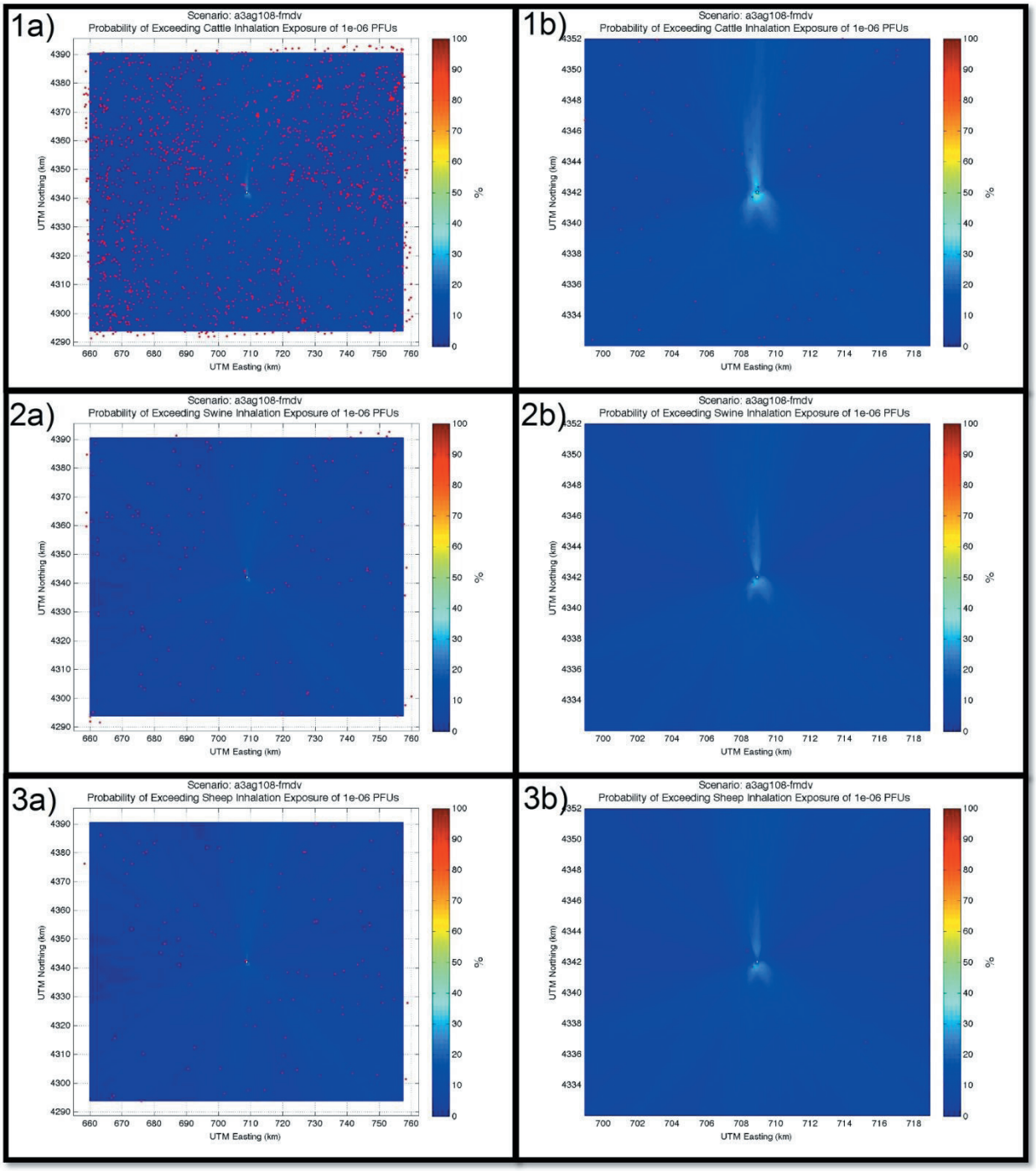


Figure 5.1.9-2: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Event AA10, High *Q* Value)

Red dots represent the location of species-specific population locations (i.e., only cattle farms are shown in 1a and 1b, swine in 2a and 2b, and sheep/goat farms in 3a and 3b).

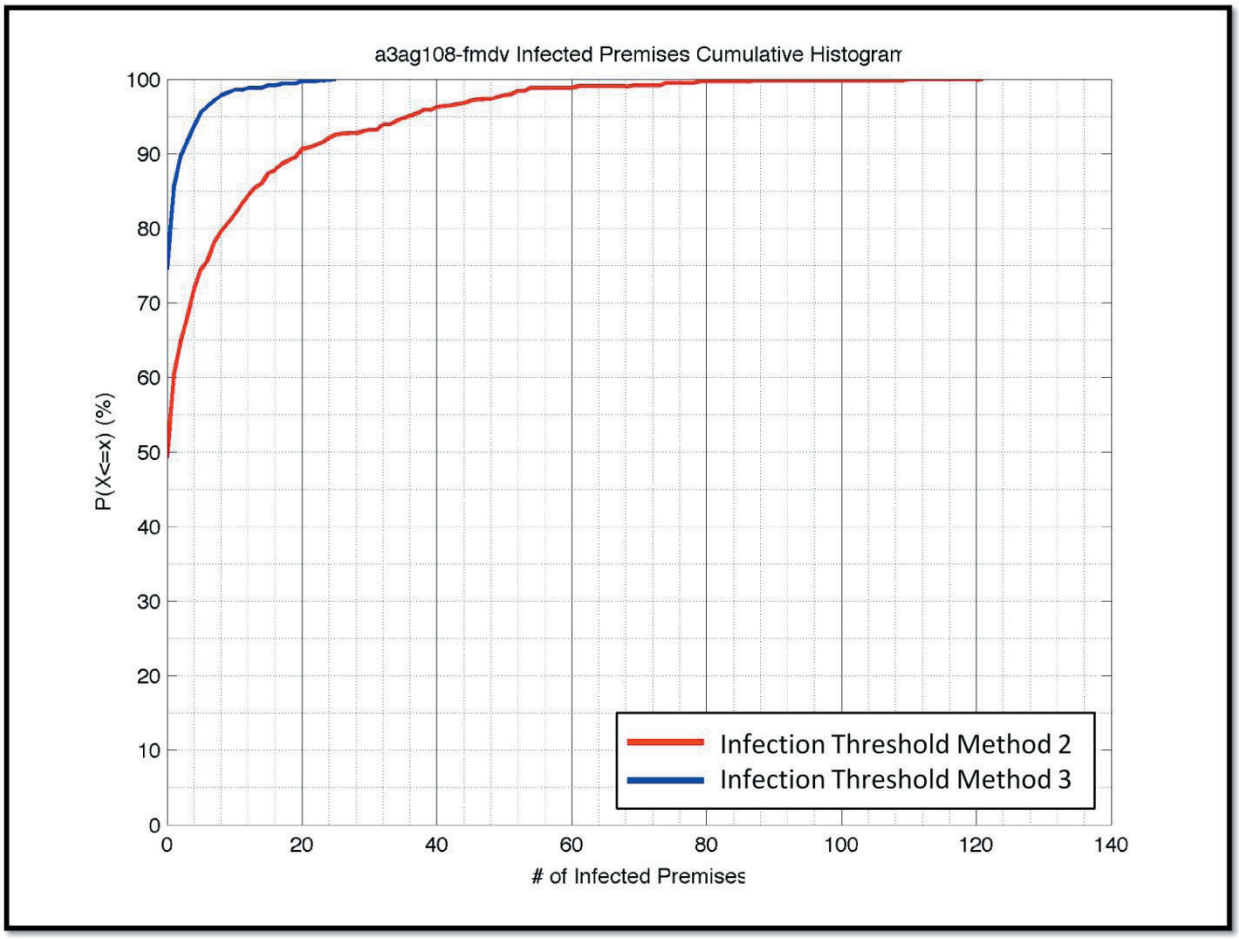


Figure 5.1.9-3: Cumulative Probability Distribution of the Number of Infected Locations (Event AA10, High *Q* Value)

5.1.9.2 BSL-3Ag Necropsy

A detailed summary of infections resulting from all BSL-3Ag Necropsy aerosol releases is provided in Table 5.1.9-3. Downwind infections occurred only during total failure of the HEPA filtration system (NA10) and only with the highest source term of approximately 10^7 PFU. Additionally, infections only resulted when utilizing the medium (baseline) infection risk threshold methodology to trigger an infection event. This event (NA10) resulted in a maximum of one location becoming infected with FMDv for any single meteorological condition. Over 95% of the meteorological conditions resulted in no infected premises, as represented by the 95th percentile value of zero. All other events associated with various degrees of HEPA degradation resulted in no premises becoming infected over all modeled source terms and meteorological conditions. A more detailed analysis of the NA10 event (high *Q* value) simulation results is provided below.

Table 5.1.9 3: BSL 3Ag Necropsy Aerosol Release Results									
Event ID	*Q* Value Range	Maximum Number of Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
NA1	High	0	0	0	0	0	0	0	0
NA1	Medium	0	0	0	0	0	0	0	0
NA1	Low	0	0	0	0	0	0	0	0
NA2	High	0	0	0	0	0	0	0	0
NA2	Medium	0	0	0	0	0	0	0	0
NA2	Low	0	0	0	0	0	0	0	0
NA3	High	0	0	0	0	0	0	0	0
NA3	Medium	0	0	0	0	0	0	0	0
NA3	Low	0	0	0	0	0	0	0	0
NA4	High	0	0	0	0	0	0	0	0
NA4	Medium	0	0	0	0	0	0	0	0
NA4	Low	0	0	0	0	0	0	0	0
NA5	High	0	0	0	0	0	0	0	0
NA5	Medium	0	0	0	0	0	0	0	0
NA5	Low	0	0	0	0	0	0	0	0
NA6	High	0	0	0	0	0	0	0	0
NA6	Medium	0	0	0	0	0	0	0	0
NA6	Low	0	0	0	0	0	0	0	0
NA7	High	0	0	0	0	0	0	0	0
NA7	Medium	0	0	0	0	0	0	0	0
NA7	Low	0	0	0	0	0	0	0	0
NA8	High	0	0	0	0	0	0	0	0
NA8	Medium	0	0	0	0	0	0	0	0
NA8	Low	0	0	0	0	0	0	0	0
NA9	High	0	0	0	0	0	0	0	0
NA9	Medium	0	0	0	0	0	0	0	0
NA9	Low	0	0	0	0	0	0	0	0
NA10	High	1	0	0	0	0	0	0	0
NA10	Medium	0	0	0	0	0	0	0	0
NA10	Low	0	0	0	0	0	0	0	0
NA11	High	0	0	0	0	0	0	0	0
NA11	Medium	0	0	0	0	0	0	0	0
NA11	High	0	0	0	0	0	0	0	0

NA10 (High *Q* Value)

Figures 5.1.9-4 through 5.1.9-6 summarize the results from the NA10 aerosol release event, with the highest source term. As might be expected, the NA10 results are almost indistinguishable from the EA10 results (presented in the following section). Nearly identical initial conditions are used in the aerosol transport simulations for the necropsy and BSL-3E/BSL-3E SP aerosol events (Table 5.1.9-1); the only difference is the amount of material released. The same conclusions are drawn for this particular release event (i.e., there is a 99.9% probability this release event will result in zero infected locations).

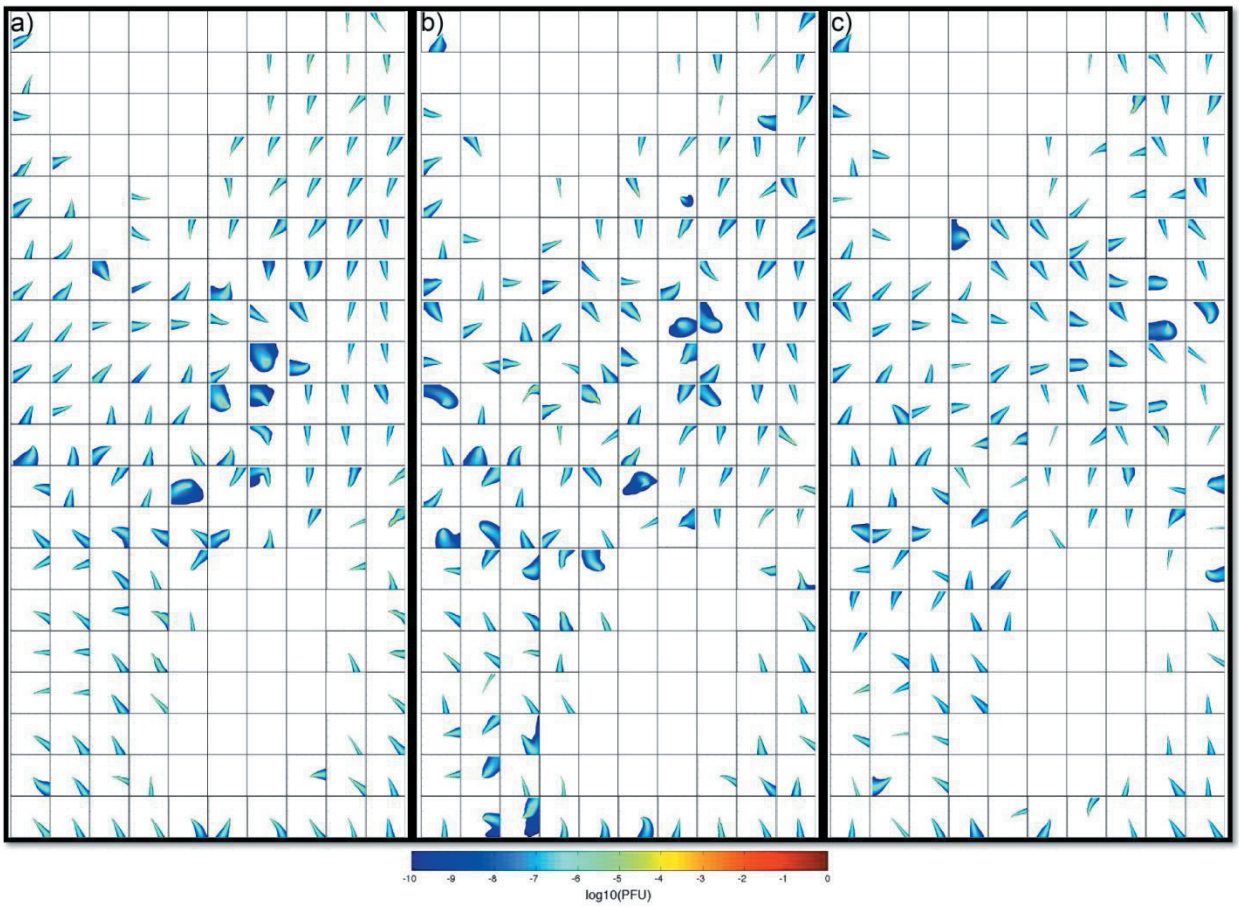


Figure 5.1.9-4: Cattle Inhalation Exposure Maps Corresponding to Each Meteorological Condition Contained in the "Working Hours" SOM Matrix (NA10, High *Q* Value)

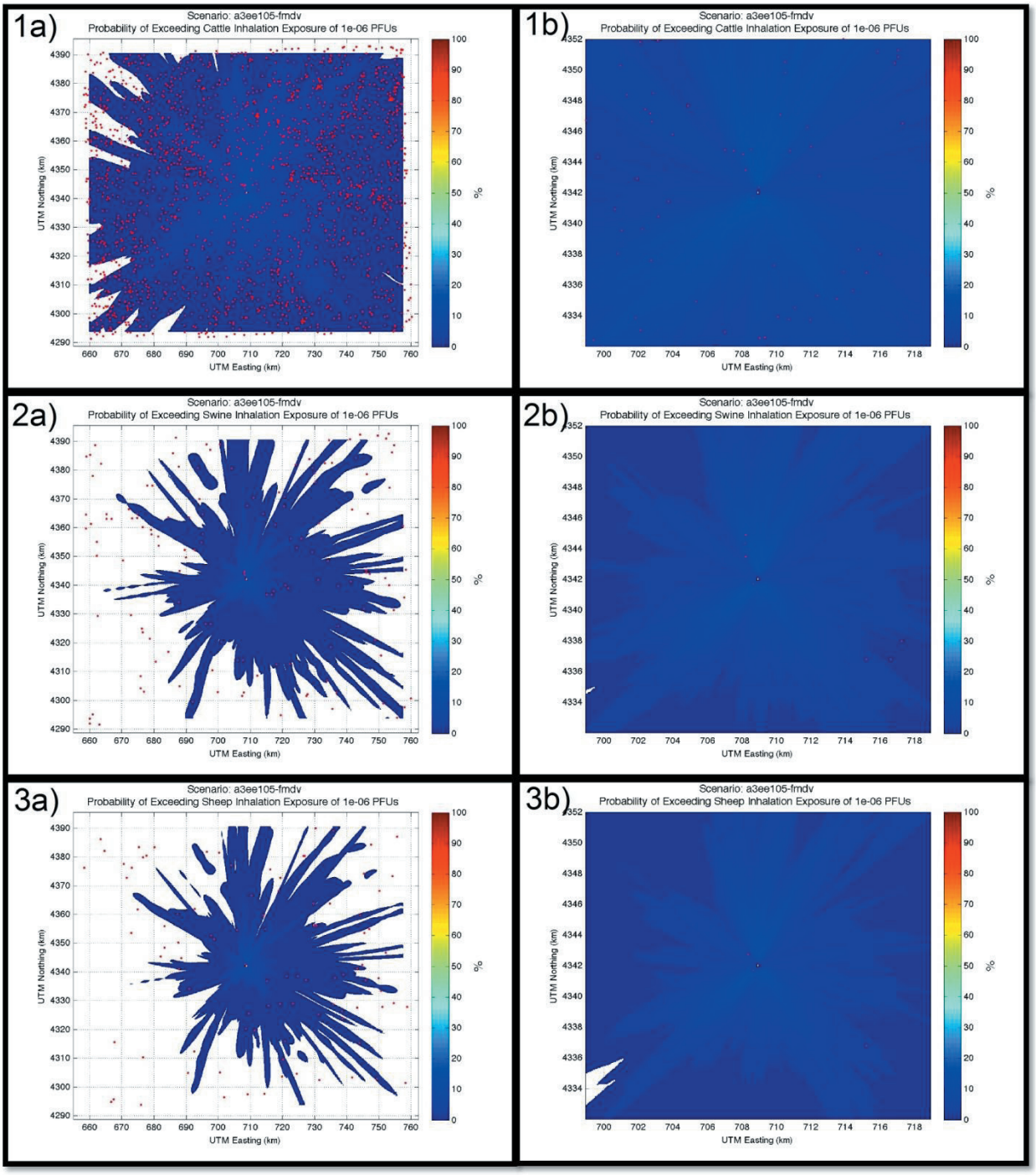


Figure 5.1.9-5: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Event NA10, High *Q* Value)

Red dots represent the location of species specific population locations (i.e., only cattle farms are shown in 1a and 1b, swine in 2a and 2b, and sheep/goat farms in 3a and 3b).

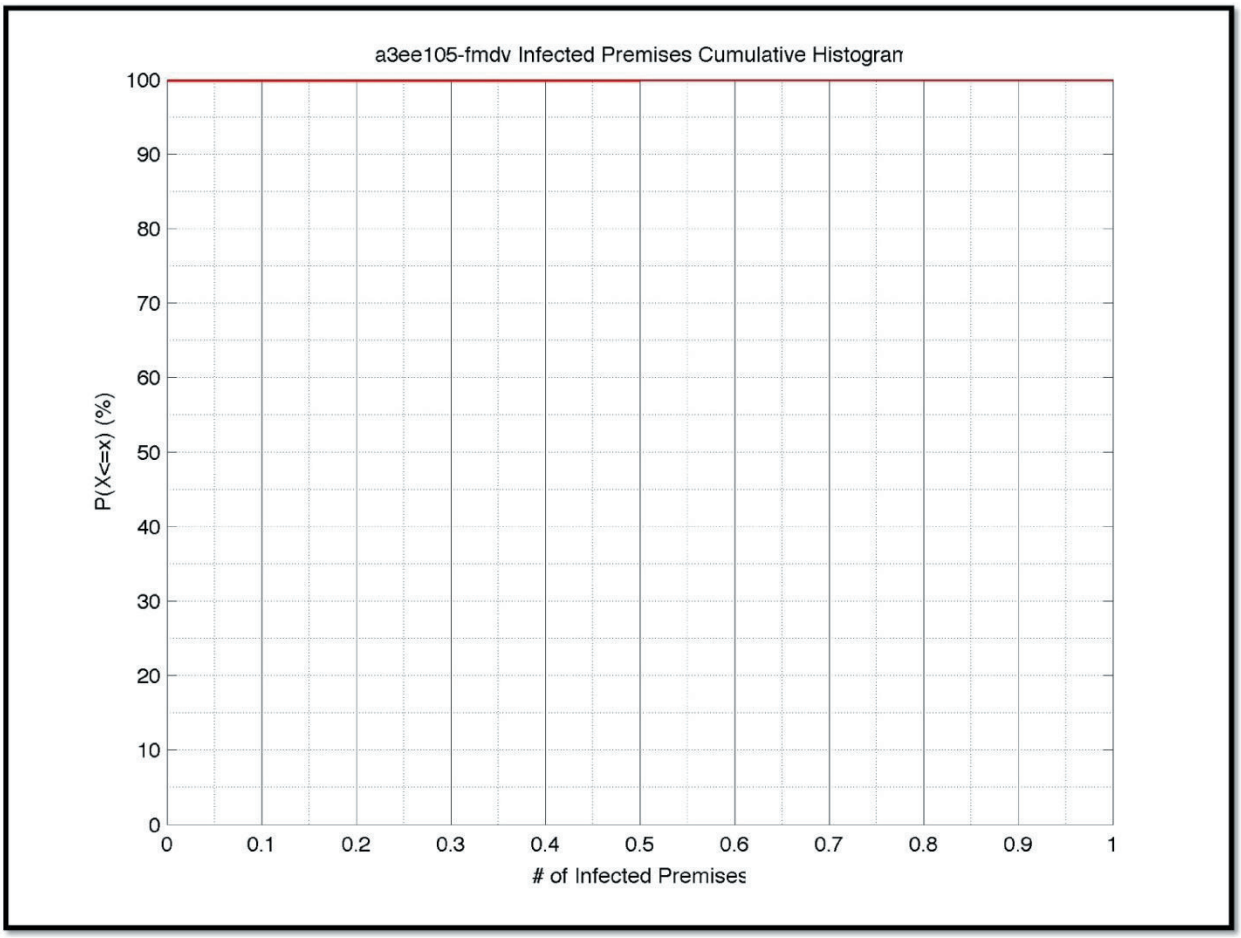


Figure 5.1.9-6: Cumulative Probability Distribution of the Number of Infected Locations (NA10, High *Q* Value)

5.1.9.3 BSL-3E and BSL-3E "Special Procedure" Laboratories

A detailed summary of infections resulting from all BSL-3E and BSL-3E "Special Procedure" room aerosol releases is provided in Table 5.1.9-4. Downwind infections occurred only during total failure of the HEPA filtration system (EA10), and only for the highest source term of approximately 10^5 PFU. Therefore, the same conclusions are drawn for this particular release event as that for the necropsy aerosol release event (NA10), i.e., there is a 99.9% probability this release event will result in zero infected locations. Furthermore, infections only resulted when utilizing the medium (baseline) infection risk threshold methodology to trigger an infection event. As shown, EA10 (high *Q* value) resulted in a maximum of one location becoming infected with FMDv for any single meteorological condition. In fact over 95% of the meteorological conditions resulted in zero infected premises, as represented by the 95th percentile value of zero. All other events associated with various degrees of HEPA degradation resulted in zero premises becoming infected over all possible source amounts and meteorological conditions. A more detailed analysis of the EA10 event (high *Q* value) simulation results is provided below.

Table 5.1.9 4: BSL 3E/BSL 3E SP Aerosol Release Results									
Event ID	*Q* Value Range	Maximum Number of Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
EA0	High	0	0	0	0	0	0	0	0
EA0	Medium	0	0	0	0	0	0	0	0
EA0	Low	0	0	0	0	0	0	0	0
EA1	High	0	0	0	0	0	0	0	0
EA1	Medium	0	0	0	0	0	0	0	0
EA1	Low	0	0	0	0	0	0	0	0
EA2	High	0	0	0	0	0	0	0	0
EA2	Medium	0	0	0	0	0	0	0	0
EA2	Low	0	0	0	0	0	0	0	0
EA3	High	0	0	0	0	0	0	0	0
EA3	Medium	0	0	0	0	0	0	0	0
EA3	Low	0	0	0	0	0	0	0	0
EA4	High	0	0	0	0	0	0	0	0
EA4	Medium	0	0	0	0	0	0	0	0
EA4	Low	0	0	0	0	0	0	0	0
EA5	High	0	0	0	0	0	0	0	0
EA5	Medium	0	0	0	0	0	0	0	0
EA5	Low	0	0	0	0	0	0	0	0
EA6	High	0	0	0	0	0	0	0	0
EA6	Medium	0	0	0	0	0	0	0	0
EA6	Low	0	0	0	0	0	0	0	0
EA7	High	0	0	0	0	0	0	0	0
EA7	Medium	0	0	0	0	0	0	0	0
EA7	Low	0	0	0	0	0	0	0	0
EA8	High	0	0	0	0	0	0	0	0
EA8	Medium	0	0	0	0	0	0	0	0
EA8	Low	0	0	0	0	0	0	0	0
EA9	High	0	0	0	0	0	0	0	0
EA9	Medium	0	0	0	0	0	0	0	0
EA9	Low	0	0	0	0	0	0	0	0
EA10	High	1	0	0	0	0	0	0	0
EA10	Medium	0	0	0	0	0	0	0	0
EA10	Low	0	0	0	0	0	0	0	0
EA11	High	0	0	0	0	0	0	0	0

Table 5.1.9 4: BSL 3E/BSL 3E SP Aerosol Release Results									
Event ID	*Q* Value Range	Maximum Number of Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
EA11	Medium	0	0	0	0	0	0	0	0
EA11	Low	0	0	0	0	0	0	0	0

EA10 (High *Q* Value)

The resulting inhalation exposure patterns for event EA10, using the high *Q* value, are summarized in Figure 5.1.9-7 for each input meteorological condition. As evident in Figure 5.1.9-7, similar exposure patterns tend to group in certain areas of the SOM; comparable results were observed in the SOM node groupings of meteorological conditions as discussed in Section 5.1.2.3. In particular, relatively narrow patterns extending north of the facility generally group in the upper right quadrant of the map, while similarly narrow patterns extending south of the facility generally cluster in the lower right. As might be expected, these patterns correspond with relatively strong surface wind speeds (Figure 5.1.3-7) and more stable atmospheric stability as denoted by low planetary boundary layer heights (Figure 5.1.3-10) and surface sensible heat flux (Figure 5.1.3-9). A mixture of eastern and western oriented patterns, with varying widths, populate the remaining quadrants of the map corresponding with relatively less stable atmospheric conditions (higher boundary layer heights and surface heat flux). Maximum cattle inhalation exposure levels are approximately 1×10^{-3} PFU.

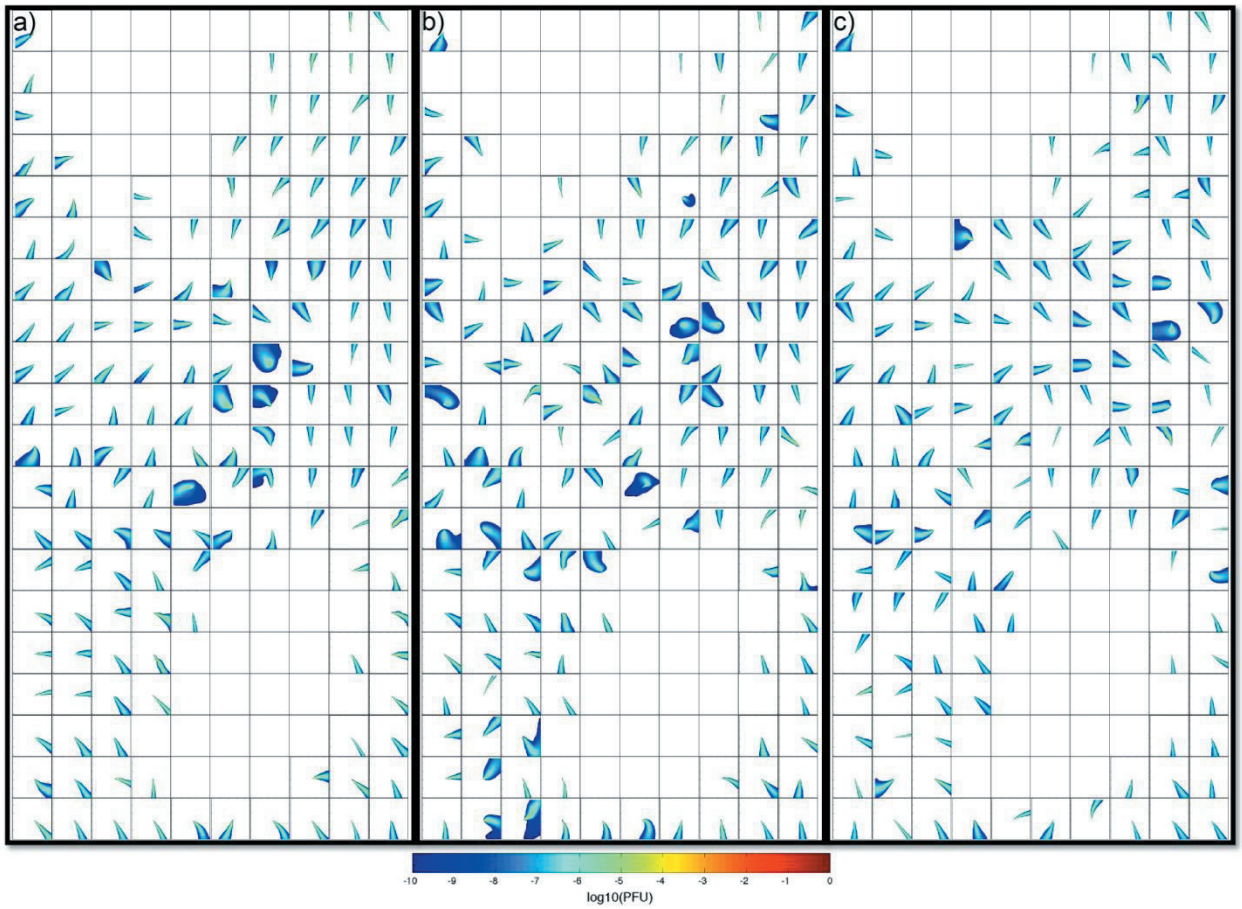


Figure 5.1.9-7: Cattle Inhalation Exposure Maps Corresponding to Each Meteorological Condition Contained in the "Working Hours" SOM Matrix (EA 10, High *Q* Value)

Each square panel represents the 1,000 × 1,000 km SCIPUFF domain depicted in Figure 5.1.7-1.

From an analysis of the farming operations, and their associated thresholds for infection, within the 100 km × 100 km computational domain, the lowest exposure level which could potentially cause infection was found to be approximately 1×10^{-5} PFU. This corresponded to a particular cattle operation, with a herd size of over 11,000 animals, approximately 20 km north-northeast of the NBAF. Therefore, a lower exposure level of 1×10^{-6} PFU was selected as the threshold of concern to generate the probability of exceedance maps, as shown in Figure 5.1.9-8. Probability maps are shown for each susceptible species: 1) cattle; 2) swine; 3) sheep/goats; and over: a) the full 100 × 100 km computational domain; and b) a 20 × 20 km domain centered on the NBAF. As shown in Panel 1a of Figure 5.1.9-8, there is essentially a nonzero risk of cattle receiving an inhalation exposure of greater than 1×10^{-6} PFU over the entire 100 km × 100 km domain, with a few zero risk areas in the northwest and southwest extremes of the domain. Within approximately 10 km of the NBAF, the risk increases, with maximum probabilities of exceedance greater than 30%, oriented just north and south of the facility (Panel 1b of 5.1.9-8). These probability distributions correlate with the observed distribution of exposure patterns, shown above (Figure 5.1.9-7), which generally shows a bimodal distribution of patterns oriented to the north and south. Additionally, this behavior correlates well with the northerly and southerly wind direction modes

found in the observed wind climatology (Figure 5.1.2-4). As shown, a number of cattle farming operations currently exist within these higher exposure risk areas, but it should be noted that higher risk does not necessarily equate to higher risk of infection, since infection is not simply a function of inhalation exposure level, but also a function of herd size (e.g., larger herds have a higher risk of infection as compared to smaller herds). For example, the cattle farming operation located just north of the NBAF and within the higher exposure risk area requires an inhalation exposure level of approximately 1×10^{-2} PFU or greater to trigger subsequent infection, based on the medium infection risk threshold formulation – four orders of magnitude higher than the threshold used to define the probability of exceedance maps shown. Probability maps of exceeding 1×10^{-2} PFU (not shown) correspondingly illustrate a 0% probability of exceeding this value anywhere within the computational domain. In other words, although close to the NBAF and in a climatologically favorable area for receiving some quantity of material released from the facility, this location has a 0% chance of receiving an infectious dose of FMDv for this particular release event. Similar probability distributions exist for pigs and sheep/goat inhalation exposures, but with lower probabilities of exceedance, due to their lower MTV capacities.

After correlating the individual inhalation exposure patterns for each meteorological condition (Figure 5.1.9-7) with the documented farming operation locations and applying the medium and low infection risk threshold methodologies, infection was triggered for only one farming operation within the 100 km × 100 km computational domain and for only one out of 451 meteorological conditions, representing a 0.1% frequency of occurrence. Consequently, there is a 99.9% probability this release event will result in zero infected locations, as illustrated by the cumulative probability distribution shown in Figure 5.1.9-9.

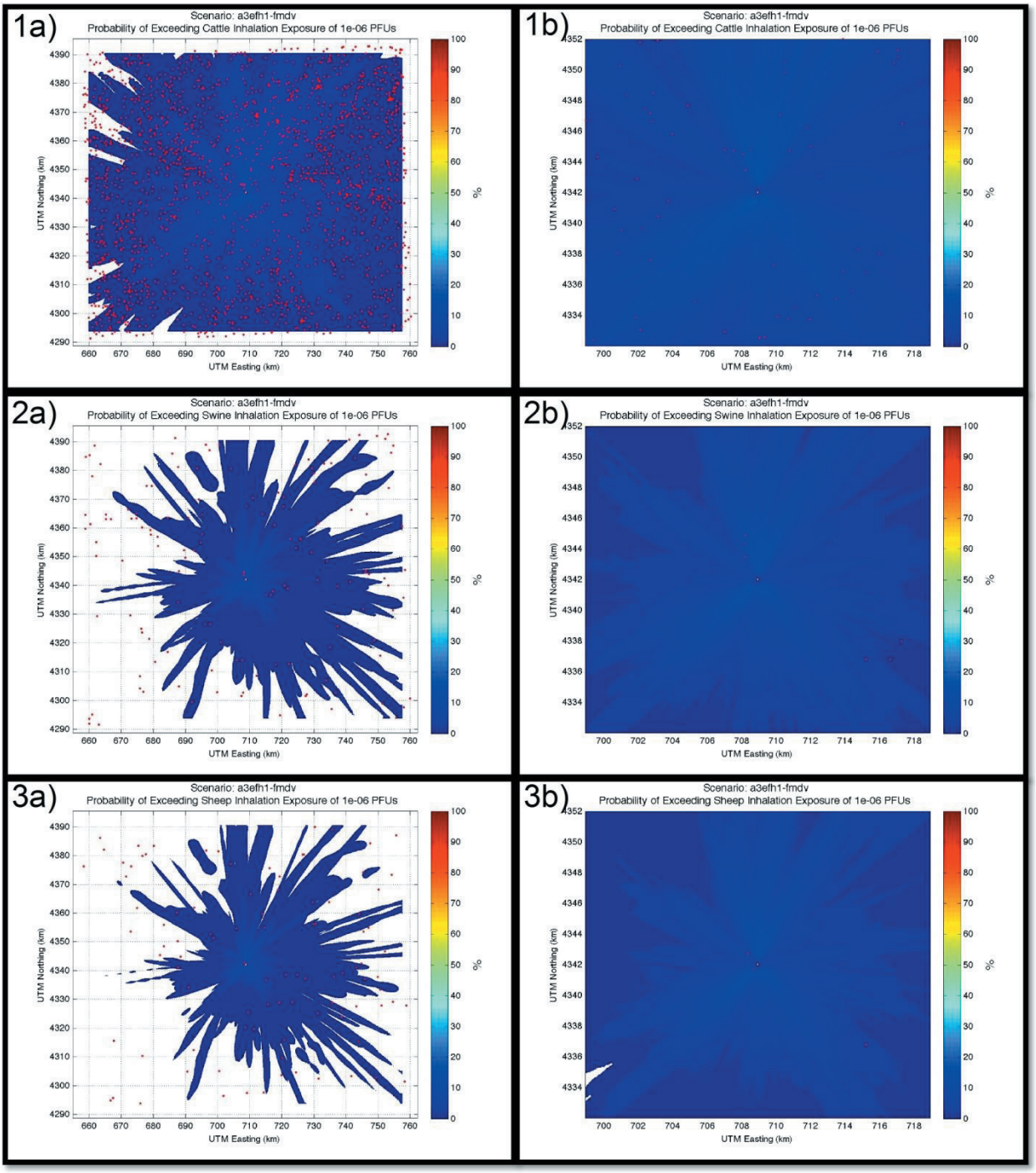


Figure 5.1.9-8: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep Over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Event EA10, High *Q* Value)

Red dots represent the location of species specific population locations (i.e., only cattle farms are shown in 1a and 1b, swine in 2a and 2b, and sheep/goat farms in 3a and 3b).

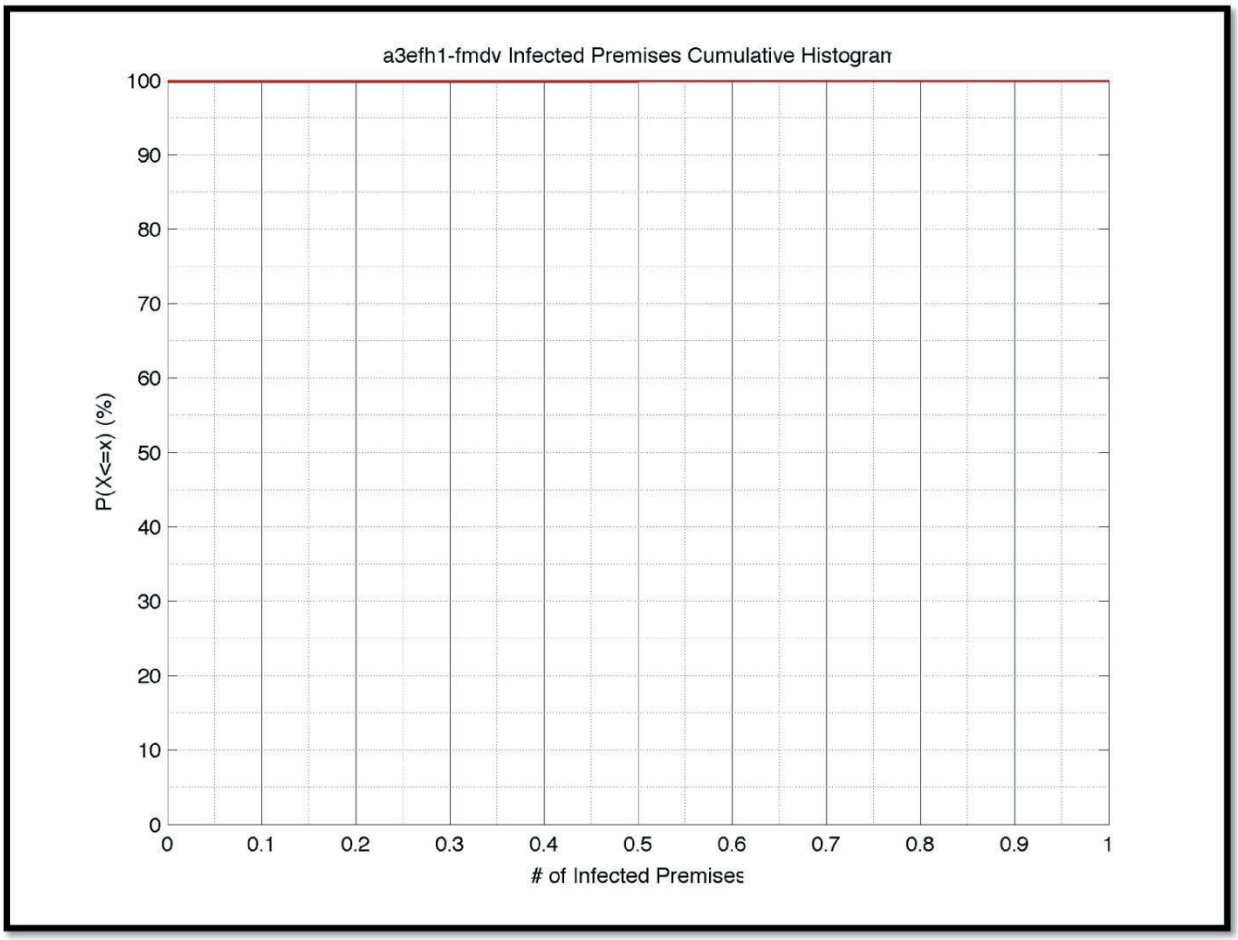


Figure 5.1.9-9: Cumulative Probability Distribution of the Number of Infected Locations (EA10, High *Q* Value)

5.1.9.4 Non-containment

A detailed summary of infections resulting from aerosol releases outside containment is provided in Table 5.1.9-5. As shown, only the high *Q* value (1.18×10^5 PFU), associated with the failure of shipment containers (events OA2 and OA3), resulted in maximum downwind infections of one farming location when utilizing the medium risk infection methodology. These results are similar to the BSL-3E/BSL-3E SP event in which the HEPA filters are completely non-functional (EA10 high *Q* value), as both events use the same initial conditions except for the height of release and initial velocity. For the non-containment aerosol releases, the height of release is set to 0 meters as compared to approximately 25 meters for the BSL-3E/BSL-3E SP aerosol releases. Consequently, as was the case with the EA10 event, over 95% of the meteorological conditions resulted in zero infected premises. Because both OA2 and OA3 were modeled with the same high *Q* value, a detailed analysis of the results was only performed for OA3, as discussed below.

Table 5.1.9 5: Non containment Aerosol Release Results									
Event ID	*Q* Value Range	Maximum Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
		Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
OA1	High	0	0	0	0	0	0	0	0
OA1	Medium	0	0	0	0	0	0	0	0
OA1	Low	0	0	0	0	0	0	0	0
OA2	High	1	0	0	0	0	0	0	0
OA2	Medium	0	0	0	0	0	0	0	0
OA2	Low	0	0	0	0	0	0	0	0
OA3	High	1	0	0	0	0	0	0	0
OA3	Medium	0	0	0	0	0	0	0	0
OA3	Low	0	0	0	0	0	0	0	0

OA3 (High *Q* Value)

As mentioned above, the results from this event are almost identical to those associated with EA10 (high *Q* value). Even so, minor differences are observed in the inhalation exposure patterns in Figure 5.1.9-10 and probability of exceedance maps in Figure 5.1.9-11, particularly in the regions immediately surrounding the NBAF (i.e., release location). Because the release occurs at ground level (0 m) versus the HVAC stack height (approximately 25 m), higher inhalation exposures exist near the release site. As a consequence, higher probabilities of exceedance (approximately 40%) also surround the immediate vicinity of the NBAF. Although not immediately apparent, these relatively minor differences also result in slightly different cumulative probability of infection distributions (Figure 5.1.9-12). The EA10 release event resulted in a 99.9% probability of having zero infected premises, due to a single farm becoming infected for one meteorological condition out of 451; however, for this non-containment release event, the same farm also receives an infectious dose for the same meteorological condition and one additional farming location (approximately 300 meters north of the facility) also becomes infected during two other meteorological events. These two other meteorological events represent 0.25% and 0.05% of all conditions, respectively. This result is directly attributable to the difference in release heights, as material released from the HVAC exhaust stack moves downwind a distance before it is effectively dispersed from the release height to ground level (as is illustrated in Figure 5.1.9-13). Consequently, the OA3 and OA2 (high *Q* value) release events have a 99.6% probability of resulting in zero infected premises compared to a 99.9% probability associated with release event EA10 (high *Q* value).

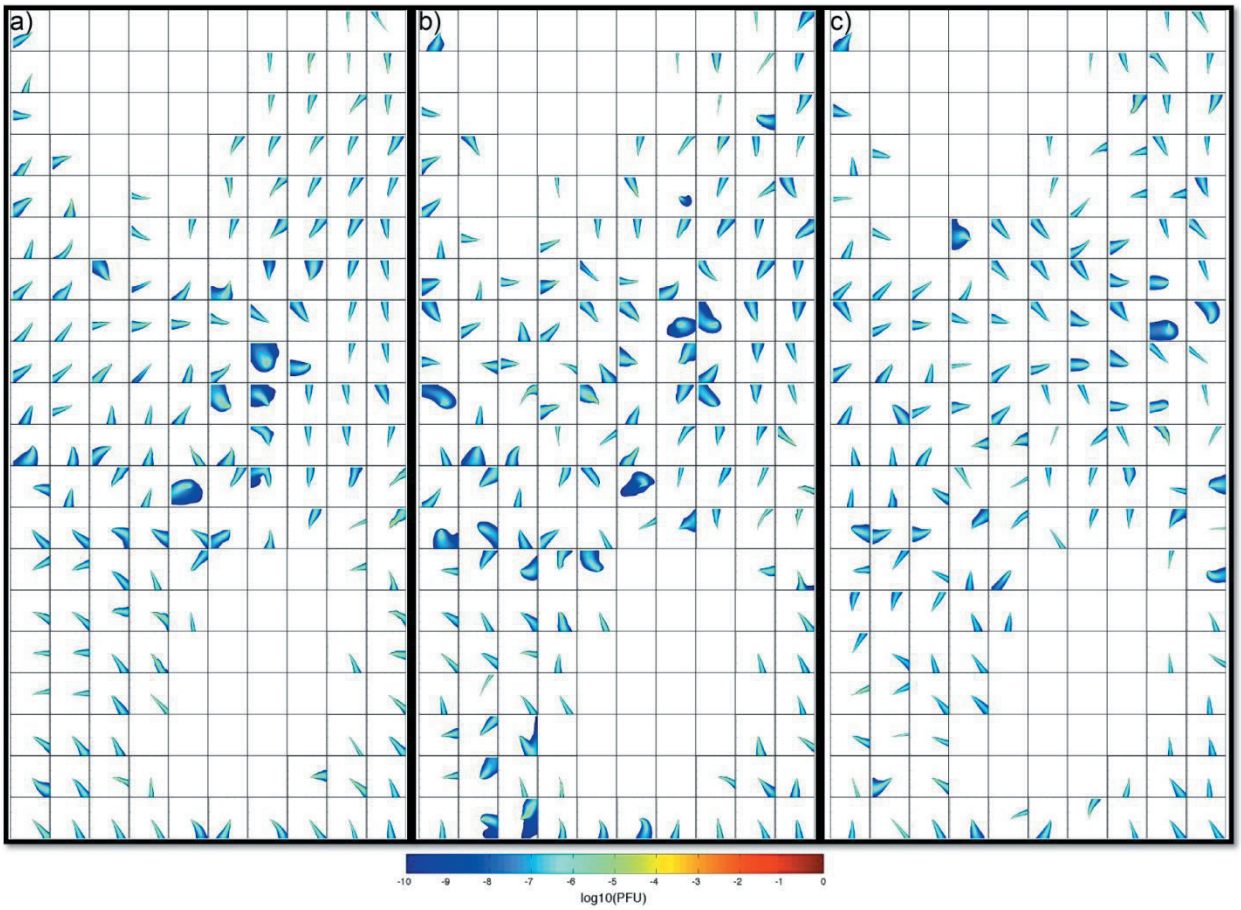


Figure 5.1.9-10: Cattle Inhalation Exposure Maps Corresponding to Meteorological Conditions Contained in the "All Hours" SOM Matrix (Event OA3, High *Q* Value)

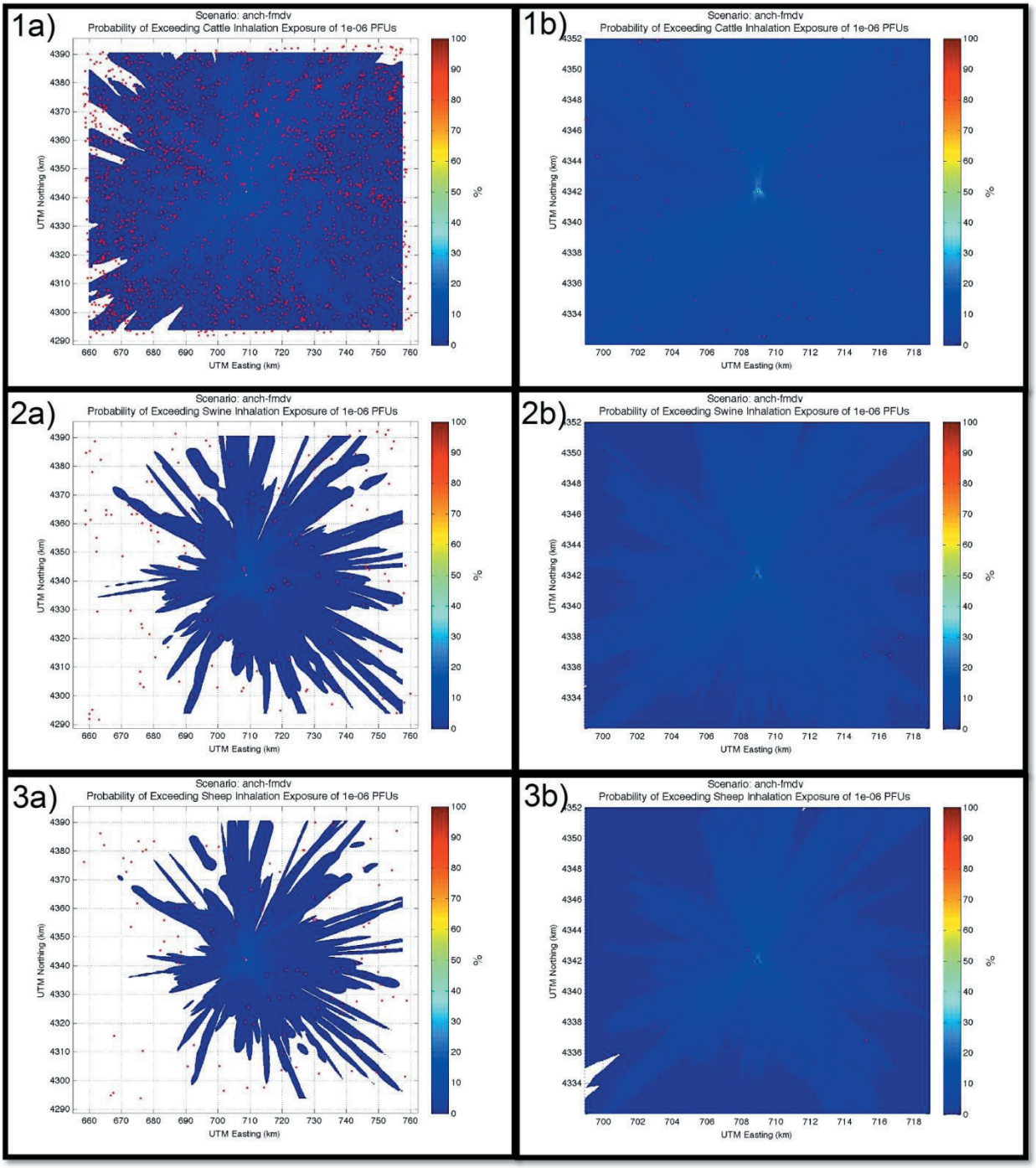


Figure 5.1.9-11: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep Over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Event OA3, High *Q* Value)

Red dots represent the location of species specific population locations (i.e., only cattle farms are shown in 1a and 1b, swine in 2a and 2b, and sheep/goat farms in 3a and 3b).

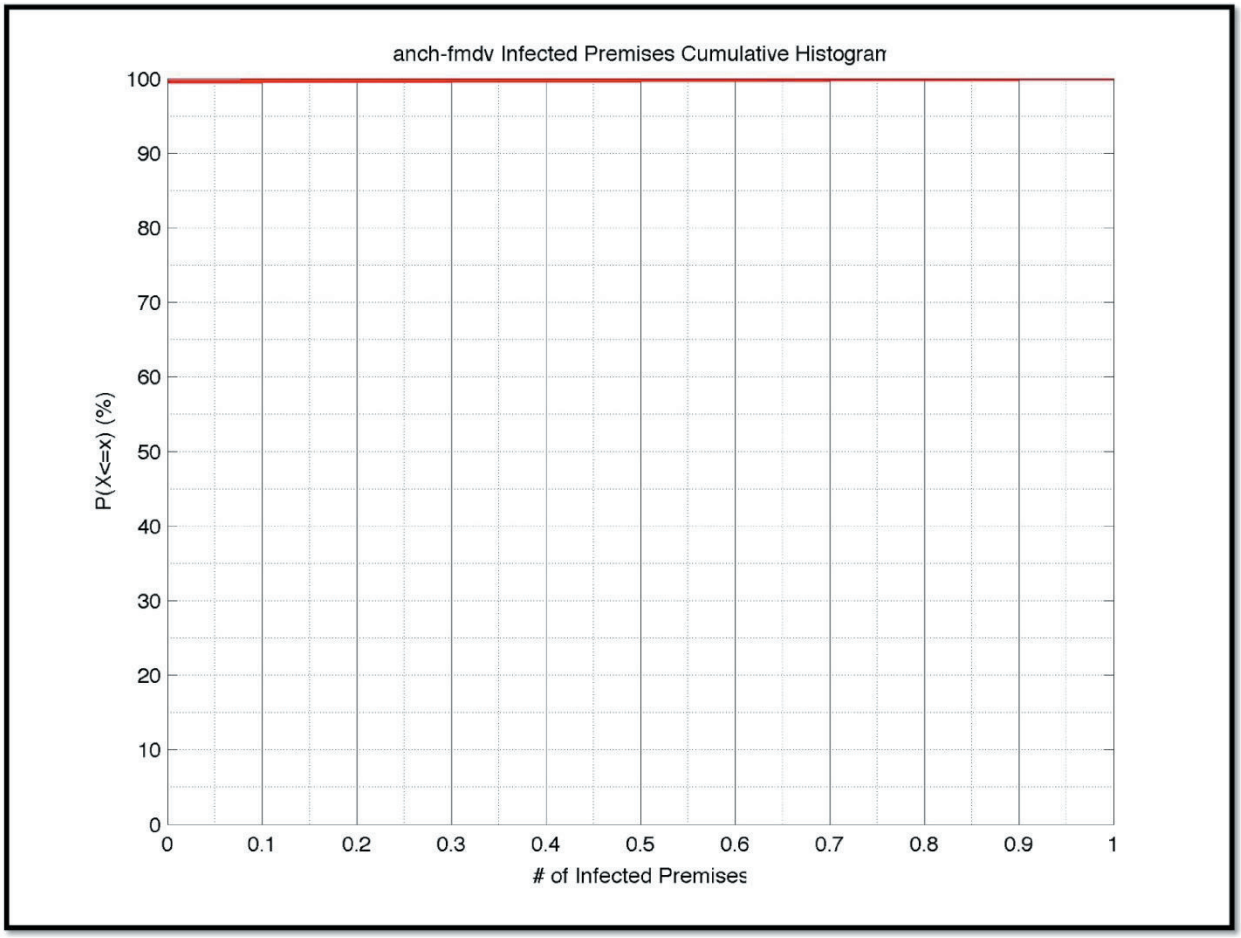


Figure 5.1.9-12: Cumulative Probability Distribution of the Number of Infected Locations (Event OA3, High *Q* Value)

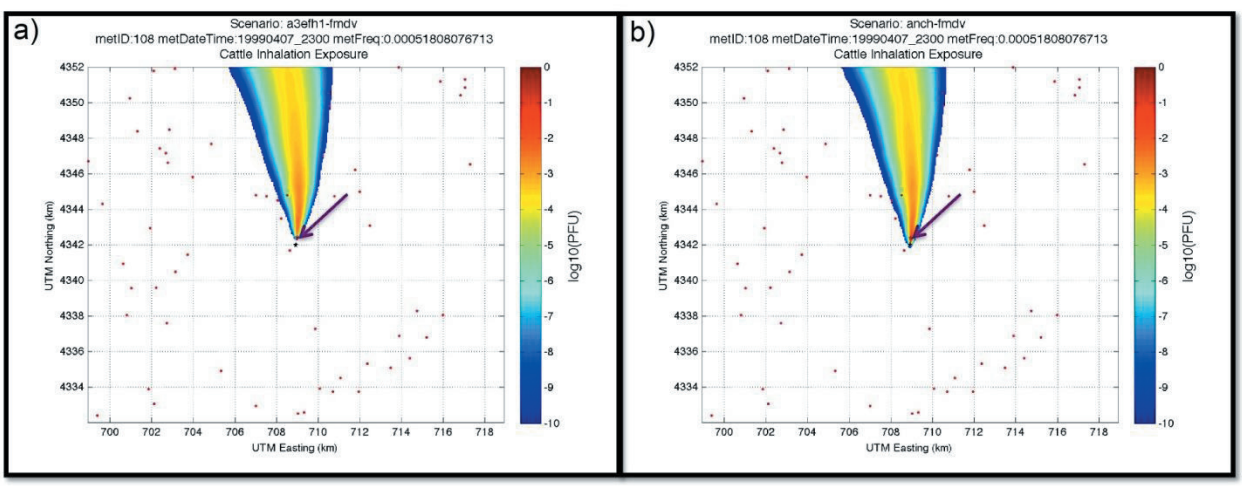


Figure 5.1.9-13: Comparison of Cattle Inhalation Exposure Between Release Event (A) EA10 and (B) OA3

The magenta dot and arrow designate the location of the farming operation, which received an infectious dose in OA3, but not in EA10.

5.1.9.5 Tornado Impact

As described in Section 4.6, for the purposes of the risk calculations, a single tornado event was included with a frequency of occurrence set to that of a tornado with wind speeds of at least 228 mph, but the source values were set to the expected values for a tornado of 254 mph. For the purposes of comparison, though, a 228 mph tornado was also modeled with the source (Q) values listed in Table 5.1.9-6, and for this design basis tornado, zero downwind premises were infected. Only tornados with wind speeds exceeding 228 mph (254 mph was the next modeled wind speed) that impact the facility result in downrange infections. The maximum number of infected premises for these tornado events ranges from a minimum of 10 for the low and medium source term to 266 for the high source term. A more detailed analysis of each of these events is provided in the subsections below.

Table 5.1.9 6: Tornado Impact Aerosol Release Results

Event ID	Modeled *Q* Value (PFU)	Maximum Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
		Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
T 228	2.08×10^{4}	0	0	0	0	0	0	0	0
T 228	6.16×10^{1}	0	0	0	0	0	0	0	0
T 228	2.50×10^{5}	0	0	0	0	0	0	0	0
T > 228	Low[a] 1.0×10^{8}	42	10	0	0	5	1	14	4
T > 228	Medium[a] 1.0×10^{8}	42	10	0	0	5	1	14	4
T > 228	High[a] 1.0×10^{10}	266	156	39	17	74	43	150	68

[a]The calculated *Q* values from Section 4.6 for the tornado event were 1.57×10^{6}, 3.58×10^{6}, and 2.48×10^{10}. However, the nearest modeled aerosol values are presented in the table. As no 10^{6} PFU case was modeled, the 10^{8} PFU results were used for both the low and medium releases.

T > 228 mph (Tornado Event with Strike on NBAF with Wind Speeds in Excess of 228 mph) (High Source Value)

Inhalation exposure results for the 453 meteorological conditions, which were correlated to documented tornado events, are summarized in Figure 5.1.9-14. When analyzing the resulting exposure patterns, there is a clear preferential orientation of the exposure footprints to the north of the release location, with only a small number of patterns oriented in the other cardinal directions. This preferred direction of travel is even more evident in the probability of exceedance distributions, illustrated in Figure 5.1.9-15, with maximum probabilities of exceeding 1×10^{-6} PFU greater than 50%. The cumulative probability of infection distributions (Figure 5.1.9-16) indicate a 0% probability of having zero infected premises resulting from this release event. The 5th, 50th, and 95th percentiles of infected premises are 39, 74, and 150, respectively, utilizing the medium infection risk threshold methodology, and 17, 43, and 68 infected premises, respectively, for the low infection risk threshold.

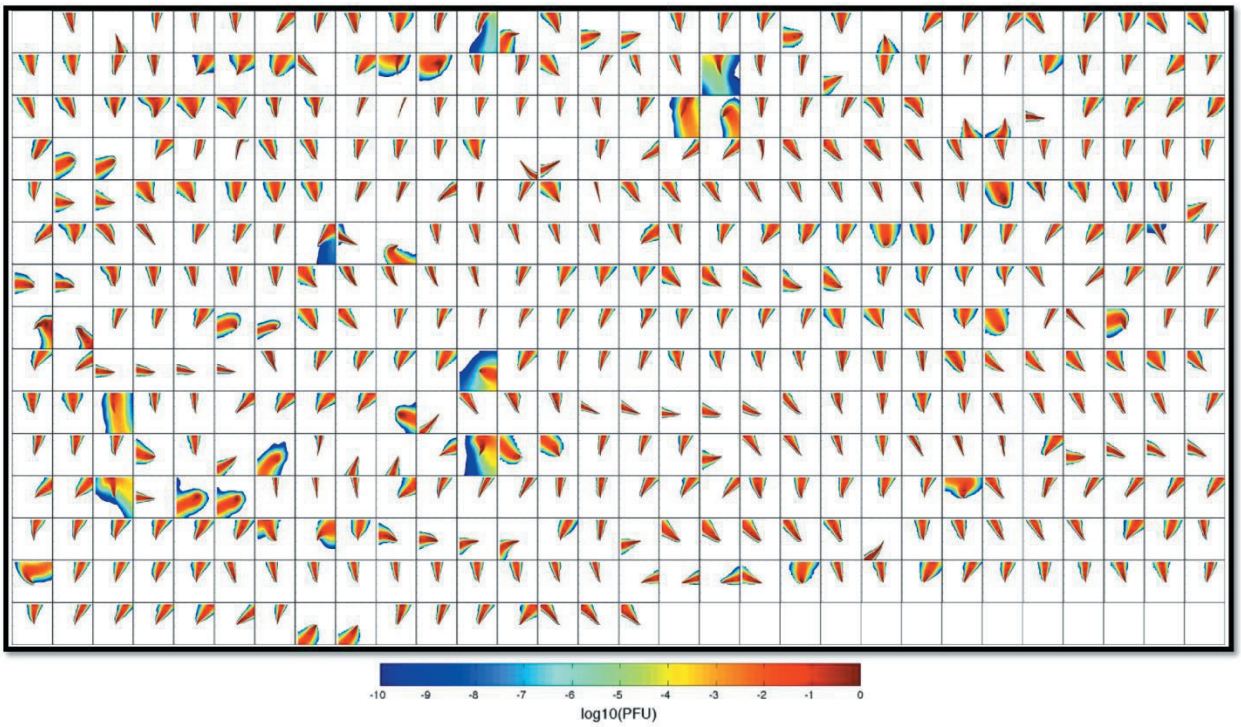


Figure 5.1.9-14: Cattle Inhalation Exposure Maps Corresponding to Meteorological Conditions Contained in the "Tornado" SOM Matrix (Tornado > 228 mph, High Q Value)

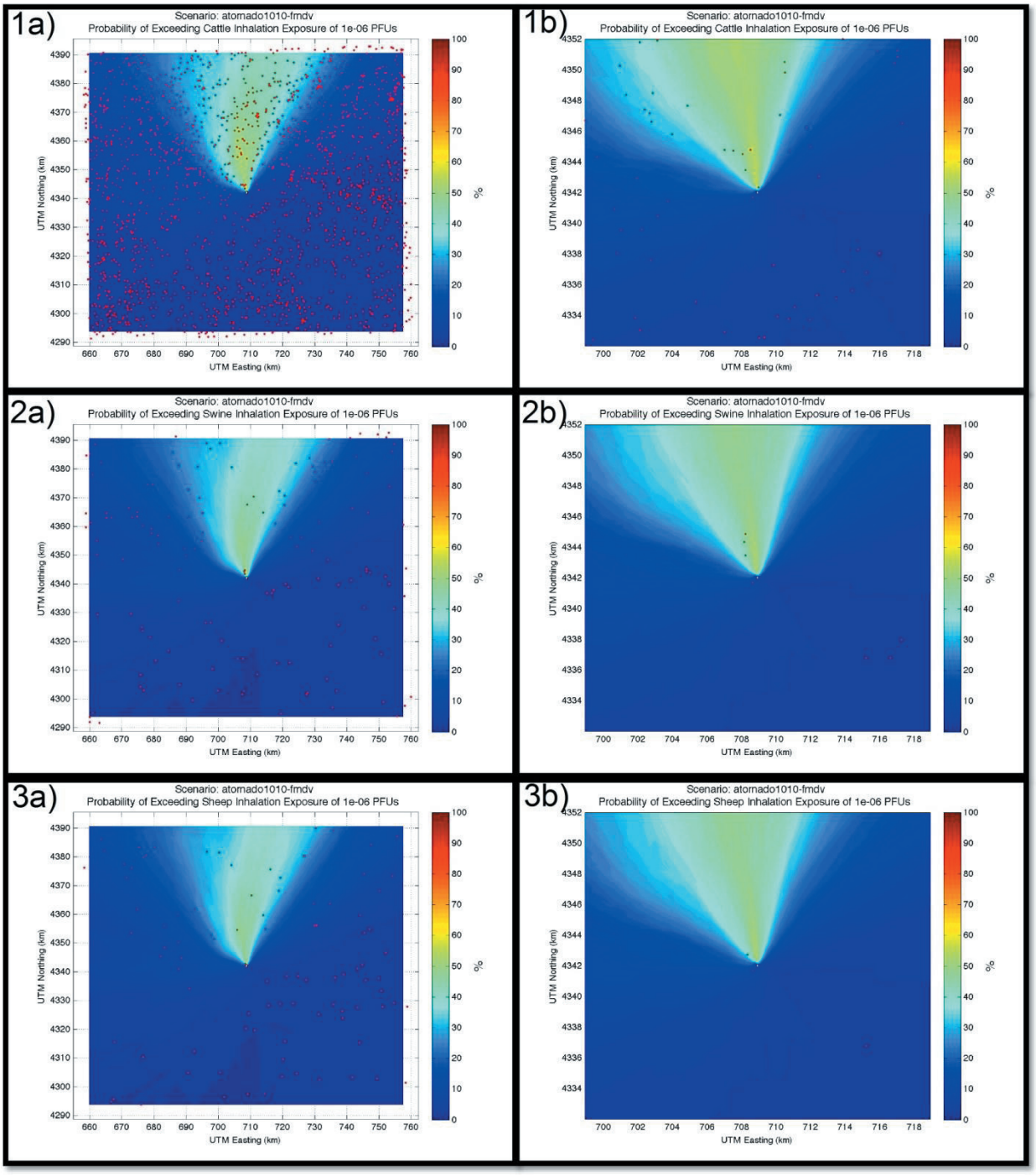


Figure 5.1.9-15: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep Over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Tornado > 228 mph, High *Q* Value)

Red dots represent the location of species specific population locations (i.e., only cattle farms are shown in 1a and 1b, swine in 2a and 2b, and sheep/goat farms in 3a and 3b).

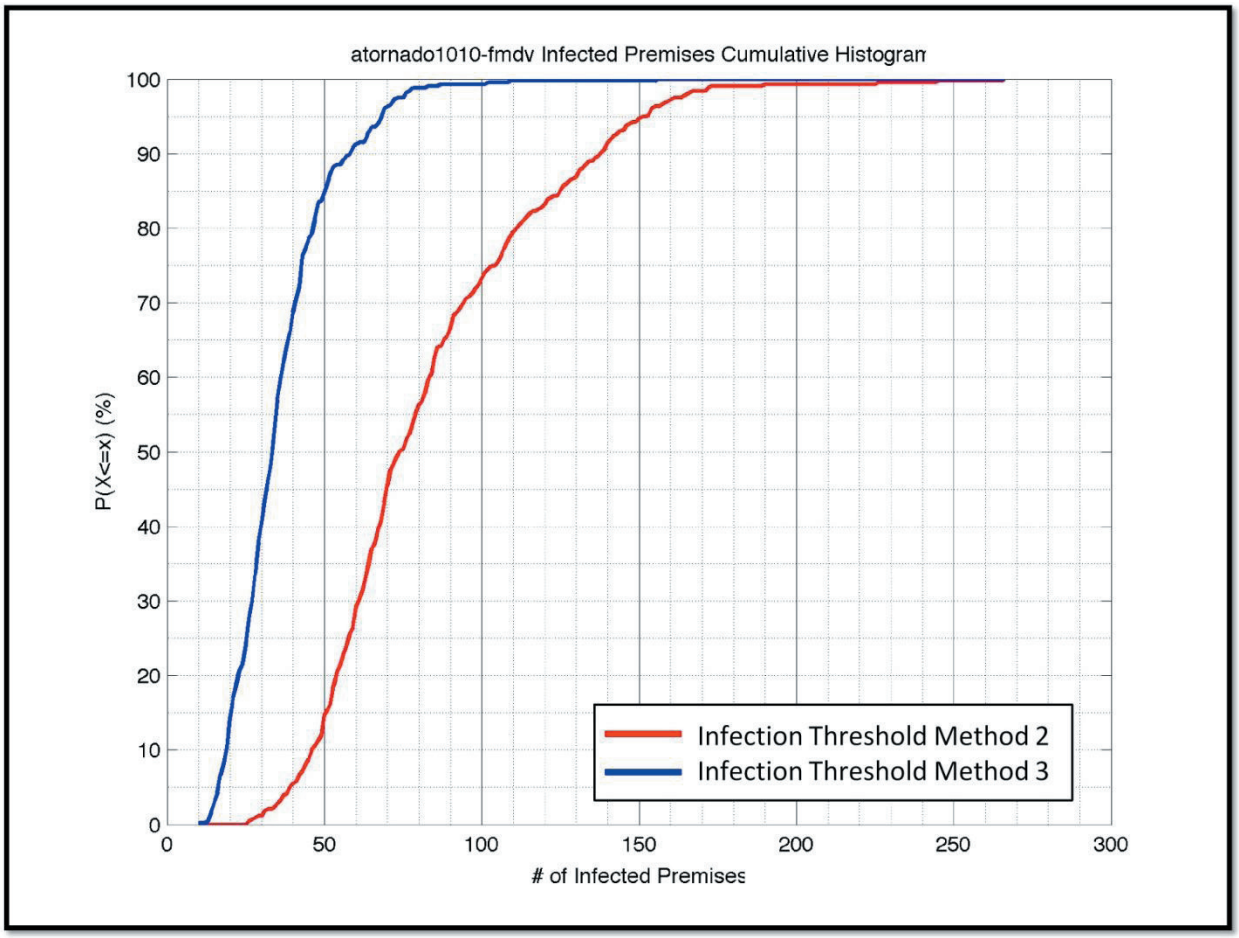


Figure 5.1.9-16: Cumulative Probability Distribution of the Number of Infected Locations (Tornado > 228 mph, High *Q* Value)

T > 228 mph (Low and Medium Source Values)

As expected, the inhalation exposure and probability of exceedance patterns for the tornado event (> 228 mph) with the low and medium *Q* value are similar to those associated with high *Q* value, but with lower overall magnitudes (Figure 5.1.9-17 and 5.1.9-18). Consequently, these events have nonzero probabilities of zero premises becoming infected; specifically, 5% and 35% for the medium and low infection risk methods, respectively (Figure 5.1.9-19). Additionally, the 5th, 50th, and 95th percentiles of infected premises are 0, 5, and 14, respectively, utilizing the medium infection risk threshold methodology, and 0, 1, and 4 infected premises, respectively, for the low infection risk threshold.

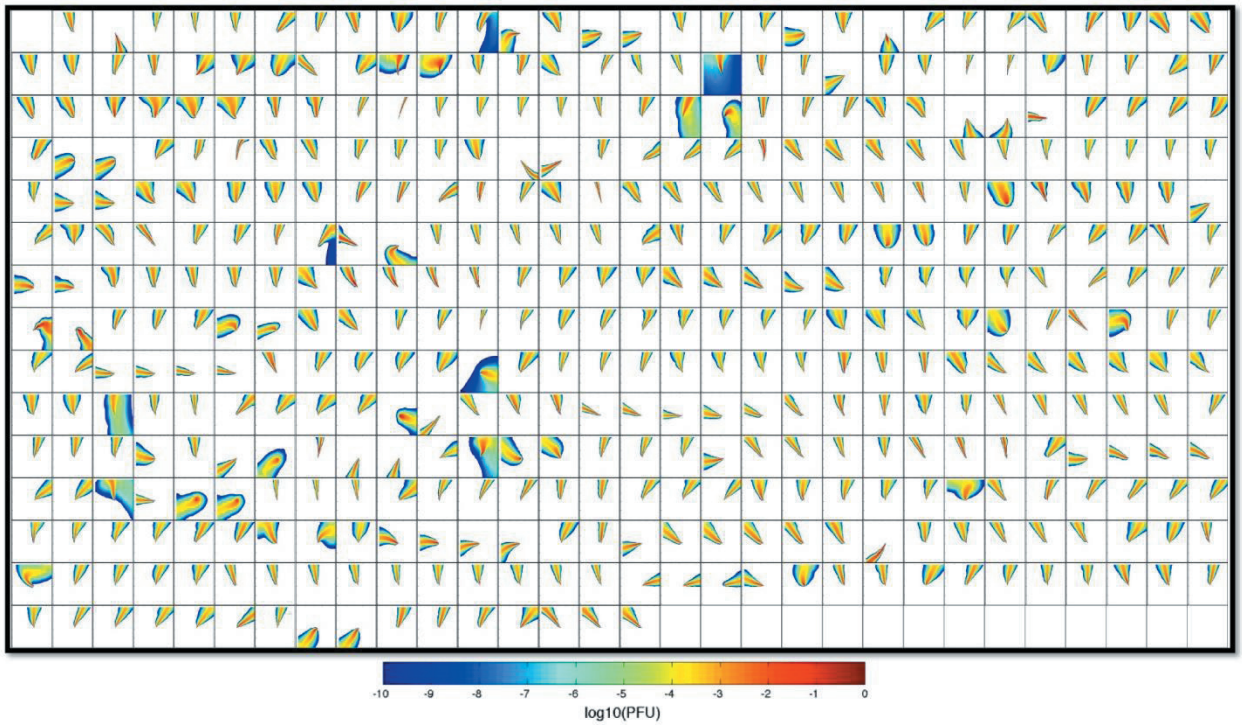


Figure 5.1.9-17: Cattle Inhalation Exposure Maps Corresponding to Meteorological Conditions Contained in the "Tornado" SOM Matrix (Tornado > 228 mph, Low and Medium *Q* Value)

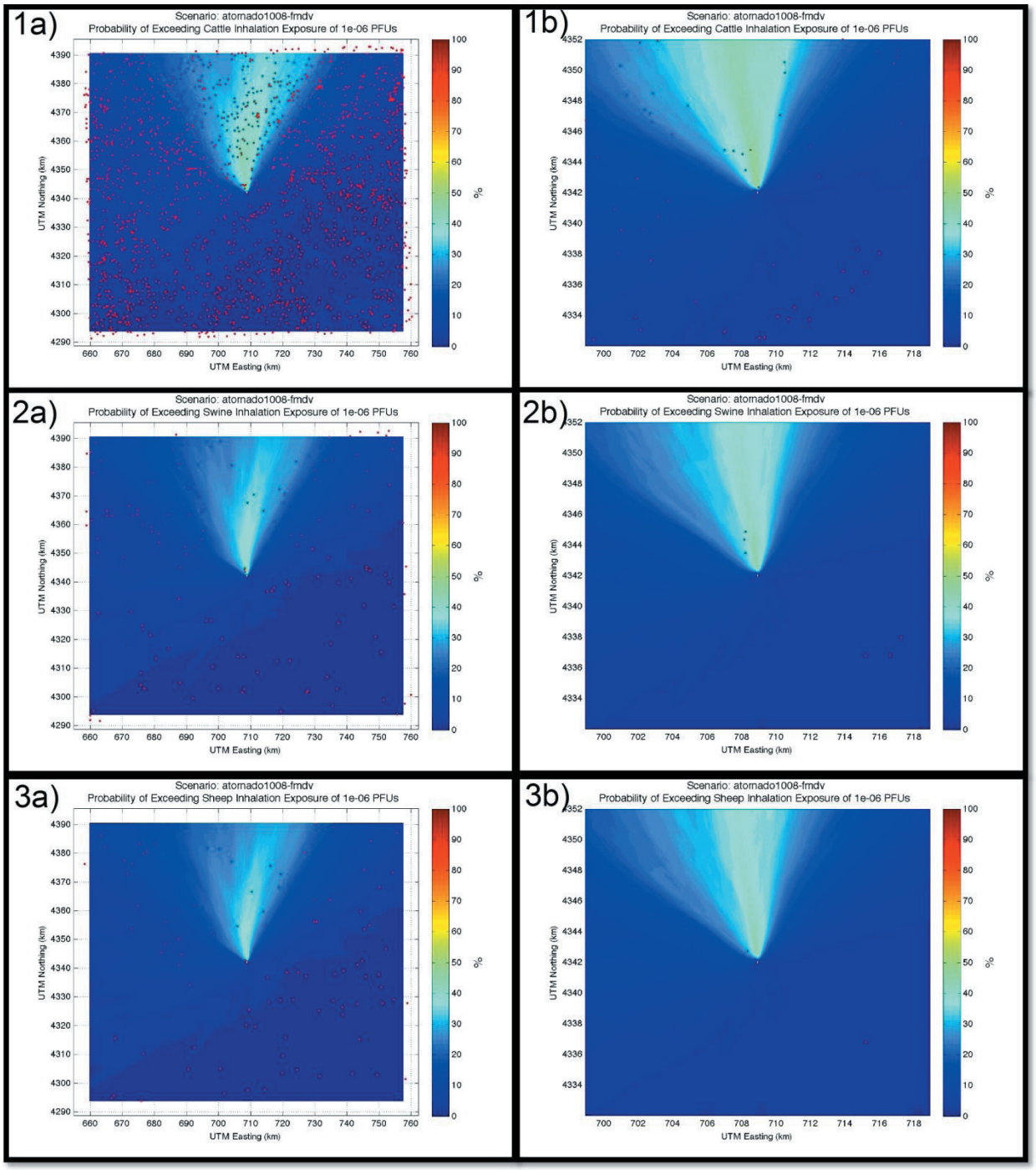


Figure 5.1.9-18: Probability of Exceeding an Inhalation Exposure of 10^{-6} PFU for: 1) Cattle; 2) Pigs; and 3) Sheep Over a) the Full 100 x 100 km Computational Domain and b) a 20 × 20 km Area Surrounding the NBAF (Tornado > 228 mph, Low and Medium *Q* Value)

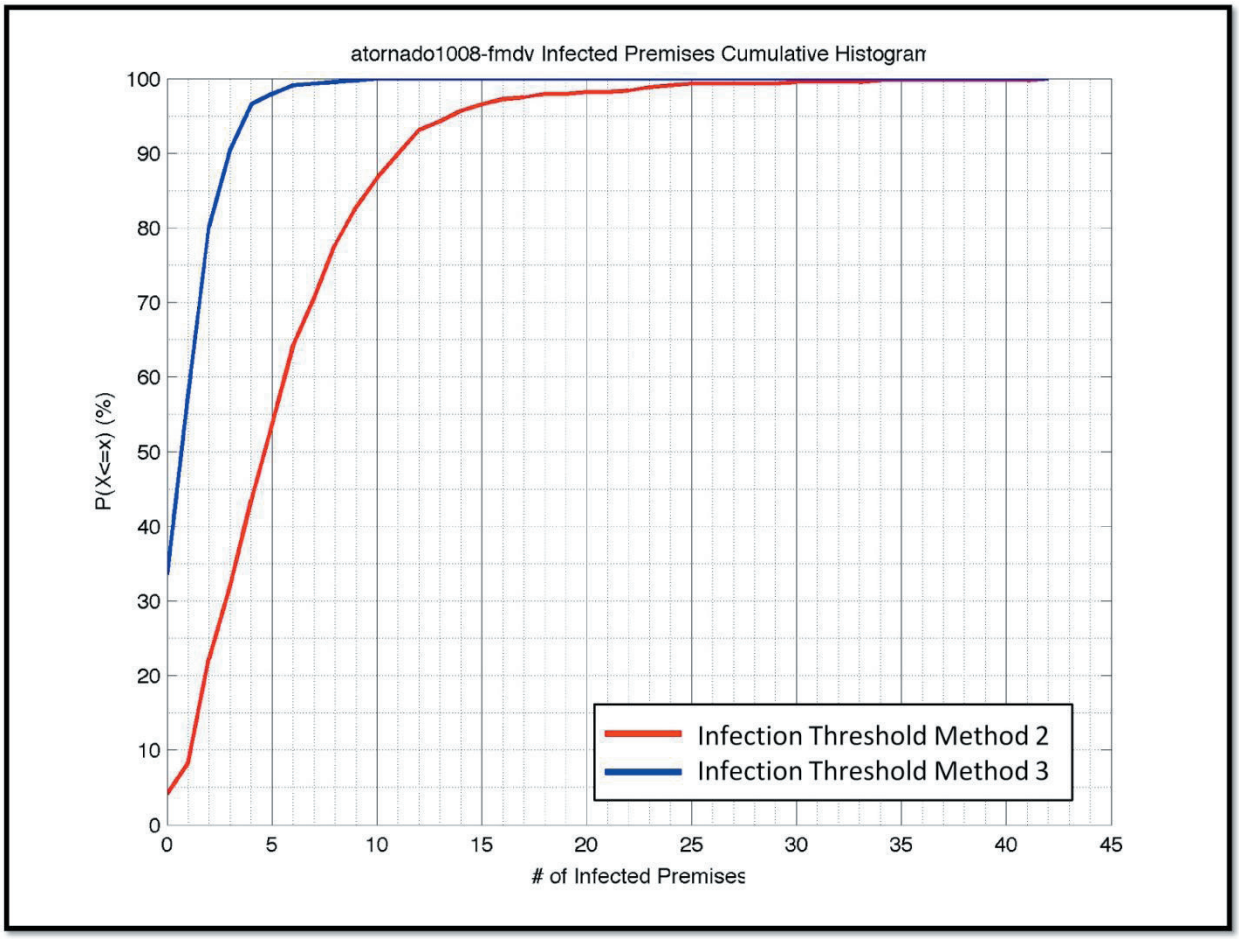


Figure 5.1.9-19: Cumulative Probability Distribution of the Number of Infected Locations (Tornado > 228 mph, Low and Medium *Q* Value)

5.1.9.6 Earthquake

A detailed summary of infections resulting from the structural failure of the NBAF due to a catastrophic earthquake is provided in Table 5.1.9-7. Maximum downwind infections of 121 were calculated for the high source (Q) value, when using the medium infection risk methodology (infection threshold method 2); 25 infected locations were obtained when using the low infection threshold risk methodology (infection threshold method 3). The high *Q* value results are identical to the results associated with BSL-3Ag non-functioning HEPA (AA10, high *Q* value) event, as identical initial modeling conditions were used for both events. The detailed results for the AA10 event are presented in Section 5.1.9.1. No premises were calculated to be infected with the medium or low source (Q) values.

Table 5.1.9 7: Earthquake Aerosol Release Results

Event ID	Modeled *Q* Value (PFU)	Maximum Infected Locations		Infected Locations					
				5th Percentile		50th Percentile		95th Percentile	
		Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
Earthquake	Low[a] 1.0×10^4	0	0	0	0	0	0	0	0
Earthquake	Medium[a] 1.0×10^5	0	0	0	0	0	0	0	0
Earthquake	High[a] 1.0×10^8	121	25	0	0	0	0	36	4

[a]The calculated *Q* values from Section 4.6 for the earthquake event were 1.51×10^4, 5.29×10^4, and 4.96×10^8. However, the nearest modeled aerosol values are presented in the table.

5.1.10 Aerosol Transport Model Sensitivity Analysis

Due to the inherent complexity of the SCIPUFF aerosol modeling system and uncertainties associated with various modeling input parameters, an analysis of the sensitivity of the aerosol model results (in terms of infected premises) to a small number of critical input parameters was performed. The input parameters included release location (x, y, z), initial Gaussian puff dimensions (σ_x, σ_y, σ_z), and Land Use/Land Cover (LULC) properties. The sensitivity of the model results to the initial released amount of infectious FMDv (Q) and input meteorological conditions is well known and directly accounted for within the aerosol release events (as described earlier) through the specification of a range of source values and input meteorological conditions. Model sensitivity was assessed by modifying the input parameters from baseline values within a pre-defined range and analyzing the effect of these changes on the number of infected premises. The baseline simulation configuration for the sensitivity analysis is provided in Table 5.1.10-1. A more detailed sensitivity analysis of each parameter set (location, puff dimension, and LULC) is provided in the sections below.

Table 5.1.10 1: Baseline Simulation Configuration

Parameter	Value
Release X Location (UTM Zone 14, km)	708.9186
Release Y Location (UTM Zone 14, km)	4342.007
Release Z Location (m)	25.908
Gaussian Puff X Dimension (m), σ_x	8.89×10^{-2}
Gaussian Puff y Dimension (m), σ_y	8.89×10^{-2}
Gaussian Puff z Dimension (m), σ_z	1.0567
LandUse/LandCover (LULC)	30 arc-second LULC Database

5.1.10.1 Release Location Sensitivity

The horizontal release location maximum and minimum range values were identified from the NBAF design plans, which assumed the maximum horizontal dimensions of the facility to be approximately 380 feet (~116 meters). Therefore, it was assumed that the horizontal release location could occur anywhere within a 116 meter × 116 meter area centered on the baseline release location (i.e., baseline location ± 58 meters). When defining the possible range of release heights (z-location), it was assumed the height could range anywhere between ground level and approximately two times the baseline height of 25.908 meters. Simulations were subsequently performed over the range of location values (Table 5.1.10-2) and are summarized in Table 5.1.10-3 and Figures 5.1.10-1 and 5.1.10-2.

Table 5.1.10 2: Release Location Value Range

Parameter	Value
Release X Location (UTM Zone 14, km)	708.9186 ± 0.058
Release Y Location (UTM Zone 14, km)	4342.007 ± 0.058
Release Z Location (m)	25.908 ± 25.908

The model output had little sensitivity when varying the horizontal location of the release, within the limits of the NBAF footprint, resulting in no more than a 2% change in maximum number of infections. Lowering the release height to ground level also resulted in almost indiscernible changes in the model results. Increasing the height of release to approximately two times the baseline height (approximately 50 meters or 164 feet) did result in appreciable changes in the model output (approximately 27% decrease in maximum infections), but this does not represent a realistic release height, given the current NBAF design. Disregarding this value and the associated results, it can be generally concluded that the Updated SSRA aerosol fate and transport simulation results are insensitive to uncertainties associated with the location of aerosol release from the NBAF.

Table 5.1.10 3: Release Location Simulation Results

Simulation ID	Maximum Infected Locations		Infected Locations					
			5th Percentile		50th Percentile		95th Percentile	
	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
Baseline	121	25	0	0	7	0	43	7
X + 58m	123	26	0	0	7	0	44	7
X 58m	120	26	0	0	7	0	42	7
Y + 58m	120	24	0	0	7	0	44	7
Y 58m	120	26	0	0	7	0	42	7
Z + 25.908m	88	16	0	0	6	0	34	4
Z 25.908m	122	29	0	0	7	0	42	6

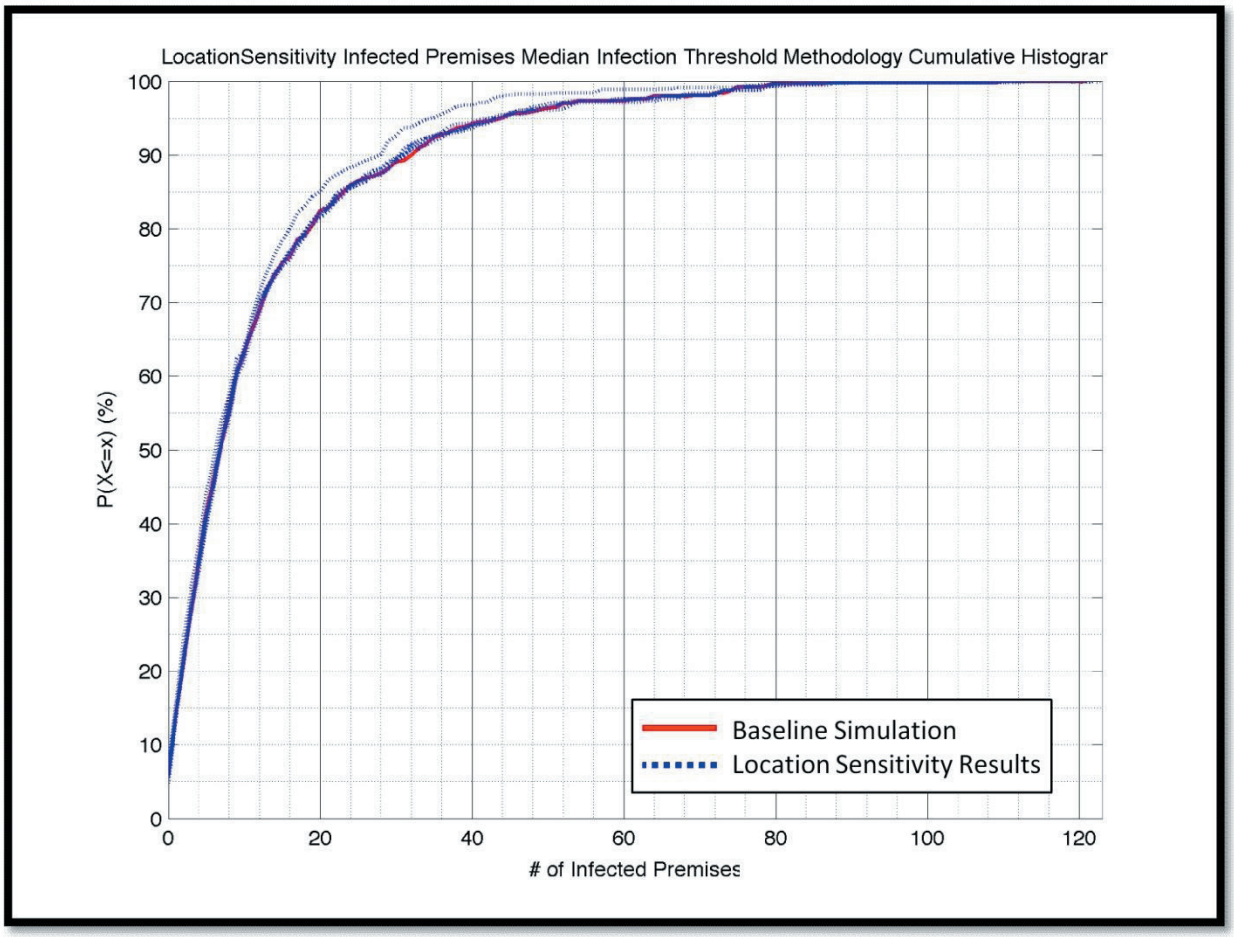


Figure 5.1.10-1: Release Location Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Medium Infection Risk Threshold Methodology

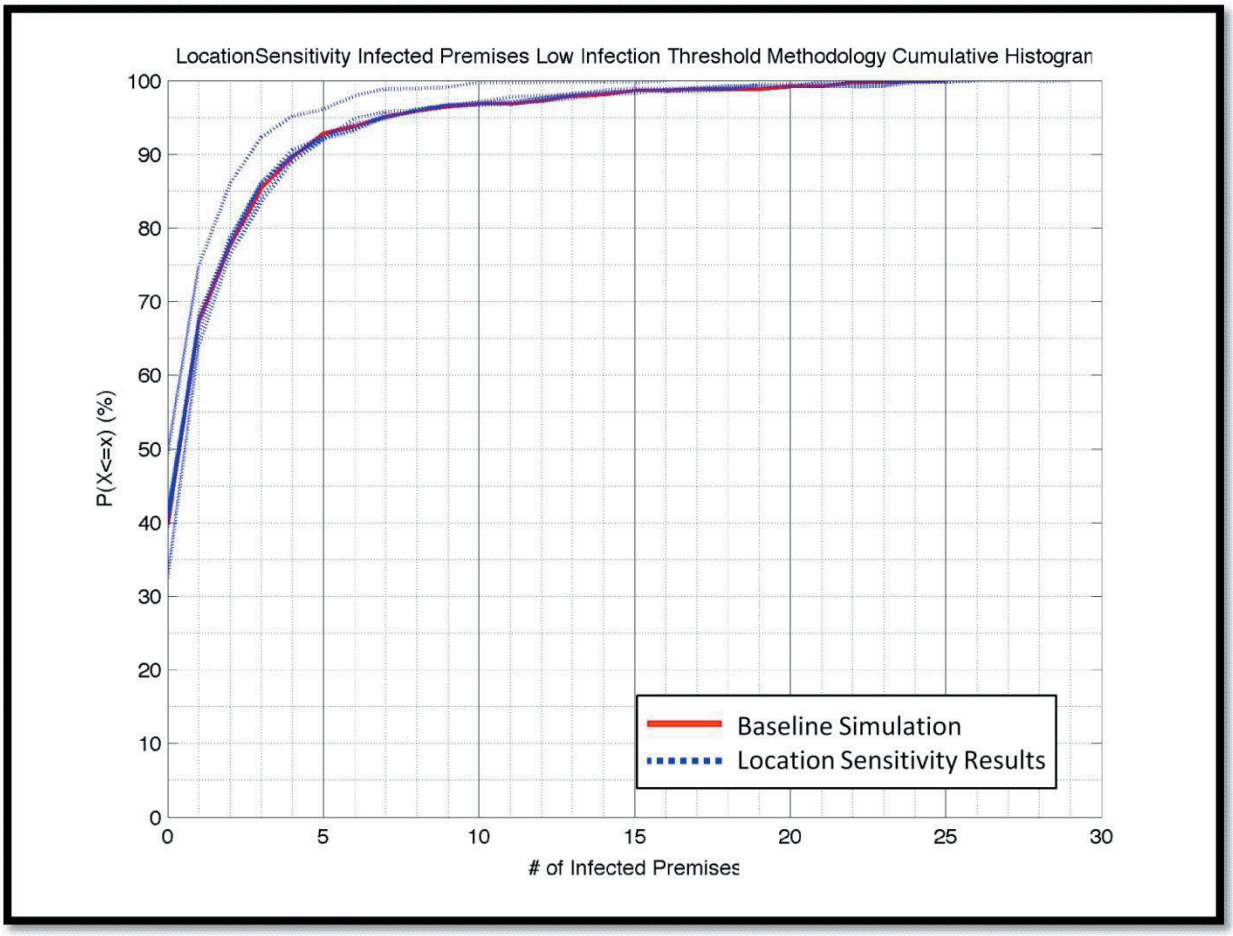


Figure 5.1.10-2: Release Location Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Low Infection Risk Threshold Methodology

5.1.10.2 Land Use/Land Cover (LULC) Sensitivity

For the Updated SSRA aerosol fate and transport simulations, LULC categories and associated surface properties were defined based on a 30 arc-second (1 km resolution) LULC database, as described in Section 5.1.7 and illustrated in Figure 5.1.7-1. In order to estimate the model sensitivity to LULC classification uncertainties, a LULC category was defined for the entire 100 km × 100 km computational domain and varied based on the predominant LULC categories found in the NBAF region (Figure 5.1.7-2). Consequently, the domain-wide LULC was defined as one of four LULC categories: 1) developed; 2) partly developed; 3) dry cropland/pasture; and 4) cropland/grassland with representative surface parameter values as illustrated in Table 5.1.10-4. These LULC categories represent a range of surface roughness and canopy height values spanning two orders of magnitude. Simulations were subsequently performed for each of these LULC categories and the results are summarized in Table 5.1.10-5 and Figures 5.1.10-3 and 5.1.10-4.

Table 5.1.10 4: LULC Value Range

LULC Category	Roughness (m)	Canopy Height (m)	Velocity Parameter Alpha	Albedo	Bowen Ratio		
					Dry	Normal	Wet
Developed	2.00E+00	2.00E+01	2.00E+00	1.60E-01	2.00E+00	1.00E+00	5.00E-01
Partly Developed	1.00E+00	1.00E+01	1.00E+00	1.60E-01	2.00E+00	1.00E+00	5.00E-01
Dry Cropland/Pasture	1.00E-02	1.00E-01	3.00E+00	1.80E-01	2.00E+00	1.00E+00	5.00E-01
Cropland/Grassland	2.00E-02	2.00E-01	2.50E+00	1.80E-01	1.00E+00	5.00E-01	2.00E-01

Table 5.1.10 5: LULC Simulation Results

Simulation ID	Maximum Infected Locations		Infected Locations					
			5th Percentile		50th Percentile		95th Percentile	
	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
Baseline	121	25	0	0	7	0	43	7
Developed	56	8	0	0	4	0	21	3
Partly Developed	109	16	0	0	4	0	38	5
Dry Cropland/Pasture	86	23	0	0	9	1	48	8
Cropland/Grassland	94	26	0	0	8	1	46	8

As compared to the location sensitivity analysis, uncertainties in LULC tend to more strongly impact the model results, with a more than 50% reduction in the number of infected premises, in some cases. However, the Updated SSRA model results represented by the baseline simulation represent a more conservative result, which is generally a preferred outcome when dealing with uncertainty in the risk assessment process. It should also be noted that the baseline LULC is a spatially varying set of LULC categories and properties, while the LULC sensitivity configurations represent a single homogeneous LULC category and associated set of surface properties for the entire 100 km × 100 km computational domain.

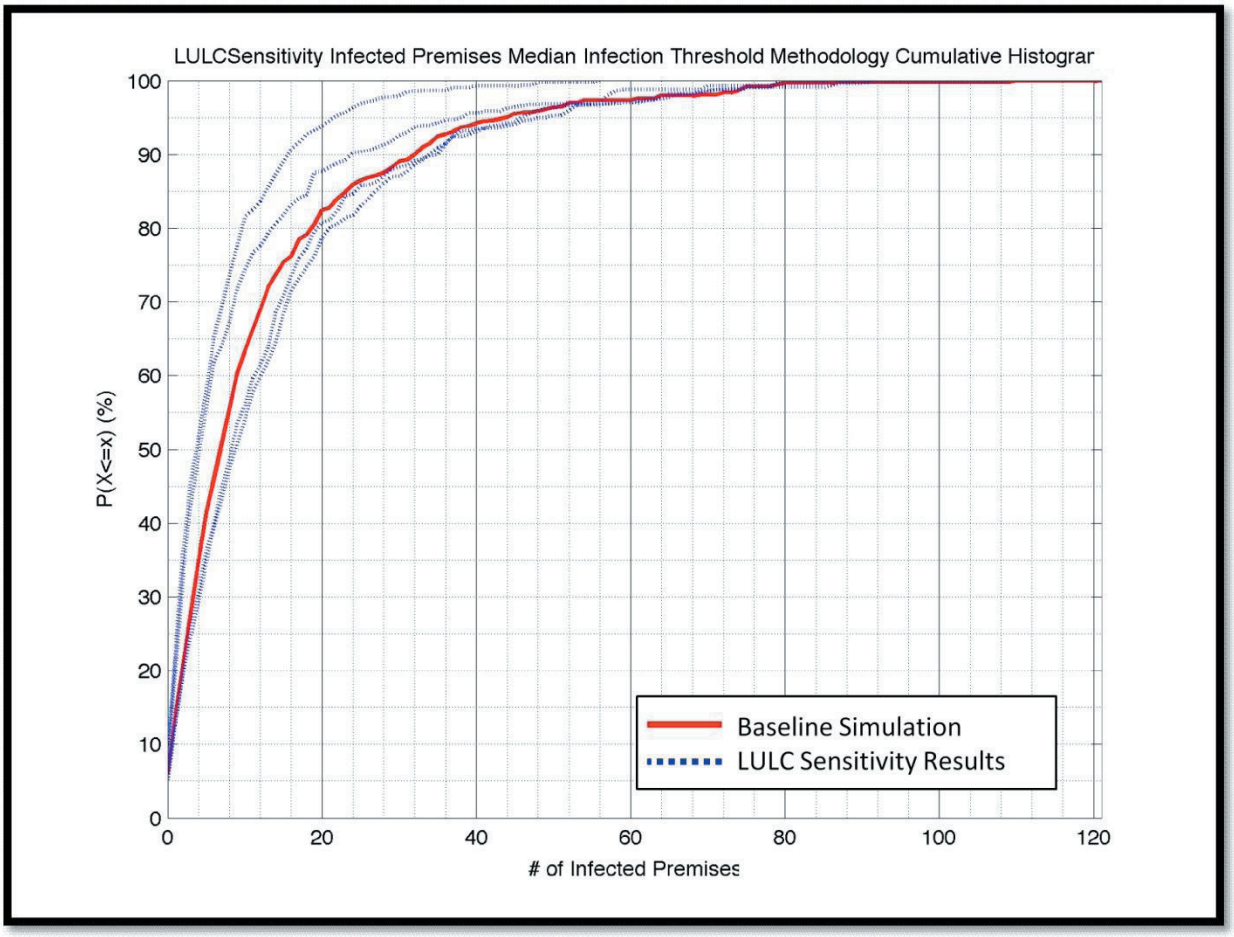


Figure 5.1.10-3: LULC Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Medium Infection Risk Threshold Methodology

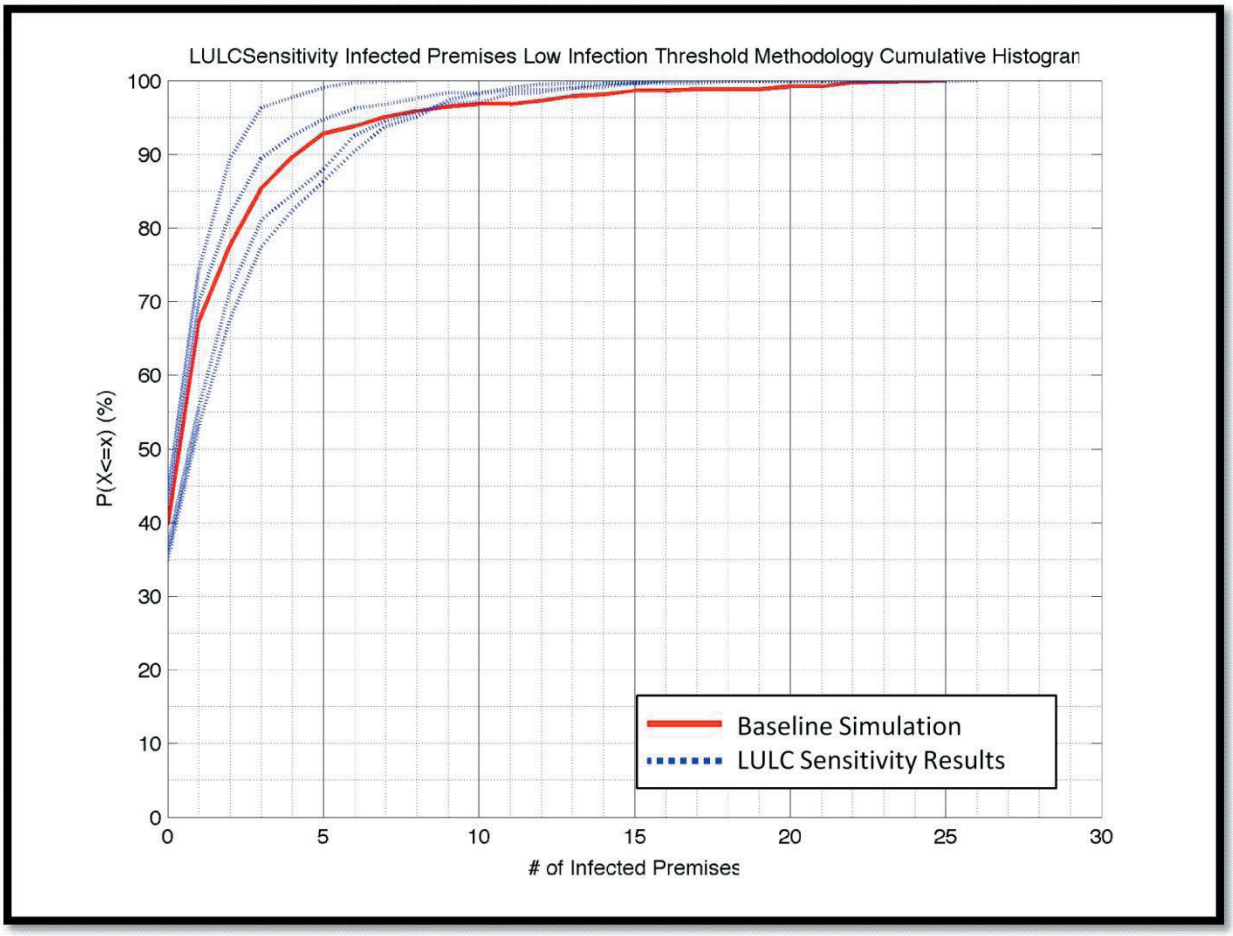


Figure 5.1.10-4: LULC Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Low Infection Risk Threshold Methodology

5.1.10.3 Initial Puff Dimensions Sensitivity

As described in Section 5.1.7, the baseline Gaussian puff dimensions were estimated based on the current designed diameter of the HVAC exhaust pipe (21 inches, 0.5334 meters) and associated exhaust exit velocity (6.34 m/s), by assuming that 3σ of the horizontal plume was equal to the pipe radius and that 3σ of the vertical plume extent was exhausted in one second from the stack. In the absence of obtaining a detailed estimate of HVAC exhaust stack dimensions and exhaust rate uncertainties, the puff dimensions were simply varied by three orders of magnitude (1 – 100 m), as shown in Table 5.1.10-6, to gauge, in a general sense, the model sensitivity to these parameters.

Table 5.1.10 6: Puff Dimension Value Range

Parameter	Values
Gaussian Puff X Dimension (m), σ_x	1, 10, 100
Gaussian Puff y Dimension (m), σ_y	1, 10, 100
Gaussian Puff z Dimension (m), σ_z	1, 10, 100

As shown in Table 5.1.10-7, varying the puff dimensions between 1 and 10 meters resulted in only minor changes from the baseline results of no more than 9%, while varying the dimensions up to 100 meters, resulted in an approximately 40% decrease in maximum number of infected locations. Again, the probability of the initial puff being greater than the size of the entire NBAF (i.e., 100 meter Gaussian moments), for the release events discussed earlier, is extremely low and in many ways unrealistic. As noted for the LULC sensitivity analysis, the baseline results for the puff dimension simulations also provide a conservative estimate as compared to the results utilizing the other possible parameter values (Figure 5.1.10-5 and Figure 5.1.10-6).

Table 5.1.10 7: Puff Dimension Simulation Results

Simulation ID	Maximum Infected Locations		Infected Locations					
			5th Percentile		50th Percentile		95th Percentile	
	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk	Med Risk	Low Risk
Baseline	121	25	0	0	7	0	43	7
1m Dimension	121	26	0	0	7	0	43	7
10m Dimension	111	26	0	0	7	0	44	7
100m Dimension	72	92	0	0	7	0	32	4

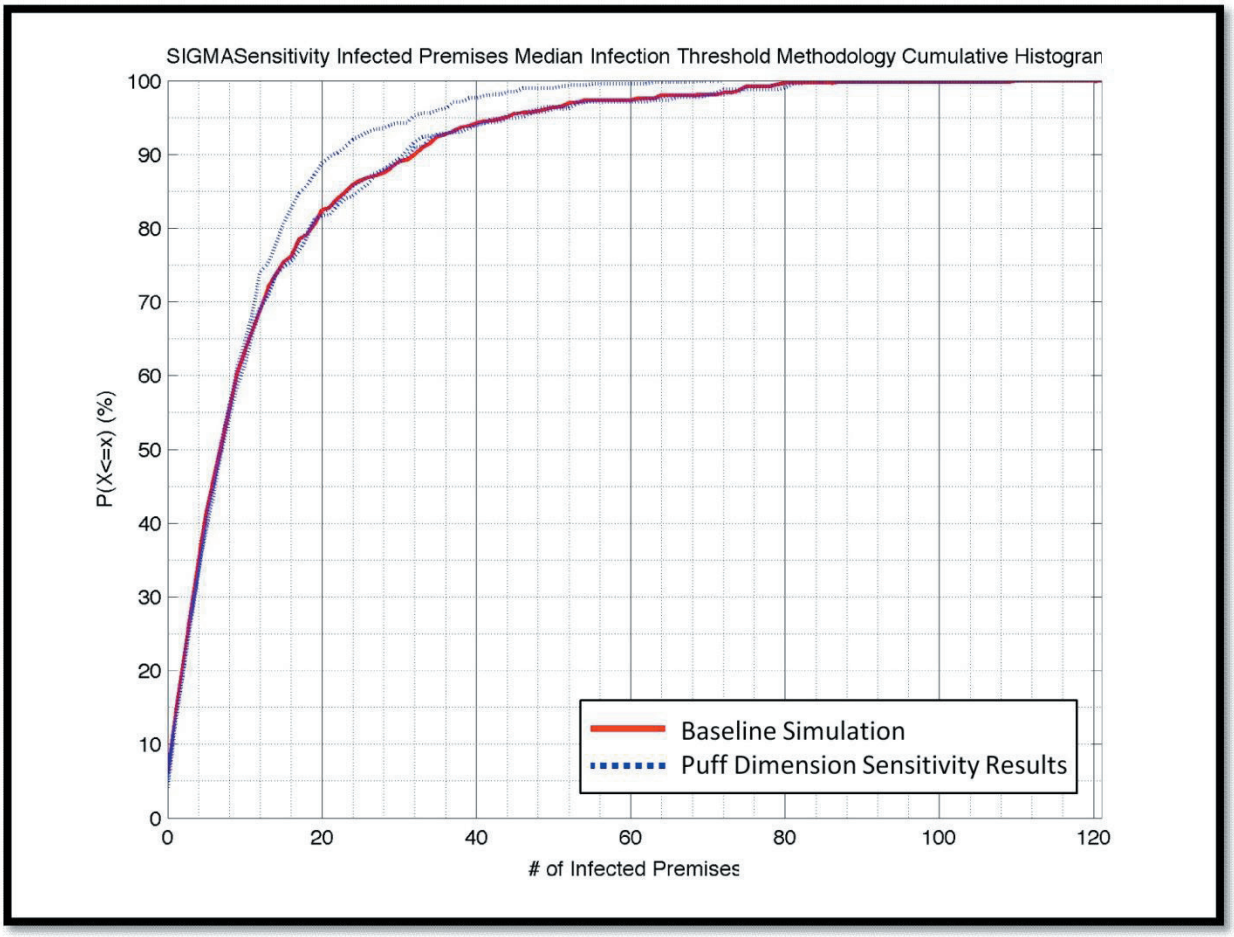


Figure 5.1.10-5: Puff Dimension Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Medium Infection Risk Threshold Methodology

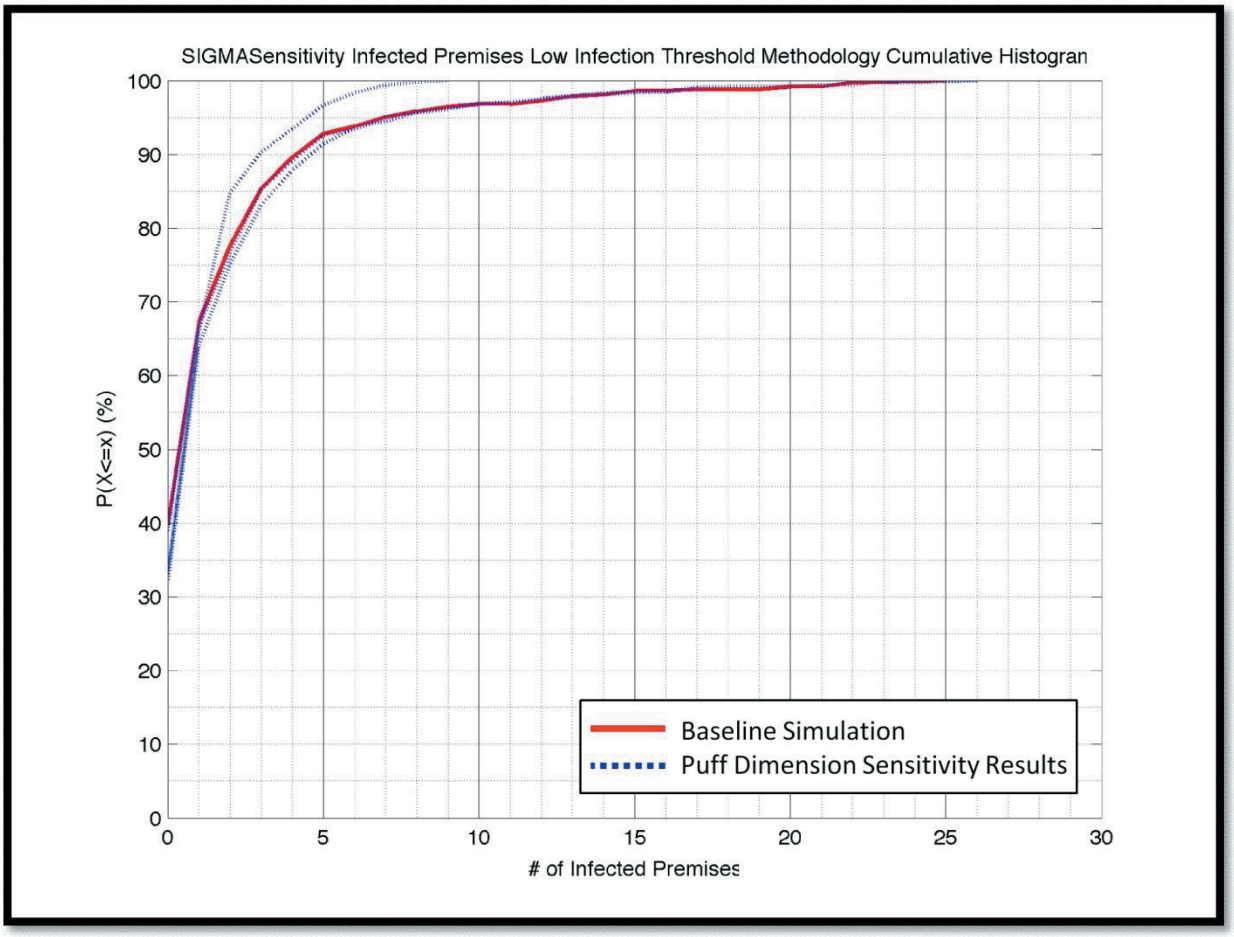


Figure 5.1.10-6: Puff Dimension Sensitivity Simulation, Cumulative Probability Distributions of the Number of Infected Locations, Utilizing the Low Infection Risk Threshold Methodology

5.2 Solid Waste

As described in previous sections, solid wastes from the NBAF will be treated with multiple disinfection or sterilization techniques prior to removal from the campus. The addition of on-site incineration (since the performance of the SSRA in 2010) greatly reduces the potential for treated waste containing any viable pathogenic material to be released to the environment. The solid waste streams originating from the modeled locations (those where FMDv may be used in research, diagnostics, or training) are generally autoclaved before removal to the BSL-3E area. Solid waste, as indicated in Figure 5.2-1, is then aggregated in the BSL-3E waste core (Figure 5.2-2). The waste core comprises four large bulk sterilizers (two pit-mounted and two floor-mounted) equipped with vaporous decontamination ports for additional, optional, decontamination processing. All waste from containment areas will be processed through one of these decontamination procedures and then incinerated on site. Treated solid components from tissue autoclaves (carcass disposal) located between the containment areas and the basement are containerized (with a semi-automated system) and moved back to the first floor, as indicated in Figure 5.2-3, for incineration. After incineration, solid residuals from the incinerator are compacted at the Transshipping Facility before being removed from the NBAF by municipal service providers.

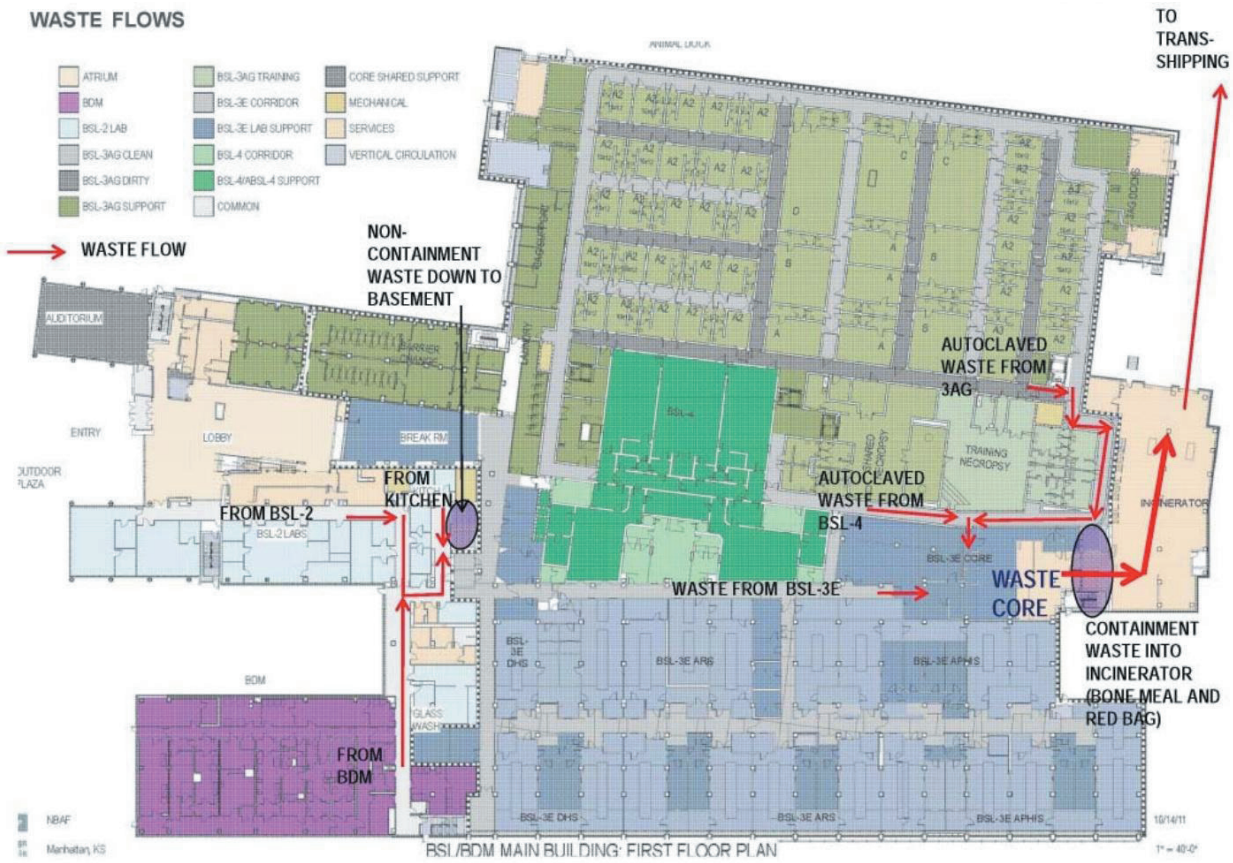


Figure 5.2-1: Aggregation of Containment Solid Waste from BSL-3Ag, BSL-3E, and BSL-4

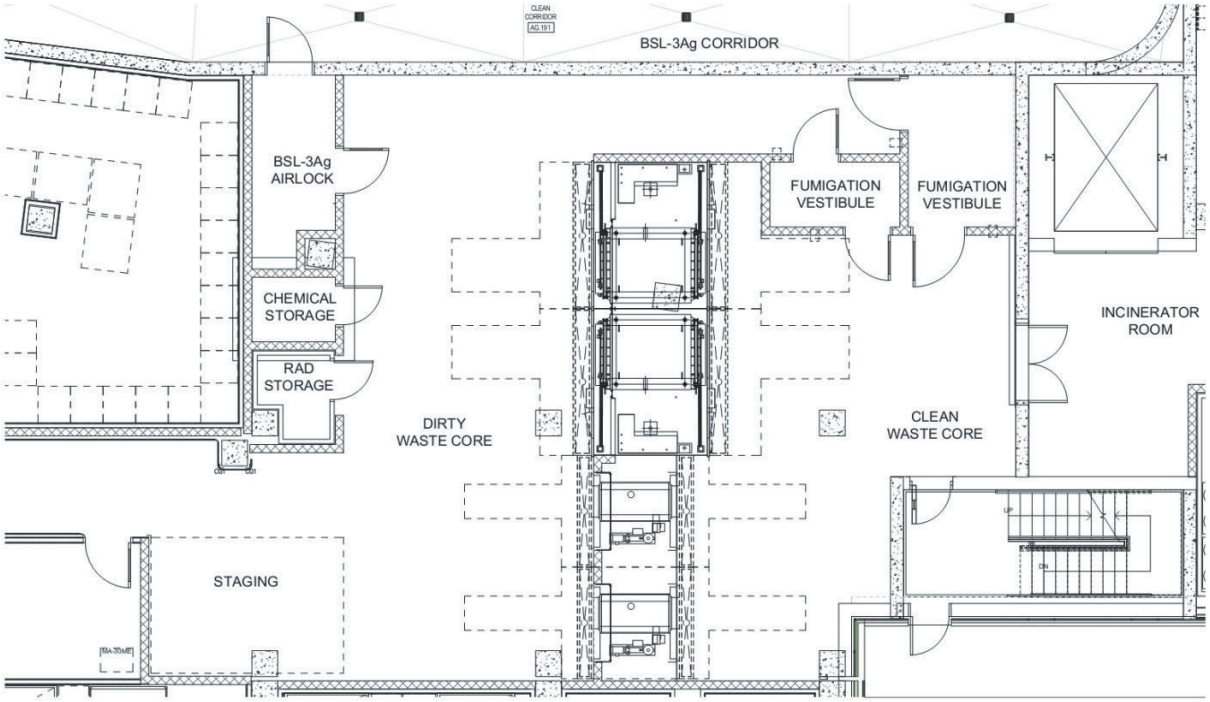


Figure 5.2-2: BSL-3E Waste Core

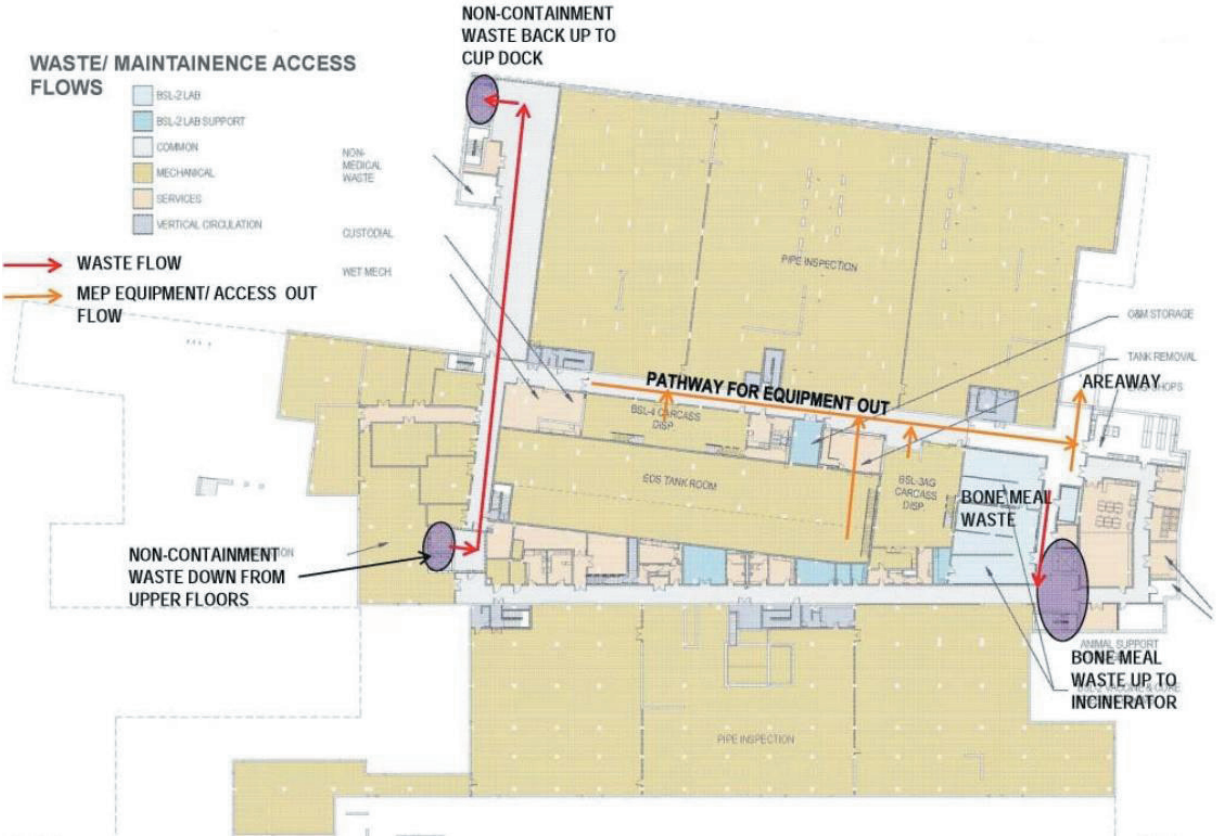


Figure 5.2-3: Tissue Autoclave Solid Residuals to Incinerator Staging

For an index infection to occur as the result of a failure in the solid waste processing and disposal pathway (non-transference), contaminated solid waste would have to leave the NBAF and be transported to a location where a susceptible species could be exposed to quantities of viable virus sufficient to cause infection. A representative event tree for an index infection is presented in Figure 5.2-4. For the solid waste pathway, the only event considered is the following: the infected waste would have to fall from the solid waste conveyance (waste truck) in the proximity of a premise with susceptible species. The lost solid waste would then have to be accessible to the animal(s) and the animal(s) would have to interact with the waste to become infected. These modeled nodes are indicated in the event tree as nodes 1-4. Because of the stability of FMDv, no loss of virus viability is modeled for the duration of the transit between the NBAF and the loss of waste.

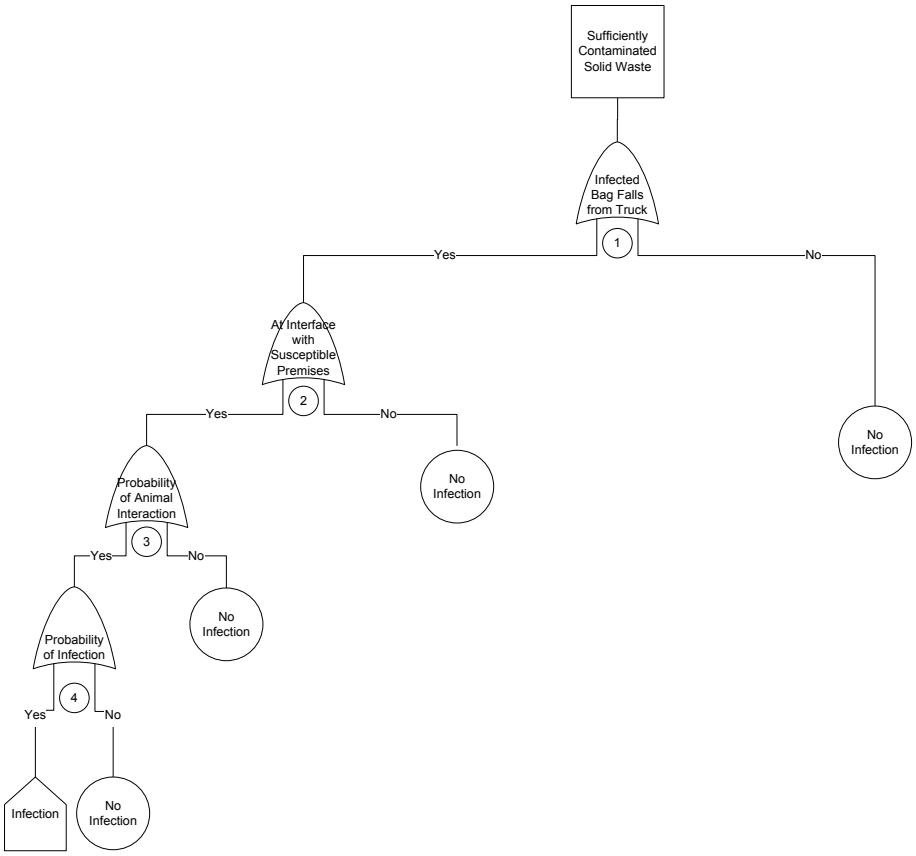


Figure 5.2-4: Conditional Event Tree for Bag of Infected Waste Falling from Truck and Infecting Susceptible Species

Although there are other possible scenarios (e.g., a bird or feral swine comes into contact with the waste at the landfill), only the scenario described above (and depicted in Figure 5.2-4) was considered for the Updated SSRA.

The events (frequency and virus source term values) related to the introduction of viable material into the off-site solid waste pathway are developed and presented in Section 4. In an event where infectious waste is introduced to the off-site solid waste pathway, the accident sequence is modeled as indicated

in the event tree. The source term (Q) developed for each event is reduced by a dilution factor that incorporates the aggregation of incinerator waste from all the laboratory areas and other solid waste sources.

The NBAF is expected to generate 21,000 lbs of ash from the incineration process per year [NDP, June 2010] or approximately 57.7 lbs of ash per day. This corresponds to approximately 2 bags of solid waste ash at approximately 30 lbs/bag per day.

In addition, residual dewatered solids from the on-site wastewater treatment plant will be removed by the municipal solid waste collection service. The NBAF Design Partnership estimates that 2 cubic yards (approximately 350 gallons) of dewatered solids will be produced each day by this process. For modeling purposes, it is assumed that the solid residuals will be containerized (bagged) and removed daily (actual pickup may be less frequent). The sources of the dewatered solid residuals (from the liquid effluent) include all domestic sources from the Main Laboratory Building and the Transshipping Facility and the treated laboratory liquid effluent. However, it is estimated that 95% of the solids (calculated from the TSS contributions) come from non-domestic sources. Commercial trash bags vary in size but bags of 60 gallons or more are not uncommon. Thus, the disposal of the dewatered solids is modeled as an additional 6 bags of solid waste per day.

It is assumed that the solid waste generated from the incinerator and from the on-site wastewater treatment plant will be combined prior to bagging, and thus any viable remaining material is evenly distributed in all eight bags. Therefore, only one-eighth of the source term would be released with the loss of a single bag. The source term (Q) is reduced by 87.5% before the probit model is used to estimate the probability of infection. The diluted source terms for the solid waste events are presented in Table 5.2-1.

Table 5.2 1: Dilution Factor Applied to Source Term

	Q (PFU)			*Q* Diluted (PFU)		
Event ID	Low	Medium	High	Low	Medium	High
AS1	2.38E-20	6.56E-16	1.24E-13	2.98E-21	8.20E-17	1.55E-14
AS2	2.38E-14	6.56E-10	1.24E-07	2.98E-15	8.20E-11	1.55E-08
AS3	2.38E-11	6.56E-07	1.24E-04	2.98E-12	8.20E-08	1.55E-05
AS4	2.38E-08	6.56E-04	1.24E-01	2.98E-09	8.20E-05	1.55E-02
AS5	2.38E-05	6.56E-01	1.24E+02	2.98E-06	8.20E-02	1.55E+01
AS6	2.38E+01	6.56E+05	1.24E+08	2.98E+00	8.20E+04	1.55E+07
NSW1	1.73E-18	3.59E-15	2.82E-10	2.16E-19	4.49E-16	3.52E-11
NSW2	1.73E-12	3.59E-09	2.82E-04	2.16E-13	4.49E-10	3.52E-05
NSW3	1.73E-09	3.59E-06	2.82E-01	2.16E-10	4.49E-07	3.52E-02
NSW4	1.73E-06	3.59E-03	2.82E+02	2.16E-07	4.49E-04	3.52E+01
NSW5	1.73E-03	3.59E+00	2.82E+05	2.16E-04	4.49E-01	3.52E+04
NSW6	1.73E+03	3.59E+06	2.82E+11	2.16E+02	4.49E+05	3.52E+10
NST1	6.91E-12	1.44E-08	1.13E-03	8.63E-13	1.79E-09	1.41E-04
NST2	6.91E-03	1.44E+01	1.13E+06	8.63E-04	1.79E+00	1.41E+05
NST3	6.91E-06	1.44E-02	1.13E+03	8.63E-07	1.79E-03	1.41E+02
NST4	6.91E+03	1.44E+07	1.13E+12	8.63E+02	1.79E+06	1.41E+11

Table 5.2 1: Dilution Factor Applied to Source Term						
	Q (PFU)			*Q* Diluted (PFU)		
Event ID	Low	Medium	High	Low	Medium	High
ES1	8.57E-21	2.91E-16	9.91E-12	1.07E-21	3.63E-17	1.24E-12
ES2	8.57E-15	2.91E-10	9.91E-06	1.07E-15	3.63E-11	1.24E-06
ES3	8.57E-12	2.91E-07	9.91E-03	1.07E-12	3.63E-08	1.24E-03
ES4	8.57E-09	2.91E-04	9.91E+00	1.07E-09	3.63E-05	1.24E+00
ES5	8.57E-06	2.91E-01	9.91E+03	1.07E-06	3.63E-02	1.24E+03
ES6	8.57E+00	2.91E+05	9.91E+09	1.07E+00	3.63E+04	1.24E+09

All of the solid waste will be processed by Riley County; however, the Riley County Sanitary Landfill is currently closed (2011). Solid waste collected from the service area (including the NBAF) may be aggregated at the Riley County Transfer Station (RCTS) (1881 Henton Road, Manhattan, Kansas) before being transferred to the NR Hamm Quarry (landfill) located near 16920 3rd Street in Perry, Kansas. This landfill is approximately 83 miles from the NBAF—about a 1.5 hour drive. The locations of the RCTS and the landfill in relation to the NBAF are shown in Figures 5.2-5 and 5.2-6, respectively. Currently, it is not known if the NBAF solid waste will be handled by the county as routine waste and aggregated with other municipal solid waste at the Riley County Transfer Station or if the NBAF waste will go directly to the Hamm Quarry. For the purposes of the Updated SSRA, this process is modeled as if the waste will be transported to the RCTS before ultimate delivery to the landfill.

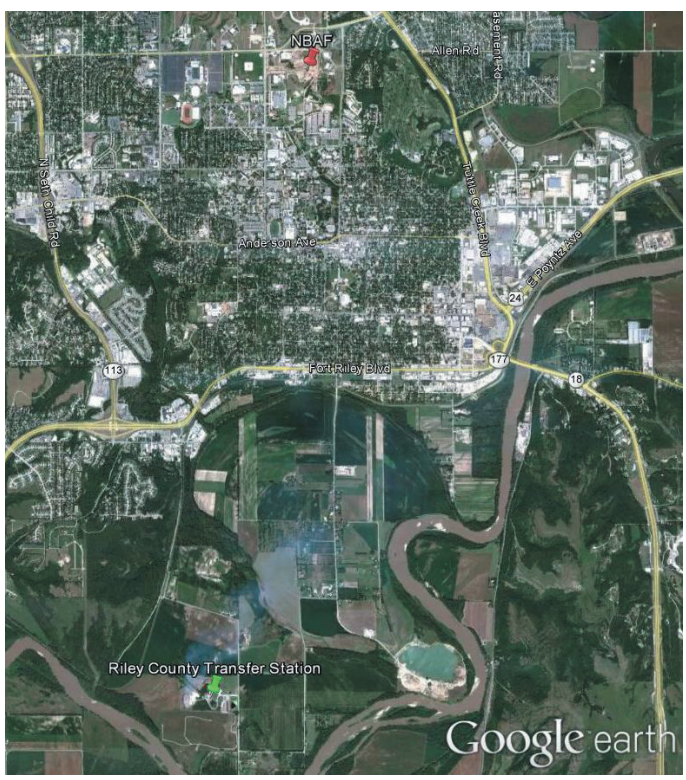


Figure 5.2-5: Relative Location of Riley County Transfer Station and Routes to the NBAF

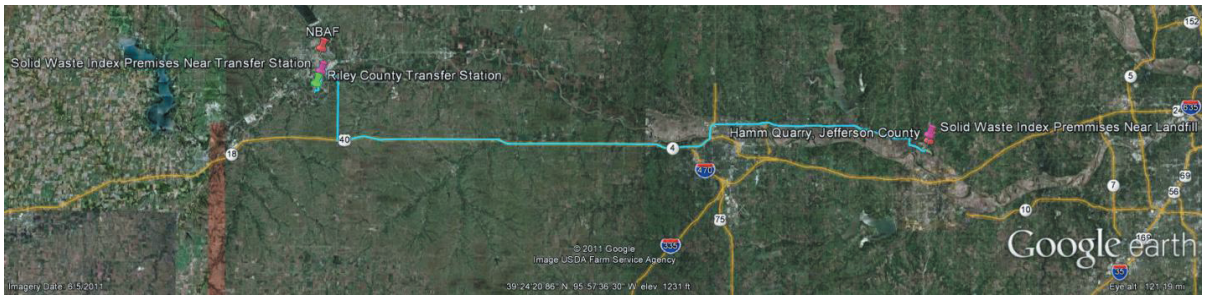


Figure 5.2-6: Relative Location of Landfill (Hamm Quarry) to the NBAF

Since the specific routing and schedule of the solid waste removal vehicles between NBAF and the RCTS have not yet been determined, three potential routes were identified, as shown in Figure 5.2-7. No data on the loss rate of bagged waste for the Manhattan solid waste providers was identified. However, the Florida Center for Solid and Hazardous Waste Management (FCSHWM) collected data on solid waste losses from three different commercial waste collection services (Alachua County, FL) in an attempt to characterize the solid waste losses that occur in transit [FCSHWM, 2003]. Sixteen vehicles were followed for multiple days to record observations on solid waste losses and associated causes. The results indicate that loss of some solid wastes occurred at 28.8% of the pickup locations and in-transit losses occurred after 20.8% of the pickups. However, the in-transit losses comprised pieces of paper and loose small plastic items. Solid waste losses were not noted to be correlated to vehicle speed. Spills, or losses, during the pickup process included most components of the solid waste load. As related to the in-transit losses after a pickup, the FCSHWM report indicates that "if properly bagged, (litter) would not have blown out of or off the truck." Uncontained polystyrene appeared to be the most problematic solid waste component. It was also noted that driver/operator performance varied considerably for the different vehicles. Some drivers made no effort to resolve potential litter/loss of solid waste while others would make special accommodations, as necessary, to minimize the potential loss of solid waste.

The FCSHWM data collection included observations from 337 solid waste pickups and subsequent transits. Since bagged waste was not observed in the litter lost from the trucks in transit, a maximum probability of 1/338 (~ 3×10^{-3}) is used as the probability of losing a bag from the truck while in transit. A smaller commercial front-loading truck (such as the Hercules) is capable of hauling 35 cubic yards of waste [E-Z Pack Manufacturing, 2011]. An average of approximately 200 gallons of trash (non-compacted waste) will fit into each cubic yard [Wastecare, 2011] so a smaller truck may carry as much as 7,070 gallons of trash. Therefore, a smaller waste truck may carry in excess of 100 bags (60 gallon) of waste. No data on specific non-NBAF waste collection routing and waste volumes has been collected and a conservative assumption of 50 bags per truckload is used as a load estimate. Thus, the probability of losing one of the eight bags of solid waste from NBAF (incinerator waste and solid residuals from the on-site wastewater treatment) is $1/338 \times 8/50 = 4.73 \times 10^{-4}$. $P_{Bag\ Loss}$ was set to 4.73×10^{-4} for each daily municipal solid waste load from the NBAF.

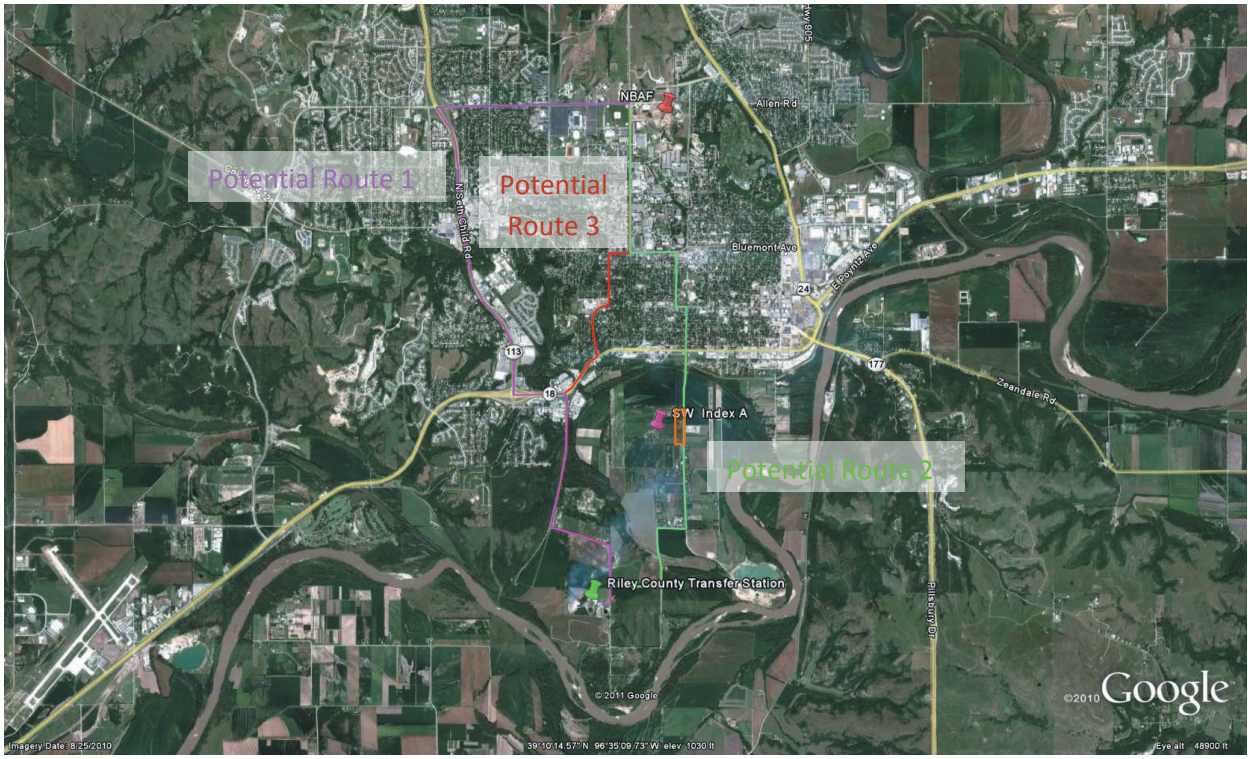


Figure 5.2-7: Potential Routes Between the NBAF and the Riley County Transfer Station

It is recommended that NBAF personnel observe (and correct, as necessary) the solid waste collection and loading process (performed by the solid waste removal contractor) at the Transshipping Facility. Any solid waste that is spilled during the loading process should be recovered, bagged, and added to the waste load. All NBAF personnel should also be required to participate in periodic waste handling training programs that emphasize the importance of properly bagging waste before disposal. It is also recommended that solid waste providers be required (by Riley county authorities) to participate in periodic awareness and loss prevention education programs.

An overlay of the routes from the NBAF to the RCTS on a map that indicated the presence of susceptible animals was used to identify susceptible premises with frontage along the identified routes. The only identified premise (identified in Figure 5.2-7 by "SW Index A") with frontage along any of the routes was located along the "green route" (Potential Route 2) on County Highway 93. This premise has a relatively small number of goats. The probability of the solid waste being lost along the interface with the susceptible premise is determined by the premise's interface length (0.5 miles, indicated in orange on Figure 5.2-7) divided by the average total route length (Table 5.2-2) of 5.8 miles, which equates to a $P_{interface}$ of 8.67×10^{-2}. (The average route length is used because the precise route has not been determined.)

Table 5.2 2: NBAF to RCTS Route Lengths

Route	Distance (miles)
1	6.9
2	5.4
3	5.0
Average	**5.8**

The exact mode of transmission from a vehicle (on the road) to the infected animal(s) is not known or understood. Likewise, the probability of interaction between lost solid waste and a susceptible animal is difficult to model. However, in the Final Report on the Potential Breaches of Biosecurity at the Pirbright Site, the UK Health and Safety Executive (HSE) concluded that vehicles with FMDv-contaminated mud (from a leaking underground intra-building sewer line) drove "along Westwood Lane," which is adjacent to the premises of suspected index cases of the 2007 outbreak [HSE, 2007]. If the lost solid waste falls within the reach of the animals, the natural curiosity of most susceptible species would make contact and interaction with the waste likely. No data on the probability or likelihood of the waste falling from the truck and then being moved across the right-of-way and through any potential perimeter fencing was found. It is unrealistic to assume that 100% of the waste (with infectious material) lost would be involved in an interaction with a susceptible species. It is also unrealistic to assume that no lost waste will be involved in any interaction with a susceptible species. In the absence of other data, the probability of interaction ($P_{interaction}$) was modeled as 0.5. The final infection frequency for each event is directly proportional to this parameter. However, the sensitivity of the outcomes to the selected $P_{interaction}$ is of little significance because the infection frequencies are so small.

The probability of infection from the solid waste (given that it leaves NBAF, falls from the truck in the proximity of a susceptible premises, and is engaged by an animal) is modeled with the probit relationship between the probability of infection and the dose. This probability varies for species and route of entry—the probit curve for aerosol infection of goats (consistent species at the premises), $P_{aerosol}$ (as developed in Section 6 and Appendix A6), is used to calculate the probability of infection if the waste contains more than a minimum infectious dose of 1 PFU. (Note that literature would support the use of a higher value for the MID [Donaldson et al., 1987] but the 1 PFU value provides a more conservative model result.) The slope and probit intercept for sheep (aerosol) are 0.7175 and 4.6268, respectively. Table 5.2-3 presents the modeled probabilities for each branch in the event tree (Figure 5.2-4).

Table 5.2 3: Solid Waste (Between NBAF and RCTS) Event Table

Node	Description	Probability (Yes)	Probability (No)
1	$P_{Bag\ Loss}$: infected bag of solid waste falls from truck (conditional upon infected waste being in truck)	4.73×10^{-4}	9.9953×10^{-1}
2	$P_{interface}$: at interface with susceptible premises	8.67×10^{-2}	9.14×10^{-1}
3	$P_{interaction}$: conditional probability of animal interaction	5×10^{-1}	5×10^{-1}
4	$P_{aerosol}$: conditional probability of infection	$P_{aerosol} = f(Q)$	$1-P_{aerosol}$

The outcome of each modeled event is determined by combining data from the Master Fault Table (Table 4.7-1) and the Event Table (Table 5.2-3) to determine the events for which an infection occurs

and the final infection frequency. For transit between the NBAF and the RCTS, the results are tabulated in Table 5.2-4 with the infection events presented in red text. As seen from this table, the highest frequency event, NST2 (incineration failure) has a frequency of 8.67×10^{-9} (95th percentile source term) events per year with a corresponding period of 1.15×10^{8} years, or approximately one event every 115 million years.

Table 5.2 4: Index Case Frequencies for Solid Waste Loss Between NBAF and RCTS

Event ID	*Q* (Diluted)			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AS1	2.98E-21	8.20E-17	1.55E-14	9.9998E-01	113	1.13E+02	0	0	0	0	0	0
AS2	2.98E-15	8.20E-11	1.55E-08	2.0000E-05	113	2.27E-03	0	0	0	0	0	0
AS3	2.98E-12	8.20E-08	1.55E-05	9.9998E-11	113	1.13E-08	0	0	0	0	0	0
AS4	2.98E-09	8.20E-05	1.55E-02	1.0000E-10	113	1.13E-08	0	0	0	0	0	0
AS5	2.98E-06	8.20E-02	1.55E+01	2.0000E-15	113	2.27E-13	0	0	6.85E-01	0	0	3.19E-18
AS6	2.98E+00	8.20E+04	1.55E+07	1.0000E-20	113	1.13E-18	4.87E-01	9.99E-01	1.00E+00	1.13E-23	2.33E-23	2.33E-23
NSW1	2.16E-19	4.49E-16	3.52E-11	9.9998E-01	42	4.22E+01	0	0	0	0	0	0
NSW2	2.16E-13	4.49E-10	3.52E-05	2.0000E-05	42	8.45E-04	0	0	0	0	0	0
NSW3	2.16E-10	4.49E-07	3.52E-02	9.9998E-11	42	4.22E-09	0	0	0	0	0	0
NSW4	2.16E-07	4.49E-04	3.52E+01	1.0000E-10	42	4.22E-09	0	0	7.69E-01	0	0	6.67E-14
NSW5	2.16E-04	4.49E-01	3.52E+04	2.0000E-15	42	8.45E-14	0	0	9.98E-01	0	0	1.73E-18
NSW6	2.16E+02	4.49E+05	3.52E+10	1.0000E-20	42	4.23E-19	9.03E-01	1.00E+00	1.00E+00	7.83E-24	8.67E-24	8.67E-24
NST1	8.63E-13	1.79E-09	1.41E-04	1.0000E+00	42	4.22E+01	0	0	0	0	0	0
NST2	8.63E-04	1.79E+00	1.41E+05	1.0000E-10	42	4.22E-09	0	4.24E-01	1.00E+00	0	3.68E-14	8.67E-14
NST3	8.63E-07	1.79E-03	1.41E+02	1.0000E-10	42	4.22E-09	0	0	8.79E-01	0	0	7.62E-14
NST4	8.63E+02	1.79E+06	1.41E+11	1.0000E-20	42	4.23E-19	9.58E-01	1.00E+00	1.00E+00	8.31E-24	8.67E-24	8.67E-24
ES1	1.07E-21	3.63E-17	1.24E-12	9.9998E-01	250	2.50E+02	0	0	0	0	0	0
ES2	1.07E-15	3.63E-11	1.24E-06	2.0000E-05	250	5.00E-03	0	0	0	0	0	0
ES3	1.07E-12	3.63E-08	1.24E-03	9.9998E-11	250	2.50E-08	0	0	0	0	0	0
ES4	1.07E-09	3.63E-05	1.24E+00	1.0000E-10	250	2.50E-08	0	0	3.80E-01	0	0	1.95E-13
ES5	1.07E-06	3.63E-02	1.24E+03	2.0000E-15	250	5.00E-13	0	0	9.68E-01	0	0	9.93E-18
ES6	1.07E+00	3.63E+04	1.24E+09	1.0000E-20	250	2.50E-18	3.62E-01	9.98E-01	1.00E+00	1.86E-23	5.12E-23	5.13E-23

The movement of the solid waste from the RCTS to the landfill is modeled in a similar manner. The Riley County Solid Waste Management Plan [Riley County, 2009] indicates that solid waste is transported from the RCTS to the landfill six days per week. Thus, the frequency of opportunity is the same as if it is assumed that solid waste from the NBAF is not disaggregated for shipment to the landfill. $P_{Bag\ Loss}$ and $P_{interaction}$ are also as previously described. $P_{Bag\ Loss}$ is not reduced by the addition of non-NBAF waste that may be added at the RTCS prior to shipment to the landfill. No reduction for this value was taken so the results would be similar even if there is direct routing of the NBAF waste to the landfill. However, the $P_{interface}$ is different (from the route between NBAF and the RCTS) because of the route length and multiple susceptible premises along the route. From an overlay of susceptible premises with the route indicated in Figure 5.2-6, it is estimated that there are approximately 60 susceptible premises that share an interface with the road. A representative length of susceptible premises frontage was derived from an assessment of 15 randomly selected premises. For these premises, the average frontage (interface between the premises and the road) was 0.74 miles (± 0.31 miles). Thus, the estimate of total susceptible premises frontage is 44.4 miles (60 × 0.74 miles). The total route length is 76.5 miles; the fraction of the total route that is fronted by susceptible premises (either side) is 0.58 ($P_{interface} = 5.8 \times 10^{-1}$).

The infection probability, $P_{aerosol}$, is based on the probit analysis for aerosol in sheep, the aerosol probit curve which has the lowest minimum infectious dose of cattle, swine, and sheep. This model was selected because premises along the route include all three species. The coefficients (see Section 6 and Appendix A6) are 0.7175 and 4.6268 for the slope and intercept, respectively. The event table for an infection resulting from solid waste lost during the transfer between the RCTS and the landfill is presented in Table 5.2-5. The resulting index case frequencies are presented in Table 5.2-6. As seen from this table, the highest frequency event, NST2 (incineration failure) has a frequency of 5.80×10^{-8} events per year (95th percentile source term) with a corresponding period of 1.72×10^{7} years, or approximately one event every 17 million years.

Table 5.2 5: Solid Waste (Between RCTS and Landfill) Event Table

Node	Description	Probability (Yes)	Probability (No)
1	$P_{Bag\ Loss}$: infected bag of solid waste falls from truck (conditional upon infected waste being in truck)	4.73×10^{-4}	9.9953×10^{-1}
2	$P_{interface}$: at interface with susceptible premises	5.80×10^{-1}	4.20×10^{-1}
3	$P_{interaction}$: conditional probability of animal interaction	5×10^{-1}	5×10^{-1}
4	$P_{aerosol}$: conditional probability of infection	$P_{aerosol} = f(Q)$	$1-P_{aerosol}$

Table 5.2 6: Index Case Frequencies for Solid Waste Loss Between RCTS and Landfill

Event ID	*Q* (Diluted)			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AS1	2.98E-21	8.20E-17	1.55E-14	9.9998E-01	113	1.13E+02	0	0	0	0	0	0
AS2	2.98E-15	8.20E-11	1.55E-08	2.0000E-05	113	2.27E-03	0	0	0	0	0	0
AS3	2.98E-12	8.20E-08	1.55E-05	9.9998E-11	113	1.13E-08	0	0	0	0	0	0
AS4	2.98E-09	8.20E-05	1.55E-02	1.0000E-10	113	1.13E-08	0	0	0	0	0	0
AS5	2.98E-06	8.20E-02	1.55E+01	2.0000E-15	113	2.27E-13	0	0	6.85E-01	0	0	2.13E-17
AS6	2.98E+00	8.20E+04	1.55E+07	1.0000E-20	113	1.13E-18	4.87E-01	9.99E-01	1.00E+00	7.59E-23	1.56E-22	1.56E-22
NSW1	2.16E-19	4.49E-16	3.52E-11	9.9998E-01	42	4.22E+01	0	0	0	0	0	0
NSW2	2.16E-13	4.49E-10	3.52E-05	2.0000E-05	42	8.45E-04	0	0	0	0	0	0
NSW3	2.16E-10	4.49E-07	3.52E-02	9.9998E-11	42	4.22E-09	0	0	0	0	0	0
NSW4	2.16E-07	4.49E-04	3.52E+01	1.0000E-10	42	4.22E-09	0	0	7.69E-01	0	0	4.47E-13
NSW5	2.16E-04	4.49E-01	3.52E+04	2.0000E-15	42	8.45E-14	0	0	9.98E-01	0	0	1.16E-17
NSW6	2.16E+02	4.49E+05	3.52E+10	1.0000E-20	42	4.23E-19	9.03E-01	1.00E+00	1.00E+00	5.24E-23	5.80E-23	5.80E-23
NST1	8.63E-13	1.79E-09	1.41E-04	1.0000E+00	42	4.22E+01	0	0	0	0	0	0
NST2	8.63E-04	1.79E+00	1.41E+05	1.0000E-10	42	4.22E-09	0	4.24E-01	1.00E+00	0	2.46E-13	5.80E-13
NST3	8.63E-07	1.79E-03	1.41E+02	1.0000E-10	42	4.22E-09	0	0	8.79E-01	0	0	5.10E-13
NST4	8.63E+02	1.79E+06	1.41E+11	1.0000E-20	42	4.23E-19	9.58E-01	1.00E+00	1.00E+00	5.56E-23	5.80E-23	5.80E-23
ES1	1.07E-21	3.63E-17	1.24E-12	9.9998E-01	250	2.50E+02	0	0	0	0	0	0
ES2	1.07E-15	3.63E-11	1.24E-06	2.0000E-05	250	5.00E-03	0	0	0	0	0	0
ES3	1.07E-12	3.63E-08	1.24E-03	9.9998E-11	250	2.50E-08	0	0	0	0	0	0
ES4	1.07E-09	3.63E-05	1.24E+00	1.0000E-10	250	2.50E-08	0	0	3.80E-01	0	0	1.30E-12
ES5	1.07E-06	3.63E-02	1.24E+03	2.0000E-15	250	5.00E-13	0	0	9.68E-01	0	0	6.65E-17
ES6	1.07E+00	3.63E+04	1.24E+09	1.0000E-20	250	2.50E-18	3.62E-01	9.98E-01	1.00E+00	1.24E-22	3.43E-22	3.43E-22

5.3 Liquid Effluent Pathway

Section 4 includes a description of the liquid effluent waste processing systems and protocols that will be used at the NBAF. The addition of the on-site wastewater pretreatment system, while not motivated by risk mitigation, affords additional mitigation for accidental pathogen release via the Manhattan sanitary sewer system. Waste streams from the Central Utility Plant (CUP) and the Visitor Center (VC) will flow directly to the on-site lift station, bypassing the on-site wastewater treatment system. However, liquid effluent from the Main Laboratory (domestic and treated) and Transshipping Facility (TF) will be pumped to the pretreatment storage area (that also provides flow equalization or flow "buffering") at the on-site wastewater treatment plant. In the case of a local denial of service, the untreated effluent can be transferred to offline storage tanks so that laboratory operations can continue without interruption (overflow capacity in excess of one day's nominal effluent) while appropriate repairs are made. The on-site treatment comprises two principal processes: 1) primary treatment to remove particulate matter; and 2) secondary treatment to remove dissolved constituents. Optional systems may be installed to enhance phosphorus and nitrogen removal. A schematic diagram of the treatment facility is provided in Figure 5.3-1.

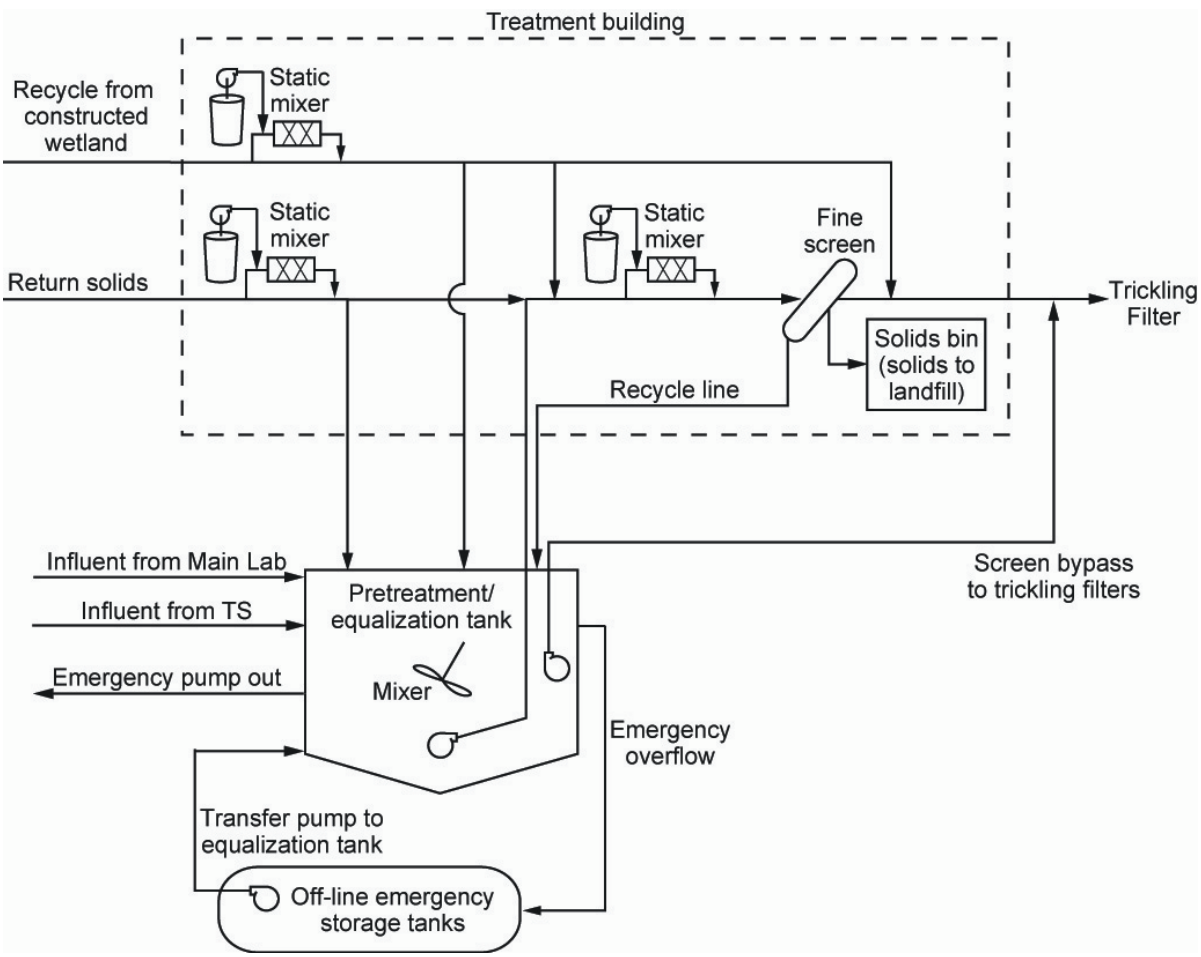


Figure 5.3-1: Schematic Illustration of On-Site Wastewater Pretreatment

Total flow expected from the Main Laboratory (including domestic effluent) is anticipated to be 250 gallons per minute (gpm) [NDP, 2011]. The fine screening in the first process removes particulate matter down to 150-300 µm. The dewatered solids are discharged to a collection hopper that is periodically emptied and removed. (This waste component is included as a component of the solid waste, see Section 5.2.) NDP reports that approximately 50% of the total suspended solids (from the influent which will contain approximately 700 mg/L) will be removed by the primary treatment. The collection and dewater process will result in the production of two cubic yards per day of solid waste [NDP, 2011]. This contribution to the solid waste pathway is described in Section 5.2.

Secondary treatment includes constructed wetlands (two cells) that will help decrease the biological oxygen demand, remaining suspended solids, and nitrogen. The designed wetlands are augmented with a carbon source to enhance nitrogen removal. While some consideration may be given to off-site beneficial reuse of some waste components, it is recommended that no off-site reuse applications are implemented until a specific reuse risk analysis is performed for the proposed applications.

As illustrated in Figure 5.3-2, liquid effluent from the campus is aggregated at an on-site lift station (near the demarcation between the NBAF and BRI property). From the lift station, the effluent is carried through a force main in a northerly direction (under the NBAF parking lot)—angling slightly to the west to avoid the Westar sub-station.

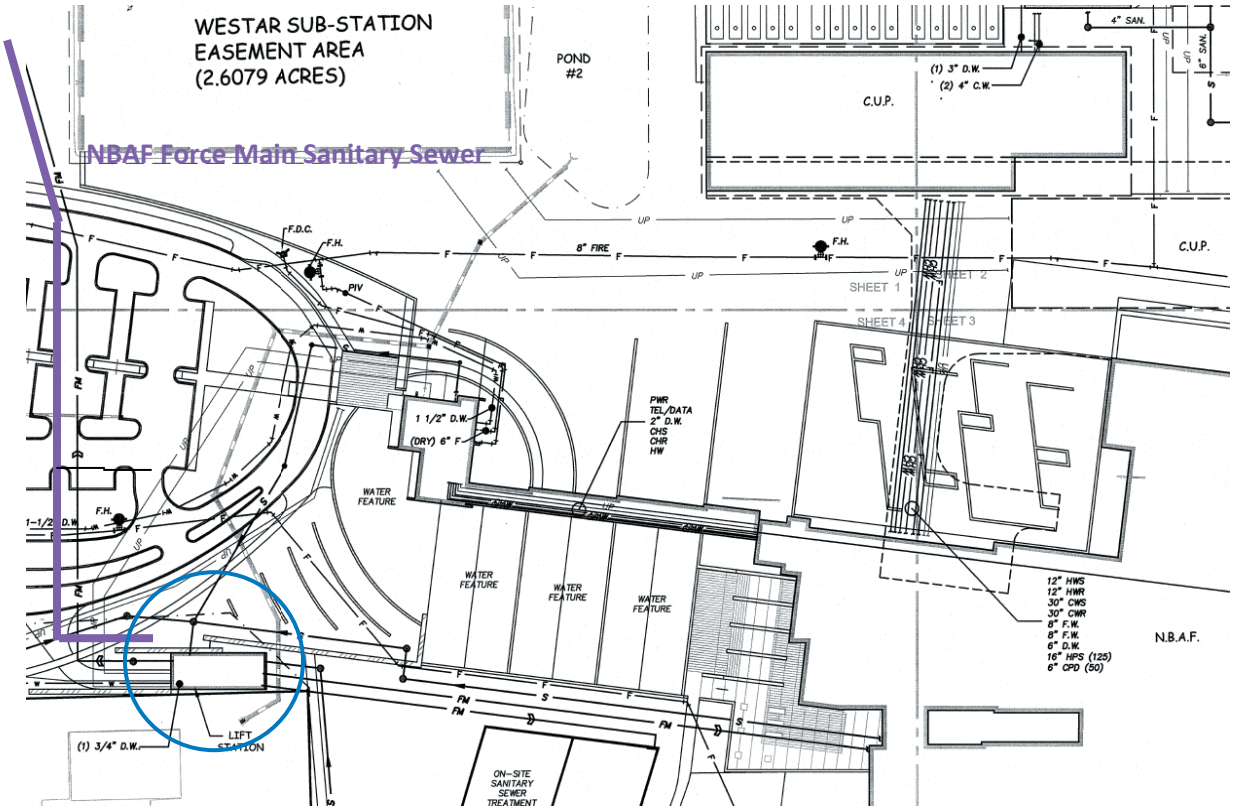


Figure 5.3-2: NBAF and Lift Station

The force main continues under Kimball Avenue. On the north side of Kimball Avenue, the force main connects with a municipal gravity line behind the Manhattan, Kansas, Fire Department station on the northeast corner of Denison Avenue and Kimball Avenue, as illustrated in Figure 5.3-3. This is the first point at which the NBAF effluent is mixed with effluent from other sources (e.g., BRI, fire station) in the sanitary sewer system. This is also the point where responsibility for the sanitary sewer line shifts from the NBAF to the city.

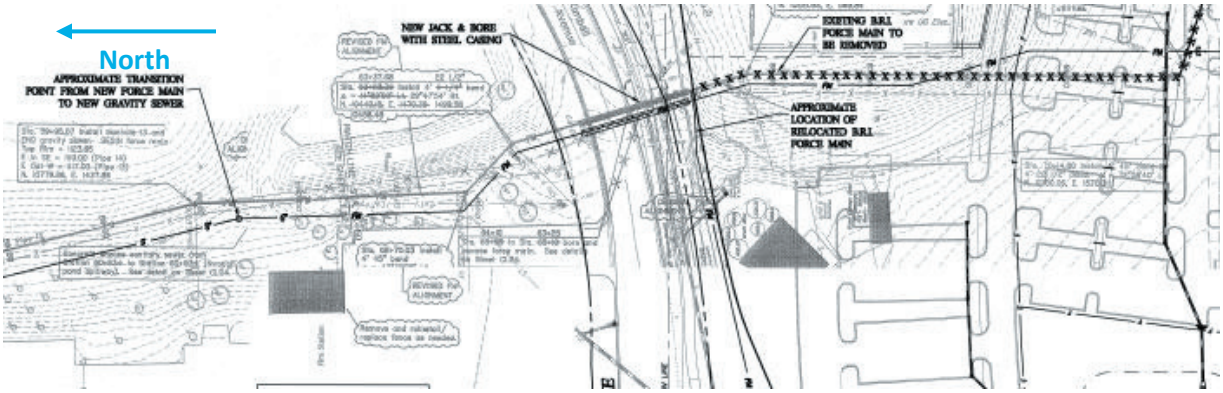


Figure 5.3-3: NBAF Lift Station to Municipal Gravity Line (Note: North to the left)

The gravity line then turns to the west and then north again—continuing north in the existing right-of-way along Denison Avenue all the way to Marlatt Avenue. Effluent then flows east all the way to Casement Road. At Hays Drive, the sewer line turns south until it reaches McCall Road. The sewer line goes west for a short distance and then south, routed under U.S. 24. The line then goes east on Linear Road to the wastewater treatment plant (WWTP) located near the confluence of the Blue River and the Kansas River. Figure 5.3-4 depicts the entire NBAF-to-WWTP sanitary sewer route. The route is approximately 6.2 miles long and during average flow conditions, NBAF effluent will take between five and ten hours to complete the route from the NBAF to the WWTP.

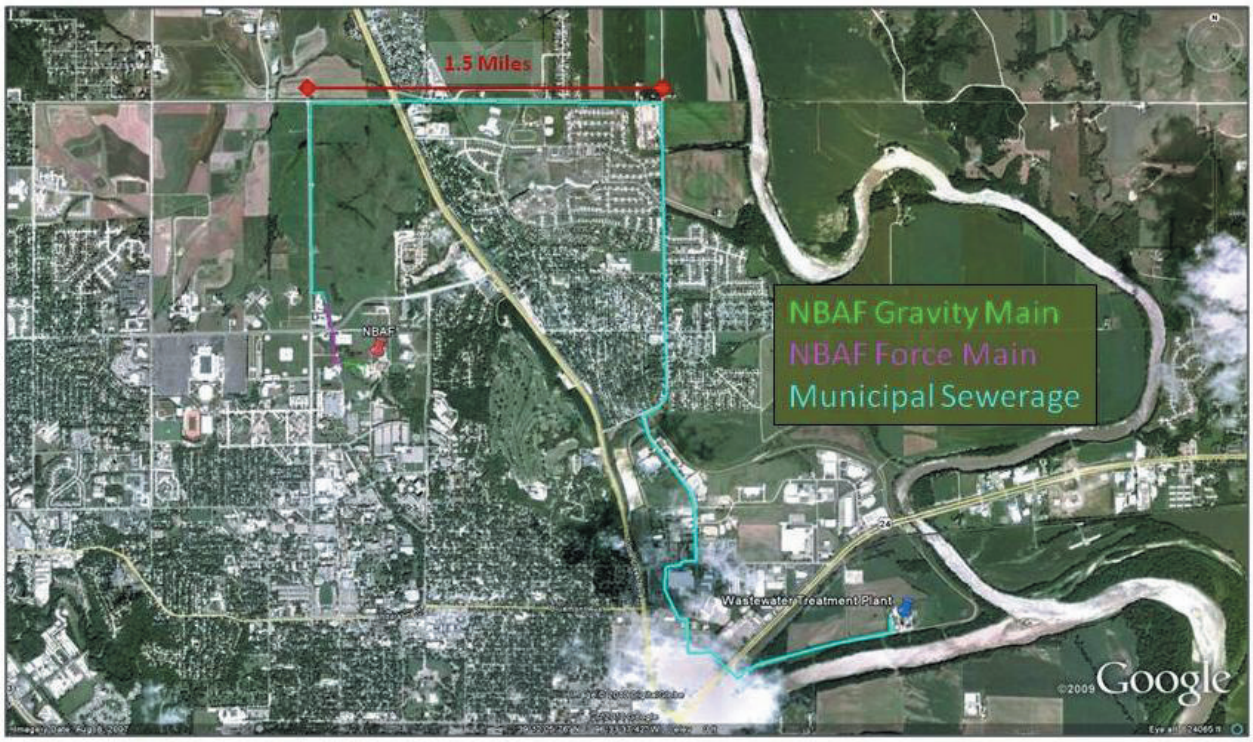


Figure 5.3-4: NBAF to WWTP Sanitary Sewer Path

The Manhattan, Kansas WWTP uses an activated sludge treatment process. Oxygen is mixed with incoming effluent (i.e., influent) to promote aerobic microbiological activity. Air is also pumped into diffusers at the bottom of each of four aeration basins in which the influent is treated to assist in the sludge activation process. From the aeration basins, the influent is processed in a clarifying basin, where solids settle. The sediments from the clarifying basin are used in the aeration basins or in aerobic digesters as waste-activated sludge. Clarified water (from the clarifying basin) is processed in the disinfection building with ultraviolet light before being discharged into the Kansas River. Manhattan, Kansas has a well-established biosolids management program. Solid residuals from the aerobic digesters are recovered and dried in a holding barn. Periodically, the residuals are applied to local (plant product) farms at a rate of up to 2 dry tons per acre.

Modeling of the sanitary sewer system was performed by estimating dilution factors along the sewerage routing based on confluence and pipe diameters. Evidence suggests that, given the right conditions, FMDv may remain viable for long periods of time in the sewer effluent. For this reason, the model did not include a decay or degradation factor for pathogen concentrations; rather, the model only included reductions in concentration due to dilution. Regardless, the activated sludge treatment process and advanced biosolids management program practices by the WWTP will mitigate the threat of viable pathogen accumulation and/or further conveyance. The resulting dilution model used in this assessment is presented in Table 5.3-1.

Table 5.3 1: Manhattan, Kansas, Sanitary Sewer Dilution Model for NBAF Effluent

Segment Start Point	Segment Stop Point	Dilution Factor	Concentration (fractional)	Concentration (decimal)	Premise(s)
NBAF Lift Station	City Gravity Line	1	N	1.0N	---
City Gravity Line	Marlatt/Denison	1/2	N/2	0.5N	A, B
Marlatt/Denison	Marlatt/Tuttle Creek	1/2	N/4	0.25N	C
Marlatt/Tuttle Creek	Marlatt/Casement	1/2	N/8	0.125N	---
Marlatt/Casement	Casement/Sarber	1/2	N/16	0.0625N	D
Casement/Sarber	WWTP	1/3	N/48	0.0208N	---

Three susceptible premises along the municipal sewer route and one premise along the Big Blue River were identified as potential index infection locations. These locations are identified in Figure 5.3-5 and labeled as Premises A, B, C, and D. Table 5.3-2 provides details on the identified premises.

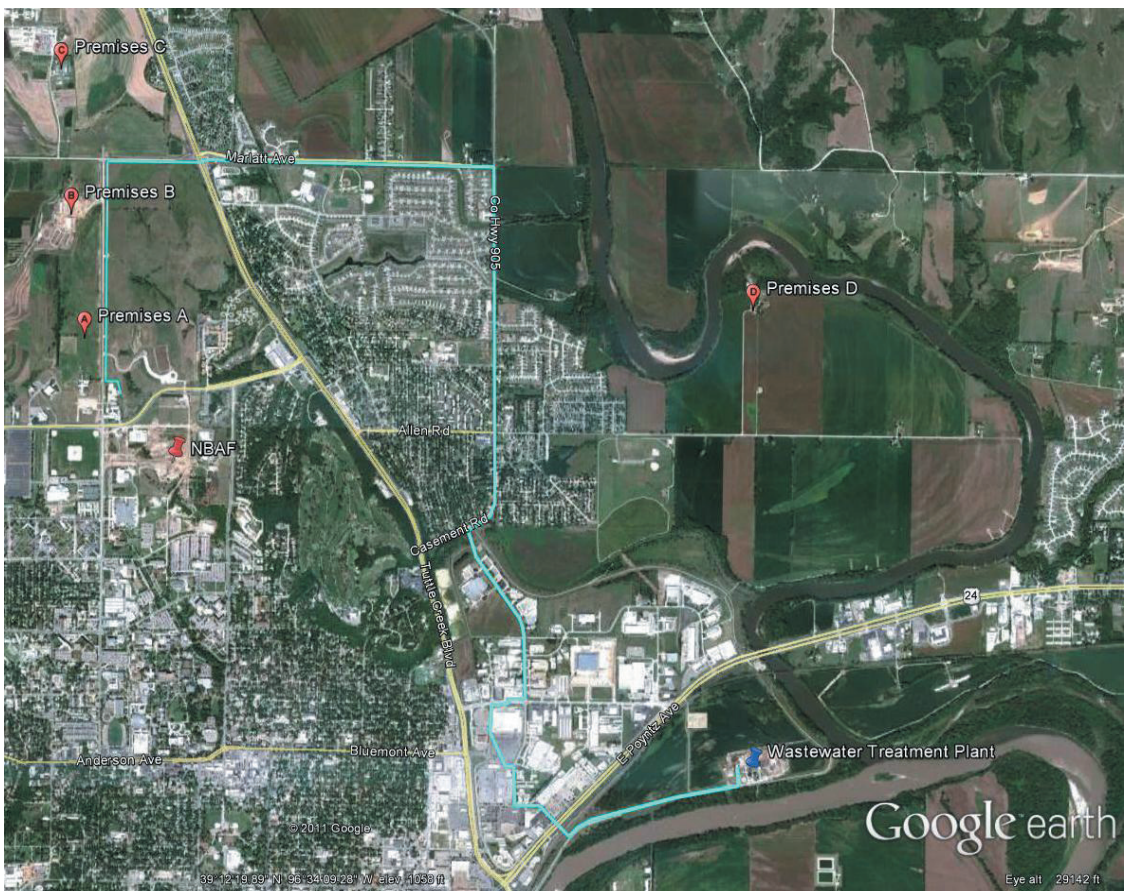


Figure 5.3-5: Potential Index Case Premises from Liquid Waste Pathway

Table 5.3 2: Potential Premises for Index Infections from Liquid Effluent Accident			
Premises	**Type**	**Latitude**	**Longitude**
A	Small (Sheep and Goats)	39° 12’ 31.97’’	-96° 35’ 12.90’’
B	Backyard (Swine and Cattle)	39° 12’ 56.16’’	-96° 35’ 16.87’’
C	Large (Swine)	39° 13’ 24.74”	-96° 35’ 19.86’’
D	Cow-Calf	39° 12’ 39.28’’	-96° 32’ 20.30’’

Premises A, B, and C are potential index locations that have a border on or near the sewer pathway and could potentially be infected by a malfunction such as a sanitary sewer overflow. Premises D is a potential index location identified because of its proximity to the Big Blue River downstream of a potential surface water feature that could be contaminated by a sanitary sewer malfunction. Premises A was selected because it is a susceptible (sheep and goats) premises that is located along the sanitary sewer pathway where the dilution factor is the smallest. Premises B was selected for the same reason and because it includes swine and cattle. Premises C was selected because it is a large swine operation and is near a sewer pathway confluence and turn. The modeled dilution factors for Premises A-C from Table 5.3-1 are presented again in Table 5.3-3. The dilution factor for Premises D, derived from the dilution model and presented in Table 5.3-1, is one-sixteenth: the modeled location of the sewer malfunction is at the intersection of the sewer pathway and a creek bed (not always wet) that flows underneath Casement to the Big Blue River (see Figure 5.3-6). However, for an event that involves a presumptive sewer malfunction near this location, viable pathogenic material would have to be transported by surface water to the Big Blue River. The median discharge rate for the Big Blue River (during summer months (July and August, 2011) when the volume is lowest) is approximately 200 cubic feet per second (1,496 gallons per second) or 1.29×10^{8} gallons per day [USGS, 2011]. Using this discharge rate is the most conservative approach to modeling the dilution because other months have higher discharge rates and would provide additional dilution. Using the “average maximum” daily flow value for NBAF liquid effluent of 37,099 gallons per day [NDP, 2011], a dilution factor of 2.86×10^{-4} is used for modeling purposes. This calculation is based on multiple assumptions that are necessary to attempt quantification of the risk including the complete mixing of sewer runoff and river water. Thus, the total dilution factor (including the sewer pathway malfunction point dilution) is modeled as 1.79×10^{-5}.

Table 5.3 3: Dilution Factors for Potential Premises	
Premises	**Dilution**
A	5.0×10^{-1}
B	5.0×10^{-1}
C	2.5×10^{-1}
D	1.79×10^{-5}

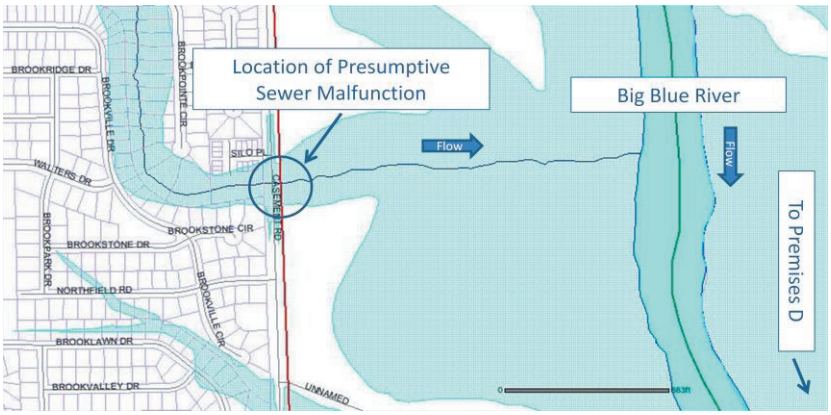


Figure 5.3-6: Presumptive Location of Sewer Failure and Runoff to Big Blue River

For an index infection to occur as the result of a failure in the liquid waste processing and disposal pathway (non-transference), contaminated liquid waste would have to be released near a location where a susceptible species could be exposed to quantities of viable virus that would cause infection or the virus would have to be transported by surface waters as modeled for Premises D. A representative event tree for an index infection is presented in Figure 5.3-7. All of the modeled nodes (1-4) are indicated in the event tree.

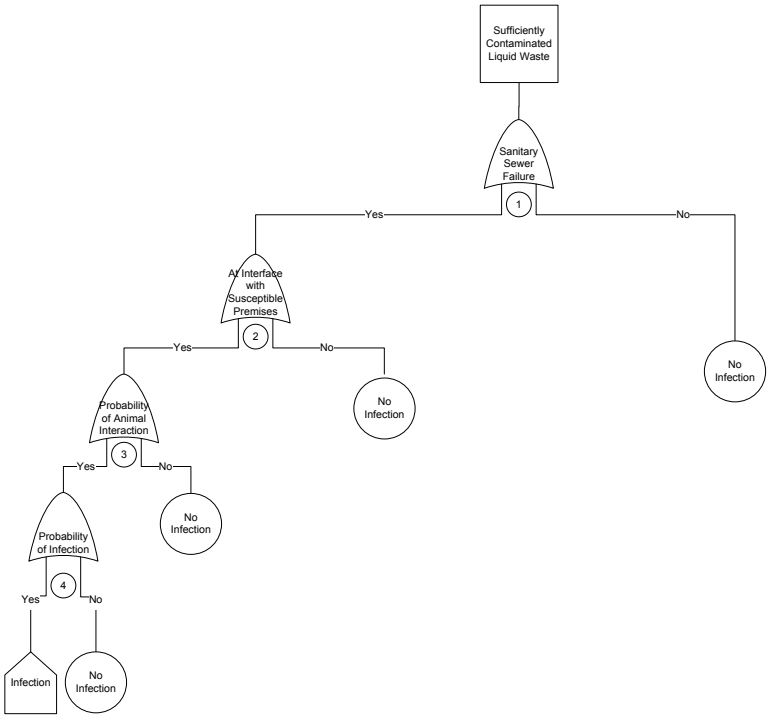


Figure 5.3-7: Conditional Event Tree for Infected Waste Being Released from Sewerage Near Susceptible Species

The events (frequency and virus source term values) related to the introduction of viable material into the liquid waste pathway are developed and presented in Section 4. When infectious waste is introduced to the municipal sewerage pathway, the accident sequence is modeled as indicated in the

event tree. The source term (Q) developed for each event is reduced by a dilution factor at each of the identified premises, as previously described. A sewerage failure, such as a sanitary sewer overflow (SSO), has the potential to release significant quantities of sewer contents. Fortunately, most relatively modern sanitary sewer systems, such as Manhattan's, use design and construction techniques combined with routine and responsive operational maintenance to minimize the number of SSOs that occur.

The City of Manhattan Sanitary Sewer Collection System Master Plan Update [CDM/BG Team, 2009] provided modeled data that predicts the Manhattan SSO locations in wet weather conditions (generally the most problematic for SSOs) with the existing sanitary sewer collection system capacity. None of the predicted SSO locations were on the sewerage routing between the NBAF and the WWTP. However, a 2008-2009 California study [California Water Boards, 2009] concluded that an average of 6.34 SSO events could occur per 100 miles of sewerage per year or 1.74×10^{-4} SSO events per mile per day. The sewerage pathway from the NBAF to the WWTP is 6.2 miles long; the projected probability of an SSO on any day along the sewerage of concern, $P_{Water\ Loss}$ is 1.08×10^{-3}.

To estimate the probability that a sewerage malfunction will occur in the proximity of the identified premises, $P_{interface}$, the length of the interface between the premises and the pathway was measured for each location, and these lengths are presented in Table 5.3-4. For Premises D, the interface length was estimated by examination of the topography near the intersection of the creek bed the sewer pathway.

Table 5.3 4: Premises to Sewer Pathway (6.2 miles) Interface Length and $P_{interface}$

Premises	Distance (miles)	$P_{interface}$
A	0.23	3.71×10^{-2}
B	0.49	7.90×10^{-2}
C	0.35	5.65×10^{-2}
D	0.15	2.42×10^{-2}

The potential infection sequence is modeled as a susceptible animal(s) having access to and ingesting contaminated surface water. Additionally, any individual animal can only ingest a limited amount of contaminated liquid. The volume of water that a susceptible animal can ingest per day varies by species, size, environment (temperature, humidity, etc.), gestation status, production (dry/lactating) status, food moisture content, and other parameters. Table 5.3-5 summarizes water consumption data for each modeled species, the selected value for modeling, and the ratio of the modeled ingestion volume to the typical daily NBAF discharge volume of 37,099 gallons. The indicated ratios are applied as another reduction in source term similar to the dilution.

Table 5.3 5: Daily Ingestion Volumes and Ratio to Liquid Effluent Discharge

Species	Description	Value (gpd)	Dilution Factor
Cattle	1,500 lbs lactating cow (40 - 80 °F)[a]	18.4 - 35.6	---
	200-1,200 lbs heifer (40 – 80 °F)[a]	2 - 14.5	---
	1,400 lbs lactating cow (< 40 – 80 °F)[b]	12 - 45.7	---
	1,400-1,600 lbs dry cow (< 40 - 80 °F)[b]	9.7 - 17.3	---
	All (35 – 95 °F)[c]	4 - 20	---
	All (36 – 90 °F, monthly averages)[d]	6 - 19	---
	Modeled Value	**40**	**1.08×10^{3}**
Swine	25-200 lbs pig[d]	0.5 - 2.5	---
	Gilts[d]	3.2 - 5.5	---
	Sows (with and without litters)[d]	4.5 - 6.0	---
	Modeled Value	**5**	**1.35×10^{4}**
Sheep	60-110 lbs feeder lamb[e]	1 - 1.4	---
	Gestating meat ewe/ram[e]	1 - 1.7	---
	Lactating meat ewe plus unweaned offspring[e]	2.4 - 2.8	---
	Gestating dairy ewe/ram[e]	1.2 - 1.9	---
	Lactating dairy ewe[e]	2.5 -3	---
	Modeled Value	**2.5**	**6.74×10^{5}**

[a]New Mexico State University, 2007. [b]University of Idaho, 2010. [c]University of Arkansas. [d]North Dakota State University, 1999. [e]Ontario Ministry of Agriculture, Food, and Rural Affairs, 2007.

As in the modeling approach used for the lost solid waste, no data on the probability or likelihood of effluent from a sewer failure reaching the susceptible species is available. Thus, as previously described, the probability of interaction ($P_{interaction}$) is set to 0.5.

The probability of infection from the contaminated liquid effluent varies by species and route of entry. Conceptually, the susceptible species will be ingesting the potentially-contaminated effluent. However, as described in Section 6.1.3, characterizing (with high confidence) the oral ID_{50} for FMDv for each species is problematic because of the insufficiency of relevant data. The available data indicate that cattle have a relatively high oral ID_{50}; the lower estimate being 4.4×10^5 PFU (see 6.1.3). The lower estimate for the oral ID_{50} for swine is 5.6×10^3 PFU; a consensus value of the oral ID_{50} for goats could not be determined. Since the contact event is likely to involve aerosolization of pathogenic material (during ingestion) and since the aerosol ID_{50} for all species is much lower than the oral ID_{50} (where available), the aerosol route of entry is used to model the probability of infection for these events. The probit fit coefficients and minimum infectious dose (MID) for each of the dose-response curves are presented in Section 6.1.2 and summarized in Table 5.3-6. Table 5.3-7 presents the modeled probabilities for each branch in the event tree (Figure 5.3-7) and Table 5.3-8 summarizes the final dilution ratios for each premises by species (bold indicates species modeled at each premises).

Table 5.3 6: Probit Model Selection and Fit Coefficients

Premises	Species	Probit Model	Coefficients	MID (PFU)
A	Sheep Goats	Sheep, aerosol	m = 0.7175 b = 4.6268	1.0
B	Swine Cattle	Cattle, aerosol	m = 0.3331 b = 4.6096	1.0
C	Swine	Swine, aerosol	m = 0.8907 b = 1.0066	1.0
D	Cow-calf	Cattle, aerosol	m = 0.3331 b = 4.6096	1.0

Table 5.3 7: Liquid Waste Event Table

Node	Label	Description	Probability (Yes)	Probability (No)
1	$P_{Water\ Loss}$	Sanitary sewerage malfunction along pathway	1.08×10^{-3}	9.9989×10^{-1}
2	$P_{interface}$	Interface with susceptible premises	A: 3.71×10^{-2} B: 7.90×10^{-2} C: 5.65×10^{-2} D: 2.42×10^{-2}	A: 9.63×10^{-1} B: 9.21×10^{-1} C: 9.44×10^{-1} D: 9.76×10^{-1}
3	$P_{interaction}$	Conditional probability of animal interaction	5×10^{-1}	5×10^{-1}
4	$P_{aerosol}$	Conditional probability of infection	$P_{aerosol} = f$(Q, species)	$1-P_{aerosol}$

Table 5.3 8: Final Dilutions for Probability of Infection Calculations

Premises	Species	Sewer Dilution	Ingestion Ratio	Final Dilution
A	Cattle	5.0×10^{-1}	1.08×10^{-3}	3.7×10^{-4}
	Swine		1.35×10^{-4}	4.6×10^{-5}
	Sheep/Goats		**6.74×10^{-5}**	**2.3×10^{-5}**
B	**Cattle**	5.0×10^{-1}	**1.08×10^{-3}**	**3.7×10^{-4}**
	Swine		1.35×10^{-4}	4.6×10^{-5}
	Sheep/Goats		6.74×10^{-5}	2.3×10^{-5}
C	Cattle	2.5×10^{-1}	1.08×10^{-3}	1.9×10^{-4}
	Swine		**1.35×10^{-4}**	**2.3×10^{-5}**
	Sheep/Goats		6.74×10^{-5}	1.2×10^{-5}
D	**Cattle**	1.79×10^{-5} (in river) (6.25×10^{-2} at failure point)	**1.08×10^{-3}**	**1.9×10^{-8}**
	Swine		1.35×10^{-4}	2.4×10^{-9}
	Sheep/Goats		6.74×10^{-5}	1.2×10^{-9}

The outcome of each modeled event is determined by combining data from the Master Fault Table (Table 4.7-1) and table 5.3-6 through 5.3-8 to determine the events for which an infection(s) occurs and the final infection frequency. For Premises A-D, the results are tabulated in Tables 5.3-9 through 5.3-12 with the potential infection events presented in red text. (It should be noted that all of these events have an extremely low frequency.)

Table 5.3 9: Index Case Frequencies for Liquid Waste Events at Premises A

Event ID	*Q* Values			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AL1	1.19E-06	3.28E-02	6.18E+00	9.5110E-01	113	1.08E+02	0	0	0	0	0	0
AL2	1.19E-05	3.28E-01	6.18E+01	9.5111E-06	113	1.08E-03	0	0	0	0	0	0
AL3	1.19E+00	3.28E+04	6.18E+06	9.5110E-11	113	1.08E-08	0	3.66E-01	9.02E-01	0	7.90E-14	1.94E-13
AL4	1.19E+01	3.28E+05	6.18E+07	9.5111E-16	113	1.08E-13	0	6.46E-01	9.78E-01	0	1.39E-18	2.11E-18
AL5	2.29E-06	6.30E-02	1.19E+01	4.8889E-02	113	5.55E+00	0	0	0	0	0	0
AL6	2.29E-05	6.30E-01	1.19E+02	4.8890E-07	113	5.55E-05	0	0	0	0	0	0
AL7	2.29E+00	6.30E+04	1.19E+07	4.8889E-12	113	5.55E-10	0	4.45E-01	9.32E-01	0	4.93E-15	1.03E-14
AL8	2.29E+01	6.30E+05	1.19E+08	4.8890E-17	113	5.55E-15	0	7.19E-01	9.86E-01	0	7.97E-20	1.09E-19
NL1	1.00E-04	1.84E-03	2.31E+00	9.9002E-01	42	4.18E+01	0	0	0	0	0	0
NL2	1.00E-03	1.84E-02	2.31E+01	9.9002E-06	42	4.18E-04	0	0	0	0	0	0
NL3	1.00E+02	1.84E+03	2.31E+06	9.9002E-11	42	4.18E-09	0	0	8.37E-01	0	0	7.00E-14
NL4	1.00E+03	1.84E+04	2.31E+07	9.9003E-16	42	4.18E-14	0	0	9.55E-01	0	0	7.98E-19
NL5	5.03E-02	9.21E-01	1.16E+03	9.9749E-03	42	4.21E-01	0	0	0	0	0	0
NL6	5.03E-01	9.21E+00	1.16E+04	9.9750E-08	42	4.21E-06	0	0	0	0	0	0
NL7	5.03E+04	9.21E+05	1.16E+09	9.9749E-13	42	4.21E-11	4.17E-01	7.57E-01	9.98E-01	3.51E-16	6.37E-16	8.40E-16
NL8	5.03E+05	9.21E+06	1.16E+10	9.9750E-18	42	4.21E-16	6.95E-01	9.21E-01	1.00E+00	5.85E-21	7.76E-21	8.42E-21
EL1	0.00E+00	0.00E+00	0.00E+00	9.9990E-01	52,500	5.25E+04	0	0	0	0	0	0
EL2	1.02E-07	3.46E-03	1.18E+02	9.9999E-05	52,500	5.25E+00	0	0	0	0	0	0
EL3	1.02E-01	3.46E+03	1.18E+08	9.9999E-15	52,500	5.25E-10	0	0	9.86E-01	0	0	1.03E-14
EL4	1.02E-06	3.46E-02	1.18E+03	1.0000E-09	52,500	5.25E-05	0	0	0	0	0	0
EL5	1.02E+00	3.46E+04	1.18E+09	1.0000E-19	52,500	5.25E-15	0	3.72E-01	9.98E-01	0	3.91E-20	1.05E-19

Table 5.3 10: Index Case Frequencies for Liquid Waste Events at Premises B

Event ID	*Q* Values			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AL1	1.19E-06	3.28E-02	6.18E+00	9.5110E-01	113	1.08E+02	0	0	0	0	0	0
AL2	1.19E-05	3.28E-01	6.18E+01	9.5111E-06	113	1.08E-03	0	0	0	0	0	0
AL3	1.19E+00	3.28E+04	6.18E+06	9.5110E-11	113	1.08E-08	0	5.10E-01	7.83E-01	0	2.34E-13	3.60E-13
AL4	1.19E+01	3.28E+05	6.18E+07	9.5111E-16	113	1.08E-13	0	6.40E-01	8.68E-01	0	2.94E-18	3.99E-18
AL5	2.29E-06	6.30E-02	1.19E+01	4.8889E-02	113	5.55E+00	0	0	0	0	0	0
AL6	2.29E-05	6.30E-01	1.19E+02	4.8890E-07	113	5.55E-05	0	0	0	0	0	0
AL7	2.29E+00	6.30E+04	1.19E+07	4.8889E-12	113	5.55E-10	0	5.48E-01	8.10E-01	0	1.29E-14	1.91E-14
AL8	2.29E+01	6.30E+05	1.19E+08	4.8890E-17	113	5.55E-15	0	6.75E-01	8.87E-01	0	1.59E-19	2.09E-19
NL1	1.00E-04	1.84E-03	2.31E+00	9.9002E-01	42	4.18E+01	0	0	0	0	0	0
NL2	1.00E-03	1.84E-02	2.31E+01	9.9002E-06	42	4.18E-04	0	0	0	0	0	0
NL3	1.00E+02	1.84E+03	2.31E+06	9.9002E-11	42	4.18E-09	0	0	7.39E-01	0	0	1.32E-13
NL4	1.00E+03	1.84E+04	2.31E+07	9.9003E-16	42	4.18E-14	0	4.77E-01	8.35E-01	0	8.48E-19	1.49E-18
NL5	5.03E-02	9.21E-01	1.16E+03	9.9749E-03	42	4.21E-01	0	0	0	0	0	0
NL6	5.03E-01	9.21E+00	1.16E+04	9.9750E-08	42	4.21E-06	0	0	4.50E-01	0	0	8.07E-11
NL7	5.03E+04	9.21E+05	1.16E+09	9.9749E-13	42	4.21E-11	5.35E-01	6.94E-01	9.38E-01	9.59E-16	1.24E-15	1.68E-15
NL8	5.03E+05	9.21E+06	1.16E+10	9.9750E-18	42	4.21E-16	6.63E-01	8.00E-01	9.69E-01	1.19E-20	1.43E-20	1.74E-20
EL1	0.00E+00	0.00E+00	0.00E+00	9.9990E-01	52,500	5.25E+04	0	0	0	0	0	0
EL2	1.02E-07	3.46E-03	1.18E+02	9.9999E-05	52,500	5.25E+00	0	0	0	0	0	0
EL3	1.02E-01	3.46E+03	1.18E+08	9.9999E-15	52,500	5.25E-10	0	3.82E-01	8.87E-01	0	8.53E-15	1.98E-14
EL4	1.02E-06	3.46E-02	1.18E+03	1.0000E-09	52,500	5.25E-05	0	0	0	0	0	0
EL5	1.02E+00	3.46E+04	1.18E+09	1.0000E-19	52,500	5.25E-15	0	5.13E-01	9.39E-01	0	1.15E-19	2.10E-19

Table 5.3 11: Index Case Frequencies for Liquid Waste Events at Premises C

Event ID	*Q* Values			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AL1	1.19E-06	3.28E-02	6.18E+00	9.5110E-01	113	1.08E+02	0	0	0	0	0	0
AL2	1.19E-05	3.28E-01	6.18E+01	9.5111E-06	113	1.08E-03	0	0	0	0	0	0
AL3	1.19E+00	3.28E+04	6.18E+06	9.5110E-11	113	1.08E-08	0	3.83E-05	2.69E-02	0	1.26E-17	8.83E-15
AL4	1.19E+01	3.28E+05	6.18E+07	9.5111E-16	113	1.08E-13	0	1.09E-03	1.50E-01	0	3.58E-21	4.91E-19
AL5	2.29E-06	6.30E-02	1.19E+01	4.8889E-02	113	5.55E+00	0	0	0	0	0	0
AL6	2.29E-05	6.30E-01	1.19E+02	4.8890E-07	113	5.55E-05	0	0	0	0	0	0
AL7	2.29E+00	6.30E+04	1.19E+07	4.8889E-12	113	5.55E-10	0	1.07E-04	4.69E-02	0	1.80E-18	7.91E-16
AL8	2.29E+01	6.30E+05	1.19E+08	4.8890E-17	113	5.55E-15	0	2.46E-03	2.16E-01	0	4.16E-22	3.65E-20
NL1	1.00E-04	1.84E-03	2.31E+00	9.9002E-01	42	4.18E+01	0	0	0	0	0	0
NL2	1.00E-03	1.84E-02	2.31E+01	9.9002E-06	42	4.18E-04	0	0	0	0	0	0
NL3	1.00E+02	1.84E+03	2.31E+06	9.9002E-11	42	4.18E-09	0	0	1.05E-02	0	0	1.33E-15
NL4	1.00E+03	1.84E+04	2.31E+07	9.9003E-16	42	4.18E-14	0	0	7.79E-02	0	0	9.91E-20
NL5	5.03E-02	9.21E-01	1.16E+03	9.9749E-03	42	4.21E-01	0	0	0	0	0	0
NL6	5.03E-01	9.21E+00	1.16E+04	9.9750E-08	42	4.21E-06	0	0	0	0	0	0
NL7	5.03E+04	9.21E+05	1.16E+09	9.9749E-13	42	4.21E-11	7.56E-05	3.86E-03	5.38E-01	9.69E-20	4.94E-18	6.89E-16
NL8	5.03E+05	9.21E+06	1.16E+10	9.9750E-18	42	4.21E-16	1.88E-03	3.81E-02	8.38E-01	2.40E-23	4.87E-22	1.07E-20
EL1	0.00E+00	0.00E+00	0.00E+00	9.9990E-01	52,500	5.25E+04	0	0	0	0	0	0
EL2	1.02E-07	3.46E-03	1.18E+02	9.9999E-05	52,500	5.25E+00	0	0	0	0	0	0
EL3	1.02E-01	3.46E+03	1.18E+08	9.9999E-15	52,500	5.25E-10	0	0	2.16E-01	0	0	3.44E-15
EL4	1.02E-06	3.46E-02	1.18E+03	1.0000E-09	52,500	5.25E-05	0	0	0	0	0	0
EL5	1.02E+00	3.46E+04	1.18E+09	1.0000E-19	52,500	5.25E-15	0	4.18E-05	5.41E-01	0	6.66E-24	8.64E-20

Table 5.3 12: Index Case Frequencies for Liquid Waste Events at Premises D

Event ID	*Q* Values			Probability (P_{loss})	Opportunity Rate (R_o, yr ^{1})	Frequency (F_{loss}, yr ^{1})	Probability of Infection (P_i)			Infection Frequency (F_{event}, yr ^{1})		
	Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
AL1	1.19E-06	3.28E-02	6.18E+00	9.5110E-01	113	1.08E+02	0	0	0	0	0	0
AL2	1.19E-05	3.28E-01	6.18E+01	9.5111E-06	113	1.08E-03	0	0	0	0	0	0
AL3	1.19E+00	3.28E+04	6.18E+06	9.5110E-11	113	1.08E-08	0	0	0	0	0	0
AL4	1.19E+01	3.28E+05	6.18E+07	9.5111E-16	113	1.08E-13	0	0	3.58E-01	0	0	5.03E-19
AL5	2.29E-06	6.30E-02	1.19E+01	4.8889E-02	113	5.55E+00	0	0	0	0	0	0
AL6	2.29E-05	6.30E-01	1.19E+02	4.8890E-07	113	5.55E-05	0	0	0	0	0	0
AL7	2.29E+00	6.30E+04	1.19E+07	4.8889E-12	113	5.55E-10	0	0	0	0	0	0
AL8	2.29E+01	6.30E+05	1.19E+08	4.8890E-17	113	5.55E-15	0	0	3.94E-01	0	0	2.85E-20
NL1	1.00E-04	1.84E-03	2.31E+00	9.9002E-01	42	4.18E+01	0	0	0	0	0	0
NL2	1.00E-03	1.84E-02	2.31E+01	9.9002E-06	42	4.18E-04	0	0	0	0	0	0
NL3	1.00E+02	1.84E+03	2.31E+06	9.9002E-11	42	4.18E-09	0	0	0	0	0	0
NL4	1.00E+03	1.84E+04	2.31E+07	9.9003E-16	42	4.18E-14	0	0	0	0	0	0
NL5	5.03E-02	9.21E-01	1.16E+03	9.9749E-03	42	4.21E-01	0	0	0	0	0	0
NL6	5.03E-01	9.21E+00	1.16E+04	9.9750E-08	42	4.21E-06	0	0	0	0	0	0
NL7	5.03E+04	9.21E+05	1.16E+09	9.9749E-13	42	4.21E-11	0	0	5.24E-01	0	0	2.88E-16
NL8	5.03E+05	9.21E+06	1.16E+10	9.9750E-18	42	4.21E-16	0	0	6.53E-01	0	0	3.58E-21
EL1	0.00E+00	0.00E+00	0.00E+00	9.9990E-01	52,500	5.25E+04	0	0	0	0	0	0
EL2	1.02E-07	3.46E-03	1.18E+02	9.9999E-05	52,500	5.25E+00	0	0	0	0	0	0
EL3	1.02E-01	3.46E+03	1.18E+08	9.9999E-15	52,500	5.25E-10	0	0	3.93E-01	0	0	2.69E-15
EL4	1.02E-06	3.46E-02	1.18E+03	1.0000E-09	52,500	5.25E-05	0	0	0	0	0	0
EL5	1.02E+00	3.46E+04	1.18E+09	1.0000E-19	52,500	5.25E-15	0	0	5.25E-01	0	0	3.59E-20

5.4 Transference

In the 2010 SSRA, release of FMDv via human vector or transport on a fomite was modeled in terms of relative risk; the quantity of pathogen (source term) was specified only as being greater than an infectious dose, and fate and transport modeling was bypassed before entering the epidemiological model. The NAS SSRA Committee suggested that a quantitative estimate of absolute risk of infection due to this pathway, termed transference, be provided. To this end, data were collected to support estimates of the amount of virus that could be released, and to enable generation of a new fate and transport model for the transference pathway. The basis of this model is a Monte Carlo simulation to describe the probability of infection (P_i) of at least one animal upon accidental release of virus. The simulations begin with an amount of virus carried by a worker or fomite in the NBAF, and describe the likelihood of the many paths the contaminant could take to reach and infect a susceptible species. Along the way, reductions in amount and viability of the virus due to time, temperature, personal hygiene (e.g., showers, hand washings), and contact losses are calculated (reductions due to personal protective equipment and decontamination procedures are included in calculation of source terms as described in Section 4). The results of this fate and transport model feed into the epidemiological model. The sections below describe: 1) the source terms (inputs) for the simulations; 2) the generation of paths to infection and their likelihoods; 3) reductions to the amount and viability of the virus; and 4) the calculations of probability of infection.

5.4.1 Source Terms

The amount of FMDv involved in a contamination event leading to release (source term) was calculated as described in Section 4. The location of this contamination along the transference pathway was described as one of five places: aerosol contamination of 1) the human respiratory tract, or contact contamination of 2) the hand of a worker; 3) the footwear of a worker; 4) any other place on a worker's body; or 5) a fomite. Source terms were all calculated as the amount of virus to which a worker wearing PPE is exposed. The effectiveness of PPE at preventing contamination of the worker's body was described Chapter 4. Each transference event modeled began with a unique starting amount and location of the contamination.

5.4.2 Paths to Infection

5.4.2.1 Data Sources

There exist innumerable paths from release event to animal infection via the transference pathway. In order to determine the most likely of these paths, employees of the Biosecurity Research Institute (BRI) at Kansas State University (K-State) were interviewed on their typical movements and behaviors both within the BRI and upon leaving the facility. The BRI is a new BSL-3E and BSL-3Ag research facility immediately adjacent to the NBAF location. This proximity allows BRI researchers and employees to serve as valid proxies for describing the behaviors of the workers at the NBAF. Because the two facilities are essentially co-located, few differences should exist between the off-site community locations frequented by a typical BRI worker and those frequented by a typical NBAF worker. BRI workers are drawn from the same community that will provide workers for the NBAF, thus the two groups will

represent similar demographics in terms of outside activities. In addition, the similarities in activities within each facility (e.g., both provide containment research space for high-consequence agricultural pathogens) ensure that behaviors within the two facilities will be comparable. FMD is not studied at the BRI, however, so some assumptions had to be made to account for behaviors that some employees displayed that would be prohibited when working with FMDv (e.g., containment workers owning farms – see Section 5.4.2.2).

A total of twenty-seven researchers and support staff at the BRI were interviewed. A wide selection of both scientific and support staff were selected in order to account for all types of personnel that will be present in the BRI; these included research scientists, laboratory technicians, a graduate student, K-State faculty, a veterinarian, lab coordinators, biosafety specialists, maintenance and building systems personnel, security personnel, and a network technician. Participants were asked questions addressing the following components of their behaviors inside and outside the facility:

1. **Locations within the facility.** Participants were asked how often they work at the BRI; how often they are in each of the containment areas, including animal holding rooms; and how often they are in each of the non-containment areas, including administrative offices, maintenance areas such as the basement and penthouse, conference rooms, break rooms, and restrooms.

2. **Destinations outside the facility.** Participants were asked how often they went to various places on campus, in the city of Manhattan, Kansas, and elsewhere. These destinations included retail and food service establishments, recreational facilities, entertainment, childcare services, and the homes of employees and family. The locations of these destinations were recorded. Participants were asked to distinguish between places they might go directly from the BRI versus at other times in their routines. The modes of transportation used for travel to and from the BRI were also collected.

3. **Contact with susceptible species.** Participants were asked how often they visited facilities that contain susceptible species, including farms, campus animal facilities, veterinarians, state and county fairs, and rodeos. The locations and species present at these facilities were recorded. Participants were asked whether they handled animals or simply were on the premises. Additionally, participants were asked the occupations of the people they live with, and whether those or other individuals with which they have regular contact handle livestock.

The responses from interviews were tabulated and counted. The mean frequencies with which subjects visited locations and handled animals were calculated. Subjects were classified as either containment or non-containment staff and separate means were calculated for each category in order to allow for different event frequencies depending on the type of facility worker. These results formed the basis of the event paths simulation in the Monte Carlo model.

5.4.2.2 Input Parameters

The multitude of paths that could occur after a release of containment and leading up to an animal infection were recreated using Monte Carlo simulation of a series of events, each with a specific probability of occurring. Table 5.4.2-1 shows these frequencies. Each simulation starts with an amount of virus on a specific site (including a fomite) of a specific category of worker (containment or non-containment). The first node of the model is whether or not the contaminated individual encounters a susceptible species. A number of respondents indicated that they rarely, if ever, come into contact with susceptible species; this node allows for the possibility that a worker carrying contamination does not ever reach a susceptible species, and therefore exits the model with a zero percent chance of infection. This rate is 39% for containment staff and 33% for non-containment staff. Thus, already more than one third of the iterations of each simulation will result in no infections. For this parameter and the one below (Table 5.4.2-1), it was assumed that no containment workers owned farms; for any interview subjects who responded to the contrary, their frequency of farm visits was set to zero.

Table 5.4.2 1: Parameter Description: Probabilities of NBAF Staff Visiting Susceptible Species

	Containment Staff	Non containment Staff
Visits susceptible species	61%	67%
Visited animal facility	**Containment Staff**	**Non containment Staff**
Farm	24%	25%
Campus facility	15%	10%
Fair	41%	45%
Rodeo	21%	20%

The second node of the event tree is what type of animal-housing facility the worker visits, given that he or she does encounter a susceptible species. The probabilities of each type of facility being visited are normalized percentages of the subjects that responded they will visit a susceptible species at some time (Table 5.4.2-1). Veterinarians were not included as an animal facility type since all interview participants who visited veterinarians visited solely small animal clinics.

The final event node determines how many days elapse between the release event and the contaminated worker handling a susceptible species. To determine these values, distributions were fit to the interview data to describe how many days per year a person will likely visit each type of facility (Table 5.4.2-2). For all facility types except farms, there were not enough data points within employee categories to accurately determine a distribution; therefore the same distribution was used for both, based on all responses. Each iteration of the simulation takes a draw from the appropriate distribution, and the length of time until animal contact is simply $(365/v)-1$, where v = the number of visits per year. The model has been capped so that the number drawn will not exceed 365, resulting in more than one visit per day. Subtracting one allows for the worker to visit a susceptible species on the same day as the release event. Included within the time-to-animal calculation is a rate at which the worker complies with the 5-day quarantine. This rate was set at 0.99, corresponding to the failure rate of persons performing repeated tasks.

Table 5.4.2 2: Parameter Description: Number of Times per Year NBAF Staff Visit Location with Susceptible Species					
Location	**Staff**	**Distribution**	**5th Percentile**	**Median**	**95th Percentile**
Farm	Containment	Pert	0.65	2.00	5.05
	Staff	**Distribution**	**Minimum**	**Mode**	**Maximum**
Farm	Non-containment	Pert	0	1	365
Campus facility	All	Pert	0	2	365
	Staff	**Distribution**	**Mean (μ)**	**Standard Deviation (σ)**	
Fair	All	Lognormal	1.67	1.71	
Rodeo	All	Lognormal	2.29	3.04	

A Pert distribution is a variant of the beta distribution that allows for significant skewing of the function, rather than maintaining symmetry. Because it is a beta distribution, it has both a maximum and a minimum value, thus avoiding long infinite tails which can result in a few exceptional individuals driving the overall probability of infection.

5.4.3 Virus Reductions

Over the course of events leading from release to infection, neither the amount nor viability of virus that was released remains constant. Reductions were calculated to account for four general factors: 1) viral survival rates on surfaces; 2) viral survival rates in the human respiratory tract; 3) loss of viral material due to personal hygiene showers and washings (not biocontainment decontamination showers); and 4) loss of viral material due to repeated contact of the contaminated site with other surfaces.

5.4.3.1 Viral Survival on Surfaces

Data Sources

Over the course of release events due to contact contamination, virus contamination of a surface (be it on a person or fomite) will lose infectivity at a determinable rate while outside of a susceptible host. Published data from two studies of survival of FMDv on solid surfaces were used to calculate rates of virus inactivation under a variety of conditions [Gailiunas et al., 1969; McColl et al., 1995]. Rates were expressed as D-values, the time required for viability to be reduced by one log (90%), using the following equation:

$$D = \frac{-t}{\log_{10}\left(\frac{[FMDv]_t}{[FMDv]_{t0}}\right)} \qquad \text{Eq. 5.4.3-1}$$

where *D* is the D-value and *t* is the time in days. The calculated D-values were used to determine which of the experimental variables (temperature, virus suspension material, virus strain, and surface) significantly affected the rate of inactivation of FMDv. Based on comparison of D-values using single-factor ANOVA, temperature was determined to be the primary factor affecting FMDv survival on

surfaces. Therefore, a temperature-dependent D-value calculation was used in the model. Results of the statistical analysis of variables are shown in Table 5.4.3-1 and described in detail below.

Table 5.4.3 1: Results of Single Variable ANOVA Analysis for Different Variables Affecting FMDV Survival on Surfaces

Variable	P value	Statistically Significant?	Source Data Reference
Temperature	<0.0001	Yes	Gailiunas et al, 1969; McColl et al, 1995
Virus source material	<0.0001	Yes	Gailiunas et al, 1969; McColl et al, 1995
Virus source material	0.001	Yes	Gailiunas et al, 1969
Virus strain	0.563	No	McColl et al, 1995
Virus strain	0.148	No	Gailiunas et al, 1969
Surface	0.176	No	Gailiunas et al, 1969

Temperature

Experimental data from McColl et al. [1995] were used to calculate D-values for FMDv at three different temperatures: 4 °C, 18 °C, and 37 °C. Additional D-values at 4 °C were calculated using data from Gailiunas et al. [1969]. ANOVA analysis showed a high level of significance ($p < 0.0001$; Table 5.4.3-1) for mean D-values between temperature groupings. Because the mean D-values varied significantly between the two data sources (T-test, $p < 0.0001$), ANOVA was performed again to compare temperature groupings from only the McColl study. Again, the differences among mean D-values were highly significant ($p < 0.0001$).

Virus source Material

Data from both sources were generated using FMDv that was collected from infected animals in eight different materials—blood, fat, lymph nodes, serum, bovine saliva, ovine blood, ovine feces, and ovine urine—or suspended in tissue culture medium [Gailiunas et al., 1969; McColl et al., 1995]. D-values were calculated from the primary data and grouped according to suspension material. ANOVA analysis was performed on all groups except ovine feces and ovine urine, which contained only one data point each; the differences among mean D-values were highly significant ($p < 0.0001$; Table 5.4.3-1). While attempting to account for differences due to the source of the data, ANOVA analysis of only data generated from McColl still showed significance ($p = 0.001$; Table 5.4.3-1). However, post-test analyses with both Tukey and Bonferroni corrections suggested that only one group, fat, varied significantly from the others. Although it is unknown how much FMDv may be present in the fat of infected animals, it was assumed that other infected animal materials such as blood and feces pose a greater risk of contaminating a researcher, and therefore no changes in D-value were made to account for source material of the virus.

Virus Strain

Data from the two sources were generated using seven different strains of FMDv: A-1, C-3, O-2, O-9, O1-BFS, O-MOR 9/91, and TAI 1/90 [Gailiunas et al., 1969; McColl et al., 1995]. D-values were calculated from the primary data and grouped according to virus strain. Initial ANOVA analysis performed on all groups indicated statistical significance ($p = 0.0003$). However, this result was determined to be due to confounding by the effect of temperature, as no single virus strain was used in both data sources. Indeed, ANOVA analysis of strain groups within each data source showed no significance (Table 5.4.3-1). Thus, virus strain was not used as a factor in determining D-value.

Surface

Data from the two sources were generated by contaminating four different surfaces with FMDv: cardboard, metal, wood, and wool [Gailiunas et al., 1969; McColl et al., 1995]. D-values were calculated from the primary data and grouped according to material contaminated. Initial ANOVA analysis performed on all groups indicated statistical significance ($p < 0.0001$). However, this was determined to be due to confounding by the effect of temperature, as no single material was used in both data sources. Indeed, ANOVA analysis of strain groups from only Gailiunas showed no significance (Table 5.4.3-1). McColl used only wool as the surface material so ANOVA was not performed. Thus, surface material was not used as a factor in determining D-value.

Input Parameters

Virus inactivation due to time and temperature was incorporated into Monte Carlo simulations in the form of D-values, or the amount of time required for viability to be reduced by one log (90%). To quantify the effect of temperature on FMDv, D-values calculated from data from both studies [Gailiunas et al., 1969; McColl et al., 1995] were plotted against temperature and a best-fit exponential decay curve was calculated (Figure 5.4.3-1). The resulting equation (Eq. 5.4.3-2) is used to approximate the D-value (D) of FMDv at any given temperature (T).

$$D_0 = 26.11e^{-0.12T} \qquad \text{Eq. 5.4.3-2}$$

Additionally, the geometric standard deviations of each of the three temperature groups were calculated. Exponential decay curves were fit to describe three geometric standard deviations above (Eq. 5.4.3-3) and below (Eq. 5.4.3-4) the baseline D-value as calculated by the above equation. These were used to bound the distribution; three standard deviations above and below the mean will contain 99% of the values in a Gaussian distribution. Equations for those curves are as follows.

$$D_{LO} = 6.65e^{-0.11T} \qquad \text{Eq. 5.4.3-3}$$

$$D_{HI} = 102.54e^{-0.13T} \qquad \text{Eq. 5.4.3-4}$$

Each iteration of the Monte Carlo simulation draws a D-value from a Pert distribution with a median that is calculated from Equation 5.4.3-2 and a minimum and maximum calculated from Equations 5.4.3-3 and 5.4.3-4, respectively.

Table 5.4.3 2: Parameter Description: Reduction Over Time for Surface Contamination	
Parameter:	D-value (in days) for surface contamination by FMDv
Function:	Pert
Minimum:	$6.65e^{-0.11T}$
Median:	$26.11e^{-0.12T}$
Maximum:	$102.54e^{-0.13T}$

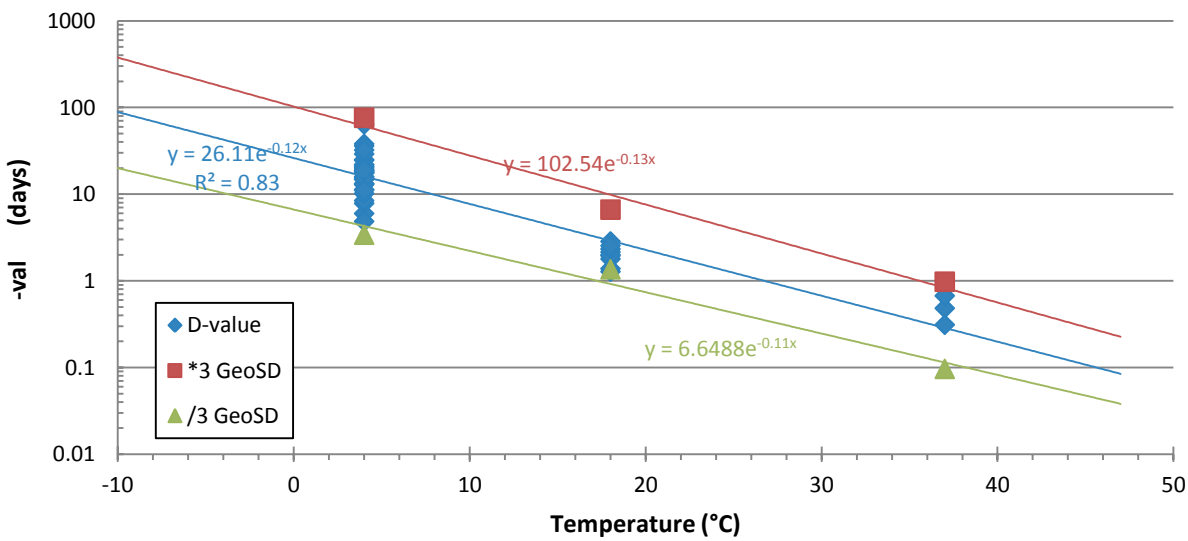


Figure 5.4.3-1: Temperature Dependence of D-values of FMDv Survival on Solid Surfaces

The temperature input used for D-value calculations is determined in each iteration of the Monte Carlo simulation by a draw from a beta distribution ranging from 20 °C to 25 °C. This is based on the assumption in the model that virus contamination on a person will most often be in a controlled environment (i.e., indoors) and thus the range represents typical room temperatures. Future versions of the SSRA may utilize an enhanced model that assigns a date to each iteration, thus allowing temperature input to be correlated to seasonality.

For all events consisting of contact contamination, the reduction in viability of the source term due to the time elapsed from contamination event to exposure of susceptible species (as described above in Section 5.4.2.2) was calculated using the D-value derived as described above in Equation 5.4.3-1.

5.4.3.2 Viral Survival in the Human Respiratory Tract

A route of FMDv contamination of human vectors is through inhalation of aerosols created by infected animals. Humans handling infected animals can inhale such aerosols and harbor FMDv in the upper respiratory tract after leaving containment areas. Still the most quantitative study addressing this issue is from Sellers [Sellers et al., 1970]. This study examined the level of FMDv in nasal swabs of 12 subjects who had handled infected animals (cattle, sheep, or pigs) at specific time intervals after leaving animal

holding rooms. Virus titers fell by 1.4-3 logs within five hours for all subjects. Only one out of the eight subjects sampled at 28 hours had detectable levels of FMDv in the nasal swab. D-values, the time it takes to achieve a one-log (90%) reduction in viability, were calculated based on the published data using Equation 5.4.3-1 above. The resulting D-values (in hours) were represented by a Pert distribution with minimum, median, and maximum values of 1.3, 2.64, and 11.67 hours, respectively, for use in the Monte Carlo simulation (Table 5.4.3-3). For all events consisting of respiratory contamination, the reduction in viability of the original Q value due to the time elapsed from contamination event to exposure of susceptible species (as described above in section 5.4.2.2) was calculated using this D-value in Equation 5.4.3-1.

Table 5.4.3 3: Parameter Description: Reduction Over Time in Human Respiratory Tract

Parameter:	D-value (in hours) for human respiratory contamination by FMDv
Function:	Pert
Minimum:	1.30
Median:	2.64
Maximum:	11.67

5.4.3.3 Personal Hygiene Showers

When the time elapsed from contamination event to exposure of susceptible species is greater than one day, additional reductions were taken to account for personal showers that workers take as part of their daily routine. In each iteration of the Monte Carlo simulations, the time elapsed in days (simulated as described above in 5.4.2-2) was rounded to the nearest integer to reflect the number of additional showers the worker takes before exposing a susceptible species to the FMDv contamination.

The value of the reduction is similar to the value for decontamination showers (described in section 4.3). While decontamination showers are regimented and the reduction value can therefore be represented by a point estimate, showers that people take as part of their normal lifestyle vary in duration and vigor; thus, a distribution was generated using the same data that the decontamination reduction value was based on [Ansari et al., 1989; Bellamy et al., 1993; Mbithi et al., 1993] (Table 5.4.3-4). The reduction value for personal hygiene showers was represented in the Monte Carlo simulation by a Pert distribution based on 5th, 50th, and 95th percentiles of 0.024, 0.089, and 0.204 (Table 5.4.3-5). Due to limitations in the current model, a single value from this distribution is drawn for one iteration (simulated person) no matter how many showers are taken of the along the path to infection. Ideally, each shower would have a separate draw from the distribution and thus a unique reduction value.

Table 5.4.3 4: Virus Reduction Values Due to Showering					
Organism	Percent Reduction	Fraction Remaining	Standard Deviation	Cleanser	Source
Rotavirus	93.80	0.0620	3.90	Liquid soap	Ansari et al., 1989
Rotavirus	86.90	0.1310	2.40	Liquid soap	Ansari et al., 1989
HAV	92.04	0.0796	4.02	Bacti-stat soap	Mbithi et al., 1993
HAV	83.35	0.1665	2.76	Bioprep hand soap	Mbithi et al., 1993
HAV	91.29	0.0871	4.47	Triclosan hand soap	Mbithi et al., 1993
Poliovirus	98.39	0.0161	1.98	Bacti-stat soap	Mbithi et al., 1993
Poliovirus	90.93	0.0907	2.86	Bioprep hand soap	Mbithi et al., 1993
Poliovirus	94.80	0.0520	3.76	Triclosan hand soap	Mbithi et al., 1993
HAV	94.56	0.0544	5.75	Bacti-stat soap	Mbithi et al., 1993
HAV	81.44	0.1856	1.59	Bioprep hand soap	Mbithi et al., 1993
HAV	88.98	0.1102	1.73	Triclosan hand soap	Mbithi et al., 1993
Poliovirus	97.28	0.0272	2.05	Bacti-stat soap	Mbithi et al., 1993
Poliovirus	88.99	0.1101	2.59	Bioprep hand soap	Mbithi et al., 1993
Poliovirus	96.63	0.0337	2.86	Triclosan hand soap	Mbithi et al., 1993
Rotavirus	84.86	0.1514		Plain soap	Bellamy et al., 1993
Rotavirus	74.00	0.2600		Water alone	Bellamy et al., 1993

Table 5.4.3 5: Parameter Description: Reduction Due to Personal Hygiene Showers (Fraction Remaining)	
Parameter:	Fraction remaining after showering/washing
Function:	Pert
5th Percentile:	0.024
Median:	0.089
95th Percentile:	0.204

Contamination found on footwear or fomites (such as eyeglasses) will not get washed in personal hygiene showers, and thus will not go through these reductions. However, a loss of material due to contact may occur as the fomite is removed and replaced before and after the shower. For each shower occurrence, a single contact reduction was taken as described below for contamination residing on footwear or a fomite.

5.4.3.4 Contact Loss

For release events consisting of contact contamination of a worker's hands, body, or footwear, or a contaminated fomite, a fraction of the amount of virus present will be transferred from the site of contamination every time it comes in contact with another surface, be it a person or object. Published data from contact transfer studies were used to determine the fraction of viral material transferred in each such contact event.

Data Sources

Data from 17 different studies of virus transfer during contact were analyzed. These studies are described in Table 5.4.3-6. Together, the studies quantified transfer of 12 different viruses between skin and eight other surfaces. Most studies examined transfer from hands or fingers to other materials, while eight of them also reported the reverse.

Table 5.4.3 6: Studies of Virus Transfer During Contact

Reference	Viruses	Transfer from	Transfer to
Ansari et al., 1988	Rotavirus	Metal, Skin	Skin, Metal
Ansari et al., 1991	RV-14, HPIV-3	Metal, Skin	Skin, Metal
Bardell, 1989	HSV-1	Skin	Skin
Bean et al., 1982	Influenza A	Metal, Tissue	Skin
Bidawid et al., 2000	Hepatitis A	Skin	Food
Gwaltney et al., 1978	Rhinovirus	Ceramic, Skin	Skin
Hall et al., 1980	RSV	Ceramic, Cloth, Tissue, Skin	Skin
Jennings et al., 1988	Rhinovirus	Skin	Skin
Julian et al., 2009	Rotavirus	Glass, Skin	Skin, Glass
Julian et al., 2010	MS2, ϕ-X174, fr (bacteriophage)	Glass, Skin	Skin, Glass
Kamph and Kramer, 2004	Hepatitis A, HSV-1, Rhinovirus, Rotavirus	Skin	Food, Skin
Mbithi et al., 1992	Hepatitis A	Metal, Skin	Skin, Metal
Pancic et al., 1980	Rhinovirus	Metal	Skin
Reed et al., 1975	Rhinovirus	Skin	Skin, Metal
Rusin et al., 2002	PRD-1	Metal, Plastic, Cloth, Food, Skin	Skin
Sattar et al., 1993	Rhinovirus	Metal	Skin
Winther et al., 2007	Rhinovirus	Plastic	Skin

The fractions of virus samples transferred were calculated if not directly reported and grouped according to material (Figure 5.4.3-2). One-way ANOVA testing determined that the mean fractions transferred were not statistically significant between groups ($p = 0.186$). Thus, all contact events were modeled the same; the fraction of virus transferred in each contact event was defined as a beta distribution ranging from 0.009 to 1 (Table 5.4.3-7).

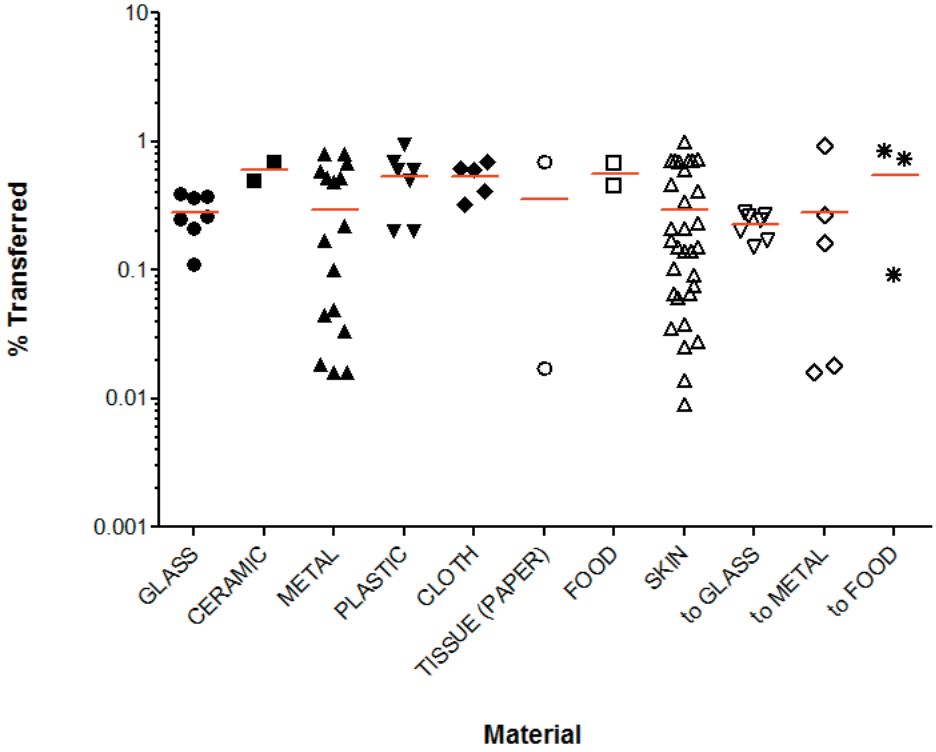


Figure 5.4.3-2: Fraction of Virus Transferred During a Single Contact Event, By Material

Input Parameters

A simplified model of contact events per day was used in the Monte Carlo simulations. The number of contacts events was interpreted as the number of destinations a worker goes during the time between the contamination event and contact with a susceptible species. These destinations include areas within the NBAF (an office, restroom, conference room, etc.) as well as destinations upon leaving the facility (a classroom, store, gym, car, or home). The rationale behind this simplification is that while a single contact event may result in loss of contaminant due to transfer, repeated contact of surfaces within a defined area over a span of time will result in both deposition of virus and re-acquisition of virus from recently contaminated surfaces. The model thus is based on the assumption that for each defined area a contaminated worker visits, the overall fraction of virus lost is equivalent to one contact event. This fraction is defined as a beta distribution ranging from 0.009 to 1 (Table 5.4.3-7). Clearly, this assumption results in a very conservative estimate of loss of viral material due to contact. This is necessary due to the difficulty in estimating the actual number of contacts an area of a person's body may make over the course of a day. Additionally, were an estimate of total contacts to be used, the fraction remaining on the contaminated worker would very quickly be reduced to below one infectious unit, and thus every contamination event would reach zero probability of infection before a susceptible species is exposed.

Table 5.4.3 7: Parameter Description: Fraction of Virus Transferred on Contact	
Parameter:	Fraction of virus transferred on contact
Function:	Pert
Minimum	0.009
Median:	0.26
Maximum:	1

The number of contact events an NBAF worker may produce in a given day was determined from interview data of BRI employees described above in Section 5.4.2.1. The frequencies at which employees visited locations within and outside of the BRI were normalized to the number of days each employee worked at the facility and summed. Within each category of worker (containment or non-containment), the range of contacts per day was defined by a gamma distribution (Table 5.4.3-8).

Table 5.4.3 8: Parameter Description: Number of Contacts per Day.		
Distribution Parameters	**Containment Staff**	**Non Containment Staff**
Function	Gamma	Gamma
Minimum	0	0
Mean	5.80	7.21
Standard Deviation	1.88	1.14
α	9.54	39.72
β	0.61	0.18

For all events consisting of contact contamination, the reduction in viability of the source term due to contact transfer of FMDv was calculated by raising the fraction of virus transferred to the nth power, where n equals the number of contacts made per day times the number of days elapsed from contamination event to exposure of susceptible species (as described above in Section 5.4.2-2). Due to limitations of the current model, a unique transfer fraction is not drawn for each contact event; this effectively models transfer rate as a function of the individual rather than each event being completely independent.

5.4.4 Probability of Infection

The final phase of the transference fate and transport model is the calculation of probability of causing an infection given that a contaminated worker handles a susceptible species. The inputs used in the model are described in the sections below, and consist of: 1) the number and species of animals contacted; 2) the amount of virus to which the animals are exposed and the routes of exposure; and 3) the probit slope and ID_{50} of FMDv.

5.4.4.1 Animals Contacted

The animal contact simulated in the transference model can occur at farms, animal holding facilities at K-State, state and county fairs, or rodeos. A few assumptions were made in order to simplify the model; these assumptions also provide a conservative estimate of the probability of infection.

Assumptions

All farms are dairies. Dairies were chosen because they represent the farm type with the most contact between workers and animals (see Section 6 and Appendix A6). Additionally, cattle are more susceptible than other susceptible species (swine and sheep), resulting in a more conservative estimate of P_i.

All species contacted are cattle. Outside of farms, all species contacted were assumed to be cattle, as they are the species most susceptible to FMDv infection, resulting in a more conservative estimate of P_i.

Only one animal is contacted at non-farm sites. It is reasonable to assume that in the scenarios of large animal teaching facilities, fairs, and rodeos, people are most often in proximity to several animals but actually contact very few. Data collected via interviews did not distinguish between proximity to animals and handling them; thus, one animal was assumed to be contacted at each such site as a likely median among both animal viewers and handlers.

Input Parameters

In each iteration of the Monte Carlo simulation, the number of cattle on a dairy farm was drawn from a lognormal distribution based on the actual sizes of dairies in Kansas (Table 5.4.4-1). These data are described in Section 6 and Appendix A6. The number of cattle contacted in dairies was assumed to be 50% of the herd size, the approximate number of dairy cattle that are milked on a given day [Carroll, 2011]; this number was capped at 500 animals. The herd size and number of animals contacted for all other facility types was assumed to be one.

Table 5.4.4 1: Parameter Description: Number of Cattle in a Dairy Herd

Parameter:	Number of cattle in a dairy herd
Function:	Lognormal
Mean (μ):	235.4
Std. Dev. (σ):	1264.6
Minimum:	1

5.4.4.2 Delivery of Virus

The amount of virus carried by a contaminated NBAF worker was calculated as described above. Two terms were used to describe the location of the contamination: respiratory contamination and total contact contamination. Each term has a unique mechanism of delivery to an animal (and thus amount delivered) and a unique probability of infection (probit slope and ID_{50}).

The entire amount of virus remaining in a contaminated worker's respiratory tract was assumed to be delivered to the animals contacted in each simulation. While this is clearly not the case, it is a necessary

assumption to make due to the lack of data on the fraction of FMDv that is exhaled by a respiratory-contaminated person, which is dependent on several factors that are difficult to estimate (including the time a person spends in contact with a susceptible animal). This approach also allows for a conservative estimate of P_i. The delivery of contact contamination to a susceptible species was treated as a single transfer event using the transfer fraction described in Section 5.4.3-4.

For each iteration of the Monte Carlo simulation that resulted in a contact with susceptible species, the amount delivered per animal was calculated in two different ways. One exposure event assumed all delivered material was dosed to a single animal; the other assumed the dose was spread equally among all animals contacted. Each delivery of virus was used to calculate a separate probability of causing at least one infection (using probit and ID_{50} values generated as described in Section 6 and Appendix A6) and the higher of the two probabilities was reported as the true P_i for a conservative estimate. This two-tiered approach was used because the probit curve is not linear and therefore at some doses the greatest risk of infection would occur if all material were transferred to a single animal whereas at other doses the greatest risk of infection would occur if the material were divided evenly between all available animals.

5.4.5 Results

The Monte Carlo analysis described above was run for all transference events described in Chapter 4 with the low, medium, and high Q values as inputs. The risk of infection due to any event with a Q value of less than one PFU was assumed to be zero, since one PFU of FMDv is less than one tenth of the aerosol ID_{50} for cattle. For all other transference events, 100 simulations consisting of 100 iterations each were run. The final probabilities of infection were averaged for all 100 iterations of a simulation. Running 100 separate simulations produced a distribution of likely P_i values of which the median (50th) percentile was determined. For the purposes of the risk calculations, only the median values were used in the risk calculations and are displayed in the following tables.

Table 5.4.5-1 lists the cumulative probability by transference event tree and across all transference pathways that at least one infection occurs outside of the NBAF. The expected frequency, F_{event}, (per year) at which a given loss-of-containment outcome will occur and result in an infection event is calculated using Equation 5.4.5-1. The probability of a given loss-of-containment outcome resulting in an infection event is termed P_{event}, and is calculated using Equation 5.4.5-2, where P_{loss} is the probability of the loss-of-containment event. (P_{loss} and F_{loss} values are presented in Section 4.5.)

$$F_{event} = F_{loss} P_i \qquad \text{Eq. 5.4.5-1}$$

$$P_{event} = P_{loss} P_i \qquad \text{Eq. 5.4.5-2}$$

P_i, F_{event}, and P_{event}, values were calculated for the low, medium, and high Q-values. To determine a cumulative probability of an infection event occurring, weighted P_i and P_{event} values were calculated using the following formulas:

$$P_{i,weighted} = 0.05P_{i,Low} + 0.95P_{i,Medium} + 0.05P_{i,High} \quad \text{Eq. 5.4.5-3}$$

$$P_{event,weighted} = P_{loss}P_{i,weighted} \quad \text{Eq. 5.4.5-4}$$

The total probability of infection events across all transference events within a single event tree, P_{tree}, is computed using Equation 5.4.5-5. The expected frequency (per year) at which any event within the event tree will occur and result in an infection, F_{tree}, is calculated by Equation 5.4.5-6, where R_o is the number of opportunities per year for a given event tree. Finally, the cumulative probability, across all thirteen transference event trees, that one or more events in a given year results in an infection is denoted as P_{1Y} and is computed by Equation 5.4.5-7.

$$P_{tree} = \sum_{k=1}^{n} \left(P_{event,weighted}\right)_k \quad \text{Eq. 5.4.5-5}$$

$$F_{tree} = P_{tree}R_o \quad \text{Eq. 5.4.5-6}$$

$$P_{1Y} = 1 - \prod_{k=1}^{13} [(1 - P_{tree})^{R_o}]_k \quad \text{Eq. 5.4.5-7}$$

Table 5.4.5 1: Cumulative Probabilities of Infection Events Occurring Across Transference Event Trees

Event ID	Originating Location	Respiratory or Contact Region	Opportunity Rate (R_o, yr ^{1})	P_{tree}	F_{tree} (yr ^{1})
ATR	AHR	Respiratory	567.5	3.56×10^{-17}	2.02×10^{-14}
ATF	AHR	Fomite	169	4.40×10^{-10}	7.44×10^{-8}
NTH1 6	Necropsy	Hand	169	5.37×10^{-12}	9.08×10^{-10}
NTH7 12	Necropsy	Hand	169	1.22×10^{-13}	2.06×10^{-11}
NTB	Necropsy	Body	169	3.42×10^{-11}	5.78×10^{-9}
ETP0 6	BSL-3E/BSL-3E SP	Hand	21,000	7.84×10^{-14}	1.65×10^{-9}
ETP7 12	BSL-3E/BSL-3E SP	Hand	21,000	8.03×10^{-13}	1.69×10^{-8}
ETB	BSL-3E/BSL-3E SP	Body	21,000	2.97×10^{-13}	6.24×10^{-9}
OTP	Non-containment	Hand	500	3.51×10^{-10}	1.76×10^{-7}
OTF	Non-containment	Foot	500	3.10×10^{-10}	1.55×10^{-7}
OTB	Non-containment	Body	500	1.20×10^{-9}	6.02×10^{-7}
OTFom	Non-containment	Fomite	1.00	0	0
OTPalm	Non-containment	Hand	1.00	0	0
			Cumulative P_{1Y} (yr ^{1})	1.04×10^{6}	

As shown in Table 5.4.5-1, the cumulative frequency that a transference event will result in an infection (P_{1Y}) is approximately 1×10^{-6} events per year, or one event approximately every 960,000 years. The greatest contributors to this cumulative frequency are the non-containment events (OTP, OTF, and OTP) in which FMDv is transferred to an individual's body resulting from a spill of infectious FMDv, and the

fomite transference events originating in the AHR (ATF). The respiratory events (ATR) resulted in very low probabilities of infection as a result of a loss-of-containment due to the rapid inactivation of FMDv in the human upper respiratory tract combined with the 5-day susceptible species contact restriction.

The ten events with the highest P_i values (weighted values) are listed in Table 5.4.5-2. The ten events with the greatest frequency (F_{event}) of loss-of-containment and an infection occurring are listed in Table 5.4.5-3. A detailed summary of all of the calculated P_i and F_{event} values for all 60 transference events is listed in Table 5.4.5-4.

As shown in Table 5.4.5-2, while all individual events start with a low probability of infection (< 4%), based solely on the Q terms, probabilities fall significantly lower after the first six events listed. These ten events represent all ten events modeled in which there is bodily contamination of the foot, body, and hand in an outside containment spill of infectious FMDv. (The other three non-containment transference events due to a spill of infectious material represent the events in which the packaging does not fail and thus, there is no release of material and a P_i of 0.) While these events may have high P_i values, the frequency at which they occur is very low due to the low probability of the associated loss-of-containment (P_{loss}).

Table 5.4.5 2: Ten Highest P_i Events

Event ID	P_{event}	P_i	F_{event} (yr ^{1})
OTF2	3.10E-10	3.12E-02	1.55E-07
OTF3	2.98E-13	3.00E-02	1.49E-10
OTB4	1.37E-10	1.38E-02	6.85E-08
OTB5	1.37E-13	1.37E-02	6.84E-11
OTP5	1.21E-13	1.21E-02	6.04E-11
OTP4	1.13E-10	1.14E-02	5.67E-08
OTB3	1.10E-12	5.58E-04	5.52E-10
OTB2	1.07E-09	5.39E-04	5.33E-07
OTP3	2.64E-13	1.33E-04	1.32E-10
OTP2	2.38E-10	1.20E-04	1.19E-07

The ten events with the greatest frequency (F_{event}) of a loss-of-containment and that an infection occurs due to that loss-of-containment are displayed in Table 5.4.5-3. The transference events that pose the greatest risk to an infection outside of the NBAF are bodily contamination due to a spill of infectious FMDv outside of containment (OTB2, OTF2, OTP2) and transfer of infectious FMDv to a fomite originating in the AHRs (ATF3). The non-containment spill events (OTB2, OFT2, OTP2) are those in which the primary and secondary packaging fails and there is either recognition of a potential exposure or the worker uses the appropriate personal protective equipment (PPE) to reduce the amount of material transferred. The fomite event (ATF3) is one in which the NBAF worker fails to perform both chemical disinfections on the fomite and thus the source term is not reduced. All ten of these events represent situations in which FMDv is transferred to a surface. As mentioned above, survival of FMDv in the

human respiratory tract, is significantly shorter than on surfaces (90% reduction in hours, rather than days), and thus the respiratory events (ATR) have event frequencies of less than 1.6×10^{-14} yr^{-1}. None of these ten events in Table 5.4.5-3 has a frequency of greater than 1×10^{-6} times per year, and the event with greatest frequency, OTB2, is expected to occur only once approximately every two million years.

Table 5.4.5 3: Ten Highest F_{event} Events

Event ID	P_{event}	P_i	F_{event} (yr^{-1})
OTB2	1.07E-09	5.39E-04	5.33E-07
ATF3	4.40E-10	1.76E-05	2.50E-07
OTF2	3.10E-10	3.12E-02	1.55E-07
OTP2	2.38E-10	1.20E-04	1.19E-07
OTB4	1.37E-10	1.38E-02	6.85E-08
OTP4	1.13E-10	1.14E-02	5.67E-08
ETP10	7.58E-13	3.06E-08	1.59E-08
NTB2	2.98E-11	3.01E-09	5.03E-09
ETB2	2.29E-13	1.15E-08	4.80E-09
ETP2	6.89E-14	4.54E-10	1.45E-09

Table 5.4.5-4: Index Case Frequencies for Transference Events

Event ID	Originating Location	Respiratory or Contact Region	*Q* Value			Probability (P_{loss})	Opportunity Rate (R_o, yr^{-1})	Frequency (F_{loss}, yr^{-1})	Median Probability of Infection (P_i)			Median Infection Frequency (F_{event}, yr^{-1})		
			Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
ATR1	AHR	Respiratory	4.08E-03	3.59E+00	3.18E+03	9.7013E-01	567.5	5.51E+02	0	4.32E-22	5.58E-16	0	2.38E-19	3.07E-13
ATR2	AHR	Respiratory	8.16E-01	7.18E+02	6.35E+05	2.4875E-02	567.5	1.41E+01	0	1.28E-18	6.69E-15	0	1.81E-17	9.44E-14
ATR3	AHR	Respiratory	1.30E-02	1.14E+01	1.01E+04	4.8750E-03	567.5	2.77E+00	0	1.78E-21	2.02E-17	0	4.92E-21	5.59E-17
ATR4	AHR	Respiratory	2.60E+00	2.29E+03	2.02E+06	1.2500E-04	567.5	7.09E-02	4.89E-22	1.11E-17	2.54E-14	3.47E-23	7.88E-19	1.80E-15
ATF1	AHR	Fomite	1.48E-14	7.78E-09	8.12E-07	9.9003E-01	567.5	5.62E+02	0	0	0	0	0	0
ATF2	AHR	Fomite	1.48E-09	7.78E-04	8.12E-02	9.9500E-03	567.5	5.65E+00	0	0	0	0	0	0
ATF3	AHR	Fomite	1.48E-04	7.78E+01	8.12E+03	2.5000E-05	567.5	1.42E-02	0	8.38E-06	2.01E-04	0	1.19E-07	2.86E-06
NTH1	Necropsy	Hand	1.71E-07	9.06E-04	2.79E+00	9.1409E-01	169	1.54E+02	0	0	8.89E-15	0	0	1.37E-12
NTH2	Necropsy	Hand	1.14E-04	6.07E-01	1.87E+03	7.5935E-02	169	1.28E+01	0	0	1.26E-09	0	0	1.62E-08
NTH3	Necropsy	Hand	1.69E-06	8.97E-03	2.76E+01	9.1868E-03	169	1.55E+00	0	0	6.66E-13	0	0	1.03E-12
NTH4	Necropsy	Hand	1.13E-03	6.01E+00	1.85E+04	7.6317E-04	169	1.29E-01	0	8.75E-14	1.48E-08	0	1.13E-14	1.91E-09
NTH5	Necropsy	Hand	1.67E-05	8.89E-02	2.74E+02	2.3083E-05	169	3.90E-03	0	0	4.77E-11	0	0	1.86E-13
NTH6	Necropsy	Hand	1.12E-02	5.95E+01	1.83E+05	1.9175E-06	169	3.24E-04	0	3.70E-12	9.92E-08	0	1.20E-15	3.21E-11
NTH7	Necropsy	Hand	6.82E-08	3.63E-04	1.12E+00	4.9254E-03	169	8.32E-01	0	0	8.90E-15	0	0	7.41E-15
NTH8	Necropsy	Hand	6.76E-07	3.59E-03	1.11E+01	4.9501E-05	169	8.37E-03	0	0	1.39E-13	0	0	1.16E-15
NTH9	Necropsy	Hand	6.69E-06	3.55E-02	1.09E+02	1.2438E-07	169	2.10E-05	0	0	1.49E-11	0	0	3.13E-16
NTH10	Necropsy	Hand	6.82E-03	3.63E+01	1.12E+05	2.4751E-05	169	4.18E-03	0	9.12E-13	9.24E-08	0	3.81E-15	3.86E-10
NTH11	Necropsy	Hand	6.76E-02	3.59E+02	1.11E+06	2.4875E-07	169	4.20E-05	0	1.11E-10	5.87E-07	0	4.65E-15	2.47E-11
NTH12	Necropsy	Hand	6.69E-01	3.55E+03	1.09E+07	6.2500E-10	169	1.06E-07	0	4.23E-09	1.22E-05	0	4.47E-16	1.29E-12
NTB1	Necropsy	Body	3.12E-06	1.66E-02	5.11E+01	9.8012E-01	169	1.66E+02	0	0	2.49E-11	0	0	4.12E-09
NTB2	Necropsy	Body	2.34E-03	1.24E+01	3.83E+04	9.9003E-03	169	1.67E+00	0	9.35E-13	6.01E-08	0	1.56E-12	1.01E-07
NTB3	Necropsy	Body	3.09E-05	1.64E-01	5.06E+02	9.8505E-03	169	1.66E+00	0	0	1.12E-10	0	0	1.87E-10
NTB4	Necropsy	Body	2.32E-02	1.23E+02	3.80E+05	9.9500E-05	169	1.68E-02	0	1.58E-11	6.27E-07	0	2.66E-13	1.05E-08
NTB5	Necropsy	Body	3.06E-04	1.63E+00	5.01E+03	2.4750E-05	169	4.18E-03	0	8.90E-15	1.64E-09	0	3.72E-17	6.88E-12
NTB6	Necropsy	Body	2.30E-01	1.22E+03	3.76E+06	2.5000E-07	169	4.23E-05	0	2.05E-10	1.47E-06	0	8.66E-15	6.21E-11
ETP0	BSL-3E/BSL-3E SP	Hand	0.00E+00	0.00E+00	0.00E+00	9.9800E-01	21000	2.10E+04	0	0	0	0	0	0
ETP1	BSL-3E/BSL-3E SP	Hand	9.11E-09	3.09E-04	1.05E+01	1.8282E-03	21000	3.84E+01	0	0	4.50E-13	0	0	1.73E-11
ETP2	BSL-3E/BSL-3E SP	Hand	6.10E-06	2.07E-01	7.06E+03	1.5187E-04	21000	3.19E+00	0	0	9.08E-09	0	0	2.90E-08
ETP3	BSL-3E/BSL-3E SP	Hand	9.02E-08	3.06E-03	1.04E+02	1.8374E-05	21000	3.86E-01	0	0	3.64E-11	0	0	1.41E-11
ETP4	BSL-3E/BSL-3E SP	Hand	6.04E-05	2.05E+00	6.99E+04	1.5263E-06	21000	3.21E-02	0	7.42E-15	1.20E-07	0	2.38E-16	3.85E-09
ETP5	BSL-3E/BSL-3E SP	Hand	8.93E-07	3.03E-02	1.03E+03	4.6165E-08	21000	9.69E-04	0	0	8.47E-11	0	0	8.21E-14
ETP6	BSL-3E/BSL-3E SP	Hand	5.98E-04	2.03E+01	6.92E+05	3.8350E-09	21000	8.05E-05	0	8.06E-13	1.31E-06	0	6.49E-17	1.05E-10
ETP7	BSL-3E/BSL-3E SP	Hand	3.64E-09	1.24E-04	4.22E+00	4.9254E-03	21000	1.03E+02	0	0	7.64E-14	0	0	7.90E-12
ETP8	BSL-3E/BSL-3E SP	Hand	3.61E-08	1.22E-03	4.17E+01	4.9501E-05	21000	1.04E+00	0	0	9.51E-11	0	0	9.89E-11
ETP9	BSL-3E/BSL-3E SP	Hand	3.57E-07	1.21E-02	4.13E+02	1.2438E-07	21000	2.61E-03	0	0	6.99E-11	0	0	1.83E-13
ETP10	BSL-3E/BSL-3E SP	Hand	3.64E-04	1.24E+01	4.22E+05	2.4751E-05	21000	5.20E-01	0	1.08E-13	6.12E-07	0	5.64E-14	3.18E-07
ETP11	BSL-3E/BSL-3E SP	Hand	3.61E-03	1.22E+02	4.17E+06	2.4875E-07	21000	5.22E-03	0	9.11E-12	3.53E-06	0	4.76E-14	1.84E-08
ETP12	BSL-3E/BSL-3E SP	Hand	3.57E-02	1.21E+03	4.13E+07	6.2500E-10	21000	1.31E-05	0	6.46E-10	2.10E-05	0	8.47E-15	2.76E-10
ETB0	BSL-3E/BSL-3E SP	Body	0.00E+00	0.00E+00	0.00E+00	9.9800E-01	21000	2.10E+04	0	0	0	0	0	0
ETB1	BSL-3E/BSL-3E SP	Body	3.70E-07	1.25E-02	4.28E+02	1.9602E-03	21000	4.12E+01	0	0	7.85E-11	0	0	3.23E-09
ETB2	BSL-3E/BSL-3E SP	Body	2.77E-04	9.41E+00	3.21E+05	1.9801E-05	21000	4.16E-01	0	9.28E-13	2.31E-07	0	3.86E-13	9.60E-08
ETB3	BSL-3E/BSL-3E SP	Body	3.66E-06	1.24E-01	4.24E+03	1.9701E-05	21000	4.14E-01	0	0	3.32E-09	0	0	1.37E-09
ETB4	BSL-3E/BSL-3E SP	Body	2.75E-03	9.32E+01	3.18E+06	1.9900E-07	21000	4.18E-03	0	2.83E-12	5.77E-06	0	1.18E-14	2.41E-08
ETB5	BSL-3E/BSL-3E SP	Body	3.63E-05	1.23E+00	4.20E+04	4.9500E-08	21000	1.04E-03	0	2.57E-15	3.97E-08	0	2.67E-18	4.13E-11

Table 5.4.5-4: Index Case Frequencies for Transference Events

Event ID	Originating Location	Respiratory or Contact Region	*Q* Value			Probability (P_{loss})	Opportunity Rate (R_o, yr^{-1})	Frequency (F_{loss}, yr^{-1})	Median Probability of Infection (P_i)			Median Infection Frequency (F_{event}, yr^{-1})		
			Low	Medium	High				Low *Q*	Medium *Q*	High *Q*	Low *Q*	Medium *Q*	High *Q*
ETB6	BSL-3E/BSL-3E SP	Body	2.72E-02	9.23E+02	3.15E+07	5.0000E-10	21000	1.05E-05	0	3.51E-10	1.27E-05	0	3.68E-15	1.33E-10
OTP1	Non-containment	Hand	0.00E+00	0.00E+00	0.00E+00	1.0000E+00	500	5.00E+02	0	0	0	0	0	0
OTP2	Non-containment	Hand	1.46E-07	4.96E-03	1.69E+02	1.9781E-06	500	9.89E-04	0	0	2.40E-03	0	0	2.38E-06
OTP3	Non-containment	Hand	1.62E-07	5.51E-03	1.88E+02	1.9801E-09	500	9.90E-07	0	0	2.66E-03	0	0	2.64E-09
OTP4	Non-containment	Hand	1.45E-01	4.91E+03	1.67E+08	9.9401E-09	500	4.97E-06	0	1.01E-02	4.61E-02	0	5.02E-08	2.29E-07
OTP5	Non-containment	Hand	1.61E-01	5.45E+03	1.86E+08	9.9500E-12	500	4.98E-09	0	1.09E-02	4.69E-02	0	5.42E-11	2.33E-10
OTF1	Non-containment	Foot	0.00E+00	0.00E+00	0.00E+00	1.0000E+00	500	5.00E+02	0	0	0	0	0	0
OTF2	Non-containment	Foot	3.67E-01	1.25E+04	4.25E+08	9.9401E-09	500	4.97E-06	0	3.00E-02	8.42E-02	0	1.49E-07	4.19E-07
OTF3	Non-containment	Foot	4.08E-01	1.38E+04	4.72E+08	9.9500E-12	500	4.98E-09	0	2.87E-02	8.28E-02	0	1.43E-10	4.12E-10
OTB1	Non-containment	Body	0.00E+00	0.00E+00	0.00E+00	1.0000E+00	500	5.00E+02	0	0	0	0	0	0
OTB2	Non-containment	Body	5.93E-06	2.01E-01	6.86E+03	1.9781E-06	500	9.89E-04	0	0	1.08E-02	0	0	1.07E-05
OTB3	Non-containment	Body	6.59E-06	2.24E-01	7.63E+03	1.9801E-09	500	9.90E-07	0	0	1.12E-02	0	0	1.10E-08
OTB4	Non-containment	Body	2.94E-01	9.96E+03	3.40E+08	9.9401E-09	500	4.97E-06	0	1.26E-02	4.85E-02	0	6.27E-08	2.41E-07
OTB5	Non-containment	Body	3.26E-01	1.11E+04	3.78E+08	9.9500E-12	500	4.98E-09	0	1.26E-02	4.75E-02	0	6.28E-11	2.36E-10
OTFom1	Non-containment	Fomite	1.48E-10	7.78E-05	8.12E-03	1.0000E+00	1	1.00E+00	0	0	0	0	0	0
OTPalm1	Non-containment	Hand	1.48E-10	7.78E-05	8.12E-03	1.0000E+00	1	1.00E+00	0	0	0	0	0	0

This document contains pre-decisional and/or deliberative process information exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C.552(b)(5). Do not release without prior approval of the Department of Homeland Security.

5.4.5.1 P_i and Event Frequency

While the transference events beginning outside of containment are among the strongest contributors to the cumulative P_i, the risk from these events could be much higher except that they occur at very low frequencies. For instance, the P_i due to contamination of footwear from a shipment where the primary and secondary containment fails and the handler fails to recognize the potential contamination (event OTF2) is close to 3%, but because it will happen approximately once every 200,000 years, the F_{event} is actually 0.000016%. Such is the case for all transference events initiating outside of containment and releasing one PFU or more of FMDv; infection event frequencies range from 5×10^{-7} to 2×10^{-18} occurrences per year (for events that have a nonzero frequency). The high frequency of infection due to these releases further underscores the importance of thorough biosafety protocols specifically written to prevent such events from occurring.

5.4.5.2 Conservative Estimation of P_i

As pointed out in several sections above, the P_i calculations reported here are very conservative estimates; the actual P_i values are likely much lower. To reiterate, the assumptions and calculations resulting in an admittedly high P_i are summarized below.

1. **Reduction of virus amount due to contact (Section 5.4.3.4).** Each contact of a contaminated body part with another surface will result in a deposition of a certain amount of virus onto that surface, thus reducing the amount of virus carried on the person. In order to simplify the model, the number of contacts a person makes throughout the day was represented by the number of locations (e.g., office, car, store, home) visited by that person. While obviously a gross underestimation of the actual number of contacts that may occur, this adaptation was necessary due to the lack of data on a reasonable number of contacts per day, and in order to avoid all viral material being lost to contacts.

2. **All farms visited are dairies (Section 5.4.4.1).** Dairies were chosen because they represent the farm type with the most contact between workers and animals (see Section 6 and Appendix A6). Additionally, cattle are more susceptible than other susceptible species (swine and sheep), resulting in a more conservative estimate of P_i.

3. **All species contacted are cattle (Section 5.4.4.1).** Outside of farms, all species contacted were assumed to be cattle, as they are the species most susceptible to FMDv infection, resulting in a more conservative estimate for probability of infection.

4. **One animal is contacted at non-farm sites (Section 5.4.4.1).** It is reasonable to assume that in the scenarios of large animal teaching facilities, fairs, and rodeos, people are most often in proximity to several animals but actually contact very few. Data collected via interviews did not distinguish between proximity to animals and handling them; thus, one animal was assumed to be contacted at each such site as a likely median among both animal viewers and handlers.

5. **Delivery of virus to a susceptible animal (Section 5.4.4.2).** Due to a lack of data available on transfer of infectious virus from a contaminated person to a susceptible animal, the dose of virus an animal receives is likely overestimated. For aerosol contamination, the entirety of the virus remaining in the upper respiratory tract is delivered to the animal(s), which clearly is not the case biologically. For contact contamination, the fraction of virus transferred by one contact event was used for the dose to the animal(s), which assumes that all virus delivered is administered intranasally.

6. **Two methods of calculating P_i (Section 5.4.2.2).** When a contaminated individual visits a site with more than one animal, P_i was calculated both as if all virus administered went to one animal and as if the amount administered was distributed evenly among all animals; The higher resulting P_i was chosen as the true P_i. In reality, the true P_i is likely somewhere in between these two values.

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