3.14 HEALTH AND SAFETY

This section presents the overall objectives, methodology, results, and conclusions related to the identification of potential hazards; the analysis of potential postulated accidents; and the evaluation of consequences associated with normal and abnormal operations of the DHS NBAF. The identification of hazards includes operations with pathogens and other identified risks related to operation of a large high-biocontainment biosafety laboratory. The analysis includes specific evaluation of accidents with potential adverse consequences and intentional acts (perpetrated by adversaries such as terrorists, criminals, employees, extremists, etc.).

The National Academy of Sciences (NAS), Committee on Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory, Boston University, National Research Council, prepared a letter report that provides a discussion of important considerations when developing a risk assessment. Much of that discussion was adopted for presenting the approach taken in the evaluation of potential health and safety impacts from operation of the proposed NBAF (NAS 2008).

The specific objective of this hazard identification, accident analysis, and risk assessment is to identify the likelihood and consequences from accidents or intentional subversive acts. In addition to identifying the potential for or likelihood of the scenarios leading to adverse consequences, this analysis provides support for the identification of specific engineering and administrative controls to either prevent a pathogen release or mitigate the consequences of such a release. The consequence analysis is related specifically to the accidental or intentional release of a pathogen and was developed and presented in a qualitative and or semiquantitative manner. The overall process for the accident and threat analysis as applied to the evaluation of potential impacts related to operation of the proposed NBAF is described in the following illustration.

The fundamental questions addressed in this analysis are (NAS 2008)

- What could go wrong (the sequence of events that could cause an infectious pathogen to escape the laboratory, set up a chain of transmission, and cause infectious disease in the surrounding community)?
- What are the probabilities (likelihood for each type of release) of such a sequence of events?
- What would be the consequences of such a sequence of events (e.g., the impacts of a release including transmission of disease, morbidity, and mortality)?

<u>Scenarios of Release of an Infectious Pathogen</u>

The NBAF analysis was prepared such that both a wide range of realistic hazard scenarios were considered, as well as the identification and detailed evaluation of a select number of high-consequence accidents. This is consistent with what the NAS indicated should be in the first phase of a risk assessment. This approach provided a realistic assessment of risks associated with the NBAF in general and illustrated the comparative risks across the six proposed sites. The hazards analysis of the NBAF operations concentrated on the identification of potential releases that required additional safety controls and determined those accidents that required additional evaluation.

As described by NAS, a second phase of a risk assessment evaluates those potential release scenarios that are highly unlikely but still provide credible high consequences. This method of approach was used for the NBAF where the selected accidents focused on the potential pathogen release from many diverse initiators such as procedural or work practice failures, including those which lead to worker exposures and infections, biobiocontainment system and equipment failures, and an appropriate array of intentional acts [addressed separately in the Threat Risk Assessment (TRA) in discussed in Section 3.14.3.4].

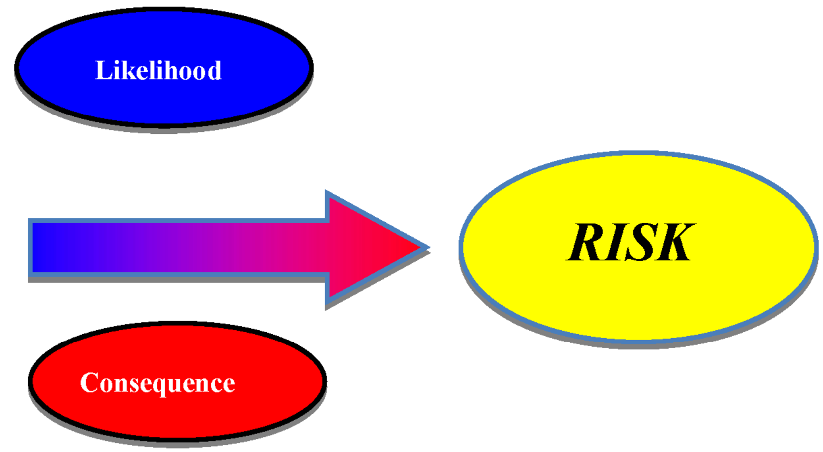
NBAF Biological Hazard/Accident/Threat/Risk Model

Likelihood is defined as the probability of a defined adverse consequence (accident results in release of pathogens or an adversary acquires, produces, and disseminates a Biological Weapon)

- *Estimated based on qualitative frequency categories*
- *Event trees identify importance of controls*
- *Event trees developed for unmitigated and mitigated conditions*

Consequence is defined as the magnitude of the impact to the workers, public, and environment from the accident or intentional act

- *Consequences calculated using deterministic values*
- *Estimated based on a bounding parameter values*
- *Consequences developed for accidents and intentional acts for both unmitigated and mitigated conditions*



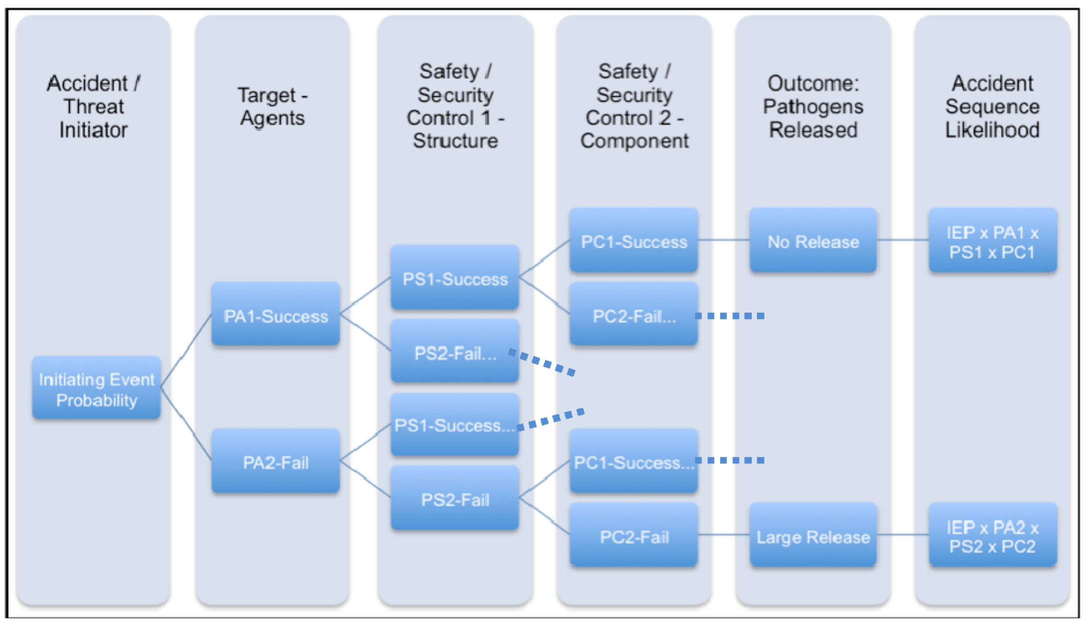
Phase I: Hazards/Threats/Vulnerability Evaluation

- Identify hazards/threats/vulnerabilities
- Develop & evaluate credible scenarios
- Determine qualitative likelihood/consequences
- Identify controls
- Identify potential candidates for detailed analysis

Phase II: Detailed Analysis of Selected Accidents/Threats for Consequence & Likelihood

- Accidents Address: Operations, Natural Phenomena, and External Events
- Threats Address: Terrorists, Disgruntled Employees, Criminals, and Psychotics

Phase II: Accident/Threat Analysis Likelihood Estimation Event Tree



The hazards evaluation, used for the NBAF analysis, identified and evaluated a wide range of realistic scenarios that were postulated to result in an adverse consequence, along with a qualitative evaluation of the protective features in place to prevent or mitigate the hazards and their adverse consequences. Safety controls include engineered safety systems (passive and active) and administrative controls (e.g., training and standard operating procedures, maintenance, and quality assurance).

The overall accident and risk analysis that examined possible sequences and post-release events focused attention on the magnitude of the possible consequences of a release by considering mechanisms of transmission, susceptibility, virulence, and other aspects that influence the growth and spread of disease. The number of accident scenarios analyzed in detail was determined from the wide array of hazard scenarios that lead to high likelihood and consequences to the workers, public, and/or the environment.

Even with the improved engineering and design of high-biocontainment biological laboratories, accidents due to human error or maintenance failures that could cause releases can occur. Recent events include 1) the infection of workers with *Brucella sp.* at one of Texas A&M University's BSL-3 laboratories in 2006; 2) a 1-hr power outage in 2007 at the new BSL-4 facility of the CDC in Atlanta, before work with pathogens begun, wherein the main and back-up power systems both failed and the negative air-pressure system—a key element of pathogen biocontainment—shut down; and 3) in 2007, a release of FMDV to livestock on farms near the Pirbright high-biocontainment laboratory in the United Kingdom due to a damaged and leaking drainage system at the facility (GAO 2007). Scenarios for evaluating the risks posed by the NBAF included potential realistic means of biological pathogen release and describe the various safety controls and barriers relied on to protect laboratory workers, the public, and the environment.

Potential pathogen release included procedural and/or operational and procedural failures, including those that led to worker exposures and infections, spills, loss of biocontainment or control, and even large facility fires. In addition, consider the contamination of the waste streams from the laboratory, intentional infection of laboratory workers, and unintentional release of laboratory animals or pests (such as mosquitoes, which are vectors for RVFV). Development of scenarios to address the numerous and varied situations that can lead to an adverse consequence provides insights into the consideration of additional measures that will enhance laboratory safety.

The NBAF risk assessment and accident analysis assumed, for purposes of providing an initial case for modeling, that a release occurred. Scenarios that include probabilistic evaluation of how a biological pathogen could be released lead to enhanced preventive measures. For example, the assessment of the spill accident highlighted the importance of laboratory worker training in reducing the likelihood of the event. In addition to laboratory-related interventions to *minimize the occurrence* of such events (that is, prevention measures), the risk assessment addressed, as an important safety control, the response capabilities to *respond* to untoward events (that is, mitigating measures).

Without the discussion of preventive and mitigating measures, scenarios would not reflect necessary management and operational aspects of the NBAF, resulting in the loss or unavailability of vital risk information for decision making. Basing scenarios on as much factual information as possible provides relevance and ensures that the various accident scenarios more accurately portray the hazards associated with work in high-biocontainment laboratories.

<u>Pathogens Considered in the NBAF Analysis</u>

The NBAF risk assessment was based on the selection of a variety of representative pathogens with appropriately diverse transmission characteristics (blood borne, transmitted on fomites, spread by aerosol, and/or requiring vectors, as well as the potential for maintenance in existing reservoir species). In addition, such aspects of transmission as high- or low-reproduction, latency, and incubation periods were considered in the assessment of risk at each of the six proposed NBAF sites. The pathogens considered in the NBAF risk assessment were FMDV, RVFV, and Nipah virus.

The characteristics of the particular infectious pathogens considered in the NBAF risk assessment make it more likely that the pathogen could lend itself to the establishment of a chain of transmission that leads to the spread of infection in livestock and endemic species (Section 3.14.4). Infectious pathogens chosen for consideration in the NBAF risk assessment require BSL-3Ag (FMDV and RVFV) or BSL-4 (Nipah virus) biocontainment precautions. These were chosen such that pathogens from both biocontainment levels are represented, and such that the greatest potential for disease spread is represented.

Biosafety biocontainment levels 3E, 3Ag, and 4 include various factors for consideration. These factors include, for example, risk to laboratory workers (and uninfected animals) and whether the pathogen is endemic (neither FMDV, RVFV, nor Nipah virus are endemic viruses in the United States). BSL-3 laboratories are used to study biological pathogens that are potentially lethal and that are transmissible by the aerosol route (CDC 2007; NAS 2008). Consideration of the specific transmissibility, morbidity, and mortality, whether they are handled at the BSL-3 or BSL-4, is also important in evaluating risk. While engineered controls are typically more stringent [e.g., air line respirators in lieu of working in a BSC in BSL-4 facilities, risks of human error may be greater in BSL-3 laboratories.

<u>Estimating the Probability of Release</u>

The potential pathogen releases considered in the NBAF analysis included estimates of likelihood (probability) that were calculated using standard yet simple models with bounding values for the specific parameters. An infectious pathogen release could have a variety of consequences, including (NAS 2008) the following:

- No subsequent transmission, following a small initial pool of infection;
- Little or no subsequent transmission, following multiple exposures;
- Limited transmission that is contained by public health measures; and
- Amplified transmission.

Based on the selected pathogens, the potential for amplified transmission was the primary focus of the NBAF risk assessment. The qualitative analysis of potential outcomes considered the impact of the local characteristics (population density, livestock availability, wildlife, and vector availability) for each of the six proposed sites as discussed in Section 3.14.4.

Risk assessment addresses both the probability and the consequences of adverse events. The scenarios and pathogens discussed were used in the risk assessment to analyze and present the likelihood of adverse events for both mitigated and unmitigated conditions. The qualitative evaluation of the likelihood of the impacts after a release was based on information available from the chemical, nuclear, and biological communities.

The amplified transmission outcome (consequence) is particularly important for the FMDV and RVFV, since these pathogens could establish a successful chain of transmission in both livestock and wildlife species in the United States. Examples of FMDV outbreaks in England and RVFV and Nipah virus outbreaks around the world illustrate the magnitude of the adverse consequences from a potential release. Drastic measures to control FMDV outbreaks in cattle can and often do lead to great economic loss.

The consequences of a release of an infectious pathogen from a high-biocontainment laboratory depend on numerous factors, such as the characteristics of the pathogen, the pathway by which it is spread, and the size and characteristics of the population that is exposed to it. The major concern for the NBAF analysis is the potential for outbreaks of disease in livestock, wildlife, and, to a lesser degree, the human population.

Modeling is another way of assessing how disease caused by a pathogen may be spread. Modeling may also be an important tool in devising appropriate mitigating strategies. Calculating the subsequent outcome of a potential release of a biological pathogen with models is difficult and uncertain. The process of *transmission*, which has a high degree of uncertainty, is a major parameter in determining the results of a release. It is also difficult and uncertain to estimate the number of contacts between animals, between people, or between animals and people (NAS 2008). In addition, since RVFV is predominantly a vector borne disease, the potential for widespread transmission is amplified by mosquitoes.

The accuracy and precision of a single model to simulate both the transmission of an aerosol-transmissible pathogen and that of a fomite-transmitted pathogen is uncertain and requires great effort to verify or validate the results (NAS 2008). Simple descriptions and qualitative discussions have distinct advantages over the use of controversial and complex models. First, the behavior of simple models are relatively well understood because the mathematics are well-established. The effect of changing inputs in simple models is relatively transparent as in the case of distinguishing between the mitigated and unmitigated accidents. More complexity and detail do not often add to confidence or accuracy of the results. Accuracy is most often determined by the data used to develop input. These data are often either not available or in a form that includes many uncertainties (NAS 2008). This is illustrated by the data available for livestock in the vicinity of each proposed NBAF site. The data were provided in terms of livestock per county without a differentiation as to the species of animal.

The focus of risk assessment performed on the NBAF was on potential bounding consequences, as well as the identification of safety controls to prevent the release or mitigate the consequences, including the need for a robust and comprehensive emergency response program. A robust emergency response program and detailed implementation plans are essential safety controls and are identified as practical aspects of managing an incident (Greenberg 1991).

The detailed analysis of potential consequences associated with operation of a NBAF was developed specifically for each of the six potential sites where the NBAF could be located. In the No Action Alternative, the risks and consequences specifically associated with the NBAF would not occur. However, since PIADC currently operates a BSL-3Ag facility, the risks and consequences presented in this analysis would be applicable to the No Action Alternative, as well. The results and conclusions are presented to inform a decision whether to construct and operate the NBAF and also to provide support for a final determination on which of the six sites is best suited to accommodate the facility, if the decision is made to construct and operate the NBAF. To support this critical decision, the analysis was developed around the specific hazards associated with the operation of a large high-biocontainment biosafety laboratory. The hazards and the subsequent accident analyses focus on the potential for a release of the three representative viral pathogens and the types of safety controls that are to be incorporated into the design and operation of the NBAF that would be relied upon to prevent a release or to mitigate the consequences of a release. As stated in Chapter 1, DHS anticipates that the NBAF would initially focus on African swine fever virus, classical swine fever virus, contagious bovine pleuropneumonia bacteria, FMDV, Japanese encephalitis virus, and RVFV research under BSL-3Ag biocontainment and protocols, as well as Hendra virus and Nipah virus research under BSL-4 biocontainment and protocols. FMDV, RVF, and Nipah virus present the most significant and unique challenges compared to any of the other pathogens currently proposed for study at the NBAF. Therefore, the accidental or intentional (criminal or terrorist activity) act that results in the release of one or more of these three pathogens is used in the following consequence analysis. In conveying the critical information necessary for the decision makers and stakeholders to fully appreciate the overall potential impacts from operations of the NBAF, specific risk ranking strategies were applied to the evaluation of the hazards and accidents. Risk ranking is first based on the likelihood of an accident or intentional release occurring and, second, the subsequent consequences for both mitigated and unmitigated events. The differentiation between the "unmitigated" and "mitigated" events provides the decision makers and stakeholders the essential information to understand and appreciate the reduction in risk to the workers, public, and environment between the unmitigated and mitigated events (DOE 2006).

3.14.1 Introduction

The consequence analysis addresses adverse events as a result of both accident(s) and intentional acts related to all hazards associated with the NBAF operation, yet focuses on the specific hazards posed by the use and handling of biological pathogens. Other hazards considered include those associated with chemicals and radioactive materials (based on references presented in the NBAF Feasibility Study). In addition, common or standard industrial hazards related to energy sources, mechanical systems, and other system or sources were reviewed to determine whether these hazards could act as an initiator in the release of a pathogen (Ericson 2005).

The approach to evaluating the consequences associated with normal and abnormal operations considered a wide array of potential adverse events ranging from the simple loss of biobiocontainment of a pathogen in a laboratory setting to the extreme significant events related to a facility biocontainment failure and a large-quantity release of a specific pathogen material external to the NBAF. In addition, the analysis considered adverse events, impacts, and consequences associated with the intentional release of pathogens, disruption of operations to the NBAF, and the theft or loss of sensitive information and pathogen materials.

Large quantity releases of a pathogen are considered to be those associated with a loss of biobiocontainment through either an unfiltered or uncontrolled release of contaminated facility air or wastewater; the loss of infected animals or insects to the environment; or the release to the environment by an infected worker. Less significant releases are considered loss of biocontainment accidents where small quantities of pathogen are released internal to the facility through packaging or sample transport failure, some equipment failure, low-level BSC failure, etc. These smaller "loss of biobiocontainment" accidents differ from loss of biocontainment accidents in that the final facility biocontainment has not been breached, or has not failed, and is still available for protecting the public and environment from pathogen contamination.

The loss of biobiocontainment results in a number of specific accident scenarios with the most serious consequences associated with the release of viral particles (virions) to the environment through a variety of pathways. The potential transport of uncontained viable virions as aerosols is a function of the virus species and its sustained viability in the presence or absence of ultraviolet radiation, humidity, ambient temperature, and other factors. It is suspected from past events that the transport of viable FMD, RVF, or Nipah virions via an atmospheric pathway can occur and could potentially result in infections at significant distances from the release point. A wide array of accidental and intentional consequence scenarios were developed to assess the potential impacts from operations of the NBAF. The intermediate steps in developing a detailed accident, consequence, and risk analysis require a knowledge and understanding of the following elements.

- Identification of the Biological Hazard
- Presence of a pathogen of sufficient virulence;
- Existence of the pathogen in sufficient quantity (infectious dose);
- Host susceptibility to infection with the pathogen;
- Ability of the pathogen to cause great impact to livestock and wildlife;
- Ability of the pathogen to become geographically disseminated; and
- Ability of the pathogen to be transmitted.

The assessment of risks for zoonotic and non-zoonotic pathogens and the identification of appropriate safety controls are also dependent on factors such as (Heckert 2007)

- Whether the agent is endemic or foreign to the region;
- The pathogen's ability to cause morbidity and mortality;
- Shedding patterns of the agent in relevant species;
- Whether active control or eradication programs exist for the disease;
- Environmental stability, quantity, and concentration of the agent;
- Use of the agents in animals and laboratories; and
- Host range of the agent and existence of surveillance programs.

For the purposes of evaluating the potential consequences associated with the operation of the NBAF, only pathogens required to be at either the biocontainment level of BSL-3, BSL-3E, BSL-3Ag, and BSL-4 were considered, since these agents represent the greatest potential for large adverse consequences, ease of dissemination, and animal-to-person, animal-to-animal, or other vector-borne transmissions. To fully evaluate the potential for the identified biological agents to pose a threat to workers, public, and the environment, it was necessary to evaluate the material forms and energy sources that might be present, which could lead to a release and subsequent transport of biological agents (Richmond 2001). Generally, the biological agents would be in the form of tissue culture fluids and media or frozen stocks and suspensions (e.g., tissue culture broth) to maintain their viability for research (Furr 2000). On occasion, some biological materials could be in the form of an aerosol, a lyophilized powder, a gel (e.g., agar media petri plates), or a solution. Specific procedures and protocols would be expected for these different physical forms of the biological agent. Depending on the form, the amount of material present and the manner in which it would be prepared or handled would be conducted in accordance with specific design and safety considerations delineated in the NBAF Institutional Biosafety Committee (IBC)-approved protocols and Agency guidelines and protocols.

Developing consequence and frequency estimates for hazard scenarios generally involves adopting numerical assumptions for the following factors:

- Failure of personnel to follow procedures, inadequate training, and other personnel failures;
- Failure of laboratory process equipment;
- Failure of the primary, secondary, and/or tertiary biobiocontainment of biological material (e.g., sample containers, transportation packaging, equipment, process vessels, etc.);
- Loss of facility biocontainment (e.g., sealed equipment, some BSCs, ventilation and filtration system, facility structure, etc.);
- Other intermediate events in the hazard sequence; and
- Failure of the biosafety program for incident response and emergency communications to the potential release of pathogen.

The evaluation of hazard scenarios relies on determining estimates of two interrelated elements: 1) the probability of a postulated accident scenario occurring and 2) the ultimate consequence of the postulated accident scenario. The methods used to evaluate the hazards from normal and abnormal operations of the NBAF are qualitative in nature and were adopted from standard practices in the biological, chemical, and nuclear industries (DOE 2006; CCPS-1; CDC 2007).

- Accidents leading to release and exposure include
  - Transportation accidents;
  - Loss of biobiocontainment of animals or insects;
  - Aircraft crash into the NBAF and other catastrophic failures in the structure;
  - Loss of primary and/or secondary biocontainment barrier failures (BSC and NBAF HEPA filters);
  - Inadvertent discharge of biological materials into air handling or liquid and solid waste pathways;
  - Operational upsets (e.g., spills, ejected containers, equipment failures);
  - Natural phenomena, such as seismic events, high winds, floods, and wild fires; and
  - Inadvertent worker exposure (e.g., LAI, needle sticks, inhalation, etc.).

- Types of intentional acts
  - Intentional release of infected animals or vectors;
  - Theft and release of a pathogen;
  - Sabotage and/or facility destruction; and
  - Theft of sensitive information and technology.

The goals and objectives of the consequence analysis are to identify hazards, develop and analyze potential credible accidents, and identify the appropriate type, level, and number of controls to insure the safe operation of the NBAF. The issues surrounding operations of the NBAF are identified and evaluated in relation to the normal and abnormal operations of the NBAF. The accidents and intentional acts are evaluated in detail to define the *bounding* credible event(s) to inform a decision to construct and operate the NBAF. Bounding accidents are those accidents where the consequences are estimated using values for the critical parameters that are at the upper end of the possible range. Constructing the accident release estimates in this manner provides high confidence that the potential accident consequences would not be exceeded. While this approach may tend to overestimate the overall risk, there is benefit in identifying the appropriate safety controls for risk reduction.

NBAF Biological Hazard

The hazard screening process was based on a thorough knowledge of the biological hazards that have been designated as research candidates for the NBAF. These animal pathogens and zoonotic agents are identified for detailed analysis under operational, accidental, and intentional release scenarios.

As presented in Chapter 1 of this EIS, DHS foresees multiple uses and goals for the NBAF. These include

- Serving as a unique BSL-3Ag and BSL-4 livestock laboratory capable of developing countermeasures for Foreign Animal Diseases (FAD), and
- Providing advanced test and evaluation capability for FAD threat detection, vulnerability assessment, and countermeasure assessment for animal and zoonotic diseases.

DHS anticipates that the facility would focus on FMDV, classical swine fever virus, African swine fever virus, RVFV, Nipah virus, Hendra virus, contagious bovine pleuropneumonia bacteria, and Japanese encephalitis virus. Of these, FMDV, RVFV, and Nipah virus currently present the most demanding and bounding challenges regarding

- Animal health impacts
- Biocontainment
- Ecologic impacts
- Economic impacts
- Emergency response
- Human health impacts
- Infectious potential
- Transmissibility and contagion

DHS plans to perform research at the NBAF to study how these pathogens enter the animal, what types of cell the pathogen affects, what effects the pathogen has on cells and animals, how newly developed countermeasures help protect the animal against the pathogen and prevent disease, and new detection methodologies (CRS 2007). To evaluate the hazards posed by these potential research areas at the NBAF, representative pathogens that bound the range of potential consequences were identified. The representative pathogens selected for the detailed hazards and accident analysis are FMDV, RVFV, and Nipah virus. The basis for the selection of these pathogens is presented below.

FMDV

FMDV, a serious animal pathogen that requires BSL-3Ag biocontainment, deserves specific discussion in the NBAF EIS. FMDV causes debilitating vesicular disease and death in all cloven-hoofed livestock and wildlife. Seven serotypes of FMDV, each of which causes FMD, spreads quickly through herds and flocks of susceptible animals. The disease causes high morbidity, which results in dramatic loss of condition and productivity, from which, most infected stock never fully recovers. The economic consequences of an outbreak are huge, and the potential loss of international markets can be devastating. Equines, poultry and fowl, and humans cannot be infected. Though humans are not considered susceptible to infection, FMDV can persist in the human upper respiratory tract for up to 48 hr, making humans potential vectors if they are exposed (CFIA 2005a).

FMDVs are highly infectious and can be transmitted by aerosols and simple contact with fomites (e.g., contaminated materials, inanimate objects, clothing, veterinary equipment, vehicles, foodstuffs, manure, soil, and vegetation). Viruses are excreted from and present in blood and body fluids, including respired air, saliva, vesicular fluids and tissues of the vesicles—which are a hallmark of the infection—semen, vaginal fluids, urine, feces, meats, and milk. Infected animals can excrete high concentrations of virus in respired air, secretions, and fluids.

RVFV

RVFV, a serious animal pathogen that requires BSL-3 biocontainment, deserves specific discussion in the NBAF EIS for several reasons, as presented below. RVFV is a BSL-3E and BSL-3Ag pathogen. RVFV causes disease and death in cattle, sheep, and goats. Abortion rates in pregnant sheep are nearly 100%, and about 90% of infected lambs die. Cattle and calves also suffer but at less dramatic clinical rates (CFIA 2005c).

The virus is transmitted to animals and humans by infected mosquitoes and possibly other biting flies. Other biting insects such as ticks and black flies appear able to harbor and transmit the virus during epidemic outbreaks. It has been shown through experiments that several North American mosquito species can be infected and are capable of transmitting the virus. Certain *Aedes* mosquitoes in Africa are known to transmit virus through their eggs, indicating that there is potential that RVFV could establish a continuous ecological cycle in the United States if it escaped from a research laboratory. One to three percent of infected humans develop severe hemorrhagic fever and/or encephalitis, which may be fatal. These patients often have sufficient virus in their blood to permit mosquito infection and transmission to other humans and animals. Contact with, or consumption of meat from, infected domestic animals is also a source of infection. RVFV is present in blood and body fluids that are highly infectious for at-risk humans, such as veterinarians and abattoir workers, and livestock via aerosols (respiratory route of transmission). RVFV from blood, body fluids, and tissues is a significant hazard because the virus can be aerosolized from animal activity and room, laboratory, or cage wash down operations.

Nipah Virus

Nipah virus, a serious zoonotic agent that requires BSL-4 biocontainment, deserves specific discussion in the NBAF EIS for several reasons. Nipah viruses are recently described zoonotic viruses causing highly fatal encephalitis in humans and can be contagious among humans under particular limited circumstances. In Malaysia, 265 cases of encephalitis with a 40% death rate were reported primarily among pig farmers. In this outbreak, it was shown that close contact with pigs, especially sick pigs, was the major risk factor for human infection. Respiratory infection of humans by aerosols from infected pigs is suspected (CFIA 2005c).

Nipah viruses exhibit an extended host range, with natural infections including swine, humans, and, to a minor extent, cats and dogs. Serologic studies imply that infection can occur in horses and bats. The viruses are carried by fruit-eating bats (absent from the Western hemisphere), and infections in humans and animals can be contracted from bats via fruit or other fomites contaminated by infected bats. Nipah viruses have been detected in respiratory secretions and urine of infected patients in Malaysia, suggesting that person-to-person transmission might be possible in some situations. None of the patients showed obvious pulmonary symptoms. Secondary human-to-human transmission of Nipah virus was not shown for outbreaks in Malaysia or Singapore, but findings from outbreaks in Bangladesh from 2001 to 2007 suggested that close family contact could result in transmission.

As part of the bounding analysis, DHS concluded that the remaining NBAF candidate pathogens, as discussed below, do not exceed those risks posed by FMDV, RVFV, and Nipah virus.

African Swine Fever Virus (ASFV) and *Classical Swine Fever Virus (CSFV)*: These diseases are viral in nature and pose many of the same concerns presented by FMDV. However, all concerns about ASFV and CSFV are equaled or exceeded by FMDV. FMDV is one of the most contagious infectious diseases known and poses the additional problems of having a broader range of hosts, being transmissible by aerosol over significant distances, and being very resistant to inactivation. ASFV and CSFV raise no concerns that are not present for FMDV.

Hendra Virus (HV): HV has significant similarities to Nipah virus. Both require BSL-4 biocontainment precautions. Both are zoonotic agents, meaning humans as well as animals can become infected. Both are carried by fruit-eating bats (i.e., these bats are reservoirs). Only three cases of human infection from HV have been reported to date, and these appear to have been acquired from body fluids or excretions of infected horses. There are no reports of HV infections in other animals. HV raises no concerns that are not present for Nipah virus.

Japanese Encephalitis Virus (JEV): JEV has significant similarities to RVFV. JEV is a zoonotic agent that is transmitted by mosquito bite, causing infection in birds, pigs, and humans; 0.3% of infections in humans are symptomatic, and fatal encephalitis is possible. Vaccines for use in humans are available for JEV. There is no vaccine for RVFV. JEV raises no concerns that are not present for RVFV.

Contagious Bovine Pleuropneumonia (CBPP): CBPP is the only proposed agent that is bacterial in nature. It is caused by *Mycoplasma mycoides* and is very infectious among cattle. Infectious aerosols are spread via the pulmonary route and, as such, close contact between animals is needed. The bacterium does not survive well outside of its host and, when exposed to normal external environmental conditions, is inactivated within hours or a few days at most. The organism does not survive in meat or meat products. Antibiotic treatment is not very effective and is recommended only in endemic areas where elimination of the organism may not be possible and sub-clinical carriers may develop. As soon as an outbreak is suspected, slaughter of suspect animals is advised. Vaccination of cattle is possible and can be helpful in eradication of disease. All of the problems posed by CBPP are posed by FMDV as well, and comparison of FMDV to CBPP shows FMDV to be a much more serious challenge in all regards. CBPP raises no concerns that are not present for FMDV.

3.14.2 NBAF Hazard and Accident Analysis Methodology

The primary hazard of the NBAF operations is the specific pathogens of FMDV, RVFV, and Nipah virus. The primary accident of interest in evaluating operation consequences is a pathogen release. The types of pathogens described previously are of the type being considered for use in the NBAF. This section presents the results of identifying potential release scenarios and accident initiators that could result in a pathogen release. In addition, hazards from normal and off-normal operations and intentional acts at the NBAF are considered for their role in a pathogen release accident. These hazards are evaluated and analyzed to develop accident scenarios and to estimate conservative consequences of these accidents to the public, workers, and environment and also to develop controls to prevent the accident or to mitigate the consequences of the accident. A detailed hazard and accident methodology used to develop those consequence and risk results is presented in Appendix E.

3.14.2.1 Hazard Evaluation Results

This hazard assessment is developed utilizing information from the NBAF initial feasibility study (NBAF-1) and identifies potential hazards inherent in the anticipated NBAF processes or activities. This hazards listing consists of broad categories of factors that are associated with accident initiation or magnitude and include pathogenic, toxicological, energetic, mechanical, or human error and others.

The methodology used for the hazard evaluation is based primarily on the method referred to as "*what if?/checklist"* analysis technique (CCPS-1). This technique is first applied in brainstorming the identification of various types of failures and scenarios that could conceivably occur in a process or facility. Once the failures and scenarios have been identified in a particular area or step of the process or activity, all pertinent aspects of the operation are considered for potential accident initiators and failure modes. After developing and listing potential failures and accident scenarios, each scenario is qualitatively evaluated to determine the potential consequences of the scenario. Safeguards that prevent, mitigate, or contain the effects of the potential accident are detailed, and each accident scenario is evaluated to determine whether additional improvements or controls should be recommended. All scenarios from the table that have adverse consequences of interest (potential for release of larger quantities of viable pathogens or are imitators to a potential release) are identified. From this list, the safeguards for each selected hazard scenario are categorized as primary and secondary biocontainment barriers and procedural controls. Procedural controls, by their design, are administrative in nature. The following Table presents the safeguards and their associated description in accordance with the expectations outlined in the BMBL (CDC and NIH 2007).

Description of Safety Controls from the 5th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)	
Safeguard	Description
Primary Biocontainment Barrier (Protective Feature)	Specific or intrinsic to the process or design element equipment (BSC, special process equipment, personnel safety suits, etc.)
Secondary Biocontainment Barrier (Protective System)	Provided by the facility and not the system and is intrinsic to the process or design element (structure, ventilation, fire suppression, etc.)
Procedural Control (Administrative)	Procedural in nature; may be a protective safety management program, a procedure, or a specific procedural step (directive language)

Each hazard scenario is analyzed in an unmitigated fashion where the effects of any primary or secondary biocontainment barriers and/or procedural controls are discounted to determine the uncontrolled impact of the accident scenario on the worker, the public, and the environment. Based on the consequence of severity definitions for the public, the worker, and the environment, which are listed in Tables 3.14.2.1-1 and 3.14.2.1-2, the hazard scenario is assigned a consequence category (DOE 2006; Bahr 1997).

The difference in the descriptions of consequences between workers and the public or environment are intended to convey the fact that the workers are provided personal protection (PPE) and are trained, whereas the public is not afforded this level of protection. Another significant difference in the assignment of consequence categories is that the worker will, in nearly all instances, be in closer proximity to the hazard than a member of the public.

Protection of the public from adverse consequences is primarily driven by engineered controls such as HEPA filtration and pressure controls that prevent large quantities of pathogens from escaping the facility in the event of an operational upset condition. Protection of the worker, because of the close proximity to the hazard, is primarily driven by administrative controls, such as protocols, procedures, and PPE.

Administrative controls such as emergency management and response, on the other hand, provided greater protection for the public than the workers. In a similar fashion, engineered controls such as BSCs and negative pressure boundaries are essential for protecting the involved and non-involved workers within the laboratories. From this discussion, it is apparent that the overall protection to the workers, the public, and the environment is provided by the integration and layering of multiple safety barriers (CCPS 1992).

The consequence categories presented in Table 3.14.2.1-1 include consequence potential from biological hazards, as well as hazardous chemicals and radioactive materials. While the principal hazard at the NBAF is biological materials, the analysis performed was comprehensive and considered both chemicals and radionuclides.

Table 3.14.2.1-1 — Frequency Categories and Definitions

Category	Definition
A	**Substantial Off-Site Consequences** • *Biological hazard*: high probability or likelihood for human life-threatening health effects (RVFV and Nipah virus) and spread of animal pathogens (FMDV, RVFV, and Nipah virus) • *Chemical hazard*: off-site concentration Emergency Response Planning Guideline (ERPG) and/or Temporary Emergency Exposure Limit (TEEL) of ≥ EPRG/TEEL-3 • *Radiological hazard:* total effective dose equivalent (TEDE) ≥ 25 rem based on 10CFR830
B	**Moderate Off-Site Consequences** • *Biological hazard*: low probability or likelihood for human life-threatening health effects (RVFV and Nipah virus) and spread of animal pathogens (FMDV, RVFV, and Nipah virus) • *Chemical hazard*: EPRG/TEEL-3 > off-site concentration ≥ EPRG/TEEL-2 • *Radiological hazard:* 25 rem > TEDE ≥ 5 rem
C	**Minimal Off-Site Consequences** • *Biological hazard*: contamination occurs with no or minimal human life-threatening health effects (RVFV and Nipah virus) and spread of animal pathogens (FMDV, RVFV, and Nipah virus) • *Chemical hazard*: EPRG/TEEL-2 > off-site concentration ≥ EPRG/TEEL-1 • *Radiological hazard:* 5 rem > TEDE ≥ 0.1 rem
D	**Negligible Off-Site Consequences** • *Biological hazard*: little contamination with little or no potential for transient human life-threatening health effects (RVFV and Nipah virus) and spread of animal pathogens (FMDV, RVFV, and Nipah virus) • *Chemical hazard*: EPRG/TEEL-1 > off-site concentration ≥ EPRG/TEEL-1 • *Radiological hazard:* 0.1 rem > TEDE ≥ 0.01 rem
E	**No Measurable Off-Site Consequences** • *Biological hazard*: none • *Chemical hazard*: off-site concentration < TEEL-0 < ERPG-1 • *Radiological hazard:* TEDE < 0.01 rem

Table 3.14.2.1-2 — Frequency Categories and Definitions

Category	Definition
A	Immediate high probability of health effects leading to loss of life
B	Long-term health effects, disability, or severe injury (possibly life threatening)
C	Lost time injury but no disability (work restriction, not life-threatening)
D	Minor injury with no disability and no work restriction
E	No measurable consequences

The expected frequency of an occurrence for each scenario including such factors as the number of operations conducted each year, complexity of the operation, failure-rate data for any equipment involved, operator-error rates, operational experience, and expert judgment is qualitatively assessed (Gertman 1994). A frequency estimate is determined for each scenario using the likelihood categories from Table 3.14.2.1-3. The overall risk for that particular accident scenario to both the public and the worker is then determined from the qualitative estimates of consequence (Tables 3.14.2.1-1 and 3.14.2.1-2) and the frequency of occurrence (Table 3.14.2.1-3). These risk-ranking values are given in Table 3.14.2.1-4 showing the values of both public and worker in the form public/worker. To support unmitigated accident analyses, the accident scenarios are evaluated without primary or secondary biocontainment barriers or procedural controls in place. That is, the consequence of each unmitigated accident scenario is based on the assumption that none of the controls are effective in mitigating or preventing the accidents. The hazards and accident analyses are developed for both unmitigated and mitigated scenarios to assess the value of various protective systems or features and to determine if additional controls that are necessary to reduce risks. For those accidents that have a low consequence and relatively low likelihood then the basic defense, in depth protection features are considered to provide reasonable assurance of adequate protection given the nature of the work. In these situations, no additional analysis is needed. Hazard and accident scenarios that result in high unmitigated risks are selected for detailed analysis, and additional controls are identified.

Table 3.14.2.1-3 — Frequency Categories and Definitions

Frequency Category	Approximate Range	Label	Description
I	$\geq 10^0$/yr	Frequent	**Likely to occur often during the life of the facility** Incidents that occur during normal operations
II	$<10^0$/yr to $\geq 10^{-2}$/yr	Occasional	**Likely to occur several times during the life of the facility** Incidents that may occur during the lifetime of the facility; these are incidents with a mean expected likelihood of occurring several times (≤50) in 50 operating years
III	$<10^{-2}$/yr to $\geq 10^{-4}$/yr	Probable	**Unlikely but possible to occur during the life of the facility** Incidents that are not anticipated to occur during the lifetime of the facility but could; these are incidents having a likelihood of occurring between 1 time in 100 operating years to 1 time in 10,000 operating years
IV	$<10^{-4}$/yr to $\geq 10^{-6}$/yr	Improbable	**Unlikely to occur during the life of the facility** Incidents that will probably not occur during the lifetime of the facility; these are incidents having a likelihood of occurring 1 time in 10,000 years to between 1 time in 1 million operating years
V	$<10^{-6}$/yr	Remote	**Should not occur during the life of the facility** These remaining incidents have a likelihood of occurring with a frequency of less than 1 time in 1 million operating years

All of the hazard and accident scenarios are evaluated based on the criteria presented in Tables 3.14.2.1-1 – 3.14.2.1-3 for assignment of qualitative likelihood and consequences values. Table 3.14.2.1-4 is then used to assign an appropriate risk rank to the specific hazard or accident scenario. The high risks are taken to those with large consequences and high frequency over the life of the facility. Similarly, low risk hazard and accident scenarios are those characterized by low frequency and low consequences. The risk ranking provides a simple method for distinguishing between accidents to determine the effectiveness of identified controls.

Table 3.14.2.1-4 — Public/Worker Risk Ranking

Matrix of Risk Rank Values Public/Worker					
Consequence Severity	Likelihood Category I	Likelihood Category II	Likelihood Category III	Likelihood Category IV	Likelihood Category V
A	1/1	1/1	2/2	2/2	3/3
B	1/1	2/1	2/2	3/3	3/4
C	1/1	2/2	3/3	3/4	4/4
D	3/2	3/3	3/4	4/4	4/4
E	4/4	4/4	4/4	4/4	4/4

Consequences are taken from Table 3.14.2.1-1 for Public and Table 3.14.2.1-2 for Workers.
Likelihood Category are taken from Table 3.14.2.1-3.
1 = High Risk, 4 = Low Risk.

This risk ranking process is applied to the hazards analysis for selecting accidents that need additional analysis. The risk ranking is also applied to the accident analysis, for both the unmitigated and mitigated scenarios, to either identify the need for additional safety controls or to determine the overall effectiveness of the safety controls to prevent or mitigate the accident. For the purposes of the hazards and accident analysis for the proposed NBAF, the interpretation of Table 3.14.2.1-4 is that risk ranks of 1 or 2 indicate that the consequences and frequency are such that mitigation or prevention measures are necessary. Risk rank 3 is considered borderline in both frequency and consequence and is regarded as the range where additional analysis is needed. Risk rank 4 represents either a very low frequency or a low consequence and can be considered as requiring no additional analysis. In the case of an unmitigated risk rank of 4, no additional analysis is performed. For a mitigated risk rank of 4, the identified safety controls are considered reasonable and adequate to either prevent the accident or to mitigate the consequences.

3.14.2.2 Hazard Screening Analysis

Initially, hazard screening is the process of identifying the scenarios producing the highest pathogenic consequence impact to the worker, the public, and the environment. Characterization of these scenarios is necessary to bound all hazard operations in the NBAF. Once this has been accomplished and the desired operational envelope has been defined, the selection process will identify design-basis accidents representative of the high-consequence scenarios. These accidents are analyzed in detail to evaluate and determine the controls required to protect the public, the worker, and the environment in the event of an accident. The selection and evaluation process is used to define and evaluate bounding design-basis accidents and to select specific controls to prevent the accident or to mitigate the accident consequence significantly. Once complete, lower-tier accidents within the same accident family will be adequately and sufficiently prevented or mitigated.

Standard industrial hazards (slips, trips, falls, wounds, electrical hazards, chemical toxicity, fire hazards, and traumatic injuries) are not included in the hazard identification and evaluation process unless the hazard directly contributes to a pathogen release (DOE 2006). Figure 3.14.2.2-1 illustrates the types of accident scenarios considered while developing the consequence analysis from an inadvertent release of biological agents (see Appendix E, Table E.3- 5 for the entire set of NBAF hazard and accident scenarios). A few examples of how specified controls reduce risk include the identified control referred to as “Procedural compliance and 2-person rule”, which reduces the risk associated with the LAI-1 scenario by ensuring proper attention is focused on handling of sharps and by ensuring equipment is maintained and is used properly. The control is an administrative control and acts to reduce the likelihood of the accident thereby reducing risk. Incident response is an administrative control and acts to reduce the risk by mitigating the consequences by ensuring appropriate medical attention, disinfection, etc. PPE in this scenario is an engineered control and can reduce risk by ensuring that exposure is mitigated in the event of equipment failure. In each of the scenarios the role of the controls is to either reduce the likelihood of the event or mitigate the consequences thereby reducing the risk.

The selection of accidents for more detailed evaluation is taken from the set of hazard scenarios. From the identification of hazards and the listing of potential accident initiating events (Table 3.14.2.2-1), accident scenarios are postulated. For the NBAF, the scenarios producing the consequence of an uncontrolled pathogen release are presented in the hazards analysis Table E.2-6 in Appendix E. From this listing, a unique set of accidents to be considered bounding is selected from the hazard analysis summary. The categories of various accidents postulated in the hazards analysis and from which the set of accidents selected for more detailed evaluation is found in Table 3.14.2.2-2. The rationale for selecting a bounding accident is based semiquantitatively on the unmitigated frequency and consequences of the accident and consideration for existing controls relied on for mitigation or prevention. Table 3.14.2.2-2 presents the accident type along with examples and a description of the bounding candidates.

Once this rationale is complete for a given set of operational hazards or accident initiating events, the bounding accidents can be selected by sorting the table based on hazard or accident type or consequence, etc. For the NBAF, the proposed scenarios were evaluated based on accident type and integrating unmitigated public and environment (P/E) consequences with the existing control set to determine the effect on risk (consequence and probability). Generally, one or two accidents are selected from each accident family for further semiquantitative analysis, as well as any unique accidents that might stand out from the others based on requiring specific controls or caused by specific phenomena. For the NBAF, the specific set of accident types considered for detailed analysis are listed above in Table 3.14.2.2-2.

3.14.2.3 Accident Analysis Methodology

After bounding and unique accidents have been selected, they are subjected to quantitative consequence analysis to determine if the control set used to prevent or mitigate the consequences contains

- The correct type of control (engineered or procedural),
- A sufficient number of controls, and
- The appropriate safety designation for the particular accident under consideration.

The accident analysis methodology used in this section consists of the following steps, consistent with Nuclear and Chemical Industry standards for format and content and consistent with the provisions set forth for assessing biological hazards and risks:

- Accident scenario description and development;
- Semiquantitative scenario probability description using appropriate techniques;
- Source term analysis, specification of the pathogens involved;
- Consequence analysis from both accident events and intentional acts; and
- Comparison of the quantity of pathogens released, through exposure pathways, to an infectious dose to support identification of suitable engineered or procedural controls.

Examples of Hazard Scenarios from Appendix E, Table E.3-5

Accident Number	Hazard	Accident Type	What-if (initiating event)	Outcome (accident progression)	Freq	Unmitigated (uncontrolled) Consequence P/E	Unmitigated (uncontrolled) Consequence W	Unmitigated (uncontrolled) Qualitative Risk highest of P/E or W	Existing Controls	Freq	Mitigated (controlled) Consequence P/E	Mitigated (controlled) Consequence W	Mitigated (controlled) Qualitative Risk P/E	Mitigated (controlled) Qualitative Risk W	Recommended Additional Controls
LAI-1	Uncontrolled *known or unknown* exposure to pathogen	Laboratory acquired infections (LAI)	**procedural violation** creates sharps (scissors, scalpels, sharp lab surfaces, other glass items including reagent bottles, vials, blood tubes, capillary tubes, microscope slides)	personnel infection (autoinoculation)	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training for sharps handling and control; PPE; incident reporting requirements; incident response; security protocol; human reliability program (HRP)	Occasional (1.0 / yr to E-2 / yr)	E	C	4	2	2-person rule for procedure compliance and equipment use; need for monitoring or detection capability to control contamination spread (fluorescence?)
LAI-4	Uncontrolled *known or unknown* exposure to pathogen	Laboratory acquired infections (LAI)	**procedural violation** results in ingestion from inadvertent contact between mucous membranes and contaminated surfaces or hands	personnel infection	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training for contamination recognition and control; procedures against eating, drinking, cosmetics application, gum, tobacco, eye drops, open wounds, etc in facility; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	C	4	3	2-person rule for procedure compliance and equipment use; need for monitoring or detection capability to control contamination spread (fluorescence?)
LAI-5	Uncontrolled *known or unknown* exposure to pathogen	Laboratory acquired infections (LAI)	**equipment malfunction** results in ingestion from inadvertent contact between mucous membranes and contaminated surfaces or hands	personnel infection	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training for contamination recognition and control; equipment maintenance and use procedures prevent misuse and proper equipment replacement protocol; procedures against eating, drinking, cosmetics application, gum, tobacco, eye drops, open wounds, etc in facility; PPE; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	C	4	3	2-person rule for procedure compliance and equipment use; configuration management governs maintenance type and frequency or equipment replacement; need for monitoring or detection capability to control contamination spread (fluorescence?)
LAI-7	Uncontrolled *known or unknown* exposure to pathogen	Laboratory acquired infections (LAI)	**equipment malfunction** results in aerosol production and inhalation (centrifuge, grinding, homogenizing, blending, vigorous shaking or mixing, sonic disruption, cell separator, etc)	personnel infection	Frequent (≥ 1.0 / yr)	A	A	1	procedures and training for recognizing and controlling aerosol production in routine lab operations (culture prep and handling, pipette use, sampling, etc) in addition to lab equipment use (centrifuge, blending, grinding, mixing, shaking, etc); equipment maintenance and use procedures prevent misuse and proper equipment replacement protocol; PPE; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	B	4	2	2-person rule for procedure compliance and equipment use; configuration management governs maintenance type and frequency or equipment replacement; BSC enclosures for aerosol-generating operations and equipment; need for monitoring or detection capability to control contamination spread (fluorescence?)
LAI-11	Uncontrolled *known or unknown* exposure to pathogen	Laboratory acquired infections (LAI)	**animal handling equipment malfunction** results in bites, scratches	personnel infection	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training for animal handling equipment use; procedures and training for equipment maintenance; PPE; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Occasional (1.0 / yr to E-2 / yr)	E	C	4	2	2-person rule for procedure compliance and equipment use; configuration management governs maintenance type and frequency or equipment replacement; need for monitoring or detection capability to control contamination spread (fluorescence?)
CONT-2	Uncontrolled *known or unknown* exposure to pathogen	Loss of containment	**animal handling or insectary equipment malfunction** results in escaped animal or insect	environmental contamination	Frequent (≥ 1.0 / yr)	A	A	1	procedures and training for animal handling and husbandry as well as for insectary operations; appropriate animal and insect facilities are provided and personnel are trained on procedures for their use and maintenance to procedures prevent misuse and proper equipment replacement protocol; PPE; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4 / yr to E-6 / yr)	D	E	4	4	2-person rule for procedure compliance and facility use, especially the insectary; configuration management governs maintenance type and frequency or equipment replacement; BSC enclosures for animal and insectary operations and equipment; need for monitoring or detection capability to control contamination spread (fluorescence?)
CONT-3	Uncontrolled *known or unknown* exposure to pathogen	contaminated solid waste (including animal)	**procedure violation** results in incomplete sterilization/disinfection of solid waste	contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0 / yr)	A	A	1	procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	D	D	3	4	2-person rule for procedure compliance and equipment use; if there is no QC on sterilization effectiveness, the mitigated half of this scenario needs updating; need for monitoring or detection capability to control contamination spread (fluorescence?)
SUIT-1	Uncontrolled *known or unknown* exposure to pathogen	suit-specific hazards	**suit breach** from crush, pinch, puncture (air-lock doors, quick disconnects, movement of equipment, suit puncture or tear)	personnel contamination	Frequent (≥ 1.0 / yr)	C	A	1	procedures and training for suit use and for recognizing and controlling pinch points; procedures and training for minimizing and recognizing aerosol production in routine lab operations (culture prep and handling, pipette use, sampling, etc) in addition to lab equipment use (centrifuge, blending, grinding, mixing, shaking, etc); suit maintenance and use procedures prevent misuse and proper equipment replacement protocol; redundant PPE; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	B	4	2	2-person rule for procedure compliance, equipment use, and for suit damage hazard control; configuration management governs maintenance type and frequency or equipment replacement; BSC enclosures for aerosol-generating operations and equipment; need for monitoring or detection capability to control contamination spread (fluorescence?)

Examples of Hazard Scenarios from Appendix E, Table E.3-5 (continued)

Accident Number	Hazard	Accident Type	What-if (initiating event)	Outcome (accident progression)	Freq	Unmitigated (uncontrolled)			Existing Controls	Freq	Mitigated (controlled)				Recommended Additional Controls
						Consequence		Qualitative Risk			Consequence		Qualitative Risk		
						P/E	W	highest of P/E or W			P/E	W	P/E	W	
NECR-1	Uncontrolled *known or unknown* exposure to pathogen	necropsy safety	**procedure violation during necropsy** results in LAI due to cut/puncture, ingestion, or inhalation	contamination and possible personnel infection	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training in use for sharps use and handling/disposal, for contamination control to prevent inadvertent ingestion (no eating, drinking, cosmetics, tobacco, etc.), and for recognizing and controlling aerosol production in routine lab operations (culture prep and handling, pipette use, sampling, etc) in addition to lab equipment use (centrifuge, blending, grinding, mixing, shaking, etc); PPE; incident reporting requirements; incident response; security protocol; HRP	Occasional (1.0 / yr to E-2 / yr)	E	C	4	2	2-person rule for procedure compliance and equipment use; if there is no QC on sterilization effectiveness, the mitigated half of this scenario needs updating; need for monitoring or detection capability to control contamination spread (fluorescence?)
ENER-1	Uncontrolled *known or unknown* exposure to pathogen	energetic event causing release	**deflagration of natural gas or other flammable process gas leak** causing BSC failure, laboratory, or main structure failure; personnel contamination, room contamination, ventilation system leakage around, through HEPA filters	contamination, personnel infection, laboratory contamination, possible environmental contamination	Occasional (1.0 / yr to E-2 / yr)	A	A	1	procedures and training for equipment use, open flame and spark control; equipment maintenance and use procedures prevent facility gas leak and accumulation; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	A	A	2	2	currently, natural gas is available to the central utility plant and should be precluded from the NBAF; flammable gas cylinders should contain limited volume if required at all for processes
ENER-5	Uncontrolled *known or unknown* exposure to pathogen	energetic event causing release	**deflagration/explosion of external (to the facility) supply of diesel, fuel oil, gasoline** leading to facility breach, personnel contamination, room contamination, possible environmental contamination	contamination, personnel infection, laboratory contamination, possible environmental contamination	Probable (E-2 / yr to E-4 / yr)	A	A	1	training and maintenance procedures developed and used; combustible control program developed and implemented; ventilation in central utility plant; recognition and control of flammable gases and ignition sources; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4 / yr to E-6 / yr)	A	A	2	2	Central utility plant to store 500,000 gal of diesel (feasibility study, section 4.10, pg 2); proximity of diesel storage to main laboratories needs to be increased
FIRE-1	Uncontrolled *known or unknown* exposure to pathogen	fire (inside BSC or outside BSC but inside laboratory)	**fire from deflagration of natural gas or other flammable process gas leak** causing BSC failure, personnel contamination, room contamination, ventilation system leakage around, through HEPA filters	contamination, personnel infection, laboratory contamination, possible environmental contamination	Probable (E-2 / yr to E-4 / yr)	A	A	1	training and maintenance procedures developed and used; combustible loading controls; flammable gas controls in place including recognition and control of flammable gases and ignition sources, gas detection, BSC ventilation used to prevent accumulation and catastrophic consequences; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4 / yr to E-6 / yr)	E	C	4	4	reliance on operating and maintenance procedures, stored energy control, and combustible loading controls to prevent and mitigate fires; frequent inspections; trained and experienced operators and maintenance personnel
LEAK-1	Uncontrolled *known or unknown* exposure to pathogen	process leak, handling error, or poor housekeeping	**unknown process piping leak or other source of contamination (equipment malfunction)** leads to contamination spread	contamination, personnel infection, laboratory contamination, possible environmental contamination	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training for equipment use; equipment maintenance and use procedures prevent misuse and proper equipment replacement protocol; PPE and sharps containers; BSC, laboratory, facility containment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	B	4	2	2-person rule for procedure compliance and equipment use; immediate decontamination available; configuration management governs maintenance type and frequency or equipment replacement; need for monitoring or detection capability to control contamination spread (fluorescence?)
LEAK-2	Uncontrolled *known or unknown* exposure to pathogen	process leak, handling error, or poor housekeeping	**procedure violation during material or waste handling or transfer** leads to contamination spread	contamination, personnel infection, laboratory contamination, possible environmental contamination	Frequent (≥ 1.0 / yr)	B	A	1	procedures and training exist for waste handling prior to treatment; for preparing and transferring the waste for treatment; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2 / yr to E-4 / yr)	E	B	4	2	2-person rule for procedure compliance and equipment use; need for monitoring or detection capability to control contamination spread (fluorescence?)
NPH-2	Uncontrolled *known or unknown* exposure to pathogen	external events and natural phenomena	**seismic event challenges or exceeds facility design criteria** and structure fails, **subsequent fire(s) start** from ignition sources in laboratories; significant environmental and public contamination	personnel and environmental contamination	Probable (E-2 / yr to E-4 / yr)	A	A	1	no seismic controls; feasibility study indicates spectral acceleration of 0.06g to 0.19g – equivalent of light-laboratory seismic resistance; with no seismic controls, ignition sources in laboratories and outside (500,000-gal diesel storage) assumed to result in fires	Probable (E-2 / yr to E-4 / yr)	A	A	1	1	increase structural design, ventilation fans, filter plenums, filter housings, etc., to accept higher accelerations (~0.5g); facility to maintain integrity and negative pressure during and after seismic event; seismic controls mesh with combustible loading controls and program to prevent or significantly mitigate attendant fires
NPH-3	Uncontrolled *known or unknown* exposure to pathogen	external events and natural phenomena	**high winds (tornado) challenge or exceed facility design criteria** and structure fails; significant environmental and public contamination	personnel and environmental contamination	Probable (E-2 / yr to E-4 / yr)	A	A	1	facility wind resistance (90-mph), no tornado considered in feasibility study	Probable (E-2 / yr to E-4 / yr)	A	A	1	1	increase structural design to withstand credible winds for the site; facility to maintain integrity and negative pressure during and after high-wind exposure

Table 3.14.2.2-1 presents a summary of the hazards identification (Ericson, 2005).

Table 3.14.2.2-1 — Results of Hazard Identification

Hazard	BSL Material/Energy Source	Controls and Safety Features
Acceleration/Deceleration • Inadvertent motion • Sloshing of liquids • Translation of objects • Impacts (sudden stops) • Failing of brakes, wheels, tires, etc. • Falling objects • Fragments or missiles	Surfaces, obstructions (slipping, tripping, bumping, dropping) can lead to an inadvertent release	- Signs and markings - Ergonomics - Secondary containers - Use of break-resistant containers
Biological Agents • Viruses • Others as appropriate	BSL-1 through 4 biocontainment strategies apply to the NBAF	- Small volumes - Standard Operating Procedures - IBC review and approval - BSCs, HEPA, autoclave
Chemical Reaction (non-fire) • Disassociation, product reverts to separate components • Corrosion, rust, etc. • Combination, new product formed from mixture	Laboratory-scale corrosives, acids, bases (household bleach, acetic acid, hydrochloric acid), bases (NaOH), and solvents – improper use can lead to an inadvertent release of biological agents	- Hazardous chemical PPE - Spill clean-up kits - Chemical Hygiene Plan - Standard Operating Procedures
Electrical • Shock • Burns • Overheating • Ignition of combustibles • Inadvertent activation • Explosion, electrical • Static, electrostatic electricity	Transformers, batteries (UPS), cable runs, operating voltages (<120 V to <600 V), high voltages (>600 V), diesel units (back-up generator), motors, pumps, switchgear, service outlets, concealed wiring – can be initiator for a facility fire.	- Electrical Safety Training - ESO inspections - Externally located electrical room.
Flammability and Fires • Presence of fuel – solid, liquid, gas • Presence of strong oxidizer – oxygen, peroxide, etc. • Presence of strong ignition force – welding torch, heaters	Electrical equipment Flammable/combustible/volatile lab-scale chemicals (alcohols, phenol, chloroform)	- Flammables storage cabinet - Flammable-rated cold storage - Limited use of hazardous chemicals
Heat and Temperature • Source of heat, non-electrical • Hot surface burns • Cold surface burns • Increased gas pressure caused by heat • Increased flammability caused by heat • Increased volatility caused by heat	Cryogenics [lab-scale dry ice (CO_2) and liquid nitrogen] Refrigerating units Heaters [thermocyclers/water-baths at >194°F (>90°C)]	- Temperature-related PPE - Non-exposed steam lines

Table 3.14.2.2-1 — Results of Hazard Identification (Continued)

Hazard	BSL Material/Energy Source	Controls and Safety Features
Internal Flooding • Source of water	Sprinkler piping Plumbing	- Design of facility
Mechanical • Sharp edges or points • Rotating equipment • Reciprocating equipment • Pinch points • Weights to be lifted • Stability/toppling frequency • Ejected parts or fragments	Sharps, rotating machinery, motors, pumps, fans, mechanical devices used for pipetting	- Standard Operating Procedures - Use of sharps, etc., required to be minimized per the BMBL (CDC 2007)
Pressure • Compressed gas • Compressed air tool pressure system exhaust • Accidental release • Objects propelled by pressure • Water hammer • Flex hose whipping	Facility pressure (HVAC) controls	- Facility design
	Autoclaves Vacuum pumps Compressed gas cylinders, receivers (carbon dioxide)	- Standard Operating Procedures - Location
External Events • Natural phenomena • Fire • Aircraft • Vehicles	Events such as earthquake, lightning, rain, snow, straight high winds, and wind generated missiles	- Facility design (sufficient to withstand NPH and external events)
	High winds	- Facility design
	Wildland and internal fire	- Facility design - Location - Viability of biological agents
	Aircraft crash	- Facility design
	Transportation and vehicle hazards	- Perimeter fence and vehicle barriers

Table 3.14.2.2-2 — Bounding Accident Categories

Type of Event	Examples	Bounding Accident Candidates
Spill or uncontrolled release of aerosolized pathogens (includes *known and unknown* releases)	• Loss of biocontainment • Over-pressurization • Personnel error leading to LAI • Equipment failure leading to LAI	• LAI – autoinoculation due to personnel error • LAI – aerosol uptake by personnel from centrifuge failure • Small spill resulting in loss of biocontainment, personnel and area contamination, but no environmental contamination • Medium-level spill resulting in loss of biobiocontainment, personnel and area contamination, but no environmental contamination • Loss of animal/insect control resulting in environmental contamination • Improper sterilization/disinfection of solid waste results in environmental contamination • Improper sterilization/disinfection of liquid waste results in environmental contamination
Chemical release	• Spill • Over-pressurization • Personnel error	• Decontamination or disinfectant failure (e.g., chlorine dioxide generator malfunction) during disinfection process resulting in incomplete sterilization and personnel exposure.
Fire	• Furnace • Mechanical or electrical • Flammable gas • Exothermic chemical reaction	• Large room or facility fire resulting in the loss of facility structure and large environmental releases
Deflagration	• Flammable gas • Exothermic chemical reaction • Flammable liquids • Steam	• Ethylene oxide deflagration in confined space during sterilization operation results in loss of biocontainment • Over-pressure event from steam feeding an autoclave results in loss of biocontainment
Natural phenomena events	• Seismic • High wind • Flood • Snow and ice	• Large, multi-laboratory spill as the result of a seismic event with and without an accompanying fire • Large, multi-laboratory spill as the result of structural damage from high winds (tornado) to a BSL-3E/Ag laboratory
External events	• Airplane crash • Wildfire • Transportation • Adjacent facility accidents	• Aircraft crash into the NBAF with subsequent release of pathogens • Transportation accident resulting when an improperly packaged sample arrives and is handled at a BSL level lower than is required • External fuel storage (diesel, fuel oil) explodes and causes loss of facility biocontainment and environmental contamination

The following methodology is used to address the representative or unique bounding accident scenarios identified in Table 3.14.2-6. As presented in Appendix E, accident scenarios that meet the screening criteria are collected into major accident categories representative of accidents with unique characteristics. Unmitigated consequences from accident scenarios that result in pathogen exposure to the worker or to the public and the environment are presented there. Numerous accident scenarios were identified as potentially having such consequences, and many of these accident scenarios were attributable to a single process or activity (a single process or activity could lead to several accident scenarios that might result in unacceptable consequences).

The essential elements of an accident analysis involves development of credible scenarios for which a hazard, such as viral pathogens including FMDV, RVFV, and Nipah virus, can lead to a release, exposure, and ultimately an adverse effect. Each of these elements is essential to understanding the mechanisms leading to the release and the overall risks associated with the accident scenario. There are basically five separate yet coupled elements in any accident or intentional act analysis. These elements can be described using the following concepts or terms: 1) the source term (ST) or quantity of pathogens potentially released, 2) the mechanisms required for a potential release and transport of the pathogens, 3) the assessment of the exposure pathways for the specific pathogens, 4) the resultant dose estimates to each specific pathogen after release, and 5) estimation of the effects from the dose. The last element is often referred to as simply the consequences.

The accident analysis methodology presented here is specifically tailored to assess the consequences from a potential release of viral pathogens from the proposed NBAF. The processes and methods for the estimation of the source term, specific release and transport mechanisms, the exposure pathways, and the evaluation of the dose are presented in the following sections. The presentation of the final effects or consequences is presented on a site-specific basis in Section 3.14.4.

3.14.2.4 Source Term Analysis

The consequence to the public or environment from an accident involving the release of a pathogen is calculated by defining the level of exposure through inhalation, ingestion, contamination, etc.; the infectivity of the pathogen (its relative ability to produce an infection); pathogenicity (its relative ability for an infection to lead to a fatal disease); and the transmissibility (potential for the disease to spread in the population).

The combination of these factors represents the potential consequences resulting from an exposure to a specified pathogen. The exposure is related to the quantity of a pathogen that is available for release or exposure and is referred to as a source term.

The following five-factor formula represents a method for determining a source term (Q) (DOE 2006).

$$Q = MAR \times DR \times RF \times RF \times LPF$$

Where:

Q = source term to the outdoor atmosphere [number of virions released]
MAR = material at risk [mass, concentration (virions)]
DR = damage ratio [dimensionless]
ARF = airborne release fraction [dimensionless]
RF = respirable fraction [dimensionless]
LPF = leak path factor [dimensionless]

MAR – MAR is defined as the amount of hazardous material available to be acted on by a given physical stress. Facility material operational limits and material inventory information are considered in defining the MAR for each accident scenario to be evaluated. Because the inventory in any individual process, activity, or room is subject to day-to-day fluctuations from routine transfers that are necessary to support operations, conservative upper-bound material inventories are used in consequence estimations. In addition to the pathogen content of the MAR, it is necessary to define its form. For a single process or activity in which various material forms could be present, the MAR was assumed to be composed of the material form that yielded the highest conservative value of ARF×RF. This form of material is typically a viable aerosol for the specified pathogens.

DR – DR represents the fraction of the MAR that is affected by the accident and with which given values of ARF×RF can be associated. DRs are scenario dependent, and their development is described in each accident scenario section. This means that phenomenological characteristics (such as temperatures and pressures) of the accident scenario must be considered. State-of-the-art computer models (e.g., CFAST or FDS for fires) are used to support such analysis when required. Other computer codes are used if the potential for an explosion is assessed as large and the magnitude of the explosion expected to be sufficiently large to cause structural damage to biocontainment or equipment in the vicinity of the explosion. Otherwise, analytical expressions are used to perform calculations necessary to support the evaluation of the DR. For the unmitigated release calculations, a conservative value of DR=1 is used unless otherwise stated and justified.

ARF and RF – ARF is that fraction of MAR × DR that is aerosolized. The RF is the fraction of the airborne material that is respirable (inhalable into the deep lung). This is assumed to include particles with an aerodynamic equivalent diameter (AED) of 10 µm or less. Because of the small sizes of viruses the RF is assumed to be 100% (1.0) in all accidents considered in the NBAF. The values of ARF and RF for each postulated accident were selected based on best available data.

For this accident analysis, ARF values range from a low of $1x10^{-7}$ to a high of $4x10^{-5}$. For spills, impacts, and other mechanical release mechanisms, there is suitable basis to suggest that the ARF for viral pathogens in the most conservative form is not likely to exceed $1x10^{-4}$ except when directly released in the form of an aerosol (the ARF for this case is 1.0). For this accident analysis, RF values range from $1x10^{-5}$ and $1x10^{-4}$ for mechanical stresses, a value of 0.1 for deflagrations and 0.01 for fires. These values were chosen to be the bounding and conservative based on analysis of powders, liquids, fires, etc. from the DOE Handbook 3010-94 and actual data from the anthrax attack on the U.S. Senate in 2001. A detailed discussion surrounding the justification for these ARF and RF selections is presented in Appendix E.

LPF – LPF is the fraction of the locally aerosolized material released to the environment. The LPF is dependent on the nature and location of the accident, as well as the condition (open or closed) of various interior and exterior doors. The LPF is also particularly sensitive to whether a fire is associated with the accident and on external wind conditions because these two aspects provide major motile forces for the source aerosol.

In most cases, the LPF values for the accident scenarios developed in this section were qualitatively estimated based on the conceptual design of the NBAF as presented in the Feasibility Study. An *unmitigated* accident is by definition one in which the aerosolized material is assumed to exit to the atmosphere without retention or mitigation (LPF=1). This unmitigated case is of formal significance because the consequence of such a release is the basis for functionally classifying controls needed to ensure that the postulated accidental release to the atmosphere is sufficiently mitigated. For a well-designed facility with a normally operating active ventilation system and high-efficiency particulate air (HEPA) filtration system with redundant filters, the LPF can be estimated to be on the order of (LPF=0.001% or 1×10^{-5}). This is based on the building being leak tight and HEPA filter efficiencies at a minimum 99.97% (Plog 2002). The Feasibility Study specifies use of standard HEPA with an efficiency of 99.97% [SIC error corrected] at 0.3 µm; however, no specific criteria have yet been established for the NBAF. The purpose of the analysis and the evaluation of the risks are to evaluate the effect of mitigation and to support potential future design considerations.

3.14.2.5 Transport, Transmission, and Exposure Estimates

Exposure to viral pathogens can result from both direct and indirect mechanisms. Types of direct mechanisms include breathing or ingesting the virus, thereby directly bringing the pathogen into the body. Another direct method is by skin contact with the pathogen. Contact often provides a mechanism for the pathogen to enter the body through cuts, abrasions, or mucus membranes. Indirect mechanisms often refer to transmission through an intermediate step such as in the case of being bitten by an infected mosquito (the transmission mode for RVFV) or a bat. This mechanism is referred to as vector-borne transmission. In this case, the receptor can be an individual or an entire population once the vector carrying the pathogen enters the ecosystem (e.g., West Nile virus). Various forms of transmission of a virus considered in the hazards and accident analyses are discussed below.

Direct Transmission

Facility operations are designed to minimize opportunities for direct transmission. Direct transmission would first require a worker to be exposed to a communicable infectious agent (autoinoculation accident scenario was modeled). Under proper laboratory procedures, the likelihood of a worker inhaling or otherwise becoming exposed (e.g., through cuts in the skin or ingestion) to an infectious agent should be low. The potential to acquire a laboratory-caused disease is further reduced through the use of effective vaccines or therapeutic measures (CDC & NIH 2007). Every NBAF worker would be required to be entered into the Human Pathogen Medical Surveillance Program. This medical program, compliant with the immunoprophylaxis policy per the guidance in the BMBL (CDC & NIH 2007), is administered as a control for safety. Workers would receive annual physical examinations and consultation about biological work hazards, and recommended vaccines would be administered by the medical staff. Additionally, an occupational medicine or similar program would be available to workers for injuries or illnesses received during the course of work activities associated with the NBAF.

Vector-Borne Transmission

Vector-borne transmission is an indirect transmission mechanism of an infectious agent that occurs when a vector bites or touches a receptor or in which the infectious agent is transferred to the receptor by a fomite. Given this discussion, vectors can be separated into two different types of vector transmission: biological and mechanical. Biological vectors can involve an arthropod (insects such as mosquitoes and arachnids including ticks or spiders) vector in whose body the infecting organism persists before becoming infective to the receptor. Mechanical vectors can involve an arthropod vector, which transmits an infective organism from one host to another but which is not essential to the lifecycle of the parasite.

FMDV and Nipah virus are not considered as having a biological vector transmission, while RVFV is transmitted via biological vectors. RVFV is predominantly a vector-borne disease, and mosquitoes are the predominant species for a biological vector. The *Aedes lineatopinnis* mosquito acts as viral reservoir (continuous source) and is depicted in Figure 3.14.2.5-1. The virus is dormant in the eggs of the mosquito *Aedes lineatopennis* in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes develop and infect ruminants. The virus can be spread by many mosquito species. In North America, *Aedes, Culex,* and *Anopheles* mosquitoes have been found to be capable vectors. Mechanical vectors such as midges and biting flies play a significant role during major epidemics (uncontrolled release and spread of the disease). The host range is primarily ruminants, with sheep (lambs) being highly susceptible, followed by goats, cattle, camels, several species of rodents, buffaloes, antelope, wildebeest, horses, donkeys, cats, dogs, monkeys, horses, and birds also being affected. In addition, humans are very susceptible to the disease with the minimum infectious dose being unknown.

Figure 3.14.2.5-1 illustrates the mechanisms involved in vector-borne transmission. The illustration indicates how a viral pathogen once in the environment can become part of the ecosystem and cycle through transmission and infection. The concentration of the viral pathogen is continuously replenished in the reservoir leading to additional uptakes and exposures to other receptors such as cows, pigs, and deer.

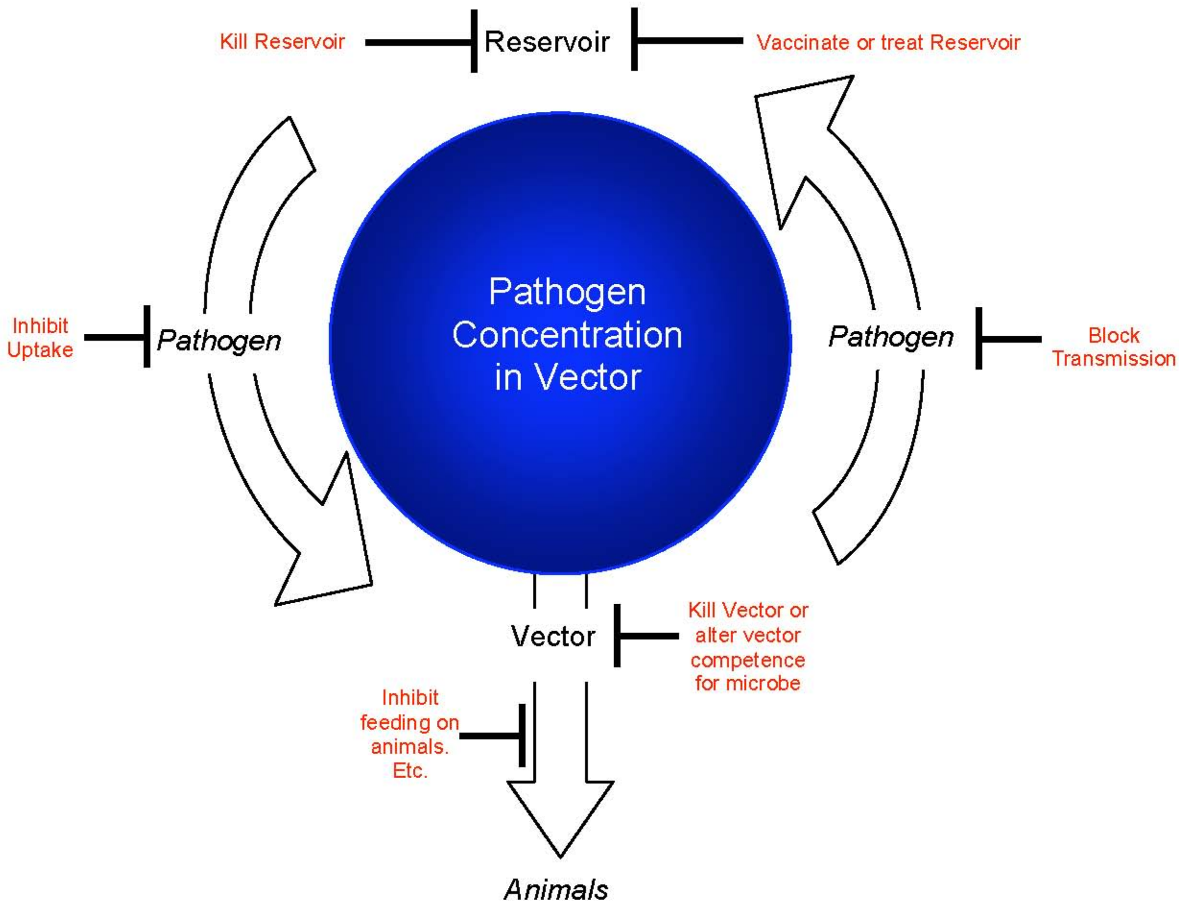


Figure 3.14.2.5-1 — Illustration of the Mechanisms Involved in Vector-Borne Transmission

Because of this potential for continuity in the environment, it is critical that RVFV not be released into the environment. Once in the environment, the virus could become established in a mosquito population and remain prevalent as a significant reservoir that can continuously cause re-infection. The figure above illustrates methods or techniques for interdicting the viral infection cycle, including vaccines, pest controls (pesticides), inhibiting the uptake of the virus, blocking transmission, and stopping the vectors.

The NBAF would be designed to severely limit the potential for possible vector-borne transmission through insects, rodents, and other mechanisms. It is anticipated that the use of pest control, vaccination, and other advanced programs would limit the potential for transmission of infectious agents from animals to humans, humans to humans, or from infected animals to insects or rodents and then to humans or animals (Fleming 2006).

Vehicle-Borne Transmission

Mechanical vectors that do not involve the insects or arachnids are often referred to as vehicles and are termed as vehicle-borne transmission. Vehicle-borne transmission refers to a situation in which a person or material (a “vehicle”) becomes surface contaminated with an infectious agent. The primary concern for vehicle-borne transmission would be via the workers’ clothing, skin, nares, or hair, as all other materials leaving the NBAF must go through a sterilizing autoclave. The BMBL guidelines established by the CDC and NIH, which would be followed by the NBAF, are designed to reduce this potential method of transmission. This would substantially reduce any potential for a worker to unknowingly transport biohazardous materials from the NBAF. This is a significant hazard at the NBAF and was addressed in both the hazards analysis and the accident analysis to provide estimates of potential consequences.

The FMDV and Nipah virus can be transmitted via vehicles such as fomites and other contaminated materials. RVFV is predominantly a vector-borne disease and is considered to be much less likely to be transmitted via typically considered vehicles.

Airborne Transmission

All air leaving the BSL-3, BSL-3E, BSL-3Ag, and BSL-4 laboratories is directed via the active ventilation system to flow through ductwork that is HEPA filtered and exit the NBAF through stacks on the building roof. All open cultures of the infectious agents in the BSL-2, BSL-3E, and BSL-4 laboratories would be handled in a BSC. Each BSC has a ventilation system, and all air emissions from operations in a BSC would pass through a HEPA filter in the BSC and, in the case of the BSL-3 and BSL-4 laboratories, two additional HEPA filters, at a minimum, in the NBAF heating, ventilation, and air conditioning (HVAC) system before exiting to the outside air. HEPA filters, at a minimum, remove 99.97% of particulates with a diameter of 0.3 µm (NSC 1996).

The U.S. Environmental Protection Agency, DOE, and NRC have specified in various handbooks, guidance, and standards the use of Gaussian Plume models for the modeling of down-wind concentrations of hazardous constituents resulting from an accidental release. In addition, the Defense Threat Reduction Agency also uses a basic Gaussian Plume model to provide estimates of potential down-wind concentrations of biological materials resulting from a release. Atmospheric transport modeling using a standard Gaussian Plume approach was used to address the potential impacts from the inadvertent release of specified biological agents from the NBAF. The potential impacts from the release of chemicals, radionuclides, and biological agents have been successfully modeled using this approach (Sorensen 1996; Donaldson 1999). The methodology, the appropriateness of the application of the atmospheric transport models employed, and the results of the estimated down-wind concentrations of a hypothetical biological agent are provided in detail in Appendix E (Panofsky 1984; Pasquill 1983).

This approach has been adopted for performing the atmospheric dispersion calculations supporting the NBAF EIS. Similar evaluations of the transport of viral pathogens have been made using the Gaussian Plume model (M.G. Garner, Bureau of Resource Sciences, Commonwealth of Australia 1995, "Potential for wind-borne spread of foot-and-mouth disease virus in Australia;" J.H. Sorensen, December 1999, "An integrated model to predict the atmospheric spread of foot-and-mouth disease virus," *Epidemiol Infect* 124:577-590, 2000; T. Mikkelsen, European Geosciences Union, 2003, "Investigation of airborne foot-and-mouth disease virus transmission during low-wind conditions in the early phase of the UK 2001 epidemic," *Atmos Chem Phys Discuss* 3:677-703, 2003). The MACCS2 code uses the ATMOS module to perform all the calculations pertaining to atmospheric transport, dispersion, and deposition (MACCS-1). The output from the ATMOS module used in the analysis of exposure to specified biological agents is referred to χ/Q, which is the concentration term in normalized units. The χ/Q value obtained from the model is multiplied by the total amount of material containing the biological agents that is estimated to have been released from the hypothetical accident. This quantity of material is referred to as the source term. The product of the source term (ST) and the χ/Q produces the total number of elements (e.g., virions, spores, molecules, cells, etc.) toward which a representative receptor is exposed.

Assuming a pathogen release from the NBAF, atmospheric dispersion is estimated using the MACCS2 computer code, which employs a simple straight-line Gaussian model. MACCS2 is a DOE/NRC-sponsored code that has been widely used in support of probabilistic risk assessments for the nuclear power industry and for consequence analyses for safety documentation throughout the DOE complex. A plume centerline, source-normalized concentration ($\tilde{c}$Q), is calculated for each hourly averaged meteorological data set. A single year of site-specific meteorological data were obtained for each of the six proposed NBAF locations. The data were obtained from the nearest measurement location recorded by the National Oceanic and Atmospheric Administration. These statistics represent the 95th percentile of the set of calculated $\tilde{c}$Q values, regardless of location on or beyond the public boundary, and is taken as representative of public exposure.

Therefore, these data are used to represent public exposure from an airborne release and are not expected to be exceeded more than 5% of the time for a randomly initiated accident. Further discussion on the dispersion calculations is presented in Appendix E.

Example normalized concentrations from the Gaussian Plume model using the MACCS2 code are presented in Table 3.14.2.5-1.

Table 3.14.2.5-1 — Example Summary Results

Receptor Location (distance from source) in meters	95th Percentile χ/Q (s/m^3) Base Case #1	95th Percentile χ/Q (s/m^3) Case #2 same as base case #1 with 5 MW fire	95th Percentile χ/Q (s/m^3) Case #3 same as base case #1 with 100 MW fire	95th Percentile χ/Q (s/m^3) Case #4 same as base case #1 with Karlsruhe-Julich coefficients
50	9.34E-02	5.21E-4	4.33E-6	1.89E-2
200	9.00E-03	4.46E-5	1.06E-6	1.78E-3
400	3.08E-03	2.01E-5	7.07E-7	6.03E-4
600	1.66E-03	1.36E-5	6.94E-7	3.25E-4
800	1.08E-03	1.17E-5	8.55E-7	2.10E-4
1,000	7.69E-04	1.38E-5	7.64E-7	1.50E-4
2,000	9.75E-05	2.09E-5	6.83E-7	2.11E-5
4,000	3.65E-05	1.40E-5	1.28E-6	5.96E-6
6,000	1.43E-05	9.66E-6	2.27E-6	3.58E-6
8,000	1.19E-05	7.33E-6	2.43E-6	2.32E-6
10,000	7.56E-06	5.44E-6	2.27E-6	1.41E-6

These results show that the base case, which is a ground-level release over fairly flat terrain, provides the bounding estimates for evaluating the potential results from an intentional or accidental release. In addition, it is apparent that the concentration falls off significantly with distance from the source.

Water-Borne Transmission

The NBAF design features, such as backflow preventers, and uniform plumbing code requirements would minimize the potential for microbes within the NBAF from migrating back through the water supply piping to the public. Also, none of the effluent water from the wastewater plant will contribute directly to any potable water source. Potable water supply wells for each proposed NBAF site are discussed in the specific affected environment section.

Water exiting through the sink drains would be combined and diluted by sanitary waste in the sewer system and would undergo a series of treatment steps at the wastewater facility. These treatment steps consist of aeration, secondary clarification, disinfection, dechlorination (for environmental discharges), water reuse system, effluent holding ponds, and sludge drying beds. It is anticipated that there would be minimal effects from water-borne transmission. Because of the potential hazards associated with this pathway, this scenario was specifically evaluated in the hazards and accident analysis.

Safety controls specifically relied upon to mitigate or prevent the inadvertent release of viable pathogens to the environment include the following:

- BSL-3 and BSL-4 laboratory floor drains and piping are segregated and isolated from sanitary waste streams;
- Vents for the drains are segregated and isolated and are provided separate HEPA filtration;

- Autoclave(s), chemical, and gas disinfection methods;
- Secondary biocontainment; and
- Facility structure, which is a safety feature designed to current conceptual design requirements.

In addition to equipment and facility systems that serve as primary and secondary barriers to the release of infectious biological materials, administrative controls serve an important support function. Multiple administrative controls and quality assurance measures are also implemented to minimize the potential for degradation of physical barriers and/or to minimize the amounts of infectious biohazardous materials that become involved in an accident with potential exposure to the workers or release to the environment and the public through the water transmission route. Administrative controls include, but are not limited to, the following programs: Quality Assurance, Qualification and Training, Fire Protection, Engineering and Maintenance, Biological Safety, and Conduct of Operations (DOE 2006; CCPS 1992; Bahr 1997; Greenberg 1991).

Potential release through drains/spills was considered in terms of the specific design and operational characteristics of the NBAF. The autoclave condensate would be directed to the waste treatment system. Dedicated biowaste gathering and treatment systems will be provided for BSL-3(E), BSL-3Ag and BSL-4 functions. Each of the laboratories and associated, procedure rooms, animal rooms and storage/centrifuge rooms are to be provided with a biological liquid waste collection and treatment system. Liquid waste would be treated by a sterilization process (with a method such as an autoclave). The biowaste system would likely employ gravity drainage to the liquid effluent decontamination system. Sanitary connections are also provided to fixtures such as floor or trench drains, lavatories, sinks, and showers. The sanitary and containment areas are segregated as appropriate to maintain the ability to control wastes that require sterilization. The emergency showers/eyewashes are not connected to the wastewater system within the biocontainment areas. There are floor drains associated with the autoclaves, which are tied into the wastewater systems for the biocontainment areas. The piping and connections provide opportunities for release that were evaluated in the accident analyses.

Three scenarios were assessed that could result in the contamination of the NBAF in the plumbing and wastewater system: 1) a flood initiates, or is associated with, a spill of infectious material that results in infectious liquid entering a floor drain; 2) a viable culture of infectious agent is discharged into a sink without adequate decontamination; and 3) a spill of infectious material enters a facility floor or sink drain. Each of these scenarios results in the same circumstance: infectious material discharged to the plumbing that has the potential to contaminate the wastewater system.

Infectious biohazardous material in the NBAF plumbing would be rendered inert through addition of chemical decontamination agents using standard operating procedures for decontamination of laboratory effluent. Proper safety controls would be used before any plumbing work would to be conducted. Workers entering the BSL-3 or BSL-4 laboratory areas would be required to wear appropriate PPE and would be briefed on potential hazards. Potentially contaminated plumbing would represent one of many scenarios where craft workers would be required to conduct work on potentially contaminated systems. Workers that access sewer lines external to the NBAF are accustomed to treating sewer effluent as potentially infectious just as any wastewater from any building. If infectious material from the NBAF were to reach the wastewater system, it would present a potential risk to laboratory workers or the operation of the treatment plant system and also poses a risk to potential release to the environment. However, chemical disinfectants are used in drain lines and all waste originating in the BSL-4, BSL-3(E), and BSL-3Ag areas of the facility will undergo thermal treatment before it is discharged to the sanitary sewer. A lab-scale volume of infectious material, even the amount postulated in the unmitigated release scenario, is a very small fraction of the thousands of gallons of fluid that flows through the plant and resides in treatment plant basins.

3.14.2.6 Evaluating Consequences

Once the source term is evaluated from the five-factor formula discussed earlier, an estimate of the potential consequences of an accident scenario can be made based on atmospheric transport. This estimate should be considered an acute exposure and would not consider long-term effects from secondary transport through water sources, biota, other vector transport, or enhanced viability in the ecosphere through other means.

To determine the airborne exposure potential, the down-wind normalized concentration term χ/Q is multiplied by the source term (ST) to obtain an estimate of the potential exposure in airborne contaminants. In the case of exposure via the inhalation pathway, the expression for determining the total quantity inhaled by an animal or human is related as follows:

$$\text{Total Exposure} = ST \times \chi/Q \times BR$$

Where:

ST = source term [units of MAR; mass, concentration, etc.]
χ/Q = normalized, time-integrated source concentration [s/m^3]
BR = breathing rate of the receptor [m^3/s]

Because the Gaussian Plume model is a time-integrated estimate of the down-wind concentration, it is independent of time. The source term released is assumed to be over the same period as the receptor is exposed, thereby removing the time of exposure and release from the calculation.

The expressions for exposure and source term are used in each of the detailed accident analyses to provide a measure of significance and as a means of comparison. The total inhaled quantity (exposure) is compared to an infectious dose. In the case of FMD, an infection is considered to result from a very small number of virions (10 infectious particles). For RVFV and Nipah virus, the minimum infectious dose is not known but is also considered to require very small numbers of virions depending on the host. The relation used to evaluate non-inhalation routes vary somewhat but are still dependent on a concentration for the source material—a mechanism for getting the pathogens onto or into the body of the animal or human—and a means of estimating the likelihood of a resulting infection.

As was the evaluation method applied to the array of hazard scenarios, the detailed accidents are also evaluated in both a mitigated and unmitigated manner. The unmitigated case does not consider the controls or barriers to be fully effective. The evaluation of unmitigated consequences is based on using bounding values for the factors addressed above (MAR×DR×ARF×RF×LPF). The evaluation of mitigated consequences then relies on the adjustment, with an appropriate basis or rationale, to be reflective of effectively engineered controls. For example, the LPF or DR is considered to be unity in the unmitigated case, leading to very large source terms and consequently large consequences. The mitigated analysis then replaces a LPF of 1.0 with a value of 1×10^{-5} to account for the effectiveness of the "leak tightness" of the facility and the efficiency of the HEPA filtration. Even this "mitigated" value for the LPF is an upper-bound estimate considering that two HEPAs at 99.97% efficient in series could stop more than 99.999999% of the virions from escaping. The value of 1×10^{-5} was specifically used to account for potential ventilation bypass in an active ventilation system.

Determining the likelihood (probability) of the selected accidents is based on using a separate calculation (e.g., event trees) from that used in the consequence, which was the five-factor formula. Breaking the individual accident scenarios into their component parts, where an individual accident sequence has a calculated probability, provides an estimate of the accident probability. Similar to the consequence analysis, the accident probability also has "unmitigated and mitigated" conditions. The "unmitigated" likelihood or accident probability is based on assigning an upper-bound failure probability for event of the tree. The "mitigated" similarly would have event failure probabilities that are reduced based on the effectiveness of the specific controls (e.g., improved training, QA, two-person rule, and formality of operations for administrative controls and improved equipment reliability because of proper selection of equipment, maintenance, and redundancies, etc.). Details of these methods are provided in Operational Accident 1 and in Appendix E for all of the accidents.

3.14.2.7 Accidents for Further Analysis

Having completed the hazard analysis and the accident selection methodology, the accidents considered bounding or unique for representing NBAF operations are presented in Table 3.14.2.7-1. All accidents produce a similar outcome that is the uncontrolled release or exposure of pathogens to the environment.

From Table 3.14.2.7-1, the following summary of bounding and unique accident scenarios is carried forward into accident analysis for quantitative evaluation of controls suitable for mitigating or preventing the consequences described in the hazard analysis:

- 2 – LAIs
- 6 – loss of biocontainment, including spills, contaminated discharges, flooding
- 3 – energetic releases, including deflagration and over-pressure events
- 2 – fire from flammable sources and routine combustible materials
- 1 – transportation scenario
- 4 – external or natural phenomena events including seismic, high winds, small airplane crash

Many of the accidents in Table 3.14.2.7-1 result from procedural violations instead of equipment failure. Examining the Hazard Analysis Table E.2-6 will discover that machine or equipment failure exists in similar scenarios and with similar frequencies of occurrence and consequences to the public, the environment, and the worker. Human error as the initiating event, however, is known to occur at a higher frequency than for equipment failure (Gertman 1994). This is the reason that procedural failures are presented in Table 3.14.2.7 1. As the accident analysis progresses, controls to prevent the accident or further mitigate the consequences will be considered; although desired, prevention of accidents is realistically not attainable, and the objective is to provide reasonable assurance of adequate protection of the workers, the public, and the environment from the hazards posed by the NBAF operations. Thus, the control set for many of the accidents will include reliance on robust conduct of engineering programs, configuration of management programs, training programs, and other programs to enhance formality of operations at all levels to reduce the frequency of human and machine errors in the occurrence of accidents.

It should be noted that with the exception of natural phenomena events and events external to BSL laboratory space (six scenarios including fuel deflagration, fuel fire, seismic, seismic with fire, tornado, and small airplane crash), the existing set of combined engineered and procedural controls appear capable of mitigating bounding accident consequences to Risk levels D and E for public and environmental receptors (Table 3.14.2.7-1). Formal quantitative accident analysis will further evaluate controls with the potential to mitigate or prevent consequences to the worker and the public and the environment.

Table 3.14.2.7-1 — Accidents from Hazard Analysis and Accident Selection Methodology

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
LAI	**Procedural violation** creates sharps (scissors, scalpels, sharp lab surfaces, other glass items including reagent bottles, vials, blood tubes, capillary tubes, microscope slides)	Personal infection (autoinoculation)	Frequent (≥ 1.0/yr)	B/A	1	Procedures and training for sharps handling and control; PPE; incident reporting requirements; incident response; security protocol; human reliability program (HRP)	Occasional (1.0/yr to E-2/yr)	E/C	4/2
LAI	**Procedural violation** results in aerosol production and inhalation (centrifuge, grinding, homogenizing, blending, vigorous shaking or mixing, sonic disruption, cell separator, etc.)	Personal infection	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training for recognizing and controlling aerosol production in routine lab operations (culture prep and handling, pipette use, sampling, etc.) in addition to lab equipment use (centrifuge, blending, grinding, mixing, shaking, etc.); PPE; BSC, laboratory, facility biocontainment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	E/B	4/2
Loss of biocontainment	**Animal handling or insectary procedural violation** results in escaped animal or insect	Environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training for animal handling and husbandry as well as for insectary operations; appropriate animal and insect facilities are provided and personnel are trained on procedures for their use and maintenance; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/E	3/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Contaminated liquid waste (including shower effluent, disinfectant wash down, animal)	**Procedure violation** results in incomplete sterilization/disinfection of liquid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and (assumed) treated again in a commercial liquid waste treatment facility; PPE; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	D/D	4/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Spill, small sample	**Procedural violation during specimen transport** results in spill (slip, trip, fall, drop, jostle, jar, impact)	Contamination, aerosol generation, and possible personnel infection	Frequent (≥ 1.0/yr)	B/A	1	Procedures and training for packaging and transporting or transferring small samples intra-site and inter-laboratory; procedures and training for recognizing and controlling aerosol generation; packaging materials and equipment available and used; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	E/B	4/2

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Spill, small to medium volume	**Procedural violation during specimen transport** results in spill (slip, trip, fall, drop, jostle, jar, impact)	Contamination, aerosol generation, and possible personnel infection	Frequent (≥ 1.0/yr)	B/A	1	Procedures and training for packaging and transporting or transferring medium-volume samples intra-site and inter-laboratory; procedures and training for recognizing and controlling aerosol generation; packaging materials and equipment available and used; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	E/B	4/2

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Release from internal flooding	**Internal flooding from failure** of process piping, fire suppression piping, or similar system (see CONT-4)	Contamination of laboratory water or solution accumulation; improper collection and treatment leads to worker contamination or possible environmental release	Probable (E-2/yr to E-4/yr)	A/A	1	Procedures and training exist for liquid waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and treated again in a commercial liquid waste treatment facility (true?); PPE; incident reporting requirements; incident response; security protocol; HRP	Remote (<E-6/yr)	D/D	4/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Energetic event causing release	**Over-pressure from blockage in steam line** leading to autoclave failure or process steam line failure, personnel contamination, room contamination, ventilation system leakage around, through HEPA filters, environmental contamination	Contamination, personnel infection, laboratory contamination, possible environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	Modern autoclave and process steam piping instrumentation and control prevent catastrophic failure if procedures and maintenance protocol exist and personnel are trained and follow procedures; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	E/C	4/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Energetic event causing release	**Deflagration of formaldehyde, ethylene oxide, or other flammable agent during laboratory disinfection or sanitization**, personnel contamination, room contamination, structural failure, loss of biocontainment, ventilation system leakage around, through HEPA filters	Contamination, personnel infection, laboratory contamination, loss of biocontainment, environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	Modern disinfection/ sanitization procedures, equipment, process instrumentation and control are available; training and maintenance procedures developed and used; flammable gas controls in place including detection, humidification, ventilation, recognition and control of ignition source used to prevent catastrophic consequences; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	E/C	4/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Energetic event causing release	**Deflagration/explosion /fire external (to the facility) of the supply of diesel, fuel oil, gasoline** leading to facility breach, personnel contamination, room contamination, possible environmental contamination	Contamination, personnel infection, laboratory contamination, possible environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	Training and maintenance procedures developed and used; combustible control program developed and implemented; ventilation in central utility plant; recognition and control of flammable gases and ignition sources; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	A/A	2/2

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Fire (inside BSC or outside BSC but inside laboratory)	**Fire from buildup of combustibles (poor combustible control in laboratories)** causing BSC failure, personnel contamination, room contamination, possible ventilation system leakage around, through HEPA filters	Contamination, personnel infection, laboratory contamination, possible environmental contamination	Occasional (1.0/yr to E-2/yr)	A/A	1	Combustible loading controls developed and implemented; training and maintenance procedures developed and used for equipment and process use; volume/mass control of chemicals to minimize stored energy; flammable gas controls in place including recognition and control of flammable gases and ignition sources, gas detection, BSC ventilation used to prevent accumulation and catastrophic consequences; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	E/C	4/4

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Fire (external event)	**Fire from fuel accumulation external to the facility; supply of diesel, fuel oil, gasoline burns** leading to facility breach, personnel contamination, room contamination, possible environmental contamination	Contamination, personnel infection, laboratory contamination, possible environmental contamination	Occasional (1.0/yr to E-2/yr)	A/A	1	Training and maintenance procedures developed and used; combustible control program developed and implemented; ventilation in central utility plant; recognition and control of flammable gases and ignition sources; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	A/A	2/2
External events and natural phenomena	**Small airplane crash into facility (DOE-STD-3014 scenario)** causes structure failure; significant environmental and public contamination	Personnel and environmental contamination	Improbable (E-4/yr to E-6/yr)	A/A	1	No different than for seismic with fire, wind, missile, or other NPH	Improbable (E-4/yr to E-6/yr)	A/A	1/1

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
Transportation	**Mis-identification and site contamination** (failure to meet Federal biomaterial transportation requirements) results in inadequate handling and personnel contamination (high-level pathogen in low-level biocontainment with inadequate PPE)	Contamination, personnel infection, equipment contamination, environmental contamination	Occasional (1.0/yr to E-2/yr)	A/A	1	Procedures and training for packaging, identifying (manifest), and transporting or transferring samples inter-laboratory; procedures and training for recognizing and controlling aerosol generation; packaging materials and equipment available and used; transport system and storage equipment maintenance and use procedures prevent misuse and proper equipment replacement protocol; PPE; BSC, laboratory, facility biocontainment; HEPA-filtered negative-pressure ventilation; incident reporting requirements; incident response; security protocol; HRP	Improbable (E-4/yr to E-6/yr)	E/B	4/3

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
External events and natural phenomena	**Seismic event exceeds facility design criteria** and structure fails; significant environmental and public contamination	Personnel and environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	No seismic controls; feasibility study indicates spectral acceleration of 0.06 g to 0.19 g—equivalent of light-laboratory seismic resistance	Probable (E-2/yr to E-4/yr)	A/A	1/1
External events and natural phenomena	**Seismic event challenges or exceeds facility design criteria** and structure fails, **subsequent fire(s) start** from ignition sources in laboratories; significant environmental and public contamination	Personnel and environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	No seismic controls; feasibility study indicates spectral acceleration of 0.06 g to 0.19 g—equivalent of light-laboratory seismic resistance; with no seismic controls, ignition sources in laboratories and outside (500,000-gal diesel storage) assumed to result in fires	Probable (E-2/yr to E-4/yr)	A/A	1/1

Table 3.14.2.7-1 — Accidents From Hazard Analysis and Accident Selection Methodology (Continued)

Accident Type	Initiating Event	Outcome	Unmitigated Frequency	Unmitigated Consequence (P/E over W)	Unmitigated Risk (higher of P/E or W)	Existing Control Set	Mitigated Frequency	Mitigated Consequence (P/E over W)	Mitigated Risk (P/E over W)
Contaminated solid waste (including animal)	**Procedure violation** results in incomplete sterilization/disinfection of solid waste	Contamination, possible personnel infection, possible environmental contamination	Frequent (≥ 1.0/yr)	A/A	1	Procedures and training exist for pre- and post-treatment waste handling; for preparing and transferring the waste for treatment; and for sampling and (assumed) confirming sterile prior to discharge to environment; treated waste is transferred and retained in a controlled repository; PPE; incident reporting requirements; incident response; security protocol; HRP	Probable (E-2/yr to E-4/yr)	D/D	3/4
External events and natural phenomena	**High winds (tornado) challenge or exceed facility design criteria** and structure fails; significant environmental and public contamination	Personnel and environmental contamination	Probable (E-2/yr to E-4/yr)	A/A	1	Facility wind resistance (90-mph), no tornado (readily apparent) considered in feasibility study	Probable (E-2/yr to E-4/yr)	A/A	1/1

3.14.3 Accident Analysis

Table 3.14.2.7-1 lists the accident scenarios that were developed based on an evaluation of the hazards analysis and for selecting potential accidents that produce bounding consequences. This selection process considered accidents from the more common hazard categorizations (spills, contaminations, laboratory equipment failure, procedure failures, LAI incidents, transport, process upsets, etc.) in addition to unique accidents with low frequencies but with unacceptably high consequences (deflagrations, natural phenomena accidents, external accidents, etc.). Nonetheless, all of the results come from scenarios proposed in the hazards analysis. These accidents include an evaluation of the sequence of events leading to the overall consequences, as well as a description of the models or other risk evaluations relied upon to produce site-specific consequences. A detailed presentation of the spill accident is provided in this section. The remaining accidents are summarized, and the details are available in Appendix E. Table 3.14.3-1 presents an overall summary of all of the accidents considered for the NBAF. Details of the accident consequences are presented on a site-specific basis in Section 3.14.4.

3.14.3.1 Operational Accidents

Operational accidents include those associated with planned and normal unplanned activities related to the NBAF. These accidents are differentiated from natural phenomena or external accidents and intentional acts because the scenarios are developed around the typical operations that are expected to occur in the NBAF. The following presentation of the spill accident is provided to illustrate the accident analysis methodology and represents a wide range of potential scenarios that could lead to a release of pathogens resulting from spills. Operational accidents brought forward from the hazards analysis for detailed evaluation includes 1) drops and spills, 2) LAIs, 3) loss of biocontainment involving infected animals, 4) improper sterilization resulting in release of contaminated liquid or solid wastes to the environment, 5) large room or facility fire resulting in a release of pathogens, and 6) an over-pressure event from a deflagration (inside or outside of the facility).

Operational Accident 1 – Spill/Uncontrolled Release of Pathogens

The presentation of this accident scenario includes additional details to illustrate the methodology. The essential details of the other accidents are provided in Appendix E. This scenario considers the release of pathogens from a small to medium spill. For the purposes of developing a reasonably credible scenario, this accident is considered to be caused by a storage container handling accident, specifically a dropped container or a type of equipment failure that results in spilled or sprayed contents and aerosol production. This scenario effectively bounds the small- and medium-level spill accidents. This accident was selected for analysis because of the potential hazard associated with aerosol production as evaluated in the hazards analysis and accident selection. In addition, this type of spill event was evaluated to potentially occur with a relatively high frequency and can be used to bound the consequence of aerosol release outside of qualified BSC or other engineered enclosures.

Spills and releases can occur from degraded containers; improper packaging of containers or materials; mechanical impact; dropped containers; equipment malfunction due to improper use or inadequate maintenance; procedure violation from packaging, handling, operation, etc.; or a combination of the set. Because pathogens are packaged or processed in various configurations, the configuration most susceptible to becoming an aerosol is examined as a bounding scenario.

Table 3.14.3-1 — Accident Scenario Summary

Accident	MAR*	Unmitigated Release	Risk Rank	Mitigated Release	Risk Rank	Safety Barriers and Procedural Controls
#1. Spill or uncontrolled release of aerosol pathogens – includes dropped containers and equipment failures resulting in aerosol production, worker inhalation exposure, internal facility contamination, and facility release	10^{10} virions (considers a maximum volume of 100 milliliters of material)	10^6 virions; ARF 1×10^{-4}	**1** **FC II** **Cnsq A/B**	10 virions; due to LPF 1×10^{-5} (biocontainment)	**4** **FC IV** **Cnsq D/C**	**Secondary Barrier – Facility Design and Construction** Active ventilation, which maintains a pressure drop across critical areas and rooms. Passive ventilation system, which includes the leak-tight facility structure, effective efficiency of HEPA filters and plenum to trap the pathogen materials resulting from a spill. **Primary Barrier – Safety Equipment and Personal Protective Equipment** Engineered systems within laboratories to provide biocontainment during process operations (BSCs, etc.) Specialized process equipment for biomaterial processing, packaging, handling, movement, storage, etc. Properly maintained equipment Appropriate PPE available Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc.
#2. Laboratory Acquired Infection (LAI) – produces a worker exposure from autoinoculation, ingestion, or contamination due to personnel error	Variable ≥ 10 virions available (sufficient to cause infection)	Single worker exposure that if not controlled, will expose the public and environment	**1** **FC I** **Cnsq B**	Single worker exposure that is readily recognized and treated; no collateral impact to the public or environment	**4** **FC III** **Cnsq E**	**Primary Barrier – Safety Equipment and Personal Protective Equipment** Specialized process equipment for biomaterial processing, packaging, handling, movement, storage, etc. Properly maintained equipment Appropriate PPE available Sharps procedures developed and implemented Training against procedures Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc.

Table 3.14.3-1 — Accident Scenario Summary (Continued)

Accident	MAR*	Unmitigated Release	Risk Rank	Mitigated Release	Risk Rank	Safety Barriers and Procedural Controls
#3. Loss of animal/insect control - resulting in environmental contamination (scenario also includes the potential for a loss of biocontainment of an animal while remaining inside the NBAF)	10^{10} virions (one infected animal capable of respiring 4×10^{4} virions per hour with greater quantities in blood and tissue. Similar quantity as a spill.)	10^{10} virions; the infected animal escapes	**1** **FC II** **Cnsq A**	None; The infected animal does not escape	**3** **FC III** **Cnsq D**	**Secondary Barrier – Facility Design and Construction** Active ventilation, which maintains a pressure drop across critical areas and rooms. Passive and Active Ventilation Systems, redundant HEPA filtration, and other safety barriers to confine material during normal operations Detection systems, alarms, door interlocks, redundant doors, etc. **Primary Barrier – Safety Equipment and Personal Protective Equipment** Animal locator systems to minimize time in the environment in the event of escape Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc.
#4. Improper sterilization/disinfection of solid or liquid waste -results in environmental contamination	10^{9} virions (considers a minimum of 10 ml released)	$\leq 10^{5}$ virions; ARF 1×10^{-4}	**1** **FC II** **Cnsq A**	None; Sterilization occurs	**3** **FC III** **Cnsq D**	**Primary Barrier – Safety Equipment and Personal Protective Equipment** Disinfection and sterilization equipment; possibly redundant processing protocol Biocontainment systems for liquid and solid waste used as surge awaiting QA approval prior to discharge to the environment Active and passive ventilation system which includes the leak tight facility and the efficiency of the HEPA filters to trap the biological material resulting from a release inside the NBAF Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc. Waste sterilization quality assurance and testing to ensure complete sterilization of infectious waste prior to discharge from facility.

Table 3.14.3-1 — Accident Scenario Summary (Continued)

Accident	MAR*	Unmitigated Release	Risk Rank	Mitigated Release	Risk Rank	Safety Barriers and Procedural Controls
#5. Large room or facility fire - resulting in the loss of facility structure and large environmental release	10^{13} virions (considers multiple laboratory areas with maximum volumes of viable pathogens. The single maximum volume considered is the 30 L cGMP.)	$\leq 10^{9}$; 1 % survive heat and gases, ARF 1×10^{-2}	**2** **FC III** **Cnsq A/A**	$< 10^{4}$ virions; LPF 1×10^{-5}	**4** **FC IV** **Cnsq D/C**	**Secondary Barrier – Facility Design and Construction** The NBAF biocontainment system, including the NBAF structure, intake and exhaust HEPA filters, and ductwork between the plenums and the structure, provides a barrier against pathogen release to the environment Fire detection and protection systems **Primary Barrier – Safety Equipment and Personal Protective Equipment** Additional safety barriers to provide redundant biocontainment in the event of a large release accident to include BSC, MAR containers, compartmentalization philosophies Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc. Operational MAR limit (Use of small quantities of pathogen in the BSCs).
#6. Over-pressure event - results from a deflagration and in loss of biocontainment	3×10^{12} virions (considers single laboratory area with maximum volumes of viable pathogens. The single maximum volume considered is the 30 L cGMP.)	3×10^{10} virions; 10 % survive heat and gases, ARF 1×10^{-1}	**2** **FC III** **Cnsq A/A**	3×10^{5} virions; reduced by biocontainment LPF 1×10^{-5}	**4** **FC IV** **Cnsq D/D**	**Secondary Barrier – Facility Design and Construction** The NBAF biocontainment system, including the NBAF structure, intake and exhaust HEPA filters, and ductwork between the plenums and the structure, provides a barrier against pathogen release to the environment **Primary Barrier – Safety Equipment and Personal Protective Equipment** Additional safety barriers to provide redundant biocontainment in the event of a large release accident to include BSC, MAR containers, compartmentalization philosophies Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc. Operational MAR limit (Use of small quantities of pathogen in the BSCs).

Table 3.14.3-1 — Accident Scenario Summary (Continued)

Accident	MAR*	Unmitigated Release	Risk Rank	Mitigated Release	Risk Rank	Safety Barriers and Procedural Controls
#7. Large, multi-laboratory spill as the result of a seismic (or high-wind) event - without an accompanying fire	10^{15} virions (considers multiple laboratory areas and numerous animals with maximum volumes of viable pathogens. The single maximum volume considered is the 30 L cGMP.)	10^{11} virions; ARF 1×10^{-4}	**2** **FC IV** **Cnsq A/A**	10^{11} virions; Mitigation can be provided by NPH design and HEPA filtration (multiple HEPA filters in series at 99.97%) reducing the release to < 100 virions	**4** **FC V** **Cnsq E/D**	**Secondary Barrier – Facility Design and Construction** The NBAF biocontainment system, including the NBAF structure, intake and exhaust HEPA filters, and ductwork between the plenums and the structure, provides a barrier against pathogen release to the environment **Primary Barrier – Safety Equipment and Personal Protective Equipment** Additional safety barriers to provide redundant biocontainment in the event of a large release accident to include BSC, MAR containers, compartmentalization philosophies Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc. Operational MAR limit (Use of small quantities of pathogen in all operations).
#8. Aircraft crash into the NBAF or external fuel storage (diesel, fuel oil, gasoline) explosion and fire - causes loss of facility biocontainment with a subsequent release of pathogen into the environment	3×10^{12} virions (considers single laboratory area with maximum volumes of viable pathogens. The single maximum volume considered is the 30 L cGMP.)	3×10^{8}; ARF 1×10^{-4} or viral pathogens destroyed in heat and gases	**2** **FC IV** **Cnsq A/A**	3×10^{8} virions; facility is breached by aircraft exposure; Mitigation can be provided by NPH design and HEPA filtration (multiple HEPA filters in series at 99.97%) reducing the release to < 1×10^{-2} virions	**4** **FC V** **Cnsq E/D**	**Secondary Barrier – Facility Design and Construction** The NBAF biocontainment system, including the NBAF structure, intake and exhaust HEPA filters, and ductwork between the plenums and the structure, provides a barrier against pathogen release to the environment **Primary Barrier – Safety Equipment and Personal Protective Equipment** Additional safety barriers to provide redundant biocontainment in the event of a large release accident to include BSC, MAR containers, compartmentalization philosophies Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, etc. Operational MAR limit (Use of small quantities of pathogen in all operations).

* MAR – also referred to as the Material Available for Release. The MAR was estimated specifically for each Bounding Accident based on maximum quantities of pathogens potentially existing in the NBAF at any time. Appendix E provides the details related to calculating the MAR for various configurations and animals.

Several types of aerosol-producing scenarios can be envisioned to occur to packages containing pathogens as they are handled prior to transport or during actual process operations outside of BSC or other engineered enclosures, including the following:

- Drops during container packaging activities prior to or during transport;
- Spills or drops during handling and movement;
- Equipment malfunction from procedural error; and
- Equipment malfunction from inadequate maintenance.

The bounding scenario is taken to be a spill from the fall and breaking of a package from the top shelf of a storage unit or the failure of equipment (centrifuge, blender, grinder, etc.) causing the contents of the package or equipment to be released and aerosolized. In all of these postulated accident scenarios, significant aerosol production is realized causing personnel exposure, laboratory and facility contamination, and a potential release from the facility.

Accident Sequence

A storage package is dropped and breaks, or process equipment (centrifuge, blender, grinder, etc.) fails, releasing pathogen-containing contents in the form of an aerosol. The formation of the aerosol is considered to occur as a result of the energy applied to the contents either as a result of a drop of from an equipment failure. The total amount of energy applied to the contents depends on the equipment (e.g., a centrifuge) failure or the height from which a container is dropped. In either case, the accident is postulated to result in a sequence composed of a number of independent events in series that have a qualitatively determined failure rates derived from hazard rates and demand failure probabilities (McCormick 1981; Fullwood 1988; Gertman 1994). A hazard rate can be interpreted as the number of times that a particular component, system, or piece of equipment fails in some specified time frame. The units of hazard rates are typically in units of time. For equipment that is needed on a continuous basis, the hazard rate is often determined in units of number of failures per hour. When a system needs to respond only in certain situations, the hazard rate is presented in number of failures per demand. These events are shown on event trees, an example of which appears in Figure 3.14.3.1-1.

The following preventive and mitigative features form the basis of this accident to determine the accident probabilities.

Preventive Features

- Packaging intact and appropriate for the material
- Container handled properly and not dropped or impacted
- PPE appropriate and used appropriately
- Proper handling and use of equipment
- Equipment is properly maintained
- Procedures in effect and followed

Mitigative Features

- Active exhaust ventilation system operates
- Passive biocontainment intact and functional
- Other biosafety systems or barriers in place and maintained

Accidents leading to the release of biological material are considered to occur if all the protective features in the prescribed sequence are compromised or fail. Should any *one* event succeed, the accident is prevented or mitigated to varying degrees, depending on precisely which features fail and which continue to function (the effectiveness of the control is also evaluated in terms of mitigated and unmitigated accident frequencies as previously described).

Accidents leading to the release of biological material are considered to occur if all the protective features in the prescribed sequence are compromised or fail. Should any *one* event succeed, the accident is prevented or mitigated to varying degrees, depending on precisely which features fail and which continue to function as intended. The accident sequence for spills is illustrated in Figure 3.14.3.1-1 as an event tree. The overall accident frequency was identified in the hazards analysis as a frequency category (FC) II, indicating that a small to medium spill could occur occasionally over the life of the facility. The event tree is used to illustrate the specific probability of an accident based on the specified initiating event. In addition, based on the number of opportunities for the initiating event and the individual accident sequence events, the overall accident frequency is estimated for the life of the facility, which is assumed to be on the order of 50 years. Each accident is assigned to a qualitative frequency category based on the estimated frequency of the initiating event and the conditional probability of the accident per individual demand for each event in the accident sequence. Weighting or averaging over the individual events determines the overall accident frequency. The estimates of the overall accident frequencies are based on the specific failure rates (probability of failure per demand or unit time) for both unmitigated and mitigated sequences.

The basis for these assignments of frequency and probability is discussed in Appendix E. They are derived from historical experience of failures in similar facilities and generic industrial data sources for equipment failure, together with well-established estimates of human error probabilities. A review of mechanical systems such as pumps, motors, and fans shows that failures can be represented in terms of failure to start and/or failure to run. For other types of mechanical systems, the overall failure can be represented by the failure to operate as expected or failure to perform to a specific level. In these cases, the failure probability could be represented as a failure per demand, for pumps or motors, or even as a failure probability per unit time, for fans or pumps, that are required to run continuously. In the case of HEPA filters, failures can result of being plugged (consequence is high pressure drop across filter), bypassing (characterized by a drop in pressure across the filter housing), or degraded efficiency (higher than expected particulates emerging through the filter). The failure probability for these situations may be represented as a single probability per demand.

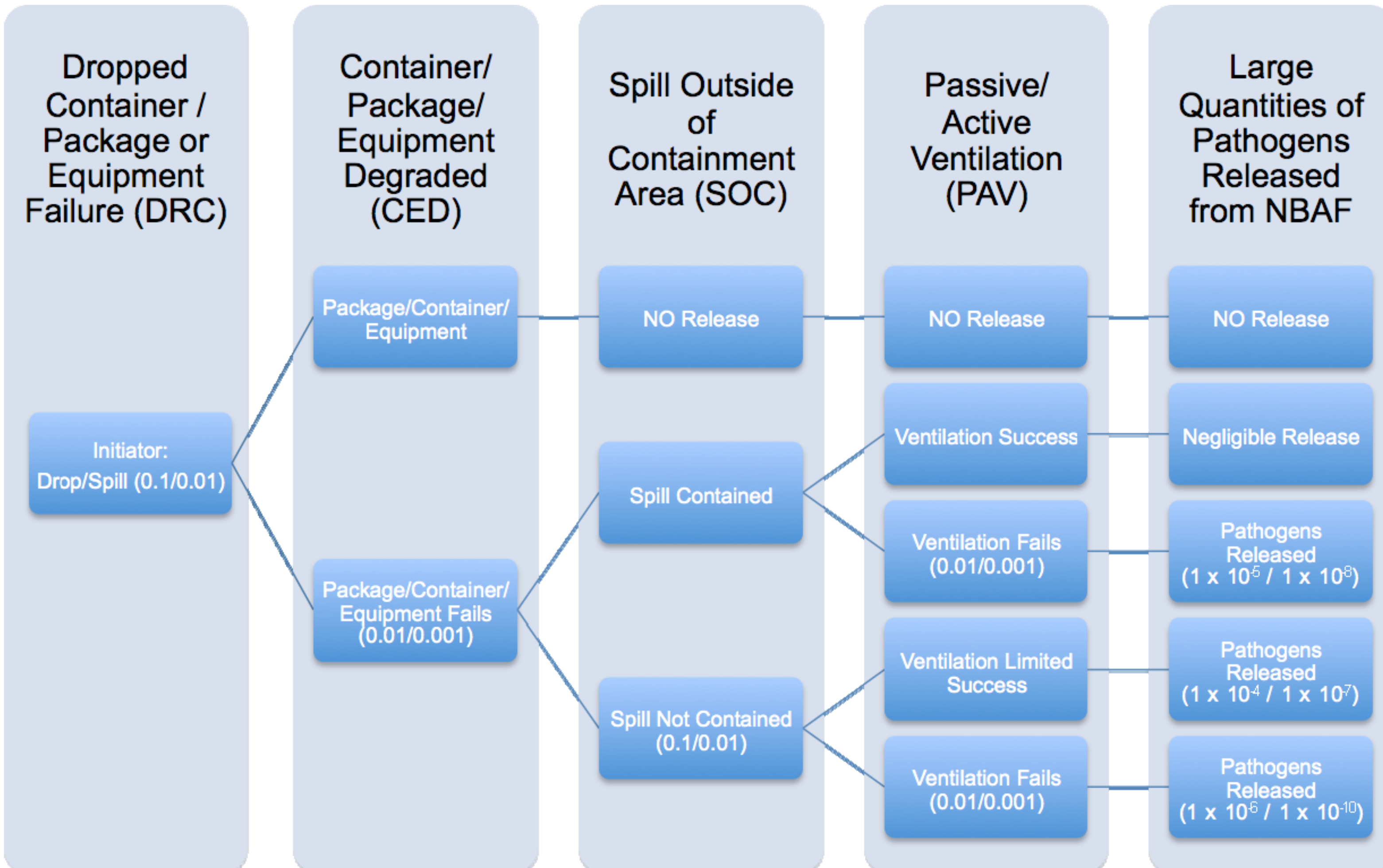
Modeling system behavior of individual components within the various safety systems was found to be unnecessary for providing upper-bound estimates on the probability of failure for mechanical systems. Data for air handling units, as might be found in a typical HVAC system, show that failure probabilities range from a lo of 4×10^{-5} to a high of 2×10^{-2} depending on the application and demand (NRC 2007). Other components including pump valves, water filters, and fans were found to exhibit failure probabilities that range from as low as 4×10^{-9} to as high as 2×10^{-2} again depending on the demand and application. Because failure of an entire system, as envisioned in the event tree depicted in Figure 3.14.3.1-1, is dependent on a variety of individual component interactions that each have small failure probabilities, it is credible and bounding to assign the failure probabilities to the events in the tree as follows. For this analysis, failure probabilities for mechanical systems and human error (reliability) were derived from generic data for various mechanical systems and different types of human activity. The failure probabilities for human error are assigned the values of 0.1 for unmitigated and 0.01 for mitigated accidents scenarios. Failure probabilities for mechanical systems are assigned the values of 0.01 for unmitigated and 0.001 for mitigated accident scenarios. Failure probability data for components of systems that would be expected in the NBAF were estimated from values related to the nuclear and chemical industries. The range of failure probability for critical safety systems was collected over a long period of time from numerous sources, providing a defensible basis for the assigned values used in this analysis (Gertman 1994; McCormick 1981; Fullwood 1988).

The basic events in the overall sequence include the initiating event, which is either a dropped container (package) or equipment failure. The second event in the sequence is that the contents leak from the container or equipment because of container degradation or improper maintenance. The third event is to evaluate the location of the event as inside or outside of biocontainment area. The fourth is evaluating the ability for the released materials to be contained by equipment or location within the facility in order to mitigate or prevent the release from the facility. This last event is referred to as active/passive ventilation. This event addresses the leak tightness of the facility by maintaining proper filtration and pressure gradients (negative pressure in the location of the release directing airflow to the HEPA filters prior to exhausting through the vents). Should all of these protective features fail, then a release of pathogens to the environment would result. Each of these events is discussed and evaluated in detail in the following sections. The analysis of the accident in some detail provides insight into the likelihood (probability) that there is a release given the initiating event. The overall frequency of the accident (unmitigated/mitigated) in a given year, and over the life of the facility, is dependent on the number of demands made for specific event. The accident frequency over the life of the facility, along with the supporting analysis, is used to designate the unmitigated and mitigated risk rank.

The spill accident sequence is represented in the form of an event tree (Figure 3.14.3.1-1) depicting several protective features. Failure of all of these protective features will produce a release of pathogens. The individual events in the accident sequence are related to safety barriers that are modeled as either administrative or engineered controls. The representation of the overall accident frequency in terms of operational years or facility life is determined by the product of the individual event demand probabilities and the total number of demands (or opportunities) for the accident to occur in a year or over the life of the facility. For this accident, the initiating event is presented in terms of a single human error without specific regard to the total number of opportunities. For this reason, the resulting accident probability is in terms of a single demand from the initiating event. To convert this initiating probability to a frequency requires knowledge of the number of handling events per year, which can be determined from knowledge of the expected operations in the NBAF. The initiating event frequency is then the product of the initiating event probability and the number of handling operations per year. The number of handling operations in any given period of time is dependent on the operating characteristics of the NBAF. These characteristics include the number of technicians or animals, the number of containers or unit operations in a given period of time, the number of days or hours per year that the safety systems are expected to be in service, and even the type and amount of specific mission research work that is ongoing. Research facilities have tendencies to fluctuate in types and amount of operations depending on mission objectives.

The event tree with the sequence of events leading to a release of pathogens as a result of a spill is presented in Figure 3.14.3.1-1. The event tree focuses on those events that have a potential to result in a release of pathogens from the NBAF. Each of the discussions that follow provides the rationale for assigning the branch event failure probabilities.

Container/Package Dropped – Equipment Failure – This is considered the initiating event, labeled Dropped - Container (DRC), and is assumed to be the result of a human error. Given the size of the NBAF, the number of laboratories (BSL-3 and BSL-4), animal holding areas, and the expected number of laboratory workers, a dropped container/package or equipment malfunction leading to a spill is considered both reasonable and credible. This accident scenario was developed because a dropped container does not automatically result in a release of pathogens. This initiating event is assigned a demand failure probability, associated with a human error, of 0.1 per demand. Since it is likely that many such opportunities for a container drop are expected to occur in a given year of operation, the overall frequency of this initiating event is much greater than 1 per year. The total number of drops or equipment failures expected in a year is qualitatively estimated based on facility operations.



The three-letter code in the event title represents the event in the sequence. The branch failure probability value is provided in parentheses for each event. For example ‘(0.1/0.01)’ for the initiating event represents the unmitigated/mitigated failure probability for that event. The unmitigated event tree represents the situation where there are minimal procedures, training, maintenance, and reliability of systems and personnel. The mitigate event tree represents a robust management, formality of operations, well-maintained and effective equipment, and rigorous implementation of procedures and controls. The final likelihood (probability) estimates for the sequence are calculated by multiplying each branch (e.g., the largest release is sequence DRC-CED-SOC-PAV), which is an unmitigated likelihood of $1\times10^{-6} = 0.1\times0.01\times0.1\times0.01$ per drop event.

Figure 3.14.3.1-1 — Small to Medium Spill and Aerosol Release Accident Scenario

Container/Package/Equipment Degraded Leading to a Spill of Contents – This is the first event in the accident sequence after the initiating event and is labeled Container-Equipment-Degradation (CED) in Figure 3.14.3.1-1. It is assumed that a storage container is dropped or some piece of process equipment fails. The event tree quantification, and the subsequent representation of the risk, based on the accident probability (per year of over the life of the facility) and the potential consequences, does not explicitly take into account that there is a wide range of potential outcomes resulting from a degraded container or package. These outcomes vary from small leaks to complete, instantaneous release of the contents. Conservatively, this accident is considered to result in the release of the entire contents of the package. In addition, it is reasonable to consider that the spilled material could be aerosolized as a result of the impact (see below for a discussion of the fraction aerosolized). The failure probability for this event is primarily based on mechanical failure or wear and tear leading to degradation is assigned a value of 0.01 per demand (per package or container or equipment being called on into service) for the unmitigated case conditional on the occurrence of the drop, as is explained in Appendix E, and a value of 0.001 for the mitigated case. While human error is also an element, because of the potential for improper maintenance of equipment or improper packaging, the failure probability is assumed to be entirely the result of mechanical failure.

Because the NBAF is a new facility, it is assumed that the packages and equipment in use would be new and degradation would not initially be a significant contributor to the failure probability. Procedures and training would be current and attention to detail is expected to be high. The likelihood of encountering degraded transport packages or process equipment may increase with operating history and could be further enhanced by personnel complacency. A robust management system with attention to formality of operations, configuration management, quality assurance, and training in place is expected to significantly reduce the likelihood of human error and mechanical failure.

Spill Outside of Biocontainment Areas – This is the second event in the accident sequence after the initiating event and is labeled Spill-Outside-Biocontainment (SOC) in Figure 3.14.3.1-1. The evaluation of whether a spill is inside or outside biocontainment areas alters the manner in which the spill can be contained. In addition, this event allows consideration of the fact that laboratory rooms where pathogens are present are separated from the non-biocontainment areas or areas with less stringent safety controls (e.g., BSL-2 laboratories, offices, and maintenance areas as opposed to BSL-3 or BSL-4 areas). The plumbing and ventilation are also separated based on the types of work and hazards that are expected. The unmitigated probability of failure for the dropped container (and subsequently the spill) to occur outside of biocontainment was assigned a value of 0.1 for the unmitigated case and a value of 0.01 for the mitigated case because this event, dropping of a package containing pathogens, outside of the appropriate biocontainment area is primarily dependent on human error as opposed to mechanical failure. The procedures for the handling of packages or equipment differ based on the types of hazardous materials contained in the package. The effectiveness of safety controls in preventing the handling of packages in areas where it is not appropriate provides a means for reducing the likelihood of the release. The overall frequency of package handling in an area where the biocontainment protection is less than what is needed for the package contents is determined based on the operational practices (demands) of the various laboratory activities.

Passive/Active Ventilation Operates – This is the last event depicted in the accident sequence. This event is labeled Passive-Active-Ventilation (PAV) in Figure 3.14.3.1-1. Once material has escaped from the breached container or failed equipment, it becomes airborne in a specific area of the facility. Taking into consideration that ventilation is expected to be operating at the time of the release, the aerosol is carried to HEPA filters where it becomes trapped with a specified efficiency of 99.97% per filter (potentially multiple filters in series). The likelihood that ventilation is operating in the critical period after a container drop is based qualitatively on an unanticipated electrical outage or a random mechanical failure. Unanticipated electrical outages are infrequent, and normal operations in the facility are suspended during planned outages. Historically, outages at similar types of biological facilities have occurred approximately four times per year and have lasted less than 2 hours. Considering the number of 2-hour periods in a year, the implication is that power could be interrupted in a given 2-hour period at the rate of 1×10^{-3}. Assuming the critical period for dispersal after the release is less than 2 hours, the probability that ventilation would shut off during the critical period of the event is on the order of 1×10^{-3} (this failure probability estimate conservatively neglects the capability of onsite back-up power to make up for the loss of off-site power during this critical time). In addition, there are other features of the active/passive ventilation system that would have to fail in order for pathogens to escape the facility in large quantities. These include the HEPA filter failure, leak tightness of the facility is compromised, or there is airflow from biocontainment areas to non-biocontainment areas. Each of these features needs to be factored into the determination of the failure probability for the PAV event; however, because this event is essentially a mechanical system, the failure probability assigned is 0.01 for unmitigated and 0.001 for the mitigated case.

Evaluation of the various accident sequences illustrated in this tree shows that three discrete accident sequences (combined event failures) can result in a potential release of a large number of virions. These sequences are

- DRC-CED-SOC-PAV
- DRC-CED-PAV
- DRC-CED-SOC

The first sequence represents the accident scenario where all of the safety controls fail (each branch in the event tree fails). This sequence is the least likely to occur and has a per demand probability (per handling operation) of 1×10^{-6} for the unmitigated case and 1×10^{-10} demand failure probability for the mitigated case. The second sequence represents the situation where the spill occurs in the appropriate area of the facility, but the passive/active ventilation controls fails resulting in a release of pathogens with a per demand probability of 1×10^{-5} for the unmitigated case and 1×10^{-8} for the mitigated case. The essential difference between these two sequences is that the human error associated with the handling of the package has been removed (event success where the location of the spill is either inside or outside a contained area). The third sequence involves the situation where the package is not in the appropriate area of the facility but the passive/active ventilation control operates. This sequence still leads to a release because the filtration and leak tightness of the facility is less stringent in these areas for the pathogens involved. The individual per demand failure probability is estimated at 1×10^{-4} for the unmitigated and 1×10^{-7} for the mitigated case. This last sequence has the highest failure probability because the entire accident is dependent on two human error events and a single mechanical failure. The evaluation of these sequences indicates the value of the engineered safety controls in contrast to those dependent on operator actions. In addition, the likelihood of the release is reduced when there are a greater number of barriers or controls that must fail before a release is possible.

The accident sequence DRC-CED is one in which the drop and spill occurs, in an appropriate area of the facility, with all subsequent protective features working. Because this accident sequence is in an area where the pressure differential is towards the region of higher biocontainment and the HEPA filtration is more stringent, there is a negligible release.

For purposes of evaluating this accident in the context of all of the remaining accidents to arrive at an overall risk ranking for the facility, it is necessary to convert these individual accident sequences into an overall spill accident frequency. This is accomplished in a qualitative fashion by considering the operational characteristics of the NBAF. Information obtained from the Feasibility Study for the NBAF included details of the mission, numbers and types of animals expected, laboratory space, and projected staff, including maintenance (DHS 2007). From these data, qualitative assessment was made to estimate the total number of potential opportunities (e.g., handling operations) there are for the initiating event to occur. The assessment also included consideration of the operating time and an expected total operating life of the facility on the order of 50 years (the operational life of the facility is based on the fact that many of the missions that the NBAF will replace are currently or have been performed in facilities that are approximately 40 to 50 years old).

Taking these factors into consideration, this accident is assigned a qualitative frequency of $\geq1\times10^{-1}$ (less than 1 accident, resulting in a release, per year) for the unmitigated case, corresponding to a FC II, and 1×10^{-5} per year for the mitigated case, corresponding to a FC IV. Since the range of the accident sequence probabilities (individual demand) was 1×10^{-4} to 1×10^{-10}, the impact of mission objectives, facility operating time, and the total number of workers and packages were sufficient to increase the frequency of a spill accident resulting in a release of pathogens to be less than 1 accident in more than 10,000 operating years of the facility for the mitigated case.

As shown in the above discussion, a completely unmitigated (assumes marginal functioning of the safety controls and high human error rates) release of material is therefore assigned to FC II occasional. Taking into account the engineered and administrative controls that can reduce the frequency of the accident, the mitigated accident frequency is assigned FC IV indicating that a spill leading to a release from the NBAF is improbable (unlikely to occur during the life of the facility) when the protective safety features have a high reliability.

To determine the unmitigated risk rank for this accident scenario the source term is calculated.

Source Term Analysis

The source term is the product of the MAR, ARF, RF, DR, and LPF as discussed in Section 3.14.2. In this accident scenario, the unmitigated source term was calculated using conservative values. The specific values for each of these five factors are discussed below and presented in Table 3.14.3.1-1.

MAR – Based on mission objectives and regulatory requirements, a particular package of biological material could contain approximately 100 milliliters (mL) of culture containing viable pathogens. While there are differences between pathogens in relation to the number of particles in a solution or gel media, it is reasonable to assume that approximately 1×10^{8} viable virions could be present in a single milliliter of culture media. This would yield a total inventory of approximately 1×10^{10} viable virions in a single package containing 100 mL of culture. The biological materials consist of various forms, but the most sensitive are those able to be easily aerosolized upon impact, such as solutions or powders. The MAR for this scenario is then taken to be 1×10^{10} virions of a specific pathogen. For purposes of evaluating the consequences, the MAR represents each of the viruses, FMDV, RVFV, and Nipah virus.

DR – For the unmitigated analysis, the DR is conservatively set at unity (1.0). In even the worst-case spill, however, it is unlikely that all of the biological material would escape the container and the DR would more likely to be much less than 1. Therefore, using a value of DR=1.0 for this consequence estimate is extremely conservative.

ARF and RF – Results of studies with powdered materials, liquids splashing, and solids being crushed on impact provide bounds on the total quantity of inventory that can become airborne as a result of a drop or a spill. As discussed in Section 3.14.2.4, the ARF is assigned a value of 1×10^{-4} and the RF is conservatively taken to be 1.0 (meaning all of the aerosol is at the respirable size).

LPF – For the unmitigated analysis in which the aerosolized material escapes the facility without being filtered or otherwise mitigated by the building biocontainment system, the LPF is set to 1.0. For the mitigated analysis, the LPF is determined by taking into account the biocontainment system (ventilation, HEPA filtration, facility structure). The LPF for the active and passive HEPA filtered system is conservatively estimated to be 1×10^{-5} for the mitigated accident scenario.

Table 3.14.3.1-1 — Small to Medium Aerosol Release Source Term Parameters

Scenario	MAR	DR	ARF	RF	LPF
Unmitigated (No credit for HEPAs, Maintenance, or Procedures)	1×10^{10} virions	1	1×10^{-4}	1	1
Mitigated (Active/Passive Ventilation, Procedures, Maintenance, etc.)	1×10^{10} virions	1	1×10^{-4}	1	1×10^{-5}

Unmitigated Source Term

The unmitigated source term (only considers the physical properties of the pathogens and the culture media, no credit is taken for safety systems) for the small- to medium-spill accident is given by:

$Q=1\times10^{10}$ virions $\times1\times1\times10^{-4}\times1\times1=1\times10^{6}$ virions

Where:

Q = Quantity of viable pathogens released from the NBAF following the spill.

Mitigated Source Term

The LPF for the NBAF, as presented in Section 3.14.2 and Table 3.14.3.1-1 above, is used to calculate the mitigated source term (considers the efficiency of the HEPA filtration and the leakage of the facility, no credit is afforded the container as a conservative estimate) is given by:

$Q=1\times10^{10}$ virions $\times1\times1\times10^{-4}\times1\times1\times10^{-5}=1\times10^{1}$ or 10 virions for the active/passive ventilated safety system, proper maintenance, and high HEPA efficiency.

Consequence Analysis

The dose to the receptor outside of the NBAF (animal or human) is represented by the exposure due to inhalation, ingestion, contact, and vector pathways. For the inhalation pathway, the results of the air transport model provide time-integrated normalized air concentrations; therefore, the estimate of the exposure to pathogens in the air is simply the source term (Q) multiplied by the time-integrated normalized air concentration and the breathing rate in units of cubic meters per second.

The inhalation exposure to air containing transported viral particles is calculated by:

$\text{Exposure} = Q\times BR\times\chi/Q$

Where:

Q = the source term (mitigated or unmitigated [virons])
BR = is the breathing rate [m^3/s]
χ/Q = the 95th percentile normalized distribution of pathogen in the air at the receptor location [s/m^3]

The typical breathing rate for humans is taken to be 3×10^{-4} m^3/s, while the breathing rate for a cow is approximately 6 m^3/hr or 1.6×10^{-3} m^3/s, and a pig is assumed to be approximately the same as a human.

For determining animal exposure from ingestion, both the total time spent grazing and the total quantity of food consumed in a specific time period are important. The estimate of the amount of grass or feed an animal consumes is approximately 100 pounds per day for a cow. The amount is expected to vary greatly depending on the species of animal such as pigs, deer, elk, etc. Because the data obtained for the livestock in the vicinity of each proposed site are taken to be cattle, the estimate of 100 pounds per day is sufficiently representative for purposes of estimating risk. The results of the atmospheric modeling also provide estimates of the quantity of virions deposited on the ground as a function of distance from the site. Therefore, to assess the potential risk to cattle grazing on grass where viral pathogens have been deposited, an estimate of the total area covered by the animal grazing is necessary. Knowing the total amount of food consumed by an animal in a given period of time and the quantity of food produced per area will provide the basis for estimating the total exposure to pathogens while grazing. Estimates of grass production per unit are of ground vary somewhat depending on the species of grass, the type of soil, and available moisture, etc. A conservative estimate for the yield for typical pasture grass is on the order of 3.5 pounds per square meter (lb/m^2). As an example, if one were to assume that a cow eats nearly 100 pounds of feed per day (8 lb/hr assuming that cows eat 12 out of 24 hours) and that there is approximately 3.5 lb/m^2, then a cow would need to cover nearly 30 m^2 per day at a average rate of 2.5 m^2 per hour to ingest 100 pounds of food.

The calculation of unmitigated and mitigated consequences uses these same relationships to provide estimates of exposure. The difference is in the magnitude of the source term (how many virions are available) for inhalation and ingestion.

Unmitigated Off-Site Consequences – Calculation of site-specific exposure values are provided in Section 3.14.4. The calculated χ/Q is site specific and varies with distance from the point of release. A typical χ /Q value at a distance of 250 m (approximate NBAF fence line) is on the order of 1×10^{-2} s/m^3 (see Table 3.14.2.5-1). This value is used to determine the unmitigated exposure results in an inhalation dose of approximately 10,000 virions or about 1,000 times the minimum infectious dose (MID) for FMDV. Because 10 virions are also taken to be the MID for both RVFV and Nipah virus, these results are applicable to all three representative viruses for the inhalation pathway. Similarly, the exposure due to ingestion at the site boundary, for which the typical ground concentrations is approximately 20 virions/ m^2 resulting in a total dose nearly 60 times the MID, is also greater than the minimum necessary to cause infection. Given that the unmitigated consequences at the site boundary are significantly higher than the MID, the identification of robust safety controls to prevent the accident or mitigate the consequences is necessary.

Mitigated Off-Site Consequences – Mitigated accident consequences, in a similar manner as the mitigated accident frequency, are estimated by evaluating the reduction in material released in an accident through the improvement of effectiveness of various controls. In the mitigated consequence analysis, as discussed above, the passive and active ventilation system is credited for reducing the LPF (amount of material that escapes from the facility through leaks and filters) to a fraction of that considered for the unmitigated case. Because the mitigated release is much smaller than the unmitigated case, there is little chance for significant down-wind transport of the pathogens in a concentration that would result in an exposure. Because of the active/passive LPF mitigation effects, the mitigated exposure levels would be 100,000 times smaller than those described for the unmitigated release. The resultant dose at the site boundary would be 1×10^{-1} or 0.1 virions (less than the MID of 10 virions). These results illustrate that focusing resources and attention on the ability for the NBAF to contain pathogens in the event of an accident (in this case a small- to medium-size spill) provides a large reduction in the risk.

Risk Ranking

Based on the evaluation of the likelihood of a specific accident (as described in the evaluation of the event tree) and the consequences (as described by estimating exposure through inhalation and ingestion) associated with this accident, specific risk ranks can be assigned for the unmitigated and mitigated spill accident.

Unmitigated Risk Rank

The unmitigated risk rank is the combination of the accident likelihood (probability) and the bounding consequences through all pathways.

The spill accident has a per drop probability, from the event tree analysis for all three large release sequences, in the range of a 1×10^{-4} to 1×10^{-6}. Considering the total opportunities for a drop to occur during the life of the facility, the unmitigated frequency for this spill accident has a range of 1×10^{-2} to 1×10^{0} or FC II (occasional) from Table 3.14.2.1-3.

The spill accident consequences were shown to be greater than the MID at the site boundary, indicating an unmitigated consequence severity category of B for the worker (long-term health effects) and A for the public/environment (exceeds the MID by more than a factor of 10 at the site boundary).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC II and consequence severity of A/B (public/worker) and the assigned risk rank is 1, which indicates that robust safety controls are required to prevent or mitigate the accident and reduce the risk. Given that the unmitigated consequences at the site boundary are significantly higher than the MID, the identification of safety controls to prevent an accident or to mitigate the consequences is essential. The following table presents the safety controls or barriers relied upon to reduce or prevent a release. The safety controls considered appropriate for reducing the risk for this accident are summarized below.

Summary of Safety Barriers and Procedural Controls

Control	Description
Safety Barriers	Active ventilation, which maintains a pressure drop across critical areas and rooms. Passive ventilation system, which includes the leak-tight facility structure, the efficiency of HEPA filters (in series at 99.97% efficient or better), and plenum to trap the spilled pathogen materials. Engineered biocontainment systems within laboratories to provide biocontainment during process operations. Robust containers and packaging that meet DOT requirements. Specialized process equipment for biomaterial processing, packaging, handling, movement, storage, etc. Properly maintained equipment. PPE available and used appropriately.
Procedural Controls	Conduct of engineering and operations consider maintenance, contamination control, PPE use, training, specialized operational procedures, monitoring and inspections, quality assurance, etc.

After taking into consideration the safety controls in the context of the spill accident, the mitigated risk rank is assigned. Determining the mitigated consequences depends on whether the accident is prevented or not. If the accident is totally prevented, for example, by robust packaging (as well as procedures, maintenance, etc.), then the spill and subsequent release is prevented or mitigated. In the case where the accident is prevented, there is no release and therefore no consequences to the public or worker. Should the accident occur, but with lower frequency, and the safety systems function as expected, then the consequences are significantly reduced as presented above. In either case, the risk is significantly reduced.

Mitigated Risk Rank

The mitigated risk rank, like the unmitigated evaluation above, is the combination of the accident likelihood (probability) and the bounding consequences through all pathways for the mitigated accident.

Through improvements in procedures, training, and quality assurance, the mitigated spill accident has a per drop probability, from the event tree analysis for all three large release sequences, in the range of a 1×10^{-7} to 1×10^{-10}. In the same manner as for the unmitigated accident frequency taking into account the total opportunities for a drop to occur during the life of the facility, the mitigated frequency for this spill accident has a range of 1×10^{-4} to 1×10^{-6} or FC IV (improbable) from Table 3.14.2.1-3.

The spill mitigated accident consequences were shown to be much less than the MID at all distances from the point of release, indicating a mitigated consequence severity category of C for the worker (lost time injury or exposure – no health effects due to proper PPE use) and D for the public/environment (negligible off-site consequences much less than infectious dose).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC IV and consequence severity of D/C (public/worker) and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.1-3).

Table 3.14.3.1-3 — Risk Rank Summary - Spill Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for HEPAs, maintenance, or procedures)	1	FC II (1×10^{-2} to 1×10^{0}) Occasional	A/B (Public/Worker) Exceeds the MID
Mitigated (Active/Passive ventilation, procedures, maintenance)	4	FC IV (1×10^{-4} to 1×10^{-6}) Improbable	D/C (Public/Worker) Negligible off-site consequences

The remaining operational accidents are briefly discussed below.

Operational Accident 2 –LAI

This scenario considers a type of release that is only a local accident where a laboratory worker through a variety of personnel errors results in an autoinoculation, ingestion, or contamination event. This scenario specifically addresses the potential for and the consequences associated with an LAI. In spite of the programs that are expected to be in place to identify and mitigate the effects and consequences of LAI, these do not explicitly prevent accident occurrence.

Several types of errors can lead to a LAI and include use of equipment that was not properly disinfected and failure to follow essential procedures for the use of equipment and disinfecting equipment. In addition, there is the potential for human error that leads to a cut or puncture, the splashing of pathogen-containing solutions into mucous membranes, or the inadvertent contamination incident. The failure to wear proper PPE is also a significant contributor to the occurrence of a LAI. The bounding scenario is taken to be an LAI as a result of personnel error as the initiating event. Mechanical failures can also lead to LAIs; however, the spill accident scenario bounds these events.

Based on mission of the NBAF, it is considered a given that laboratory workers will be in contact with sufficient numbers of viable pathogens (virions of RVFV) that an infection could result from an exposure. For this particular accident scenario, the form of the pathogen is less significant than the exposure pathway and the occurrence of the LAI itself. This accident scenario is essentially only applicable to RVFV and Nipah virus. FMDV is not considered to be available as a LAI, and humans are not considered susceptible to the disease. While humans can be infected with the Nipah virus, there are no documented cases of acquiring the disease through a LAI.

Unmitigated Off-Site Consequences – The exposure to the laboratory worker results in an infection or an LAI with the potential for subsequent infections resulting from vehicles and vectors. This accident scenario is essentially only applicable to RVFV. FMDV is not considered to be available as a LAI, and humans are not considered susceptible to the disease. While humans can be infected with the Nipah virus, there are no documented cases of acquiring the disease through a LAI.

Mitigated Consequences – There are no off-site consequences (no public exposure) associated with this mitigated accident scenario. The potential subsequent infections are also considered to be negligible, unless the mitigation controls fail or are ignored (another procedural violation by the worker). The mitigation controls that need to work include recognizing and reporting the event, followed by prompt medical attention to prevent infection and subsequent public contact. In addition, proper procedures, PPE, and attention to disinfection and decontamination of equipment provide a significant barrier against this accident.

Risk Ranking

Based on the evaluation of the likelihood and the consequences associated with this accident, the following risk ranks were assigned for the unmitigated and mitigated accident scenarios.

Unmitigated Risk Rank

FC I (frequent)
Worker Consequence Category of B (long-term health effects)
Risk Rank=1 (safety controls are required to prevent or mitigate the accident)

After considering the safety controls in the context of the LAI accident, the mitigated risk rank is assigned. Determining the mitigated consequences depends on whether the accident is prevented or not. If the accident is prevented through the proper use of PPE and other systems, then the LAI does not occur and there are no consequences. Should the accident occur, but with lower frequency, the consequences are essentially unchanged and the LAI occurs.

Mitigated Risk Rank

FC III (probable) is unlikely but possible to occur during the life of the facility
Worker Consequence Category of E (no measurable consequences; LAI is prevented)
Risk Rank=4 (no additional safety controls are required to prevent or mitigate the accident)

Using Table 3.14.2.1-4, the combination of the accident likelihood and consequence severity and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.1-4).

Table 3.14.3.1-4 — Risk Rank Summary – LAI Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for PPE, maintenance, or procedures)	1	FC I ($\geq 1 \times 10^0$) Frequent	B (Worker) LAI long-term health effects
Mitigated (PPE, procedures, maintenance)	4	FC III (1×10^{-2} to 1×10^{-4}) Probable	E (Worker) No Measurable consequences

Operational Accident 3 – Loss of Infected Animal/Insect

This scenario considers the release of pathogens resulting from a loss of biocontainment any of the BSL-3 or BSL-4 facilities or an insectary. This includes potential hosts from the outside environment accessing the BSL-3 or BSL-4 facilities, becoming infected, and returning to the outside environment. This accident was selected for analysis because of the hazard associated with loss of biocontainment as evaluated in the hazards analysis. In addition, this type of loss of biocontainment can have a unique impact on the surrounding ecosystem. The potential for viral pathogens such as RVFV and FMDV to become established in the environment has far reaching consequences. The release of a pathogen as a result of loss of biocontainment of a vector is a credible scenario and appropriate for detailed analysis.

A loss of biocontainment or biocontainment of an animal can occur as a result of inattentive laboratory workers coupled with a series of mechanical failures including isolation doors, interlocks, alarms, and detection devices. In this accident scenario, it is assumed that an infected animal contains sufficient viable pathogens to be considered as a source of infection in the environment. The bounding scenario is taken to be a loss of biocontainment of an infected animal and subsequent release of this animal to the environment outside of the NBAF.

The infected animal can contain an inventory of approximately 1×10^{10} viable virions (e.g., viable FMDV pathogens are found in blood, saliva, and respired air of an infected cow, in large quantities). Should an infected animal get out of the NBAF undetected, the animal could act as a reservoir for a specific pathogen for a long period of time. The animal would in effect be a source for an atmospheric transport pathway. This mechanism would not necessarily be credible for all pathogens. Because the source of pathogens is inside the infected animal, the unmitigated respirable source term from this accident is related to animal respiration rate and other factors (external contamination, breathing, perspiration, sneezing, drooling, waste excretion, etc.). The ability for the released animal to act as a source is related to the time the animal is in the environment.

Unmitigated Risk Rank

For the unmitigated accident conditions, it is assumed that more than sufficient viral pathogens could be released for transport down-wind as an aerosol. Accident consequences are described on a site-specific basis in Section 3.14.4. Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC II. Public/Environment Consequence Category A (high likelihood for environmental life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=1 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC III (probable) is unlikely but possible to occur during the life of the facility. Worker Consequences Category C (lost time injury or exposure – no health effects due to proper PPE use). Public/Environment Consequence Category D (negligible off-site consequences much less than infectious dose). Risk rank=3 (consider additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC III and consequence severity of D/C (public/worker) and the assigned risk rank is 3, which indicates that the risk is borderline and additional considerations of safety controls considered is recommended to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.1-5).

Table 3.14.3.1-5 — Risk Rank Summary – Animal Release Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for biocontainment, monitoring, or procedures)	1	FC II (1×10^{-2} to 1×10^{0}) Occasional	A (Public) Exceeds the MID potential to spread disease
Mitigated (Biocontainment, procedures, monitoring, response)	3	FC III (1×10^{-2} to 1×10^{-4}) Probable	D/C (Public/Worker) Negligible off-site consequences

Operational Accident 4 – Release of Contaminated Wastes

This scenario considers the release of pathogens caused by improper sterilization or disinfection of solid or liquid waste with the end result of pathogens released to the environment. The pathways of concern are for vehicle-borne and water-borne transmission of viable biological agents. Because the viral agents considered in this hazard and accident analyses include those pathogens, which are resistant to environmental factors for extended periods of time, these two pathways are particularly significant. The hazards evaluation identified a number of scenarios for which incomplete or inadequate sterilization could result in high consequences to receptors outside of the NBAF.

The release of biological materials that are incompletely sterilized can occur for a variety of reasons. The equipment used to perform disinfections or sterilization fail to function properly and monitors and testing are not performed, or are not adequate, prior to release to sanitary or other waste handling units. The time period for sterilization is too short as a result of human error or equipment malfunction. There could also be leaks in systems designed to contain the infectious materials. Degraded containers, mechanical systems, and facility structures (piping and drains, etc.) or any combination could all lead to a release of infectious biological materials.

Several different types of accidents involving liquid or solid waste materials containing viable pathogens could occur as they are handled or processed that include the following:

- Inappropriate disposal of biological materials;
- Failure to completely sterilize the biological materials prior to disposition; and
- Systems designed to handle infectious wastes malfunction.

Several decontamination and sterilization technologies were initially reviewed in the NBAF Feasibility Study including chemical, incineration, rendering, autoclave, and digestion. The bounding scenario is taken to be a release of post-sterilized solid or liquid waste containing significant quantities of viable pathogens into either the commercial solid or liquid waste handling systems.

The biological material (MAR) considered in this accident scenario was on the order of 1×10^{9} virions with a release fraction of 1×10^{-4} for an unmitigated source term of 1×10^{5} virions released from the facility.

Unmitigated Risk Rank

For the unmitigated accident conditions, it is assumed that more than sufficient viral pathogens could be released for transport in the environment, even though the release would be localized, as was the recent case in England with FMDV (England 2007). Accident consequences are described on a site-specific basis in Section 3.14.4.

Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC II.

Public/Environment Consequence Category A (high likelihood for environmental life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=1 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC III (probable) is unlikely but possible to occur during the life of the facility. Worker Consequences Category C (lost time injury or exposure – no health effects due to proper PPE use) and Public/Environment Consequence Category D (negligible off-site consequences much less than infectious dose). Risk rank=3 (consider additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC III and consequence severity of D/C (public/worker) and the assigned risk rank is 3, which indicates that the risk is borderline and additional considerations of safety controls considered is recommended to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.1-6).

Table 3.14.3.1-6 — Risk Rank Summary – Waste Release Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for HEPAs, maintenance, or procedures)	1	FC II (1×10^{-2} to 1×10^{0}) Occasional	A (Public) Exceeds the MID potential to spread disease
Mitigated (Active/Passive ventilation, procedures, maintenance)	3	FC III (1×10^{-4} to 1×10^{-6}) Probable	D/C (Public) Negligible off-site consequences

<u>Operational Accident 5 – Large Room or Facility Fire</u>

Fires in the NBAF were evaluated in the hazards analysis and were found to result in significant consequences to both the laboratory workers (involved and non-involved) and the public. In addition, a subsequent release of pathogens would also pose a significant risk to the environment.

Facility-wide or room fires can result from mechanical failures, flammable materials, and as a result of exothermic reactions. Because the initial hazards identification identified one or more specific fire initiators, this fire accident analysis was developed to reasonably bound the potential consequences associated with this hazard. The accident scenario involves a series of individual and separate events that ultimately lead to the potential for release of one or more pathogens. The events include both human error (e.g., failure to follow procedures, mixing incompatible chemicals, etc.) and mechanical failures (e.g., fire detection and alarm system failure, failure of fire protection system, etc.) that could ultimately lead to the release of pathogens. It is noted that in areas where the heat is significant (increased temperatures can result in destroying significant quantities pathogens), there is a potential for reducing the total source term that is released.

Operations and processes that may be encountered in the NBAF could include the use of volatile or flammable chemicals, as well as energy sources, along with sufficient combustible materials being co-located such that a resulting fire is not precluded from consideration. The assumed accident progression begins when a laboratory worker engaged in cleaning, processing, or other types of activities is found in a situation where there is a combination of fuel, heat, ignition source, and oxygen. This situation can occur inside a BSC, in a laboratory room, or any location in the NBAF. Once a fire is initiated in a location within the NBAF, a number of events must occur for the fire to become sufficiently large that spreading to other areas is possible.

The biological material (MAR) considered in this accident scenario was estimated to be on the order of 1×10^{13} virions considering multiple laboratory areas with maximum volumes of viable pathogens. The single maximum volume considered is the 30 l cGMP. Assuming that many of the pathogens are destroyed in the fire and a release fraction of 1×10^{-2}, the unmitigated source term is estimated at 1×10^{9} virions released from the facility.

Unmitigated Risk Rank

For the unmitigated accident conditions, it is assumed that more than sufficient viral pathogens could be released for transport in the environment. Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC III (probable). Public/Environment and Worker Consequence Category A (high likelihood for life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=2 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC IV (improbable) is unlikely to occur during the life of the facility. Worker Consequences Category C (lost time injury or exposure – no health effects due to proper PPE use). Public/Environment Consequence Category D (negligible off-site consequences much less than infectious dose). Risk rank=4 (no additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC IV and consequence severity of D/C (public/worker) and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table Table 3.14.3.1-7).

Table 3.14.3.1-7 — Risk Rank Summary – Large Fire Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for fire suppression, ventilation, HEPAs, maintenance, or procedures)	2	FC III (1×10^{-2} to 1×10^{-4}) Probable	A/A (Public/Worker) Exceeds the MID
Mitigated (Active/passive ventilation, fire suppression)	4	FC IV (1×10^{-4} to 1×10^{-6}) Improbable	D/C (Public/Worker) Negligible off-site consequences

Operational Accident 6 – Over-Pressure Event from a Deflagration

Operations and processes that may be encountered in the NBAF could include the use of chemicals (gas or liquid) that are volatile or flammable. The NBAF feasibility study indicates that natural gas is supplied to the facility for use in laboratory rooms. In addition, the disinfectant gases formaldehyde and ethylene oxide are also flammable and are potential agents for use in large-volume disinfection operations in the NBAF. Because of the potential for flammable or combustible chemicals and natural gas to be routinely used in the facility, an accident scenario involving a deflagration was postulated.

The assumed accident progression begins when a laboratory worker is engaged in cleaning, processing, or another type of activity that requires natural gas or a flammable chemical. A situation develops where there is a buildup of gas inside a BSC or another enclosed area that reaches the lower flammable limit (LFL). During normal operations, this is considered an improbable event but is evaluated here for completeness.

The free volume of a BSC is approximately 4,700 l, thereby providing a sufficiently small confined space to support reaching the LFL. This means a flammable mixture in the BSC is possible and must be controlled. For purposes of scenario development, the existence of a heat or ignition source is also assumed. For purposes of evaluating the worst-case potential release that could affect the public, it is further assumed that a deflagration occurs. Because the specific chemicals are not identified, the deflagration is the result of the buildup of natural gas (recognizing that natural gas is not piped to the BSCs).

The most significant aspect of the deflagration is the resultant pressure wave, which could provide sufficient energy to breach the BSC and release biological materials in aerosol form. This scenario also assumes that approximately 10% of the viable pathogens survive the deflagration and are released.

The biological material (MAR) considered in this accident scenario was on the order of 3×10^{12} virions considering a single laboratory area with maximum volumes of viable pathogens. The single maximum volume considered is the 30 l cGMP. Assuming many of the pathogens are destroyed in the fire and a release fraction of 1×10^{-1} the unmitigated source term is estimated at 3×10^{10} virions released from the facility.

Unmitigated Risk Rank

For the unmitigated accident conditions, it is assumed that more than sufficient viral pathogens could be released for transport in the environment. Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC III (probable). Public/Environment and Worker Consequence Category A (high likelihood for life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=2 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC IV (improbable) is unlikely to occur during the life of the facility. Worker Consequences Category C (lost time injury or exposure – no health effects due to proper PPE use). Public/Environment Consequence Category D (negligible off-site consequences much less than infectious dose). Risk rank=4 (no additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC IV and consequence severity of D/C (public/worker) and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.1-8).

Table 3.14.3.1-8 — Risk Rank Summary – Large Fire Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for fire suppression, ventilation, HEPAs, maintenance, or procedures)	2	FC III (1×10^{-2} to 1×10^{-4}) Probable	A/A (Public/Worker) Exceeds the MID
Mitigated (Active/passive ventilation, fire suppression)	4	FC IV (1×10^{-4} to 1×10^{-6}) Improbable	D/C (Public/Worker) Negligible off-site consequences

3.14.3.2 Natural Phenomena Accidents

This section addresses accident scenarios associated with weather-related initiating events such as floods, high winds, lightning, earthquakes, tornadoes, and hurricanes. For the purposes of this accident analysis, the effects from natural phenomena events are combined into a single bounding analysis. The current design of the NBAF defines the seismic capacity of the facility to meet a 0.19-g seismic event and a 90-mph wind. The Basic Wind Speed denoted in the Structural Basis of Design is a code-specified reference wind speed index. It is based on 3-second wind gusts measured at a height of 33 feet above grade as recorded at airports. While wind speeds are expected to vary over time, larger magnitude wind speeds occur much less often than lesser wind speeds. The Basic Wind Speed as noted in the NDP reports is expected to occur on the average of only once over a fifty-year period. However, because of code specified building importance modification factors and normal factors of safety incorporated into the structural design, the facility will withstand wind pressures of 170% of the code specified 50-year wind pressures. The building's structural system will actually be capable of resisting a wind speed that is expected to occur only once over a 500 year period. Incorporation of the importance modification factors, for containment of the pathogens, the design basis wind speed for the NBAF would be increased from 90 mph to 119 mph for all sites except Plum Island where the design basis wind speed would increase from 120 mph to 156 mph thereby reducing the likelihood as well as the consequences associated with a severe wind event. The proposed NBAF sites show a relatively low probability of a significant seismic event with a return period on the order of 50 years based on the 2008 USGS National Seismic Hazard Maps. These maps illustrate the seismic hazards consistent with commercial building codes. Executive Order 12699, "Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction" January 5, 1990, required all new federal facilities to be designed to ensure safety of the public (DOE 1996; DOE 2000; Executive Order 12699).

> "…Section 1. Requirements for Earthquake Safety of New Federal Buildings.
> The purposes of these requirements are to reduce risks to the lives of occupants of buildings owned by the Federal Government and to persons who would be affected by the failures of Federal buildings in earthquakes, to improve the capability of essential Federal buildings to function during or after an earthquake, and to reduce earthquake losses of public buildings, all in a cost-effective manner. A building means any structure, fully or partially enclosed, used or intended for sheltering persons or property.
>
> Each Federal agency responsible for the design and construction of each new Federal building shall ensure that the building is designed and constructed in accord with appropriate seismic design and construction standards. This requirement pertains to all building projects for which development of detailed plans and specifications initiated subsequent to the issuance of the order. Seismic design and construction standards shall be adopted for agency use in accord with sections 3(a) and 4(a) of this order…"

Design and evaluation criteria for of essential facilities (e.g., hospitals, fire and police stations, centers for emergency operations) are considered as Seismic Use Group III of IBC 2000. Critical safety controls or barriers are those for which failure to perform their intended safety function poses a significant potential hazard to public health, safety, and the environment because biological materials are present and could be released from the facility as a result of that failure. In the case of the NBAF, the critical safety equipment is required to prevent or mitigate events with the potential to release significant quantities of viral pathogens outside the facility. Design considerations for these critical safety barriers are to limit facility damage as a result of design basis natural phenomena events so that hazardous materials can be controlled and confined, occupants are protected, and the functioning of the facility is not interrupted. Because the safety analyses determined that high-biocontainment biological materials are required for worker safety, a higher design requirement designation is appropriate for the safety equipment necessary to prevent a release. Given the risks posed by the potential seismic and other natural phenomena, accident provisions for design consideration of the facility structure and critical safety equipment should be consistent with those used for facilities designed to standards above that for the model building code requirements for essential facilities (DOE 2000; DOE 1996).

In addition, all of the proposed NBAF sites are located within regions that experience severe weather where wind speeds could exceed the 90-mph criteria specified in the Feasibility Study for the NBAF. Tornado and hurricane events are a significant potential at the proposed sites and can occur with wind speeds in excess of 150 mph (Pasquill 1983; Panofsky 1984).

In addition, other natural phenomena events have a significant potential for adversely impacting the NBAF and operations. These include lightning strikes that can result in facility fires (previously analyzed) or widespread equipment failures including loss of the active biocontainment systems. Floods also have the potential to adversely impact the operations of the NBAF. A significant flood could produce a loss of power and result in floodwater infiltration of waste biocontainment systems, subsequently releasing pathogens to the environment.

For the purposes of this accident analysis, the seismic event was considered as the potentially bounding natural phenomena accident because the dispersion and dilution of pathogens would be much greater in a high-wind event, and floods, while a potential threat, would likely result in localized consequences. Additional details for all of the NPH accidents are provided in Appendix E.

The high-wind and seismic event accident analysis was developed without considering a subsequent fire in the NBAF. Facility fire was previously evaluated both in the hazards analysis and as an accident and was determined to result in significant consequences to the laboratory workers (involved and non-involved), as well as the public and the environment.

The central difference between the natural phenomena events and other accidents is that the natural phenomena events have a greater potential to impact the entire facility. Internally initiated fires require time and combustible materials to grow to a facility-wide event. A storm (tornado, hurricane, or high straight line winds) and a seismic event will act on the entire facility simultaneously. Because of the extent of the impact, the amount of infectious biological material (and chemicals or radioactive substances) available for release is greater.

The assumed accident progression begins when the NBAF experiences a significant natural phenomena event. In the situation of a major storm, there is the potential that actions can be taken in advance to containerize infectious materials prior to the storm occurring. This is not possible with a seismic event where there is no warning system available. For purposes of estimating potential consequences, either event is conservatively assumed to occur when the facility is in normal operational mode.

The biological material (MAR) considered in this accident scenario was on the order of 1×10^{15} virions considering the entire NBAF is at risk with maximum volumes of viable pathogens in all available areas. The single maximum volume considered is the 30 l cGMP. The release fraction is taken to be 1×10^{-1} and the the unmitigated source term estimated at 1×10^{11} virions released from the facility.

Unmitigated Risk Rank

For the unmitigated accident conditions, it is assumed that more than sufficient viral pathogens could be released for transport in the environment. Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC IV (improbable). Public/Environment Consequence Category A (high likelihood for environmental life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=2 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC V (remote) should not occur during the life of the facility. Worker Consequences Category D (lost time injury or exposure – no health effects due to proper PPE use). Public/Environment Consequence Category E (negligible off-site consequences much less than infectious dose). Risk rank=4 (no additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC IV and consequence severity of D/C (public/worker) and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.2-1).

Table 3.14.3.2-1 — Risk Rank Summary – NPH Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for NBAF structure, ventilation HEPAs)	2	FC IV (1×10^{-4} to 1×10^{-6}) Improbable	A/A (Public/Worker) Exceeds the MID
Mitigated (NBAF structure, ventilation HEPAs)	4	FC V ($\leq 1\times10^{-6}$) Remote	E/D (Public/Worker) Negligible off-site consequences

3.14.3.3 External Events

This section addresses all man-made external events such as aircraft crash, transportation events (affecting the facility), loss of power, etc. The aircraft crash into the NBAF or the external fuel storage (diesel, fuel oil, or gasoline) resulting in an explosion and fire is considered the bounding external event. This accident is expected to cause loss of facility biocontainment with a subsequent release of viral pathogens into the environment.

The details of the aircraft crash accident including an estimate of the likelihood are provided in Appendix E. Even though it is unlikely that an aircraft crash in the external fuel storage (diesel, fuel or oil) will explode, the unmitigated consequences and risks were postulated to evaluate the potential for a large quantity of virions to be released. The more likely scenario is an aircraft crash into the structure resulting in a large amount of energy being imparted to equipment or storage inside of the facility. The consequence analysis considered in this scenario was formulated to evaluate the largest potential release to evaluate the value of the NBAF structure as a barrier to a release of pathogens.

The likelihood of an accidental aircraft crash into the facility is dependent on the size of the aircraft, whether it is fixed-wing or rotary, the proximity to an airport (commercial or general aviation), and the design of the facility. The design of the facility is important with respect to area and height. In general, the probability of impact from a small, general aviation aircraft is greater than that of commercial airliner; however, the damage potential is greater for the commercial aircraft. The highest probability of accidental aircraft crashes occurs on take-off and landing when the aircraft are moving slower and are at lower altitudes. The proximity of the proposed NBAF to airports was evaluated for each of the proposed locations based on the available site-specific data and on the conceptual design of the NBAF (DOE 2006a). These results are to be provided in Appendix E.

A penetration of the NBAF with sufficient force to result in a release of pathogens was considered the most credible unmitigated accident scenario. Based on the preliminary wind-load design specification for the NBAF, a simple energy balance was derived between a wind speed greater than 90 mph and a small aircraft engine and drive shaft assembly traveling with a velocity of 100 knots. Based on the energy balance, it is credible that the aircraft would penetrate the facility, likely resulting in a release of pathogens to the environment.

For the situation where the proposed external fuel storage (diesel, fuel oil, or gasoline) explodes or is involved in a large fire and causes the loss of facility biocontainment with a subsequent release of pathogens to the environment, the critical determination was whether there was sufficient energy available to fail the NBAF structure. Based on the proposed proximity of the fuel storage facility to the NBAF and the quantity of fuel expected to be available, there is reason to suspect that a fire (and less likely an explosion), whether accidental or intentional, could catastrophically fail the NBAF biocontainment capabilities and result in a release of pathogens to the environment.

The biological material (MAR) considered in this accident scenario was on the order of 3×10^{12} virions considering the entire NBAF is at risk with maximum volumes of viable pathogens in the area struck by the aircraft. The single maximum volume considered is the 30 L cGMP. The release fraction is taken to be approximately 1×10^{-4} to account for pathogen survival and release fraction. The unmitigated source term is estimated at 3×10^{8} virions released from the facility.

Unmitigated Risk Rank

For the unmitigated accident conditions. it is assumed that more than sufficient viral pathogens could be released for transport in the environment. Based on the overall accident scenario and the various sequences, the unmitigated frequency for this accident is assigned a FC IV (improbable). Public/Environment Consequence Category A (high likelihood for environmental life-threatening effects) off-site consequences are much greater than minimum infectious dose. Risk rank=2 (additional safety controls required to prevent or mitigate the accident).

Mitigated Risk Rank

FC V (remote) should not occur during the life of the facility. Worker Consequences Category D (lost time injury or exposure – no health effects due to proper PPE use). Public/Environment Consequence Category E (negligible off-site consequences much less than infectious dose). Risk rank=4 (no additional safety controls to prevent or mitigate the accident).

Using Table 3.14.2.1-4, the combination of the accident likelihood of FC IV and consequence severity of D/C (public/worker) and the assigned risk rank is 4, which indicates that the robust safety controls considered are sufficient to prevent or mitigate the accident and greatly reduce the risk. The overall risk summary is presented in the following table (Table 3.14.3.3-1).

Table 3.14.3.3-1 — Risk Rank Summary – Spill Accident

Scenario	Risk Rank	Accident Frequency	Consequence Severity
Unmitigated (No credit for NBAF structure, ventilation HEPAs)	2	FC IV (1×10^{-4} to 1×10^{-6}) *Improbable*	A/A (Public/Worker) Exceeds the MID
Mitigated (NBAF structure, ventilation HEPAs)	4	FC V ($\leq 1 \times 10^{-6}$) Remote	E/D (Public/Worker) Negligible off-site consequences

3.14.3.4 Intentional Acts and the Threat Risk Assessment (TRA)

The Threat and Risk Assessment (TRA) was developed outside of the EIS process in accordance with the requirements stipulated in federal regulations. The purpose of the TRA was to identify potential vulnerabilities and weaknesses associated with the NBAF and are used to recommend the most prudent measures to establish a reasonable level of risk for the security of operations of the NBAF and public safety. Because of the importance of the NBAF mission and the associated work with potential high-biocontainment biological pathogens, critical information related to the potential for adverse consequences as a result of intentional acts was also necessary to be incorporated into the NEPA process.

TRA was developed in accordance with federal regulations as specified in Title 9—Animals and Animal Products, Chapter I - Animal and Plant Health Inspection Service, Department of Agriculture, Part 121 - Possession, Use, and Transfer of Select Agents and Toxins, §121.11 Security—which states

> "…(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.
>
> (b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request…
>
> …(e) In developing a security plan, an individual or entity should consider the document entitled, ''Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents,' in Morbidity and Mortality Weekly Report (December 6, 2002); 51 (No. RR–19):1–6.

The referenced section of *Morbidity and Mortality Weekly Report* (December 6, 2002) 51 (No. RR–19):1–6, "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents," provides additional guidance for performing the risk assessment. While the TRA cannot be specifically incorporated for obvious security reasons, the essential results are provided in this section to address the risk associated with intentional acts. Specifically, security considerations for microbiological and biomedical facilities guidance and analysis were performed as part of the Threat Assessment, which is comprised of three major types or groupings of threats to a biotech or biomedical facility.

- Criminal activity by animal/environmental rights activists;
- Intellectual property compromise by competitive intelligence agents; and
- Bioterrorists or criminals attempting to obtain biological pathogens for inappropriate use.

The threat assessment combines information from the analysis of assets, threats, and vulnerabilities to determine the level of risk posed by operating the NBAF.

Because the NBAF could ultimately be located at any of the six sites, the TRA focused on the major types of threats, their credibility, and likelihood to a high-consequence biotech/biomedical facility or institute. In addition, the TRA evaluated specifically those elements that are essential in developing a robust security plan. The applicable federal regulations established those elements as

1. The sufficiency to safeguard the select agent or toxin against unauthorized access, theft, loss, or release; and
2. A site-specific risk assessment to provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.

The adversaries identified in the TRA included the following:

- Criminal activity by animal/environmental rights activists and referred to as extremists or psychopaths;
- Intellectual property compromise by competitive intelligence agents and referred to as terrorists, which includes foreign intelligence services, corporate espionage, and terrorist organizations;
- Bioterrorists or criminals attempting to obtain biological pathogens for inappropriate use; and
- Employees who are compromised or disgruntled and are known to pose a potential risk to the facility through disruption to the operations and mission or personnel injury and death.

Each of these threats (or adversaries) was evaluated in detail in the TRA. In addition to the types of threats, the scope of the TRA also included analysis of the physical and operational vulnerability of the NBAF to these threats. Recommendations were evaluated and provided to effectively mitigate the resultant risks from the identified threats. The scope of the TRA for the NBAF therefore included evaluation of the threats, analysis of the vulnerabilities (both on the conceptual NBAF and for each proposed site), and the identification and evaluation of mitigation measures necessary to reduce the risks to acceptable levels.

The TRA specifically analyzed and presented the risks and effective mitigation strategies for ensuring secure operation of the NBAF. The following objectives were addressed in detail as part of the TRA:

- Identification and evaluation of threats;
- Determining their likelihood in relation to the NBAF;
- Identification of the critical assets associated with the NBAF;
- Assessing the potential consequences associated with the impact or loss of identified NBAF assets;
- Quantifying the vulnerability of the physical and operational security of the proposed NBAF;
- Calculating the cumulative risks associated with the threats and consequences with respect to each proposed NBAF site; and
- Providing effective mitigation measures to ensure secure operations against the identified threats.

A discussion of the threat and risk assessment methodology is presented in terms of the critical components including

- Vulnerability Assessments
- Operational Risk Assessments
- Targeting Evaluations

An essential element of identifying and evaluating the potential threats is a thorough knowledge of potential adversaries, including their motivations, capabilities, and activities. As part of the TRA analysis, critical adversary data were obtained from three separate threat intelligence–gathering tasks. The collection of information necessary to identify credible threats and assess their activities was based on different threat levels and intelligence. Information was obtained from 1) statistics related to crimes against persons and property; 2) regional, national, and international intelligence gathering related to a wide variety of threats; and 3) information gained from site-specific security perspectives.

Threats, which are also commonly referred to as adversaries, were separated into specific categories (i.e., insiders and outsiders) based on the federal regulations and associated guidance. Each of the threat categories also includes analysis of the adversaries' tactics, skills, and capabilities. The objectives associated with each threat category from simple theft to potential for total destruction of the NBAF and contamination or infection of nearby animal populations.

The methodology used to analyze the targets of the identified threats and the results of this analysis was the CARVER method, which focuses on six key factors (Criticality, Accessibility, Recoverability, Vulnerability, Effect, and Recognizability) that are necessary to quantify a specific targets' likelihood of being attacked by a specific adversary. The CARVER method provided the means for calculating the probability of attack, which is a fundamental part of the risk equation.

The physical and operational security aspects of a baseline case were evaluated for the purpose of identifying vulnerabilities of the NBAF. The analysis specifically addressed security elements such as sensing, assessment, and response (referred to as SAR, comparable to the terms deterrence, detection, delay, and response used in other vulnerability assessment methodologies) and other aspects of a particular adversary attack.

Numerous threat and consequence scenarios were developed and analyzed to assess the vulnerabilities of the proposed NBAF against the range of adversaries identified as potentially credible threats. The results of the analysis of the threat and consequences scenarios were factored into a series of recommended mitigation measures to the NBAF physical and operational security elements to effectively mitigate the risks. Specific aspects addressed the evaluation of controls including security design elements, building and perimeter security measures, and operational security aspects necessary to respond to the identified threats.

Risk Evaluations and Analysis

Risk evaluation and analysis is dependent on the collection of information necessary to quantify the basic components of the generalized risk equation. Because each of the terms in the risk equation are in part dependent on the identification of specific assets and their assigned value, it is imperative that the assets and priorities are clearly defined. In addition, the risk equation is dependent on a wide array of potential threats or adversaries. Collection of detailed information was necessary to identify various adversaries and assess their specific capabilities necessary to compromise security systems in a particular attack. The modeling of the security system in terms of operational and physical elements was used to simulate the vulnerability for a specified threat, target, and effect. The security system model provides for the quantification of vulnerability in terms that can be coupled to the "Threat" and "Target" functions.

Assets and Priorities

Assets and priorities were identified based on the types of consequences or on the overall impact from their loss. For the purposes of the NBAF and the identified regulatory framework for developing the TRA, the critical assets identified include

- Select agents or pathogens;
- Animals;
- Sensitive or critical research conducted in the NBAF;
- Personnel, laboratory workers, and researchers;
- Technology and related foundation of the NBAF mission; and
- The structures, systems, and components relied upon to maintain biocontainment of biological materials or sensitive information.

The effect or impact associated with the loss of each of these assets differs somewhat depending on a specific adversary's motives or intent. For example, the effect or impact associated with the theft of a select agent or pathogen by a terrorist could be to cause widespread harm to people or the environment, while the effect resulting from a criminal theft may be the loss of mission or the subsequent impact from a release of the pathogen. In a separate example, the loss of sensitive information or technology could have immediate and direct impacts on the safety and health of the public resulting from transfer of the technology by terrorists, or the impact could be the loss of mission and compromise of national security. Each of these impacts or consequences is associated with different motives and different threats. The TRA comprised a wide array of threat-consequence scenarios to address the different threats, assets, and consequences.

Types of Risks

Because of the differences among the various threats, assets, and consequences, the types of risks are inherently different. TRA recognized three different categories of risk.

1. Health, Safety, and Environmental – These are risks associated with the impacts or effects related to the direct and indirect health and safety of workers, the public, and the environment resultant from the intentional release of select agents or pathogens from the NBAF;
2. Loss of Mission – These are risks associated with the impacts from the direct and indirect disruption or loss of mission of the NBAF; and
3. Loss of Sensitive Information and Technology – These are the impacts or effects related to the loss of sensitive information or technology developed or retained in the NBAF.

The threat-consequence scenarios were developed to address each of these types of risks. The quantification of the risks was based on methods and techniques that allowed for direct comparison across different risks. The calculation of the risks could then be ranked to determine those security measures that achieved the most effective mitigation or prevention.

The quantification of the threat variable in the risk equation provides a measure of the significance of a specified adversary and the value of the asset being targeted. Using this method for quantifying the risks affords decision makers the opportunity to discriminate across adversaries and assets in determining what level of security is necessary to reduce the risks.

The threats were separated into two potential adversary groups: insiders and outsiders. Risk estimation was then be used to develop mitigation controls to address both of these groups. Preventative measures address the frequency component of risk (i.e., how often will an undesirable event occur), while mitigation controls affect the potential consequences (i.e., how bad will it be if it occurs).

Internal threats are addressed through mitigation measures that involve administrative controls such as

- Preemployment screening or Personnel Security Programs;
- Contractor screening and monitoring;
- Perimeter security procedures;
- Behavior observation programs;
- Inventory reduction; and
- Emergency response planning.

External threats most often involve mitigation measures that rely on engineered controls such as

- Inventory isolation and control;
- Relocation of storage;
- Obscuring storage;
- Improvements to physical perimeter systems (e.g., double fence line, lighting, motion sensor alarms, video cameras, Jersey barriers, etc.); and
- Preplanning/coordination with local emergency response agencies.

Security systems developed using the concept of "Rings of Protection" provide multiple barriers against intrusion. This is comparable to the Layers of Protection concept used in process safety management referred to as "defense in depth." An example of a Ring of Protection structure would likely include

Ring 1: Internal policies and practices;
Ring 2: Perimeter security systems and procedures;

Ring 3: Storage inventory management; and
Ring 4: Policing by on-site security and local authorities.

Vulnerability Assessments

To evaluate the vulnerability of a particular security system, it was necessary to characterize the features of the system in terms of barriers to the adversary coupled with the ability and timeliness of a potential response to interdict the adversary before an asset is compromised or lost. The description of the security system in these terms provides the framework for developing a threat-consequence scenario in separate components or event sequences.

A variety of deductive and inductive methods were employed to identify and evaluate specific vulnerabilities in the security systems represented by the baseline and upgraded NBAF models. These methods included classical "What-If?" analysis, failure modes and effects analysis, and a comprehensive hazards analysis. The deductive method chosen to estimate the overall vulnerability estimates included the use of event and fault trees. These techniques have been used successfully in the nuclear and chemical industry for both safety and security risk estimation for many years. These methods are described in detail in a variety of documents including: *Probabilistic Safety Assessment in the Chemical and Nuclear Industries,* the *NRC's NUREG-0492 Fault Tree Handbook,* and *Risk Analysis and the Security Survey.* Each of the documents presents variants of this approach used for calculating the risk associated with safety or security applications.

This technique used in this TRA for the quantification of the security system vulnerability relied upon a combination of event and fault trees, which are considered to be effective deductive tools for obtaining critical information about a system. The fault tree technique is a systematic method for acquiring information about a system, which is used in making critical decisions related to consequence mitigation and prevention. For the NBAF, risks are directly related to the vulnerability of the security systems to specific threats.

The vulnerability of the systems was evaluated based on a wide array of potential threat-consequence scenarios. In much the same way the hazard scenarios were developed for the accidents, these threat-consequence scenarios were screened to identify a select number of scenarios that were evaluated in detail to estimate the likelihood and the consequences for the baseline case and the upgraded NBAF conditions. This is similar in process to the unmitigated and mitigated analyses previously discussed. The specific scenarios evaluated would clearly identify specific vulnerabilities in the systems and are therefore not included in what can be presented as the following consequence categories:

- Agent Theft
- Intentional Release
- Information Security/Cyber Attack
- Sabotage/Physical Destruction
- Technology Transfer of Pathogen Information

For each of the consequence categories, the evaluation of risks and the associated identification of critical security features to mitigate the consequences or prevent the attack were incorporated into the TRA. The analysis, like that for the accidents, was comprehensive and bounding. The evaluation demonstrated that the risks from intentional acts could be reduced to very low levels with the identified security features.

Overall Summary of Risk Results

The results of the TRA provided threat/consequence information valuable in ranking of each of the six sites relative to one another. The details of what constituted vulnerability or the specific nature of an adversarial attack are not included in these results. A qualitative discussion of site differentiators is provided in the following paragraphs.

Taking into account the various attack vectors and security features that are specific to a specific region or area, a relative ranking system was developed. Because of factors such as proximity to transportation, demographics and transient populations, waterways, and access to roads, trains, and airports, differences in risk estimates arose when applied to a specific proposed NBAF site. The overall risks associated with intentional acts for any proposed NBAF site could be reduced by incorporating system recommendations. There is about a factor of 1.5 risk differential that separates any one NBAF site from another. This means that the highest risk site is only 50% greater risk than the lowest risk site. For purposes of comparison, the difference is the baseline risk and the NBAF risk incorporating security features was approximately a factor of 100 for the most sever threat/consequence scenarios. Taking into consideration the risk reduction against the facility-specific aspects, the differences in the proposed NBAF sites are relatively small.

3.14.4 Site-Specific Consequences

This section provides the summary of consequences from operations, accidents, and intentional acts for each of the proposed sites. Site-specific consequences are based on the estimates of pathogens released from the bounding accidents and the estimation of exposure as described in Section 3.14.3. The exposure to pathogens is based on the results of the transport of viral pathogens as aerosols after release and are calculated using the Gaussian Plume model. Tables 3.14.4-1 and 3.14.4-2 present summary results for several down-wind distances of the normalized air and ground concentrations. These results are multiplied by the estimated quantity of pathogens released in a specific accident to arrive at the estimated concentrations for each accident and site.

For each site, the normalized time-integrated air and ground concentrations are presented for both near- and far-field perspectives. The near-field presentation focuses on distances up to 1 kilometer (km) from the release. The results of the Gaussian Plume model for the 95% estimates of the air concentrations—for ground-level releases—tend to be greatest at distances close to the point of release. In addition, the ground deposition typically is greatest close to the release point. By focusing on distances less than 1 km from the release, an opportunity to discern subtle differences in the air and ground concentrations is provided. For small accidents (and mitigated large accidents), the majority of pathogens that would be released will be within this area. The initial response to an accident will also focus on the magnitude of the problem close to the source. The far-field perspective is provided for distances out to 10 km to illustrate the potential down-wind transport of pathogens in the unmitigated accidents.

The consideration of the use of flat terrain, no building wake, the same boundary layer height, a ground level release, and a single year of site-specific meteorological data for each of the sites resulted in the Kansas, Mississippi, Texas, and New York sites having the same 95% χ/Q values up to 10 km distances from the release. These results illustrate that there is little differentiation between any of the sites based purely on the meteorology. Site-specific consequences, however, consider the exposed populations of humans, animals, and the environment.

Table 3.14.4-1 — Unmitigated Site-Specific χ/Q Normalized Air Concentration Estimates

Radial Distance From Release Point (meters)	GA	KS	MS	NY	NC	TX
	χ/Q Normalized Air Concentration (s/m^3)					
50	9.34×10^{-2}	1.61×10^{-1}	1.61×10^{-1}	1.61×10^{-1}	8.11×10^{-2}	1.61×10^{-1}
200	9.00×10^{-3}	1.57×10^{-2}	1.57×10^{-2}	1.57×10^{-2}	7.80×10^{-3}	1.57×10^{-2}
600	1.66×10^{-3}	2.91×10^{-3}	2.91×10^{-3}	2.91×10^{-3}	1.44×10^{-3}	2.91×10^{-3}
1,000	7.69×10^{-4}	1.35×10^{-3}	1.35×10^{-3}	1.35×10^{-3}	6.66×10^{-4}	1.35×10^{-3}
6,000	1.43×10^{-5}	2.54×10^{-5}	9.08×10^{-5}	9.08×10^{-5}	1.46×10^{-5}	4.02×10^{-5}
10,000	7.56×10^{-6}	1.18×10^{-5}	1.55×10^{-5}	3.01×10^{-5}	5.44×10^{-6}	1.36×10^{-5}

Table 3.14.4-2 — Unmitigated Site-Specific Normalized Ground Concentration Estimates

Radial Distance From Release Point (meters)	GA	KS	MS	NY	NC	TX
	Normalized Ground Concentration (1/m^2)					
50	1.54×10^{-4}	1.59×10^{-4}	2.12×10^{-4}	2.38×10^{-4}	9.97×10^{-5}	1.64×10^{-4}
200	2.76×10^{-5}	1.92×10^{-5}	3.03×10^{-5}	3.19×10^{-5}	1.73×10^{-5}	1.98×10^{-5}
600	5.95×10^{-6}	3.16×10^{-6}	6.08×10^{-6}	6.95×10^{-6}	4.49×10^{-6}	3.86×10^{-6}
1,000	2.73×10^{-6}	1.93×10^{-6}	2.89×10^{-6}	3.00×10^{-6}	2.33×10^{-6}	2.05×10^{-6}
6,000	1.29×10^{-8}	1.66×10^{-8}	2.73×10^{-8}	3.14×10^{-8}	1.30×10^{-8}	2.27×10^{-8}
10,000	5.92×10^{-9}	8.22×10^{-9}	1.16×10^{-8}	1.91×10^{-8}	5.73×10^{-9}	1.01×10^{-8}

The resultant ground concentrations differ between each of the sites due to the different rainfall estimates, which influence the wet deposition rates.

A summary of the accidents is provided in Table 3.14.3-1 to present the scenario, the available biological material considered in the event for both the unmitigated and mitigated cases, along with a brief summary of the safety barriers and procedural controls relied upon to either mitigate or prevent a release.

For each of the accidents considered in this analysis, specific concentration terms were developed based on site-specific meteorological data obtained from the nearest measurement location. From these data, normalized concentration terms for the air and ground deposition were determined on a site-specific basis. Tables 3.14.4-3 and 3.14.4-4 present the air and ground concentrations for each site for the spill accident to illustrate the potential for infections to result down-wind of the NBAF. Since Nipah virus and RVFV are not considered to be any more infectious than FMDV, the minimum infectious dose of 10 virions also serves as a reasonably conservative estimate of the infectious dose for these viruses.

For a specific example, since the breathing rate for a cow is estimated to be on the order of 1.6×10^{-3} m^3/s and using the calculated air concentration for the Kansas site at a distance of 50 m for the spill event of 1.6×10^5 virions s/m^3,then the total exposure to the cow via inhalation is on the order of 2.6×10^2 (260) virions (50 m is the minimum calculated distance for the Gaussian Plume model). This exposure is approximately 25 times greater than the minimum infectious dose and therefore would represent a relatively high likelihood for the cow to acquire the disease via the inhalation of the virions in the air.

[*Note: The air concentration of 1.6×10^5 virions is the product of the χ/Q value from Table 3.14.4.3-1 for the Kansas site at 50 m (1.6×10^{-1} s/m^3) and the source term for the spill accident 1×10^6 virions released.*]

For calculation of the ground concentration and a resultant exposure, the results are not independent in time as were the χ/Q values. Therefore, to assess the potential risk to cattle grazing on grass where viral pathogens have been deposited, an estimate of the total time that the receptor is exposed is necessary. As a an example, if one were to assume that a cow eats nearly 100 pounds of feed per day (8 lb/hr assuming that cows eat 12 hours out of 24) and that the yield for typical pasture grass in on the order of approximately 3.5 pounds per square meter; then a cow would need to cover nearly 30 m^2 per day at a average rate of 2.5 m^2 per hour to meet the food intake of a 100 pounds.

Consider the unmitigated ground concentration for the Kansas site at a distance of 1 km for the seismic event (source term of 1×10^{11} virions) is 1.9×10^5 virions per m^2,, the exposure to a cow for a single day would be on the order of 5.7×10^6 virions or 5.7×10^5 (570,000) times greater than the infectious dose. It is unlikely that a release of this magnitude would go unnoticed or without intervening emergency response. Assuming that the grazing time is limited to a single hour, a reasonable time period before emergency plans could be implemented; the unmitigated exposure would not be reduced significantly.

[*Note: The ground concentration of 1.9×10^5 virions is the product of the "normalized ground concentration" value from Table 3.14.4.3-2 for the Kansas site at 1 km (1.9×10^{-6} 1/m^2) and the source term for the spill accident 1×10^{11} virions released.*]

Site-specific consequences are developed using the source terms provided from the accident analysis of Section 3.14.3 and are summarized in Table 3.14.3-1. The site-specific consequences are presented for both unmitigated, without the benefit of safety controls, and mitigated, taking credit for the safety controls that reduce quantity of pathogens released in an accident, consequences.

The determination of the consequences for all of the accidents is based on the specific hazards posed by FMDV, RVFV, and Nipah virus. FMDV has a known infectious dose, are highly infectious, and are transmitted mainly by aerosols and simple contact with fomites (contaminated materials, inanimate objects, clothing, veterinary equipment, vehicles, foodstuffs, manure, soil, and vegetation). Viruses are excreted from, and present in blood and body fluids, including respired air, saliva, vesicular fluids, and tissues of the vesicles, which are a hallmark of the infection, semen, vaginal fluids, urine, feces, meats, and milk. Infected animals can excrete high concentrations of virus in respired air, secretions, and fluids. For example, cattle may excrete up to 1.26×10^5 or 126,000 virions respired in a 24-hour period. Therefore, there are nearly 1×10^4 infectious doses of the FMDV respired from a single bovine animal per hour. Swine (pigs) have been measured at rates up to 3.9×10^8 virions/24 hours in expired air. Doses as low as 10 to 20 virions could infect a sheep and a steer, respectively (J.H. Sorensen, December 1999, "An integrated model to predict the atmospheric spread of foot-and-mouth disease virus," *Epidemiol Infect* 124:577-590, 2000). The minimum dose of natural aerosol to infect a pig has not been determined, but some observations suggest that it is probably much higher than that for other species (A. Donaldson, August 1999, "Airborne spread of foot-and-mouth disease," *Microbiology Today*, Vol. 26, p. 118-119). The Canadian Food Inspection Agency presents in the Pathogen Safety Data Sheet for Foot and Mouth Disease that as few as 10 infectious particles can produce disease. The minimum infectious dose for the Nipah and RVFV are not readily known and are, for the purposes of evaluating hazards and accidents, conservatively assumed to be the same as that for FMDV (10 infectious particles or virions) (CFIA 2005a; CFIA 2005b; CFIA 2005c; Goh KJ 2000; NEEG 2007).

Furthermore, based on mission objectives and regulatory requirements, an individual package containing biological materials may contain approximately 100 mL. Typical concentrations of viral pathogens are estimated based on a specific volume of culture medium. Culture media is used to grow and maintain cells at an appropriate temperature and gas mixture (typically, 37°C, 5% CO_2) in a cell incubator. Culture conditions vary widely for each cell type, and variation of conditions for a particular cell type can result in different phenotypes being expressed. Aside from temperature and gas mixture, the most commonly varied factor in culture systems is the growth medium. Recipes for growth media can vary in pH, glucose concentration, growth factors, and the presence of other nutrient components. The growth factors used to supplement media are often derived from animal blood, such as calf serum. Nearly all of the culture media are essentially in the form of liquids or gels.

For the purposes of the hazard and accident analysis, the concentration in a milliliter (1/1,000 of a liter or a cubic-centimeter) is taken to be approximately 1×10^8 viable virions. Therefore, there could be a total inventory of approximately 1×10^{11} viable virions per liter of media. The biological materials consist of various forms but are considered to aerosolize upon impact. Using these concentrations of virions in typical media and the numbers of virions respired from a typical infected cow, estimates for the site-specific consequences from the MAR for each accident were developed.

Table 3.14.4-3 — Unmitigated Site-Specific Air Concentration Estimates From a Spill Release of Aerosol Pathogen

Radial Distance From Release Point (meters)	GA	KS	MS	NY	NC	TX
	Air Concentration (virions s/m^3)					
50	9.3×10^4	1.6×10^5	1.6×10^5	1.6×10^5	8.1×10^4	1.6×10^5
200	9.0×10^3	1.6×10^4	1.6×10^4	1.6×10^4	7.8×10^3	1.6×10^4
600	1.7×10^3	2.9×10^3	2.9×10^3	2.9×10^3	1.4×10^3	2.9×10^3
1,000	7.7×10^2	1.4×10^3	1.4×10^3	1.4×10^3	6.7×10^2	1.4×10^3
6,000	1.4×10^1	2.5×10^1	9.1×10^1	9.1×10^1	1.5×10^1	9.1×10^1
10,000	7.6	1.2×10^1	1.6×10^1	3.6×10^1	5.4	1.6×10^1

Note: Source Term = 1×10^6; MAR = 1×10^{10} virions * ARF = 1x 10^{-4}

Table 3.14.4-4 — Unmitigated Site-Specific Ground Concentration Estimates From a Spill of Aerosol Pathogen

Radial Distance From Release Point (meters)	GA	KS	MS	NY	NC	TX
	Ground Concentration (virions/m^2)					
50	1.5×10^2	1.6×10^2	2.1×10^2	2.4×10^2	1.0×10^2	1.6×10^2
200	2.8×10^1	1.9×10^1	3.0×10^1	3.2×10^1	1.7×10^1	2.0×10^1
600	6.0	3.2	6.0	7.0	4.5	3.9
1,000	2.7	1.9	2.9	3.0	2.3	2.0
6,000	1.3×10^{-2}	1.7×10^{-2}	2.7×10^{-2}	3.1×10^{-2}	1.3×10^{-2}	2.3×10^{-2}
10,000	5.9×10^{-3}	8.2×10^{-3}	1.2×10^{-2}	1.9×10^{-2}	5.7×10^{-3}	1.0×10^{-2}

Note: Source Term = 1×10^6; MAR = 1×10^{10} * virions ARF = 1x 10^{-4}

The risk ranking assigned for the specific accidents and summarized in Tables 3.14.3-1 and 3.14.4-5.

The unmitigated accident risk ranking resulted in a risk rank of either 1 or 2. These rankings were the result of operational accident frequencies between 1×10^{-2} and 1×10^0 (NPH and aircraft crash accident frequencies were lower because of the likelihood of the initiating events was much smaller). Likewise the consequences for the unmitigated operational, NPH, and external accidents were all “A” to the public and “A” or “B” to the worker, indicating high potential for large quantities of virions to be released.

The mitigated accident risks were significantly reduced (often by more than one category for both frequency and consequence) by factoring in improvements in safety barriers and controls. Two of the mitigated accidents (loss of an infected animal and release of contaminated wastes) had risk ranks of 3, indicating the need for considering additional controls. This risk rank was assigned because the mitigated accident frequency only dropped by one bin from a FC II to a FC III after factoring in the controls. Overall, however, the risk reduction in the mitigated accidents illustrates the effectiveness of the safety controls.

Table 3.14.4-5 — Accident Risk Rank Summary

Accident	Accident Case	Risk Rank	Frequency Category	Severity Category
Operational Accident 1	Unmitigated Mitigated	1 4	II IV	A/B D/C
Operational Accident 2	Unmitigated Mitigated	1 4	I III	B E
Operational Accident 3	Unmitigated Mitigated	1 3	II III	A E
Operational Accident 4	Unmitigated Mitigated	1 3	II III	A D
Operational Accident 5	Unmitigated Mitigated	2 4	III IV	A/A D/C
Operational Accident 6	Unmitigated Mitigated	2 4	III IV	A/A D/D
NPH	Unmitigated Mitigated	2 4	IV V	A/A E/D
Aircraft	Unmitigated Mitigated	2 4	IV V	A/A E/D

These risk ranks, however, do not provide information that can be used to discriminate between the proposed NBAF sites to assess the site-specific impacts from a postulated release of FMDV, RVFV, or Nipah virus. To evaluate the site-specific risks, a coupling of the risk ranks for the accidents, which are generic in that all of the release scenarios, could occur at any of the proposed NBAF sites, with the site-specific characteristics is necessary.

Since risk is the product of the likelihood and consequence of an accident and the accident frequency is a characteristic of the NBAF structure and operations, then the frequency of the accidents can be assumed to be constant across the proposed sites. In other words, moving from one site to another does not change the accident frequency; therefore, only the change in consequences is needed to assign a site-specific risk.

Therefore, based on the unmitigated air and ground concentrations possible from a release of viral pathogens as a result of the postulated accidents a coupled site-specific risk ranking was developed to compare released inventories to potential infections down-wind from the NBAF (Asante-Duah 2002; Greenberg 1991; Cohrssen 1989). The data presented in the table are based on the 10 virion minimum infectious dose for each of the three pathogens. While other livestock would have a different MID for each of the viruses, the bounding scenario is to consider all of the livestock to be at the same level of susceptibility.

The risk ranking, based on the change in site-specific consequences, ranges from a minimum of "none" to a maximum of "high" based on the MID. A review of the site-specific unmitigated air and ground concentrations shows that a minimum of 1×10^4 (10,000) virions is necessary to be released before there is a credible possibility for multiple infections down-wind of the release. For example, a potential infection is expected to result from a release such that the exposure (inhalation, contact, or ingestion) of at least 10 virions. Taking the air concentration at 50 m of 1.6×10^{-1} for the Mississippi site, the product of the ST, a cow's breathing rate, and the air concentration ($1.6\times10^{-1} * 1.6\times10^{-3} * 1\times10^4$) yields nearly 3 virions, which is less than one-third of the MID of 10 virions, indicating that no infection would likely result. The risks presented in the accident analysis section were based on qualitative estimates of exposure based on the magnitude of the unmitigated and mitigated source terms. This phase of the risk ranking takes the site independent consequences calculated in the accident analysis and incorporates the site-specific aspects for population, wildlife, agriculture, and other environmental factors for the purpose of differentiating one proposed site from another. Table 3.14.4-6 presents the site-specific consequence basis for assigning site-specific risk ranks.

Table 3.14.4-6 — Site-Specific Risk Ranking Based on Potential Infections

Site-Specific Risk Category	Label	Description	Viable Pathogens Released
I	High	Likelihood of receptor infection approaches certainty (dose is greater than 10 times the infectious dose)	$VP > 1\times10^6$
II	Moderate	Likelihood of receptor infection increases with concentration (dose is equal to or greater than the infectious dose)	$1\times10^4 < VP \leq 1\times10^6$
III	None or Low	Likelihood of receptor infection approaches zero (dose is less than MID)	$VP \leq 1\times10^4$

The interpretation of the site-specific risk ranks includes the unmitigated and mitigated site-independent accident frequencies. Because these frequencies do not change from one site to another, they are not repeated in the following site-specific discussions.

In each of the site-specific cases, the effective mitigation of risk is dependent on the incorporation of robust safety controls into the design, construction, and operation of the NBAF. The need for robust safety controls is emphasized in federal regulations and executive orders to ensure that operation of the facility does not result in adverse consequences to the workers, public, or environment. To meet this objective, it is essential that the identified safety controls, including both the primary and secondary barriers, are able to meet their intended safety function during normal and credible abnormal conditions. Because of the nature of the pathogens anticipated in the operation of the NBAF, the need for the increased assurance on the performance of safety equipment. This specifically means safety controls need to ensure that viral pathogens are contained during all operations, external mishaps, and after credible natural phenomena events.

Table 3.14.4-7 presents a summary of the site-specific risk ranks.

Table 3.14.4-7 — Summary of Site-Specific Risk Ranks

Site		Site-Specific Risk Rank[a]	Site-Independent Accident Risk Range[b]	Accident Frequency Range[c]	Accident Severity Range[d]
Georgia	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	II - Moderate	3 - 4	III - IV	D/C – E/D
Kansas	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	II - Moderate	3 - 4	III - IV	D/C – E/D
Mississippi	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	II - Moderate	3 - 4	III - IV	D/C – E/D
Plum Island	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	III - Low	3 - 4	III - IV	D/C – E/D
North Carolina	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	II - Moderate	3 - 4	III - IV	D/C – E/D
Texas	Unmitigated		1 - 2	I - II	A/A – A/B
	Mitigated	II - Moderate	3 - 4	III - IV	D/C – E/D

[a]The primary differentiator among sites is the ability for FMDV, RVFV, and Nipah virus to become established and spread considering the hosts, vectors, and vehicles.
[b]Site-independent accident frequencies do not vary across sites.
[c]NPH and Aircraft Crash accidents have unmitigated frequency IV and mitigated frequency V.
[d]Accident Severity Categories were assigned based on the NBAF operations and structure not on location.

The evaluation of site-specific consequences in Section 3.14.4.1 – 3.14.4.6 illustrates that with the exception of Plum Island, each of the proposed sites resides in an area where the wildlife, vegetation, agriculture, and human populations provide ample opportunity for each of the viruses (FMDV, RVFV, and Nipah virus) to become established and spread once released from the NBAF. For this reason, the focus of the hazards, accident, and risk analysis was on the biocontainment of the viruses within the NBAF and the importance of both the engineered and administrative controls to prevent or mitigate accidents.

3.14.4.1 Georgia Site

Site-specific consequences for the proposed site in Georgia, located near Athens, are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural, uses near each site the consequences are presented individually for each proposed site. In the case of the Georgia site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could result in the event of a release as postulated in the accidents.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.1-1 illustrates the near-field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.1-1 and 3.14.4.1-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentration tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release at the proposed Georgia NBAF Site.

The normalized air concentrations for the Georgia site range from 9×10^{-2} at distances of 200 m to 7.7×10^{-4} at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of 2.8×10^{-5} to a low of 2.7×10^{-6}. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the more significant accidents such as over-pressure, seismic, and fire events.

As with the previous discussion, the majority of the NBAF would be within the 200-m radial distance. Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas. The site boundary would be located at approximately 250 m from the center of the NBAF. For the purposes of the analysis, it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.3.1.1 presents the discussion of the vegetation in the vicinity of the proposed NBAF site. The area is predominantly wooded forestland with small streams, lakes, and wetlands at distances greater than 10 km from the site. Within the immediate area of the site is mainly pastureland currently used for grazing livestock.

Section 3.8.3.1.4 presents the terrestrial wildlife in the vicinity of the proposed Georgia NBAF Site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Mammals include both white tail deer and wild boar. The wildlife and livestock in the vicinity of the site are prime candidates for acquiring or transmitting the FMD and RVFV and to some extent the Nipah virus in pigs. While the FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability, however, the unmitigated concentrations near the facility are potentially significant.

The location of the proposed NBAF site in Georgia provides a significant opportunity for the spread of viruses via vectors and infected wildlife. In addition, the atmospheric modeling indicates that down-wind transport is a credible scenario given a sufficiently large release of pathogens.

For this site, as with all of the sites except Plum Island, New York, there is a potential for viral pathogens to be transported significant distances by the wind. The results of the modeling indicate that this transport pathway is not limited (Figure 3.14.4.1-2), as was the case for Plum Island. It is considered likely that deer or wild boar could act to spread disease over long distances. In addition, common vectors such as mosquitoes can be transported long distances.

The potential for acquiring and spreading diseases from the FMDV, RVFV, and Nipah virus is also illustrated by consideration of the livestock in the vicinity of the proposed site. The counties surrounding the proposed NBAF site in Georgia contain significant numbers of livestock potentially exposed in the event of a release. Data related to the distribution of livestock in the vicinity of the NBAF were obtained from a DHS tasking response dated August 6, 2007. The specific task was to collect information about livestock in the areas of the proposed NBAF sites to support the determination as to whether accidental laboratory release at these locations could have the potential to affect nearby livestock (DHS 2007). The normalized concentrations presented in Figure 3.14.4.1-2 up to distances of 10 km from the proposed NBAF site includes Clarke and Oconee counties. Data provided on livestock density indicate that there is on the order of 20 to 30 livestock, mostly cattle, per square kilometer in the vicinity of the proposed NBAF.

The area within a 10-km radius of the proposed NBAF would be approximately 78.5 km^2 containing as many as 2,300 cattle. For the unmitigated accidents, concentrations on the order of 1×10^4 or greater occur at distances greater than 10 km for the high source term accidents. At relatively close proximity to the site (less than 1 km), the unmitigated concentrations in the air and on the ground show the potential for a large number of infections from any of the three viruses. The number of livestock outside of the 10-km radius increases significantly (>100,000 animals) and are at risk from the postulated unmitigated releases.

The far-field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations, falls off sharply with distance. The normalized air concentration falls to less than 1×10^{-4} s/m^3 at distances greater than 2 km. At these distances, the quantity of material released would need to be much greater than 1×10^4 (10,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by more than an order of magnitude at distance of 10 km.

Tables 3.14.4.1-3 and 3.14.4.1-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 400 m, indicating that the viral pathogens will not be transported in significant quantities far from the site. This result illustrates the localized effects of the mitigated accidents. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would be less than the MID (10 virions) at distances greater than 2 km. Emergency planning and rapid response to a possible release will afford an opportunity to mitigate the consequences of the postulated accidents.

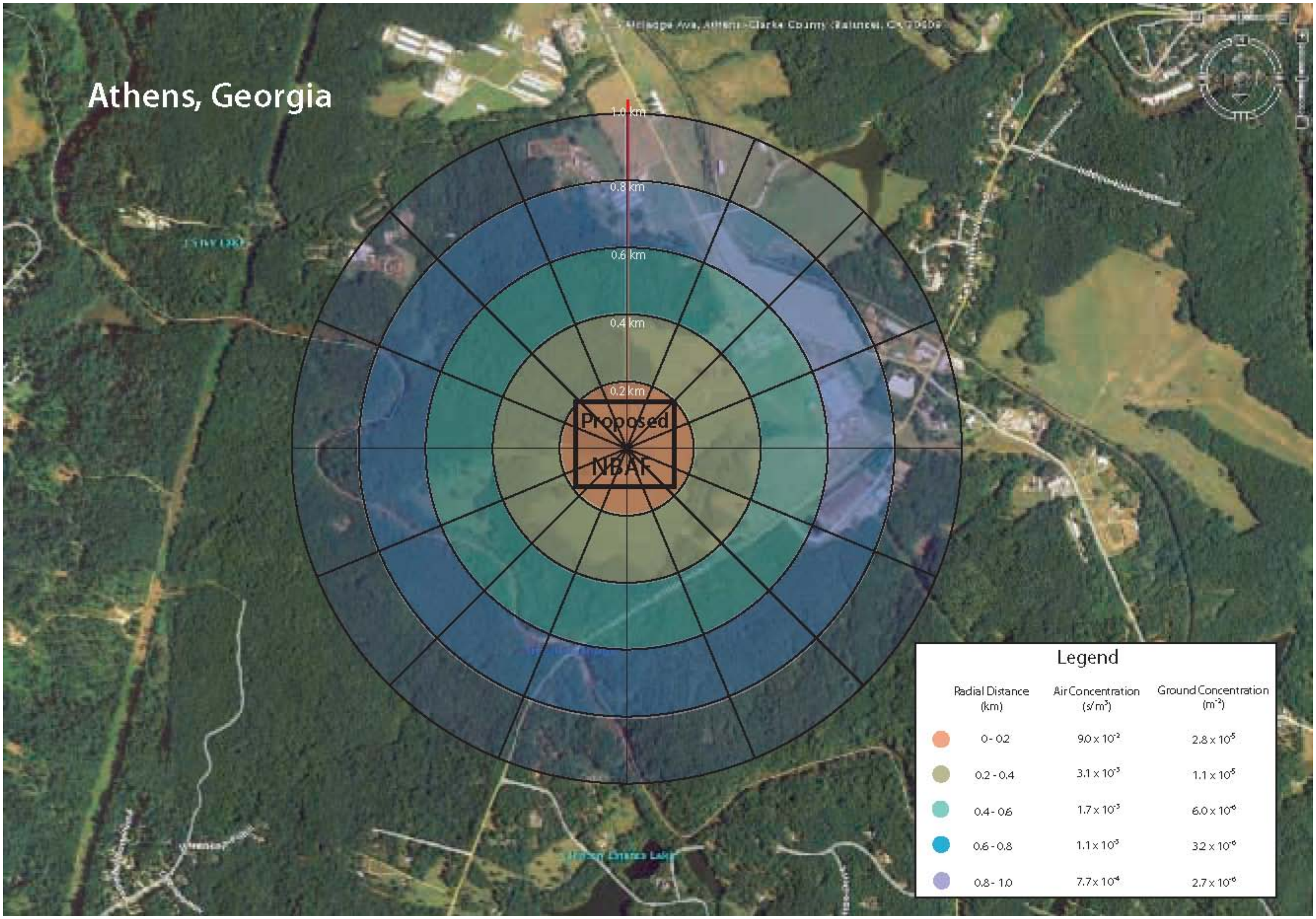


Figure 3.14.4.1-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

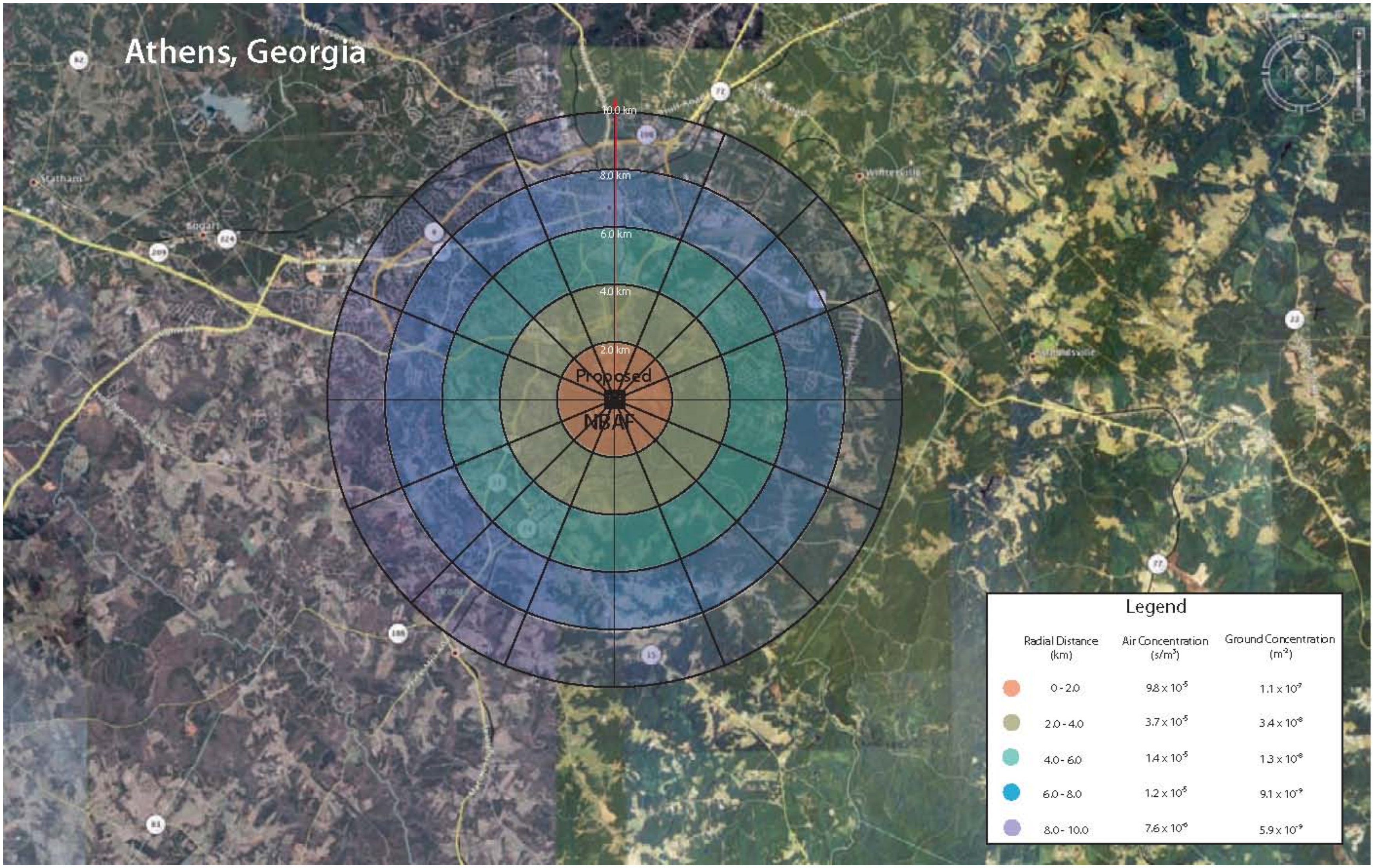


Figure 3.14.4.1-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.1-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) Georgia Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	9.3E-02	9.3E+04	9.3E+08	9.3E+03	9.3E+07	2.8E+09	9.3E+09	2.8E+07
200	9.0E-03	9.0E+03	9.0E+07	9.0E+02	9.0E+06	2.7E+08	9.0E+08	2.7E+06
400	3.1E-03	3.1E+03	3.1E+07	3.1E+02	3.1E+06	9.2E+07	3.1E+08	9.2E+05
600	1.7E-03	1.7E+03	1.7E+07	1.7E+02	1.7E+06	5.0E+07	1.7E+08	5.0E+05
800	1.1E-03	1.1E+03	1.1E+07	1.1E+02	1.1E+06	3.2E+07	1.1E+08	3.2E+05
1,000	7.7E-04	7.7E+02	7.7E+06	7.7E+01	7.7E+05	2.3E+07	7.7E+07	2.3E+05
2,000	9.8E-05	9.8E+01	9.8E+05	9.8E+00	9.8E+04	2.9E+06	9.8E+06	2.9E+04
4,000	3.7E-05	3.7E+01	3.7E+05	3.7E+00	3.7E+04	1.1E+06	3.7E+06	1.1E+04
6,000	1.4E-05	1.4E+01	1.4E+05	1.4E+00	1.4E+04	4.3E+05	1.4E+06	4.3E+03
8,000	1.2E-05	1.2E+01	1.2E+05	1.2E+00	1.2E+04	3.6E+05	1.2E+06	3.6E+03
10,000	7.6E-06	7.6E+00	7.6E+04	7.6E-01	7.6E+03	2.3E+05	7.6E+05	2.3E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

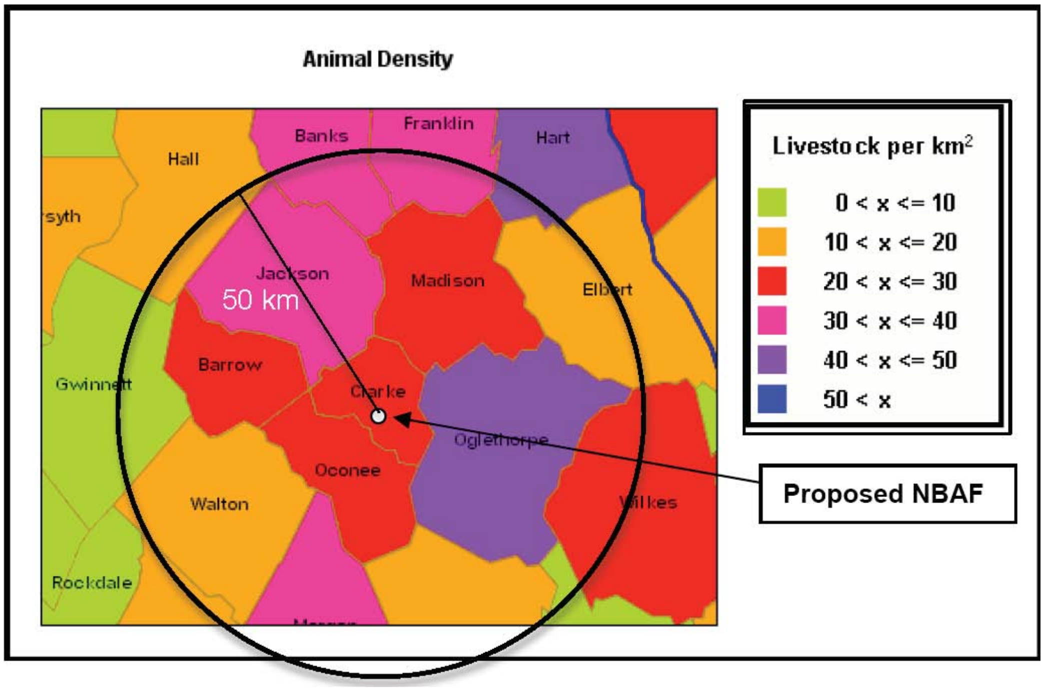
Table 3.14.4.1-2 — Unmitigated Accident Specific Ground Concentration (virions/m^2) Georgia Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.5E-04	1.5E+02	1.5E+06	1.5E+01	1.5E+05	4.6E+06	1.5E+07	4.6E+04
200	2.8E-05	2.8E+01	2.8E+05	2.8E+00	2.8E+04	8.3E+05	2.8E+06	8.3E+03
400	1.1E-05	1.1E+01	1.1E+05	1.1E+00	1.1E+04	3.4E+05	1.1E+06	3.4E+03
600	5.9E-06	5.9E+00	5.9E+04	5.9E-01	5.9E+03	1.8E+05	5.9E+05	1.8E+03
800	3.2E-06	3.2E+00	3.2E+04	3.2E-01	3.2E+03	9.5E+04	3.2E+05	9.5E+02
1,000	2.7E-06	2.7E+00	2.7E+04	2.7E-01	2.7E+03	8.2E+04	2.7E+05	8.2E+02
2,000	1.1E-07	1.1E-01	1.1E+03	1.1E-02	1.1E+02	3.3E+03	1.1E+04	3.3E+01
4,000	3.4E-08	3.4E-02	3.4E+02	3.4E-03	3.4E+01	1.0E+03	3.4E+03	1.0E+01
6,000	1.3E-08	1.3E-02	1.3E+02	1.3E-03	1.3E+01	3.9E+02	1.3E+03	3.9E+00
8,000	9.1E-09	9.1E-03	9.1E+01	9.1E-04	9.1E+00	2.7E+02	9.1E+02	2.7E+00
10,000	5.9E-09	5.9E-03	5.9E+01	5.9E-04	5.9E+00	1.8E+02	5.9E+02	1.8E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

County & Surrounding Counties	Number of Herds	Number of Livestock
Clarke	53	7511
Oconee	224	11078
Barrow	302	13356
Oglethorpe	252	52598
Madison	474	22072
Jackson	608	26285
	1913	**132900**



Livestock Proximal to the Georgia Site

The accident analysis conservatively estimates a final mitigated source term of $3{\times}10^5$ virions for the over-pressure event and $1{\times}10^4$ virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. In the event this accident occurs, there is a good chance that the viruses will not be contained without timely emergency response.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. The livestock and wildlife (deer and boar) in the vicinity of the Georgia site provides ample opportunity for FMDV to establish in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites and with the large human population in the area, the ability for the FMDV to spread over large areas also exists. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the Georgia site would provide an environment for RVFV to be easily transmitted once released. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV, and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV, and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Because Nipah virus is transmitted by direct contact with bodily fluids, mechanical transmission, and aerosol transmission, there is substantial opportunity for the Nipah virus to spread in the area. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area.

The final risk rank for the mitigated accident scenarios for the proposed NBAF Georgia Site is III (none) for all accidents except over-pressure and fire, which are designated as risk rank II (moderate) for distances close to the release. Because of the potential for easy spread of FMDV, RVFV, and Nipah virus diseases via infected livestock, wildlife, and vectors, the overall risk for the Georgia site is designated as risk rank II (moderate).

Table 3.14.4.1-3 — Mitigated Accident Specific Air Concentration (virions/m^3) Georgia Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	9.3E-02	9.3E-01	0.0	0.0	9.3E+02	2.8E+04	9.3E+00	0.0
200	9.0E-03	9.0E-02	0.0	0.0	9.0E+01	2.7E+03	9.0E-01	0.0
400	3.1E-03	3.1E-02	0.0	0.0	3.1E+01	9.2E+02	3.1E-01	0.0
600	1.7E-03	1.7E-02	0.0	0.0	1.7E+01	5.0E+02	1.7E-01	0.0
800	1.1E-03	1.1E-02	0.0	0.0	1.1E+01	3.2E+02	1.1E-01	0.0
1,000	7.7E-04	7.7E-03	0.0	0.0	7.7E+00	2.3E+02	7.7E-02	0.0
2,000	9.8E-05	9.8E-04	0.0	0.0	9.8E-01	2.9E+01	9.8E-03	0.0
4,000	3.7E-05	3.7E-04	0.0	0.0	3.7E-01	1.1E+01	3.7E-03	0.0
6,000	1.4E-05	1.4E-04	0.0	0.0	1.4E-01	4.3E+00	1.4E-03	0.0
8,000	1.2E-05	1.2E-04	0.0	0.0	1.2E-01	3.6E+00	1.2E-03	0.0
10,000	7.6E-06	7.6E-05	0.0	0.0	7.6E-02	2.3E+00	7.6E-04	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.1-4 — Mitigated Accident Specific Ground Concentration (virions/m^2) Georgia Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.5E-04	1.5E-03	0.0	0.0	1.5E+00	4.6E+01	1.5E-02	0.0
200	2.8E-05	2.8E-04	0.0	0.0	2.8E-01	8.3E+00	2.8E-03	0.0
400	1.1E-05	1.1E-04	0.0	0.0	1.1E-01	3.4E+00	1.1E-03	0.0
600	5.9E-06	5.9E-05	0.0	0.0	5.9E-02	1.8E+00	5.9E-04	0.0
800	3.2E-06	3.2E-05	0.0	0.0	3.2E-02	9.5E-01	3.2E-04	0.0
1,000	2.7E-06	2.7E-05	0.0	0.0	2.7E-02	8.2E-01	2.7E-04	0.0
2,000	1.1E-07	1.1E-06	0.0	0.0	1.1E-03	3.3E-02	1.1E-05	0.0
4,000	3.4E-08	3.4E-07	0.0	0.0	3.4E-04	1.0E-02	3.4E-06	0.0
6,000	1.3E-08	1.3E-07	0.0	0.0	1.3E-04	3.9E-03	1.3E-06	0.0
8,000	9.1E-09	9.1E-08	0.0	0.0	9.1E-05	2.7E-03	9.1E-07	0.0
10,000	5.9E-09	5.9E-08	0.0	0.0	5.9E-05	1.8E-03	5.9E-07	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

3.14.4.2 Kansas Site

Site-specific consequences for the proposed Manhattan, Kansas, site, are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural uses near each site, the consequences are presented individually for each proposed site. In the case of the Kansas site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could be produced as a result of a postulated release.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.2-1 illustrates the near field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.2-1 and 3.14.4.2-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentration tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release at the proposed Kansas NBAF site.

The normalized air concentrations for the Manhattan, Kansas, site range from 1.6×10^{-2} at distances of 200 m to 1.4×10^{-3} at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of 1.9×10^{-5} to a low of 1.9×10^{-6}. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the larger accidents such as over-pressure, seismic, and fire events.

As with the previous discussion, the majority of the NBAF would be within the 200-m radial distance. Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas. The site boundary would be located at approximately 250 m from the center of the NBAF. For the purposes of the analysis, it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.4.1.1 presents the discussion of the vegetation in the vicinity of the proposed NBAF site. The area outside of the 4-km distance from the site is predominantly prairie grassland with streams or rivers, as well as a few intermittent wetlands. Within the immediate area of the site is mainly disturbed pastureland, currently used for grazing livestock, and a significant presence of industrial and residential areas.

Section 3.8.4.1.4 presents the terrestrial wildlife in the vicinity of the proposed Kansas NBAF site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Major mammals include white tail deer, mule deer, elk, bison, and wild boar. The wildlife and livestock in the vicinity of the site are prime candidates for acquiring or transmitting the FMD and RVFV and to some extent the Nipah virus in pigs. While the FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability, the unmitigated concentrations near the facility are potentially significant.

The location of the proposed NBAF site in Kansas provides a significant opportunity for the spread of viruses via vectors and infected wildlife. In addition, the atmospheric modeling indicates that down-wind transport is a credible scenario given a sufficiently large release of pathogens.

For this site, as with all of the sites except Plum Island, New York, there is a potential for viral pathogens to be transported significant distances by the wind. The results of the modeling indicate that this transport pathway is not limited (Figure 3.14.4.2-2), as was the case for Plum Island. It is considered likely that deer, elf, bison, and wild boar could act to spread disease over long distances. In addition, common vectors such as mosquitoes can be transported long distances.

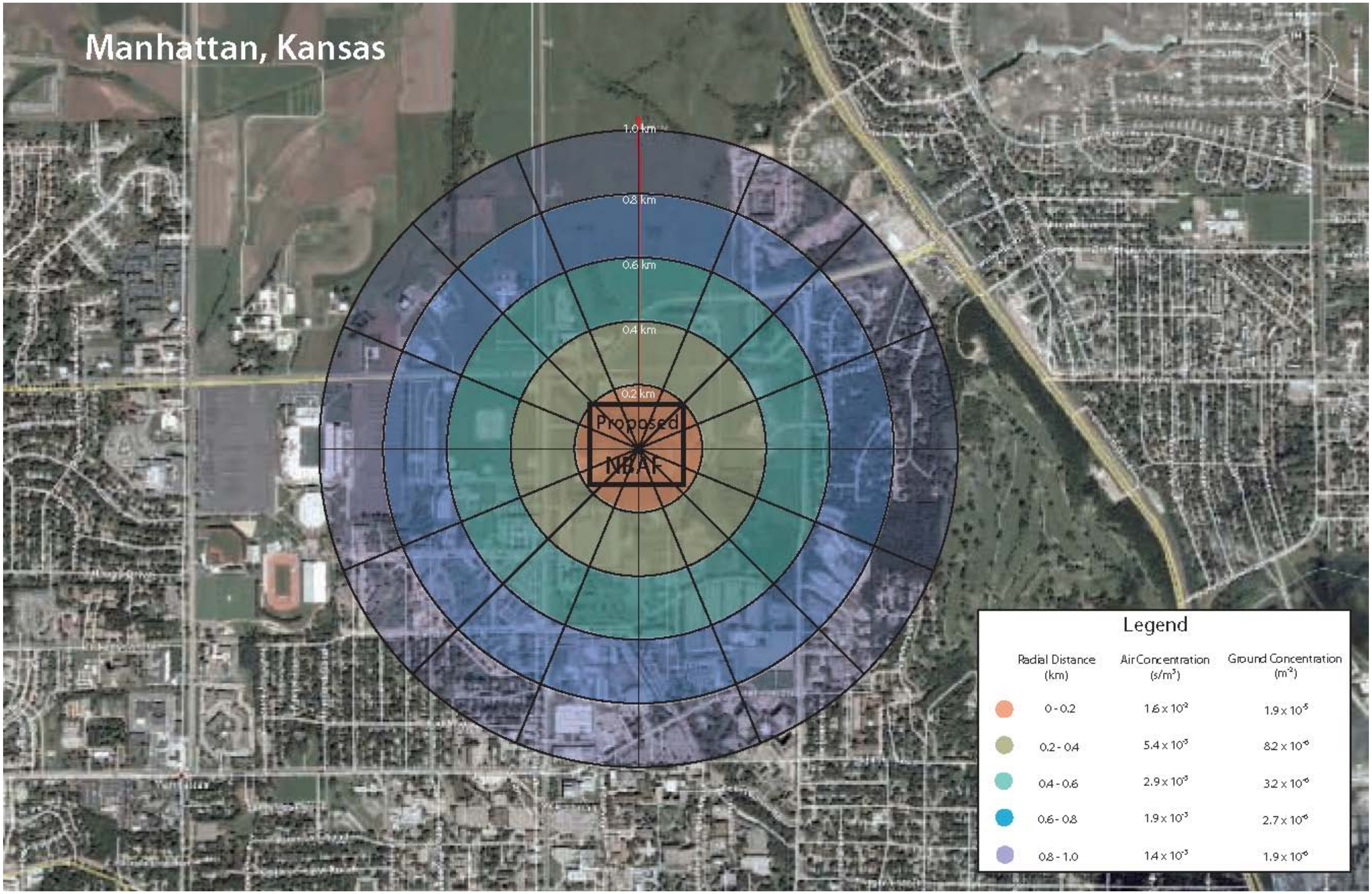


Figure 3.14.4.2-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

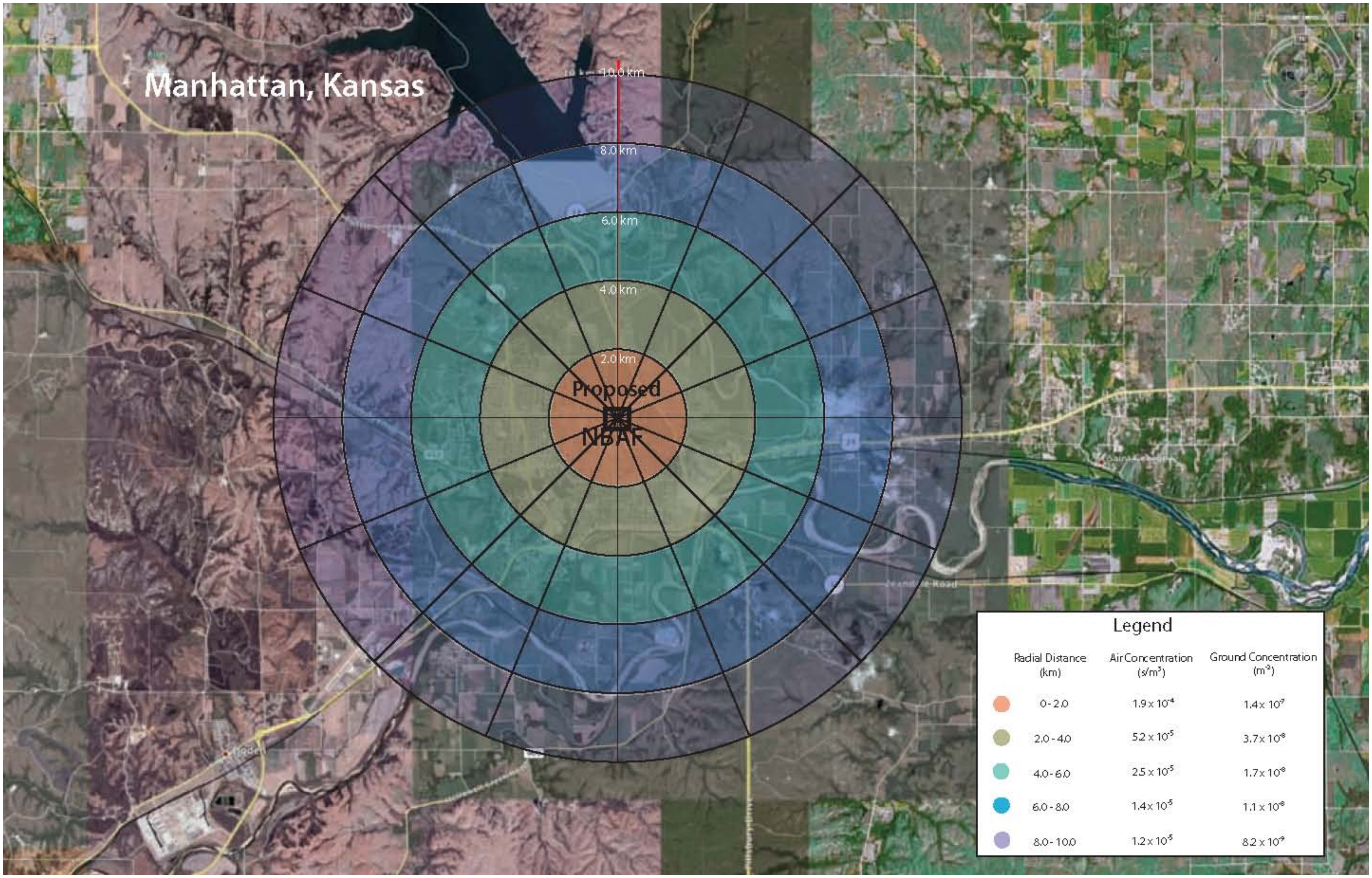


Figure 3.14.4.2-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.2-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) Kansas Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.6E-01	1.6E+05	1.6E+09	1.6E+04	1.6E+08	4.8E+09	1.6E+10	4.8E+07
200	1.6E-02	1.6E+04	1.6E+08	1.6E+03	1.6E+07	4.7E+08	1.6E+09	4.7E+06
400	5.4E-03	5.4E+03	5.4E+07	5.4E+02	5.4E+06	1.6E+08	5.4E+08	1.6E+06
600	2.9E-03	2.9E+03	2.9E+07	2.9E+02	2.9E+06	8.7E+07	2.9E+08	8.7E+05
800	1.9E-03	1.9E+03	1.9E+07	1.9E+02	1.9E+06	5.6E+07	1.9E+08	5.6E+05
1,000	1.4E-03	1.4E+03	1.4E+07	1.4E+02	1.4E+06	4.1E+07	1.4E+08	4.1E+05
2,000	1.9E-04	1.9E+02	1.9E+06	1.9E+01	1.9E+05	5.7E+06	1.9E+07	5.7E+04
4,000	5.2E-05	5.2E+01	5.2E+05	5.2E+00	5.2E+04	1.6E+06	5.2E+06	1.6E+04
6,000	2.5E-05	2.5E+01	2.5E+05	2.5E+00	2.5E+04	7.6E+05	2.5E+06	7.6E+03
8,000	1.4E-05	1.4E+01	1.4E+05	1.4E+00	1.4E+04	4.3E+05	1.4E+06	4.3E+03
10,000	1.2E-05	1.2E+01	1.2E+05	1.2E+00	1.2E+04	3.5E+05	1.2E+06	3.5E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

Table 3.14.4.2-2 — Unmitigated Accident Specific Ground Concentration (virions/m^2) Kansas Site

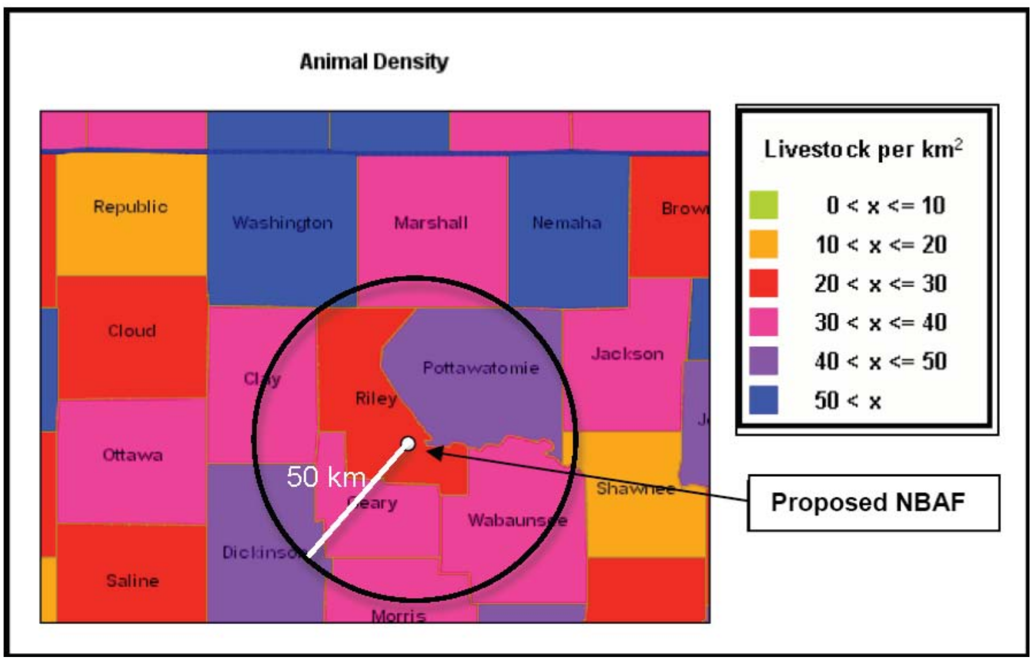
		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.6E-04	1.6E+02	1.6E+06	1.6E+01	1.6E+05	4.8E+06	1.6E+07	4.8E+04
200	1.9E-05	1.9E+01	1.9E+05	1.9E+00	1.9E+04	5.7E+05	1.9E+06	5.7E+03
400	8.2E-06	8.2E+00	8.2E+04	8.2E-01	8.2E+03	2.5E+05	8.2E+05	2.5E+03
600	3.2E-06	3.2E+00	3.2E+04	3.2E-01	3.2E+03	9.5E+04	3.2E+05	9.5E+02
800	2.7E-06	2.7E+00	2.7E+04	2.7E-01	2.7E+03	8.2E+04	2.7E+05	8.2E+02
1,000	1.9E-06	1.9E+00	1.9E+04	1.9E-01	1.9E+03	5.8E+04	1.9E+05	5.8E+02
2,000	1.4E-07	1.4E-01	1.4E+03	1.4E-02	1.4E+02	4.3E+03	1.4E+04	4.3E+01
4,000	3.7E-08	3.7E-02	3.7E+02	3.7E-03	3.7E+01	1.1E+03	3.7E+03	1.1E+01
6,000	1.7E-08	1.7E-02	1.7E+02	1.7E-03	1.7E+01	5.0E+02	1.7E+03	5.0E+00
8,000	1.1E-08	1.1E-02	1.1E+02	1.1E-03	1.1E+01	3.4E+02	1.1E+03	3.4E+00
10,000	8.2E-09	8.2E-03	8.2E+01	8.2E-04	8.2E+00	2.5E+02	8.2E+02	2.5E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where “E” represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

The potential for acquiring and spreading diseases from the FMDV, RVFV, and Nipah virus is also illustrated by considering the livestock in the vicinity of the proposed Kansas site. The counties surrounding the proposed NBAF site in Kansas contain significant numbers of livestock potentially exposed to any off-site release. Data related to the distribution of livestock in the vicinity of the NBAF were obtained from a DHS tasking response dated August 6, 2007. Data were collected related to livestock in the areas of the proposed NBAF sites to support the determination as to whether accidental laboratory releases at these locations could have the potential to affect nearby livestock (DHS 2007). The normalized concentrations presented in Figure 3.14.4.2-2 up to distances of 10 km from the proposed NBAF is fully contained by Riley and Pottawatomie counties. Data provided on livestock density indicates that there is on the order of 20 to 50 livestock, mostly cattle, per square kilometer in this area.

County & Surrounding Counties	Number of Herds	Number of Livestock
Riley	262	46431
Washington	523	155747
Clay	333	55616
Geary	139	41601
Wabaunsee	379	75753
Pottawatomie	589	91424
Marshall	562	75935
	2787	**542507**



Livestock Proximal to the Manhattan Campus Site

The area within a 10-km radius of the proposed NBAF would be approximately 78.5 km^2 and could comprise greater than 3,000 cattle. For the unmitigated accidents, concentrations on the order of 1×10^4 or greater occur at distances greater than 10 km for the high source term accidents. At relatively close proximity to the site (less than 1 km), the unmitigated concentrations in the air and on the ground show the potential for a large number of infections from any of the three viruses. The number of livestock outside of the 10-km radius increases significantly (>500,000 animals) and are at risk from the postulated unmitigated releases.

The far-field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations, falls off sharply with distance. The normalized air concentration falls to less than 5×10^{-4} s/m^3 at distances greater than 2 km. At these distances, the quantity of material released would need to be much greater than 5×10^3 (5,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by more than an order of magnitude at distance of 10 km.

Tables 3.14.4.2-3 and 3.14.4.2-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 400 m, indicating that the viral pathogens will not be transported in significant quantities far from the site. This result illustrates the localized effects of the mitigated accidents. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would be less than the MID (10 virions) at distances greater than 2 km. Emergency planning and rapid response to a possible release will afford an opportunity to mitigate the consequences of the postulated accidents.

The accident analysis conservatively estimates a final mitigated source term of 3×10^5 virions for the over-pressure event and 1×10^4 virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. In the event that this accident occurs, there is a good chance that the viruses will not be contained without timely emergency response.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. The livestock and wildlife (deer and boar) in the vicinity of the Kansas site provides ample opportunity for FMDV to establish in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites, and with the large human population in the area the ability for the FMDV to spread over large areas also exists. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the Kansas site would provide an environment for RVFV to be easily transmitted once released. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV, and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV, and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of

Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Because Nipah virus is transmitted by direct contact with bodily fluids, mechanical transmission, and aerosol transmission, there is substantial opportunity for the Nipah virus to spread in the area. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area.

The final risk rank for the mitigated accident scenarios for the proposed NBAF Kansas site is III (none) for all accidents except over-pressure and fire, which are designated as risk rank II (moderate) for distances close to the release. Because of the potential for easy spread of FMDV, RVFV, and Nipah virus diseases via infected livestock, wildlife, and vectors, the overall risk for the Kansas site is designated as risk rank II (moderate).

Table 3.14.4.2-3 — Mitigated Accident Specific Air Concentration (virions/m^3) Kansas Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-01	1.6E+00	0.0	0.0	1.6E+03	4.8E+04	1.6E+01	0.0
200	1.6E-02	1.6E-01	0.0	0.0	1.6E+02	4.7E+03	1.6E+00	0.0
400	5.4E-03	5.4E-02	0.0	0.0	5.4E+01	1.6E+03	5.4E-01	0.0
600	2.9E-03	2.9E-02	0.0	0.0	2.9E+01	8.7E+02	2.9E-01	0.0
800	1.9E-03	1.9E-02	0.0	0.0	1.9E+01	5.6E+02	1.9E-01	0.0
1,000	1.4E-03	1.4E-02	0.0	0.0	1.4E+01	4.1E+02	1.4E-01	0.0
2,000	1.9E-04	1.9E-03	0.0	0.0	1.9E+00	5.7E+01	1.9E-02	0.0
4,000	5.2E-05	5.2E-04	0.0	0.0	5.2E-01	1.6E+01	5.2E-03	0.0
6,000	2.5E-05	2.5E-04	0.0	0.0	2.5E-01	7.6E+00	2.5E-03	0.0
8,000	1.4E-05	1.4E-04	0.0	0.0	1.4E-01	4.3E+00	1.4E-03	0.0
10,000	1.2E-05	1.2E-04	0.0	0.0	1.2E-01	3.5E+00	1.2E-03	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.2-4 — Mitigated Accident Specific Ground Concentration (virions/m^2) Kansas Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-04	1.6E-03	0.0	0.0	1.6E+00	4.8E+01	1.6E-02	0.0
200	1.9E-05	1.9E-04	0.0	0.0	1.9E-01	5.7E+00	1.9E-03	0.0
400	8.2E-06	8.2E-05	0.0	0.0	8.2E-02	2.5E+00	8.2E-04	0.0
600	3.2E-06	3.2E-05	0.0	0.0	3.2E-02	9.5E-01	3.2E-04	0.0
800	2.7E-06	2.7E-05	0.0	0.0	2.7E-02	8.2E-01	2.7E-04	0.0
1,000	1.9E-06	1.9E-05	0.0	0.0	1.9E-02	5.8E-01	1.9E-04	0.0
2,000	1.4E-07	1.4E-06	0.0	0.0	1.4E-03	4.3E-02	1.4E-05	0.0
4,000	3.7E-08	3.7E-07	0.0	0.0	3.7E-04	1.1E-02	3.7E-06	0.0
6,000	1.7E-08	1.7E-07	0.0	0.0	1.7E-04	5.0E-03	1.7E-06	0.0
8,000	1.1E-08	1.1E-07	0.0	0.0	1.1E-04	3.4E-03	1.1E-06	0.0
10,000	8.2E-09	8.2E-08	0.0	0.0	8.2E-05	2.5E-03	8.2E-07	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

3.14.4.3 Mississippi Site

Site-specific consequences for the proposed site in Mississippi, located near the Flora Industrial Park Site are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural uses near each site, the consequences are presented individually for each proposed site. In the case of the Mississippi site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could result in the event of a release as postulated in the accidents.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.3-1 illustrates the near-field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.3-1 and 3.14.4.3-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentrations tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release at the proposed Mississippi NBAF site.

The normalized air concentrations for the Flora, Mississippi, site range from 1.6×10^{-2} at distances of 200 m to 1.4×10^{-3} at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of 3×10^{-5} to a low of 2.9×10^{-6}. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the larger accidents such as over-pressure, seismic, and fire events.

As with the previous discussion, the majority of the NBAF would be within the 200-m radial distance. Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas. The site boundary would be located at approximately 250 m from the center of the NBAF. For the purposes of the analysis it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.5.1.1 presents the discussion of the vegetation in the vicinity of the proposed NBAF site. The area outside of the 4-km distance from the site is predominantly wooded forestland with streams or rivers, as well as wetlands. Within the immediate area of the site is mainly pastureland currently used for grazing livestock.

Section 3.8.5.1.4 presents the terrestrial wildlife in the vicinity of the proposed Mississippi NBAF site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Mammals include both white tail deer and wild boar. The wildlife and livestock in the vicinity of the site are prime candidates for acquiring or transmitting the FMD and RVFV and to some extent the Nipah virus in pigs. While the FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability, however, the unmitigated concentrations near the facility are potentially significant.

The location of the proposed NBAF site in Mississippi provides a significant opportunity for the spread of viruses via vectors and infected wildlife. In addition, the atmospheric modeling indicates that down-wind transport is a credible scenario given a sufficiently large release of pathogens.

For this site, as with all of the sites except Plum Island, New York, there is a potential for viral pathogens to be transported significant distances by the wind. The results of the modeling indicate that this transport pathway is not limited (Figure 3.14.4.3-2) as was the case for Plum Island. It is considered likely that deer or wild boar could act to spread disease over long distances. In addition, common vectors such as mosquitoes can be transported long distances.

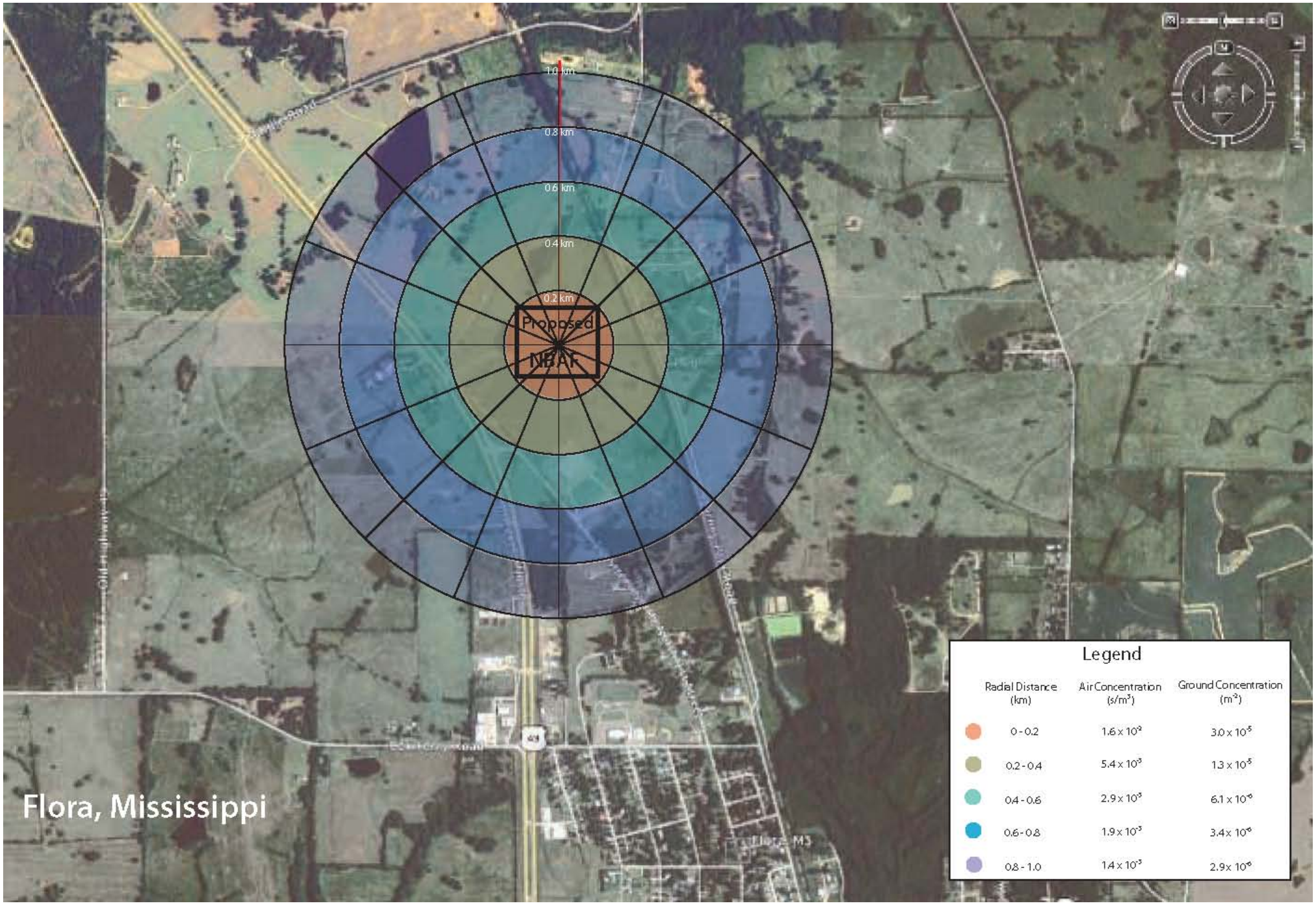


Figure 3.14.4.3-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

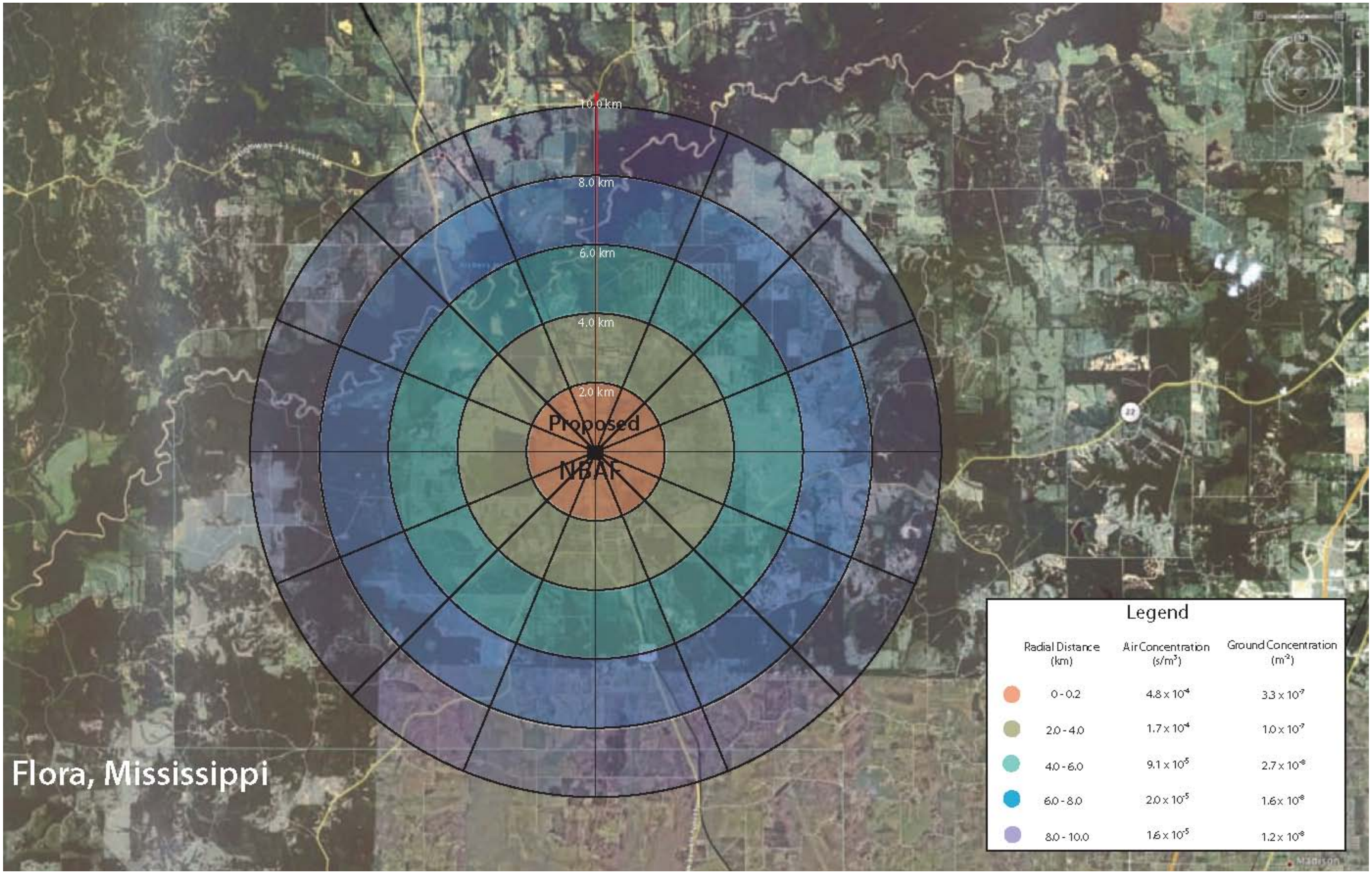


Figure 3.14.4.3-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.3-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) Mississippi Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.6E-01	1.6E+05	1.6E+09	1.6E+04	1.6E+08	4.8E+09	1.6E+10	4.8E+07
200	1.6E-02	1.6E+04	1.6E+08	1.6E+03	1.6E+07	4.7E+08	1.6E+09	4.7E+06
400	5.4E-03	5.4E+03	5.4E+07	5.4E+02	5.4E+06	1.6E+08	5.4E+08	1.6E+06
600	2.9E-03	2.9E+03	2.9E+07	2.9E+02	2.9E+06	8.7E+07	2.9E+08	8.7E+05
800	1.9E-03	1.9E+03	1.9E+07	1.9E+02	1.9E+06	5.6E+07	1.9E+08	5.6E+05
1,000	1.4E-03	1.4E+03	1.4E+07	1.4E+02	1.4E+06	4.1E+07	1.4E+08	4.1E+05
2,000	4.8E-04	4.8E+02	4.8E+06	4.8E+01	4.8E+05	1.4E+07	4.8E+07	1.4E+05
4,000	1.7E-04	1.7E+02	1.7E+06	1.7E+01	1.7E+05	5.0E+06	1.7E+07	5.0E+04
6,000	9.1E-05	9.1E+01	9.1E+05	9.1E+00	9.1E+04	2.7E+06	9.1E+06	2.7E+04
8,000	2.0E-05	2.0E+01	2.0E+05	2.0E+00	2.0E+04	5.9E+05	2.0E+06	5.9E+03
10,000	1.6E-05	1.6E+01	1.6E+05	1.6E+00	1.6E+04	4.7E+05	1.6E+06	4.7E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Source Term = MAR * ARF * RF * DR * LPF

Table 3.14.4.3-2 — Unmitigated Accident Specific Ground Concentration (virions/m^2) Mississippi Site

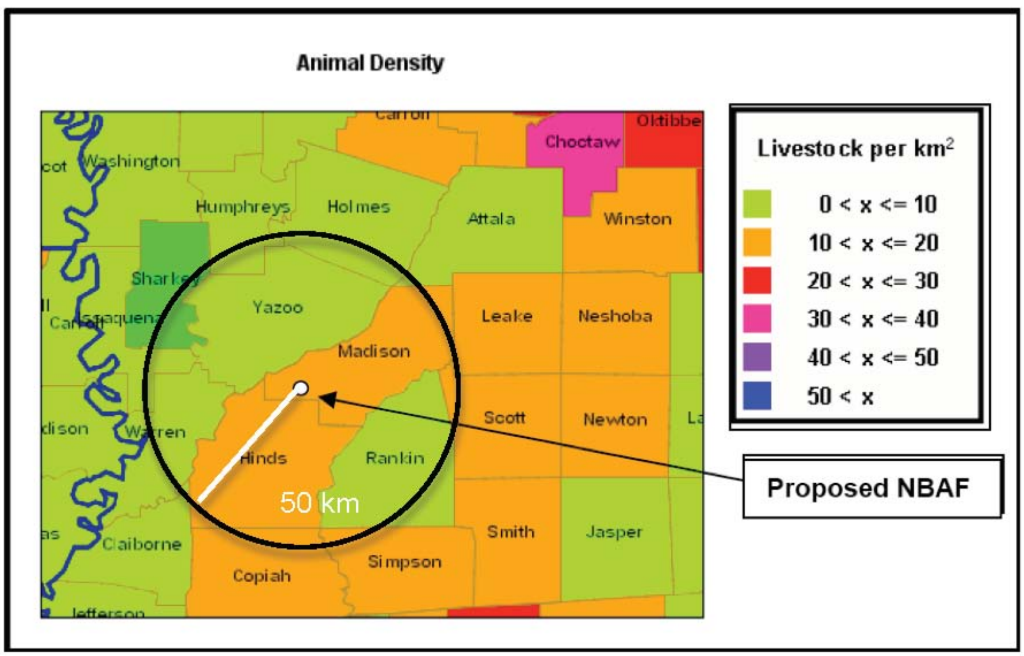
		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	2.1E-04	2.1E+02	2.1E+06	2.1E+01	2.1E+05	6.4E+06	2.1E+07	6.4E+04
200	3.0E-05	3.0E+01	3.0E+05	3.0E+00	3.0E+04	9.1E+05	3.0E+06	9.1E+03
400	1.3E-05	1.3E+01	1.3E+05	1.3E+00	1.3E+04	3.8E+05	1.3E+06	3.8E+03
600	6.1E-06	6.1E+00	6.1E+04	6.1E-01	6.1E+03	1.8E+05	6.1E+05	1.8E+03
800	3.4E-06	3.4E+00	3.4E+04	3.4E-01	3.4E+03	1.0E+05	3.4E+05	1.0E+03
1,000	2.9E-06	2.9E+00	2.9E+04	2.9E-01	2.9E+03	8.7E+04	2.9E+05	8.7E+02
2,000	3.3E-07	3.3E-01	3.3E+03	3.3E-02	3.3E+02	9.8E+03	3.3E+04	9.8E+01
4,000	1.0E-07	1.0E-01	1.0E+03	1.0E-02	1.0E+02	3.0E+03	1.0E+04	3.0E+01
6,000	2.7E-08	2.7E-02	2.7E+02	2.7E-03	2.7E+01	8.2E+02	2.7E+03	8.2E+00
8,000	1.6E-08	1.6E-02	1.6E+02	1.6E-03	1.6E+01	4.9E+02	1.6E+03	4.9E+00
10,000	1.2E-08	1.2E-02	1.2E+02	1.2E-03	1.2E+01	3.5E+02	1.2E+03	3.5E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

The potential for acquiring and spreading diseases from the FMDV, RVFV, and Nipah virus is also illustrated by considering the livestock in the vicinity of the proposed Mississippi site. The counties surrounding the proposed NBAF site in Mississippi contain significant numbers of livestock potentially exposed to any off-site release. Data related to the distribution of livestock in the vicinity of the NBAF was obtained from a DHS tasking response dated August 6, 2007. The specific task was to collect information about livestock in the areas of the proposed NBAF sites to support the determination as to whether accidental laboratory releases at these locations could have the potential to affect nearby livestock (DHS 2007). The normalized concentrations presented in Figure 3.14.4.3-2 up to distances of 10 km from the proposed NBAF site extends into the Yazoo, Madison, and Hinds counties. Data provided on livestock density indicate that there is on the order of 10 to 20 livestock, mostly cattle, per square kilometer in this area.

County & Surrounding Counties	Number of Herds	Number of Livestock
Madison	324	191448
Yazoo	231	13370
Attala	268	10533
Hinds	624	35300
Rankin	424	18231
Scott	450	23639
Leake	440	20270
Holmes	238	11765
	2999	**324556**



Livestock Proximal to the Flora Industrial Site

The area within a 10 km radius of the proposed NBAF would be approximately 78.5 km^2 containing fewer than 1,600 cattle. For the unmitigated accidents, concentrations on the order of 1×10^4 or greater occur at distances greater than 10 km for the high source term accidents. At relatively close proximity to the site (less than 1 km), the unmitigated concentrations in the air and on the ground show the potential for a large number of infections from any of the three viruses. The number of livestock outside of the 10-km radius increases significantly (>300,000 animals) and are at risk from the postulated unmitigated releases.

The far-field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations falls off sharply with distance. The normalized air concentration falls to less than 5×10^{-4} s/m^3 at distances greater than 2 km. At these distances, the quantity of material released would need to be much greater than 5×10^3 (5,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by more than an order of magnitude at distance of 10 km.

Tables 3.14.4.3-3 and 3.14.4.3-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 400 m, indicating that the viral pathogens will not be transported in significant quantities far from the site. This result illustrates the localized effects of the mitigated accidents. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would be less than the MID (10 virions) at distances greater than 2 km. Emergency planning and rapid response to a possible release will afford an opportunity to mitigate the consequences of the postulated accidents.

The accident analysis conservatively estimates a final mitigated source term of 3×10^5 virions for the over-pressure event and 1×10^4 virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. In the event this accident occurs, there is a good chance that the viruses will not be contained without timely emergency response.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. The livestock and wildlife (deer and boar) in the vicinity of the Mississippi site provide ample opportunity for FMDV to establish in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites and with the large human population in the area, the ability for the FMDV to spread over large areas also exists. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the Mississippi site would provide an environment for RVFV to be easily transmitted once released. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV, and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV, and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Because Nipah virus is transmitted by direct contact with bodily fluids, mechanical transmission, and aerosol transmission, there is substantial opportunity for the Nipah virus to spread in the area. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area.

The final risk rank for the mitigated accident scenarios for the proposed NBAF Mississippi site is III (none) for all accidents except over-pressure and fire, which are designated as risk rank II (moderate) for distances close to the release. Because of the potential for easy spread of FMDV, RVFV, and Nipah virus diseases via infected livestock, wildlife, and vectors, the overall risk for the Mississippi site is designated as risk rank II (moderate).

Table 3.14.4.3-3 — Mitigated Accident Specific Air Concentration (virions/m^3) Mississippi Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-01	1.6E+00	0.0	0.0	1.6E+03	4.8E+04	1.6E+01	0.0
200	1.6E-02	1.6E-01	0.0	0.0	1.6E+02	4.7E+03	1.6E+00	0.0
400	5.4E-03	5.4E-02	0.0	0.0	5.4E+01	1.6E+03	5.4E-01	0.0
600	2.9E-03	2.9E-02	0.0	0.0	2.9E+01	8.7E+02	2.9E-01	0.0
800	1.9E-03	1.9E-02	0.0	0.0	1.9E+01	5.6E+02	1.9E-01	0.0
1,000	1.4E-03	1.4E-02	0.0	0.0	1.4E+01	4.1E+02	1.4E-01	0.0
2,000	4.8E-04	4.8E-03	0.0	0.0	4.8E+00	1.4E+02	4.8E-02	0.0
4,000	1.7E-04	1.7E-03	0.0	0.0	1.7E+00	5.0E+01	1.7E-02	0.0
6,000	9.1E-05	9.1E-04	0.0	0.0	9.1E-01	2.7E+01	9.1E-03	0.0
8,000	2.0E-05	2.0E-04	0.0	0.0	2.0E-01	5.9E+00	2.0E-03	0.0
10,000	1.6E-05	1.6E-04	0.0	0.0	1.6E-01	4.7E+00	1.6E-03	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.3-4 — Mitigated Accident Specific Ground Concentration (virions/m^2) Mississippi Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	2.1E-04	2.1E-03	0.0	0.0	2.1E+00	6.4E+01	2.1E-02	0.0
200	3.0E-05	3.0E-04	0.0	0.0	3.0E-01	9.1E+00	3.0E-03	0.0
400	1.3E-05	1.3E-04	0.0	0.0	1.3E-01	3.8E+00	1.3E-03	0.0
600	6.1E-06	6.1E-05	0.0	0.0	6.1E-02	1.8E+00	6.1E-04	0.0
800	3.4E-06	3.4E-05	0.0	0.0	3.4E-02	1.0E+00	3.4E-04	0.0
1,000	2.9E-06	2.9E-05	0.0	0.0	2.9E-02	8.7E-01	2.9E-04	0.0
2,000	3.3E-07	3.3E-06	0.0	0.0	3.3E-03	9.8E-02	3.3E-05	0.0
4,000	1.0E-07	1.0E-06	0.0	0.0	1.0E-03	3.0E-02	1.0E-05	0.0
6,000	2.7E-08	2.7E-07	0.0	0.0	2.7E-04	8.2E-03	2.7E-06	0.0
8,000	1.6E-08	1.6E-07	0.0	0.0	1.6E-04	4.9E-03	1.6E-06	0.0
10,000	1.2E-08	1.2E-07	0.0	0.0	1.2E-04	3.5E-03	1.2E-06	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

3.14.4.4 Plum Island Site

Site-specific consequences for the proposed NBAF site at Plum Island, located at the eastern end of Long Island, New York, are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural use near each site, the consequences are presented individually for each proposed site. In the case of the Plum Island site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could result in the event of a release as postulated in the accidents.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.4-1 illustrates the near-field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.4-1 and 3.14.4.4-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentration tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release.

The near-field results presented in Figure 3.14.4.4-1 illustrate that significant fraction of the island falls with 1 km of the proposed NBAF. The normalized air concentrations range from $1{\times}10^{-2}$ at distances of 200 m to $1.4{\times}10^{-3}$ at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of $3.2{\times}10^{-5}$ to a low of $3{\times}10^{-6}$. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the larger accidents such as over-pressure, seismic, and fire events.

The majority of the NBAF would be within the 200-m radial distance. Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas (BSL-3 and BSL-4 areas), which are generally located in the interior of the facility. At a distance of approximately 250 m from the center of the NBAF, the site boundary would be located. For the purposes of the analysis, it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.2.1.4 presents the terrestrial wildlife in the vicinity of Plum Island. The island is predominately populated by numerous species of birds, with many being waterfowl that are migratory in nature. In addition, there are significant populations of white tail deer on the mainland The presence of deer on the island, while not precluded (deer have not been found on the island since 2004 due to an eradication program), are not prevalent to the degree they are on the mainland. The FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability; however, the unmitigated concentrations near the facility are potentially significant.

While it is possible for the viral pathogens to be transported significant distances by the wind, the results of the modeling indicates that this transport pathway is limited (Figure 3.14.4.1-2). The location of the Plum Island provides a barrier against the spread of viruses. It is considered unlikely that deer can get on and off of the island, but common vectors such as mosquitoes can be transported long distances.

Mosquito species vary in their breeding habits, biting behavior, host preferences and flight range. Most mosquitoes disperse less than two kilometers; some move only a few meters away from their original breeding place, others can fly some 5 or 10 kilometers, and a few species will disperse up to 50 kilometers downwind from the larval habitats (ICPMR, 2008).

RVFV can remain dormant in mosquito eggs for years and when eggs hatch after rainfall the mosquito harbors the virus.

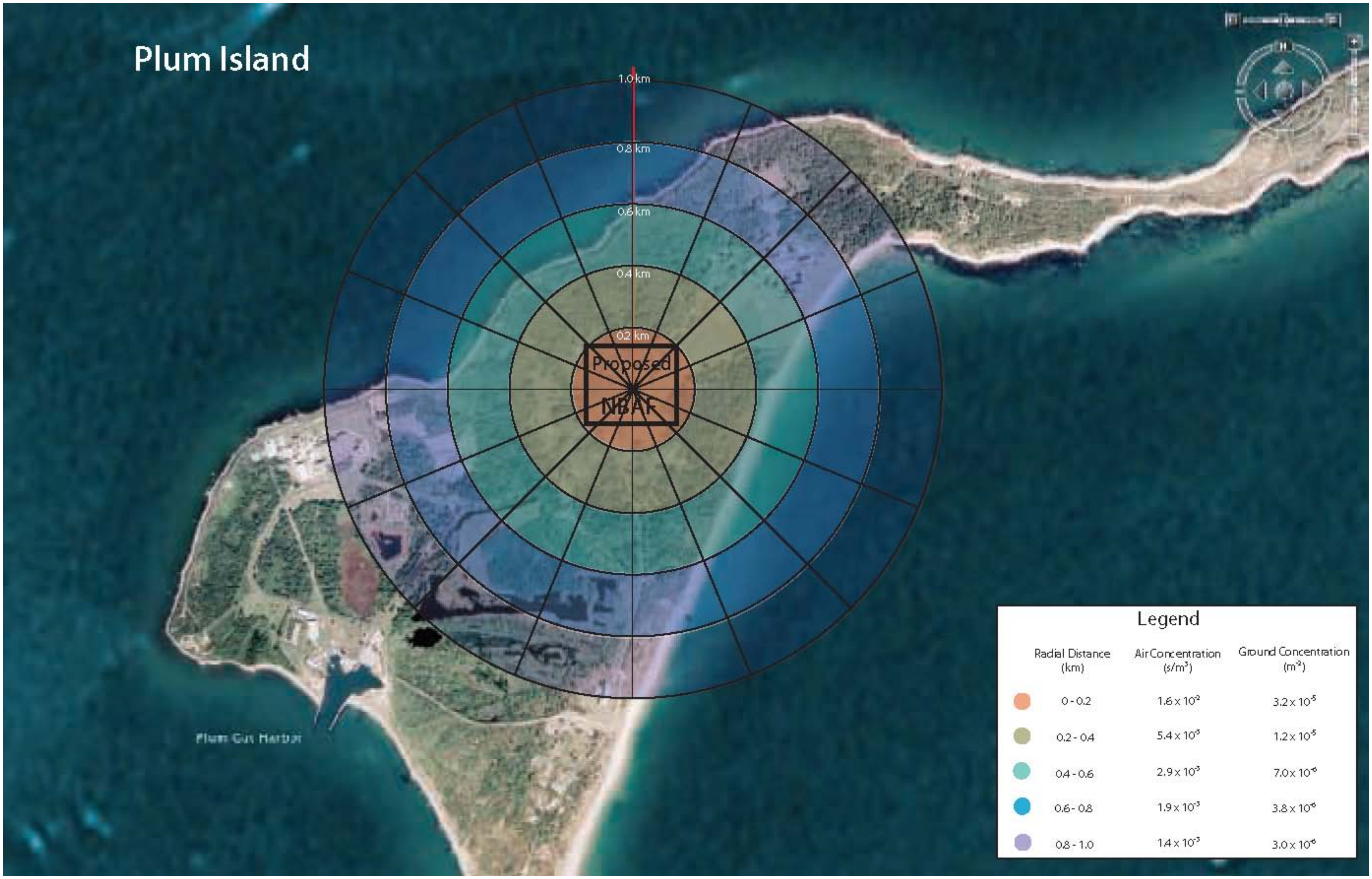


Figure 3.14.4.4-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.4-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) Plum Island Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	1.0E+10	1.0E+11	3.0E+08
50	1.6E-01	1.6E+05	1.6E+09	1.6E+04	1.6E+12	1.6E+11	1.6E+10	4.8E+07
200	1.6E-02	1.6E+04	1.6E+08	1.6E+03	1.6E+11	1.6E+10	1.6E+09	4.7E+06
400	5.4E-03	5.4E+03	5.4E+07	5.4E+02	5.4E+10	5.4E+09	5.4E+08	1.6E+06
600	2.9E-03	2.9E+03	2.9E+07	2.9E+02	2.9E+10	2.9E+09	2.9E+08	8.7E+05
800	1.9E-03	1.9E+03	1.9E+07	1.9E+02	1.9E+10	1.9E+09	1.9E+08	5.6E+05
1,000	1.4E-03	1.4E+03	1.4E+07	1.4E+02	1.4E+10	1.4E+09	1.4E+08	4.1E+05
2,000	4.8E-04	4.8E+02	4.8E+06	4.8E+01	4.8E+09	4.8E+08	4.8E+07	1.4E+05
4,000	1.7E-04	1.7E+02	1.7E+06	1.7E+01	1.7E+09	1.7E+08	1.7E+07	5.0E+04
6,000	9.1E-05	9.1E+01	9.1E+05	9.1E+00	9.1E+08	9.1E+07	9.1E+06	2.7E+04
8,000	5.9E-05	5.9E+01	5.9E+05	5.9E+00	5.9E+08	5.9E+07	5.9E+06	1.8E+04
10,000	3.0E-05	3.0E+01	3.0E+05	3.0E+00	3.0E+08	3.0E+07	3.0E+06	9.0E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

Table 3.14.4.4-2 — Unmitigated Accident Specific Ground Concentration (virions/m^2) Plum Island Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	1.0E+10	1.0E+11	3.0E+08
50	2.4E-04	2.4E+02	2.4E+06	2.4E+01	2.4E+05	7.2E+06	2.4E+07	7.2E+04
200	3.2E-05	3.2E+01	3.2E+05	3.2E+00	3.2E+04	9.6E+05	3.2E+06	9.6E+03
400	1.2E-05	1.2E+01	1.2E+05	1.2E+00	1.2E+04	3.7E+05	1.2E+06	3.7E+03
600	6.9E-06	6.9E+00	6.9E+04	6.9E-01	6.9E+03	2.1E+05	6.9E+05	2.1E+03
800	3.8E-06	3.8E+00	3.8E+04	3.8E-01	3.8E+03	1.1E+05	3.8E+05	1.1E+03
1,000	3.0E-06	3.0E+00	3.0E+04	3.0E-01	3.0E+03	9.0E+04	3.0E+05	9.0E+02
2,000	3.3E-07	3.3E-01	3.3E+03	3.3E-02	3.3E+02	9.8E+03	3.3E+04	9.8E+01
4,000	8.5E-08	8.5E-02	8.5E+02	8.5E-03	8.5E+01	2.5E+03	8.5E+03	2.5E+01
6,000	3.1E-08	3.1E-02	3.1E+02	3.1E-03	3.1E+01	9.4E+02	3.1E+03	9.4E+00
8,000	2.8E-08	2.8E-02	2.8E+02	2.8E-03	2.8E+01	8.5E+02	2.8E+03	8.5E+00
10,000	1.9E-08	1.9E-02	1.9E+02	1.9E-03	1.9E+01	5.7E+02	1.9E+03	5.7E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Source Term = MAR * ARF * RF * DR * LPF

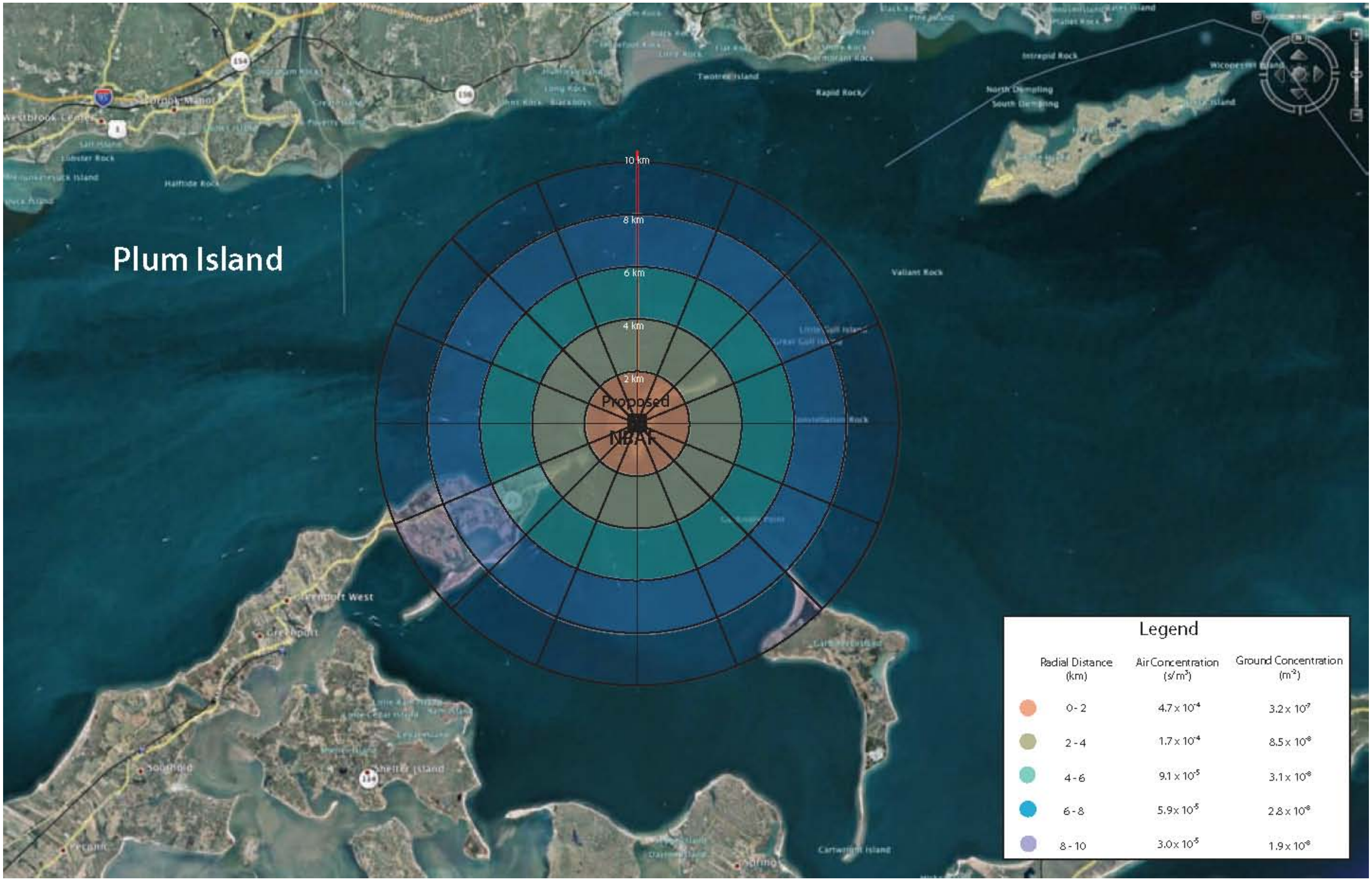


Figure 3.14.4.4-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

The far field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations illustrates the island's protective features against the spread of pathogens. The island is nearly 2 km from the mainland and at this distance the normalized air concentration falls to approximately 5×10^{-4} s/m^3, which indicates that the quantity of material released has to be much greater than 1×10^4 (10,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by an order of magnitude at a distance of 10 km.

Tables 3.14.4.4-3 and 3.14.4.4-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 600 m, indicating that the viral pathogens will not be transported in significant quantities off of the island. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would still be less than the MID (10 virions) at distances greater than 2 km. Since there are no cows roaming free on the island and the presence of deer is minimal, it is reasonable to conclude that the ground concentrations even from the most significant accidents will not result in an infection off of the island.

The accident analysis conservatively estimates a final mitigated source term of 3×10^5 virions for the over-pressure event and 1×10^4 virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. Should this accident occur on Plum Island, the release has a good chance of being contained on the island.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. There are no livestock and very limited wildlife (deer) in the vicinity of the Plum Island site. Therefore, there is little opportunity for FMDV to become established in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites and with the large human population in the area, the ability for the FMDV to spread over large areas exists if contaminated individuals or animals can get off of the island. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area but less than that for the other five proposed sites.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the Plum Island site could provide an environment for RVFV to be transmitted once released; however, with the limitations afforded by the open water, the chances of spreading the disease are less than for the other five proposed NBAF sites. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV, and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area but less than that for the other five proposed sites.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Even though Nipah virus is transmitted by direct contact with bodily fluids, mechanical transmission, and aerosol transmission, there is little opportunity for the Nipah virus to spread off of the island. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area but less than that for the other five proposed sites.

The final risk rank for the mitigated accident scenarios for the proposed NBAF Plum Island Site is III (none) for all accidents except over-pressure and fire, which are designated as II (moderate) for distances close to the release. Given the low likelihood of infected animals or vectors getting off of the island, thereby significantly reducing the potential for the spread of disease, the overall risk for the Plum Island site is designated as III (low or none).

Table 3.14.4.4-3 — Mitigated Accident Specific Air Concentration (virions/m^3) Plum Island Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-01	1.6E+00	0.0	0.0	1.6E+03	4.8E+04	1.6E+01	0.0
200	1.6E-02	1.6E-01	0.0	0.0	1.6E+02	4.7E+03	1.6E+00	0.0
400	5.4E-03	5.4E-02	0.0	0.0	5.4E+01	1.6E+03	5.4E-01	0.0
600	2.9E-03	2.9E-02	0.0	0.0	2.9E+01	8.7E+02	2.9E-01	0.0
800	1.9E-03	1.9E-02	0.0	0.0	1.9E+01	5.6E+02	1.9E-01	0.0
1,000	1.4E-03	1.4E-02	0.0	0.0	1.4E+01	4.1E+02	1.4E-01	0.0
2,000	4.8E-04	4.8E-03	0.0	0.0	4.8E+00	1.4E+02	4.8E-02	0.0
4,000	1.7E-04	1.7E-03	0.0	0.0	1.7E+00	5.0E+01	1.7E-02	0.0
6,000	9.1E-05	9.1E-04	0.0	0.0	9.1E-01	2.7E+01	9.1E-03	0.0
8,000	5.9E-05	5.9E-04	0.0	0.0	5.9E-01	1.8E+01	5.9E-03	0.0
10,000	3.0E-05	3.0E-04	0.0	0.0	3.0E-01	9.0E+00	3.0E-03	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.4-4 — Mitigated Accident Specific Ground Concentration (virions/m^2) Plum Island Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	2.4E-04	2.4E-03	0.0	0.0	2.4E+00	7.2E+01	2.4E-02	0.0
200	3.2E-05	3.2E-04	0.0	0.0	3.2E-01	9.6E+00	3.2E-03	0.0
400	1.2E-05	1.2E-04	0.0	0.0	1.2E-01	3.7E+00	1.2E-03	0.0
600	6.9E-06	6.9E-05	0.0	0.0	6.9E-02	2.1E+00	6.9E-04	0.0
800	3.8E-06	3.8E-05	0.0	0.0	3.8E-02	1.1E+00	3.8E-04	0.0
1,000	3.0E-06	3.0E-05	0.0	0.0	3.0E-02	9.0E-01	3.0E-04	0.0
2,000	3.3E-07	3.3E-06	0.0	0.0	3.3E-03	9.8E-02	3.3E-05	0.0
4,000	8.5E-08	8.5E-07	0.0	0.0	8.5E-04	2.5E-02	8.5E-06	0.0
6,000	3.1E-08	3.1E-07	0.0	0.0	3.1E-04	9.4E-03	3.1E-06	0.0
8,000	2.8E-08	2.8E-07	0.0	0.0	2.8E-04	8.5E-03	2.8E-06	0.0
10,000	1.9E-08	1.9E-07	0.0	0.0	1.9E-04	5.7E-03	1.9E-06	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where “E” represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

3.14.4.5 North Carolina Site

Site-specific consequences for the proposed site in North Carolina, located near the city of Butner, are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural uses near each site, the consequences are presented individually for each proposed site. In the case of the North Carolina site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could result in the event of a release as postulated in the accidents.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.5-1 illustrates the near-field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.5-1 and 3.14.4.5-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentration tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release at the proposed North Carolina NBAF site.

The normalized air concentrations for the North Carolina site range from 1.6×10^{-2} at distances of 200 m to 1.4×10^{-3} at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of 2.0×10^{-5} to a low of 2.1×10^{-6}. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the more significant accidents such as over-pressure, seismic, and fire events.
As with the previous discussion, the majority of the NBAF would be within the 200-m radial distance.
Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas. The site boundary would be located at approximately 250 m from the center of the NBAF. For the purposes of the analysis, it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.7.1.1 presents the discussion of the vegetation in the vicinity of the proposed NBAF site. The area outside of the immediate area of the NBAF site is characterized as recovering clear-cut forest area. At greater distances the vegetation includes wooded forestland with numerous lakes, streams or rivers, and wetlands. In addition, there are large agricultural areas for crops and grazing.

Section 3.8.7.1.4 presents the terrestrial wildlife in the vicinity of the proposed North Carolina NBAF site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Mammals include both white tail deer and grey fox. Within 3 km of the proposed site are significant areas of industrial and residential development. Section 3.8.7.1.4 presents the terrestrial wildlife in the vicinity of the proposed North Carolina NBAF site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Major mammals include white tail deer and coyote. The wildlife and livestock in the vicinity of the site are prime candidates for acquiring or transmitting the FMD and RVFV and to some extent the Nipah virus when pigs are present. While the FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability, the unmitigated concentrations near the facility are potentially significant.

The location of the proposed NBAF site in North Carolina provides a significant opportunity for the spread of viruses via vectors and infected wildlife. In addition, the atmospheric modeling indicates that down-wind transport is a credible scenario given a sufficiently large release of pathogens.

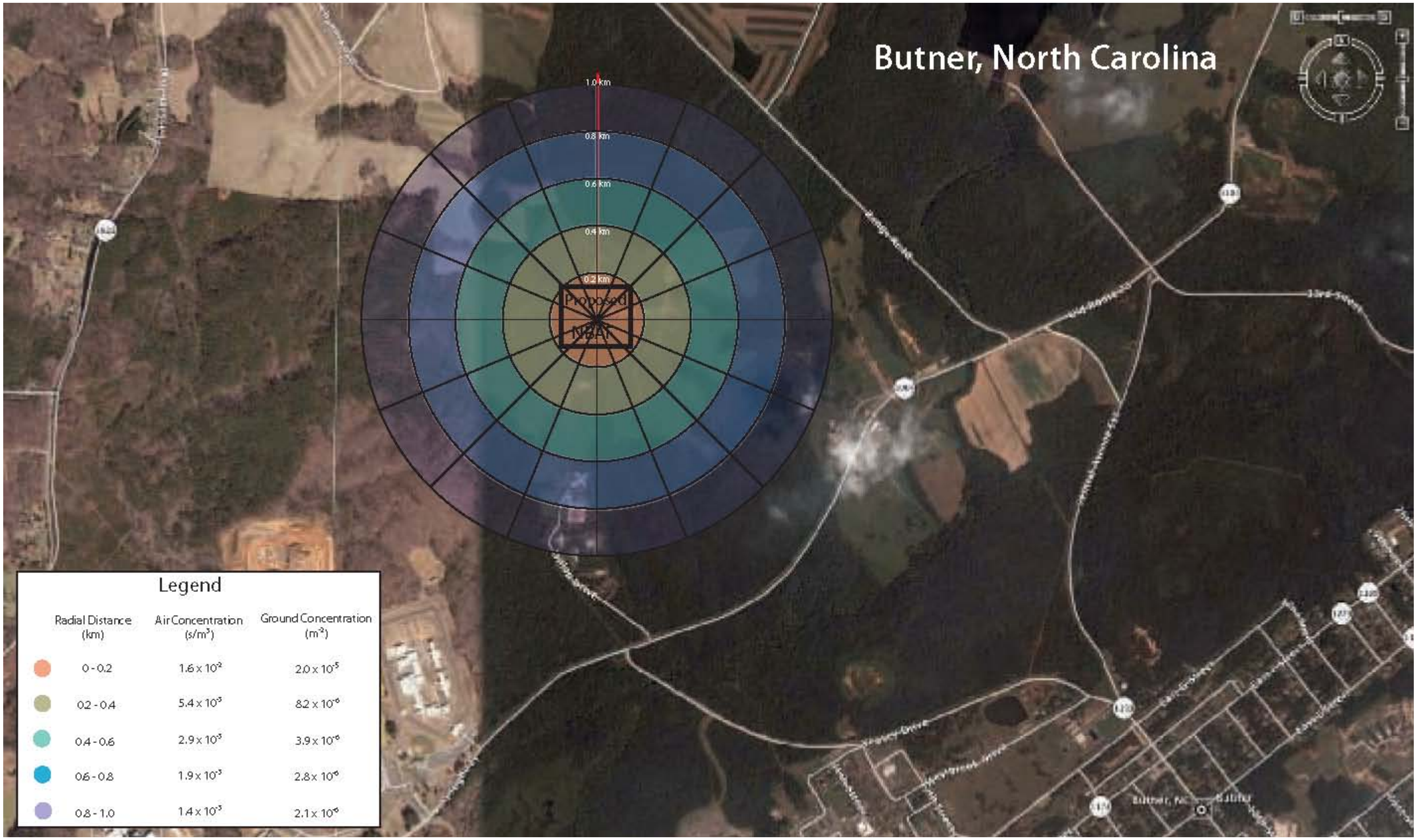
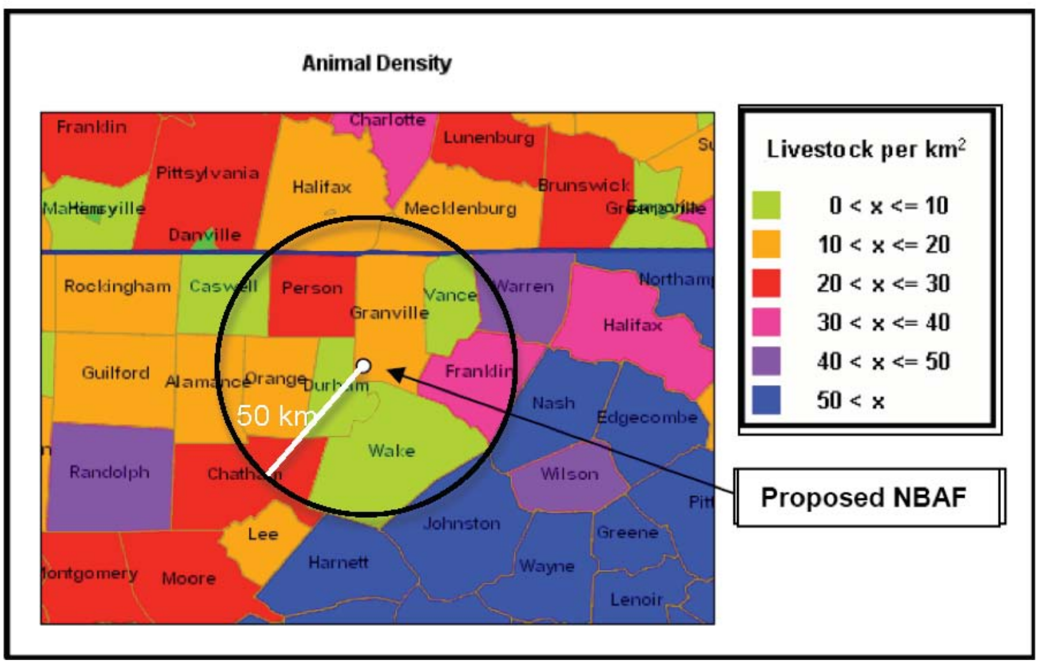


Figure 3.14.4.5-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

For this site, as with all of the sites except Plum Island, New York, there is a potential for viral pathogens to be transported significant distances by the wind. The results of the modeling indicate that this transport pathway is not limited (Figure 3.14.4.5-2), as was the case for Plum Island. It is considered likely that deer could act to spread disease over long distances. In addition, common vectors such as mosquitoes can be transported long distances.

The potential for acquiring and spreading diseases from the FMDV, RVFV, and Nipah virus is also illustrated by consideration of the livestock in the vicinity of the proposed North Carolina site. The counties surrounding the proposed NBAF site in North Carolina contain significant numbers of livestock potentially exposed in the event of a release. Data related to the distribution of livestock in the vicinity of the NBAF were obtained from a DHS tasking response dated August 6, 2007. Data were collected related to livestock in the areas of the proposed NBAF sites to support the determination as to whether accidental laboratory release at these locations could have the potential to affect nearby livestock (DHS 2007). The normalized concentrations presented in Figure 3.14.4.3-2 up to distances of 10 km from the proposed NBAF are fully contained by Durham and Granville counties. Data provided on livestock density indicate that there is on the order of 0 to 30 livestock, mostly cattle, per square kilometer in this area.

County & Surrounding Counties	Number of Herds	Number of Livestock
Granville	301	16674
Halifax, VA	460	31693
Mecklenburg, VA	355	24054
Person	197	22583
Durham	101	4611
Wake	270	13835
Franklin	238	40263
Vance	77	2346
	1999	**156059**



Livestock Proximal to the North Carolina Site

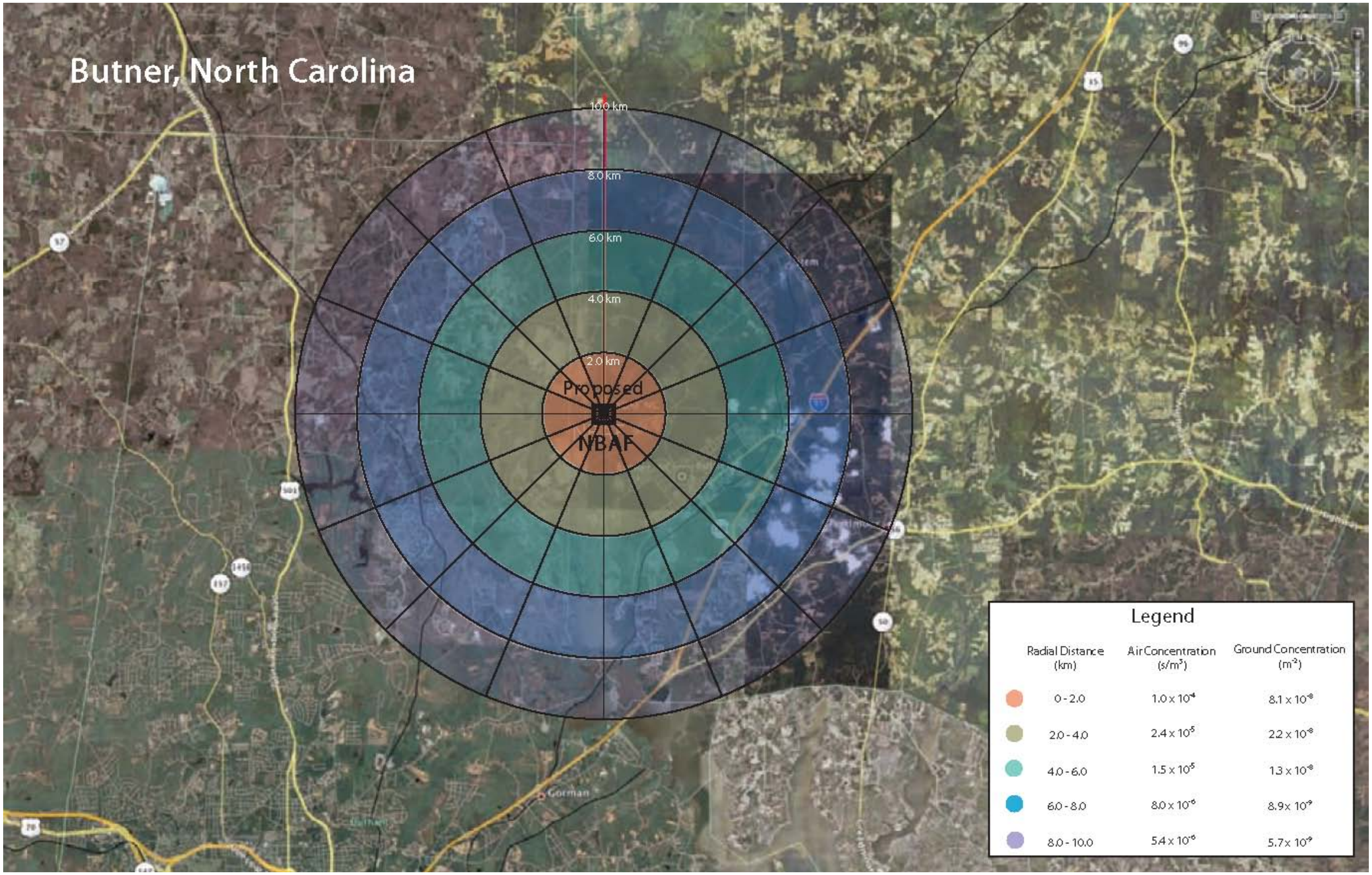


Figure 3.14.4.5-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.5-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) North Carolina Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	8.1E-02	8.1E+04	8.1E+08	8.1E+03	8.1E+07	2.4E+09	8.1E+09	2.4E+07
200	7.8E-03	7.8E+03	7.8E+07	7.8E+02	7.8E+06	2.3E+08	7.8E+08	2.3E+06
400	2.7E-03	2.7E+03	2.7E+07	2.7E+02	2.7E+06	8.0E+07	2.7E+08	8.0E+05
600	1.4E-03	1.4E+03	1.4E+07	1.4E+02	1.4E+06	4.3E+07	1.4E+08	4.3E+05
800	9.3E-04	9.3E+02	9.3E+06	9.3E+01	9.3E+05	2.8E+07	9.3E+07	2.8E+05
1,000	6.7E-04	6.7E+02	6.7E+06	6.7E+01	6.7E+05	2.0E+07	6.7E+07	2.0E+05
2,000	1.0E-04	1.0E+02	1.0E+06	1.0E+01	1.0E+05	3.0E+06	1.0E+07	3.0E+04
4,000	2.4E-05	2.4E+01	2.4E+05	2.4E+00	2.4E+04	7.3E+05	2.4E+06	7.3E+03
6,000	1.5E-05	1.5E+01	1.5E+05	1.5E+00	1.5E+04	4.4E+05	1.5E+06	4.4E+03
8,000	8.0E-06	8.0E+00	8.0E+04	8.0E-01	8.0E+03	2.4E+05	8.0E+05	2.4E+03
10,000	5.4E-06	5.4E+00	5.4E+04	5.4E-01	5.4E+03	1.6E+05	5.4E+05	1.6E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

Table 3.14.4.5-2 — Unmitigated Accident Specific Ground Concentration (virions/m^2) North Carolina Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.0E-04	1.0E+02	1.0E+06	1.0E+01	1.0E+05	3.0E+06	1.0E+07	3.0E+04
200	1.7E-05	1.7E+01	1.7E+05	1.7E+00	1.7E+04	5.2E+05	1.7E+06	5.2E+03
400	7.4E-04	7.4E+02	7.4E+06	7.4E+01	7.4E+05	2.2E+07	7.4E+07	2.2E+05
600	4.5E-06	4.5E+00	4.5E+04	4.5E-01	4.5E+03	1.3E+05	4.5E+05	1.3E+03
800	2.9E-06	2.9E+00	2.9E+04	2.9E-01	2.9E+03	8.7E+04	2.9E+05	8.7E+02
1,000	2.3E-06	2.3E+00	2.3E+04	2.3E-01	2.3E+03	7.0E+04	2.3E+05	7.0E+02
2,000	8.1E-08	8.1E-02	8.1E+02	8.1E-03	8.1E+01	2.4E+03	8.1E+03	2.4E+01
4,000	2.2E-08	2.2E-02	2.2E+02	2.2E-03	2.2E+01	6.5E+02	2.2E+03	6.5E+00
6,000	1.3E-08	1.3E-02	1.3E+02	1.3E-03	1.3E+01	3.9E+02	1.3E+03	3.9E+00
8,000	8.9E-09	8.9E-03	8.9E+01	8.9E-04	8.9E+00	2.7E+02	8.9E+02	2.7E+00
10,000	5.7E-09	5.7E-03	5.7E+01	5.7E-04	5.7E+00	1.7E+02	5.7E+02	1.7E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Source Term = MAR * ARF * RF * DR * LPF

The area within a 10-km radius of the proposed NBAF would be approximately 78.5 km^2 and could be fewer than 1,000 cattle. For the unmitigated accidents, concentrations on the order of 1×10^4 or greater occur at distances greater than 10 km for the high source term accidents. At relatively close proximity to the site (less than 1 km), the unmitigated concentrations in the air and on the ground show the potential for a large number of infections from any of the three viruses. The number of livestock outside of the 10-km radius increases to as many as 156,000 animals, which are at risk from the postulated unmitigated releases.

The far-field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations falls off sharply with distance. The normalized air concentration falls to less than 1×10^{-4} s/m^3 at distances greater than 2 km. At these distances, the quantity of material released would need to be much greater than 1×10^3 (1,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by nearly two orders of magnitude at a distance of 10 km.

Tables 3.14.4.5-3 and 3.14.4.5-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 400 m, indicating that the viral pathogens will not be transported in significant quantities far from the site. This result illustrates the localized effects of the mitigated accidents. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would be less than the MID (10 virions) at distances greater than 2 km. Emergency planning and rapid response to a possible release will afford an opportunity to mitigate the consequences of the postulated accidents.

The accident analysis conservatively estimates a final mitigated source term of 3×10^5 virions for the over-pressure event and 1×10^4 virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. In the event this accident occurs, there is a good chance that the viruses will not be contained without timely emergency response.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. The livestock and wildlife (deer and boar) in the vicinity of the North Carolina site provides ample opportunity for FMDV to establish in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites and with the large human population in the area, the ability for the FMDV to spread over large areas also exists. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the North Carolina site would provide an environment for RVFV to be easily transmitted once released. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV, and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Because Nipah virus is transmitted by direct contact with of bodily fluids, mechanical transmission, and aerosol transmission, there is substantial opportunity for the Nipah virus to spread in the area. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area.

The final risk rank for the mitigated accident scenarios for the proposed NBAF North Carolina site is III (none) for all accidents except over-pressure and fire, which are designated as risk rank II (moderate) for distances close to the release. Because of the potential for easy spread of FMDV, RVFV, and Nipah virus diseases via infected livestock, wildlife, and vectors, the overall risk for the North Carolina site is designated as risk rank II (moderate).

Table 3.14.4.5-3 — Mitigated Accident Specific Air Concentration (virions/m^3) North Carolina Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	8.1E-02	8.1E-01	0.0	0.0	8.1E+02	2.4E+04	8.1E+00	0.0
200	7.8E-03	7.8E-02	0.0	0.0	7.8E+01	2.3E+03	7.8E-01	0.0
400	2.7E-03	2.7E-02	0.0	0.0	2.7E+01	8.0E+02	2.7E-01	0.0
600	1.4E-03	1.4E-02	0.0	0.0	1.4E+01	4.3E+02	1.4E-01	0.0
800	9.3E-04	9.3E-03	0.0	0.0	9.3E+00	2.8E+02	9.3E-02	0.0
1,000	6.7E-04	6.7E-03	0.0	0.0	6.7E+00	2.0E+02	6.7E-02	0.0
2,000	1.0E-04	1.0E-03	0.0	0.0	1.0E+00	3.0E+01	1.0E-02	0.0
4,000	2.4E-05	2.4E-04	0.0	0.0	2.4E-01	7.3E+00	2.4E-03	0.0
6,000	1.5E-05	1.5E-04	0.0	0.0	1.5E-01	4.4E+00	1.5E-03	0.0
8,000	8.0E-06	8.0E-05	0.0	0.0	8.0E-02	2.4E+00	8.0E-04	0.0
10,000	5.4E-06	5.4E-05	0.0	0.0	5.4E-02	1.6E+00	5.4E-04	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.5-4 — Mitigated Accident Specific Air Concentration (virions/m^3) North Carolina Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.0E-04	1.0E-03	0.0	0.0	1.0E+00	3.0E+01	1.0E-02	0.0
200	1.7E-05	1.7E-04	0.0	0.0	1.7E-01	5.2E+00	1.7E-03	0.0
400	7.4E-04	7.4E-03	0.0	0.0	7.4E+00	2.2E+02	7.4E-02	0.0
600	4.5E-06	4.5E-05	0.0	0.0	4.5E-02	1.3E+00	4.5E-04	0.0
800	2.9E-06	2.9E-05	0.0	0.0	2.9E-02	8.7E-01	2.9E-04	0.0
1,000	2.3E-06	2.3E-05	0.0	0.0	2.3E-02	7.0E-01	2.3E-04	0.0
2,000	8.1E-08	8.1E-07	0.0	0.0	8.1E-04	2.4E-02	8.1E-06	0.0
4,000	2.2E-08	2.2E-07	0.0	0.0	2.2E-04	6.5E-03	2.2E-06	0.0
6,000	1.3E-08	1.3E-07	0.0	0.0	1.3E-04	3.9E-03	1.3E-06	0.0
8,000	8.9E-09	8.9E-08	0.0	0.0	8.9E-05	2.7E-03	8.9E-07	0.0
10,000	5.7E-09	5.7E-08	0.0	0.0	5.7E-05	1.7E-03	5.7E-07	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

3.14.4.6 Texas Site

Site-specific consequences for the proposed Texas site, located near the city of San Antonio, are depicted in terms of the accidents postulated in Section 3.14.3. Each of the accidents has the potential to release pathogens to the environment. Because of the differences in topography, weather, and agricultural uses near each site, the consequences are presented individually for each proposed site. In the case of the Texas site, the site-specific atmospheric data were used to provide estimates of time-integrated down-wind air and ground concentrations that could result in the event of a release as postulated in the accidents.

To assess the site-specific consequences from the postulated bounding accidents, it is first necessary to evaluate the results of the transport modeling and the development of specific air and ground concentrations of viral pathogens estimated to have been released in each accident. Figure 3.14.4.4-1 illustrates the near-field effects of a potential release and the subsequent down-wind transport in air along with the deposition onto the ground as a result of settling or washout (NUREG 3332). Tables 3.14.4.6-1 and 3.14.4.6-2 present the resultant air and ground concentrations for each unmitigated accident at specific radial distances. The combination of these concentrations tables and the figures representing the near- and far-field results provides the basis for evaluating the impacts to the population and environment after a hypothetical release at the proposed Texas NBAF site.

The normalized air concentrations for the San Antonio, Texas, site range from 1.6×10^{-2} at distances of 200 m to 1.4×10^{-3} at a distance of 1,000 m (1 km) from a release. The ground concentrations for these same radial distances range from a high of 2.0×10^{-5} to a low of 2.1×10^{-6}. Taking into consideration the source terms for each of the specific accidents, the normalized air and ground concentration values represent the potential for significant concentrations in the air and on the ground for the more significant accidents such as over-pressure, seismic, and fire events.

As with the previous discussion, the majority of the NBAF would be within the 200-m radial distance.

Significant releases of pathogens from the NBAF as a result of accidents could be expected to occur only from the higher biocontainment areas. The site boundary would be located at approximately 250 m from the center of the NBAF. For the purposes of the analysis, it is assumed that distances past 200 m essentially represents an off-site release. Section 3.8.8.1.1 presents the discussion of the vegetation in the vicinity of the proposed NBAF site. In the general area in and around the proposed NBAF site, the vegetation is predominantly prairie grassland typical of the southwestern United States with wooded areas that are generally scrubby. The area contains few water sources within 10 km of the site and essentially no wetlands. Within the immediate area of the site is mainly disturbed pastureland, currently used for grazing livestock, and a significant presence of industrial and residential areas.

Section 3.8.4.1.4 presents the terrestrial wildlife in the vicinity of the proposed Texas NBAF site. Numerous species of mammals, birds, reptiles, and insects (mosquitoes and ticks) inhabit the area around the proposed site. Major mammals include white tail deer and coyote. The wildlife and livestock in the vicinity of the site are prime candidates for acquiring or transmitting the FMD and RVFV and to some extent the Nipah virus when pigs are present. While the FMDV, RVFV, and Nipah virus each have different characteristics related to transmission and viability, the unmitigated concentrations near the facility are potentially significant.

The location of the proposed NBAF site in Texas provides a significant opportunity for the spread of viruses via vectors and infected wildlife. In addition, the atmospheric modeling indicates that down-wind transport is a credible scenario given a sufficiently large release of pathogens.

For this site, as with all of the sites except Plum Island, New York, there is a potential for viral pathogens to be transported significant distances by the wind. The results of the modeling indicate that this transport pathway is not limited (Figure 3.14.4.6-2), as was the case for Plum Island. It is considered likely that deer could act to spread disease over long distances. In addition, common vectors such as mosquitoes can be transported long distances.

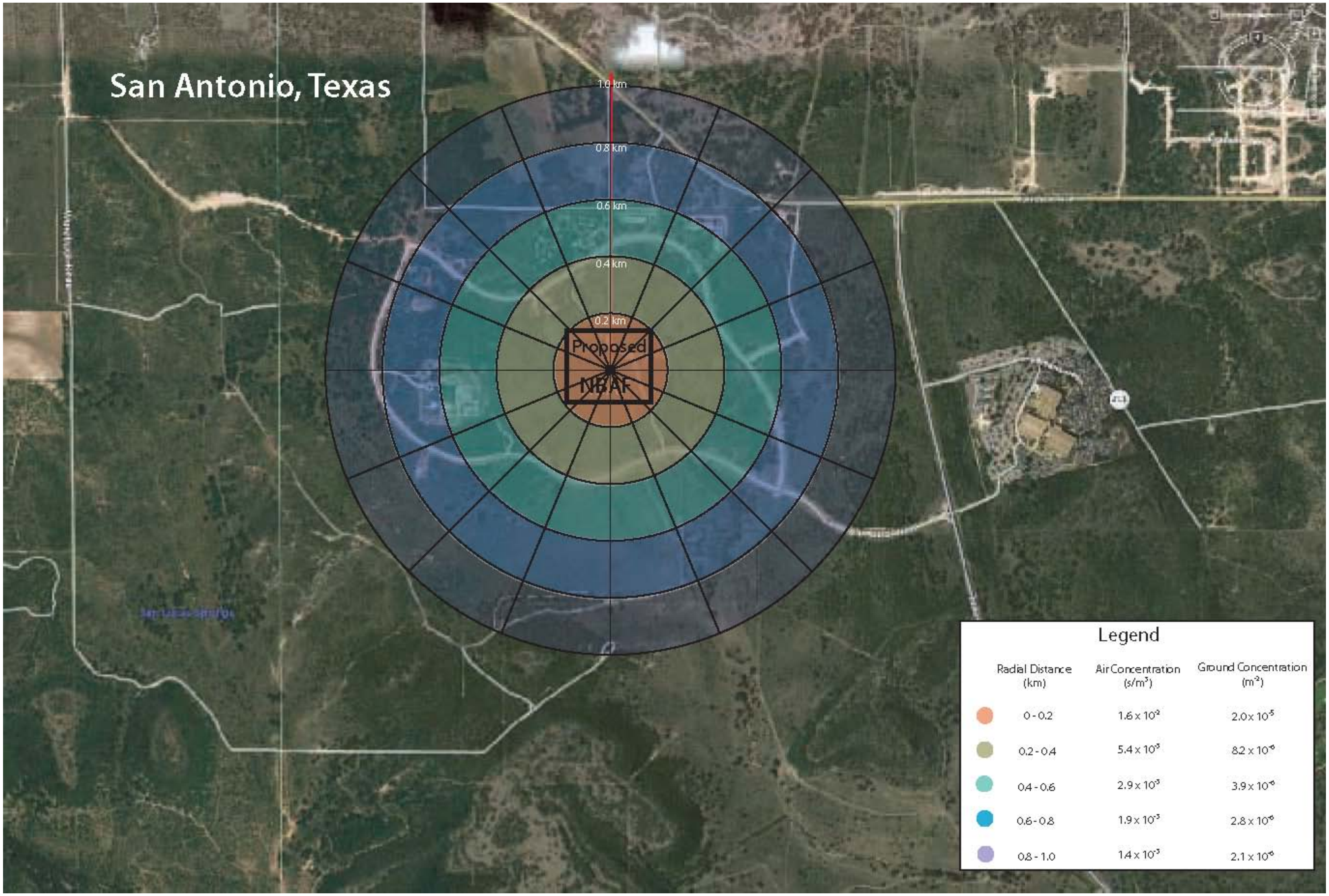


Figure 3.14.4.6-1 — Near Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

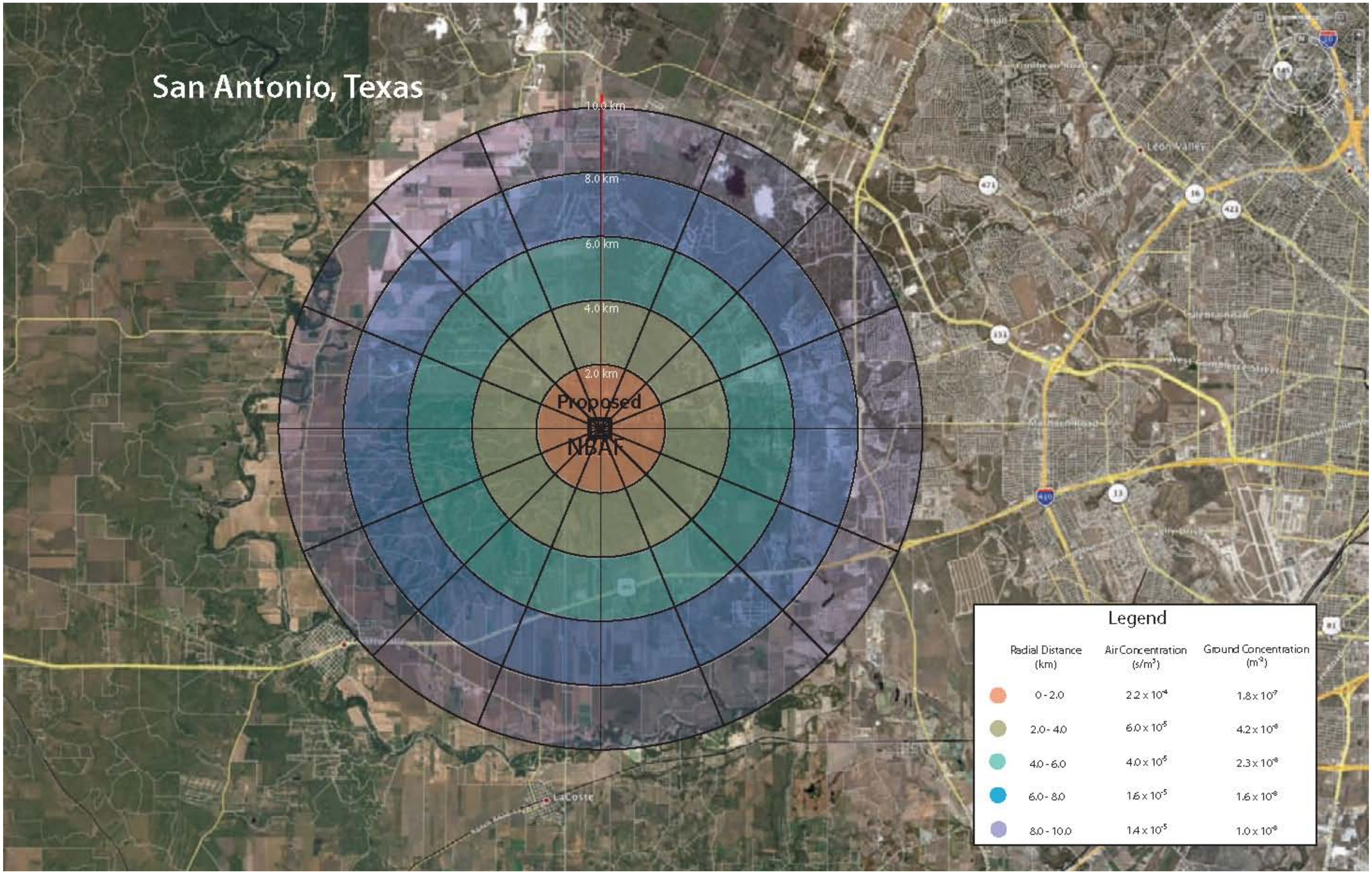


Figure 3.14.4.6-2 — Far Field Distribution of Viral Pathogens Based On Time-Integrated Atmospheric Transport

Table 3.14.4.6-1 — Unmitigated Accident Specific Air Concentration (virions/m^3) Texas Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.6E-01	1.6E+05	1.6E+09	1.6E+04	1.6E+08	4.8E+09	1.6E+10	4.8E+07
200	1.6E-02	1.6E+04	1.6E+08	1.6E+03	1.6E+07	4.7E+08	1.6E+09	4.7E+06
400	5.4E-03	5.4E+03	5.4E+07	5.4E+02	5.4E+06	1.6E+08	5.4E+08	1.6E+06
600	2.9E-03	2.9E+03	2.9E+07	2.9E+02	2.9E+06	8.7E+07	2.9E+08	8.7E+05
800	1.9E-03	1.9E+03	1.9E+07	1.9E+02	1.9E+06	5.6E+07	1.9E+08	5.6E+05
1,000	1.4E-03	1.4E+03	1.4E+07	1.4E+02	1.4E+06	4.1E+07	1.4E+08	4.1E+05
2,000	2.2E-04	2.2E+02	2.2E+06	2.2E+01	2.2E+05	6.7E+06	2.2E+07	6.7E+04
4,000	6.0E-05	6.0E+01	6.0E+05	6.0E+00	6.0E+04	1.8E+06	6.0E+06	1.8E+04
6,000	4.0E-05	4.0E+01	4.0E+05	4.0E+00	4.0E+04	1.2E+06	4.0E+06	1.2E+04
8,000	1.6E-05	1.6E+01	1.6E+05	1.6E+00	1.6E+04	4.9E+05	1.6E+06	4.9E+03
10,000	1.4E-05	1.4E+01	1.4E+05	1.4E+00	1.4E+04	4.1E+05	1.4E+06	4.1E+03

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.
[a]Source Term = MAR * ARF * RF * DR * LPF

Table 3.14.4.6-2 — Unmitigated Accident Specific Ground Concentration (virions/m²) Texas Site

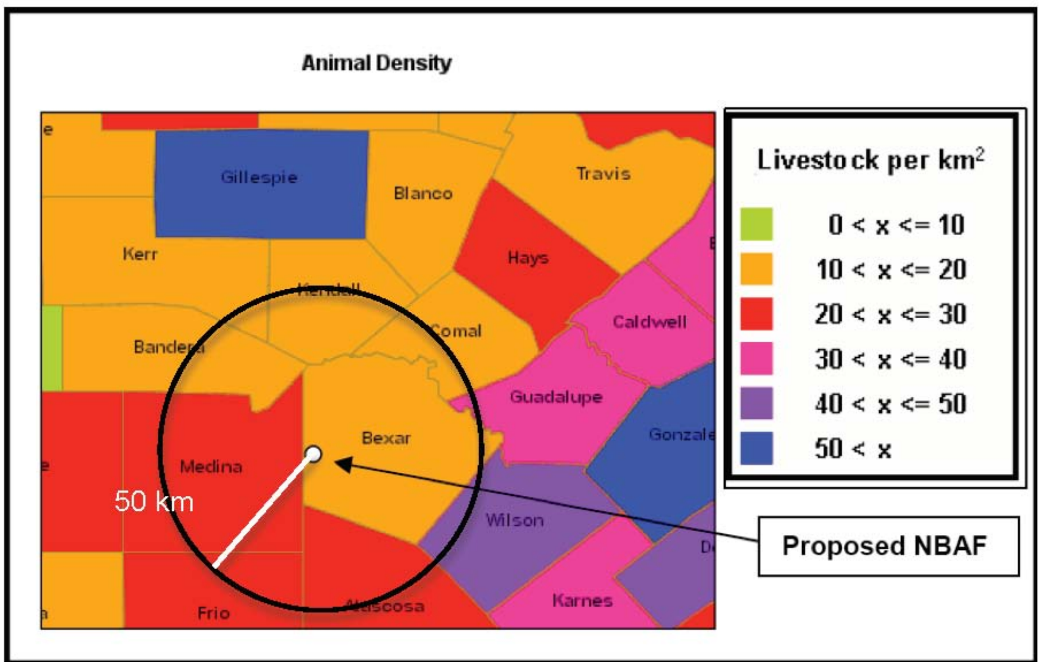
		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m²)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Unmitigated Source Term[a]						
		1.0E+06	1.0E+10	1.0E+05	1.0E+09	3.0E+10	1.0E+11	3.0E+08
50	1.6E-04	1.6E+02	1.6E+06	1.6E+01	1.6E+05	4.9E+06	1.6E+07	4.9E+04
200	2.0E-05	2.0E+01	2.0E+05	2.0E+00	2.0E+04	5.9E+05	2.0E+06	5.9E+03
400	8.2E-06	8.2E+00	8.2E+04	8.2E-01	8.2E+03	2.5E+05	8.2E+05	2.5E+03
600	3.9E-06	3.9E+00	3.9E+04	3.9E-01	3.9E+03	1.2E+05	3.9E+05	1.2E+03
800	2.8E-06	2.8E+00	2.8E+04	2.8E-01	2.8E+03	8.5E+04	2.8E+05	8.5E+02
1,000	2.1E-06	2.1E+00	2.1E+04	2.1E-01	2.1E+03	6.2E+04	2.1E+05	6.2E+02
2,000	1.8E-07	1.8E-01	1.8E+03	1.8E-02	1.8E+02	5.3E+03	1.8E+04	5.3E+01
4,000	4.2E-08	4.2E-02	4.2E+02	4.2E-03	4.2E+01	1.2E+03	4.2E+03	1.2E+01
6,000	2.3E-08	2.3E-02	2.3E+02	2.3E-03	2.3E+01	6.8E+02	2.3E+03	6.8E+00
8,000	1.6E-08	1.6E-02	1.6E+02	1.6E-03	1.6E+01	4.7E+02	1.6E+03	4.7E+00
10,000	1.0E-08	1.0E-02	1.0E+02	1.0E-03	1.0E+01	3.0E+02	1.0E+03	3.0E+00

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where “E” represents power of 10.

[a]Source Term = MAR * ARF * RF * DR * LPF

The potential for acquiring and spreading diseases from the FMDV, RVFV, and Nipah virus is also illustrated by consideration of the livestock in the vicinity of the proposed Texas site. The counties surrounding the proposed NBAF site in Texas contain significant numbers of livestock potentially exposed in the event of a release. Data related to the distribution of livestock in the vicinity of the NBAF were obtained from a DHS tasking response dated August 6, 2007. Data were collected related to livestock in the areas of the proposed NBAF sites to support the determination as to whether accidental laboratory release at these locations could have the potential to affect nearby livestock (DHS 2007). The normalized concentrations presented in Figure 3.14.4.6-2 up to distances of 10 km from the proposed NBAF are fully contained by Bexar and Medina counties. Data provided on livestock density indicate that there is on the order of 10 to 30 livestock, mostly cattle, per square kilometer in this area.

County & Surrounding Counties	Number of Herds	Number of Livestock
Bexar	1823	58410
Kendall	815	33554
Bandera	630	23983
Medina	1529	73909
Atascosa	1344	92413
Wilson	1839	94654
Comal	684	18120
Guadalupe	1896	64846
	10560	**459889**



Livestock Proximal to the Texas Research Park Site

The area within a 10-km radius of the proposed NBAF would be approximately 78.5 km^2 and could comprise nearly 1,600 cattle. For the unmitigated accidents, concentrations on the order of 1×10^4 or greater occur at distances greater than 10 km for the high source term accidents. At relatively close proximity to the site (less than 1 km), the unmitigated concentrations in the air and on the ground show the potential for a large number of infections from any of the three viruses. The number of livestock outside of the 10-km radius increases significantly (>450,000 animals) and are at risk from the postulated unmitigated releases.

The far-field distribution of viral pathogens via air transport, in terms of normalized time-integrated air and ground concentrations, falls off sharply with distance. The normalized air concentration falls to less than 2×10^{-4} s/m^3 at distances greater than 2 km. At these distances, the quantity of material released would need to be much greater than 5×10^3 (5,000 virions) before there is a significant potential for an infection to result. The normalized air concentration falls off by nearly an order of magnitude at distance of 10 km.

Tables 3.14.4.6-3 and 3.14.4.6-4 present the accident-specific air and ground concentrations for the mitigated scenarios. It is evident from the mitigated air concentration results and a cow's breathing rate of 1.6×10^{-3} m^3/s that only the significant accidents of a large facility fire or an over-pressure event (deflagration) are considered to have a potential for resulting in an infection after a release. In the event that either of these accidents occurs, the mitigated results show that the elevated air concentrations are limited to distances less than 400 m, indicating that the viral pathogens will not be transported in significant quantities far from the site. This result illustrates the localized effects of the mitigated accidents. In a similar manner, the ground concentrations are limited to short distances from the release point. Taking into consideration that a cow would cover a 30-m^2 area in a single day, the resultant dose would be less than the MID (10 virions) at distances greater than 2 km. Emergency planning and rapid response to a possible release will afford an opportunity to mitigate the consequences of the postulated accidents.

The accident analysis conservatively estimates a final mitigated source term of 3×10^5 virions for the over-pressure event and 1×10^4 virions for the large fire. The risk values indicated that the higher efficiency HEPAs, NBAF structure, fire suppression system, and other appropriate controls were sufficient to mitigate or prevent the accidents. In addition, the release of contaminated wastes and the loss of an infected animal were assigned site-independent risk ranks of 3, indicating that additional controls should be considered to effectively reduce the likelihood of the accident. The consequences in these two scenarios were assigned public severity category D based on the accident being prevented. The effectiveness of the sterilization of wastes and the biocontainment of the animals were the primary controls. In the event this accident occurs, there is a good chance that the viruses will not be contained without timely emergency response.

Site-Specific Consequences for FMDV

FMDV spreads quickly through herds and flocks of susceptible animals. With an incubation period of as little as 12 hours, the disease can spread quite rapidly. Cattle are often considered to act as indicators because of the low infectious dose, sheep act as maintenance hosts, and swine act as amplifiers of FMDV. The livestock and wildlife (deer and boar) in the vicinity of the Texas site provides ample opportunity for FMDV to establish in the environment upon a release. FMDV can persist in the human upper respiratory tract for up to 48 hours, making humans potential vectors if they are exposed. In addition, the ability for FMDV to be spread by fomites and with the large human population in the area, the ability for the FMDV to spread over large areas also exists. The consequences of a large release of FMD virions would be as severe as that of RVFV or Nipah virus in this area.

Site-Specific Consequences for RVFV

RVFV is an acute mosquito-borne (vector-based) viral disease affecting mainly ruminants (e.g., cattle, sheep, deer) and humans. In animals, RVF causes abortions and high mortality in young. In humans, RVF causes severe influenza-like syndrome. The area around the Texas site would provide an environment for RVFV to be easily transmitted once released. The inhalation pathway to humans and wind-borne dispersal of infected vectors can transmit RVFV, and infected livestock and people movement are a means of spreading RVFV. Mosquitoes are a reservoir for RVFV, and the virus can remain dormant in the eggs of the mosquito in dry soil of grassland depressions. With adequate rainfall, the infected mosquitoes could develop and infect ruminants. The virus can be spread by many mosquito species. The consequences of a large release of RVF virions would be as severe as that of FMDV or Nipah virus in this area.

Site-Specific Consequences for Nipah Virus

In pigs, the Nipah virus appears to cause a high rate of febrile illness but a low rate of sickness and death, yet it can appear as sudden death syndrome in mature swine. In humans, Nipah virus is characterized by severe febrile encephalitis, fever, headache, dizziness, and vomiting with a high mortality rate. The host range of Nipah virus is in pigs, cats, dogs, and possible in horses and goats. Because Nipah virus is transmitted by direct contact with bodily fluids, mechanical transmission, and aerosol transmission, there is substantial opportunity for the Nipah virus to spread in the area. The consequences of a large release of Nipah virions would be as severe as that of RVFV or FMDV in this area.

The final risk rank for the mitigated accident scenarios for the proposed NBAF Texas site is III (none) for all accidents except over-pressure and fire, which are designated as risk rank II (moderate) for distances close to the release. Because of the potential for easy spread of FMDV, RVFV, and Nipah virus diseases via infected livestock, wildlife, and vectors, the overall risk for the Texas site is designated as risk rank II (moderate).

Table 3.14.4.6-3 — Mitigated Accident Specific Air Concentration (virions/m^3) Texas Site

		Accident Type						
Radial Distance (meters)	Normalized Air Concentration 95% χ/Q (s/m^3)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-01	1.6E+00	0.0	0.0	1.6E+03	4.8E+04	1.6E+01	0.0
200	1.6E-02	1.6E-01	0.0	0.0	1.6E+02	4.7E+03	1.6E+00	0.0
400	5.4E-03	5.4E-02	0.0	0.0	5.4E+01	1.6E+03	5.4E-01	0.0
600	2.9E-03	2.9E-02	0.0	0.0	2.9E+01	8.7E+02	2.9E-01	0.0
800	1.9E-03	1.9E-02	0.0	0.0	1.9E+01	5.6E+02	1.9E-01	0.0
1,000	1.4E-03	1.4E-02	0.0	0.0	1.4E+01	4.1E+02	1.4E-01	0.0
2,000	2.2E-04	2.2E-03	0.0	0.0	2.2E+00	6.7E+01	2.2E-02	0.0
4,000	6.0E-05	6.0E-04	0.0	0.0	6.0E-01	1.8E+01	6.0E-03	0.0
6,000	4.0E-05	4.0E-04	0.0	0.0	4.0E-01	1.2E+01	4.0E-03	0.0
8,000	1.6E-05	1.6E-04	0.0	0.0	1.6E-01	4.9E+00	1.6E-03	0.0
10,000	1.4E-05	1.4E-04	0.0	0.0	1.4E-01	4.1E+00	1.4E-03	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)

Table 3.14.4.6-4 — Mitigated Accident Specific Ground Concentration (virions/m^2) Texas Site

		Accident Type						
Radial Distance (meters)	Normalized Ground Concentration 95% (1/m^2)	Small-Medium Spill	Loss of Animal	Improper Sterilization	Large Room Fire	Over-Pressure Event	Seismic	Air craft crash
		Mitigated Source Term[a]						
		10	0	0	10,000	300,000	100	0
50	1.6E-04	1.6E-03	0.0	0.0	1.6E+00	4.9E+01	1.6E-02	0.0
200	2.0E-05	2.0E-04	0.0	0.0	2.0E-01	5.9E+00	2.0E-03	0.0
400	8.2E-06	8.2E-05	0.0	0.0	8.2E-02	2.5E+00	8.2E-04	0.0
600	3.9E-06	3.9E-05	0.0	0.0	3.9E-02	1.2E+00	3.9E-04	0.0
800	2.8E-06	2.8E-05	0.0	0.0	2.8E-02	8.5E-01	2.8E-04	0.0
1,000	2.1E-06	2.1E-05	0.0	0.0	2.1E-02	6.2E-01	2.1E-04	0.0
2,000	1.8E-07	1.8E-06	0.0	0.0	1.8E-03	5.3E-02	1.8E-05	0.0
4,000	4.2E-08	4.2E-07	0.0	0.0	4.2E-04	1.2E-02	4.2E-06	0.0
6,000	2.3E-08	2.3E-07	0.0	0.0	2.3E-04	6.8E-03	2.3E-06	0.0
8,000	1.6E-08	1.6E-07	0.0	0.0	1.6E-04	4.7E-03	1.6E-06	0.0
10,000	1.0E-08	1.0E-07	0.0	0.0	1.0E-04	3.0E-03	1.0E-06	0.0

Note: Scientific notation in this table, for example 5.4E+02, is also expressed as 5.4×10^2 where "E" represents power of 10.

[a]Mitigated Source Term = MAR * ARF * RF * DR * LPF reduced by application of safety controls (Primary and Secondary Barriers)