Appendix C
Hazard Analyses

1. Introduction

Risk assessments and hazard analyses are widely accepted tools used by health and safety managers to examine activities, predict outcomes, and provide a basis for decision making. For the purposes of this programmatic environmental impact statement (PEIS), health consequences to members of the public from potential releases of harmful biological and chemical material from a Chemical and Biological Defense Program (CBDP) facility were evaluated for representative research, development, test, and evaluation (RDT&E) activities using both quantitative and qualitative hazard analysis methods. It should be noted that hazard analyses are required for all CBDP RDT&E activities, per universal (i.e., benchmark) guidelines (CDC/NIH 1999)[1] and regulations (29 *Code of Federal Regulations* [CFR] 1910.119, *Process Safety Management of Highly Hazardous Chemicals*).

1.1 Quantitative Hazard Analysis

Maximum credible event (MCE) analysis has been chosen as the quantitative risk assessment tool for this PEIS. An MCE analysis is a realistic worst-case scenario that applies credible information about existing safeguards. MCE analyses as applied herein assess the range of possible consequences that could arise as the result of biological mishaps or chemical accidents, based on the effectiveness of existing safeguards—the engineering controls, design features, and adherence to standard operating procedures by the workforce that prevent the release of etiologic or chemical agents from CBDP facilities. Although the MCE nomenclature comes from Army Regulation (AR) 385-61, *The Army Chemical Agent Safety Program*, 12 October 2001, which requires such analyses for all activities using chemical agents, and AR 385-69, *Biological Defense Safety Program*, which requires such analyses for all Biological Defense Research Program (BDRP) activities, the requirements for similar analyses for all CBDP activities performed by all entities are embedded in more universal guidelines and regulations noted above.

Exposure by respiratory intake of a biological agent in aerosol form or chemical agent in vapor form was selected as the measurement endpoint for all the MCEs for a number of reasons. First, the generation, release, and downwind transport of potentially hazardous biological or chemical material are major aspects of the testing program. Second, the aerosol and vapor forms are the physical states most apt for a biological or chemical agent to escape control. Third, the human respiratory system is the most vulnerable and most important receptor at risk. Finally, the airborne exposure route has the most rapid response to contaminants.

The intent in this part of the PEIS is to create robust, programmatic MCE analyses that can be extended to all CBDP activities at all locations. Sections 2 through 5, below, present MCEs developed for selected agents that are considered to be the most infectious (biologics) or the most volatile and toxic (chemicals). Consequently, the scenarios presented below represent the most extreme circumstance in a particular risk category of activity (biosafety level [BSL]-3, BSL-4, chemical surety materiel [CSM] laboratory accident) conducted in the CBDP, as the vast

[1] Bibliographic references appear in Section 7 of the PEIS.

majority of RDT&E activities actually performed in these categories under the CBDP occur using significantly less hazardous substances and at much smaller concentrations.

The Hazard Prediction and Assessment Capability (HPAC) modeling system developed by the Defense Threat Reduction Agency was used to quantify risk for the MCE scenarios. This modeling software provides the means to accurately predict the effects of hazardous nuclear, biological, and chemical (NBC) material releases into the atmosphere and their impact on civilian and military populations. It was developed to model NBC and radiological and high-explosive collateral effects resulting from conventional weapon strikes against potential target facilities by enemy weapons of mass destruction. The HPAC system also can predict downwind hazard areas resulting from a nuclear weapon strike or reactor accident and has the capability to model biological and chemical weapon strikes or accidental releases from CBDP facilities.

The HPAC modeling software incorporates information from databases that provide site-specific weather and terrain information, atmospheric transfer models that calculate the dispersion of the released material, and human effects models that quantify the effect of the released material on the human population. The HPAC model utilizes very conservative assumptions (i.e., maximizes potential risks). By simulating a hypothetical incident at a specific location, this software can analyze existing data for the release of CBDP agents and plot the projected health impacts within a contoured area. Where specific location information was required to model impacts, data from a particular example site of the PEIS have been used and are identified as such. For the MCE scenarios below, 12 HPAC simulations were calculated using historical site-specific meteorological data for each calendar month.

1.2 Qualitative Hazard Analyses

Sections 6 through 10, below, present hazard analyses for scenarios of potential release of biological or chemical materials from CBDP RDT&E activities that are not readily characterized quantitatively. These include potential public health impacts due to release of biological material during shipment, escape of infected animals, terrorist acts, external acts, and use of biological or chemical simulants.

2. Biological Aerosol Releases from a BSL-3 Laboratory

Two MCE analyses were developed for work in BSL-3 facilities. Both scenarios were evaluated for local conditions at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

2.1 Biological Agent Release

The first MCE scenario for a BSL-3 laboratory accident occurs during the processing of 1 liter (0.26 gallons) of a slurry containing *Coxiella burnetii*, the causative agent of Q fever, to prepare an experimental vaccine. The infective dose for this species of bacteria ranges from 1 to 10 organisms. During this process, a centrifuge rotor holding six 250-milliliter (8.45-fluid-ounce) polypropylene centrifuge tubes is fitted with O-rings; each tube contains 165 milliliters (5.58 fluid ounces) of slurry. The 990 milliliters (33.46 fluid ounces) of slurry contain a total of 9.9×10^{12} (9.9 trillion) human infective doses (HID_{50}) of the organism. One HID_{50} is the dose that infects 50% of exposed humans.

In this scenario, a laboratory worker fails to use rubber O-rings to seal the centrifuge tubes and fails to properly tighten the safety centrifuge caps designed to prevent leakage into the centrifuge compartment that houses the rotor. All six tubes spill slurry into the rotor cups, and some of this slurry leaks into the rotor compartment, which is not sealed against the release of organisms in a small-particle aerosol. It is assumed that 10% of the slurry spills, of which 1% leaks into the rotor compartment, where 0.1% of the leakage is aerosolized. It is further assumed that 90% of the aerosol settles as liquid droplets inside the chamber. Thus, 10% (spilled from tubes) x 1% (leaked from rotor cups) x 0.1% (aerosolized) x 10% (did not settle out) = 0.00001% of the original slurry placed in the centrifuge tubes for processing would be released into the room.

The most serious consequence of this laboratory accident would be the release of enough concentrated aerosol to override the air filter system, allowing the subsequent release of a significant number of infectious doses into the surrounding community. Following the assumptions above, 9.9×10^5 HID_{50} are presented to the filter. Further assuming that the air filter system is 95% efficient, approximately 5×10^4 HID_{50} (5% not removed x 9.9×10^5 HID_{50}) would be released to the atmosphere from the exhaust stack. Using a simple Gaussian plume dispersion model in HPAC with weather condition parameters of USAMRIID for each calendar month, the worst-case total exposure of a person breathing ground-level air would be less than 1 HID_{50} of *Coxiella burnetii* at a distance less than 2 meters (6.56 feet) from the stack. This concentration of organisms would pose no risk to human health.

2.2 Biological Toxin Release

The second MCE analysis for a BSL-3 laboratory accident involves activities with type A botulinum toxin. This scenario assumes that a 250-milliliter (8.45-fluid-ounce) centrifuge tube holds 240 milliliters (8.11 fluid ounces) of a solution containing 50%-pure type A botulinum toxin at a concentration of 2×10^9 mouse intraperitoneal lethal doses ($MIPLD_{50}$) per milliliter. One $MIPLD_{50}$ is the amount of toxin required to cause death in 50% of injected mice. The dosages used in toxin solution challenges in mice are very different from the toxin aerosol respiratory exposures in humans. The human dose required to produce the same effect is estimated at about 2,380 times greater than the mouse dose; that is, the dose of an aerosolized solution of botulinum toxin that results in death for 50% of human respiratory exposures ($HRLD_{50}$) corresponds to a toxin solution containing 2.38×10^3 $MIPLD_{50}$. Thus, the initial volume of toxin solution is estimated to contain $240 \times 2 \times 10^9 / 2.38 \times 10^3 = 2.02 \times 10^8$ $HRLD_{50}$.

During this scenario, a centrifuge tube breaks in a centrifuge located in a Class II biosafety cabinet (BSC), spilling all of the toxin-containing solution within the rotor compartment of the centrifuge, where the rotor generates an aerosol of 1- to 5-micron-size particles from 1% of the spill, and 96% of the aerosol settles as liquid droplets inside the chamber. Thus, approximately 8.1×10^4 $HRLD_{50}$ (2.02×10^8 $HRLD_{50}$ x 1% aerosolized x 4% not settled out) would be released into the BSC. With an inward face air velocity of at least 22.86 meters (75 feet) per minute at the work opening of the Class II BSC, essentially all of this aerosol is forced to pass through the BSC's high-efficiency particulate air (HEPA) filters (99.97% efficiency), and the HEPA-filtered aerosol enters the biological containment suite duct system, where it passes through a Baggy Filter (95% efficiency). Consequently, approximately 1.2 $HRLD_{50}$ (8.1×10^4 $HRLD_{50}$ x 0.03% remaining after the HEPA filter x 5% remaining after the Baggy Filter) is discharged from the

exhaust stack to the atmosphere. Within inches of the exhaust stack, the toxin-containing aerosol undergoes essentially infinite dilution in the atmosphere, as well as rapid physical degradation. Thus, the concentration of toxin released through the exhaust stack would quickly become negligible and would pose no risk to human health.

3. Biological Aerosol Release from a BSL-4 Laboratory

The MCE scenario for a BSL-4 laboratory accident involves activities with the Ebola virus at USAMRIID. The HID of Ebola virus is unknown. In mice, a dose that would kill half of exposed animals (LD_{50}) is less than 0.03 plaque-forming units (PFUs). Since the lethality of Ebola in mice is 100% (all infected mice die), it can reasonably be assumed that the infective dose for mice is twice the LD_{50} (0.06 PFUs). Because the HID is unknown, the infective dose for mice will be used as a conservative approximation that will result in an overestimate of the risk.

For the purposes of this MCE analysis, the highest volume used in centrifugation would be six 250-milliliter (8.45-fluid-ounce) bottles of cell culture supernatant that contain 10^8 PFUs per milliliter each, for a total of 1.5×10^{11} PFUs. It is assumed that 1.5×10^{11} PFUs are equivalent to 2.5×10^{12} HIDs. Assuming that all six bottles break, a viral aerosol would be created within the rotor. It is also assumed that the rotor gasket fails to contain any aerosol generated. Most of the liquid in the bottles would be contained within the centrifuge rotor (97%). Of the 45 milliliters (1.52 fluid ounces) of liquid (3% of the total) that emerge from the centrifuge rotor, 10% would be aerosolized, and of the aerosolized fraction, 90% would settle as liquid droplets. Thus, 0.03% of the total liquid volume (0.45 milliliters [0.015 fluid ounces]), which corresponds to 7.5×10^8 HIDs, would leave the centrifuge in aerosol form.

This is an overestimate, since technicians and investigators do not fill bottles to the top to avoid spillage. The rotor in the centrifuge would be sealed by a gasket and, upon completion of centrifugation, the entire rotor would then be removed from the centrifuge and opened within a BSC.

Any potential aerosol from the centrifuge chamber would be exhausted through the duct system of the laboratory suite. The exhaust air passes through two HEPA filters (nominal efficiency of 99.97% each) in series. After passage through the first filter, 2.25×10^5 HIDs would remain. After passage through the second filter, 68 HIDs would discharge into the exhaust stack and be released into the atmosphere. Assuming no biological decay due to ultraviolet light exposure, heat, or humidity, the dispersion of the released aerosol would result in a worst-case total exposure of 1 HID at a distance much less than 1 meter (3.3 feet) from the exhaust discharge stack. This release would not pose a hazard to the surrounding community, as the fence surrounding Fort Detrick is more than 250 meters (820 feet) from the exhaust discharge stack port.

Because laboratory work is normally performed during the day, ultraviolet rays from the sun would destroy or inactivate a large number of the virus particles potentially released. Other meteorological variables such as high wind speed, low humidity, and/or high temperatures would further accelerate the biological decay of infective particles. Laboratory personnel would not

have been exposed, since the aerosol should be contained within the BSC. However, they would receive an appropriate medical evaluation immediately following such an incident.

4. CSM Laboratory Accident

The MCE scenario for chemical agents at a CBDP facility involves a spill of the most volatile chemical agent (MVCA) in the smallest laboratory at the facility. The largest volume (in liters) of MVCA used in any single operation comprises the agent vapor challenge (AVC) to the filtration systems. The AVC concentration (AVCC), in units of milligrams per cubic meter (mg/m^3), is calculated by multiplying the evaporation rate of the spilled MVCA, in units of milligrams per minute per square meter ($mg/min\text{-}m^2$), by the spill size in square meters (m^2) and dividing by the exhaust airflow in units of cubic meters per minute (m^3/min). The exhaust airflow is calculated by multiplying the volume of the smallest laboratory in cubic meters (m^3) by the required number of air changes per minute for the ventilation system. The evaporation rate and spill size are determined using the MVCA chemical property and required laboratory airflow velocity parameters in the HPAC.

The MCE scenario involves spilling 4 liters (1.06 gallons), approximately the largest volume of the MVCA (GB, or sarin) that is used in any single operation in a laboratory, in a large AVC to the filtration systems and a stack emission. The AVCC is calculated as noted above. Parameters required to calculate the evaporation rate and spill size include location of the spill (inside the facility); temperature (22.2 degrees Celsius [72 degrees Fahrenheit]); atmospheric stability (worst-case daytime condition, neutral); wind speed (0.51 meters per second, about 100 linear feet per minute face velocity of hoods in the laboratory rooms); spill surface (nonporous, laboratory surfaces of stainless steel or epoxy-covered concrete); time of evaporation (20 minutes for laboratory workers to decontaminate the spill); and season (summer, since it has the highest temperatures). The HPAC computed 1,152 $mg/min\text{-}m^2$ for the evaporation rate and 5.269 m^2 (approximately 56.7 square feet) for the spill size.

The worst-case exhaust airflow rate in a laboratory must be determined to calculate the AVCC. Typically, laboratories have an exhaust system allowing for 10 air changes per hour. The AVC equation indicates that the lower the exhaust rate, the higher the AVCC to the filter systems. The worst-case exhaust rate would be from the smallest laboratory room where the scenario spill of agent could occur, which is 318 m^3 (about 11,230 cubic feet). Exhausting this volume 10 times per hour, or 53 m^3/min, would result in an AVCC to the filtration systems of 115 mg/m^3.

Prior to discharging the exhaust air from each laboratory to the air, contaminants are removed through a vapor filtration system. These systems contain double beds of carbon filters, and the exhaust air goes through the two filter beds in series. Each carbon filter has to pass a leakage test upon installation and must reduce the agent concentration to 0.01% of its original level. Theoretically, the AVCC would be reduced to 0.00000115 mg/m^3 (115 mg/m^3 x 0.01% x 0.01%) prior to discharge from the stack into the atmosphere using a vapor filtration system with two carbon beds in series. Applying a safety factor of 10 to account for conditions that degrade carbon and reduce filtration efficiency, the stack emission GB concentration is estimated as 0.0000115 mg/m^3, well within the 0.0001 mg/m^3 short-term exposure limit proposed by the Centers for Disease Control and Prevention (*Airborne Exposure Limits for Chemical Warfare Agents GA, GB, and VX*, 67 *Federal Register* 894, 18 January 2002). HPAC calculations based

on conditions at the Edgewood Chemical Biological Center (ECBC) indicated a 1% lethality distance from the stack as essentially zero and a no-effects distance well within the installation boundaries.

5. CSM Transport

GB was chosen for the downwind hazard analysis because it poses the greatest vapor hazard of all agents that will be transported. The worst-case scenario comprises a 40-liter (10.56-gallon) spill, the largest volume of any agents that would be transported in any given shipment.

Two different spill scenarios were simulated: (1) a spill on a paved surface (minimal absorption), and (2) a spill on a graveled road surface (significant absorption). In each of these cases, the spill was assumed to be a rapid release (pouring) of liquid GB onto the roadway. Representative locations were chosen for the scenarios at two different CBDP example sites, Dugway Proving Ground (DPG)[2] and ECBC[3]. Causative factors for the spill were not specified because they would not influence the modeling results. Under these worst-case conditions, the downwind 1% lethality distance would be 783 meters (approximately 0.5 miles), and the downwind no-effects distance would be 6,422 meters (approximately 4 miles). This scenario is extremely unlikely and is presented solely for comparison purposes. It has an effective probability of zero when matched with the hazard analysis results for causative factors.

Immediate containment and cleaning would take place in the case of any spill. A spill of just 1 liter (0.26 gallons) would be very unlikely. If such a spill did occur, the no-effects distance on a paved road would be 925 meters (approximately 0.6 miles). There are no residents located within this distance from either the DPG or ECBC representative location.

6. Biological Material Shipment

Special regulations apply to the shipment of etiologic agents in general and to BDRP etiologic agents in particular. The packaging, labeling, shipping, and transport of etiologic agents are regulated by 42 CFR 72 (*Interstate Shipment of Etiologic Agents*), 49 CFR 172 and 173 (U.S. Department of Transportation regulations concerning shipment of hazardous materials), 9 CFR 122 (*U.S. Department of Agriculture [USDA]-Restricted Animal Pathogens*), and International Air Transport Association rules. In addition, special rules apply for the transport of materials regulated by the U.S. Food and Drug Administration (21 CFR 312.120, *Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests*). Etiologic agents used in the BDRP under the purview of the Army must be packed, labeled, marked, prepared, and shipped in accordance with AR 385-69 as well as the applicable federal, state, and local regulations. Private couriers are used for transport of etiologic agents used in the BDRP, rather than the U.S. Postal Service. BSL-4 agents or USDA-restricted animal pathogens must be accompanied by a courier or other responsible party assigned to monitor shipment and final receipt. The quantities of potentially infectious material shipped during the conduct of BDRP activities are very small.

There have been no recorded cases of illness attributable to the release of infectious material during transport, although incidents of damage to the outer packaging of properly packaged

[2] State Route 36 through Lookout Pass.
[3] Near the ECBC building complex in the Edgewood Area.

materials have been reported (World Health Organization 2002, U.S. Department of Transportation 2001). The more restrictive transportation requirements for shipments involving biological defense infectious material described in AR 385-69 are based on extensive drop, crush, and other rupture-causing testing events. No individual has become ill from a transportation-related incident in the more than 60 years in which the military has been performing such activities.

7. Infected Animal Escape

The likelihood of an infected animal (e.g., arthropod, small mammal, or nonhuman primate [NHP]) escaping a CBDP laboratory is remote. The design and construction of a BSL-3 laboratory makes it extremely difficult for an infected laboratory animal to escape into the environment. Simultaneous breakdowns of multiple controls and barriers would have to occur for that to happen.

Special precautions must be taken to prevent the escape of a potentially infected arthropod from a CBDP facility. Such an escape would pose the risk of altering the ecological balance due to the introduction of a new species and may also introduce an exotic disease into the environment. There is always a chance that an arthropod may escape from its cage during routine manipulations. If the escaped arthropod is potentially infected, the standard operating procedure in the CBDP facilities is to postpone work until the escaped arthropod is found, captured, and killed.

If a mosquito happened to escape unobserved, it would have to traverse a series of at least six doors or barriers, nearly all of which would present an opposing airflow due to the pressurization pattern in the biological containment suite, before that mosquito could reach the hallway. Furthermore, its likelihood of survival within the suite would be greatly impaired due to the low relative humidity and rapid airflow, and mosquito traps are constantly in use to further diminish the probability of mosquito escape. For the above-mentioned reasons, if a potentially infected mosquito did escape from its cage, it would be extremely unlikely to survive and escape from the biological containment suite to the hallway.

Ticks (including exotic species) also are used in the CBDP facilities. Although ticks cannot fly, they are much less vulnerable to unfavorable environmental conditions than are mosquitoes, and they can survive for longer periods of time. The three most probable ways that a tick could escape from a laboratory are: (1) freeing itself from its sealed cage and crawling out of the suite unnoticed, (2) attaching itself to an unnoticing laboratory worker and being unintentionally carried out of the suite, or (3) crawling unnoticed into the bedding of an animal cage, which is then discarded from the suite. For all studies conducted with ticks, a special laboratory is used to prevent them from escaping. This special room has a raised door threshold, and the doorway is completely surrounded with a substance known to capture ticks. A further precautionary measure requires that ticks be handled only on a special table designed to inhibit possible tick escape. This table has a “moat” around the perimeter that contains the same tick-trapping substance used on the doorway. For these reasons, it is highly unlikely that a tick could escape from the suite. There has never been a tick observed outside of the CBDP special tick laboratory.

Similarly, it is highly unlikely that an infected rodent could escape from a CBDP facility. An infected rodent would first have to escape from its specially designed cage (primary barrier). The most likely scenario for such an escape would occur when transferring a laboratory animal between cages, which is performed in an animal room with a sealed floor, walls, and ceiling and a tightly fitted closed door. Any escaped animal, therefore, would be contained in the animal room (secondary barrier). Similarly, if a rodent escapes from its cage due to a faulty cage lid, it would be contained in the secondary enclosure. In either case, the animal caretaker would place a cage or net over the escaped animal, scoop it up, and place it in a separate cage.

If an animal did manage to escape its cage, it would have difficulty leaving the animal room and gaining access to the laboratory suite corridor. Animal room doors in CBDP facilities are specially fitted to block escape. The doors are made to open inward, which minimizes the chances of an animal escaping when the door is opened. Even if an escaped animal somehow gained access from the secondary enclosure into the suite corridor, it would still be contained within the CBDP facility. No animal room opens to a hallway with a door that leads directly outside the CBDP facility. If the animal somehow managed to gain access through a hallway door, it would still have to reach an outside door. All outside doors are either locked or monitored by security personnel. Daily observations of the animals are performed at CBDP facilities to reduce the possibility of an escaped or missing animal going undetected. If a small animal such as a rodent did get loose in a CBDP facility, traps would be placed throughout the building. Transportation of infected animals is kept to a minimum in the CBDP facilities. Therefore, if only one of the many control barriers prevails, no rodent or small animal would be able to escape outside a CBDP facility.

The design and construction of the CBDP facilities and the multiple control barriers also make it highly unlikely that an NHP could escape outside the building. NHPs would be most likely to escape when being transferred between cages. If an NHP escapes, two or three experienced personnel go into the animal room to net it. The animal room door is kept closed, and the rest of the floor and building are alerted to keep their doors closed and personnel out of the escape area until the NHP is caught and returned to its cage. Some personnel are trained to use a dart gun to capture an NHP that manages to surmount the primary barrier. Caretakers, investigators, and veterinary technicians observe the animals daily and would notice a missing NHP. Furthermore, if an NHP is loose, the other NHPs in the room become quite noisy, which would immediately alert the caretakers.

If an NHP did manage to escape its locked cage, it would have difficulty leaving the animal room and gaining access to the laboratory suite corridor. Even if the escaped NHP managed to reach the suite corridor, there are no doors that lead directly out of the facility. All outside doors are either locked or monitored by security personnel. If only one of these control barriers prevails, no NHP would be able to escape the building. All animal transportation is minimized in the CBDP facilities to lessen the possibility of an animal escape. When transporting NHPs between laboratory suites, the animals are anesthetized. When NHP cages are cleaned, the cages are closed to prevent the NHPs from escaping. It is highly unlikely that an NHP could escape from a CBDP facility to the outside environment. No NHPs have ever escaped to the outside environment from a CBDP laboratory.

In the highly unlikely event that an infected animal does overcome all CBDP facility barriers and escape to the outside, it would face additional insurmountable hazards. Most small experimental animals have been specially bred. These bred animals have always been maintained in ideal environments and do not have the experience or genetic hardiness to survive outside the laboratory. Therefore, the probability of an escaped laboratory animal from a CBDP facility reaching a populated animal reservoir and making intimate contact with a susceptible host is negligible.

8. Terrorist Acts

Since the events of 11 September 2001 and the anthrax-contamined letters, it is clear that the United States is vulnerable to significant acts of terrorism. In the context of MCE analyses, acts of terrorism are not considered as reasonably foreseeable events. The probability of such attacks upon a site of CBDP execution is impossible to predict and could include incidents such as airplane crashes, bombs, or theft of biological and/or chemical material.

9. External Acts

Means of accidental release of biological test materials from a CBDP facility include laboratory-associated mechanical failures, human errors, external accidents, and man-made or natural disasters. Theoretically, human error or multiple mechanical failures could lead to accidental release of biological test material. However, redundancy of safety equipment and procedures, operational safeguards, monitoring systems, and the overall excellent safety record of chemical and microbiology laboratories suggest that this is not a significant risk.

In the event of a fire or an explosion in a biological containment laboratory, any test under way would be immediately terminated upon discovery of the event, and appropriate safety measures would be taken to assure zero release of the infectious material or toxin while the fire was being contained. If a fire intensified enough to cause structural damage to the BSC and laboratory chambers, the heat would destroy any pathogen, toxin, or chemical agent. Therefore, fire is not a credible hazard with regard to the potential release of infectious biological materials, toxins, or chemical agents from CBDP facilities.

10. Simulants

Simulants are used in CBDP RDT&E activities instead of the actual chemical or biological agents to minimize hazards for workers, public health, and the environment. A simulant is a chemical or an organism that has at least one physical property similar to that of the biological or chemical agent under study and is less hazardous than the agent. It should be reasonably safe for handling and use without significant environmental or human health effects. Most CBDP RDT&E activities using simulants, particularly field testing, are conducted at DPG. Less extensive use of simulants occurs at other sites, e.g., the Naval Surface Warfare Center Dahlgren Laboratory. The following discussion, although focused on DPG, applies for all RDT&E activities under the CBDP involving stimulant use.

Use of simulants is mandatory for outdoor (field testing) activities under the CBDP, since use of an actual chemical or biological agent in open-air testing is prohibited within the United States (Public Law 91-121, *Defense Appropriation Act of 1970*, as extended under Title 50 of the U.S.

Code, Paragraph 1512). Risk management policies set forth in AR 385-10 apply; however, there are no benchmark regulations or guidelines that explicitly address the use of simulants.

In CBDP RDT&E laboratory activities, the potential worker health and safety and potential environmental impacts of simulants are mitigated by use of engineering controls and by adherence to standard operating procedures that were developed for work with actual chemical or biological agents (see Sections 2.3.5.1 and 2.3.5.2 of the PEIS). However, open-air testing requires evaluation of candidate simulants on a case-by-case basis.

An environmental review, usually an environmental assessment (EA), is required for any stimulant, biological or chemical, that has been proposed for use in a test. Environmental reviews of simulant use in laboratory work, field testing, or training at DPG since 1991 have been documented (DPG 2001). It should be noted that environmental reviews were conducted even when the stimulant material had been previously evaluated and approved for a different program. For example, triethylphosphate (TEP), a chemical stimulant, was evaluated for field testing in 1991, 1992, 2000, and again in 2001. This recognizes the variety of methods available for dissemination of simulants in outdoor tests, including aerial spray (from aircraft or from tethered balloons), spray from ground vehicles, explosive dissemination, air cannons, and various atomization devices. Environmental reviews also have been conducted even when a simulant material proposed for laboratory testing had been previously evaluated and approved for field testing or vice versa. For example, TEP was evaluated for laboratory testing in 1998 despite its having been the subject of EAs for field testing in 1991 and 1992, as noted above.

The National Environmental Policy Act review process for microorganisms proposed for use as biological simulants considers risk to both humans and the environment. Biological simulants used for indoor testing could include killed organisms (for example, gamma-irradiated vaccine strains of pathogens). In outdoor testing, organisms rated higher than BSL-1 are not allowed. Use of live genetically engineered microorganisms in outdoor testing would require a permit from the USDA. Use of the biological simulant *Bacillus thuringiensis* has been limited to specific conditions because its biological toxin accumulates in soil and may be active for at least 2 years.

Use of a simulant in any CBDP RDT&E activity is also subject to applicable federal or state environmental regulations. DPG provides quarterly reports required by Utah regulatory agencies, including information on planned use of biological agents and simulants in support of testing activities and summaries of the outdoor biological and chemical simulant tests that were conducted.