Section 2

2.0 DESCRIPTION OF THE PROPOSED ACTION

The Department of Defense (DoD) has decided to prepare a document that analyzes the potential environmental impacts associated with the execution of the DoD Chemical and Biological Defense Program (CBDP), comprised of research, development, and acquisition (RDA) activities. The proposed action is the execution of an integrated program designed to protect our soldiers, sailors, marines, and airmen from the evolving chemical and biological (CB) threats they may encounter on the battlefield.

The *Chemical and Biological Defense Program Programmatic Environmental Impact Statement (CBDP PEIS)* will update and expand the current programmatic documentation, providing information on and analysis of the changes that have occurred in the biological defense (BD) program over the last decade; enlarging the scope of the current programmatic documentation to include the chemical defense (CD) program; facilitating future government decision making by allowing future environmental analyses under the CBDP to be tiered from it; and sharing with the public the features of the CBDP that demonstrate DoD's commitment to protect the environment and to ensure public health and safety during the execution of this operationally mandated program.

2.1 Background

Although numerous environmental documents have been prepared analyzing the potential environmental consequences of various CBDP elements, no single document covers the program as a whole. Prior programmatic National Environmental Policy Act (NEPA) documents covering elements of the CBDP are:

- *Biological Defense Research Program Final Programmatic Environmental Impact Statement* (U.S. Army Medical Research and Development Command, April 1989), which covered the research and development activities of that program
- *Joint Vaccine Acquisition Program Final Programmatic Environmental Assessment* (U.S. Department of the Army and Joint Program Office for Biological Defense (JPO BD), September 1997), which covered the development, production, storage, testing, and fielding of vaccines against validated biological warfare agents

In addition, programmatic NEPA documents have been prepared for each specific CBDP item, with notification to the interested and affected public, as one of the criteria for transition to production.

2.2 Analytic Framework

This NEPA analysis will focus on RDA activities, subdivided into three discrete components, and the application of mitigation matters, falling into two categories. It will comprise detailed evaluations of how the controls on potential environmental impacts have worked in practice at

the selected example sites, with particular attention to programmatic concerns, as discussed in Section 1.3.3.

2.2.1 CBDP Research, Development, and Acquisition Components

Section 1.2.2.3 introduced the conceptual subdivision of RDA activities under the CBDP into discrete, functional components for purposes of environmental impact analysis. These components are categorized as Research, Development, Test, and Evaluation (RDT&E); Operations, Maintenance, and Waste Management (OMWM); and Administration.

2.2.1.1 Research, Development, Test, and Evaluation

This component has several segments, as enumerated in Section 1.2.2.3.a, some or all of which are applicable to each individual site of program execution. These segments may involve the use and handling of hazardous biological materials, chemical surety materiel (CSM), and/or toxic industrial chemicals from transfer to the laboratory, test chamber, or outdoor test area through performance of experimental or test procedures and decontamination of spent materials, equipment, and facilities.

Prototype development is a major segment of the RDT&E category. This includes development for the purposes of several commodity areas:

- Contamination Avoidance materiel, e.g., detector systems for CB agents
- Collective Protection materiel, e.g., shelters
- Decontamination materiel, e.g., decontaminants or application systems
- Individual Protection materiel, e.g., personal protection equipment (PPE)
- Medical Systems materiel, e.g., vaccines

Testing of CBDP prototype materiel is another major segment of the RDT&E component. Equipment prototypes may be tested for performance relative to operational specifications using biological or chemical agents in the laboratory. Detection, Collective Protection, and PPE prototypes also may be tested in open-air conditions using simulants.

The care and use of laboratory animals is considered as a separate segment of the RDT&E component. The laboratory animal segment includes receipt, housing, feeding, and watering of the animals; use of the animals in experimental or test protocols; and disposal of animal remains and bedding.

Use of human subjects is also considered as a separate segment of the RDT&E component. Medical systems prototypes, such as vaccines, are tested using human volunteers.

Support work for RDT&E activities is considered as another segment of CBDP activities. This is comprised of handling of supplies and materials that are not unique to the particular subject of study, such as glassware, plasticware, general laboratory chemicals and reagents, etc. Minor

maintenance of laboratory equipment by laboratory personnel is also included in the RDT&E support work segment.

2.2.1.2 Operations, Maintenance, and Waste Management

The OMWM component includes several segments, as enumerated in Section 1.2.2.3.b, all of which are applicable for each individual site of program execution. Operations and maintenance (O&M) activities include all utility systems such as water, steam, electrical, drainage, heating, ventilating, and air conditioning. Routine structural repairs and maintenance of the buildings and grounds also are included in the O&M segment. These activities are similar to common practices at commercial and industrial facilities.

Receipt and distribution of all supplies and materials is another segment of the OMWM component. This may involve handling and storage of hazardous biological materials, CSM, and/or toxic industrial chemicals within the installation but outside the laboratories, test chambers, or outdoor test areas.

The waste management segment includes collection, handling, storage, treatment, disposal, and monitoring of waste streams, as enumerated below and discussed in detail in Section 2.3.4. Some or all of the waste generated from RDT&E component activities potentially could contain residues of hazardous biological materials, CSM, and/or toxic industrial chemicals, as follows:

- Exhaust discharges from buildings, laboratories, hoods, incinerator stacks, etc.
- Solid waste streams, including both general refuse and discarded residues of spent supplies and materials, such as animal waste, but not including other solid waste streams noted below
- Wastewater streams, including both sanitary and potentially contaminated wastewater (resulting from RDT&E procedures involving toxic or hazardous materials [HAZMATs] or organisms)
- Hazardous and toxic waste, as designated by the U.S. Environmental Protection Agency (EPA) and various states
- Medical and infectious waste
- Radiological waste

2.2.1.3 Administration

The administration component includes program management, planning, and design and publication of CBDP accomplishments in open scientific literature. Program management activities are comprised of management, accountability, and projection of the CBDP budget; administration of personnel, contracts, and program activities; and review, analysis, and planning of program activities to achieve CBDP mission objectives. Planning and design activities include idea formation and paperwork for preparation of RDT&E test methods and equipment needs, as well as project planning at the task and subtask levels. Administrative activities, while not directly involving hazardous biological materials, CSM, and/or toxic industrial chemicals,

may prescribe or determine procedures for RDT&E or OMWM activities that do entail such materials. The CBDP activities at all example sites are analyzed in Sections 5.2 through 5.13 with respect to environmental and health consequences and mitigation measures.

2.2.2 Waste Management Impact Mitigation

The assessment of waste management impact mitigation focuses on how—and to what degree—CBDP component activities affect waste generation, collection, storage, and disposal at the example sites and within the CBDP. This addresses the current capabilities and procedures for accumulation, storage, treatment, and disposal of sanitary and/or industrial wastewater, solid and hazardous waste, and air emissions. Waste management facilities, both inside and outside the installation or property boundaries of the example sites, are identified. This includes on-site or publicly owned treatment works; on-site or contractor solid waste landfills; treatment, storage and disposal facilities (TSDFs) permitted under the Resource Conservation and Recovery Act (RCRA) of 1976; and under- and aboveground storage tanks.

The assessment at the example sites involves both quantitative and qualitative considerations of waste management practices, including implementation of pollution prevention initiatives to reduce the amount of waste generated or stored, and mitigation of potential impacts on the environment. Determinations are made regarding CBDP component activity and alternative impacts on wastewater treatment capacities, discharge permits, wetlands, and recipient stream water quality. Current CBDP activities are reviewed to determine the extent and nature of air emissions, hazardous and solid waste, and wastewater. Analysis criteria are based on applicable federal and state environmental regulations as well as installation planning procedures and guidelines for waste management.

2.2.3 Safety, Health, and Security Impact Mitigation

The assessment of safety, health, and security impact mitigation at each example site includes measures for the protection of both the workforce at the site and the general population of the surrounding area who may be affected by CBDP activities. The analysis of risks considers potential exposures to hazardous and/or toxic chemicals; high-hazard biological materials (for the purposes of this document, those materials requiring biosafety level (BSL)-3 and -4 containment facilities and procedures); lasers; and radiation. The workforce analysis also considers compliance with Occupational Safety and Health Administration (OSHA) criteria and guidelines, safety plans and procedures, and personnel training.

2.3 Benchmark Regulations and Guidelines for CBDP Activities

Mitigation measures to minimize environmental and health impacts comprise the processes and procedures used in CBDP RDA activities to ensure compliance with applicable federal, state, and local regulatory requirements. CBDP activities must be conducted in compliance with DoD and other federal guidelines and regulations, including those of the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), U.S. Nuclear Regulatory Commission (NRC), OSHA, U.S. Department of Agriculture (USDA), U.S. Department of Transportation (DOT), and the EPA. CBDP activities at military installations are subject to service-specific regulations of the Army, Navy, Air Force, or Marine

Corps. The NEPA requirement for evaluation of environmental impacts is implemented for the military services by Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, 29 March 2002 (32 CFR 651); Office of the Chief of Naval Operations Instruction (OPNAVINST) 5090.1B, Chapter 2, "Procedures for Implementing NEPA," 9 September 1999; and Air Force Instruction (AFI) 32-7061, *Environmental Impact Analysis Process*, 24 January 1995.

This section summarizes these benchmarks for environmental analysis of CBDP activities. Sections 2.3.1, 2.3.2, and 2.3.3, respectively, present benchmark regulations and guidelines for animal care and use, human subjects, and CSM, which were identified in Section 1.3.2 as known concerns for RDA activities under the CBDP. Sections 2.3.4 and 2.3.5, respectively, present benchmark regulations and guidelines for mitigation of waste management impacts and mitigation of safety, health, and security impacts. Section 2.4 then reviews CBDP activities at the example sites with respect to the benchmarks and identifies additional applicable state, local, and site-specific regulations, guidelines, and mitigating measures.

2.3.1 Animal Care and Use

The Animal Welfare Act, as amended, 7 *United States Code* (USC) 2131 *et seq.*, mandates the humane treatment of animals. This mandate is further focused on the proper care and use of laboratory animals in 42 USC 283e and 289d, *Animals in Research*, and by USDA regulations (9 *Code of Federal Regulations* [CFR] 3, *Animal and Plant Health Inspection Service–Standards*). Facilities testing animals with vaccines against etiologic agents must also comply with rules promulgated under 21 USC 154, *Regulations for Preparation and Sale of Viruses, Serums, Toxins, Antitoxins, and Analogous Products*.

Specific policy implementation for DoD agencies is found in Department of Defense Directive (DoDD) 3216.1 entitled *The Use of Laboratory Animals in DoD Programs*, dated 17 April 1995. In addition to the above statutes and regulations, the *Guide for the Care and Use of Laboratory Animals* (National Research Council 1996) and other publications that provide national standards and guidance for the acquisition, transportation, housing, control, maintenance, handling, protection, treatment, care, use, and disposal of animals shall be applicable to all DoD agency activities using laboratory animals. DoD organizations or facilities maintaining animals for use in research, testing, or training shall apply for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. Animal facilities and animal care and use programs are reevaluated at 3-year intervals by the AAALAC. Laboratory animals shall be legally obtained from suppliers licensed by the USDA.

2.3.2 Human Subjects

All research involving human subjects funded by DoD is subject to the provisions of 10 USC 980, *Limitation on Use of Humans as Experimental Subjects.* Human subjects involved in CBDP RDT&E activities are treated according to DoD regulations (32 CFR 219) and, when applicable, FDA regulations (21 CFR 50), both bearing the title *Protection of Human Subjects*. DoD research involving human subjects is also governed by the provisions of DoDD 3216.2, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*, 25 March 2002, as implemented for the Army by AR 70-25, *Use of Volunteers as Subjects of Research*, dated 25 January 1990; for the Navy by Secretary of the Navy Instruction

(SECNAVINST) 3900.39C, *Protection of Human Subjects,* dated 25 February 2002; and for the Air Force by Air Force Instruction (AFI) 40-402, *Protection of Human Subjects in Biomedical and Behavioral Research,* dated 1 September 2000.

2.3.3 Chemical Surety Materiel

DoDD 5210.65, *Chemical Agent Security Program*, 15 October 1986, sets forth policy and responsibilities for safeguarding chemical agents, which are defined as chemical substances (excluding riot control agents, chemical herbicides, smoke, flame, and industrial chemicals) intended for use in military operations to kill, seriously injure, or incapacitate enemy forces through their physiological effects. This benchmark directs DoD components that have custody or possession of chemical agents to establish standards for chemical agent storage facilities and reliability programs for personnel whose regularly assigned duties involve access to, or security of, chemical agents. The Secretary of the Army is designated as the Single Manager for conventional ammunition (which includes chemical agents) and is directed to: issue regulations to implement the prescribed policy; maintain current, evaluated information concerning threats to chemical agent security and disseminate to the appropriate commanders and law enforcement officials; establish maximum allowable limits of concentration and quantity for dilute solutions not defined as chemical agents that are stored and maintained by the Single Manager for conventional ammunition; and formulate procedures for coordinated effective responses for chemical accidents or incident control.

Chemical surety is a system of control measures designed to provide protection to workers, local populations, and the environment by ensuring that chemical agent operations are conducted safely, that chemical agents are secure, and that personnel meet the highest reliability standards. CSM is comprised of chemical agents and their associated weapon systems or storage and shipping containers that are either adopted or being considered for military use.

CSM includes chemical agents, precursor chemicals, and toxins that are accountable under the Chemical Warfare Convention (CWC). The United States is obligated to not produce, acquire, retain, transfer, or use the listed chemicals unless they are applied to research, medical, pharmaceutical, or protective purposes. The types and quantities of chemicals are strictly limited to those that can be justified for such purposes, and the aggregate amount of such chemicals at any given time cannot exceed 1 metric ton (approximately 2,200 pounds), in accordance with the Verification Annex of the CWC, Part VI.

AR 50-6, *Chemical Surety,* 26 June 2001, includes provisions for accountability and transportation of CSM and response to chemical accidents or incidents. Accidents are distinguished from incidents in that the latter result from deliberate acts. Safety (see Section 2.3.5.2) is the primary concern for accidents, whereas security (see Section 2.3.5.5) is the primary concern for incidents. Supplementary provisions for physical security of CSM appear in AR 190-59, *Chemical Agent Security Program*, 27 June 1994. SECNAVINST 5510.29A, *Chemical Agent Security Program*, 31 March 1987, presents the Navy counterpart of AR 50-6 and AR 190-59.

The scope of the Chemical Surety Program does not include recovered chemical warfare materiel or experimental chemical agents in quantities up to 1 liter (approximately 1.056 quarts). Certain industrial chemicals, although designated as chemical agents in the CWC, are not considered as CSM. These chemicals, which are not manufactured primarily for the specific purpose of producing human casualties or rendering equipment, facilities, or areas dangerous for human use, are controlled consistent with industrial safety practices and benchmark safety regulations, as listed in Section 2.3.5.2. Other listed categories of non-CSM include diluted (RDT&E dilute solutions) or chemically neutralized chemical agents; neat chemical agents in amounts not exceeding their respective threshold quantities; or material contaminated with unrecoverable chemical agents, such as soil or filters.

The chemical Personnel Reliability Program (PRP) ensures that emotionally stable, trustworthy, and physically fit personnel are assigned positions that allow access to or responsibility for the custody, safety, and security of CSM. Only authorized individuals approved in the chemical PRP are allowed access to exclusion and/or limited areas.

2.3.4 Waste Management Mitigation

Executive Order 13148, *Greening the Government through Leadership in Environmental Management*, 21 April 2000, requires federal government agencies to include environmental management in their policies, operations, planning, and management. DoDD 4715.1, *Environmental Security,* 24 February 1996, established policy for the military services and other DoD components to comply with U.S. laws and regulations, executive orders, and other legal requirements for preventing pollution and minimizing adverse environmental impacts. The paragraphs that follow present specific mitigation for potential waste management impacts. Environmental compliance programs for waste management mitigation that must be followed at military service installations comprise AR 200-1, *Environmental Protection and Enhancement*, 21 March 1997, for Army installations; OPNAVINST 5090.1B for Navy installations; and the AFI 7000 series for Air Force installations.

2.3.4.1 Air Emissions

The Clean Air Act (CAA) of 1970 and amendments to the CAA in 1990 (42 USC 7401) set requirements to prevent or mitigate air pollution. The EPA promulgated 40 CFR 50, *National Ambient Air Quality Standards* (NAAQS), under the CAA, set for six criteria pollutants: carbon monoxide (CO), lead (Pb), nitrogen oxides (NO_x), ozone (O_3), particulate matter (PM), and sulfur dioxide (SO_2). In nonattainment areas for one or more of the NAAQS criteria pollutants, e.g., ozone, federal government installations are required to review new actions that could worsen an existing NAAQS violation, cause a new NAAQS violation, delay the State Implementation Plan attainment schedule of the NAAQS, and/or contradict other requirements.

Under the CAA Amendments, hazardous air pollutants (HAPs) also are regulated. As of January 2002, emissions of 192 HAPs are subject to regulatory limits. Title I of the CAA Amendments of 1990 and 40 CFR 68, *Chemical Accident Prevention Provisions,* require facilities to have a risk management plan (RMP) if their inventories of one or more HAP chemicals exceed their respective maximum storage threshold quantities. The RMP establishes a program to reduce the

possibility of HAP emissions. The CAA Amendments also address chlorofluorocarbons (CFCs), halons, and other ozone-depleting chemicals under Title VI, *Stratospheric Ozone Protection*.

Incinerators, including medical waste incinerators, located and operated at CBDP facilities are subject to EPA regulations issued under the CAA and CAA Amendments, including 40 CFR 60, *Standards of Performance for New Stationary Sources*; 40 CFR 61, *National Emission Standards for Hazardous Air Pollutant*; 40 CFR 63, *National Emission Standards for Hazardous Air Pollutants by Source Categories*; and 40 CFR 65, *Consolidated Federal Air Rule*. Medical waste incinerators are subject to performance standards for new units, or to emission guidelines for units existing as of 1996, which appear in 40 CFR 60.52c and 60.33e, respectively.

Compliance with CAA provisions is required for Air Force installations under AFI 32-7040, *Air Quality Compliance,* 9 May 1994; for Army installations under AR 200-1, *Environmental Protection and Enhancement*, 21 February 1997; and for Navy installations under Chief of Naval Operations Instruction (OPNAVINST) 5090.1B, *Environmental and Natural Resources Program Manual,* 1 November 1994, Chapter 5, "Clean Air Ashore."

2.3.4.2 Solid Waste

Disposal of solid waste (other than hazardous or medical/infectious waste) is generally regulated by the state and local governments. For military service installations, AR 420-49, *Utilities Services,* 28 May 1997, Chapter 3, "Solid Waste Management"; Navy Energy and Environmental Support Activity, NEESA 5.0-004, *Solid Waste Management Plan (SWMP) Guide*; and AFI 32-7042, *Solid and Hazardous Waste Compliance,* 12 May 1994, address collection, storage, processing, and disposal.

2.3.4.3 Wastewater

Under the Clean Water Act (CWA) (33 USC 1251 *et seq.)*, it is unlawful to discharge any radiological, chemical, or biological warfare agent, any high-level radioactive waste, or any medical waste (see Section 2.3.4.5) into navigable waters. Pollutant discharges from any point source into waters of the United States require a permit under 40 CFR 122, *National Pollutant Discharge Elimination System (NPDES)*, which provides uniform national effluent limitations for municipal and industrial wastewater treatment facilities as the primary means for detection and enforcement of compliance with the CWA. The NPDES program is administered by the EPA, and the states have been delegated the authority to administer and monitor NPDES permits within their jurisdictions under 40 CFR 123, *NPDES State Program Requirements*.

NPDES permits typically specify limits on the volume of treated effluent to be discharged and concentration limits of various chemical, physical, and/or biological parameters in the effluent, based on the treatment technology and the characteristics and designated uses of the receiving stream. NPDES permits also typically specify requirements for routine sampling and analysis of the effluent. Indirect discharges to publicly owned treatment works (POTW) are required to meet uniform nationwide prescribed pretreatment standards under 40 CFR 403, *General Pretreatment Regulations for Existing and New Sources of Pollution*. The local POTWs administer industrial waste pretreatment programs embodying pretreatment standards for various industrial categories, which appear in 40 CFR 405 through 471.

Military installations and contractor operations are required to meet NPDES standards for direct discharges of wastewater. Discharges to POTWs from Army installations are required to meet local pretreatment regulations. Tenants or off-post facilities that discharge wastewater to an Army installation's wastewater treatment facilities are subject to pretreatment standards established by the installation commander, in accordance with AR 420-49. For Air Force installations, AFI 32-7041, *Water Quality–Compliance*, 13 May 1994, applies. For Navy installations, OPNAVINST 5090.1B, Chapter 7, "Clean Water Ashore," applies.

2.3.4.4 Hazardous Waste

Hazardous waste, as defined in 40 CFR 261.3, are regulated under RCRA, as amended by the Superfund Amendments and Reauthorization Act of 1986. Enforcement and administration of RCRA regulations (40 CFR 260 through 266, 268, and 270 through 273) by the EPA have been delegated to certain state governments that have adopted legislation and regulations equivalent to, or more stringent than, RCRA.

OPNAVINST 4110.2, *Hazardous Material Control and Management*, 20 June 1989, establishes uniform policy, guidance, and requirements for the life-cycle control of hazardous material acquired and used by the Navy. This instruction applies to all Navy organizations and shore activities involved in the planning, procurement, acquisition, stowage, distribution, requisition, use, or other disposition of hazardous material (including disposal of used HAZMATs and hazardous waste in the United States and its territories). For Air Force installations, AFI 32-7042 and Air Force Pamphlet 32-7043, *Hazardous Waste Management Guide,* 1 November 1995, apply.

AR 200-1 designates the Defense Reutilization Marketing Office as the disposal agent for hazardous waste generated at Army installations.

2.3.4.5 Medical and Infectious Waste

The definition of medical waste in the Medical Waste Tracking Act of 1988 (42 USC 6992 *et seq.*) specifically includes cultures and stocks of infectious agents and associated biologicals; pathological waste; waste human blood and blood products; contaminated waste materials including sharps; animal carcasses, body parts, and bedding; waste from surgery or autopsy; laboratory waste; dialysis waste; and discarded medical equipment. This includes contamination by exposure to infectious agents, patient blood, or isolates (blood, excretion, exudates, or secretion from quarantined humans or animals). DOT regulations for shipping and packaging of HAZMATs (49 CFR 173.134) define medical waste as "waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in activities pertaining to the diagnosis, treatment, or immunization of human beings or animals or the production or testing of biological products." Similar definitions are used by other regulatory agencies.

According to guidelines jointly issued by the CDC and NIH, all waste contaminated or potentially contaminated with infectious material must be rendered noninfectious before disposal, which is accomplished by a combination of chemical disinfection and steam sterilization (autoclave) methods (CDC/NIH 1999).

2.3.4.6 Radiological Waste

Management of radiological waste is subject to NRC regulations (10 CFR 20, *Standards for Radiation Protection,* Subpart K, *Waste Disposal*). Packaging and shipment of all radiological waste material must also be in accordance with DOT regulations (49 CFR 172, *Hazardous Materials Table–Special Provisions* and 49 CFR 173, *Shippers – General Requirements for Shipments and Packaging*) and other applicable federal, DoD, and state regulations, as well as disposal facility requirements.

2.3.5 Safety, Health, and Security Mitigation

OSHA, of the U.S. Department of Labor, promulgates and administers regulations for workplace safety. DoD Instructions (DoDIs) 6055.1 (*DoD Occupational Safety and Health Program*, 19 August 1998) and 6055.5 (*Industrial Hygiene and Occupational Health*) extend this to military and civilian DoD personnel. OSHA benchmark regulations specifically relevant for the CBDP are discussed in Sections 2.3.5.1 and 2.3.5.2, respectively, for biological safety and chemical safety.

AR 385-10, *The Army Safety Program,* dated 25 February 2000, includes all applicable federal, state, local, DoD, and Department of the Army (DA) regulations and requirements that must be complied with at DA installations and DA-contracted sites that conduct activities with potentially hazardous material. This AR applies to activities conducted by either civilian or military personnel and defines safety management and responsibility, personnel training, PPE and clothing, waste-handling procedures, inspections, spill and emergency procedures, hazard communication, and other elements essential to safety. Safety programs of the Air Force and Navy are incorporated into Safety and Occupational Health programs and discussed under Occupational Health (Section 2.3.5.4).

2.3.5.1 Biological Safety

The CDC and NIH jointly developed guidelines for laboratory practices, techniques, facilities, and equipment recommended to contain etiologic agents of varying degrees of pathogenicity and virulence. These guidelines were published by the U.S. Department of Health and Human Services, Public Health Service, as *Biosafety in Microbiological and Biomedical Laboratories* (CDC/NIH 1999). Safety practices and procedures for laboratory work with genetically engineered microorganisms (GEMs) are detailed within the *Guidelines for Research Involving Recombinant DNA (rDNA) Molecules* (NIH 2002).

While the other services and entities follow these guidelines, as applicable, the Army established regulations involving the use of etiologic agents in research activities by DA and its contractors mandating adherence to the CDC/NIH guidelines and providing further safety requirements, including AR 385-69 (32 CFR 626)*, Biological Defense Safety Program*, dated December 1993. These regulations set forth responsibility for safety studies and review of biological defense RDT&E projects and prescribe safety precautions and procedures applicable to contractor operations. DA Pamphlet (PAM) 385-69 (32 CFR 627)*, The Biological Defense Safety Program*, dated December 1993, provides requirements for safety in use, handling, shipment, storage, and disposal of etiologic agents.

Prior to work involving etiologic agents by DA activities and Army contractors in the Biological Defense Research Program (BDRP), a hazard analysis and job safety evaluation are required by AR 385-69. This must include examination of the maximum credible event (see Section 5.12). The hazard analysis considers the range of potential consequences that might result from an accident during each type of potentially hazardous activity to assess whether existing safeguards are adequate to protect human health and the environment in the event of an accident. Initial and regular periodic safety inspections are required during operation. BDRP facilities must coordinate emergency preparedness with local emergency service providers and maintain formalized agreements describing the details of emergency support. In addition, AR 385-69 requires commanders of major commands with a BD RDT&E mission to conduct periodic safety management evaluations of their subordinate command BD RDT&E programs.

2.3.5.1.a *Biological Safety Cabinets*

The biological safety cabinet (BSC) is the principal device for containment of splashes of infectious materials or aerosols generated by microbiological procedures. The CDC/NIH guidelines divide BSCs into three classes according to the necessary degree of protection of laboratory personnel and the environment and the potential to prevent external contamination of the materials being manipulated inside the BSC. All three classes provide high-efficiency particulate air (HEPA) filtration of the exhaust air from the BSC. Class I and Class II BSCs have open fronts for entry of room air, but a Class III BSC provides HEPA filtration for ducted inlet air. Class I and Class II differ with respect to the internal airflow and engineering controls. Airflow in a Class I BSC is not recirculated. Class II BSCs are subdivided into four categories (A1, A2, B1, and B2) based on extent of recirculation, use of negative pressure (suction) relative to the room to induce inlet airflow, or use of an exhaust air duct. Recirculation, when used, requires HEPA filtration.

2.3.5.1.b *Biosafety Levels*

BD testing activities are conducted using facilities, equipment, and practices appropriate for the health risk associated with the microorganism under test. Four BSLs have been defined under the guidelines (CDC/NIH 1999), as follows:

- BSL-1 applies for strains of viable microorganisms not known to consistently cause disease in healthy adults. This designation usually applies to educational laboratories. Standard microbiological laboratory practices are followed in BSL-1 laboratories, including the requirement of sinks for washing hands.
- BSL-2 applies for moderate-risk agents that are present in the community and can cause disease of varying severity but can be used safely in activities conducted on an open bench with proper microbiological techniques. This designation usually applies to clinical or diagnostic facilities. Besides standard microbiological laboratory practices, BSL-2 laboratories have limited access, post biohazard warning signs, institute sharps precautions, and develop a biosafety manual or standard operating procedure (SOP) to define any needed waste decontamination or medical surveillance. BSL-2 laboratories require a Class I or II BSC or other physical containment device for all manipulation of agents that cause splashes or aerosols of infectious materials, as well as availability of an

autoclave for decontamination. Procedures that cannot be conducted in a BSC require use of PPE, including laboratory coats, gloves, and face protection, as necessary.

- BSL-3 applies for indigenous or exotic agents that have potential for respiratory transmission and may cause serious or potentially lethal infection, i.e., risk of personnel exposure to infectious aerosols. This designation usually applies to clinical, research, or production facilities. In addition to BSL-2 safety practices, BSL-3 laboratories require controlled access, decontamination of all waste, decontamination of laboratory clothing before laundering, and baseline serum sampling of laboratory personnel. In BSL-3 laboratories, a Class I or Class II BSC must be used for all open manipulation of agents. If a procedure cannot be conducted in a BSC, use of PPE is required, including protective clothing, gloves, and respiratory protection. BSL-3 laboratories are required to have secondary contamination barriers, including physical separation from unrestricted traffic corridors; self-closing double-door access; ventilation that ensures air flow into the laboratory (negative pressure) with no recirculation of exhausted air; and availability of autoclaves and fumigation chambers for decontamination.
- BSL-4 applies for dangerous or exotic agents that have a high risk of a life-threatening disease for which there is no available vaccine or therapy. In addition to BSL-2 and 3 practices, BSL-4 laboratories require all clothing to be changed before entrance into the laboratory; showers on every exit from the laboratory; and decontamination of all materials leaving the laboratory. All procedures must be conducted in BSCs, in either a Class III BSC or a Class I or II BSC by personnel using full-body air-supplied positive pressure suits. In addition to the BSL-3 secondary contamination barriers, BSL-4 laboratories are required to be in isolated zones or separate buildings; to have dedicated systems for air supply and exhaust, vacuum, and decontamination; and other requirements specified in the guidelines (CDC/NIH 1999).

2.3.5.1.c *Animal Biosafety Levels*

The guidelines (CDC/NIH 1999) define four animal BSLs (ABSLs) for laboratory work involving the use of animals infected or potentially infected with etiologic agents. The ABSL numbers generally correspond to the numbers of the BSL required for particular agents, as described above.

- ABSL-1 facilities require use of standard animal care and management practices, including appropriate medical surveillance. Standard safety equipment is used, as required for normal care of the animal species. In addition to BSL-1 secondary contamination barriers, ventilation with no recirculation of exhaust air is required for ABSL-1, and directional airflow is recommended.
- ABSL-2 facilities require adherence to BSL-2 laboratory practices and decontamination of all infectious waste and of animal cages prior to washing, in addition to the standard animal care and management practices of ABSL-1. Safety equipment required for ABSL-2 facilities corresponds to that for BSL-2 laboratories and includes primary containment appropriate for the animal species, handwashing sinks and mechanical cage washing in the animal room, and respiratory protection for personnel, in addition to the ABSL-1 requirements.

- ABSL-3 facilities require adherence to BSL-3 practices, as well as decontamination of cages before removal of bedding and use of disinfectant footbaths, as needed, in addition to the ABSL-2 practices. Safety equipment required for ABSL-3 facilities corresponds to that for BSL-3 laboratories and includes containment equipment for housing animals and cage dumping activities, in addition to the containment barriers for ABSL-2 facilities noted above.
- ABSL-4 facilities require adherence to BSL-4 practices, in addition to the ABSL-3 practices. Safety equipment required for ABSL-4 facilities corresponds to that for BSL-4 laboratories and includes the contamination barriers for ABSL-3 facilities.

2.3.5.1.d *Shipment of Etiologic Agents*

Biological agents are shipped for test purposes or for analysis. Biological agents and simulants are packaged, labeled, and shipped in accordance with the regulatory requirements of the Public Health Service (42 CFR 72, *Interstate Shipment of Etiologic Agents*) and DOT regulations (49 CFR 172 and 173). Facilities that transfer or receive certain etiologic agents listed in the Appendix of 42 CFR 72 are also required to apply for registration with the CDC in accordance with 42 CFR 72.6, *Additional Requirements for Facilities Transferring or Receiving Select Agents*.

2.3.5.2 Chemical Safety

Safety standards generally applicable to chemical hazards in a laboratory setting are provided in 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*, which includes development of a chemical hygiene plan (CHP); medical monitoring; preparation of written training and operational protocols; use of material safety data sheets (MSDSs) and labels; standards for hoods and ventilation; PPE and clothing; records; waste disposal; and certification of safety apparatus. Plan implementation and managerial responsibilities are also detailed in this OSHA regulation. Work areas must provide detailed, written SOPs for the safe use, handling, and disposal of hazardous material.

Another benchmark OSHA regulation, 29 CFR 1910.1200, *Hazard Communication*, specifically addresses evaluation of hazards, particularly hazards associated with chemicals, and informing employees about the nature of the hazards and appropriate protective measures. This information transmittal is accomplished through comprehensive programs involving container labels, warning signs, MSDSs, and employee training. This OSHA regulation applies for all personnel who work with or may be exposed to hazardous chemicals under normal conditions of use or in a foreseeable emergency. Certain provisions that overlap 29 CFR 1910.1450 do not apply for laboratory personnel. DoDI 6050.5, *DoD Hazard Communication Program*, 6 May 1996, requires DoD components to comply with the OSHA standards of 29 CFR1910.1200 and 1910.1450.

Air Force Occupational Safety and Health Standard (AFOSHSTD) 48-22, *Occupational Exposure to Hazardous Chemicals in Laboratories*, dated 21 March 1994, implements the corresponding OSHA standard (29 CFR 1910.450) for Air Force laboratories. This is

supplemented by AFOSHSTD 91-68, *Chemical Safety*, 1 October 1997, and AFOSHSTD 91-119, *Process Safety Management of Highly Hazardous Chemicals*, 1 March 1996.

Chemical surety safety programs at Army installations that store and handle CSM are required to meet or exceed guidelines contained in AR 385-61, *The Army Chemical Agents Safety Program*, dated 12 November 2001, and DA PAM 385-61, *Toxic Chemical Agent Safety Standards*, dated 31 March 1997. AR 385-61 implements DoDI 4120.13, *Safety Program for Chemical Agents and Weapons Systems*, 9 July 1987, and Chapter 11 of DoD 6055.9-STD. This regulation states DA policy on the management of the Chemical Agent Safety Program; assigns responsibility for safety studies and reviews of chemical agents and associated weapon systems; and prescribes general safety precautions and procedures. It also applies to Army contractors, provided that terms of regulation are incorporated by reference in the contract. The Navy counterpart is SECNAVINST 3400.3, *Safety Program for Chemical Agents and Weapons Systems*, 14 July 1989.

Army installations, major commands, and contractor facilities with a chemical agent mission are required under AR 50-6 to establish Chemical Accident or Incident Response and Assistance (CAIRA) Plans and conduct training exercises, in accordance with DA PAM 50-6, *CAIRA Operations*, 17 May 1991. Emergency response forces are established, including Initial Response Forces at the installation level and a Service Response Force at the DA level, for follow-on support in sustained operations. DA PAM 50-6 sets forth policies and procedures for response force management, contamination control, agent and munitions operations, medical support, security, environmental monitoring, remedial operations, and ancillary support. Also, AR 50-6 and DA PAM 50-6 discuss initial and regular periodic inspections for chemical defense activities.

2.3.5.3 Radiological Safety

OSHA standards applicable for radiological safety include 29 CFR 1910.97, *Nonionizing Radiation*, and 29 CFR 1910.1096, *Ionizing Radiation*. DoDI 6055.8, *Occupational Radiation Protection Program*, 6 May 1996, covers routine exposure of DoD personnel to ionizing radiation during performance of official duties.

NRC licenses for radiological operations include safety requirements under 10 CFR 36, *Licenses and Radiation Safety Requirements for Irradiators*. Irradiators are defined as facilities that apply radioactivity from sealed sources to objects or materials in air or water, with radiation dose rates exceeding 500 rads[1] per hour at 1 meter (approximately 3.2 feet) from the sealed radioactive source. The license and safety requirements do not apply for irradiators in which both the sealed source and the test subject are contained within a device and are not accessible to personnel.

[1] rad = radiation absorbed dose—The basic unit of absorbed dose equal to the absorption of 0.01 joules per kilogram (100 ergs per gram) of absorbing material.

2.3.5.4 Occupational Health

OSHA regulations require training programs in bloodborne pathogens (29 CFR 1910.1030), as well as hazard communication (29 CFR 1910.1200), and occupational exposure to hazardous chemicals in the laboratory (29 CFR 1910.1450).

Prior to beginning any activity with etiologic agents, workers are provided vaccines when available (CDC/NIH 1999). Personnel assigned to work in BSL-3 laboratories are offered the additional protection of investigational vaccines in those instances in which they are available. FDA requirements for administration of Investigational New Drugs (INDs), including vaccines, are followed in the Special Immunization Program (SIP) protocols. Prior to vaccination, SIP participants are required to undergo complete medical evaluations and must receive medical clearance. Workers must be informed of possible adverse reactions to the vaccine and sign an informed consent document prior to vaccination. Joining the SIP is considered as equivalent to human clinical trial status, and participation is voluntary. Guidelines and regulations for human subjects are discussed in Section 2.3.2.

The Navy Occupational Safety and Health (NAVOSH) Program focuses on the elimination or control of hazards that can result in instantaneous traumatic injury or death; prevention of harmful effects from long-term exposure to toxic chemicals or harmful physical agents; and treatment of work-related injuries. The NAVOSH Program is implemented through SECNAVINST 5100.10H, *Department of the Navy Policy for Safety, Mishap Prevention, Occupational Health, and Fire Protection Programs*, 15 June 1999, and OPNAVINST 5100.8G, *Navy Safety Occupational Health and Safety Program*, 24 May 1989. The major functional component of NAVOSH is a long-term surveillance program. This involves the identification and evaluation of occupational health hazards; recommendation of controls to lower workplace health risk; medical surveillance of employees who are potentially exposed to biological, chemical, or physical agents; and the diagnosis and treatment of occupational injuries and illnesses (OPNAVINST 5100.23E, *NAVOSH Program Manual*, 15 January 1999).

The Air Force Occupational and Environmental Safety, Fire Prevention, and Health (AFOSH) Program is implemented under AFI 91-301, *AFOSH Program*, 1 June 1996, and AFI 91-302, *AFOSH Standards*, 18 April 1994.

The Army Occupational Health Program is defined in Chapter 5 of AR 40-5, *Preventive Medicine*, 14 November 1990. Medical surveillance is required according to AR 385-69 for all personnel performing work for the DA that involves the use of etiologic agents. This consists of baseline and ongoing yearly physical examinations, laboratory tests, and x rays to monitor the program participants' health. Blood test results are analyzed for potential exposures as well as to monitor levels of immunity.

DoDI 6055.7, *Mishap Investigation, Reporting, and Recordkeeping*, 10 April 1989, requires recordkeeping of accidents. Records of safety audits and corrective measures; SOP reviews; risk assessments of new procedures; training; testing and certification of laboratory safety equipment; safety committee meeting minutes; and comments made by outside auditors or inspectors must be maintained for 3 years.

2.3.5.5 Security

Facilities that transfer or receive certain etiologic agents must apply for registration with the CDC in accordance with 42 CFR 72.6, as noted in Section 2.3.5.1.d, above. Permit holders must provide documentation and reports for all incoming and leaving transfers of the listed agents.

DoDD 5200.8, *Security of DoD Installations and Resources*, sets forth policies on physical security for DoD components. For military installations, the requirements for access control and guards are defined jointly in AR 190-16, Air Force Joint Instruction 31-102, OPNAVINST 5530.15A, and Marine Corps Order 5500.13A, all titled *Physical Security*, 30 September 1993. Additional security requirements for Army CBDP activity sites are presented in AR 190-59.

2.3.6 Contract Administration

CBDP activities conducted by contractors are subject to contract terms and conditions that require compliance with applicable federal, state, and local laws and regulations covering mitigation of waste management impacts and safety and health impacts. Federal Acquisition System regulations for DoD components (48 CFR 223, *Environment, Conservation, Occupational Health, and Drug-Free Workplace*) set forth policies and provide appropriate contract clauses. Acquisition activities under the CBDP also are regulated by DoDD 5000.1, *The Defense Acquisition System*, 23 October 2000, and DoD 5000.2-R, *Mandatory Procedures for Major Defense Acquisition Programs and Major Automated Information System Acquisition Programs*, 5 April 2002. A "total system" approach is mandated, which includes environmental compliance and potential impacts on the environment. Toward that end, Program Managers are required to prepare a Programmatic Environmental, Safety, and Occupational Health Evaluation (PESHE) document including Environment, Safety, and Occupational Health (ESOH) risks; a strategy for integrating ESOH considerations into the systems engineering process; identification of ESOH responsibilities; a method for tracking progress; and a compliance schedule for NEPA.

Contractors must certify that they are in compliance with the applicable federal, state, and local environmental and safety laws and regulations. Contracting agencies under the CBDP require considerable information regarding contractor safety and environmental programs. For example, the Joint Vaccine Acquisition Program requested bidders to conduct an Environmental and Safety Analysis, including safety inspections and development of reporting memoranda, to provide evidence that facilities, safety equipment, environmental controls, and operating procedures were in place (DA and JPO BD 1997).

Contract administration activities at Brooks Air Force Base and the Marine Corps Systems Command are reviewed with respect to potential environmental impacts and compliance with the above benchmarks in Sections 2.4.8 and 2.4.9, respectively. Both of these sites are associated with the CBDP only through contract administration activities.

2.4 Existing CBDP Activities at the Example Sites

2.4.1 Edgewood Chemical Biological Center

The Edgewood Chemical Biological Center (ECBC) is located within the Edgewood Area of Aberdeen Proving Ground (APG) in Harford County, Maryland. Information about the Edgewood Area of APG, including details of the existing environment, is presented in Section 4.2. This section discusses CBDP activities and mitigation measures at ECBC as a basis for the environmental impact analysis in Sections 5.2 through 5.14.

ECBC is a subordinate activity of the Soldier and Biological Chemical Command (SBCCOM) under the U.S. Army Materiel Command (AMC). Its mission is to protect the warfighter and U.S. interests through the application of science, technology, and engineering in CB defense. SBCCOM is the principal Army command for nonmedical CBDP activities, and ECBC is the principal research and development center for CB defense technology, engineering, and service (ECBC 2001a).

CBDP activities occur in 23 buildings/sites at the Edgewood Area of APG, comprising about 80,776 square meters (869,471 square feet) of laboratories; 26,007 square meters (279,932 square feet) of administrative offices; and 26,389 square meters (284,054 square feet) of storage facilities (ECBC 2000a). An estimated 46,452 square meters (500,000 square feet) of this is used to conduct CBDP-related activities (ECBC 2001b).

2.4.1.1 Research, Development, Test, and Evaluation Activities

Contamination Avoidance is the principal commodity area for ECBC. The Center also serves activities under Decontamination, Collective Protection, and Individual Protection commodity areas (SBCCOM 1999). The RDT&E activities include work with CSM and biological material designated BSL-1 or -2.

2.4.1.1.a Chemical Surety Materiel

The CB Services Directorate of ECBC provides risk management services for CSM and biological materiel. This directorate uses CB agent handling experience and chemical weapons expertise to address risk management for CSM as well as munitions clearing and demilitarization problems (ECBC 2000b).

CSM is used in 64 laboratories that occupy about 14,002 square meters (150,715 square feet) in five buildings. Two of these buildings are certified under the Contractor Performance Certification Program for testing and analysis with CSM (ECBC 2001b, SBCCOM 2002a). A third building contains chemical laboratories and testing facilities (ECBC 2001b) for decontamination systems and technologies from basic research to laboratory-scale prototypes to evaluate the performance of detectors and protective materials against toxic chemical agents (SBCCOM 2002a).

Two additional separate buildings contain chemical testing chambers designed for total containment in the testing of military and industrial chemical-related equipment and explosive/toxic munitions. Each of these buildings also has a surety laboratory for toxic

material. Both of these facilities are permitted to handle CSM and explosives up to approximately 644 liters—a 0.91-metric-ton container (170 gallons—a 1.0-short-ton [ton] container) of military-unique chemical materiel or industrial materiel, 2.3 kilograms (5 pounds) of explosives without chemical materiel, and 0.45 kilograms (1.0 pounds) of explosives when combined with chemical materiel. Both facilities have their own neutralization systems that can process up to 37,854 liters (10,000 gallons) of liquid hazardous/nonhazardous waste generated from testing (SBCCOM 2002a, 2002b).

The Chemical Transfer Facility (CTF) is designated under AR 50-6 as the "Single Small-Scale Facility" for production of chemical agents listed in the CWC for protective purposes. It consists of storage rooms, laboratories, and a room encompassing 1,232 square meters (13,264 square feet) that is used for transferring small quantities of material from storage containers (SBCCOM 2002a). It includes a glove box for handling unknown materials suspected of contamination with CB agents (ECBC 2001b). The CTF also provides double-containment and observable storage tanks equipped with leak detection. The Army's stocks of chemical agents used in chemical defense research and development are stored in the CTF. Every room in the CTF is serviced by a filtered ventilation system and low-level detection equipment (SBCCOM 2002a). Each individual room in the CTF is placed under negative pressure to pull make-up air from the hallway into the rooms. The exhaust air from each CTF room is drawn through a chemical, biological, and radiological (CBR) vapor filtration unit (see Section 2.4.1.2.c) (SBCCOM 2002b).

2.4.1.1.b High-Hazard Biological Agents

The McNamara Life Sciences Building provides approximately 9,881 square meters (106,362 square feet) of laboratory space for CBDP RDT&E activities (ECBC 2001b), including a BSL-3 laboratory suite and BSL-2 laboratories; a surgical suite; a percutaneous suite; inhalation suites; a necropsy laboratory; an electrophysiology laboratory; and supporting analytical/clinical chemistry, physiology, enzymology, teratology, biochemistry, microbiology, pathology, molecular and cellular biology, and aquatic toxicology laboratories. A separate building houses a BSL-2 laboratory for testing of optical-based CB sensors using samples of bacterial simulants, attenuated bacterial agents, chemical contaminants, environmental samples, pollens, molds, fungi, and smuts (SBCCOM 2002a).

Laboratories in several other ECBC buildings support CB filtration activities, chemical analyses, and nuclear magnetic resonance studies. These CB filtration facilities have the capabilities to evaluate novel air purification processes for Collective and Individual (respiratory) Protection applications. Additional support facilities include experimental fabrication shops for prototypes and small-scale production, as well as the Electro-Optics Laboratory for research and development on technologies for remote sensing system development (ECBC 2001b, SBCCOM 2002a).

The Process Engineering Facility (PEF) Building supports biotechnology research and development of cell-based manufacturing processes for producing proteins, enzymes, antibodies, and other cellular products. Laboratories in the PEF conduct in vitro cytotoxicity tests on human and animal cell cultures under Good Laboratory Practice protocols and studies on the effect of

systemic exposure on gene expressions using gene arrays. The PEF Building also contains the Critical Reagent Program Repository and supporting laboratory facilities for storage and validation of all immunological biodetection reagents for DoD programs (SBCCOM 2002a).

The Surface Spectroscopy and Electron Microscopy Laboratory Building is used for biological and forensic research with specialization in morphological and compositional characterization, surface analysis, and fine-particle technology (SBCCOM 2002a).

ECBC has provided the necessary biosafety, health, and waste management training for qualified scientists to conduct research up to BSL-2, to include CBDP activities. In addition, ECBC has several qualified scientists meeting the necessary ECBC and U.S. Army requirements to conduct laboratory operations at BSL-3. However, ECBC has conducted no CBDP research at the BSL-3 laboratory as of May 2002 (SBCCOM 2002b, 2002c).

2.4.1.1.c *Aerosol Testing*

Aerosol testing is conducted at ECBC using indoor laboratory facilities. One building is dedicated for aerosol research and contains laboratories and test silos (ECBC 2001b). The Optical Characterization Laboratory in another building supports research on optical characteristics of aerosols and vapors containing chemical or biological contaminants. The Aerosol Science and Technology Team conducts basic and applied research on clouds and single particles of natural or synthetic materials. Complete characterization of aerosol particle size and mass concentrations are routinely performed using test facilities for both CB aerosols. A feature known as the "Stealth Tube" allows researchers to test their equipment and applications in a realistic, controlled environment (SBCCOM 2002a).

2.4.1.1.d *Animal Care and Use*

The care and maintenance of laboratory animals at ECBC is conducted in accordance with the benchmark guidelines and regulations described in Section 2.3.1, with Public Health Service policy, and with ECBC SOPs VServ 01, *Veterinary Care and Contact Procedures*, and VServ 03, *Animal Room Procedures* (SBCCOM 2002b). Animal facilities and animal care and use programs are evaluated at ECBC every 3 years by AAALAC International. The McNamara Life Sciences Building, the only animal facility at ECBC, has full accreditation (AAALAC 2001).

The Chemistry RDA animal census for 2000 counted 80 rabbits, 71 ferrets, and 46 rats (ECBC 2001b). These small animals are obtained from Charles River Laboratories, Inc., in Wilmington, Massachusetts, and Covance Research Products in Denver, Pennsylvania. ECBC did not use large animals in CBDP activities in 2000 (SBCCOM 2002d). The animals are contained in the following types of housing: rabbits individually in metal cages, other rodents in plastic shoeboxes, and minipigs in individual pens inside the building. The veterinary medicine and laboratory resources at ECBC are handled by the Veterinary Services Team of Research and Technology Directorate, which also directs the Institutional Animal Care and Use Committee (IACUC) (SBCCOM 2002b).

2.4.1.1.e *Vaccine Development*

Vaccine development is not conducted at ECBC (SBCCOM 2002c).

2.4.1.1.f *Genetically Engineered Microorganisms*

GEMs are not currently used in CBDP activities at ECBC, and there are no future plans to work with them in the CBDP (SBCCOM 2002b). Historically, only one ECBC SOP has been prepared for work with rDNA in the CBDP, but that work was not performed in the CBDP during 1999 through 2001 (SBCCOM 2002b).

2.4.1.1.g *Human Subjects*

ECBC test protocols must be reviewed for human participation by the Human Use Committee. Eighteen protocols were reviewed during 2000, covering testing of respirators, PPE, and Collective Protection equipment (SBCCOM 2002c).

2.4.1.1.h *Radiological Testing*

One building at ECBC contains radiological laboratories (ECBC 2001b). ECBC holds six permits, which allow ECBC personnel to conduct CBDP-related work with small amounts of radioactive materials (SBCCOM 2002b). ECBC holds three NRC licenses in the radiological laboratories, including NRC license No. 19-10306-01 for broadscope work and NRC license No. SUB-1142 for depleted uranium work. Under the broadscope license, a wide variety of radiological material may be utilized for research and development activities, ranging from general chemistry to agent material. The depleted uranium license was issued for attenuation studies in one facility, which also conducted neutron-generation studies with a neutron generator; however, the generator has been removed to the radiological waste storage site and is scheduled for disposal at an off-site facility in the fall of 2002. The license will be terminated upon removal of the depleted uranium from APG. The nonfunctional neutron generator and the removal of the depleted uranium make the building nonviable (SBCCOM 2002d).

2.4.1.1.i *Open-Air Laser Testing*

The Optical Sensor Experimental and Development Laboratory is used primarily for the detection of CB agents in the air using the Light Detection and Ranging systems, laser-based point sensors, and supporting experimental facilities (SBCCOM 2002a). A total of 16 ECBC scientists and engineers work with open-air lasers (SBCCOM 2002e).

2.4.1.1.j *Support Work*

U.S. Army Edgewood Research, Development, and Engineering Center (ERDEC) Regulation 40-3, *U.S. Army Edgewood Chemical Biological Center CHP*, and ERDEC-SP-058, *Preparation of Standing Operating Procedures, Version 1.3*, provide procedures for care, use, and/or decontamination of laboratory tools, such as glassware, plasticware, sharps, and nonhazardous chemicals and reagents used to support CBDP-related work.

2.4.1.2 Operations, Maintenance, and Waste Management Activities

The Directorate of Public Works (DPW) of APG is responsible for providing utility services and assisting with environmental and energy consumption aspects of operations. DPW responsibilities also include maintenance (Casole 2002a).

2.4.1.2.a Operations

The potable water supply and distribution system at the Edgewood Area is owned by APG and operated by DPW. Its water source is the Van Bibber impoundment of Winter's Run, which is located about 3.2 kilometers (2 miles) north of the Edgewood Area of APG (USACOE 2000a). Further information on the water treatment plant (WTP) appears in Section 4.2.9.1. In times of drought, additional water supply is acquired from a Harford County WTP located in Abington, Maryland, about 4.8 kilometers (3 miles) north of the Edgewood Area. During calendar year 2001, the Edgewood Area of APG consumed approximately 1.44 billion liters (381,077,000 gallons) of water. Of this, approximately 546,551,194 liters (144,384,000 gallons) had to be acquired from Harford County from late August to December due to severe drought conditions (Gentry 2002).

The water requirements for CBDP-related activities at ECBC are not known. Water usage for individual ECBC buildings is not metered (Wiggins 2002).

The Edgewood Area of APG consumed 95,687,781 kilowatt hours (kWh) during fiscal year 2001 from the Baltimore Gas and Electric Company (BGEC) through an electrical substation in the Edgewood Area (Testerman 2002a, USACOE 2000a). An instantaneous peak electrical demand of 20 megawatts was recorded for the Edgewood Area in 2001 (Testerman 2002a). The electrical requirements of CBDP-related activities at ECBC are not known; electrical usage for individual ECBC buildings in the Edgewood Area is not metered (Testerman 2002b).

The Edgewood Area does not receive natural gas service. Its central heating system uses high-pressure steam purchased from the Harford County Waste-to-Energy Plant (WEP) (USACOE 2000a). The steam is also used for cooling and sterilization. The WEP generates 226.8 million kilograms (500 million pounds) of steam per year (Poulton 2002). APG purchases steam from the WEP throughout the year. This accounts for approximately 90% of the steam generated by the WEP during the winter and 75% to 85% of the steam during the summer (Bradley 2002).

Fuels supplied to the Edgewood Area of APG during calendar year 2001 included about 1,684,318 liters (444,951 gallons) of gasoline; 1,033,444 liters (273,008 gallons) of diesel fuel; and 13,488,497 liters (3,563,295 gallons) of heating oil (Baldwin 2002).

2.4.1.2.b Maintenance

The DPW is responsible for providing maintenance, repair operations, and management of facilities; professional engineering and architectural design for modification and construction of facilities; engineering management services of the installation and supported activities; and housing operations and management. The DPW is also responsible for directing and coordinating the development and implementation of peacetime and emergency master plans and

utilizing real estate and real property facilities (APG DPW 2002). Janitorial maintenance occurs on a scheduled basis. The DPW provides facility repairs and maintenance on an as-needed basis or by work order request (SBCCOM 2002b).

2.4.1.2.c *Waste Management*

- *Air Emissions*

The State of Maryland has adopted the NAAQS and incorporated them into the Code of Maryland Regulation (COMAR) 26.11.04, *Ambient Air Quality Standards* (Maryland Department of the Environment (MDE) 2002a). Any federal actions producing emissions of O_3 or its precursors at the Edgewood Area must not cause or contribute to any new violation of the air quality standard or delay the timely attainment of any air quality standard since Harford County has been designated as a non-attainment area for ozone (MDE 2002b).

The air quality program at APG is in accordance with the benchmark federal and DoD regulations enumerated in Section 2.3.4.1 and APG Regulation (APGR) 200-30, *Environmental Quality–Air Quality,* which prescribes policies, assigns responsibilities, and establishes procedures for the control of air emissions generated by all activities, tenants, commands, organizations, and personnel within the boundaries of the installation. The Directorate of Safety, Health, and Environment (DSHE) Environmental Compliance Division (ECD), Environmental Engineering Branch (EEB), is responsible for the air quality program at APG (USACOE 2000a).

The Maryland Department of the Environment (MDE) Air and Radiation Management Administration (ARMA) is the primary air quality regulatory authority in the state. The Edgewood Area of APG holds MDE ARMA Title V Operating Permit No. 24-025-00082, issued under the CAA (USACOE 2000a). The permit, which expires on 31 October 2004, includes four boilers between 10 to 100 million British thermal units (Btu) per hour and various miscellaneous equipment. Air emission certifications for toxic air pollutants (TAPs) and criteria pollutants are submitted every year as required by law.

In addition, the U.S. Army Garrison (USAG) holds five permits for emergency generators (with no control devices) at ECBC facilities associated with CBDP activities (Permit Nos. 12-9-0231-N and 12-9-0232-N, issued 23 June 1998, and Permit Nos. 12-9-0278-N, 12-9-0279-N, and 12-9-0280-N, issued 27 October 1995). Operational time for these emergency generators is capped at no more than 408 hours. No air permit violations or incidents occurred in the years 1996 through 2000 (ECBC 2001b). ECBC annual emissions of criteria pollutants average 0.55 metric tons (0.61 tons) of NO_x, 0.05 metric tons (0.06 tons) of volatile organic compounds (VOCs), 0.006 metric tons (0.0061 tons) of SO_2, and 0.032 metric tons (0.0356 tons) of PM_{10}[2] (SBCCOM 2002b).

[2] The particulate matter subscript denotes the upper limit of the diameter of particles included. Thus, PM_{10} includes only those particles equal to or less than 10 micrometers (0.0004 inches) in diameter.

MDE has implemented regulations (COMAR 26.11.13) governing acceptable ambient levels for approximately 600 TAPs, substances (other than the NAAQS criteria pollutants) that cause or are suspected to cause adverse human health effects (Advanced Sciences, Inc. 1990). As of 2000, approximately 131 TAPs are emitted at the Edgewood Area, 39 of which exceed the screening levels established by MDE as maximum threshold levels to which the surrounding population may be exposed without unreasonable acute or chronic health risks (COMAR 26.11.15 and 10.18.02.02.03). An air quality modeling study conducted by the State of Maryland indicated that the emissions of TAPs from the Edgewood Area would have minor or negligible ambient impacts and would not endanger human health (USACOE 2000a).

Emissions from chemical agent operations are vented to the atmosphere through a series of CBR filtration units, each comprised of a prefilter, a HEPA filter, and an impregnated charcoal bed. A single CBR unit is 99.97% efficient for PM at 0.3 micrometers and reduces a vapor challenge concentration by 99.99%. The CBR units are used in a series, so that the redundant filter will capture a failure or breakthrough.

Emissions of "greenhouse gases," including carbon dioxide (CO_2), methane, nitrous oxide, CFCs, halons, and tropospheric ozone, were evaluated for the entire APG installation. CO_2 serves as a surrogate for greenhouse gases on the basis of all fuels purchased and consumed at APG. The approximately 114,305 metric tons (126,000 tons) of CO_2 emitted annually from APG accounts for less than 0.1% of man-made emissions from the Maryland/ Washington, D.C., area. APG is also in the process of eliminating use of CFCs and halons, which have been addressed in Title VI of the CAA Amendments as chemicals that deplete stratospheric ozone (USACOE 2000a).

ECBC has received only one odor complaint during the years 1997 through 2001. An employee reported mustard HD (bis-(2-chloroethyl) sulfide) agent odors while entering an ECBC building in March 1997 (SBCCOM 2002b).

- *Solid Waste*

ECBC disposed of, via a licensed hazardous waste contractor, a combined total of 34,474 kilograms (38 tons) of municipal and hazardous solid waste from RDT&E activities in 2000. Two-thirds of this waste was generated from CBR filters and PPE. Laboratory waste, including excess chemicals, accounted for 11,794 kilograms (13 tons) of the total (SBCCOM 2002b). It is estimated that 2,142 kilograms (4,723 pounds) of nonhazardous solid waste were generated during calendar year 2000, comprised of animal waste, microbiological laboratory waste, and sharps (ECBC 2001b, SBCCOM 2002c). Solid waste and recycling at APG are handled by the ECD, EEB, of the DSHE, within APG's USAG.

Collection, storage, processing, and disposal of solid waste at APG are in accordance with the benchmark regulations and guidelines discussed in Section 2.3.4.2. An Integrated Solid Waste Management Program is maintained in accordance with APGR 200-50, *Integrated Solid Waste Management at Aberdeen Proving Ground*, which incorporates the applicable federal, state, local, and Army regulations for the management of nonhazardous solid waste

and encompasses source reduction, resource recovery and reuse, recycling, and disposal (USACOE 2000a).

The DPW contracts with haulers to collect municipal solid waste for disposal at the Harford County WEP (USACOE 2000a). The WEP is an incinerator for municipal solid waste located on leased land in the southern part of the Edgewood Area of APG. Approximately 90% of Harford County's municipal solid waste is disposed at the WEP, in addition to the nonhazardous waste from APG (Bradley 2002). The WEP operates under Refuse Disposal Permit No. 2000-WIN-0100 and Air Permit No. 12-00212, issued by MDE (Harford County 1996, Poulton 2002).

- *Wastewater*

All of the buildings on the Edgewood Area of APG discharge sanitary wastewater into a central sanitary sewer system (CSSS) for treatment at a wastewater treatment plant (WWTP) located on the Edgewood Area and operated by APG. Individual building discharges to the CSSS are not measured. The Edgewood Area WWTP treats an average of 3,028,320 liters (800,000 gallons) per day as of 2000 and has a capacity for 7.57 million liters (2.0 million gallons) per day (USACOE 2000a). It discharges treated wastewater into the Bush River under NPDES Permit No. MD0021229 and State Discharge Permit No. 90-DP-2531 issued by MDE. These permits will expire on 30 June 2003 (MDE 1998, USACOE 2000a).

Seven CBDP ECBC buildings discharge laboratory wastewater into the CSSS, subject to limitations of APGR 200-41, *Water Quality, Wastewater Discharge Management* (ECBC 2001b, SBCCOM 2002c). Flow-through tanks on the ground floor of the McNamara Building are used for laboratory wastewater containment prior to discharge into the CSSS (ECBC 2001b). Laboratories that do not discharge wastewater into the CSSS contain and dispose of their liquid waste as hazardous or nonhazardous waste by the APG hazardous waste contractor, in accordance with APGR 200-60, *Hazardous Waste Management* (SBCCOM 2002b).

APGR 200-41, *Water Quality, Wastewater Discharge Management*, and the NPDES permit require that logs be maintained for the laboratory wastewater discharges to the CSSS. The logs must be submitted twice each year to the ECD of APG's USAG. APGR 200-41 further requires that daily laboratory discharges into the CSSS must not exceed the following in each individual laboratory: 4 liters (approximately 1.05 gallons) with a maximum concentration of 500 milligrams per liter (mg/L) of metals (antimony, beryllium, copper, nickel, thallium, and zinc); 4 liters of other inorganic materials; and 4 liters with a maximum concentration of 500 mg/L of pesticides. Allowable laboratory wastewater discharges containing organic materials are determined on a case-by-case basis by the ECD (ECBC 2001b).

- *Hazardous Waste*

MDE has primacy over the RCRA program in Maryland. The applicable regulations are codified in COMAR 26.13, *Disposal of Controlled Hazardous Substances* (CHSs), Maryland's term for hazardous waste. One CHS generator identification number is assigned to the APG Commander, and the USAG is designated as the responsible organization for

environmental compliance at APG, including waste management. APGR 200-60 delineates the hazardous waste program responsibilities for the installation. The Hazardous Waste Management (HWM) Branch of DSHE within USAG oversees the management of hazardous waste at APG using an electronic tracking system (USACOE 2000a).

APGR 200-60 applies to all waste-generating organizations and implements the state regulations. Tenant activities that generate waste transfer accountability for it to the USAG via the electronic tracking system upon disposal.

Hazardous waste must be quantified and characterized chemically for proper disposal. Activity Environmental Coordinators review and approve this information before the waste can be moved to a 90-day RCRA storage site. Satellite accumulation sites (SASs) are utilized for small quantities of hazardous waste generated in their vicinity. The installation Environmental Coordinator reviews the records and approves the shipment to a permitted off-site commercial TSDF. APG customarily ships RCRA waste directly from the SASs and/or 90-day storage sites.

Eleven buildings have SASs for RCRA hazardous waste. In addition, two buildings have both 90-day storage facilities and SASs, and another building has a 90-day storage site for RCRA hazardous waste. The CTF has a 90-day storage site and a SAS in addition to its TSDF for RCRA hazardous waste (ECBC 2001b). Four other buildings located within the Edgewood Area are used as 90-day RCRA waste storage facilities (SBCCOM 2002b). These sites comprise approximately 1,807 square meters (19,450 square feet) of ECBC land (ECBC 2001b).

USAG was issued CHS Permit No. A-190 by MDE. The permit expired on 14 May 1998, but it has been extended by MDE pending action on application for renewal (Mann 2002a). ECBC generated approximately 32,331 kilograms (71,277 pounds) of CHSs from CBDP-related activities in 2000 (ECBC 2001b). The CTF is included in the CHS permit for treatment and storage of agent-related waste. APG's USAG is listed as the permit facility/owner, and ECBC is the operator of the CTF.

Approximately 2,268 kilograms (5,000 pounds) of RCRA hazardous waste were generated during 2000 from the CTF, and an estimated 90% of this waste was coded MD02 (CSM waste). The remaining waste is specified with a "D" code, which indicates ignitability, corrosivity, reactivity, or toxicity characteristics (ECBC 2001b).

Hazardous waste generators store the collected hazardous waste containers in an approved SAS with spill containment. The hazardous waste must have proper documentation prior to removal from the SAS by ECBC workers, who transport it to a 90-day storage site. From there, the USAG's chemical waste contractor collects it for direct shipment off post to a commercial TSDF, or occasionally for storage at the USAG APG licensed storage facility until it can be shipped to a commercial TSDF (SBCCOM 2002b).

Inspections of hazardous waste management facilities under Permit A190 are conducted by MDE and EPA Region 3. SASs and 90-day sites are inspected in accordance with RCRA requirements by APG's USAG and by ECBC. Inspections during the years 1995 through 1999 noted four violations. The violations were for inadequate aisle space in the drum storage area; storage of waste without screening for CSM; piping to the neutralization system not visible for inspection; and procedures for assessing tanks, ancillary equipment, and secondary containment not included in the schedule (ECBC 2001b).

ECBC does not generate toxic or nontoxic waste gas (SBCCOM 2002b). Sharps used during chemical laboratory operations are not to be disposed as medical waste (*ECBC Chemical Sharps Guidance* document). Prior to disposal, sharps exposed to a chemical agent must be properly decontaminated, packed in rigid plastic containers, documented for the Hazardous Waste Tracking System, and removed for disposal by incineration (ECBC 2001b). Chemical sharps must have a signed certification that they were never exposed to infectious materials.

CSM waste is disposed of according to the benchmark guidelines discussed in Sections 2.3.4.4 and 2.3.5.2; DA PAM 385-61, *Toxic Chemical Agent Safety Standards*; APGR 200-60; and ERDEC-SP-058.

Radioactively labeled chemical surety waste is collected separately from other CSM waste, decontaminated in accordance with the delisting procedure and disposed of as radiological waste in accordance with NRC regulations and ERDEC Regulation 385-6 (SBCCOM 2002b).

- *Medical and Infectious Waste*

The handling, transport, and disposal of medical waste at APG is in accordance with the benchmark regulations and guidelines discussed in Section 2.3.4.5 and U.S. Army Medical Command (MEDCOM) Regulation 40-35, *Regulated Medical Waste Management.* This regulation applies to waste that is potentially infectious for humans and may pose a risk to individuals or to community health if not handled or disposed of properly. The *APG Special Medical Waste Management Document,* DSHE APG, June 2001, provides guidance regarding disposal of excess and waste pharmaceuticals and other waste items generated in APG's microbiological, toxicological, and animal research activities that warrant special management under the COMAR regulations.

State of Maryland regulations (COMAR 26.13.11-13, 26.13.02.02A, 26.13.01, and 10.06.06) for special medical waste (SMW) are administered by MDE, Waste Management Administration. SMW is defined in COMAR 26.13.11.02 as a solid waste composed of anatomical material, blood, blood-soiled articles, contaminated materials, microbiological laboratory waste, or sharps. Contaminated materials include feces of an individual diagnosed as having a disease that may be transmitted to other humans through the feces, articles soiled with such feces, or articles that came into contact with a known infectious agent.

Prior to collection for disposal, all organisms, toxins, microbiological waste, and materials used in activities of BSL-2 and higher must be deactivated by autoclaving. This is in

accordance with the benchmark guideline (CDC/NIH 1999). Autoclaved materials are not classified as SMW under COMAR 26.13.11.03E and may be disposed of as general solid waste, provided that packaging, labeling, and treatment are in compliance with COMAR 26.13.12.05.

The waste disposed from ECBC via a medical waste contract consists predominantly of deactivated microbiological laboratory waste. CBDP activities during 2000 at ECBC generated 89.4 kilograms (197 pounds) of animal waste packaged in five 113.4-liter (30-gallon) boxes. An additional 1.13 metric tons (1.25 tons) of animal waste were generated in 2000 for non-CBDP-funded studies. In addition, approximately two hundred 113.4-liter (30-gallon) boxes of microbiological laboratory waste were generated from CBDP and non-CBDP laboratory activities, combined (ECBC 2001b). Approximately 85% of the waste material disposed of through ECBC's medical waste contract is attributed to CBDP activities.

DSHE manages a contract with Stericycle of Baltimore, Maryland, which provides medical waste disposal services for ECBC by incineration or autoclaving at a permitted facility (USACOE 2000a).

- *Radiological Waste*

ECBC collects radioactive waste materials from the laboratories and places them in the radioactive waste storage bay in accordance with NRC benchmark guidelines and ERDEC Regulation 385-6. The Operations Support Command (OSC) uses commercial carriers to collect and transport all radiological waste from APG to a contracted facility in Rock Island, Illinois, for incineration. OSC contractors also pack, check, and inventory the waste on site. The OSC acts as the contract manager between ECBC and OSC-approved disposal facilities for radiological waste (SBCCOM 2002b).

One 208-liter (55-gallon) drum of solid radioactive waste and half of a 208-liter (55-gallon) drum of liquid radioactive waste were generated in 2000 by ECBC during CBDP-related activities (ECBC 2001b). During work with unsealed radionuclides, individual containers, appropriately labeled with warnings of radioactivity, must be provided in each room for radioactive waste characterized as aqueous liquids, nonaqueous liquids, or solid material. All radiological waste is packaged in accordance with OSC and applicable state and disposal contractor facility requirements, as well as the benchmark regulations discussed in Section 2.3.4.6. A mandatory yellow radioactive waste tag marked with isotope, activity in millicuries, quantities, and date information must be attached to the containers prior to collection. Nonexpendable items must be decontaminated after exposure to radiation sources, if required. According to ERDEC Regulation 385-6, users of radioactive materials must maintain records of materials disposed of as radioactive waste.

Any radioactive waste contaminated or potentially contaminated with a biological agent must have the biological agent deactivated first, using the appropriate decontamination procedure, as discussed for medical waste. The radioactive waste can then be treated as discussed above. Animal carcasses exposed to radioactive materials must be sealed in plastic bags,

properly labeled, and frozen until the radioactive waste disposal contractor collects it, unless the carcasses meet NRC requirements for exemption.

2.4.1.3 Safety, Health, and Security Mitigation

ECBC activities are conducted in accordance with the benchmark federal laws, DoD and DA regulations, and guidelines discussed in Section 2.3.5. ECBC safety policies and procedures also incorporate applicable state and local regulations and accepted general, CB, and radiological safety practices. ECBC safety procedures are conducted in accordance with AMC Regulation 385-100, *Safety Manual*, 26 September 1995, and APGR 385-4, *The APG Safety and Occupational Health Program*, as well as specific regulations for CB safety discussed below (SBCCOM 2002b).

An SOP must be prepared for each hazardous activity. ERDEC-SP-058, *Preparation of Standing Operating Procedures, Version 1.3*, dated August 2001, provides general information to be included in ECBC SOPs for biological or chemical safety. This includes biological hazard descriptions, general biolaboratory precautions, storage, emergency procedures, work with killed microorganisms, and rDNA work for biological laboratories. It also provides general requirements for an SOP with respect to chemical agents, including hazard descriptions of the agents; ventilation requirements; monitoring; protective clothing and PPE; fire fighting and first aid; general precautions; chemical agent decontamination procedures; emergencies; an exposure check log; and a preoperational checklist for hazardous operations.

2.4.1.3.a <u>*Safety*</u>

- *Biological Safety*

The basic level of containment for BSL-1 agents includes standard microbiological practices. BSL-2 practices, safety equipment, and facilities include required primary containment equipment, such as BSCs or safety centrifuge cups, for activities with high potential for splashing or generating an aerosol. Other activities may use good microbiological techniques performed on an open bench (ERDEC-SP-058).

The etiologic agents studied at ECBC within the CBDP comprise a variety of toxins and organisms of military interest, including bacteria, viruses, and rickettsiae. Live BSL-3 agents were not used in CBDP-related activites at ECBC in 2000 and 2001. The agents are killed prior to use, since the research is focused on methodologies for detection (ECBC 2001b). The killed organism has a lower BSL than the viable organism, which allows for the work to be conducted in BSL-2 laboratories. A certificate from the supplier must accompany killed pathogens procured by ECBC to ensure that the shipment is free of living organisms (ERDEC-SP-058). The certificate must include the name of the supplier, the date and method of sterilization, and the test procedure used to ensure that live organisms are not present.

The supervisors are responsible for laboratory safety, which includes providing SOPs; ensuring that employees have read and signed the SOPs; ensuring all employees are medically cleared and well trained for work with microorganisms; providing appropriate PPE

for personnel; and ensuring work areas are secure from unauthorized personnel. The supervisor has to report all incidents/accidents to the Chief of Safety/Surety/Security Office within 1 hour of the event. The laboratory supervisor is also responsible for assessing risks and for appropriately applying the recommended BSLs (ERDEC-SP-058). The laboratory supervisor will request an assessment by the ECBC Biosafety Committee should an organism not have a recommended BSL per CDC/NIH guidelines.

Other responsibilities for biological work safety are delegated to the ECBC Risk Reduction Office (RRO) and the Kirk U.S. Army Health Clinic (KUSAHC). The ECBC RRO assists supervisors in developing engineering controls and appropriate laboratory practices for the operations; conducts, at a minimum, annual inspections of the work areas; investigates accidents/incidents and recommends corrective action to reduce reoccurrence; and provides appropriate training and information programs for safe handling of biological specimens. The RRO also provides technical guidance associated with biohazard classification, engineering, administrative and work practice controls, and the selection of PPE and protective clothing. The KUSAHC is required at times to medically clear personnel to handle microorganisms and treat injuries, if necessary, according to AR 40-5.

ECBC SOP CR8-7NP014, *Growth and Processing of Simulant Bacteria*, sets forth responsibilities and policy for the preparation of small quantities of simulant bacteria for research purposes using the following BSL-1 microorganisms: *Bacillus subtilis var. niger*; *Bacillus thuringiensis*; MS-2 bacteria phage; and *Ochrobactrum anthropi*. This process must be conducted in a BSC, and the microorganisms must be manipulated according to biosafety guidelines and regulations discussed in Section 2.3.5.1. Details of PPE, documentation, ventilation requirements, first aid/emergency equipment, decontamination, and general information on equipment, compressed gases, flammable liquids, and preoperational settings are included in this SOP.

- *Chemical Safety*

The ECBC CHP sets forth policies, procedures, and responsibilities for handling hazardous chemicals in the laboratory, including military-unique chemical agents or acutely toxic materials. Specific duties are assigned to the Chemical Hygiene Office (CHO), the RRO, and the Environmental Quality Office (EQO), as well as to laboratory supervisors and personnel. The CHO reviews the CHP on an annual basis and revises the document to reflect current regulatory practice; develops and implements guidance for handling hazardous chemicals in the laboratory; and conducts preoperational surveys of all new laboratory operations using hazardous chemicals in conjunction with the RRO and the EQO. The RRO and EQO review SOPs for all laboratory operations using hazardous chemicals and review construction and renovation plans and specifications to ensure appropriate design criteria are incorporated. Hood certification and approval procedures for hood performance are conducted by the RRO. The CHO ensures that supervisors are familiar with the CHP. The RRO conducts laboratory inspections periodically, investigates all reported hazardous chemical accidents, and coordinates participation in a hazard analysis of each new operation. The EQO provides guidance on handling and disposal of hazardous waste, as well as assistance visits to laboratories where hazardous waste is generated or stored.

The CHP requires administrative and work practice controls for ECBC facilities, including identification and warning signs and labels; handling and storage of chemicals and glassware; work and care within chemical hoods; and care and use of PPE. Details on disposal of chemical waste; cleaning up chemical spills; and special procedures for handling acutely toxic compounds, carcinogens, and reproductive hazards are also provided in the CHP.

The procedures in the CHP include chemical handling (storage, inspections, labeling, and inventories for each room), as well as specific procedures for flammable and combustible liquids, water-reactive chemicals, shock-sensitive chemicals, toxic chemicals (including acutely toxic gases), and compressed gases. Design and performance criteria of chemical hoods, glove boxes, gas cabinets, filtration and vacuum systems, and maintenance of glove boxes are included in the CHP.

In addition to the benchmark guidelines and regulations discussed in Section 2.3.5.2, safety considerations for CSM are addressed in ECBC-SP-007, *Chemical Agent Accountability Program of the U.S. Army ECBC,* October 1999. Another SOP, CR4-1SP026-97K, *Small Quantity Agent Operations in the Chemical Transfer Facility*, provides procedures for small-quantity operations (less than 4 liters [about 1 gallon]) specific for the CTF; agent transfers; ampoule sealing; preparing agent demilitarization solutions; and related work to be done in laboratory hoods at the CTF. This SOP also provides procedures for mixing and the chemical reactions of specific chemical agents and discusses the hazards involved with these procedures, safety requirements, preoperational procedures, and replacement of the reactor and parts.

Responsibilities for implementation of occupational health and safety procedures are provided in ERDEC-SP-058, Appendix O. The supervisors must ensure that all personnel are registered in the occupational health program and have received the Hazardous Waste Operations and Emergency Response training required under OSHA regulations (29 CFR 1910.120). Supervisors also must inform personnel of their rights under the OSHA Hazard Communication Standard (29 CFR 1910.1200) and must instruct personnel in the proper use of the appropriate MSDS for a laboratory operation. Appropriate SOPs, manuals, permits, and other documentation must be made available at the site of the laboratory operation by the supervisor. Prior to the start of any operation, the supervisor ensures that adequate medical support is arranged at the Edgewood Clinic and the KUSAHC. The operator must report any violations of operating procedures and/or conditions that could adversely affect health and safety.

Work with small quantities of chemical agents must be performed in a certified hood or within a certified glove box. Ventilation safety requirements specified in Appendix D of ERDEC-SP-058 require that all laboratory hoods must be approved prior to the start of any operation. A valid hood verification sticker should be found on the hood. A flow rate check of the laboratory hoods must be conducted prior to the start of an operation. If the results differ by more than 20% of the average face velocity noted on the hood certification sticker, operations must not commence; the ECBC RRO must be immediately notified for hood recertification.

Specific ventilation requirements are detailed in AR/DA PAM 385-61. Facility ventilation provides a suitable negative pressure between the static storage cubicles and the other areas of the building. A CBR filter system draws in ventilation exhaust prior to discharging it to the outside atmosphere. In case of filter failure or blockage, each facility is equipped with a forced-air backup system and an emergency generator under power failure conditions. Each facility monitors the negative pressure between agent storage and operating areas and nonagent areas quantitatively with hydrostatic gauges that are equipped with warning lights and audible alarms.

All operations that may generate air contaminants at or above the exposure limit are conducted in laboratory hoods following safety procedures according to AR/DA PAM 385-61. Operations must halt if the hood alarm indicates air flow below the acceptable level until this level is reestablished. All apparatus and containers must be kept at least 20 centimeters (approximately 8 inches) behind the hood face. Personnel must not place their heads inside the hood to perform work. Hazardous waste, even if decontaminated, must not be kept in hoods over a long period of time. The hood sash must be kept at a level indicated on the approval sticker during operations. Foot traffic past the open face of the hood should be minimized. The slot in front of the lower hood baffle must be kept free of obstructions. The laboratory doors must be closed during operations that require use of a hood.

Glove boxes are to be approved by the RRO prior to the initiation of an operation. A negative pressure of at least 0.6 centimeters (0.25 inches) of water must be maintained below that of the surrounding area. Make-up air should be allowed into the glove box to prevent a buildup of toxic chemical concentrations, and filters and backflow dampers should be used to protect the make-up air sources. An inward airflow of at least 27.4 linear meters (90 linear feet) per minute must be maintained in the glove box during temporary openings if any toxic chemical is contained in it or if the glove box is contaminated with a toxic chemical. A leak test is required prior to conducting pressurized operations with toxic materials in a glove box.

For monitoring of chemical agents and toxic materials, a detection capability with a sensitivity of equal to or better than the Immediately Dangerous to Health Level must be maintained, either within or immediately outside the laboratory (ERDEC-SP-058).

AR/DA PAM 385-61 provides information on appropriate PPE, respiratory protection, and protective clothing for work with chemical agents, as well as monitoring requirements. These regulations apply for entering storage rooms with chemical agents, removal of reactors and parts from a glove box, transfer of solutions from the reactor to storage drums, drum sampling, hood operations, transporting CSM from a storage cubicle to a laboratory, and handling a chemical agent or primary agent containers. Used containers are resealed, decontaminated, and overpacked. Agent containers are decontaminated, tested for residual agent until a negative result is obtained, and double packed for storage and shipment. The work areas are then decontaminated. ECBC SOPs provide specific details on hermetically sealing glass ampoules with a chemical agent, preparing RDT&E dilute solutions in the hood, and preparing decontamination solutions.

- *Radiological Safety*

  AR 385-11, *Ionizing Radiation Protection,* includes general requirements for radiation safety. This regulation covers monitoring and dosimetry, general precautions, protective clothing and equipment, responsibilities, and contaminant action levels.

2.4.1.3.b *Occupational Health*

In addition to general laboratory safety guidelines, the ECBC CHP provides occupational health and safety procedures for work with hazardous chemicals, including guidelines associated with medical surveillance, air monitoring, first aid, personal hygiene, protective clothing, training, emergencies, and housekeeping (SBCCOM 2002b). KUSAHC provides preventive medicine services in accordance with the established *Interservice Support Agreement*, AR 40-5; DA PAM 40-8, *Occupational Health Guidelines for the Evaluation and Control of Occupational Exposure to Nerve Agents GA, GB, GD, and VX*; DA PAM 40-173, *Occupational Health Guidelines for the Evaluation and Control of Occupational Exposure to Mustard Agents H, HD, and HT*; and APG Regulation 385-4. All government and contractor personnel conducting laboratory work for CBDP RDT&E activities participate in the Medical Surveillance Program (ECBC 2001b).

In accordance with the benchmark regulations noted in Section 2.3.5.4, AR 385-69 and the CHP, ECBC coordinates emergency preparedness with the USAG, which in turn coordinates with local emergency service providers and maintains formalized agreements describing the details of emergency support. ECBC depends on the APG Fire Department for emergency services including fire, emergency medical service, and HAZMATs response. Emergency response procedures are conducted in accordance with the APG Disaster Control Plan (SBCCOM 2002b).

APG's Biological Accident or Incident Response and Assistance (BAIRA) Plan, dated 28 October 1996, and the CAIRA Plan, dated 7 March 2002, provide SOPs to implement in case of a biological or chemical accident or incident or other types of emergencies. These SOPs identify points of contact, response actions, evacuation routes, and notification requirements. All accident/incident/mishap reporting at ECBC is in accordance with the benchmark guidelines and regulations noted in Section 2.3.5.4, as well as the CHP.

There have been no laboratory-acquired illnesses (LAIs) from CBDP-related activities conducted by ECBC within the years 1995 through 2001. Only two accidents related to work with biological or chemical materials have occurred during the performance of ECBC CBDP-related activities. During 1999, a chemical accident was reported when waste containing a trace amount of CSM leaked from a metal can enclosed in a plastic bag onto a laboratory floor. None of the personnel reported symptoms of exposure. According to safety protocol, a report of findings was prepared and a corrective action was issued. A chemical accident was reported in 2000 when an alarm from a miniature chemical-agent monitoring system located outside the glove box of the CTF sounded. The concentration of the airborne chemical was measured to be above its exposure limit. No personnel were working near this location, and personnel elsewhere in the building did not show symptoms of exposure (SBCCOM 2002b).

Safety inspections at ECBC are conducted in accordance with AR 385-61 and AR 385-69. The CHP establishes responsibility for the RRO to conduct laboratory inspections periodically and to investigate all reported chemical accidents.

The U.S. Army ECBC, EQO, has established the Army Programs Internal Operating Procedure (IOP) for Environmental Compliance Inspections (IOP 1-98), specifically for ECBC. This IOP outlines policy, procedures, and responsibility for building inspections and requires that all ERDEC facilities be inspected at least annually. Environmental Compliance Inspections (ECIs) must be performed by qualified environmental professionals or EQO personnel approved by the Environmental Compliance Officer (ECO), following ECI procedures and using ECO-approved inspection checklists and inspection schedules. An ECI may be conducted within the same day of notification of inspection to determine actual operating conditions and practices. The scope of the ECI includes questioning supervisors and other personnel about chemical spill containment and reporting, safe handling of chemical and/or waste handling practices, and storage facility procedure requirements; comparison of personnel training records with the training requirements; and inventory lists in each room where HAZMATs or chemical waste are generated or stored. The ECO and the immediate supervisor or activity head are immediately notified of imminent hazard/danger situations. Copies of the findings and recommended corrective actions are provided to the directorate environmental coordinator and site manager, and follow-up inspections are conducted for noncompliant practices.

2.4.1.3.c <u>*Security*</u>

APG has implemented regulatory safeguards for the physical protection of private and government property and the security interests of the government according to APGR 190-6, *Military Police, Physical Security Program*, 24 June 1993. Entry, exit, and internal control of personnel, material, and vehicles on APG are in accordance with APGR 190-4, *Military Police, Movement Control within the Installation*. Since 11 September 2001, hunting and trapping have been prohibited on APG grounds.

All visitors require an escort while on ECBC grounds. Personnel at ECBC are required to wear photo identification card necklaces into most facilities. Some facilities allow only restricted staff. Additional security measures include requiring personnel and visitors to sign in and pass through a gate to gain access to a building.

Security concerns regarding chemical agents and personnel who work directly with them or work in the laboratory with them are discussed in AR 190-59. ECBC-SP-007, *Chemical Accountability Program of the U.S. Army Edgewood Chemical Biological Center*, sets forth policies, procedures, and responsibilities for conducting physical inventories and maintaining consumption, transfer, and destruction records and reports for chemical agents in accordance with AR 50-6. A stock record card is prepared every time a chemical agent is used during laboratory operations.

2.4.2 U.S. Army Medical Research Institute of Chemical Defense

USAMRICD is located within the Edgewood Area of APG in Harford County, Maryland. Information about the Edgewood Area of APG, including details of the existing environment, is presented in Section 4.2. This section discusses CBDP activities and mitigation measures at USAMRICD as a basis for the environmental impact analysis presented in Sections 5.2 through 5.14.

USAMRICD is a subordinate activity of the U.S. Army Medical Research and Materiel Command (USAMRMC). Its mission is to preserve combat effectiveness by timely provision of medical countermeasures in response to Joint Service Chemical Warfare Defense Requirements. USAMRICD is the principal DoD research site for medical chemical defense (USAMRICD 2001a). Medical Systems is the principal commodity area for USAMRICD, with goals of developing medical materiel to provide effective medical defense against CB agent threats facing U.S. forces on the battlefield (ODASD 2000). The mission of USAMRICD also includes research on pharmacological countermeasures for biological warfare agents (USAMRDC 1992).

USAMRICD RDT&E activities occur in three buildings on the Edgewood Area of APG containing laboratories, HAZMATs storage, general storage, and administrative offices. There are 110 laboratories in these buildings with 855.3 square meters (9,206 square feet) of BSL-1 and BSL-2 laboratory space; 5,628 square meters (60,578 square feet) of general chemistry laboratories conducting work with CSM; and 7,661.2 square meters (82,465 square feet) of general laboratories conducting work with hazardous industrial chemicals (USAMRICD 2001b). Other APG facilities associated with USAMRICD include 10 buildings that house administrative, support, and training activities (USAMRDC 1992).

2.4.2.1 Research, Development, Test, and Evaluation Activities

The Medical Systems chemical defense research conducted at USAMRICD includes the development of chemical countermeasures such as antidote therapy, topical skin protectant barriers, reactive topical skin protectants, and pretreatment measures, as well as development of treatment regimes that reverse or reduce the toxicity of chemical agents for improved management of casualties. In addition, fundamental and applied research is performed on the biochemistry, pathology, pharmacology, physiology, and toxicology of chemical warfare agents and their medical countermeasures. Development of medical countermeasures includes subjecting the candidate pretreatment, treatment, protectant, or decontaminant to an extensive drug screening program, which includes a systematic battery of tests designed to promote to advanced development those drugs that are the safest and most effective (USAMRICD 2001a).

2.4.2.1.a Chemical Surety Materiel

CSM is a known issue for USAMRICD CBDP-related RDT&E activities. As of 2001, CSM used at USAMRICD included several blister agents (vesicants), several nerve agents, and several toxic industrial chemicals (USAMRICD 2001a). Only small quantities of CSM are used in CBDP-related activities at USAMRICD. The total inventory of neat chemical agent on USAMRICD premises was 92 milliliters (mL), approximately 3 fluid ounces, as of March 2002

(Casole 2002a). This does not include exempt CSM—solutions of chemical agents that have been diluted sufficiently to be handled as non-CSM hazardous substances.

2.4.2.1.b *High-Hazard Biological Agents*

Highly hazardous biological materials are not used in CBDP-related activities at USAMRICD. Only biological toxins are used for CBDP research on pharmacological countermeasures.

2.4.2.1.c *Aerosol Testing*

No aerosol testing is conducted during CBDP-related activities at USAMRICD (Casole 2002b).

2.4.2.1.d *Animal Care and Use*

Care and maintenance of laboratory animals at USAMRICD are performed in accordance with the benchmark guidelines and regulations described in Section 2.3.1. USAMRICD animal facilities and animal care and use programs were inspected by AAALAC International in 2001, which resulted in continued full accreditation (Casole 2002a).

The Veterinary Medicine and Laboratory Resources Division (VMLRD) provides laboratory research support, animal care, postgraduate training in laboratory animal medicine, review of experimental animal research protocols, and consultation in matters regarding the care and use of animals. The VMLRD directs the Laboratory Animal Care and Use Committee (LACUC) (USAMRICD 2001a).

USAMRICD uses only the minimum number of animals required to obtain statistically valid experimental results and the animal species most appropriate to the experimental objective. According to USAMRICD Memorandum 70-9, *Research, Development, and Acquisition Research Protocols*, all proposed USAMRICD research or USAMRICD-sponsored research requiring the use of laboratory animals must have descriptions of the protocols or pilot protocols for the research to be conducted. The LACUC reviews the justification for the use of animals. The Branch Chief, Division Chief, Chief of Research Operations Division, the Chairman of the LACUC, and the Commander of USAMRICD review and approve the research protocols (USAMRDC 1992).

USAMRICD obtains small animals from Charles River Laboratories. Large animals are obtained from Archer Farms. The 2001 animal census for USAMRICD included 891 mice; 49 monkeys; 33 rabbits; 667 rats; 4,200 guinea pigs; and 106 pigs (Casole 2002a).

2.4.2.1.e *Vaccine Development*

Vaccine development activities are not conducted at USAMRICD (Casole 2002b).

2.4.2.1.f *Genetically Engineered Microorganisms*

GEMs are not used during CBDP-related activities at USAMRICD (USAMRICD 2001b).

2.4.2.1.g *Human Subjects*

The CBDP-related testing activities at USAMRICD do not involve human subjects (Casole 2002b).

2.4.2.1.h *Radiological Testing*

USAMRICD research using several radionuclides is conducted under NRC License No. BML 19-00294-24, which expires on 31 March 2011 (Casole 2002a). The provisions of the license state that USAMRICD cannot use radioactive materials in applications potentially resulting in the release of radioactivity exceeding the limits set in 10 CFR 20.1301(a), *Standards for Radiation Protection*. The dose rate to any individual cannot exceed 0.002 rem[3] in any one hour, and the total effective dose per year must be less than 0.1 rem (Casole 2002b).

2.4.2.1.i *Open-Air Laser Testing*

Open-air laser testing is not conducted at USAMRICD (USAMRICD 2001b).

2.4.2.1.j *Support Work*

CBDP support work at USAMRICD is conducted in accordance with USAMRICD SOPs 87-335-RS-GP, *General Provisions of CSM*, and 91-077-RS-02, *General Provisions for the Biosafety Program and Operations*, 5 April 2000, and USAMRICD Memorandum 385-4, *Safety, Chemical Hygiene Plan*. These documents provide procedures for care, use, and/or decontamination of laboratory tools, such as glassware, plasticware, sharps, and nonhazardous chemicals and reagents used to support CBDP-related work.

2.4.2.2 Operations, Maintenance, and Waste Management Activities

The DPW of APG is responsible for providing utility services and assisting with environmental and energy consumption aspects of operations. Structural repairs and maintenance of buildings are performed on an as-needed basis (Casole 2002a).

2.4.2.2.a *Operations*

The potable water supply and distribution system at the Edgewood Area is owned by APG and operated by DPW. Its water source is the Van Bibber impoundment of Winter's Run, which is located 3.2 kilometers (2 miles) north of the Edgewood Area of APG (USACOE 2000a). Further information on the WTP appears in Section 4.2.9.1. In times of drought, additional water supply is acquired from a Harford County WTP located in Abington, Maryland, 4.8 kilometers (3 miles) north of the Edgewood Area. During calendar year 2001, the Edgewood Area of APG consumed approximately 1.44 million liters (381,077,000 gallons) of water. Of this, approximately

[3] rem = roentgen equivalent man—A unit of dose equivalent. The dose equivalent in rem equals the absorbed dose in rad (see Section 2.3.5.3) in tissue multiplied by the appropriate quality factor and possibly other modifying factors. Derived from "roentgen equivalent man," referring to the dosage of ionizing radiation that will cause the same biological effect as 1 roentgen of x-ray or gamma-ray exposure. One rem equals 0.01 sievert. A roentgen is a unit of exposure to ionizing x or gamma radiation equal to or producing one electrostatic unit of charge per cubic centimeter of air, approximately equal to 1 rad.

546,551,194 liters (144,384,000 gallons) had to be acquired from Harford County from late August to December due to severe drought conditions (Gentry 2002).

The average water requirement for CBDP-related activities at USAMRICD is estimated to be 12,113 liters (3,200 gallons) per day, with a peak water requirement of 13,627 liters (3,600 gallons) per day, assuming that all CBDP laboratories are functioning on a given day (Casole 2002c). Water usage of the individual buildings on the installation is not metered (USAMRICD 2001b, Wiggins 2002). Some laboratories have water-cooled instrumentation, in addition to the routine use of water in a working laboratory facility (Casole 2002c).

The Edgewood Area of APG consumed 95,687,781 kWh during fiscal year 2001 from the BGEC through an electrical substation in the Edgewood Area. The instantaneous peak electrical demand was 20,000 kilowatts (Testerman 2002a, USACOE 2000a). The electricity requirements of USAMRICD CBDP-related activities are estimated to average 2,000 to 4,000 kilowatts, with a peak requirement of 4,500 kilowatts (USAMRICD 2001b, Flynn 2002). Electrical usage of individual USAMRICD buildings in the Edgewood Area is not metered (Testerman 2002b).

The Edgewood Area does not receive natural gas service. Its central heating system uses high-pressure steam purchased from the Harford County WEP (USACOE 2000a). The steam is also used for cooling and sterilization. The WEP generates 226.8 million kilograms (500 million pounds) of steam per year (Poulton 2002). APG purchases steam from the WEP throughout the year. This accounts for approximately 90% of the steam generated by the WEP during the winter and 75% to 85% of the steam during the summer (Bradley 2002).

Fuels supplied to the Edgewood Area of APG during calendar year 2001 included 1,684,318 liters (444,951 gallons) of gasoline; 1,033,444 liters (273,008 gallons) of diesel fuel; and 13,488,497 liters (3,563,295 gallons) of heating oil (Baldwin 2002).

2.4.2.2.b <u>*Maintenance*</u>

DPW of APG is responsible for providing maintenance, repair operations, and management of facilities; professional engineering and architectural design for modification and construction of facilities; engineering management services of the installation and supported activities; and housing operations and management. DPW is also responsible for directing and coordinating the development and implementation of peacetime and emergency master plans and utilizing real estate and real property facilities (APG DPW 2002). Janitorial maintenance occurs on a daily basis. DPW provides facility repairs and maintenance on an as-needed basis or by work order request (Casole 2002a).

2.4.2.2.c <u>*Waste Management*</u>

- *Air Emissions*

  The State of Maryland has adopted the NAAQS and incorporated them into COMAR 26.11.04, *Ambient Air Quality Standards* (MDE 2002a). Any federal actions producing emissions of O_3 or its precursors at the Edgewood Area must not cause or contribute to any new violation of the air quality standard or delay the timely attainment of any air quality

standard since Harford County has been designated as a nonattainment area for ozone (MDE 2002b).

The air quality program at APG is in accordance with the benchmark federal and DoD regulations enumerated in Section 2.3.4.1 and APGR 200-30, which prescribes policies, assigns responsibilities, and establishes procedures for the control of air emissions generated by all activities, tenants, commands, organizations, and personnel within the boundaries of the installation. The DSHE's ECD EEB is responsible for the air quality program at APG (USACOE 2000a).

The MDE ARMA is the primary air quality regulatory authority in the state. The Edgewood Area of APG holds MDE ARMA Title V Operating Permit No. 24-025-00082, issued under the CAA (USACOE 2000a). The permit, which expires on 31 October 2004, includes four boilers between 10 to 100 million Btu per hour and miscellaneous other equipment. The MDE ARMA also issued Permit No. 12-0082 to the USAG covering air emissions from RDT&E activities. The air emission inventory for this permit is provided in the calendar year 2000 *Air Toxics Emission Certification Report*.

MDE has implemented regulations (COMAR 26.11.13) governing acceptable ambient levels for approximately 600 TAPs (Advanced Sciences, Inc. 1990). As of 2000, approximately 131 TAPs are emitted at the Edgewood Area, 39 of which exceed the screening levels established by MDE as maximum threshold levels to which the surrounding population may be exposed without unreasonable acute or chronic health risks (COMAR 26.11.15 and 10.18.02.02.03). An air quality modeling study conducted by the State of Maryland indicated that the emissions of TAPs from the Edgewood Area would have minor or negligible ambient impacts and would not endanger human health (USACOE 2000a).

Air emissions from USAMRICD laboratories are vented to the atmosphere through HEPA filters and carbon filters that remove more than 99.9% of PM and organic vapors prior to discharging to the atmosphere (Casole 2002b).

Emissions of "greenhouse gases," including CO_2, methane, nitrous oxide, CFCs, halons, and tropospheric ozone, were evaluated for the entire APG installation. CO_2 serves as a surrogate for greenhouse gases on the basis of all fuels purchased and consumed at APG. The approximately 114,305 metric tons (126,000 tons) of CO_2 emitted annually from APG accounts for less than 0.1% of man-made emissions from the Maryland/Washington, D.C., area. APG is also in the process of eliminating use of CFCs and halons, which have been addressed in Title VI of the CAA Amendments as chemicals that deplete stratospheric ozone (USACOE 2000a).

There have been no complaints regarding odors at the USAMRICD facilities conducting CBDP-related activities (Casole 2002d).

- *Solid Waste*

USAMRICD generates an estimated 896 kilograms (1,976 pounds) of solid waste per year from CBDP-related activities (USAMRICD 2001b). Solid waste and recycling at APG are handled by the ECD, EEB, of the DSHE within APG's USAG.

Collection, storage, processing, and disposal of solid waste at APG are conducted in accordance with the benchmark regulations and guidelines discussed in Section 2.3.4.2. An integrated Solid Waste Management Program is maintained in accordance with APGR 200-50, which incorporates the applicable federal, state, local, and Army environmental regulations for the management of nonhazardous solid waste encompassing source reduction, resource recovery and reuse, recycling, and disposal (USACOE 2000a).

DPW contracts with haulers to collect nonhazardous solid waste for disposal at the Harford County WEP (USACOE 2000a). The WEP is an incinerator for municipal solid waste located on leased land in the southern part of the Edgewood Area of APG. Approximately 90% of Harford County's waste is disposed of at the WEP, in addition to the nonhazardous waste from APG (Bradley 2002). The WEP operates under Refuse Disposal Permit No. 2000-WIN-0100 and Air Permit No. 12-00212 issued by MDE (Harford County 1996, Poulton 2002).

- *Wastewater*

All of the buildings on the Edgewood Area of APG discharge sanitary wastewater into a CSSS for treatment at a WWTP located on the Edgewood Area and operated by APG. Individual building discharges to the CSSS are not measured. The Edgewood Area WWTP treats an average of 3,028,320 liters (800,000 gallons) per day as of 2000 and has a capacity for 7.57 million liters (2.0 millon gallons) per day (USACOE 2000a). It discharges treated wastewater into the Bush River under NPDES Permit No. MD0021229 and State Discharge Permit No. 90-DP-2531 issued by MDE. These permits will expire on 30 June 2003 (MDE 1998, USACOE 2000a).

Four USAMRICD buildings discharge allowable untreated laboratory wastewater into the CSSS (Casole 2002b). Laboratories that do not discharge wastewater into the CSSS contain and dispose of their liquid waste as hazardous or nonhazardous waste by the APG Hazardous Waste Contractor in accordance with APGR 200-60 (Casole 2002b).

APGR 200-41, *Water Quality, Wastewater Discharge Management*, and the NPDES permit require that logs be maintained for permitted laboratory wastewater discharges to the CSSS. The logs must be submitted twice a year to the ECD of APG's USAG. APGR 200-41 further requires that daily laboratory discharges into the CSSS must not exceed the following in each individual laboratory: 4 liters (approximately 1.05 gallons) with a maximum concentration of 500 mg/L of metals (antimony, beryllium, copper, nickel, thallium, and zinc); 4 liters of other inorganic materials; and 4 liters with a maximum concentration of 500 mg/L of pesticides. Allowable laboratory wastewater discharges containing organic materials are determined on a case-by-case basis by the ECD (Casole 2002b).

- *Hazardous Waste*

Each APG activity has developed and implemented a Hazardous Materials Management Plan in accordance with the guidelines and regulations noted in Section 2.3.4.4 and State of Maryland regulations COMAR 26.13.01 to 26.13.13. The HWM Branch of DSHE within APG's USAG oversees the management of hazardous waste at APG using an electronic tracking system (USACOE 2000a). USAG of APG is responsible for the disposal of all hazardous waste at APG (USAMRICD 2001b).

USAG was issued RCRA Permit No. A-190 by MDE. The permit expired on 14 May 1998, but MDE has allowed an extension, pending action on the USAG application for permit renewal (Mann 2002b).

Hazardous waste must be quantified and characterized chemically for proper disposal. DSHE Activity Environmental Coordinators review and approve this information before the waste can be moved to a 90-day RCRA storage site. SASs are utilized for small quantities of hazardous waste generated in their vicinity. The installation Environmental Coordinator reviews the records and approves the shipment to a permitted off-site commercial TSDF. APG customarily ships RCRA waste directly from the SASs and/or 90-day storage sites.

USAMRICD generates approximately 2,307 kilograms (5,086 pounds) of hazardous waste from CBDP-related activities per year as of 2000 (USAMRICD 2001b). This consists of spent organic solvents, waste formaldehyde, solutions containing acetonitrile, waste photographic fixative, flammable liquids, mercury, grease, and oil. USAMRICD follows APGR 200-60 guidance for management of liquid hazardous waste (Casole 2002b). Other regulations and guidance that discuss hazardous waste management include USAMRICD Memorandum 385-4, *Safety, Chemical Hygiene Plan*; USAMRICD SOP 87-335-VA-12, *Disposal of Decontaminated/Detoxified Chemical Agent Waste*; and USAMRICD SOP 87-335-RS-GP, *General Provisions for Chemical Surety*.

USAMRICD requires that its hazardous waste generators store hazardous waste in an approved SAS with safety features for spill containment, located outside one of the laboratory buildings. The hazardous waste must have proper documentation prior to its removal by APG's USAG to one of the installation-wide receiving points. It is the responsibility of USAG to hire the hazardous waste disposal contractor (USAMRICD 1991, 2001a).

Waste toxic gases must either remain in an unused form or be neutralized or decontaminated, as directed by the senior officer or supervisor according to USAMRICD SOP 91-317-YY-08, *Exposures of Cell Cultures to Edemagenic Gases*. According to this SOP, charcoal (HEPA) filter units from systems venting toxic gases are to be double bagged and disposed of as hazardous waste. USAMRICD SOP 91-203-YY-06, *Exposures to Pulmonary Toxicants*, requires that empty cylinders used in association with toxic gases must be returned to the Logistics Branch for disposal as a hazardous waste (USAMRICD 1991, Casole 2002b).

Chemical surety waste is disposed of in accordance with the benchmark regulations discussed in Sections 2.3.4.4 and 2.3.5.2 and DA PAM 385-61. USAMRICD SOP 87-335-RS-GP specifies procedures for collection, decontamination, and disposal of chemical surety waste, including excess CSM, solutions containing CSM, spent decontaminant used on CSM or CSM-contaminated items, all solid items contaminated with CSM, or contaminated solutions created as a result of CSM use, degradation, or an accident.

Contaminated surety liquid and 3X decontaminating solutions must be disposed of as hazardous waste, as noted above under the wastewater discussion. All hood sinks are sealed to prevent possible release of CSM into the CSSS. Decontaminated liquid CSM waste is stored in chemical-resistant containers; it must never be released into the lab sinks or floor drains in the designated Exclusion Area for CSM. Solid CSM waste is placed in chemical-resistant containers with adequate decontaminant to submerge all solids; the spent liquid decontaminant is transferred into a liquid CSM waste carboy prior to turning in the decontaminated solid waste for collection and disposal. Laboratory equipment, tools, or glassware contaminated with CSM must be permanently marked, then decontaminated, and double bagged prior to removal from the laboratory hood. This CSM waste must be containerized, properly documented, and logged into APG's hazardous waste tracking system. The USAG-contracted disposal company can then pick up the CSM waste for off-site disposal (Casole 2002e).

Radioactively labeled CSM waste is collected separately from other CSM waste, decontaminated, and disposed of in accordance with USAMRICD SOP 87-335-RS-GP.

- *Medical and Infectious Waste*

The handling, transport, and disposal of medical waste at APG is in accordance with the benchmark regulations and guidelines discussed in Section 2.3.4.5 and MEDCOM Regulation 40-35. This MEDCOM regulation applies to waste that is potentially infectious for humans and may pose a risk to individuals or to community health if not handled or disposed of properly. The *APG Special Medical Waste Management* D*ocument,* DSHE APG, June 2001, provides guidance regarding disposal of excess and waste pharmaceuticals and other waste items generated in APG's microbiological, toxicological, and animal research activities that warrant special management under the COMAR regulations.

State of Maryland regulations (COMAR 26.13.11-13, 26.13.02.02A, 26.13.01, and 10.06.06) for SMW are administered by MDE, Health and Mental Hygiene. SMW is defined in COMAR 26.13.11.02 as a solid waste composed of anatomical material, blood, blood-soiled articles, contaminated materials, microbiological laboratory waste, or sharps. Contaminated materials include feces of an individual diagnosed as having a disease that may be transmitted to other humans through the feces; or articles soiled with such feces; or articles that came into contact with a known infectious agent.

Prior to the collection for disposal, all organisms, toxins, microbiological waste, and materials used in activities of BSL-2 and higher must be deactivated by autoclaving. This is in accordance with the benchmark guideline (CDC/NIH 1999). Autoclaved materials are not

classified as SMW under COMAR 26.13.11.03E and may be disposed of as general solid waste, provided that packaging, labeling, and treatment are in compliance with COMAR 26.13.12.05.

USAMRICD 91-077-RS-02 provides the procedures for the decontamination and disposal of solid, liquid, animal, and radiological waste contaminated with or potentially contaminated with biological materials. This waste, if not autoclaved, undergoes decontamination using commercial liquid bleach or stock solution containing 2.5% sodium hypochlorite and 0.25 Normal (approximately 1%) sodium hydroxide. Biologically contaminated solid waste is treated by soaking 4 to 16 hours in decontaminant; it is then placed in a plastic-lined biohazard box. Biologically contaminated liquid waste is treated with decontaminant 4 to 16 hours; it is then neutralized, solidified, double bagged, sealed, and labeled as Biological Waste. Biologically contaminated animal bedding and waste is wetted down with decontaminating solution, solidified by adding clean bedding, placed in a leak-proof plastic-lined paper bag, sealed, and labeled as Biological Waste. It requires cold storage and may be overpacked for off-site disposal by a licensed medical waste hauler. The biohazard boxes and bags are stored in a designated waste storage area pending collection for disposal.

Animal cage racks used in the laboratory are washed, dipped, or wiped with a 1:10 dilution of the stock decontaminant solution. The racks are then set aside overnight before rinsing and delivery to the cage wash area for cleaning. Leftover rinse water will be disposed of as decontaminated liquid waste.

The annual quantities of SMW generated from USAMRICD CBDP-related activities are estimated at 112,311 kilograms (247,600 pounds) of animal waste and 1,134 kilograms (2,500 pounds) of sharps (USAMRICD 2001b).

DSHE manages a contract with Stericycle of Baltimore, Maryland, which provides medical waste disposal services for USAMRICD by incineration or autoclaving at a permitted facility (USACOE 2000a). Previously, a medical waste incinerator located on the Edgewood Area of APG was used for this, but it has been shut down since 1993.

- *Radiological Waste*

As of 2001, USAMRICD generates approximately 189 liters (50 gallons) of radioactive waste per year during CBDP-related activities (USAMRICD 2001b).

During work with unsealed radionuclides, individual containers, appropriately labeled with warnings of radioactivity, must be provided in each room for radioactive waste characterized as aqueous liquids, nonaqueous liquids, or solid material. All radiological waste is packaged in accordance with OSC and applicable state and disposal contractor facility requirements, as well as the benchmark regulations discussed in Section 2.3.4.6. A mandatory yellow radioactive waste tag marked with isotope, activity in millicuries, quantities, and date information must be attached to the containers prior to collection. Nonexpendable items must be decontaminated after exposure to radiation sources, if required. According to

USAMRICD Memorandum 385-2, *Safety Radiation Protection*, users of radioactive materials must maintain records of materials disposed of as radioactive waste.

Any radioactive waste contaminated or potentially contaminated with a biological agent must have the biological agent deactivated first, using the appropriate decontamination procedure, as discussed for medical waste. The radioactive waste can then be treated as discussed above. Animal carcasses exposed to radioactive materials must be sealed in plastic bags, properly labeled, and frozen until the radioactive waste disposal contractor collects it, unless the carcasses meet NRC requirements for exemption.

According to SOP 90-282-RS-04, *Radioactive Materials Safety*, dated 1 May 2001, commercial carriers collect and transport all radiological waste from APG to a contracted facility in Rock Island, Illinois, for incineration (USAMRICD 2001b). OSC contractors also pack, check, and inventory the waste on site. OSC acts as the contract manager between USAMRICD and OSC-approved disposal facilities for radiological waste.

2.4.2.3 Safety, Health, and Security Mitigation

USAMRICD activities are conducted in accordance with the benchmark federal laws, DoD and DA regulations, and guidelines discussed in Section 2.3.5. USAMRICD safety policies and procedures also incorporate applicable state and local regulations and accepted general, CB, and radiological safety practices.

All operations at USAMRICD involving potentially HAZMATs, including chemicals, chemical agents, radioisotopes, and biological agents, must have SOPs prepared in accordance with USAMRICD Memorandum 385-1, *Occupational Safety and Health Program*. The Safety and Chemical Operations Branch (SCOB) reviews SOPs initially based on their Job Hazard Analysis of the operation. SOPs must be reviewed and signed by all employees upon initial assignment to perform the specific operations or procedures. SOPs are reviewed on an annual basis, and employees are required to sign them annually. All relevant SOPs must be posted in each work area.

2.4.2.3.a *Safety*

- *Biological Safety*

USAMRICD activities under the CBDP conform to the benchmark regulations and guidelines for biological safety listed in Section 2.3.5.1. In addition, USAMRICD SOP 91-077-RS-02 establishes the safety policy, responsibilities, and procedures for biological defense RDT&E operations at USAMRICD. This SOP provides additional information on standard microbiological laboratory practices, special work practices, PPE requirements, labeling and posting of hazards, decontamination procedures, emergency preparedness, authorization for use of agents, inventory and storage, and transport of biological materials.

Supervisors in charge of biological operations are responsible for the safe work performance, enforcement of SOPS, and general laboratory safety. These supervisors must ensure that personnel who work with biological toxins receive annual training in handling biohazardous

materials. In each laboratory, a Biological Agent Custodian is responsible for maintaining an up-to-date inventory of biological agents, and the supervisor is responsible for submitting this inventory to the Biological Safety Officer on a semiannual basis.

An operation-specific SOP must be created for each operation and approved according to USAMRICD Memorandum 385-1, *Occupational Safety and Health Program*. All workers must read and sign these SOPs, which must be kept available at the work site. The operation-specific SOPs must incorporate the CHP and SOP 91-077-RS-02 by reference.

Standard microbiological practices must be implemented while conducting work with BSL-1 agents and work may be conducted on an open bench top (USAMRICD SOP 91-077-FS-02). A sink must be available, although safety equipment is not required.

Operations at USAMRICD involving BSL-2 agents require the use of Class I or Class II BSCs or other physical containment devices during manipulation of agents that causes splashes or aerosols. These laboratories must follow procedures as defined in the benchmark guidelines (CDC/NIH 1999) and DA PAM 385-69, and signs should be posted indicating limited access. Toxin or infectious agent work must be performed in accordance with USAMRICD Memorandum 385-6, *Hazardous Waste Permit*. An autoclave must be available during work with BSL-2 agents unless other decontamination methods are employed.

The engineering controls to minimize potential exposure to biological materials include maintaining negative air pressure so that air will flow into the laboratories from the surrounding areas and entry corridors. Facilities for work with toxins must have a ventilation system that performs a minimum of six air exchanges per hour. The air within the laboratories conducting BSL-2 work passes through a HEPA filter before discharging into the atmosphere.

The laboratory environment should be easily cleanable to facilitate housekeeping. The bench tops must be impervious to water and resistant to organic solvents, acid, alkali, and moderate heat. An operational hand washing facility, emergency shower, and eyewash station must be readily accessible and within 7.6 meters (25 feet) of the laboratory hood where biological work is conducted.

BSCs and fume hoods must be tested and certified annually; any unit that fails must not be used until repairs are completed. BSCs or approved fume hoods must be used for containment of aerosol-producing equipment, unless other physical means for containment are provided. An approved method of decontamination must be available for equipment and waste generated during work with biological material.

Access into laboratories conducting biological operations is restricted to personnel who meet specific entry requirements, have been informed of the potential hazards, and have official business during biological operations. Warning signs with the universal biohazard symbol must be posted on the access door to the laboratory work area when infectious agents or

toxins are in use. This sign must include the identity of the agent, the name and phone number of the responsible person, and specifications for all special requirements for entry into the laboratory.

SOP 91-077-RS-02 establishes uniform safety procedures for research involving GEMs in accordance with benchmark guidelines (NIH 2002). It is used in conjunction with USAMRICD 385-4, *Chemical Hygiene Plan*. The principal investigator (PI) must prepare and submit protocols involving rDNA research to the USAMRICD Institutional Biosafety Committee for review, evaluation, and approval.

- *Chemical Safety*

The CHP, USAMRICD Memorandum 385-4, sets forth policies, procedures, and responsibilities for the handling of hazardous chemicals comprised of flammable and combustible liquids, water-reactive chemicals, shock-sensitive chemicals, toxic chemicals, and compressed gases. (Safety considerations for CSM, etiologic agents, toxins, and radionuclides are covered in other documents.) Specific duties are assigned to the USAMRICD Commander, the CHO, the SCOB, the USAMRICD Environmental Coordinator, and the KUSAHC.

Supervisors of operations in laboratories using hazardous chemicals must ensure that SOPs are available, that personnel are informed of hazards, and that they conduct operations safely. The supervisors also must provide PPE and training for the workers on the use and maintenance of PPE and perform periodic inspections of laboratories containing hazardous chemicals. Employees must report hazardous conditions, exposures, accidents, or abnormal circumstances.

The CHP provides general storage requirements of chemicals, requirements for inventories to be kept in each laboratory, and information on the storage, maintenance, transfer, and distribution of hazardous chemicals. It identifies engineering controls, including design and performance criteria for fume hoods, glove boxes, BSCs, local exhaust ventilation, air balance, and filtration and ventilation systems. The CHP also lists procedures for handling acutely toxic compounds, carcinogens, reproductive toxins, and procedures for instrument safety.

The benchmark guidelines and regulations discussed in Section 2.3.5.2 are supplemented by specific safety provisions for CSM in USAMRICD SOP 87-335-RS-GP*, General Provisions for CSM*, and USAMRICD SOP 87-201-RS-01, *General Provisions for Exempt CSM*. These general provisions apply to CSM operations for all experimental agents of like class and concentration in the designated chemical surety area. These SOPs require an initial hazard analysis and exposure monitoring to be performed and documented during the first 5 days of new CSM operations according to APG's monitoring plan. Additional monitoring of CSM operations is conducted quarterly. Laboratory personnel must coordinate monitoring with ECBC's agent monitoring branch and maintain a log of the initial and quarterly monitoring. The SCOB monitors the results.

CSM is stored in a triple-compartment concrete pedestal security container located in a room in the designated CSM area. The security container is placed within a double laboratory hood, which serves as an exclusion zone. This room is considered a permanent limited area, since it immediately surrounds the designated chemical exclusion area. Temporary limited areas where CSM is used but not stored and the agent is in an accessible form include single-hood and multiple-hood laboratory rooms. The supervisor controls access of personnel into temporary limited areas during CSM presence. All rooms where CSM is used are restricted areas. Rooms where CSM work is performed must be licensed for that use. At the entrance of each approved CSM laboratory, a completed USAMRICD form must be posted noting the type of agent, safety rules, and the names of the supervisors.

All CSM operations must have an agent custodian responsible for maintaining physical custody and accountability of the agent from the time of issue to the time of detoxification/ decontamination and an additional operator (a "buddy system" requirement). During CSM work, only personnel necessary to the operations who possess chemical PRP clearances are permitted in the laboratory. Food, beverages, tobacco, and cosmetics are prohibited within the restricted areas.

Fume hoods are provided in each laboratory conducting work with CSM. Both working and storage hoods are surveyed at least twice a year and during maintenance repairs. The fume hoods are required to have an average face velocity of 30.5 ± 3.0 linear meters (100 ± 10 linear feet) per minute through the working opening. Performance testing must be conducted prior to approval for chemical agents to be used in a hood. Fume hoods will be set at a working opening if they cannot maintain face velocity at every sash opening. Fume hoods with design features that maintain face velocity at every sash opening will have the face velocity set at a working height that provides some splash protection for the laboratory personnel. All operations within a CSM hood must keep equipment at least 20 centimeters (approximately 8 inches) behind the hood sash/face plane, which will be marked with paint or tape. If absorbent paper is placed in the hood as part of the operation, then the setback line is transferred to the absorbent paper before operations begin. Operators must verify airflow on a daily basis prior to receiving custody of CSM. All room doors remain closed during CSM operations, and personnel traffic is minimized in front of the hoods.

Prior to work with CSM, personnel must attend health and safety meetings covering identification of symptoms of agent exposure, buddy system aid, and evacuation procedures. Simulants and dry runs are part of the training performed prior to personnel conducting work with CSM.

Labeling of primary containers of CSM must include the agent name and class designation to identify contents. All secondary containers must have a completed DANGER-TOXIC CHEMICAL form affixed on them.

Levels E and F PPE must be worn in rooms where the agent is characterized as "at risk" for workers. Operators and buddies must wear Level E PPE when CSM work is in progress. Handling CSM requires triple gloves, inner and outer nitrile gloves with butyl gloves in the

middle. A full-front tested impervious laboratory apron must be worn over lab coats or smocks for splash protection. Used aprons are decontaminated, double bagged, and monitored. Level F must be worn by employees in the laboratory who do not handle agent or contaminated materials.

- *Radiological Safety*

NRC license No. BML 19-00294-24 requires USAMRICD to have a health physicist Radiation Safety Officer (RSO) who assumes responsibility for providing radiological surveys and ensures compliance with NRC regulations relating to the safe use of radioisotopes. A Radiation Protection Committee and the RSO must approve the operations and work areas where radioactive materials are utilized. Use, handling, and storage of radioactive material must be conducted to minimize exposure of occupational workers and to prevent exposure of nonoccupational workers (USAMRDC 1992).

USAMRICD conducts CBDP-related activities with radioactive materials in accordance with the benchmark NRC regulations listed in Section 2.3.4.6. USAMRICD SOP 90-282-RS-04, *Radioactive Materials Safety,* and USAMRICD Memorandum 385-2 specify safety requirements for the use, storage, inventory, and receipt of radioactive materials, including PPE and protective clothing and personnel training protocols. No laboratory or area where radioactive materials are present can have food, drinks, cosmetics, or tobacco used or stored (USAMRDC 1992).

USAMRICD Memorandum 385-6, *Hazardous Material Permit*, requires that all laboratories used for storage of, or operations involving, radioactive materials must have an approved USAMRICD radiological permit. HEPA- and charcoal-filtered fume hoods are mandatory for all laboratory operations involving radioactive materials. The Industrial Hygiene Section of the KUSAHC must verify proper operation of these fume hoods twice a year (USAMRDC 1992). Volatile products generated from fixed sources of radioactivity in these laboratories, such as gas chromatographs, must be vented to hoods. Wipe tests of the sources are conducted on a semiannual basis.

2.4.2.3.b *Occupational Health*

USAMRICD Memorandum 385-1, *Occupational Safety and Health Program* (OSHP), implements applicable federal, state, local, DoD, DA, and U.S. Army Medical Research and Development Command requirements and policies for occupational health. This program includes workplace safety and health protection for employees and visitors, safety management and responsibilities, training, PPE, waste handling procedures, and inspections. It also requires a Hazard Communication Program following the OSHA standard (29 CFR 1910.1200) for all personnel handling, using, or storing hazardous chemicals (USAMRDC 1992). The Commander of USAMRICD is responsible for maintaining the OSHP and ensuring its compliance with all applicable laws, regulations, and policies. Another duty of the Commander is to establish and monitor the USAMRICD Safety and Health Committee. Adherence to all safety standards, regulations, and procedures is required of all employees, and failure to comply is cause for disciplinary action (USAMRDC 1992).

All operations involving potentially HAZMATs, including chemicals, chemical agents, radioisotopes, and biological agents must have SOPs. USAMRICD Memorandum 385-1 provides the necessary requirements in preparing and disseminating SOPs, including review by the SCOB in conjunction with a Job Hazard Analysis. SOPs must be reviewed and signed annually by all employees performing the relevant operations or procedures. All relevant SOPs must be posted in each work area.

The USAMRICD Commander must approve all experimental protocols. USAMRICD Memorandum 70-9, *Research, Development, and Acquisition Research Protocols,* outlines the policies, procedures, and responsibilities for preparing research protocols. Experimental protocols must be reviewed for compliance with safety regulations, chemical needs, waste disposal methods, animal use, radioactive materials, hazardous waste minimization guidelines, regulations for storage and disposal of HAZMATs and waste, and adequacy and appropriateness of the SOPs.

Proper immunization and/or tests are required for personnel who handle certain agents or who work in laboratories where the agents could potentially be present. Vaccination of at-risk personnel must follow the American College of Physicians recommendations (American College of Physicians 1994); a resource list of available immunizations for these personnel is provided in DA PAM 385-69. Pentavalent toxoid must be provided for personnel working regularly with cultures or toxins associated with botulism. Serum-derived or recombinant vaccines must be provided for personnel working regularly with human blood and blood products, tissues, and body fluids.

Baseline serum samples are collected from laboratory and other at-risk personnel and stored. Baseline cholinesterase samples are required for at-risk CSM personnel to work in or enter a room where an organophosphate agent is present. CSM organophosphate operations must cease a half hour prior to the end of the workday for each worker to be inspected for symptoms of agent exposure. Medical alert devices are issued to and worn by employees potentially exposed to chemical agents during the work performance. Immunodeficient individuals or pregnant women are not allowed in BSL-2 laboratories or animal rooms.

KUSAHC maintains the Health Hazard Information Module database for all USAMRICD laboratories, conducts industrial hygiene surveys in laboratories where hazardous chemicals are used, provides air sampling in the laboratories, assists in the annual audit, and conducts periodic occupational medicine surveillance for military and civilian employees who work with hazardous chemicals.

All personnel must participate in the OSHP and Medical Surveillance Program. USAMRICD has provided the necessary safety, health, and waste management training for qualified scientists to be certified for work with CSM. In addition, USAMRICD has several qualified scientists approved to conduct research up to BSL-2, to include CBDP activities (USAMRICD 2001b).

All personnel conducting work with exposure or potential exposure to radiation or radioactive materials must be enrolled as radiation workers. This requires a radiation physical examination,

training from the RSO or designee, and on-the-job training from the supervisor (USAMRICD 2001b).

USAMRICD Memorandum 385-1 requires that PIs on projects involving biological toxins must be formally trained and hold appropriate credentials for supervision of the specific laboratory work. It also requires that personnel working with biological toxins must have a level of competency that equals or exceeds standards for a Biological Laboratory Technician or have completed Clinical Laboratory Technical Training. Personnel who work with toxic chemical agents must participate in a Toxic Aid Briefing at least once a year. Prior to clearance for work with chemical agents, personnel must be certified for completion of training in the use of exempt CSM. Workers handling HAZMATs, including chemical agents, must be certified for completion of training in the use of HAZMATs.

In addition to the benchmark regulations in Sections 2.3.5.4 and 2.3.5.2, USAMRICD follows the APG Disaster Control Plan, which covers all emergencies that occur on the installation (Casole 2002a). The APG BAIRA Plan, dated 28 October 1996, and CAIRA Plan, dated 7 March 2002, provide SOPs to implement in case of a biological or chemical accident or incident or other types of emergencies. These SOPs identify points of contact, response actions, evacuation routes, and notification requirements.

The CHP establishes a written emergency plan for USAMRICD. The plan includes an emergency alarm system and procedures for evacuation, shutdown, and return. The CHP also covers safety procedures in response to ventilation failure and fires. In the event of an emergency where biological or chemical agents are present, all personnel will be removed from the immediate area except those responsible for emergency operations. The responsible personnel will call 911 and notify appropriate supervisors, the SCOB, and the USAMRICD Commander.

Any person exposed to the biological agent should be removed from the source and decontaminated. All potentially hazardous work with biological agents must cease, and the biological agents must be secured. All contaminated PPE must be decontaminated and removed, and laboratory hoods must have their hood sash closed. MSDSs are located in each room.

In the event of an emergency where chemical agents are present, an Agent Aid Kit will be utilized to treat exposed personnel. These kits are present in each room where agent operations are conducted. Alarm systems are used to alert those working in the building that a chemical accident has occurred, and different tones specify the severity. USAMRICD Memorandum 420-3, *Evacuation Procedures*, is available in all CSM laboratories and must be reviewed and signed annually by workers.

All CB emergency events must be properly documented. The evacuation and shutdown procedures are included in USAMRICD SOPs 87-335-RS-GP and 91-077-RS-02.

Personnel working with radiological materials or near radiation and the first-line supervisor are responsible for response actions in the event of an emergency. Persons not directly associated with the emergency response must leave the area. The RSO is responsible for surveying the area

where the emergency occurred; stopping ventilation or other circulating devices that might spread the contamination; and clearing the area for reentry and continuation of operations. The RSO must also assist in decontamination procedures. Contaminated clothing from the emergency response personnel must be discarded in a designated container. KUSAHC will be notified in case of emergency.

The USAG of APG provides full-time fire and ambulance service to USAMRICD.

There have been no biological mishaps, chemical accidents, or LAIs at USAMRICD during the execution of CBDP-related activities from 1995 through 2001 (USAMRICD 2001b, Casole 2002d). All accident/incident reporting at USAMRICD is conducted in accordance with the benchmark guidelines and regulations noted in Section 2.3.5.4, as well as the CHP and the OSHP.

In addition to the benchmark regulations discussed in Section 2.3.5.4, AR 385-69, and DA PAM 385-69, inspection procedures are outlined in USAMRICD Memorandum 385-1. Regular inspections of USAMRICD facilities are conducted quarterly by APG's USAG environmental division and annually by the DoD Explosives Safety Board. According to USAMRICD SOP 91-077-RS-02, the Chief of the SCOB must ensure inspections of BSL-1 and BSL-2 laboratories on a quarterly basis by a Safety and Occupational Health professional. The inspection reports record hazards and the corrective actions taken to establish compliance in the laboratories. The supervisors must also conduct at least weekly inspections of work areas and take corrective actions promptly. In addition, the DA Inspector General conducts an inspection at intervals of 18 to 24 months. There were no deficiencies described as immediately dangerous to life or health recorded for USAMRICD facilities from 1995 through 2001 (USAMRICD 2001b, Casole 2002b).

2.4.2.3.c *Security*

APG has implemented regulatory safeguards for the physical protection of all private and government property on APG and the security interests of the Government according to APGR 190-6. Entry, exit, and internal control of personnel, material, and vehicles are in accordance with APGR 190-4. Since 11 September 2001, hunting and trapping have been prohibited on APG grounds.

USAG of APG is responsible to ensure that USAMRICD's work with CSM is considered in the preparation of the physical security plan, tactical defense plan, and the site vulnerability assessment, in accordance with Support Agreement W23HYY-02-02074-910. USAG also provides security guard support including patrol checks of surety area, response force deployment, static manned posts, and control and maintenance of guard force procedures and training (Casole 2002b).

Access to the USAMRICD laboratory buildings is limited by security systems. A computer-coded access badge must be worn for admittance to USAMRICD buildings and access to the internal corridors. Visitors must relinquish their drivers' licenses or other forms of photo

identification and place their names in the visitor register to obtain an access badge (Casole 1991).

Admittance to the Exclusion (Chemical Restricted) Area is severely restricted in compliance with AR 50-6, which requires that areas surrounding receptacles containing more than 1 mL of CSM are designated as exclusion areas and that access to these areas constitutes access to the agent itself in the absence of positive protective measures. Armed DoD guards control access to these areas, and only those USAMRICD employees approved in the chemical PRP and assigned to work there are allowed access. Visitors with a demonstrated need to be in the area may also be allowed access, but they must be escorted at all times. For access into the Exclusion Area, the general access badge must be exchanged for an Exclusion Area-specific badge, which must be displayed at all times. The Exclusion Area is further protected by an intrusion monitoring system capable of detecting unauthorized attempts to enter or exit, which is utilized during times when the area is not occupied. The building is externally monitored by patrols at random times throughout the 24-hour day. Violation of these security systems or activation of any of several strategically located panic buttons generates an armed response (USAMRDC 1992).

CSM within the Exclusion Area must be locked within a vault that can withstand earthquakes, hurricanes, and nuclear explosions. This vault is located inside the bottom of a fume hood that incorporates full-containment engineering controls in a double-locked room. Two individuals and two sets of keys must be present for access to the fume hoods and storage vaults (Casole 1991).

USAMRICD SOP 87-335-RS-GP requires that two chemical PRP-authorized individuals must be present during any operation involving CSM and that both of them must be familiar with the experimental protocol and all associated security and safety measures that must be followed in its execution. As further safety and security precautions, these individuals must be able to see and hear each other at all times. Chemical PRP-authorized individuals must be continually observed by their fellow workers and their supervisors. This is intended to ensure that any change in the attitude, behavior, or health (whether on or off duty) is brought to the attention of the certifying official for appropriate action, which may necessitate the worker's removal from this type of assignment (USAMRDC 1992).

Supervisors in charge of biological operations are responsible for ensuring accountability of biological agents and submitting an inventory of biological agents to the Biological Safety Officer on a semiannual basis. The CSM Storage Custodian maintains custody and accountability of CSM at USAMRICD at all times between issue and decontamination or detoxification.

2.4.3 Naval Surface Warfare Center Dahlgren Laboratory

The Naval Surface Warfare Center Dahlgren Laboratory (NSWCDL) is located in King George County, Virginia. Information about the area, including details of the existing environment, is presented in Section 4.3. This section discusses CBDP activities and mitigation measures at NSWCDL as a basis for the environmental impact analysis presented in Sections 5.2 through 5.14.

NSWCDL is the host activity at the Naval Surface Warfare Center, a field command within the Naval Sea Systems Command. It is the U.S. Navy's main RDT&E facility for engineering and fleet support for surface warfare systems, surface ship combat systems, ordnance, mines, and amphibious warfare systems.

All CBDP laboratory operations are conducted in the Chemical and Biological Defensive Warfare Laboratory (CBL), a 3,252-square-meter (35,000-square-foot) building located in the extreme northeastern portion of Mainside, in the Advanced Concepts Complex (Mersiowsky 2002).

2.4.3.1 Research, Development, Test, and Evaluation Activities

The CBL Building was constructed for RDT&E activities in support of several CBDP commodity areas. The commodity areas and current RDT&E objectives include: Contaminant Avoidance (point sampling and advanced warning detectors for chemical agents and biological agents); Individual Protection (PPE); Collective Protection; Decontamination (procedures for handling personnel and equipment contaminated by chemical or biological agents); and Modeling/Simulation (computer simulation techniques for predicting and studying the hazards associated with releases of chemical or biological agents). Non-CBDP RDT&E activities are also conducted in the CBL (Martens 2001).

2.4.3.1.a Chemical Surety Materiel

Chemical operations are conducted in the Chemical Suite, which includes a general chemistry laboratory and a toxic laboratory. CSM is used in analyses on chemical warfare threats to, and impacts on, Navy operations. The objectives are to gain information on chemical agents' physical, chemical, and toxicological properties and on the development of detection systems and protective systems such as chemical warfare decontamination facilities (Martens 2002a). Chemical simulants will be used in the CBL and elsewhere at NSWCDL in lieu of chemical warfare agents mentioned in the Chemical Weapons Treaty (Martens 2000).

2.4.3.1.b High-Hazard Biological Agents

Biological operations are conducted in the Biotechnology Suite, which includes BSL-2 and BSL-3 laboratories and an autoclave room. The suite also contains storage rooms. Biological agents are used in analyses on potential biological warfare threats. The objectives are to provide information on biological agents' physical, chemical, and toxicological properties and in testing detection and decontamination systems. The etiologic agents that are used in the BSL-3 lab include ricin, botulinum toxin, *Yersina pestis,* and *Bacillus anthracis*.

2.4.3.1.c *Aerosol Testing*

Aerosol testing is not conducted at NSWCDL.

2.4.3.1.d *Animal Care and Use*

NSWCDL does not use animals for testing. The CBL Building does not have facilities built to house any animals.

2.4.3.1.e *Vaccine Development*

Vaccine development activities are not conducted at NSWCDL.

2.4.3.1.f *Genetically Engineered Microorganisms*

GEMS are not used in CBDP activities at NSWCDL.

2.4.3.1.g *Human Subjects*

The testing activities at NSWCDL do not involve human subjects.

2.4.3.1.h *Radiological Testing*

RDT&E activities in the CBL involve using sensors or equipment that contains radioactive material in sealed sources. This use does not require an NRC license. Oversight for radioactive sources under NSWCDL control is provided by the NSWCDL Radiation Safety Officer and is coordinated under a permit with the Navy Radiation Affairs Support Office that interfaces with the NRC.

2.4.3.1.i *Open-Air Laser Testing*

Open-air laser testing to support the CBDP is not conducted at NSWCDL.

2.4.3.1.j *Support Work*

The CHP addresses use and handling of nonhazardous and hazardous materials and supplies and minor maintenance of laboratory equipment (see Section 2.4.3.3.a, below).

2.4.3.2 Operations, Maintenance, and Waste Management Activities

2.4.3.2.a *Operations*

The potable water usage at NSWCDL averages 1,589,868 liters (420,000 gallons) per day, with peak consumption of 3,039,676 liters (803,000 gallons) per day. Potable water usage for CBDP activities accounts for only 1% of the total consumption (NSWCDL 2001a).

NSWCDL's Maintenance and Utilities Office (MUO), a part of the installation's Public Works Division, operates and maintains the electrical generation and distribution system. NSWCDL purchases electrical power from Virginia Dominion Power of Richmond, Virginia, averaging 11.5 megawatt-hours (mWh) per day, with peak usage of 16.8 mWh per day. The buildings

where CBDP activities are conducted account for approximately 1% of the installation's total power consumption (Martens 2002a).

Fuel oil, mainly for heating buildings, is purchased from local and out-of-state commercial providers, currently Southern States Petroleum Service, Fredericksburg, Virginia, and Mansfield Oil Company, Gainesville, Georgia. The CBDP facilities, excluding two office support buildings, are heated by 50,729 liters (13,041 gallons) of fuel oil annually, approximately 2.3% of the 2,181,212 liters (576,278 gallons) consumed annually by the installation (NSWCDL 2001a).

2.4.3.2.b *Maintenance*

The MUO provides maintenance, repair, and/or alteration services for NSWCDL buildings, quarters, and industrial structures and performs minor construction work. It installs, operates, and maintains all department mechanical systems. Grounds and road maintenance are generally contracted out, except for smaller jobs such as snow and leaf removal, and street cleaning. Public Works personnel do the routine maintenance to support the laboratories, including the CBL Building (Martens 2002b).

2.4.3.2.c *Waste Management*

- *Air Emissions*

  Annual emissions of criteria pollutants from NSWCDL during fiscal year 2002 included 10.52 metric tons (11.57 tons) of CO, 44.11 metric tons (48.52 tons) of NO_x, 1.41 metric tons (1.55 tons) of PM_{10}, 17.06 metric tons (18.77 tons) of SO_2, and 2.69 metric tons (2.96 tons) of VOCs. Accurate information for the other point sources in King George County is not available for any year. Pollutants attributed to CBDP activities are estimated at 2% of the above figures.

  Nonroutine operations involving the atmospheric release of either minor quantities of nonhazardous chemical or biological simulants, or small quantities of hazardous chemical or biological simulants on NSWCDL will be examined on a case-by-case basis, if and when the situations arise. In all such cases, environmental and safety issues will be examined, documented, and approved by the NSWCDL Safety and Environmental Office prior to conducting any such operations (Martens 2000).

- *Solid Waste*

  CBDP activities accounted for approximately 1% of the 4,131.8-metric-ton (4,554.5-ton) average annual total of solid waste generated at NSWCDL during the baseline years of 1996 through 2001. NSWCDL recycles paper and cardboard, which are collected by the Naval District of Washington's Morale, Welfare, and Recreation Recycling Program. Additional recycled items include furniture, appliances, computers, vehicles, tires, scrap iron and steel, brass, copper, aluminum, toner, and foam peanuts. Other office and household solid waste and sewage sludge (generated by NSWCDL's Sewage Treatment Plant) are collected by a contractor and hauled to the King George County Landfill, a large commercial landfill

located approximately 19.3 kilometers (12 miles) from NSWCDL. The installation's municipal solid waste incinerator has not been used since 1999 (Kennedy 2001).

- *Wastewater*

CBDP activities accounted for approximately 1% of the 1,177,259 liters (311,000 gallons) per day average of sanitary wastewater generated during 1996 through 2001at NSWCDL. Sanitary wastewater at NSWCDL is discharged to the sanitary sewer system for treatment at the installation's Sewage Treatment Plant, which operates under Virginia Pollutant Discharge Elimination System (VPDES) Permit No. VA0021067 under the NPDES program. The treated effluent discharges into Upper Machodoc Creek. Storm-water runoff from industrial areas of the installation discharges into Upper Machodoc Creek or Gambo Creek, subject to VPDES Permit No. VA0073636 (Martens 2001).

- *Hazardous Waste*

NSWCDL facilities and procedures for storage, handling, and disposal of hazardous waste are in accordance with the Virginia Waste Management Act, Chapter 60, which closely follows the federal standards under RCRA. All hazardous waste generated on NSWCDL is taken to the Hazardous Waste Storage Building, a 90-day storage facility, for interim storage, processing, and shipment for subsequent disposal. NSWCDL has utilized numerous permitted off-site TSDFs.

NSWCDL holds RCRA Permit No. VA7170024684, issued by the State of Virginia, Department of Environmental Protection. The installation generated approximately 70,154 kilograms (154,661 pounds) of hazardous waste during 2001; CBDP activities accounted for 657.3 kilograms (1,449 pounds), approximately 1% of the installation total. NSWCDL did not have any RCRA permit violations within the 10 years from 1992 through 2001 for any hazardous waste resulting from operations supporting the CBDP (Martens 2001).

- *Medical and Infectious Waste*

In accordance with the benchmark guidelines discussed in Section 2.3.4.5, all waste contaminated or potentially contaminated with infectious material must be rendered noninfectious before disposal. This decontamination is accomplished by a combination of chemical disinfection and steam sterilization (autoclave) methods. In the Biotechnology Suite, solid waste materials are collected in biohazard containers located in the BSL-2 and BSL-3 laboratories and in the Autoclave room. Potentially contaminated liquid or solid biological materials are decontaminated chemically (using a 5% sodium hypochlorite solution) and by autoclaving, in accordance with SOP B51-105-01-A, *Standard Operating Procedures for the Biotechnology Laboratory*. Following decontamination, this waste is handled and disposed of as medical waste. All autoclaved waste is picked up by a contractor for off-site incineration.

NSWCDL annually generated approximately 925.3 kilograms (2,040 pounds) of regulated medical waste, on average, during 1996 through 2001, consisting primarily of sharps and solid infectious waste. CBDP activities accounted for an average of 762.0 kilograms (1,680

pounds) of solid infectious waste, more than 80% of the installation total. Solid infectious waste may include agar plates, petri dishes, PPE, and general laboratory materials used in the Biotechnology Suite. NSWCDL facilities for the handling and disposal of regulated medical waste are in accordance with the requirements of state regulations for medical and infectious waste (Virginia Waste Management Act, Chapter 120). NSWCDL medical waste is transported for disposal by incineration by Stericycle, an outside contractor (Martens 2001).

- *Radiological Waste*

Excluding Comprehensive Environmental Response, Compensation, and Liability Act-generated waste, NSWCDL disposed of 1.06 metric tons (1.17 tons) of radiological waste in 1998. The CBDP contribution has been less than 45.4 kilograms (100 pounds) per year.

2.4.3.3 Safety, Health, and Security Mitigation

RDT&E activities in the CBL involve using materials that require special handling to mitigate potential risks to human health. This includes high-hazard biological agents; hazardous or toxic chemicals; and sensors or equipment containing radioactive sources (Martens 2001). These CBDP activities adhere to the benchmark regulations and guidelines enumerated in Section 2.3.5 pertaining to occupational health and safety, including the safe use, handling, and disposal of potentially hazardous CB materials. Additional applicable Navy regulations, state and local laws, and site-specific regulations and procedures are discussed below.

2.4.3.3.a Safety

- *Biological Safety*

All operations in the BSL-2 and BSL-3 laboratories involving the use of biological materials are conducted in accordance with the benchmark guidelines for biological safety described in Section 2.3.5.1 (CDC/NIH 1999) and SOP B51-105-01-A. Operations must have prior approval by the NSWCDL Safety and Environmental Office.

The BSL-2 laboratory is only for work with inactivated agents such as cross-linked ricin, botulinum toxin, *Yersina pestis*, or *Bacillus anthracis* (Martens 2001). The spores of *Bacillus anthracis* used in CBDP activities are gamma irradiated by the supplier, who provides a certificate with each shipment to verify that the material is suitable for use in a BSL-2 laboratory (Martens 2002b). BSL-2 operations may be conducted in the BSL-3 laboratory or the BSL-2 laboratory.

An environmental assessment prepared by NSWCDL (Department of the Navy 2002) systematically reviewed the CDC/NIH BSL ratings (CDC/NIH 1999) and related risk criteria for bacteria, viruses, toxins, and parasites and identified the biological agents to be studied in the BSL-2 and BSL-3 laboratories. All procedures involving the manipulation of infectious material are conducted within BSCs or other physical containment devices, or by personnel wearing appropriate PPE.

Access to all laboratories in the Biotechnology Suite is permitted only to personnel conducting the operations and to visitors approved by the Biotechnology Laboratory

Director. All workers must sign the "Read and Understand" Statement concerning SOP B51-105-01-A and the Hazard Control briefing. All visitors receive a Hazard Communications briefing.

Biological containment areas have signs posted at the entrance indicating their BSL-2 or BSL-3 designation, emergency personnel telephone numbers, and the required PPE. In all laboratories in the Biotechnology Suite, scrubs and smocks are required. These protective garments must remain in the laboratory at all times to avoid the transfer of contaminated materials outside the laboratory. Used scrubs and smocks from the BSL-2 laboratory are bagged, autoclaved, and washed at least monthly or discarded into approved medical waste disposal containers. In the BSL-3 laboratory, disposable laboratory coats, aprons, and shoe covers are used and immediately placed into medical waste bags, autoclaved, and then removed from the laboratory to an off-site incinerator. Powered air-purifying respirators are required in the BSL-3 laboratory (SOP B51-105-01-A). These respirators are stored in the BSL-3 laboratory. They are stored, inspected, used, and maintained in accordance with SOP B51-613-02-A. This SOP also provides details about the NSWCDL Respiratory Protection Program, its manager, training requirements, and fit testing.

Engineering controls are used to prevent contamination of other areas. All of the laboratories are maintained under negative air pressure, resulting in a flow of air into each laboratory. In the Molecular laboratory and BSL-3 laboratory, air is supplied evenly throughout the laboratories by means of ceiling diffusers. The air in the Molecular laboratory is extracted through ceiling exhausts and through the fume hood, when in use, into a plenum in the ceiling and then exhausted from the building. Air in the BSL-3 laboratory is extracted through the BSCs, which provide directional airflow and HEPA filtration of the exhaust air. HEPA filters are checked annually, both visually and for flow capacity, and replaced as needed. Used HEPA filters are autoclaved and disposed of as infectious waste. The extracted air from each BSC is independently exhausted from the building. The BSL-3 laboratory also has two doors in series to prevent contamination.

The laboratories are separated from other areas and have controlled access. All laboratories in the Biotechnology Suite are equipped with sinks operated by foot pedals to prevent contamination. Other safety features include sprinkler systems, emergency showers, eyewash stations, and hand-held emergency eyewash/drench hoses (SOP B51-105-01-A).

All BSL-3 agents must be stored in the locked refrigerator in the BSL-3 laboratory. BSL-2 agents are stored in the locked refrigerator in the BSL-2 laboratory. The containers must be clearly labeled to identify the material and associated hazards. MSDSs for each chemical and material stored in the Biotechnology Suite are maintained in binders, and copies are kept on file in the Molecular laboratory and the BSL-3 laboratory (NSWCDL SOP B51-105-01-A 2001).

Packaging, shipment, or transport of biological materials is in accordance with the benchmark regulations and guidelines discussed in Section 2.3.5.1.d. All packages are inspected and certified by the Biotechnology Laboratory Director prior to shipment.

- *Chemical Safety*

NSWCDL policies and procedures for the safe handling and use of hazardous chemicals are contained in the CHPs, which are prepared separately for each building with chemical laboratories. Each CHP details SOPs for handling controlled substances, chemical acquisition and storage, potential health risks, environmental monitoring, PPE, use of fume hoods, safety procedures, inspections, and laboratory audits. It also describes plan implementation and managerial and laboratory worker responsibilities.

All chemical operations in the CBL Building are conducted in accordance with the benchmark guidance and regulations listed in Section 2.3.5.2 and approved SOPs, as listed in the CHP. Operations must have prior approval by the NSWCDL Safety and Environmental Office (NSWCDL SOP B51-105-01-A 2001).

- *Radiological Safety*

NSWCDL does not conduct testing that involves radioactive materials. RDT&E equipment containing radioactive materials is considered as a sealed source under NRC regulations. Oversight is provided as discussed in Section 2.4.3.1.h.

2.4.3.3.b Occupational Health

The occupational health and safety of NSWCDL personnel is overseen by the NAVOSH Program. Personnel performing operations in the Biotechnology Suite must complete the required medical monitoring procedures and tests. Individuals determined to be at an increased risk for infection are denied access to the BSL-3 laboratory and can be granted access to the Molecular laboratory only with permission of the Biotechnology Laboratory Director based on a hazard assessment for current laboratory operations. All SOPs, reference materials, MSDSs, and BSC maintenance information must be maintained by the Director (NSWCDL SOP B51-105-01-A 2001).

The Hazardous Materials Emergency Response Plan provides facility-specific guidance to the individuals and organizations responsible for responding to HAZMAT incidents on the installation. Several NSWCDL fire department personnel have the required training to be HAZMAT emergency responders. If additional support is needed, or in HAZMAT emergencies that would require Level A PPE, the Virginia Department of Emergency Management Regional Team can be called (Martens 2002a).

The NSWCDL Fire Division is the first responder on the installation for fires, injuries, HAZMAT spills, and other emergencies. If an ambulance is needed, NSWCDL's Fire Department will call the Dahlgren Rescue Squad (King George County, Virginia) to transport ill or injured persons to Mary Washington Hospital, Fredericksburg, Virginia (NSWCDL Fire Division 2001). Biotechnology Suite exposures and accidents are handled under NSWCDL SOP B51-105-01-A. NSWCDL has Mutual Aid Agreements with King George County, Virginia; Colonial Beach, Virginia; and Charles County, Maryland, for fire and medical emergency response, if necessary (Martens 2002a).

All spills and accidents must be reported to the Laboratory Director. Medical evaluation, surveillance, and treatment are provided as needed. Emergency procedures have been established in the event of an accident resulting in physical trauma, chemical spill, or potential exposure to HAZMATs. These procedures are outlined in the Biotechnology Suite SOP (Martens 2001). NSWCDL's other regulations and instructions for preventing and handling accidents or incidents include: Spill Prevention, Control, and Countermeasures Plan and Emergency Operations Plan (Safety and Environmental Office 1996). No LAIs or accidents were reported at NSWCDL during 1995 through 2001 (Martens 2001).

Laboratory personnel must inspect all the laboratories at the end of each day of operation. They must also inspect all PPE and laboratory equipment prior to each use. The Biotechnology Biosafety Officer inspects eyewashes weekly and maintains a record of all inspections. The laboratory hoods and BSCs are inspected annually by the Industrial Hygiene Group. The Biotechnology Laboratory Director ensures that all procedures, test plans, protocols, medical monitoring, and maintenance records are maintained (NSWCDL SOP B51-105-01-A 2001).

2.4.3.3.c *Security*

The CBL Building is located within the restricted area of NSWCDL. Access to the restricted area is controlled by fences and security procedures, including manned gates, and use of badges and passes. The restricted area is patrolled by NSWCDL security personnel (Martens 2001).

Entry to the laboratories is permitted only to personnel involved directly in the research. Entry to the CBL Building is controlled by proximity card-reader locks and monitored by an attendant at the main entry point. Visitors to the Biotechnology Suite must obtain approval from the Biotechnology Laboratory Director. All visitors are escorted at all times.

Laboratory access is controlled through multiple locks. Entrance into the Molecular lab or the Chemistry labs is through doors equipped with core locks that require a key, and with proximity card-reader locks. Entrance to the BSL-3 lab is through the Molecular lab, a door equipped with a cipher lock, and a second door with a proximity card-reader lock (Martens 2002a). The Tissue Culture room and the BSL-2 laboratory have key-locked doorways. Entry to the Autoclave room is controlled through a cipher lock on the doorway. Laboratory refrigerators and freezers that house biological agents are equipped with door locks, and the only keys are in the possession of the Biotechnology Laboratory Director and the Biotechnology Biosafety Officer. Only qualified personnel are granted access to CB storage areas (NSWCDL SOP B51-105-01-A 2001).

Laboratory personnel must keep a record of all highly toxic materials worked with each day in the lab. The Director must maintain a logbook of all biological agents used in the laboratory, including the personnel using the agent, the date of use, and the amount of agent used (NSWCDL SOP B51-105-01-A 2001).

2.4.4 U.S. Army Medical Research Institute of Infectious Diseases

The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is located at Fort Detrick, Maryland. Information about the Fort Detrick area, including details of the existing environment, is presented in Section 4.4. This section discusses CBDP activities and mitigation measures at USAMRIID, as a basis for the environmental impact analysis discussed in Sections 5.2 through 5.14.

USAMRIID is a subordinate activity of USAMRMC, under the U.S. Army MEDCOM. Its mission is to conduct research to develop strategies, products, information, procedures, and training programs for medical defense against validated biological warfare agents and naturally occurring infectious agents of military relevance. USAMRIID is the principal DoD research site for medical BD and is the lead medical research laboratory for definitive identification of biological agents and diagnosis of their associated diseases within the BDRP (USAMRIID 2002a). Medical Systems is the principal commodity area for USAMRIID, with a primary objective of developing medical materiel and equipment items that provide effective medical defenses against biological threats facing U.S. forces on the battlefield (ODASD 2000). RDT&E activities have included development of medical countermeasures for viral hemorrhagic fevers and arboviral illnesses and development of laboratory and field diagnostic assays for agents considered to be biological warfare or endemic disease threats.

The main USAMRIID operations are located in two buildings in the southeastern portion of Area A at Fort Detrick (USAMRIID 2001a). The larger building contains BSL-3 and BSL-4 laboratories; hospital facilities; HAZMAT, general, and record storage; and offices (administration). These laboratories, which account for 21,263 square meters (228,874 square feet) of the 23,138 total square meters (249,059 total square feet) of floor space in the building, are used for aerosol testing and for research on highly hazardous biological warfare and infectious agents and GEMs (USAMRIID 2000a, USAMRIID 2001a). The smaller building supports vaccine and diagnostic assay development, with laboratories at all four BSLs occupying about 6,867 square meters (73,920 square feet) of floor space. This building also provides support facilities for laboratory animals, including cage washing and housing of nonhuman primates (NHPs) (USAMRIID 2000a). Additional USAMRIID facilities in Area A include a dairy barn and about 626 square meters (6,734 square feet) of laboratory space for virology recombinant work using the vector vaccinia virus within BSL-2 (and, when applicable, BSL-1) laboratories in another building, where USDA is the primary tenant (Federline 2000, USAMRIID 2002b).

USAMRIID activities in Area B of Fort Detrick are conducted at the Large-Animal Research Facility (LARF), a 48.6-hectare (120-acre) animal farm with 43.7 hectares (108 acres) of pasture and four buildings. The LARF buildings consist of a 259-square-meter (2,792-square-foot) research barn; a 1,128-square-meter (12,139-square-foot) administrative facility; and two storage facilities for cages, hay, and farm equipment, with a combined total 574 square meteres (6,181 square feet) of floor space. The LARF also uses the dairy barn on Area A for storage of animal cages and hay (Federline 2000, USAMRIID 2000a).

2.4.4.1 Research, Development, Test, and Evaluation Activities

The medical biological defense research conducted at USAMRIID includes the development of medical countermeasures, vaccines, drugs, and diagnostic tools for use in the laboratory and field (USAMRIID 2002a). All four levels of BSL laboratories are used in RDT&E activities at USAMRIID. The two main USAMRIID buildings in Area A together include 4,523 square meters (48,683 square feet) of BSL-3 facilities and 601 square meters (6,465 square feet) of BSL-4 facilities, arranged into airtight biological containment suites with airlocks, changing rooms, offices, conference rooms, animal rooms, and Class II or Class III BSCs (USAMRIID 2000a). Engineering controls and other features of these suites are discussed in Section 2.4.4.3.a, below.

The hospital facilities consist of two wards. A specialized maximum-safety patient containment ward is used to provide medical care for patients who may have acquired a highly hazardous disease in an endemic area or who may have been accidentally exposed to infectious agents within the laboratory (USAMRIID 2002a). A 15-bed research ward formerly used for clinical trials of vaccines and drugs is not currently functional as a hospital facility.

2.4.4.1.a Chemical Surety Materiel

Testing of CSM is not conducted at USAMRIID.

2.4.4.1.b High-Hazard Biological Agents

The development of vaccines, diagnostic assays and reagents, and antiviral compounds requires the use of etiologic agents in research and laboratory work. Etiologic agents are also required for validation of Good Laboratory Practice procedures and data (USAMRIID 2001a).

The Safety and Radiation Protection Office (SRPO) maintains a registry of bacterial, viral, fungal, and toxin agents for each USAMRIID facility. Bacteria studied at USAMRIID include BSL-1, BSL-2, and BSL-3 agents, comprising *Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis, Staphylococcus aureus*, *Salmonella* species, *Clostridium botulinum*, *Bacillus* species, and *Yersinia pestis*. Viruses studied at USAMRIID include BSL-1, BSL-2, BSL-3, and BSL-4 agents, comprised of the following types of virus: yellow fever, Hantaan, Venezuelan equine encephalitis (VEE), Eastern equine encephalitis, Western equine encephalitis, Lassa fever, Marburg, Ebola, and monkeypox, but not smallpox. One BSL-2 fungus, *Candida albicans*, is used in quality control studies for diagnostic assay development. Other vaccine and diagnostic assay developments include the use of the following bacterial toxins: botulinum toxin (*Clostridium botulinum*), cholera toxin (*Vibrio cholerae*), and enterotoxins (*Staphylococcus aureus*). Other toxins studied at USAMRIID include saxitoxin and ciguatoxin (from marine organisms), ricin (from the castor bean), snake and fish toxins, and T-2 mycotoxins (from fungi) (USAMRIID 2000a).

2.4.4.1.c Aerosol Testing

USAMRIID's Department of Aerobiology and Product Evaluation is responsible for aerosol testing research. Its mission is to conduct and support research on the pathogenesis, prophylaxis, and therapy of disease or intoxication caused by exposure of aerosolized biological warfare

agents through the respiratory tract. USAMRIID requires that such research be conducted within BSL-3 or BSL-4 laboratories (USAMRIID 2001a). Aerosol testing of etiologic agents is conducted in both main USAMRIID buildings. Class III BSCs in the smaller building support aerosol testing for vaccine and therapeutic agent efficacy by exposing laboratory animals with aerosols generated from liquids that contain etiologic agents (USAMRIID 2000a).

2.4.4.1.d *Animal Care and Use*

USAMRIID's Veterinary Medicine Division (VMD) has responsibility for animal care and use. Its mission is to provide support, research, training, and consultation in laboratory animal medicine, veterinary care, comprehensive animal husbandry, and animal care and use procedures. This includes reviewing research protocols to ensure proper and lawful animal use. The responsibilities of the Chief of VMD, who must be a board-certified veterinarian in Laboratory Animal Medicine**,** include being the principal advisor to the Commander and USAMRIID on animal care and use laws, and serving as Chairman of the LACUC (USAMRIID 2000a).

USAMRIID follows the federal benchmark regulations and guidelines for animal care and use discussed in Section 2.3.1. All aspects of the animal facilities and programs at USAMRIID are handled by LACUC. Animal care is characterized in SOPs related to environmental conditions; sanitation; acquisition, quarantine, and distribution of animals; randomization and identification of animals; animal handling including sentinel and quality control; animal status and diagnostics; food and fluids; administration of test materials; anesthesia, treatment, and euthanasia; and sample collection. For example, medical and routine care and use of animals at the LARF follow guidelines and procedures established in USAMRIID SOP UIR501, *Standard Operating Procedure, Large-Animal Research Facility*, dated 29 March 1995 (USAMRIID 2001a).

The Council on Accreditation of AAALAC conducted an inspection at USAMRIID in March 2001. Full accreditation for the animal facilities and programs was renewed on 26 June 2001 (AAALAC 1998, USAMRIID 2002b).

All studies are designed to minimize the use of laboratory animals. The total number of laboratory animals at USAMRIID varies in response to test requirements. In fiscal year 2001, there were approximately 28,218 laboratory animals at USAMRIID, with 97.4% rodents (mice, hamsters, guinea pigs, and chinchillas); 1.4% rabbits; 0.8% NHPs; and 0.2% large animals. All of the NHPs are housed in both main USAMRIID buildings on Area A of Fort Detrick; none are housed at LARF. Most of them have been assigned to research or training protocols (USAMRIID 2002b). A census of large animals at LARF in 2001 counted 7 horses, 24 goats, 40 sheep, and 13 geese. As of 2001, approximately 139 animals are housed at off-post facilities for future research or training activities at Fort Detrick (USAMRIID 2002b). All laboratory animals are contained in some form of animal cage, e.g., cage tops with filters and laminar flow enclosures (USAMRIID 2000a).

USAMRIID obtains small animals primarily from commercial vendors, with the exception of strain-13 guinea pigs, which are bred at USAMRIID (USAMRIID 2000a). The primary sources for small animals include the National Cancer Institute, Charles River Laboratories, Jackson

Laboratories, and Covance Laboratories. Large animals are obtained from commercial vendors, including Green Springs Farm (sheep and goats) and Cackle Hatchery and Metzer Farms (geese) (USAMRIID 2002b).

2.4.4.1.e *Vaccine Development*

USAMRIID, as of 2001, was conducting research on new vaccines for toxins, such as staphylococcal enterotoxins and ricin toxin and improved vaccines for diseases such as anthrax, VEE, plague, and botulism. Vaccines may be developed by changing the disease-causing properties through attenuation or reduction of virulence or toxicity (USAMRIID 2002a). Vaccine development relies heavily on rDNA work, as noted in Section 2.4.4.1.f (USAMRIID 2001a).

2.4.4.1.f *Genetically Engineered Microorganisms*

New approaches to vaccine development in use at USAMRIID include use of rDNA and other common tools of molecular biology (USAMRIID 2001a).

2.4.4.1.g *Human Subjects*

Human volunteers play an important role in the medical research effort conducted by USAMRIID. They may be used in studies conducted on an outpatient basis when it is determined that there are minimal risks. Studies conducted on an inpatient basis require that human volunteers be admitted to the Clinical Research Ward.

In addition to the benchmark regulations and directives pertaining to human subjects enumerated in Section 2.3.2, human subjects involved in USAMRIID research are covered by USAMRIID Regulation 70-25, *Use of Human Subjects in Research*, dated 24 February 2000. This regulation created the Human Use Committee and assigned it with the responsibility for reviewing research protocols involving human subjects to ensure the scientific and ethical merits of the studies and to fully protect and safeguard the rights and welfare of human subjects. The USAMRMC and the Office of the Army Surgeon General also review research protocols involving human subjects (USAMRIID 2001a).

As of 2001, USAMRIID has 70 medical research volunteer subjects (MRVSs), all highly trained laboratory technicians who requested the opportunity to participate in USAMRMC clinical trials associated with the development of vaccines and drugs. The MRVSs are essential to the mission and unique to USAMRIID, since the first phase of human testing puts volunteers through a long-term clinical trial that entails thorough monitoring (USAMRIID 2002a).

2.4.4.1.h *Radiological Testing*

USAMRIID holds NRC License No. 19-11831-03 (Type B broad license) for use of various radioisotopes, valid through 30 April 2011 (USAMRIID 2000a, USAMRIID 2002b). USAMRIID also held NRC License No. 19-11831-01 (byproduct material) for use of two gamma cell irradiators, which expired on 31 May 2002. The latter will be eliminated upon approval of an amendment to NRC license No. 19-11831-03 to include the irradiators (USAMRIID 2002b).

Radiological testing at USAMRIID is conducted in accordance with the benchmark regulations and guidance listed in Section 2.3.4.6. USAMRIID Regulation 358-11, *Radiation Protection Program*, dated 24 September 2001, serves in lieu of a formal SOP for laboratories that use radioactive materials (USAMRIID 2002b).

2.4.4.1.i *Open-Air Laser Testing*

Open-air testing with lasers is not conducted at USAMRIID.

2.4.4.1.j *Support Work*

The CHP addresses use and handling of nonhazardous materials and supplies and minor maintenance of laboratory equipment.

2.4.4.2 Operations, Maintenance, and Waste Management Activities

2.4.4.2.a *Operations*

USAG is responsible for the O&M of utilities at Fort Detrick, including USAMRIID. As of 2000, USAMRIID uses an estimated 227,229,991 liters (60,028,000 gallons) of potable water annually, approximately 13% of the 1.72 billion liters (454,296,000 gallons) per year of water produced from Fort Detrick's WTP. The Potomac Edison Power Company, a subsidiary of Allegheny Energy, provides electricity for Fort Detrick. USAMRIID activities account for approximately 7.5% of the 140,361,000-kWh-per-year total consumption by Fort Detrick. The Washington Gas Company provides approximately 613,761,600 ccf[4] of natural gas for Fort Detrick annually. Of this, USAMRIID consumes an estimated 927,100 ccf per year, approximately 0.15% of the total natural gas. Commercial suppliers provide 792,879 liters (209,457 gallons) of fuel oil and 242,129 liters (63,964 gallons) of diesel per year for Fort Detrick; USAMRIID accounts for 5,546 liters (1,465 gallons) per year of the fuel oil (about 0.7% of the total used by Fort Detrick) and 6,178 liters (1,632 gallons) per year of the diesel fuel (about 2.5% of the total used by Fort Detrick). Of the 280,497,168 kilograms (618,380,000 pounds) of steam generated annually by the Fort Detrick Central Boiler Plant, approximately 19.5% is used by USAMRIID activities (USAMRIID 2000a).

2.4.4.2.b *Maintenance*

The Operations and Maintenance Division (OMD) of USAG is responsible for maintaining the buildings and grounds at Fort Detrick. The maintenance system is evaluated for potential problems so that corrective actions may be planned in an efficient and cost-effective manner. The OMD also supports the Energy Conservation Program at Fort Detrick by ensuring that energy-consuming equipment and systems of installation facilities operate at maximum efficiency (Fort Detrick OMD 2002).

[4] ccf = 100 cubic feet.

2.4.4.2.c *Waste Management*

- *Air Emissions*

The State of Maryland has adopted the NAAQS and incorporated them into the Ambient Air Quality Standards (COMAR 26.11.04) (MDE 2002a). Any federal actions producing emissions of O_3 or its precursors at Fort Detrick must not cause or contribute to any new violation of the air quality standard or delay the timely attainment of any air quality standard since Frederick County has been designated as a nonattainment area for O_3 (MDE 2002b).

The air quality program at Fort Detrick is in accordance with the benchmark federal and DoD regulations enumerated in Section 2.3.4.1. Fort Detrick complies with the requirements of AR 200-1 concerning the emission of pollutants into the air to protect human health and to meet all applicable federal, state, and local regulations. The USAG Environmental Office is responsible for the air quality program at the installation (Wolf 2002).

The MDE ARMA, the primary air quality regulatory authority in the state, issued Air Permit to Operate (PTO) No. 10-00131 to the Fort Detrick USAG for two medical waste incinerators located in Area A of the installation. The original permit expired 31 March 1999; however, MDE has granted automatic extensions through 2002 on two temporary PTOs, Nos. 10-000131-2-0066 and 10-000131-2-0067 (Wolf 2002, Fort Detrick Environmental Office 2002). The MDE ARMA also issued PTO No. 2000-WIN-0341, valid through 25 June 2005, for two municipal solid waste incinerators located on Area A (Fort Detrick Environmental Office 2002).

According to Title V of the CAA, Fort Detrick is considered a major source of air pollution because emissions of criteria pollutants NO_x and SO_2 exceed major source thresholds of 25 and 100 ppm, respectively. This required the installation to submit a Title V permit application under Part 70 of the CAA to MDE in July 1997 for operation of the incinerators and other air emission sources on the installation (USAG 1998). The application was in review as of 1 December 2001, when the EPA took over the Title V permitting process from MDE. Therefore, Fort Detrick submitted a Title V permit application under Part 71 of the CAA to the EPA on 3 June 2002 (MDE ARMA 2002, Wolf 2002).

The State of Maryland emission standards program regulating TAPs includes all Title V HAPs. Since emission data for Fort Detrick indicates that TAP emissions are not more than approximately 9 metric tons (10 tons) per year for any single TAP or more than approximately 22.7 metric tons (25 tons) per year for any combination of TAPs, the installation is not required to meet emission control requirements for HAPs or TAPs (USAG 1998, Wolf 2002).

Fort Detrick completed its required Risk Management Plan to reduce the possibility of HAP emissions of chlorine. The total storage of chlorine on the installation exceeds its 680-kilogram (1,500-pound) maximum threshold; however, none of this is associated with a USAMRIID facility (Wolf 2000, Wolf 2002).

- *Solid Waste*

The Fort Detrick Solid Waste Management Section is responsible for disposing of all solid waste generated at USAMRIID under MDE Refuse Disposal Permit No. 2000-WIN-0341, which expires 25 June 2005. Ultimate disposal of solid waste is at the Fort Detrick Landfill on Area B of the installation, either in its original form or as ash produced by the incineration of solid waste, conducted at the Incinerator Complex on Area A. The Solid Waste Management Section also handles the incineration activities (USAMRIID 2001a, Fort Detrick Environmental Office 2002).

As of 2000, USAMRIID typically generates approximately 150,350 kilograms (331,460 pounds) of municipal solid waste and incinerates 57,370 kilograms (126,478 pounds) of it per year (USAMRIID 2000a). The incinerator ash is tested for Toxicity Characteristic Leaching Procedure (TCLP) on a quarterly basis for the municipal solid waste ash and semiannually for the medical waste ash (Dressler 2002).

- *Wastewater*

As of 2000, USAMRIID generates approximately 165,876,228 liters (43,820,000 gallons) of sanitary wastewater on an annual basis, including an estimated 93,885,491 liters (24,802,000 gallons) of potentially contaminated wastewater directly generated from laboratory activities (USAMRIID 2000a). All potentially contaminated wastewater is discharged to the laboratory sewer system and treated at the Steam Sterilization Plant (SSP) on Area A of Fort Detrick. The SSP also provides treatment for 1,025,843 liters (271,000 gallons) per year of influent originating from non-CBDP activities. The SSP operates 24 hours per day through the year, barring occasional steam outages. Influent entering the SSP undergoes grinding before flowing into six 189,270-liter (50,000-gallon) holding tanks in the basement of the SSP building. It is then pumped into nine 189,270-liter (50,000-gallon) aboveground holding tanks, which are located in a concrete spill-containment basin outside the SSP building. The potentially contaminated wastewater is fed from these tanks into four steam sterilizers, where live steam is injected to maintain a temperature of 121.1 degrees Celsius (°C) (250 degrees Fahrenheit [°F]) for either 20 minutes or 11 minutes, depending on the sterilizer tank. Heat exchangers cool the discharging treated wastewater to preheat the influent to the sterilizers (USAG 1997). Sterilized effluent from the SSP is discharged into the sanitary sewer system (USAMRIID 2000a, USAG 1998).

All sanitary wastewater at Fort Detrick, including the SSP effluent, undergoes conventional primary and secondary treatment at the Fort Detrick WWTP located on Area C. The treated effluent is discharged into the Monocacy River under NPDES Permit No. MD0020877 and State Discharge Permit No. 97-DP-2527, issued by MDE. The NPDES permit, which expires 31 August 2003, allows a maximum discharge of 4.6 million liters (1.2 million gallons) per day (USAG 1997, Fort Detrick Environmental Office 2002).

Fort Detrick discharges storm-water runoff subject to provisions of NPDES Permit No. 97-SW, which requires the installation to maintain a Storm Water Pollution Prevention Plan (SWPPP). The SWPPP identifies potential sources of pollution and pollutants of concern associated with industrial activity for the runoff, and it minimizes potential contamination of

storm-water runoff by implementation of Best Management Practices (USAG 1997). This permit expires on 30 November 2002 (Fort Detrick Environmental Office 2002).

- *Hazardous Waste*

As of 2000, approximately 4,711 kilograms (10,385 pounds) of hazardous waste are generated each year from USAMRIID activities (USAMRIID 2000a). USAMRIID Regulation 385-30, *Chemical Hygiene Plan*, sets forth the procedures and policies for handling hazardous chemicals from procurement to final disposal of unused chemicals and hazardous waste. Area A of Fort Detrick is registered as a hazardous waste generator, No. MD8211620267, under RCRA regulations (USAMRIID 2000a, Fort Detrick Environmental Office 2002).

The Defense Reutilization Marketing Office contracts for disposal of hazardous waste at Fort Detrick (USAMRIID 2001a). The Hazardous Material Management Office has responsibility for handling and storing hazardous waste on Fort Detrick. The primary TSDF utilized by Fort Detrick is Cyclechem, Inc., in Lewisberry, Pennsylvania, which places the waste into storage pending shipment to a permitted TSDF for incineration. There is no on-site disposal or destruction of hazardous waste at Fort Detrick (Leodore 2002).

- *Medical and Infectious Waste*

As of 2000, USAMRIID generates an estimated total of 3,965 kilograms (8,742 pounds) of regulated medical waste per year, consisting predominantly of sharps and animal waste (USAMRIID 2001a). The USAMRIID SRPO oversees destruction and transportation of medical waste (USAMRIID 2000a). All medical waste is contained in bags and incinerated in Fort Detrick's medical waste incinerators, which are located in the incinerator complex in Area A. Ash from the incinerated medical waste is then transported to the Fort Detrick landfill on Area B for disposal (USAMRIID 2001a).

Animal carcasses from LARF are included in the medical waste sent for disposal in the medical waste incinerators on Area A. Since research activities at LARF do not generate infectious waste, animal bedding and waste from there are disposed by spreading on the pastures adjoining LARF, in accordance with USAMRIID SOP UIR501 (USAMRIID 2000a).

The medical waste incinerators operate under temporary PTO Nos. 10-000131-2-0066 and 10-000131-2-0067, issued by the MDE ARMA (see Section 2.4.4.2.c). The SRPO conducts sampling and analysis of ash from the incinerators, with quarterly testing of free liquids and semiannual testing of TCLP, and reports the results to MDE under terms of the PTOs (USAMRIID 2000a).

- *Radiological Waste*

Radiological waste generated by USAMRIID activities includes the licensed radioisotopes, uranyl acetate, and sealed instruments or articles containing radioisotopes (USAMRIID 2001a). Packaging procedures are conducted in accordance with the benchmark NRC and

DOT regulations listed in Section 2.3.4.6, as well as applicable state and disposal facility requirements and Fort Detrick Regulation 385-3, *Microbiological Safety*, dated 1 November 1990. Packaged radiological waste is sent to the Radioactive Waste Storage Facility on Area A, which is operated by the Directorate of Installation Services (DIS). The Radiation Waste Manager coordinates the disposal of all radiological waste in accordance with MEDCOM Regulation 40-42, dated 20 March 2002, and other applicable regulations (USAMRIID 2002b).

Commercial carriers transport all radiological waste from Fort Detrick to a contracted facility where the waste ultimately is incinerated. The OSC acts as the contract manager between USAMRIID and OSC-approved disposal facilities for radiological waste (USAMRIID 2001a).

2.4.4.3 Safety, Health, and Security Mitigation

USAMRIID activities are conducted in accordance with safety policies and procedures, which incorporate accepted general, biological, chemical, and radiological safety practices, as well as the safety regulations listed in Section 2.3.5. These benchmarks ensure the health and safety of workers at the installation and the public.

2.4.4.3.a <u>*Safety*</u>

The SRPO is responsible for the safety program for USAMRIID, including preparation of regulations and initial training in biological containment laboratory operations and hazard communication. The Facility Safety Plan (FSP), USAMRIID's *Safety Program Manual* (USAMRIID 1995), details the significant potential operational hazards and mitigation measures established to ensure that USAMRIID facilities are operated in a safe manner. Safety regulations relevant to USAMRIID operations are included in the FSP, along with site-specific safety provisions for USAMRMC, USAG, and each USAMRIID division (USAMRIID 2000a).

The policies, responsibilities, and procedures of the FSP are contained in USAMRIID Regulation 385-14, *Safety Program*, dated 3 June 1991. This regulation provides procedures for the development, approval, and implementation of SOPs. Other USAMRIID regulations noted below provide requirements for facility engineering and work practice controls, emergency preparedness, training, SOPs, and other safety guidelines and requirements (USAMRIID 2001a).

- *Biological Safety*

  USAMRIID research activities using etiologic agents follow the benchmark regulations and guidelines on biological safety enumerated in Section 2.3.5.1. In addition, USAMRIID Regulations 385-3, *Microbiological Safety*, 1 November 1990, and 385-4, *Institutional Biosafety Committee*, 1 November 1990, establish the policies and responsibilities for the microbiological safety program. The Institutional Biosafety Committee reviews all microbiological research, including work involving rDNA (USAMRIID 2000a).

  USAMRIID activities with etiologic agents use BSL-2, BSL-3, and BSL-4 containment facilities and their associated engineering controls. USAMRIID Regulation 385-9, *Biosafety*

Level 2 Operations, dated 1 December 1990, was established to provide operating procedures for work with moderate risk agents. USAMRIID Regulation 385-69, *Biocontainment Laboratory Operation (BSL- 3 and 4)*, dated 1 March 1995, provides operating procedures for activities involving work with the higher risk level BSL-3 and BSL-4 agents. All experimental studies must be conducted in Class II or Class III BSCs, and the animals must be contained in cages within Class III BSCs or in partial containment cages. The Commander of USAMRIID is responsible for determining the appropriate BSL/ABSL (USAMRIID 2000a, USAMRIID 2001a, USAMRIID 2002b).

Safety protocol for BSL-3/ABSL-3 and BSL-4/ABSL-4 suites includes engineering and work practice controls. The laboratories are locked at all times. Two sets of doors must be entered to access biological containment areas. An electronic key card system restricts entry to the laboratories from access corridors or other laboratories to authorized personnel. A clearly demarcated zone separates the laboratory areas from nonlaboratory areas. Personnel must change into long-sleeved laboratory clothing and pass through a room-sized airlock prior to entering the suite. Before leaving the laboratories, personnel must deposit their laboratory clothing in a laundry container, then shower and change into street clothes in the anteroom. Upon exiting biological containment areas, personnel must wash their hair if they did not wear a cap in the suite. Shoes that are worn in these areas must be left in the change room (USAMRIID 2000a).

USAMRIID regulations in the FSP restrict the flow of people, equipment, animals, and experimental materials into the suites to prevent cross-contamination of adjacent areas or a breach in containment. Entry to BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities is limited to personnel directly involved with the work, as mandated in DA PAM 385-69 and USAMRIID Regulation 385-69. Authorized personnel must be informed of the potential hazards associated with entry and the safeguards necessary for their safety. The suites must have signs posted on the entry doors indicating the BSL-3/ABSL-3 or BSL-4/ABSL-4 designation, agent(s) in use, and individuals to contact in case of an emergency (USAMRIID 2000a).

Common PPE worn in all laboratories includes gloves, respirators, goggles, face shields, and hearing protection (as needed). Other PPE requirements are specific for each laboratory, depending on the BSL/ABSL designation. Personnel must wear a fully fastened laboratory coat in BSL-1 and BSL-2 areas or special laboratory clothing in BSL-3/ABSL-3 and BSL-4/ABSL-4 areas. In BSL-4/ABSL-4 laboratories, personnel also are required to wear a one-piece positive-pressure protective suit ventilated by its own air supply system. Personnel are required to wear a surgeon's mask, latex gloves, and other appropriate PPE during the handling of animals. Personnel must wear a mask, goggles, and gloves during decontamination and removal activities of animals or equipment from a Class III BSC (USAMRIID 2000a).

Prior to leaving BSL-3/ABSL-3 and BSL-4/ABSL-4 suites, decontamination must be performed by using germicides to disinfect room surfaces and exterior surfaces of certain items. Positive pressure suits must be decontaminated with a chemical disinfectant shower prior to a worker leaving a BSL-4 laboratory. In addition, potentially contaminated work

materials must be rendered innocuous by chemical disinfection or autoclaving prior to removal from BSL-3/ABSL-3 and BSL-4/ABSL-4 suites. All waste from BSL-4/ABSL-4 suites is autoclaved twice prior to removal from the suites.

BSL-3 and BSL-4 facilities at USAMRIID meet or exceed criteria for engineering controls set forth in the guidelines (CDC/NIH 1999). The airflow in the BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories is controlled to achieve the required containment. Each suite is composed of several rooms with individual temperature controls. In the larger USAMRIID building, each BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratory is an airtight suite, while the smaller building may be considered as a single large suite. Each suite has its own dedicated air-handling system, including backup exhaust fans and HEPA filters. The BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories are maintained under negative air pressure relative to their surrounding hallways, ensuring a net flow of air into each suite. Office space in both buildings (outside the suites) is maintained under positive pressure to the hallway. Also, air pressure differentials are maintained within each suite to ensure internal airflow from change rooms and entry airlocks; through in-suite conference rooms, offices, and central hallways; and to the research laboratories and animal rooms. The airlocks are constructed with double doors and electronically controlled magnetic locks to ensure that only one door can be open at a time, which helps to maintain the required pressure differentials. Magnehelic gauges mounted adjacent to the door of each laboratory and equipment room and above the emergency exit door of each suite provide visible indications of the pressure differentials.

The BSCs within the suites are also maintained under negative pressure. Class II Type A BSCs are used in both BSL-3/ASBL-3 and BSL-4/ASBL-4 suites. However, Class III BSCs are used exclusively in BSL-3/ABSL-3 suites to ensure that a highly hazardous etiologic agent is not introduced into laboratory air. Air passes through a HEPA filter upon discharging from Class III BSCs and is then conveyed directly into the laboratory exhaust system. All BSCs are inspected and certified for performance semiannually or annually according to USAMRIID Regulation 385-7, *Biological Safety Cabinet and Chemical Fume Hood Monitoring and Certification Program*, dated 3 February 1997, and USAMRIID Regulation 385-68, *Class III Biological Safety Cabinet and Glove Box Monitoring and Field Certification Program*, dated 15 April 1998 (USAMRIID 2000a).

Utility systems for the suites were designed to ensure containment of etiologic agents. Each laboratory suite has a dedicated once-through air handling and exhaust system with a HEPA filter (two HEPA filters in series for air from the BSL-4 laboratory). Filtered exhaust air is vented to the outside of the building and is discharged in low-traffic areas at least 15 meters (50 feet) away from any fresh air intakes. Liquid waste from laboratory sinks, BSCs, autoclaves, showers, and toilets is discharged directly into the laboratory sewer system to be decontaminated centrally at the SSP (see Section 2.4.4.2.c). HEPA filters protect the sewer line vents. The central vacuum system serving the BSL-3/ABSL-3 and BSL-4/ABSL-4 suites has in-line HEPA filters at each service lift, which are designed for in-place decontamination and replacement. Traps and/or filters are used to prevent backflow contamination in liquid and gas mains (USAMRIID 2000a, USAMRIID 2001b).

The walls, floors, and ceilings of rooms within the suites are constructed as a sealed, pest-proof internal shell to facilitate cleaning and decontamination. The walls and floors are painted with epoxy, and all wall penetrations are sealed. The floor drains are connected to the liquid waste decontamination/holding tank system to ensure containment of spent disinfectants and decontaminants. The holding tanks discharge into the laboratory sewer system and, ultimately, to the SSP.

All of the air supply systems in the BSL-3 and BSL-4 laboratories have alarms, backup supply compressors, emergency breathing-air tanks, and a HEPA filter. The positive-pressure suits worn in BSL-4 suites contain an emergency air supply (i.e., bottled compressed air), which serves as a further backup system to the supplied airline. Unique to the BSL-4/ABSL-4 areas are a duplicate exhaust fan and a battery-operated emergency power source that is activated automatically during any power outage to provide emergency lighting and alarms. Heat detectors are mounted on the ceilings in each suite. Visible and audible fire alarm systems are present in both main USAMRIID buildings (USAMRIID 2000a).

Each suite has two steam autoclaves for sterilization. Materials exiting the laboratory are decontaminated via a pass-through autoclave. The autoclave door that opens to the corridor outside of the suite is sealed to the outer wall and is automatically controlled to ensure that it cannot be opened until the autoclave sterilization cycle is complete. Also, the airlock may be sealed for decontamination of large items prior to removal from a BSL-3/ABSL-3 or BSL-4/ABSL-4 containment area (USAMRIID 2000a). Items that cannot be autoclaved are decontaminated via a pass-through surface decontamination system, fumigation chamber, and ultraviolet light treatment chamber. The fumigant is paraformaldehyde (PFA), or in rare cases, ethylene oxide. Procedures for sterilizing items are specified in USAMRIID Regulation 385-69 and USAMRIID Regulation 385-17, *Area Decontamination Procedure Using Paraformaldehyde* (USAMRIID 2001a).

Etiologic agents must be packaged or transported in accordance with AR 385-69 and USAMRIID Regulation 385-13, *Shipment of Materials*, dated 3 April 2000. Proper primary and secondary containers are used by USAMRIID laboratory personnel to package etiologic agents. The packaging process is completed by personnel in the Materiel Control Branch, Logistics Division. Prior to transport by commercial carrier, the packaged etiologic agents are sent to the USAG Transportation Office for a chain-of-custody record. Researchers are prohibited from transporting etiologic agents on their person (USAMRIID 2000a).

- *Chemical Safety*

Chemical safety at USAMRIID is in accordance with the benchmark guidelines described in Sections 2.3.3 and 2.3.5.2, as well as USAMRIID Regulation 385-29, *Hazard Communication Program*, dated 29 December 1999, and the CHP, which are included in the FSP. The CHP establishes policies and procedures for the handling of hazardous chemicals and meets the requirements of 29 CFR 1910.1450, including the following safety tests or procedures: medical monitoring, preparation of written training protocols and SOPs, use of MSDSs and labels, and certification of safety apparatus.

In addition, work areas must provide detailed SOPs for the safe use, handling, and disposal of hazardous material. An inventory of chemicals is maintained by the CHO. Information about handling controlled substances, chemical acquisition and storage, potential health risks, environmental monitoring, PPE, use of fume hoods, safety procedures, inspections, and laboratory audits is provided in the CHP and laboratory-specific procedures (USAMRIID 2001a).

USAMRIID periodically decontaminates the BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities, including the BSCs and HEPA filters in the ventilation systems, using PFA to prevent the release of infectious microorganisms from containment areas. The EPA granted Quarantine Exemption Permit No. 99-DD-01 (effective 6 July 1999 through 5 July 2002), exempting this PFA use from notification and reporting requirements under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Decontamination policies, responsibilities, and procedures are provided in USAMRIID Regulations 385-2, *Decontamination of Equipment and Materials Using Paraformaldehyde*, dated 19 June 1998, and 385-17, *Decontamination of Containment Areas with Paraformaldehyde*, dated 19 February 1999 (USAMRIID 2001a). Between 1997 and 1999, an annual average of 26.8 kilograms (59 pounds) of PFA was used. Formaldehyde gas, which is produced when PFA flakes or prills are heated, effectively destroys the infectious substances present in the laboratories, equipment, materials, and air-handling systems. The formaldehyde gas is then neutralized using ammonium bicarbonate powder (USAMRIID 2000a). Before workers can reenter the suites, the air is tested to confirm that the formaldehyde concentration is below the OSHA action level of 0.5 ppm (USAMRIID 2000a, USAMRIID 2001a).

- *Radiological Safety*

NRC guidelines for radiological safety (see Section 2.3.4.6) apply for work at USAMRIID using the gamma irradiation cells or radioisotopes. The SRPO has responsibility for radiological safety.

2.4.4.3.b *Occupational Health*

All USAMRIID personnel working in BSL-3 or BSL-4 containment areas are enrolled in a medical monitoring program and in the SIP, as required under the benchmark regulations and guidelines noted in Section 2.3.2. Laboratory workers and support staff in the SIP are immunized with investigational or licensed vaccines, when available, before beginning any activity with etiologic agents. Prior to immunization, SIP participants undergo complete medical evaluations and must receive medical clearance. They must be informed of possible adverse reactions to the vaccine and sign an informed consent document prior to immunization. Joining the SIP is considered to be equivalent to human clinical trial status, and participation is voluntary (USAMRIID 2000a). A worker who cannot be immunized for medical reasons when a vaccine is available for an etiologic agent is not permitted to work with that agent and is not allowed in any laboratory where work with that agent is being conducted (USAMRIID 2001b).

Maintenance workers, engineering staff, and other support personnel who are required to enter BSL-3 and/or BSL-4 facilities also may be enrolled in the SIP and receive biosafety training. This includes personnel from the DIS and the Fort Detrick Fire Department (FDFD)

(USAMRIID 2001b). They must have specific authorization for such entry by the USAMRIID Commander. They are required to use appropriate PPE, even though decontamination of areas and equipment is required prior to service by the maintenance and engineering staff (USAMRIID 2000a). Personnel determined to be at an increased risk of acquiring infections or for whom infection would be unusually hazardous according to their medical baseline evaluations are denied entrance into BSL-3 and/or BSL-4 laboratories.

Regulations for laboratory safety procedures, first aid, fire fighting, inspections, decontamination, access, and emergency preparedness are contained in the FSP. Personnel must read the contents of USAMRIID Regulation 385-69 and confirm that they understand it with their signature. The FSP also contains chemical safety regulations including USAMRIID SOP 385-29, *Hazard Communication Program,* and the CHP.

The CHP addresses the OSHA hazard communication requirement, as listed in Sections 2.3.5.2 and 2.3.5.4 (USAMRIID 2001b). USAMRIID Regulation 385-16, *Bloodborne Pathogens Exposure Control Plan*, dated 30 July 2002, establishes policies and procedures to address the OSHA requirement in that area (29 CFR 1910.130).

If a potential for exposure to hazardous chemicals is present, OSHA regulations require training for all personnel prior to work assignments or new tasks. Accessibility to MSDSs is discussed in the safety training. Written safety policies and procedures must be available for all laboratory personnel in accordance with these regulations. USAMRIID personnel are continually updated with information on new exposures or procedure changes (USAMRIID 2001a).

All personnel entering the USAMRIID workforce attend the Newcomers Training Briefing, which consists of fire, medical, and general safety information; OSHA and other federal regulations; USAMRIID regulatory requirements; and other pertinent information on USAMRIID and its operations. This briefing is provided by the SRPO and Logistics Division, Company Commander, and Headquarters personnel. Workers handling laboratory chemicals are trained in the complete CHP, but workers who may handle other chemicals are provided the Hazard Communication Program (USAMRIID 2000a).

The SRPO provides individuals working in BSL-3 and BSL-4 laboratories with training programs on Bloodborne Pathogens (annual), Respiratory Protection (annual), and Laboratory Safety Operations and Positive-Pressure Protective Suit Training for personnel working in BSL-4 laboratories. The SRPO also provides training for individuals working with radioactive material under the Radiation Safety Program. The SRPO and Logistics Division maintain training documents within a computerized database and paper copies of training attendance. Each USAMRIID division maintains its own Minimal Essential Training Requirements document (USAMRIID 2000a).

USAMRIID coordinates emergency preparedness with local emergency service providers and maintains formalized agreements describing the details of emergency support, in accordance with AR 385-69. The Fort Detrick Provost Marshall's Office is responsible for providing

emergency services for USAMRIID. The FDFD emergency services include HAZMAT response and emergency medical service (USAMRIID 2000a).

Emergency medical service is coordinated between the Army, Frederick County, and the Frederick County Volunteer Fire and Rescue Companies, as stated in the Mutual Aid Agreement signed on 1 October 1998. FDFD personnel initially respond to USAMRIID for a medical incident requiring removal of an individual from a laboratory area. The FDFD personnel then transfer the individual in medical distress to volunteers in the Frederick County Volunteer Fire and Rescue Association, Inc., for transportation to a local hospital. The first responders have been familiarized with the operations and configurations of USAMRIID laboratories by quarterly training exercises with the assistance of medical personnel from the Medical Division of USAMRIID. Non-Fort Detrick emergency service personnel do not enter USAMRIID laboratory areas (USAMRIID 2001b).

Prior to work involving etiologic agents, a job safety evaluation and hazard analysis are required under the benchmark guidelines and regulations discussed in Section 2.3.5.4 and AR 385-69. These procedures, which must include examination of the maximum credible event (see Section 5.12), provide careful consideration of the range of potential consequences that might result from an accident or incident during a potentially hazardous activity. In the event of an accident, review of the hazard analysis in follow-up reports provides a way to assess whether existing safeguards are adequate to protect human health and the environment (USAMRIID 2001a).

USAMRIID Regulation 385-40, *Accident/Illness/Incident of Potential Hazard Exposure - Reporting, Records, and Investigations*, dated 2 January 1991, and a flowchart referred to as USAMRIID Accident and Illness Reporting, dated 2 January 1998, require the immediate reporting of any accident or illness (USAMRIID 2000b). The SRPO of USAMRIID investigates all such reports, and the USAG Safety Office receives copies of the report forms, which are kept in the individual's medical record. Responsibilities and procedures for reporting exposures and potential exposures are included in the USAMRIID Safety Policy Regarding Illness Reporting by Employees, dated 13 May 2000 (Hawley and McKinney 2000). Personnel who are exposed to etiologic agents or who become ill from a suspected occupational disease are hospitalized and treated in the USAMRIID medical support facility (USAMRIID 2000a).

From 1997 to 2002, two LAIs have been reported at USAMRIID. In addition, there was a potential LAI in 1994 when one person experienced symptoms suggestive of eye exposure to staphylococcal enterotoxin B. The cause of these symptoms could not be determined.

One documented LAI occurred in March 2000 when a scientist developed glanders (a disease that normally affects horses, mules, donkeys, and other domestic animals but is not communicable via casual person-to-person contact) from working with *Burkholderia mallei*. The individual was hospitalized and recovered after treatment with appropriate antibiotics. USAMRIID's investigation of the incident indicated that the scientist had contracted the disease from working ungloved in the BSL-3 laboratory, a breach in safety procedures. The individual also violated another important safety procedure in delaying reporting the disease (USAMRIID 2000a).

The other LAI incident began on 31 January 2002, when an active-duty military veterinary technician reported to the USAMRIID Medical Division with symptoms of fever, pain to the back of the head, dizziness, low back pain, burning pain in his joints, sweats, and chills that began the previous day. The technician had handled and bled monkeys exposed to aerosolized VEE virus, subtype IIIa (representative strain Mucambo), on several occasions during the preceding 3 weeks. Laboratory tests confirmed that the technician was infected with that virus. The technician was referred to the Frederick Memorial Hospital in Frederick, Maryland. Seven other individuals directly involved with the aerosol procedure or veterinary support were subsequently evaluated. Since there was no breach of existing safety protocols, an epidemiological and safety investigation was initiated, and all animal aerosol challenges were suspended pending the results (Hawley 2002).

Safety inspections are integral to USAMRIID operations, in accordance with the requirements in AR 385-69 and USAMRIID Regulation 385-69. The Basic Checklist from DA PAM 385-69 (32 CFR 627) is utilized for inspections of the laboratories and animal and support facilities (Hawley 2000). Supervisors are responsible for conducting inspections of their work areas on a weekly basis. Monthly inspections of BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities are conducted in accordance with AR 385-69. Monthly inspections are conducted by the Division Safety Representatives, and the reports are submitted to the SRPO. Quarterly biosafety inspections of BSL-2, BSL-3, and BSL-4 suites and annual inspections of administrative areas are conducted by SRPO personnel (USAMRIID 2000a).

2.4.4.3.c *Security*

Security personnel continuously monitor the electronic access system and magnetic locking system that control the entry of workers and visitors to USAMRIID facilities. Physical security is monitored via exterior and interior closed-circuit television cameras. Parking near USAMRIID facilities is controlled, and a safe zone with barricades surrounding the facilities was established to protect the structure of each USAMRIID building.

The containment suites have restricted access based on a badge system that utilizes proximity readers to identify personnel. The badge system also utilizes electronic keypads for entry of personal identification numbers. Electronic access into the containment suites is permitted only to authorized individuals with medical clearance, appropriate immunization administered through the SIP, documented training, and demonstrated need.

The Agent Repository, the main storage area for etiologic agents, is located in a containment suite (USAMRIID 2000a). Only designated USAMRIID personnel are able to access the Agent Repository, which is restricted by a keypad entry system. The Fort Detrick Provost Marshall's Office electronically monitors the access procedure, and voice confirmation is required upon entry and exit through that office. Additional security measures include frequent changes in passwords and background checks for all USAMRIID personnel (USAMRIID 2001a).

Working amounts of etiologic agents are stored and secured in laboratories where RDT&E activities are conducted. Etiologic agents are stored in secured refrigerators or freezers in restricted-access laboratories or suites. The registry of agents maintained by SRPO is distributed quarterly to USAMRIID Headquarters personnel and each Division Chief for verification. Any request to work with an etiologic agent must be approved by the Commander, USAMRIID, and the SRPO. Upon completion of work with etiologic agents, the agents are disposed of by autoclaving or by chemical treatment for some toxins.

USAMRIID holds CDC Select Agent Registration No. 19970516-348 as of 12 February 1999. The registration requires documentation and reports to CDC for all incoming and outbound transfers of the listed agents (see Section 2.3.5.1). USAMRIID also has been granted permits by USDA for the transportation and use of restricted animal-derived material, specifically, serum and tissue specimens from domestic and wild animals (USAMRIID 2000a).

2.4.5 Dugway Proving Ground

Dugway Proving Ground (DPG) is located in northwestern Utah, approximately 129 kilometers (80 miles) southwest of Salt Lake City. Information about the DPG area, including details of the existing environment, is presented in Section 4.4. The CBDP activities and mitigation measures at DPG presented in this section are analyzed with respect to environmental and health consequences in Sections 5.2 through 5.14. Information on the DPG area, including discussion of the existing environment, appears in Section 4.5.

DPG is operated by the U.S. Army Developmental Test Command, which is a major subordinate command of the Army Test and Evaluation Command. The Developmental Test Command is the Army's premier testing organization for weapons and equipment. DPG's primary mission is to plan, conduct, analyze, and report the results of exploratory, developmental, and production tests of CB defense systems, smoke and obscurant illumination material, and delivery systems (DPG 2001). DPG is DoD's Major Range and Test Facility Base and primarily serves as a CB testing center (DPG 2001). DPG's functional group, which oversees the Chemical Test Division and Life Sciences Division, is the West Desert Test Center (WDTC).

CBDP activities occur in several buildings and outdoor areas of DPG. BD testing laboratory functions are based in the Baker Area. The Carr Activity Center is a primary storage location for materials and equipment required to support the various testing, training, and support activities conducted at DPG. It includes several test facilities and chambers. The Ditto Technical Center, the primary mission support center for DPG activities, also houses a chemical defense testing facility (DPG 2001).

Both indoor and outdoor facilities at DPG are used for CBDP activities. The outdoor facilities include two decontamination pads and 18 open-air test grids, which are used for CBDP field tests as well as for conventional munitions testing. Sampling positions on the grids were constructed to permit fast and efficient collection of air samples (Directorate of Environmental Programs DPG 2001, DPG 2001). Indoor facilities for CBDP activities at DPG include several laboratory buildings and large-scale chambers.

The Life Sciences Test Facility (LSTF), a 2,973-square-meter (32,000-square-foot) building at the Baker Area, has facilities for testing activities with both biological agents and simulants, with laboratories and chambers capable of working at BSL-1 through BSL-3. Also located in this area are the Baker Test Facility, which is used for training and some simulant testing activities, and various support facilities including a change house and a decontamination site for vehicles that have been used in outdoor testing activities.

In the Carr Area, the Bushnell Materiel Test Facility (BMTF) houses three test chambers with climatic and environmental controls: the Multipurpose Test Chamber for large items such as tanks and fighter aircraft; the Closed-System Chamber for small items; and the Agent Transfer Chamber, which contains two fume hoods used for chemical agent sampling, transfers, and dissemination. Also located in the Carr Area is the Chemical Agent Test Chamber, which is comprised of environmental test chambers, support structures, and equipment for testing chemical agents and industrial chemicals. It has two test chambers located side by side. The

Defensive Test Chamber, a stainless steel chamber for both BD and CD testing, is located southwest of Carr. The Defensive Test Chamber can replicate a variety of environmental conditions including wind speed and temperature.

The Ditto Technical Center includes the Combined Chemical Test Facility (CCTF), with over 3,252 square meters (35,000 square feet) of floor space in two laboratory buildings. The CCTF is used for testing of protective clothing and masks, detectors, and decontamination systems using chemical agents and simulants.

The Suppressive Shield Facility, which is located north of Camel's Back Ridge, is used for large shrapnel-producing detonations and weapons emissions characterization. Energetics, chemical simulants, decontaminants, and biological simulants can be used in this indoor facility (Directorate of Environmental Programs DPG 2001, DPG 2001).

2.4.5.1 Research, Development, Test, and Evaluation Activities

DPG's testing activities under the CBDP are associated with the Contamination Avoidance, Collective Protection, Individual Protection, and Decontamination commodity areas for both BD and CD. DPG is the nation's only CD proving ground. The BD work at DPG also is associated with the Medical Systems commodity area for production and standardization of antigens and antibodies and vaccine characterization (DPG 2001).

2.4.5.1.a Chemical Surety Materiel

Indoor and outdoor CD testing activities take place at DPG. Outdoor CD testing focuses on the Decontamination and Contamination Avoidance commodity areas. Decontamination tests are primarily conducted on decontamination pads. These pads are used to study how a chemical agent can be transferred onto an object and how best to decontaminate the object. Testing is also done on the effectiveness of decontamination equipment. Contamination Avoidance work involves testing detectors at the outdoor test grids using various dissemination systems. Only chemical simulants are allowed into the open air for test purposes. Indoor CD testing activities involve PPE, small-scale decontamination, and detector tests in test chambers or the laboratories (DPG 2001).

2.4.5.1.b High-Hazard Biological Agents

Indoor BD testing includes assaying test samples and conducting various detector, PPE, and decontamination tests, production and standardization of antigens and antibodies, and vaccine characterization. DPG has facilities for tests that require BSL-1, BSL-2, and BSL-3. There are no BSL-4 testing activities conducted at the installation. The BSL-2 laboratories are used for culture preparation, analytical tests, and handling and preparation of biological simulants.

2.4.5.1.c Aerosol Testing

The BSL-3 suite consists of multipurpose test rooms, a BSL-3 cultivation and assay room, a special-containment aerosol chamber for BSL-3 testing with pathogenic microorganisms and toxins, and the aerosol chamber support room (DPG 2001). All outdoor BD tests are conducted using only biological simulants. Aircraft or ground vehicles disseminate the simulants as

aerosols to test equipment under simulated battlefield conditions. In addition, the effects of wind and weather on dispersion patterns, decontamination procedures, and equipment penetration can be examined.

2.4.5.1.d *Animal Care and Use*

Laboratory animals are used at DPG mostly for antigen production, but occasionally they support BD testing such as vaccination tests. Animals such as rabbits and mice are injected with small amounts of antigen, and then the antibodies produced by the animals are collected. Animals are maintained in the animal care/holding area in the LSTF. Exposed animals are maintained in one of the multipurpose test rooms. Whenever animals are used, DPG adheres to the benchmark policies and regulations enumerated in Section 2.3.1.

The Life Sciences Division of DPG received full AAALAC accreditation in June 1997 and was reaccredited in 2000 (Mohr 2002). In accordance with USDA regulations for animal use, DPG established an Installation Animal Use Committee, which reviews and evaluates each proposed use of animals and prepares an animal use protocol. The Committee also inspects all animal use facilities. The DPG Commander must approve the use of animals (DPG 2001).

2.4.5.1.e *Vaccine Development*

Vaccine development is not conducted at DPG as of 2002.

2.4.5.1.f *Genetically Engineered Microorganisms*

GEMS are not used in CBDP activities at DPG.

2.4.5.1.g *Human Subjects*

Some DPG tests do use human subjects. Man-in-simulant testing is done on a regular basis with methyl salicylate.

2.4.5.1.h *Radiological Testing*

The Life Sciences Division of DPG holds NRC License No. 12-00722-06, which expires 31 August 2008, for use of radioactive materials for testing purposes. The LSTF may use radionuclides as tracer materials under this license.

2.4.5.1.i *Open-Air Laser Testing*

Open-air laser testing is conducted at DPG. Many of the standoff detector systems use lasers (DPG 2001).

2.4.5.1.j Support Work

The CHPs address use and handling of nonhazardous materials and supplies and minor maintenance of laboratory equipment (see Section 2.4.5.3.a).

2.4.5.2 Operations, Maintenance, and Waste Management Activities

Two functional groups at DPG have responsibilities for OMWM activities: Base Operations and Special Staff. Base Operations provides basic services that support installation operations including maintenance, security, supply operations, and utilities. The Special Staff unit manages DPG's health and safety and environmental programs, fire fighting, and response to medical and HAZMAT emergencies (DPG 2001).

2.4.5.2.a Operations

Electrical power consumption at DPG amounted to 25,104,000 kWh in 2001. It is estimated that approximately 25% of the electrical power is used for conducting CBDP activities.

Approximately 3,312,373 liters (875,039 gallons) of fuel oil and 1,952,263 liters (515,735 gallons) of liquid propane gas were used to heat the buildings at DPG in 2001. Of the major buildings conducting CBDP activities, the LSTF used 340,523 liters (89,957 gallons) of fuel oil; the CCTF used 347,905 liters (91,907) gallons of fuel oil; and the BMTF used 2,180 liters (576 gallons) of fuel oil and 213,084 liters (56,291 gallons) of liquid propane gas in 2001. This accounts for approximately 21% of the fuel oil and 11% of the liquid propane gas when compared to the entire installation's fuel consumption (Pendley 2002a).

DPG potable water well production rates averaged approximately 3,406,860 liters (900,000 gallons) per day in 2000. Specific water usage is not known for the CBDP facilities, because the buildings are not individually metered (Pendley 2002a).

2.4.5.2.b Maintenance

The maintenance responsibilities of the Base Operations unit include maintenance of paved and unpaved roads and all public grounds on the installation, building repairs, and equipment maintenance. A separate group within the WDTC provides, maintains, and operates instruments for testing activities.

2.4.5.2.c Waste Management

DPG's waste management activities are conducted in accordance with a Chemical Agent Waste Management Plan, a Hazardous Waste Management Plan, a Pollution Prevention Plan, a Laboratory Quality Assurance Plan for Regulatory Compliance Analyses, and DPG SOP OI-144-I, *Standard Operating Procedure/Operating Instruction for Hazardous and Solid Waste Generating, Reporting, Packaging, Disposal and Recycling*, as well as the benchmark regulations and guidelines outlined in Section 2.3.4.4.

- *Air Emissions*

  DPG holds an air emissions permit (Approval Order No. DAQE-130-00) issued by the Utah Division of Air Quality for the LSTF.

- *Solid Waste*

DPG generates an average of about 4,409 metric tons (4,860 tons) per year of solid waste based on 2000 and 2001 data. This includes sanitary, construction, and demolition waste; autoclaved biological agent-related and medical-related waste; nonhazardous portions of munition and energetic waste; and smoke, obscurant, and illuminant-related waste. The amounts of solid waste from CBDP activities cannot be calculated, since tonnage is not weighed for individual buildings (Bate 2002).

This solid waste is disposed of in the English Village Landfill, a Class II Noncommercial Solid Waste Landfill operated under Solid Waste Permit No. 9615, issued by the Utah Solid and Hazardous Waste Control Board. Class II landfills can accept a maximum of 18,000 kilograms (approximately 20 tons) of waste per day. The landfill, which is located about 4.8 kilometers (3 miles) west of English Village, encompasses about 60.7 hectares (150 acres). Over 60% of the landfill capacity remains as of 2001 (DPG 2001).

- *Wastewater*

DPG has four independent wastewater treatment systems in service, located at the Baker, Carr, and Ditto areas and the English Village. These systems consist of collection lines and treatment lagoons. Hazardous waste, chemical agents, and simulants cannot be disposed of into the wastewater collection lines that discharge into the wastewater treatment lagoons (Directorate of Environmental Programs DPG 2001).

The Utah Division of Water Quality (UDWQ) issued Groundwater Discharge Permit No. UGW450007, which expires 7 January 2004, for the English Village Wastewater Treatment Facility. The effluent from this lagoon is conveyed into an open ditch, which outfalls into a pond and runoff area west of the lagoon. The other three wastewater lagoons are considered "permitted by rule," exempting them from UDWQ's requirement of a groundwater discharge permit.

The daily average influent rates to the lagoons, as measured in 1999, were about 90,850 liters (24,000 gallons) per day to Baker Lagoon; 5,035 liters (1,330 gallons) per day to Carr Lagoon; and 465,612 liters (123,002 galllons) per day to the English Village Wastewater Treatment Facility. Data for the Ditto Lagoon were not available.

- *Hazardous Waste*

Chemical agent-related waste (CAW) at DPG is regulated as hazardous waste by the State of Utah under the Utah Administrative Code, Title R315, *Environmental Quality, Solid and Hazardous Waste.* In accordance with the installation's CAW Management Plan, the generators are responsible for transferring CAW to a satellite accumulation point (SAP) or a 90-day storage area for separation by type of agent and decontamination. After analytical results confirm that no chemical agent is present, the decontaminated CAW is managed like other hazardous waste (AGEISS 1999, DPG 2001).

The other types of hazardous waste generated by CBDP activities at DPG include spent charcoal/carbon filters, corrosives, laboratory chemicals, and solvents. Under the installation's Hazardous Waste Management Plan, this waste is taken to a SAP for sampling by the hazardous waste management contractor and analysis by a Utah-certified laboratory, so that the waste may be stored safely and the appropriate treatment and disposal method chosen. The waste is then moved to a 90-day storage area or to the Central Hazardous Waste Storage Facility (CHWSF), an indoor 16-bay facility with five chemical storage cabinets, located about 6.4 kilometers (4 miles) west of the main entrance to DPG. The CHWSF has operated since 1994 under a RCRA Part B permit issued by the State of Utah, which allows storage of the specified hazardous waste for up to 1 year. A licensed and permitted hazardous waste transporter removes the hazardous waste to an off-installation TSDF for ultimate disposal. The total hazardous waste generated at DPG for 1996, 1997, and 1998 averaged about 12,787 kilograms (28,190 pounds) per year (AGEISS 2000, DPG 2001).

- *Medical and Infectious Waste*

Biological agent-related waste, which includes potentially infectious waste, animal waste, PPE, agar solutions, and petri dishes, is sterilized with steam in an autoclave. Medical waste generated by the Life Sciences Division primarily consists of sharps such as razor blades, scalpels, and syringes. The sharps are collected in approved biological sharps containers, sealed shut, and autoclaved. Once autoclaved, this waste is considered to be noninfectious solid waste under Utah Administrative Code, Rule R315-316, *Infectious Waste Requirements*, and is disposed of at the English Village Landfill. It is estimated that 18 cubic meters (approximately 24 cubic yards) of medical- and biological-related waste is disposed of annually (DPG 2001).

- *Radiological Waste*

During the baseline years of 1996 through 1998, no radioactive material was used at DPG, and no radioactive waste was produced. When radiological waste is generated, it is managed according to SOP WD-L 335, *Safe Use of Radioactive Substances for Biological Investigations*. The radioactive waste is collected in approved containers and turned over to a radioactive waste contractor for disposal off the installation (DPG 2001).

2.4.5.3 Safety, Health, and Security Mitigation

CB simulants are used during outdoor testing at DPG. Simulants are used in place of the actual CB agent being studied because they have similar properties, but present less of a hazard than the agent itself. CB simulants are required for outdoor CBDP testing, because the release of biological or chemical agents into the open air is strictly prohibited by law (50 USC 1512). A simulant is a chemical or an organism that shares at least one physical property of the biological or chemical agent under study. The simulant must be less hazardous than the agent and should be reasonably safe for handling and use without significant environmental or human health effects. Chemical simulants used include volatile or semivolatile organic compounds. Sulfur hexafluoride has been used as a vapor simulant. The organisms used as biological simulants for open-air testing outside of the LSTF are classified as BSL-1 (organisms commonly found in nature that have been determined to present minimal risk to humans or the environment).

Environmental assessments have been prepared for the use of the chemical and biological simulants at DPG (DPG 2001).

2.4.5.3.a *Safety*

- *Biological Safety*

The DPG Biological Safety Committee provides oversight for all biological testing activities at DPG. This committee is required to review testing plans to ensure that the tests are conducted safely and in compliance with guidelines (CDC/NIH 1999) and applicable benchmark regulations (see Section 2.3.5.1). Organisms that are BSL-3 or lower and that have been approved through the environmental and test review process can be used for BD testing at DPG. The LSTF is the only DPG facility where biological agents can be used for testing purposes.

Specific DPG SOPs for BD testing include WD-L SOP 326, *The Laboratory Safety Manual*; WD-L SOP 327, *Control and Audit of Infectious Microorganisms and Toxins;* WD-L SOP 328, *Safety Guide for Work with Toxins at the LSTF*; WD-L SOP 330, *Safety Guide for Working in the High-Containment, Biosafety Level 3 Laboratories in the LSTF*; WD-L SOP 332, *Chemical Hygiene Plan for the Safe Storage, Handling, and Use of Hazardous Chemicals in WD-L;* and WD-L SOP 335, *Safe Use of Radioactive Substances for Biological Investigation.*

DPG Regulation (DPGR) 70-3, *Test Coordination and Conduct Manual,* requires that any indoor tests that use biological agents include procedures to verify that the assigned laboratory or test chamber meets the following specific BSL requirements: to verify that test personnel meet required safety, occupational health, and medical requirements; to ensure health clinic and emergency response personnel are readily available in case of an emergency; to review microbiological techniques to ensure test personnel understand and are competent to perform the required test procedures; and to inspect engineering controls and test equipment.

At the LSTF, safety is achieved through administrative and engineering controls in accordance with the guidelines (CDC/NIH 1999). The engineering controls include: HEPA filters for the air vents; waste drain air vents and vacuum lines; fume control hoods; three Class III BSCs; self-closing double doors to the BSL-3 area; air lock rooms between the BSL-2 and BSL-3 laboratories; and use of negative air pressure to prevent air from flowing out of the test area. The building has eight autoclaves to sterilize laboratory equipment. Numerous emergency showers and eyewash sinks are located throughout the LSTF (DPG 2001). The administrative controls consist of record keeping, training, PPE, and compliance with the safety-related regulations and procedures. Required record keeping includes records of accidents, investigation and inspection reports, and inventory and etiologic substances usage. The training covers proper handling and use of hazardous chemicals and biological agents as well as evacuation procedures. All personnel must wear the required PPE (DPG 2001).

HEPA-filtered exhaust air from hoods and BSCs, engineering controls for biosafety at the LSTF, are incorporated into the air emissions permit. The filtered air from dedicated ventilation hoods is directly vented outside of the laboratory building. The other facilities that conduct CBDP activities also have engineering controls to prevent materials from being released into the atmosphere. At the BMTF, the three test chambers are equipped with both HEPA filters and vapor filtration (carbon) units. The BMTF also has a vapor filtration system designed for the specific gaseous waste streams from the BMTF. The system consists of a large-particle prefilter, a HEPA filter, five banks of carbon filters, and a final HEPA filter. The CCTF also has vapor and air filtration. Exhaust air from all the laboratory areas is charcoal filtered before venting to the atmosphere. Air from the fume hoods is discharged through HEPA and charcoal filters in series.

Limits are applied to the maximum quantities of a particular type or strain of biological agent that can be present in the LSTF at any time or that can be used in a single aerosol test in the LSTF. All infectious biological agents must be handled in an appropriate BSC. All toxic materials must be handled in fume hoods, glove boxes, or an appropriate BSC.

The test equipment must be decontaminated after use. The decontamination procedures described in WD-L SOP 326 include the use of chlorine bleach, gaseous formaldehyde, and vaporized hydrogen peroxide. When a test with biological agents is complete, the test officer submits a formal notice and certifies in writing that the biological agent has been properly disposed of, either by destruction or by return to the secured biological holding area. When a biological agent is destroyed, a certificate of destruction records the method and date of destruction, name of the responsible person, and witnesses.

Biological agents are shipped to DPG for test purposes or shipped from DPG to other locations for analysis. Biological agents and simulants are packaged, labeled, and shipped in accordance with the benchmark regulatory requirements enumerated in Section 2.3.5.1.d (DPG 2001).

- *Chemical Safety*

Besides the benchmark regulations for CD testing safety (see Section 2.3.5.2), applicable DPG regulations include DPGR 50-1, *Chemical Surety Program*, and DPGR 385-4, *Chemical Agent Safety Regulation*. SOPs for CD testing safety include DP-0000-M-101, *Operation of the Bushnell Materiel Test Facility*; DP-000-S-121, *Operation of the Defensive Test Chamber*; DP-0000-S-106, *Emergency and Decon Procedures for the Chemical Agent Test Chamber*; DP-0000-M-70, *Laboratory Toxic Agent Operations and Safety;* and WDC-SAF-002, *Chemical Hygiene Plan for the Chemical Laboratory*.

Additional requirements for all CD testing include procedures to verify that test and monitoring personnel have proper training; that engineering controls are in place and functioning correctly; and that emergency response equipment specific for the type of chemical agent test is available in sufficient quantities and functioning correctly. Responsibilities for proper use of respiratory protection and other PPE, including fitting and all required inspections, rest with each facility at DPG.

In ongoing CD tests, an operational readiness inspection must be conducted before the commencement of any new chemical agent operation and before implementing any changes to operations. In the case of new tests, or the restart of existing tests, a preoperational safety check must be conducted. The on-installation transport of chemical agents to the chamber facilities must be in accordance with SOPs and supporting hazard analyses.

Engineering controls at the BMTF, CCTF, Chemical Agent Test Chamber, and Defensive Test Chamber include HEPA air filtration and/or vapor filtration to remove chemical agent materials before exhaust air is released to the atmosphere; negative air pressure; fume hoods; glove boxes; double doors; and air lock rooms. These facilities also have emergency generators, tanks for handling spent decontamination solutions and spills, and showers and eyewash stations (DPG 2001). Administrative controls for chemical testing include record keeping, training, the use of PPE, and compliance with safety-related regulations, pamphlets, and SOPs.

Administrative controls for CD testing require that all personnel working with chemical agents must be trained in the use and handling of chemical agents, PPE, and decontamination procedures. Neat or highly concentrated chemical agents require more stringent safety, security, and accountability controls, including the requirement that testing be conducted in the presence of at least two individuals. In the BMTF and CCTF, individual containers for neat chemical agent storage are no larger than 1 liter (0.26 gallons). Neat chemical agents may be stored in refrigerators in a metal can or over a metal spill tray. Containers of neat chemical agents are marked with a label indicating "TOXIC CHEMICAL" and other descriptive information.

- *Radiological Safety*

Radiological safety is covered in the CHPs.

2.4.5.3.b *Occupational Health*

Protective measures to ensure worker health and safety include training and medical monitoring of personnel, in accordance with the benchmark regulations and guidelines listed in Section 2.3.5. The Employee Health Monitoring Program for the LSTF is in accordance with both the guidelines for biosafety (CDC/NIH 1999) and AR 385-69.

The DPG Commander is responsible for enforcing DA safety regulations and applicable DoD and OSHA requirements for all persons employed at the installation. A comparison of injury/illness rates for DPG to those for the general, manufacturing, and chemical industries (using the OSHA database for major industries in the United States) showed that DPG had lower rates (DPG 2001).

Wildland fires are common in and around DPG, particularly in the summer months. DPGR 420-8, *Fire Prevention and Protection Program*, and DPG's Fire Management Plan (Horman et al. 2000) establish responsibilities and procedures for prevention, control, and extinguishing fires on the installation. DPG has its own fire department and provides engineering and administrative controls to ensure that fire would not result in a release of chemical or biological agents. All

vegetation is removed from areas around the laboratory buildings. The buildings are constructed to withstand natural disasters, and all buildings containing chemical or biological agents are under 24-hour security monitoring (DPG 2001).

There are two separate emergency evacuation plans for DPG workers. The Disaster Control Plan (DPG 1986) serves as the master plan for emergency response at DPG and specifies emergency evacuation procedures for a natural or man-made disaster. The LSTF Emergency Evacuation Plan, as described in WD-L SOP 329, *Emergency Evacuation Plan, Life Sciences Division,* prescribes the procedures for safe and effective evacuation of personnel working in high-hazard areas.

In accordance with AR 385-69, DPG must coordinate emergency preparedness with local emergency service providers and maintain formalized agreements describing the specifics of emergency support. DPG has agreements or is included in agreements with the Deseret Chemical Depot for responsibilities in the event of a chemical accident/incident; Evans U.S. Army Community Hospital, Latter Day Saints Hospital, University of Utah Hospital, and three other regional medical centers for treatment of CB operations patients; Utah Highway Patrol and Tooele County Sheriff's Department for accident/incident support; Tooele Army Depot Health Clinic for medical support; and the Tooele Fire Department for firefighting support. The Tooele County Emergency Operations Plan provides guidance for county personnel in the event of a natural or man-made disaster, including hazards that may result from DPG activities (DPG 2001).

SOP DP-0000-M-80, *CAIRA*, documents the procedures that have been established in the event of an accident resulting in physical trauma, chemical spill, or potential exposure to HAZMATs. Similarly, the Biological Emergency Response and Assistance Program stipulates procedures to follow in case of a biological mishap or suspected exposure and provides direction for notifying DoD authorities and local and state officials (DPG 1996).

There were no accidents or injuries at DPG facilities while performing CBDP activities in the 10-year period 1992 through 2001 (McBride 2002). There have been no LAIs at DPG over the 25-year period 1977 through 2001 (Mohr 2002).

The Safety Officer ensures that safety inspections are performed at least quarterly and/or prior to the start of hazardous operations, in accordance with WDL-SOP 326. Laboratory inspections are performed by the Safety Officer at the end of "hot" operations to check for proper decontamination and to ensure documentation of proper decontamination. The Safety Officer also maintains all required safety records such as Safety Audits, Risk Assessments, Training, Engineering Control, Equipment Certificates, Safety Committee Minutes, and Inspection Reports.

Inspections of the BSL-3 laboratories are overseen by the Biosafety Officer, in accordance with WDL-SOP 330. The BSCs are certified annually, and face-velocity testing is conducted semiannually for all BSCs and fume cabinets. The PI ensures that daily checks are done prior to the start of any hazardous operations and that weekly safety audits are performed. The PI also

documents all the work being done including dates, logs of microorganisms used, processes, and personnel involved. The PI also maintains a current inventory of all agents used and registers each type of agent.

2.4.5.3.c *Security*

Access to DPG is granted only to those individuals with an established need to enter the installation. A car pass or visitor's pass, issued by the DPG Law Enforcement and Security Division, is required for access. Visitors are escorted by DPG personnel while on the installation. The entrance gate is manned by DPG security personnel 24 hours a day, 7 days a week.

Approximately 95% of the installation perimeter is fenced, including the entire boundary shared with the public (Pendley 2002b). The unfenced portion, which adjoins Hill Air Force Base, is posted with warning signs every 183 meters (600 feet). The entire peripheral area of DPG is checked regularly by ground patrols (DPG 2001).

Within DPG, English Village and the surrounding area is an uncontrolled-movement area, but it is patrolled by a police force. Just west of this area is the Special Authorization Area, where intermittent activities such as the rifle/pistol range practice and the National Guard training require clearance from Range Control. CB testing facilities have appropriate security measures permanently in place to prevent unauthorized access, in accordance with the benchmark security regulations listed in Section 2.3.5.5 (DPG 2001).

Some chemical agents are sent directly to DPG by the test customer; all other chemical agents are ordered through the Ammunition Accountability Branch (AAB), which is responsible for the storage of chemical agents at DPG and accounting for how the agents are used. Most chemical agents arrive at DPG on military aircraft under technical escort. When an aircraft shipment arrives, it is met by both AAB and Technical Escort Unit personnel. AAB personnel sign for the chemical agent and are provided chemical agent hazard forms. Quality Assurance Specialist Ammunition Surveillance inspects all chemical agent shipments prior to their acceptance into storage by AAB. Chemical agent shipments transported to DPG by motor vehicle are escorted into the installation in accordance with operating procedures and supporting hazard analyses (DPG 2001).

Registration and controlled storage are required for chemical agents and for BSL-2 or BSL-3 biological agents at DPG. The secured storage area consists of refrigerators and freezers within a double-locked biological holding room in the LSTF. In addition, an inventory is maintained of all items in the holding area, and all withdrawals and returns are logged. An inventory of biological agent holdings at LSTF is conducted annually. AAB conducts quarterly inventories of chemical agents. During these inventories, the amounts of chemical agents stored in various locations are determined, and all use of chemical agents during the quarter must be accounted for (DPG 2001).

2.4.6 University of Texas Medical Branch

The University of Texas Medical Branch (UTMB) campus is located within the eastern portion of the City of Galveston, Galveston County, Texas. Information about this area, including discussion of the existing environment, can be found in Section 4.6. This section discusses CBDP activities and mitigation measures at UTMB as a basis for the environmental impact analysis presented in Sections 5.2 through 5.14.

UTMB is a nonmilitary contractor for medical research activities under the CBDP. The primary contracting agencies planning to work with the University under the CBDP are the Space and Naval Warfare Systems Command and DARPA. Contamination Avoidance and Medical Systems are the principal commodity areas. High-hazard biological agents are a known issue for this site.

Laboratories located in three buildings on the UTMB campus are used to support CBDP activities. The BSL-1 and BSL-2 laboratories occupy 598 square meters (6,434 square feet), and the BSL-3 laboratories provide an additional 75 square meters (807 square feet) of floor space. Another building, which housed CBDP activities between 1997 and 2001, provided BSL-1, BSL-2, and BSL-3 laboratories (UTMB 2001a).

2.4.6.1 Research, Development, Test, and Evaluation Activities

2.4.6.1.a Chemical Surety Materiel

CSM testing is not conducted at UTMB.

2.4.6.1.b High-Hazard Biological Agents

High-hazard biological agents are used for various CBDP-related tests at UTMB. The BSL-3 laboratories are used for work with the Powassan virus. The BSL-1 and BSL-2 laboratories are used for work with the Langat, Pinchinde, and VEE viruses (UTMB 2001a).

UTMB holds CDC Permit No. 2001-12-103 “to import or transfer etiological agents or vectors of human disease,” issued 20 December 2001 and effective through 20 December 2002 (UTMB 2002a). UTMB also holds USDA Permit No. 46533 issued 31 October 2001 with expiration on 31 October 2002 for “the importation and transportation of controlled materials, organisms, and vectors” (UTMB 2002a).

2.4.6.1.c Aerosol Testing

Aerosol testing is not conducted as part of CBDP activities at UTMB.

2.4.6.1.d Animal Care and Use

Laboratory animals are required for various CBDP activities at UTMB. In the year 2000, 312 guinea pigs and 2,277 mice were used. The Animal Resources Center (ARC) is comprised of a number of animal facilities in several facilities. The Main ARC and the Medical Research Building are the largest and most complete. The ARC provides the following services for

UTMB: protocol consultation, animal model development, husbandry, special and veterinary care, stock rederivation, training and education, and grant development.

The Council on Accreditation of AAALAC conducted an inspection of UTMB in March 2001, which resulted in continued full accreditation. Animal facilities and the animal care and use programs have been accredited since 1995 (UTMB 2002d).

2.4.6.1.e *Vaccine Development*

Vaccine development activities are not conducted at UTMB.

2.4.6.1.f *Genetically Engineered Microorganisms*

GEMs are not used in CBDP activities at UTMB.

2.4.6.1.g *Human Subjects*

Human volunteers are not involved in the CBDP activities at UTMB.

2.4.6.1.h *Radiological Testing*

CBDP activities at UTMB do not involve radiological testing.

2.4.6.1.i *Open-Air Laser Testing*

Open-air laser testing is not conducted at UTMB.

2.4.6.1.j *Support Work*

The *UTMB Safety Manual* addresses the use and handling of nonhazardous materials and supplies and minor maintenance of laboratory equipment (see Section 2.4.6.3).

2.4.6.2 Operations, Maintenance, and Waste Management Activities

2.4.6.2.a *Operations*

Reliant Energy/Houston Lighting and Power provides power for UTMB. As of 2001, electrical power consumption averages 9,399,310 kWh per month, with a peak loading of 11,221,065 kWh per month. CBDP activities require an estimated 0.35% of that total. Natural gas is provided to the UTMB campus by Southern Union. Monthly natural gas use at UTMB as of 2001 averages 47,612 ccf,[5] with a peak monthly demand of 81,329 ccf. An estimated 0.032% of the natural gas is required for CBDP activities. The City of Galveston Department of Water provides potable water to the UTMB campus. Monthly water use averages 69,685,534 liters (approximately 18,409,028 gallons) for the entire UTMB campus, with a peak monthly demand of 99,560,471 liters (approximately 26,301,176 gallons) as of 2001 (UTMB 2001a). Potable water requirements for CBDP activities are estimated to account for 0.15% of that total (UTMB 2002a).

[5] ccf = 100 cubic feet.

2.4.6.2.b *Maintenance*

UTMB Facilities Operations and Management (FOAM) is responsible for safety and maintenance on campus. Their responsibilities include construction projects, master and capital planning and space utilization; repairs and proactive maintenance and exterior maintenance; and providing utilities distribution, energy management, and waste management (UTMB 2002b).

2.4.6.2.c *Waste Management*

- *Air Emissions*

  UTMB holds an air emission source permit for a wet scrubber system (No. C-18655). Permitted annual maximum emissions of criteria pollutants from the scrubber system include 2.9 metric tons (3.2 tons) of PM, 4.8 metric tons (5.3 tons) of SO_2, 14.6 metric tons (16.1 tons) of NO_x, 9.4 metric tons (10.4 tons) of CO, and 3.0 metric tons (3.3 tons) of VOCs. A retrofit of the incinerator scrubber system is expected to be completed in October 2002 and will lower the emissions from the incinerator to meet all applicable regulatory requirements of the EPA and Texas Natural Resources Conservation Commission (TNRCC) (UTMB 2002a).

- *Solid Waste*

  General solid waste generated by UTMB is estimated at approximately 4,082 metric tons (4,500 tons) annually, of which less than 0.01% is generated by CBDP activities. Browning Ferris Industries is the contractor for collection and disposal of general solid waste (UTMB 2002a).

- *Wastewater*

  UTMB discharges an annual average of 755,798,248 liters (approximately 199,661,396 gallons) of sanitary wastewater into the City of Galveston sewer system. UTMB holds permits for discharge of industrial wastewater from three specific outfalls under the City of Galveston's industrial wastewater pretreatment program. These discharges are subject to outfall-specific limits for water quality parameters, including total suspended solids (TSS); biological oxygen demand (BOD); chemical oxygen demand (COD); metals (arsenic, cadmium, total chromium, lead, mercury, nickel, selenium, silver, and zinc); hexavalent chromium; cyanides; chlorine; oil and grease; pH; and temperature (UTMB 2001a).

- *Hazardous Waste*

  The management of HAZMATs at UTMB is subject to regulation by the Texas Department of Health, TNRCC, and the City of Galveston, in addition to benchmark regulations listed in Section 2.3.4.4. Chapter 10 of the *UTMB Safety Manual* prepared by the University's Health and Safety Services (HSS) addresses the disposal of HAZMATs. It also outlines types of hazardous waste and discusses the source reduction/waste minimization program (UTMB 2001a).

  HSS administers the hazardous waste management program at UTMB. HSS arranges the transportation and disposal of hazardous waste with licensed contractors and has the

responsibility to ensure that the materials are properly packaged and labeled in accordance with EPA and DOT regulations and to maintain hazardous waste disposal records. Department managers must also keep appropriate records on the amounts of hazardous waste generated and the level of source reduction and waste minimization. Management of each department is responsible for reporting any information regarding potential sources of hazardous waste to HSS. Management must also provide safety training to all personnel who will be handling hazardous waste (UTMB 2001a).

UTMB generates an annual average of 52,682 kilograms (116,142 pounds) of CBDP-related hazardous waste and 59.4 kilograms (131 pounds) from other activities as of 2001. Ensco, Inc., is contracted by UTMB to handle the disposal of hazardous waste. UTMB holds TNRCC Permit No. 70134 for the Chemical Accumulation Facility, a 90-day RCRA storage facility for hazardous waste. The permit was originally issued on 3 June 1982 and has been amended according to waste stream changes or additions, most recently on 26 February 2001 (UTMB 2001a).

Complete written procedures on the disposal of hazardous waste are found in the UTMB policy on *Recycling/Disposal of Chemicals and Biohazardous Material (Medical Waste),* which is included in Chapter 10 of the *UTMB Safety Manual.* All personnel are required to follow these procedures and complete a Chemical Transfer form with appropriate signatures when disposing of hazardous waste. Personnel are encouraged to minimize hazardous waste and provide suggestions on hazardous waste reduction programs. The Environmental Protection Management Program of HSS is responsible for collection of all chemical waste; assistance in developing programs to reduce the amount of hazardous waste generated; and participation in the cleanup of HAZMAT spills (UTMB 2001a).

Texas state law (30 Texas Administrative Code [TAC] 335, Subchapter Q) requires that any industry generating hazardous waste must prepare a 5-year Source Reduction/Waste Minimization Plan, along with annual progress reports. UTMB outlines its Source Reduction Waste Minimization Program in the Hazardous Material Disposal chapter of the *UTMB Safety Manual* (UTMB 2001a).

- *Medical and Infectious Waste*

UTMB identifies medical waste according to the Texas Department of Health definition (TAC Title 2, Chapter 401) as microbiological waste, including cultures and stock of infectious agents; cultures of specimens from medical, pathology, research, and clinical laboratories; discarded live and attenuated vaccines; and disposable culture dishes and devices used to transfer, inoculate, and mix cultures. Medical waste also includes pathological waste such as human materials removed during surgery, labor and delivery, autopsy, or biopsy; sharps; and animal waste from animals intentionally exposed to pathogens (UTMB 2001a).

UTMB annually as of 2001 generates approximately 817 metric tons (900.6 tons) of medical and infectious waste, which consists of animal waste, sharps, and solid infectious waste (UTMB 2001a). Less than 0.01% of this is generated by CBDP activities (UTMB 2002a).

Policies and procedures for medical waste disposal, as well as responsible parties and their duties, are the same as those for hazardous waste. The off-site incinerator used to dispose of this waste is operated by Enviroclean, Inc., of Galveston (UTMB 2001a).

- *Radiological Waste*

The UTMB *Radiation Safety Manual,* prepared by HSS, addresses the disposal of radioactive material. All radioactive waste must be segregated and disposed of according to guidelines in the *Radiation Safety Manual*. The Radiation Safety Program of HSS receives and processes all radioactive materials at UTMB and records the information on a Radionuclide Data form. The end user is responsible to complete the form listing the total amount that was disposed of and return the original to Radiation Safety for record keeping. Additionally, a Radioactive Waste Disposal form identifying the contents of each radioactive waste container must be completed and attached to the container when it is ready for removal. The Environmental Protection Management Program of HSS provides appropriate containers for radioactive waste disposal and collects all radioactive waste (UTMB 2001a).

If appropriate under regulations in the UTMB policy *Disposal of Hazardous Waste*, radioactive waste materials that are soluble or dispersible in water can be released into the sanitary sewage system. Certain materials listed in the *Radiation Safety Manual* are prohibited from sewage disposal because of their chemical or biological nature (UTMB 2001a).

2.4.6.3 Safety, Health, and Security Mitigation

The *UTMB Safety Manual* outlines general safety procedures and training; accident investigation; fire protection; and laboratory, electrical, chemical, and biological safety. HSS provides advice, assistance, and technical services for the development and implementation of all environmental health and safety programs at UTMB, which includes Occupational Safety and Fire Prevention, Radiation Safety, Biological and Chemical Safety, and Environmental Protection Management.

Most safety policies at UTMB are formulated by one of the following four committees that report to HSS: General Safety Committee, Biological Safety Committee, Chemical Safety Committee, and Radiation Safety Committee (RSC). The UTMB Institutional Safety Officer of the University is assigned as the primary contact with federal, state, and local regulatory agencies with respect to safety. This position has responsibility for biological, chemical, radiation, and fire safety, as well as occupational health, hazardous waste, and environmental matters. The Institutional Safety Officer has the authority to require immediate termination of any operation that presents an imminent hazard to personnel and take any action deemed necessary to control the situation; to enter and inspect any area at any reasonable time with or without prior notification; to specify appropriate equipment for detection and control of hazards; and to recommend policy and procedures as necessary (UTMB 2001a).

2.4.6.3.a *Safety*

- *Biological Safety*

Chapter 9 of the *UTMB Safety Manual* addresses biological safety and identifies responsible parties and their duties. It also provides general guidelines for handling of biological agents, shipment of hazardous agents, transportation and transfer of biological agents, disinfection and sterilization, use of Class I and II BSCs, centrifugation procedures, handling of spills and biohazardous materials, notification of use for biological agents and rDNA, laboratory moves or closures, respiratory protection program, and reproductive hazards (UTMB 2001a).

Many of the activities regarding biological safety in the laboratories and protocols for the use of hazardous biological agents and rDNA are overseen by the Biological and Chemical Safety Program of HSS. The Program also oversees the annual certification of BSCs by an outside contractor; reviews and approves purchases of BSCs and other safety-related equipment; and surveys laboratories for compliance with approved standards and policies of UTMB and the benchmark guidelines (CDC/NIH 1999).

A Notification of Use (NOU) form is required for use of biological agents, rDNA, or other select agents when they meet the criteria specified in the Biological Safety chapter of the *UTMB Safety Manual.* NOU applications and registration documents for research involving biological agents or rDNA are reviewed and approved by the Biological Safety Committee. An NOU must also be submitted when the BSL of a project changes.

The Biological Safety Committee is responsible for all use of biohazardous agents in vitro and in vivo, as well as for rDNA uses in research laboratories. Its mission is "to support the University's fundamental objectives of teaching, research and healthcare delivery by promoting the safe use and handling of biological agents and assuring that all activities involving these agents are in compliance with the applicable guidelines, codes and regulations." General policies and standards for the safe use of biohazards at UTMB are established by this Committee. Categories of biohazardous agents are defined by the Committee to determine if specialized policies are needed for their safe use. Appropriate BSLs are assigned by the Committee in accordance with CDC/NIH policies. ABSL assignments are determined according to the respective BSL for each infectious agent used by the Animal Research Committee (UTMB 2001a).

All nondisposable equipment that is required to be sterile should be suitable for sterilization by heat. Chemical disinfectants are recommended only when sterility is not needed, disinfection by cleaning is insufficient, disinfection by heat cannot be arranged, or as a temporary measure until heat sterilization can be completed. Hycolin, a soluble phenolic disinfectant approved for use with bacteria and fungi, is applied as a 1.5% aqueous solution made up twice each week. It must be used for bacterial culture spillage, normally in all laboratories other than virology. Sodium hypochlorite or commercial bleach is used in aqueous solutions at concentrations ranging from 1,000 ppm for general disinfection purposes to 10,000 ppm for blood and virus spillage. Formaldehyde may be used only for fumigating BSCs and in restricted laboratories under supervision. When bleach or a phenolic cannot be used, 70% aqueous ethanol may be used for disinfection. Hibitane (chlorhexidine)

can be used for cell work; for surface work, it is applied at a concentration of 0.025% in 70% aqueous ethanol. According to the SOPs for the CBDP BSL-3 laboratory, the Biological Safety Officer or Laboratory Director must approve all disinfectants prior to ordering or use (UTMB 2001a).

PPE must be worn daily while working with all animal colonies, as indicated by UTMB's Infection and Control Program. Clean scrubs are required daily (or more often if needed), along with boots, rubber apron, gloves, and eye and ear protection (UTMB 2001a).

- *Chemical Safety*

Chemical safety in each department is the responsibility of the Department and the PI, who prepares safety guidelines for each laboratory and trains personnel in handling chemicals safely. The PI must also file a chemical inventory with the HSS Biological and Chemical Safety Program and report significant changes in the use of hazardous chemical agents. Personnel are monitored by the PI for safe handling practices and are encouraged to report any changes, or suspected changes, in their health. The Department and the PI also prepare and submit safety plans, as required for the use of hazardous chemicals. Chapter 8 of the *UTMB Safety Manual* addresses chemical safety (UTMB 2001a).

In addition to overseeing the safety practices in the departments, the HSS Biological and Chemical Safety Program has responsibility for coordinating ventilation surveys of chemical fume hoods, repair of exhaust fan motors, and the certification of BSCs. This program also monitors and recommends improvements to the work environment to reduce the risk of potentially hazardous exposure to chemicals, by working with FOAM to evaluate the design of facilities where chemical agents will be used (UTMB 2001a).

The Chemical Safety Committee is responsible for ensuring that all activities involving chemicals comply with all guidelines, standards, codes, and regulations. Technical procedures for the labs and safety plans for the use and storage of hazardous chemicals are reviewed by the Committee. It also reviews and approves the qualifications of applicants who submit a proposal for research. MSDSs are provided for the laboratories, as required under OSHA regulations (29 CFR 1910.122) and the State of Texas Hazard Communication Act (UTMB 2001a).

- *Radiological Safety*

UTMB holds Radioactive Material License No. L01299 issued by the Texas Department of Health and renewed on 11 January 1999 (UTMB 2002a). Under the terms of this license, the RSC can authorize qualified individuals to use radioactive materials and/or to supervise users at UTMB. The authorized user is held directly responsible for all aspects of radiation safety associated with his/her use of radioactive materials and must comply with all NRC regulations, State of Texas Regulations for the Control of Radiation (25 TAC 289), the *UTMB Radiation Safety Manual*, and policies of the RSC. The maximum amount of radioactive material approved for use at UTMB is 87 curies, of which 6.04 millicuries are available for CBDP activities (UTMB 2001a).

General policy for the use of radioactive materials and radiation-producing equipment, as well as approval for their use, is the responsibility of the RSC. An annual review of the radiation safety program is conducted by the Committee to ensure that requirements of 25 TAC 289 and the University's radioactive materials license are being met.

The UTMB Institutional Safety Officer also serves as the RSO and reports to the Director of HSS. The Radiation Safety staff of HSS oversee the use of radioactive materials at UTMB and assist the RSC in the development of general policies for control of radiation. They evaluate operational techniques and procedures, equipment, and physical facilities. They are responsible for receiving and inspecting all packages containing radioactive materials, as well as processing outgoing shipments in accordance with federal and state regulations. An inspection program and monthly wipe tests are also conducted by Radiation Safety staff. Additionally, the staff respond to emergencies and investigate accidental exposures (UTMB 2001a).

Procedures specific to each laboratory area are provided wherever radioactive materials are used. Laboratory personnel are required to routinely survey their work areas for contamination. Certain laboratory incidents must be reported immediately to Radiation Safety. These include incidents involving contamination of personnel or a large area that cannot be contained by the individual; release of radioactive material into the environment; loss of radioactive material; excess radiation exposure to lab personnel or the general public; and loss or damage to personnel dosimeters. Other less serious incidents must be reported within 1 week (UTMB 2001a).

Those requesting use of radioactive materials in animals must apply for a Radioactive Materials Use permit and describe the precautions and procedures to be used for laboratory animal handling and care. The applications are reviewed by the RSC, based on the hazard category of the radionuclide and the applicant's experience and training. Upon approval, an Animal Protocol Review is prepared by HSS to outline safety procedures for the requested use of radioactive materials and other hazardous agents (UTMB 2001a).

2.4.6.3.b *Occupational Health*

To ensure there are no unnecessary risks or hazards to participants, other staff members, or the public, the qualifications of applicants wishing to undertake research are considered prior to approval of their applications (UTMB 2001a).

Requirements regarding employee safety training and orientation are outlined in the *UTMB Safety Manual.* All personnel at UTMB are required to participate in safety training and orientation according to the benchmark policies of the Joint Commission on Accreditation of Healthcare Organizations, the College of American Pathologists, state and federal regulations, and hospital policies. HSS staff or qualified training specialists conduct the training and orientation programs (UTMB 2001a).

Every employee or student at UTMB who is assigned to work in a laboratory where chemicals or biological agents are used is required to attend the Laboratory Safety Orientation Program when hired. A refresher course is required every 2 years after the initial orientation (UTMB 2001a).

All employees in the State of Texas who are, or may be, exposed to hazardous chemicals are required by the Texas Hazard Communication Act (Texas Statutes 502.001 through 502.020) to participate in specialized chemical training prior to working with or in an area containing hazardous chemicals. The required training includes information on the interpretation of chemical container labels and MSDSs and instructions on handling, cleanup procedures, and disposal of hazardous chemicals. Each employee must be provided information specific to the chemicals he or she will be using, including chemical location, toxic effects, target organs, safe handling, necessary protective equipment, and first aid treatment (UTMB 2001a).

Employees who may have significant contact with laboratory animals are given a brochure describing common potential health risks and are required to register with the Employee Health Center. Orientation and training programs for employees of the ARC and instruction in the safe, humane handling and care of animals are provided by the IACUC manager. Annual safety training is mandatory for personnel working in NHP areas (UTMB 2001a). The PIs are responsible for ensuring that research and laboratory assistants are trained in the safe and humane handling and care of animals, as well as safe handling and proper disposal of potentially contaminated specimens derived from animals (UTMB 2001a).

There have been no LAIs from CBDP-related activities conducted by UTMB (Zimmerman 2001).

UTMB participates in the USAMRIID SIP (see Section 2.4.4.3.b), which is coordinated by the HSS Biological and Chemical Safety Program. The Institutional Biosafety Committee approves requests for immunization and the Employee Health Center conducts the initial physicals and serology. After the records are sent to the SIP office in Fort Detrick, Maryland, the staff members are sent to USAMRIID for evaluation and immunization (UTMB 2001a).

Employees who work with biological agents having FDA-approved vaccines or investigational vaccines participate in the UTMB Research Immunization Program. USAMRIID or the CDC provides the vaccines, subject to approval by the Biological Safety Committee. In addition, the Committee approves any baseline serum samples that are drawn and stored (UTMB 2001a).

Immunizations are also provided to employees with significant exposure to infectious agents that can be transmitted from animal hosts to humans. Employees at risk of exposure to human blood or body fluids are encouraged to have hepatitis B immunizations. A tuberculin skin test is given to all new employees with no history of previous tuberculosis or positive skin test reactions. In the case of a positive result, a chest x ray and further evaluation is provided. Personnel who work with animals are required to have tuberculosis screening annually, or at 6-month intervals for those working with NHPs. Rabies vaccines are offered to employees with significant exposure to animal species known to carry and transmit rabies, but are not required in cases of

known adverse reactions. Vaccines are administered only after informed consent (UTMB 2001a).

FOAM staff members are required to undergo the same health and safety training, orientation, monitoring, and testing as RDT&E staff, based on the location and scope of work. All facility work conducted by FOAM staff in BSL-1 and BSL-2 laboratories is done under the direction of the PI, laboratory staff, or the department administrator. FOAM staff members do not have access to BSL-3 facilities except under direct supervision of either the PI, his/her designee, or a member of HSS (UTMB 2002a).

The *Environment of Care Master Plan* includes a section titled "Emergency Preparedness Management Plan," which is a condensed version of the *Master Institutional Emergency Preparedness Plan* for the University. The Plan is reviewed annually, and it undergoes a comprehensive revision every 3 years. Emergency preparedness drills are conducted on campus at least twice every year and at least 4 months apart.

To minimize the risks of fire-related occupational hazards, the Occupational Safety and Fire Prevention Program conducts inspection, testing, and servicing of fire-fighting equipment and fire protection systems. They test the fire alarm systems and prepare fire evacuation and safety management plans (UTMB 2001a).

The *UTMB Hazardous Materials Spill Contingency Plan* was created to minimize hazards in the event of an accidental release of HAZMATs into the environment. The Incident Commander, usually the Institutional Safety Officer or a program manager, coordinates all response activities and resources. All spills are to be reported immediately to HSS, which records the essential information using an Incident Report form. HSS emergency personnel respond to control, stabilize, and decontaminate the affected area. Emergency response equipment and supplies have been assembled by HSS at various locations on campus and can be transported to the site by a spill response vehicle that is available at all times. When possible, a site plot plan is used to identify the hazard area, access and escape routes, evacuee assembly areas, and locations of emergency support services. A report of the entire incident must be prepared to include: the history of the incident, personnel involved, actions taken, record of any exposures, sampling and testing results, and a history of resultant injuries or illnesses. HSS spill response personnel are trained in accordance with OSHA requirements under 20 CFR 1910.120, with additional weekly in-service training, annual refreshers, and specialized training courses (UTMB 2001a).

UTMB policy states that in the case of an injury at work, the employee should immediately report to his/her supervisor or ask a coworker to notify the supervisor. The supervisor and affected employee are then required to notify the Workers' Compensation Insurance of all work-related injuries and exposures as soon as possible after the incident. The employee is instructed to seek evaluation and treatment at the Employee Health Center, or in the case of an emergency, a supervisor or fellow employee will call 911. After hours and on weekends, employees are instructed to seek medical attention at the UTMB Emergency Services Department. The General Safety Services branch of HSS investigates accidents and work-related safety concerns (UTMB 2001a).

Semiannual safety inspections of the facilities and equipment are conducted by the General Services branch of HSS. The supervisor of each laboratory has the responsibility of ensuring that other required safety inspections are conducted. The Radiation Safety Program of HSS is responsible for conducting leak tests of sealed radioactive sources; wipe tests of laboratories where radioactive materials are used; inspection of packages with radioactive materials; and radiation surveys of microwave ovens and electron microscopes. The Biological and Chemical Safety Program of HSS conducts ventilation surveys of chemical fume hoods, certification of BSCs and laminar flow cabinets, evaluation for the presence of asbestos, and monitoring for exposure to toxic chemicals. The Occupational Health and Fire Prevention Program inspects, tests, and services fire-fighting equipment and fire protection systems, as well as testing fire alarm systems.

Documentation of personnel training, immunizations, hazardous waste disposal, and use of radioactive materials is maintained by HSS. Records of each employee's training include the date and type of training, as well as the signature of both the employee and the training instructor. Whenever an employee receives any type of immunization or follow-up, a form is completed and signed by the appropriate personnel in the Employee Health Center and then returned to the ARC Administrative Office and recorded in their immunization database.

HAZMATs are tracked from their receipt at UTMB through their disposal. HSS maintains these records and submits disposal reports as required by state law. Department managers must also maintain records on the amounts of hazardous waste generated, as well as the level of source reduction and waste minimization. Records of radioactive materials are kept in accordance with the Texas Regulations for Control of Radiation (25 TAC 289). Radioactive materials used at UTMB are documented by the HSS Radiation Safety Program. Upon disposal of the materials, the end user and Radiation Safety keep copies of these records (UTMB Office of Environmental Health 1998).

2.4.6.3.c *Security*

UTMB has its own licensed police department on duty 365 days a year. Upon hiring, all personnel are subject to a security review by the UTMB Campus Police. Photo identification key cards are given to each employee, allowing them access only to areas specified by the employee's department (UTMB 2001a). With this card, the date and time, as well as an individual's name and identification number, can be tracked when they enter any of the buildings or laboratories. Within minutes of notification to Campus Police, any individual's access can be revoked by the requesting department or by HSS (UTMB 2002a).

Security is maintained in buildings where CBDP activities take place. All BSL-1 and BSL-2 laboratories are locked at all times when not in use. The UTMB Campus Police have responsibility for evening security in all campus buildings and check all laboratory doors to ensure they are locked for the night (UTMB 2002a).

The building housing the CBDP BSL-3 laboratory and all laboratories in that building have access controlled by key card at all times. The Director of the BSL-3 laboratory, the Assistant Administrator of Pathology, and the designated Health and Safety representative have the

authority to immediately revoke card access to any individual through the Campus Police (UTMB 2002a).

The other two buildings currently housing CBDP activities also have access controlled by key card; one of these buildings is locked 24 hours a day, while the other is locked after 5:30 p.m. Access into the laboratories in these buildings requires that the key card be programmed with the appropriate entry sequence, with permission from the individual's department. The animal facilities are locked 24 hours a day and accessible only with a number code that is controlled and held by the Director of the ARC, Senior Husbandry Supervisor, and the designated Health and Safety representative (UTMB 2002a).

2.4.7 Battelle Memorial Institute, West Jefferson

The Battelle Memorial Institute (BMI) owns and operates a research complex on a 480.4-hectare (1,187-acre) site in West Jefferson, Ohio. This facility is used for RDT&E projects under contract for various clients. Information on the area, including details of the existing environment, is presented in Section 4.8. This section discusses CBDP activities and mitigation measures, as a basis for the environmental impact analysis presented in Sections 5.2 through 5.14.

The Medical Research and Evaluation Facility (MREF) complex, which is located in the middle portion of the site, is a 2,433-square-meter (26,185-square-foot) concrete block, two-story structure, housing a BSL-3 suite; a CSM research laboratory; supporting barns; equipment/supply storage; offices; and a 243-square-meter (2,620-square-foot) animal holding facility. Additional facilities for CBDP activities are in a 1,242-square-meter (13,368-square-foot) concrete block/metal-skin building located in the southern portion of the site. This facility includes a BSL-3 suite. CBDP activities in BSL-1 and BSL-2 laboratories utilize 659 square meters (7,093 square feet) of floor space.

2.4.7.1 Research, Development, Test, and Evaluation Activities

Medical Systems is the principal CBDP commodity area for RDT&E activities at the BMI West Jefferson site.

2.4.7.1.a Chemical Surety Materiel

The CSM research laboratory provides 209 square meters (2,250 square feet) of floor space for work with chemical agents. Other laboratories add approximately 531 square meters (5,717 square feet) of floor space for CBDP work with hazardous industrial chemicals (BMI 2002).

2.4.7.1.b High-Hazard Biological Agents

The BSL-3 laboratories provide 520 square meters (5,600 square feet) of floor space for work with anthrax, botulinum toxin, plague, and tularemia. Vaccine testing using the actual pathogens or toxins is limited to those agents.

The larger BSL-3 suite is used by 8 BMI workers on a full-time basis and by 37 other workers on a part-time basis, as of 2001. Five BMI workers use the smaller BSL-3 suite on a part-time basis.

2.4.7.1.c Aerosol Testing

The testing includes challenge studies in which vaccinated animals are exposed to the etiologic agent by aerosol or by injection. Outdoor aerosol testing is not conducted at the BMI West Jefferson site.

2.4.7.1.d Animal Care and Use

The care and use of laboratory animals at the BMI West Jefferson site is in accordance with the benchmark guidelines and regulations listed in Section 2.3.1. AAALAC International inspected

BMI animal facilities and programs at the West Jefferson site in 2001 and continued full accreditation. The IACUC oversees all aspects of the animal facilities and programs at the BMI West Jefferson site.

Cage cards identify experimental animals, the treatment they are undergoing, and related biohazards. Animal inventories are required daily, and laboratory animal care logbooks must be maintained. The building in which animals are maintained is kept locked at all times. The CBDP activities utilize mice, guinea pigs, rabbits, and NHPs. All studies are designed to minimize the use of laboratory animals. The actual numbers of animals required are based upon the level of CBDP activities. A CBDP animal census at BMI West Jefferson during 2002 reported 79,359 mice, 129 monkeys, 534 rabbits, and 6,637 guinea pigs (BMI 2002).

2.4.7.1.e *Vaccine Development*

Advancing BD vaccine candidates through the development process includes both in vivo and in vitro laboratory studies to fully characterize a vaccine's chemical composition and purity, as well as to determine effective and safe dosages, possible side effects, and efficacy. The required testing is conducted using pilot and production lots of candidate vaccines that have been produced elsewhere and transported to the BMI West Jefferson site. Such testing must be conducted in the laboratory using animal models before a vaccine's first use in clinical testing with humans. As integral components of vaccine development, and required for FDA licensure, these studies must be conducted in accordance with the FDA Regulation *Good Laboratory Practice for Nonclinical Laboratory Studies* (21 CFR 58), which prescribes the required laboratory practices, facilities and equipment, organization and personnel qualifications, experimental protocols and conduct of laboratory studies, and record keeping and reporting.

2.4.7.1.f *Genetically Engineered Microorganisms*

GEMs are not used in CBDP activities at the BMI West Jefferson site.

2.4.7.1.g *Human Subjects*

The CBDP activities at the BMI West Jefferson site that involve the use of human research subjects are conducted only under the auspices of a SIP. Specifically, certain employees are enrolled in protocols that meet both FDA requirements for receipt of IND vaccines and CDC/NIH guidelines that workers at risk of exposure to etiologic agents be immunized prior to beginning work when vaccines are available (CDC/NIH 1999).

2.4.7.1.h *Radiological Testing*

The BMI West Jefferson site holds NRC License No. SNM-7 and has developed associated SOPs, policies, and safety management (U.S. DoD 1999). However, radioisotopes are not used for CBDP activities.

2.4.7.1.i *Open-Air Laser Testing*

Open-air laser testing is not conducted at the BMI West Jefferson site.

2.4.7.1.j *Support Work*

The CHPs address use and handling of nonhazardous materials and supplies and minor maintenance of laboratory equipment (see Section 2.4.7.3.a).

2.4.7.2 Operations, Maintenance, and Waste Management Activities

2.4.7.2.a *Operations*

Electricity for the BMI West Jefferson site is provided by American Electric Power. The average consumption is 281,465 kWh per year, with a peak annual consumption of 412,275 kWh, as of 2001. The average consumption for CBDP activities is 261,104 kWh per year, with peak annual use of 389,924 kWh (BMI 2002).

Fuel Services Group provides natural gas service to BMI. The average consumption is 2,804 ccf[6] per year, with a peak consumption of 4,753 ccf per year (BMI 2002).

Potable water used at BMI comes from on-site wells. The BMI West Jefferson site operates and maintains its own water supply, under Ohio EPA License No. 98-4930212 (expiration 31 December 2002) for public water supply systems. Water for the middle portion of the property is softened prior to use. This water supply is metered and averages approximately 22,157,740 liters (5,853,474 gallons) annually. The water supplied to the southern area is untreated. This water supply, which is not metered, amounts to an estimated 2,973,053 liters (785,400 gallons) of water annually (U.S. DoD 1999).

2.4.7.2.b *Maintenance*

The Biofacility Coordinator is responsible for monitoring of the mechanical systems in the MREF complex in the central portion of the BMI West Jefferson site. This includes maintaining records of all checks and tests such as; BSC air flow or pressure differential, pressure drops across each filter, air flow directionality, particulate testing of the HEPA filters, and alarm function tests (BMI 2002).

2.4.7.2.c *Waste Management*

SOPs for decontamination, collection, handling, and disposal of waste are included in the Facility Safety and Security Plan (FSSP) for the Biofacility, as well as FSSP SOP BIO-009 (BMI 2002). FSSP SOPs MREF-23, -25, and -32 ensure compliance with Ohio EPA regulatory requirements, BMI policies, and waste disposal contractor requirements.

- *Air Emissions*

  The BMI West Jefferson site has two permitted air emission sources, a pathological waste incinerator (Ohio EPA No. 0149000077N001) and a decontamination oven (Ohio EPA No. 0149000077P004). The incinerator permit expired 1 September 1997; however, it can continue in operation pending renewal under provisions of Section 119.06 of the Ohio Revised Code (ORC). BMI submitted the renewal application 4 June 1996.

[6] ccf = 100 cubic feet.

The pathological waste incinerator emits 0.0436 kilograms of PM per 100 kilograms (0.0436 pounds of PM per 100 pounds) of waste, in compliance with the permit requirement not to exceed 0.01 kilograms of PM per 100 kilograms (0.01 pounds of PM per 100 pounds) of waste. The Ohio EPA permit limits operation to 20% of capacity (see *Medical and Infectious Waste*, below).

- *Solid Waste*

An estimated 13,608 kilograms (15 tons) of general solid waste are collected annually from CBDP activities at the BMI West Jefferson site. This is transported for off-site disposal at the Franklin County landfill. The BMI solid waste comprises about 0.002% of the 609,625 metric tons (672,000 tons) of nonhazardous solid waste disposed of annually at that facility (U.S. DoD 1999).

- *Wastewater*

Noninfectious sanitary wastewater undergoes secondary treatment at the middle area WWTP, which processes approximately 22,210,456 liters (5,867,400 gallons) per year under NPDES Permit No. 4IN00004*GD (BMI 2002). CBDP activities account for approximately 18,840,208 liters (4,977,072 gallons) of this total. Treated effluent discharged into Big Darby Creek is subject to the following limits: 20 mg/L TSS; 20 mg/L combined BOD and COD; 2,000 fecal coliform per 100 mL; 0.038 mg/L residual chlorine; pH of 6.5 to 9 standard units; and a minimum of 6 mg/L of dissolved oxygen. During the years 1996 through 2001, one exceedance of a permit limit (residual chlorine) was recorded (BMI 2002). Discharges from the cooling tower have seasonal maximum temperature limits of 21.1^{o}C (approximately 70°F) in the winter and 29.4^{o}C (approximately 85°F) in the summer.

- *Hazardous Waste*

The BMI West Jefferson site is registered as a generator of hazardous waste (No. OHT400013892) under the Ohio Administrative Code (OAC) hazardous waste management regulations that have been promulgated under RCRA (U.S. DoD 1999). Details on handling and disposal of hazardous waste are included in FSSP SOP MREF-25. Ensco, Inc.; Trade Waste Incineration, Inc.; and Laidlaw Environmental Services, Inc., are contracted by BMI for disposal of hazardous waste (U.S. EPA 2002a).

The hazardous waste generated from the CBDP activities is estimated at approximately 267 kilograms (588 pounds) annually as of 2002 (BMI 2002). The Satellite Accumulation Area in the middle area handles the following amounts of hazardous waste annually: 77.1 kilograms (170 pounds) of D001 (ignitable); 11.8 kilograms (26 pounds) of D002 (corrosive); 5 grams (0.18 ounces) of D003 (reactive); 117.0 kilograms (258 pounds) of various toxicity characteristic categories (D004 through D043); and 72.6 kilograms (160 pounds) of various listed solvent residues and unused chemicals (BMI 2002).

- *Medical and Infectious Waste*

Regulated medical and infectious waste generated annually at the site was estimated to consist of 56,246 kilograms (124,000 pounds) of animal waste and bedding; 528 kilograms

(1,165 pounds) of sharps; 767 kilograms (1,690 pounds) of solid infectious waste; and 552,668 liters (146,000 gallons) of liquid infectious waste (BMI 2002).

In accordance with guidelines (CDC/NIH 1999), all waste contaminated or potentially contaminated with infectious material must be rendered noninfectious before disposal. This decontamination is accomplished by a combination of chemical disinfection and steam sterilization (autoclave) methods. Heat-sensitive chemical strips are included in each autoclave load, and test strips containing heat-resistant bacterial spores are included monthly to verify that temperatures capable of inactivating the etiologic agent were achieved. The results of these verification procedures are recorded (U.S. DoD 1999). The sharps are autoclaved before collection for off-site disposal by Stericycle, Inc. (BMI 2002), a registered transporter of infectious waste under Ohio EPA Permit No. 00-T-00199, which expires 23 February 2003 (Ohio EPA 2002).

The pathological waste incinerator (Comtro, Model No. A-24), which is located adjacent to the MREF, is rated to burn 90.7 kilograms (200 pounds) per hour. Ohio EPA Air Emissions Permit No. 0149000077N001 limits operation to 20% of capacity. The incinerator typically burns paper, cardboard, wood, animal carcasses, plastic bags, and laboratory clothing, with a normal operating schedule 8 hours a day, 5 days a week, for 40 weeks each year (see *Air Emissions*, above, for stack testing results for incinerator emissions). The incinerator ash, which is estimated at 3,311 kilograms (7,300 pounds) per year, is disposed of in a sanitary landfill.

BMI holds Ohio EPA Infectious Waste Generator License No. 25-G-00203, which includes autoclaving as a treatment for infectious waste. All Ohio facilities for treatment of infectious waste must meet applicable requirements under OAC Rules 3745-27-32 through 39 and Rule 3745-27-39, under statutory authority of ORC Sections 3734.02 and 3734.021. Animal waste meeting the Ohio EPA definition of infectious waste is rendered noninfectious in the BSL-3 autoclaves and then incinerated in the on-site pathological waste incinerator (U.S. DoD 1999).

Liquid infectious waste generated in the MREF is initially decontaminated by autoclaving or chemical disinfection and is then collected in a 3,785-liter (1,000-gallon) holding tank for treatment with steam. When the tank is about three-quarters full, its contents are heated to 121.1°C (250°F) for 60 minutes of additional decontamination. The measured temperature and pressure are recorded in logbooks, and the effectiveness of this heat treatment is verified by the use of both chemical and biological testing prior to discharge to the on-site WWTP noted above (U.S. DoD 1999).

- *Radiological Waste*

Radiological waste is not generated as a part of CBDP activities at the BMI West Jefferson site (BMI 2002).

2.4.7.3 Safety, Health, and Security Mitigation

CBDP activities at the BMI West Jefferson site adhere to the benchmark guidelines and regulations listed in Section 2.3.5, as well as applicable state and local laws and regulations pertaining to safety, handling, and disposal of potentially hazardous materials such as chemicals or etiologic agents. Safety review and oversight at BMI West Jefferson are implemented through several committees that establish the policies and guidelines for working with HAZMATs. Environmental, safety, and health representatives are assigned at both of the buildings, with responsibility for assisting management with safety issues. The committees review procedures, conduct hazard analyses and dry runs of procedures, document monthly inspections, and provide daily guidance about safety. They have authority to stop activities if unsafe practices are observed (U.S. DoD 1999).

Both buildings have established FSSPs that detail the significant potential hazards associated with their operations and the mitigation measures employed to ensure safe operation. The FSSPs contain extensive descriptions of engineering controls (e.g., ventilation systems) and administrative (work practice) controls, emergency preparedness, training, and other elements essential to safety.

Approved written SOPs must be available for all new and recurring activities. SOPs for a given activity are prepared prior to the beginning of an operation and must be verified by dry runs (without the actual use of the etiologic agent or HAZMAT). SOPs must be reviewed and approved by relevant BMI safety committees and personnel and the facility manager prior to implementation of the work (U.S. DoD 1999).

2.4.7.3.a Safety

- *Biological Safety*

  The Biosafety Committee and Risk Assessment Committee provide safety oversight of the biofacility and establish general policies and guidelines regarding the scope of work conducted with HAZMATs. The Environmental Safety and Health Officer (ESHO) provides safety guidance. Major facility changes, revisions of the FSSPs, and initiation of work with additional agents or new hazards require approval by the Biosafety Committee. The ESHO reviews all facility construction plans and modifications to ensure appropriate safety provisions (BMI 2002).

  The BSL-3 suites were constructed and are operated in accordance with the benchmark guidelines and regulations for biological safety enumerated in Section 2.3.5.1. All work conducted in the BSL-3 laboratories is conducted within BSCs suitable for the given work. The BSCs are certified annually by an outside contractor. BMI operations and facilities exceed the CDC/NIH requirements for BSL-3 containment in that all exhaust air passes through two sets of prefilters and HEPA filters before venting to the outside of the building. The first set is located within the BSC. A second HEPA filter set is located in the facility maintenance room, a short distance from the laboratories. The incoming laboratory air is also HEPA filtered. A contractor tests the HEPA filters using dioctyl phthalate every 2 years.

PPE and protective clothing required for entrance to the containment areas are specified, based on the agents in use at the facility, the procedures conducted with the agents, and other applicable safety controls (e.g., type of BSC). The ESHO selects the PPE, monitors it for adequacy and maintenance, and trains assigned staff in proper use and maintenance of PPE. All personnel entering the BSL-3 support area, including visitors or supervisory personnel, must wear either a blue scrub suit or a laboratory coat over street clothes (BMI 2002).

Sanitary procedures are followed to minimize the risk of transporting an agent outside the workplace (FSSP SOP BIO-007 and 010). Protective clothing and other PPE are donned in a changing area prior to entering the containment facility. Upon leaving, personnel wash their hands and remove the PPE before exiting the containment facility. They then enter a separate change room, remove all facility-provided clothing, and shower before exiting into the change room.

All equipment, disposable clothing, and supplies must be either chemically decontaminated or autoclaved before removal from the containment facility. Chemical decontamination is used for reusable items that would be damaged by autoclaving (BMI 2002). Any potentially contaminated laboratory equipment must be either decontaminated before removal for repair or maintenance or proven not to be contaminated, in accordance with FSSP SOP MREF-23 (BMI 2002).

To limit movement of potentially contaminated materials, autoclaves are positioned between rooms or hallway areas, enabling items to be sterilized before being passed to outer "clean" areas. The flow of people, equipment, animals, and experimental materials within the buildings is restricted, as detailed in the FSSPs and SOPs to protect worker health and safety and to prevent breaching of containment or cross-contamination of adjoining areas.

BMI is registered with the CDC under 42 CFR 72.6 to transfer or receive selected agents. All transfers under this regulation are documented (U.S. DoD 1999). Unpacking of primary material containers and handling of materials in open containers occurs in Class II and III BSCs within the facility. Other material transfers within the facility and outside the BSCs are packaged in accordance with the benchmark guidelines and regulations listed in Section 2.3.5.1.d. Specifications for the safe handling and storage of etiologic agents in the MREF are detailed in FSSP SOP BIO-5 (BMI 2002).

- *Chemical Safety*

Small quantities of hazardous chemicals are used in CBDP RDT&E activities. The handling and use of hazardous chemicals is in accordance with benchmark guidelines and regulations for chemical safety listed in Section 2.3.5.2.

BMI corporate policies and procedures for the safe handling and use of chemicals are contained in the CHP. The ESHO oversees its implementation. The CHP and associated laboratory-specific SOPs provide information about handling controlled substances, chemical acquisition and storage, potential health risks, environmental monitoring, PPE, use of fume hoods, safety procedures and inspections, and laboratory audits.

The MREF Manager has responsibility for the safety program in that facility, with full authority to prepare and enforce safety policies. The MREF Environment, Safety, Surety, and Health Committee assists in the evaluation of these policies (BMI 2002). The ESHO, who serves as the CHO for the MREF, advises and assists the MREF Manager. General safety and security information are found in the MREF FSSP for the Chemical Agent Laboratory, including responsibilities of supervisors and laboratory workers.

FSSP SOPs MREF-11 and 12 cover storage and transfer of chemical agents within the MREF. The storage vault for chemical agents (in a ventilated hood in the vault room) is equipped with two locks. Agents are stored there until used or destroyed. Entry into this storage facility is restricted to personnel authorized by the Chemical Agent Manager.

- *Radiological Safety*

The BMI West Jefferson site holds NRC license No. SNM-7 and has developed policies for radiological safety and associated SOPs (U.S. DoD 1999). However, radioisotopes are not used for CBDP activities as of 2001.

2.4.7.3.b *Occupational Health*

The BMI West Jefferson site is in accordance with the benchmark guidelines and regulations for occupational health and safety outlined in Section 2.3.5.3. Personnel performing maintenance and repair activities in the MREF must comply with requirements of SOPs for the RDT&E activities, including personal hygiene (FSSP SOP MREF-5); PPE (FSSP SOP MREF-8); and work and training requirements (FSSP SOP MREF-3 and 6) (BMI 2002).

Personnel training requirements for the Biofacility are covered in detail in FSSP SOP BIO-004. All personnel who handle hazardous substances, including maintenance and contractor employees, receive training in safe handling of the substances in accordance with OSHA standard 29 CFR 1910.1450. Everyone working directly with etiologic agents, or who otherwise has a potential for exposure, receives appropriate training. Training for the BSL-3 facility covers signs and symptoms of etiologic agent exposure, information on sources of exposure, possible adverse health effects, practices and controls to limit exposures, environmental and medical monitoring procedures, worker responsibilities in health protection programs, handling of laboratory mishaps, and emergency procedures (BMI 2002).

BMI implements a Medical Surveillance Program to ensure workers' suitability for work with chemical agents or etiologic agents and to provide preassignment health assessment and annual physical examinations for early detection of possible exposure to these agents. The preassignment health assessment must be completed prior to employment to determine each employee's initial suitability, as well as baseline health data. After each examination, the evaluating physician is required to sign a certificate to be retained by the employee for inspection upon request by authorized personnel (BMI 2002).

Under the SIP, vaccines, when available, are administered to workers having the potential for exposure to etiologic agents. Whenever possible, vaccines licensed by the FDA are used. Vaccines under FDA regulatory control as INDs are not given until the worker has signed a

formal consent form. Prior to vaccination, workers must be informed of the possible adverse reactions to vaccination. Workers unable to undergo vaccination for medical reasons are not permitted to work with etiologic agents or in areas where they may be exposed to etiologic agents (U.S. DoD 1999).

In the event of potential exposure to an etiologic agent, prompt medically appropriate treatment is initiated under medical supervision provided by BMI. The treatment may include antibiotics that are known to be effective against the etiologic agent, alone or in combination with other drugs and life support measures.

When a chemical agent is in use, a full-time registered nurse is on site, first-aid equipment is available in the immediate work area, and a physician is on call for immediate response in case of exposure.

BMI's Employee Reliability Program (ERP) fulfills the benchmark chemical PRP requirements discussed in Section 2.3.3. Participation in the ERP is required for personnel having access to or controlling access to chemical agents and the MREF Facilities Manager (acting as Chemical Agent Manager). Assessment of the reliability of individuals participating in or under consideration for the ERP includes a preplacement interview and screening process, medical examinations and evaluation, and an acceptance interview, as specified in the MREF FSSP (BMI 2002).

In accordance with the benchmark guidelines and regulations discussed in Section 2.3.5.4, BMI coordinates emergency preparedness with local emergency service providers and maintains formalized agreements describing particulars of emergency support. New work is coordinated with the Jefferson County Fire Department, Prairie Township Fire Department, Madison County Police Department, and the Madison County Health Commissioner. The agreements are reviewed and updated annually.

BMI has developed a CAIRA Plan in accordance with AR 50-6 and DA PAM 50-6 to assure the availability, practicability, and usefulness of procedures for controlling the effects of chemical accidents or incidents at the MREF. The CAIRA Plan is exercised quarterly. FSSP SOP MREF-45 outlines the plan of action and chain of command. The CAIRA Plan includes SOPs for personnel response to an emergency, as outlined in FSSP SOP MREF-18. This SOP applies for personnel performing maintenance and repair activities in the MREF as well as for laboratory staff. Evacuated personnel advise management of any first-hand information regarding the event and assist if requested. Additional SOPs included in the CAIRA cover first aid (FSSP SOP MREF-19) and cleanup and decontamination (FSSP SOP MREF-24) (BMI 2002).

The Accident/Incident Investigation and Reporting Program is detailed in BCO SIH-PP-02 (BMI 2002).

One mishap has occurred during CBDP activities at the BMI West Jefferson site in the years 1996 through 2001. A staff member reported a needle stick on 3 October 2000, after removing a syringe used to dose a guinea pig with anthrax. The needle passed through an alcohol-soaked

gauze pad and penetrated the staff member's left index finger. The syringe contained a $1x10^4$ dilution of anthrax spores. The guinea pig was dosed with 0.1 mL of this dilution, from which a minimal residual amount may have remained on the needle. A scrub of the affected area was done according to protocol, and Bactroban and DSD were applied. The staff member had previously received an 18-month anthrax boost on 11 September 2000 and a tetanus vaccine in 1995. The staff member was assessed by the medical director and started an antibiotic regimen of 500 milligrams of ciprofloxicin twice a day for 30 days. No complications were reported (BMI 2002).

Procedures for regulatory compliance inspections of facilities and equipment are detailed in BMI SOP MREF XII-005-02. The SOP ensures compliance with FDA Good Laboratory Practice Regulations (21 CFR 58) and EPA Good Laboratory Practice Standards (40 CFR 160 and 792). The purpose of the SOP is to maintain consistency of relations with the agencies and to standardize communications, provide for documentation, and assure management of rapid and comprehensive accounting/corrective action regarding each inspection (BMI 2002). An audit plan is developed in the first quarter of each year to identify facility inspections for the year. All laboratory areas are inspected at least twice per year (BMI 2002).

Trained Quality Assurance Unit staff members conduct the inspections along with the MREF Facility Manager, Coordinator, or other designee. Prior to each inspection, a checklist is prepared that includes maintenance and calibration of instruments and equipment, proper labeling and conditions in storage areas, accuracy and timeliness of SOP manuals, and general cleanliness of the laboratory. The checklist also includes items of concern from the previous inspection, to verify that corrective action has been completed.

A written report of findings from each inspection or audit is prepared by the inspector and sent to the responsible manager. If action is required, the manager must submit a written response. The inspector will then follow up on corrective actions and sign and date a routing sheet upon satisfactory review of the responses. Detailed procedures for documenting and reporting findings from all inspections are outlined in MREF SOP XII-001-02 (BMI 2002).

Two safety inspections of facilities at the BMI West Jefferson site were conducted by the DA Inspector General during the years 1998 through 2001. In August 1998, no deficiencies were noted. One deficiency was noted in June 2000; several items in the chemical laboratory facility had not been marked to indicate the level of decontamination to which they had been subjected. This deficiency was corrected (BMI 2002).

2.4.7.3.c *Security*

The BMI West Jefferson site is patrolled by armed guards at all times. Bar gates restrict vehicular traffic access onto the property during off-duty hours, and video surveillance is provided for key locations throughout the site (U.S. DoD 1999).

Procedures for staff and visitor access to the Biofacility are outlined in FSSP SOP BIO-001, -002, and -003. Badge readers and a numeric keypad, in conjunction with electronic door releases, control access to the Biofacility and the BSL-3 laboratory within it. A record is

maintained of all individuals allowed to enter the BSL-3 exposure area. The Biofacility Coordinator is responsible for ensuring the development of policies and procedures for entry to the BSL-3 laboratory. Only individuals who are aware of the potential biohazards and who comply with all laboratory procedures are allowed entry (BMI 2002).

Specifics on entry and exit controls to MREF are found in FSSP SOPs MREF-2, -4, -5, -6, -11, -14, -37, -38, and -43, as well as in the Physical Security Plan located in Appendix C of the MREF FSSP. The entrance to the restricted-access area (RAA) of MREF is controlled by a double turnstile system. Access through the first turnstile requires a barcode, card key, and a personal identification number; entry through the second turnstile requires a positive visual identification by the security officer on duty. The facility's exterior doors are equipped with intrusion alarms, and additional surveillance is provided by security cameras. Visitors must sign in and remain with an MREF escort at all times. During actual chemical agent testing, access to the RAA is limited to authorized individuals (BMI 2002).

All personnel allowed unescorted access to the RAA are designated on an entry control roster (ECR), which is maintained by BMI and periodically reviewed by the MREF Manager. Those on the ECR must have completed the appropriate orientation and training programs for their duties in the facility. This includes all U.S. military personnel with unescorted entry status, who must be certified as having completed orientation and reliability programs, as well as completing all appropriate BMI training programs. Personnel performing maintenance and repair activities in the MREF must comply with requirements of SOPs for the RDT&E activities, including visitor access (FSSP SOP MREF-2) (BMI 2002).

The MREF Facilities Manager/Coordinator, or other authorized person, checks the MREF at the close of business to ensure that storage containers, hoods, and doors are secure and chemical agents properly stored. All security checks are recorded in a logbook. Instructions for after-hours security checks are detailed in Appendix C of the MREF FSSP.

2.4.8 Brooks Air Force Base

At Brooks Air Force Base, located near San Antonio, Texas, the 311th Human Systems Wing awards contracts, develops interagency agreements, and administers these arrangements for nonmedical CD development and testing activities for all services. Decontamination is the principal commodity area, but this site also serves activities under Contamination Avoidance, Individual Protection, and Collective Protection.

No direct RDT&E or OMWM activities under the CBDP are conducted at this site. The contract award procedures conform to the benchmark federal government and DoD acquisition regulations listed in Section 2.3.6.

2.4.9 Marine Corps Systems Command

The Marine Corps Systems Command (MARCORSYSCOM), located near Quantico, Virginia, is the principal Marine Corps site for activities under the CBDP. MARCORSYSCOM awards contracts, develops interagency agreements, and administers these arrangements from this site for nonmedical development and production activities. Individual Protection is the principal commodity area, but this site also serves activities under Collective Protection, Contaminant Avoidance, and Decontamination.

No direct RDT&E or OMWM activities under the CBDP are conducted at this site. The contract award procedures conform to the benchmark federal government and DoD acquisition regulations listed in Section 2.3.6 (Grosser 2001).