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MANAGEMENT PRE-START REVIEW FINAL REPORT

FOR THE

BIOSAFETY LEVEL 3 (BSL-3) FACILITY (B368)

LAWRENCE LIVERMORE NATIONAL LABORATORY

ROBERT W. HULL, LOS ALAMOS TECHNICAL ASSOCIATES INC.
JOHN O'BRIEN, LLNL
TERRY OWENS, UC OFFICE OF THE PRESIDENT
VICKI SALVO, LLNL
DINA SASSONE, LANL
STANISLAW TUHOLSKI, LLNL
SKY TSAN, LLNL

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FOR THE
BIOSAFETY LEVEL 3 (BSL-3) FACILITY (B368)

Prepared by:

ROBERT W. HULL, LOS ALAMOS TECHNICAL ASSOCIATES INC.
TEAM LEAD - MANAGEMENT/OPERATIONS/SAFETY BASIS

DATE

Co-Authored by:

JOHN O'BRIEN, LLNL
ELECTRICAL ENGINEERING

DATE

TERRY OWENS, UC OFFICE OF THE PRESIDENT
SECURITY

DATE

VICKI SALVO, LLNL
ENVIRONMENTAL/WASTE MANAGEMENT/REGULATORY COMPLIANCE

Date

DINA SASSONE, LANL
BIOSAFETY/INDUSTRIAL HYGIENE/MEDICAL

Date

STANISLAW TUHOLSKI, LLNL
STRUCTURAL ENGINEERING

Date

SKY TSAN, LLNL
MECHANICAL ENGINEERING

Date

EXECUTIVE SUMMARY

A Lawrence Livermore National Laboratory (LLNL) Management Pre-Start Review (MPR) Team was formed to independently verify the operational readiness of Building 368 (B368) Biosafety Level III (BSL-3) Facility to conduct research with biological pathogens and toxins including those considered Select Agents.

Review objectives and criteria were developed from the DOE/NNSA and LLNL requirements. These were provided in the Implementation Plan for the Biosafety Level III (BSL-3) Facility Management Pre-Start Review (BSL-3 MPR) at Lawrence Livermore National Laboratory that was reviewed and approved by DOE/NNSA-LSO.

The formal part of the LLNL MPR for the BSL-3 Facility was begun in August of 2005 but work on the MPR was stopped in October of 2005 due to the need for LLNL to reassess organizational and operational controls and respond to Centers for Disease Control and Prevention inquiries related to a shipping incident involving select agents. The MPR was restarted in mid-June of 2006. Preliminary facility tours and familiarization with project documents took place in June of 2005. The Independent Management Review Team consists of seven members led by a Team Leader with expertise in management, operations, and safety basis experience with biosafety laboratories. Other team members have expertise in electrical engineering, security, environmental/waste management/regulatory compliance, biosafety/industrial hygiene / medical, structural engineering, and mechanical engineering. The MPR Team reviewed various documents, including authorization basis, safety, emergency preparedness, and various operations, configuration, and management plans. They also reviewed building plans, equipment repair/maintenance documents, training records, and many standard operating procedures.

The MPR resulted in three Pre-Start Findings, one Post-Start/Critical Finding, and four observations which are shown on Tables 1, 2, and 3, respectively. Based upon this review the Team feels that the B368 Facility can be operated safely provided the Pre-Start Findings are satisfactorily closed. The Team therefore seen no reason not to expeditiously proceed towards the startup of this facility in accordance with the processes defined in DOE Order 425.1C, and the LLNL ES&H Manual.

Details of the MPR Team evaluations of the various Subject (functional) Areas of the review are contained in the completed MPR Assessment Forms in Appendix A. Findings are described in completed MPR Deficiency Forms in Appendix B. The format of these forms is consistent with DOE-STD-3006.

Table 1 – List of Pre-Start Findings

CRAD & Finding No.	Subject Area	MPR Team Finding	Related MSA Open Item No
CRAD No. 2 Finding No. 2	Safety, Health and Quality Assurance Management	Adequate and correct procedures for the medical area need to be prepared	NA
CRAD No. 3 Finding No. 3	Industrial Safety and Health	Functions, assignments, responsibilities, and reporting relationships are not clearly defined	NA
CRAD No. 13 Finding No. 6	Emergency Preparedness-1	Emergency response exercise did not adequately demonstrate ability to perform key processes of 3-blanket wrap, maintaining biocontainment integrity, minimizing cross contamination, and protecting health of other worker	NA

Table 2 – Post-Start Findings

CRAD & Finding No.	Subject Area	MPR Team Finding	Related to MSA Open Item No
CRAD No. 1 Finding No. 1	Environmental	B368 equipment that is "important to safety" must operate according to manufacturer's specifications	NA

Table 3 – List of Observations

CRAD & Finding No.	Subject Area	MPR Team Observation	Related to MSA Open Item No
CRAD No. 7 Finding No. 4	Operations-1	B368 Operations Plan needs to be completed, approved, and implemented to assure proper graded approach startup	NA
CRAD No. 8 Finding No. 5	Operations-2	Several NHI SOPs have incorrect or incomplete statements and may not be prepared in accordance the LLNL ES&H Manual requirements for preparing work documents	NA
CRAD No. 16 Finding No. 7	Training-1	NHI SOP 1.3 and the B368 Operations Plan need to address worker qualification and competency	NA
CRAD No. 18 Finding No. 8	Security	There is a discrepancy between two statement in the Biological Select Agents and Toxins Security Plan concerning when select agent inventories should be accomplished	NA

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ACRONYMS

AC	Administrative Control
ADAM	Associate Director Assurance Manager
ADFM	Associate Director Facility Manager
AM	Assurance Manager
BBRP	Biology & Biotechnology Research Program
BIO	Biosciences Directorate
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety Level
BSO	Biosafety Officer
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CRAD	Criteria and Review Approach Document
DAP	Discipline Action Plan
DHS	Department of Health Services
DOE	Department of Energy
EA	Environmental Assessment
EPD	Environmental Protection Department
ES&H	Environment, Safety, & Health
FABD	Final Authorization Basis Document
FM	Facility Manager
FONSI	Finding of No Significant Impact
FPOC	Facility Point of Contact
FSP	Facility Safety Plan
HCD	Hazards Control Department
HSD	Health Services Department
HWM	Hazardous Waste Management (former name for RHWM)
IBC	Institutional Biosafety Committee
IMR	Independent Management Review
IMRT	Independent Management Review Team
IP	Implementation Plan
IRB	Institutional Review Board
IRF	Individual Review Forms
ISM	Integrated Safety Management
ISMS	Integrated Safety Management System
LBOC	Laboratory Biosafety Operations Committee
LLFD	Lawrence Livermore Fire Department
LLNL	Lawrence Livermore National Laboratory
LSO	Livermore Site Office
LTRAIN	Livermore Training Records and Information Network
MCR	Management Criteria and Review
MDD	Material Distribution Division
MOU	Memorandum of Understanding
MPR	Management Pre-Start Review
MRT	Management Review Team
M&TE	Measuring and Test Equipment
NAI	Nonproliferation, Arms Control and International Security Directorate
NCAR	Nonconformance and the Corrective Action Reports
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association

NHI	Nonproliferation, Homeland and International Security Directorate
NIH	National Institutes of Health
OJT	On-the-Job Training
ORR	Operational Readiness Review
OSR	Operational Safety Requirement
PI	Principal Investigator
POA	Plan of Action
POC	Point of Contact
QAP	Quality Assurance Plan
RA	Readiness Assessment
RHWM	Radioactive and Hazardous Waste Management Division (formerly HWM)
RI	Responsible Individual
SA	Select Agent
SAAI	Select Agent Authorizing Individual
SAC	Select Agent Center
SAFM	Select Agent Facility Manager
SAM	Select Agent Manager
SAR	Safety Analysis Report
SER	Safety Evaluation Report
SEP	Safety and Environmental Protection Directorate
SLC	Senior Laboratory Coordinator
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SPR	Security Program Representative
S&D	Storage and Disposal Group
SSC	Structures, Systems, and Components
TAP	Team Action Plan
TC	Training Coordinator
TIM	Training Implementation Matrix
TSR	Technical Safety Requirements
USQ	Unreviewed Safety Question
VHP	Vaporized Hydrogen Peroxide
WSS	Work Smart Standard

1.0 INTRODUCTION

This Management Pre-Start Review (MPR) report documents the conduct and results of the Independent Management Review (IMR) performed for the operation of a modular Biosafety Level III (BSL-3) laboratory facility at Lawrence Livermore National Laboratory. The MPR was conducted in accordance with the approved Implementation Plan for the Biosafety Level III (BSL-3) Facility (IP, June 20, 2005).

This laboratory facility was installed adjacent to Building 361 at Site 200 in Livermore, California, and is designated as Building 368. Building 368 was assembled on-site as an approximately 1,600 ft², one-story permanent prefabricated BSL-3 laboratory facility which has three individual BSL-3 laboratory rooms. Rooms 102 and 103 are standard BSL-3 laboratories. Room 100 is an Animal BSL-3 laboratory capable of work with small animals. The building also has a mechanical room (Room 109), clothes-change/shower rooms (Rooms 104 and 107) with a small adjoining exterior entry corridor (Room 106), and an equipment air lock (Room 101) which connects the central anteroom (Room 105) to another exterior door on the opposite side from the main entry. The building has one more building exit through corridor (Room 108) which serves as an emergency exit.

In accordance with the LLNL ES&H Manual, Volume 1, Part 2 this MPR was commenced following the programmatic declaration of readiness by Patsy Gilbert, B368 Facility Manager, on August 29, 2005. This review was conducted by an independent Management Review Team (MRT) consisting of professional expert staff in disciplines related to the design, construction, and operations associated with Building 368. The team is comprised of a Team Leader who is an external consultant, a representative of the University of California Office of the President, a representative of Los Alamos National Laboratory, and the remaining members are LLNL employees who are considered impartial insofar as they did not and will not, for the foreseeable future, participate in the design, construction and operation of this facility. Respective team member credentials are provided in Appendix C of this document.

2.0 PURPOSE

The process for conducting the management pre-start review of Building 368 to conduct work at a Biosafety Level 3 is specified in the Readiness Review Memorandum of Understanding for the Building 368 Biosafety Level 3 Facility (RR MOU, February 2005). This MPR is in accordance with the RR MOU and was conducted to confirm the LLNL management declaration that BSL-3 operations can be safely conducted in Building 368. To this end, the MPR report will answer the following questions about the facility:

- Was the building constructed in accordance with the approved design drawings and specifications?
- Does the facility meet the requirements and guidance of the CDC/NIH to operate safely at biosafety level III (BSL-3) and animal BSL-3 (ABSL-3)?

- Are the proper LLNL regulating documents in place to provide control over reasonably-foreseeable planned activities in these laboratories?
- Is a training plan in place to insure that management, workers, emergency responders, and other affected personnel have the proper knowledge and skills to perform the work safely?
- Is the facility designed to and will it be operated in conformance with the applicable DOE and other regulatory requirements as formulated in the LLNL ES&H Manual and Work Smart Standards?
- Will the facility be operated so that there is no undue risk to employees, the public, and the environment?
- Are roles and responsibilities clearly defined?
- Are all of the above properly and adequately documented?

The BSL-3 Facility MPR will verify that the necessary approved requirements documentation is in place and that procedures, personnel, equipment, and systems support the approved requirements. The review used the Criteria and Review Approach Documents (CRADs) listed in Appendix A of the Implementation Plan and also shown on the respective MPR Assessment Forms in Appendix A of this document.

3.0 SCOPE

The scope of this review has physical and administrative boundaries that are separated into Plant and equipment (hardware) readiness; process/programmatic systems readiness; management programs (procedures, plans, etc.) readiness and management and personnel readiness. The Criteria and Review Matrix in Appendix C of the Implementation Plan identifies which MPR Team member was assigned to cover the criteria under each area of this scope. These Team members or Primary Reviewers were responsible to the Team Leader for the conduct of the system review indicated.

Plant and Equipment (B368 Facility Hardware) Readiness

Plant and Equipment Readiness encompasses plant equipment and systems. These include but are not limited to: Building Electrical Systems; Standby Power Generator; Uninterrupted Power Supply (UPS) System; Fire Alarm System; Fire Sprinkler System; Heating, Ventilation and Air Conditioning System; Air Filtration/HEPA Filtration Systems; Domestic Water Distribution Systems; and Building Structure.

Process/Programmatic Systems Readiness

Process/Programmatic Systems Readiness encompasses equipment and systems. These include but are not limited to: Pass-Through Autoclave System; Vaporized Hydrogen Peroxide (VHP) System; Class II Biological Safety Cabinets; Tissue Digester System; Waste Holding-Tank/Sump System; Animal Caging System; Medical Surveillance/Immunoprophylaxis; Personal Protective Equipment; Biosurety/Biosecurity Systems; and Physical Security Systems.

Management Programs Readiness

Management programs readiness encompasses procedures, plans, etc. These include but are not limited to: Institutional plans and procedures (ES&H Manual documents, Select Agent Emergency Management Plan, Select Agent Inventory System, Incident Reporting System, discipline action plans); BBRP plans and procedures (Biogovernance MOU, team responsibilities MOUs, Conduct of Operations workbook, Directorate Quality Assurance Plan, Directorate ES&H Management Plan, Configuration Management Plan, Maintenance Plan, Calibration Plan, Self-assessment Plan, Training Plan); Building Plans and Procedures (Construction Files, Preliminary Authorization Basis Document, Final Authorization Basis Document, Fire Hazard Analysis/Fire Department Run Cards); Security Plan, Facility Safety Plan (FSP-368), Standard Operating Procedures, Activity Approvals (IBC, LBOC, IACUC, CDC/APHIS, IWS); and compliance with legal declarations and LLNL BSL-3 EA.

Management and Personnel Readiness

Management and personnel readiness includes, for example, staff qualifications (BIO training, BSL-3 Field Lab Training, ES&H, Security, Emergency), Medical Surveillance (Physical Exams, vaccinations, serum banking), Briefings for non-resident staff (Emergency responders, security forces, custodial and maintenance staff), Conduct of Operations Matrix, and Post-Authorization Start-Up Plan.

4.0 CONDUCT OF THE LLNL MPR

The LLNL MPR Team evaluated the objectives listed in the LLNL MPR Implementation Plan against the criteria described in the CRADs provided in Appendix D of the Implementation Plan and shown on the MPR Assessment Forms in Appendix A of this report.

The MPR Team members were selected from available resources within LLNL, UC, LANL, and a qualified sub-contractor. Selection was based on their experience and expertise in specific subject (functional) areas. Consideration was also given to members with experience and qualifications in conducting performance-based readiness reviews, completion of readiness review training, and organizational independence.

The Team developed performance objectives and criteria within the defined scope of their assigned Subject Areas. These were recorded in the IP that was approved by the MPR Team Leader and reviewed by DOE/NNSA-LSO. LLNL MPR field work was commenced after receipt of comments from DOE/NNSA-LSO.

An initial site visit was conducted the week of June 6th, 2005 in order to familiarize the team with the facility and associated documents. The MPR officially started the week of

October 10th, 2005 but was not concluded until a second site visit was conducted the week of June 5th, 2006.

All team members assessed their assigned Subject Areas as described in the IP. During the October 2005 site visit, preliminary findings were discussed daily and informally recorded. Team members performed the follow-up necessary to validate the accuracy of preliminary findings and provided the basis for classifying the final findings in accordance with the criteria presented in paragraph 9.2 of the IP. The June 2006 site visit was conducted to reexamine outstanding issues and reevaluate issues associated with shipping/receiving of pathogens.

Team members prepared input to this MPR Final Report for their assigned functional areas and indicated their concurrence with the report by signing the signature sheet at the front. The assessment activities of each team member were documented on assessment forms (Form 1s), which appear in Appendix A of this report.

The LLNL MPR was an on-site evaluation of readiness in accordance with the defined scope of the review described in the IP.

The MPR was conducted in accordance with the MPR Implementation Plan and the LLNL Environmental, Health and Safety (ES&H) Manual, Volume I, Chapter 2, and is consistent with the applicable portions of the DOE Standard "Planning and Conduct of Operational Readiness Reviews" (ORR) (DOE STD-3006-95) and the DOE/NNSA "LSO Procedures for Startup and Restart of Facilities" (LSO/LSOD-SOP-000162.02) using a graded approach. Although the standard is for nuclear facilities, the Core Requirements given in the Standard are appropriate to the review of a pathogens research facility when tailored by utilizing a graded approach. The Criteria and Review Matrix given in Appendix C of the Implementation Plan gives the breadth and depth of this review by stating the specific areas to be evaluated. The applicable DOE Standard Core Requirement numbers and the Criteria and Review Approach Documents (CRADs) developed using a graded approach are included in Appendix D of the IP

In preparation for the official review sessions, the BSL-3 Facility Project Manager provided the MPR Team with the required documentation as listed in Section 8.0 of this document.

Team members were responsible for reviewing those areas of Building 368 readiness within their area of expertise as defined by CRADs. Interviews with staff responsible for the team member's review area were conducted as needed. Activities such as training exercises, drills and demonstrations of equipment were observed. Team members were responsible for recommending which findings must be corrected prior to BSL-3 operations using the MPR Deficiency Form which is standard Form 2. If a finding was recommended as a "pre-start", the requirement or standard is referenced in the form. This is a finding that must be

corrected prior to startup of any part of the BSL-3 facility operations. If a finding was recommended as a “post-start/critical” then that finding can be corrected after the start-up of the facility, but must be corrected prior to the start of a specific piece of equipment, operation, or procedure. If a finding is a “post-start” finding that is not critical that finding can be corrected after start up of the facility.

The MPR began immediately after the LLNL declaration of readiness and the Team members started their reviews of specific system documents and procedures. Prior to the start of the MPR, team members reviewed documentation related to the facility for orientation purposes. An initial inspection tour was conducted during the first week of MPR in October of 2005 but members revisited the facility multiple times to confirm or examine the status of corrective actions or address specific issues not recognized upon the initial visit.

MPR Team meetings were conducted ad hoc throughout the MPR. MPR Team members conducted interviews individually and together as necessary to minimize impact to site personnel. Meetings were held by the Team Leader throughout the review to discuss expectations, issues, findings, and conclusions. The BSL-3 Facility Project Manager made sure that B368 project personnel were available to provide quick clarifications and requested information as required.

It is important to note that during the course of the MPR that operational control of B368 was moved from the BIO Directorate to Nonproliferation, Arms Control and International Security (NAI) whose name later changed to Nonproliferation Homeland and International Security (NHI). The titles of these three organizations are reflected in the large number of references found in Section 8.0. During the start of the MPR the control of the facility was with BIO but the programmatic control was with NAI. When the last site visit was conducted in June of 2006 all control had been shifted to NHI.

Another major change that led to identifying the large number of references occurred between the two MPR site visits. This was the creation of the Select Agent Center (SAC) and a whole new organization to run it. The B368 BSL-3 facility is now part of the SAC. The SAC is staffed with individuals whose home organization is NHI and others who are matrixed in from BIO. Due to the complexity of trying to capture this change it was necessary to create the Contacts Listing shown in Appendix D of this document which greatly exceeds the list shown in the Implementation Plan (Appendix A).

5.0 MPR EVALUATION

The LLNL MPR Team reviewed the Readiness Objectives from DOE Order 425.1C using the criteria and approaches described in the CRADs provided in Appendix A of the LLNL MPR Implementation Plan which are also reproduced on the respective Assessment Forms in Appendix A of this report for ease of reference.

As described in the CRADs, the assessment was performed through document review, personnel interviews, and physical walk downs of the facility. There was an additional opportunity to observe a video of a B368 Emergency Response exercise which proved to be quite useful. Walkdowns or tours of the facility were conducted on several occasions with the support of the B368 Construction Manager, Senior Laboratory Coordinator, Select Agent Facility Manager, Room Responsible Person (for the ABSL-3 laboratory), Facility Point of Contact, Fire Protection specialist, and various other support personnel associated with the construction and operation of the facility or its equipment.

Identified deficiencies were classified as either pre-start or post-start findings. Pre-start findings require that corrective actions be implemented prior to NNSA authorization to commence operations at B368. Post-start findings require NNSA-approved action plans prior to NNSA authorization of startup, but do not require that the corrective actions be completed prior to startup. If an MPR Finding duplicates the same issue from the Management Self Assessment of Readiness it will be noted as such and a Form 2 will not be prepared in order to avoid duplication of closure efforts.

During the review process, the team members identified certain deficiencies that were judged to have impact on the safe operation of the facility. These were noted as “observations” that provide recommendations for consideration by facility management. These do not affect the startup of operations.

The following sections provide brief summaries of each of the four subject areas. Detailed assessment forms are compiled in Appendix A and Deficiencies in Appendix B of this report.

5.1 Plant and Equipment Readiness

Extensive work was done by Team members to examine the facility commissioning report, as-built drawings, manufacturer’s equipment documentation, design specifications and testing and numerous other references and consultations to determine the sufficiency and operability of the facility and its equipment. Many issues were identified during or prior to the conduct of this MPR concerning the plant and its equipment. Initially there were problems with the HVAC including difficulties with air balance and maintenance of negative air-pressure in some rooms. There were also problems with the building HEPA filtration but all the ventilation and filtration-related issues have been resolved. The MPR Team spent some time trying to resolve an issue concerning the quantity of water generated by the deluge fire sprinkler system as it related to the sizing capacity of floor drains. It was necessary to consult a LLNL fire protection engineer to answer the question which was satisfactorily resolved. Other issues related to floor drain openings in the ABSL-3 laboratory, and the ability of anteroom doors to “self-close” from a prescribed angle of opening. The B368 facility “hardware” is considered both sufficient and adequate to meet operational specifications.

5.2 Process/Programmatic Systems Readiness

The number and types of problems encountered with process/programmatic systems is not out of the ordinary but yet significant. There were, for example, problems with the autoclave, the VHP decontamination system, the need/location for equipment seismic restraints, waste water retention tanks, sumps, and emergency shower and eyewash stations. As the findings and observations reveal, all but one of these issues has been completed and that is for the tissue digester. Finding Number 1 in Appendix B explains that the tissue digester continues to have problems and has never worked according to the manufacturer's specifications. Measures are being taken to resolve this finding which is Post-Start/Critical for operation of the animal (ABSL-3) laboratory. Other equipment already installed in the facility, such as incubators, freezers and refrigerators were found to be working satisfactorily. Tests were conducted to evaluate concerns about heat buildup in the animal laboratory with all equipment operating (except the tissue digester which administratively won't be working when animals are present in the facility). Results showed this is not a problem.

5.3 Management Programs Readiness

Numerous documents were consulted and many interviews were made with individuals from the Lab Worker level to the Associate Directors. Management up to the NHI and BIO ADs has taken a great interest and involvement in this project as evidenced by their preparation of the Institutional Select Agent Management Structure (ISAMS) document. This was prepared not as a band-aid to fix organizational conflicts but was intended to clarify the management of the SAC and operation of B368. Unfortunately this clarification has led to some additional misunderstandings or uncertainties about the roles, responsibilities, and reporting relationships with regard to some of the newly-created functions.

The Select Agent shipping incident which occurred last year has had a significant impact on the current status of process/programmatic systems in a positive way. It is inconceivable that the current systems would allow for that incident to be repeated.

As shown by a review of the Assessment forms in Appendix A, there was much scrutiny by the Team of the management program readiness. Management programs, such as the IRB, IBC, and LBOC are now further strengthened by the addition of a Select Agent Authorizing Individual (SAAI) who is intimately familiar with health, safety, and regulatory concerns about the handling and experimentation with human and animal BSL-3 pathogens. These are supported by the NHI Directorate's implementation of the Select Agent Center (SAC) and delegation of authority to senior management officials directly responsible for the facility (e.g., the NHI AD FM, NHI APL-SAC). While this is considered a strength it is also a source of some potential problems. The difficulties observed here probably result from the organizational movement of the facility from one Directorate to another along with changes in personnel and management for the newly created SAC. This is revealed in findings that pertain to adequate and correct

preparation of work procedures and development of an operational plan that allows for a graded approach to startup of the facility.

Institutional support from the Safety and Environmental Programs (SEP) Directorate in the nature of Environmental Protection Department, Hazards Control Department, and Health Services Department is adequate and sufficient to support this operation.

The Team feels that these issues are easily resolvable but need to be taken care of prior to the startup of the facility so that personnel all understand their respective roles, responsibilities, and functions.

5.4 Management and Personnel Readiness

Two Pre-Start Findings have to do with procedures for medical and emergency response. While overall this subject area is in good shape there is concern about these two specific issues because of potential health and safety impacts.

With regard to medical procedures the issue is not with the HSD technical competence (which is excellent) but rather with adequate and correct procedures which would affect LLNL's ability to identify and track the effects of employee pathogen exposures. Upgrading biological capabilities to working with BSL-3 pathogens can substantially increase risks to workers and all those they come into contact with. These medical procedures need to be specific for working with the new health hazards and some issues (e.g., immunizations, serum banking, and medical surveillance) must reflect conscious decision by upper management to accept certain risks. For example, the LLNL ES&H Manual discussion on medical surveillance allows for voluntary compliance in many instances but is silent on the circumstances that require mandatory compliance. Is the current practice of filling out a questionnaire in years following a physical exam adequate to identify concerns with individuals working with BSL-3 pathogens? It is unclear whether this is a cost-saving issue or an attempt to not infringe on a workers' right to privacy. Similar questions can be asked about voluntary immunizations and serum banking after the initial year. Facilities like the US Army's USAMRIID facility at Ft. Detrick, MD have a great deal of experience with this issue and should be contacted to at least gain their insight into how they have dealt with them.

The concerns with emergency response is similar in that the effect of not having adequate procedures and training to insure control of pathogens is a risk issue to LLNL and NNSA. A 3-blanket wrap is a fundamental procedure for emergency responders. The effects of a simple thing like a responder not removing contaminated outer gloves at the correct time during the performance of a 3-blanket wrap can easily result in a victim becoming contaminated. The consequences can be far reaching due to the characteristics of some BSL-3 pathogens to survive and spread in the environment. The Team couldn't get an adequate perspective on how non-B368 emergency responders (i.e., those without a background in pathogens) understand the necessity for the attention to detail and the consequences. No written procedures were offered that addressed the 3-blanket wrap or other emergency rescue activities as it appeared that the primary method of passing along the knowledge is through OJT. Written

procedures and formalized training along with more demonstrations of competency through conducting emergency exercises should take care of this concern.

6.0 LESSONS LEARNED

The MPR Team is constituted of highly knowledgeable specialists from a variety of professional technical areas who are very familiar with the DOE/NNSA and LLNL construction and operational environment. Their knowledge of, for example, the electrical, mechanical, and security systems within the DOE/NNSA control is essential to insuring compliance with DOE Orders and appropriate building code requirements. Without their knowledge and experience this MPR would not have been as thorough as it was nor as successful.

Given that this is the first such facility like this within DOE/NNSA complex it was essential that the Team Leader be well versed in the design, construction, and operation of biosafety laboratories and be able to provide guidance and context to others on the team. A lessons learned to be applied to similar endeavors of this type would be for the Team Leader to be similarly qualified and to begin the project with a comprehensive training/orientation presentation to the Team, explaining the interconnectivity and dependency of systems, and the regulatory and biosafety compliance requirements. Providing such a review early in the tasking, rather than parsing out such information during the process, as was done for this readiness review, would expedite the review.

7.0 CONCLUSION

The review by the independent MPR Team resulted in three pre-start findings, one post-start finding, and four observations (See Appendices A and B). Contingent upon closure of the pre-start findings, the Team concludes the LLNL B368 BSL-3 Facility can be operated safely.

8.0 REFERENCES [Documents used to conduct the MPR]

- 1 Air Techniques International (ATI), Oak Ridge Filter Test Facility, Filter Test Report 21 Oct 04.
- 2 Alameda County Environmental Health Permit to Operate #PT0305526 valid 7/1/04-6/30/05
- 3 B365 Waste Retention Tank System Plan; 365-WRT-SOP-01 Rev. 1 Jan 2006
- 4 B368 Facilities Maintenance MOA - Plant Engineering (MOA-MNT-0001), Rev. 1, March 1, 2006 [replaces 5&6]
- 5 B368 Facilities Maintenance MOA - Plant Engineering (MOS-MNT-0001), July 2005 [replaced by 4]
- 6 B368 Facilities Maintenance MOA - Utel (MOA-MNT-0001), August 2005 [replaced by 4]
- 7 B368 SOP Review Course, Training Roster (BR3001), 7/7/05
- 8 B368 SOP Training Roster (BR3001), 5/5/05
- 9 B368 Tissue Digester Operator Training Roster, 5/16/05
- 10 B368 VHP Operator Training Roster, 3/16/05
- 11 Beneficial Occupancy Letter - PFN#: 361-03-001, 6/17/05
- 12 Biology and Biotechnology Research Program Building 365 Wastewater Retention Tank, Hypochlorite Injection System, Operational Plan, Rev. 1, 3/03
- 13 Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
- 14 Biosciences Directorate Critical Measuring and Test Equipment Calibration Plan (BR-CP-05), 2/9/05 [deleted; included in 53]
- 15 Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
- 16 Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
- 17 Biosciences Directorate Quality Assurance Plan, 2/9/05 [replaced by 89]
- 18 Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
- 19 BR0092/R Biosciences ES&H Orientation and refresher
- 20 BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
- 21 BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
- 22 BR9800 Select Agent Security
- 23 Britz-Heidbrink Inc. As-Built Drawings - PFN#: 361-003-001, 8/8/05
- 24 Britz-Heidbrink Inc. As-Built Fire Alarm Drawings 8/5/05
- 25 Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
- 26 Building 368 Biosafety Manual
- 27 Building 368 Conduct of Operations, March 2006
- 28 Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
- 29 Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
- 30 Building 368 Fire Hazards Analysis (HC-T2-05-022), 5/9/05
- 31 Building 368 Management Plan, 6/30/05 [replaced by 68]
- 32 Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)

- 33 Building 368 Select Agent Security Plan, 7/29/05 [replaced by 74]
- 34 California Code of Regulations (CCR) 22, section on hazardous waste satellite accumulation areas
- 35 California Health and Safety Code, sections 117600-118360
- 36 CDC/APHIS Registration
- 37 CDC/APHIS/NIH Inspections
- 38 CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
- 39 CDC/NIH, Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Edition, September 2000.
- 40 Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
- 41 Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
- 42 Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
- 43 Clinical and Laboratory Standards Institute, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition, M29-A3, Vol. 25, No. 10
- 44 Clinical Reference Guide - Biohazards Medical Surveillance, 7/05
- 45 Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
- 46 Department of Health Services - Consultation
- 47 Department of Health Services - Serum Banking Program, 3/28/03
- 48 Design Specification Bid Set
- * Department of Energy Order 425.1C
- 49 Durrant E-Mail Dated 9/12/05 inre Panelboard Short Circuit Ratings.
- 50 Environmental Assessment (EA) for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California (DOE/EA-1442), 12/02, and Finding of No Significant Impact (FONSI), 12/16/02
- 51 Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
- 52 EP0006-COR and EP0006-HZ/HZRW
- 53 Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
- 54 Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
- 55 Final Report for the Vaporized Hydrogen Peroxide (VHP®) Testing of LLNL's Building 368, Claire Fritz, VHP Process Engineer, STERIS Corporation, July 18, 2005
- 56 Final Structural Calculations Volume 1 Dated June 30, 2004.
- 57 Final Structural Calculations Volume 2 Dated November 30, 2004.
- 58 Final Structural Calculations Volume 3 Dated August 18, 2005.

- 59 Fire Department Run Cards (Blank - to be completed when facility begins operation)
- 60 Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
- 61 Foot Candle Calculations Dated 8/19/03, and Durrant Group E-Mail Dated 9/12/05.
- 62 Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
- 63 Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
- 64 HS 4431 - BSL-3 Operator Training Roster, 3/14/05
- 65 HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
- ** Implementation Plan for the Biosafety Level III (BSL-3) Facility Management Pre-Start Review (BSL-3 MPR) at Lawrence Livermore National Laboratory, June 20, 2005
- 66 Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
- 67 Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
- 68 Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
- 69 IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
- 70 IWS#10024.01r@ Laboratory Animal Anesthesia Machine
- 71 Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
- 72 Lawrence Livermore Fire Department - Tactical Plan, Response to Emergencies in Building 368, 3/29/05
- 73 LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
- 74 LLNL Biological Select Agents and Toxins Security revision 5, dated Dec., 13, 2004 [Rev. 6, 3/9/06]
- 75 LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
- 76 LLNL Environment Safety& Health Manual [available internal/external on-line]
- 77 LLNL Final Acceptance Letter - PFN#: 361-03-001, 9/19/05
- 78 LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]
- 79 LLNL LiveLink computer-server document storage and retrieval system for B368 records management
- 80 LLNL Procurement & Materiel Department, Material Distribution Division (MDD) Operating Procedures, Section 200.20; Infectious Substances and Etiologic Agents, receiving and shipping instructions: Issue Date 8/1/05 [7/10/06]
- 81 LLNL Wastewater Discharge Permit for 2005-2006, document no. WGMG05:071, dated June 7, 2005
- 82 LLNL Work Smart Standards
- 83 Material Distribution Division (MDD) Operating Procedures, Section 302.16, Subject: Infectious Substances and Etiologic Agents [deleted]
- 84 Mechanical calculations, dated August 29, 2005

- 85 Medical Waste Permit Application, Medical Waste Management Plan, and Emergency Action Plan for B-368 Biosafety Level 3 Facility, document no. PRA05-037, June 2005
- 86 MESA3 HVAC Balance - 06/05; Test Report #3861.1, LLNL Building 368, Livermore, CA.
- 87 NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
- 88 NAI Integrated Safety Management Plan, February 2005 [replaces 16]
- 89 NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
- 90 NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
- 91 NAI Stop Work Policy, Rev.1, January 2006
- 92 NAI/BBRP MOU NAI/O 04-03-030 Addendum - BSL-3 MOU Responsibility Assignment, 9/22/04 [deleted]
- 93 NEPA Review of Proposed Changes to the BSL-3 Facility (Biosafety Cabinets), 12/10/05
- 94 NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2002
- 95 Nuclear Work Center MS PowerPoint Presentation, Bill Kemp, July 25, 2005
- 96 Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
- 97 Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
- 98 RHWM Division Procedure WPT 109, titled, Retention Tank System Operations"
- 99 Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
- 100 SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
- 101 SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
- 102 SOP 1.10 Integrated Pest Management Program [Rev. 1, 4/6/06]
- 103 SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
- 104 SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
- 105 SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
- 106 SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
- 107 SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
- 108 SOP 1.4 Medical Surveillance and Certification of Workers [1/11/05]
- 109 SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
- 110 SOP 1.6 Quality Control for Building 368 [1/11/05]
- 111 SOP 1.7 Inventory of Select Agents in B368 [Rev. 1, 4/19/06]
- 112 SOP 1.8 Internal Exchange of Select Agents [4/28/06]
- 113 SOP 2.1 Access Control in B368 [4/6/06]
- 114 SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
- 115 SOP 2.3 Technical Procedures in ABSL-3 [deleted]
- 116 SOP 2.4 Euthanasia Acceptable Methods [deleted]

- 117 SOP 2.5 Euthanasia CO2 Gas [deleted]
- 118 SOP 2.6 Isoflurane Anesthesia Machine [deleted]
- 119 SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
- 120 SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
- 121 SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
- 122 SOP 3.4 Incubator Use in B368 [1/11/05]
- 123 SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]
- 124 SOP 4.1 Contamination Control in B368 Laboratories [1/11/05]
- 125 SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
- 126 SOP 4.3 Vaporous Hydrogen Peroxide (VHP) [Rev. 5, 7/6/06]
- 127 SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
- 128 SOP 5.1 General Laboratory Practices for B368 [1/11/05]
- 129 SOP 5.2 Pipetting in B368 [1/11/05]
- 130 SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
- 131 SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
- 132 SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
- 133 SOP 5.9 Janitorial Maintenance for Building 368 [deleted]
- 134 SOP 6.1 Maintenance Access and Service in B368 [1/11/05]
- 135 SOP 6.2 Routine Facility Monitoring for B368 [deleted]
- 136 Space and Site Planning Findings and Determination, F&D 04-002, (Building 368), 11/10/2003
- 137 Steris™ Installation/Startup Verification Procedure for an Eagle 3000 Stage 3 Small/Medium Sterilizer SN 810480401 [8/16/05]
- 138 Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
- 139 Technical Safety Services Inc., Biological Safety Cabinet Certification Report, No. 354189, 5/31/05.
- 140 The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
- 141 Training record for the RHWM Field Technician who inspects and operates the retention tank system on a daily basis
- 142 Training records for individuals working within B-368
- 143 Treatment Permit for the Tissue Digester and Autoclave in B-368 issued by the California Department of Health Services, dated 7-1-05
- 144 US Department of Health, Education, and Welfare, Public Health Service/NIH, Laboratory Safety Monograph; A supplement to the NIH Guidelines for Recombinant DNA Research, 1/2/79
- 145 World BioHazTec Site Survey Comments Form, Draft Final Inspection, 7/7/05

* and ** are documents that were left off the documents listing during production of the assessment forms. They are not herein renumbered due to the effect upon the numbering references (i.e., those which were replaced by other documents).

Appendix A

MPR Assessment Forms

*Note that in this appendix when records/documents show that they are replaced or superseded by a certain reference that the reference number refers to the number in the References List in Section 8 of the main document!

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 1	CRITERIA MET	
Environmental	DATE: 6/11/06	YES	NO

Objective:

Environmental protection measures are available and adequate to ensure the protection of the environment and facility staff training is adequate.

Criteria:

- 1) Building 368 has been integrated into the existing Environmental Protection programs. (CR-01-01)
- 2) Training and qualification programs for Environmental Protection personnel have been established and implemented. Training specific to B368 where necessary, has been accomplished. (CR-03-02)
- 3) Environmental Protection personnel possess a level of knowledge commensurate with their responsibility. (CR-04-03)
- 4) An effective environmental protection and monitoring and waste management program has been implemented that will ensure compliance with the permits and other approvals associated with applicable environmental laws. Procedures have been developed to ensure that hazardous materials and wastes are handled in accordance with legislative requirements, Federal and State regulations, and DOE Orders. (CR-14)
- 5) All safety, process, and utility systems are currently operable and in satisfactory condition. (CR-08-02)

Approach:

Record Review: Team members reviewed the documentation which establishes the roles, responsibilities, and interfaces. Reviewed environmental permits issued for operations and storage associated with operations and verified that the permit requirements will be implemented upon startup. Team members reviewed the necessary records and program procedures to ensure that biological and hazardous wastes are handled in accordance with appropriate legislation, Federal and state regulations, other Federal or state requirements. Members reviewed planned operations for consistency with descriptions of operations in the NEPA Environmental Assessment and FONSI and other regulatory approval documents. Members reviewed the commissioning report and subsequent vendor equipment-testing reports verifying environmental protection systems (air filtration, wastewater retention) have been tested and are operational. Members reviewed training records and SOPs demonstrating staff training and familiarity with environmental protection system operations. Review certifications of equipment important to environmental protection. Review NHI waste

management practices and proposed satellite accumulation area operations. Specific records and documents reviewed or referred to are as follows:

1. Alameda County Environmental Health Permit to Operate #PT0305526 valid 7/1/04-6/30/05
2. B365 Waste Retention Tank System Plan; 365-WRT-SOP-01 Rev. 1 Jan 2006
3. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
4. B368 SOP Training Roster (BR3001), 5/5/05
5. B368 Tissue Digester Operator Training Roster, 5/16/05
6. B368 VHP Operator Training Roster, 3/16/05
7. Biology and Biotechnology Research Program Building 365 Wastewater Retention Tank, Hypochlorite Injection System, Operational Plan, Rev. 1, 3/03
8. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
9. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
10. BR0092/R Biosciences ES&H Orientation and refresher
11. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
12. Building 368 Conduct of Operations, March 2006
13. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
14. Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
15. Building 368 Management Plan, 6/30/05 [replaced by 68]
16. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
17. California Code of Regulations (CCR) 22, section on hazardous waste satellite accumulation areas
18. California Health and Safety Code, sections 117600-118360
19. Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
20. Environmental Assessment (EA) for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California (DOE/EA-1442), 12/02, and Finding of No Significant Impact (FONSI), 12/16/02
21. Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
22. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
23. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
24. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
25. LLNL LiveLink computer-server document storage and retrieval system for B368 records management
26. LLNL Wastewater Discharge Permit for 2005-2006, document no. WGMG05:071, dated June 7, 2005
27. Medical Waste Permit Application, Medical Waste Management Plan, and Emergency Action Plan for B-368 Biosafety Level 3 Facility, document no. PRA05-037, June 2005

28. MESA3 HVAC Balance - 06/05; Test Report #3861.1, LLNL Building 368, Livermore, CA.
29. Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
30. RHWM Division Procedure WPT 109, titled, "Retention Tank System Operations"
31. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
32. SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
33. SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]
34. SOP 4.1 Contamination Control in B368 Laboratories [1/11/05]
35. SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
36. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
37. Space and Site Planning Findings and Determination, F&D 04-002, (Building 368), 11/10/2003
38. Steris™ Installation/Startup Verification Procedure for a Eagle 3000 Stage 3 Small/Medium Sterilizer SN 810480401 [8/16/05]
39. Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
40. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
41. Training record for the RHWM Field Technician who inspects and operates the retention tank system on a daily basis
42. Training records for individuals working within B-368
43. Treatment Permit for the Tissue Digester and Autoclave in B-368 issued by the California Department of Health Services, dated 7-1-05

Interviews:

- | | |
|-----------------|--|
| ◆ BIO DAD PR | BIO Deputy Associate Director for Programs |
| ◆ BIO ES&H | BIO ES&H Officer |
| ◆ BIO TC | BIO Training Coordinator |
| ◆ HCD Team 2 EA | ES&H Team 2, Environmental Analyst |
| ◆ RHWM | Hazardous Waste Management Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, ES&H Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, Industrial Hygienist |
| ◆ IBC Co-Chair | Institutional Biosafety Committee Co-Chair |
| ◆ Lab Worker | BSL-3 Microbiologist/Technician |
| ◆ NEPA Rep. | NEPA Program Representative |
| ◆ NHI BSL-3 FPM | NHI BSL-3 Facility Program Manager |
| ◆ SAFM | Select Agent Facility Manager |
| ◆ SAM | Select Agent Manager (Select Agent Center) |
| ◆ SLC | Senior Laboratory Coordinator |

Shift Performance: None

Discussion of Results (by Criteria):

- 1) Institutional support for Environmental Protection programs are explained in the Team and Discipline Action Plans for B368 and through the LLNL on-line ES&H Manual (Volume III – Environment – Controls and Hazards). Interviews with ES&H Team 2 personnel and B368 managers confirmed this.
- 2) Training and qualifications for ES&H Team 2 personnel is driven institutionally through the Hazards Control Department, but these personnel are also included in B368-specific training. These personnel are current on Environmental Protection training.
- 3) The Hazards Control Department has assigned personnel to ES&H Team 2 with knowledge and experience environmental programs (air, water, waste, etc.) monitoring and compliance. They have direct and immediate access to more experience or senior technical staff as needed.
- 4) Various procedures listed above have been developed by NHI for B368 to address waste generation, disposal, and treatment. These procedures allow for control of waste within LLNL permits specifications and according to regulations, assuming all systems are functioning appropriately. There has been a problem with the Tissue Digester generating excessive amounts of water that when discharged to the retention tank allowed it to overflow. Studies and testing determined that this is excess cooling water due to some fault in the temperature sensing unit. The retention tank system is a two-tank system designed to switch manually (now modified to switch automatically) between a full to an empty tank. The amount of cooling water exceeded the capacity of the two tanks. Repair of the sensing unit or re-routing the cooling water to the sanitary discharge is being considered at this point. Also due to a problem with the sizing of the hot-water boiler the digester must be run for a longer period at a lower temperature than specified by the manufacturer (i.e., WR²). There is a variance for this treatment unit from the California regulators so that annual temperature calibration data for this unit is not required. While there is no finding with this issue there is concern that NHI develops methods to document that the unit is functioning as required.
- 5) With the exception of the Tissue Digester, all safety, process, and utility systems are currently operable according to manufacturers' specifications and in satisfactory condition.

Conclusion(s): The criteria for this CRAD can be considered to be met with the exception of #4, but since the offending problem is only to be used for animal carcass disposal and there are no animal studies identified for the near future this will be considered a Post-Start /Critical Finding. Prior to startup of the ABSL-3 as an animal laboratory this piece of equipment must be functioning as specified by the manufacturer. In the interim, procedures should be prepared for the tissue digester to provide indisputable documentation of destruction of all organic material.

Issue(s): Tissue Digester must be repaired to meet manufacturers specifications and California waste treatment regulations. Procedures for documenting treatment must be prepared and approved prior to use of the equipment for biohazardous waste treatment.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Safety, Health, and Quality Assurance Management	CRAD NO: 2 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

SH&QA support services are available and adequate to ensure safe accomplishment of work.

Criteria:

- 1) Building 368 has been integrated into the existing SH&QA programs. (CR-01-01)
- 2) Training and qualification programs for SH&QA personnel have been established and implemented. Training specific to Building 368, where necessary, has been accomplished. (CR-03-02)
- 3) SH&QA personnel possess a level of knowledge commensurate with their responsibility. (CR-04-03)
- 4) Sufficient numbers of qualified SH&QA personnel are available to support Building 368 operations. (CR-06-01)
- 5) Adequate SH&QA facilities and equipment are available to support operations. (CR-06-02)
- 6) A routine drill program and operations drill program has been established and implemented. (CR-11)
- 7) Adequate and correct procedures exist for SH&QA services to Building 368.

Approach:

Record Review: Team members reviewed the Hazard Control Team Action and Discipline Action Plans. Members reviewed the Tactical Plans and the Incident Reporting System. Members reviewed the NHI Directorate Quality Assurance and Self Assessment Plans. One member reviewed drill reports for Building 368. The Team also reviewed selected SH&QA personnel training and/or qualifications. The following documents and records were reviewed or referenced for this CRAD:

1. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
2. B368 SOP Training Roster (BR3001), 5/5/05
3. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
4. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]

5. Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
6. Biosciences Directorate Quality Assurance Plan, 2/9/05 [replaced by 89]
7. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
8. BR0092/R Biosciences ES&H Orientation and refresher
9. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
10. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
11. BR9800 Select Agent Security
12. Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
13. Building 368 Biosafety Manual
14. Building 368 Conduct of Operations, March 2006
15. Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
16. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
17. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
18. CDC/NIH, Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Edition, September 2000.
19. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
20. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
21. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
22. Clinical and Laboratory Standards Institute, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition, M29-A3, Vol. 25, No. 10
23. Clinical Reference Guide - Biohazards Medical Surveillance, 7/05
24. Department of Health Services - Consultation
25. Department of Health Services - Serum Banking Program, 3/28/03
26. Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
27. EP0006-COR and EP0006-HZ/HZRW
28. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
29. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
30. Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
31. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
32. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05

33. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
34. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
35. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
36. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
37. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
38. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
39. Lawrence Livermore Fire Department - Tactical Plan, Response to Emergencies in Building 368, 3/29/05
40. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
41. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
42. LLNL Environment Safety& Health Manual [available internal/external on-line]
43. LLNL Work Smart Standards
44. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
45. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
46. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
47. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
48. NAI Stop Work Policy, Rev.1, January 2006
49. NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2002
50. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
51. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
52. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
53. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
54. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
55. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
56. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
57. SOP 1.4 Medical Surveillance and Certification of Workers [1/11/05]
58. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
59. SOP 1.6 Quality Control for Building 368 [1/11/05]
60. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
61. SOP 2.3 Technical Procedures in ABSL-3 [deleted]
62. SOP 2.4 Euthanasia Acceptable Methods [deleted]
63. SOP 2.5 Euthanasia CO2 Gas [deleted]
64. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
65. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
66. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
67. SOP 3.4 Incubator Use in B368 [1/11/05]
68. SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
69. SOP 5.1 General Laboratory Practices for B368 [1/11/05]

- 70. SOP 5.2 Pipetting in B368 [1/11/05]
- 71. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
- 72. Training records for individuals working within B-368
- 73. US Department of Health, Education, and Welfare, Public Health Service/NIH, Laboratory Safety Monograph; A Supplement to the NIH Guidelines for Recombinant DNA Research, 1/2/79
- 74. World BioHazTec Site Survey Comments Form, Draft Final Inspection, 7/7/05

Interviews:

- ◆ ALT BSO Alternate Biosafety Officer
- ◆ BIO DAD OP BIO Deputy Associate Director for Operations
- ◆ BIO DAD PR BIO Deputy Associate Director for Programs
- ◆ BIO AD BIO Directorate Associate Director
- ◆ BIO ES&H BIO ES&H Officer
- ◆ BIO TC BIO Training Coordinator
- ◆ BSO Biosafety Officer
- ◆ EP EEP Emergency Programs, Exercises and Employee Preparedness
- ◆ EP OI FDS Emergency Programs, Overview and Integration, Facility Drill Specialist
- ◆ FPOC Facility Point of Contact
- ◆ HCD Team 2 Hazards Control Team 2, ES&H Technician
- ◆ HCD Team 2 Hazards Control Team 2, Industrial Hygienist
- ◆ IBC Co-Chair Institutional Biosafety Committee Co-Chair
- ◆ LBOC Chair Laboratory Biosafety Operations Committee Chairman
- ◆ NHI AD NHI Associate Director
- ◆ NHI ADFM NHI Associate Director Facility Manager
- ◆ NHI APL-SA NHI Associate Program Leader for Select Agent Science
- ◆ NHI BSL-3 FPM NHI BSL-3 Facility Program Manager
- ◆ NHI DAD OP NHI Deputy Associate Director for Operations
- ◆ SAFM Select Agent Facility Manager
- ◆ SAM Select Agent Manager (Select Agent Center)
- ◆ SLC Senior Laboratory Coordinator

Shift Performance: None. Unable to observe a drill but did review a movie/DVD of one held in 2005.

Discussion of Results (by Criteria):

- 1) Institutional support for B368 activities is described in the Facility Safety Plan Building 368 (as amended by the Major Change Memo) and explained in LLNL ES&H Manual in Volume I, *ES&H Management* and Volume IV, *Other Institutional ES&H Documents* (e.g., Quality Assurance and Configuration Management Plans). The Facility Safety Plan

describes support from the ES&H Teams, the Environmental Protection Department, and the Health Services Department. Other B368-specific SH&QA documents tier from the FSP, such as the respective Team and Discipline Action Plans, and the B368 Configuration Management Plan. The NAI Quality Management Plan for Science, Engineering and Facilities provides guidance for all NHI (i.e., NAI) QA programs. Interviews with ES&H Team 2 personnel and B368 managers confirmed that Building 368 has been integrated into the existing ESH program but there has been a limited involvement from QA.

- 2) Training programs for SH&QA personnel have been established and implemented by LLNL. These programs are shown in ES&H Manual Volume IV, Part 40: Training; Document 40.2; Environment, Safety, and Health Training and Education. B368 specific training for SH personnel are available and two individuals (FPOC and HCD Team 3 ES&H Technician) have not completed all training because it was recently decided they would be entering the BSL-3 facility while it is operational. Both are currently scheduled for the training and it is expected that the training will be accomplished prior to the submittal of this report. No interviews were conducted with QA personnel due to scheduling conflicts.
- 3) SH&QA personnel do possess a level of knowledge commensurate with their responsibility.
- 4) Sufficient numbers of qualified SH&QA personnel are available to support Building 368 operations. The LLNL institutionally supports this facility and will provide additional support as required. A BSO and Alternate BSO are supported by the institution.
- 5) Adequate SH&QA facilities and equipment are available to support operations due to the institutional support.
- 6) A routine drill program and operations drill program has been established and implemented. The Emergency Programs group works closely with the SAFM to ensure that drills are conducted on a regular basis. Concerns about the adequacy of the drills are given in CRAD 14 (Emergency Preparedness -2).
- 7) For the most part adequate and correct procedures exist for SH&QA services to Building 368. Many are institutional and found in the ES&H Manual on-line and others are identified as SOP's in the reference list above. One problem found was related to a lack of appropriately-written medical procedures for B368 as they pertain to, for example, immunizations, serum-banking, and medical surveillance (generally stated in the LLNL ES&H Manual). LLNL ES&H Manual Volume 1, Part 3: Safety Analysis and Work Plans and Procedures; Document 3.4 Preparation of Work Procedures should be followed in the preparation of procedures. The documents offered to the Team to support these medical procedures do not follow the ES&H Manual requirements. As for content of the procedures, there is some controversy over whether immunizations for those handling specific pathogens should be required or not. There is the conflict between employee rights versus protection of the public. The same controversy exists over whether medical surveillance after the baseline is voluntary or required, and additionally whether the frequency is annual or every three years. There are also differences of opinion on when serum banking should be performed (once initially versus annually). These issues need to be resolved in accordance with the BMBL, the Clinical and Laboratory Standards Institute (incorporated by reference from the BMBL), and/or other authoritative references and affirmatively stated in the appropriate medical procedure so that B368 staff can be

made aware of the requirements. A recommendation is to consult with the Medical Staff at the US Army Research Institute for Infectious Diseases and take their suggestions into consideration since they have many years experience with this. One publication by them (*Experience in the Medical Management of Potential Laboratory Exposures to Agents of Bioterrorism on the Basis of Risk Assessment at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID)*) by Janice M. Rusnak, MD, Mark G. Kortepeter, MD, John Aldis, MD, and Ellen Boudreau, MD, Journal of Environmental Medicine, Volume 46, Number 8, August 2004) addresses some of this issue. Dr. Rusnak is still at USAMRIID. I don't know about the other physicians.

Conclusion(s): Most SH&QA criteria have been met. Outstanding B368-specific training for the FPOC and ES&H Technician will be accomplished prior to the submittal of this report. Procedures for the medical area need to be prepared in accordance with LLNL ES&H requirements and authoritative references. This is a Pre-Start Finding because the medical requirements for B368 staff need to be known to them before they begin working in the facility. Many of the other B368 SOPs should also be reviewed with respect to the LLNL ES&H Manual for writing work procedures as they are not 100% compliant.

Issue(s): Develop adequate and approved medical procedures for B368 staff in accordance with LLNL ES&H Manual requirements, BMBL, and other authoritative guidance.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 3	CRITERIA MET	
Industrial Safety and Health	DATE: 6/11/06	YES	NO

Objective:

Occupational safety and industrial hygiene (including chemical safety) programs are established, sufficient numbers of qualified personnel are provided, and adequate facilities and equipment are available to ensure services are adequate for safe operations.

Criteria:

- 1) Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented.
- 2) Operations have adequate facilities and equipment and are adequately staffed with qualified personnel who are knowledgeable of the facility and hazards. Personnel have been trained in the appropriate use of safety related equipment. Personnel have been trained to anticipate, recognize, evaluate, and respond to hazards that may be present in the workplace.
- 3) Job hazards analyses are conducted routinely by experienced engineering, industrial safety, industrial hygiene personnel, and plant workers in a coordinated effort to mitigate risks from hazardous operations.
- 4) Level of knowledge of operations support personnel is adequate based on reviews of examinations and examination results and selected interviews of operations support personnel. (CR-4)
- 5) Occupational safety and hygiene/chemical safety support personnel demonstrate the ability to carry out normal, abnormal, and emergency procedures under their cognizance. (CR-X)

Approach:

Record Review: Team members reviewed the documentation (e.g. administrative procedures, organizational charts, position descriptions, or internal memoranda) that establishes the roles, responsibilities, interfaces, and staffing levels for the industrial safety and hygiene/chemical safety organization that supports operations. Members also reviewed the necessary records and program procedures to ensure that industrial safety and hygiene/chemical safety programs have been implemented and are consistent with DOE Orders and applicable industry standards. Review the procedures for conducting a job hazards analysis. Documents reviewed or referenced for this CRAD are as follows:

1. Air Techniques International (ATI), Oak Ridge Filter Test Facility, Filter Test Report 21 Oct 04.
2. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
3. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
4. Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
5. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
6. BR0092/R Biosciences ES&H Orientation and refresher
7. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
8. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
9. Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
10. Building 368 Biosafety Manual
11. Building 368 Conduct of Operations, March 2006
12. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
13. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
14. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
15. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
16. Clinical and Laboratory Standards Institute, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition, M29-A3, Vol. 25, No. 10
17. Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
18. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
19. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
20. Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
21. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
22. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
23. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
24. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
25. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.

26. LLNL Environment Safety & Health Manual [available internal/external on-line]
27. LLNL Work Smart Standards
28. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
29. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
30. NAI Stop Work Policy, Rev.1, January 2006
31. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
32. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
33. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
34. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
35. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
36. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
37. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
38. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
39. SOP 2.3 Technical Procedures in ABSL-3 [deleted]
40. SOP 2.4 Euthanasia Acceptable Methods [deleted]
41. SOP 2.5 Euthanasia CO2 Gas [deleted]
42. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
43. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
44. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
45. SOP 3.4 Incubator Use in B368 [1/11/05]
46. SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
47. SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
48. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
49. SOP 5.2 Pipetting in B368 [1/11/05]
50. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
51. Training records for individuals working within B-368

Interviews: Team members interviewed the occupational safety and hygiene/chemical safety personnel to determine if they are familiar with their roles, responsibilities, and interfaces with the operations organization. They also interviewed operations and maintenance personnel to determine if they have been trained to anticipate, recognize, evaluate, and control industrial safety and hygiene/chemical safety hazards.

- ◆ ALT BSO Alternate Biosafety Officer
- ◆ BIO ES&H BIO ES&H Officer
- ◆ BSO Biosafety Officer
- ◆ HCD Team 2 EA ES&H Team 2, Environmental Analyst
- ◆ FPOC Facility Point of Contact
- ◆ RHWM Hazardous Waste Management Technician
- ◆ HCD Team 2 Hazards Control Team 2, ES&H Technician
- ◆ HCD Team 2 Hazards Control Team 2, Industrial Hygienist
- ◆ NHI APL-SA NHI Associate Program Leader for Select Agent Science
- ◆ NHI BSL-3 FPM NHI BSL-3 Facility Program Manager

- ◆ RRP Room Responsible Person (ABSL3)
- ◆ SAFM Select Agent Facility Manager
- ◆ SLC Senior Laboratory Coordinator

Shift Performance: None

Discussion of Results (by Criteria):

- 1) The Facility Safety Plan Building 368 (FSP), the Institutional Select-Agent Management Structure (ISAMS), and the LLNL Biogovernance Administrative Memo documents together explain the functions, assignments, responsibilities, and reporting relationships for the operation of B368 as part of the Select Agent Center. The ISAMS does not track exactly with the FSP (e.g., the organization chart doesn't show and the text doesn't explain the SAFM, SAAI, FPOC, and RRP) and, for example, it looks like the SAFM (if it were shown) would report to the SAM but the FSP says SAFM reports to the NHI AD FM. It would appear that all functions are not clearly defined, understood, and effectively implemented. For example, interviews with B368 personnel showed there was confusion on who was the primary and alternate FPOC. Also the FSP describes the SAAI position but does not identify to whom this individual reports. The FSP references the ISAMS and the ISAMS first sentence says "This document defines the structure for the management of select-agent and BSL-3 work at LLNL."
- 2) B368 operations do have adequate facilities and equipment and are adequately staffed with qualified personnel who are knowledgeable of the facility and hazards. Facility personnel have been trained in the appropriate use of safety related equipment. ES&H support staff and Lab Workers have been trained to anticipate, recognize, evaluate, and respond to hazards that may be present in the workplace.
- 3) Safety planning and analysis at LLNL is described in the ES&H Manual (i.e., Document 2.2 Managing ES&H for LLNL Work; Document 3.3 Facility Safety Plans and Integration Work Sheets with Safety Plans). The ES&H Manual provides guidance on assessing the hazards using first an Integration Work Sheet (IWS) but may lead to the need for a Job Hazards Analysis. These are conducted routinely by the ES&H Team 2 Industrial Hygienist with additional support from engineering, and plant workers in a coordinated effort to mitigate risks from hazardous operations.
- 4) The level of knowledge of operations support personnel is adequate based on interviews of trainers, review of training records, and selected interviews of operations support personnel.
- 5) There was no opportunity to observe occupational safety and hygiene/chemical safety support personnel demonstrating their ability to carry out normal, abnormal, and emergency procedures. However, they were queried about those procedures and showed a good working knowledge of them. It is important to note that these support staff are co-located with the facilities they are supporting and they are embedded in organization such that they have an excellent knowledge of the facilities, personnel, equipment and even history of safety incidents.

Conclusion(s): All but the first criteria for the CRAD have been met. While there has been considerable effort put into re-organizing the Select Agent work through the establishment of the Select Agent Center under NHI, there is still some lingering organizational uncertainty reflected in documents and personnel interviews. Conflicts between the FSP and the ISAMS should be resolved and staff trained to the appropriate reporting, responsibility, and authorization matrix. This is a Pre-Start Finding.

Issue(s): Resolve the discrepancies between the FSP and ISAMS and train personnel to the appropriate organizational changes.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 4	CRITERIA MET	
Biological	DATE: 6/11/06	YES	NO

Objective:

Biological safety programs are established, sufficient numbers of qualified personnel are provided, and adequate facilities and equipment are available to ensure services are adequate for safe operations.

Criteria:

- 1) Plans, procedures, reviews and approval processes are in place to ensure compliance with *Biosafety in Microbiological and Biomedical Laboratories (BMBL 4th Edition)* as required by WSS. (CR-14)
- 2) Operations have adequate facilities and equipment and are adequately staffed with qualified personnel who are knowledgeable of the facility and biological hazards. Personnel have been trained in the appropriate use of safety related equipment. Personnel have been trained to anticipate, recognize, evaluate, and respond to biohazards that may be present in the workplace. (CR-03-01, CR—04-01, CR-04-02)
- 3) Job hazards analyses are conducted routinely by experienced engineering, industrial safety, industrial hygiene personnel, and plant workers in a coordinated effort to mitigate risks from hazardous operations. (CR-13)
- 4) Level of knowledge of operations support personnel is adequate based on reviews of examinations and examination results and selected interviews of operations support personnel. (CR-4)
- 5) Procedures for packaging, shipping, and receiving are adequate to insure safe transfer of biological materials and organisms to and from Building 368.

Approach:

Record Review: Team members reviewed the documentation (e.g. administrative procedures, organizational charts, position descriptions, or internal memoranda) that establishes the roles, responsibilities, and interfaces for approval of work in Building 368. Members also reviewed documentation of administrative controls in effect for work in Building 368 in the ES&H Manual, the BMBL and other applicable documents. They reviewed documentation of the work control process within LLNL, particularly the process for approval by the Laboratory Biosafety Operations Committee, the Institutional Biosafety Committee, the Centers for Disease Control (CDC), the IWS process and other work approval processes. They also reviewed the procedures for conducting a job hazards analysis. Team members reviewed records of Building-, system- and equipment-specific staff training. They also

reviewed procedures for conducting work in Building 368 and maintaining a safe and secure working environment. Members reviewed the initial Operations Plan and subsequent training plans. Team members evaluated in detail the revised shipping and receiving procedures. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
2. B368 SOP Training Roster (BR3001), 5/5/05
3. B368 Tissue Digester Operator Training Roster, 5/16/05
4. B368 VHP Operator Training Roster, 3/16/05
5. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
6. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
7. BR0092/R Biosciences ES&H Orientation and refresher
8. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
9. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
10. BR9800 Select Agent Security
11. Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
12. Building 368 Biosafety Manual
13. Building 368 Conduct of Operations, March 2006
14. Building 368 Management Plan, 6/30/05 [replaced by 68]
15. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
16. Building 368 Select Agent Security Plan, 7/29/05 [replaced by 74]
17. CDC/APHIS Registration
18. CDC/APHIS/NIH Inspections
19. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
20. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
21. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
22. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
23. Clinical and Laboratory Standards Institute, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition, M29-A3, Vol. 25, No. 10
24. Clinical Reference Guide - Biohazards Medical Surveillance, 7/05
25. Department of Health Services - Consultation
26. Department of Health Services - Serum Banking Program, 3/28/03
27. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
28. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]

29. Final Report for the Vaporized Hydrogen Peroxide (VHP®) Testing of LLNL's Building 368, Claire Fritz, VHP Process Engineer, STERIS Corporation, July 18, 2005
30. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
31. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
32. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
33. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
34. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
35. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
36. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
37. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
38. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
39. LLNL Biological Select Agents and Toxins Security revision 5, dated Dec., 13, 2004 [Rev. 6, 3/9/06]
40. LLNL Environment Safety & Health Manual [available internal/external on-line]
41. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]
42. LLNL Work Smart Standards
43. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
44. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
45. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
46. NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2002
47. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
48. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
49. SOP 1.10 Integrated Pest Management Program [Rev. 1, 4/6/06]
50. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
51. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
52. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
53. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
54. SOP 1.4 Medical Surveillance and Certification of Workers [1/11/05]
55. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
56. SOP 1.6 Quality Control for Building 368 [1/11/05]
57. SOP 1.7 Inventory of Select Agents in B368 [Rev. 1, 4/19/06]
58. SOP 1.8 Internal Exchange of Select Agents [4/28/06]
59. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
60. SOP 2.3 Technical Procedures in ABSL-3 [deleted]
61. SOP 2.4 Euthanasia Acceptable Methods [deleted]

62. SOP 2.5 Euthanasia CO2 Gas [deleted]
63. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
64. SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
65. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
66. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
67. SOP 3.4 Incubator Use in B368 [1/11/05]
68. SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]
69. SOP 4.1 Contamination Control in B368 Laboratories [1/11/05]
70. SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
71. SOP 4.3 Vaporous Hydrogen Peroxide (VHP) [Rev. 5, 7/6/06]
72. SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
73. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
74. SOP 5.2 Pipetting in B368 [1/11/05]
75. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
76. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
77. SOP 5.9 Janitorial Maintenance for Building 368 [deleted]
78. SOP 6.2 Routine Facility Monitoring for B368 [deleted]
79. Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
80. Training records for individuals working within B-368
81. US Department of Health, Education, and Welfare, Public Health Service/NIH, Laboratory Safety Monograph; A supplement to the NIH Guidelines for Recombinant DNA Research, 1/2/79
82. World BioHazTec Site Survey Comments Form, Draft Final Inspection, 7/7/05

Interviews:

- | | |
|---------------------|--|
| ◆ ALT BSO | Alternate Biosafety Officer |
| ◆ BIO DAD OP | BIO Deputy Associate Director for Operations |
| ◆ BIO DAD PR | BIO Deputy Associate Director for Programs |
| ◆ BIO ES&H | BIO ES&H Officer |
| ◆ BIO TC | BIO Training Coordinator |
| ◆ BSO | Biosafety Officer |
| ◆ HCD Team 2 EA | ES&H Team 2, Environmental Analyst |
| ◆ HCD Team 2
FPE | ES&H Team 2, Fire Protection Engineer |
| ◆ FPOC | Facility Point of Contact |
| ◆ RHWM | Hazardous Waste Management Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, ES&H Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, Industrial Hygienist |
| ◆ IBC Co-Chair | Institutional Biosafety Committee Co-Chair |
| ◆ Lab Worker | BSL-3 Microbiologist/Technician |
| ◆ MDD BS | Material Distribution Division Business Services |
| ◆ MDD OM | Material Distribution Division Operations Manager |
| ◆ MDD TL | Material Distribution Division Team Leader Shipping and Distribution |

◆ MDD TSM	Material Distribution Division Traffic and Shipping Manager
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: None

Discussion of Results (by Criteria):

- 1) Plans, procedures, reviews and approval processes are in place to ensure compliance with *Biosafety in Microbiological and Biomedical Laboratories (BMBL 4th Edition)* as required by WSS. The NHI AD is responsible for ensuring compliance with this requirement but has delegated to the APL for Select Agent Science the authority for all facility-based safety documents. The APL has further delegated authority for work authorization to the SAAI. The SAM has day-to-day responsibility for select agent work in conformance with the BMBL. The BSO and ALT BSO are also committed to compliance with the BMBL. There is both institutional control and staff commitment to comply with this criteria.
- 2) This is the same #2 criteria in CRAD #3. The answer is the same. Operations do have adequate facilities and equipment and are adequately staffed with qualified personnel who are knowledgeable of the facility and biological hazards. Personnel have been trained in the appropriate use of safety related equipment. Personnel have also been trained to anticipate, recognize, evaluate, and respond to biohazards that may be present in the workplace.
- 3) This is also the same #3 criteria as CRAD #3. The answer is the same. Job hazards analyses are conducted routinely by the ES&H Team 2 Industrial Hygienist who is experienced and utilizes engineering, and plant workers in a coordinated effort to mitigate risks from hazardous operations.
- 4) The level of knowledge of operations support personnel is adequate based on interviews of trainers, review of training records, and selected interviews of operations support personnel.
- 5) Procedures for packaging, shipping, and receiving have undergone a great deal of scrutiny since the incident in 2005. Procedures for both NHI and MDD have undergone extensive rewriting and are now adequate to insure safe transfer of biological materials and organisms to and from Building 368 and shipment outside LLNL. The Team cannot verify, as of the date of this report submittal that re-training to the new revised SOPs has been completed. However, we are assured by the NHI BSL-3 FPM that the training is scheduled and will be conducted prior to operation of the BSL-3 facility.

Conclusion(s): All criteria for this CRAD have been met.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Management	CRAD NO: 5 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

Line management has established programs to ensure safe accomplishment of work.

Criteria:

- 1) Personnel exhibit an awareness of public and worker safety, health, and environmental protection requirements and through their actions, demonstrate a high priority commitment to comply with these requirements. (CR-01-02)
- 2) The LLNL Sitewide ISM program has been implemented by line management at Building 368. (CR-01-02)
- 3) Functions, assignment, responsibilities, and reporting relationships (including those between line operating organization and ES&H support organizations) are clearly defined, understood, and effectively implemented with line management responsibility for control of safety. (CR-02)
- 4) The WSS requirements have been applied to Building 368 and it's conformance with those requirements has been determined. (CR-14)
- 5) Building 368 has been integrated into the feedback and improvement processes of LLNL Sitewide and NHI. (CR-15)
- 6) A clear management structure is established, approved, and in place. This structure is implemented and is understood by the operators and operations support personnel.

Approach:

Record Review: Team members reviewed the organizational structure to determine if there are clear lines of authority and responsibility for safety. Members reviewed NHI and related documents that implement the LLNL ISM program, including how WSS requirements have been implemented. Members also reviewed NHI documents from the feedback and improvement processes. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B368 Facilities Maintenance MOA - Plant Engineering (MOA-MNT-0001), Rev. 1, March 1, 2006 [replaces 5&6]
2. B368 Facilities Maintenance MOA - Plant Engineering (MOS-MNT-0001), July 2005 [replaced by 4]
3. B368 Facilities Maintenance MOA - Utel (MOA-MNT-0001), August 2005 [replaced by 4]
4. Beneficial Occupancy Letter - PFN#: 361-03-001, 6/17/05

5. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
6. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
7. Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
8. Biosciences Directorate Quality Assurance Plan, 2/9/05 [replaced by 89]
9. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
10. BR0092/R Biosciences ES&H Orientation and refresher
11. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
12. Building 368 Conduct of Operations, March 2006
13. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
14. Building 368 Management Plan, 6/30/05 [replaced by 68]
15. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
16. Building 368 Select Agent Security Plan, 7/29/05 [replaced by 74]
17. CDC/APHIS Registration
18. CDC/APHIS/NIH Inspections
19. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
20. Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
21. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
22. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
23. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
24. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
25. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
26. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
27. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
28. LLNL Environment Safety & Health Manual [available internal/external on-line]
29. LLNL Final Acceptance Letter - PFN#: 361-03-001, 9/19/05
30. LLNL LiveLink computer-server document storage and retrieval system for B368 records management
31. LLNL Work Smart Standards
32. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
33. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
34. NAI/BBRP MOU NAI/O 04-03-030 Addendum - BSL-3 MOU Responsibility Assignment, 9/22/04 [deleted]
35. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
36. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
37. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]

38. Space and Site Planning Findings and Determination, F&D 04-002, (Building 368),
11/10/2003

Interviews:

◆ ALT BSO	Alternate Biosafety Officer
◆ BIO DAD OP	BIO Deputy Associate Director for Operations
◆ BIO DAD PR	BIO Deputy Associate Director for Programs
◆ BIO AD	BIO Directorate Associate Director
◆ BIO ES&H	BIO ES&H Officer
◆ BIO TC	BIO Training Coordinator
◆ BSO	Biosafety Officer
◆ FPOC	Facility Point of Contact
◆ HCD Team 2	Hazards Control Team 2, ES&H Technician
◆ HCD Team 2	Hazards Control Team 2, Industrial Hygienist
◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ NHI AADA	NHI Assistant Associate Director for Assurances
◆ NHI AD	NHI Associate Director
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: None.

Discussion of Results (by Criteria):

- 1) Personnel do exhibit an awareness of public and worker safety, health, and environmental protection requirements and through their actions, demonstrate a high priority commitment to comply with these requirements. B368 personnel and support staff were interviewed along with NHI, BIO, and EPD managers and it was demonstrated to a person that they were committed to performing the work as safely as possible. Everyone showed a genuine interest in finding answers to questions and finding solutions to any issues that arose during this readiness review.
- 2) The LLNL Sitewide ISM program has been implemented by line management at Building 368. The pre-existing processes established by the LBOC, IBC, and Institutional Review Board demonstrate a commitment to thorough and in-depth evaluation of any potential

biological work and implementation of the ISMS program to assure protection of workers, the public, and the environment.

- 3) This is the same as criteria #1 in CRAD #3 which was determined to be inadequate. Functions, assignment, responsibilities, and reporting relationships (including those between line operating organization and ES&H support organizations) are not clearly defined, understood, and effectively implemented with line management responsibility for control of safety.
- 4) There has been no opportunity to determine whether WSS requirements are applied to Building 368 since it is non-operational. The FSP, Conduct of Operations Plan, Configuration Management Plan, and others suggest that NHI is fully intending to follow the WSS requirements and has put appropriate processes in place to insure that.
- 5) Building 368 has been integrated into the feedback and improvement processes of LLNL Sitewide and NHI. The NAI Integrated Safety Management Plan provides for insuring that adequate feedback and improvement along with implementation of lessons learned are achieved. The LBOC and IBC are instrumental in sharing feedback and process improvement and have been functioning in that capacity for several years. Interviews of staff and managers indicated that the program is effective.
- 6) This criteria is linked with criteria #3 above which was found to be inadequate. There has been an attempt at creating a clear management structure and it wouldn't require a great deal of work to complete this process. There is a management structure which is established, approved, and in place. This structure is implemented but is not universally understood by the operators and operations support personnel because of a lack of clarity in a few positions.

Conclusion(s): There are recognized problems with defining the management and operations structure. These were described in the discussion and conclusions to CRAD #3 and won't be repeated here.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 6	CRITERIA MET	
Maintenance	DATE: 6/11/06	YES	NO

Objective:

A maintenance management program is established, sufficient numbers of qualified personnel are provided, and adequate facilities and equipment are available to ensure maintenance services are adequate for safe operations.

Criteria:

- 1) The maintenance organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. It is adequately staffed with qualified personnel. (CR-02, CR-06-01, CR-06-02))
- 2) A program is in place to confirm and periodically reconfirm the condition and operability of equipment important to safety. (CR-08-01)
- 3) The LLNL training program for maintenance personnel has been adequately implemented to provide safe support for the operations. (CR-03-02)
- 4) Maintenance personnel demonstrate knowledge of the operations, equipment, and facilities. These personnel also give adequate attention to health, safety, and environmental protection issues. (CR-04-03)
- 5) Maintenance personnel demonstrate the ability to carry out normal, abnormal, and emergency procedures applicable to their assignments. (CR-04-03)

Approach:

Record Review: Team members reviewed the documentation which establish the roles, responsibilities, and interfaces. They also reviewed the Facility Safety Plan and the Calibration Plan. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Air Techniques International (ATI), Oak Ridge Filter Test Facility, Filter Test Report 21 Oct 04.
2. B368 Facilities Maintenance MOA - Plant Engineering (MOA-MNT-0001), Rev. 1, March 1, 2006 [replaces 5&6]
3. B368 Facilities Maintenance MOA - Plant Engineering (MOS-MNT-0001), July 2005 [replaced by 4]

4. B368 Facilities Maintenance MOA - Utel (MOA-MNT-0001), August 2005 [replaced by 4]
5. B368 Tissue Digester Operator Training Roster, 5/16/05
6. B368 VHP Operator Training Roster, 3/16/05
7. Biology and Biotechnology Research Program Building 365 Wastewater Retention Tank, Hypochlorite Injection System, Operational Plan, Rev. 1, 3/03
8. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
9. Biosciences Directorate Critical Measuring and Test Equipment Calibration Plan (BR-CP-05), 2/9/05 [deleted; included in 53]
10. Britz-Heidbrink Inc. As-Built Drawings - PFN#: 361-003-001, 8/8/05
11. Britz-Heidbrink Inc. As-Built Fire Alarm Drawings 8/5/05
12. Building 368 Management Plan, 6/30/05 [replaced by 68]
13. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
14. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
15. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
16. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
17. Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
18. Design Specification Bid Set
19. Durrant E-Mail Dated 9/12/05 re Panelboard Short Circuit Ratings.
20. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
21. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
22. Final Report for the Vaporized Hydrogen Peroxide (VHP®) Testing of LLNL's Building 368, Claire Fritz, VHP Process Engineer, STERIS Corporation, July 18, 2005
23. Final Structural Calculations Volume 1 Dated June 30, 2004.
24. Final Structural Calculations Volume 2 Dated November 30, 2004.
25. Final Structural Calculations Volume 3 Dated August 18, 2005.
26. Foot Candle Calculations Dated 8/19/03, and Durrant Group E-Mail Dated 9/12/05.
27. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
28. IWS#10024.01r@ Laboratory Animal Anesthesia Machine
29. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
30. LLNL Environment Safety & Health Manual [available internal/external on-line]
31. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]
32. LLNL LiveLink computer-server document storage and retrieval system for B368 records management
33. Mechanical calculations, dated August 29, 2005
34. MESA3 HVAC Balance - 06/05; Test Report #3861.1, LLNL Building 368, Livermore, CA.
35. NAI/BBRP MOU NAI AO 04-03-030 Addendum - BSL-3 MOU Responsibility Assignment, 9/22/04 [deleted]

36. Nuclear Work Center MS PowerPoint Presentation, Bill Kemp, July 25, 2005
37. Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
38. Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
39. RHWM Division Procedure WPT 109, titled, Retention Tank System Operations"
40. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
41. SOP 1.10 Integrated Pest Management Program [Rev. 1, 4/6/06]
42. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
43. SOP 2.1 Access Control in B368 [4/6/06]
44. SOP 2.4 Euthanasia Acceptable Methods [deleted]
45. SOP 2.5 Euthanasia CO2 Gas [deleted]
46. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
47. SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
48. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
49. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
50. SOP 3.4 Incubator Use in B368 [1/11/05]
51. SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]
52. SOP 4.3 Vaporous Hydrogen Peroxide (VHP) [Rev. 5, 7/6/06]
53. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
54. SOP 5.9 Janitorial Maintenance for Building 368 [deleted]
55. SOP 6.1 Maintenance Access and Service in B368 [1/11/05]
56. SOP 6.2 Routine Facility Monitoring for B368 [deleted]
57. Space and Site Planning Findings and Determination, F&D 04-002, (Building 368), 11/10/2003
58. Steris™ Installation/Startup Verification Procedure for a Eagle 3000 Stage 3 Small/Medium Sterilizer SN 810480401 [8/16/05]
59. Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
60. Technical Safety Services Inc., Biological Safety Cabinet Certification Report, No. 354189, 5/31/05.
61. Training record for the RHWM Field Technician who inspects and operates the retention tank system on a daily basis
62. Treatment Permit for the Tissue Digester and Autoclave in B-368 issued by the California Department of Health Services, dated 7-1-05

Interviews: Interviewed personnel to determine if they are familiar with their support and interface responsibilities to the operations organization. Interviewed personnel responsible for developing, reviewing, and approving work packages. Interviewed personnel responsible for prioritizing work requests and establishing maintenance schedules. Interviewed maintenance personnel to assess their understanding of the maintenance program.

- ◆ FPOC Facility Point of Contact
- ◆ RHWM Hazardous Waste Management Technician
- ◆ HCD Team 2 Hazards Control Team 2, ES&H Technician

- ◆ HCD Team 2 Hazards Control Team 2, Industrial Hygienist
- ◆ IBC Co-Chair Institutional Biosafety Committee Co-Chair
- ◆ LBOC Chair Laboratory Biosafety Operations Committee Chairman
- ◆ B368 CM LLNL Plant Engineering, Design & Construction Division, B368 Construction Manager
- ◆ NHI ADFM NHI Associate Director Facility Manager
- ◆ NHI APL-SA NHI Associate Program Leader for Select Agent Science
- ◆ NHI BSL-3 FPM NHI BSL-3 Facility Program Manager
- ◆ NHI DAD OP NHI Deputy Associate Director for Operations
- ◆ RRP Room Responsible Person (ABSL3)
- ◆ SAAI Select Agent Authorizing Individual
- ◆ SAFM Select Agent Facility Manager
- ◆ SAM Select Agent Manager (Select Agent Center)
- ◆ SLC Senior Laboratory Coordinator

Shift Performance: None

Discussion of Results (by Criteria):

- 1) The division of responsibility and Laboratory policy for implementing maintenance is established in the in Volume II, Part 15 of the ES&H Manual. Responsibility for maintenance activities in B368 is shared between the Program (NHI) who owns the facility and several institutional organizations, including the Maintenance / Operations Department and Hazard Control. However, according to the FSP, the SAFM is responsible for the maintenance of B368 in coordination with the SAM (i.e., for scheduling of activities). The FPOC supports the SAFM by assisting in day-to-day maintenance. The FSP is a little confusing by stating that the FPOC also supports the SAM and SLC in the same way even though neither of them have responsibility for maintenance. Appendix D of the FSP describes the B368 Equipment Maintenance Interface. The ISAMS is silent on the issue of maintenance. Plant Engineering is responsible for the maintenance of common real property and installed equipment (RP&IE) while NHI is responsible for the maintenance of programmatic equipment. Functions, assignments, responsibilities, and reporting relationships are generally clearly defined. It is adequately staffed with qualified personnel.
- 2) A program is in place to confirm and periodically reconfirm the condition and operability of equipment important to safety. This is documented in Section 6 of the FSP, the SOPs and in the B368 Conduct of Operations Plan, Configuration Management Plan, and through the NHI ISMS program. An MOU exists with LLNL Plant Engineering to provide maintenance on infrastructure-related equipment. A maintenance window will be conducted on a basic maintenance period of every 6 months.
- 3) The LLNL training program for maintenance personnel has been adequately implemented to provide safe support for the operations. The FPOC and ES&H Team 2 Technician have been trained in some limited maintenance but equipment such as the tissue digester, VHP decontamination system, biosafety cabinets (BSCs), freezers, incubators,

etc. are covered by manufacturers warranties. Periodic maintenance of building HEPA filtration is provided institutionally by LLNL, but HEPA testing and replacement for BSCs is provided by a contracted vendor. Procedures are in place to allow manufacturers' representatives to safely conduct their work

- 4) Maintenance personnel have demonstrated knowledge of the operations, equipment, and facilities. These personnel also give adequate attention to health, safety, and environmental protection issues because they have been required to attend all of the B368 worker training so they can safely enter the facility.
- 5) Maintenance personnel have demonstrated their ability to carry out normal, abnormal, and emergency procedures applicable to their assignments. The FPOC and ES&H Team 2 Technician who perform the limited maintenance participate in the emergency response procedures and are fully knowledgeable of those procedures.

Conclusion(s): For the most part all of the criteria for this CRAD have been met. The issue of lack of clarity in roles and responsibilities for maintenance is consistent with the finding in CRAD #3 so it won't be repeated here as an additional finding. Finding a solution to CRAD #3 should also fix this issue.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Operations-1	CRAD NO: 7 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

The training and qualification program for operations personnel and their level of knowledge is adequate and commensurate with their responsibilities.

Criteria:

- 1) The LLNL training program for operations personnel has been adequately implemented to provide safe support for the operations of Building 368. (CR-03-01)
- 2) Technical qualifications of operations personnel are adequate (CR-03-03)
- 3) The selection and training of Managers ensures competence commensurate with responsibilities. (CR-03-04)
- 4) Operations and management personnel demonstrate knowledge of the operations, equipment, and facilities. These personnel also give adequate attention to health, safety, and environmental protection issues. (CR-04-01, CR-04-02)
- 5) Operations and management personnel demonstrate the ability to carry out normal, abnormal, and emergency procedures applicable to their assignments. (CR-04-01, CR-04-02)
- 6) Graded operations testing has been performed to confirm the adequacy of operator training. (CR-12-03)

Approach:

Record Review: Team members reviewed a sample of the training materials and training records but did not observe examinations. Members reviewed the technical qualifications of selected personnel. Members were able to review some operator certification records and but not records of on-the-job training since the facility is not yet operational. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
2. B368 SOP Training Roster (BR3001), 5/5/05
3. B368 Tissue Digester Operator Training Roster, 5/16/05
4. B368 VHP Operator Training Roster, 3/16/05
5. Biology and Biotechnology Research Program Building 365 Wastewater Retention Tank, Hypochlorite Injection System, Operational Plan, Rev. 1, 3/03
6. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]

7. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
8. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
9. BR0092/R Biosciences ES&H Orientation and refresher
10. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
11. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
12. Building 368 Biosafety Manual
13. Building 368 Conduct of Operations, March 2006
14. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
15. Building 368 Management Plan, 6/30/05 [replaced by 68]
16. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
17. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
18. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
19. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
20. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
21. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
22. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
23. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
24. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
25. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
26. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
27. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
28. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
29. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
30. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
31. IWS#10024.01r@ Laboratory Animal Anesthesia Machine
32. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
33. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
34. LLNL Environment Safety& Health Manual [available internal/external on-line]
35. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]

36. LLNL LiveLink computer-server document storage and retrieval system for B368 records management
37. LLNL Procurement & Materiel Department, Material Distribution Division (MDD) Operating Procedures, Section 200.20; Infectious Substances and Etiologic Agents, receiving and shipping instructions: Issue Date 8/1/05 [7/10/06]
38. LLNL Work Smart Standards
39. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
40. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
41. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
42. NAI Stop Work Policy, Rev.1, January 2006
43. NAI/BBRP MOU NAI/O 04-03-030 Addendum - BSL-3 MOU Responsibility Assignment, 9/22/04 [deleted]
44. NEPA Review of Proposed Changes to the BSL-3 Facility (Biosafety Cabinets), 12/10/05
45. Nuclear Work Center MS PowerPoint Presentation, Bill Kemp, July 25, 2005
46. Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
47. Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
48. RHWM Division Procedure WPT 109, titled, Retention Tank System Operations"
49. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
50. SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
51. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
52. SOP 1.10 Integrated Pest Management Program [Rev. 1, 4/6/06]
53. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
54. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
55. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
56. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
57. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
58. SOP 1.4 Medical Surveillance and Certification of Workers [1/11/05]
59. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
60. SOP 1.6 Quality Control for Building 368 [1/11/05]
61. SOP 1.7 Inventory of Select Agents in B368 [Rev. 1, 4/19/06]
62. SOP 1.8 Internal Exchange of Select Agents [4/28/06]
63. SOP 2.1 Access Control in B368 [4/6/06]
64. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
65. SOP 2.3 Technical Procedures in ABSL-3 [deleted]
66. SOP 2.4 Euthanasia Acceptable Methods [deleted]
67. SOP 2.5 Euthanasia CO2 Gas [deleted]
68. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
69. SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
70. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
71. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
72. SOP 3.4 Incubator Use in B368 [1/11/05]
73. SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]

74. SOP 4.1 Contamination Control in B368 Laboratories [1/11/05]
75. SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
76. SOP 4.3 Vaporous Hydrogen Peroxide (VHP) [Rev. 5, 7/6/06]
77. SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
78. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
79. SOP 5.2 Pipetting in B368 [1/11/05]
80. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
81. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
82. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
83. SOP 5.9 Janitorial Maintenance for Building 368 [deleted]
84. SOP 6.1 Maintenance Access and Service in B368 [1/11/05]
85. SOP 6.2 Routine Facility Monitoring for B368 [deleted]
86. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
87. US Department of Health, Education, and Welfare, Public Health Service/NIH, Laboratory Safety Monograph; A supplement to the NIH Guidelines for Recombinant DNA Research, 1/2/79

Interviews: Team members interviewed operators and supervisors to assess their understanding of facility processes, procedures, and limitations to the activities authorized to take place in Building 368 during operations. They also interviewed operations and management personnel to assess their understanding of their actions when responding to abnormal and emergency conditions as well as their understanding of how these actions relate to the safety basis for operations. Members determined if these personnel have an adequate knowledge of health, safety, and environmental protection issues.

◆ BIO ES&H	BIO ES&H Officer
◆ BSO	Biosafety Officer
◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ NHI AADA	NHI Assistant Associate Director for Assurances
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ PI	Principal Investigators
◆ RI	Responsible Individual
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: None

Discussion of Results (by Criteria):

- 1) Training for B368 operations personnel is described in SOP 1.3 and has been adequately implemented to provide safe support for the initiation of operations in Building 368. Additional OJT will be required during the qualification of workers as operations are ramped up. This will allow for workers to get familiar with the facility, equipment, and implementation of new SOPs. The Team understands that the reference, *Building 368 Operations Plan for Project Employing B368 BSL-3 Facility*, currently in draft will be completed to show the plan for a gradual stepping up of activities commensurate with training and completion of more and more complex work. The Team believes this is a good idea, but does not want to make it a Pre-Start Finding. This is a strong recommendation that it should be completed and approved prior to the start of activities.
- 2) Technical qualifications of operations personnel are adequate. The SLC and Laboratory Workers are already very experienced in BSL-1 and BSL-2 operations and have some BSL-3 experience. They are also experienced in the safe handling of many of the pathogens projected for study in the BSL-3 facility.
- 3) Managers were recruited and selected for their competence commensurate with responsibilities. The BIO Directorate is matrixing several senior management personnel to NHI to ensure that the Select Agent Center is staffed with personnel having the right technical and managerial skills and experience.
- 4) Operations and management personnel have demonstrated adequate knowledge of the operations, equipment, and facilities through training and hands-on testing and operation during the construction and readiness process. These personnel also give adequate attention to health, safety, and environmental protection issues.
- 5) Operations and management personnel have demonstrated their ability to carry out normal, abnormal, and emergency procedures applicable to their assignments during training and drill exercises.
- 6) Graded operations testing has not yet been performed to confirm the adequacy of operator training. This will be performed during the startup of operations.

Conclusion(s): These criteria have been met with the caveat that the Draft Operations Plan be completed, approved, and utilized to startup the facility through a graded operations approach.

Issue(s): This is an Observation that the Draft B368 Operations Plan and utilization for startup of the facility through a graded operations approach should be completed and implemented.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Operations-2	CRAD NO: 8 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

The formality and discipline of operations is adequate to conduct work safely, and programs are in place to maintain this formality and discipline.

Criteria:

- 1) Functions, assignments, responsibilities, and reporting relationships for the operating organization are clearly defined, understood, and effectively implemented. (CR-02)
- 2) Adequate procedures for operations have been prepared, approved, and are ready for implementation. The procedures are consistent with the FABD and appropriately implement the OSRs. (CR-10-03, CR-09-02)
- 3) An Operations Plan ensures that operations procedures have been tested to confirm the viability of the procedures for full operations. (CR-12-02)
- 4) Procedures are kept current and accurate, including incorporation of temporary modifications and design changes. Procedures and procedure changes are adequately reviewed and approved prior to their implementation. Temporary changes or revisions are adequately controlled. (CR-09-02)

Approach:

Record Review: Team members reviewed the organizational structure to determine if there are clear lines of authority and responsibility for safety. Members reviewed the FABD, the Facility Safety Plan, and operating procedures. They reviewed Change Control procedures for documentation and facilities equipment and systems. Review guidance for preparation of standard operating procedures from the LLNL ES&H Manual. Members reviewed documents that explained the evaluation and authorization of experimentation in the B368 facility. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
2. B368 SOP Training Roster (BR3001), 5/5/05
3. B368 Tissue Digester Operator Training Roster, 5/16/05
4. B368 VHP Operator Training Roster, 3/16/05
5. Biology and Biotechnology Research Program Building 365 Wastewater Retention Tank, Hypochlorite Injection System, Operational Plan, Rev. 1, 3/03
6. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]

7. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
8. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
9. BR0092/R Biosciences ES&H Orientation and refresher
10. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
11. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
12. Building 368 Biosafety Manual
13. Building 368 Conduct of Operations, March 2006
14. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
15. Building 368 Management Plan, 6/30/05 [replaced by 68]
16. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
17. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
18. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
19. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
20. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
21. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
22. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
23. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
24. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
25. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
26. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
27. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
28. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
29. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
30. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
31. IWS#10024.01r@ Laboratory Animal Anesthesia Machine
32. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
33. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
34. LLNL Environment Safety& Health Manual [available internal/external on-line]
35. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]

36. LLNL LiveLink computer-server document storage and retrieval system for B368 records management
37. LLNL Procurement & Materiel Department, Material Distribution Division (MDD) Operating Procedures, Section 200.20; Infectious Substances and Etiologic Agents, receiving and shipping instructions: Issue Date 8/1/05 [7/10/06]
38. LLNL Work Smart Standards
39. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
40. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
41. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
42. NAI Stop Work Policy, Rev.1, January 2006
43. NAI/BBRP MOU NAI/O 04-03-030 Addendum - BSL-3 MOU Responsibility Assignment, 9/22/04 [deleted]
44. NEPA Review of Proposed Changes to the BSL-3 Facility (Biosafety Cabinets), 12/10/05
45. Nuclear Work Center MS PowerPoint Presentation, Bill Kemp, July 25, 2005
46. Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
47. Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
48. RHWM Division Procedure WPT 109, titled, Retention Tank System Operations"
49. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
50. SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
51. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
52. SOP 1.10 Integrated Pest Management Program [Rev. 1, 4/6/06]
53. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
54. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
55. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
56. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]
57. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
58. SOP 1.4 Medical Surveillance and Certification of Workers [1/11/05]
59. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
60. SOP 1.6 Quality Control for Building 368 [1/11/05]
61. SOP 1.7 Inventory of Select Agents in B368 [Rev. 1, 4/19/06]
62. SOP 1.8 Internal Exchange of Select Agents [4/28/06]
63. SOP 2.1 Access Control in B368 [4/6/06]
64. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]
65. SOP 2.3 Technical Procedures in ABSL-3 [deleted]
66. SOP 2.4 Euthanasia Acceptable Methods [deleted]
67. SOP 2.5 Euthanasia CO2 Gas [deleted]
68. SOP 2.6 Isoflurane Anesthesia Machine [deleted]
69. SOP 3.1 Building 368 Medical Waste Steam Sterilization [1/11/05]
70. SOP 3.2 Using B368 Biosafety Cabinets (BSC) [Rev. 1, 4/19/06]
71. SOP 3.3 Centrifuge Safety for Building 368 [1/11/05]
72. SOP 3.4 Incubator Use in B368 [1/11/05]
73. SOP 3.6 Medical Waste Tissue Digestion in B368 [1/11/05]

74. SOP 4.1 Contamination Control in B368 Laboratories [1/11/05]
75. SOP 4.2 BioSafety Cabinet Spill Response for B368 [Rev. 1, 2/13/06]
76. SOP 4.3 Vaporous Hydrogen Peroxide (VHP) [Rev. 5, 7/6/06]
77. SOP 4.4 Hazardous Waste Removal from B368 [1/11/05]
78. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
79. SOP 5.2 Pipetting in B368 [1/11/05]
80. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
81. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
82. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
83. SOP 5.9 Janitorial Maintenance for Building 368 [deleted]
84. SOP 6.1 Maintenance Access and Service in B368 [1/11/05]
85. SOP 6.2 Routine Facility Monitoring for B368 [deleted]
86. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
87. US Department of Health, Education, and Welfare, Public Health Service/NIH, Laboratory Safety Monograph; A supplement to the NIH Guidelines for Recombinant DNA Research, 1/2/79

Interviews:

◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ PI	Principal Investigators
◆ RI	Responsible Individual
◆ RO	Responsible Official (Select Agent)
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance:

Observe operations technicians during normal (or simulated) abnormal and emergency procedures as necessary.

Discussion of Results (by Criteria):

- 1) This is the same criteria from CRAD #3. Functions, assignments, responsibilities, and reporting relationships for the operating organization are not clearly defined, understood, and effectively implemented. This finding will not be repeated.
- 2) B368 has adequate procedures for operations that have been prepared, approved, and are ready for implementation. The procedures are consistent with the FABD, FSP, and appropriately implement the OSRs. Procedures should be evaluated for compliance with the ES&H Manual requirements for the preparation of work procedures (i.e., ES&H Manual Volume I, Part 3: Safety Analysis and Work Plans and Procedures; Document 3.4: Preparation of Work Procedures)
- 3) There is a Draft Operations Plan that will ensure that operations procedures are tested to confirm the viability of the procedures for full operations. This plan needs to be completed and implemented.
- 4) Most procedures are kept current and accurate, including incorporation of temporary modifications and design changes. Procedures and procedure changes are adequately reviewed and approved prior to their implementation. Temporary changes or revisions are adequately controlled. Note there are several observations concerning incomplete SOPs. One observation is that SOP 5.1 states that all waste will be autoclaved which is not technically correct. This doesn't leave room for other treatment options like the tissue digester. Another observation is that SOP 3.1 does not reflect the need to annually collect and report under the California treatment permit the calibration of the temperature measurement sensor for the autoclave. SOP 5.3 does not explain the doffing of PPE particularly the "bunny" suit and PAPR. SOP 5.1 mentions "sharps" but doesn't address the best management practices, such as, using safety needles (note there is an institutional description in the ES&H Manual but it doesn't provide adequate detail).

Conclusion(s): All criteria for this CRAD have been met. The Draft B368 Operations Plan needs to be completed and implemented (an Observation for CRAD #7). Several observations were noted for minor changes to SOPs (Criteria #4).

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Operations-3	CRAD NO: 9 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

There are sufficient number of qualified personnel to conduct operations safely and adequate facilities and equipment to support operations.

Criteria:

- 1) Sufficient numbers of qualified operations personnel, including operators, supervisors, and managers, are available to carry out facility operations. Staffing levels are consistent with the safety basis. (CR-06-01)
- 2) Operators have access to the necessary equipment to support facility/process operations. (CR-06-02)

Approach:

Record Review: Team members reviewed the safety basis and other related documents to determine required staffing levels. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
2. Building 368 Conduct of Operations, March 2006
3. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
4. Building 368 Management Plan, 6/30/05 [replaced by 68]
5. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
6. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
7. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
8. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
9. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
10. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
11. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
12. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006

13. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]
14. LLNL Work Smart Standards
15. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
16. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
17. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
18. NAI Stop Work Policy, Rev.1, January 2006
19. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
20. SOP 1.11 Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
21. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
22. SOP 2.2 Animal Care Operations and Cage Changing [4/6/06]

Interviews:

◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ PI	Principal Investigators
◆ RI	Responsible Individual
◆ RO	Responsible Official (Select Agent)
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: There was no opportunity to observe operations technicians during normal (or simulated) abnormal and emergency procedures.

Discussion of Results (by Criteria):

- 1) This is the same criteria evaluated in CRAD #5 with the same result. Sufficient numbers of qualified operations personnel, including operators, supervisors, and managers, are available to carry out facility operations. Staffing levels are consistent with the safety basis.
- 2) Operators do have access to the necessary equipment to support facility/process operations.

Conclusion(s): All criteria for this CRAD have been met.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 10	CRITERIA MET	
Structures, Systems and Components	DATE: 6/11/06	YES	NO

Objective:

The design and modification of building/utility systems is controlled and the systems are operable,

Criteria:

- 1) Change control and configuration management programs assure control of modification of building/utility systems. (CR-07-02)
- 2) All building/utility systems are currently operable and in satisfactory condition. (CR-08-02)
- 3) Building/utility systems are consistent with the description, procedures, and accident analysis included in the NHI FABD. (CR-09-01)
- 4) Process systems are consistent with the description, procedures, and accident analysis included in the NHI FABD (CR-09-01)
- 5) Functional Performance Tests of building/utility systems have been conducted to confirm operability of equipment. (CR-12-01)

Approach:

Record Review: Team members reviewed the FABD for Building 368. Members reviewed change control and configuration management procedures. They also reviewed the commissioning report for building/utility equipment important to safety. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B365 Waste Retention Tank System Plan; 365-WRT-SOP-01 Rev. 1 Jan 2006
2. B368 Facilities Maintenance MOA - Plant Engineering (MOA-MNT-0001), Rev. 1, March 1, 2006 [replaces 5&6]
3. B368 Facilities Maintenance MOA - Plant Engineering (MOS-MNT-0001), July 2005 [replaced by 4]
4. B368 Facilities Maintenance MOA - Utel (MOA-MNT-0001), August 2005 [replaced by 4]
5. Biosciences Directorate Critical Measuring and Test Equipment Calibration Plan (BR-CP-05), 2/9/05 [deleted; included in 53]
6. Britz-Heidbrink Inc. As-Built Drawings - PFN#: 361-003-001, 8/8/05
7. Britz-Heidbrink Inc. As-Built Fire Alarm Drawings 8/5/05
8. CDC/NIH, Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Edition, September 2000.

9. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
10. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
11. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
12. Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
13. Design Specification Bid Set
14. Durrant E-Mail Dated 9/12/05 re Panelboard Short Circuit Ratings.
15. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
16. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
17. Final Report for the Vaporized Hydrogen Peroxide (VHP®) Testing of LLNL's Building 368, Claire Fritz, VHP Process Engineer, STERIS Corporation, July 18, 2005
18. Final Structural Calculations Volume 1 Dated June 30, 2004.
19. Final Structural Calculations Volume 2 Dated November 30, 2004.
20. Final Structural Calculations Volume 3 Dated August 18, 2005.
21. Foot Candle Calculations Dated 8/19/03, and Durrant Group E-Mail Dated 9/12/05.
22. IWS#10014.02 Hypochlorite Feed System for B365 WRT, 23 May 05
23. IWS#10024.01r@ Laboratory Animal Anesthesia Machine
24. Mechanical calculations, dated August 29, 2005
25. MESA3 HVAC Balance - 06/05; Test Report #3861.1, LLNL Building 368, Livermore, CA.
26. NEPA Review of Proposed Changes to the BSL-3 Facility (Biosafety Cabinets), 12/10/05
27. Nuclear Work Center MS PowerPoint Presentation, Bill Kemp, July 25, 2005
28. Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
29. Radioactive and Hazardous Waste Management Division's Retention Tank System Operations, procedure no. WRT 109-Rev. 2, FS&C 0048, Rev. 1-10-03
30. RHWM Division Procedure WPT 109, titled, "Retention Tank System Operations"
31. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
32. SOP 6.1 Maintenance Access and Service in B368 [1/11/05]
33. Space and Site Planning Findings and Determination, F&D 04-002, (Building 368), 11/10/2003
34. Steris™ Installation/Startup Verification Procedure for a Eagle 3000 Stage 3 Small/Medium Sterilizer SN 810480401 [8/16/05]
35. Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
36. Technical Safety Services Inc., Biological Safety Cabinet Certification Report, No. 354189, 5/31/05.
37. Treatment Permit for the Tissue Digester and Autoclave in B-368 issued by the California Department of Health Services, dated 7-1-05
38. World BioHazTec Site Survey Comments Form, Draft Final Inspection, 7/7/05

Interviews:

◆ HCD Team 2 EA	ES&H Team 2, Environmental Analyst
◆ HCD Team 2 FPE	ES&H Team 2, Fire Protection Engineer
◆ FPOC	Facility Point of Contact
◆ RHWM	Hazardous Waste Management Technician
◆ HCD Team 2	Hazards Control Team 2, ES&H Technician
◆ HCD Team 2 FPE	ES&H Team 2, Fire Protection Engineer
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ B368 CM	LLNL Plant Engineering, Design & Construction Division, B368 Construction Manager
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance:

Perform walkthroughs to spot check that systems are consistent with the FABD. Observe any ongoing system operability checks or tests.

Discussion of Results (by Criteria):

- 1) According to the FSP and the B368 Configuration Management Plan the B368 does not contain Configuration Items (CI) by definition. However, 9 items are identified as “Important to Safety” in the FABD and SER and are considered CM Level 3 CI and managed by the Plan. The SAFM is identified as the owner of all the CI for B368 and would be responsible for change control and configuration management programs to assure control of modification of building/utility systems. This criterion is met.
- 2) The building and all utility systems are new. They have been tested and are currently operable and in satisfactory condition.
- 3) Building/utility systems are consistent with the description, procedures, and accident analysis included in the NHI FABD. Yes this is true.
- 4) Process systems are consistent with the description, procedures, and accident analysis included in the NHI FABD. This is also true.
- 5) Functional Performance Tests of building/utility systems have been conducted to confirm operability of equipment. Tests of all building/utility systems have been run successfully although initial results for the VHP system showed leaks in the electrical/utility room and a problem with a damper that didn’t permit the system to function in automatic mode. These issues have been resolved.

Conclusion(s): All these criteria have been met for this CRAD.

Issue(s): None

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Safety Envelope-1	CRAD NO: 11 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

Facility safety documentation is in place that describes the "safety envelope" of the facility. The safety documentation should characterize the hazards/risks associated with the facility and should identify mitigating measures (systems, procedures, administrative controls, etc.) that protect workers and the public from those hazards/risks. A system to maintain control over the design and modification of facilities and safety-related systems is established.

Criteria:

- 1) The safety documentation addresses appropriate hazards/risks associated with operations. Administrative controls are in place to ensure that repairs (or modifications) are adequately analyzed to identify and to ensure that design changes are documented and approved prior to implementation. (CR-4)

Approach:

Record Review: Team members reviewed the safety basis documentation to assess whether the safety basis adequately includes appropriate hazards/risks associated with operations. Safety basis documentation includes, for example, the Building Design Specifications, the FABD, the Facility Safety Plan, and the Configuration Management Plan. Members reviewed the design of the facility to ensure that it has been reflected in drawings and documents available to operators and maintenance personnel. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Britz-Heidbrink Inc. As-Built Drawings - PFN#: 361-003-001, 8/8/05
2. Britz-Heidbrink Inc. As-Built Fire Alarm Drawings 8/5/05
3. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
4. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
5. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
6. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
7. Cornerstone Commissioning Inc., Final Commissioning Report, Lawrence Livermore National Laboratories, Building 368, Bio-Safety Lab Level 3, July 7, 2005
8. Design Specification Bid Set

9. Durrant E-Mail Dated 9/12/05 re Panelboard Short Circuit Ratings.
10. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
11. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
12. Final Report for the Vaporized Hydrogen Peroxide (VHP®) Testing of LLNL's Building 368, Claire Fritz, VHP Process Engineer, STERIS Corporation, July 18, 2005
13. Final Structural Calculations Volume 1 Dated June 30, 2004.
14. Final Structural Calculations Volume 2 Dated November 30, 2004.
15. Final Structural Calculations Volume 3 Dated August 18, 2005.
16. Mechanical calculations, dated August 29, 2005
17. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
18. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
19. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
20. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
21. SOP 1.2.2 Laboratory Biosafety Operations Committee (LBOC) Requirements [1/11/05]
22. SOP 1.2.3 Institutional Biosafety Committee (IBC) [1/11/06]

Interviews: Team members interviewed personnel associated with developing/processing facility modifications to determine if they understand configuration management requirements for the facility.

◆ BIO DAD OP	BIO Deputy Associate Director for Operations
◆ BSO	Biosafety Officer
◆ HCD Team 2 EA	ES&H Team 2, Environmental Analyst
◆ HCD Team 2 FPE	ES&H Team 2, Fire Protection Engineer
◆ FPOC	Facility Point of Contact
◆ RHWM	Hazardous Waste Management Technician
◆ HCD AB	Hazards Control Department - Safety Analyst/Authorization Basis Section
◆ HCD AB SL	Hazards Control Department -Authorization Basis Section Leader
◆ HCD Team 2	Hazards Control Team 2, Industrial Hygienist
◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ B368 CM	LLNL Plant Engineering, Design & Construction Division, B368 Construction Manager
◆ NHI AADA	NHI Assistant Associate Director for Assurances
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RRP	Room Responsible Person (ABSL3)

- ◆ SAAI Select Agent Authorizing Individual
- ◆ SAFM Select Agent Facility Manager
- ◆ SAM Select Agent Manager (Select Agent Center)
- ◆ SLC Senior Laboratory Coordinator

Shift Performance: Perform a facility walk down to determine that there are no uncontrolled modifications to safety systems. This walk down should evaluate the accuracy of drawings and other documentation for plant operation and maintenance.

Discussion of Results (by Criteria):

- 1) The FABD for B368 (with the SER and change control forms) addresses appropriate hazards/risks associated with operations. The FSP and B368 Configuration Management Plan identify administrative controls that are in place to ensure that repairs (or modifications) are adequately analyzed to identify and to ensure that design changes are documented and approved prior to implementation. It is incumbent upon the NHI AD FM and the SAFM to monitor this process and have the authority to stop any action that might take the operations outside the safety envelope. Several walkdowns were conducted to evaluate the as-built with design specifications and to observe the operability of the systems. At this time all systems have been shown to be operable and in conformance with the FABD.

Conclusion(s): All criteria for this CRAD have been met.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Safety Envelope-2	CRAD NO: 12 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

A program is in place to confirm and periodically reconfirm the condition and operability of safety systems, including safety-related process systems. This includes examinations of records of tests and calibrations of the safety system and other instruments monitoring limiting conditions of operation or that satisfy safety requirements. All safety-related process and utility systems are currently operable and in satisfactory condition.

Criteria:

- 1) Confirmation of compliance with safety requirements, including clearly defined surveillance intervals and periodic self-assessments, is required by procedures. Adequate surveillance test procedures and acceptance criteria have been established to support safe operation and are consistent with the approved operating basis for the facility. (CR-5)
- 2) Procedures implement applicable safety requirements and the associated limiting conditions for operation. The parameters indicating compliance with the safety requirements can be measured or physically verified. (CR-1, CR-8)

Approach:

Record Review: Team members reviewed the FABD, Facility Safety Plan and Configuration Management Plan and Change Control procedures. Members reviewed commissioning report and functional performance test results. They also reviewed schedules for testing and recertification of equipment important to safety. Select Operational Safety Requirement administrative controls and determine if associated operating and maintenance procedures implement the requirements. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
2. Biosciences Directorate Critical Measuring and Test Equipment Calibration Plan (BR-CP-05), 2/9/05 [deleted; included in 53]
3. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]
4. Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
5. Biosciences Directorate Quality Assurance Plan, 2/9/05 [replaced by 89]

6. Building 368 Conduct of Operations, March 2006
7. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
8. Building 368 Management Plan, 6/30/05 [replaced by 68]
9. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
10. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
11. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
12. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
13. Durrant E-Mail Dated 9/12/05 RE: Panelboard Short Circuit Ratings.
14. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
15. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
16. LLNL Work Smart Standards
17. Mechanical calculations, dated August 29, 2005
18. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
19. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
20. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
21. Procured-Services Worksheet (PWS) Requisition #Z96112, TSS Inc.
22. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
23. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
24. SOP 1.2.1 Integration Work Sheet (IWS) Requirements for Work in B368 [1/11/05]
25. SOP 6.2 Routine Facility Monitoring for B368 [deleted]
26. Steris™ VHP B368 Testing Logs - Labs & HEPA filter banks Feb thru May 2006
27. Technical Safety Services Inc., Biological Safety Cabinet Certification Report, No. 354189, 5/31/05.
28. World BioHazTec Site Survey Comments Form, Draft Final Inspection, 7/7/05

Interviews: Team members interviewed personnel associated with the Configuration Management program to assess their understanding of program requirements and responsibilities.

- | | |
|----------------|---|
| ◆ BIO DAD OP | BIO Deputy Associate Director for Operations |
| ◆ HCD AB | Hazards Control Department - Safety Analyst/Authorization Basis Section |
| ◆ HCD AB SL | Hazards Control Department -Authorization Basis Section Leader |
| ◆ IBC Co-Chair | Institutional Biosafety Committee Co-Chair |
| ◆ LBOC Chair | Laboratory Biosafety Operations Committee Chairman |
| ◆ B368 CM | LLNL Plant Engineering, Design & Construction Division, B368 |

	Construction Manager
◆ NHI AADA	NHI Assistant Associate Director for Assurances
◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RRP	Room Responsible Person (ABSL3)
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: None.

Discussion of Results (by Criteria):

- 1) Since the facility is non-operational it is not possible to confirm compliance with safety requirements, including clearly defined surveillance intervals and periodic self-assessments required by procedures. The requirements are in place in the FSP (see Section 6: Maintenance, Inspection, and Quality Assurance of Systems Important to Safety and Equipment) and the B368 Configuration Management Plan. Surveillance testing procedures and acceptance criteria have been established to support safe operation and are consistent with the approved operating basis for the facility (per the FABD) and a Maintenance Window of 6 months has been established to perform required testing. The NHI AD FM and SAFM will insure compliance with these requirements and are aware of their responsibilities.
- 2) As described in Section 6 of the FSP, procedures implement applicable safety requirements and the associated limiting conditions for operation. For example, Fire Detection and Suppression Systems will be tested in accordance with NFPA 72, National Fire Alarm Code. The parameters indicating compliance with the safety requirements can be measured or physically verified according to manufacturers specifications or recognized industry consensus standards.

Conclusion(s): All criteria for this CRAD have been met to the extent practical to determine.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 13	CRITERIA MET	
Emergency Preparedness-1	DATE: 6/11/06	YES	NO

Objective:

An emergency preparedness program is established, sufficient numbers of qualified personnel are provided, and adequate facilities and equipment are available to ensure emergency preparedness is adequate for safe operations. Level of knowledge of emergency preparedness personnel is adequate.

Criteria:

- 1) The emergency preparedness organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. There are adequate facilities and equipment and is adequately staffed with qualified personnel who are knowledgeable of facility operations and hazards. These personnel also give adequate attention to health, safety, and environmental protection issues. (CR-1, CR-3, CR-6)
- 2) An effective emergency preparedness program has been established. Drills and exercises are conducted and an adequate response capability exists.
- 3) Emergencies are promptly recognized and classified, and parameters associated with the emergency are monitored to detect changed or degraded conditions.
- 4) Ensure timely implementation of protective actions for workers, collocated workers, and the public.
- 5) Emergencies are promptly reported and appropriate notifications are made.
- 6) The Emergency Plan is approved and implemented.

Approach:

Record Review: Team members reviewed the Building 368 Emergency Management Plan. They also reviewed the documentation (e.g. administrative procedures, organizational charts, position descriptions, and internal memorandums) that establishes the roles, responsibilities, interfaces, and staffing levels for the Emergency Preparedness group that supports operations during emergency events. Members reviewed several drill records and one video that described the drills that have been conducted. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Biosciences Directorate ES&H Self-assessment Plan (BR-SAP-05), 2/8/05 [replaced by 87]

2. Biosciences Directorate Integrated Safety Management System Implementation Plan, BR-ISM-05 4/2005 [replaced by 88]
3. Biosciences Directorate Quality Assurance Plan, 2/9/05 [replaced by 89]
4. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
5. BR0092/R Biosciences ES&H Orientation and refresher
6. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
7. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
8. Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
9. Building 368 Conduct of Operations, March 2006
10. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
11. Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
12. Building 368 Fire Hazards Analysis (HC-T2-05-022), 5/9/05
13. Building 368 Management Plan, 6/30/05 [replaced by 68]
14. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
15. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, US Dept. of Health and Human Services, May 1999
16. CDC/NIH, Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd Edition, September 2000.
17. Change Control Form for Safety Basis Documents; B368 Form Number 2005-001, March 13, 2006 [flammable gases and open flames] [currently in draft]
18. Change Control Form for Safety Basis Documents; B368 Form Number 2005-002, October 28, 2005 [pathogen library]
19. Change Control Form for Safety Basis Documents; B368 Form Number 2005-003, December 15, 2005 [HVAC dampers]
20. Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
21. EP0006-COR and EP0006-HZ/HZRW
22. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
23. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
24. Fire Department Run Cards (Blank - to be completed when facility begins operation)
25. Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
26. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
27. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
28. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
29. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05

30. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
31. Lawrence Livermore Fire Department - Tactical Plan, Response to Emergencies in Building 368, 3/29/05
32. LLNL Biogovernance Administrative Memo, Vol. 36, No. 36, May 16, 2006
33. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
34. LLNL Environment Safety & Health Manual [available internal/external on-line]
35. LLNL Health Services Department, Operation of the Decontamination Facility B663, 1/22/01 [Rev. 1, 3/30/04]
36. LLNL Procurement & Materiel Department, Material Distribution Division (MDD) Operating Procedures, Section 200.20; Infectious Substances and Etiologic Agents, receiving and shipping instructions: Issue Date 8/1/05 [7/10/06]
37. LLNL Work Smart Standards
38. Material Distribution Division (MDD) Operating Procedures, Section 302.16, Subject: Infectious Substances and Etiologic Agents [deleted]
39. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
40. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
41. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
42. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
43. NAI Stop Work Policy, Rev.1, January 2006
44. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
45. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
46. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
47. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]
48. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
49. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
50. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05

Interviews: Team members interviewed those emergency preparedness personnel who are responsible for providing support to operations during emergency events to determine if they are familiar with their roles, responsibilities, and interfaces with the operations organization. Interview these personnel to determine if their level of knowledge of plant operations and hazards is adequate.

- | | |
|--------------|---|
| ◆ ALT BSO | Alternate Biosafety Officer |
| ◆ BIO ES&H | BIO ES&H Officer |
| ◆ BSO | Biosafety Officer |
| ◆ EP EEP | Emergency Programs, Exercises and Employee Preparedness |
| ◆ EP OI FDS | Emergency Programs, Overview and Integration, Facility Drill Specialist |
| ◆ FPOC | Facility Point of Contact |
| ◆ FC | Hazards Control Emergency Management, Fire Captain |
| ◆ HCD Team 2 | Hazards Control Team 2, ES&H Technician |

- ◆ HCD Team 2 Hazards Control Team 2, Industrial Hygienist
- ◆ HSD Health Services Department - Occupational & Environmental Medicine
- ◆ RRP Room Responsible Person (ABSL3)
- ◆ SAFM Select Agent Facility Manager
- ◆ SLC Senior Laboratory Coordinator

Shift Performance: Observed an Emergency Drill through a movie/DVD.

Discussion of Results (by Criteria):

- 1) The emergency preparedness organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. The only parts of this criterion that weren't met were the last two concerning knowledge of hazards and adequate attention to health safety and environmental protection issues. Emergency Drill personnel were not aware of the need to maintain biocontainment and in the May 2005 video showed personnel propping-open doors all the way into the BSL-3 laboratories for an extended period of time. They also did not observe problems with the execution of the 3-blanket wrap where rescuers re-contaminated the victim/patient and themselves. They finally did not detect problems at the health care facility whereby medical personnel contaminated themselves and only treated the patient for physical injuries assuming that the patient had been adequately decontaminated. They also assumed he was not exposed to a communicable disease and sent him home without quarantine. It was not apparent that they checked with verifiable sources as to his pathogen exposure.
- 2) An effective emergency preparedness program has been established. Drills and exercises are conducted and an adequate response capability exists but some re-training is required to deal with isolation techniques and disposal of contaminated clothing and PPE that might contain Select Agent pathogens.
- 3) Emergencies in the functional and tabletop exercises were promptly recognized and classified, and parameters associated with the emergency were monitored to detect changed or degraded conditions.
- 4) Documentation suggests that emergency personnel did respond to drill exercises in a timely fashion. Only in the case of the video (i.e., May 2005) was the Team able to evaluate whether adequate protective actions were implemented for workers, collocated workers, and the public and in this case they did not and they were not aware of it (i.e., specifically the breach in biocontainment and problems with the 3-blanket wrap).
- 5) Systems and training are in place to insure that emergencies are promptly reported and appropriate notifications are made in accordance with B368 SOP 1.5.
- 6) The B368 Select Agent Center Emergency Response Procedure is approved and implemented.

Conclusion(s): It is a Prestart Finding that procedures be put in place to insure that: 1) emergency response actions not breach biocontainment unless it is a life or death situation, 2) emergency response personnel be properly trained in the execution of a 3-blanket wrap so as not to re-contaminate the victim/patient nor themselves and the transport vehicle, and 3) that medical staff obtain accurate patient information, don't assume the patient has been

adequately decontaminated, and quarantine the patient in the case of a potential communicable-disease exposure. This may require the preparation of another “medical” work procedure since this aspect of the response is from the Health Services Department.

Issue(s): It is a Prestart Finding to prepare emergency response procedures and training to insure proper execution of a rescue without endangering workers, the public and the environment.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 14	CRITERIA MET	
Emergency Preparedness-2	DATE: 6/11/06	YES	NO

Objective:

Level of knowledge of operations support personnel is adequate based on reviews of examinations and examination results and selected interviews of operations support personnel.

Criteria:

- 1) Emergency preparedness support personnel demonstrate the ability to carry out emergency procedures under their cognizance. Emergency preparedness support personnel demonstrate a working knowledge of facility systems and components related to safety. These personnel also give adequate attention to health, safety, and environmental protection issues. (CR-4)

Approach:

Record Review: Team members reviewed the Building 368 Emergency Management Plan. Members also reviewed the drill records that describe the drills that have been conducted and review the results from each. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
2. Building 368 Fire Hazards Analysis (HC-T2-05-022), 5/9/05
3. Building 368 Management Plan, 6/30/05 [replaced by 68]
4. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
5. Environmental Protection Department, Discipline Action Plan (DAP), BBRP/B368, ES&H Team 2, 3/22/05
6. EP0006-COR and EP0006-HZ/HZRW
7. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
8. Fire Department Run Cards (Blank - to be completed when facility begins operation)
9. Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05

10. Hazards Control Department, Chemical/Biological Safety Discipline Action Plan (DAP) for Biosciences Directorate Building 368 and other facilities involved in B368 operation (e.g., B365), 3/23/05
11. Health Physics Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
12. Industrial Safety Discipline Action Plan (DAP), ES&H Team 2, Bioscience Directorate (CY 2005), Facility (BSL-3): B-368, 3/21/05
13. Lawrence Livermore Fire Department - Tactical Plan, Response to Emergencies in Building 368, 3/29/05
14. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
15. LLNL Environment Safety & Health Manual [available internal/external on-line]
16. LLNL Work Smart Standards
17. Medical Waste Permit Application, Medical Waste Management Plan, and Emergency Action Plan for B-368 Biosafety Level 3 Facility, document no. PRA05-037, June 2005
18. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
19. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
20. SOP 5.3 Use of Personal Protective Equipment in B368 [1/11/05]

Interviews: Team members interviewed available emergency preparedness support personnel.

- ◆ EP EEP Emergency Programs, Exercises and Employee Preparedness
- ◆ EP OI FDS Emergency Programs, Overview and Integration, Facility Drill Specialist
- ◆ FC Hazards Control Emergency Management, Fire Captain
- ◆ HCD Team 2 Hazards Control Team 2, ES&H Technician
- ◆ HCD Team 2 Hazards Control Team 2, Industrial Hygienist
- ◆ HSD Health Services Department - Occupational & Environmental Medicine

Shift performance: Observe Emergency Drill if schedule allows.

Discussion of Results (by Criteria):

- 1) This criterion is similar to that for CRAD 13. The findings are the same with a couple of caveats. Some emergency preparedness support personnel (ES&H Team 2, SAFM, and FPOC) demonstrated their ability to carry out emergency procedures under their own cognizance during exercises and interviews. They demonstrated a working knowledge of facility systems and components related to safety and from interviews the Team understands that these personnel put systems in safe shut-down mode as required by the situation. They gave adequate attention to health, safety, and environmental protection issues as they would be expected to do from their training and experience. The problem is mainly with emergency response personnel that do not have a background working with pathogens.

Conclusion(s): No additional finding – this is a repeat of the concern expressed in CRAD #13.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 15	CRITERIA MET	
Fire Protection	DATE: 6/11/06	YES	NO

Objective:

A fire protection program is adequate, sufficient numbers of qualified personnel are provided and adequate facilities and equipment are available to ensure fire protection support services are adequate for safe operations. (CR-1, CR-2, CR-6)

Criteria:

- 1) The fire protection organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. It has adequate facilities and equipment and is adequately staffed with qualified personnel who are knowledgeable of facility operations and hazards. These personnel also give adequate attention to health, safety, and environmental protection issues. Fire protection equipment has been identified, selected, maintained, and tested to ensure adequate detection and suppression is provided for personnel and equipment. (CR-1, CR-2, CR-6)
- 2) Fire safety programs have been established that ensure plant personnel can prevent and respond to fire hazards. Personnel have been trained to anticipate, recognize, evaluate, and control those hazards. (CR-1, CR-2, CR-6)

Approach:

Record Review: Team members reviewed the documentation (e.g. administrative procedures, organizational charts, position descriptions, and internal memorandums) that establish the roles, responsibilities, interfaces, and staffing levels for the fire protection group that supports operations. Members reviewed training records or other documentation that demonstrate operations personnel have been trained to anticipate, recognize, evaluate, and control fire hazards. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Building 368 Facility Drill, 6/1/05 Safety and Environmental Protection Directorate [latest drill 3/2006]
2. Building 368 Fire Hazards Analysis (HC-T2-05-022), 5/9/05
3. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
4. Fire Department Run Cards (Blank - to be completed when facility begins operation)

5. Fire Protection Engineering, Discipline Action Plan (DAP) (Biosciences), ES&H Team 2, 3/22/05
6. Lawrence Livermore Fire Department - Tactical Plan, Response to Emergencies in Building 368, 3/29/05
7. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
8. LLNL Environment Safety& Health Manual [available internal/external on-line]
9. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
10. SOP 1.5 Emergency Response Procedure in B368 [1/11/05]
11. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05

Interviews: Team members interviewed the fire protection personnel to determine if they are familiar with their roles, responsibilities, and interfaces with the operations organization. Members also interviewed operations personnel and the "first response team" to determine if they have been trained to anticipate, recognize, evaluate, and control fire hazards.

◆ ALT BSO	Alternate Biosafety Officer
◆ BIO ES&H	BIO ES&H Officer
◆ BSO	Biosafety Officer
◆ FPOC	Facility Point of Contact
◆ FC	Hazards Control Emergency Management, Fire Captain
◆ HCD Team 2	Hazards Control Team 2, ES&H Technician
◆ HCD Team 2	Hazards Control Team 2, Industrial Hygienist
◆ Lab Worker	BSL-3 Microbiologist/Technician
◆ RRP	Room Responsible Person (ABSL3)
◆ SAFM	Select Agent Facility Manager
◆ SLC	Senior Laboratory Coordinator

Shift Performance: Walk down the facilities to determine if the fire protection systems, to include detection, suppression, and prevention equipment are adequate. Also, determine that housekeeping and material control eliminate hazards for the work force. Observe the fire protection facilities and equipment and assess their adequacy to support operations.

Discussion of Results (by Criteria):

- 1) According to LLNL Fire Department personnel the fire protection organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. Concerns about B368 will be addressed on Run Cards once the facility is operational. The Fire Department has adequate facilities and equipment and is adequately staffed with qualified personnel who are knowledgeable of facility operations and hazards. These personnel also give adequate attention to health, safety, and environmental protection issues although they are unaware of some of the concerns about working in a Biocontainment Facility such as the BSL-3 and ABSL-3 laboratories. Fire protection equipment has been identified, selected, maintained, and tested to ensure adequate detection and suppression is provided for personnel and equipment.

- 2) Fire safety programs have been established that ensure LLNL plant personnel can prevent and respond adequately to fire hazards. Personnel have been trained to anticipate, recognize, evaluate, and control those hazards although they need some additional training to understand the issues with biohazards.

Conclusion(s): This is not an additional finding since it is the same issue as CRAD #13.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Training-1	CRAD NO: 16 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

Training and qualification programs for operations and operations support personnel have been established, documented, and implemented. Training has been performed. (Core Requirements CR-03 and CR-05)

Criteria:

- 1) A training plan is developed and implemented that describes the qualification process, maintenance of proficiency, and evaluations by facility and training management.
- 2) Classroom training is conducted in accordance with formal lesson plans based on established learning objectives. Written and oral examinations are used to evaluate trainee comprehension of training content.
- 3) Training programs incorporate formal on-the-job training (OJT) and hands-on evaluation of skills.
- 4) The qualification program includes requirements for successful completion of written, oral, operational evaluations for operations and maintenance personnel.
- 5) The qualification programs are based on the latest modifications to the facility.
- 6) Training has been completed and documented for the latest revisions of procedures used by operations and operations support personnel.

Approach:

Record Review: Team members reviewed procedures to ensure the criteria above are implemented. Reviewed training and qualification records, including results of written, oral, and operational evaluations as necessary, to ensure the training program is being formally administered and controlled. Members reviewed training records to determine if they are maintained in an auditable manner and support management information needs by providing required data on each individual's training participation, performance, and qualification/certification. They also reviewed the evaluation/self-assessment program for involvement by facility and training management in program, instructor (classroom and OJT), and training materials assessment. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
2. B368 SOP Training Roster (BR3001), 5/5/05
3. B368 Tissue Digester Operator Training Roster, 5/16/05

4. B368 VHP Operator Training Roster, 3/16/05
5. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
6. BR0092/R Biosciences ES&H Orientation and refresher
7. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities
8. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
9. BR9800 Select Agent Security
10. EP0006-COR and EP0006-HZ/HZRW
11. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
12. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
13. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
14. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
15. LLNL Environment Safety & Health Manual [available internal/external on-line]
16. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
17. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
18. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
19. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
20. SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
21. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
22. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
23. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
24. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
25. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
26. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
27. Training record for the RHWM Field Technician who inspects and operates the retention tank system on a daily basis
28. Training records for individuals working within B-368

Interviews: Team members interviewed training personnel to determine if they have sufficient experience and qualifications for assessing operations and maintenance personnel.

- | | |
|----------------|--|
| ◆ ALT BSO | Alternate Biosafety Officer |
| ◆ BIO ES&H | BIO ES&H Officer |
| ◆ BIO TC | BIO Training Coordinator |
| ◆ BSO | Biosafety Officer |
| ◆ FPOC | Facility Point of Contact |
| ◆ RHWM | Hazardous Waste Management Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, ES&H Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, Industrial Hygienist |
| ◆ HSD | Health Services Department - Occupational & Environmental Medicine |
| ◆ IBC Co-Chair | Institutional Biosafety Committee Co-Chair |

◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ RO	Responsible Official (Select Agent)
◆ RRP	Room Responsible Person (ABSL3)
◆ SPR	Security Program Representative
◆ SAFM	Select Agent Facility Manager
◆ SLC	Senior Laboratory Coordinator

Shift Performance: Observe a classroom lecture or field training activity for adequacy if the schedule allows.

Discussion of Results (Criteria):

- 1) A B368 training plan has been developed and implemented that describes worker qualification, but does not specifically describe maintenance of proficiency (presumed by continued work within the facility). This plan identifies evaluations by Select Agent Center facility and ES&H management. Training requirements for the B368-specific facility and support personnel are given in SOP 1.3 and ES&H Manual Volume IV, Part 40: Training; Document 40.2; Environment, Safety, and Health Training and Education. The specific Organizational Training Requirements (OTRs) are determined by the LBOC and/or the IBC in conjunction with the SAM, SAFM, SLC, and/or the BSO. The qualification process for workers is described in the FSP under Section 4.9 for the B368 SLC.
- 2) Classroom training is conducted in accordance with formal lesson plans based on established learning objectives. Written and oral examinations prepared by the BSO, SAFM, SAM, and SLC are used to evaluate trainee comprehension of training content.
- 3) Training programs will incorporate formal on-the-job training (OJT) and hands-on evaluation of skills once the facility becomes operational. This cannot be evaluated at this time.
- 4) The specific requirements for the qualification program have not been determined but should be included in the Draft Building 368 Operations Plan for Projects Employing B368 BSL-3 Facility (identified as an observation in an earlier CRAD). It is expected that the qualification program will include requirements for successful completion of written, oral, operational evaluations for operations and maintenance personnel.
- 5) There has been no opportunity to evaluate the qualification programs that will be based on the latest modifications to the facility this since the procedure is still in Draft form and the facility is not yet operational. SOP 1.3 should reflect the qualification process and competency for workers
- 6) For the most part training has been completed and documented for the latest revisions of procedures used by operations and operations support personnel. Due to some changes in personnel, procedures, and decisions concerning who will have access to the facility there are a couple more support staff (e.g., FPOC and ES&H Team 2 Technician) who will require some B368-specific training. This should be accomplished prior to the submittal of this report.

Conclusion(s): Issues discussed in this CRAD were described earlier concerning the Draft Building 368 Operations Plan for Projects Employing B368 BSL-3 Facility and will not result in

a finding. Training is essentially complete although the OJT for B368 workers will be conducted when the facility is operational. It is an Observation that SOP 1.3 should address worker qualification and competency evaluation.

Issue(s): None

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA: Training-2	CRAD NO: 17 DATE: 6/11/06	CRITERIA MET	
		YES	NO

Objective:

The training and qualification programs encompass the range of duties and activities required to be performed. (Core Requirement CR-03)

Criteria:

- 1) Requirements for training and continuing training have been adequately defined and programs have been developed. Continuing training includes conduct of realistic drills to maintain proficiency in responding to abnormal and accident situations.
- 2) Training programs for operations and maintenance personnel include training on the requirements contained in the approved operating basis for the facility
- 3) Training programs for operations and maintenance personnel emphasize the importance of compliance with procedures and safety requirements
- 4) Training for technical staff personnel is based on an assessment of position duties and responsibilities.

Approach:

Record Review: Team members reviewed training course content for incorporation of safety requirements, technical safety requirements, and procedure compliance. Review the continuing training program plan and drill schedule to verify its adequacy to support safe operations. Members also verified that the current facility safety analysis report, operating procedures, technical and professional references, and facility/industry operating experience are used to identify facility specific training content and information for use in developing training materials. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

29. B368 SOP Review Course, Training Roster (BR3001), 7/7/05
30. B368 SOP Training Roster (BR3001), 5/5/05
31. B368 Tissue Digester Operator Training Roster, 5/16/05
32. B368 VHP Operator Training Roster, 3/16/05
33. Biosciences Directorate Training Plan (BR-TP-05), 2/9/05 [replaced by 90]
34. BR0092/R Biosciences ES&H Orientation and refresher
35. BR-1001 Basic Biosafety & Biosurety for BIO, PowerPoint Presentation, General Class for Supervisors and Researchers in BIO Facilities

36. BR1003 Biosafety in the BSL Pathogens Laboratory (being updated to include Basic Biosafety BSL3 Facility)
37. BR9800 Select Agent Security
38. EP0006-COR and EP0006-HZ/HZRW
39. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
40. HS 4431 - BSL-3 Operator Training Roster, 3/14/05
41. HS 4431 BSL-3 Operator Training - PowerPoint Presentation, Undated
42. Laboratory Training Records and Information Network (LTRAIN) at the internal LLNL website https://www-ais.llnl.gov/llnl_only/docs/hr/ltrain/.
43. LLNL Emergency Response video/DVD "HS-9100 Drill, B368, 5/9/05"
44. LLNL Environment Safety & Health Manual [available internal/external on-line]
45. NAI Integrated Safety Management (ISM) Self-assessment Plan Rev.8, January 2005 [replaces 15]
46. NAI Integrated Safety Management Plan, February 2005 [replaces 16]
47. NAI Quality Management Plan for Science, Engineering, and Facilities, Rev.3, August 2003 [replaces 17]
48. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
49. SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
50. SOP 1.11 - Safe Plan of Action Standard Operating Procedure (SPA) [2/13/06]
51. SOP 1.3 Training of workers for Building 368 [Rev. 1, 7/13/06]
52. SOP 5.1 General Laboratory Practices for B368 [1/11/05]
53. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
54. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
55. The BSL-3 Facility Medical Waste Management and Emergency Action Plans (UCRL-MI-214701), 8/26/05
56. Training record for the RHWM Field Technician who inspects and operates the retention tank system on a daily basis
57. Training records for individuals working within B-368

Interviews: Team members interviewed training personnel responsible for continuing training, and drill scenario development and implementation. They also interviewed personnel responsible for establishing training needs for operations and maintenance personnel.

◆ ALT BSO	Alternate Biosafety Officer
◆ BIO ES&H	BIO ES&H Officer
◆ BIO TC	BIO Training Coordinator
◆ BSO	Biosafety Officer
◆ EP EEP	Emergency Programs, Exercises and Employee Preparedness
◆ EP OI FDS	Emergency Programs, Overview and Integration, Facility Drill Specialist
◆ FPOC	Facility Point of Contact
◆ RHWM	Hazardous Waste Management Technician
◆ HCD Team 2	Hazards Control Team 2, ES&H Technician
◆ HCD Team 2	Hazards Control Team 2, Industrial Hygienist
◆ HSD	Health Services Department - Occupational & Environmental Medicine

◆ IBC Co-Chair	Institutional Biosafety Committee Co-Chair
◆ LBOC Chair	Laboratory Biosafety Operations Committee Chairman
◆ RO	Responsible Official (Select Agent)
◆ RRP	Room Responsible Person (ABSL3)
◆ SPR	Security Program Representative
◆ SAFM	Select Agent Facility Manager
◆ SLC	Senior Laboratory Coordinator

Shift Performance: None.

Discussion of Results (by Criteria):

- 1) Requirements for training and continuing training have been adequately defined and programs have been developed in accordance with the ES&H Manual (Volume IV, Part 40: Training; Document 40.2 Environment, Safety, and Health Training and Education), the FABD, and the FSP. Some continuing training includes conduct of realistic drills to maintain proficiency in responding to abnormal and accident situations. Most of these operations personnel are also involved in B365 drills because they are currently working in that facility and B368 is not operational. This expands their breadth and depth of experience with an operational facility.
- 2) Training programs for operations and maintenance personnel include training on the requirements contained in the approved FABD and Configuration Management Plan for the B368 facility.
- 3) All training programs for operations and maintenance personnel emphasize the importance of compliance with procedures and safety requirements. Compliance with the BMBL is emphasized and information from it is used to demonstrate points in training.
- 4) Training for technical staff personnel is based on an assessment of position duties and responsibilities stated in SOP 1.3.

Conclusion(s): All criteria for this CRAD have been met.

Issue(s): None.

BSL-3 MPR ASSESSMENT FORM (FORM 1)

SUBJECT AREA:	CRAD NO: 18	CRITERIA MET	
Security	DATE: 6/11/06	YES	NO

Objective:

Security documentation is in place that describes the "security envelope" of the facility. Security systems are operational. The operation of security systems and administrative controls are understood by staff. A system to maintain control over the design and modification of facilities and security systems is established.

Criteria:

- 1) The security documentation addresses appropriate security risks associated with use of Select Agents. Security systems described in security documentation has been appropriately installed and are operational. Building workers, facility staff, and institutional support staff are familiar with the building-specific security requirements and their roles and responsibilities. Administrative controls are in place to ensure that repairs (or modifications) to security systems are adequately analyzed to identify and to ensure that design changes are documented and approved prior to implementation. (CR-4)

Approach:

Record Review: Team members reviewed security documentation to assess whether threats have been adequately assessed and vulnerabilities have been accounted for. This documentation includes the Building 368 Biological Risk and Threat Assessment, the Building 368 Security Plan and the LLNL Institutional Security Plan. They also reviewed the design of the facility to insure protective measures and security and surveillance systems have been implemented. They reviewed the facility and institutional operating procedures to ensure protective measures are in place to secure Select Agents. Team members also reviewed the Facility Safety Plan, Standard Operating Procedures and the Building 368 Management Plan to determine if roles and responsibilities are adequately defined. The following documents and records were reviewed or referenced in the course of evaluating this CRAD:

1. Biosciences Directorate - Conduct of Operations Matrix [replaced by 27]
2. BR9800 Select Agent Security
3. Building 368 Biological Risk and Threat Assessment (LLNL) (July 14, 2005)
4. Building 368 Configuration Management Plan, 8/9/05, new rev. 5/06
5. Building 368 Management Plan, 6/30/05 [replaced by 68]

6. Building 368 Operations Plan for Project Employing B368 BSL-3 Facility, Draft 2/05 (also Draft IWS)
7. Building 368 Select Agent Security Plan, 7/29/05 [replaced by 74]
8. Facility Safety Plan Building 368 (UCRL-AM-211917), May 2006 [Major Change Memo 5/16/06]
9. Final Authorization Basis Document for the Biosafety Level 3 (BSL-3) Facility at Lawrence Livermore National Laboratory, 2/4/05 [see 41, 42, & 43]
10. Incident Analysis Report: Handling, Inventorying, Packaging, and Shipping of Select Agents in Building 365 during August and September 2005, SN: IA 0518-C
11. Institutional Select-Agent Management Structure, 12/22/05 [supersedes 31]
12. LLNL Biological Select Agents and Toxins Security revision 5, dated Dec., 13, 2004 [Rev. 6, 3/9/06]
13. LLNL Institutional Security Plan
14. NAI Safety and Security Training Program Plan Rev.7, January 2005 [replaces 18]
15. Safety Evaluation Report, March 2005, Final Authorization Basis Document for the Biological Safety Level 3 (BSL-3) Facility (B368) at Lawrence Livermore National Laboratory, 4/22/05
16. SC 9800 BSL-3 Security Training - PowerPoint Presentation (Undated)
17. SOP 1.1 Roles and Responsibilities in Building 368 [deleted]
18. SOP 1.7 Inventory of Select Agents in B368 [Rev. 1, 4/19/06]
19. SOP 1.8 Internal Exchange of Select Agents [4/28/06]
20. SOP 2.1 Access Control in B368 [4/6/06]
21. SOP 5.7 Receiving Biological Materials [Rev. 2, 7/6/06]
22. SOP 5.8 Shipping Biological Materials [Rev. 2, 7/6/06]
23. Training records for individuals working within B-368

Interviews: Team members interviewed staff that would be working in the facility to determine if they understand their roles and responsibilities and the protocols for protection of Select Agents. Members also interviewed workers and facility staff to determine if they understand the operation of security systems. The also interviewed personnel associated with developing/processing facility modifications to determine if they understand requirements to maintain security in the facility.

- | | |
|----------------|---|
| ◆ ALT RO | Alternate Responsible Official (Select Agent) |
| ◆ BIO DAD OP | BIO Deputy Associate Director for Operations |
| ◆ BIO DAD PR | BIO Deputy Associate Director for Programs |
| ◆ BIO AD | BIO Directorate Associate Director |
| ◆ FPOC | Facility Point of Contact |
| ◆ HCD Team 2 | Hazards Control Team 2, ES&H Technician |
| ◆ HCD Team 2 | Hazards Control Team 2, Industrial Hygienist |
| ◆ IBC Co-Chair | Institutional Biosafety Committee Co-Chair |
| ◆ Lab Worker | BSL-3 Microbiologist/Technician |
| ◆ LBOC Chair | Laboratory Biosafety Operations Committee Chairman |
| ◆ B368 CM | LLNL Plant Engineering, Design & Construction Division, B368 Construction Manager |
| ◆ NHI AD | NHI Associate Director |

◆ NHI ADFM	NHI Associate Director Facility Manager
◆ NHI APL-SA	NHI Associate Program Leader for Select Agent Science
◆ NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager
◆ NHI DAD OP	NHI Deputy Associate Director for Operations
◆ RO	Responsible Official (Select Agent)
◆ RRP	Room Responsible Person (ABSL3)
◆ SPR	Security Program Representative
◆ SAAI	Select Agent Authorizing Individual
◆ SAFM	Select Agent Facility Manager
◆ SAM	Select Agent Manager (Select Agent Center)
◆ SLC	Senior Laboratory Coordinator

Shift Performance: One Team member performed a facility walk down to observe operation of security systems and determined that there are no uncontrolled modifications. This walk down evaluated the accuracy of drawings and other documentation for security system operation and maintenance.

Discussion of Results (by Criteria):

- 1) The Biological Select Agents and Toxins Security Plan (Rev. 6, March 9, 2006) addresses appropriate security risks associated with use of Select Agents. Security systems described in this security documentation have been appropriately installed and will be fully operational when the building is ready for occupancy. Building workers, facility staff, and institutional support staff are familiar with the building-specific security requirements and their roles and responsibilities because of B368 security-specific training (BR9800 Select Agent Security). Administrative controls are in place and monitored by the SAFM and FPOC to ensure that repairs (or modifications) to security systems are adequately analyzed to identify and to ensure that design changes are documented and approved prior to implementation.

Conclusion(s): All criteria for this CRAD have been met. There is one observation, Section 14.1 Inventory states that the RO and BSO will review the inventory records annually whereas Section 5.1 The Responsible Official (RO) says he will review the SA or toxin inventory quarterly. Is this a discrepancy? Even though not required you might consider making BSL-3 security training an annual requirement due to the sensitivity of the issues.

Issue(s): None.

Appendix B

MPR Deficiency Forms

MPR DEFICIENCY FORM (FORM 2)

CRAD #1	Finding <u> X </u> Observ. <u> </u>	Prestart <u> </u> Post-Start Crit <u> X </u> Post-Start <u> </u>	Issue No.: 1 Date: 6-11-06
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ISSUE:

During testing the tissue digester caused the retention tanks to overflow leading to a potential concern about pathogens being released to the environment. Secondly, the unit does not achieve the design specification temperature/pressure so that the time of operation is lengthened to compensate for the lowered temperature. The unit needs to operate according to the manufacturer’s specifications.

REQUIREMENT:

CRAD #1 criteria numbers 4 and 5 are not met. Additionally, the tissue digester is described in the FSP as a building system “important to safety” (Section 6.1) and therefore must be operated and maintained according to manufacturer’s specifications.

REFERENCE(S):

Facility Safety Plan Building 368, May 2006 with Major Change Memo May 16, 2006.

DISCUSSION:

NHI must ensure that the tissue digester is “operated and maintained according to the manufacturer’s instructions” (FSP Section 5.4.2.1). Currently the digester produces excessive cooling water causing the retention tank(s) to overflow during testing. The digester is also not being supplied steam at a temperature/pressure that is optimal for the equipment due to a sizing problem with the boiler. This causes the digester to not achieve the designed temperature and the digestion cycle is significantly lengthened.

Testing and studies performed by WR2 and LLNL determined that the excess cooling water is due to some fault in the temperature sensing unit. The retention tank system is a two-tank system designed to switch manually (now modified to switch automatically) between a full to an empty tank. The amount of cooling water discharged during at least one test exceeded the capacity of the two tanks. Repair of the sensing unit or re-routing the cooling water to the sanitary discharge is being considered as potential solutions at this point. Also due to a problem with the sizing of the hot-water boiler the digester must be run for a longer period at a lower temperature than specified by the manufacturer (i.e., WR²).

There is a variance for this treatment technology from the California regulators so that annual temperature calibration data for this unit is not required. There is no finding with this temperature issue but there is a concern that NHI develop methods to document that the unit is functioning as required to destroy all pathogens.

CONCLUSION:

Since the offending problem is only to be used for animal carcass disposal and it is our understanding that there are no animal studies identified for the near future this will be considered a Post-Start /Critical Finding. Prior to startup of the ABSL-3 as an animal laboratory this piece of equipment must be functioning as specified by the manufacturer. In the interim, procedures should be prepared for the tissue digester to provide indisputable documentation of destruction of all organic material.

MPR DEFICIENCY FORM (FORM 2)

CRAD #2	Finding <u> X </u> Observ. <u> </u>	Prestart <u> X </u> Post-Start Crit <u> </u> Post-Start <u> </u>	Issue No.: 2 Date: 6-11-06
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ISSUE:

Adequate and correct procedures meeting LLNL ES&H Manual requirements need to be prepared for the medical area (e.g., immunizations, serum banking, and medical surveillance). In order to adequately prepare these procedures it is necessary for NHI to determine the mandatory requirements for medical surveillance, serum banking, immunizations and associated titer testing programs. The LLNL ES&H Manual allows for voluntary participation in various medical programs but the upgrading of pathogens work at LLNL now increases the potential risk of spreading communicable diseases and concerns for non-involved workers and the public must be taken into consideration.

REQUIREMENT:

CRAD #2 criteria #7 states that “adequate and correct procedures exist for SH&QA services to Building 368.”

REFERENCE(S):

This requirement is mandated in LLNL ES&H Manual Volume 1, Part 3: Safety Analysis and Work Plans and Procedures; Document 3.4 Preparation of Work Procedures

DISCUSSION:

The documents offered to the Team to support the need for these medical procedures does not follow the ES&H Manual requirements. As for content of the procedures, there is some controversy over whether immunizations for those handling specific pathogens should be required or not. There is the conflict between employee rights versus protection of the public. The same controversy exists over whether medical surveillance after the baseline is voluntary or required, and additionally the frequency of exams versus the use of questionnaires. There are also differences of opinion on when serum banking should be performed (once initially versus annually). These issues need to be resolved in accordance with the BMBL, the Clinical and Laboratory Standards Institute (incorporated by reference from the BMBL), and/or other authoritative references and affirmatively stated in the appropriate medical procedure so that B368 staff can be made aware of the requirements.

A recommendation is to consult with the medical staff at the US Army Research Institute for Infectious Diseases (Ft. Detrick, MD) and take their suggestions into consideration

since they have many years experience with this. A publication by one of their physicians (*Experience in the Medical Management of Potential Laboratory Exposures to Agents of Bioterrorism on the Basis of Risk Assessment at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID)*) by Janice M. Rusnak, MD, Mark G. Kortepeter, MD, John Aldis, MD, and Ellen Boudreau, MD, Journal of Environmental Medicine, Volume 46, Number 8, August 2004) addresses some of this issue.

CONCLUSION:

Procedures for the medical area need to be prepared in accordance with LLNL ES&H requirements and authoritative references. This is a Pre-Start Finding because the medical requirements for B368 staff need to be known to them before they begin working in the facility.

MPR DEFICIENCY FORM (FORM 2)

CRAD #3	Finding <input checked="" type="checkbox"/> Observ. _____	Prestart <input checked="" type="checkbox"/> Post-Start Crit _____ Post-Start _____	Issue No.: 3 Date: 6-11-06
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ISSUE:

Functions, assignments, responsibilities, and reporting relationships are not clearly defined due to conflicts between B368 authoritative documents, such as the FSP and ISAMS. Conflicts between these and other B368 documents need to be resolved.

REQUIREMENT:

CRAD criteria #1 states “Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented.” According to the NAI ISMS Plan, the first step is to Plan the Work and in doing so “Identify the work management chain...and define the role, responsibilities, and authority of every individual in that work management chain.”

REFERENCE(S):

Facility Safety Plan Building 368 (FSP), the Institutional Select-Agent Management Structure (ISAMS), and the LLNL Biogovernance Administrative Memo, and NAI Integrated Safety Management Plan.

DISCUSSION:

The roles and responsibilities of identified positions in the ISAMS and FSP do not match. For example, the ISAMS organizational chart doesn't show and the text doesn't explain all the key positions, such as, the SAFM, SAAI, FPOC, and RRP. In the ISAMS, for example, it looks like the SAFM (if it were specifically identified) would report to the SAM but the FSP says SAFM reports to the NHI AD FM. Interviewed personnel were not clear on some of these relationships. For example, interviews with some B368 personnel showed there was confusion on who was the primary and alternate FPOC. Also the FSP describes the SAAI position but does not identify to whom this individual reports. With regard to B368 maintenance the FSP states that the SAFM is responsible (i.e., Section 4.3). Under the description of duties in the FPOC (Section 4.5) the FSP states that the FPOC will assist the SAFM, SAM, and SLC with maintenance but the other two functions do not have maintenance responsibilities. In section 4.8 of the FSP it states that the SAM is responsible for “maintaining all records” although other B368 documents identify others with specific records management responsibilities. This is not an extensive analysis of the conflicts but rather emblematic of the issue.

The FSP references the ISAMS and the ISAMS first sentence says “This document defines the structure for the management of select-agent and BSL-3 work at LLNL.” So it appears that the FSP defers to the ISAMS as the authoritative source. This seems to be contradictory to standard LLNL process particularly when they conflict

CONCLUSION:

While there has been considerable effort put into re-organizing the Select Agent work through the establishment of the Select Agent Center under NHI, there is still some lingering organizational uncertainty reflected in documents and personnel interviews. Conflicts between the FSP and the ISAMS should be resolved and staff trained to the appropriate reporting, responsibility, and authorization matrix.

MPR DEFICIENCY FORM (FORM 2)

CRAD #7	Finding _____ Observ. ___X_	Prestart _____ Post-Start Crit _____ Post-Start _____	Issue No.: 4 Date: 6-11-06
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ISSUE(S): (Criteria #1)

The B368 Operations Plan which is now in rough draft needs to be completed and implemented to demonstrate how startup of this facility will be done using a graded approach based upon complexity and risk.

REQUIREMENT(S):

CRAD criteria #6 is “Graded operations testing has been performed to confirm the adequacy of operator training (CR-12-03).” Starting up of operations using a graded approach is also an integral component of the Integrated Safety Management System for LLNL and NHI.

REFERENCE(S):

LLNL Work Smart Standards, NAI Integrated Safety Management Plan, and Draft Building 368 Operations Plan for Projects Employing B368 BSL-3 Facility (28 February, 2005). DOE/NNSA “LSO Procedures for Startup and Restart of Facilities” (LSO/LSOD-SOP-000162.02)

DISCUSSION:

The Team understands that the reference, *Building 368 Operations Plan for Project Employing B368 BSL-3 Facility*, currently in draft will be completed to show the plan for a gradual stepping up of activities commensurate with training and completion of more and more complex work. This is consistent with LLNL WSS and ISMS strategy and is a Best Management Practice.

CONCLUSION:

The Draft Operations Plan needs to be completed, approved, and utilized to startup the facility through a graded operations approach.

MPR DEFICIENCY FORM (FORM 2)

CRAD #8	Finding _____ Observ. <input checked="" type="checkbox"/>	Prestart _____ Post-Start Crit _____ Post-Start _____	Issue No.: 5 Date: 6-11-06
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ISSUE:

Incorrect statements or incomplete descriptions are found in several NHI B368 SOPs. Also, many of the NHI procedures are non-compliant with LLNL ES&H Manual requirements for the preparation of work procedures in that they don't include all the required fields.

REQUIREMENT:

CRAD criteria #2 states "Adequate procedures for operations have been prepared, approved, and are ready for implementation..."

REFERENCE(S):

ES&H Manual Volume I, Part 3: Safety Analysis and Work Plans and Procedures; Document 3.4: Preparation of Work Procedures.

DISCUSSION:

Note there are several observations concerning incomplete SOPs. One observation is that SOP 5.1 states that all waste will be autoclaved which is not technically correct. This doesn't leave room for other treatment options like the tissue digester. Another observation is that SOP 3.1 does not reflect the need to annually collect and report under the California treatment permit the calibration of the temperature measurement sensor for the autoclave. SOP 5.3 does not explain the doffing of PPE particularly the "bunny" suit and PAPR. SOP 5.1 mentions "sharps" but doesn't address the best management practices, such as, using safety needles (note there is an institutional description in the ES&H Manual but it doesn't provide adequate detail). These comments do not represent an exhaustive review of the NHI SOPs. These are also not written in strict conformance to the LLNL ES&H Manual requirements.

CONCLUSION:

Several observations were noted requiring changes to NHI SOPs. Someone should perform a review of the procedures with respect to the ES&H Manual document that explains how to write a work procedure.

MPR DEFICIENCY FORM (FORM 2)

CRAD #13	Finding <u> X </u> Observ. <u> </u>	Prestart <u> X </u> Post-Start Crit <u> </u> Post-Start <u> </u>	Issue No.: 6 Date: 6-11-06
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ISSUE:

Review of a video of an emergency response drill for B368 showed that the emergency response exercise did not adequately demonstrate key processes. These are 1) conducting the 3-blanket wrap, 2) maintaining the integrity of the B368 biocontainment envelope, 3) minimizing contamination of response personnel and equipment, and 4) assuring control of individuals potentially exposed to communicable pathogens.

REQUIREMENT:

CRAD criteria #1 states "...These personnel also give adequate attention to health, safety, and environmental protection issues (CR-1, CR-3, CR-6)"

REFERENCE(S):

ES&H Manual Volume II; Part 22: Emergencies/Earthquakes; Document 22.1; Emergency Preparedness and Response.

DISCUSSION:

It was obvious from the video that Emergency Drill personnel were not aware of the need to maintain biocontainment and in the May 2005 video, personnel were seen propping-open doors all the way into the BSL-3 laboratories for an extended period of time. They also did not observe problems with the execution of the 3-blanket wrap where rescuers re-contaminated the victim/patient and themselves and possibly the patient transportation vehicle. They finally did not detect problems at the health care facility whereby medical personnel contaminated themselves and only treated the patient for physical injuries assuming that the patient had been adequately decontaminated. They also assumed he was not exposed to a communicable disease and sent him home without quarantine. It was not apparent that they checked with verifiable sources as to his pathogen exposure. Additional exercises need to be conducted paying special attention to these issues. It is important that the exercise evaluator be well versed in these issues.

CONCLUSION:

It is a Prestart Finding that procedures be put in place to insure that: 1) emergency response actions not breach biocontainment unless it is a life or death situation, 2) emergency response personnel be properly trained in the execution of a 3-blanket wrap so as not to re-contaminate the victim/patient nor themselves and the transport vehicle, and 3) that medical staff obtain accurate patient information, don't assume the patient has been adequately decontaminated, and quarantine the patient in the case of a potential communicable-disease exposure. This may require the preparation of another "medical" work procedure since this aspect of the response is from the Health Services Department.

It is a Prestart Finding to prepare emergency response procedures and training to insure proper execution of a rescue without endangering workers, the public and the environment.

MPR DEFICIENCY FORM (FORM 2)

CRAD #16	Finding _____ Observ. <input checked="" type="checkbox"/>	Prestart _____ Post-Start Crit _____ Post-Start _____	Issue No.: 7 Date: 6-11-06
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ISSUE:

NHI SOP 1.3 should address worker qualification and competency evaluation.

REQUIREMENT:

CRAD criteria #4 and #5 state "The qualification program includes requirements for successful completion of written, oral, operational evaluations for operations and maintenance personnel. The qualification programs are based on the latest modifications to the facility."

REFERENCE(S):

LLNL ES&H Manual Volume IV, Part 40: Training; Document 40.1 LLNL Training Program Manual.

DISCUSSION:

The NHI BSL-3 FPM notified the Team that the SLC was in the process of preparing an SOP that would address qualification and competency of workers. This may be a modification to SOP 1.3. The Operations Plan for Building 368 should also address this as it is part of the graded approach to increasing complexity of operations for safety.

CONCLUSION:

An SOP to address this issue is should be forthcoming to correct the observation.

MPR DEFICIENCY FORM (FORM 2)

CRAD #18	Finding _____ Observ. <input checked="" type="checkbox"/>	Prestart _____ Post-Start Crit _____ Post-Start _____	Issue No.: 8 Date: 6-11-06
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ISSUE:

There is a discrepancy between two statements in the Biological Select Agents and Toxins Security Plan concerning when inventories are conducted by the RO.

REQUIREMENT:

CRAD criteria #1 states "...Building workers, facility staff, and institutional support staff are familiar with the building-specific security requirements and their roles and responsibilities..."

REFERENCE(S):

CDC/APHIS Registration and The Biological Select Agents and Toxins Security Plan (Rev. 6, March 9, 2006).

DISCUSSION:

Section 14.1 of the security plan "inventory" states that the RO and BSO will review the inventory records annually whereas Section 5.1 of the plan states that the Responsible Official (RO) will review the SA or toxin inventory quarterly. Is this a discrepancy? Additionally, even though not required you might consider making BSL-3 security training an annual requirement due to the sensitivity of the issues.

CONCLUSION:

The security plan needs to minimally reflect the requirements of the CDC registration.

Appendix C

MPR Team Qualifications

ROBERT HULL, Team Leader & Management/Operations/Safety Basis

CORPORATE MANAGER FOR ENVIRONMENT, SAFETY AND HEALTH (ES&H), LATA INC.

Duties and Responsibilities

- Oversees preparation and implementation of Company ES&H documents.
- Implements worker training programs and ensures all workers have required training and current certifications for work performed on Hazardous Chemical and Radioactive Waste Sites.
- Responsible for review and approval of Company environment and safety-related procedures.
- Develops and coordinates implementation of protocols for high-hazard material sampling.
- Audits and assess all hazardous activities and facilities for compliance with safety protocols.
- Provides direct supervision of all company safety personnel and Safety Coordinators
- Performs incident/accident investigation, tracking, reporting, development and implementation of corrective actions in accordance with LATA's Quality Management System Description (QMSD).

Experience Summary

Mr. Hull has over 30 years of technical and managerial experience in conducting environment, safety and health (ES&H) investigations, QA and regulatory audits and assessments, and other governmental inspections. He has 14 years of experience within the DOE complex. He is LATA's Corporate Manager for Environment Safety and Health and Radiation Safety Officer and, as such, is responsible for LATA's employee compliance with various DOE complex As Low As Reasonably Achievable (ALARA) programs. He is also responsible for the development and implementation of LATA's Integrated Safety Management System (ISMS) process at all LATA and LATA Managed Venture locations.

Relevant Projects and Assignments

- He is currently overseeing the preparation of a safety program for handling and sampling of shock sensitive and reactive hazardous chemicals in drums, lab packs, and gas cylinders for Material Disposal Area B at Los Alamos National Laboratory (LANL). This includes participation in the development of the DSA for this NNSA NES site.
- Biosafety/Biosecurity consultant to DOE NNSA and M&O contractor programs for the design, operation, and risk evaluation of pathogen research facilities including review of authorization basis documents. Includes NEPA reviews for Biosafety Level III operations at LANL, LLNL, and preliminary reviews at two other DOE facilities.
- Chemical and biological weapons consultant to DoD, US State Department, US Attorney, FBI, and the United Nations Monitoring Verification and Inspection Commission. Provided training to inspectors and law enforcement agencies and personnel in the production and identification of weapons and weapons manufacture.

Key Expertise

- Written dozens of HASPs, SAPs, QAPPs, and Work Plans for government facilities and prepared documents for NNSA NES site ORRs
- Designed and supervised safety programs for high-hazard projects (Level B/C PPE)
- 20 years experience in industrial hygiene and safety as a Bioenvironmental Engineer and Military Public Health Officer for US Air Force Contingency Hospitals in CA and NM
- Biosafety/Biosecurity support to DOE, DoD, US State Department, US Attorney's Office, and the FBI
- DOE "L" Clearance; DoD Secret Clearance

- He has worked at numerous military installations, civilian governmental facilities (e.g., Waste Isolation Pilot Plant (WIPP), LANL, Yucca Mountain Project (YMP), Nevada Test Site (NTS), Sandia National Laboratories (SNL), Rocky Flats Environmental Testing Site (RFETS), Rocky Mountain Arsenal (RMA), and Lawrence Livermore National Laboratory (LLNL), and various commercial petrochemical, semiconductor, and chemical processing facilities. As an OSHA-authorized Outreach Trainer, Mr. Hull, teaches health and safety to LATA employees and subcontractors in the areas of 29 CFR 1910, general industry, and 29 CFR 1926, construction. Classes cover all areas of these regulations, such as, personal protective equipment (PPE), control of hazardous energy, powered platforms, powered tools, and machinery and machine guarding. He is currently supporting DOE in construction of biosafety labs at LANL and LLNL.
- Health and Safety Coordinator for the Yucca Mountain Site Characterization Project (YMP), Nevada for six years ending in 1999. Responsible for supporting all LANL Technical Coordination Office (TCO) activities at the Yucca Mountain Project. This involved reviewing work packages and job-hazard analyses for all research conducted in the tunnel. While respiratory protection was a major issue (i.e., silica dust) other areas including lockout-tagout were major issues due to the potential for explosive atmospheres and special confined spaces. He conducted self-assessments and provided support on DOE-directed health and safety audits at the YMP Exploratory Studies Facility (ESF). He led a team to assess Health and Safety for LANL personnel and evaluated implementation of all safety-related DOE Orders or other applicable state, local, and federal regulations through LANL and YMP for all underground and field testing/drilling research.
- Technical Lead for several Authorization Basis assessments at NTS, LANL, and INEEL consisting of Basis for Interim Operations (BIOS) and Documented Safety Analysis (DSA) for several nuclear environmental sites (NES). Participated in several reviews of AB documents for the LANL BSL-3 and LLNL BSL-3 facilities.
- Technical lead for environment, safety, and health support activities on the LANL Site-Wide Environmental Impact Statement (SWEIS) Project. H&S liaison between the DOE Support Contractor and the respective subject matter experts within each LANL organization. The extensive YMP drilling operations necessitated the conduct of internal self-inspections and audits for LANL worker safety. Participated in DOE H&S audits and audit responses on LANL's behalf.
- Led a team to develop a Health and Safety assessment evaluating and comparing YMP and LANL implementation of DOE Orders and, where applicable, the corresponding OSHA regulatory drivers found in the US Code of Federal Regulations. Interacted with the DOE Office of Civilian Radioactive Waste Management on issues regarding proper implementation of DOE Orders and OSHA regulations. Performs field monitoring and industrial hygiene sample collection and analysis at the Low-Level Radioactive Waste Repository.
- Lead Bioenvironmental Engineer and consultant for the DOD in both operations and research and development activities, including industrial hygiene, radiation protection, and environmental protection programs. He was for many years chief of Bioenvironmental Engineering at two military bases where he established safety programs and conducted safety evaluations for operations as diverse as hydrazine refueling operations for military aircraft to non-destructive assay operations for critical weapons components. At these bases he managed H&S programs that covered all types of industrial operations including machine shops, transport and fighter aircraft maintenance operations (including painting with highly hazardous protective coatings), non-conventional weapons storage facilities, and various construction projects. Other areas that Mr. Hull was responsible for include the HAZMAT Pharmacy, Hazard Communications Programs, Emergency Response, and Military Public Health. As the section chief, Mr. Hull was responsible for risk communication to senior military personnel and training of workers in risks and risk mitigation.
- Developed and provided technical oversight of air, noise, and water pollution studies at various military installations. These studies involve the implementation of safety engineering, industrial

hygiene, and health physics programs of the Air Force Occupational Safety and Health Office and Installation Restoration Programs (equivalent to CERCLA). Performed air quality sampling for hazardous and radioactive constituents, asbestos surveys, and provided training to both active and reserve components in several fields. Assisted active duty personnel in writing numerous operating and QA instructions, base regulations, and in addressing ECAMP auditing discrepancies. Designed his former unit's HAZCOM program and provided the training on a quarterly basis.

Employment History

2005-present: (concurrent) LATA-Sharp Remediation Services (LSRS) LLC, Corporate Manager Environment, Safety & Health (ES&H), and Corporate Radiation Safety Officer

1992-present: LOS ALAMOS TECHNICAL ASSOCIATES (LATA), Corporate Manager ES&H, and Corporate Radiation Safety Officer

1986-1992: HARDING LAWSON ASSOCIATES, Senior Technical Associate; Managing Associate

1983-2006: (concurrent) U.S. AIR FORCE RESERVE, Bioenvironmental Engineer and Military Public Health Officer

1974-1986: U.S. GEOLOGICAL SURVEY, Water Resources Division, Hydrologist, Geochemist, and Research Scientist

1972-1976: FLORIDA STATE UNIVERSITY, Uranium-Thorium Radioisotope Research Laboratory, Research Assistant

1966-1970: *US AIR FORCE SECURITY SERVICE, INTELLIGENCE OPERATIONS ANALYST*

Education

Doctoral Studies, Environmental Engineering, Stanford University, 1984-1986

M.S., Environmental Engineering, Stanford University, 1982

M.S., Geochemistry and Environmental Geology, Florida State University, 1981

B.S., Geology, Florida State University, 1973

Selected Professional Development and Certifications

Environmental, Health and Safety Law Program, Institute for Applied Management and Law, 1995

Workshop on Emergency Planning and Community Right-To-Know, US EPA, 1997

Risk Management Training (40CFR68), US EPA, 1999

Chemical Safety Audit Training (165.19), US EPA, 1999

Radiation Safety at Superfund Sites, US EPA, 1998

Calculating and Understanding: Risk of Radionuclides Released to the Environment, RAC, 1997

Medical Effects of Nuclear Weapons, Defense Nuclear Agency, Armed Forces
Radiobiology Research Institute, 1991
Instructor Course: OSHA 501/503 Occupational Safety and Health Standards for General
Industry, OSHA Institute, current since 1999
Instructor Course: OSHA 500/502 Occupational Safety and Health Standards for
Construction Industry, OSHA Institute, current since 1999
Supervisor, Hazardous Waste Operations and Emergency Response, OSHA Institute,
1986-present
OSHA 2015 Hazardous Materials Course, OSHA Institute, 2005
OSHA 309A Electrical Standards, OSHA Institute, 1999
Explosives Ordnance Disposal (EOD) Orientation, US Army, Fort Ord, CA 1991
Registered Radiation Safety Compliance Officer, NREP, 1996 (#104)

Awards and Honors:

- *1992, AIR FORCE MERITORIOUS SERVICE MEDAL, Operation Desert Storm, Travis AFB, CA*
- *1996, AIR FORCE COMMENDATION MEDAL, for managing Radiological Surveillance/Control Teams for Broken Arrow Digit Pace II exercise, Kirtland AFB, NM*
- *1998, LANL ACHIEVEMENT AWARD from Laboratory Director John Browne, for LANL Site-Wide Environmental Impact Statement Support in performing Biological, Chemical, and Radiological Risk Analysis for LANL existing and proposed operations..*
- *1999, Manager, DOE Albuquerque Operations Office, R. E. Glass, In Recognition of Your Outstanding Commitment and Dedication in the Preparation of the Los Alamos National Laboratory Site-Wide Environmental Impact Statement.*
- *2000, LANL ACHIEVEMENT AWARD from LANL Environment Safety and Health (ESH) Division Director, Dennis J. Erickson, for Outstanding Research and Development as Recognized by the ESH Division Review Committee in April 2000 and for Improved ES&H Protection of the Public.*

John H. O'Brien, Electrical Engineering

WORK EXPERIENCE

Lawrence Livermore National Laboratory 1979 to Present - Plant Engineering Department:

Line Item Electrical Project Engineer responsible for generating electrical design criteria, and providing technical direction and design coordination with outside A/E firms and Laboratory operations departments, for projects including SKIF, EPSRU, MSTRP, and AVLIS.

Electrical Design Engineer responsible for planning and design of electrical utility installations, including system planning, and design of unit substations, medium voltage underground and overhead distribution systems, facility electrical power and related protection schemes, communication systems, and interior and street/area lighting.

1968 to 1979— Electronics Engineering Department:

Assistant Program Manager NSS Waste Management / Safeguards Program, providing general assistance to Program Leader in fiscal and contract matters, participating in developing policies, procedures, and in developing budget and establishing priorities for allocation of resources, fiscal data reports to monitor disbursement of budget, and facilitate interaction with Budget Office, DOE, and NRC and with outside contractors and consultants.

Field Test Systems Division (FTSD), Device Control and Communications System Group, Electronics Engineer responsible for conception, design, development and fielding of control systems for implementation of Nevada Automated Diagnostic System Network (NADNET).

FTSD, Diagnostic Systems Group, Electronics Engineer responsible for design and development of unique control and monitoring subsystems for diagnostic instrumentation of Nevada Automated Diagnostic System central facility (NADCEN); work on prototype system for remote monitoring of levels of atmospheric contaminants at Savannah River Laboratory nuclear reactor site for reporting via telephone link to L — Division data center in Livermore.

L — Division Analog Data Center, Project Engineer responsible for determining and applying criteria to the design of front-end computer systems for data acquisition and real-time control of physics experiments.

Computation Project Group, Electronics Engineer responsible for design and development of special-purpose system peripherals and related interfaces for enhancement of Octopus System.

SUBJECT MATTER EXPERTISE

Design and implementation of comprehensive electrical engineering systems.

EDUCATION/CERTIFICATION

1968 BS Electrical Engineering and Computer Science, University of California, Berkeley.

California Registrations as Professional Engineer:

1. Electrical Engineer
2. Control Systems Engineer

1979 MBA Business Management, Saint Mary's College, Moraga, California.

HONORS

University of California, College of Engineering, Honor Student
Pi Beta Pi National Engineering Honor Society
Elected to Eta Kappa Nu Electrical Engineering Honor Society

Terry Owens, Security

Terry Owens is the Manager for Safeguards and Security for the UC Office of the President, Laboratory Management Office. In this capacity, he is responsible for administering Safeguards and Security aspects of the University's contract with the U.S. Department of Energy (DOE) to manage and operate Lawrence Berkeley, Lawrence Livermore and Los Alamos National Laboratories. His duties include implementing a performance-based management methodology for the Safeguards and Security in concert with DOE.

Owens joined the Laboratory Management Office in Oct 1999 after completing a 30-year career in the U.S. Air Force. He served in a variety of positions with the Air Force Office of Special Investigations including overseas tours in Germany, Japan, the Philippines and Thailand. His specialized investigative experience included managing programs designed to protect technology and information systems from espionage. He also managed polygraph resources; oversaw programs dealing with personnel and executive protection. He kept senior Air Force commanders informed about the terrorist threat and he advised commanders on actions that they should consider implementing in order to enhance the security of Air Force personnel and resources.

Owens holds a bachelor's degree in political science from DePauw University, Greencastle, Indiana and a master's degree in business administration from Southern Illinois University, Edwardsville, IL.

Victoria Janine Salvo, Environmental/Waste Management/Regulatory Compliance

EDUCATION:

M.S. Environmental Management, University of San Francisco, 1997.

B.A. Biology, University of California at Santa Cruz, 1991.

Hazardous Materials Management, State of California Certification, through the University of California at Berkeley.

EXPERIENCE:

- Environmental Analyst in the Permits and Regulatory Affairs Group (PRAG) in the Environmental Protection Department (EPD) at LLNL, from 11/98 – present.
 - Manages the Site Treatment Plan (STP) and determines disposal options for low-level legacy wastes for the Radioactive and Hazardous Waste Management Division (RHWM).
 - Author of Document 36.1 entitled, “Hazardous, Radioactive, and Biological Waste Management Requirements” of LLNL’s ES&H Manual.
 - Prepares detailed hazardous waste management permit modifications, negotiates the best compliance solutions with regulators, and provides guidance to waste generators and TSDF operators to ensure compliance with environmental regulations and LLNL policies.
 - Laboratory contact and lead for regulatory agency inspections of medical waste generation and treatment areas, Hazardous Waste Management permitted facilities, and waste generator areas. Work includes security and escort arrangements, pre-inspections of program areas, and collection of documentation requested by the agencies.
 - LLNL Biosafety Operations Committee (LBOC) member responsible for the first-level review of projects consisting of microorganisms.
 - Reviewed and revised OSPs, FSPs, and IWSs pertaining to programmatic operations on ES&H Teams 2, 4, and 5.
 - Controller/evaluator for LLNL, county, and statewide emergency exercises. EPD OSC member.

- Developed and implemented a new pilot program in EPD for proper management of household batteries considered hazardous. Guidance will be provided site-wide once the pilot program has completed.

- Instructor for the following EPD courses:
 - EP0006/6R (Hazardous Waste Generation and Certification and Review Courses),
 - EP0053 (Waste Accumulation Area Operations Course), and

- Low-level radioactive waste certification (as part of a QA process for waste acceptance to NTS).
 - Developed the curriculum for a new course which addresses waste management and safety procedures for medical waste generators, Health and Safety Technicians responding to incidents involving blood or other potentially infectious materials, and HWM personnel who handle and transport waste containing potentially infectious materials prior to treatment or disposal. BBRP adopted the course as BR1001, “Working with Biological Materials”, which is now used as the mechanism to deliver pertinent biosafety and biological waste management information site-wide.

- Environmental Analyst in the Environmental Operations Group (EOG) in EPD at LLNL from 9/95 – 11/98. Overall responsibility drew heavily upon knowledge of applicable regulations and internal Lab policies to provide environmental compliance support necessary to assist LLNL Programs in meeting environmental compliance requirements.
 - Provided independent oversight of existing facilities on ES&H Teams 2 and 3, and addressed environmental impacts of proposed program operations. Utilized broad knowledge of environmental regulations to identify potential environmental problems with respect to hazardous waste, air, and water issues and worked with program personnel in maintaining environmental compliance.
 - Updated the Waste Accumulation Area (WAA) Contingency Plan for the main site and prepared the Contingency Plans for Consolidation WAAs.

- Environmental Analyst in the Chemical Tracking (ChemTrack) Group in the Environmental Protection Department at LLNL, full-time from 9/93 - 9/94; half-time from 9/94 - 4/95.
 - Led Supplemental Labor employees in completing a chemical inventory of facilities in several Laboratory Programs, coordinated inventory schedules with

directorates representatives, and selected chemicals to be tracked according to the SARA/Community Right-To-Know regulatory requirements.

- Authored Chemical Tracking Quality Assurance Field Procedures and led four chemical technicians' QA efforts. Duties also included analyses of QA results and generation of a final QA Project Report for Environmental Protection Department management personnel.
- Environmental Scientist in the Tank Assessments and Guidance Group (TAGG) in the Environmental Protection Department at LLNL , full-time from 2/93 - 9/93, and from 4/95 - 9/95. Environmental Analyst half-time from 9/94 - 4/95.
 - Prepared several tank Closure Plans and Reports under the Tank Upgrade Project (TUP). Work included interpretation of local, state, and federal regulatory requirements, analyses of soil and tank sampling results, and supervision of tank closure activities at construction sites.
 - Performed lab-wide risk assessment field surveys on transformers, sectionalizing switches, and generators for the Spill Prevention Control and Countermeasures (SPCC) Project.
- Additional pertinent EPD and BBRP experience has included:
 - Environmental Scientist in the Wastewater and Tank Systems (WATS) Group as the Documentation Coordinator for the Building Drain Investigation (BDI) Project from 2/92 through 2/93. Tracked all project documentation and completion status for dye testing all internal drain lines in 515 facilities, issued a detailed report on Dye Testing Procedures for each type of drain line investigated.
 - Environmental Technician in the WATS Group in the Environmental Protection Department at LLNL from 6/91 through 9/91. Work consisted of collecting storm drain and soil samples, and preparing samples for analyses offsite.
 - Laboratory Technician in the Biomedical Department at LLNL from 6/88 through 9/88, 6/89 through 9/89, and 6/90 through 9/90. The majority of this work consisted of immunological projects involving antigen/antibody assays.

**Dina Mary Sassone, Biosafety/Industrial Hygiene/Medical
CIH, CSP, SM (NRM), CBSP**

EXPERIENCE:

Industrial Hygiene Project Leader, Los Alamos National Laboratory 2001-present

Currently Project Leader for the Laboratory Industrial Hygiene and Safety Manual (LIHSM) Update Project. The LIHSM is based on and references current work smart standards (WSS) as defined in the University of California's (UC) contract with the DOE, current OSHA regulations, consensus standards, and general good work practices for health and safety program management. As the Project Leader, interact regularly with both operational and programmatic customers, have extensive knowledge of applicable requirements, regulations and consensus standards for industrial hygiene and industrial safety, and created a formal process for the peer review and publication of each manual chapter based on the HSR-5 Quality Management Plan. Manages the schedule and peer review of all the chapters. Drafts appropriate sections of chapters. Works with subject matter experts, deployed and divested industrial hygiene and safety personnel to ensure appropriateness of text. Worked with Health, Safety, and Radiation and other management to perform Management Self Assessments of operations in 2004, including management competence and integrated work management. Interact regularly with NNSA site and headquarters personnel, as well as biosafety and industrial hygiene peers at LBNL, LLNL, and UC campuses.

Biosafety Officer, Los Alamos National Laboratory 1998-present

As the LANL Biological Safety Officer, responsible for managing and ensuring the effectiveness of the LANL biosafety program, providing recommendations for biological safety and biotoxin safety for biological operations at LANL. Implemented the LANL Biosafety Program. Participating team member of the BSL-3 Team, including provision of biosafety requirements to the owning division and A/E firm, review of plans, specifications, and drawings, and creating necessary safety-related documents. Participating as a full voting member of the Institutional Biosafety Committee. Created biosafety and biosecurity documents as part of a UC National Laboratory team, and with NNSA/DOE headquarters personnel. Serves as the Responsible Official for the CDC Select Agent Transfer Program.

Industrial Hygiene Team Leader, Los Alamos National Laboratory 1998-2001

Lead and managed the Industrial Hygiene Team of the Environment, Health and Safety Division at Los Alamos National Laboratory, including planning, implementation, and development of industrial hygiene aspects of the following programs: beryllium, cafeteria inspections, carcinogens, confined space, ergonomics, hazard communication, health hazard assessment, hearing conservation, ventilation, indoor air quality, nonionizing radiation, occupational safety and health inspections, and reproductive

health hazards. Managed a team of up to 24 individuals, both deployed and centralized. Performed performance review of all team members, and provided salary and performance scale rating recommendations to Group Management. Interfaced with Facility Managers and ESH Team Leaders in providing service and support to organizations within LANL both for general support, and program-specific support.

Prior to appointment as Team Leader, worked with a team of safety and facility management professionals to create the Hazard Analysis and Control for Facility Work LIR, and helped ensure effective implementation and necessary changes through briefings Facility Management Personnel, as well as oversight via internal and DOE assessments. Worked with other national laboratories on Voluntary Protection Program (VPP) issues, helped create and track Appendix F performance measures for Industrial Hygiene and safety issues.

Office Health and Safety Manager 1992-1998, Foster Wheeler Environmental Corporation

Developed and reviewed numerous health and safety plans for hazardous waste operations and construction activities, performed inspections/audits of projects for clients including DOE, DOD, US and Fish and Wildlife Service, and performed industrial hygiene surveys for private industry. Appointed as Task Manager/Project Manager for health and safety projects at Los Alamos National Laboratory (LANL). Participated in the development of LANL safety and health requirements and programs. Assisted in several improvement and data gathering initiatives for the LANL chemical inventory database. Aided in the development and self-assessment of performance measures. Performed trend analysis of injury/illness data, inspection data, and management walkaround data. Evaluated occupational health and safety management systems, including those of the Occupational Health and Safety Administration, International Standards Organization, the American Industrial Hygiene Association, and the Chemical Manufacturers Association. Wrote programs and procedures for DOE and other clients, including several hospitals. Helped create numerous corporate health and safety programs and procedures for Foster Wheeler. Provided support to DOE Headquarters on HAZWOPER, and co-taught a hazardous material seminar for a federal agency.

Industrial Hygiene Program Administrator 1990 – 1992, EG&G, Rocky Flats Plant, Golden Colorado

Administered the respiratory protection program for a 6000-employee Department of Energy facility, compared quantitative fit-test methods, and evaluated DOE-approved supplied breathing air garment primarily used by HEPA filter test technicians. Functioned as the health and safety liaison officer for environmental restoration projects at Rocky Flats; drafted and approved health and safety plans, and audited/performed oversight of field activities.

Project Consultant 1989-1990, Occusafe, Inc.

Provided industrial hygiene and environmental services to various clients nationwide. Support included asbestos sampling and evaluation, chemical plants, and DOE contractor support.

Industrial Hygienist/Lead Industrial Hygienist 1985-1989, Army Environmental Hygiene Agency and Fitzsimmons Army Medical Center, Aurora, Colorado.

Performed numerous industrial hygiene surveys at Army and National Guard installations in a 23-state region; provided consultative assistance using accepted guidelines and standards; and coordination of industrial hygiene samples for the region with Army industrial hygiene laboratories. Surveys included several unique military operations. As lead Industrial hygienist: provided hygiene services to Army and National Guard Installations in an eight-state region; administered an industrial hygiene program at Fitzsimmons and Rocky Mountain Arsenal which included extensive bioaerosol sampling and evaluation of biological hazards; reviewed engineering plans and specifications for health and safety issues, created guidance for and taught classes in hearing conservation, respiratory protection, hazard communication, asbestos, lead, and other hazardous materials; identified occupational health and safety hazards, performed air and bulk sampling; and provided recommendations for health and safety control.

Industrial Hygienist/Assistant Toxicologist 1983-1985, Chematox Laboratory, Boulder, Colorado.

Conducted industrial hygiene surveys for clients in the Denver Metropolitan area; analyzed industrial hygiene and toxicology samples; and gave expert testimony on sampling and analysis performed.

EDUCATION:

B.S. Environmental Health, Colorado State University, 1982. (included several courses in microbiology, public health, and industrial hygiene)

M.S. Mineral Resource Ecology (Environmental Science), Colorado School of Mines, 1992.

Continuing Education: Courses in biological safety, bioaerosols, asbestos, construction, hazardous waste, ergonomics, risk management, PCBs, Federal Facilities Environmental Compliance, statistical analysis for industrial hygiene sampling and decision making, audits, confined space, respiratory protection, and ventilation. Completed the LANL Management Institute Spring 2002.

PROFESSIONAL AFFILIATIONS:

American Board of Industrial Hygiene (ABIH), Certified Industrial Hygienist (CIH)

Board of Certified Safety Professionals, Certified Safety Professional (CSP)

National Registry of Microbiologists, Specialist Microbiologist in Biological Safety Microbiology (SM (NRM))

American Biological Safety Association/Certified Biosafety Professional (CBSP)

American Industrial Hygiene Association (AIHA), Full member

Member of the AIHA Biosafety and Environmental Microbiology Committee (current secretary, chair in 2006)

AIHA Rio Grande Local Section

American Conference of Governmental Industrial Hygienists

SELECTED PUBLICATIONS/PRESENTATIONS:

"Risk Management", AIHA, Rocky Mountain Section, Technical Conference, 1993.

"Design and Implementation of Health and Safety Programs for Hazardous Waste Remediation Projects", American Industrial Hygiene Conference and Exposition, 1993.

"Environmental Monitoring Using a Real-Time Analytical Platform", 17th Annual Army Environmental R&D Symposium.

"Facility-Specific Implementation of an Institutional Health and Safety Program", American Industrial Hygiene Conference and Exposition, 1995.

"Chemical Safety Program", American Industrial Hygiene Conference and Exposition, 1996.

"Comparison of extremely low frequency (ELF) magnetic field personal exposure monitors"

McDevitt, J. J. (James J.) ; Brysse, P. N. (Patrick N.) ; Bowman, J. D. (J. David) ; Sassone, D. M. (Dina M.) ; LA-UR-01-952, Los Alamos National Laboratory

“Preliminary hazard analysis for the biosafety level 3 Laboratory (New Construction) at Los Alamos National Laboratory” Heindel, G. D. (George D.) ; Sassone, D. M. (Dina M.) ; Wilson, J. S. (Julie S.) LAUR 1337, Los Alamos National Laboratory, 2001

“Review and Assessment of new Biological Safety Level 3 (BSL-3) Laboratories American Industrial Hygiene Conference and Exposition”, 2004.

Active DOE "Q" clearance

STANISLAUS JOHN TUHOLSKI, STRUCTURAL ENGINEER

- Objective** To participate as an active member of the BSL-3 project design review team.
- Education**
- **University of California at Berkeley** Berkeley, CA
Master of Science in Structural Engineering Mechanics and Materials
05/07/95 GPA 3.46/4.0
 - **University of Notre Dame** South Bend, Indiana
Bachelor of Science, Civil Engineering with emphasis in Structures
05/12/94 GPA 3.1/4.0
- Honors** Deans List, Notre Dame Scholar, Eagle Scout
- Courses** Structural Dynamics, Steel Design, Concrete Design, Earthquake Resistant Design, Non-Linear Dynamics, Finite Element Methods, Advanced Mechanics of Materials
- Training**
- DOE/LLNL – Earned Value Management System Training 01/05
 - Explosion Effects Training – University of Missouri - Center for Explosion Resistant Design 02/05
- Skills**
- The ability to assimilate technical concepts and to develop them as solutions to practical problems.
 - Served as the principal peer reviewer of several large public works projects for the University of California.
 - Extensive seismic design and retrofit experience with the Uniform Building Code, International Building Code and DOE STD 1020 PC1 and PC2 criteria.
 - Experience using Drain-2DX, SAP2000, ETABS and FEAP to solve dynamics problems in the field of earthquake engineering.
- Activities** Volunteer Stroke and Turn Official for the Woodlands Swim Team - Walnut Creek, CA
- Experience**
- Structural Engineer/Design Manager** - Lawrence Livermore National Laboratory, Design and Construction Division, 10/04 to present.
- Energetic Materials Processing Center (25 million) – Served as design manager, responsible for the technical content of design documents for the state of the art explosive machining and assembly complex.
 - B332 – Vault Bracing Review – Principal structural peer reviewer

of seismic retrofit design completed by outside consultant to meet DOE – STD 1020 PC3 criteria.

Project Manager/Associate – Forell/Elsesser Structural Engineers, Inc., 6/95 to 10/04.

- Asian Art Museum of San Francisco Base Isolation Retrofit (120 million), Terascale Computing Facility (70 million) at LLNL and Building 321 ETCU Retrofit at LLNL (7 million) – Managed and directed structural design team including analysis, detailing and construction administration tasks completed by sub-consultants and staff. Interfaced with client and project team.
- Stanford SEQ (60 million) – Performed non-linear pushover and elastic dynamic analysis on (4) 3 story buildings including a laboratory and auditorium. Participated in construction administration.
- Composed numerous GSA and FBO seismic evaluation reports including the Social Security Administration Building in Huntington Park, US Mint in San Francisco, US Embassy Buildings in Asmara and Djibouti and US Courthouse in Reno.
- Managed FEMA 356 non-linear evaluation of Tolman Hall at University of California at Berkeley.
- Managed ASCE 31 Evaluations of (6) historic classroom buildings at Stanford University.
- Designed parts and portions of all major seismic systems, detailed tenant improvement components and mechanical anchorage systems.

**Security
Clearance**

“C” Clearance – “Q” Clearance currently in process

Licenses

California Registered Civil Engineer CE#57692
California Registered Structural Engineer SE#4630

Sky Tsan, Mechanical Engineer

RECENT LLNL EXPERIENCE:

Group Leader, Mech. & Elec. Design / D&C Division, Plant Engineering7/2006 to present

Responsible for managing the mechanical and electrical engineering design group. Provide leadership and technical guidance to the group to meet the goals of the division and the department. Forecast and adjust staffing level to meet work load requirements. Evaluate and coach performance of employees.

Group Leader, Mechanical Engineering / D&C Division, Plant Engineering12/2003 to 6/2006

Responsible for managing the mechanical engineering group. Provide leadership and technical guidance to the group to meet the goals of the division and the department. Forecast and adjust staffing level to meet work load requirements. Evaluate and coach performance of employees.

Facilities Engineering Manager / Nuclear Materials Technology Program (NMTP) 10/2002 to 12/2003

Responsible for managing the facility engineering team and facility upgrade projects for one Category 2 (B-332) and three Category 3 (B-239, B-331, and B-334) non-reactor nuclear facilities:

- Managed and supervised NMTP facility engineering team. Provided leadership to individual engineers and the team to meet facility requirements
- Managed facility modification projects. Developed and managed budgets, schedules, and resources
- Established and maintained qualifications of safety-critical equipment. Established work priorities according to their safety significance
- Identified options, and made recommendations and presentations for all necessary modifications to the facilities and approved the resulting proposed facility modifications
- Developed and maintained NMTP System Engineer Program in accordance with DOE O 420.1A, and integrated it into NMTP Work Control/Design Change Control Procedures.
- Responsible as subject matter expert on facility requirements for engineered designs of programmatic systems to be installed in NMTP facilities
- Ensured that all work on the facilities meets DOE standards, LLNL engineering practices, and any other applicable requirements and/or standards.

Facility Engineer, Conventional Facility / National Ignition Facility (NIF)7/2001 to 10/2002

Responsible for providing engineering supports for the proper operations and maintenance of this \$150M conventional facility of NIF Project:

- Developed and executed test plans and procedures to operate HVAC systems in schemes other than original design to determine the limits and tolerance of system performance, evaluate impact of equipment failure, and improve the reliability, maintainability, and availability of HVAC systems
- Expanded existing FLAIR (Failure Logging and Information Retrieval) system to incorporate and manage MEL (Master Equipment List), organize maintenance records, and track trouble reports
- Approved task codes of preventive maintenance work for equipment on MEL
- Interfaced with other Area Engineers and Area Integration Managers for environmental control issues
- Ensured that as-built documents and maintenance and operation manuals were complete, records of change orders were complete, and design basis and final calculations were recovered
- Developed a change control process for as-built documents with Plant Engineering and with NIF users
- Interfaced with NIF Information Technology Group to use SQL server to backup trending data recorded by HVAC control system and generate reports
- Managed trainings provided by manufacturers and vendors of equipment
- Developed bench marks for vibration levels to evaluate quality of maintenance work
- Prioritized deficiencies of design, construction, and operations, and informed NIF Site Manager of the required repairs/modifications and associated costs
- Provided budget inputs to NIF Site Manager.

Design Manager / Decontamination and Waste Treatment Facility (DWTF) 11/94 to 6/2001

Responsible for all aspects of the engineering and design work, from initial concept development to final project acceptance, of this \$63M, 78,000-sq.ft., Category 3 non-reactor nuclear facility:

- Managed scope, budget, and schedule of design for outside A/E firm and LLNL project team
- Interacted with outside A/E firm, LLNL project team and LLNL management
- Worked with clients to develop design criteria, reviewed and approved criteria changes
- Conducted formal design reviews at various design phases for each construction package
- Provided technical guidance during construction to meet design intent
- Conducted final acceptance tests for safety significant or critical equipment and systems
- Ensured that the design and construction meet DOE standards, LLNL policies and standards, building codes, industrial standards, and applicable federal/state/local regulations
- Worked with DOE representatives during audits and management reviews

- Worked with Permits and Regulatory Affairs Group/EPD to obtain RCRA Part B Permit from State of California to conduct waste treatment processes
- Provided assistance for preparation of safety analysis report and other safety-related documents
- Developed specifications and procured programmatic waste processing equipment.

Lead Mechanical Engineer / Decontamination and Waste Treatment Facility 11/93 to 6/2001

Responsible for the mechanical systems of the DWTF Project, including building mechanical systems, mechanical utilities, process off-gas and treatment system, contamination controls, and process piping for various gases and chemicals.

EDUCATION:

M.S. (major - architectural engineering, minor - mechanical engineering) 1978-1979
University of Texas at Austin

B.S. in architectural engineering 1970-1974
National Cheng-Kung University, Taiwan

REGISTRATION & CERTIFICATION:

Registered Mechanical Engineer in California
Certified Associated Testing, Adjusting, and Balancing (TAB) Engineer

RECENT TECHNICAL TRAININGS:

Direct Digital Controls for HVAC Systems Logic Controllers	Introduction to Programmable
HVAC System Commissioning	Unreviewed Safety Question (USQ)
Testing, Adjusting, and Balancing of HVAC Systems (Fundamental & Advanced)	

OTHER PROFESSIONAL EXPERIENCE:

Lead HVAC Engineer	(SAI Engineers, Santa Clara, California)	1988-1989
Chief Engineer	(Air Systems Inc., San Jose, California)	1987-1988
Project Mechanical Engineer	(Stetson-Harza, Utica, New York)	1985-1987
Project Mechanical Engineer	(Blum Engineers, Dallas, Texas)	1984-1985
Project Mechanical Engineer	(Friberg & Associates, Fort Worth, Texas)	1979-1984

Appendix D
MPR LLNL Contacts List

Abbreviation	Title	Individual Name
ALT BSO	Alternate Biosafety Officer	Leslie Hofher
1st ALT RO	Alternate Responsible Official (Select Agent), 1st	Leslie Hofher
2nd ALT RO	Alternate Responsible Official (Select Agent), 2nd	Allan Casamajor
3rd ALT RO	Alternate Responsible Official (Select Agent), 3rd	Al Jin
BIO DAD OP	BIO Deputy Associate Director for Operations	Sarah Wenning
BIO DAD PR	BIO Deputy Associate Director for Programs	Al Ramponi
BIO AD	BIO Directorate Associate Director	Elbert Branscomb
BIO ES&H	BIO ES&H Officer	Anselmo Dueñas
BIO TC	BIO Training Coordinator	Laura O'Brien
BSO	Biosafety Officer	Brynte Johnson
EP EEP	Emergency Programs, Exercises and Employee Preparedness	Susan Broadway
EP OI FDS	Emergency Programs, Overview and Integration, Facility Drill Specialist	John Richards
EPD PC	Environmental Protection Department Pretreatment Coordinator	Allen Grayson
HCD Team 2 EA	ES&H Team 2, Environmental Analyst	Roneet Levy
HCD Team 2 FPE	ES&H Team 2, Fire Protection Engineer	Mike Jones
FPOC	Facility Point of Contact	Frank Baily/Patsy Gilbert
RHWM	Hazardous Waste Management Technician	Shelly Leasure
HCD AB	Hazards Control Department - Safety Analyst/Authorization Basis Section	Son Nguyen
HCD AB SL	Hazards Control Department -Authorization Basis Section Leader	Tom Altenbach
FC	Hazards Control Emergency Management, Fire Captain	Michael McLaughlin
HCD Team 2	Hazards Control Team 2, ES&H Technician	Todd Cobble
HCD Team 2	Hazards Control Team 2, Industrial Hygienist	Christine Little
HSD	Health Services Department - Occupational & Environmental Medicine	William Pereira, M.D., MPH
IBC Co-Chair	Institutional Biosafety Committee Co-Chair	Patsy Gilbert
LBOC Chair	Laboratory Biosafety Operations Committee Chairman	Patsy Gilbert
Lab Workers	Laboratory Workers	Brent Ricks, Gilda Vanier
B368 CM	LLNL Plant Engineering, Design & Construction Division, B368 Construction Manager	Dean Yoshida
MDD BS	Material Distribution Division Business Services	Kimberly Dremalas
MDD OM	Material Distribution Division Operations Manager	Kory Porter
MDD TL	Material Distribution Division Team Leader Shipping and Distribution	Dave Shepard
MDD TSM	Material Distribution Division Traffic and Shipping Manager	Bob Garrett

NEPA Rep.	NEPA Program Representative	Amit Basu
NHI AADA	NHI Assistant Associate Director for Assurances	David Counts
NHI AD	NHI Associate Director	Ray Juzaitis
NHI ADFM	NHI Associate Director Facility Manager	Jeff Johnson
NHI APL-SA	NHI Associate Program Leader for Select Agent Science	Eric Gard
NHI BSL-3 FPM	NHI BSL-3 Facility Program Manager	Bruce McDowell
NHI DAD OP	NHI Deputy Associate Director for Operations	Dan Knight
PTS DA	Physical and Technical Security Design Associate	
PI	Principal Investigators	Mary McBride, various others
RI	Responsible Individual	various
RO	Responsible Official (Select Agent)	Brynte Johnson
RRP	Room Responsible Person (ABSL3)	Marilyn Ramsey
SPR	Security Program Representative	Michel Dahlstrom
SAAI	Select Agent Authorizing Individual	Paul Jackson
SAFM	Select Agent Facility Manager	Patsy Gilbert
SAM	Select Agent Manager (Select Agent Center)	Monica Borucki
Steris Rep.	Steris Corporation, VHP Process Engineer	Claire Fritz
TMA Member	Threat Mitigation Analysis Group Member	