KSU's Operating Assurance Model for Safety and Research Quality

TRADELINE; 2012 International Conference on Biocontainment Facilities

Scott Rusk
Kansas State University
Biosecurity Research Institute

May 14, 2012

KANSAS STATE UNIVERSITY

BRI Biosecurity Research Institute

Kansas State University's Biosecurity Research Institute (BRI)

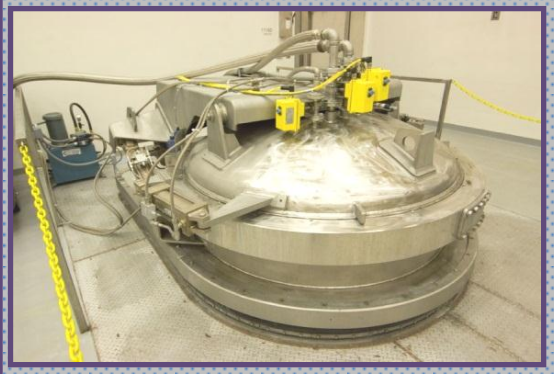
Leading through research and education to protect agriculture and the public from biological threats.

Biosecurity Research Institute Overview

- Enhanced BSL-3 laboratories, insectary and vivarium
- BSL-3Ag domestic livestock holding
- Training and education facilities
- Enhanced BSL-3 food processing

Biosecurity Research Institute Overview

- Supporting infrastructure
  - On-site high pressure steam generation (36Mbtu)
  - On-site waste treatment (12,000g liquid / 5000lb digester)
  - Redundant electrical
  - Stand-by generator (2000kw)
  - On-site chillers (130T each)
  - Zoned redundant HVAC systems



State-of-the-Art BSL-3 and BSL-3Ag Labs

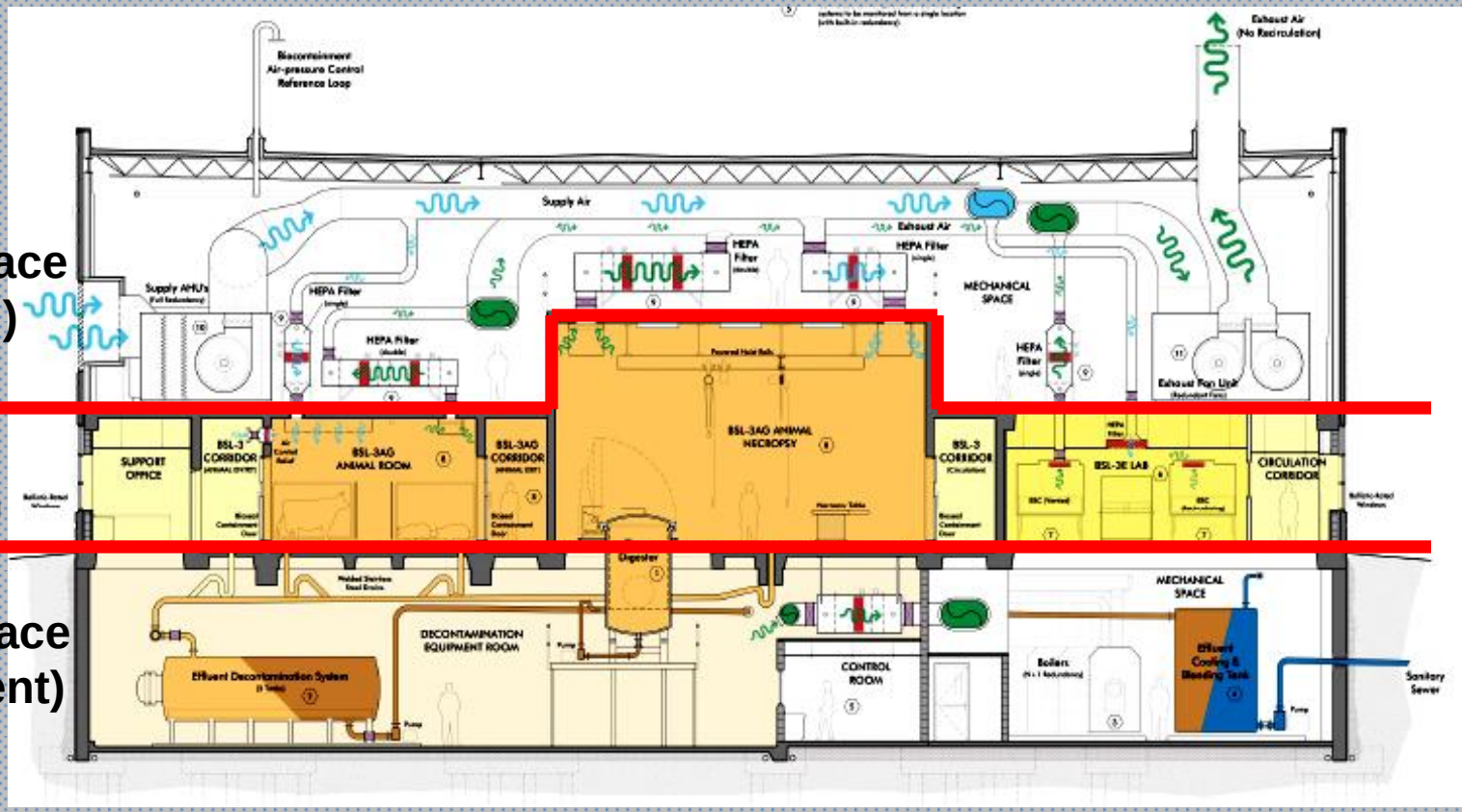
113,000 ft^2 Facility

41,000 ft^2 Research & Education Space

Mechanical space (air handling)

Laboratory & Administration

Mechanical space (waste treatment)



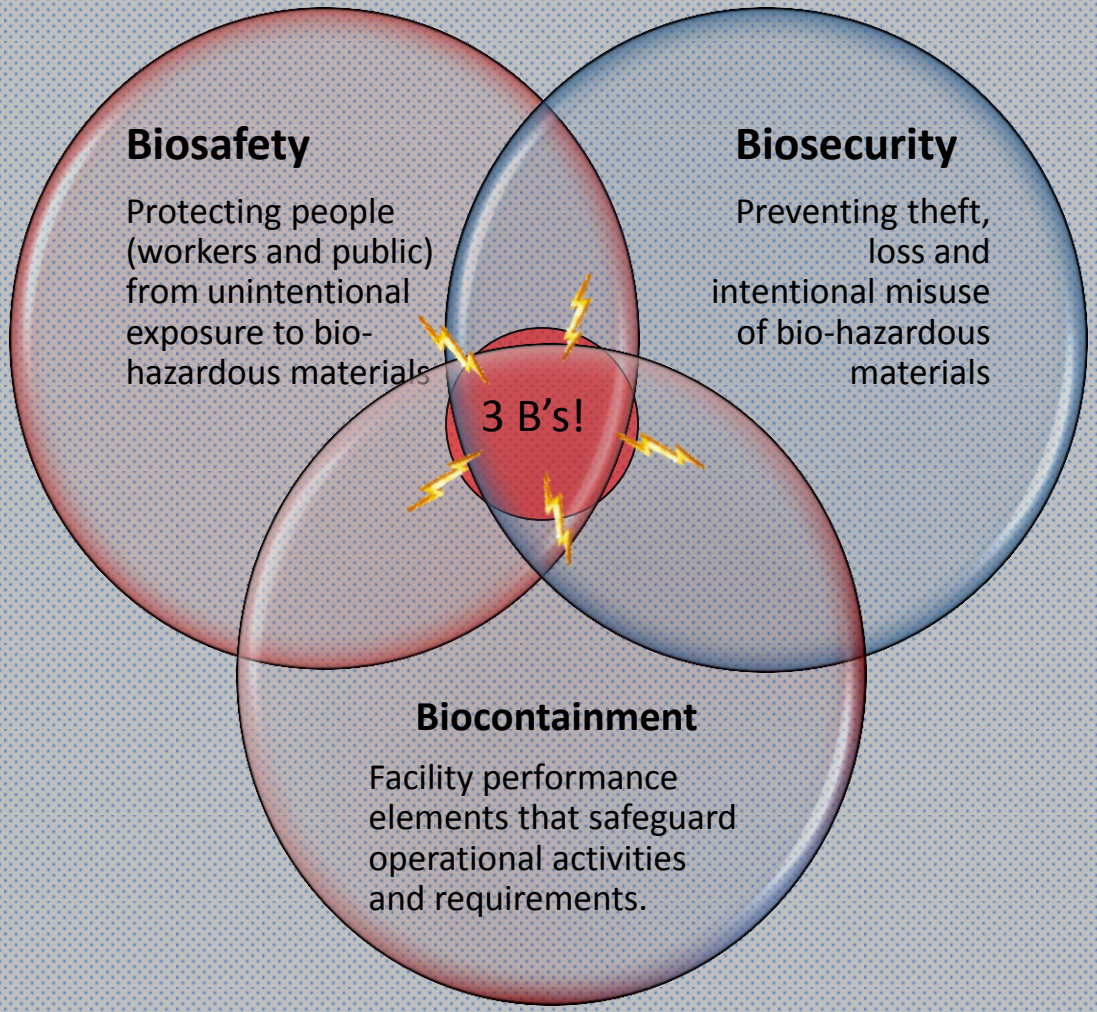
Operating Assurance Model for Safety and Research Quality

Basis:

Biocontainment operations management is complex.

- Coordination of procedures and protocols for day-to-day repairs (predictive, preventive and responsive maintenance approaches) and requirements for facility systems performance monitoring and verification must all work in tandem with achieving compliance requirements of biosafety, biosecurity and biocontainment.
- Management approaches require extensive communication and operating procedures within, and among, all levels of operational program responsibilities in order to realize goals of safety and research quality.

Integration



Biosafety, Biosecurity and Biocontainment Integration

Why?

The Organization's;

- Commitment to Quality
- Mission and Policy Statement
- Research Goals and Objectives

Managing Risk
- Human error
- Injury/illness
- Delays
- Loss of confidence
- Cost controls

Bottom line answers:

- Chance of success increases!
- It is the right thing to do.

Biosafety, Biosecurity and Biocontainment Integration

Who Cares??

Expectations of safe and successful biocontainment operations by:

- Employees
- Community
- Researchers
- Funding Sources
- Owners/Administrators
- State & Federal Agencies

Biosafety, Biosecurity and Biocontainment Integration

Who to include?

- Researchers
- Repair mechanics
- Laboratory support
- Office Staff
- Security
- Biosafety
- Engineers
- Building controls specialists
- Animal care
- Computing support
- Your boss and their boss!!

What to include?

- Policy
- Communications
- Procedures & Protocols
- Infrastructure
- Compliance coordination
- Research schedules
- Performance documentation

How to: Integration

Make a commitment.

- Mission and policy based.

Educate *"senior level"* and facility staff.

- Benchmark facilities and regulatory compliance advantages

Develop a plan.

- Objectives, scope, goals.

Utilize resources and existing information.

- Baseline facility performance data
- Centralized Maintenance Management System
- Design and engineering records
- Preventive Maintenance Plans/Manuals
- TRAINING

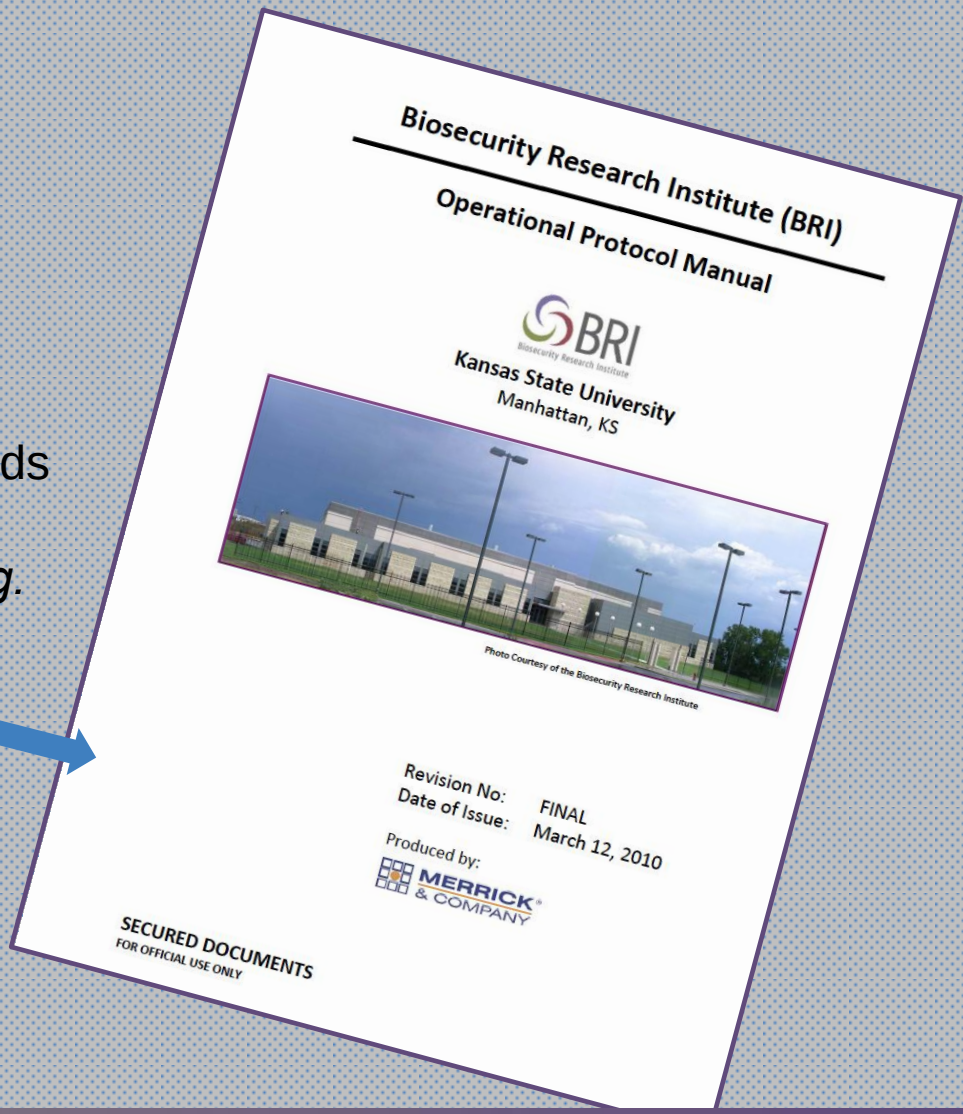
How to: Integration

Implement a program.

- Forced communications.
  - Signatory authorities
- Condition of performance standards
- Key in on critical elements.
  - *"What if" can be never ending.*

Create the Tool

- Operational Protocol Manual



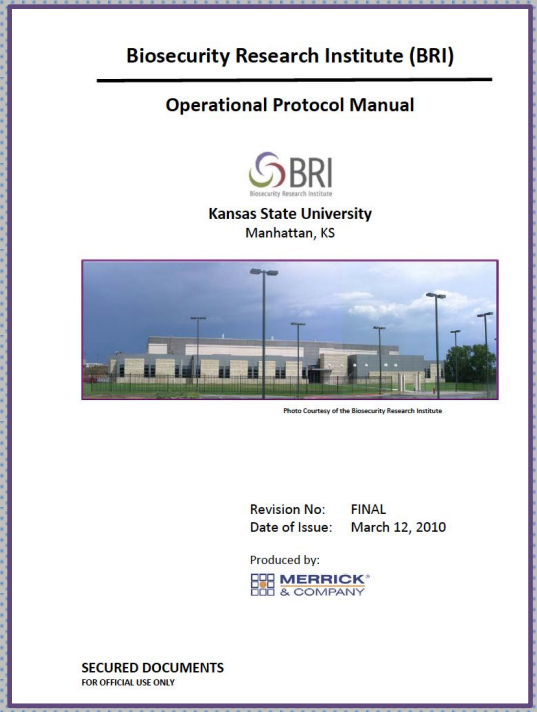
Operational Protocol Manual

Objective:

- Ensure safe, secure, and functional facilities that support and promote the science and education mission

Goals:

- Continuous facility operations with minimal unscheduled shutdowns
- Scheduled shutdowns minimally impact science programs
- Manage facility operational procedures in a manner that prevents hazardous exposures to people or environment.
- Meet or exceed facility baseline biocontainment performance criteria.



Biosecurity Research Institute (BRI)

Operational Protocol Manual

BRI
Biosecurity Research Institute

Kansas State University
Manhattan, KS

Photo Courtesy of the Biosecurity Research Institute

Revision No: FINAL
Date of Issue: March 12, 2010

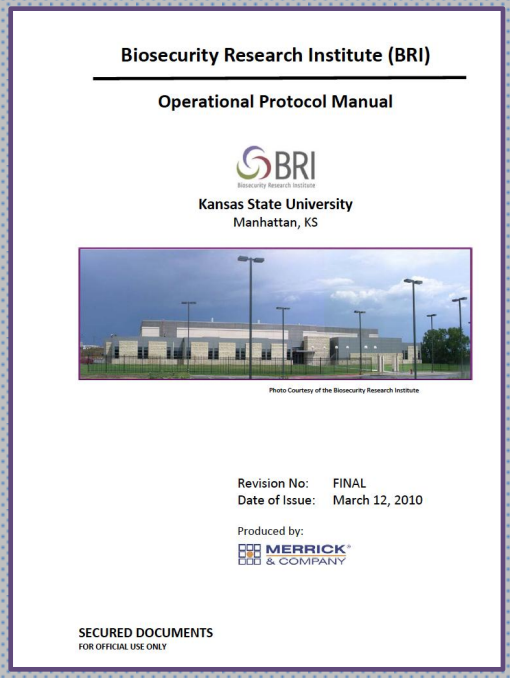
Produced by:
MERRICK & COMPANY

SECURED DOCUMENTS
FOR OFFICIAL USE ONLY

Operational Protocol Manual

Content:

- Facility description (general and specific)
- Descriptions of key biocontainment systems
- Roles and responsibilities (management, line supervision and workers organization chart)
- Documentation / Reference materials
  - Policies
  - Procedures
  - Task Instructions
  - Maintenance Records
  - Location of Reference Documents
  - Equipment Manuals
  - Approval and Permits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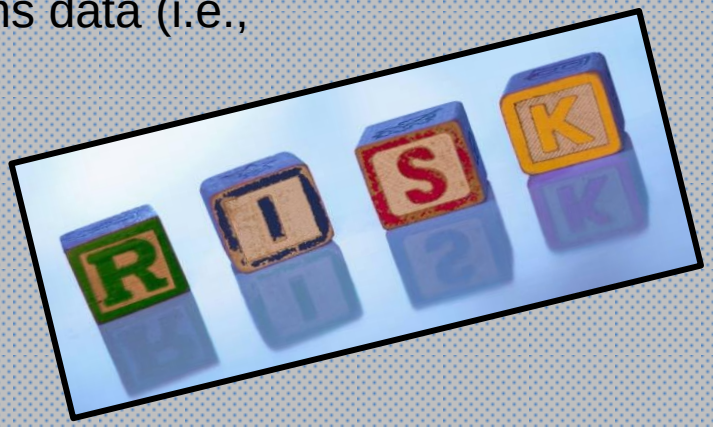
Operational Protocol Manual

Determinations of key systems / equipment to include:

Operations work activity impact

- Integrity of biocontainment capacity/capability (i.e., expected performance)
- Contamination assessment (i.e., risk of exposure)
- Communication levels (i.e., who needs to know?)
- Updating changes in facility operations data (i.e., altering baseline information)
- Annual performance documentation.



Operational Protocol Manual

Linkage to work request, work order tracking system = CMMS

Standard Operating Procedures

- Scheduled Activity
- Unscheduled Activity

"Permit for Containment Work" concept

Specific Task Instructions

- Equipment or system
  - Shutdown/isolation
  - Decontamination
  - Preventive Maintenance
  - Testing

Operations Task Instructions

BIOSECURITY RESEARCH INSTITUTE	
Task Instruction Name: Air Handling Unit (AHU-A-01 / AHU-A-02) Shutdown & Isolation	
Document Number: SI-HVAC-02	**Effective Date:** TBD
Approved By:	**Date Last Revised:** 03/12/2010

Purpose and Scope: The purpose of this task is to shut down and isolate one of two Air Handling Units (AHU-A-01 / AHU-A-02) serving the BSL-3Ag spaces in Area A for maintenance, testing, and inspection purposes.

Responsible Parties: FE/BSO/Maintenance

Schedule: As needed per preventative or corrective maintenance requirements.

Lab Operation Impact: MEDIUM – AHU's serving Area A are completely redundant but redundancy is lost during shutdown

Equipment and Supplies Required: Lockout/Tagout equipment; necessary tools and supplies to perform work activities (i.e. motor inspection, etc)

Instructions

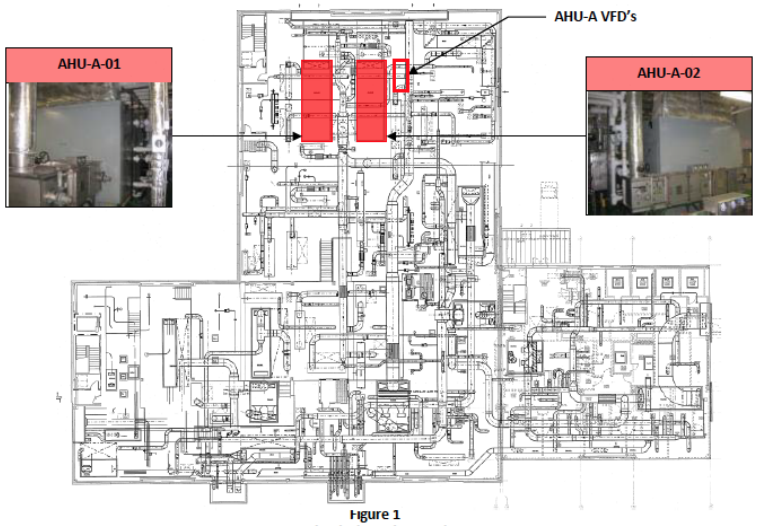


Figure 1
Mechanical Penthouse Plan

BIOSECURITY RESEARCH INSTITUTE	
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Document Number: SI-HVAC-02	**Effective Date:** TBD
Approved By:	**Date Last Revised:** 03/12/2010

Resp.	Task
Originator	1) Identify the HVAC issue to be addressed. Communicate with the Facility Engineer (FE) to initiate the **Work Order**.
FE	2) Coordinate with the BSO on the work to be performed and the anticipated impact. Initiate the **Biosafety Level 3/3Ag Maintenance Work Request Form** and forward to BSO, along with Work Order, for approval.
BSO	3) Coordinate with FE and confirm in writing that the scientific program is notified and that the area, site, and equipment are in a safe condition for Maintenance to perform the Work Order. Submit signed **Biosafety Level 3/3Ag Maintenance Work Request form** (Prior Approvals section).
FE	4) FE will provide to Maintenance the **Work Order** and the signed **Biosafety Level 3/3Ag Maintenance Work Request form** confirming that the work can be performed.
Maintenance	5) Shutdown designated AHU (AHU-A-01 or AHU-A-02) a) From BMS workstation, access the AHU-A-01/AHU-A-02 graphic (Figure 2) and right-click the SF-1 Varicone Control object (**SF1-VC**); Select **Commands, Operator Override**, and reduce **Value** by 10%; allow system to stabilize for 1 minute and repeat until **Value** = 0% b) Right-click the System Enable object (**SYST-ENA1** or **SYST-ENA2**) and select **Commands, Operator Override** and change **Value** to **Disable**, click **Send** (Figure 3) c) Verify system recovers and stabilizes and that all rooms remain operational and maintain desired dP
Maintenance	6) Isolate the designated AHU a) Proceed to associated VFD and place disconnect switch into OFF position. b) Move Hand-Off-Auto (HOA) switch to the OFF position c) Perform Lock-out / Tag-out procedures according to facility SOPs d) Close steam, chilled water, hot water isolation valves at AHU-P as necessary to perform work.
Maintenance	7) Perform **Work Order**
FE / Maintenance	8) Place AHU back in service a) At associated VFD, switch disconnect to ON position b) Switch HOA switch to AUTO c) Reopen any isolation valves that were closed during isolation
Maintenance	9) Restart AHU-A-01/AHU-A-02 a) From BMS workstation, access AHU-A-01/AHU-A-02 graphic and right-click the System Enable object (SYST-ENA1 or SYST-ENA2); select Commands, Release Operator Override, and "Send" b) Right click SF-1 Varicone Control (SF1-VC) and select Commands, Operator Override, and increase value by 10%; allow system to stabilize for 1 minute and repeat until Value = 100% c) Verify system recovers and stabilizes and that all rooms remain operational and maintain desired dP
Maintenance	10) Document to the FE in writing that the work has been completed and provide signed **Biosafety Level 3/3Ag Maintenance Work Request form** (Verification section).
FE	11) FE will verify that the maintenance/repair work has been completed and systems sufficiently tested prior to placing system back in service. FE will notify BSO in writing

Operations Task Instructions

BIOSECURITY RESEARCH INSTITUTE	
Task Instruction Name: Air Handling Unit (AHU-A-01 / AHU-A-02) Shutdown & Isolation	
Document Number: SI-HVAC-02	**Effective Date:** TBD
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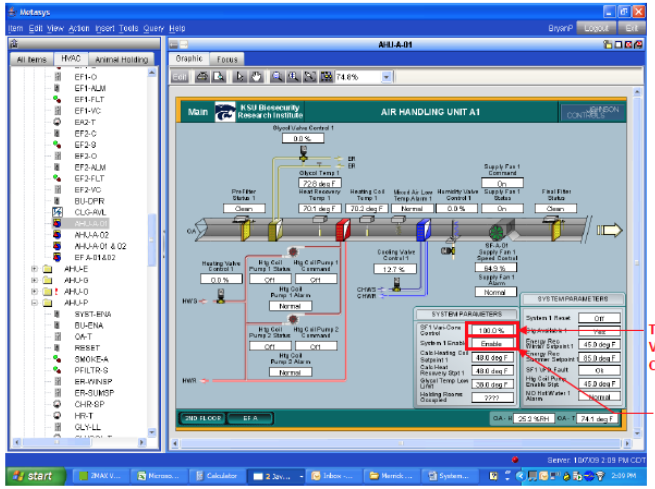


Figure 2
BMS graphic AHU-A-01 (AHU-A-02 is similar)

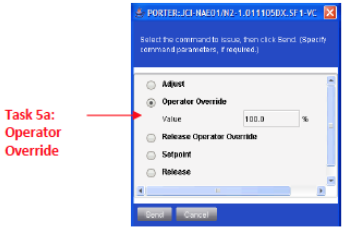


Figure 3
BMS Command Window

BIOSECURITY RESEARCH INSTITUTE	
Task Instruction Name: Air Handling Unit (AHU-A-01 / AHU-A-02) Shutdown & Isolation	
Document Number: SI-HVAC-02	**Effective Date:** TBD
Approved By:	**Date Last Revised:** 03/12/2010

Figure 4
AHU-A-01 & AHU-A-02 VFDs

BIOSECURITY RESEARCH INSTITUTE			
Task Instruction Name: Air Handling Unit (AHU-A-01 / AHU-A-02) Shutdown & Isolation			
Document Number: SI-HVAC-02		**Effective Date:** TBD	
Approved By:		**Date Last Revised:** 03/12/2010	

Comments/Notes			
FE	**Completed By:**	**Signature:**	**Date:**

Comments/Notes			
BSO	**Completed By:**	**Signature:**	**Date:**

Operations Task Instructions

BIOSECURITY RESEARCH INSTITUTE	
Task Instruction Name: Typical HEPA Filter Housing Isolation (Supply & Exhaust)	
Document Number: SI-HEPA-01	**Effective Date:** TBD
Approved By:	**Date Last Revised:** 03/12/2010

Purpose and Scope: The purpose of this task is to shut down and isolate an individual HEPA filter (Supply or Exhaust) unit serving a space within containment for maintenance, testing and inspection purposes	
Responsible Parties: Facility Engineer (FE)/ Biosafety Officer (BSO)/Maintenance	
Schedule: As needed per preventative or corrective maintenance requirements.	**Lab Operation Impact:** HIGH – associated space will be shut down and isolated
Equipment and Supplies Required: Lockout/Tagout equipment; necessary tools and supplies to perform work activities (i.e. motor inspection, etc)	

Instructions

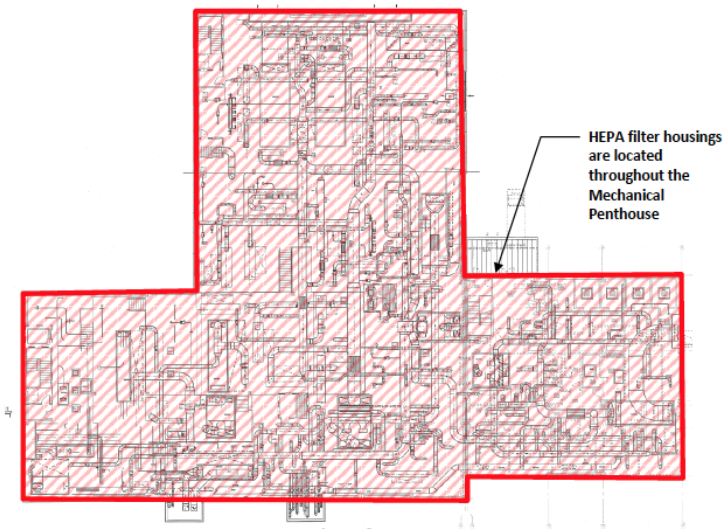


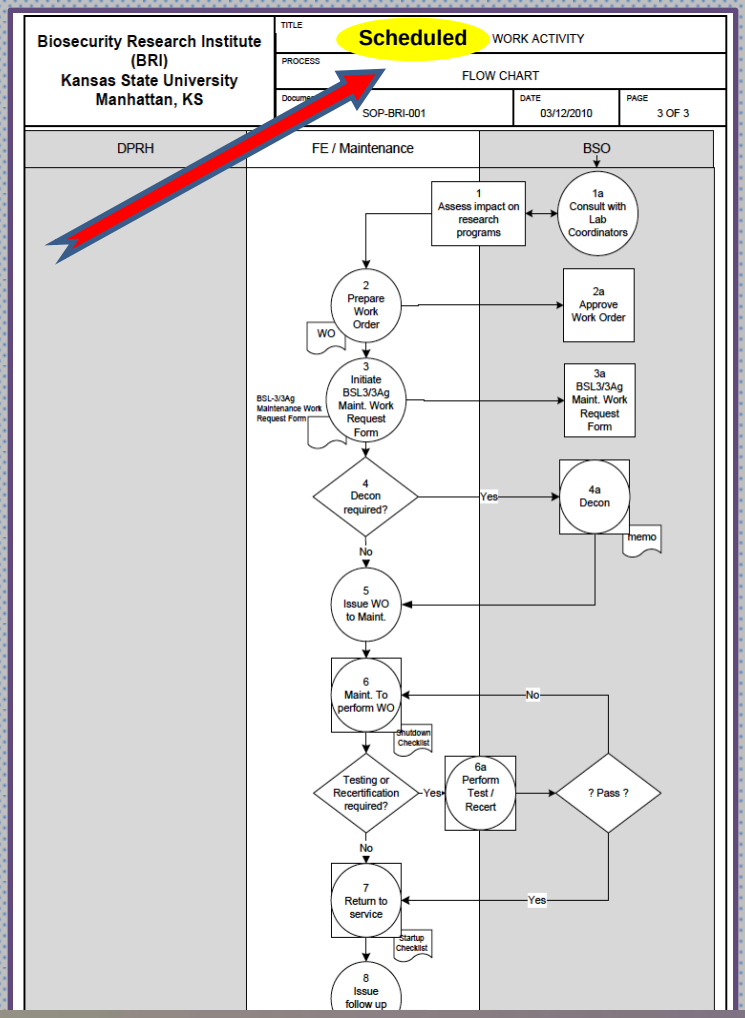
Figure 1
Mechanical Penthouse Plan

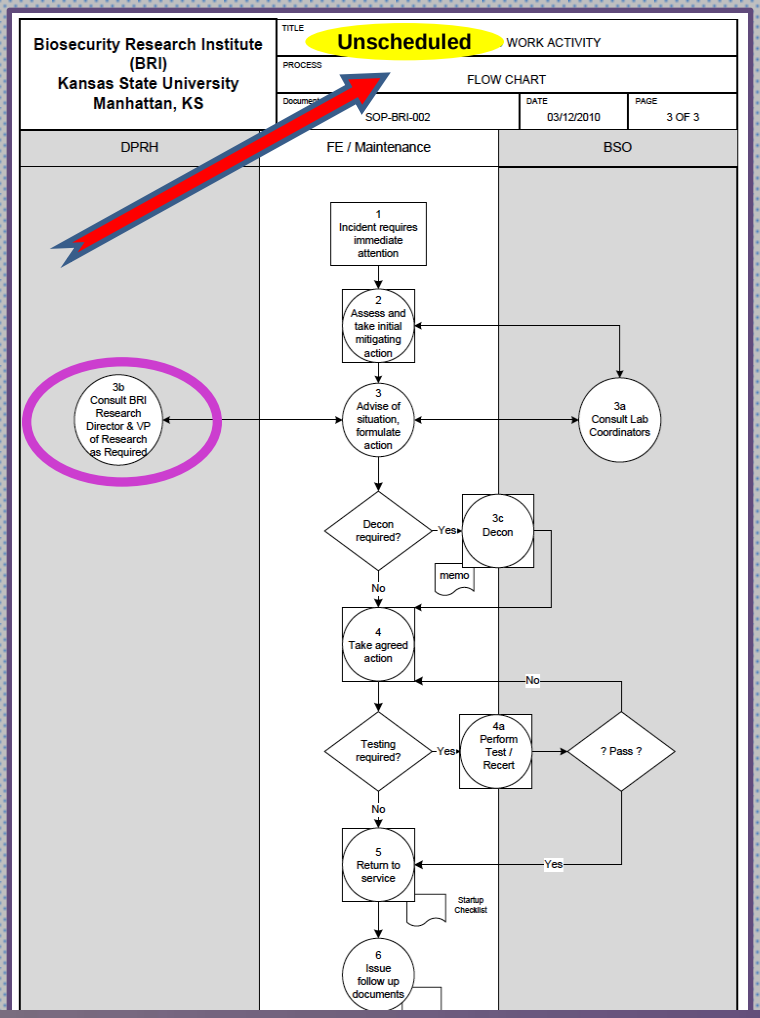
BIOSECURITY RESEARCH INSTITUTE	
Task Instruction Name: Typical HEPA Filter Housing Isolation (Supply & Exhaust)	
Document Number: SI-HEPA-01	**Effective Date:** TBD
Approved By:	**Date Last Revised:** 03/12/2010

Figure 5
Typical 2-stage Horizontal (Exhaust) HEPA Filter Housing

Figure 6
Typical Single Stage Vertical (Supply) HEPA Filter Housing

Communications and Flow Charts

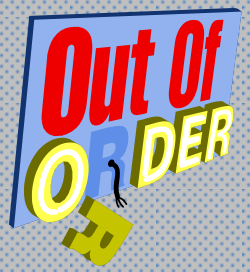


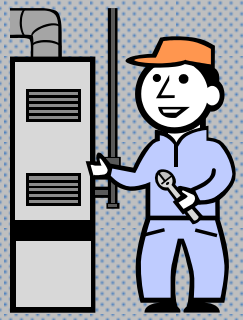


Work Order

Examples:

- Annual performance verification
- HEPA Filter Certification
- Plumbing Repairs
- Waste Treatment System repairs
- Boiler servicing
- DI water system maintenance
- Preventive maintenance programs
- Lights out
- Surfaces and coatings repair





DM Active Work Order Form 7/26/2011

Work Order No. 20110726014 Job No.
Symptom REMOVE BSC AND MODIFIY CONTROLS--SYSTEM REVALIDATION

Requested By BRYAN PHILLIPS
Request No.
Priority
Work Type
Shift
Cost Center
Maintenance Code

Date Issued 7/26/2011
Date Required 7/26/2011
Date Started 7/26/2011
Actual Downtime
Date Completed / /
Time Completed

Equipment No. Equipment Name Location

Employee No. Employee Name Labor Code Est. Hours Actual DM Hours

Part No. Part Name Qty Allocated Qty. Pulled

Task No. Description Labor Code

Description

WO Desc.

1. CHECK AND REPAIR ALL SURFACE FINISHIES AS NEEDED. THIS INCLUDES CAULKING, PAINTING OF WALL AND FLOORS.

2. RELAMP AS NEEDED.

3. CHECK AND ADJUST DOOR CLOSURES AS NEEDED. DO THIS TASK AFTER THE HVAC HAS BEEN R TO NORMAL. COMMUNICATE WITH BRYAN.

4. VERIFIY DOOR INTERLOCK OPERATIONS.

5. CHECK OPS OF THE FIRE ALARM HORNS AND STROBES.

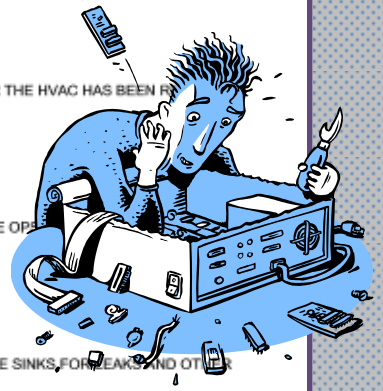
6. PERFORM THE AREA AND ROOM FUNCTION TESTS AS DESCRIBED IN THE OP FOR HISTORY ARCHIVE.

7. DETERMIN IF THE ROOM PREFILTERS NEED TO BE REPLACED.

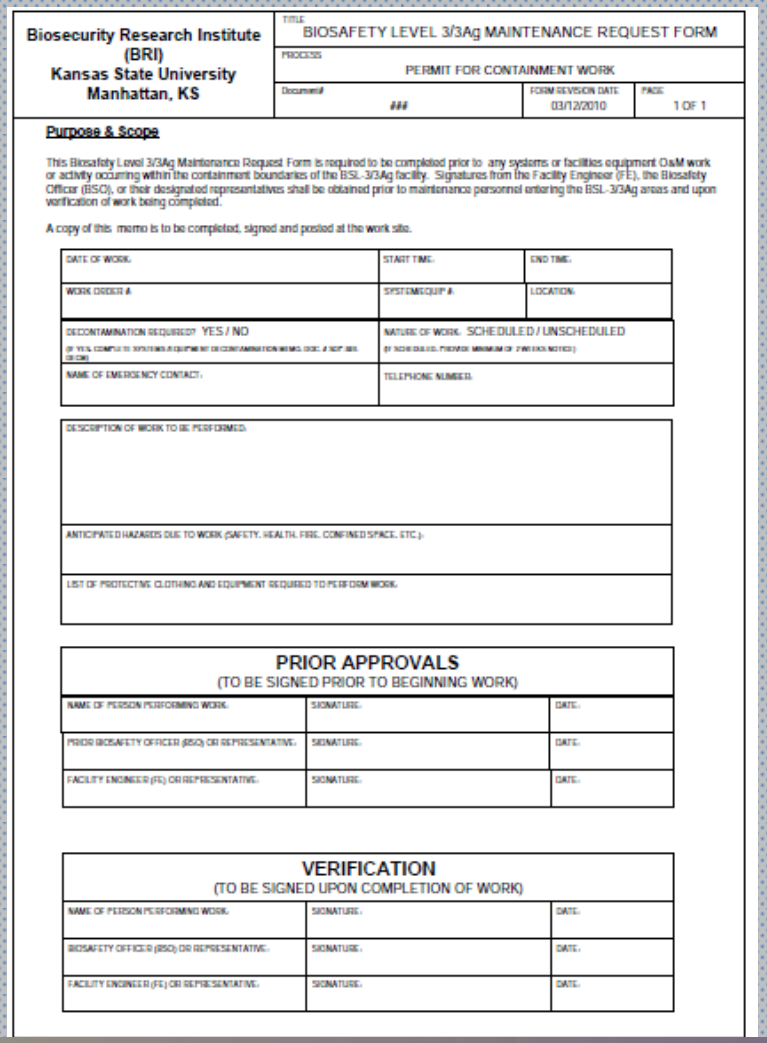
8. CLEAN AND ADJUST THE SHOWER MIXING VALVES. WHEN APPLICABLE.

NSPECT ALL FAUCETS FOR DRIPS. REPAIR AS NEEDED. LOOK UNDER THE SINKS FOR LEAKS AND OTHER ISSUES. (INSECTS, CORROSION ECT..)

USERDMA.RPT Page 1 of 1



Permit for Containment Work



Biosecurity Research Institute (BRI)
Kansas State University
Manhattan, KS

TITLE: BIOSAFETY LEVEL 3/3Ag MAINTENANCE REQUEST FORM

PROCESS: PERMIT FOR CONTAINMENT WORK

Document#	FORM REVISION DATE	PAGE
###	03/12/2010	1 OF 1

Purpose & Scope

This Biosafety Level 3/3Ag Maintenance Request Form is required to be completed prior to any systems or facilities equipment O&M work or activity occurring within the containment boundaries of the BSL-3/3Ag facility. Signatures from the Facility Engineer (FE), the Biosafety Officer (BSO), or their designated representatives shall be obtained prior to maintenance personnel entering the BSL-3/3Ag areas and upon verification of work being completed.

A copy of this memo is to be completed, signed and posted at the work site.

DATE OF WORK:	START TIME:	END TIME:
WORK ORDER #:	SYSTEM/EQUIP #:	LOCATION:
DECONTAMINATION REQUIRED? YES / NO (IF YES, COMPLETE SYSTEMS & EQUIPMENT DECONTAMINATION MEMO, DOC. # XXX-XXX-XX-XX-XXX)	NATURE OF WORK: SCHEDULED / UNSCHEDULED (IF SCHEDULED, PROVIDE MINIMUM OF TWO (XX) NOTICE)	
NAME OF EMERGENCY CONTACT:	TELEPHONE NUMBER:	

DESCRIPTION OF WORK TO BE PERFORMED:

ANTICIPATED HAZARDS DUE TO WORK (SAFETY, HEALTH, FIRE, CONFINED SPACE, ETC.):

LIST OF PROTECTIVE CLOTHING AND EQUIPMENT REQUIRED TO PERFORM WORK:

PRIOR APPROVALS
(TO BE SIGNED PRIOR TO BEGINNING WORK)

NAME OF PERSON PERFORMING WORK:	SIGNATURE:	DATE:
PRIOR BIOSAFETY OFFICER (BSO) OR REPRESENTATIVE:	SIGNATURE:	DATE:
FACILITY ENGINEER (FE) OR REPRESENTATIVE:	SIGNATURE:	DATE:

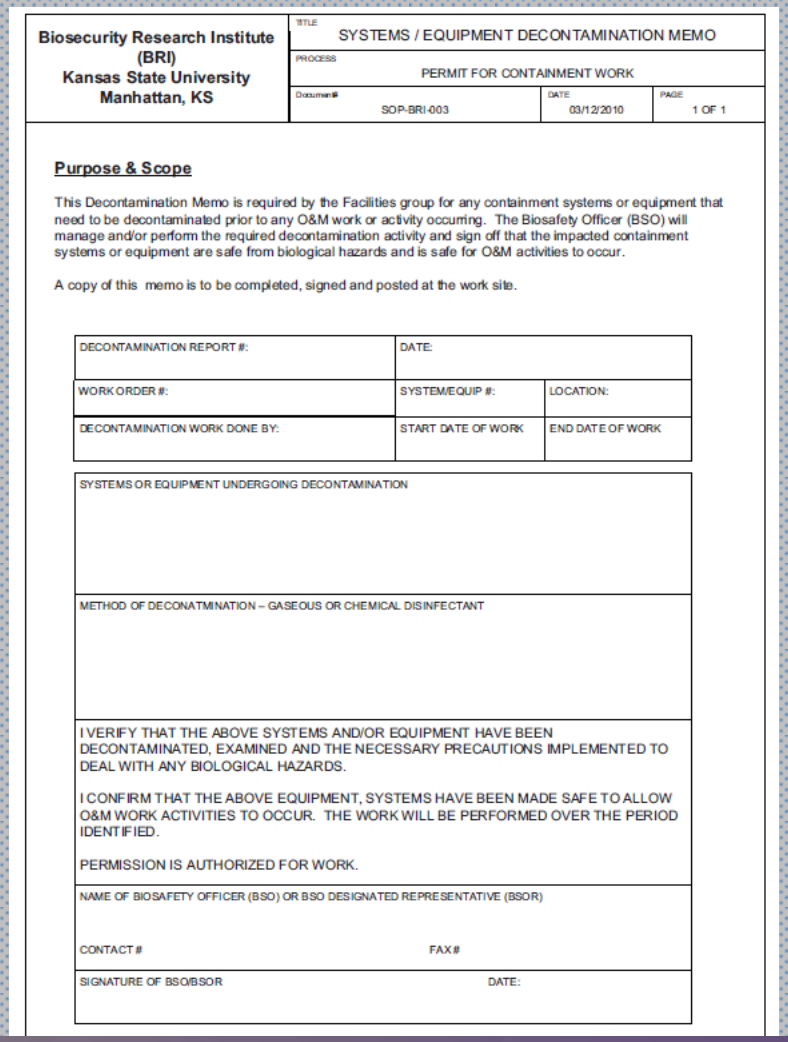
VERIFICATION
(TO BE SIGNED UPON COMPLETION OF WORK)

NAME OF PERSON PERFORMING WORK:	SIGNATURE:	DATE:
BIOSAFETY OFFICER (BSO) OR REPRESENTATIVE:	SIGNATURE:	DATE:
FACILITY ENGINEER (FE) OR REPRESENTATIVE:	SIGNATURE:	DATE:

- Used for any O&M work/activity within biocontainment boundary
- Also used for any O&M work on biocontainment support systems
- Describes decontamination Requirements (Y/N)
- Describes the approved work to be performed
- Describes anticipated hazards
- Describes PPE requirements
- Signatures/approval required prior to beginning the work

Decontamination Memo

- Requested by facility operations group
  - Process is linked to work request and work order system
- Describes equipment or areas in the room that were decontaminated
- Describes method of decontamination
- Verification of successful decontamination by signature



Biosecurity Research Institute (BRI)
Kansas State University
Manhattan, KS

TITLE: SYSTEMS / EQUIPMENT DECONTAMINATION MEMO
PROCESS: PERMIT FOR CONTAINMENT WORK
Document#: SOP-BRI-003 | DATE: 03/12/2010 | PAGE: 1 OF 1

Purpose & Scope

This Decontamination Memo is required by the Facilities group for any containment systems or equipment that need to be decontaminated prior to any O&M work or activity occurring. The Biosafety Officer (BSO) will manage and/or perform the required decontamination activity and sign off that the impacted containment systems or equipment are safe from biological hazards and is safe for O&M activities to occur.

A copy of this memo is to be completed, signed and posted at the work site.

DECONTAMINATION REPORT #:	DATE:	
WORK ORDER #:	SYSTEM/EQUIP #:	LOCATION:
DECONTAMINATION WORK DONE BY:	START DATE OF WORK	END DATE OF WORK

SYSTEMS OR EQUIPMENT UNDERGOING DECONTAMINATION

METHOD OF DECONATMINATION – GASEOUS OR CHEMICAL DISINFECTANT

I VERIFY THAT THE ABOVE SYSTEMS AND/OR EQUIPMENT HAVE BEEN DECONTAMINATED, EXAMINED AND THE NECESSARY PRECAUTIONS IMPLEMENTED TO DEAL WITH ANY BIOLOGICAL HAZARDS.

I CONFIRM THAT THE ABOVE EQUIPMENT, SYSTEMS HAVE BEEN MADE SAFE TO ALLOW O&M WORK ACTIVITIES TO OCCUR. THE WORK WILL BE PERFORMED OVER THE PERIOD IDENTIFIED.

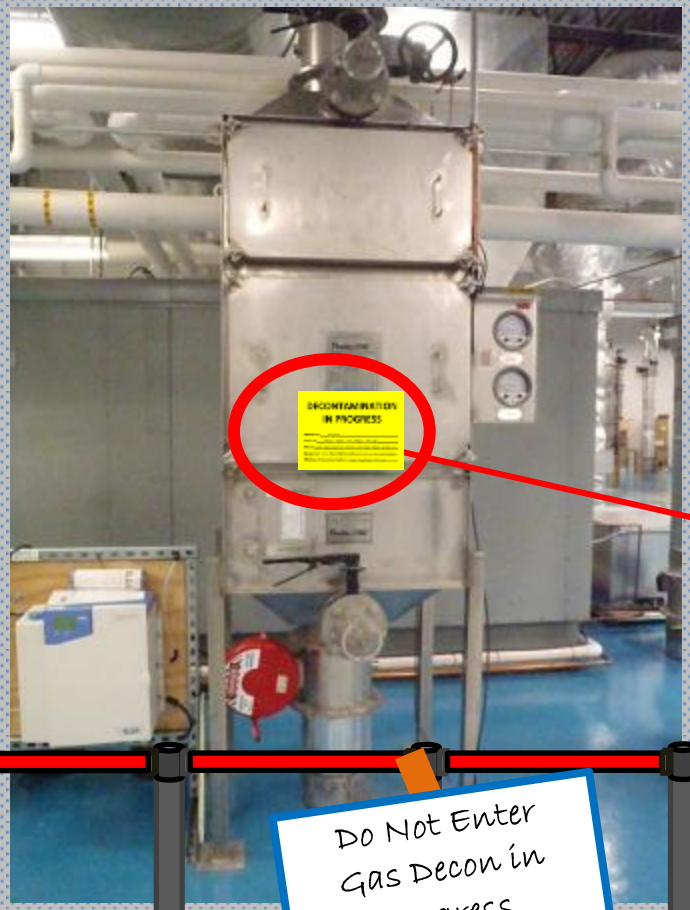
PERMISSION IS AUTHORIZED FOR WORK.

NAME OF BIOSAFETY OFFICER (BSO) OR BSO DESIGNATED REPRESENTATIVE (BSOR)

CONTACT # FAX#

SIGNATURE OF BSO/BSOR DATE:

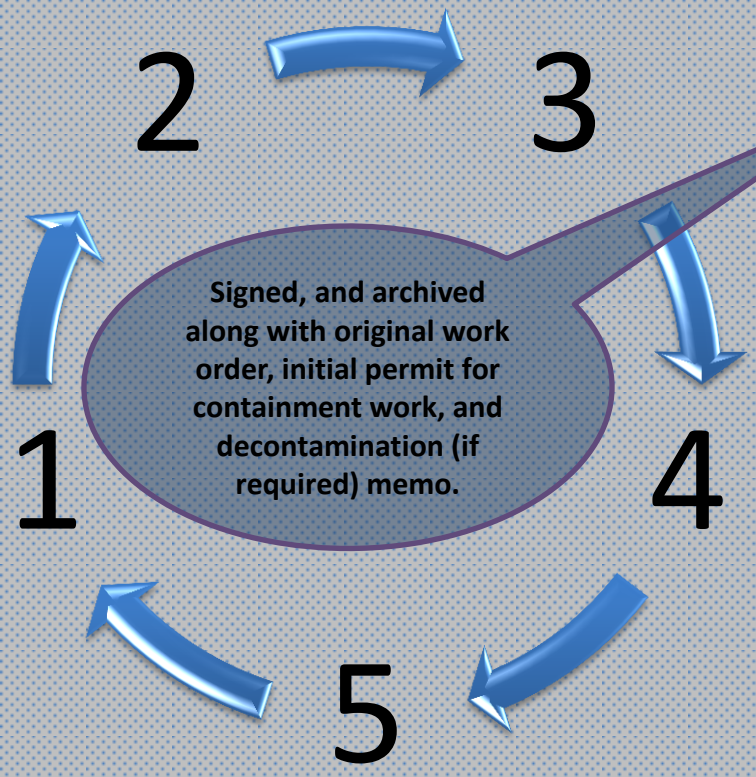
HEPA Housing Signage



- Be aware of
  - Barrier belts
  - DO NOT ENTER signage
  - *Decontamination In Progress*

Courtesy of:
Hao Vu
Biosafety Specialist
Kansas State University

Maintenance Request Close-out



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Purpose & Scope

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A copy of this memo is to be completed, signed and posted at the work site.

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WORK ORDER #:	SYSTEM/EQUIP #:	LOCATION:
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NAME OF EMERGENCY CONTACT:	TELEPHONE NUMBER:	

DESCRIPTION OF WORK TO BE PERFORMED:

ANTICIPATED HAZARDS DUE TO WORK (SAFETY, HEALTH, F&E, CONFINED SPACE, ETC.):

LIST OF PROTECTIVE CLOTHING AND EQUIPMENT REQUIRED TO PERFORM WORK:

PRIOR APPROVALS
(TO BE SIGNED PRIOR TO BEGINNING WORK)

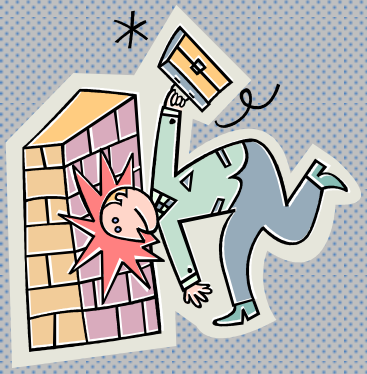
NAME OF PERSON PERFORMING WORK:	SIGNATURE:	DATE:
PRIOR BIOSAFETY OFFICER (BSO) OR REPRESENTATIVE:	SIGNATURE:	DATE:
FACILITY ENGINEER (FE) OR REPRESENTATIVE:	SIGNATURE:	DATE:

VERIFICATION
(TO BE SIGNED UPON COMPLETION OF WORK)

NAME OF PERSON PERFORMING WORK:	SIGNATURE:	DATE:
BIOSAFETY OFFICER (BSO) OR REPRESENTATIVE:	SIGNATURE:	DATE:
FACILITY ENGINEER (FE) OR REPRESENTATIVE:	SIGNATURE:	DATE:

The Tradeline Three

1. Big Ideas
   - **This model is a low cost effort with a high return on investment.**
     - Assurances of safe and efficient operations of biocontainment facilities can be realized.
   - **Negative impacts to overall mission are minimized.**
     - Research schedules can be maintained.
       - » Happy scientists



2. Recommendations
   - **Take baby steps before finalizing the entire program.**
   - **Be flexible and willing to re-direct process and procedures.**
3. Findings
   - **Obstacles**
     - Staying on task
     - *Ego's and turf preservation*
     - Organizational and culture differences
     - Training and promoting mindset.

THANK YOU

Questions?

Discussion?

TRADELINE; 2012 International Conference on Biocontainment Facilities

KSU's Operating Assurance Model for Safety and Research Quality

Scott Rusk
Kansas State University
Biosecurity Research Institute

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