# KSU's Operating Assurance Model for Safety and Research Quality

#### TRADELINE; 2012 International Conference on Biocontainment Facilities

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# 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<sup>2</sup> Facility 41,000 ft<sup>2</sup> Research & Education Space









# 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 <u>safety</u> and <u>research quality</u>.





#### Integration **Biosafety Biosecurity** Protecting people Preventing theft, (workers and public) loss and from unintentional intentional misuse exposure to bioof bio-hazardous hazardous materials materials 3 B's! **Biocontainment** Facility performance elements that safeguard operational activities and requirements.







# **Biosafety, Biosecurity and Biocontainment Integration**

Why?

The Organization's;

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

Bottom line answers:

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

Managing Risk

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







# **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









#### **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.







### 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
  - o Procedures
  - Task Instructions
  - Maintenance Records
  - Location of Reference Documents
  - Equipment Manuals
  - Approval and Permits





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.







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
  - o Shutdown/isolation
  - o Decontamination
  - Preventive Maintenance
  - o Testing







# **Operations Task Instructions**

SIR	EARCH 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 t Handling Units (AHU-A-01 / AHU-A-02) serving th testing, and inspection purposes. Responsible Parties: EC/RSD/Maintenance	o shut down and isolate one of two Air ne BSL-3Ag spaces in Area A for maintenance,
Responsible Parties. PE/BSO/Maintenance	Lab Operation Impact: MEDIUM – AHU's
Schedule: As needed per preventative or corrective maintenance requirements.	serving Area A are completely redundant but redundancy is lost during shutdown
Equipment and Supplies Required: Lockout/Tag	out equipment; necessary tools and supplies to
perform work activities (i.e. motor inspection, et	c)
AHU-A-01	AHU-A VFD's

<u>SBRI</u>	BIOSECURITY RESEARCH	INSTITUTE
Task Instruct	ion Name: Air Handling Unit (AHU-A-01 /	AHU-A-02) Shutdown & Isolation
Document N	umber: SI-HVAC-02	Effective Date: TBD
Approved By		Date Last Revised: 03/12/2010
Resp.	T	ask
Originator	<ol> <li>Identify the HVAC issue to be addressed. to initiate the Work Order.</li> </ol>	Communicate with the Facility Engineer (FE
FE	<ol> <li>Coordinate with the BSO on the work to Initiate the Biosafety Level 3/3Ag Mainte BSO, along with Work Order, for approva</li> </ol>	be performed and the anticipated impact. enance Work Request Form and forward to al.
BSO	<ol> <li>Coordinate with FE and confirm in writing that the area, site, and equipment are in the Work Order. Submit signed Biosafet form (Prior Approvals section).</li> </ol>	g that the scientific program is notified and a safe condition for Maintenance to perform y Level 3/3Ag Maintenance Work Request
FE	4) FE will provide to Maintenance the Work	Corder and the signed Biosafety Level 3/3A
Maintenance	5) Shutdown designated AHU (AHU-A-01 or	ming that the work can be performed. AHU-A-02)
	<ul> <li>a) From BMS workstation, access the A right-click the SF-1 Varicone Control Override, and reduce Value by 10%; repeat until Value = 0%</li> <li>b) Right-click the System Enable object Commands, Operator Override and</li> <li>c) Verify system recovers and stabilizes maintain desired dP</li> </ul>	HU-A-01/AHU-A-02 graphic (Figure 2) and l object (SF1-VC); Select Commands, Operat: allow system to stabilize for 1 minute and (SYST-ENA1 or SYST-ENA2) and select change Value to Disable, click Send (Figure 3 and that all rooms remain operational and
Maintenance	<ol> <li>Isolate the designated AHU         <ul> <li>Proceed to associated VFD and place</li> <li>Move Hand-Off-Auto (HOA) switch ticle</li> <li>Perform Lock-out / Tag-out proceduit</li> <li>Close steam, chilled water, hot water perform work.</li> </ul> </li> </ol>	e disconnect switch into OFF position. o the OFF position res according to facility SOPs r isolation valves at AHU-P as necessary to
Maintenance	7) Perform Work Order	
FE / Maintenance	<ul> <li>8) Place AHU back in service         <ul> <li>a) At associated VFD, switch disconnect</li> <li>b) Switch HOA switch to AUTO</li> <li>c) Reopen any isolation valves that were</li> </ul> </li> </ul>	t to ON position re closed during isolation
Maintenance	<ul> <li>Provide the second state of the s</li></ul>	A-01/AHU-A-02 graphic and right-click the SYST-ENA2); select Commands, Release 1-VC) and select Commands, Operator ; allow system to stabilize for 1 minute and s and that all rooms remain operational and
Maintenance	<ol> <li>Document to the FE in writing that the w Biosafety Level 3/3Ag Maintenance Work</li> </ol>	ork has been completed and provide signed rk Request form (Verification section).
FE	<ol> <li>FE will verify that the maintenance/repair sufficiently tested prior to placing system</li> </ol>	ir work has been completed and systems





### **Operations Task Instructions**





## **Operations Task Instructions**

Task 7a: Close Bubble Tight Damper to

isolate HEPA filter

housing



SBRI	BIOSECURITY RES	EARCH INSTITUTE
Task Instruction Na	me: Typical HEPA Filter Hou	sing 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

Task 7a: Close Bubble Tight Damper to isolate HEPA filter housing



-Task 6a: Close Bubble Tight Dampers to isolate

Figure 6 room 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





Symptom       REMOVE BSC AND MODIFIY CONTROLS-SYSTEM REVALIDATION         Requested By       BRVAN PHILLIPS       Date Issued       7/26/2011         Priority       Date Started       7/26/2011         Work Type       Actual Downtime	Work Order No.	20110726014	Job No.		
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# **Permit for Containment Work**

security Research Institute	BIOSAFET	FY LEVEL 3/3Ag I	MAINTENANCE REQ	UEST FORM
(BRI) Kansas State University	PROCESS	PERMIT FOR (	CONTAINMENT WORK	
Manhattan, KS	Document#		FORM REVISION DATE 03/12/2010	PAGE 1 OF 1
Purpose & Scope			•	
This Biosafety Level 3/3Ag Maintenance Reque or activity occurring within the containment bour Officer (BSO), or their designated representativ renfication of work being completed.	st Form is required t tdaries of the BSL-3 es shall be obtained	o be completed prior to 13Ag facility. Signatures prior to maintenance per	any systems or facilities equip from the Facility Engineer (FE rsonnel entering the BSL-3/3A	ment O&M work ;), the Biosafety ig areas and upon
A copy of this memo is to be completed, signed	i and posted at the w	rork site.		
DATE OF WORK		START TIME.	END TIME.	
WORK ORDER &		SYSTEMEQUIP &	LOCATION-	
DECONTAMINATION REQUIRED? YES / NO		NATURE OF WORK. SCH	EDULED / UNSCHEDULED	
(# YES, COMPLETE SYSTEMS & QUIPMENT OF CONTAMINITION (# CM)	NUMBER OF A STREET	(F NOR DALID, FROMDE MINI	MUM OF 2 WELKS ACTICS)	
NAME OF EMERGENCY CONTACT.		TELEPHONE NUMBER		
		1		
DESCRIPTION OF WORK TO BE PERFORMED.				
				_
ANTICIPATED HAZARDS DUE TO WORK (SAFETY, HE	ALTH, FIRE, CONFINEDS	PACE. ETC.).		
LIST OF PROTECTIVE CLOTHING AND EQUIPMENT IS	EDURED TO PERFORM	WICE.		_
	,			
(TO BE S	PRIOR AP	PROVALS TO BEGINNING WO	ORKO	
NAME OF PERSON PERFORMING WORK.	SIGNATURE		DATE.	
PRICE BOSAFETY OFFICER (850) OR REPRESENTA	TIVE. SEDATURE.		DATE.	_
FACILITY ENGINEER (FE) OR REPRESENTATIVE	SIGNATURE		DATE-	
(TO DE S	VERIFIC	ATION	/OPK)	
NAME OF PERSON PERFORMING WORK.	SIGNATURE.	on centra of a	DATE	—
ROSAFETY OFFICER (RSD) OR REPRESENTATIVE.	SIONATURE.		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	SYSTEM	MS / EQUIPMENT DE	CONTAMINATIC	N MEMO
(BRI) Kansas State University	PROCESS	PERMIT FOR CONT	AINMENT WORK	
Manhattan, KS	Documen#	DP-BRI-003	DATE 03/12/2010	PAGE 1 OF 1
Purpose & Scope This Decontamination Memo is require need to be decontaminated prior to an manage and/or perform the required d systems or equipment are safe from bi A copy of this memo is to be complete	ed by the Facilities y O&M work or ac econtamination a iological hazards ed, signed and po	s group for any containm tivity occurring. The Bio ctivity and sign off that th and is safe for O&M acth sted at the work site.	ent systems or eq safety Officer (BS te impacted contai vities to occur.	uipment that O) will nment
DECONTAMINATION REPORT #:		DATE		
WORK ORDER #:		SYSTEM/EQUIP #:	LOCATION:	
DECONTAMINATION WORK DONE BY:		START DATE OF WORK	END DATE OF WOR	к
METHOD OF DECONATMINATION - GAS	SEOUS OR CHEMIC/	L DISINFECTANT		
I VERIFY THAT THE ABOVE SYS DECONTAMINATED, EXAMINED DEAL WITH ANY BIOLOGICAL H I CONFIRM THAT THE ABOVE E O&M WORK ACTIVITIES TO OCC IDENTIFIED.	STEMS AND/OR I AND THE NECE AZARDS. QUIPMENT, SYS CUR. THE WORI	EQUIPMENT HAVE BEE SSARY PRECAUTIONS TEMS HAVE BEEN MA K WILL BE PERFORMEI	N IMPLEMENTED DE SAFE TO ALLI D OVER THE PER	TO DW HOD
NAME OF BIOSAFETY OFFICER (BSO) (	OR WORK.	D REPRESENTATIVE (BSOR	)	
CONTACT#		FAX#		
SIGNATURE OF BSO/BSOR		DATE:		





### **HEPA Housing Signage**





### **Maintenance Request Close-out**



Biosecurity Research Institute	BIOSAFETY LEVEL 3/3Ag	MAINTENANCE REQ	UEST FORM
(BRI) Kansas State University	PROCESS PERMIT FOR	CONTAINMENT WORK	
Manhattan, KS	Documental ###	FORM REVISION DATE 03/12/2010	PAGE 1 OF 1

#### Purpose & Scope

This Bioadety Lewik 3/3A Mainteence Request Form is required to be completed prior to any systems or facilities equipment 0.4M work or activity occurring vithin the containment boundaries of the BSI-3/3A facility. Signatures from the Facility Repriner (FE), the Biosofety Officer (BSO), or their designated representatives shall be obtained prior to maintenance personnel entering the BSL-3/3Ag areas and upon vertification of work being completed.

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

DATE OF WORK:	START TIME:	END TIME:
WORK ORDER #:	SYSTEMEQUIP #:	LOCATION:
DECONTAMINATION REQUIRED? YES / NO If yes confight systems acquired of contamination memo, doc. 4 sof-484-	NATURE OF WORK: SCH IF SCHEDULED, PROVIDE ANNI	EDULED / UNSCHEDULED
NAME OF EMERGENCY CONTACT:	TELEPHONE NUMBER:	

ESCREPTION OF WORK TO BE PERFORME

INTICIPATED HAZARDS DUE TO WORK (SAFETY, HEALTH, FIFE, CONFINED SPACE, ETC.):

LIST OF PROTECTIVE CLOTHING AND EQUIPMENT REQUIRED TO PERFORM WORK.

PR (TO BE SIGNE	IOR APPROVALS ED PRIOR TO BEGINNING WORK)	
NAME OF PERSON PERFORMING WORK:	SIGNATURE SUM	DATE:
PROR BIOSAFETY OFFICER (BSO) OR REPRESENTATIVE:	MARKE SALANDIE	DATE
	SIGNATURE	DATE:

(TO BE SIG	VERIFICATION NEC UPON COMPLETION OF WORK)	
NAME OF PERSON PERFORMING WORK:	BIONATURE:	DATE:
BIOSAFETY OFFICER (850) OR REPRESENTATIVE:	SIGNATURE	DATE:
FACILITY ENGINEER (FE) OR REPRESENTATIVE		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.
    - 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

Acknowledgements:

Stephen Higgs; KSU Biosecurity Research Institute Bryan Phillips; KSU, Biosecurity Research Institute Julie Johnson; KSU, Biosecurity Research Institute Hao Vu; KSU, Biosecurity Research Institute Gilles Tremblay; Merrick & Company Art Wyatt; Merrick & Company Chris Kiley; Merrick & Company



Scott Rusk

Kansas State University Biosecurity Research Institute

May 14, 2011

