Recommendations for Non-Select Agents

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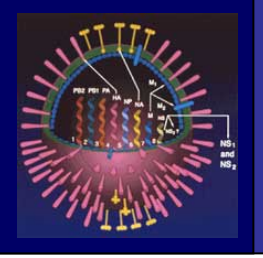
National Institute for Agricultural Security

Overview

- **LGU's and Ag Security**
- **HNSA Project**
  - Workshop
  - Decision Aid
  - Evaluation
  - Federal Developments
- **Managing HNSA**
  - Report
  - Workbook
  - Resources
- **Further Developments**



HNSA Project

- **Project Committee**
  - National Institute for Ag. Security
  - 4 Representative Pilot States
    - Regional / Large-Small / Types of Ag
    - **Oklahoma State University**
    - Colorado State / Utah State University
    - Michigan State University
    - West Virginia University
- **All State Ag Experiment Stations**
  - ESS/ARD

HNSA Project - Workshop

- **Convene SMEs from pilot states**
- **Cross university + expertise**
  - University biosafety and environmental safety
  - Legal counsel and law enforcement
  - Experiment Station Directors
  - Laboratory and field station managers
  - Scientific specialists
    - Plant and animal pathology, microbiology, food safety

HNSA Project - Workshop

- **Federal Agencies**
  - USDA CSREES, ARS, APHIS
    - NPDN, NADN
  - DHS Office of University Programs
  - White House Council on Homeland Security
  - Congressional Research Service
- **Logistics**
  - April 22-23, 2004
  - Washington, DC

HNSA Project - Workshop

- **On Line Library**
- **Agenda**
  - Background on legislation and regulations
  - Agency activities
  - University approaches
- **Workgroups**
  - Hazard definitions, Biocontainment
  - Biosecurity, Risk assessment

HNSA Project - Workshop

- **Recommended Guidelines**
  - Minimize “bother-work,” avoid --
    - Unnecessary paperwork
    - Duplicating existing requirements
    - Contradicting existing requirements
    - Confusing managers
    - Confusing scientists
  - Harmonize requirements across the campus
    - Make sure Ag is linked to university biosafety committees

HNSA Project - Workshop

- **Recommended Guidelines**
  - Facilitate easy interaction with federal partners and federal labs
  - Aim at national guidelines, but allow for local adaptation
  - Narrow the scope of what needs to be addressed
  - Minimize the need for new regulations or an expansion of the Select Agent List

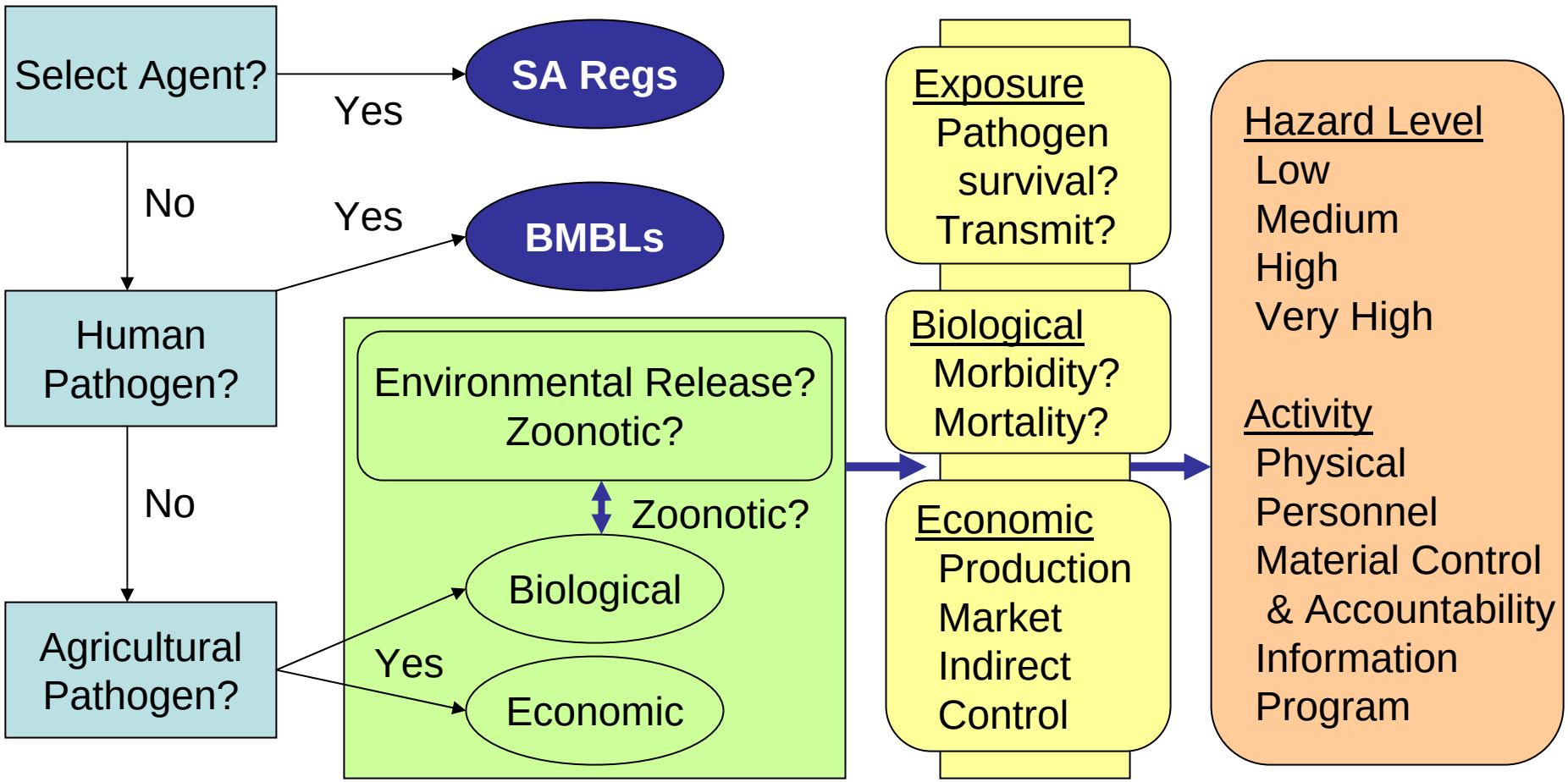
HNSA Project - Workshop

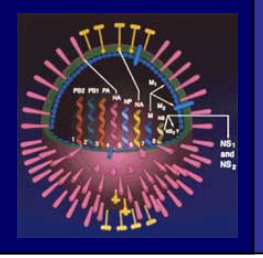
- **Recommended Guidelines**
  - Integrate with existing guidelines
    - Is it a Select Agent?
      - Requirements in place.
    - Does it impact human health?
      - Harmonize with CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL 4th Ed.)
    - Does it need to be contained?
      - Utilize ARS Guidelines for BL3 & non-BL3 facilities

HNSA Project - Workshop

- **Manage based on risk**
  - Adapt Sandia Lab's tiered approach to managing hazardous materials based on risk
- **Develop Decision-Aid?**
  - Need to develop voluntary guidance first
  - Develop a quantitative approach?
  - Develop a work-book?

HNSA Project – Decision Aid





HNSA Project – Decision Aid

Hazard Classification	Basis for Classification	Ranking Scale		Score
A1. Human Impact	Human health effects	0	None	**2**
		1	BSL 1	
		2	BSL 2	
		3	BSL 3	
		4	BSL 4	
A2. Mortality	Modifying factors to human impact	1	Low	**2**
		2	Moderate	
		3	High	
		4	Very High	
A3. Morbidity	Modifying factors to human impact	1	Low	**2**
		2	Moderate	
		3	High	
		4	Very High	

HNSA Project – Decision Aid

B. Economic Impact	Production, natural resource or trade effects	0	None	**2**
		1	Low	
		2	Moderate	
		3	High	
		4	Very High	
C. Magnitude of Impact				
C1 Crop or Animal Factors	Impact on crops and/or animals	0	Low	**3**
		1	Moderate	
		2	High	
		3	Very high	
C2 Persistence	Survivability and viability in the environment	0	Short half-life,	**3**
		1	Moderate half-life	
		2	Long half-life	
		3	Very long half-life	

HNSA Project – Decision Aid

C3 Control Methods	Availability and effectiveness of antidote and/or treatments	0	Available/Effective	**3**
		1	Available/Somewhat effective	
		2	Somewhat available/Somewhat effective	
		3	Unavailable/Ineffective	
C4 Method of Transmission	Method of disease transmission	0	Direct inoculation	**3**
		1	Human contact	
		2	Ingestion	
		3	Inhalation	

HNSA Project – Decision Aid

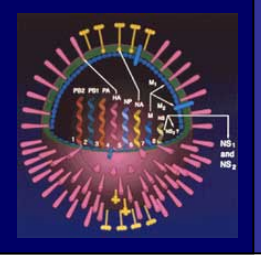
C5 Potential for Production	Ease of mass production and preparation for distribution	0	Difficult **with specialized** skills/equipment needed	**1**
		1	Difficult with **no specialized** skills/equipment needed	
		2	Easy **with specialized** skills/equipment needed	
		3	Easy with **no specialized** skills/equipment needed	

HNSA Project – Decision Aid

HAZARD INDEX (HI)		
Human Impact (H)	BSL * Mortality * Morbidity	**8**
Agricultural Impact (A)	Economic Impact * (Crop/Animal Impact + Persistence + Control + Transmission + Production)	**26**
TOTAL SCORE (TS)		**34**

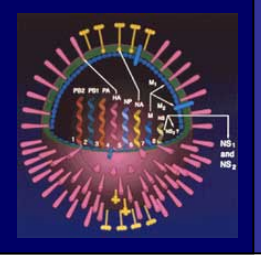
HNSA Project – Decision Aid

AGRO-SECURITY LEVEL (ASL)				
Human Impact (H)	None	0	0	**HI-2 Mod**
	Low	1	0 < x <= 1	
	Moderate	2	1 < x <= 8	
	High	3	8 < x <= 27	
	Very High	4	27 < x <= 64	
Agricultural Impact (A)	None	0	0	**HI-3 High**
	Low	1	0 < x <= 5	
	Moderate	2	5 < x <= 20	
	High	3	20 < x <= 45	
	Very High	4	45 < x <= 60	
Agro-Security Level (ASL)				**HI-3 High**



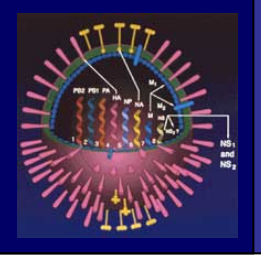
HNSA Project – Decision Aid

AGRO-SECURITY LEVEL ACTIONS						
#	A - Physical	B - Personnel	C - Material Control and Account-ability	D – Transfer	E - Information	F – Program
ASL-1 Low						
1.	Locked doors - especially when lab is unattended	Verification of employment history and education background.	Laboratory records (e.g. lab notebooks).	PI should be aware of all transfers.	Prudent policies regarding network security, passwords, email use.	PI ensures that the lab meets all recommend ations.
2.		Guests allowed with PI approval.		Transfers should be documented in lab records.		



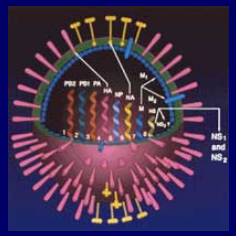
HNSA Project – Decision Aid

ASL-2 Medium						
1.	Access controls that provide reasonable assurance. Only authorized personnel enter (e.g. controlled keys).	Basic personnel suitability check.	Stored & used within an access controlled area.	Transfers controlled and documented in inventory records. ..	Prudent policies regarding security information, network security, passwords, email use	Facility representative should oversee implementation of appropriate biosecurity, ensure biosecurity training, and conduct self audits.
2.		Visitors should be escorted, and visitor logs kept.	Consistent inventory methodology	Use of timely shipping methods.		
3.		Temporary workers should be escorted or approved.	Lab notebooks document material use (who/when)	Notification of successful receipt.		
4.		Badges or, for small groups, knowledge of persons.				



HNSA Project – Decision Aid

ASL-3 High						
1.	Electronic access controls and a minimal level of intrusion detection	Background investigation.	Stored & used in an electronic access controlled area.	Biosecurity Officer must pre-approve all transfers.	Strong policies regarding security information, network security, passwords, email use.	Biosecurity Officer should oversee implementation of appropriate biosecurity, ensure biosecurity training, and conduct self audits.
2.	MOU with local law enforcement	Visitors must be escorted, and visitor logs kept.	Secure facility-based inventory practices.	Chain of Custody during transfer.		
3.		Temporary workers must be pre-approved and escorted.	Usage logs kept, documenting who & when ASL-3 are accessed.	Transfer documented in inventory records.		
4.		Photo badges	Two-person rule for access to stocks.	Use of timely shipping methods. Notification of successful receipt.		



BMPs for Handling Hazardous Non-Select Agents at Ag Experiment Stations

HNSA Project – Decision Aid

ASL-4 Very High						
1.	Multiple-level electronic access controls.	Comprehensive background investigation.	Stored and used in multiple-level electronic access controlled area.	Biosecurity Officer must pre-approve all transfers	Strong policies regarding security information, network security, passwords, email use.	Biosecurity Officer should oversee implementation of appropriate biosecurity, ensure biosecurity training, and conduct self audits.
2.	Intrusion detection.	All visitors and temporary workers subject to same checks as workers.	Secure facility-based inventory practices.	Chain of Custody during transfer.		
3.	MOU with local law enforcement	Photo badges.	Usage logs kept, documenting who & when ASL-4 are accessed.	Transfer documented in inventory records.		
4.	Local guard force.		Two-person rule for access to stocks.	Use of timely shipping methods.		
5.				Notification of successful receipt.		

HNSA Project – Evaluation

- **Presented to Experiment Station Directors**
  - AES/ARD Director Workshop, Sept. 26, 2004
- **General agreement on guidelines**
  - Minimize new paperwork and bureaucracy
  - Harmonize with existing requirements
    - Work with Biosafety / Environmental safety offices
  - Tiered management approach, based on risk
  - Allow for local circumstances

HNSA Project – Evaluation

- **Decision aid**
  - General concept ok, but -
    - Risk calculations need considerable development
    - Knowledge gaps
      - Exposure: Pathogen survival outside the host
      - Zoonotic: Animal-human interactions
      - "Shock:" Indirect economic impacts
    - Local data may not exist
    - Assignment to categories will be too arbitrary
    - Management for consistency will be unwieldy

HNSA Project – Evaluation

- **Posted online resources**
- **Decision aid**
  - Subsequent Discussions
    - Trying to run before we can walk
    - Calibrate with “larger” federal & university efforts
  - Suggest
    - Reconsider quantitative approach to risk calculations
    - Transition to a workbook approach?

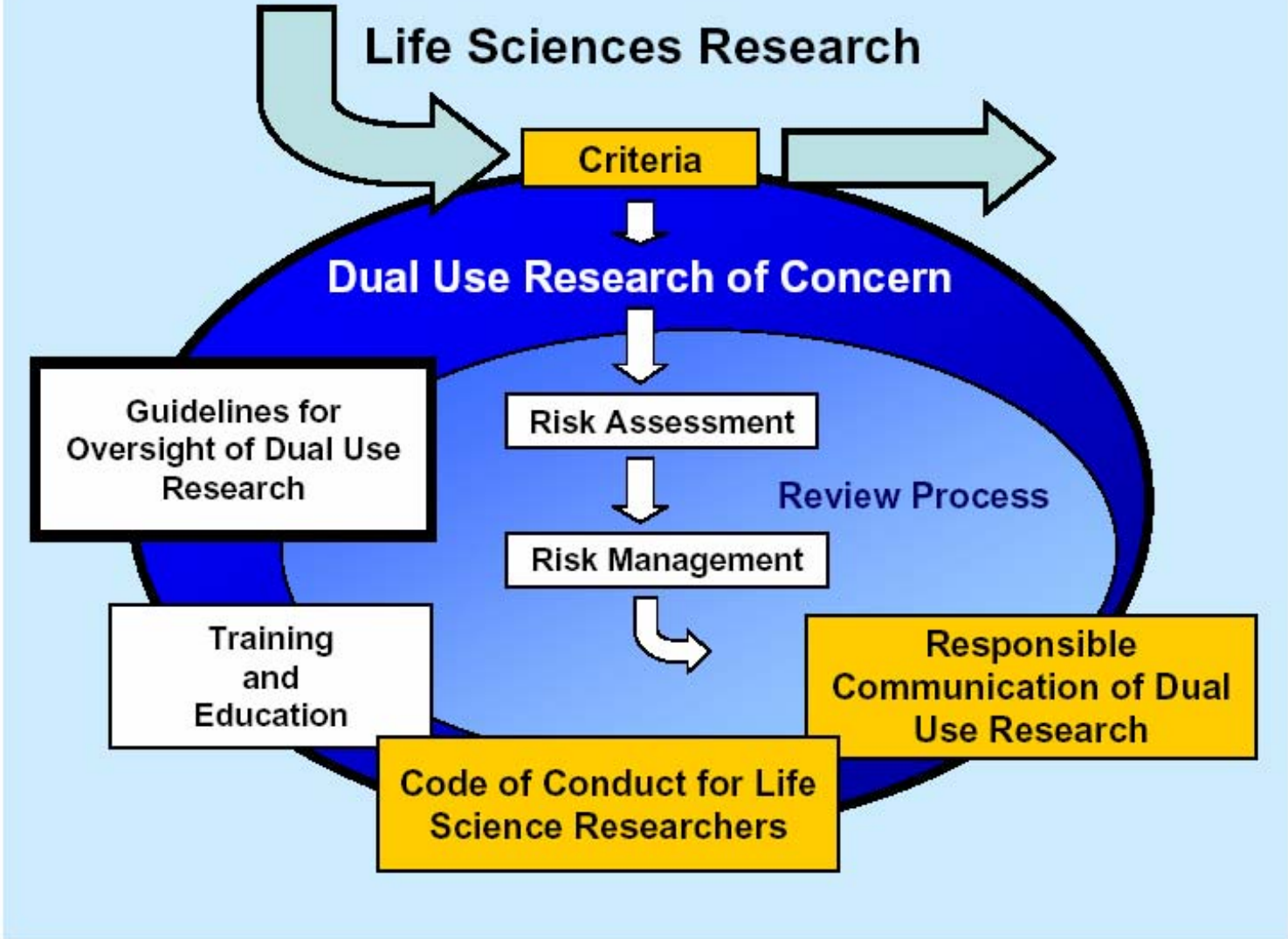
HNSA Project - Federal

- **Calibrating with federal developments**
  - Select Agents
    - HHS/CDC: Final Rule - April 18, 2005
    - Security Plan Information – March 8, 2007
  - Laboratory biosecurity guidance
    - WHO - September 2006
  - Human Pathogens
    - BMBL Update. 5th Edition – February 2007

HNSA Project - Federal

- **DHS**
  - National Biodefense Analysis and Countermeasures Center (NBACC)
    - Bioterrorism Risk Assessment (BTRA)
    - Probabilistic Risk Assessment: Agriculture 2008
- **National Science Advisory Board for Biosecurity (NSABB)**
  - Began June 30, 2005
  - Draft Report of the Working Group on Oversight Framework Development – April 19, 2007

National Science Advisory Board for Biosecurity

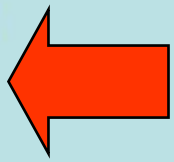


NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

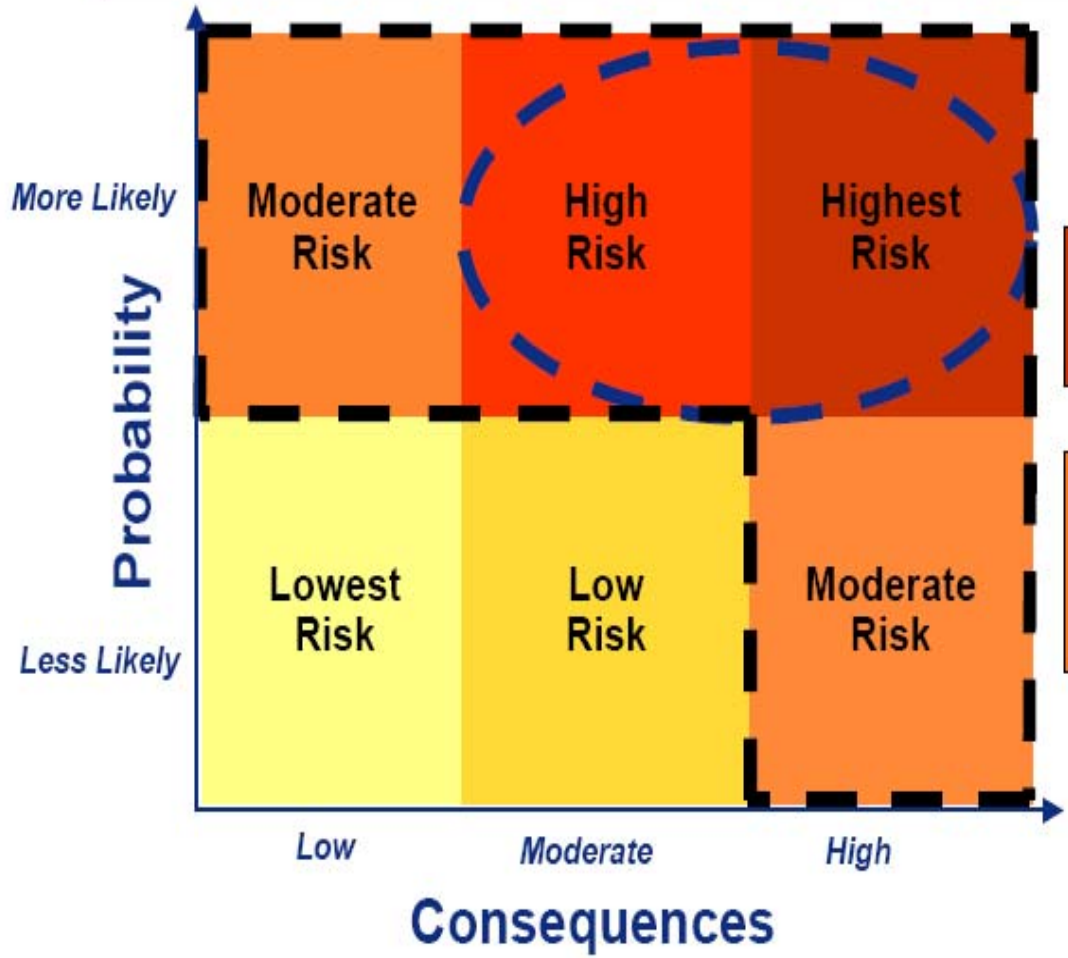
Draft Criteria for Dual Use Research of Concern

Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to:

- Public health
- Agriculture
- Plants
- Animals
- Environment
- Materiel



Management Risk Decision



- Protect against unacceptable risk scenarios
- Develop incident response plans for acceptable risk scenarios

Sandia National Laboratories

NSABB: Local Oversight

Figure 1 : Steps in local oversight of dual use research

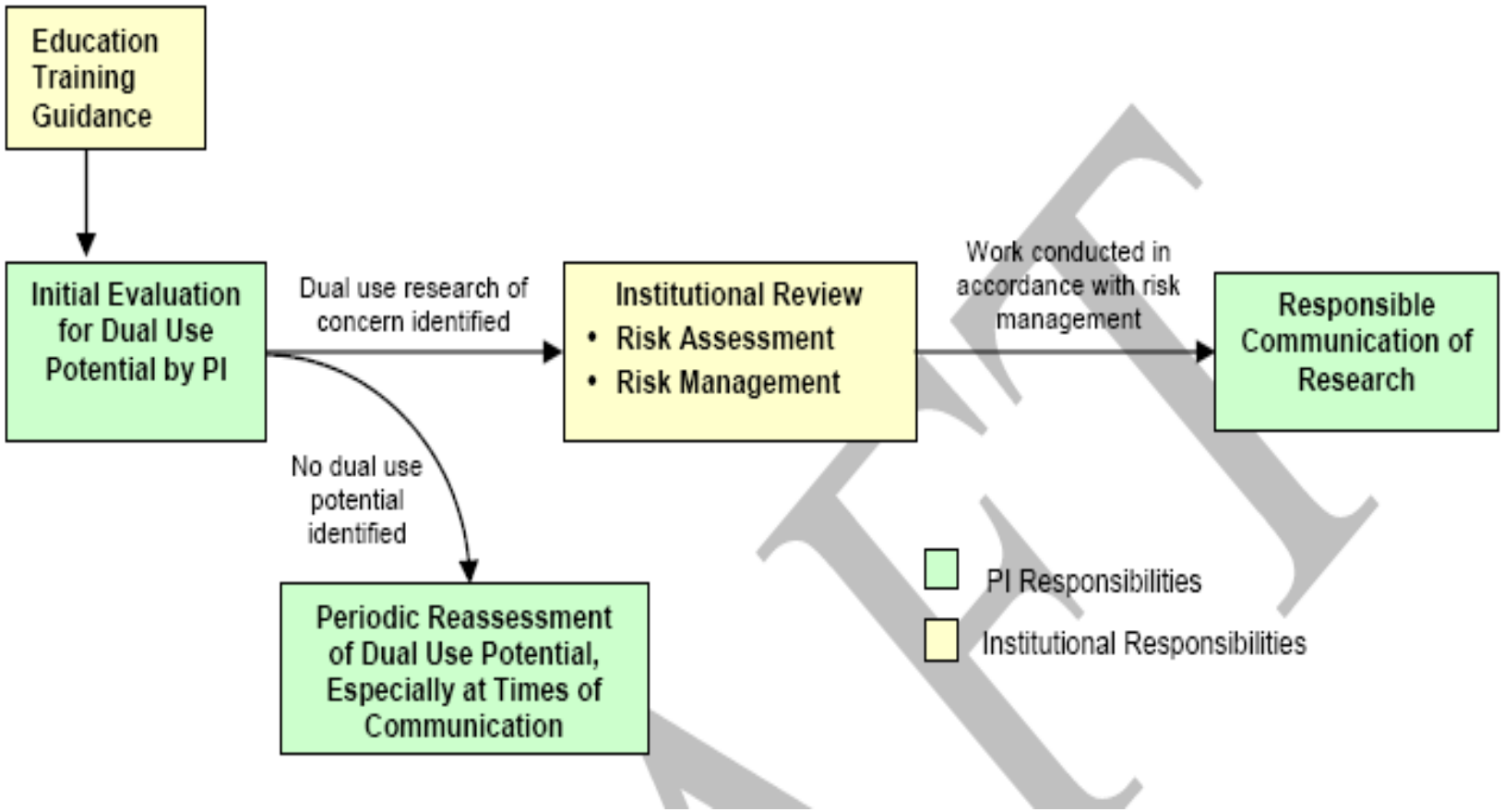
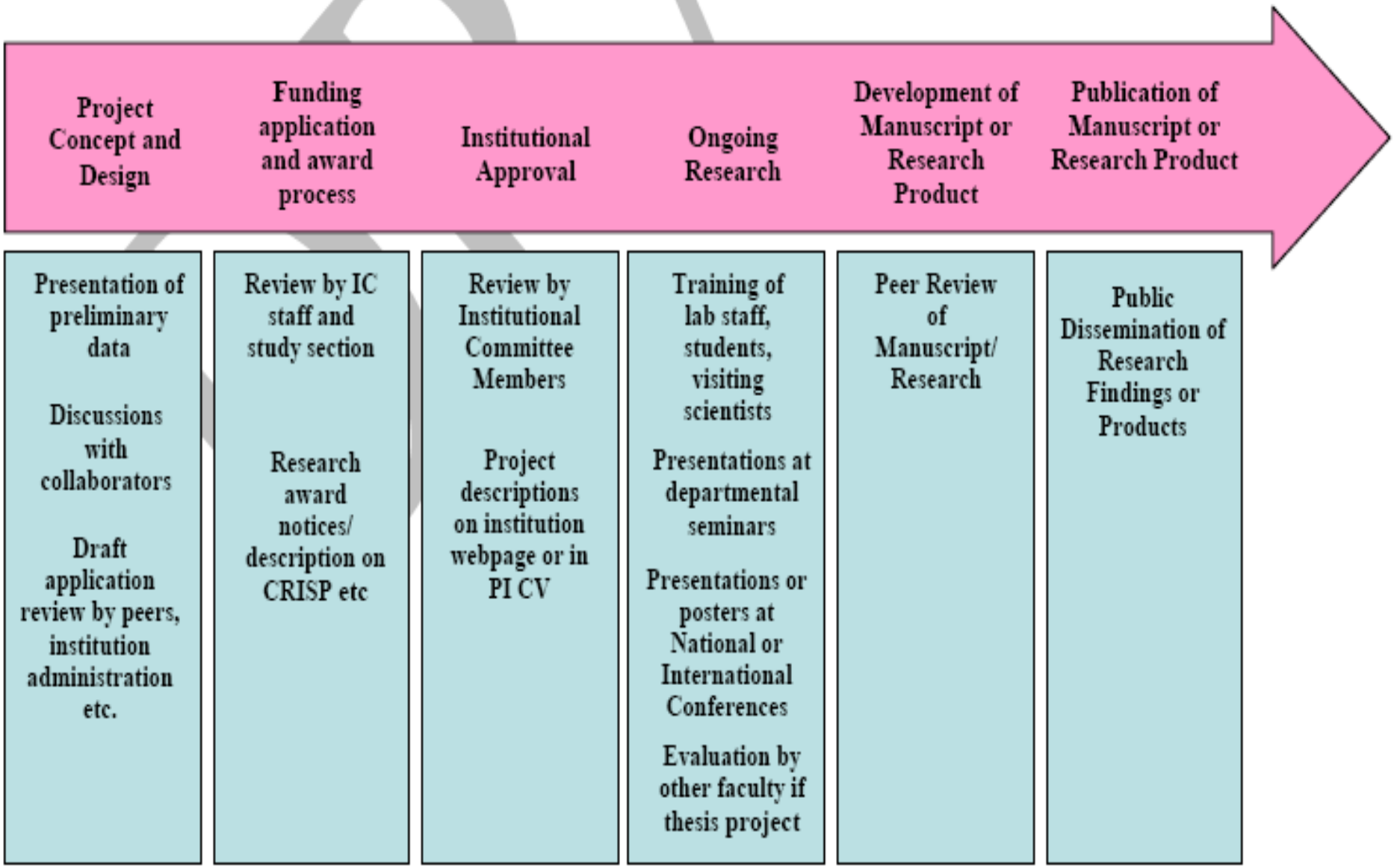


Figure 2. Examples of Points of Communication of Dual Use Research During the Research Process



Managing HNSA

- **Incorporated**
  - Workshop guidelines
  - Federal developments *(Briefed ES Directors 06)*
    - Select Agents: HHS/USDA Guidance *(2007)*
    - Lab security: ARS BL3 and Non-BL3 Facilities
    - Human health and safety: BMBLs 5th Ed. *(2006)*
    - NSABB Framework *(2007)*
- **Three outcomes**
  - HNSA Project Resources
  - HNSA Project Report
  - HNSA Project Workbook

HSNA Project Resources

1. **Definitions**
   - A. Acronyms and Abbreviations
   - B. Terms and Definitions
2. **Legislation**
   - A. P.L. 107-56. US Patriot Act of 2001
   - B. P.L. 107-188. Bioterrorism Preparedness & Response Act of 2002
3. **Select Agents**
   - A. HHS USDA Select Agents and Toxins
   - B. National Select Agent Registry Updates
   - C. HHS-USDA. SA Final Rule
   - D. HHS-USDA. SA and Toxins - Security Information
   - E. HHS-USDA. SA and Toxins - Security Plan Template

HSNA Project Resources

4. Biosafety Levels

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

- **Table of Contents – Liked to Chapters-**
- **Summary of Recommended Biosafety Levels for Infectious Agents**

5. Risk-Based Management

A. Conceptual Framework for Biosecurity Levels

B. USDA-ARS Security Policies for BL3 Facilities

C. USDA-ARS Security Policies for NON-BL3 Facilities

D. NSABB WG - Draft Oversight Framework Development

HSNA Project Report

Executive Summary

The HNSA Project

- Hazardous Agents
- The Agricultural Research System
- The Agricultural Research Service
- The Land Grant Colleges
- The Agricultural Experiment Stations
- The National Institute for Agricultural Security

Security Concerns

- OIG Report
- Incidents

Addressing the Challenge

- Team Approach
- HNSA Subject Matter Expert Workshop

HSNA Project Report

- Preliminary HNSA Management Aide
- Agency Developments
- Draft HSNA Management Workbook

HNSA Workshop

- Workshop Agenda
- Workshop Participants
- Working Group Teams
- HNSA Online Resources

Federal Developments

- HHS and USDA
- National Academy of Sciences
- National Science Advisory Board for Biosecurity
- DHS Biological Terrorism Risk Assessment

HNSA Workbook

- **Assess status**
  - Security plans?
    - What ifs?
  - Communication within university
    - POC within station and agriculture college
    - POC Biosafety and Environmental safety
  - Communication with law enforcement
    - Local
    - FBI and Agencies
- **Assess hazards**
  - Select agents?
  - Dual use?
- **Assess process**
  - PIs / Station / College / University

HNSA Workbook

- **HNSA Plan**
  - Site Specific Risk Assessment
  - Pathogen Specific Risk Assessment
    - Linked to SA plans (very high)
    - High, medium, low
    - Biological
    - Economic
  - Threat Assessment
    - Inside / outside / natural
  - Vulnerability Assessment
    - High, medium, how
  - Tiered Protection
- **Entity security conference**

HNSA Workbook

- **Infrastructure and materials**
  - Physical security
  - Operational security
  - Inventory control
- **Information systems**
  - Internal communications
  - External communications
- **Access control**
  - Access definition
  - Access control
    - Recording access
    - Routine maintenance
    - Unescorted access
    - Public access

HNSA Workbook

- **Transportation and movement**
  - Internal and external
  - Inspection and evaluation
- **Event management**
  - Loss or compromise of access control
    - Staff changes, students
  - Loss of HNSA materials
- **Understanding and compliance**
  - Process definition
  - Internal requirements
    - Records / reporting
  - Education and training

Further Developments

- **Review by AES Directors**
  - Next ESS/ARD meeting in September 2007 Further refinement of the Workbook?
- **Education and training?**
  - On line training?
- **Further development of a quantitative model?**
  - In collaboration with broader university and federal efforts