Self-Audit of Biosafety Practices
Keeping Your Ducks in a Row
High Containment Research Oversight

- High risk, greater consequences – requires enhanced oversight
  » Personnel illness/injury
  » Environmental consequences (agriculture)
  » Regulatory violations

- Integration of research goals
  » Goal is to support and facilitate research, not impede or hinder
Needed Research Oversight Programs

- Occupational Medicine
- Training
- Emergency Response
- Regulatory Compliance
  - Select Agents - USDA and CDC
  - USDA APHIS transport permits
    - Veterinary Services (VS)
    - Plant Protection and Quarantine (PPQ)
    - Biotechnology
  - Institutional Biosafety Committee (IBC)
  - Institutional Animal Care and Use Committee (IACUC)
Needed Research Oversight Programs

- Occupational Medicine
- Training
- Emergency Response
- Regulatory Compliance
- Others
Needed Research Oversight Programs

- Occupational Medicine
  - Training
  - Emergency Response
  - Regulatory Compliance
- Others
Needed Research Oversight Programs
HOW TO KEEP TRACK OF IT ALL?...HERDING THE DUCKS
How to Juggle it All? ...Leverage

- Leverage all necessary resources and commitments from appropriate stakeholders from the very start:
  - Ensures safe operating conditions
  - Strong indicator of a successful research program

{A magic wand doesn’t hurt either}
Let’s Start at the Very Beginning, a Very Good Place to Start…

• New Research Project Initiation Checklist
  » Early introduction
  » Comprehensive requirements summary
  » Flexibility to include research and support staff needs
  » Ensures requirements are met before research begins
New Research Project Initiation Checklist

• Forces interaction with all support groups
  » Builds relationships from the start
  » Fosters creativity
New Research Project Initiation Checklist

NEW RESEARCH PROJECT INITIATION CHECKLIST (BRI-0001-F11)

Items on this checklist must be completed prior to beginning a project in the BRI. PIs are responsible for accurately completing the checklist and getting any necessary institutional approvals.

Name

College Department

PIs approved designate

Approved designate is a person designated by the PI to be responsible for activities in Pat Roberts Hall laboratories in the absence of the PI.

Project Title

Authorized Project Personnel (list all persons who will be conducting work on this project in Pat Roberts Hall, including the PI and approved designate)

Name Title Phone Email Office Address


New Research Project Initiation Checklist
Medical Surveillance

Training

Laboratory Setup

Animal Use

New Research Project Initiation Checklist
Continuous Process: Preparation

Success is in the details

Project Approved
Pre-Planning
Walk-through
Planning
Start

Repeat as necessary
Active Research Monitoring (Audits)

- Single Annual Assessment (Snapshot)
- Continuous Assessment (Profile)
Audit Approaches

Single Annual Snapshot vs. Continuous Process

Single Annual Snapshot
- Surprises (Reactive)
- Routine/Frequent: Keeps safety staff in close contact with researchers
- Not Routine/Infrequent: Encourages communication
- Focus on finding failure
- Safety staff bears most responsibility

Continuous Process
- No Surprises (Proactive)
- Routine/Frequent: Bad Cops, Safety staff = Partners
- Not Routine/Infrequent: Discourages communication
- Focus on preventing failure
- Researchers empowered to take responsibility

Surprises (Reactive) vs. No Surprises (Proactive)
Single Annual Assessment (Snapshot)

- Annual comprehensive inspection
- May coincide with annual whole facility shut down for validation
- Expectations are clarified during annual trainings and orientation
- Incorporated into trainings and daily activities
Continual Assessment (Profile)

- Weekly eyewash log
- Daily BSC operations log
- Daily respirator evaluation
- Daily autoclave verification
- Weekly, monthly, and annual housekeeping
- Scheduled inventory audits
- Quarterly self audits by researchers
- Others
Eating the Whole Elephant at Once

- Not very palatable
Eating the Elephant One Bite at a Time

• Much more palatable
Continuous Assessment: One Bite at a Time

- Continuous process gives researchers shared responsibility for safety culture
  - Prioritizing
  - Continuous Sampling
  - Deputizing
Continuous Assessment: Prioritizing

• Focus on a few most critical safety issues
  » Top Ten List
  » High risk vs. low risk activities
Continuous Assessment: Sampling

• Spot checks by safety staff
  » Early detection
  » Early prevention and mitigation
  » Minimal intrusion and interruption
  » Increased dialogue and opportunity to develop relations
Continuous Assessment: Deputizing

• Continuous process gives researchers shared responsibility for safety culture
  » Laboratory user groups – sharing of best practices
  » Local safety committees – sharing of oversight responsibilities
Continuous Assessment: Simplicity and Moderation

- Periodic Scheduled Meetings
- Active Research Monitoring
- Routine Maintenance & Support Activities
- Refresher Training
- Unscheduled Maintenance & Support Activities
Continuous Assessment: After Action Review

- Project Complete
- Decon
- Return to Standby Mode
- Analyze & Debrief
- Implement Lessons Learned
- End
External Audits

• Eating the elephant one bite at a time works the same for external audits.
• Self audit using same checklists inspectors will use
  » Ensures fixes done ahead of time
  » Tab documents to show where requirements are addressed
  » Research & support staff more at ease
  » Makes inspectors’ jobs easier
  » No surprises in inspection report
Value Added Audits

• True value of audits is how you use the collected data.
  » Does it increase awareness and accountability?
  » Does it increase healthy communication?
  » Does it promote change?
  » Is the targeted change sustainable?
  » Does it make you safer?