Five Key Elements for Biosafety Program Success

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The Consultant Perspective – EH&E

- Life sciences audits/gap assessments
  - Research and Development
  - Commercial
  - Clinical Manufacturing
  - QA/QC
- Large and small institutions
- Varying EHS infrastructures and support
- External and internal audits

Biosafety Program Analysis

- Data pooled from over 400 individual laboratories over the past 18-24 months
- Programs evaluated against:
  - CDC, USDA, NIH and OSHA regulations
  - Internally developed checklists based on industry best practices

Biosafety Program Analysis

- Analysis includes a:
  - Document review
  - Site inspection
  - Interview with EHS, laboratory, and support staff
- Grading system for findings depending on the nature and severity noncompliance

Top 5 Areas for Improvement

- Communication
- Training
- Program Management
- Institutional Biosafety Committee Management
- Infrastructure
  - Physical
  - Personnel

Communication

EHS should work to bring laboratory, administrative, and operations staff as well as technical decision makers to the table to align policies in a meaningful way.

Communication

Observation:

Lack of clear, consistent communication between environmental health and safety, biosafety and scientific staff – and among departments.

Recommendation:

- Formalized safety committee
  - EHS partners/champions within lab infrastructure
  - Representation from all lab support services (facilities, operations, chemical safety, biological safety, site leadership, scientists, etc.)
- Positive outreach strategies:
  - Biosafety office hours
  - Lab “drop ins’
  - Maintaining high visibility
- Newsletter, signage, etc.

Training – Evidence of Competency

Policy

Compliance

Competency

Training

Observation:

- No processes in place to re-enforce training and ensure competency
- Heavy reliance on online training due to the ease of reaching large number of staff
- Results in knowledge gaps and no evidence of competency

Recommendation:

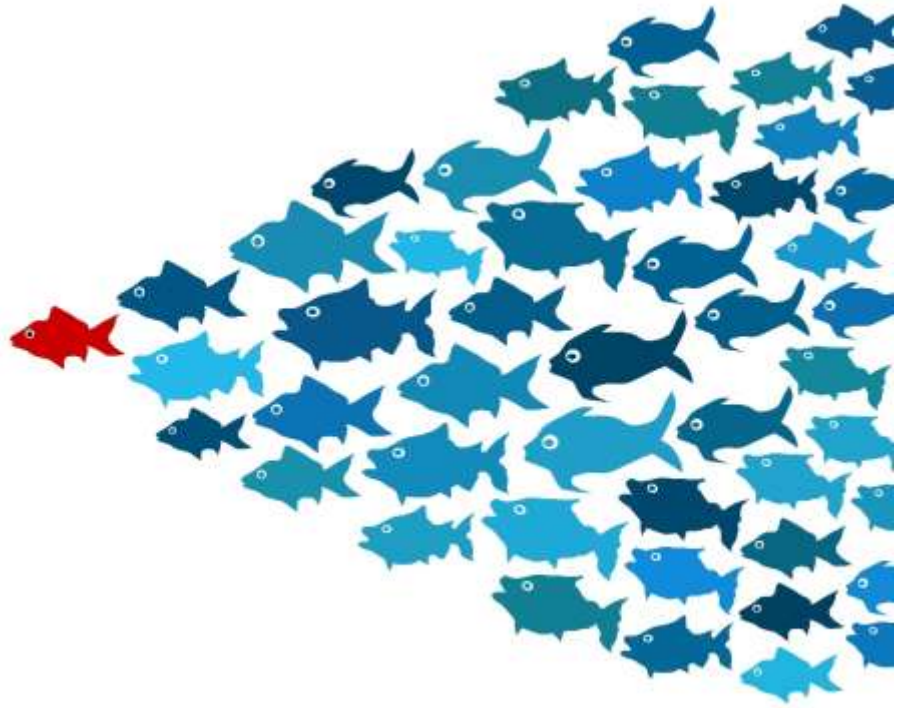
- Hands on or classroom-based training should supplement online based biosafety trainings
- Consider a module approach:
  - Spill clean up
  - Incident response tabletop exercise
  - Biosafety Cabinet demonstrations
  - PPE donning and doffing

OVERALL PROGRAM MANAGEMENT

Common issues faced by biosafety program staff are leadership buy-in and limited resources, which includes personnel, infrastructure, technical expertise and time.

Leadership's Role in Program Management

Is it better to have leadership from the top down or take a more grassroots approach?



http://blog.rozee.pk/2010/05/12/effective-team-leader/

Overall Program Management

Observation:

- Lack of resources
  - Limited budget
  - Staff
  - Time
- Poor information management
  - Training records
  - Document Reviews
  - Communication of policies
  - Audit gaps, noncompliance, deficiencies/citations
- Roles and responsibilities not well defined
- ***Lack of program metrics***

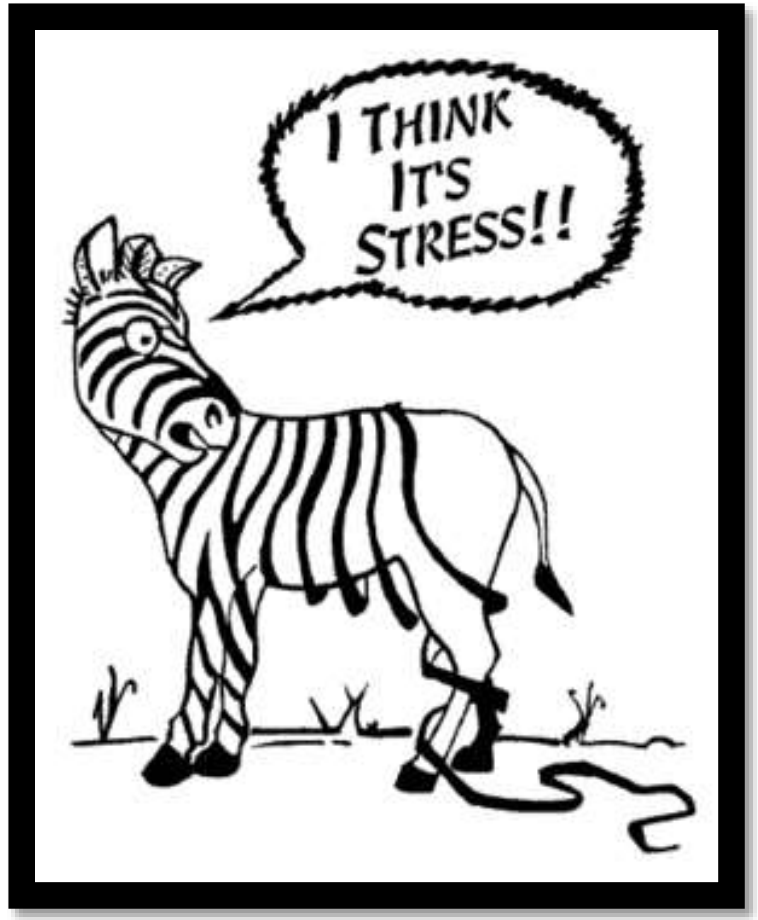
Recommendation:

- Centralized document management system
- Compliance calendar
- Clearly defined staff roles and responsibilities:
  - Biosafety Officer
  - Chemical Hygiene Officer
  - EHS specialist
- Proportional resources allocated to account for growth
- Program tracking initiatives (i.e., metrics)

Lack of Personnel – High Workloads

Whether it is a new start-up or a well-developed company outgrowing its EHS capacity, the common denominator is a lack of personnel to adequately handle the workload.

- Overburdens EHS staff
- Slows laboratory functionality
  - Onboarding new procedures
  - Risk assessments
  - New staff training



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Program Infrastructure

- A succinct infrastructure is required that biosafety/safety officers can rely on for leadership.
- Building and maintaining a culture of laboratory safety cannot be done by biosafety staff alone.
  - Top managers/technical decision makers must be part of the process to prevent competing ideologies such as production and profitability from undermining safety .
- Foundation for a strong biosafety program relies on consistency throughout the organization.
  - Leadership not just from the top down but spread throughout ranks

The Importance of Metrics

- Justification for more resources
- Know your audience: scientists and scientific leadership will appreciate data
- Use scientific evidence (i.e., peer reviewed science) to back up your metrics
- Avoid the overly engineered solutions – start simple
- Track the effectiveness of mitigation measures
- How are you self auditing your program?

INSTITUTIONAL BIOSAFETY COMMITTEE MANAGEMENT

IBCs are a critical component to biosafety programs that help facilitate SOP reviews, risk assessments, as well as transparency within an organization.

Institutional Biosafety Committee Management (IBC)

- NIH regulations are a large driving force
- Allows for SOP reviews, risk assessments and community input on lab operations and infrastructure
- Accountability and transparency
- Local or municipal rDNA regulations are catching on!

IBC Management

Observation:

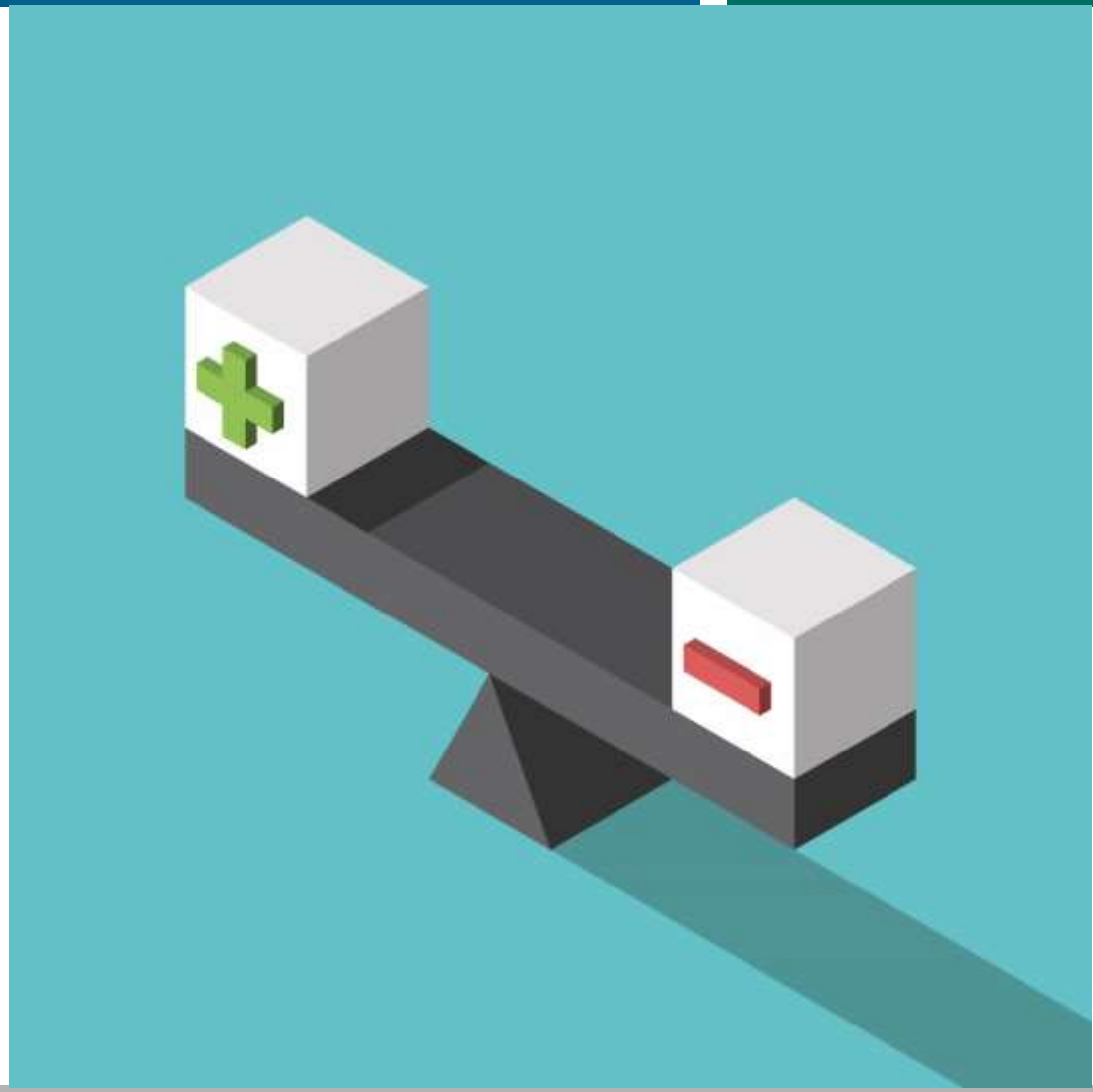
- No formal risk assessment process
  - Performed infrequently or inadequate process
  - Performed by wrong personnel
  - Not standardized
- No occupational health representation
- Lack of IBC altogether (for those organizations with no regulatory precedent)

Recommendation:

- IBCs should be formalized with dedicated resources (i.e., an IBC coordinator or chairperson)
- Document management systems streamline SOP reviews and risk assessment
- Occupational health representation is necessary
- Risk assessments should be performed by qualified individuals

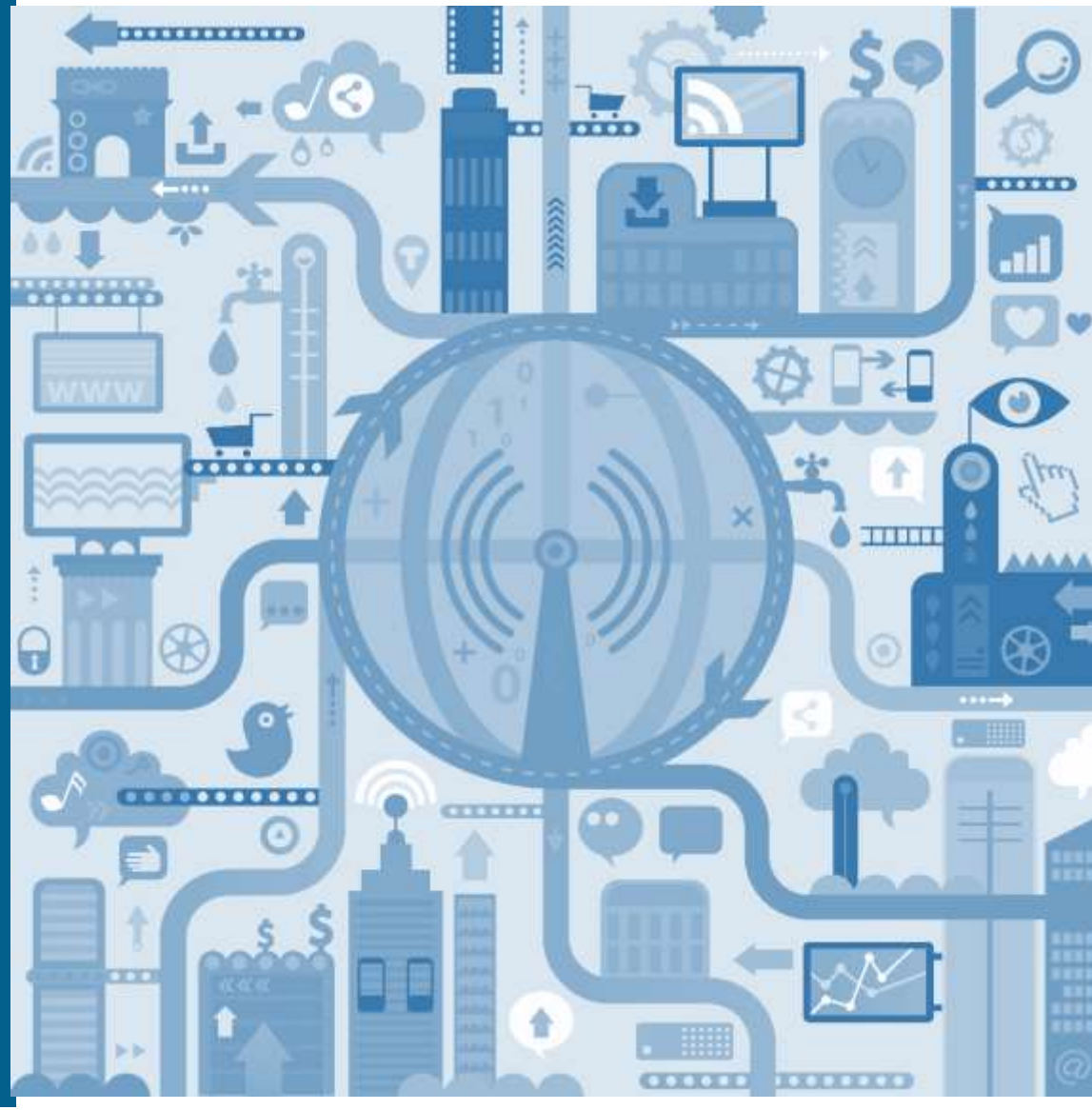
IBC Management

- The benefits of good IBC practices:
  - Keep permits current (CDC/USDA Import Program)
  - Centralize documentation
  - Inspection readiness
  - Laboratory operations efficiency improves
- The drawbacks:



INFRASTRUCTURE

Engineering controls, whether primary or secondary containment, form the foundation for safe work practices in biosafety



What makes up your infrastructure?

Infrastructure

Observation:

- Engineering controls are inadequate
  - Lack of BSCs or improperly used BSCs
  - Loads are “maxed out”, no flexibility or room for growth
- Heating, ventilation, and air conditioning (HVAC) maintenance is not routinely conducted
- EHS/Biosafety personnel not incorporated into lab design process
  - Permitting requirements
  - “Managing what’s given”

Recommendation:

- Energy optimization initiatives
  - Can more controls be accommodated
- Compliance calendar for routine preventative maintenance
- Operation optimization initiatives
  - 5S or 6 Sigma
- Biosafety staff should be involved in the lab planning and design process
  - Placement of BSCs
  - Workflows
  - Waste streams

Self Audits – Achieving an Inspection Ready Lab

Policy

- Biosafety, Biosecurity, Incident Response, Occupational Health
- Security Risk Assessments, Inventory Records, Access Records
- Inspections, Audits, Infrastructure Maintenance and Performance Validations

Compliance

- Does the policy align with the regulations and guidance documents?
- Guidance documents: Biosafety, Training, Incident Response, Information Systems Security Controls, Occupational Health, Security Plan, HVAC Performance Testing, etc.

Competency

- Are staff properly vetted in these policies and trainings?
- Ex. Biosafety competencies – working in a BSC, packing and shipping biological materials, exposure response procedures, spill clean up procedures

Questions?

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