Containment & Certification
Where the lines blur
containment - cost - environment

- 16th National Conference on Building Commissioning
- Michael L. Weiss PhD ABD
- April 23, 2008 / Newport Beach, CA.

standard commissioning non Containment

- concentration is found mainly on the mechanical, electrical and plumbing systems. more advanced projects look at envelope and consider that total building.
- a failure in the process does have cost and schedule impact but rarely affects more than the individual project.

Hypothesis

Commissioning when expanded to address bio safety concerns & certification strategies has become the leading model for Containment compliance delivery

- movement of change
  - Began with altruism & regulation
  - Energized because of conflicting guidelines, Complexity & Safety Concerns
  - NIAID
  - USDA
  - GMP facilities

CERTIFICATION

Definition...

the systematic review of all safety features and processes associated with the laboratory. This process assures that all reasonable facility controls and prudent practices are in place to minimize, to the greatest extent possible, the risks associated with laboratory operations and the use of bio-hazardous materials.

CERTIFICATION

- safety features and processes associated with the laboratory expand basic commissioning into intensive highly evolved and expanded process which incorporates numerous processes and safety programs which are mandated by Federal and Foreign Entities. The process incorporates both hard and soft systems previously not addressed.

CONTAINMENT - COST - ENVIRONMENT

Consequences of Failure in containment

- Hoof & Mouth Disease and the culling of the domestic herds in the UK was a direct consequence of a breach of containment in a bio-Containment facility
- In the United States breaches of containment and or protocols have inflected serious health consequences in the staff of major well know bio containment facilities

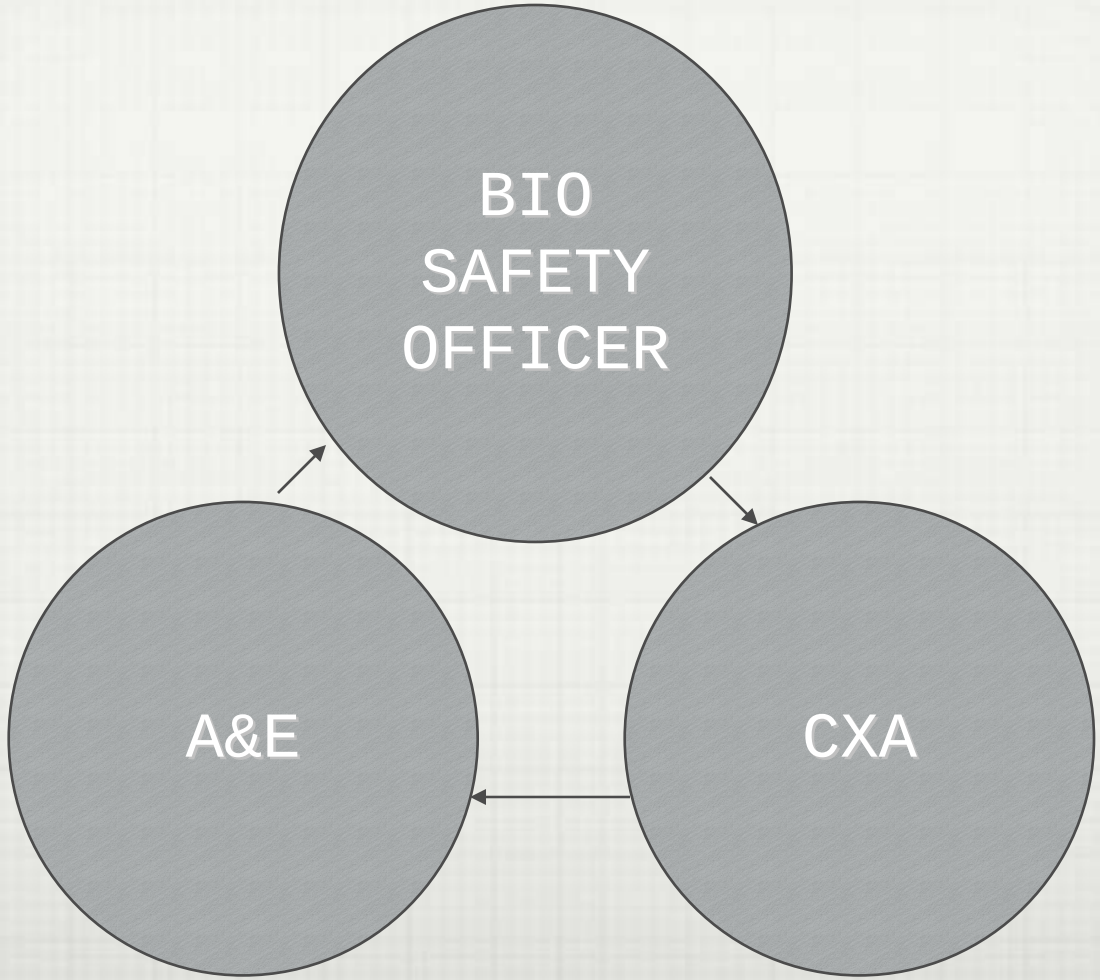
Consequences of Failure

- the Spanish Influenza outbreak of 1918 killed between 21-50 million humans world wide.
- Today researchers are using, altering, and modifying the 1918 strain in facilities across the united states
- a breach of containment in an animal facility can pose catastrophic loss to the domestic and wild animal populations, business and the environment

NIAID recommended Planning team

- Scientific investigators
- Occupational health & safety & or Bio Safety officer or responsible officer
- veterinarian / vivarium Manager
- laboratory /vivarium planner
- facilities engineer
- cost estimator
- commissioning authority
- fire protection engineer
- Peer review Panel

Preferred Model
Containment Work group



bio fact

- consider that a major design change after 35% dd will result in schedule delays and additional fees
- bio-containment design is a complex puzzle
  - community relations
  - Security
  - Environmental impact
  - site planning
  - science
  - biosafety
  - architecture engineering

OVERLOOKING AND NOT UNDERSTANDING ONE COULD HAVE MAJOR IMPACT ON THE PROGRAM

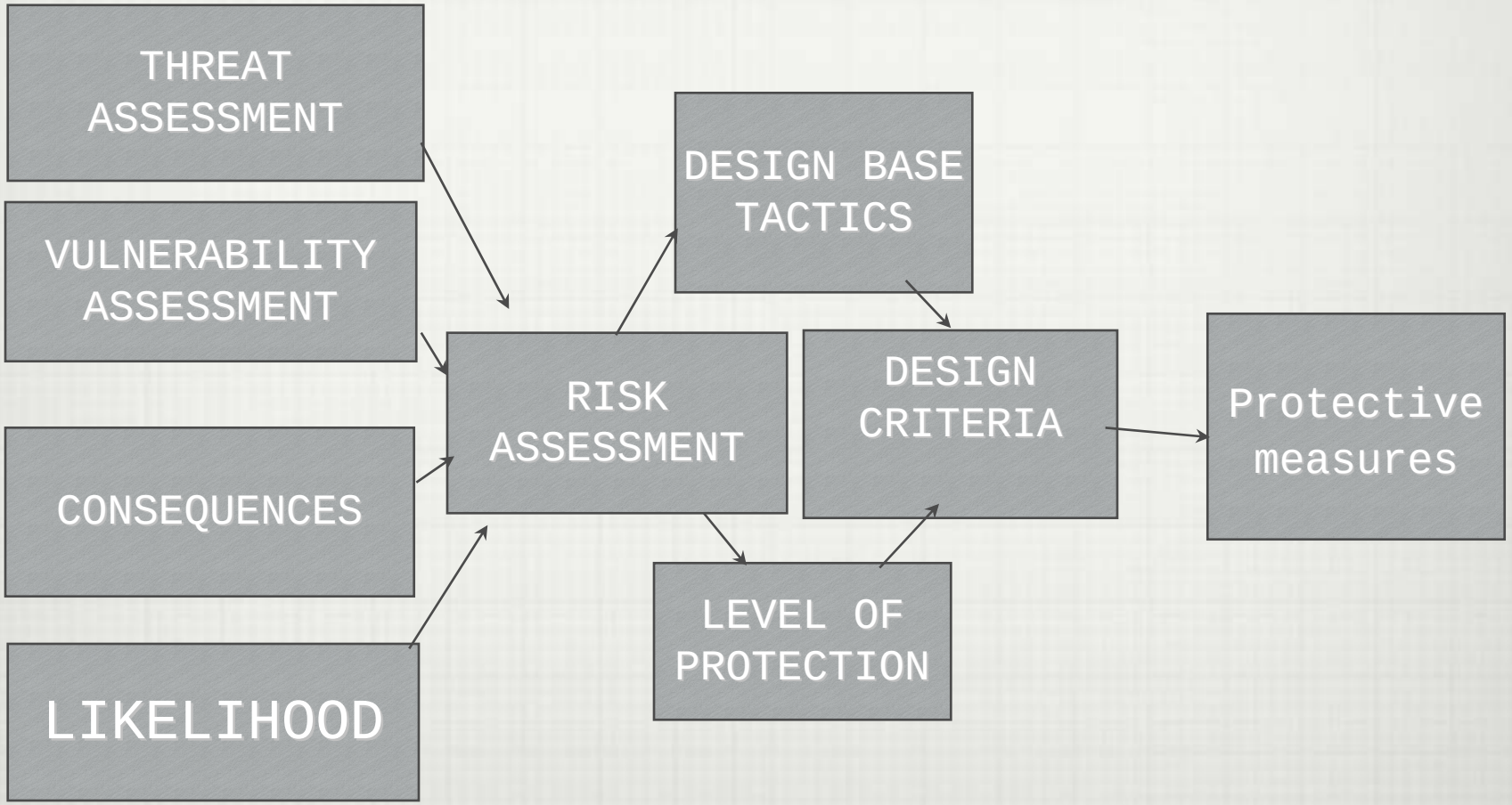
Critical Factors in bio-containment & commissioning

- community relations (NIMBY)
- threat & risk assessment- bio-security
- user expectations
- design requirements (bsl-3, 3e, 4, absl-3,4, 3AG)
- defining the science program
- Standard operating procedures design impact
- Scientific Equipment Selection
- Value Engineering
- Operations and Maintenance
- Project Cost

Threat Risk Analysis & Biosecurity

- The objectives of the TRA are:
  - to identify local, national and international threats that could compromise the safety of the general public, the environment, the security of the personnel, the research, and the facility.
- Objectives of biosecurity:
  - to protect pathogens from unauthorized and malevolent acts

Threat & Risk Assessment & Biosecurity



TRA & BIOSECURITY HAVE MAJOR IMPACT ON DESIGN

user expectations

- We don’t always speak the same language
  - Science- GMP= Good Manufacturing Practices
  - Construction= guaranteed maximum price
- a lack of understanding of biosafety principles and application leads to :
  - commissioning problems
  - maintenance issues
  - reliance on SOP’s as a design solution

defining the science program change is costly

- agents studied (Bsl-3,4 and usda agents, Avian influenza require more building infrastructure than TB
- staffing requirements (investigators, admin, animal care personnel, biosafety staff, O&M engineers, security personnel)
- Animal use (species, animal census, caging), multi-species vivarium will require additional infrastructure and cost more
- equipment requirements (aerobiology, imaging, microscopy etc.)
- Decontamination (autoclaving, effluent decon, gas decontamination, tissue digesters, etc).

standard operating procedures

- SOP’s should drive the design of your facilities not the other way around.
- SOP’s should not be a substitute for lack of design features

regulations certifications-commissioning

- CFR 42/PART 73/Patriot Act – April 19, 2005
- BioSafety in Microbiological and Biomedical Laboratories 5th Edition
- NIJ/ASCLD Forensics Laboratories Handbook
- USDA 242.1 ARS Facilities Design Standards
- NIH Guidelines for Research Involving Recombinant DNA Molecules EC
- EC Directive on the Contained Use of Genetically Modified Organisms
- Laboratory Biorisk Management Standard
- Directive on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work
- World Health Organization-Laboratory Safety Manual
- Health Canada

bio fact
consider yourself lucky

- when working on US projects their are up to 70 regulatory bodies which may/ could impact compliance and your project
- in the UK there are 270 health and safety regulatory compliance bodies

scientific equipment selection

- Evaluation of equipment type including options could save both space and cost, i.e. pass-through autoclave with decon port that could also serve as a fumigation room.
- Change/modification to selected scientific equipment could have major design and cost impacts:
  - Infrastructure
  - Size of existing travel path
  - Size of existing room
- Consider the implication of equipment options on design, operation and cost, i.e. Class III cabinet

value engineering

- Participate in the VE process
- make sure that the proposed be items are evaluated by the project team, not just the architect/engineer only.
- Understand the implications of the proposed VE items to the program and building operations, i.e. banking Hepa filers.
- Evaluate the impact of the proposed ve items on future use and flexibility

challenge assumption

- Why 100?
  - 100 FPM
  - 100% OA
  - 100 FC
  - Class 100
  - 100 PPM
- Consider as starting points not end points

bio fact
HEPA variations

Housing Type Options x3

Damper Options x3

Actuator Options x3

Filter Options X3

Redundancy Options (N, 2N, N+1) x3

Decon Options (BIBO, In Situ)x2

Filtr Frame Options (wood, AL, SS, Galv. Plastic)x5

Sealting Options (Gel, Gasket, DIN) x3

Filter Separation Options (Al separator, sep. less) x2

14,480 Variations

high containment certification

Appropriate site and protocol specific administrative controls and proper engineering controls are being used

- Personal protective equipment (PPE) is appropriate and undergoes regular inspection to maintain personal safety for the tasks being performed

- Decontamination systems for waste and other potentially infectious materials, including spill management, has been adequately considered and proper procedures are in place to mitigate environmental and personnel contamination

- Proper standard operating procedures (SOPs)

certification requirements

Administrative Controls	Engineering procedures	Bio-seal inspections
SOP	Document Retention	Decon Procedures
Maintenance	Evaluate Finshes	Room Layout and Equipment
Communication Systems	Emergency Equipment	Redundancy
Signage	Autoclaves	BSC Filters
Centrifuges	HVAC	Engineering Controls
Directional Airflow	Pressurization	Emergency Operations
Security	Interlocks	Alarms
Discharge assessment	ACR	BSC Certification
HEPA Validation	Effluent Decon	Sterilization
Caging	Vibration	Noise
Vacuum	Bio-haz Materials storage	Radioactive Use & Storage
Safety SOPs	Occupational Monitoring	Human Pathogen Registration
Select Agent Registration	Dual Use	DNA Registration

complexity and Containment facilities

- Depends on the type
  - BSL3 or 4, ABSL3 or 4, BSL2+ or 3+,

    ABSL 2+ or 3+
  - Animal / non-animal
  - Species (if animal)
  - Agent(s) to be handled
  - Aerosolized or non-aerosolized agent(s)
  - Multi-agent / multi-specie / multi-protocol

operations and maintenance

- containment vs maintenance
- special requirements by outside utility vendors
- existing institutional standards and operational procedures impact on equipment selections and SOP’s
- Security requirements
- fire department access

what is the impact on
containment - cost - environment?

- Operations
  - Space conditioning
  - Protocol compliance
  - Maintenance
  - System(s) performance

lessons learned
absolutely avoid absolutes

- All codes & regulations vs. all **applicable** codes & regulations
- No (zero) settlement, movement, noise transfer, etc.
- All, any, every, never, none…….

complexity

- The more complex a facility the more unusable it becomes
- If it is too hard to comply then compliance will be compromised (door wedges)
- Design should strive to achieve simplicity
  - In use
  - Operation
  - Flow
  - Security
- KISS (not the heavy metal band)

> THE ABILITY TO SIMPLIFY MEANS TO ELIMINATE THE UNNECESSARY SO THAT THE NECESSARY MAY SPEAK.”
> - HANS HOFMANN, PAINTER (1880-1966)

myth of “more is better”

- Over sized
- Over ventilated
- Over flexible
- Over redundant
- Over secure
- Over stiff
- Over designed

case study

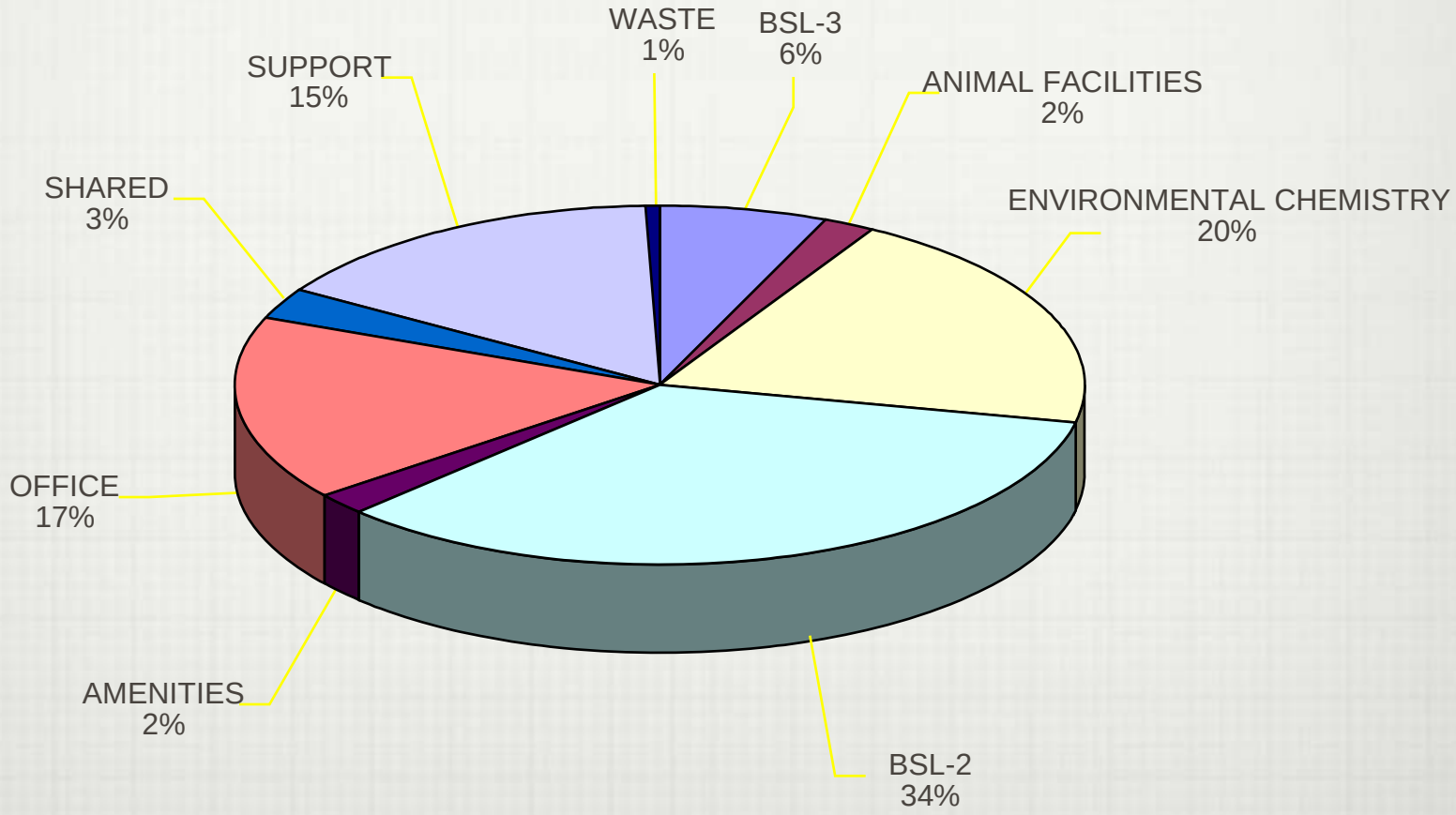
New Jersey Public Health, Environmental and Agriculture Laboratory

project status

- Location: West Trenton, NJ
- Gross SF: 200,000
- Net SF: 116,000
- Efficiency 58%

- Construction Budget: $118,900,000
- Current Cost Estimate: $118,900,00
- Phase: Construction
- Completion Date: Q1 2010
- Mid Point Construction: Q1 2009

program breakdown - NJPHEAL



size right – right size

- Program
- Criteria
- Redundancy
- Energy systems
- Fume hood diversity
- BSC
- Freezer storage centralized vs. de-centralized ultra low’s

The Goldilocks Moment

How do we get to: *“….this one is just right!”*

- Intelligence
- Challenge
- Think differently

“We can't solve problems by using the same kind of thinking we used when we created them.” -
Albert Einstein, physicist, Nobel laureate (1879-1955)

Conclusion

Challenge:

- The status quo
- Rules of thumb
- Regulated criteria
- “The way we have always done it!”

the success of a containment project will depend on...

- strong community relations
- team consideration of the total project approach and effective communications
- Timely dissemination of scientific requirements and SOP’s
- Participation of user in the ve process
- consideration of total project cost

Questions and Answers

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