WHY DO BIOCONTAINMENT FACILITIES FAIL?





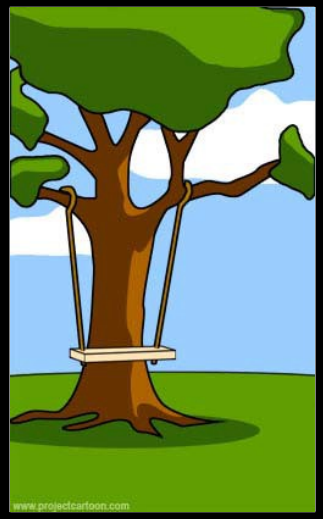

October 5, 2016

MERRICK & COMPANY

Engineering | Architecture | Commissioning | Design-Build | Surveying | GeoSpatial Solutions

PROJECTS . . .

As explained by the user

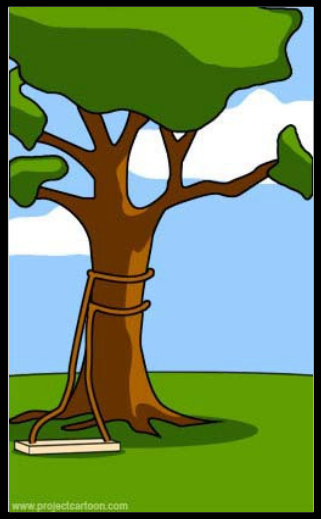


As understood by the project manager

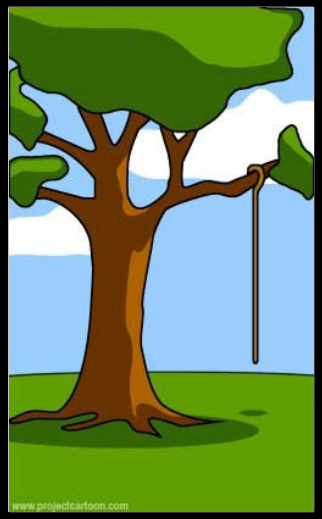
As the idea was presented for funding

As presented to the user

As designed by the architect



As interpreted by the engineer



As the contractor built

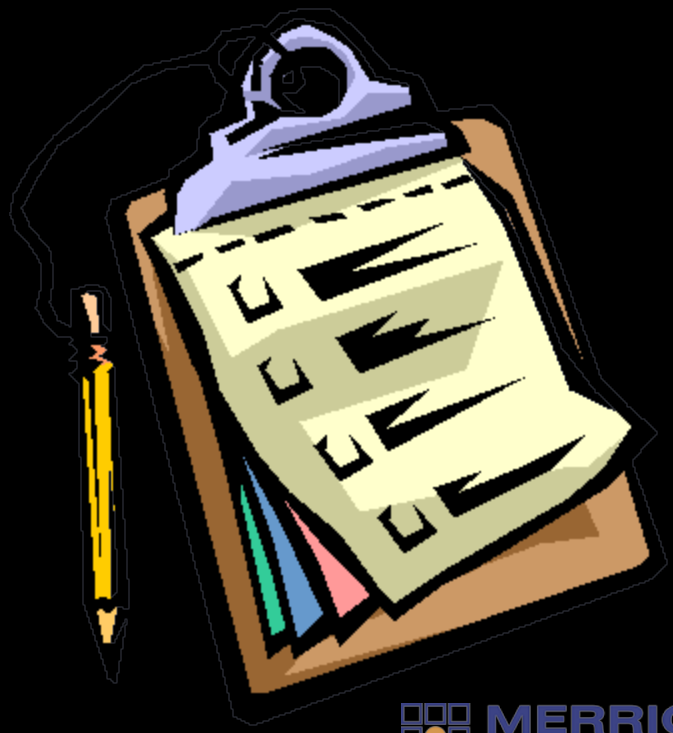
What the users really wanted and needed

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

Common causes of lab failure occur during:

1. Planning/Programming Issues
2. Experience Issues
3. Procurement Methods
4. Commissioning Issues
5. Maintenance Issues



MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

1. Planning/Programming Issues

-Limited pre-planning of the project

-Determine:

Scope (needs & wants)
Budget
Schedule

-DON’T SKIMP HERE!

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

1. Planning/Programming Issues

-Project Requirements
- Size
- Pathogens
- Risk analysis
- Biosafety Level(s)
- Redundancy

-Funds do not match the program of the project
- Revise . . .

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

1. Planning/Programming Issues

-Planning team does not have skill or knowledge of containment that is required.

Engage experienced planners

Consult colleagues

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

1. Planning/Programming Issues

-Starting a project without full program identified.
- Rush to start
- Costly mistakes can be made
  - changes
  - delays
  - budgetary issues arise

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

2. Experience Issues

-Owners may have no experience building a high containment lab.

- High expectations
- Higher than expected costs
- Extend construction time

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

2. Experience Issues

-Biosafety officers and users not included in the planning.

Project personnel don’t understand the need for BSO

Risk assessment direct funds to the lab requirements

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

2. Experience Issues

-Design team not experienced in containment labs.

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

2. Experience Issues

-Contractors may have no experience building a containment lab.

.

WHY DO BIOCONTAINMENT FACILITIES FAIL?

3. Procurement Methods

-No prequalification of bidding contractors.

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

3. Procurement Methods

-Lowest bid by any contractor.
Institution policies
Legal requirements

MERRICK® & COMPANY

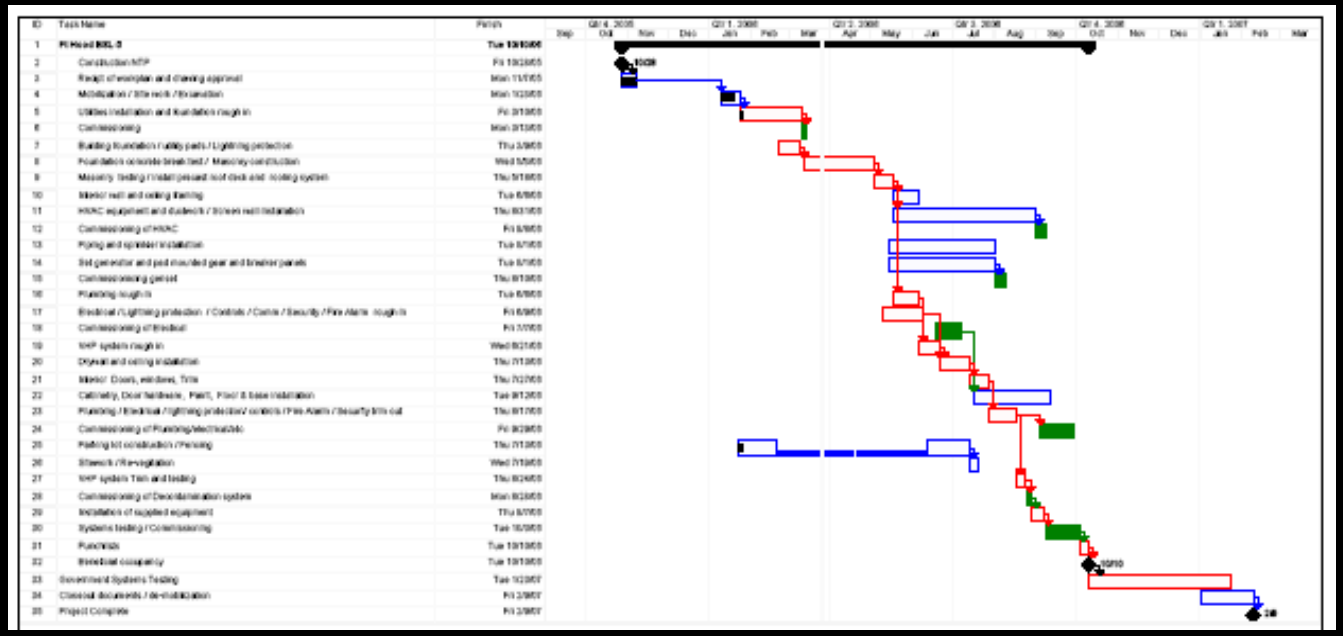
WHY DO BIOCONTAINMENT FACILITIES FAIL?

3. Procurement Methods

-Contract funding extends only to initiate the project and not for the full project completion.

Funds to start the project

Limited funds to complete

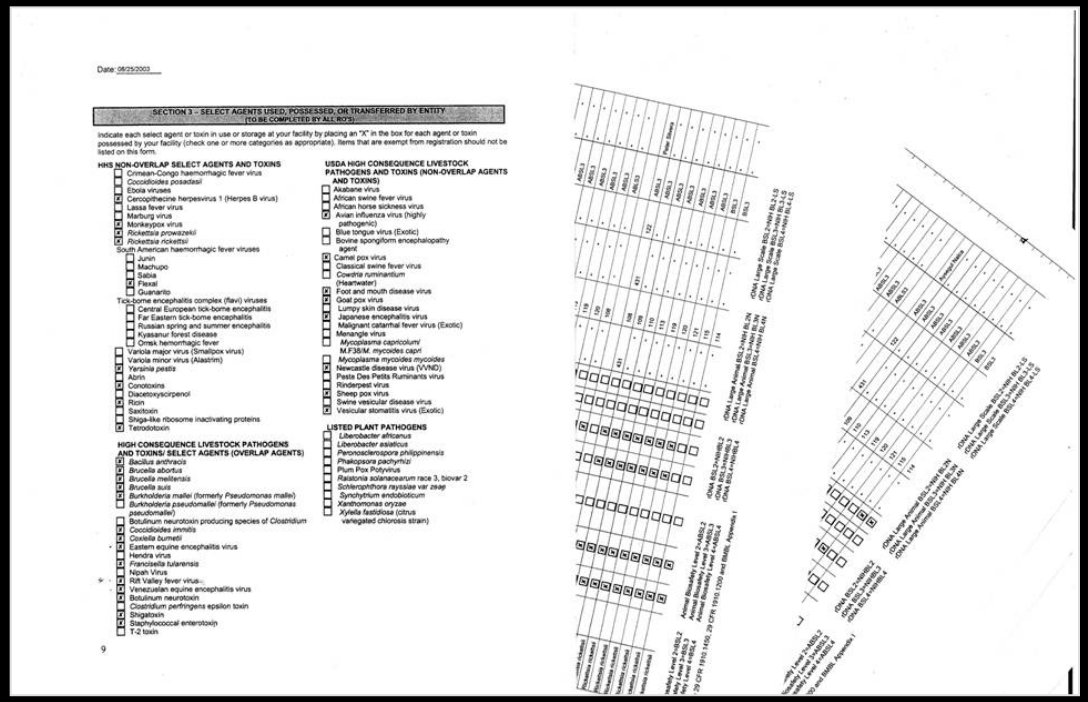


MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

4. Commissioning (Cx) Issues

-Not starting early in project



Date: 08/25/2003

SECTION 3 – SELECT AGENTS USED, POSSESSED, OR TRANSFERRED BY ENTITY
(TO BE COMPLETED BY ALL RO'S)

Indicate each select agent or toxin in use or storage at your facility by placing an "X" in the box for each agent or toxin possessed by your facility (check one or more categories as appropriate). Items that are exempt from registration should not be listed on this form.

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- Crimean-Congo haemorrhagic fever virus
- *Coccidioides posadasii*
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- *Rickettsia prowazekii*
- *Rickettsia rickettsii*
- South American haemorrhagic fever viruses
  - Junin
  - Machupo
  - Sabia
  - Flexal
  - Guanarito
- Tick-borne encephalitis complex (flavi) viruses
  - Central European tick-borne encephalitis
  - Far Eastern tick-borne encephalitis
  - Russian spring and summer encephalitis
  - Kyasanur forest disease
  - Omsk hemorrhagic fever
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- Botulinum neurotoxin producing species of *Clostridium*
- *Coccidioides immitis*
- *Coxiella burnetii*
- Eastern equine encephalitis virus
- Hendra virus
- *Francisella tularensis*
- Nipah Virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxin
- *Clostridium perfringens* epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxin
- T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- *Cowdria ruminantium* (Heartwater)
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Exotic)
- Menangle virus
- *Mycoplasma capricolum/ M.F38/M. mycoides capri*
- *Mycoplasma mycoides mycoides*
- Newcastle Disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

- *Liberobacter africanus*
- *Liberobacter asiaticus*
- *Peronosclerospora philippinensis*
- *Phakopsora pachyrhizi*
- Plum Pox Potyvirus
- *Ralstonia solanacearum* race 3, biovar 2
- *Schlerophthora rayssiae var zeae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*
- *Xylella fastidiosa* (citrus variegated chlorosis strain)

9

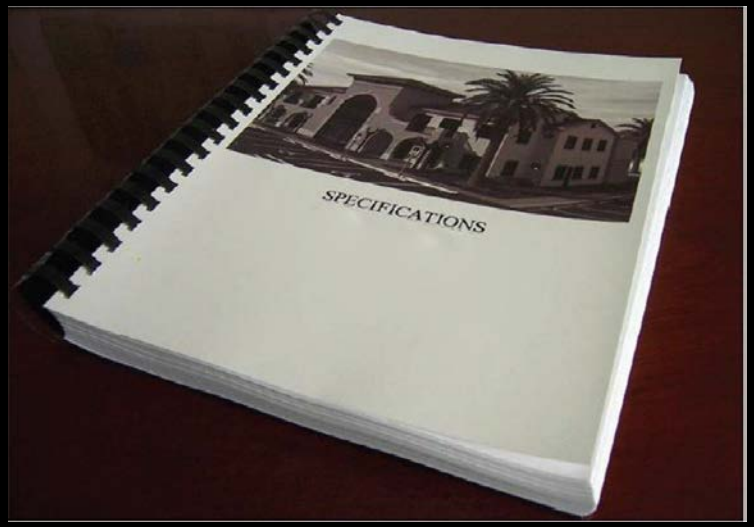
MERRICK & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

4. Commissioning (Cx) Issues

-Contract specifications do not support the commissioning process or show requirements of the contractor.

Commissioning activities not written into the contract documents



MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

4. Commissioning (Cx) Issues

-Contractor does not know or does not support Cx
Time and effort requirements to assist Cx not identified

MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

4. Commissioning (Cx) Issues

-Issues found during Cx work resolved slowly or not at all.

Major impact on schedule

Possible failure of lab to operate at desired containment levels

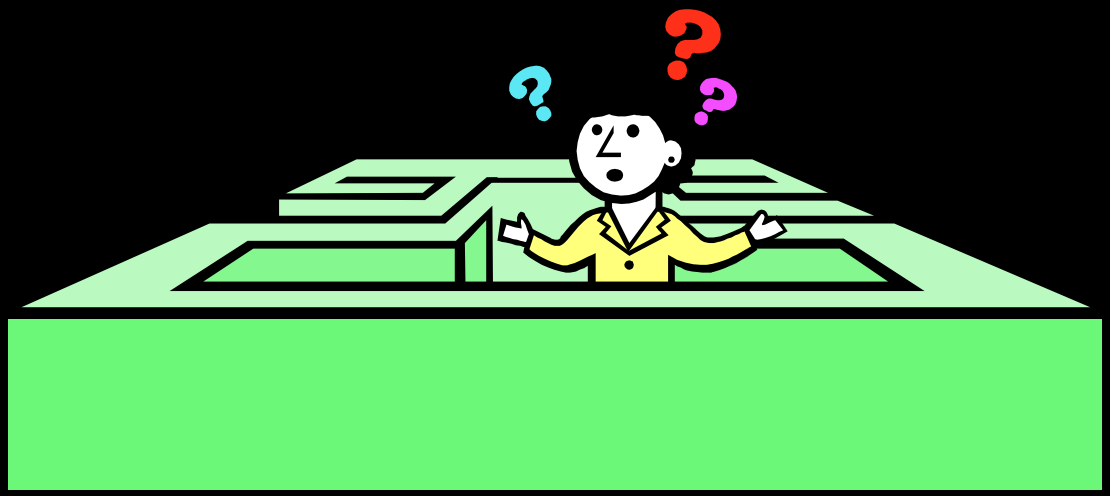
MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

5. Maintenance Issues

-Limited or no maintenance budget

Possibly among the highest cost builds to operate; energy and staffing



MERRICK® & COMPANY

WHY DO BIOCONTAINMENT FACILITIES FAIL?

5. Maintenance Issues

-Poorly trained maintenance staff
Containment requirements
Fear of the unknown

MERRICK® & COMPANY

OPPORTUNITIES FOR SUCCESSFUL BIOCONTAINMENT LABORATORIES

Lessons Learned:

1. **Invest in the planning stages and the feasibility studies for the project. Conduct risk assessments to determine the fundamental biosecurity and biosafety requirements (is a BSL -x necessary?)**

2. **Work with a multidisciplinary team with expertise in biocontainment and biosafety. (Consultants , BSO, PIs, other users)**

3. **Clarify guidelines and regulations required.**

4. **Contract prequalified and preselected design and construction partners. Emphasis should be given to the experience and technical competence rather than the lowest price.**

MERRICK® & COMPANY

OPPORTUNITIES FOR SUCCESSFUL BIOCONTAINMENT LABORATORIES

Lessions Learned:

5. **Provide for permanent technical presence on site during construction to monitor, coordinate, and solve problems.**

6. **Implement commissioning at the beginning of the project.**

7. **Implement an Operation & Preventive Maintenance program.**

8. **Implement a recommissioning program.**

Joby Evans, PE, CxA, CAC

Joby.evans@merrick.com

o: 404-789-2715
c: 404-805-7558

Merrick & Company
160 Clairemont Ave
Suite 600
Decatur, GA 30030

MERRICK® & COMPANY