SAND2011-1041C

Intercountry Training Workshop on the Principles and Practices of Biosafety in Influenza Laboratories

Casablanca, Morocco
February 21-24, 2011

International Biological Threat Reduction,
Sandia National Laboratories, USA

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Risk Assessment

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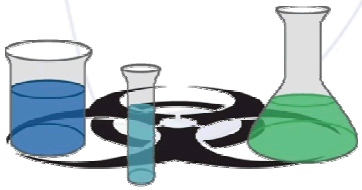

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Why Risk Assessment?

- **Laboratory Biosafety**

  A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent

- **Laboratory Biosecurity**

  A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm

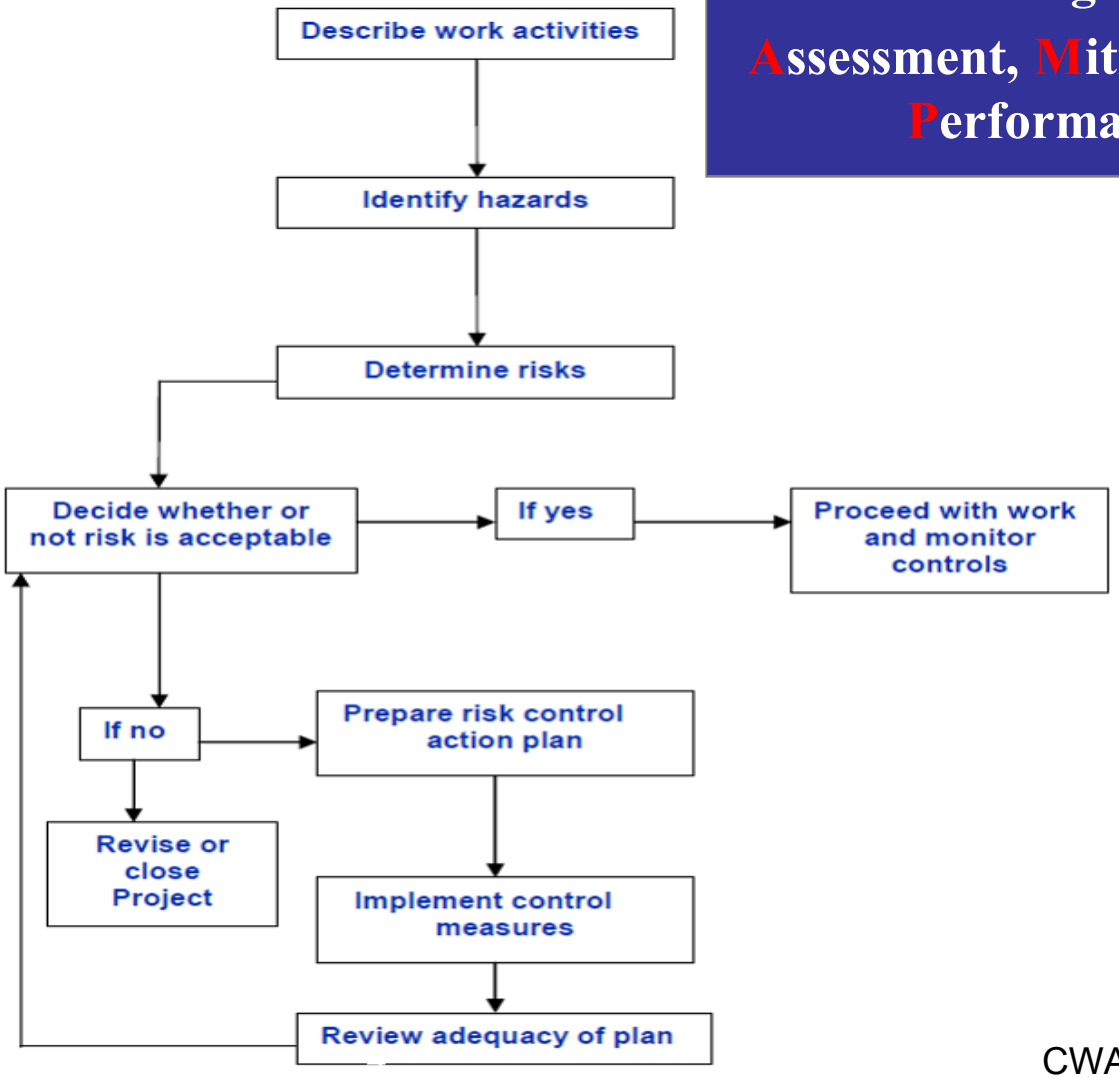
- **Identification of preventive measures is determined by the RISK ASSESSMENT**

Why Risk Assessment?

- Identify preventive measures used for laboratory biosafety
- Identify preventive measures used for laboratory biosecurity
- Use one post-it for each of your ideas

Risk Governance Strategy:

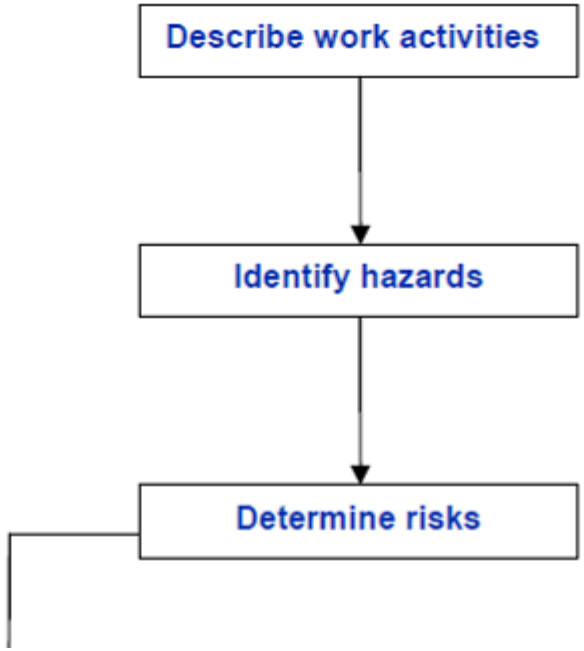
Biorisk Management = Assessment, Mitigation, Performance



CWA:15793

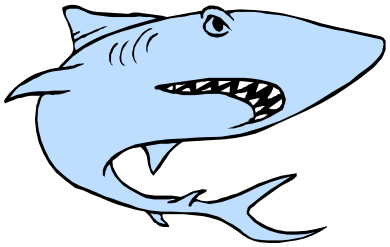
Biorisk Management =

Assessment, Mitigation, Performance



What is a hazard?

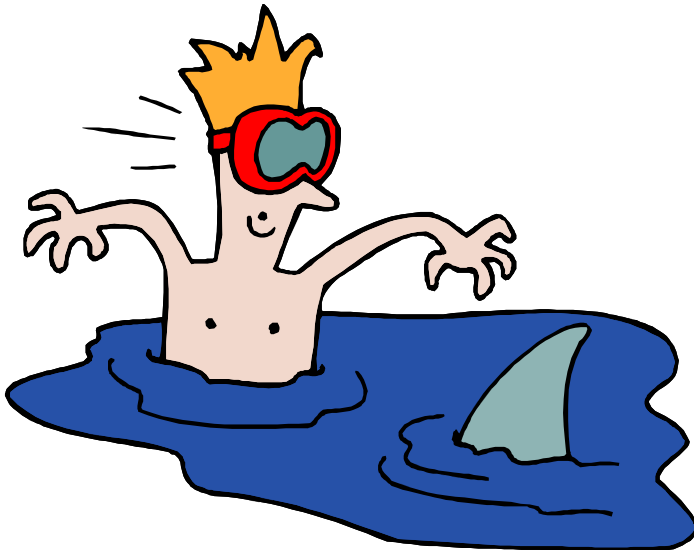
- **Hazard** is a source or object that can cause harm



- **Hazard** is not a risk without a specific environment or situation

How do you determine risk?

- Risk is the likelihood of an event with a hazard (or a hazard and threat) that has consequences



- **In your group, conduct a biosafety risk assessment based upon the provided case studies.**
  - Identify the factors that influence the likelihood of the risk. What are the routes of infection? What are the possible routes of exposure?
  - Identify the factors that influence the consequences of the risk. What are the consequence of disease and to whom?
  - Is this risk high, moderate, or low? Why?

What would be different if the risk was the laboratory's work being stolen by an outsider?

What is the hazard now?

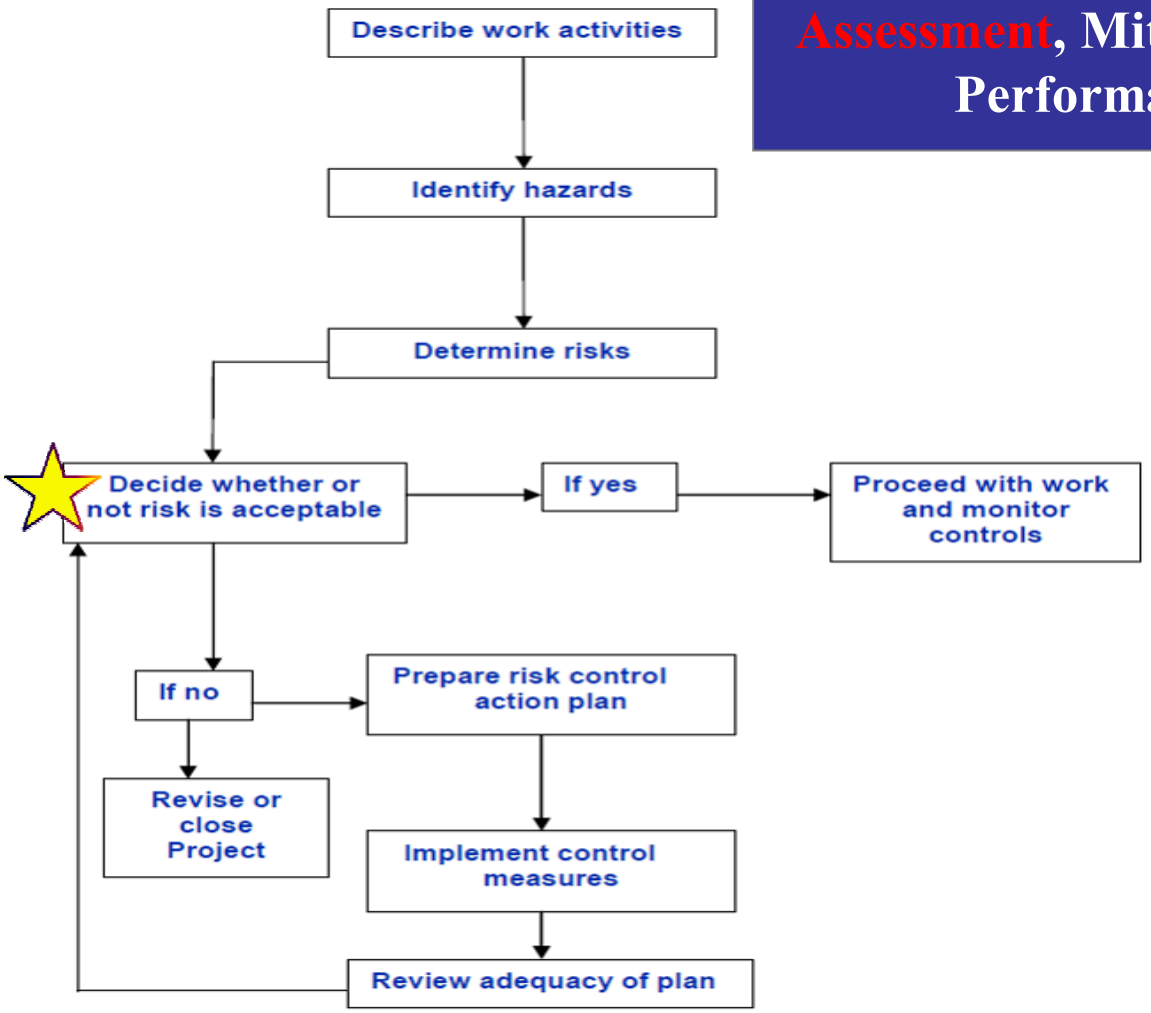
Hazard, Threat, and Risk

- A **hazard** is a source or object that can cause harm

- *A **threat** is a person who has intent to cause harm to other people, animals, or the institution*

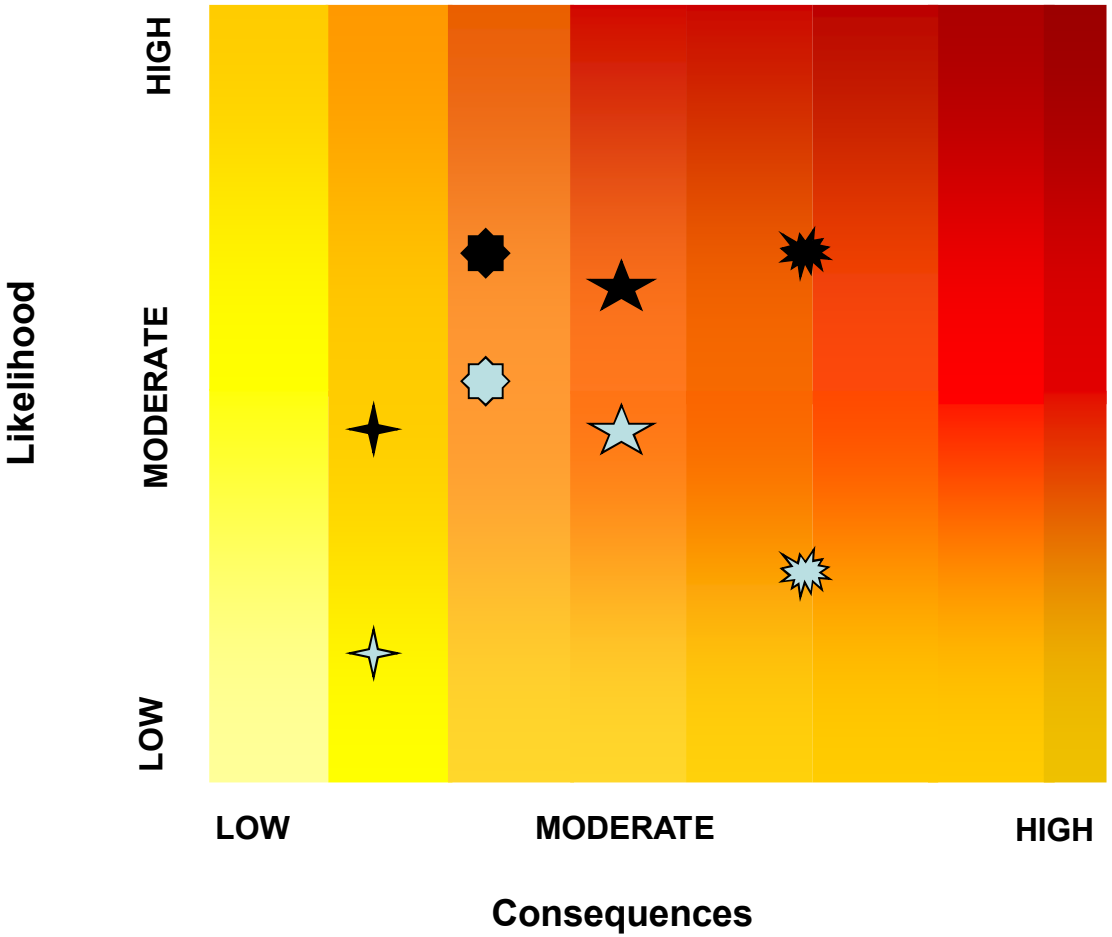
- A **risk** can be based on either a hazard, or a hazard and a threat

Biorisk Management = Assessment, Mitigation, Performance



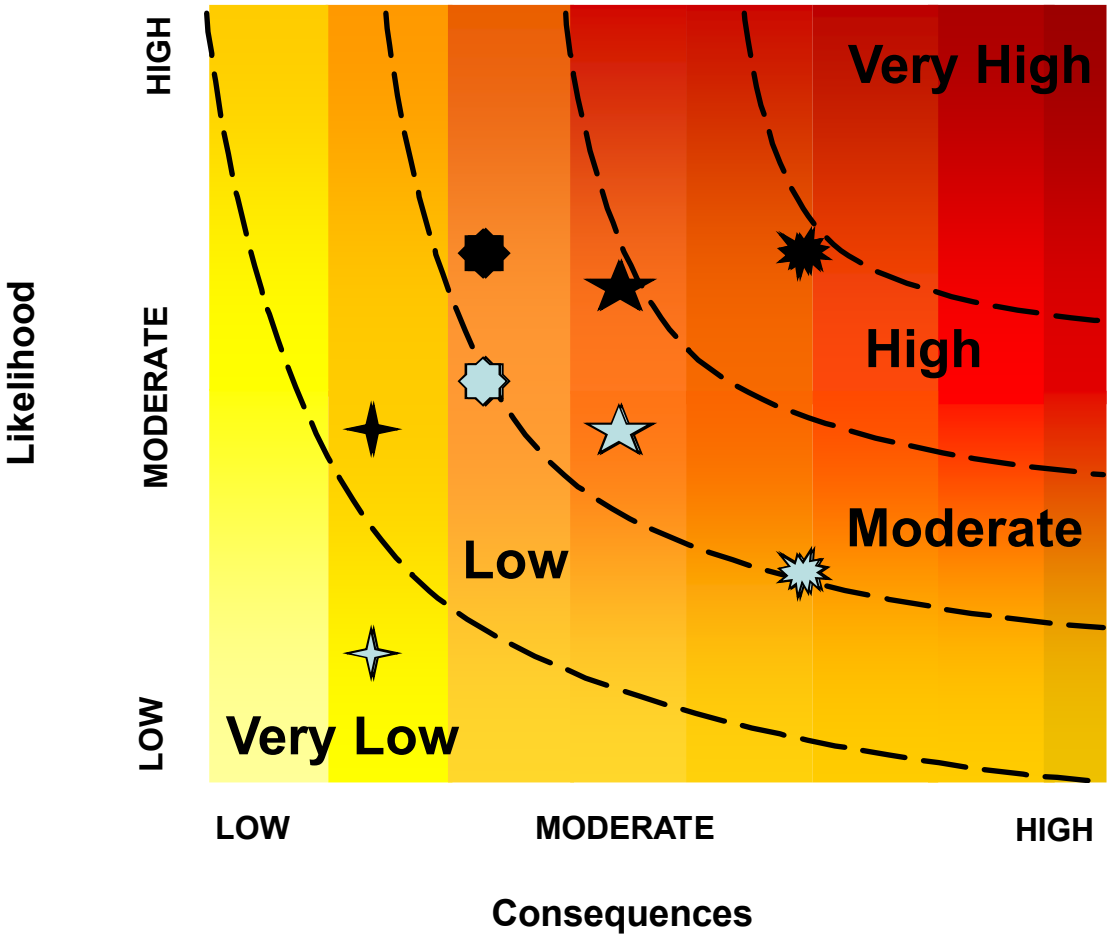
Risk Characterization

- **Evidence-based**



Risk Characterization

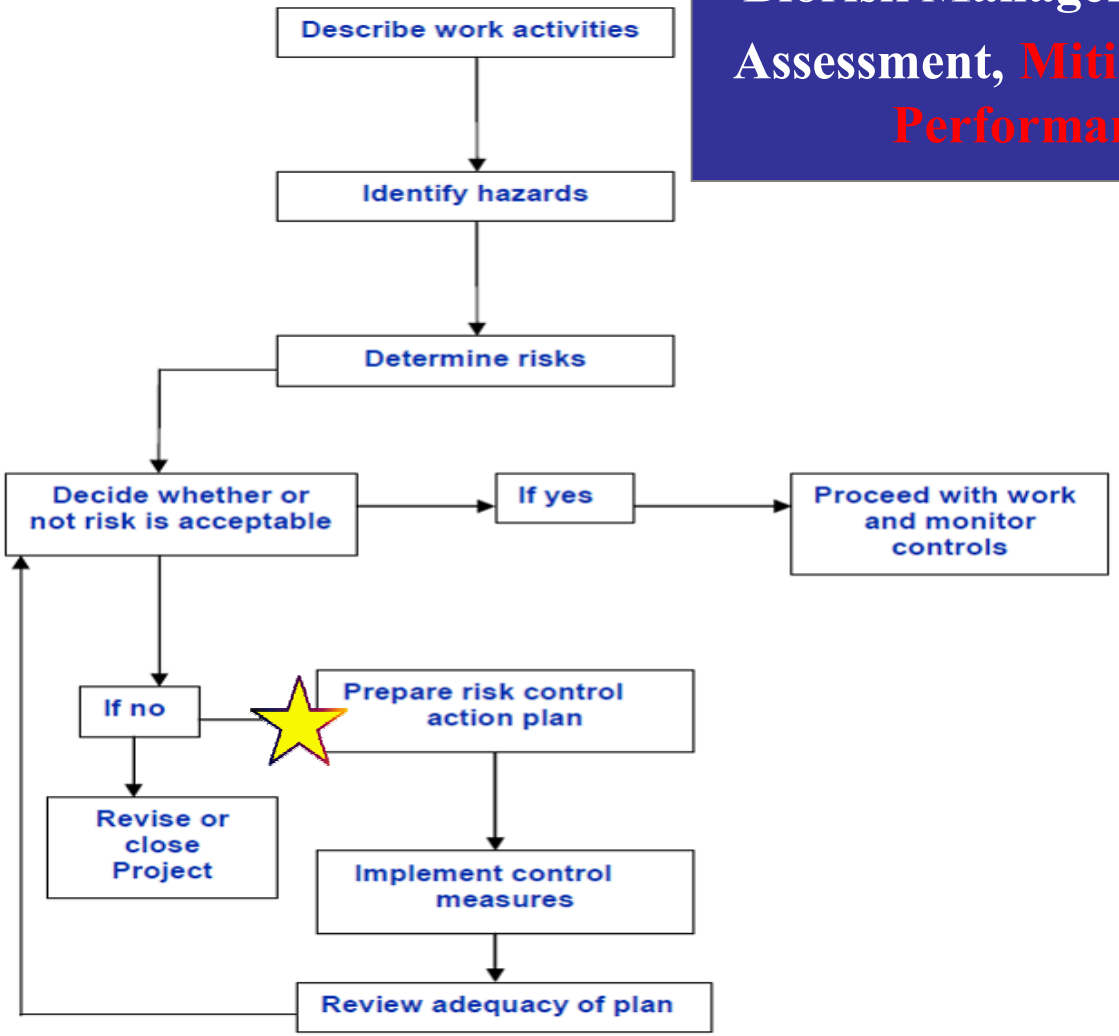
- **Value based: what is acceptable?**



Protect against unacceptable risk scenarios

Develop incident response plans for acceptable risk scenarios

Biorisk Management = Assessment, Mitigation, Performance



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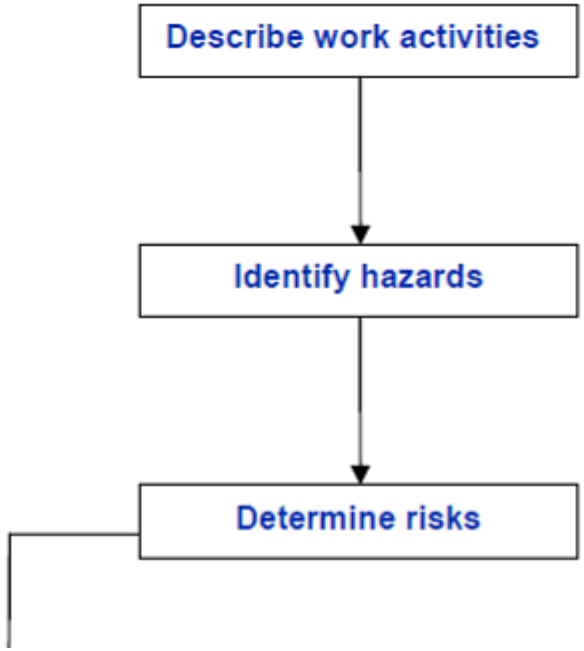

Risk Assessment: Small Group Activity

- **Consider the scenario you have been given**
  - Define the risks in this scenario
- **Choose one risk to assess**
  - Define the hazard and/or threat
  - What is the risk of this scenario?
    - **High, medium, low?**
- **Report to the class**

Summary

- Assessing the risk and determining likelihood and consequence will allow for strategic decisions on control measures
- Ideally we will consider first elimination or substitution
- A combination of control measures should be used based on their effectiveness and our ability of implementation

Awareness and Implementation of CWA 15793:2008

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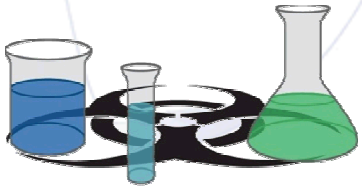

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What is a Biorisk Management Program?

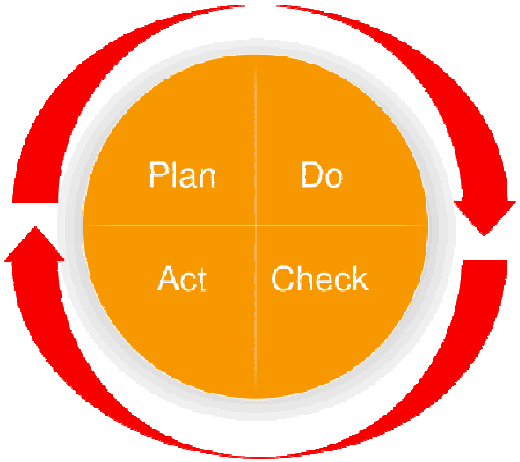
- **Program management: The process of managing several related projects, often with the intention of improving an organization's performance-*Wikipedia***
- **Biorisk management program: A laboratory program that seeks to effectively and efficiently manage an institutions biorisks**
  - Defines management practices for biosafety and biosecurity, location of the hazards, biological agents and their products
  - Establishes systems and policies to manage the laboratory biorisk
    - **Resources, institutional guidelines and operating procedures, training programs and oversight**
  - Integral in the day-to-day operations of the institute / organization, both in normal times and times of emergency

Why establish a Biorisk Management Program?

- **To provide assurance that risk is being managed effectively and proportionately**
- **To identify, assess and manage risks in a structured way using recognized approaches with reasonable controls that are proportionate and appropriate to the risk**
  - To understand risks
  - To demonstrate that risks are identified
  - To ensure risk is managed responsibly by management
  - To ensure that a system is in place to identify and manage risk on an ongoing basis

Requirements of a Management System

- **In a management system, all aspects of a PDCA cycle have to be addressed:**
  - Structured approach for achieving objectives and goals
  - Based on identified tasks and controls
  - Defined roles and responsibilities
  - Documented for reference and change control
  - Competence requirements, including on-going development
  - Records of controls, competence and performance

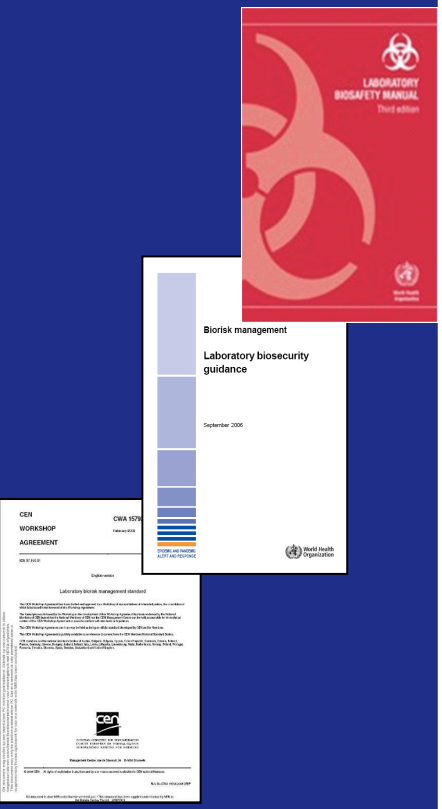


How can a Biorisk Management Program be utilized?

Opportunity to use as a basis for:

- Good biosafety and biosecurity practices and guidance
- Regulatory support and basis for new or revised legislation
- Framework for biorisk management systems
- Audits and inspections
- Customised protocols and other tools
- Certification and accreditation activities
- Support for funding
- International collaboration and recognition
- Training

International Laboratory Biorisk Management Documents



- **Technical: World Health Organization**
  - Laboratory Biosafety Manual (2004)
  - Biorisk Management: Laboratory Biosecurity Guidance (2006)

- **Management: CEN Workshop Agreements**
  - CWA 15793 Laboratory Biorisk Management Standard
  - CEN WS 55 – CWA 15793 Guidance Document (under development)
  - CEN WS 53 – Biosafety Professional Competence

What is CEN?

- **CEN = Comité Européen de Normalisation**
- **CEN has 30 national members**
- **CEN members produce technical specifications, technical reports, and European Standards (EN)**

- **CEN Workshop Agreements (CWA) produced by**
  - Any interested parties
  - Consensus documents
  - Valid for 3 years
    - **Withdraw, renew, amend, or convert (CEN Technical Specification, European standard, or ISO standard)**

CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards such as**
  - ISO 9001 / 14001 and OSHAS18001
- **The Standard is performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization
- **Does not replace national regulations**
  - Compliance with regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs

Purpose of the CWA 15793:2008

- **The Standard is used for:**
  - Improving overall laboratory biorisk performance
  - Increasing awareness and the adoption of performance approaches for biosafety and biosecurity
  - Effective management of complex laboratory safety and security processes
  - Improving international laboratory collaboration and safety harmonization
  - Basis for new or revised legislation or regulations
  - Support laboratory certification/accreditation, audits/inspections

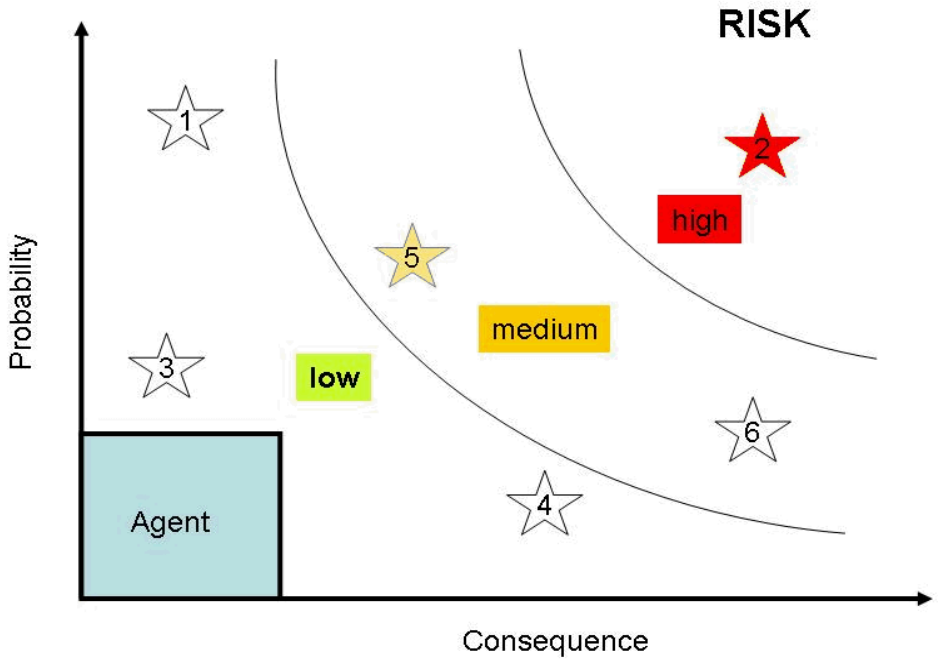
CWA 15793:2008

- **International Approach**
  - Extensive definition section
  - Not country specific
  - Based on international, acceptable best practices
  - Local solutions possible
  - The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

Topics Covered in CWA 15793

- **Examples**
  - Biorisk Management Policy
  - Planning for hazard identification, risk assessment and risk control
  - Roles, responsibilities and authorities
  - Personnel training, awareness and competence
  - Operational Control
  - Inactivation of biological agents and toxins
  - Emergency response and contingency plans
  - Checking and corrective action
  - Performance measurement
  - Records, document and data control
  - Inspection and audit

Risk Assessment



Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- **The standard is not a technical document**
- **Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives**
- **Provides Biorisk management framework for the day-to-day functions of the institute / organization**
  - **During normal operations and times of emergency**

Key Differences

Content & Requirements	CWA 15793	BMBL, LBM etc.
PDCA	yes	no
Management Policy	yes	no
Roles & Responsibilities	yes	minimal
Comprehensive Risk Assessment	yes	minimal
Performance Objectives	yes	none
Performance Measurements (Audits)	yes	Minimal or limited to local regulations
Document Control	yes	Limited to local regulations
Accredited Certification		no
Technical Biorisk Details	no	yes

Reasons for Implementing CWA 15793

- **Enables organizations to:**
  - Establish and maintain a biorisk management system to control or minimize risk to acceptable levels to employees, the community and others
  - Provide assurance that the requirements are in place and implemented effectively
  - Provide a framework that can be used as basis for training and awareness raising
  - Seek and achieve certification or verification by an independent third party

- **Document available on CEN website**

  ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf
- **Development of a "Guidance Document"**
  - Kick-off meeting in Brussels, Feb 2010
  - Seoul Korea, June 2010
  - Atlanta GA USA, Dec 2010
- **Training and education seminars and workshops**

Sterilization, Decontamination and Waste Management

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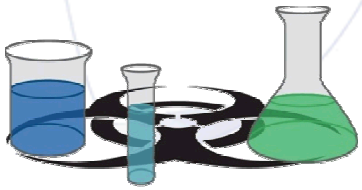

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Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

AMP Model

Biorisk Management

Assessment Mitigation Performance

- **What kinds of waste exist in the laboratory?**
  - Write one type of waste per *post-it note*

- **Categorized the waste into groups**
  - What are the risks for each of the categories of waste you determined?

Definitions

- **Sterilization - act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms**
- **Disinfectant - an agent, usually chemical, that inactivates viruses or kills vegetative microbes**
  - Removes ability (or disables) ability to infect
- **Antiseptic - a substance that prevents or arrests the growth or action of microbes, either by inhibiting their activity or by destroying them**
  - Septic – containing disease causing organism, anti - remove
- **Decontamination - disinfection or sterilization of contaminated articles to make them suitable for use**
  - Remove contamination
- **Sanitizer - an agent that reduces the numbers of vegetative bacteria only**

Decontamination is part of Biosafety Level Requirements

Table 3. ***Summary of biosafety level requirements***

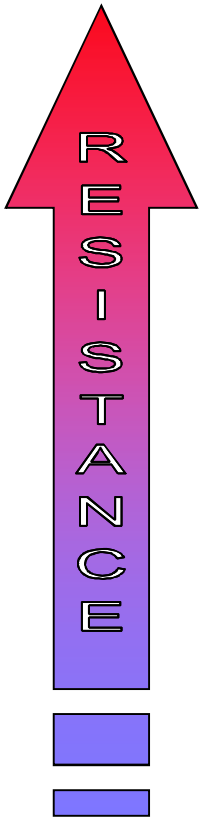
	BIOSAFETY LEVEL			
	1	**2**	**3**	**4**
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

- **How in a typical laboratory do you sterilize? (Discuss in your group methods you use and write them on your flip chart)**
  - Also discuss key considerations, concerns, and validation methods.
- **How in a typical laboratory do you disinfect? (Discuss in your group methods you use and write them on your flip chart)**
  - Also discuss key considerations, concerns, and validation methods.
- **How in a typical laboratory do you decontaminate? (Discuss in your group methods you use and write them on your flip chart)**
  - Also discuss key considerations, concerns, and validation methods.

Class Activity: Choosing Disinfectants

- **The disinfectant needs to be appropriate for the biological agent of interest**



Prions
Bacterial spores
Coccidia (*Cryptosporidium*)
Mycobacterium
Nonlipid viruses
(*e.g.* hep A, polio)
Fungi
Rickettsiae, chlamydiae
Vegetative bacteria
Lipid-containing viruses
(*e.g.* HIV)

- **Complete the table on selecting a disinfectant and be prepared to discuss your answers**

Handling Dangerous Pathogens in BSL2 and BSL3 Laboratories

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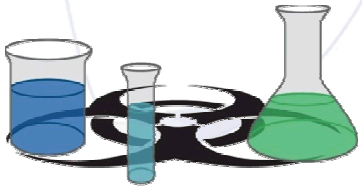

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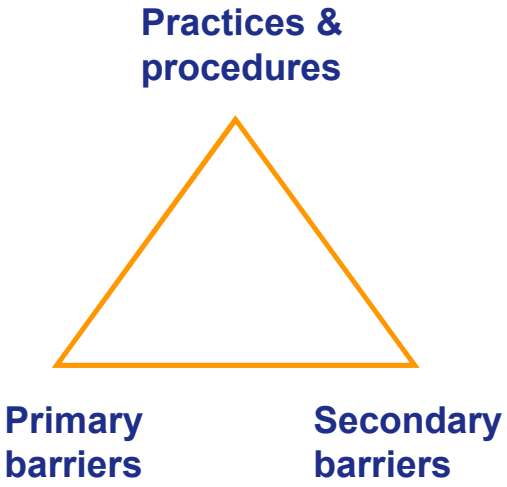
Components of Biosafety

- **Primary Containment Barriers (safety equipment)**
  - The protection of personnel and the immediate laboratory environment from exposure to infectious agents
- **Secondary Containment Barriers (engineering & architectural controls)**
  - The protection of the environment external to the laboratory from exposure to infectious agents
- **Practices and Procedures (administrative controls)**
  - The protection of personnel and the environment through proper practices and procedures

Biosafety Levels

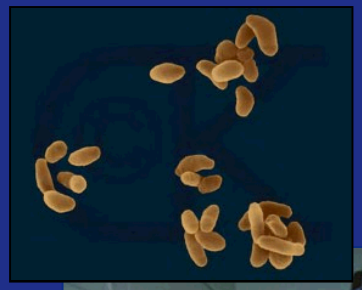
- **Biosafety Levels**
  - Four biosafety levels provide increasing degrees of protection
  - What's the right balance of practices & procedures, primary barriers and secondary barriers?

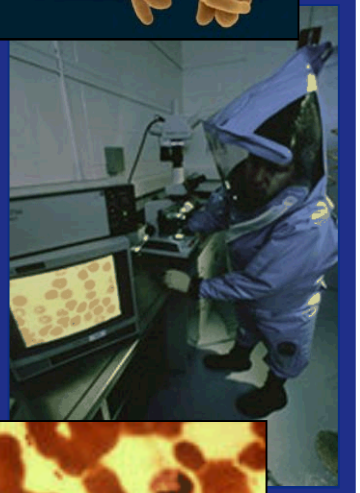


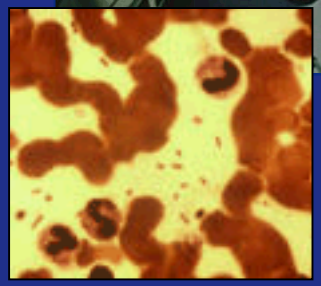
- **Rearrange your preventive measures post-its into the three elements of biosafety**
- **Report out to the class**

Laboratory Biosafety and Biosecurity

Francisella tularensis







Yersinia pestis

- **Laboratory Biosafety:**

  A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological hazard

- **Laboratory Biosecurity:**

  A set of preventive measures designed to reduce the risk of intentional removal (theft) of a valuable biological material

- **Common strategy:**

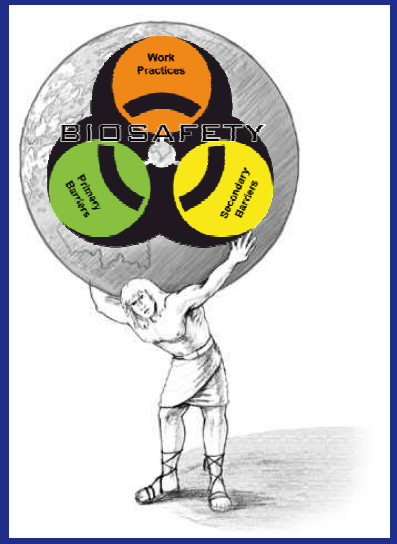
  Implement graded levels of protection based on a risk management methodology

Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:

- ✔ Increased focus on "awareness" to change current culture
- ✔ Clarify terminology
- ✔ Development of targeted "training strategies"
- ✔ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✔ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

Laboratory Biosecurity Supports Laboratory Biosafety

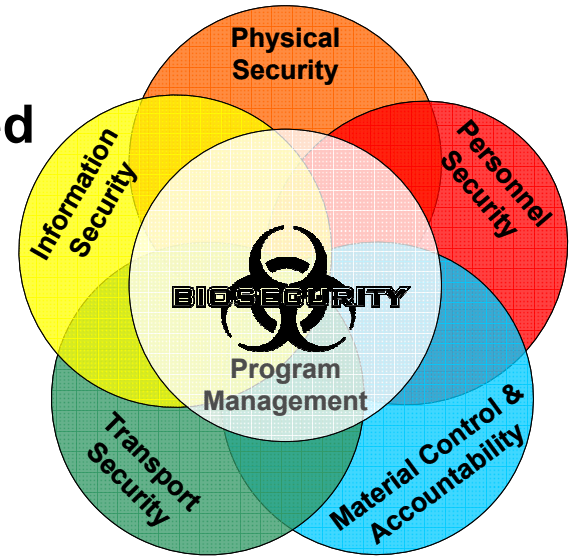


- **Laboratory biosecurity supports laboratory biosafety**
  - Limits the number of individuals who may be exposed to the hazards
  - Limits access to those who are professionally qualified and properly trained to be there
  - Access control procedures and records can be used to support investigations of laboratory safety or security incidents

Elements of a Biosecurity System

- **Biosecurity system components**
  - Physical security
  - Personnel security
  - Material handling and control measures
  - Transport security
  - Information security
  - Program management practices

- **Each component implemented based on results of risk assessment**



- **Rearrange your preventive measures post-its into the six elements of biosecurity**

- **Report out to the class**

Elements of Laboratory Biosecurity

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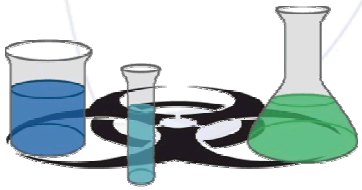

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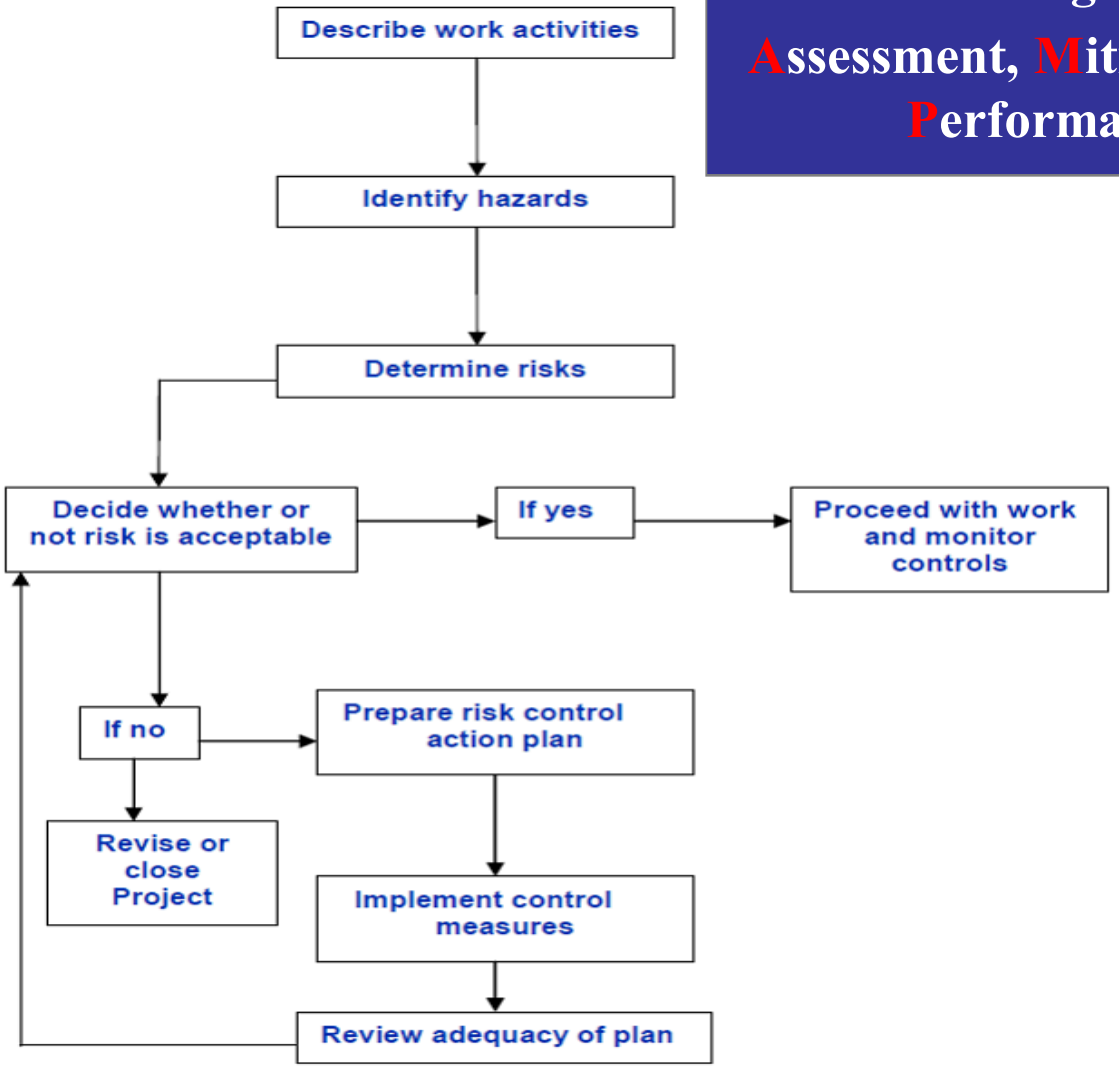
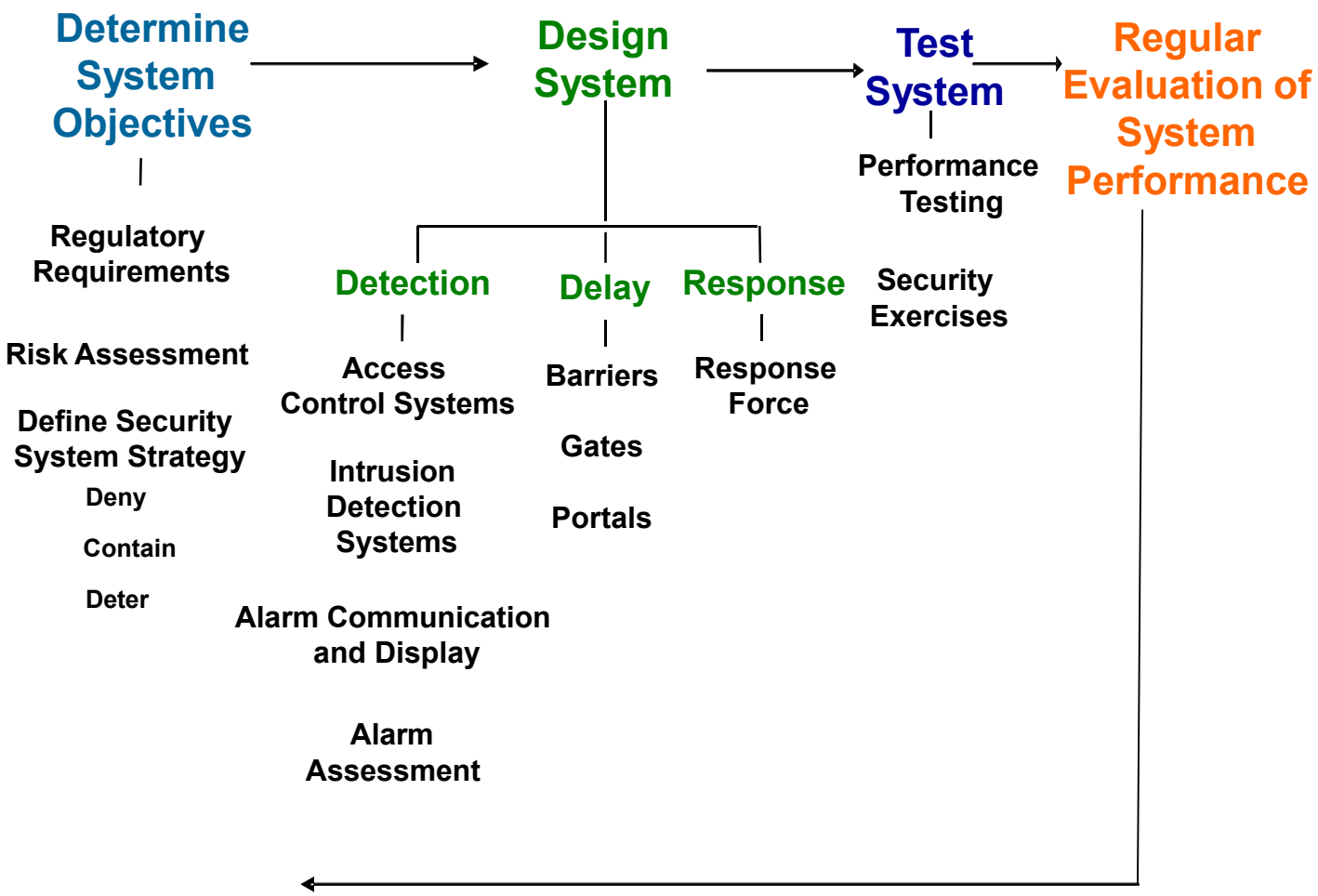
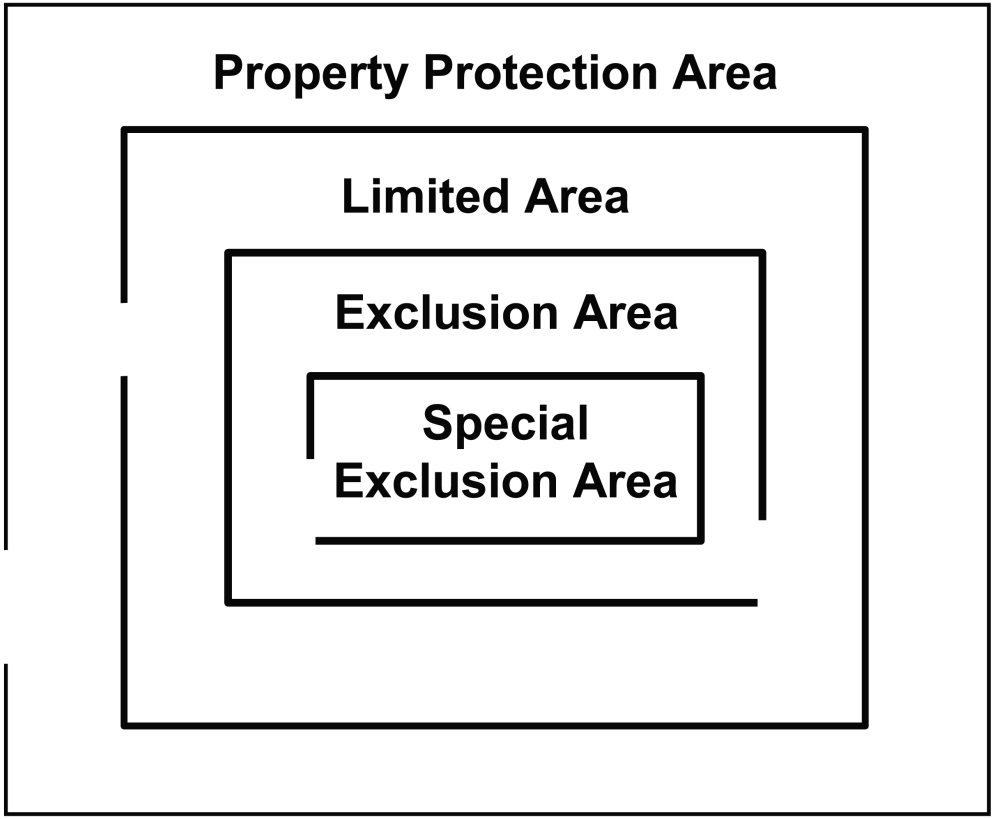


Physical Security System



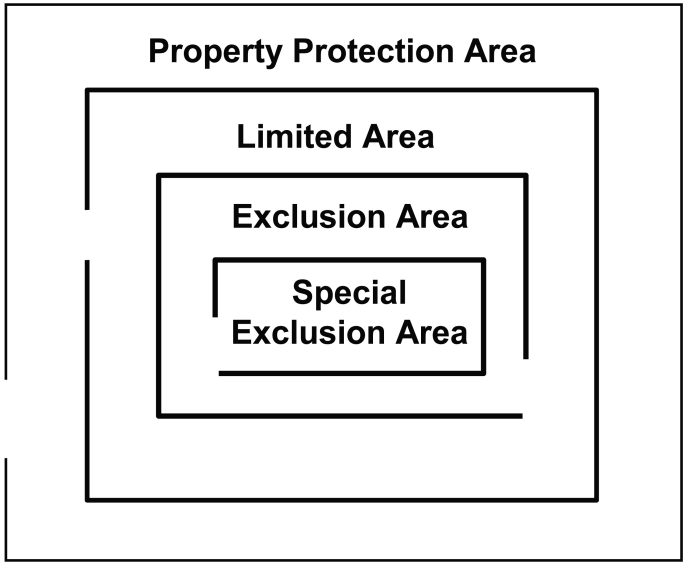
Goal: Achieve desired performance as defined by system objectives
Method: Low and high technology alternatives usually available

- **Security risk mitigation measures should be implemented in a graded manner based on risk**



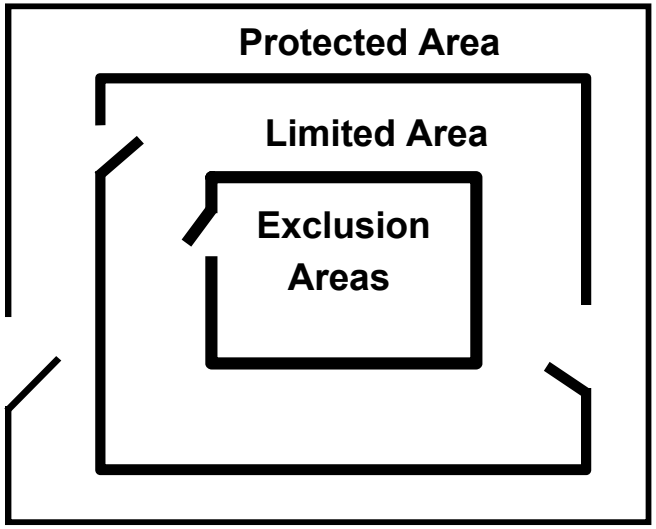
Class Activity: Graded Protection

- **What types of assets would belong in the following areas?**
  - Property Protection Areas
  - Limited Areas
  - Exclusion Areas
  - Special Exclusion Areas



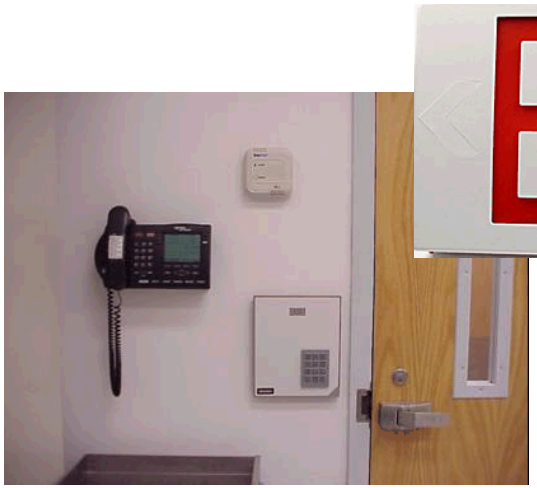
Physical Security: Concentric Layers of Security

- **Property Protection Areas**
  - Low risk assets
    - **Grounds**
    - **Public access offices**
    - **Warehouses**
- **Limited Areas**
  - Moderate risk assets
    - **Laboratories**
    - **Sensitive or administrative offices**
- **Exclusion Areas**
  - High risk assets
    - **Containment laboratories**
    - **Computer network hubs**



Purpose of Controlling Access

- Allow entry of authorized persons
- Prevent entry of unauthorized persons
- Allow exit of authorized persons



Basis of Access Controls

- **Something you have**
  - Key
  - Card
- **Something you know**
  - Personal Identification Number (PIN)
  - Password
- **Something you are**
  - Biometric feature (i.e., fingerprints)
- **Combining factors greatly increases security**

Information Security

- **Protect information that is too sensitive for public distribution**
  - Label information as restricted
  - Limit distribution
  - Restrict methods of communication
  - Implement network and desktop security

- **Biosecurity-related sensitive information**
  - Security of dangerous pathogens and toxins
    - **Risk assessments**
    - **Security system design**
  - Access authorizations

Personnel Security

- **Determines who should be authorized to have access**
- **Visitor controls**
- **Personnel screening**
- **Badges**
- **Training**
  - Personnel should be aware of the rules in your facility, and able to recognize unauthorized persons

- **In your group, identify the people that may have or need to have access to laboratories and/or laboratory areas**
  - Consider anyone that may be in the facility or on the campus
  - List each type of person on a sticky note
- **Group the people you identified into categories**
  - What are the categories and how did you group them?

- **What are the risks associated to the people in each group of having laboratory access?**
  - For each group, outline some of the risks
- **What are the risks associated from the people in each group of having laboratory access?**
  - For each group, outline some of the risks

- **What measures should you consider for each of these groups prior to giving them access?**
  - For each of the risks you identified, identify measures that can be used to reduce the potential or the consequences to the group or from the group resulting from laboratory access
  - Do all of the groups require the same access?
  - Do all of the groups require the same measures?

Question Who works in your lab?

- Are they reliable?
- Are they trustworthy?
- Are the capable of working safely?
- And why are these questions important?

Personnel Management

- **Knowing who has access to your laboratory is very important for controlling Biological Risks**

Biosafety Risks	Biosecurity Risks

- **A Personnel Management program works to address these concerns.**

Personnel Management Measures Depend on the Risk

- **Not all positions present the same risk**
- **Not all situations present the same risk**

Different Activities in the Laboratory → *Different Levels of Risk*

Different Personnel Reliability Requirements

The Higher the Risks → ***The More Stringent the Requirements!***

Components of a Personnel Management Program

- **Personnel Reliability**
- **Occupational Health**
  - Fit testing
  - Assessment of pre-existing conditions
  - Vaccines
- **Training**
  - Lab specific - PPE, GLP, BSC, MC&A, …
  - Facility procedure

Personnel Reliability

The objective of a Personnel Reliability program is to help judge a person's integrity.

Approaches for Vetting Individuals

- Interviews
- Skill testing
- Personality testing
- Drug testing
- Public records

Occupational Health

- **The objectives of an Occupational Health program are to:**
  - Set and enforce medical standards for safe work in the laboratory (**Pre-work Requirements**)
  - Determine and react to potential exposures in the laboratory. (**Exposure Surveillance**)

Training

- **The goal of training within Personnel Management is to ensure people understand:**
  - The **risks** they are faced with.
  - The risk-mitigation **measures** at their facility
    - **Incident and Accident Response**
    - **Donning and Doffing PPE**
    - **Entering the Lab**
    - **Inventories**
    - **Identifying Who Should Not be in the Lab, etc.**

Personnel Reliability Discussion

- **What are the most commonly used methods of personnel reliability screening, if any, in your country? at your institution?**
- **What are the major limitations to personnel reliability screening in your country? at your institution?**
  - Lack of available data? Institutional interest? Individual researcher interest?
- **Have there ever been any personnel reliability incidents in your institution?**
- **What are some of the ways you can improve personnel reliability at your institution?**

Discussion Additional Points

- Personnel Reliability programs do not protect against an Outsider Threat – only the Insider Threat! (Physical Security protects against the Outsider).
- However, Physical Security and Personnel Reliability should go hand-in-hand.
- Granting access to the laboratory and its materials is a privilege and should be treated as such.
- All individuals working in a laboratory should understand the hazards of the workplace and how to mitigate them!
- Generally, it is important for the employer to ask all of the tough questions early on, because it is more difficult to do so later after the individual is hired
- The degree of screening should correspond to the level of risk determined by the risk assessment!

Personnel Management Conclusion

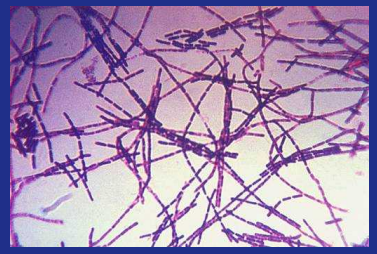
Biosafety Risks	Biosecurity Risks

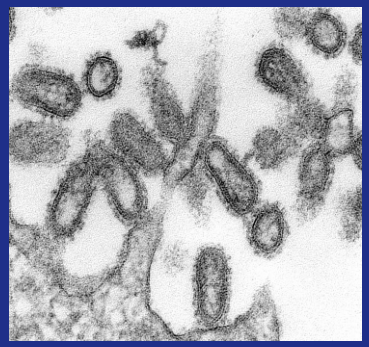
- **The aim is to ensure people you give access to your laboratory are:**
  - Responsible and trustworthy.
  - Able to understand the importance of safety and security.
  - Able to follow proper safety and security procedures in the laboratory.
  - Willing to report accidents and incidents.
  - Are not at increased risk of infection.
  - Properly trained to your laboratory requirements.

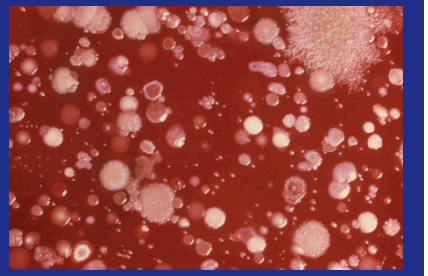
Review

- What are the reasons for limiting laboratory access?
- How do you determine if someone can or should have access?
- How can you control access?

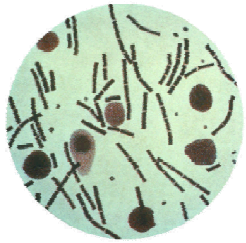
Material Control and Accountability





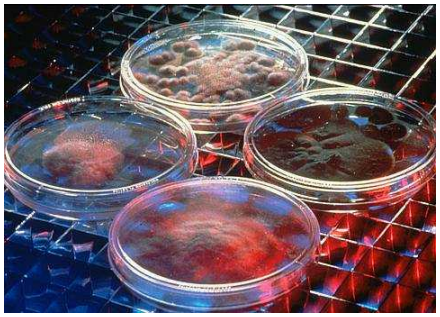


- **Agent**
  - What agents are high risk?
  - Viable? Whole organism or DNA?
- **Quantity**
  - Any amount can be significant
  - A threshold amount for toxins
- **Form**
  - Repository stocks, working samples, in host, contamination
- **Detail—what level is adequate for MC&A?**
  - Material as *items*
  - Each vial as a separate inventory record?
- **Capture—when does MC&A start & stop?**
  - Naturally occurring; clinical samples; disposition



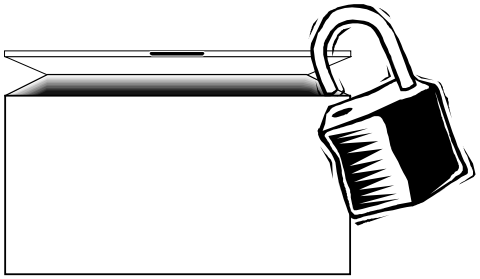
Material Control and Accountability

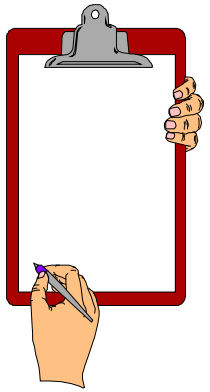
- **Control is either…**
  - Engineered / Physical
  - Administrative



- **Containment is part of material control**
  - Containment Lab / Freezer / Ampoule

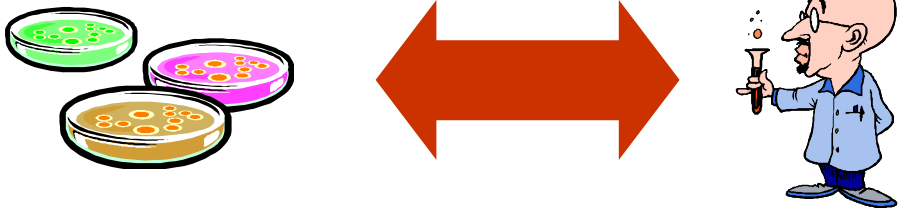
- **Procedures are essential for material control**
  - For both normal and abnormal conditions





Material Control and Accountability

- **All material should have an associated "accountable person"**
  - The person best in a position to answer questions about the associated material
  - Not someone to blame!
  - Ensure that no material is "orphaned"
- **Procedures should ensure accountability**
  - Experimental work: laboratory procedures
  - Inventory: know what you have
  - Reporting: document routine MC&A practices
  - Audit/ assessment: is this working?
    - **Ensures effective *implementation* of MC&A**
  - Training: personnel understand requirements



Material Control & Accountability Examples

- **Moderate risk biological agents**

  Seed stocks cataloged and records stored securely

  - **Transfers in and out**
  - **Source**
  - **Strain**
  - **Form**
  - **Responsible individual**

  Working stocks, including infected animal status, tracked through laboratory notebooks

- **High risk biological agents**

  Moderate plus

  - **Increased control over working stocks**

Material Accountability Problems: Discussion

- What are some examples of material accountability problems?
- How could they be prevented?
- How should management address these problems?

Transport Security

- **Aims to deter theft while materials are outside of laboratories by implementing biosecurity measures during the transport process**
- **May involve personnel from**
  - Labs
  - Shipping areas
  - Receiving areas
  - Disposal areas (autoclave and incinerator rooms)
- **Move materials safely and securely**
  - SOPs
  - Leak-proof containers
  - Pre-approval?
  - Chain of custody?

Biorisk Program Management

- **Overarching component of laboratory biosecurity and biosafety programs**
- **Guides and provides oversight to both biosecurity and biosafety**
  - Defines program objectives
  - Ensures program has appropriate resources
  - Addresses sustainability of program
  - Training program
- **Delineated in a written plan or manual**
  - Comprehensive guidance
  - Incident response plans
- **Manuals specific for each institution**
  - Should be based on laboratory-specific risk assessment

Determining the Needs for BSL3 Facilities

International Biological Threat Reduction,
Sandia National Laboratories, USA

SAND No. 2008-2050C, 2008-0480P, 2005-7039C, 2005-3288C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

Levels of Containment

- **BSL-1**
  Defined organisms
  Not known to cause disease in healthy adults
  - Cells, e-Coli etc
- **BSL-2**
  Moderate-risk agents that occur naturally in the community
  Disease of varying severity.
  - Diphteria, tetanus, pertussis
- **BSL-3**
  Indigenous or exotic agents, aerosol transmission
  Serious and potentially lethal infection
  - HIV, TB (10 –30 years)
- **BSL-4**
  Dangerous or exotic, high-risk agents
  Life-threatening diseases
  - Ebola, Marburg (70%)

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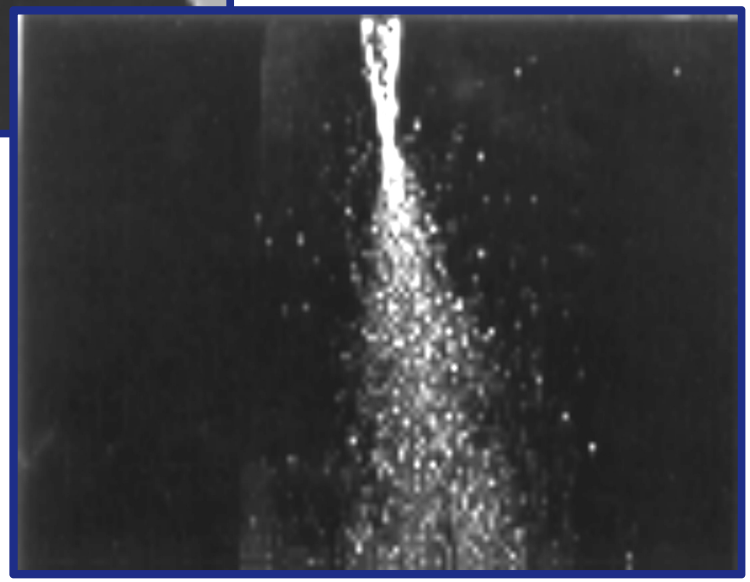
WHEN ARE AEROSOLS FORMED?

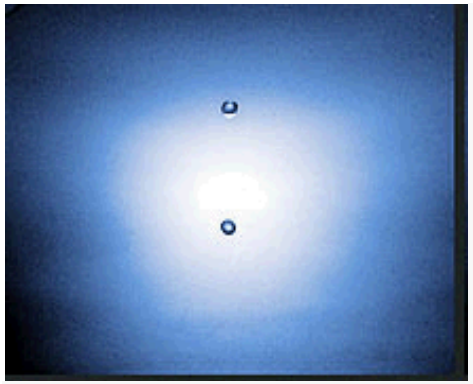
Sneezing

Sneezing

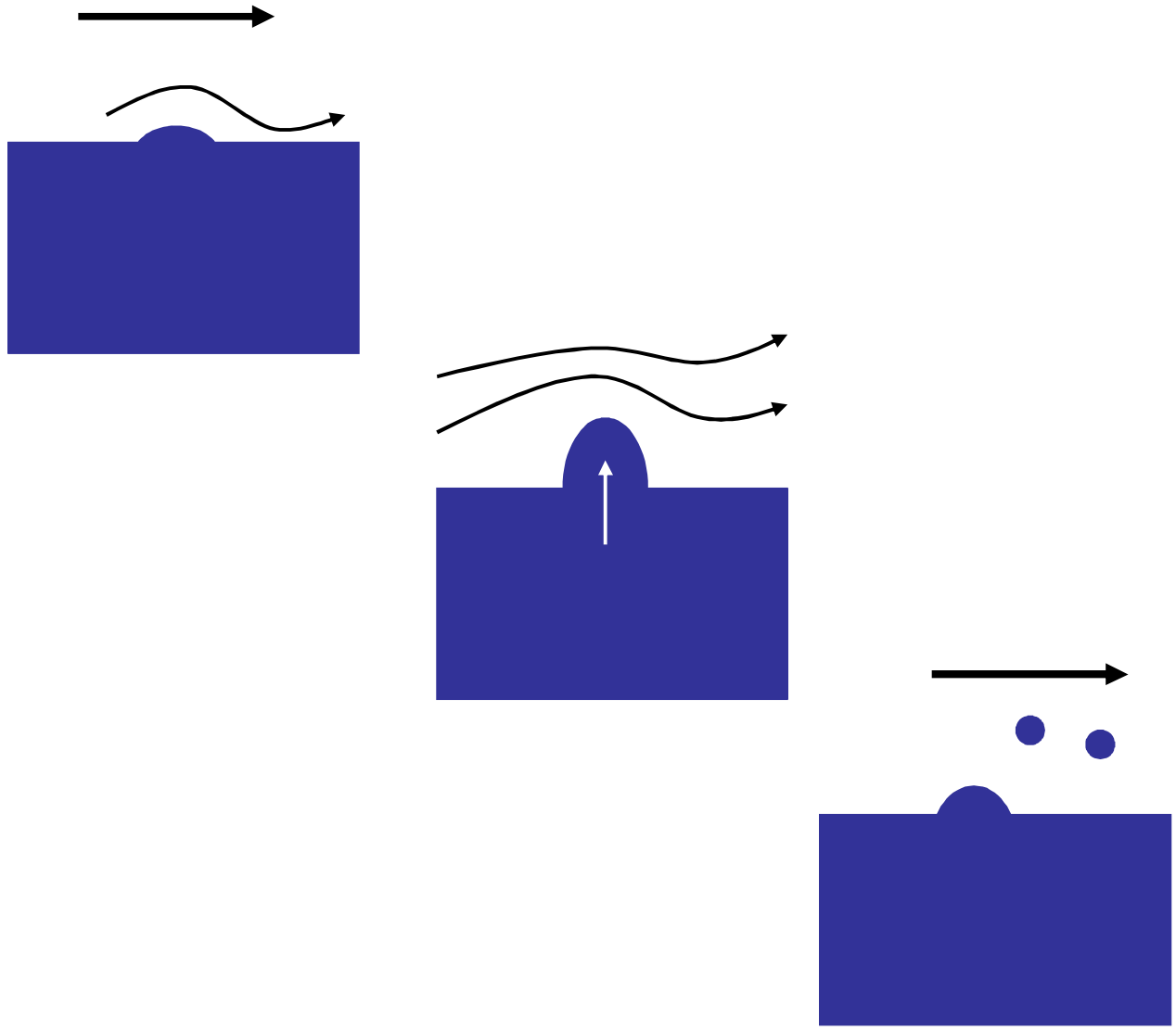
Do Syringes Form Aerosols?



What if it is Only a Couple of Drops?

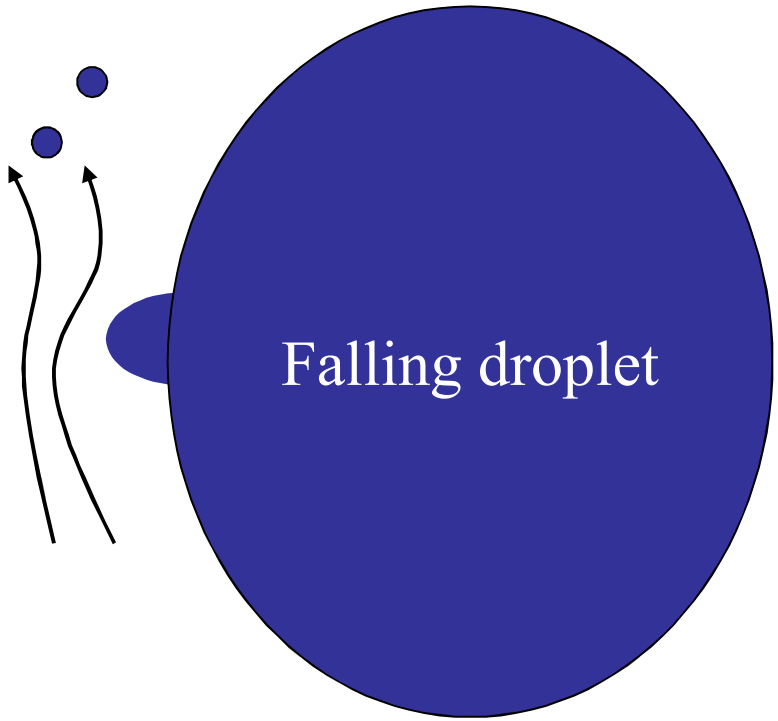


Aerosol Formation



Slide courtesy of Per Staugaard

Aerosol Formation



Slide courtesy of Per Staugaard

WHEN WILL EXPOSURE HAPPEN?

Exposure

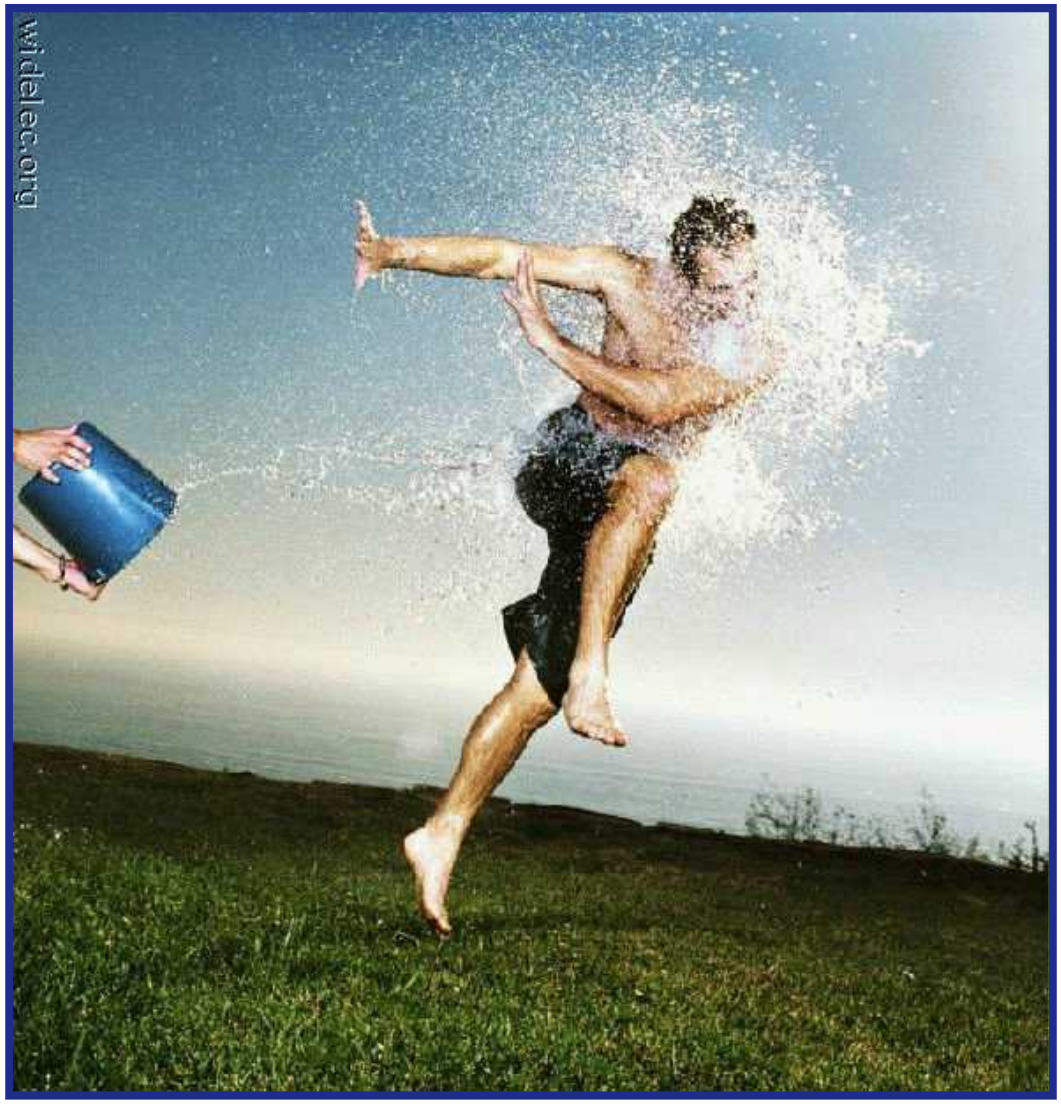
When You Do NOT Have a Barrier Between You and Your Agent

Exposure

When You Did Not Foresee the Outcome of Your Next Move

Exposure

When the Agent is Released by Somebody Around You ....and You are *NOT* Wearing PPE



Exposure

On Purpose

By Accident

Will Exposure be Equal for All Exposed?

No Not Necessarily

By Accident

Do People Always Wear PPE?

By Accident

Sometimes They Might!

By Accident

Can You Always Foresee and Predict an Exposure?

Not Always

By Accident

Can You Always Foresee and Predict an Exposure?

Not Always

By Accident

Can You Always Foresee and Predict an Exposure?

Not Always

By Accident

Circumstances Might Change...

Procedures in the Lab Might Drift Over Time ...

– Just as the Tide Changes

By Accident

Exposure in the army

By Accident

Muddy exposure

By Accident

Can You Always Foresee and Predict an Exposure?

Do You Always Know What You Have in the Test Tube?

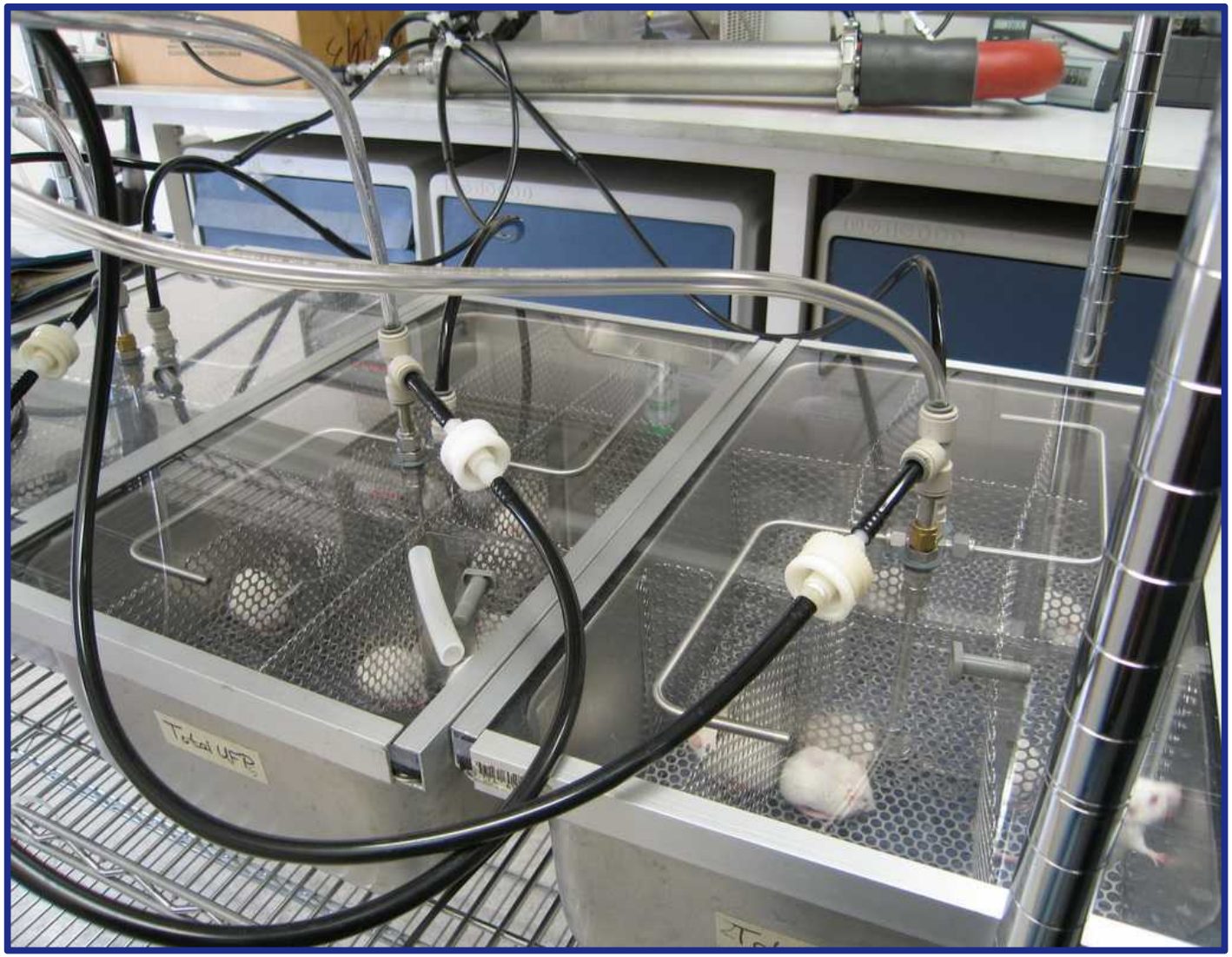
By Accident

Exposures happen.....

When You ***THINK*** .... You are in Control.....

Aerosol Inhalation Studies

When you DELIBERATELY expose animals for aerosols



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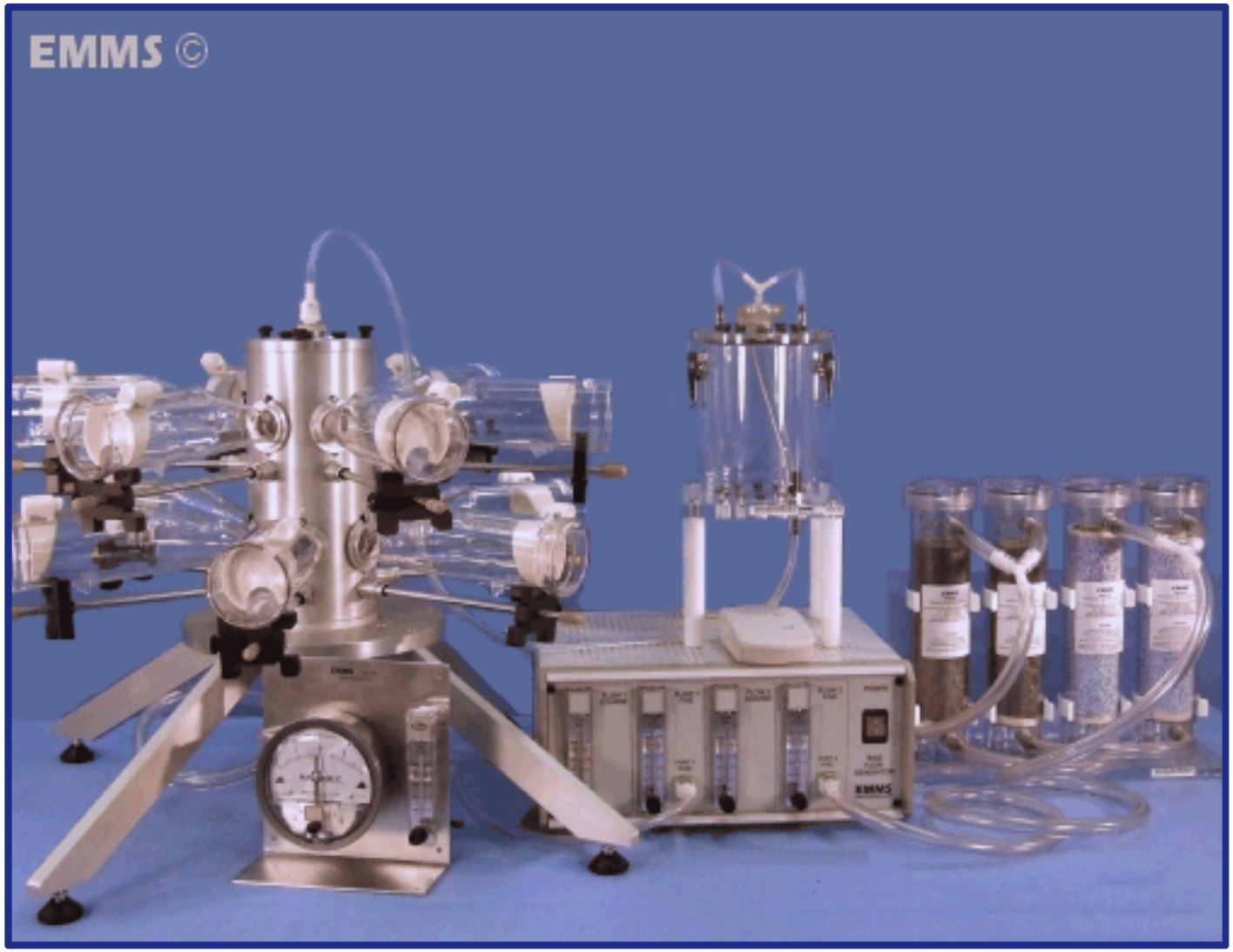
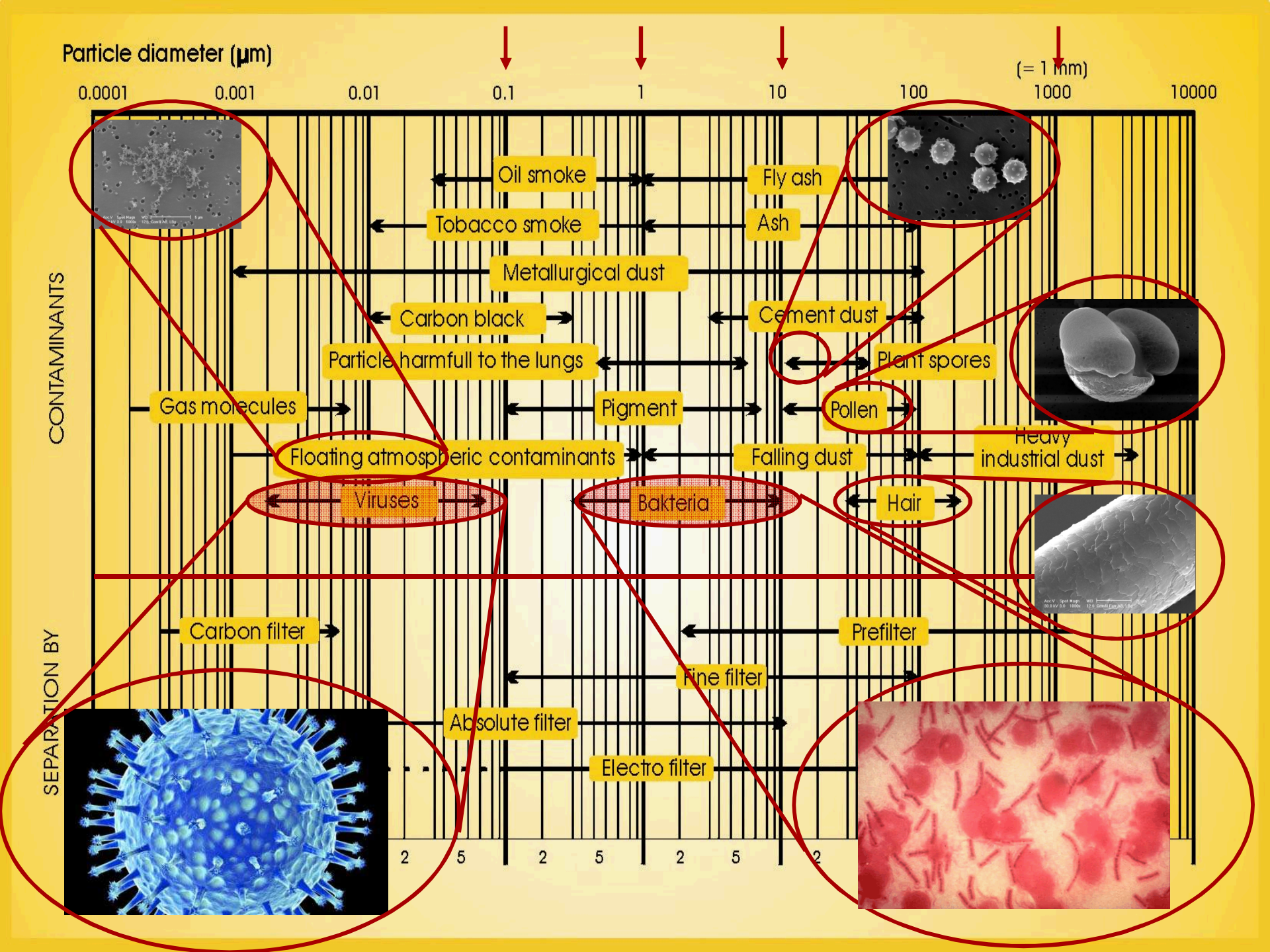



Particle diameter (µm)
0.0001
0.001
0.01
0.1
1
10
100
1000
(= 1 mm)
10000
CONTAMINANTS
Oil smoke
Fly ash
Tobacco smoke
Ash
Metallurgical dust
Carbon black
Cement dust
Particle harmfull to the lungs
Plant spores
Gas molecules
Pigment
Pollen
Floating atmospheric contaminants
Falling dust
Heavy industrial dust
Viruses
Bakteria
Hair
SEPARATION BY
Carbon filter
Prefilter
Fine filter
Absolute filter
Electro filter
2
5
2
5
2
5
2

Airquality

How clean is the air?

Environment	Particles/L
Clean room	1
Arktis	10,000
Ocean	100,000
Countryside	1,000,000
City	100,000,000
Highway (local)	1,000,000,000
Tobacco smoke	100,000,000,000

Slide courtesy of Mark Huza

Airquality

What is in the air?

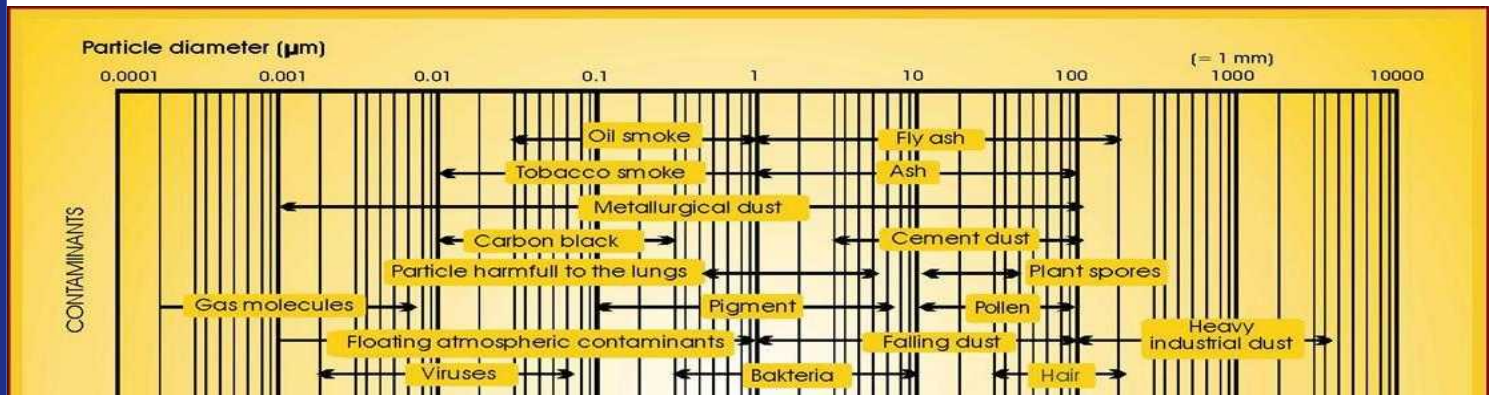
Slide courtesy of Mark Huza

- **We eat 1 kg/day**
- **We drink 2 kg/day**
- **We breathe air, 24 kg/day**

- **We Dissipate**
  - 70 Watt when we sleep (candle)
  - 300 Watt when we are working hard

Sedimentation in Still Air

D Particle	Time to Do 2.5 m
150 µm	5.4 s
20 µm	3.5 min
5 µm	55 min
0.5 µm	3 days
0.1 µm	34 days



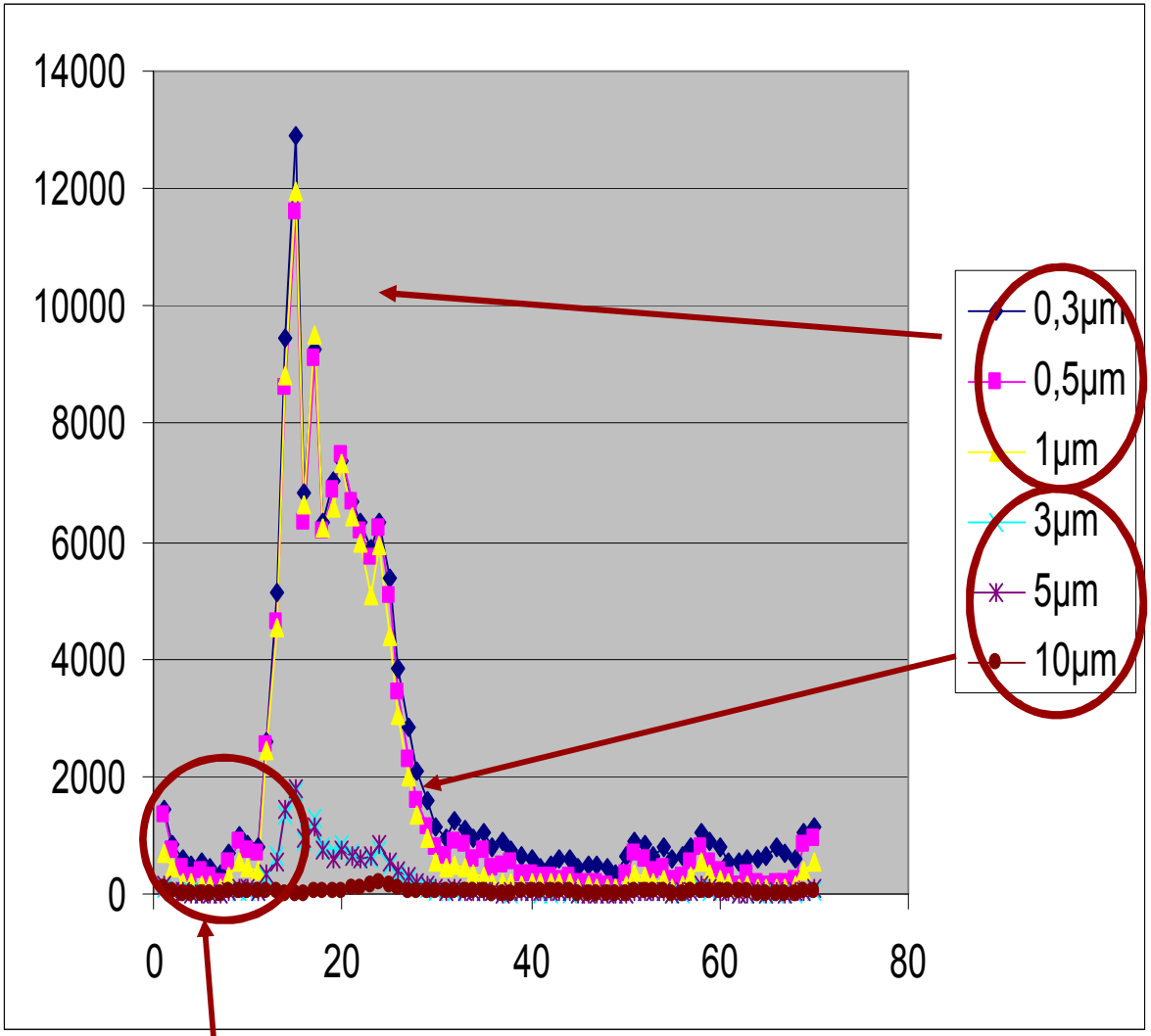
Slide courtesy of Mark Huza

Masks

Which Mask Will Protect Best?

Aerosols Remain in the Air for Up to 30 Min After a Spill Has Occurred

Aerosols Remain in the Air for Up to 30 Min After a Spill Has Occurred



Background before spill

Aerosols: Small Group Activity

- **Which procedures in the lab can create aerosols?**
- **Which equipment in the lab are likely to create aerosols?**
- **Present to class**

HOW DO SPILLS OCCUR?

Temporary Lack of Focus

When Someone Not Fully Trained … Tries to Help

When You Trip
Keep The Laboratory Tidy!

Actions Not Completely Thought Through

Can Spills Be Controlled?

What Does Large Scale Spills Look Like?

… Or Maybe Like This?

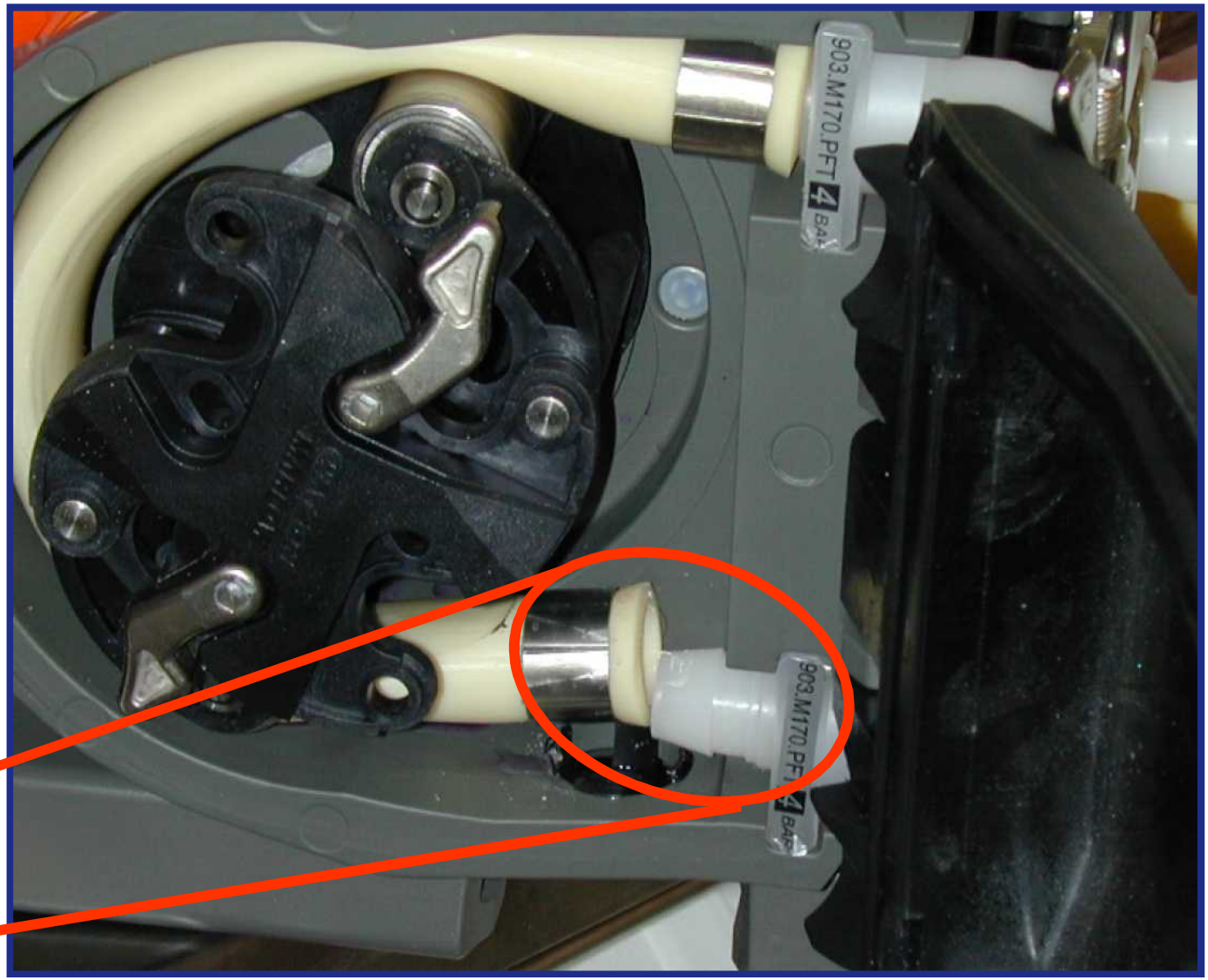
wikileaks.org

Containers Tumbling Over - Pipettes

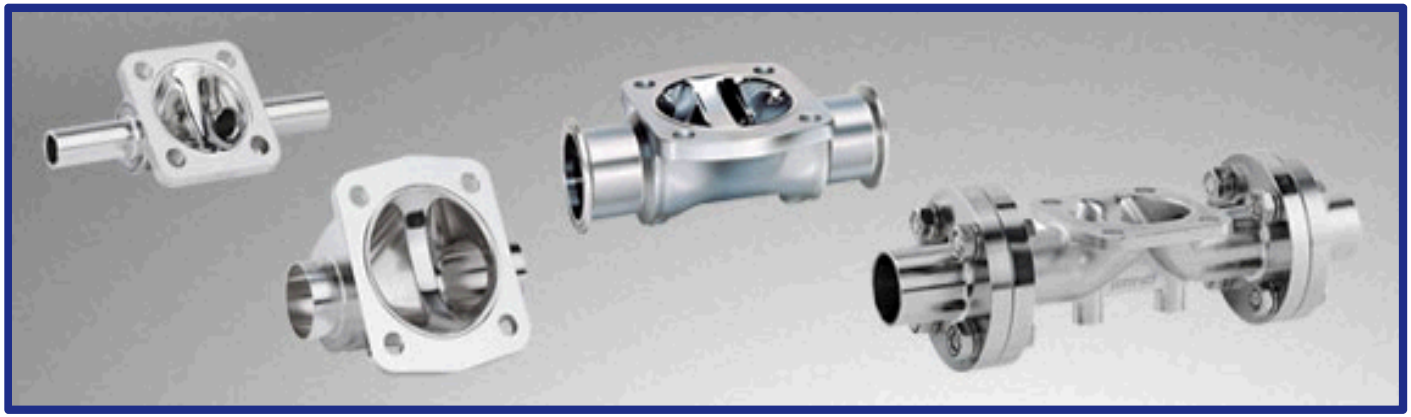
Tubes Not Fixed

Tubes Not Clearly Marked

Tube Not Fixed



Membrane Splits

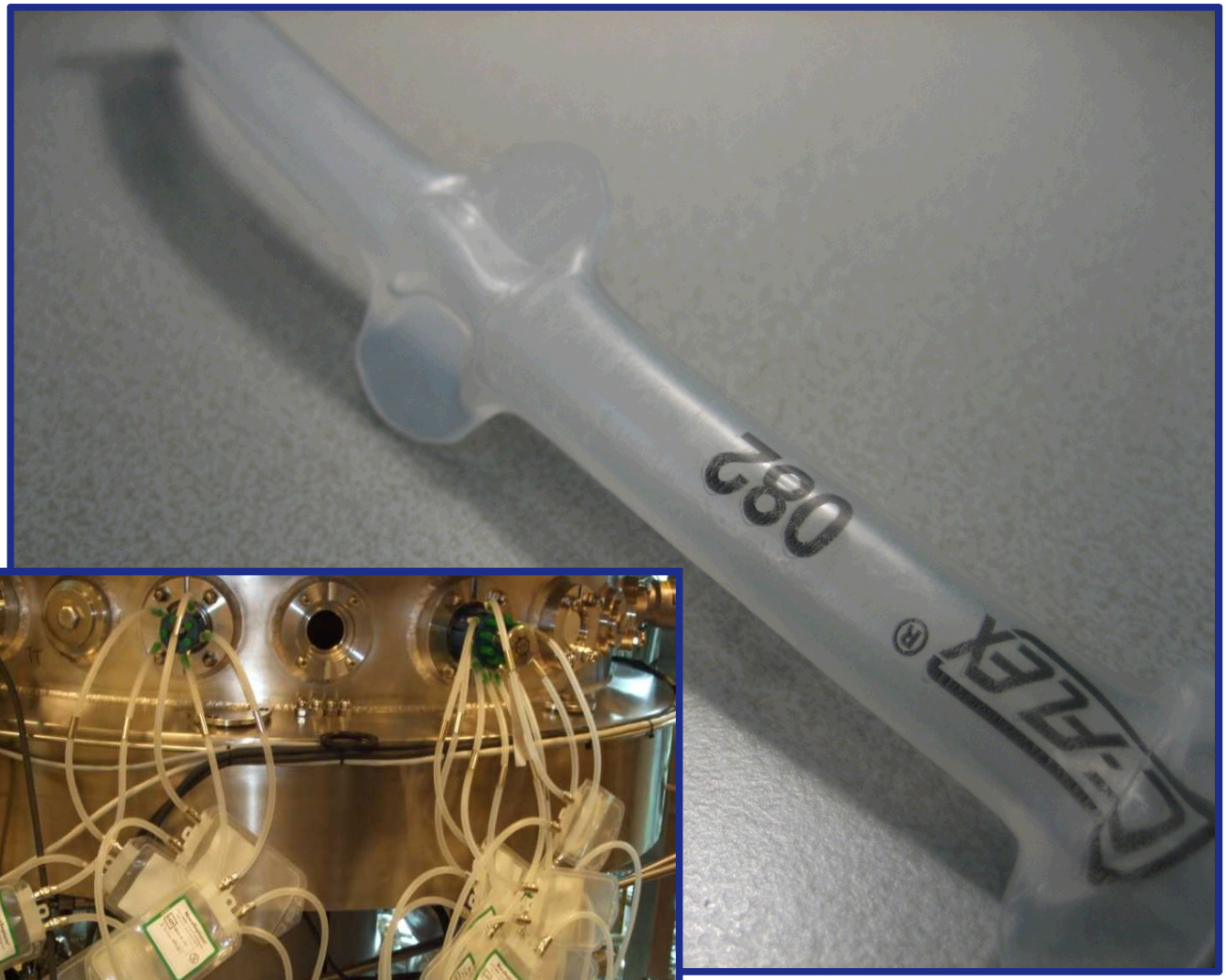


Wrong Tools

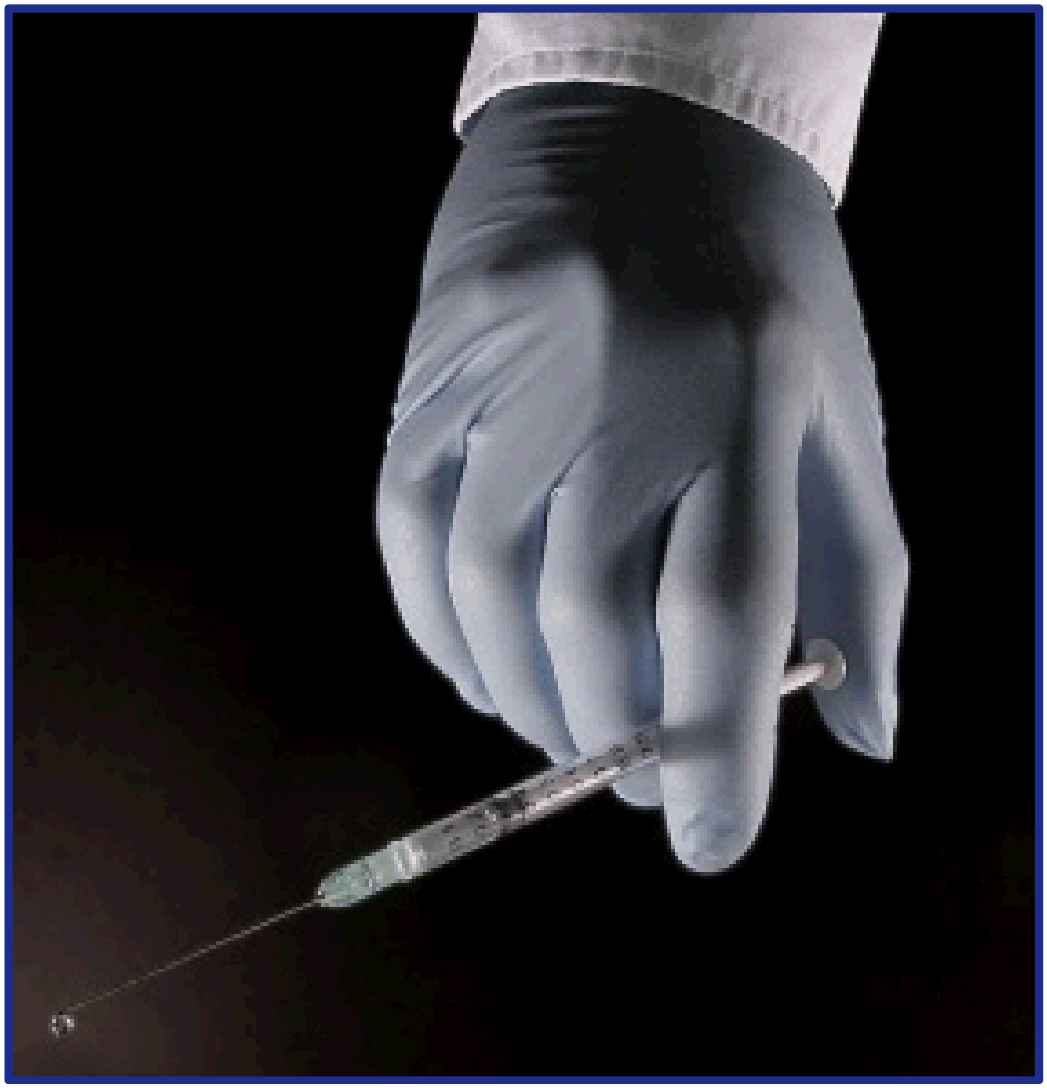
Welding Not Sealed

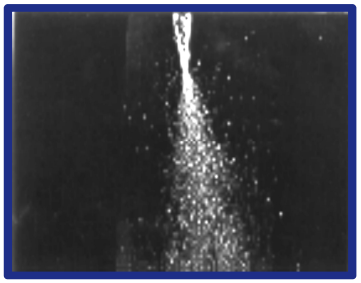
How Do Spills Occur?

Welding Not Sealed



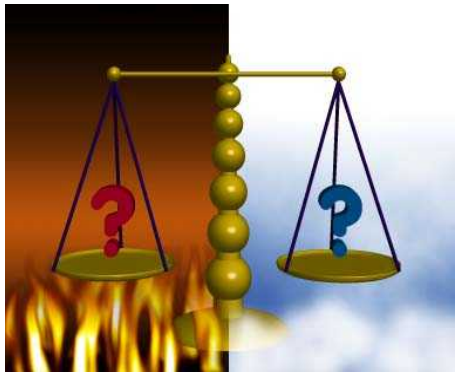
Syringe Plunger





Closure Not Fastened

Risks and Concerns? Spills and Releases



Worker's Health

Death / Injury

BSOs

Biosecurity

Terror / Costs

Architects

Contractors

Suppliers

Engineers

Environment

Costs / Image & Profile

Biosafety

Death / Disease

Managers

Designers

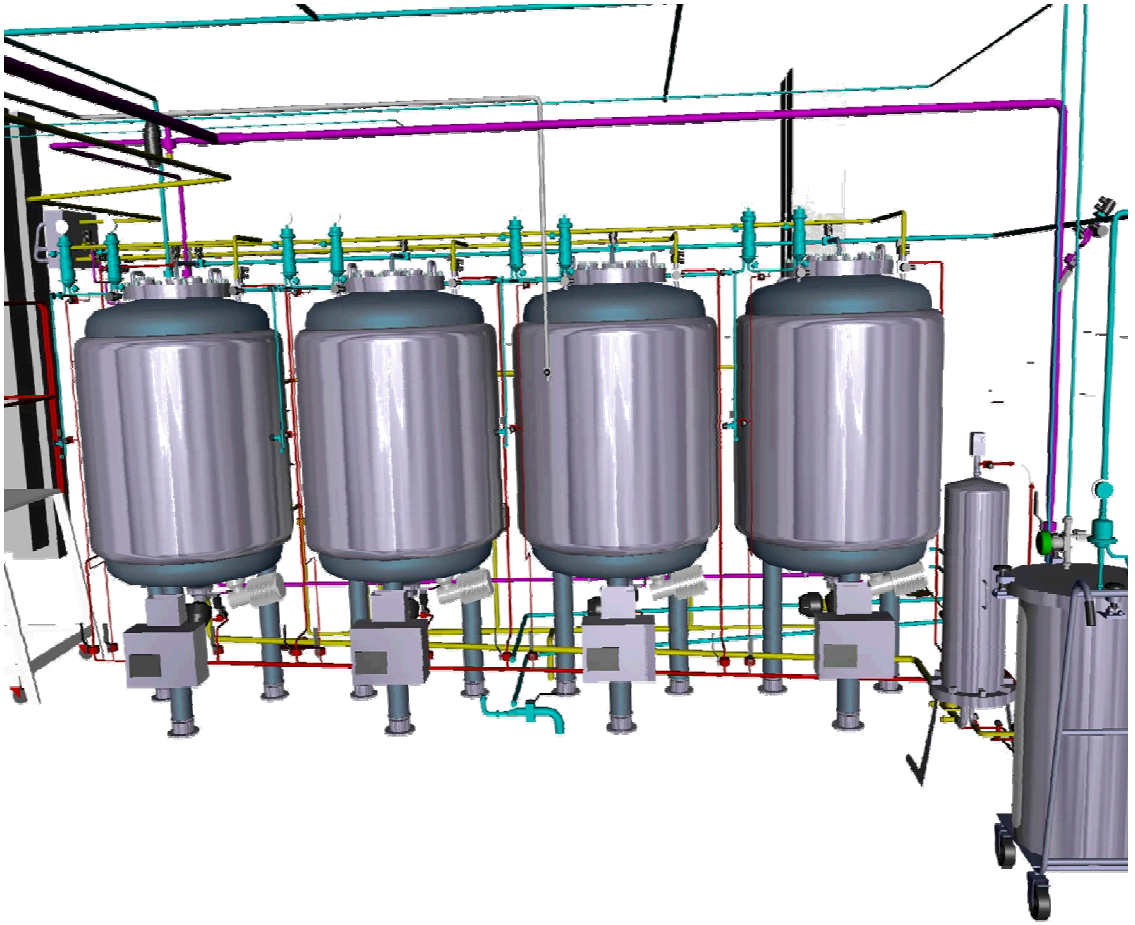
GMP & Animal Welfare

Workers

Product Safety / Costs

All the Stakeholders

Scale Can Make a Difference



3 Aspects of Large Scale Spills

- **Volume**
  - Largest vessel?
    - **Loosing a bottom valve?**
      - Dilution? Leaking pipes
- **Distance**
  - How far does it flow?
    - **Pumps, pressure**
      - Transfer of liquid
- **Aerosols**
  - How much?

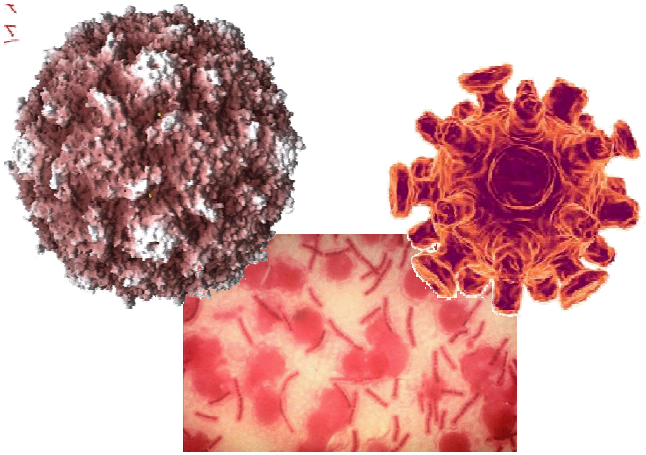
Spills: Small Group Activity

- Which procedures in the lab can have caused spills
- Could they have been avoided
- Did they have any consequences?
- Did any proedures change?

- Present to class

Agents: Small Group Activity

- Which agents do you work with today which could have severe consequences if you were exposed to them?
- Which agenst can you foresee in the future?
- Present to class



BSL3 Construction Costs

International Biological Threat Reduction,
Sandia National Laboratories, USA

SAND No. 2008-2050C, 2008-0480P, 2005-7039C, 2005-3288C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

One of the most challenging and complex tasks in the world

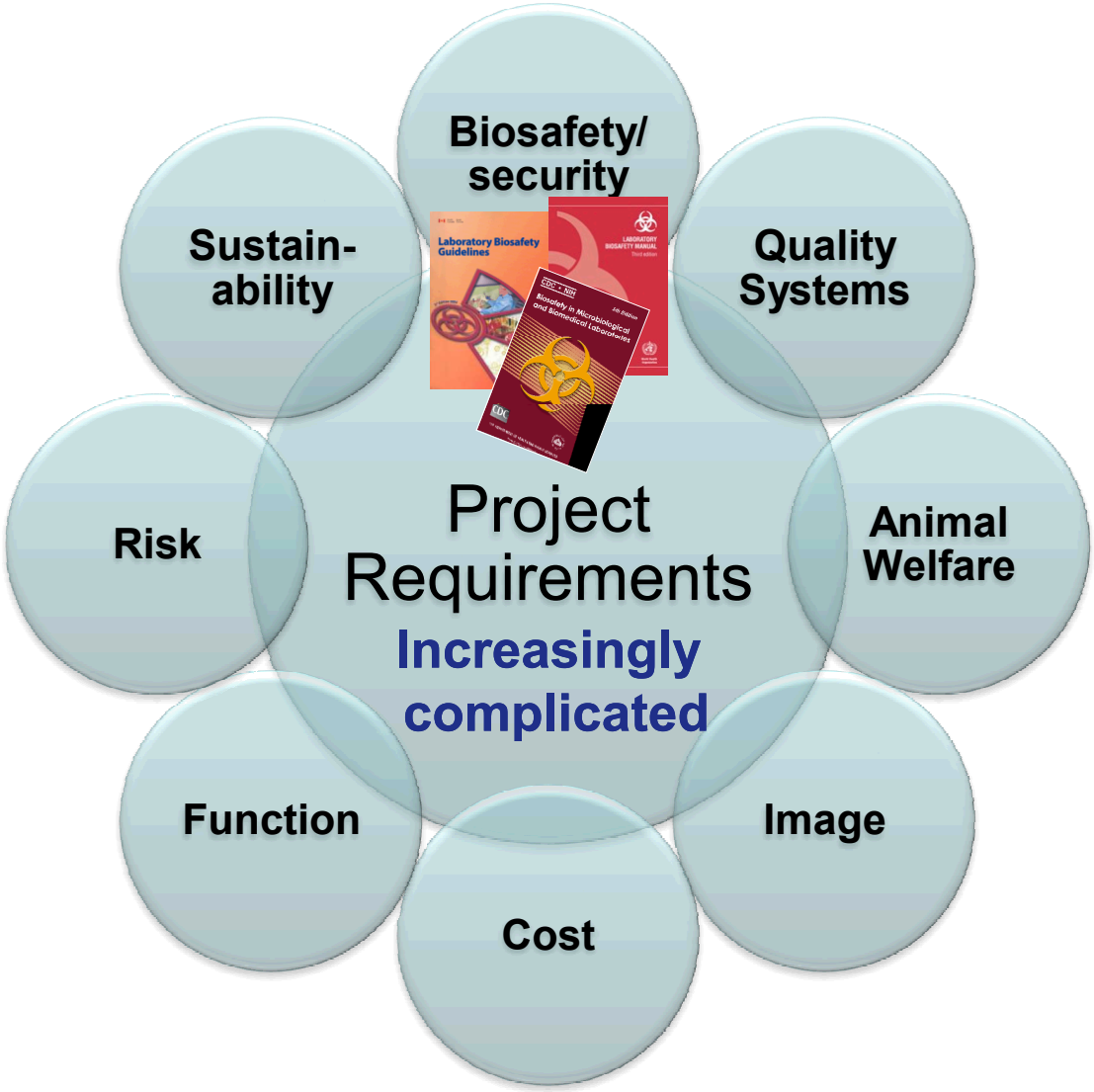
CONTAINMENT BUILDING PROJECTS

- And one of the most expensive !

CONTAINMENT BUILDING PROJECTS

What

an array of competing requirements that are not fully defined at the start and must be figured out in stages…

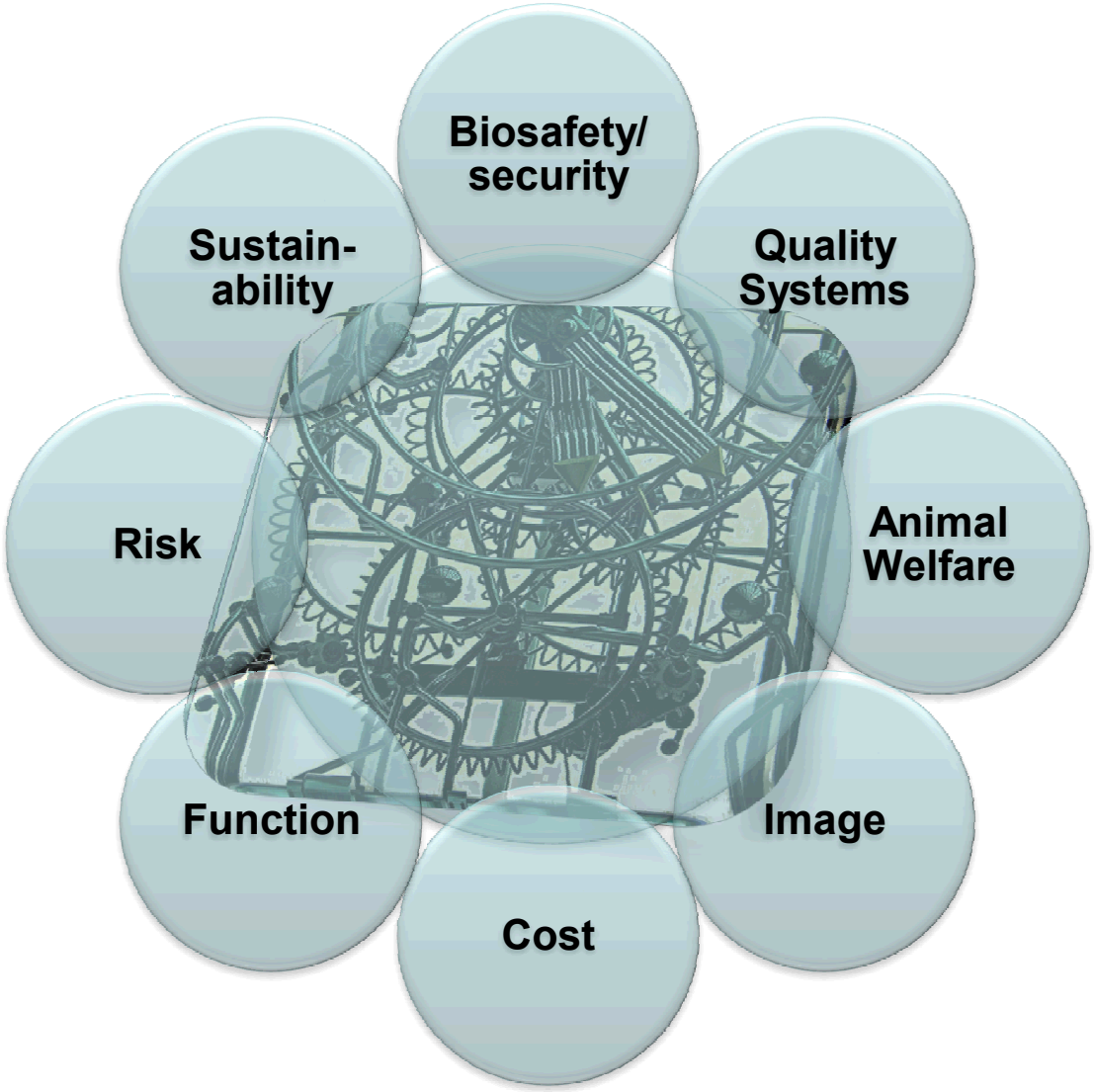


Slide courtesy of Randy Kray

Fact

problems of high complexity requires lots of different expertice

you need to go outside for peer review



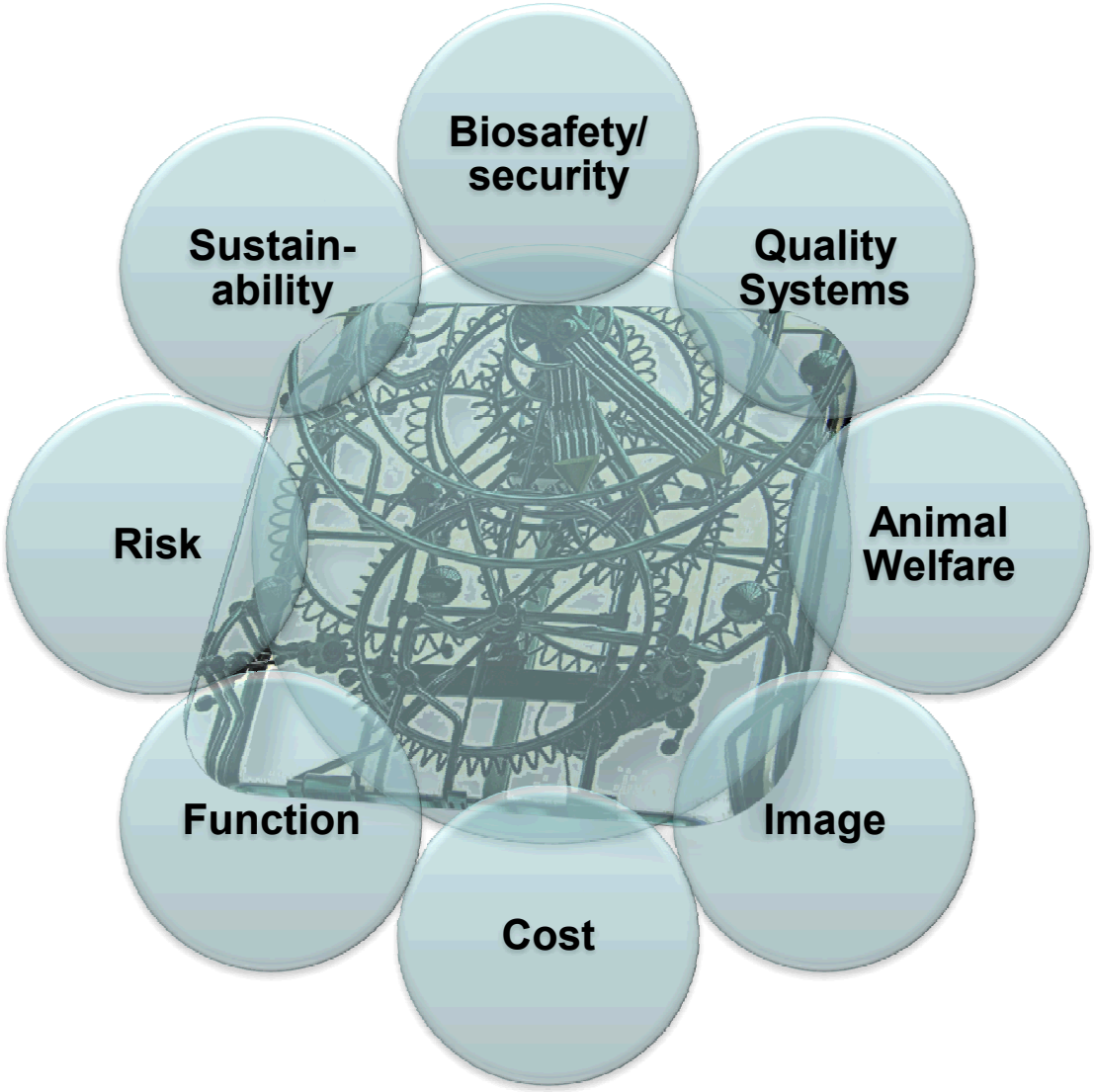
How

- do you reconcile these competing requirements?

- do you keep everyting visible?

- do you make sure that noting is lost of falls short of expectaions?

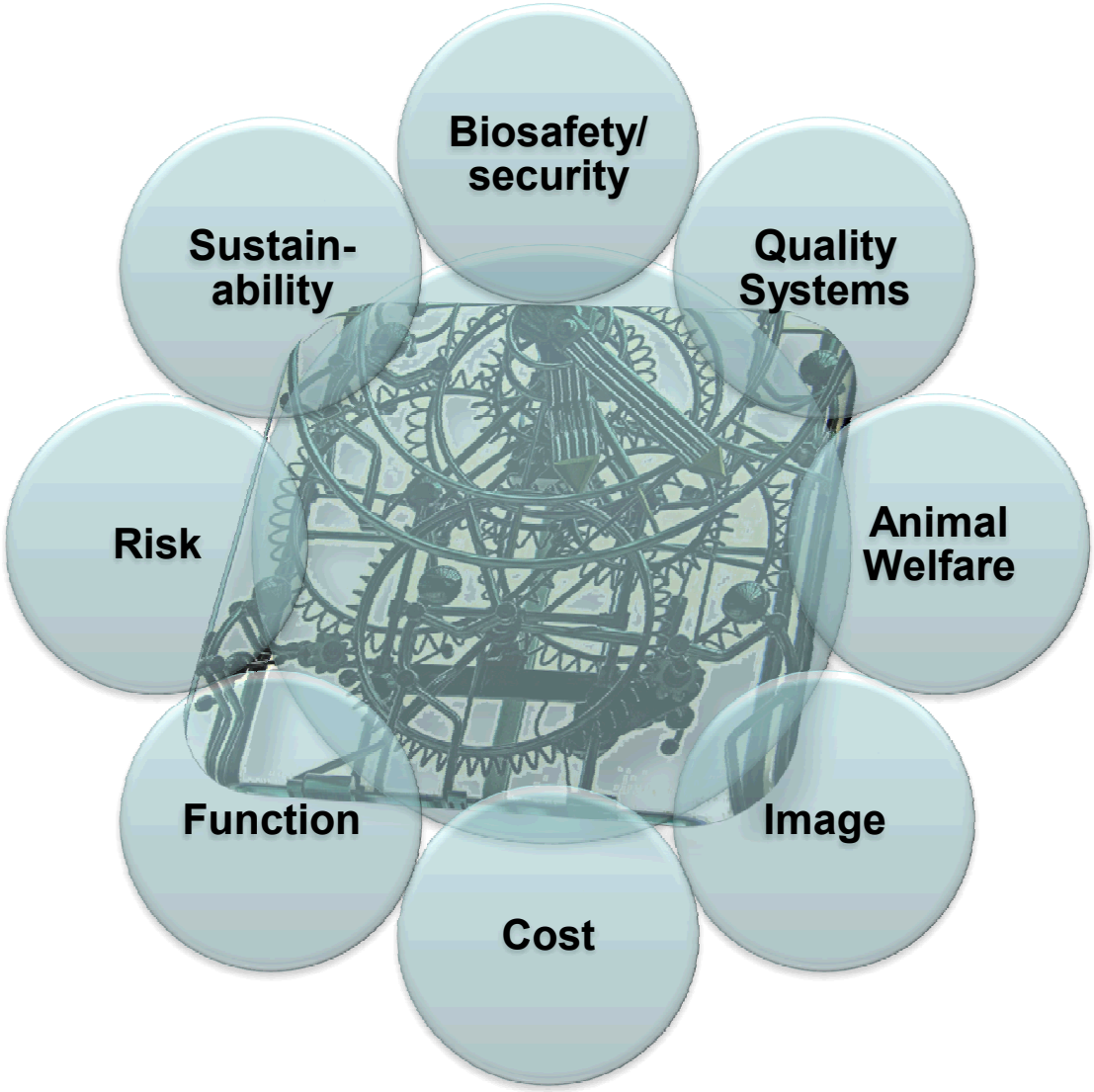
- do you get the expectations right?



How

- do you ensure that the peer reviewing experts gets all the right information?

- do you structure your information so it is easily accessible for external assessment and audit by regulators?



Planning Overview

- **Review existing national and international standards, regulations, and guidelines**
- **Conduct both biosafety and biosecurity risk assessments**
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  - Reevaluate financial requirements throughout project, and ensure that adequate resources exist to support all operations

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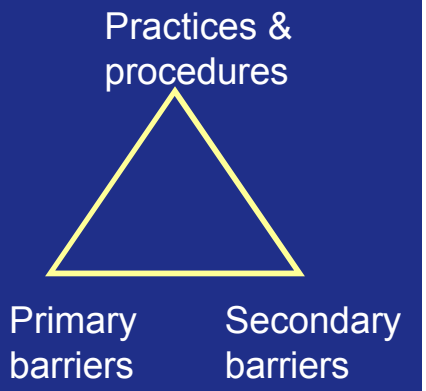
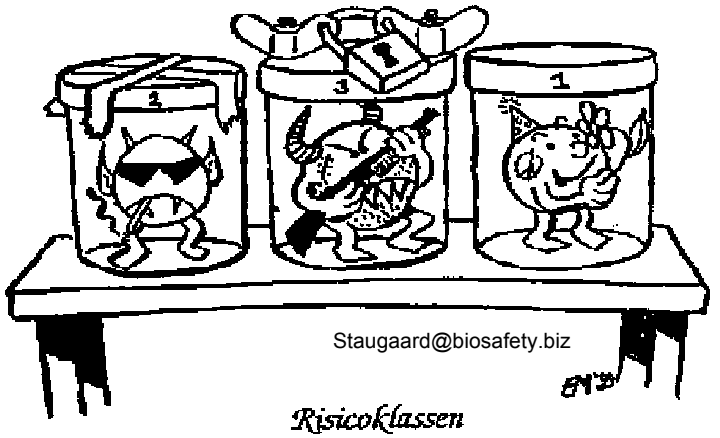
Biosafety Levels

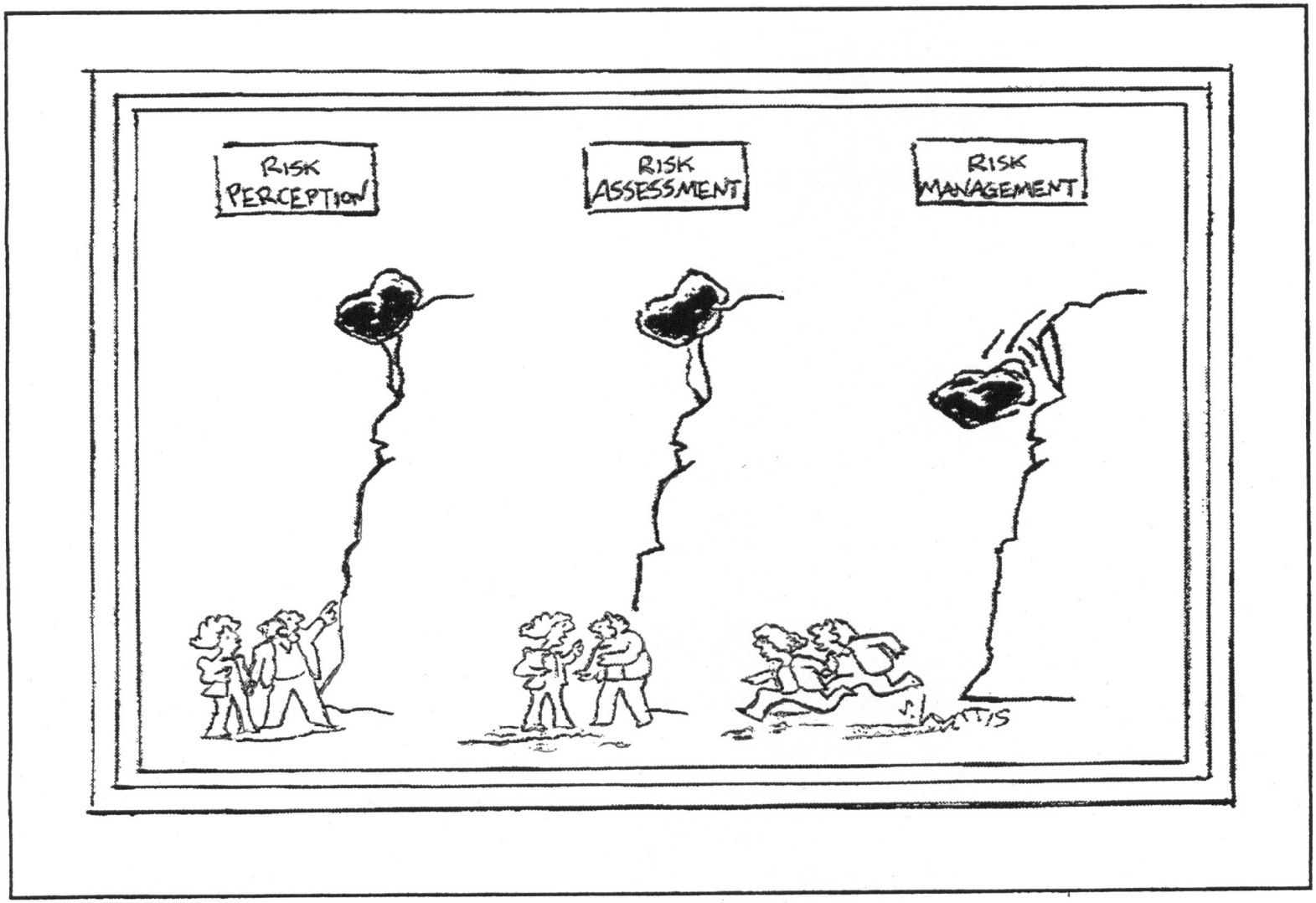


- **Biosafety Levels**
  - Four biosafety levels provide increasing degrees of protection
  - What's the right balance of practices & procedures, primary barriers and secondary barriers?



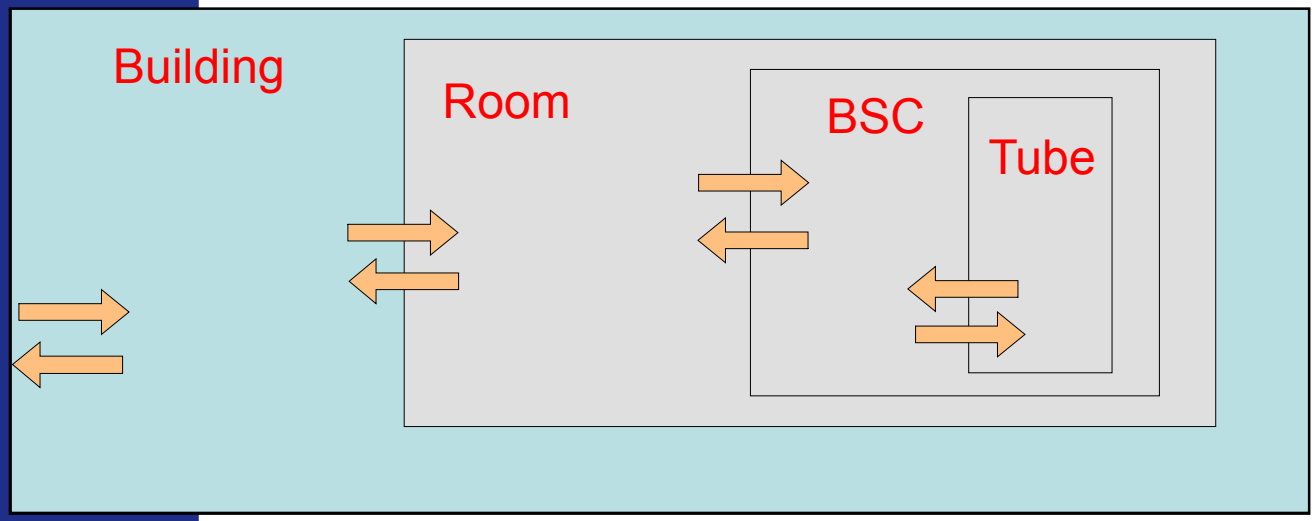
- **Applications:**
  - Labs (BSL1, 2, 3, 4)
  - (Small) Animal Containment (ABSL1, 2, 3, 4)
  - Large Animal Containment (BSL3 AG)
  - Plant Containment (BSL1-P, 2-P, 3-P, 4-P)

Risk Assessment



Containment barrieres

- **Containment laboratories consist of a series of open and closed systems**
  - Primary: Separate the worker from the agent
  - Contain splashes



Tertiary containment...1

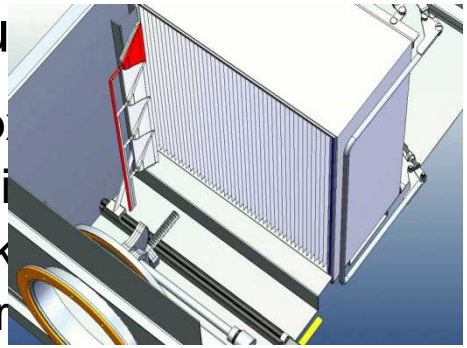
- **Building characteristica**
  - BSL-1 - none
  - BSL-2 - none
  - BSL-3
    - Isolated areas
    - Decisions about exhaust air
    - Requirements of safe handling of infectious waste
    - Decontamination facility

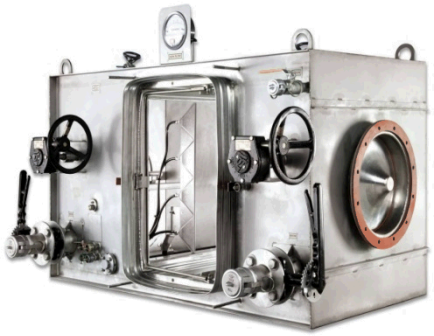
Tertiær containment… 2

- **BSL-4**
  - Separate building/extreme isolation
  - All waste products MUST be handled correct
  - Space for dedicated support/back up systems
  - Decontamination facilities
  - Extreme decontamination before preventive maintenance

Secondary Containment

- **High risk rooms**
  - **MIGHT** generate large amounts of aerosols
    - **HEPA filters on exhaust**
      - Dou
    - **Filter bo**
      - Bag i
      - Gask
      - Filter
      - Dampers
      - Auto





Biosafety for protection of …

- The employee
- Colleagues
- Other persons with access to the lab
- Environment

Containment barriers…..1

- **Barriers are achieved by…**
  - Physical separation
  - Practices and procedures
  - Decontamination
  - Filtration

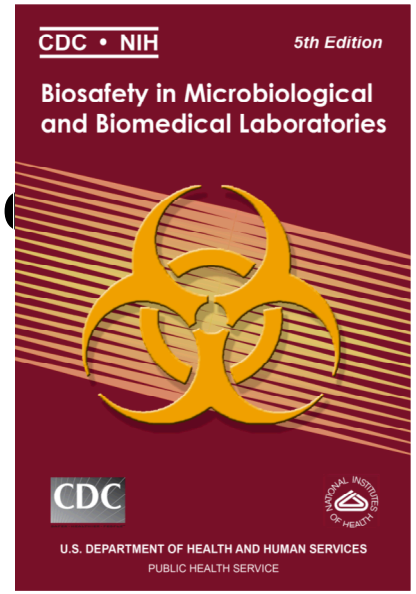
Containment barriers…..2

- **Barriers are broken by…**
  - Personnel
  - Air, gasses, liquid waste etc.
  - Materials
  - Products

Fact Is
Most Bugs WALK out of the l

Riskgroups and Biosafety levels are NOT the same

- Find your agent on the list for your country/continent
- Make a risk assessment depending on what you are doing with the agent
- THEN choose biosafety l



Risk Groups

- **Risk groups are based on**
  - Severeneess of disease
  - Individual and community risk
  - The host
  - Access to profylactic treatment
  - Whether the disease is endemic already

Biosafety

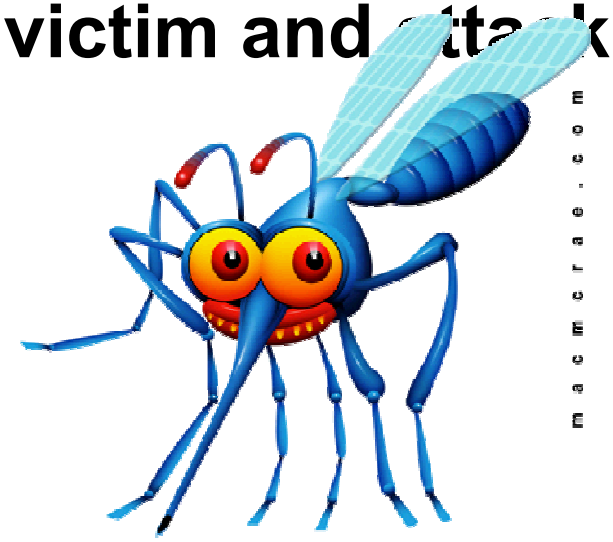
- **Biosafety levels are based on a risk assessment**
  - Information about the specific agent to be used
  - The work that is planned to be done
    - **Aerosoles**
    - **Scale**
  - The worker (host) and factors (training, health status etc)

Levels of Containment

- **BSL-1**
  Defined organisms
  Not known to cause disease in healthy adults
  - Cells, e-Coli etc
- **BSL-2**
  Moderate-risk agents that occur naturally in the community
  Disease of varying severity.
  - Diphteria, tetanus, pertussis
- **BSL-3**
  Indigenous or exotic agents, aerosol transmission
  Serious and potentially lethal infection
  - HIV, TB – 10 –30 years
- **BSL-4**
  Dangerous or exotic, high-risk agents
  Life-threatening diseases
  - Ebola, Marburg – 70%

Insects

- Are a great challenge
- Have own motor and propellas
- Have own free will
- Contrary to bacteria, they are able to decide on a victim and attack it



Biosafety 1 - 4 (BSL)

- **Determined by a risk assessment**
- **Implemented by risk management**
- **BSL is a combination of:**
  - Management controlls
  - Administrative controls
  - Work methods and procedures
  - PPE
  - Evaluation of health risks

Biosafety Level Recommendations

	Directional Airflow	Double Door Entry	Autoclave Available	Pass-Through Autoclave	Seamless Floors	Monolithic Ceilings	HEPA Filtered Exhaust	HEPA Filtered Supply	Supply/Exhaust Interlock	Personal Shower	Airlock Entry	Pressure Differential	HEPA Plumbing Vents	Effluent Decontamination	Pressure Decay Testing	Breathing Air System	Chemical shower
BSL-2 Laboratory	☣		☣														
BSL-3 Laboratory	☣	☣		☣	☣	☣											
BSL-3 Laboratory - Q Fever	☣	☣		☣	☣	☣	☣			☣							
BSL-3 Animal Facility	☣	☣		☣	☣	☣	☣			☣							
BSL-3 AG Lab & Animal	☣	☣		☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣		
BSL-4 Lab & Animal	☣	☣		☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣

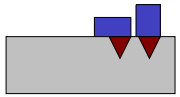
Biosafety Levels Advantages and Disadvantages: Small Group Activity

- List 3 advantages to working in a BSL3 laboratory.
- List 3 disadvantages to working in a BSL3 laboratory.
- Report to the class

Facility Costs for BSL 2-4 & GMP

BSL-2

Penthouse



Lab. floor

Basement

Diagrammatic Sections

Decon

Lab. Area
(1,000 SM)

Entry

Diagrammatic Plans

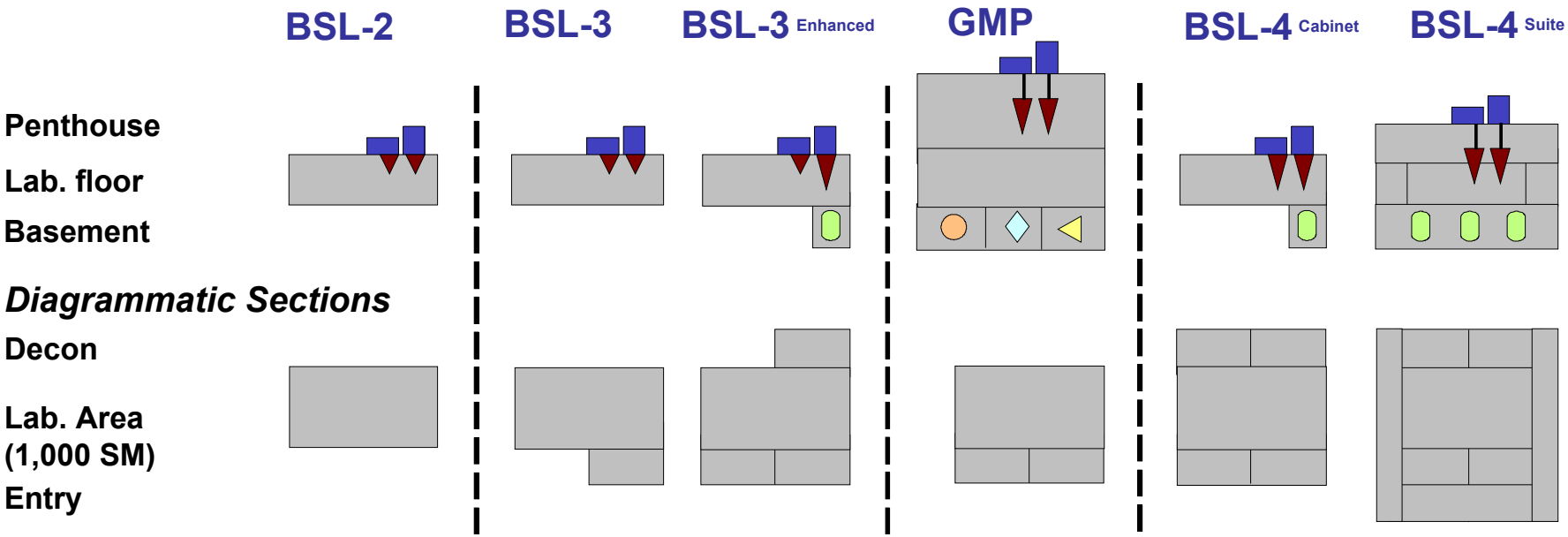
Square Meters (SM)

Cost/SM

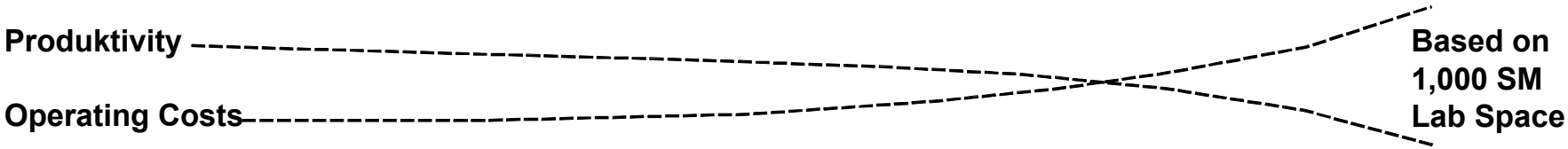
Cost (dollars)

Note; Comparison of costs at least 10 years old. But ratio of cost between different structures still correct

Facility Costs for BSL 2-4 & GMP



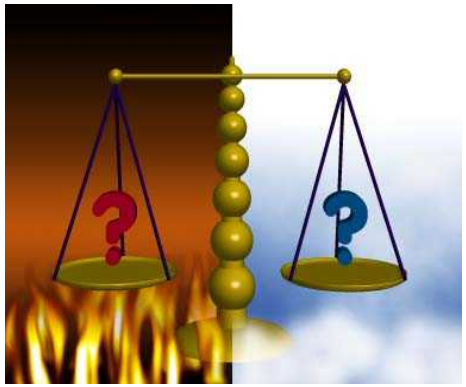
	BSL-2	BSL-3	BSL-3 Enhanced	GMP	BSL-4 Cabinet	BSL-4 Suite
Square Meters (SM)	1,000	1,100	1,400	5,800	1,600	5,000
Cost/SM	$1,890	$2,520	$3,708	$3,571	$6,183	$9,000
Cost (dollars)	1,890,000	2,772,000	5,191,200	20,715,000	9,892,800	45,000,000



Note; Comparison of costs at least 10 years old. But ratio of cost between different structures still correct

Once Again …

Risk / Cost



BSOs

Worker's Health

Death / Injury

Architects

Environment

Costs / Image & Profile

Engineers

Suppliers

(Bio)-Security

Terror / Assets / Costs

Managers

Biosafety

Death / Disease

Designers

GMP/Animal Health

Product / Animal Safety / Costs

Workers

All the stakeholders

Everybody Has a Piece of the Puzzle

Roles and Responsibilities: Small Group Activity

- **Which groups in your institution should have a role in planning, designing, and constructing a BSL3 laboratory?**

Planning Overview

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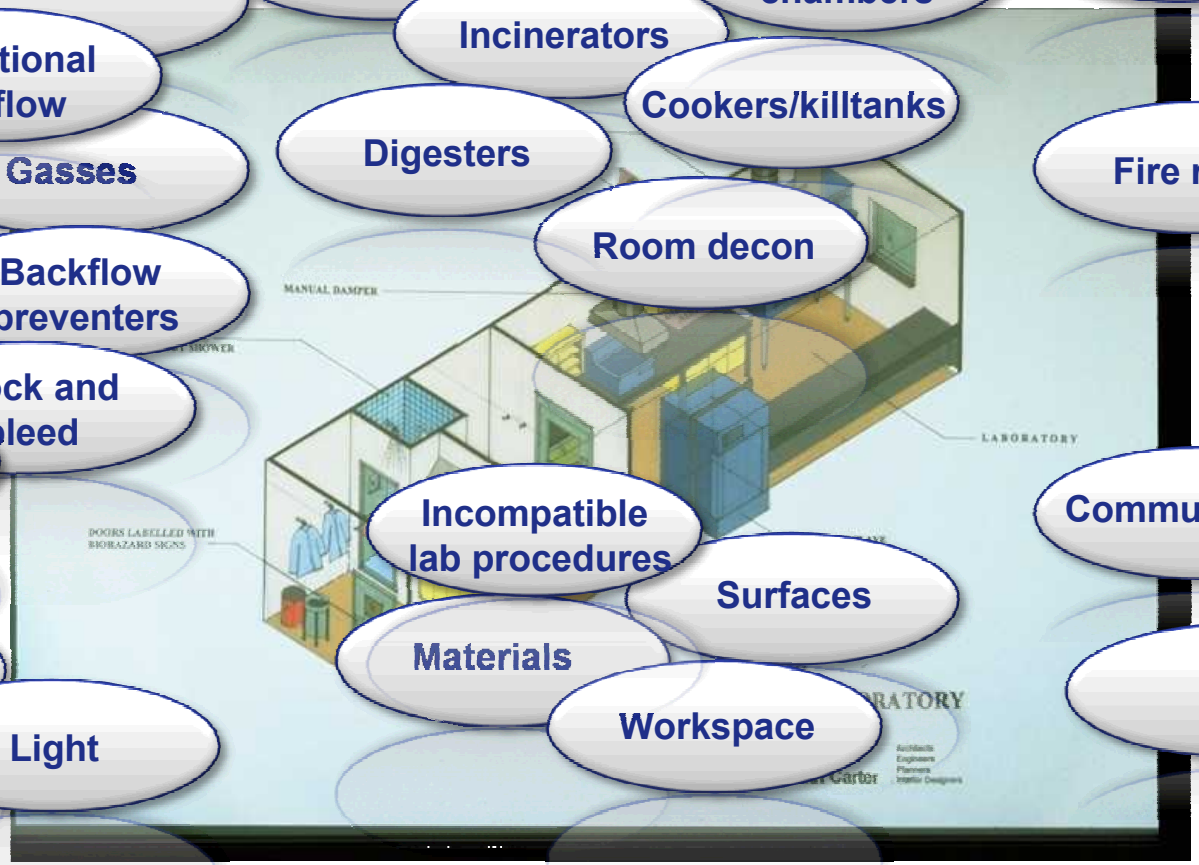
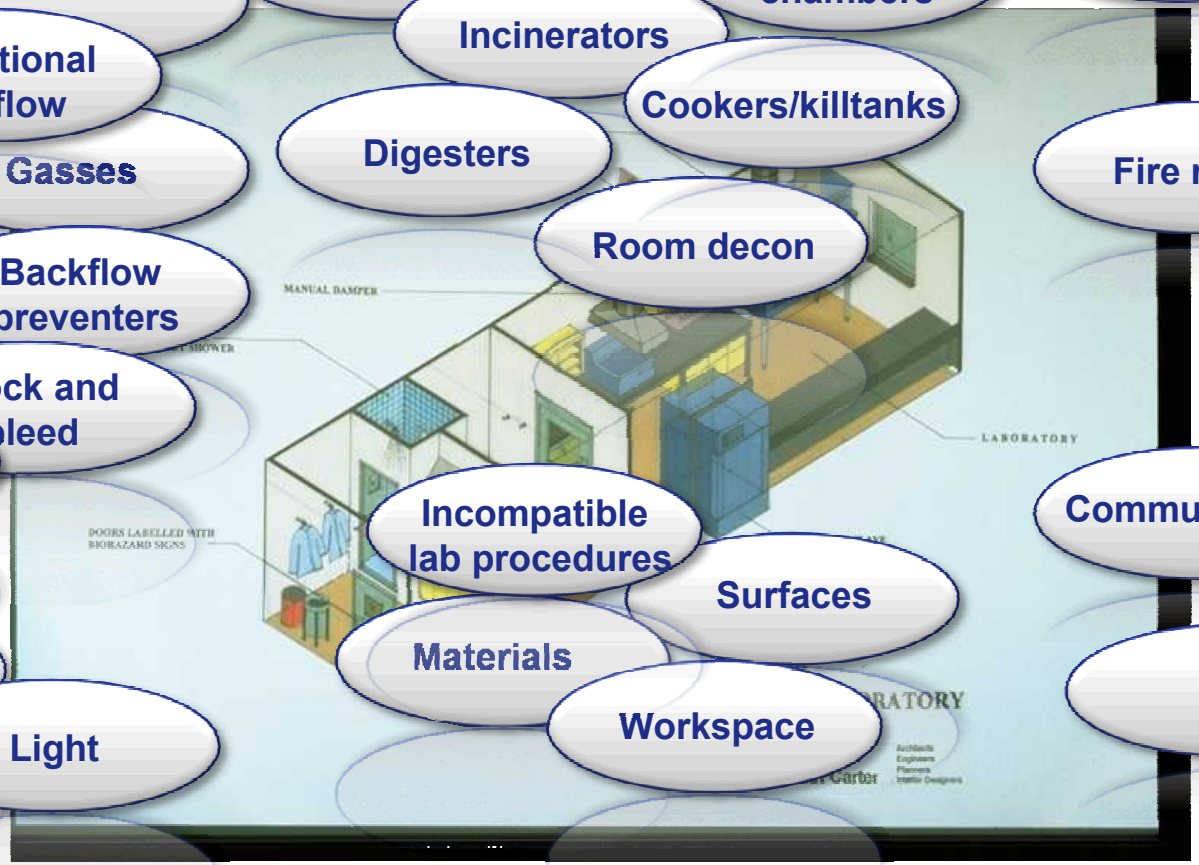
Containment Room



HVAC systems
Decontamination strategy
Isolation
Ordinary showers
Emergency showers
Emergency routes
APR doors
AHU
Pressure Control
Autoclaves
Access doors
Dunk tanks
Fumigation chambers
BSC
Fume hoods
Incinerators
Shared utilities
Directional airflow
Cookers/killtanks
Digesters
Fire rating
Utilities
Gasses
Room decon
Fire extinguishing system
Backflow preventers
Water
Bllock and bleed
Airgaps
Alarm systems
Incompatible lab procedures
Communication
Surfaces
Generators
Lab equipment
Materials
UPS
Light
Workspace
Emergency light
LMS

Containment Room



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Light
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Emergency light
LMS

Surfaces: Small Group Activity

- **Which surfaces do you have in your lab today?**
- **Rank them in the order of ability to be easily cleaned**
- **Present to class**

Why are surfaces so important?

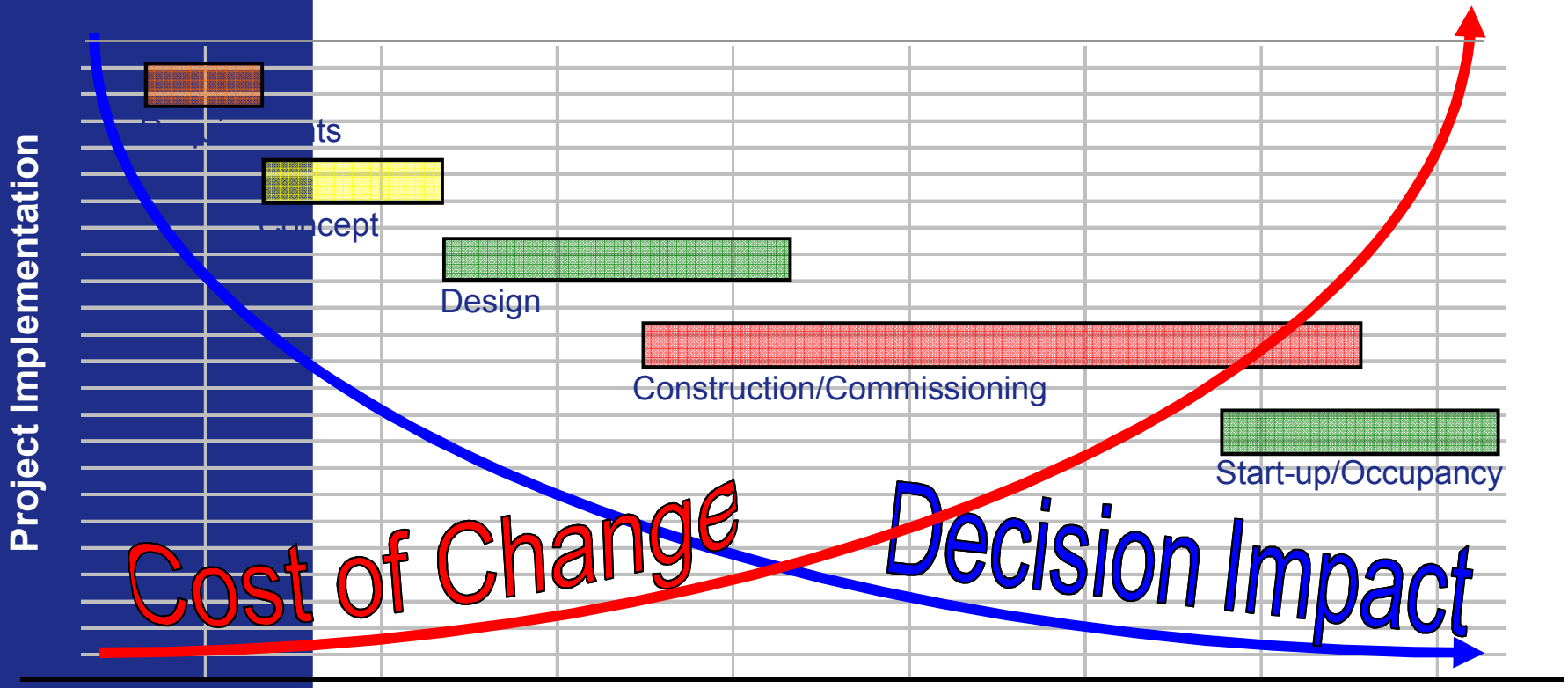
Uneven, cracked or pitted surfaces can hide microorganisms and are difficult to disinfect

High bacterial levels recovered from various surfaces after cleaning

Surface	Organisms / 100 cm^2
Wood	22,500
Concrete	12,500
Brick	76,500
Plastic	13,900
Metal	100

When Should Decisions Be Made?

the lon



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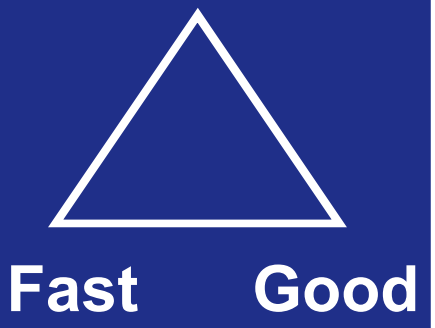
Slide Courtesy R.Kray

Do You Want to Pay NOW – or Later?

BUILDING COSTS

↔

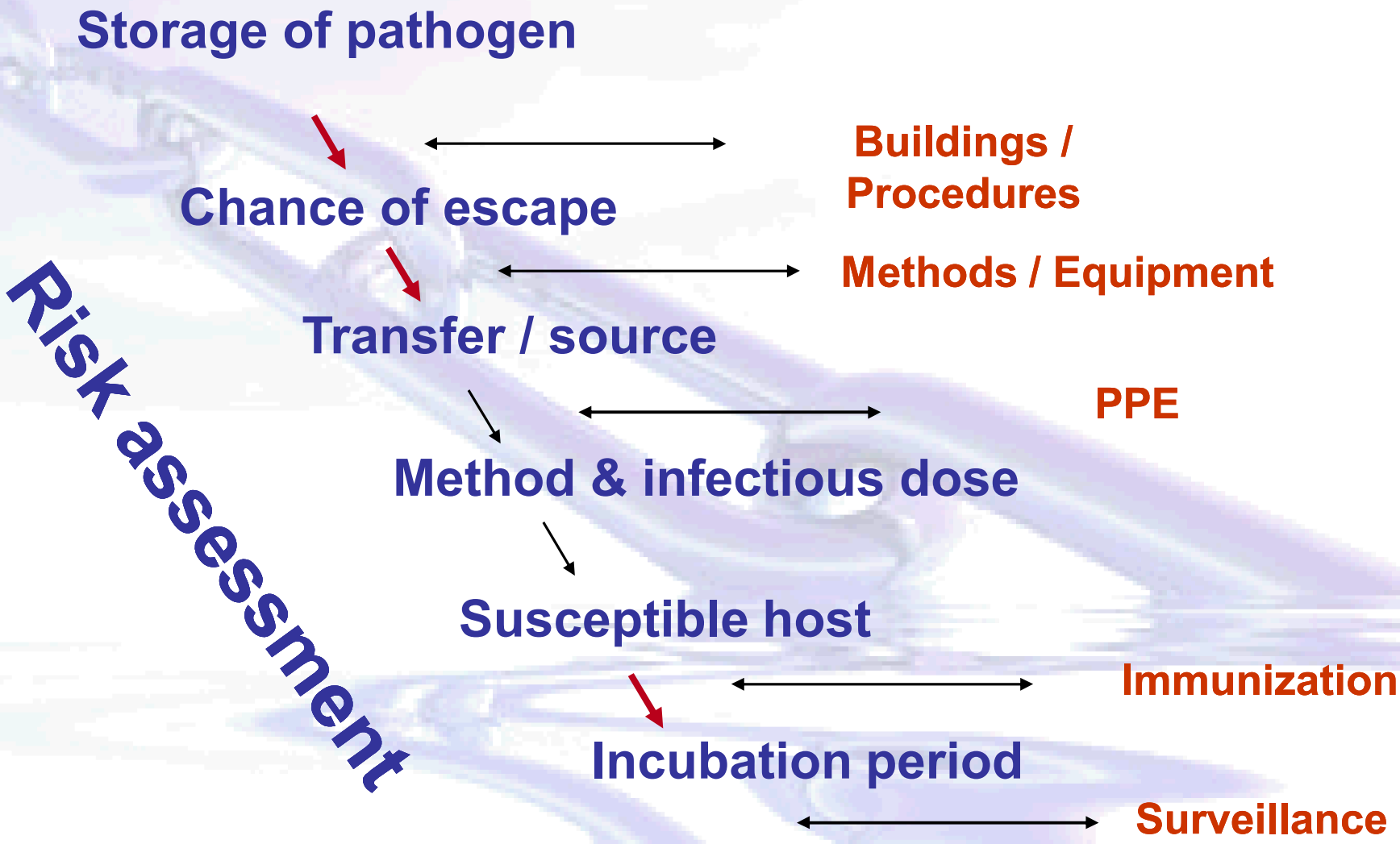
TOTAL COST OF OWNERSHIP



You can *only* have 2 out of 3!

THE BUILDING TRIANGLE

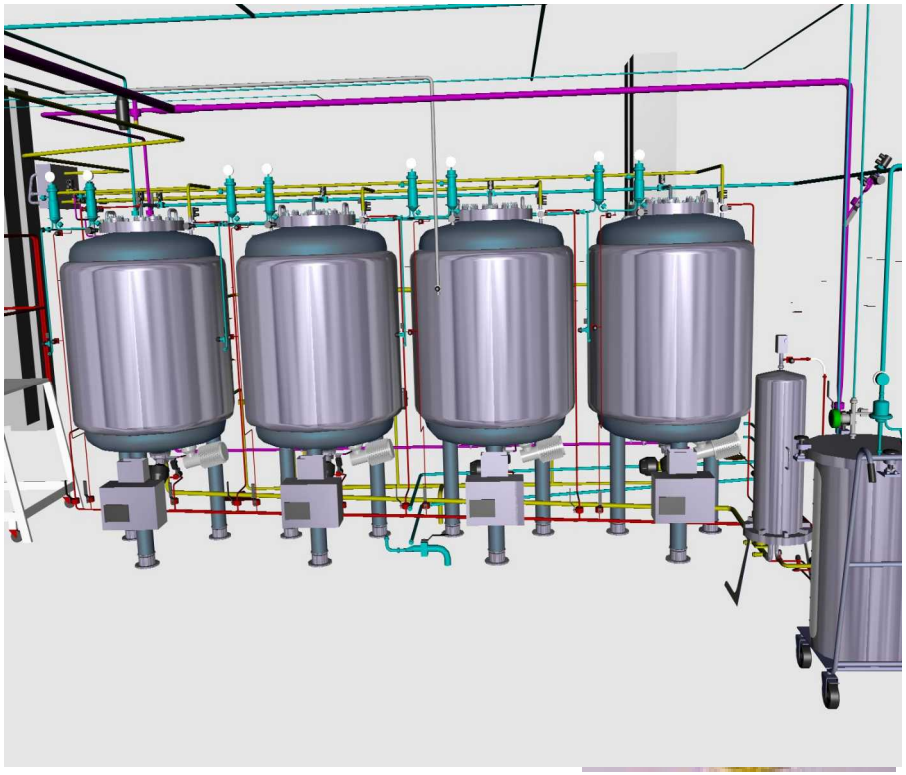
Chain of Infection



Biosafety Risk Assessment

- **Evaluate**
  - Reservoir
  - Volume
  - Concentration
  - Possible ways of escape
  - Route of transmission
  - Infectious dose
  - Susceptible hosts
  - Incubation period
  - Decontamination principles

Scale can make a difference



Mechanical - Risk Assessment

- In Different Situations
  - During production
  - Planned start up / shut down
  - Unplanned start up / shut down
  - Fire / power failure
  - CIP / SIP
- For Different Aspects of Production
  - Temperature (high, low)
  - Pressure (high, low)
  - Flow (fast, slow, reverse)
  - Volume / level (high, low)
  - Mixing / surface tension/bubbles
  - pH, Redox / density
  - Leakage / breakage
  - Tanks / pumps / pipes / valves
  - Computer / alarms / communication
- Key Words
  - None / too much / forgotten
  - More / less
  - Part of
  - Added
  - Reversed / wrong direction
  - Wrong component / object
  - Leaking / lost
  - Too fast / slow / late
  - Too hard / soft
  - Too long / short
  - Too hot / cold

Risk Assessment

RA

Risk assessment identifies how the critical system performs

Consequence Category Descriptions

Consequence	Description
Performance/Facilities	All risks that can impact on the ability to deliver the work programme through impairment to facilities or damage to assets, including buildings, essential infrastructure (e.g. power/water), laboratories and specialised equipment.
Image/Reputation	All risks that can impact on the reputation of the organisation and its customer/ collaborator/ public perception, including standing in the scientific community.
Health and Safety	All risks that could result in harm to an individual's health or general well being. Could include exposure to organisms and/or a resulting infection. However, non-biological threats are also included (e.g. burns, physical injury, asphyxiation, etc.), many of which may result from hazards created by the control mechanism in place to manage biorisk.
Environment	All risks that could result in a release of biological or other potentially harmful material to the environment either on or off site.
Legal/Regulatory	All risks that could bring the organisation into non-compliance with applicable legislation.
Financial	All risks that have the potential to result in costs to carry out remedial work.
Security	All risks that could result in a breach of security. These could be physical breaches, unauthorised access to information, or corruption of essential data and control systems.

Table courtesy of DNV

Risk Assessment

RA

Risk assessment identifies how the critical system performs.

Likelihood	Description	Frequency
1. Rare	Very unusual events that do not tend to occur in this sector. May require a freak combination of factors for an incident to occur.	Less than 1 in 100 years.
2. Unlikely	The event could occur at some time and has been known in this sector. Not likely to happen but could were a rare variety of factors to combine.	At least one in 30 years.
3. Possible	The event does occur in this sector and would require a combination of factors.	At least one in 10 years.
4. Common	Has happened in this or similar Institutes. Not certain to happen but an additional factor may result in an incident.	At least once per year.
5. Certain	Almost inevitable and the event is expected in most circumstances.	Once per month.

Table courtesy of DNV

Basic Design: Design equipment, filter boxes, chose materials and construction methods with spills in mind?

NO →

Yes ↓

Detailed Design: Verify the material resistance against decon agent and verify the flow of air, waste, people, etc.?

NO →

Yes ↓

Construction Phase: Focus on slopes, drains, holding volume, surfaces, airlocks and floor tightness?

NO →

Yes ↓

Commissioning: Test that it DOES work?

NO →

Yes ↓

Before going hot: Do the ”spills” and write the SOPs?

NO →

Yes ↓

Preventive Maintenance: Train and retrain the staff?

NO →

Yes ↓

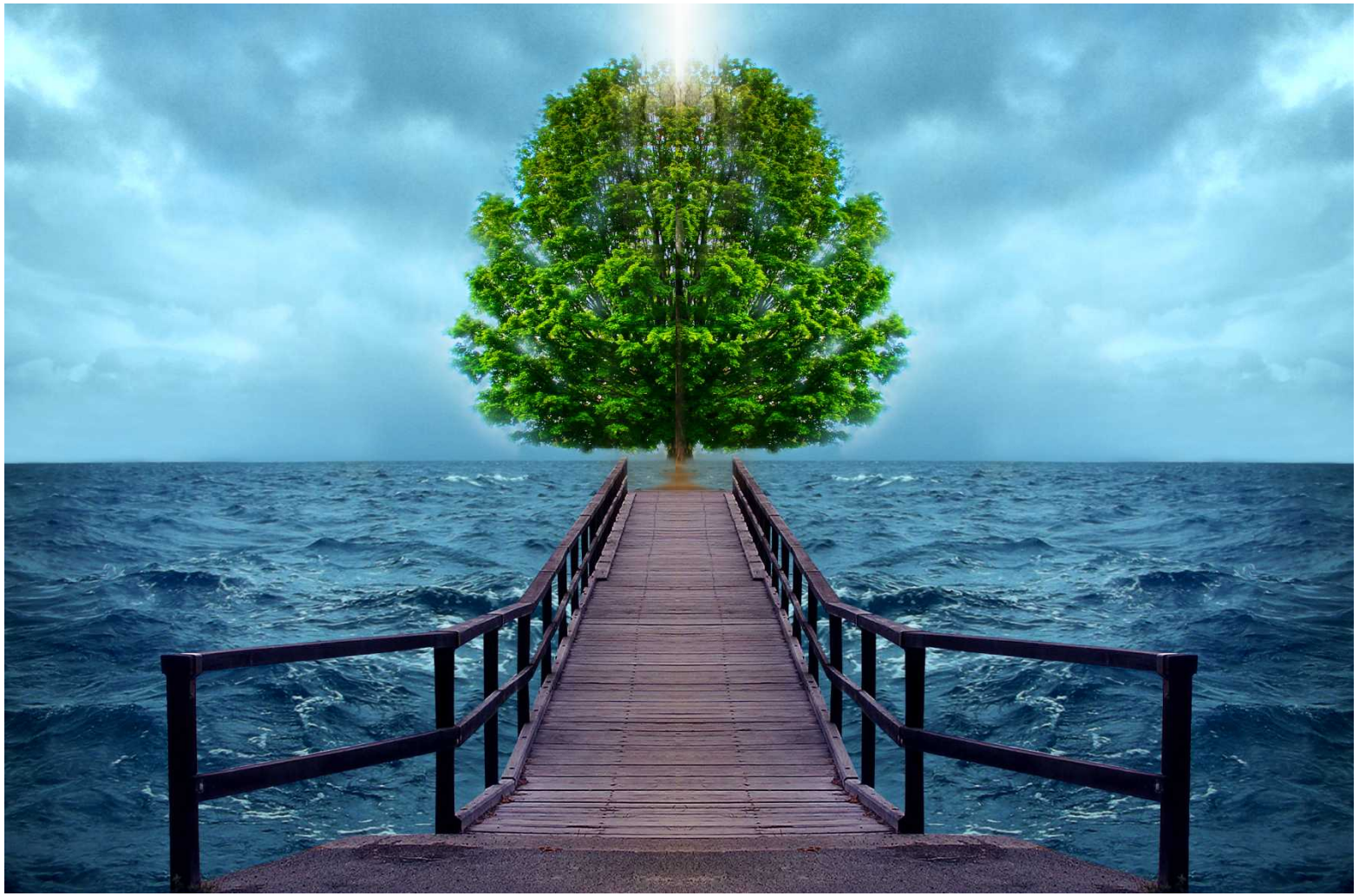
Incident

Disaster

Design Errors

- Can be caught early in the design phase ....
- If you use the time and effort wisely

Impact On the Environment



Risk Assessment: Small Group Activity

- How do you assess risk in your own labs?
- Write down your own answers, and then share with others at your table
- If you wish, share with the class

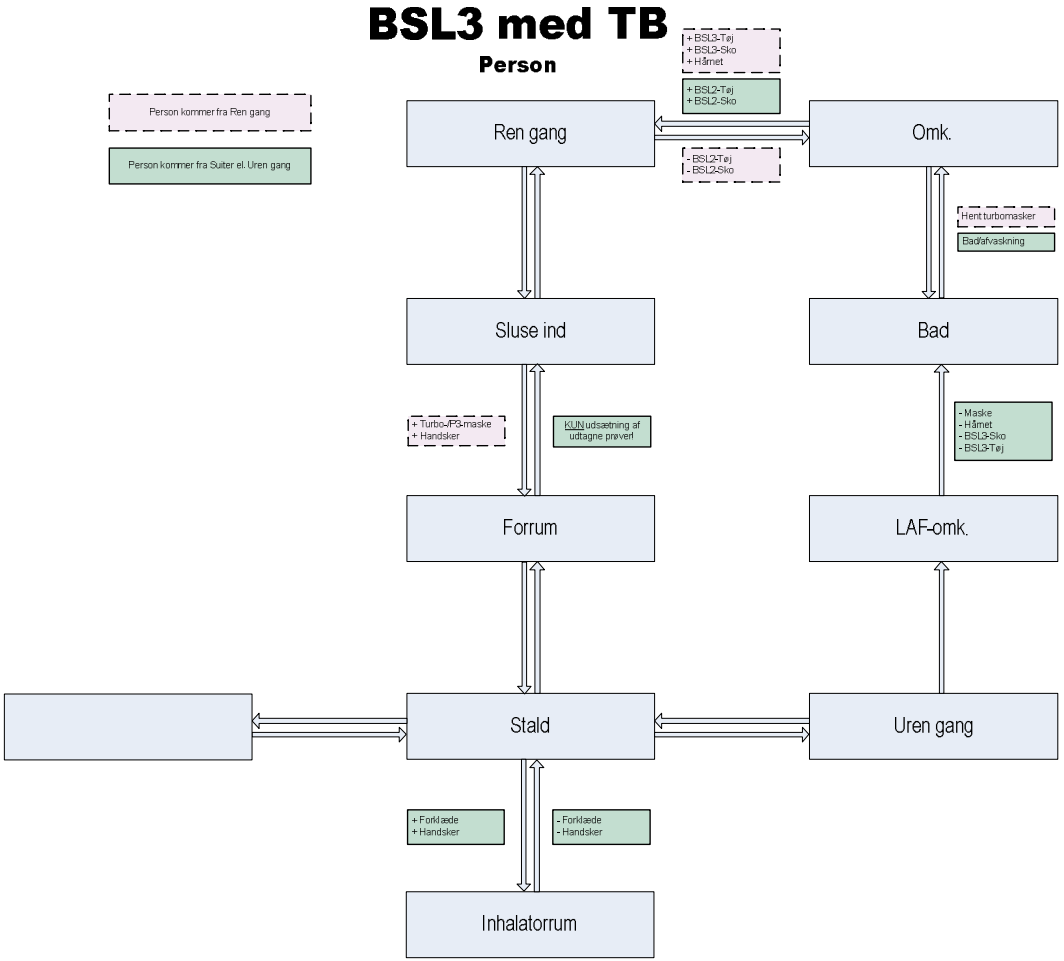
COMMUNICATION TOOLS

Flow of People Within the BSL-3 Area

Schematic Design

Design Development

Construction Documents

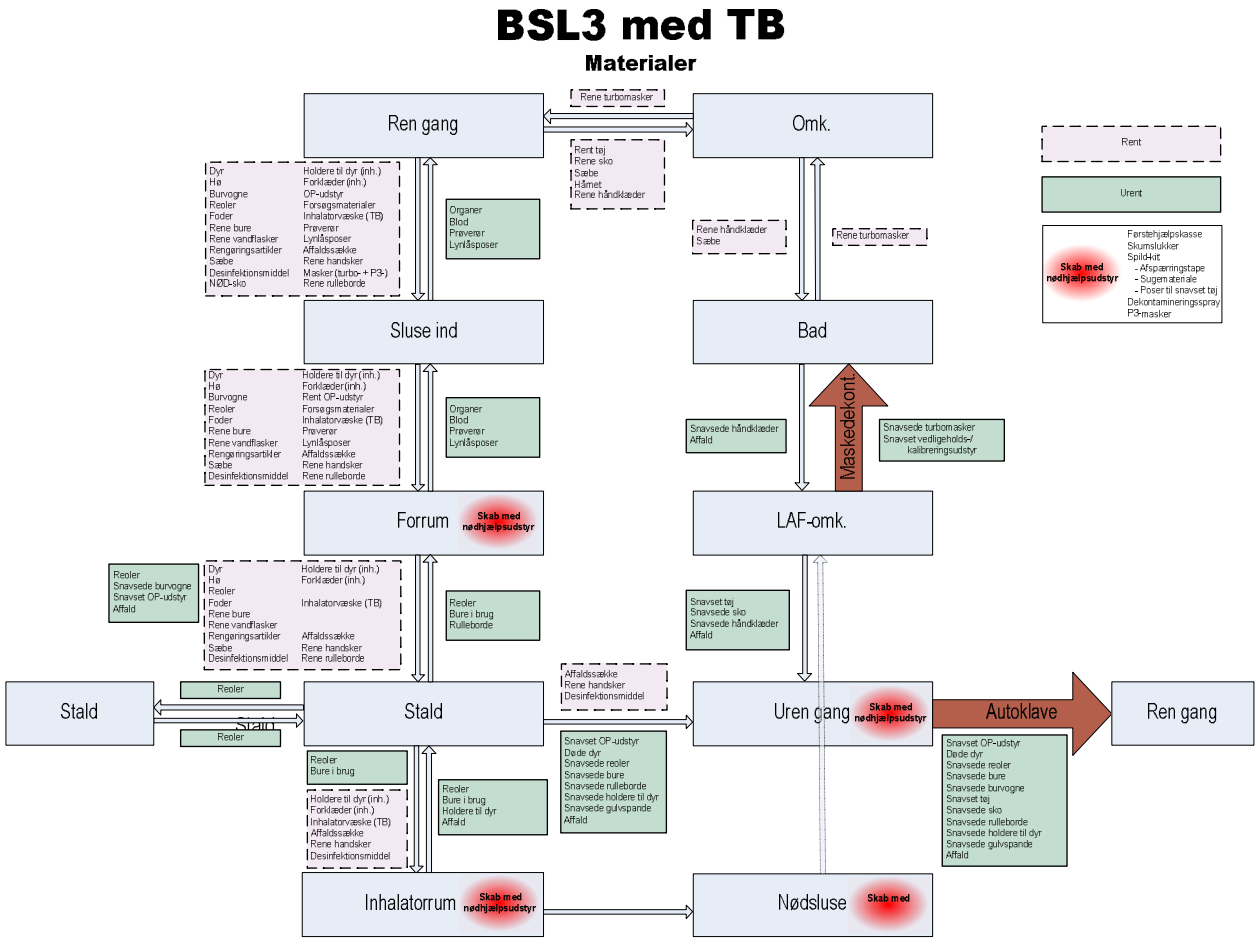


Flow of Materials Within the BSL-3 Area

Schematic Design

Design Development

Construction Documents

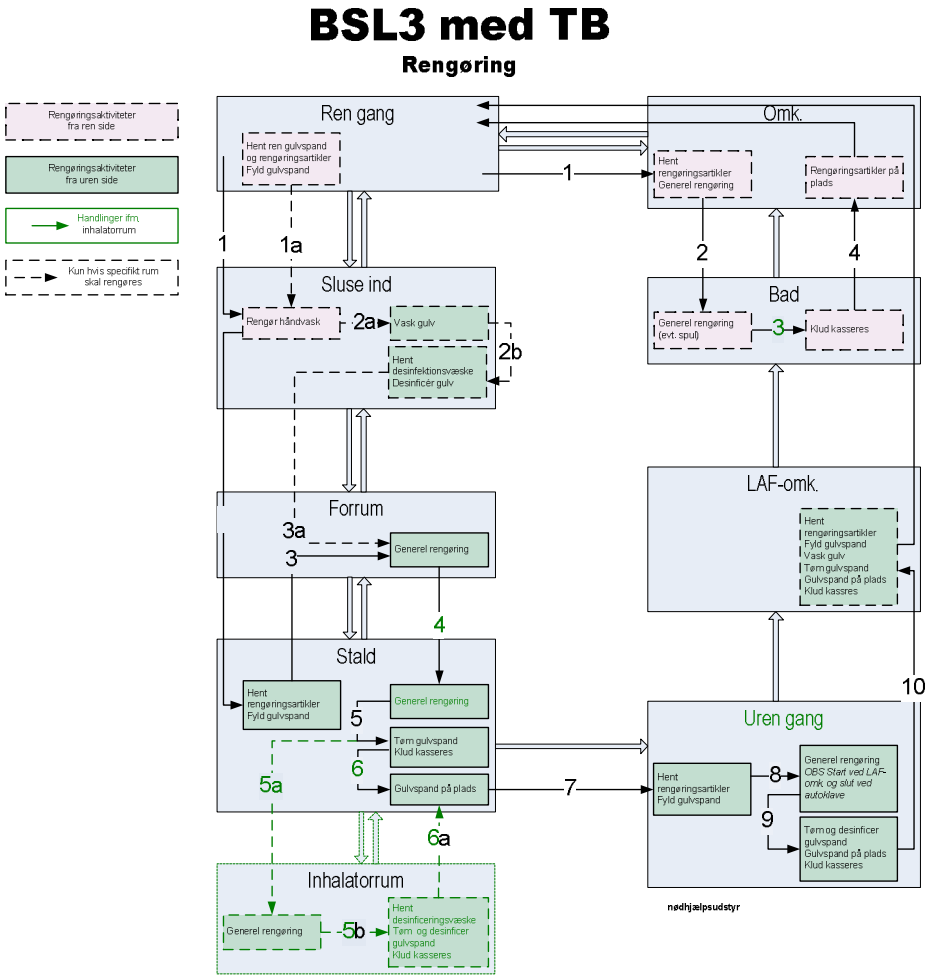


Cleaning Flow Within the BSL-3 Area

Schematic Design

Design Development

Construction Documents

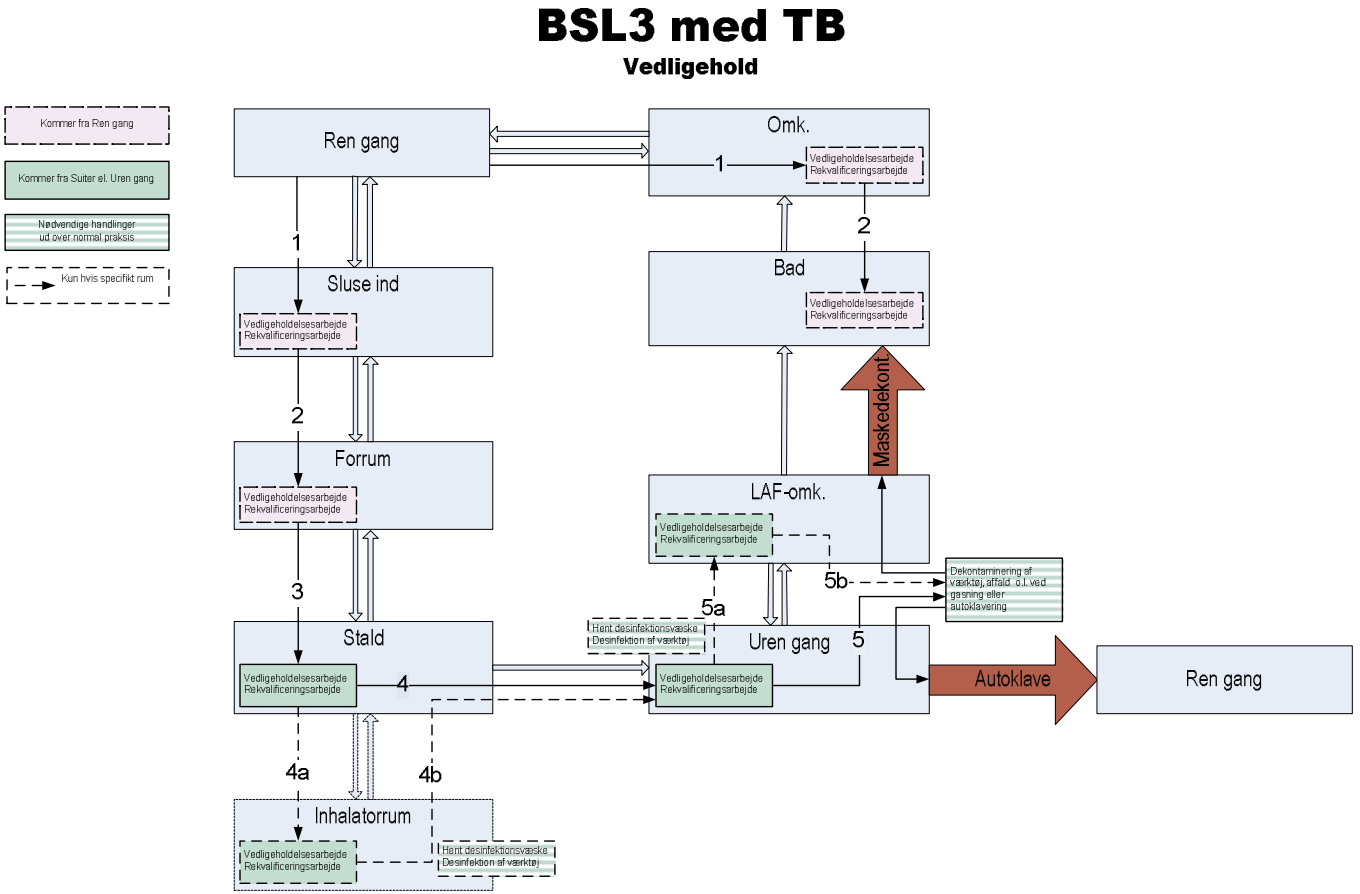


Maintenance Within the BSL-3 Area

Schematic Design

Design Development

Construction Documents



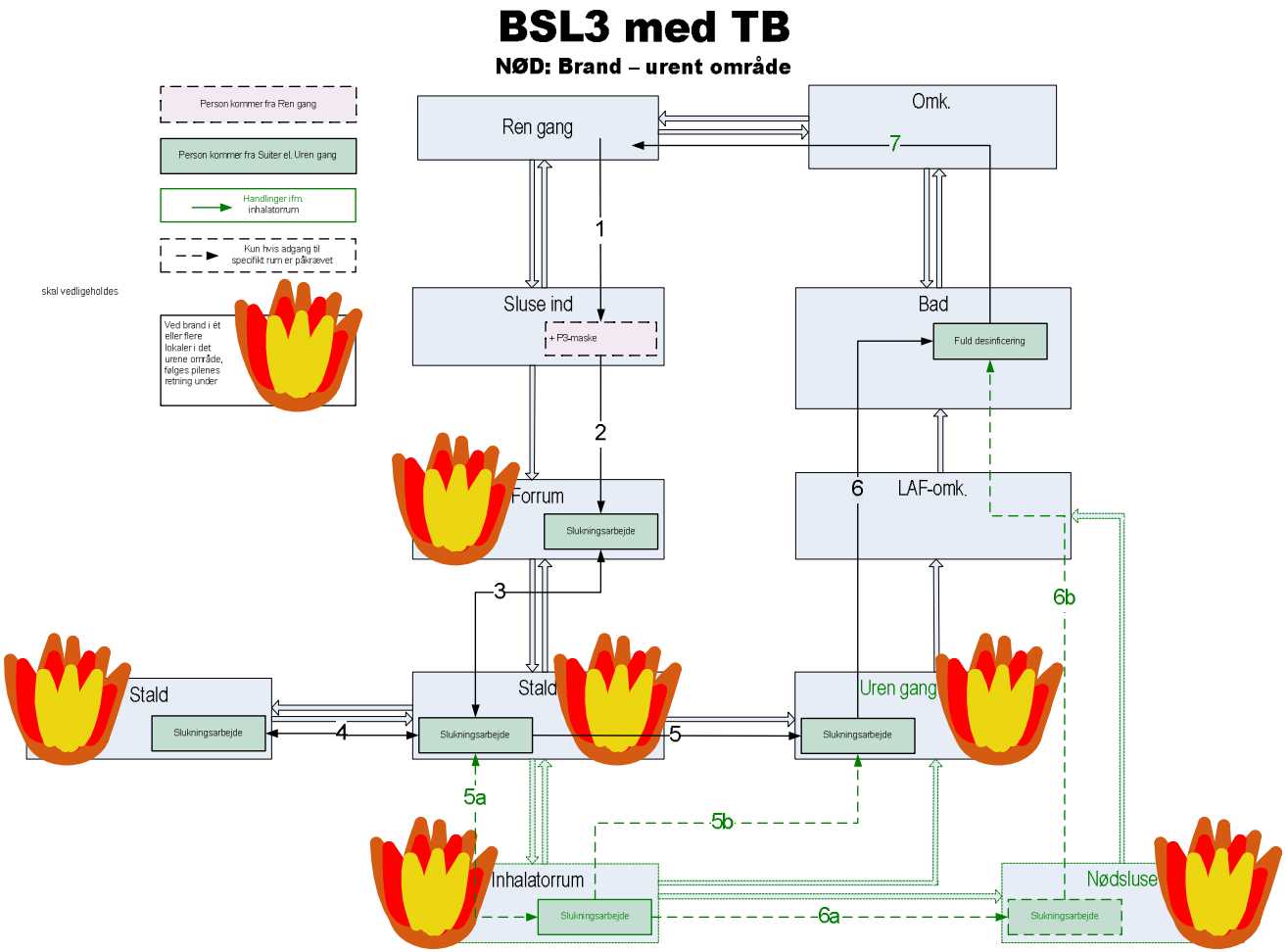
VHK19

Fire Within the BSL-3 Area

Schematic Design

Design Development

Construction Documents



Slide 203

VHK19 removed seasickness

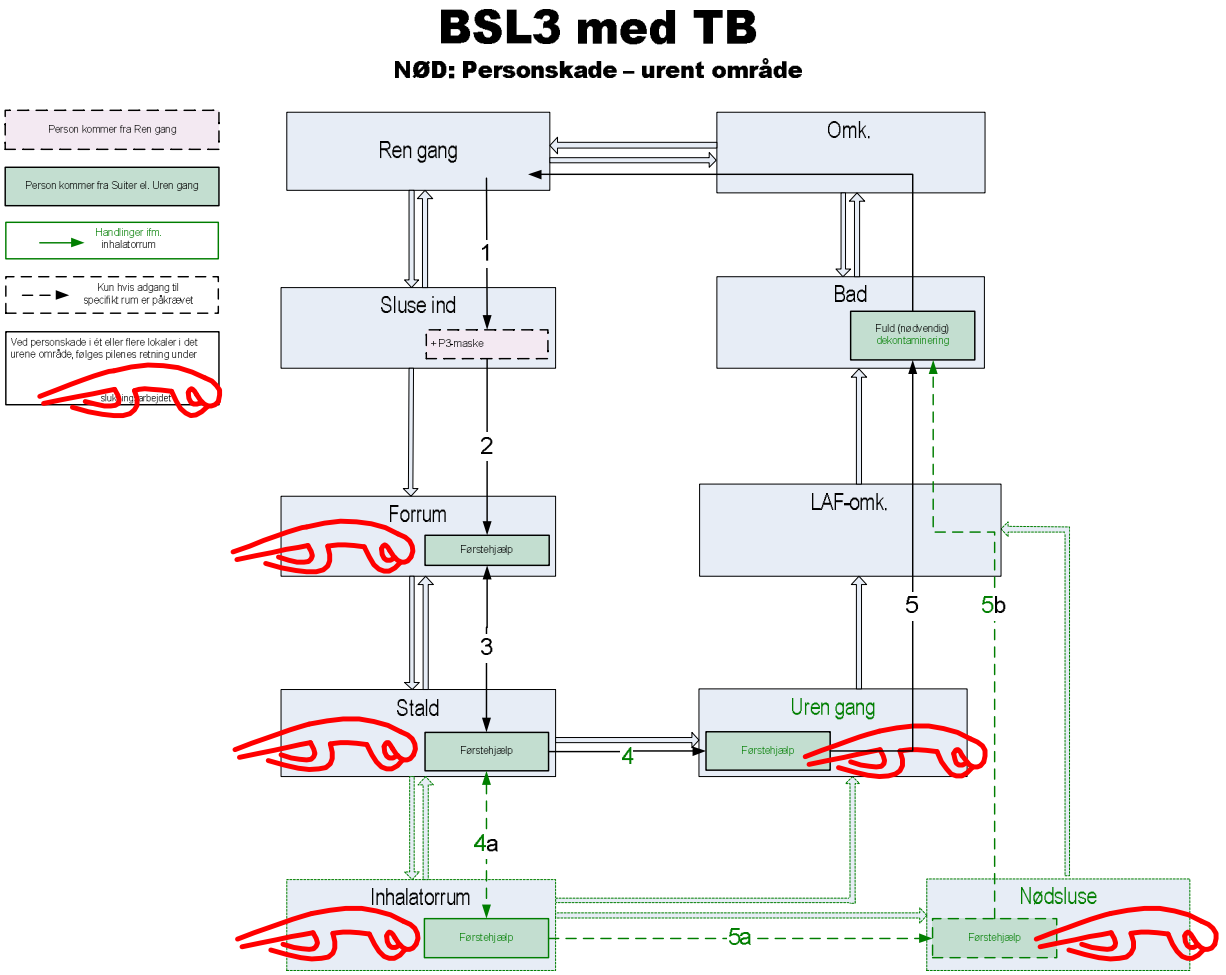
Vibeke Halkjær-Knudsen, 7/20/2010

Evacuation of Injured People from BSL-3

Schematic Design

Design Development

Construction Documents



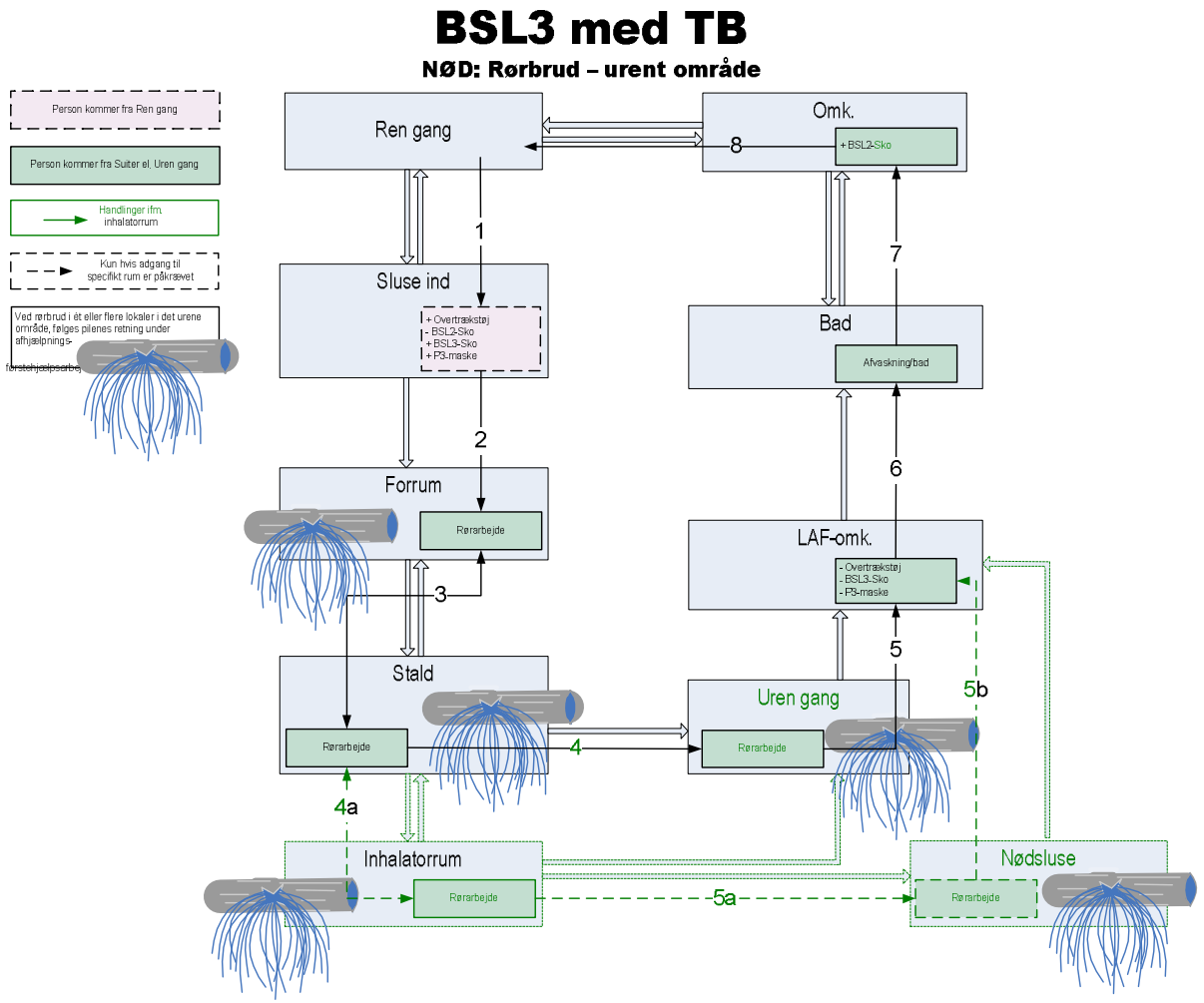
Water Flooding the BSL-3 Area

Schematic Design

Design Development

Construction Documents

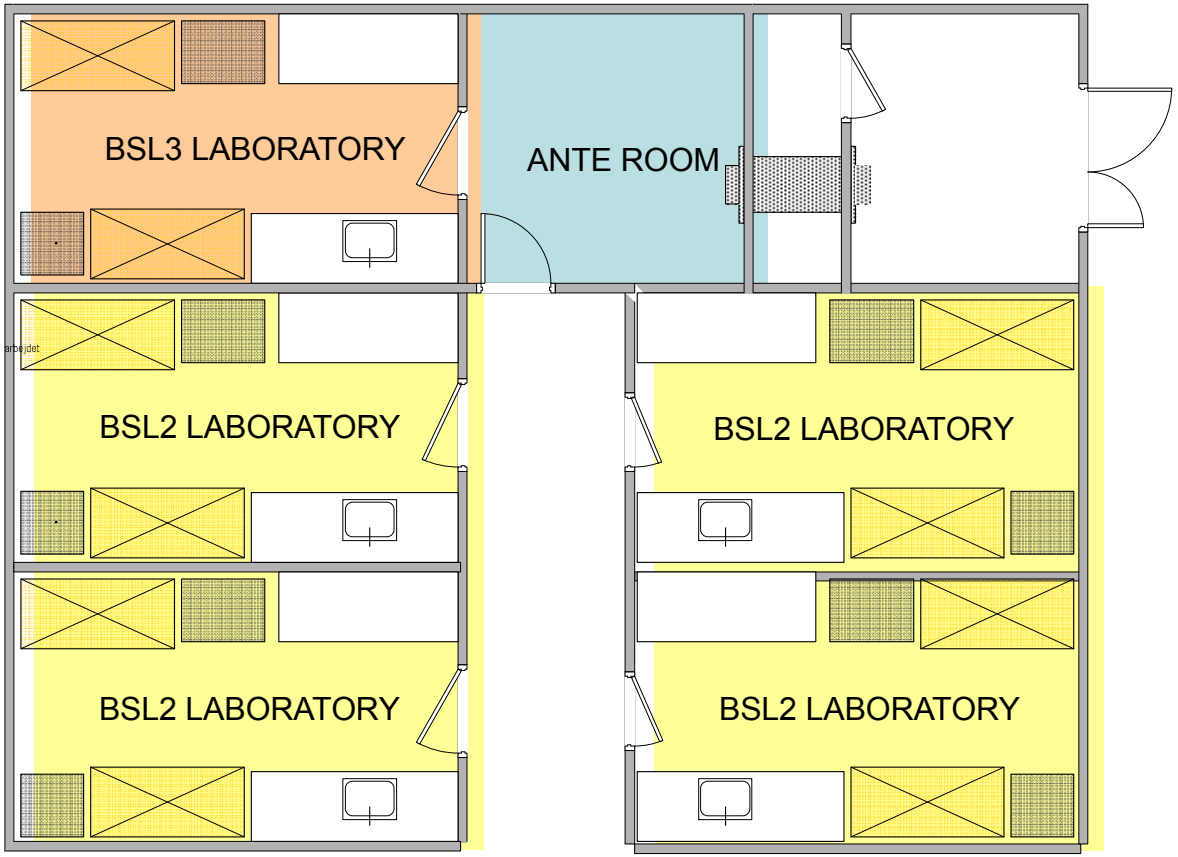
s



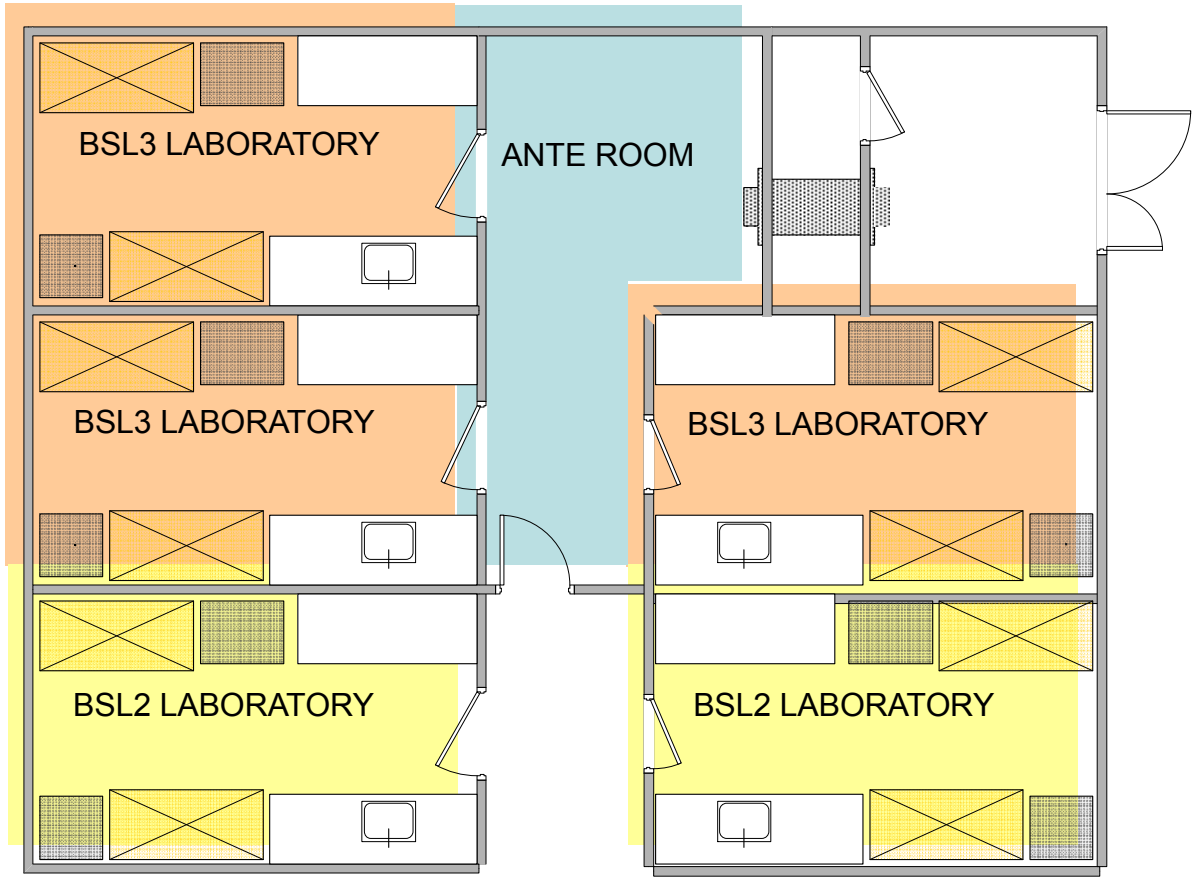
Biosafety Levels Advantages and Disadvantages: Small Group Activity

- Choose a laboratory process performed today in the lab
- Make a flowsheet of the process
- Report to the class

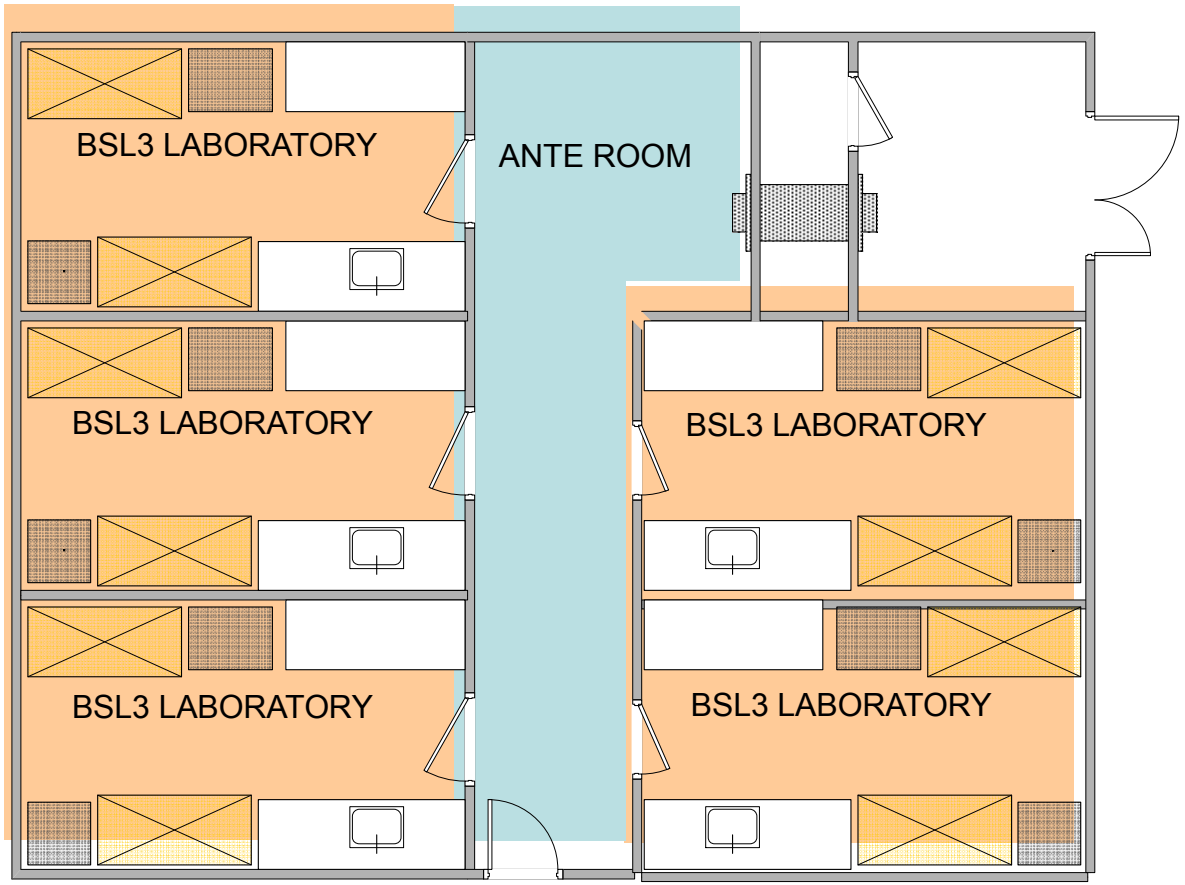
Designing for Future Flexibility



Designing for Future Flexibility



Designing for Future Flexibility



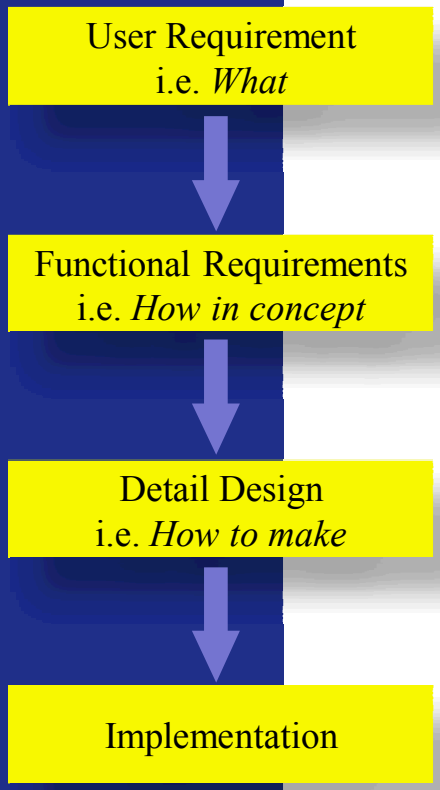
STAYING IN CONTROL OF THE PROCESS

Planning Overview

- **Review existing national and international standards, regulations, and guidelines**
- **Conduct both biosafety and biosecurity risk assessments**
- **Prepare a Design Intent document—the owner's project requirements**
  - Describe facility and scientific goals and needs
  - Determine applicable guidelines and regulations
  - Detail functional requirements
  - Requirements for lab equipment
- **Determine staffing requirements**
- **Outline the commissioning and design qualification plan**
- **Determine resources required for project and subsequent operations and maintenance**
  - Reevaluate financial requirements throughout project, and ensure that adequate resources exist to support all operations

Qualification Process

Enhanced Design Review/ Design Qualification Process



Comprehensive Qualification Process

Enhanced Design Review/ Design Qualification Process

User Requirement
i.e. *What*

Functional Requirements
i.e. *How in concept*

Detail Design
i.e. *How to make*

Implementation

Comprehensive Qualification Process

Performance Qualification

erational Qualification

tallation Qualification

Implementation

Why Is It So Expensive?

THE PLANNING AND DESIGN PHASE

And Why Does It Take So Long Time?

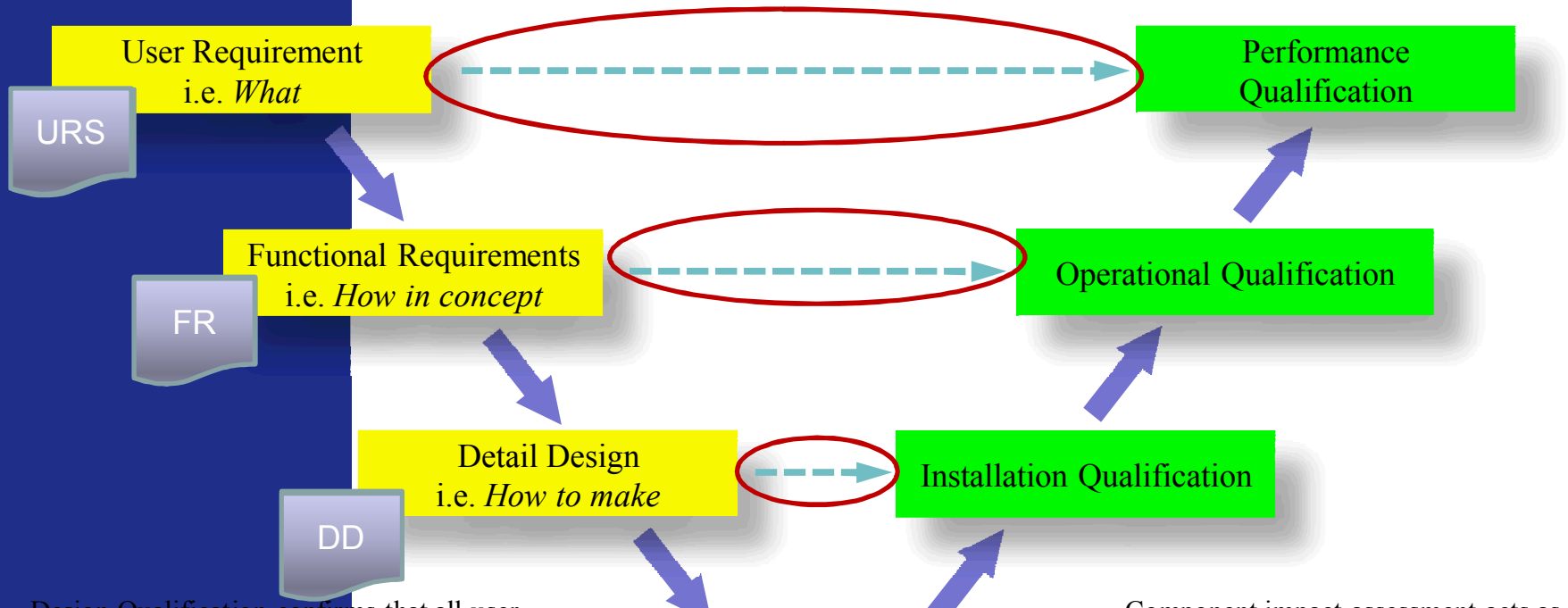
THE PLANNING AND DESIGN PHASE

Documentation takes time

The V Model

Enhanced Design Review/ Design Qualification Process

Comprehensive Qualification Process



Design Qualification confirms that all user requirements and general regulatory requirements have been included in the design

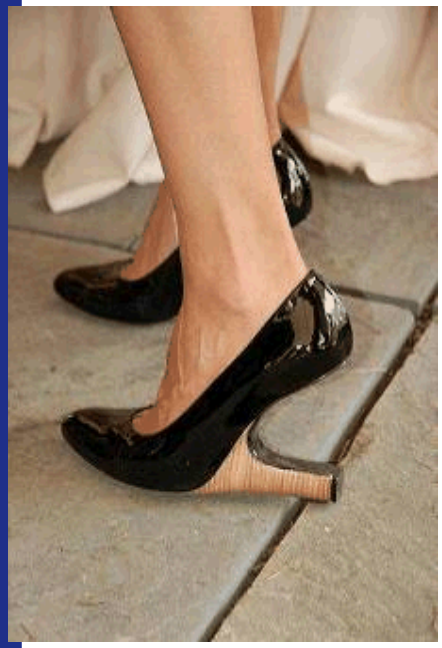
Component impact assessment acts as a "filter" of the design to identify the critical elements for Qualification

Design Qualification – Proving that the Design *Will* Work

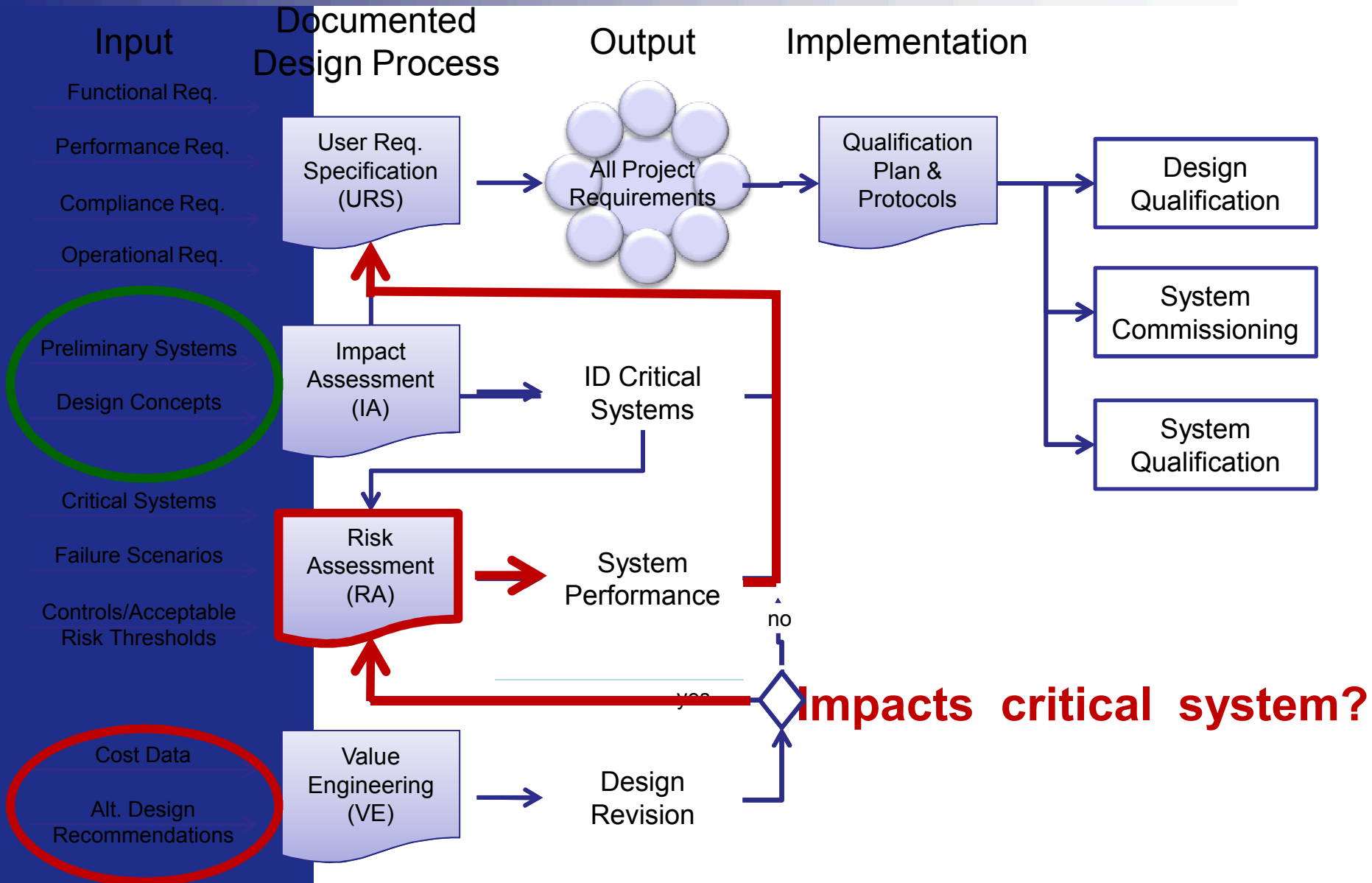
- **Documented verification that the proposed design…**

  is suitable for its intended purpose

- **The compliance of the design with regulatory requirements is *demonstrated and documented***



Document Control Process



How Do We do That?

URS

Every requirement is numbered and its significance is identified.

It is tracked for the entire project.

No	Requirement	Method	Consequennce if not achieved		To be done during	
1	Der skal foreligge en installationsbeskrivelse. Beskrivelsen skal beskrive hovedtræk i anlæggenes opbygning. Rationaler for valget af projektspecifikke og/eller kritiske løsninger, der afviger fra "standard-løsninger" skal ligeledes indgå i beskrivelsen.	Godkendelse af IC-dokumentation	VE1	Besvær ved ombygning/ vedligehold	C	DC, IC
2	Der skal foreligge rationaler for, hvilke komponenter der er kritiske, og hvilke der er ukritiske. Rationalerne skal være en del af installationsbeskrivelsen.	Godkendelse af IQ-dokumentation	-	Manglende sporbarhed/ forståelse	Q	IQ
3	Kritiske komponenter skal være opmærket med komponentnummer ifølge TEK/S-006-011 og registreret i en stykliste, som opfylder kravene i TEK/S-007-04 og TEK/S-014-01. For hver kritisk komponent skal der foreligge et datablad.	Godkendelse af installation	VE2	Ufuldstændig anlægs-dokumen-tation	Q	DQ, IQ

How Do We do That?

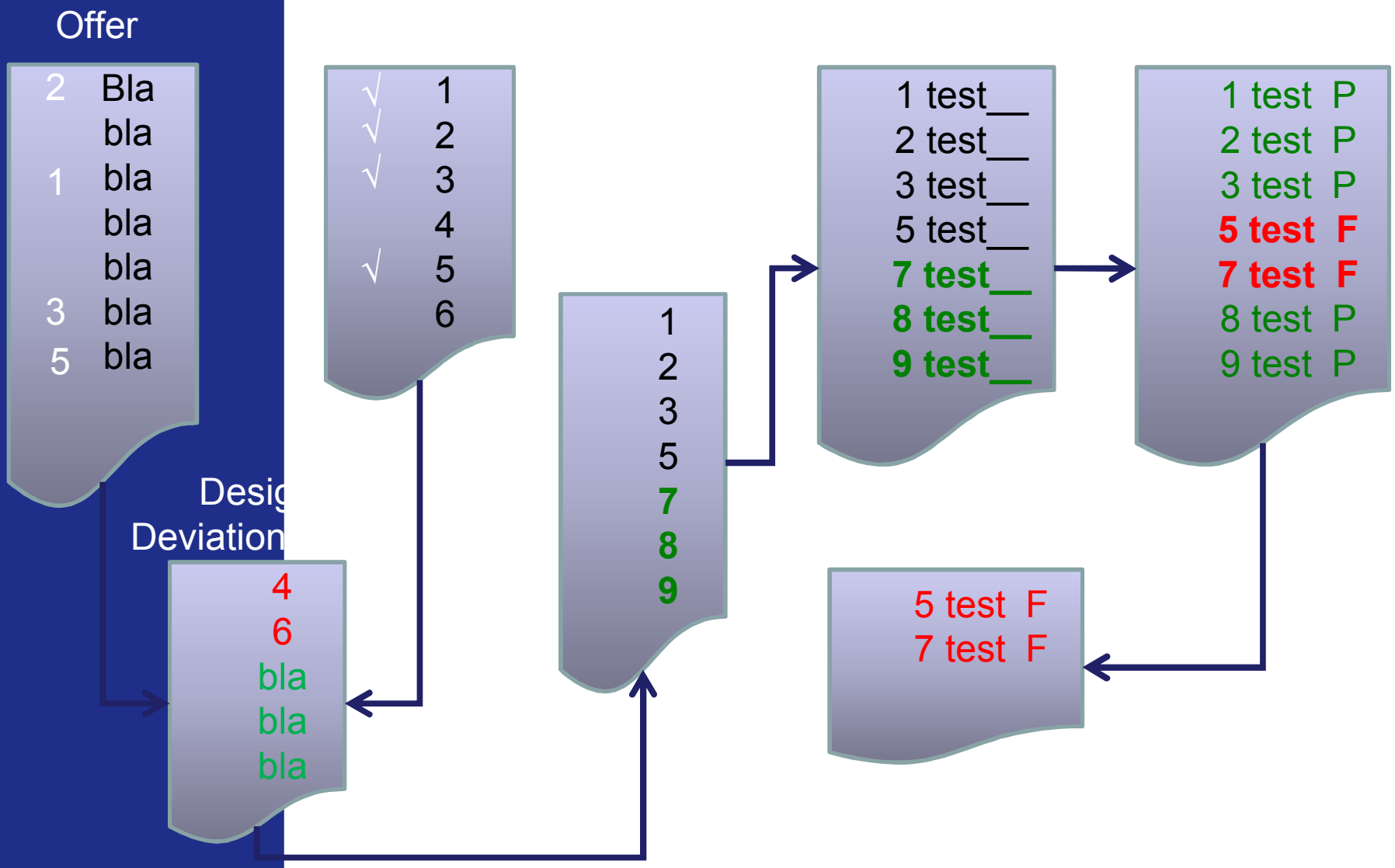
Test protocol

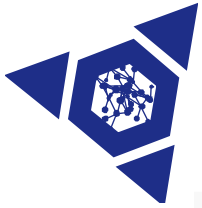
Easy to write:

- change the coloumns
- add acceptance criteria
- signatures
- dates

No	Requirement	Method	Consequennce if not achieved	Acceptance criteria Dates Signature
1	Der skal foreligge en installationsbeskrivelse. Beskrivelsen skal beskrive hovedtræk i anlæggenes opbygning. Rationaler for valget af projektspecifikke og/eller kritiske løsninger, der afviger fra "standard-løsninger" skal ligeledes indgå i beskrivelsen.	Godkendelse af IC-dokumentation	VE1	Besvær ved ombygning/ vedligehold	
2	Der skal foreligge rationaler for, hvilke komponenter der er kritiske, og hvilke der er ukritiske. Rationalerne skal være en del af installationsbeskrivelsen.	Godkendelse af IQ-dokumentation	-	Manglende sporbarhed/ forståelse	
3	Kritiske komponenter skal være opmærket med komponentnummer ifølge TEK/S-006-011 og registreret i en stykliste, som opfylder kravene i TEK/S-007-04 og TEK/S-014-01. For hver kritisk komponent skal der foreligge et datablad.	Godkendelse af installation	VE2	Ufuldstændig anlægs-dokumen-tation	

How


Offer
2 Bla
bla
1 bla
bla
bla
3 bla
5 bla
√ 1
√ 2
√ 3
4
√ 5
6
1
2
3
5
7
8
9
1 test__
2 test__
3 test__
5 test__
7 test__
8 test__
9 test__
1 test P
2 test P
3 test P
5 test F
7 test F
8 test P
9 test P
Desig
Deviation
4
6
bla
bla
bla
5 test F
7 test F



..... Are We Happy Now?

OK, NOW WE HAVE THE DESIGN FIXED

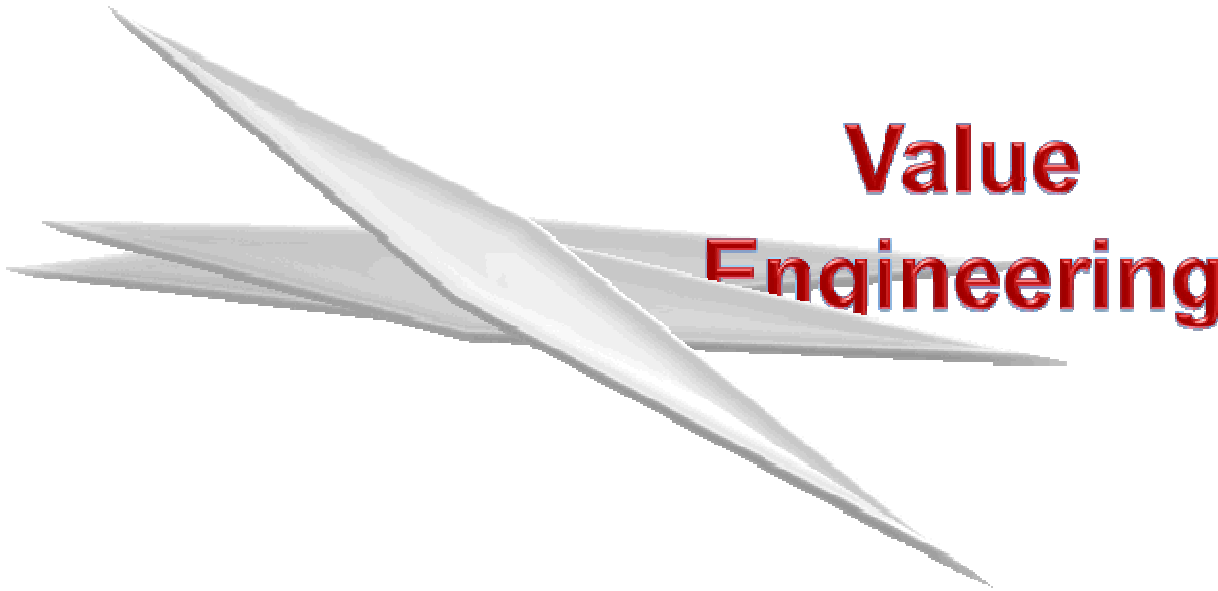
.....We Do Not Have Money Enough - What Can We Do?

BUDGET RESTRICTIONS

Construction Cost Versus Total Cost of Ownership

Value
Engineering

Construction Cost Versus Total Cost of Ownership



BSL3 Maintenance Costs

International Biological Threat Reduction,
Sandia National Laboratories, USA

SAND No. 2008-2050C, 2008-0480P, 2005-7039C, 2005-3288C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

Maintaining the Facility

- **Review existing national and international standards, regulations, and guidelines**
- **Conduct both biosafety and biosecurity risk assessments**
- **Prepare a Design Intent document—the owner's project requirements**
  - Describe facility and scientific goals and needs
  - Determine applicable guidelines and regulations
  - Detail functional requirements
  - Requirements for lab equipment
- **Determine staffing requirements**
- **Outline the commissioning and design qualification plan**
- **Determine resources required for project and subsequent operations and maintenance**
  - Reevaluate financial requirements throughout project, and ensure that adequate resources exist to support all operations

No matter how we look at it.....

CONTAINMENT BUILDINGS ARE EXPENSIVE TO MAINTAIN

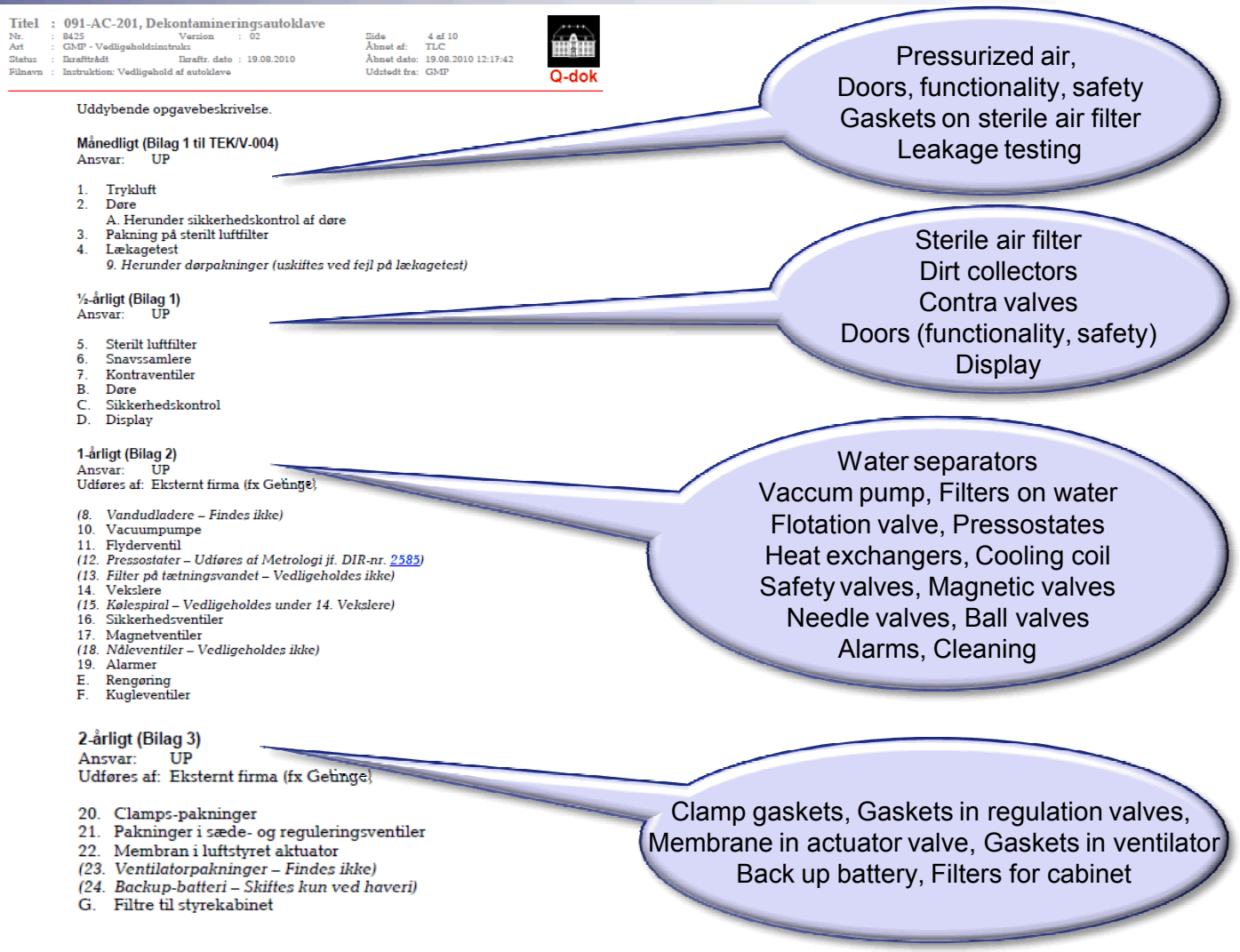
.....Do we pay up front during the building phase – or will we have to pay the rest of the service life of the building?

BUILDING VERSUS MAINTENANCE COSTS

Preventive Maintenance

Decon Autoclave

Monthly
½ Yearly
Yearly
Biannualy



Titel : 091-AC-201, Dekontamineringsautoklave
Nr. : 8425 Version : 02 Side 4 af 10
Art : GMP - Vedligeholdsinstruks Åbnet af: TLC
Status : Ikrafttrådt Ikraftr. dato : 19.08.2010 Åbnet dato: 19.08.2010 12:17:42
Filnavn : Instruktion: Vedligehold af autoklave Udstedt fra: GMP
Q-dok

Uddybende opgavebeskrivelse.

Månedligt (Bilag 1 til TEK/V-004)
Ansvar: UP

1. Trykluft
2. Døre
   A. Herunder sikkerhedskontrol af døre
3. Pakning på sterilt luftfilter
4. Lækagetest
   9. Herunder dørpakninger (uskiftes ved fejl på lækagetest)

½-årligt (Bilag 1)
Ansvar: UP

5. Sterilt luftfilter
6. Snavssamlere
7. Kontraventiler
B. Døre
C. Sikkerhedskontrol
D. Display

1-årligt (Bilag 2)
Ansvar: UP
Udføres af: Eksternt firma (fx Getinge)

(8. Vandudladere – Findes ikke)
10. Vacuumpumpe
11. Flyderventil
(12. Pressostater – Udføres af Metrologi jf. DIR-nr. 2585)
(13. Filter på tætningsvandet – Vedligeholdes ikke)
14. Vekslere
(15. Kølespiral – Vedligeholdes under 14. Vekslere)
16. Sikkerhedsventiler
17. Magnetventiler
(18. Nåleventiler – Vedligeholdes ikke)
19. Alarmer
E. Rengøring
F. Kugleventiler

2-årligt (Bilag 3)
Ansvar: UP
Udføres af: Eksternt firma (fx Getinge)

20. Clamps-pakninger
21. Pakninger i sæde- og reguleringsventiler
22. Membran i luftstyret aktuator
(23. Ventilatorpakninger – Findes ikke)
(24. Backup-batteri – Skiftes kun ved haveri)
G. Filtre til styrekabinet

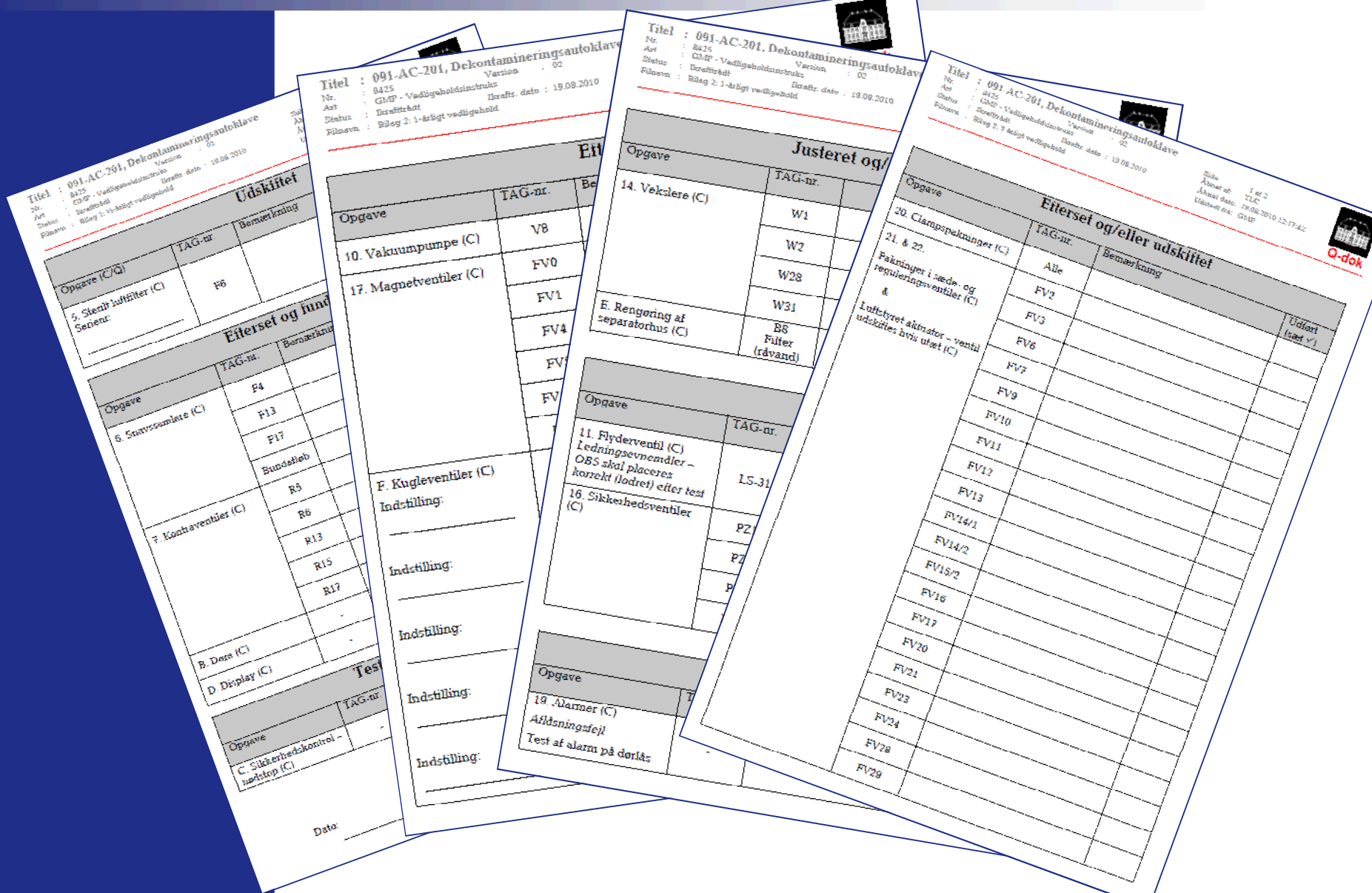
Pressurized air,
Doors, functionality, safety
Gaskets on sterile air filter
Leakage testing

Sterile air filter
Dirt collectors
Contra valves
Doors (functionality, safety)
Display

Water separators
Vaccum pump, Filters on water
Flotation valve, Pressostates
Heat exchangers, Cooling coil
Safety valves, Magnetic valves
Needle valves, Ball valves
Alarms, Cleaning

Clamp gaskets, Gaskets in regulation valves,
Membrane in actuator valve, Gaskets in ventilator
Back up battery, Filters for cabinet

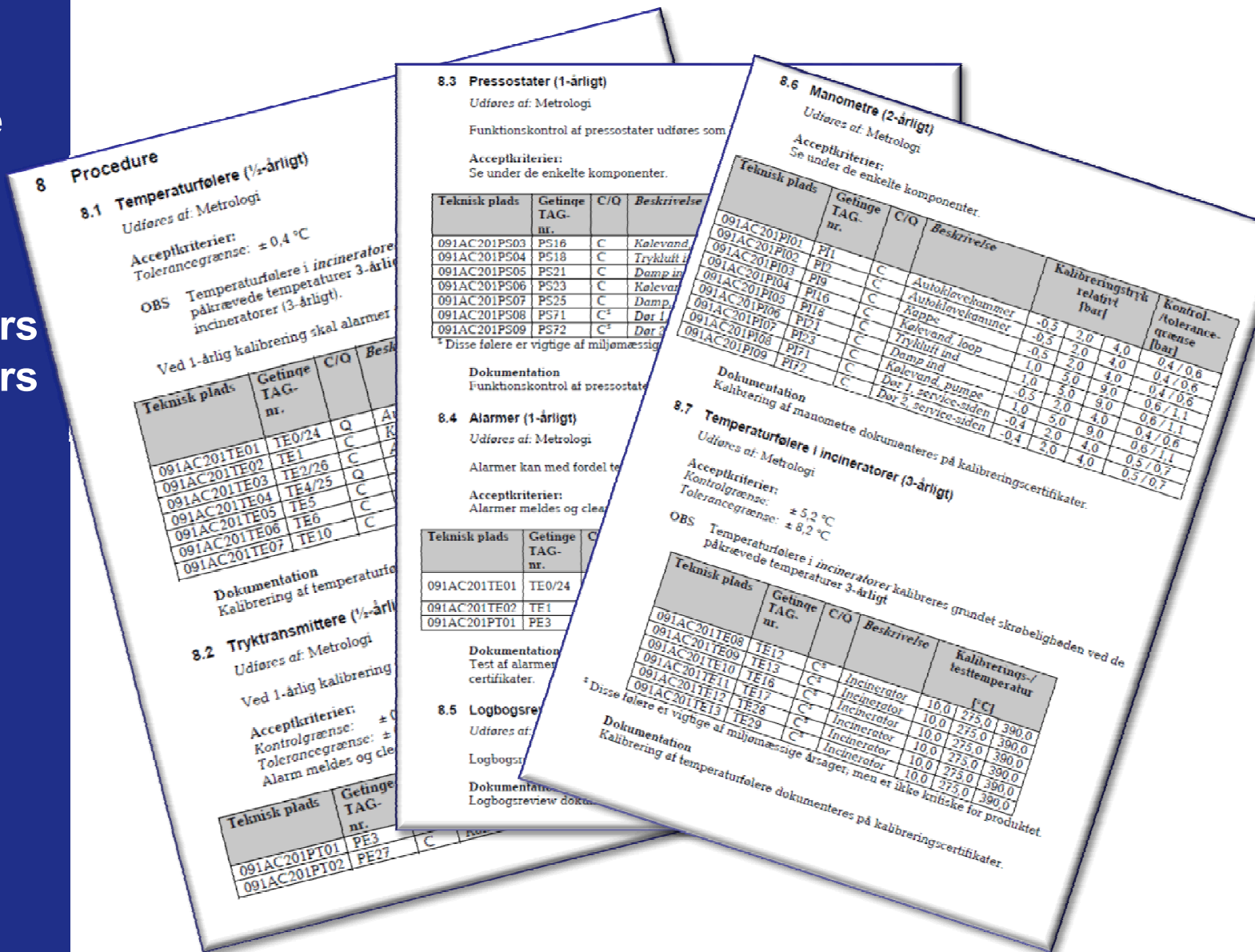
Preventive Maintenance



Requalification

Decon Autoclave

½ Yearly
Yearly
Every 2 years
Every 3 years



Biosafety Level Recommendations

	Directional Airflow	Double Door Entry	Autoclave Available	Pass-Through Autoclave	Seamless Floors	Monolithic Ceilings	HEPA Filtered Exhaust	HEPA Filtered Supply	Supply/Exhaust Interlock	Personal Shower	Airlock Entry	Pressure Differential	HEPA Plumbing Vents	Effluent Decontamination	Pressure Decay Testing	Breathing Air System	Chemical shower
BSL-2 Laboratory	☣		☣														
BSL-3 Laboratory	☣	☣		☣	☣	☣											
BSL-3 Laboratory - Q Fever	☣	☣		☣	☣	☣	☣			☣							
BSL-3 Animal Facility	☣	☣		☣	☣	☣	☣			☣							
BSL-3 AG Lab & Animal	☣	☣		☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣		
BSL-4 Lab & Animal	☣	☣		☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣	☣

Do NOT build them unless.....

CONTAINMENT LABORATORIES

High Containment Laboratories

- You *really* need them
- You know what agents you will be using
- You know what procedures you will be performing
- You have time enough to design properly
- You have involved all the stakeholders
- You have money enough to invest in the right solutions
- You have money enough to maintain the systems
- You have an educated staff to run the lab
- You have a technical department that can maintain the utilities
- You have a dedicated project manager at the building site at all times