



BIORISK MANAGEMENT WORKSHOP FOR VACCINE MANUFACTURERS

Singapore

5 – 6 February 2018

Dr Paul J Huntly



Course Objectives



- Introduce current practices and principles of biorisk management as they can be applied to vaccine manufacturing
- Share practical experience and views in relation to the challenges faced in conducting biorisk management activities
- Provide platform to discuss potential challenges and issues of concern



Schedule – Day 1 (PM)



1330 – 1400	Background and introductions
1400 - 1530	Overview of biosafety, biosecurity and containment principles
1530 – 1545	BREAK
1545 -1700	Current and evolving standards, regulations and oversight mechanisms - WHO LBM, GAPIII and TRS 926



Schedule – Day 2 (AM – Part 1)



0900 – 1030

Overview of facility-related containment principles and issues

Primary, secondary and tertiary containment

HVAC

Kill tanks

Autoclaves, pass-throughs and dunk tanks

Room decontamination and shutdown strategies

1030 – 1050

BREAK



Schedule – Day 2 (AM – Part 2)



1050 – 1230

Overview of biorisk management system-related principles and issues

Developing an effective programme

Identifying and incorporating requirements

Policy and leadership

Key roles, recruitment and competency

Integration with QMS, GMP, etc.

Managing emergencies and incidents

Biosecurity

Review, oversight and certification

1230 – 1330

LUNCH



Schedule – Day 2 (PM)



1330 – 1500	Small group discussion on practical issues and challenges
1500 – 1515	Break
1515 – 1630	Presentation and problem solving with open discussion
1630 – 1700	Q&A and Conclusions



BACKGROUND & INTRODUCTION

|| About Riskren



- Founded in Singapore to work primarily in fields of:
 - Laboratory biorisk management
 - Hospital acquired infections
 - Biological weapons control and threats from non-state actors
- Team experienced in working around the world with many laboratory categories:
 - BSL 1 to 4
 - ABSL
 - Pharmaceuticals and vaccines...
- Disease-specific programmes and situations
 - TB
 - Polio
 - Smallpox...

Thought leadership

Experienced

Practical

Independent

What We do



- National and strategic initiatives
- Development of regulations, standards and guidelines
- Management system development
- Risk assessment and design review
- Independent audit and inspection services
- Certification
- Tools and software
- Training and communication



Our Experience



- World Health Organisation
- Det Norske Veritas (DNV Biorisk)
- European Commission
- US State Department
- American Society for Microbiology
- Developing Country Vaccine Manufacturers Network (DCVMN)
- National Institute for Hygiene and Epidemiology (NIHE) Vietnam
- Eijkman Institute, Jakarta
- Canadian Science Centre, Winnipeg
- LG Lifesciences
- Viroclinics
- AJ Vaccines

Introduction

- Your name and organization?
- Background and experience?
- Your involvement in risk assessment?
- What do you expect to get from this course?



Your organisation

Background
Experience

Existing situation

Expectation



OVERVIEW OF BIOSAFETY, BIOSECURITY AND CONTAINMENT PRINCIPLES

|| Biosafety vs Biosecurity

Biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents, or their accidental release

(WHO Laboratory Biosafety Manual, 3rd Edition)

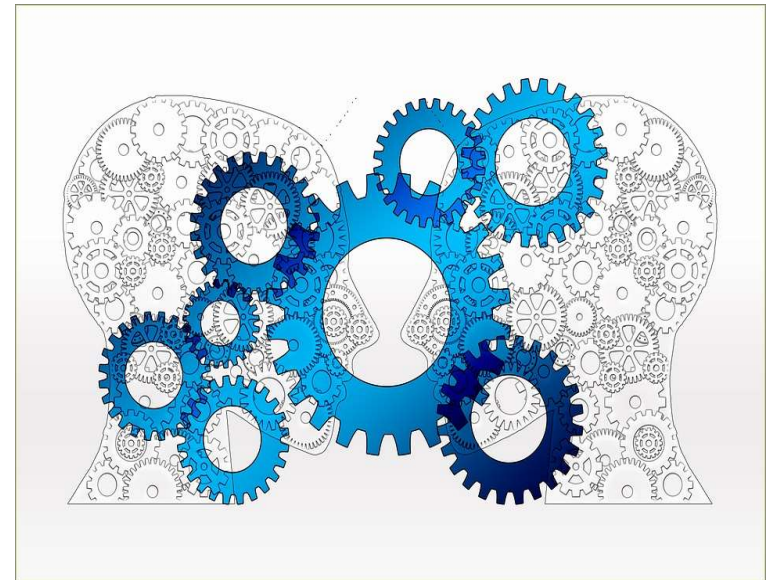
Biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.

(CWA 15793:2011)



Basic Principle 1 - Transmission

- Critical but often poorly often understood area
- Agents often have several transmission routes, with one often being characterized as being the most likely
- Vaccination *may* prevent infection but does not necessarily prevent transmission (e.g. polio)
- Some routes of transmission may not be credible in 'natural situation' but can become plausible when culturing
- Infectious dose may be critical issue, together with other factors, e.g. survival in environment



Basic Principle 2 - Routes of Transmission

- Contact transmission
 - Can be through direct contact, indirect contact or ingestion
- Airborne transmission
 - Inhalation of aerosols or small particles carrying microbes for >2m from source
 - Direct transmission from droplets / particles in suspension in air or deposition onto contaminated wounds
- Blood borne transmission
 - Percutaneous inoculation or transfusion
 - Injury (cut, prick)

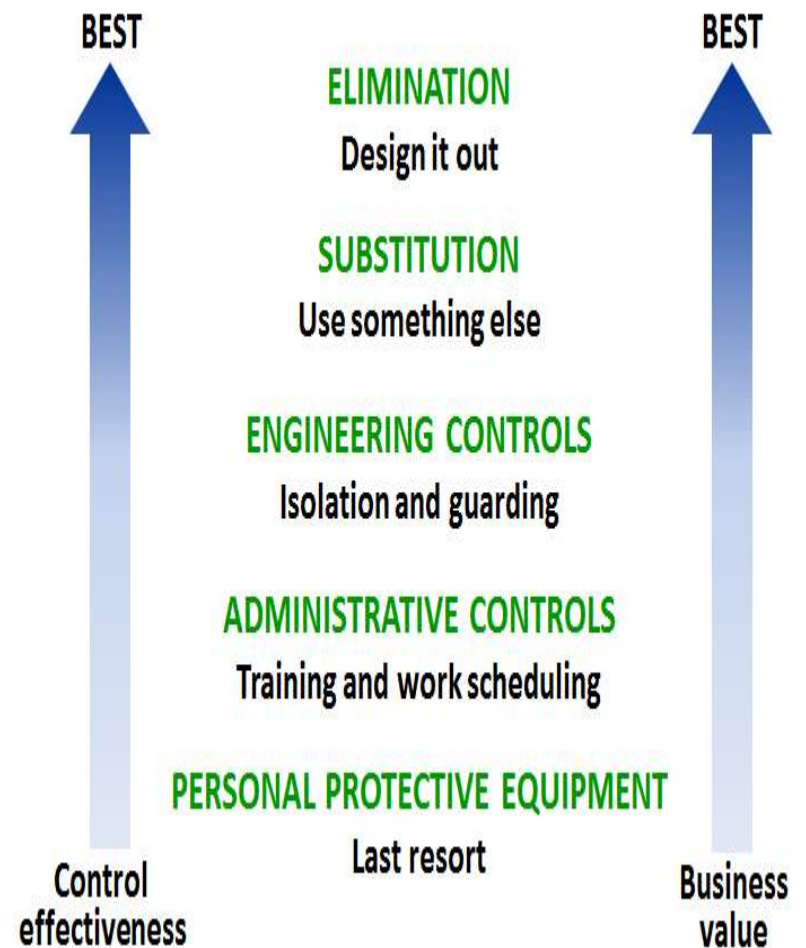




Basic Principle 3 - Exposure

- Main objective should be to prevent exposure
- If no exposure, there is no infection
- Often difficult to manage situations once exposure has occurred but relatively easy to prevent exposure
- Exposure prevention can be described through the hierarchy of controls

Hierarchy of Control



What is Containment?



Pathogenicity

- pathogenicity is the ability of a biological agent to cause illness
- pathogenicity of the infectious or suspected infectious agent, including disease incidence and severity (i.e., mild illness versus high mortality, acute versus chronic disease) is key
- the more severe the potentially acquired disease, the higher the risk
- Also may have infection without symptoms, but individual still infectious

	risk category 1	risk category 2	risk category 3	risk category 4
pathogenic	-	possible	possible severe	severe
spreading to population	-	unlikely	likely	very likely
profylaxe /treatment	-	yes	yes	no
examples	<i>E.coli</i> K12 Aspergilli <i>Lactobacilli</i> Yeast	<i>Legionella</i> <i>Salmonella</i> Influenza	<i>Coxiella burnetii</i> <i>Brucella</i> Avian Influenza	Variola Lassa virus Ebola virus

Biosafety level – Biological Labs

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

WHO Laboratory Biosafety Manual 3rd Edition (pg. 2)




Biological containment facilities

- No conclusive definition for different facility types – guideline / risk based
- Organisms categorised by risk group from 1 to 4
- Facilities (and management controls) defined by containment levels ranging from 1 to 4 (e.g. BSL₃, PC₃, ACDP₃, CL₃...)
- Recent growth of such facilities around the world, including in developing countries
- Combination of engineering and management controls
- Relative sophistication can create confusion and practical difficulties in design, construction and operation



■ Agents do you work with?

- How do they fit into the risk group characterisation?
- Under what containment levels are they handled?
- How can they be transmitted?
- How is this reflected in the controls you currently have in place (e.g. equipment, PPE, facility design)?

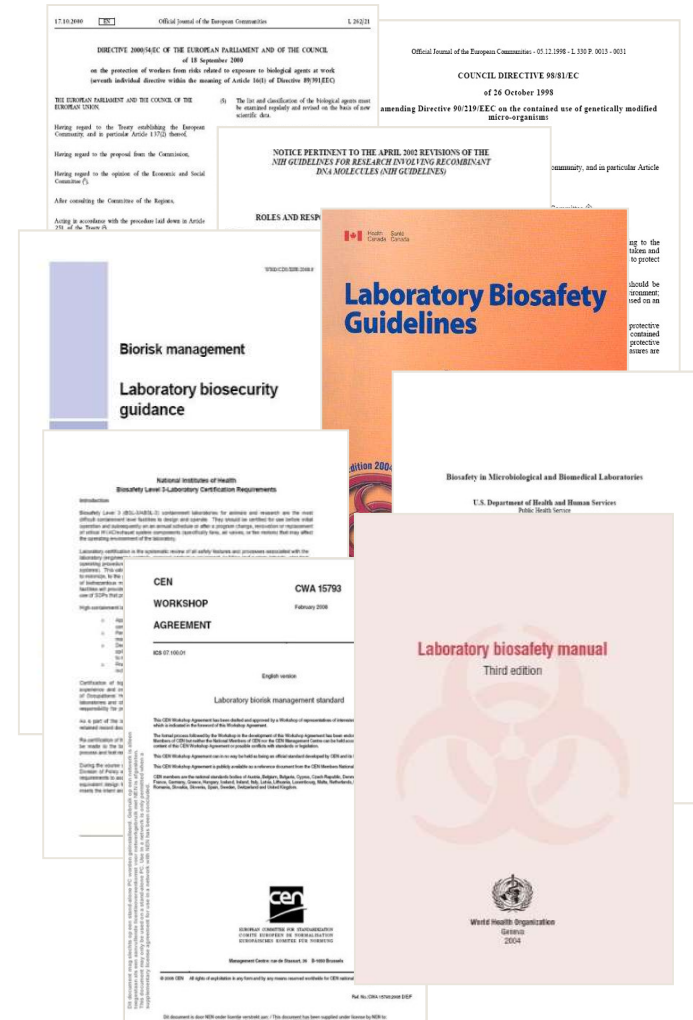


CURRENT AND EVOLVING STANDARDS, REGULATIONS AND OVERSIGHT MECHANISMS



The basis

- Many reference documents available:
 - *Laws or regulatory requirements*
 - *Standards*
 - *Guidelines*
 - Reference documents
 - Published papers
 - Text books
 - Internet articles
 - Training materials
 - Etc...



A vertical bar on the left side of the slide, composed of several thin, parallel lines of varying heights and colors (black, grey, brown, red).

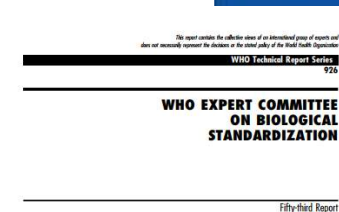
Standards vs. guidelines

- Laws
 - Usually country-specific
 - Compliance mandatory
- Standards
 - Based upon requirements
 - Use word 'shall'
 - May incorporate guidance to explain the requirements
- Guidelines
 - Are NOT normally set of requirements
 - Should be considered and addressed as appropriate
 - Terms:
 - Should – recommendation
 - May – allowance
 - Can – possibility

Relevant standards / guidelines

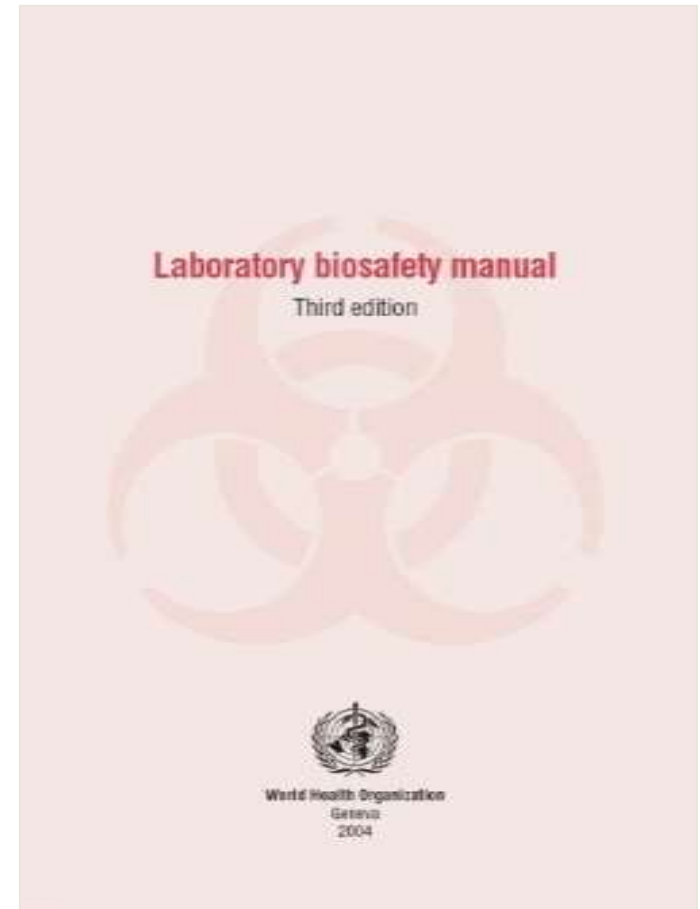


- WHO Laboratory Biosafety Manual
- Global Action Plan (GAPIII)
- GAPIII Containment Certification Scheme (GAPIII-CCS)
- TRS 926



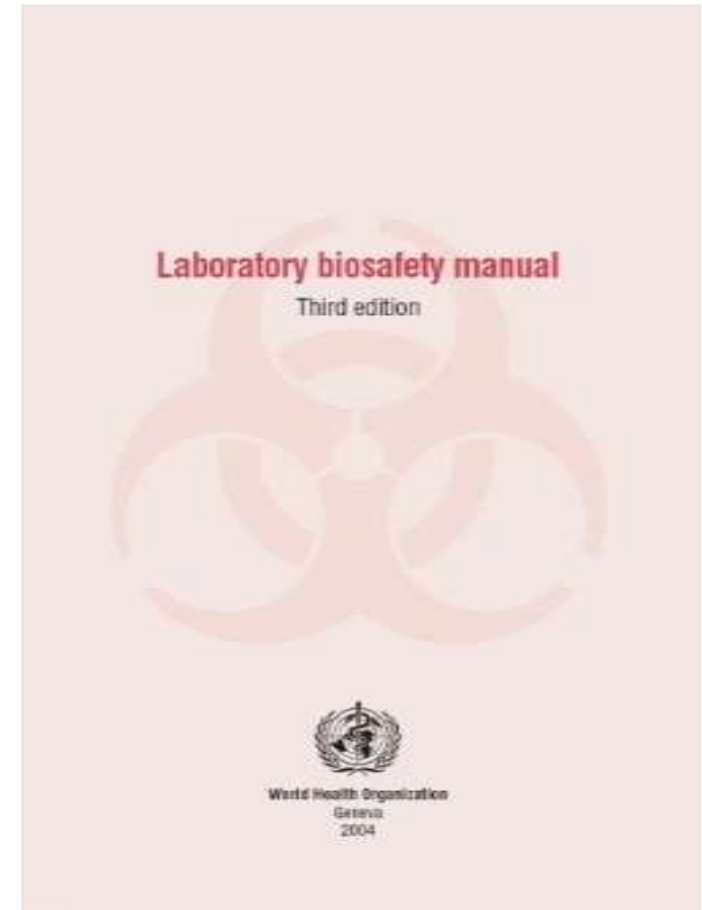
WHO Laboratory Biosafety Manual (LBM)

- First published in 1983, current version 2004
- New version being drafted
- To provide practical guidance on biosafety techniques for use in *laboratories* at all levels
- Limited attention to biosecurity
- Emphasises need for SOPs, training, BSO and committee



WHO Laboratory Biosafety Manual (LBM)

- Not management system-orientated
- Not production-specific
- Being used as default document for basic information under GAPIII and TRS 926
- No similar document currently available for production environments





GAPIII

- Endorsed by World Health Assembly in 2015
- Requirement for poliovirus containment post-eradication
- Currently being rolled out across around 28 countries and 90 facilities
- Approximately 25 vaccine manufacturers from around the world
- May become a basis for other similar standards and schemes in future
- Based upon CWA 15793; Laboratory biorisk management





CWA 15793

- Define the scope for managing biorisks in biological facilities
- Facilitate the identification of current best practice in the field
- Allow for a variety of solutions when managing biorisks within a containment facility
- Drive continuous improvement
- Enable you to assure stakeholders of responsible and proportionate biorisk management



CEN
WORKSHOP
AGREEMENT

CWA 15793
February 2008

ICS 07.100.01

English version

Laboratory biorisk management standard


This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.


EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPAISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

© 2008 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

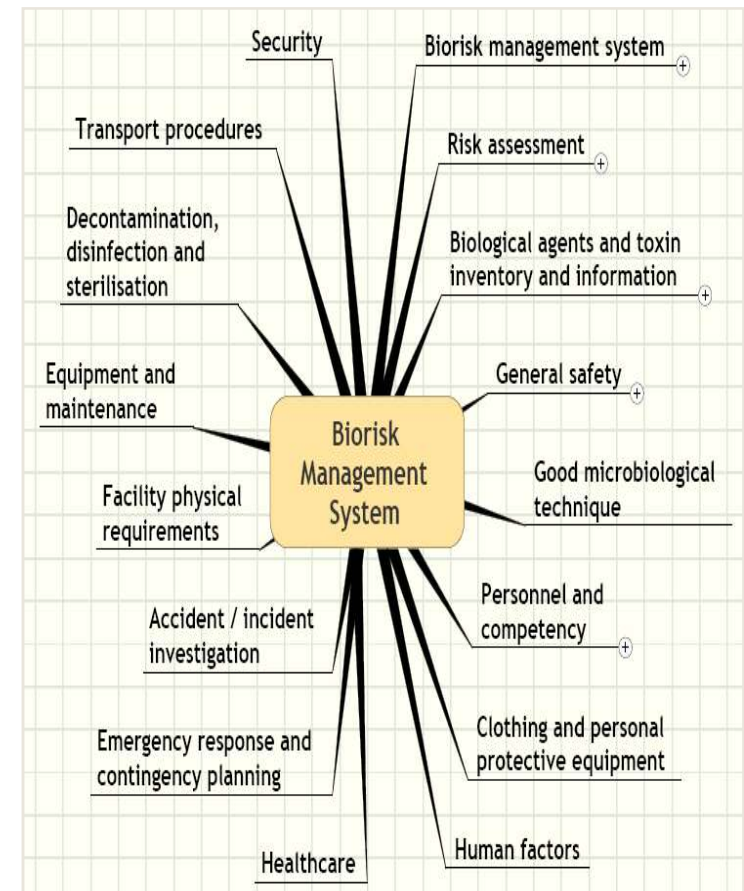
Ref. No.: CWA 15793:2008 D/EF

Dit document is door NEN onder licentie versprekt aan: / This document has been supplied under license by NEN to:
Det Norske Veritas Pte Ltd. 2008/03/12

Dit document mag slechts op een stand-alone PC worden geïnstalleerd. Gebruik op een netwerk is alleen toegestaan als een aanvullende licentieovereenkomst voor netwerkgebruik met NEN is afgesloten.
This document may only be used on a stand-alone PC. Use in a network is only permitted when a supplementary license agreement for use in a network with NEN has been concluded.

GAPIII annexes

- Annex 2
 - For certification of PEFs holding WPV/VDPV
 - Annex 3
 - For certification of PEFs holding only OPV/Sabin
- Annex 2 vs Annex 3:
 - Identical except for certain facility containment-specific areas applying in Phase III for containment of all wild poliovirus
- Annex 6
 - Surveillance laboratories





CCS

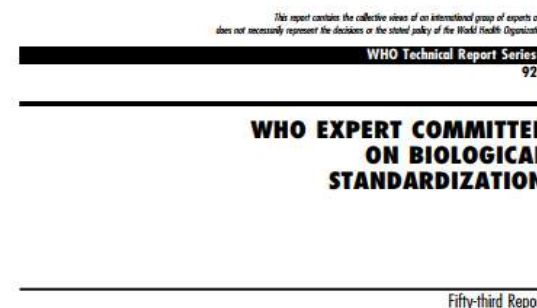
- Endorsed by SAGE 2016
- Supersedes Annex 4 of GAPIII: WHO will no longer verify containment
- PEFs are certified by their National Authority of Containment with oversight by GCC
- Defines certification scheme and associated processes:
 - Planning, execution, follow-up
 - Qualified and competent auditors
 - Definition of NCs
 - Oversight mechanism, etc.





TRS 926

- Addressing poliovirus production issues for manufacturers
- First released 2004 to cover wild (Salk) strains post-eradication
- Currently being redrafted
- Potential conflicts and issues with GAPIII:
 - Oversight mechanism – NRA vs NAC
 - Requirements; some currently less stringent and others more so
 - No biosecurity
- Target to publish October 2018





Standards and guidelines

What standards and guidelines do you use when defining controls associated with biosafety and biosecurity?





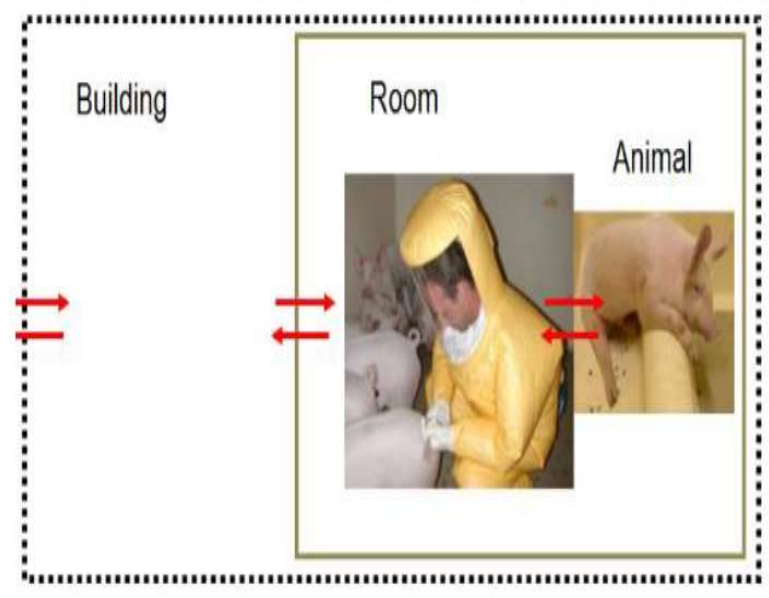
OVERVIEW OF FACILITY- RELATED CONTAINMENT PRINCIPLES AND ISSUES



PRIMARY, SECONDARY AND TERTIARY CONTAINMENT

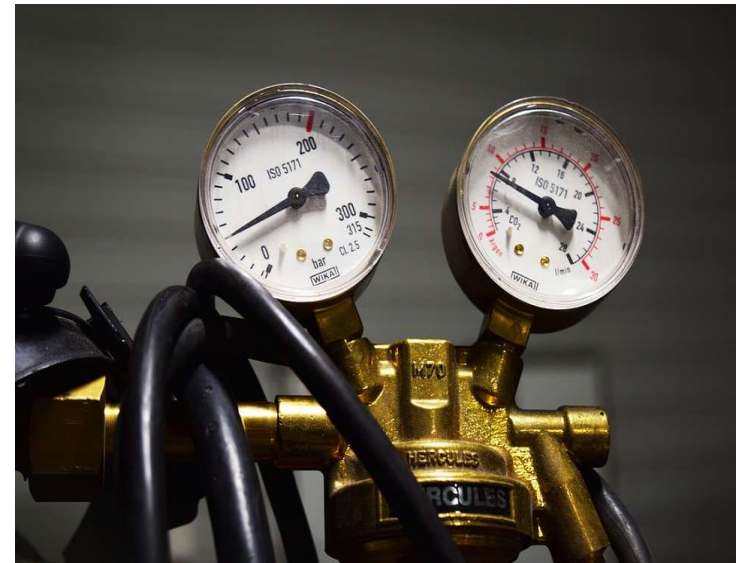
Containment barriers

- Primary containment (barriers):
 - Protection of personnel and the immediate environment from exposure to infectious agents
- Secondary containment (barriers):
 - Protection of the environment external to the facility from exposure to infectious materials
- Tertiary containment (barriers):
 - Represents an additional organisational barrier with the physical operation with items such as walls, fences, security, quarantine and animal exclusion zones



Containment - Integrity & Tests Riskren

- Ability to provide an assurance that system will not fail
- Often achieved through testing, alarms and other associated mechanisms
- Need for confidence based upon criticality of system and will be reflected in the standards and test methodologies
- Can be applied to:
 - Rooms and other spaces
 - Duct and piping (including production equipment, filter housings, etc.)
 - PPE (e.g. positive pressure suits)
 - Pressure vessels (e.g. autoclaves, kill tanks)
 - Pass through boxes
- Methods include:
 - Pressure decay testing
 - Bubble testing
 - Smoke testing
- Can be qualitative or quantitative
- Often important aspect in ensuring containment achieved



Primary containment

One definition of primary containment could be:

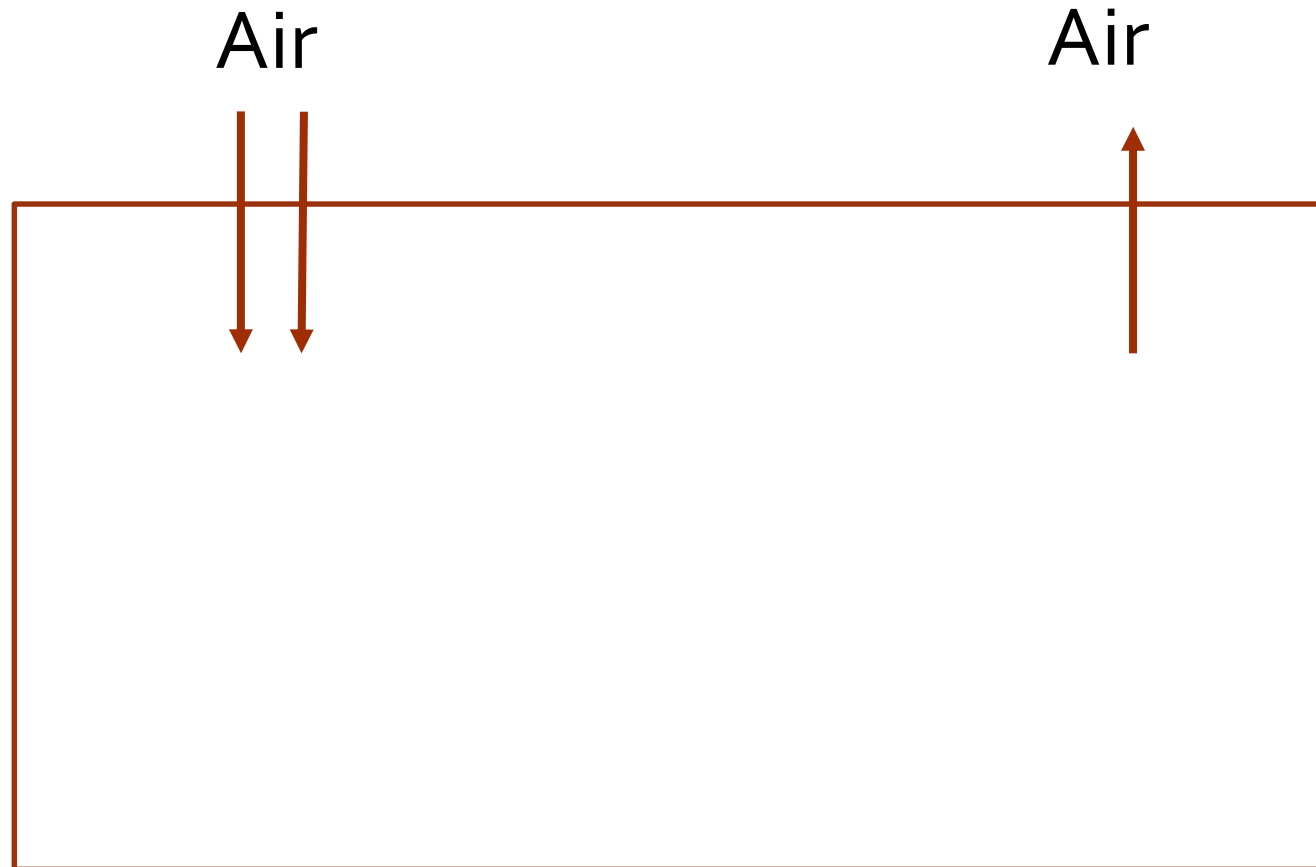
Primary containment is the main means of preventing leaks and spills using equipment in direct contact with the agents being handled, stored or transported.

- How would you define the terms 'closed system' and 'primary containment'?
- What equipment do you currently rely upon to ensure primary containment?
- How effective is that equipment and associated procedures at guaranteeing zero leaks and spills?

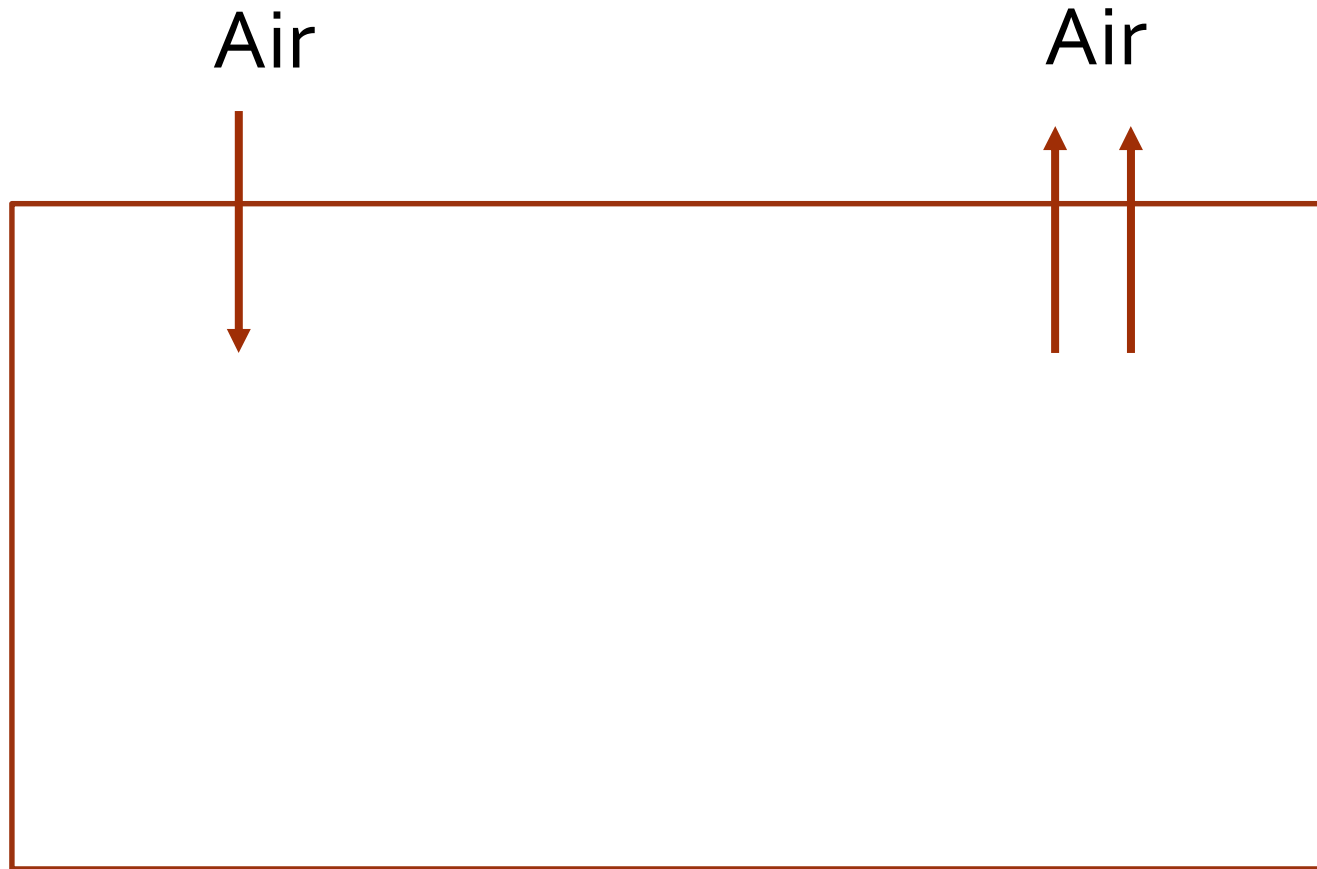


HVAC

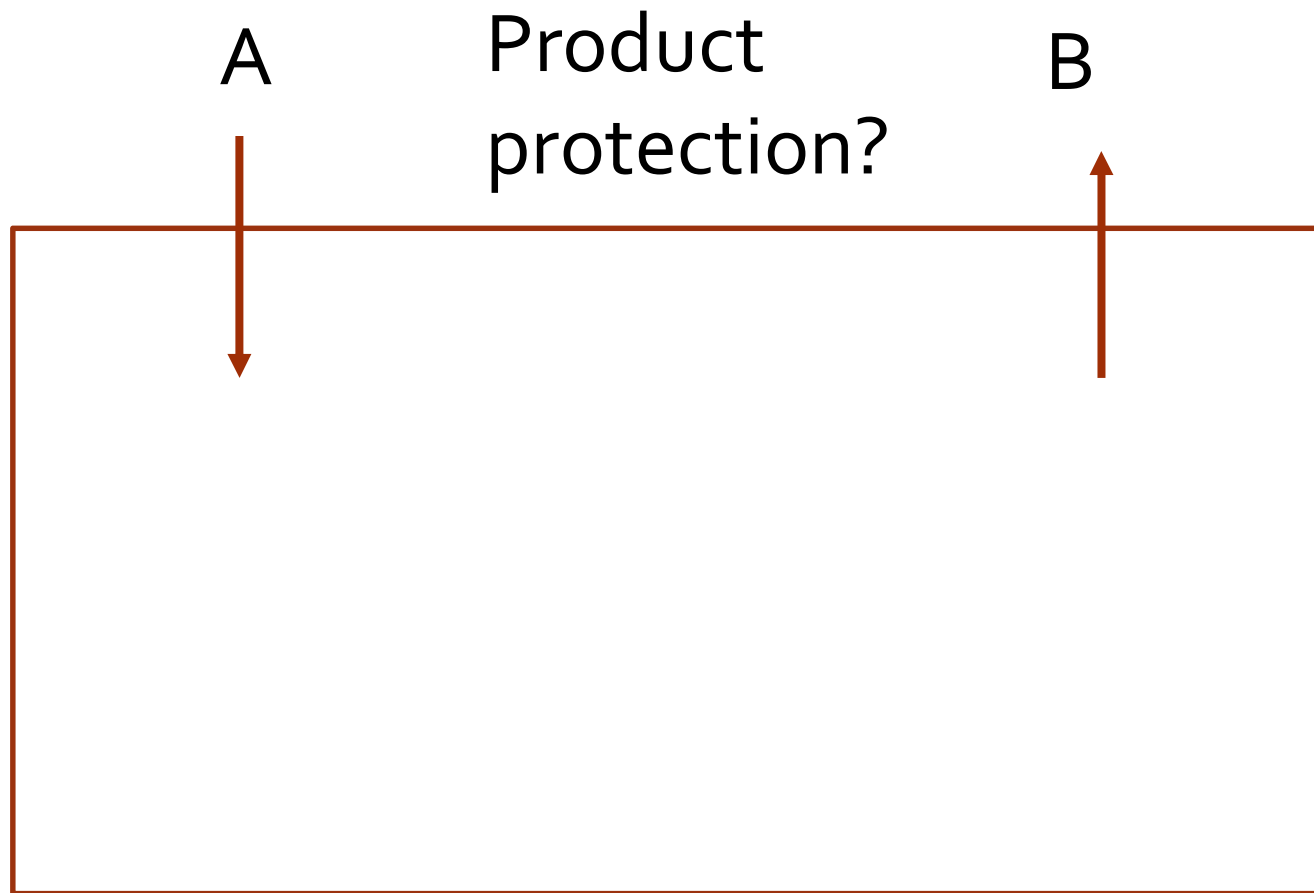
Positive or negative pressure?



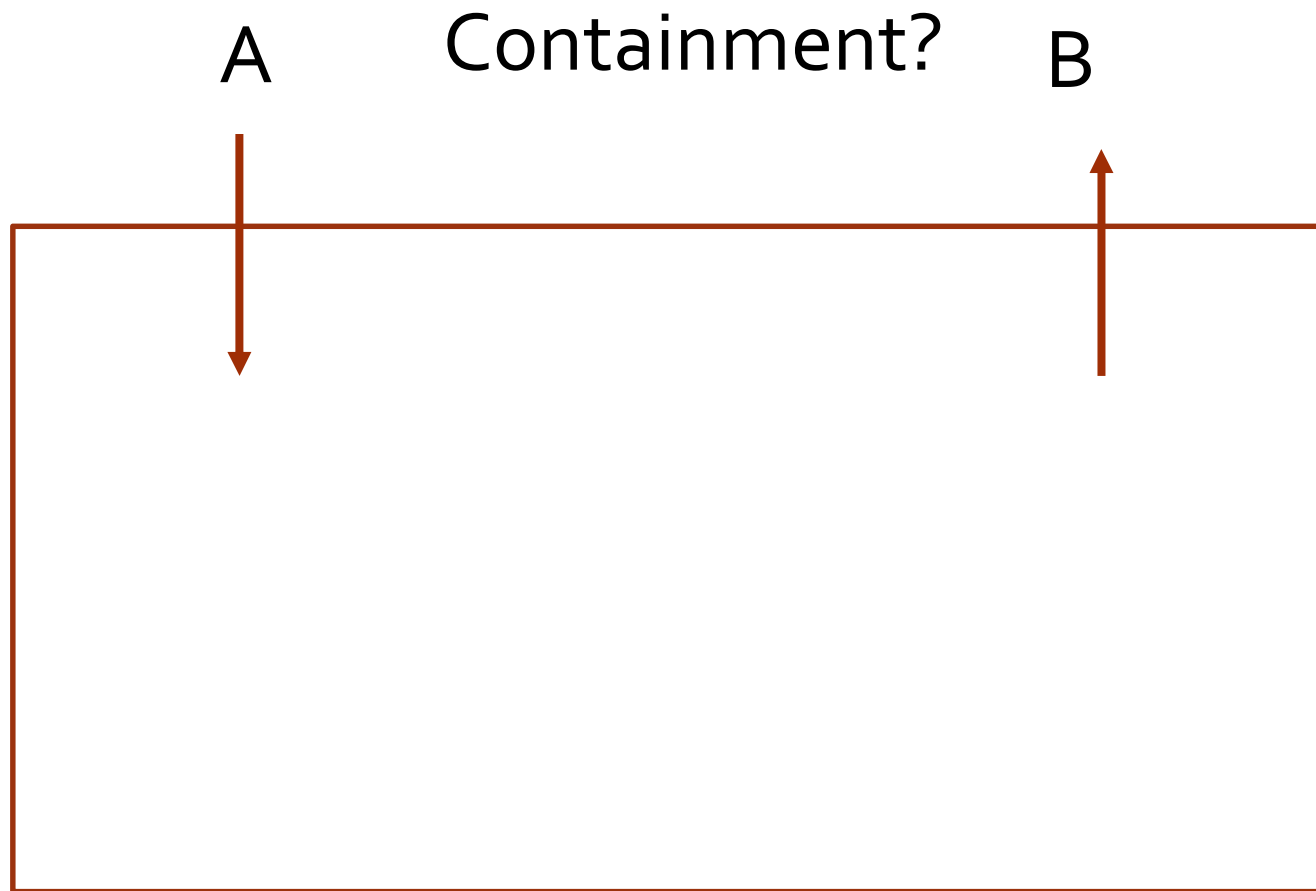
Positive or negative pressure?



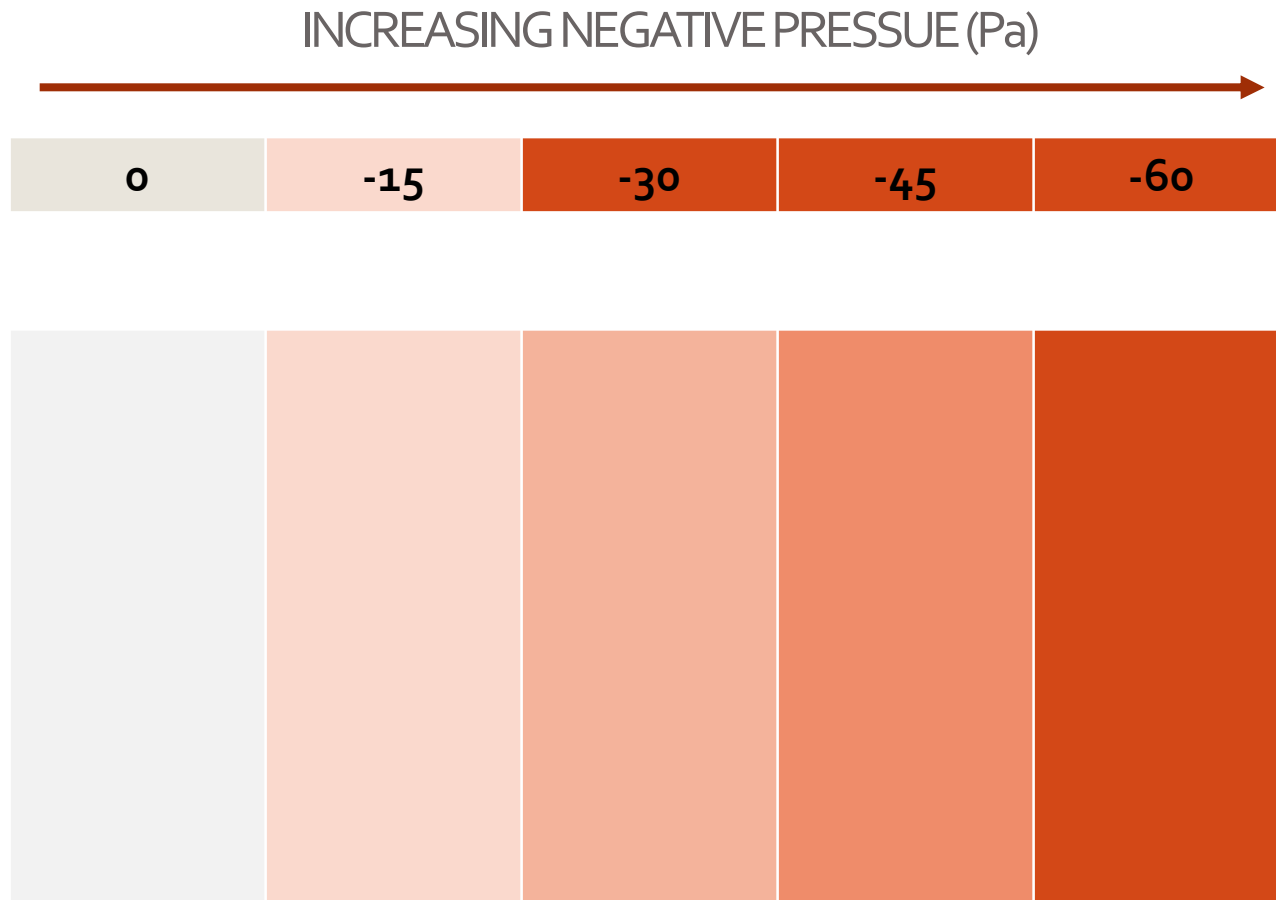
|| Filtration?



|| Filtration?

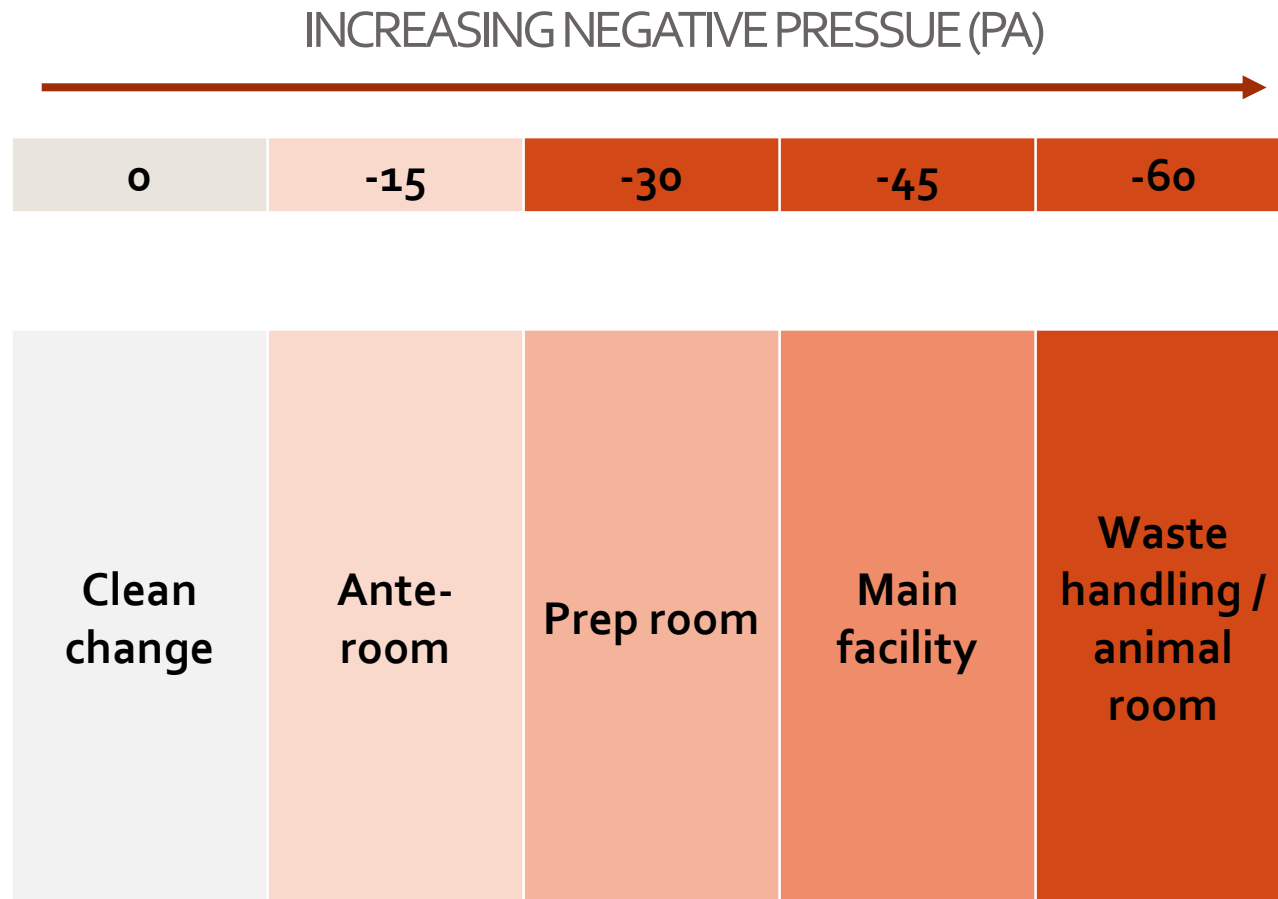


Pressure cascades





Containment pressure cascades





Pressure hierarchy for containment



Dynamic Air Barrier

- Air Supply and Extract Systems
 - ▣ Air Supply Fans
 - ▣ Extract Fans
 - ▣ Air Valves
 - ▣ Isolation Dampers
 - ▣ Humidification Systems
 - ▣ Heat Recovery Systems
- Filtration Systems
 - ▣ Filter Housings
 - ▣ Filters
 - ▣ Isolation Dampers
- Controls
 - ▣ Building Automation Systems



Pharmaseal Exhaust Housing with duct connection plenum.



HEPA filters on the exhaust of a BSL₃ lab



Requirements?



- Can effectively maintain required pressure cascades – normal and failure scenarios
- Can effectively contain air
- Can be adequately sealed / isolated
- Can be decontaminated
- Can be tested and alarmed
- Etc.

Common problems



- Clean room vs containment
 - Positive vs negative pressure
 - >15 ACH vs <12 ACH
- Maintaining pressure differentials and avoiding release through *sustained positive pressurization*
- Ability to isolate and decontaminate
- Breakdown, shutdown and decontamination strategies
- Cost:
 - Recirculation
 - Redundancy



DECONTAMINATION, DISINFECTION AND STERILISATION

Definitions



- Decontamination is the collective of processes like disinfection and sterilization.
- Disinfection: a chemical/physical process for reduction of the micro-organisms to an acceptable level
- Sterilization: a physical process to inactivate all micro-organisms

|| The perfect disinfectant



- Broad spectrum high efficiency
- Not affected by organics like protein, soap, hardness of water or the pH
- Not toxic, corrosive or inflammable
- Odorless
- Stable
- No environmental burdening
- Inexpensive

|| Heat is the best!



Why is heat considered to be the 'gold standard' when it comes to disinfection and sterilisation?



KILL-TANKS

Kill tank



- For heat decontamination system, equipment be provided to process, heat and hold contaminated liquid effluent to temperature, pressure and time sufficient to decontaminate all biohazard materials that can be studied at the facility in the future
- System can operate at wide range of temperatures and holding times to process effluent economically and efficiently

Kill tanks

- Liquid effluents from contained areas can be collected and decontaminated in central liquid waste sterilisation system before discharge into sanitary sewer.
- Used in manufacturing facilities, containment laboratories and possibly for high risk isolation environments
- Effluents from production vessels, sinks / showers, cabinets, floors and autoclave chambers are normally sterilised by heat treatment
- Under certain conditions, liquid wastes may be decontaminated by chemical treatment systems
- Double containment piping system with leak alarms and annular space decontaminating capability may be considered for these systems

■ Kill-tank issues and questions



- In- or outside containment
- Thermal or chemical treatment of liquid waste
- Continuous flow or batch
- Fill and kill tanks?
- Cold spots / inappropriate mixing and need for validation
- Filter(s) on kill-tank:
 - Sterilized in line
 - Integrity test
 - Double?
- Corrosion and leaks



AUTOCLAVES, PASS- THROUGHS AND DUNK TANKS

Autoclave

- The name is a combination of two ancient words: auto- which is Greek for self, and clave-which is Latin for key. When combined the two words mean "self-locking".
- Moist heat kills more effective because the mass transfer of heat by steam is very efficient
 - Moist heat (steam): 121°C during ±30 minutes
 - Dry heat: 160 - 170°C during 2-4 hours
- Duration varies with temperature.
- Some loads require many hours (e.g. autoclaving large animal carcasses).

■ 'Typical' autoclaving cycles



- 115°C for 30 minutes
- 121°C for 15 minutes
- 134°C for 3 minutes

- Overall cycle times vary depending on load characteristics
- Time and amount of steam needed for sterilization depends greatly on thermal capacity of load
- Varies also with nature of agents, bacterial spores particularly resistant

Types of autoclaves



Critical aspect: exhaust of
contaminated air and
contaminated condensate



Double-door autoclave

Riskren[®]



Points to consider for autoclaves

- During vacuum process contaminated air will leave the chamber: filters may therefore be needed on exhaust (as well as supply?)
- Condensate in chamber is contaminated and has to either be sterilised as part of the process or sent to the kill tank
- In case process is interrupted chamber should be kept closed and isolated until next successful sterilisation run
- Maintenance from outside the containment perimeter

Pass throughs and dunk tanks

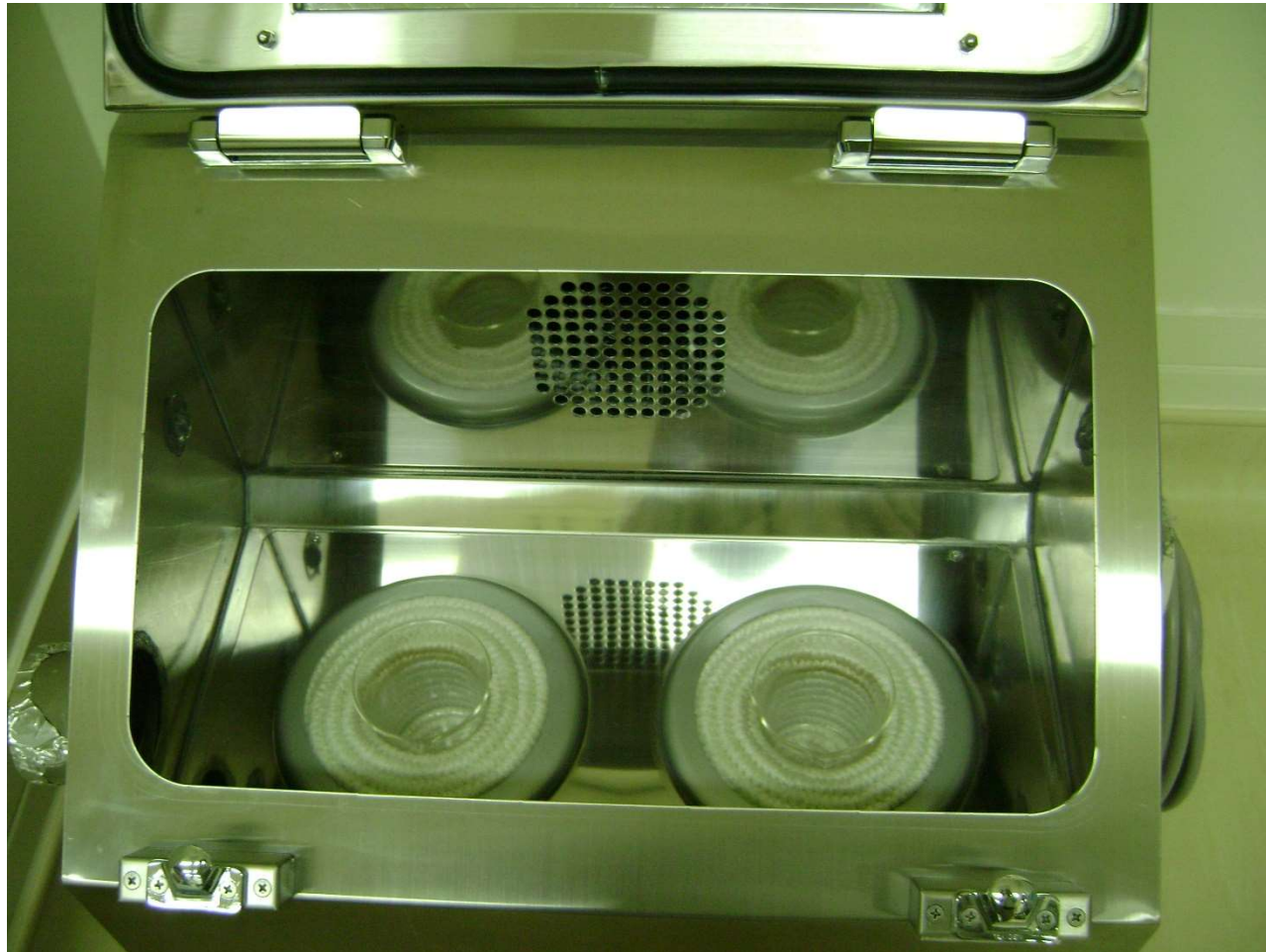
- Means of getting material into either a clean area without introducing contamination and / or removing potentially contaminated material from a contained space
- Principles similar – operation and design may be different

Pass throughs

- May be passive or active, i.e. simply draw air using the pressure gradient or have associated ventilation arrangements
- GMP / containment or both
- Need for decontamination and if so which type:
 - VHP
 - Formaldehyde
 - UV
 - Other?
- Interlocks and alarms
- Security







Material airlocks

- Large pass throughs that allow for the entry / exit into controlled spaces
- Effectively act as large pass throughs but on a larger scale
- Can be used for transfer of equipment for maintenance, large amounts of materials, etc.
- Need ensure decontaminant reaches all required areas, e.g. tubes, pipes, etc.

■ Dunk tank

- Effectively a liquid pass through
- Material placed in a chamber and held under the surface for a specified time to provide required contamination
- Extensively used in containment
- Need select appropriate disinfectant and ensure:
 - Adequate contact time
 - Appropriate active ingredient
 - Maintain concentration of active compound over time
 - Does not dry out
 - Address security issues

■ Dunk tank

- Need select appropriate disinfectant and ensure:
 - Adequate contact time
 - Appropriate active ingredient
 - Maintain concentration of active compound over time
 - Does not dry out
- Considerations:
 - Corrosion
 - Communications (window and intercom)
 - Security issues



ROOM DECONTAMINATION AND SHUTDOWN STRATEGIES

Room decontamination strategies

- Containment philosophy is not generally based upon environmental monitoring
- Principle more geared towards assumed clean or potentially contaminated areas with gas decon required for the latter
- Spill normally will require decontamination of the space
- Drives the room decontamination strategy and associated approach to shutdown



Issues



- Negative pressure cascades may result in the spread of contamination from one area to another
- Areas where spills are more likely are often designed so they can be decontaminated with gas without the need to shutdown the entire facility
- Requires sophisticated and costly design measures and associated procedures

Gas

- Most commonly used 'gases' are formaldehyde and VHP
- Formaldehyde
 - Cheap
 - 'Easy'
 - Permeates readily
 - Potential harm to workers and the environment
- VHP
 - No residue
 - Clean
 - Automated
 - Breaks down to water and oxygen
 - Can be increased issues with validation(?)
 - Compatibilities (e.g. wet surfaces, hot surfaces)

■ Shutdown strategy

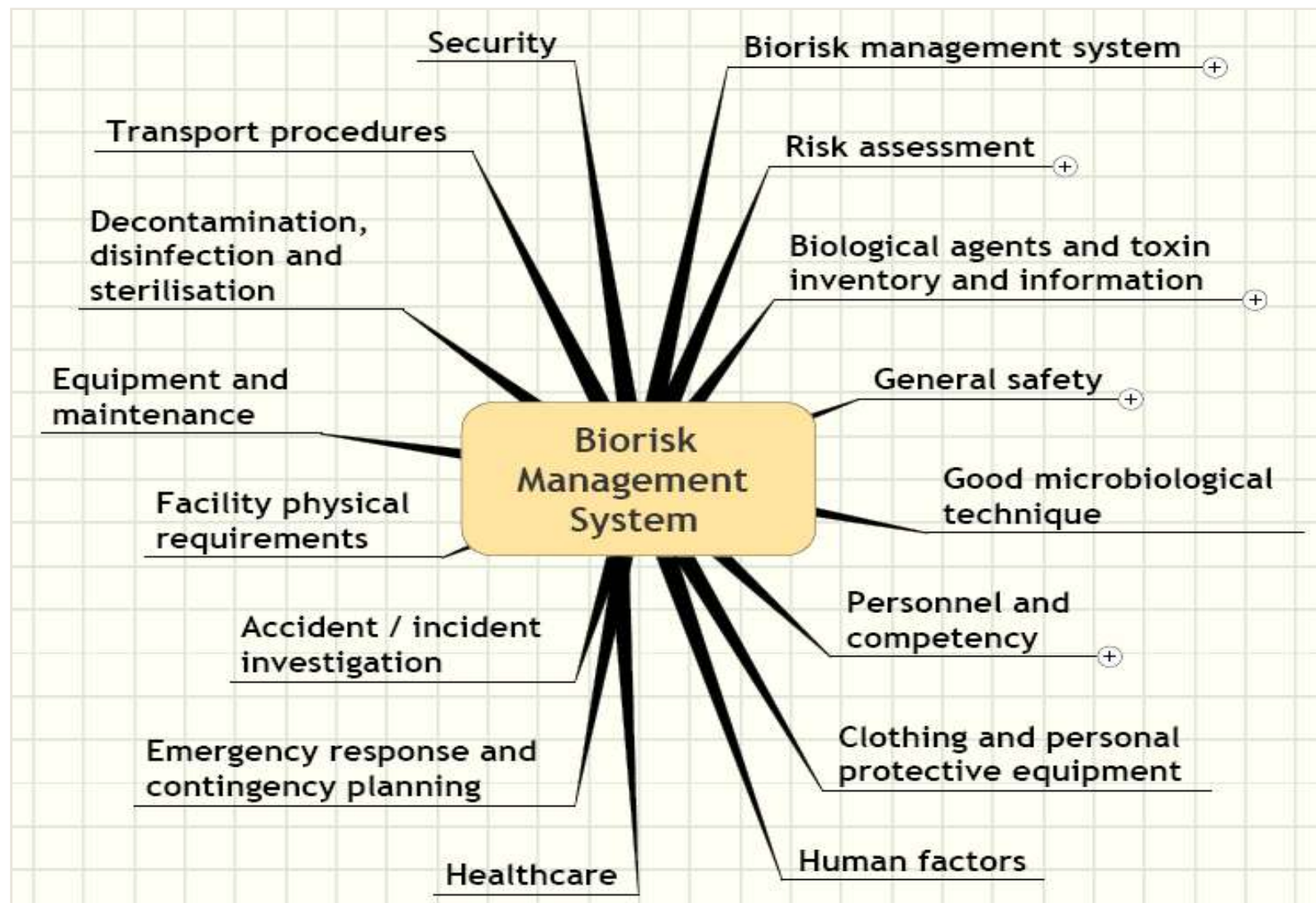


- Critical decision
- Can add cost and complexity with little benefit
- Can prevent major disruption to production in event need shut down after a spill (GAPIII?)
- Has major impact on design and layout, including process flows and HVAC



OVERVIEW OF BIORISK MANAGEMENT SYSTEM- RELATED PRINCIPLES AND ISSUES

Biorisk Management Elements





Why adopt a biorisk management philosophy and approach?



- Management system approaches already common in many laboratories, particularly for quality / environment
- Safety / security management systems common in many other major hazard industries
 - Oil & gas
 - Nuclear
 - Chemical
 - Transportation
- Many accidents with biological agents caused by systematic management failure





DEVELOPING AN EFFECTIVE PROGRAMME

What does a programme mean?

- Risks are identified, assessed and managed in a structured way using recognised approaches and the controls are reasonable and proportionate to the risk
- Activities are proactively planned, conducted and reviewed
- Roles, responsibilities and authorities are clearly defined and the people are competent
- Combines controls related to engineering, instructions and people
- Necessary links are in place between related and dependent activities – i.e. is there a systematic approach
- Workers understand and follow the system to the required level
- The system is 'alive' – it evolves and develops in a controlled and proactive manner



IDENTIFYING AND INCORPORATING REQUIREMENTS

GAPIII

- Legal requirements

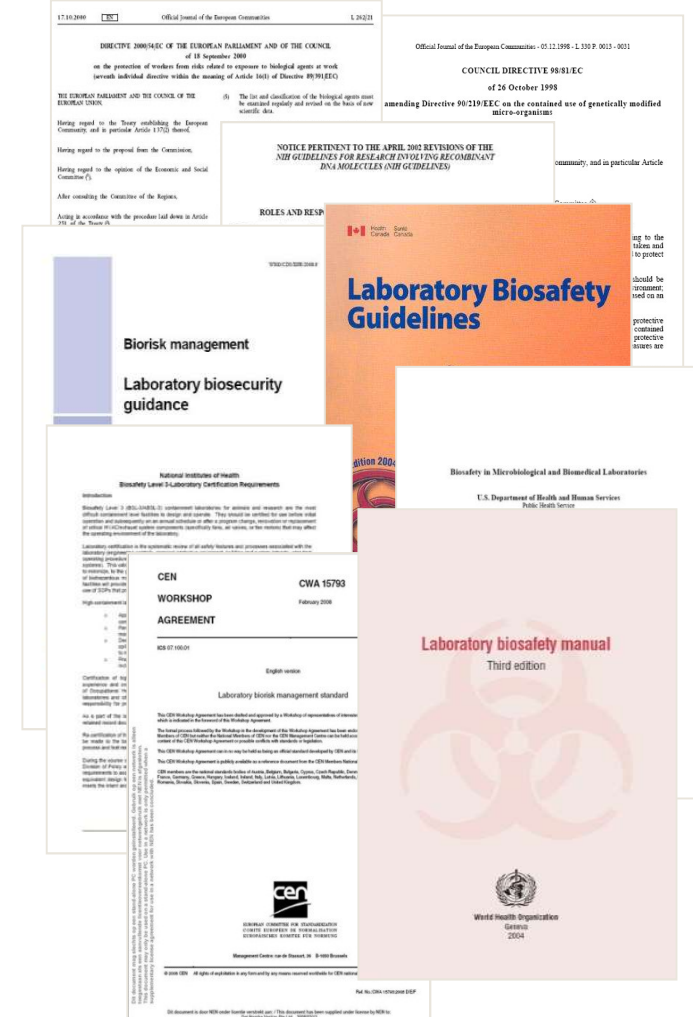
 Element 1.10, p110

- All relevant requirements (including legal) shall be identified and fulfilled

Requirements at the heart of the system



- Which standards and norms should be identified, interpreted and adopted
- May be laws, standards, guidelines
- Company policies, regulations from related areas (e.g. general safety, chemical safety, environmental controls, etc.)
- Will relate to all of the 16 elements, so need allocate accordingly to suitably qualified individuals and groups
- Translate into Policies, procedures, emergency plans, etc.
- Legal register and systematic process, including for required revisions / updates





POLICY AND LEADERSHIP

|| Agree?

The Biorisk Management System element examines the **system and policy** in place to manage the facility biorisk. **Effective management and organization** are vital to the success of any activity, and **management commitment and leadership** lays the foundation upon which a solid biorisk management system is built. Management must have **clear strategies and objectives** from which **roles and responsibilities** are allocated, implemented and monitored. Without effective management commitment and appropriate organizational structures, all other initiatives aimed towards managing risk will be ineffective. **The way management thinks and acts**, has a major impact on performance.

GAPIII

- Biorisk management policy
- Top management responsibility
- Overall biorisk management objectives, commitment to continual improvement

 Element 1.1, p100

■ Role of Top management

- Fundamental requirement
- 'Tone from the top'
- Identifying and allocating resource
- Setting and monitoring against targets and objectives
- Not just safety and security critical – also business critical
- Major potential financial impacts
- Will not work unless driven by management



KEY ROLES, RECRUITMENT AND COMPETENCY

■ Roles, responsibilities and authorities

 Element 1.3, p101

- Top management to ensure roles, responsibilities and authorities are defined, documented and communicated
 - Top management
 - Senior management
 - Biorisk management committee
 - Biorisk management advisor
 - Scientific management
 - Occupational health management
 - Facility management
 - Security management
 - Animal handling

|| Who is key?

- Based on your experience, pick the top three individuals from this list and justify your selection
- Who else would you include in the list of key roles?
- What challenges might you face regarding recruitment and competence of such individuals?



INTEGRATION WITH QMS, GMP, ETC.

Two concepts – 1. chalk and cheese



2. Ice cream - silo



2. Ice cream - integration



|| Considerations?

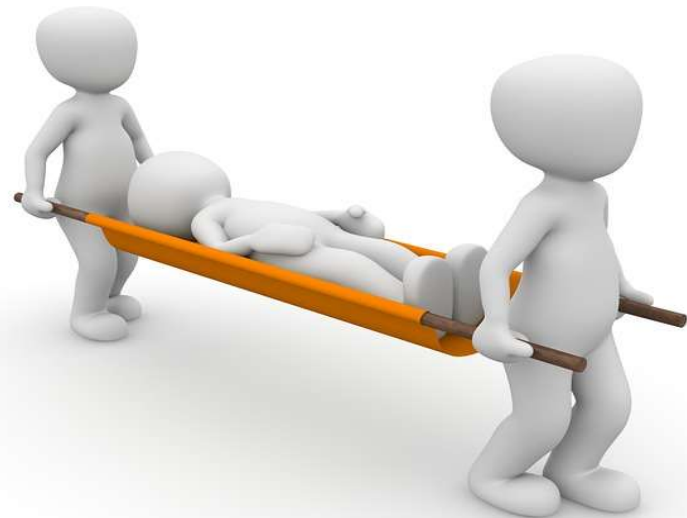
- Integrations is ideal but can be challenging:
 - Different maturity levels
 - Potential conflicts
 - Certification issues
 - Skill sets
- Use GMP / QMS as a skeleton but keep biorisk management system at least partly discrete initially
- Beware joint audits, especially in the early years!!!



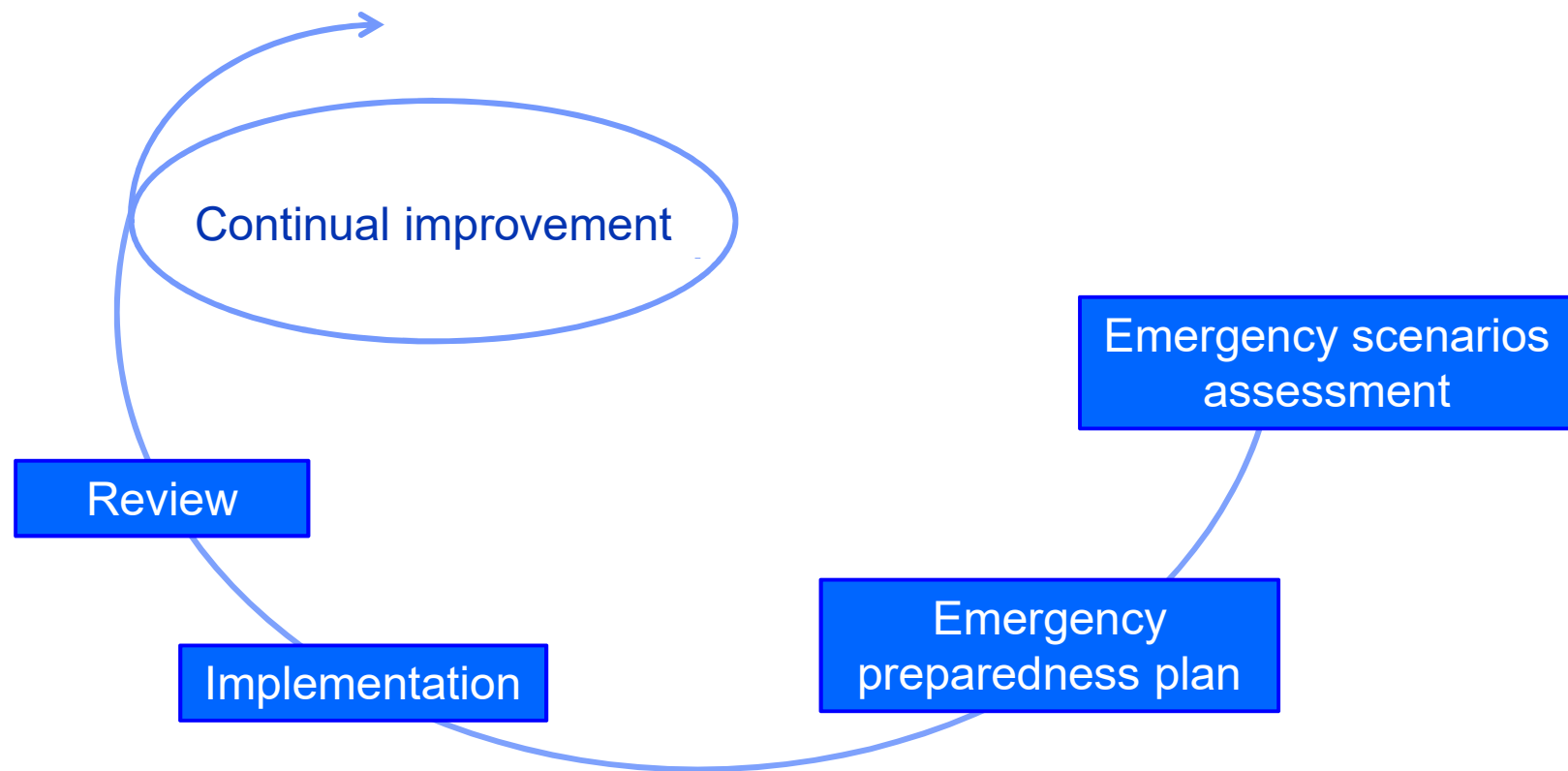
MANAGING EMERGENCIES AND INCIDENTS

Emergency Response

- This is a planning issue and requires a systematic and practical approach
- Not all will be bio-related, but some will be high profile and potentially problematic
- During an emergency, waste streams and volumes may be different to those during normal operations
- Bio-emergency
 - Influenza
 - Ebola
 - Infected worker
- Non-bio-emergency
 - Fire
 - Major transport disaster
 - Natural disaster



Emergency planning



Emergency response and contingency planning



- Emergency response and contingency plans
 - Plans and procedures to identify potential incidents and emergency situations
 - Includes general safety, security & medical issues
- Emergency scenarios
 - Identify credible and foreseeable emergency scenarios that may impact the organization's biorisks

 Element 10.1, p137 - 138

Emergency scenarios



- a) Infected / potentially infected worker or other contact
- b) Accident or illness to worker and need for evacuation
- c) Fire
- d) Flood
- e) Breach of security
- f) Explosion
- g) Potential loss of biological agents or toxins through theft or any other reason
- h) Unexpected virulence(unknown biological agents expected to be avirulent)
- i) Physical facility and equipment failure, including control system failure, including failure of disinfection regime
- j) Utility failure, including electricity, gas, steam and water supplies
- k) Major spillage / aerosol release
- l) Environmental release
- m) Natural disaster (e.g. earthquake, disease pandemics etc)
- n) Act of terrorism or deliberate vandalism
- o) Intense media attention

Emergency response and contingency planning

- Emergency planning covers all aspects of biorisk and includes general safety, security and medical issues.

 Element 10.2.2, p138

- A system shall be established to effectively manage a confirmed facility-associated poliovirus infection until the individual is free of poliovirus in stools for three consecutive days. This includes procedures for:
 - Isolating infected individuals, particularly from children and the unimmunized;
 - Securing collection and disinfecting stool and associated waste;
 - Educating families and frequent contacts on the risk posed by the poliovirus infection and procedures for isolation;
 - Communicating to relevant national and local officials to evaluate needs to implement community immunization response plans;
 - Notifying WHO;
 - Disinfecting areas potentially contaminated by infected individuals.



Key issues?

- During an emergency, volumes of waste may grow and change in nature
- Concern may be raised over the material and normal disposal routes / processes may become unavailable
- Suppliers may be overwhelmed become unavailable, including disinfectants, PPE and other essential equipment
- Alternative means may need to be found for waste storage / disposal
- Staff concern may also be a key factor, e.g. unwillingness to handle materials





BIOSECURITY

Security

- Physical security

 Element 16.1, p158 - 160

- Risk assessment to identify controls for security of cultures, specimens, samples and potentially contaminated materials or waste

- Information security

 Element 16.2, p160

- Policy and procedure to identify sensitive information
- Review and approval process for release of information
- Review and control process for sensitive information

Security



- Personnel control

 Element 16.3, p160 - 161

- Policy for personnel reliability defined and implemented

- Personal security

 Element 16.4, p161

- Personal security support for staff

- Contractors, visitors and suppliers

 Element 16.5, p161

- Ensure that suppliers, contractors, visitors and sub-contractors adhere to the requirements of the organization's biorisk management system and do not compromise the biorisk management of the facility

Considerations?

- Approach calls for a philosophy that everywhere you see biosafety you should also see biosecurity
- Biosecurity has always been the 'little brother'
- Security personnel don't understand bio and bio people don't understand security – competence and recruitment issues?
- Insider vs outsider
- Has implications for intellectual property, reputation, etc.



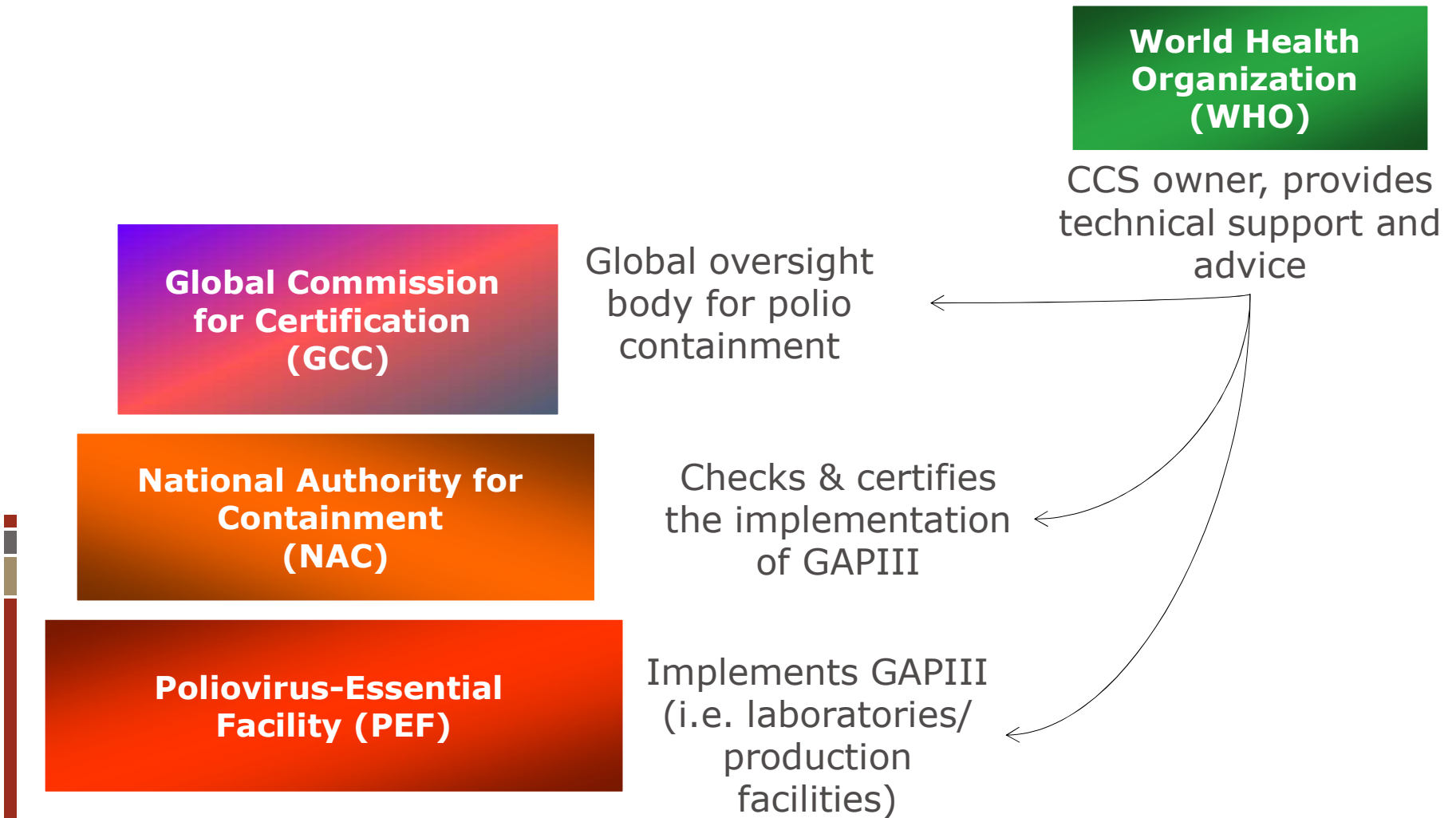
REVIEW, OVERSIGHT AND CERTIFICATION

■ Certification

- Has never been an internationally recognised and required biorisk management certification scheme
- The need for independent assessment brings an entirely different level of focus and rigour to any standard
- This area being addressed by GAPIII and the related CCS and will build competence and expectations within the regulatory agencies, bringing containment expertise to the discussion as perhaps never before
- Expect what starts in GAPIII to expand to other areas of potential concern in coming years



GAPIII CCS hierarchy



Types of CCS certificates

- **Certificate of Containment (CC)**

- To be achieved and maintained by PEF in post eradication era under GAP III

- **Interim Certificate of Containment (ICC)**

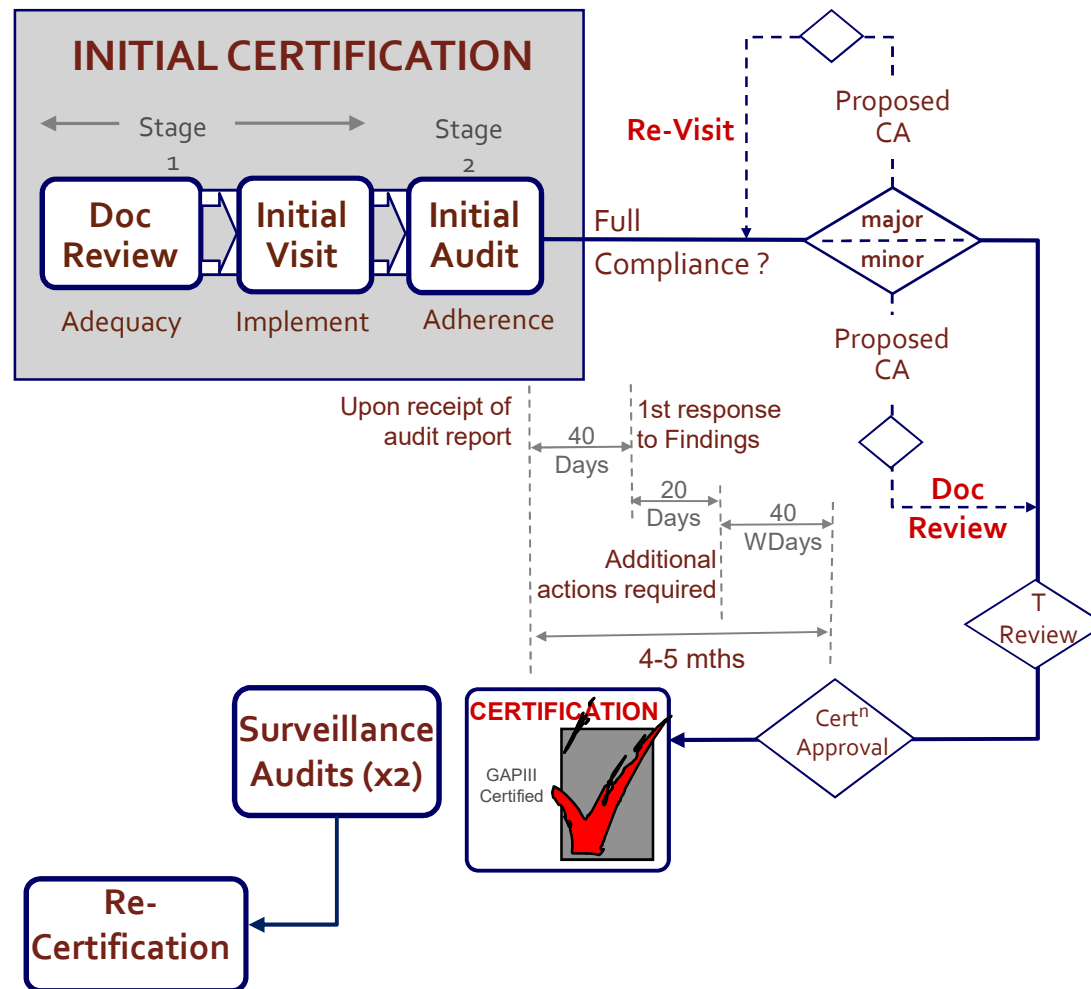
- For facilities not meeting all requirements, but requiring short term approval while more permanent conditions are finalized for CC or cessation of work

- **Certificate of Participation (CP)**

- For facilities engaging in the CCS certification process who may not yet be meeting all requirements and may yet to have been formally assessed against GAPIII requirements or cessation of work

Only facilities holding a valid CP/IC are /CC are allowed to pursue work and storage of poliovirus

Certification Scheme



Findings Resolution

- Major NC's** shall be closed; effectiveness of the correction, root cause analysis and corrective action are verified, usually through a site visit.
- Minor NC's** may be open but 100% resolved; clients planned correction, root cause analysis and corrective action were reviewed and accepted. Close at next surveillance audit.
- Observations;** Client shall respond with a decision if any actions will be taken. Follow up at next surveillance audit.



SMALL GROUP DISCUSSION ON PRACTICAL ISSUES AND CHALLENGES



QUESTIONS AND CONCLUSIONS?



Proactive Understanding

www.riskren.com