Singapore Standards Council

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

Launch of SS 696:2023 Specification For High Containment (BSL-3) Facility

Venue: Robertson 4 @ The Robertson House

20 Feb 2024, 9 AM – 12 PM

Meeting Logistics

WiFi Access

#TheRobertsonHouse_MeetingRoom

No password required

Video Recording

This meeting will be recorded for the purpose of creating accurate meeting minutes. When speaking, please use a microphone to facilitate sound recording.

Exit and Washroom

Accessible on either side of the corridor, in the lobby, and by the swimming pool.

Beverage and Refreshment

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CoRE-SDO Introduction

Background

In April 2023, the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School, appointed by Enterprise Singapore, established a new Standards Development Organisation (SDO), to provide support for the Biomedical and Health Standards Committee (BHSC), its Technical Committees (TCs) and Working Groups (WGs).

Team

Ms Yang Fan (Head)

Ms Tan Li Ping (Assistant Manager)

Mr Wong Siow Kay (Scientific Officer)

Website coresdo.org

LinkedIn core-sdo

DukeNUS Centre of Regulatory Excellence | Standards Development Organisation

CoRE-SDO Steering Committee

Prof John LIM (Chair)
Executive Director
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

A/Prof Silke VOGEL (Deputy Chair)
Deputy Director
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

Dr Tarun MAHESHWARI (Member)
Head
Business Development and Industry Alliance
Duke-NUS Medical School

Dr YONG Chern Chet (Member)
Chair
Biomedical and Healthcare Standards Committee
Head of Asian Ecosystem
22Health Ventures

BHSC

Ms Wai Ling LEUNG (Member)
Deputy Director-General
Quality & Excellence
Enterprise Singapore

Mr Aik Lam KHOR (Alternate Member)
Director (Manufacturing)
Standards Division
Enterprise Singapore

Meeting Agenda

Start Time	Topic	Speaker
9:00 AM	**Welcome Address**	**Dr YONG Chern Chet** Chair, Biomedical and Health Standards Committee
9:10 AM	Keynote: **Biorisk Management Oversight**	**A/Prof Raymond LIN** Director, National Public Health Laboratory
9:25 AM	Presentation: **Singapore Biorisk Management Regulatory Framework**	**Dr SE THOE Su Yun** Deputy Director, Biosafety Branch, Ministry of Health
9:45 AM	Break	
10:05 AM	Presentation: **SS 696:2023 — Enhancements in Design and Engineering**	**Mr Dan YOONG** Managing Director, World BioHazTec Asia Pacific
10:25 AM	Presentation: **SS 696:2023 — Administrative, Operational, and Performance Requirements**	**Dr Sabai PHYU** Director, Laboratory Biorisk Consultancy & Training
10:45 AM	Break	
10:50 AM	**Q&A**	**Panel Discussion**
12:00 PM	End	

For information

Welcome Address

Dr Yong Chern Chet

Chair, Biomedical and Health Standards Committee (BHSC)

Head of Asian Ecosystem, 22Health Ventures

Keynote

Biorisk Management Oversight

A/Prof Raymond Lin

Director, National Public Health Laboratory, interim Communicable Diseases Agency

Senior Consultant, Aged and Ancillary Services Regulations and Transformation/ Biosafety

Ministry of Health

Biorisk Management Oversight

Raymond Lin *FRCPA, MBBS*

Director, National Public Health Laboratory, interim Communicable Diseases Agency

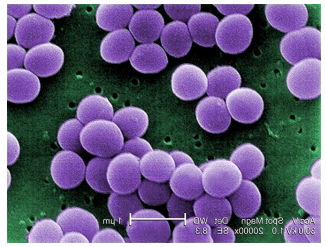
Senior Consultant, Aged and Ancillary Services Regulations and Transformation/ Biosafety

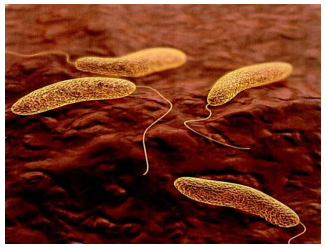
Ministry of Health

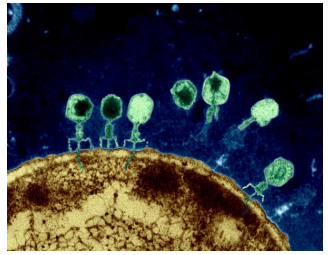
Content

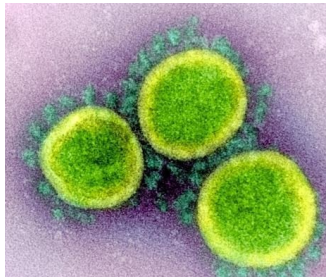
1. Biological Agents & Pathogens
2. Dual Nature of Pathogen Research
3. Benefits versus Risks
4. Biorisk Management Oversight

Biological Agents & Pathogens









Biological Agents are widely found in the natural environment. They include bacteria, viruses, fungi and parasites. Most of these agents are harmless, but some cause disease in humans.

Pathogens are microorganisms that cause disease in their hosts.
Virulence refers to biological properties which enable pathogens to cause severe disease.

Potential Adverse Effects from Pathogens

Disease

- In an individual
- Source of pathogen: endogenous, other humans, animal, environment

Outbreak

- Sudden increase in cases, clustered in time and place
- e.g. due to common risk exposure

Epidemic

- Unexpected increase in cases in a specific geographic area
- Due to several factors

Pandemic

- An epidemic which spreads over countries and continents
- Often indicates new biological agent, or new strain

Laboratory research on biological agents can result in -

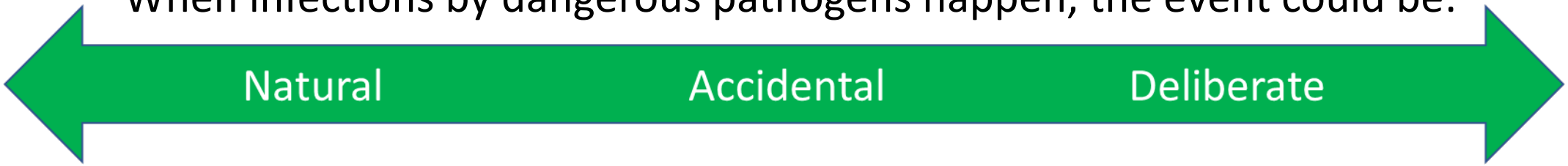
Good outcomes

- Knowledge discovery
- Treatment
- Vaccines
- Diagnostic device

Bad outcomes

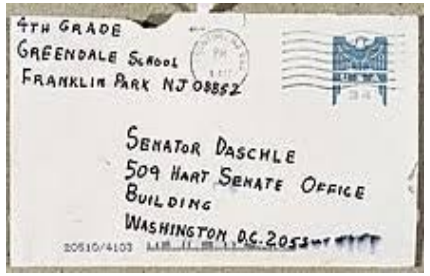
- Disease and death in laboratory
- Spread to community
- Release to environment
- Deliberate use in bioterrorism

When infections by dangerous pathogens happen, the event could be:

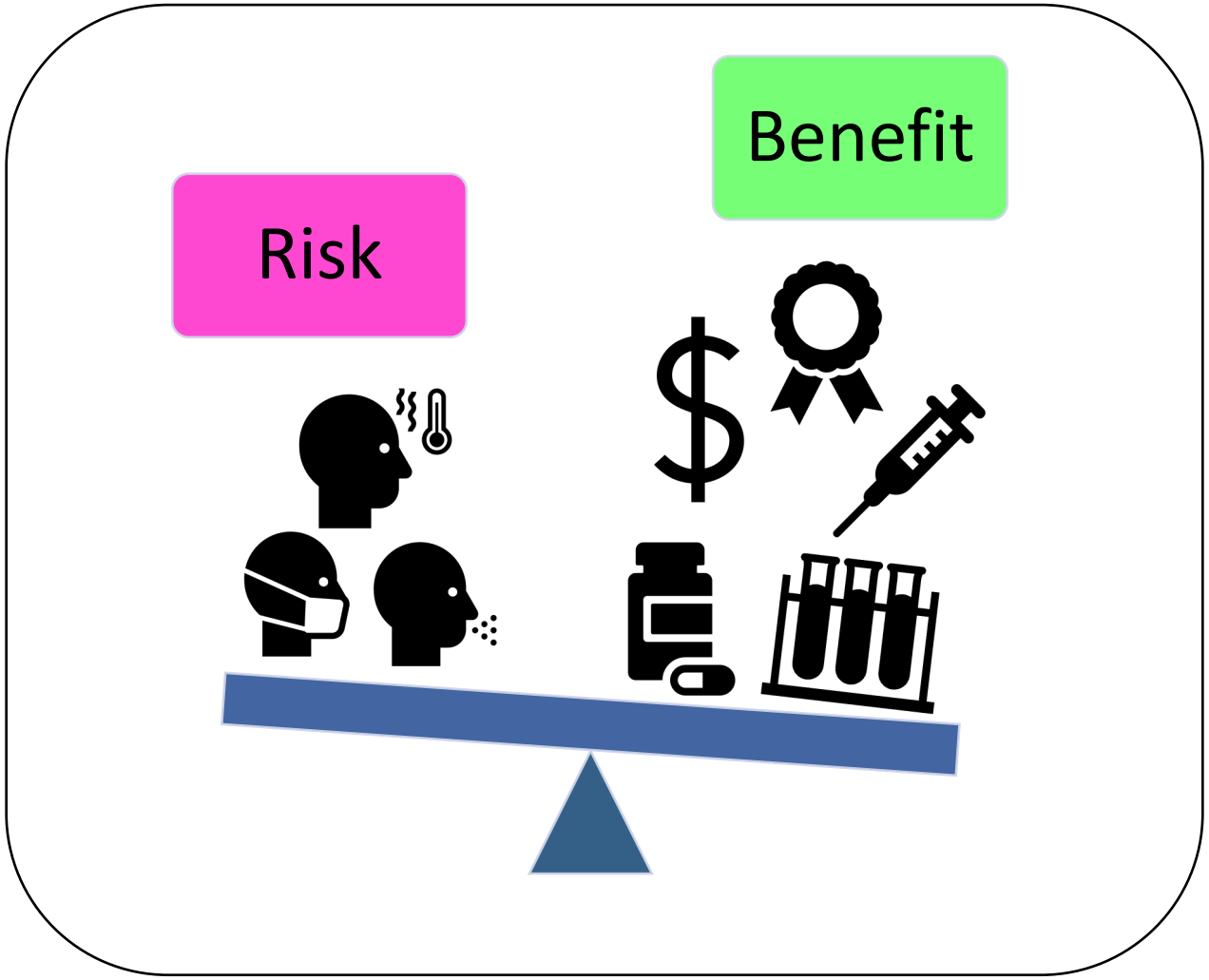


Recorded Incidents & Events

- Elizabeth R Griffin, 22, died in 1997 as a result of an ocular exposure to a macaque (herpes B) virus that occurred while carrying out research work at the Yerkes Primate Research Centre.
- Accidental release of *Bacillus anthrax* in 1979. The release of *B. anthracis* spores in the city of Sverdlovsk had resulted in 79 cases of inhalational anthrax infections, with a mortality rate of 86%.
- In July 1993, a liquid suspension of *Bacillus anthracis* was aerosolized from the roof of an eight-story building in Kameido, Tokyo, Japan, by the religious group Aum Shinrikyo. A retrospective case-detection survey conducted in 1999 did not identify any potential human anthrax cases associated with the incident. The use of an attenuated *B. anthracis* strain, low spore concentrations, ineffective dispersal, a clogged spray device, and inactivation of the spores by sunlight were all likely contributing factors to the lack of human cases.
- Bioterrorism event in 2001. An attack through an “intentional release” of *B. anthracis* through postal system in the United States had resulted in 11 cases of inhalational anthrax infections, of which 5 death and 7 cutaneous anthrax infections. It also led to more than 20,000 people having to take antibiotics for post-exposure prophylaxis.



Assessment: Benefits versus Risks



Aim: To reap benefits while minimising risks to the individual and community. A safe environment involves

⇒ Restricting to legitimate use

⇒ Restricting to legitimate users

⇒ Sustaining an effective biorisk management oversight system

Self Governance or Regulations?


Self-governance does not
mean no one is responsible.
It means everyone is.
Heather Marsh
quotefancy

Regulations

Getting the Balance Correct

- Empowering stakeholders
- Personal responsibility
- Lower cost
- Research culture

- Lack of oversight
- Low compliance
- Low awareness
- Cannot enforce

- Effective oversight
- Enforcement & compliance

- Administrative delay and obstacles
- Higher cost
- Scientists' aversion to regulation

Self Governance

Bottom Up

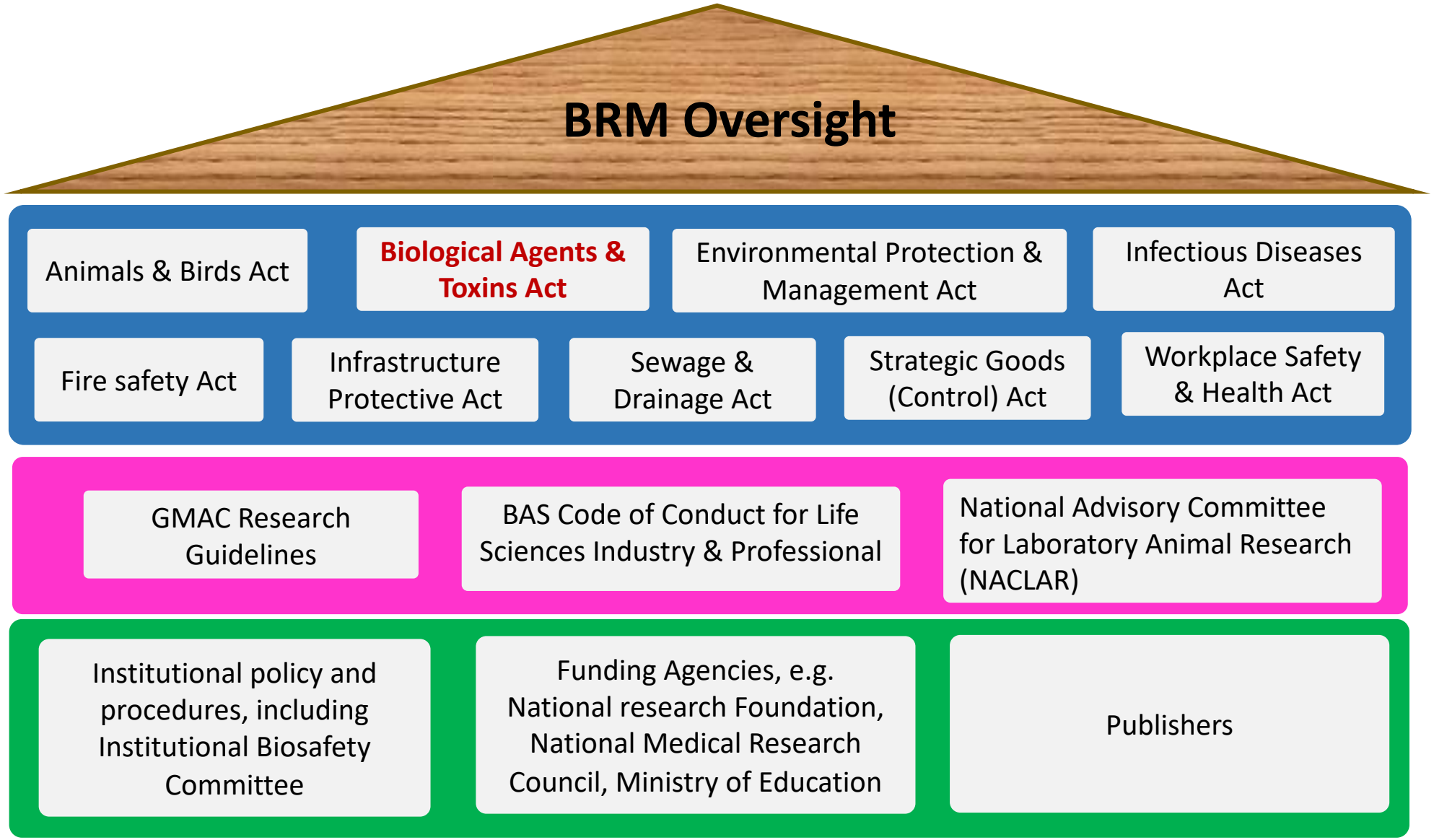
Integrated Oversight

Top Down

Regulations

Effective, clear and enforceable **regulations** together with responsible research **culture and training** will provide a safe and enabling environment for beneficial laboratory research on biological agents

Integrated BRM Oversight



Multi-pronged approach

National Legislations

Self awareness & responsibilities

Others: Funding & institutional oversight

BIOLOGICAL AGENTS AND TOXINS ACT (BATA) 2005

An Act to

- ❑ regulate the possession, use, import, transshipment, transfer and transportation of
- ❑ regulate biological agents, inactivated biological agents and toxins,
- ❑ provide for safe practices in the handling of such biological agents and toxins.


thank you

Presentation

Singapore Biorisk Management Regulatory Framework

Dr Se Thoe Su Yun

Deputy Director (Biosafety), Aged and Ancillary Services Regulations & Transformation

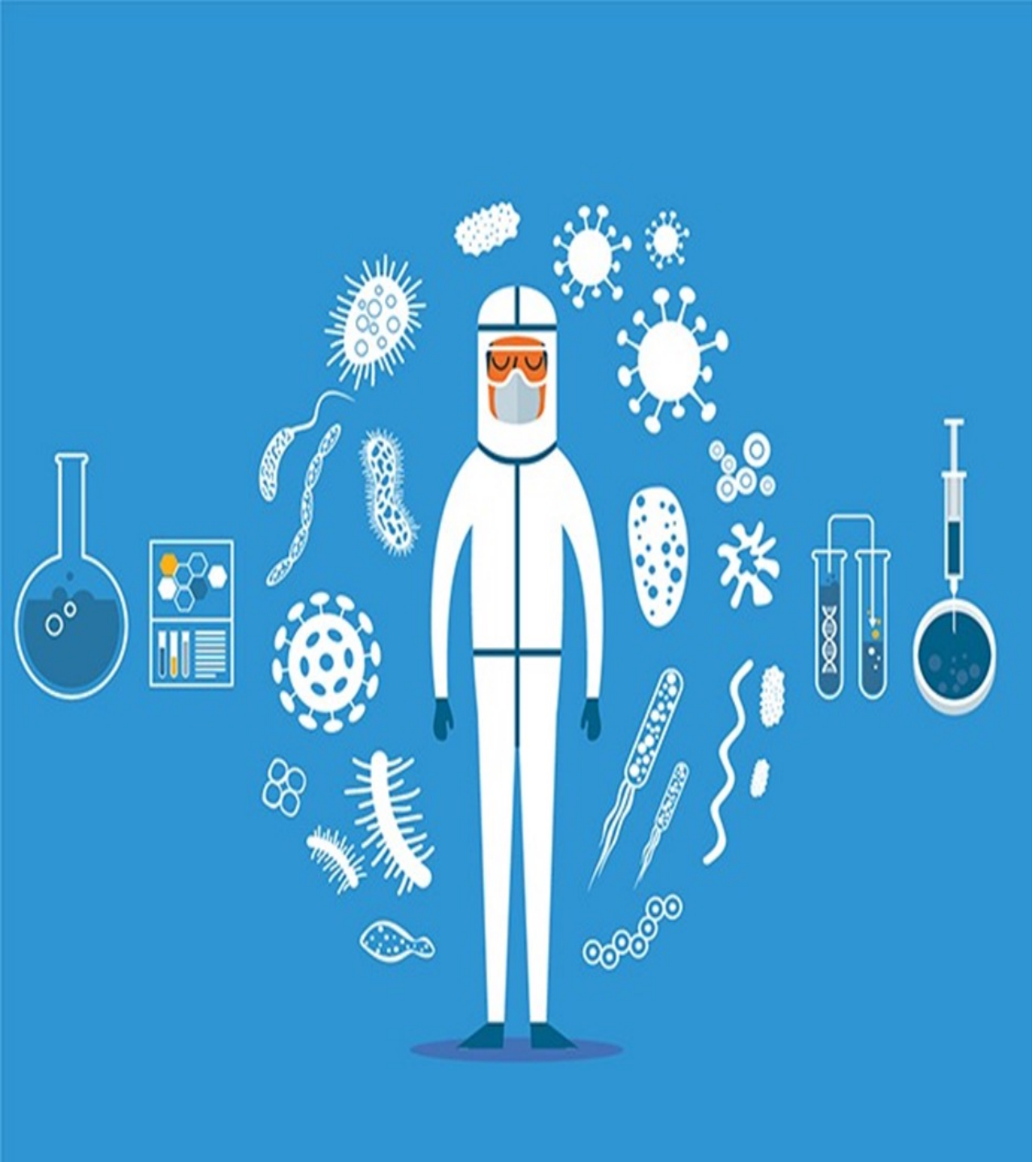
Ministry of Health

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

SINGAPORE BIORISK MANAGEMENT REGULATORY FRAMEWORK

Se Thoe Su Yun (PhD)
Deputy Director (Biosafety)
Aged and Ancillary Services Regulations & Transformation
Ministry of Health
20 Feb 2024



AGENDA

1. Biological Agents and Toxins Act (BATA)
2. Biorisk Management Compliance Verification & Monitoring
3. Development of the BRM Standard for BSL3 Facility (SS 696:2023)
4. Implementation Timeline

BIOLOGICAL AGENTS & TOXINS ACT (BATA)

An Act to prohibit or otherwise

- regulate the possession, use, import, transshipment, transfer and transportation
- regulate biological agents, inactivated biological agents and toxins
- provide for **safe practices** in the handling of such biological agents and toxins.

First Reading (19 Sep 2005)
Commencement (3 Jan 2006)
Full Enforcement (3 Jul 2006)

BATA CONTROL

WHAT

Biological agents human pathogens (First to Fourth Schedule)

Microbial toxins (Fifth Schedule)

Inactivated biological agents (inactivated First and Second Schedule)

Activities which include import, transhipment, possession, use, large scale production, inactivation, transfer & transportation of biological agents & toxins

WHO

Any **person who "possesses" or carries out activities** involving biological agents and toxins

HOW

Risk-based control

More controls & requirements for higher risk biological agents and/or toxins

BATA REQUIREMENTS
EFFECTIVE BIORISK MANAGEMENT SYSTEM

Import & Transhipment

Possession & Use

Transfer & Transportation

Disposal

Export *(Singapore Customs)*

From START to END

BATA CONTROL

WHAT

Biological agents human pathogens (First to Fourth Schedule)

Microbial toxins (Fifth Schedule)

Inactivated biological agents (inactivated First and Second Schedule)

Activities which include import, transhipment, possession, use, large scale production, inactivation, transfer & transportation of biological agents & toxins

WHO

Any **person who "possesses" or carries out activities** involving biological agents and toxins

HOW

Risk-based control

More controls & requirements for higher risk biological agents and/or toxins

RISK-BASED CONTROL

RISK-BASED CONTROL OF *SCHEDULED* BIOLOGICAL AGENTS & TOXINS

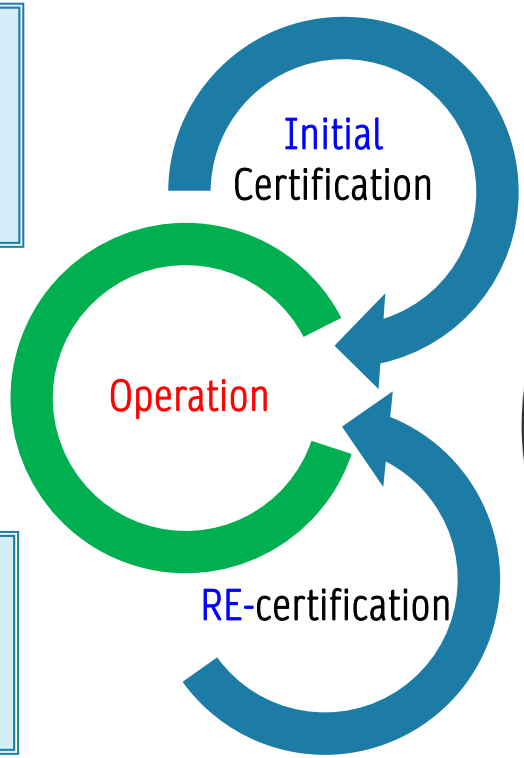
Dealing/Schedule	2nd Sch BA (RG4)	1st Sch BA (RG3)	3rd & 4th Sch BA (RG2)	Inactivated (S1 & S2) BA	5th Sch Toxin
Transport thru **Mail or Public** Transport			**PROHIBITED**		
Additional Transport Requirement *(Packaging, Driver, Vehicle)*	√	√	√ (3rd)	X	√
Permit to **Import**	√	√	√	√	√
Permit to **Tranship**	√	√	X	X	√
Approval to **Possess**	√	√	X	X	√
Special Approval to **Use**	√	X	X	X	X
Large Scale Production *(10L or more/any one time)*	**Prohibit**	√	√ (3rd)	X	X
Temporary Storage *Area that is Safe & Secure*	√	√	X	X	√
Notification of **Transfer** *(Security)*	√	√ (P2)	X	X	√
Notification of **Failure of Receipt** of Import/Tranship/Tranfer *(Security)*	√	√ (P2)	X	X	√

COMPLIANCE VERIFICATION & MONITORING (MOH HC/BSL3 CERTIFICATION SCHEME)

- New BSL3 facility (newly built or retrofitted)
- Certification by MOH-Approved Facility Certifier (AFC)
- Using **MOH High Containment (BSL3) Facility Certification Checklist**

- **Successfully certified by MOH-AFC**
- **Register with MOH as "Certified Facility" (CF)**
- **Approval to operate**

- Exiting "CF"
- Annual recertification by MOH-AFC using **MOH High Containment (BSL3) Facility Certification Checklist**



MOH HIGH CONTAINMENT (BSL3) FACILITY CERTIFICATION CHECKLIST

Part 1: Facility Design, Fittings and Access Control

A facility's layout, design and installation are important in maintaining efficient containment (secondary containment) of infectious material, animal or toxin. This section of the checklist specifies the requirements of the different features which provide for containment, such as engineering, architecture (e.g. surface finishing, installations) and administrative controls.

S/N	Checked Item	Yes	No	N/A	Comments
Part 1.1 Air Conditioning and Mechanical Ventilation (ACMV)					
1.1.1	The facility must have an ACMV system which maintains negative air pressure gradient relative to the non-containment area.	☐	☐	☐	
1.1.2	The ACMV system is designed: (a) With directional airflow from the least to the most contaminated area;	☐	☐	☐	
	(b) With differential pressure of 12.5Pa[8] or more between pressure zones;	☐	☐	☐	
	(c) With visual displays of differential pressure available at the entrance of each pressure zone	☐	☐	☐	
	(d) With monitoring and alarm systems to alert users of system abnormalities and/or failure; and	☐	☐	☐	
	(e) To ensure containment barrier is not compromised. This includes in the event of any ACMV failure scenarios.	☐	☐	☐	
1.1.3	Exhaust air of the facility is:				

Checklist items are divided into 6 parts with 133 items

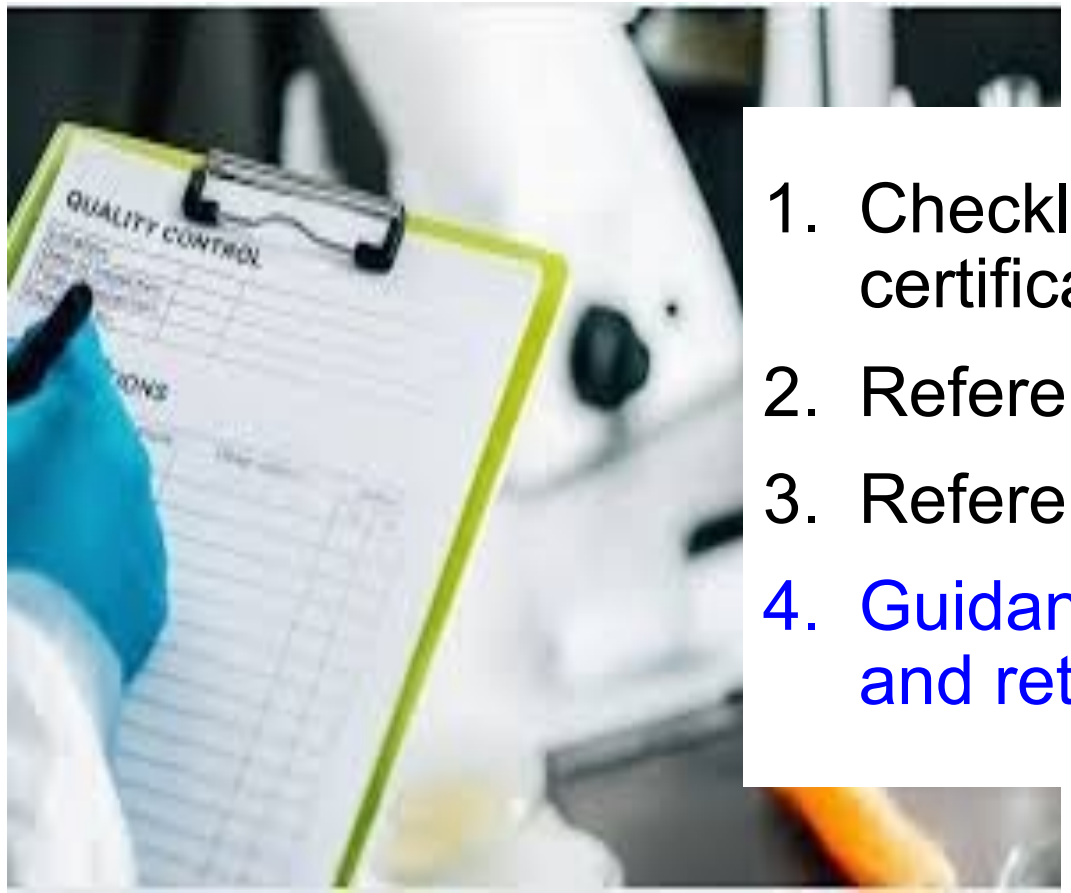
Part 1: Facility Design, Fittings and Access Control
Part 2: Biosafety Equipment
Part 3: Sterilisation, Decontamination & Waste Management
Part 4: Administrative Control
Part 5: Personnel Training and Competency
Part 6: Laboratory Practices

A **checklist** is a simple to-do list, serves to
(a) keep track on what to check and
(b) ensure that the work-completion is according to the requirements

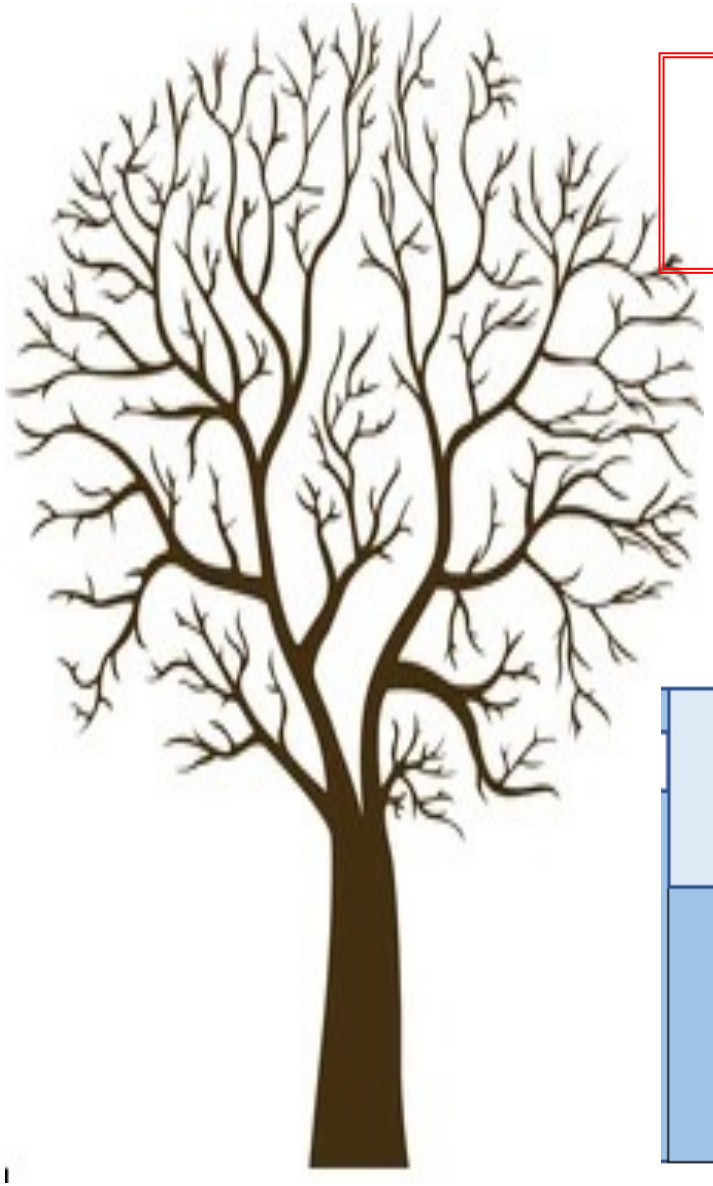
	ACMV
1.1	The facility must have an ACMV system which maintains negative air pressure gradient relative to the non-containment area.
1.2	The ACMV system is designed:
a	With directional airflow from the least to the most contaminated area
b	With differential pressure of 12.5Pa or more between pressure zones;
c	With visual displays of differential pressure available at the entrance of each pressure zone

Checked items only specified the intended requirements with **little details of the requirements**

APPLICATION OF THE MOH HIGH CONTAINMENT (BSL3) FACILITY CERTIFICATION CHECKLIST

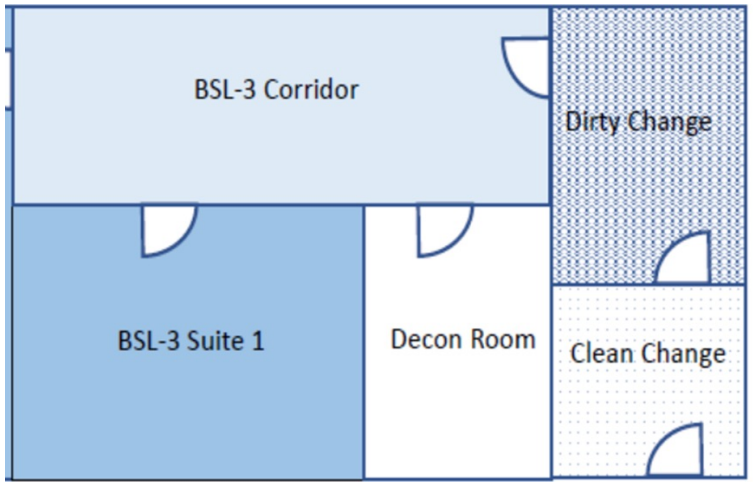


1. Checklist for facility certification/recertification
2. Reference for internal Audit
3. Reference for pre-certification testing
4. Guidance in designing, constructing and retrofitting new BSL3 facilities



Checked items only specified the intended requirements with **little details of the requirements**

1. Containment barrier
2. Pressure zone
3. Direction of airflow



Room for interpretation

Operational & Compliance Challenges

Need more detailed information, for clarity and to prevent misinterpretation

DEVELOPMENT OF THE SINGAPORE STANDARD SS 696:2023

1. Developed by a workgroup composed of 21 members from various sectors with diversified expertise, including academic, research, commercial companies, and regulatory authorities.
2. Public consultations were carried out and existing BSL3 facilities were consulted.
3. Comments/feedback received were addressed.
4. SS 696:2023 was released in September 2023.

CONTENTS OF SS 696:2023

SS 696:2023

SS 696:2023

Key sections

4. Physical containment requirements & recommendations

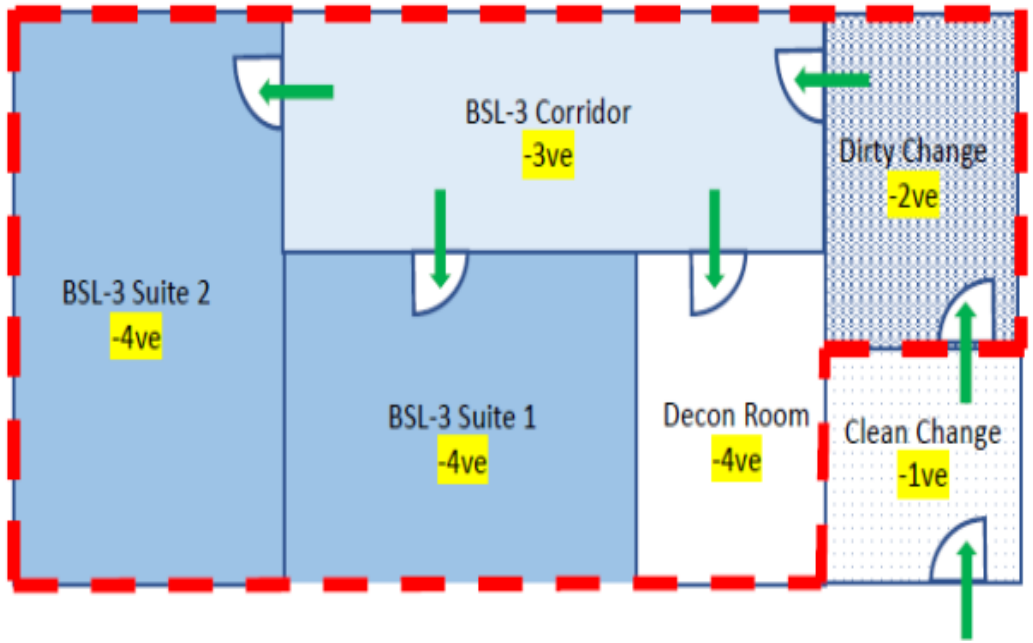
5. Administrative control and operational practice requirements & recommendations

6 Performance verification requirements and recommendations.

MORE DETAILS & BETTER CLARTY

Enhanced with clear definitions, more defined roles and responsibilities in overseeing and management of the BRM, ERP, more detailed requirements, guidance notes as well as examples (figures, annexes and references)

Example: Figure showing containment barrier, differential pressure and direction airflow



Examples:
Nine annexes with details of what and how to achieve the specific requirements

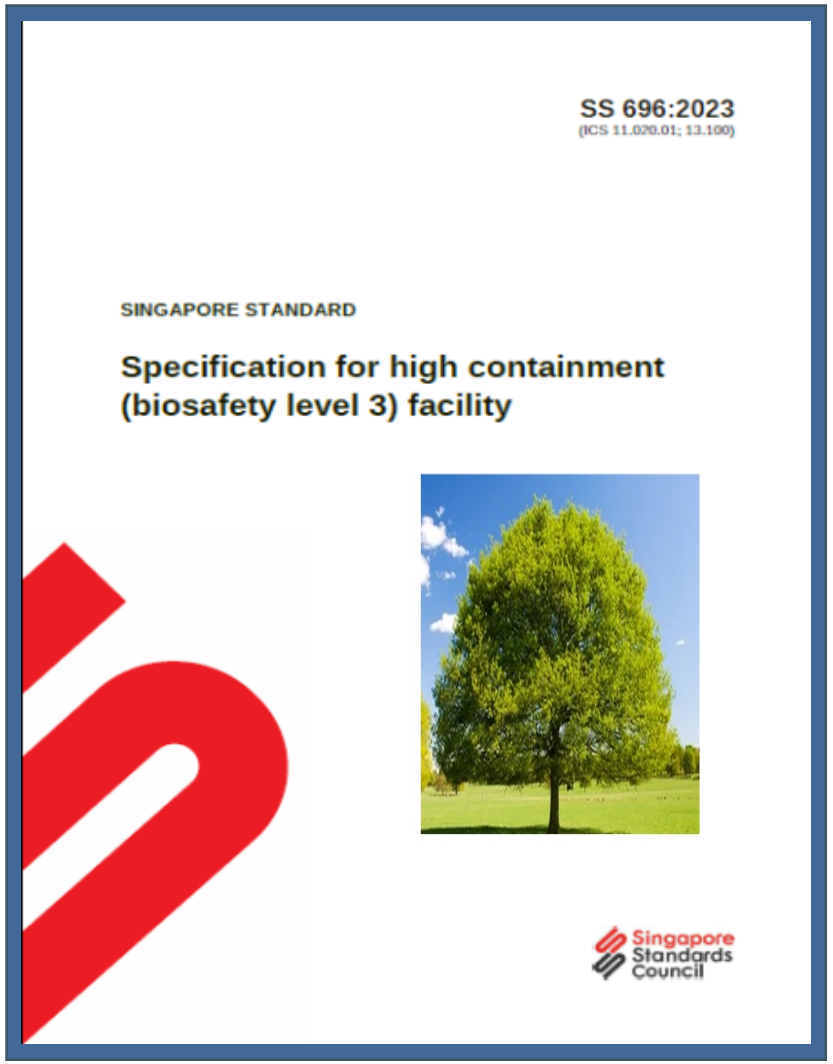
Annexes	
A. Facility design document	B. Spatial decontamination of facility
C. Sample list of key requirements to be covered in a commission process	D. BRM committee
E. Risk assessment & mitigation	F. Validation & verification of autoclave process & performance
G. Development and validation of inactivation protocols	H. Installation of electrical system & wiring
I. Sample of continuous performance verification	

EXPANDED THE SCOPE

Cover the following aspects:

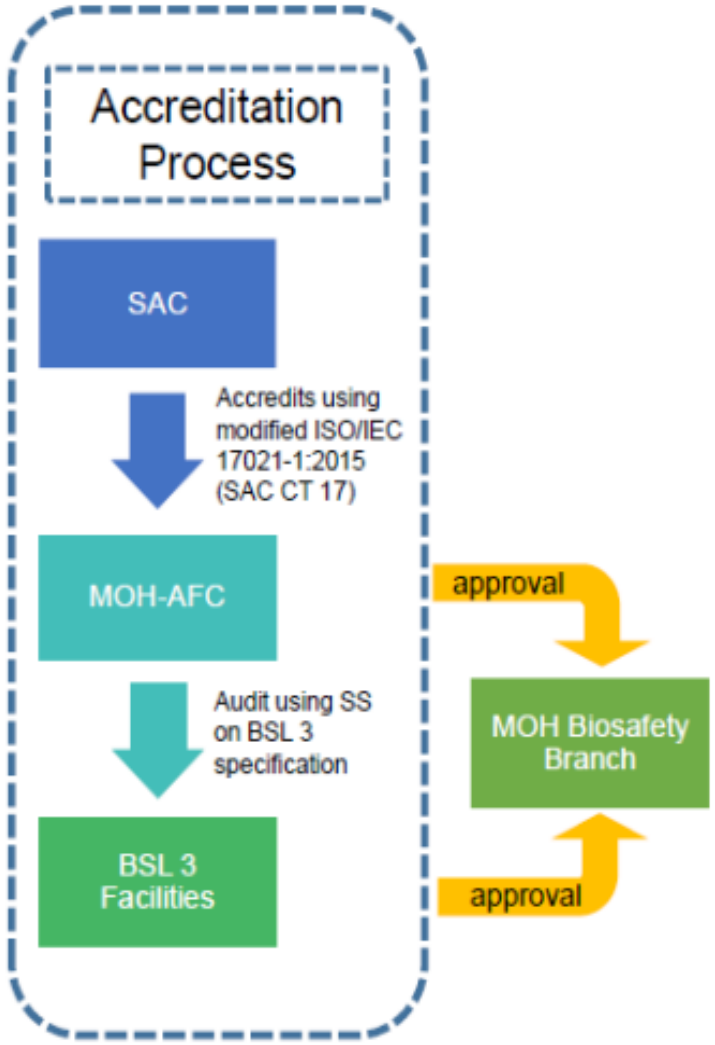
1. Animal BSL3 facility involving animals that can be housed within a primary containment device
2. Animal BSL3 facility involving loose pen animal work
3. Arthropod BSL3 facility

MORE THAN A CERTIFICATION CHECKLIST



1. Guidance document for designing, construction or retrofitting
   i. BSL3 facility
   ii. ABSL3 facility involving animals that can be housed in primary containment device
   iii. ABSL3 facility involving loose-pen animals
   iv. Arthropod BSL3 facility
2. Guidance document for facility certification, to comply with the BATA
3. Internal BRM performance verification, monitoring and/or improvement.

ACCREDITATION SCHEME FOR MOH-AFC



Objective – MOH

- To level up capabilities of bio-facilities in the management of biosafety and biosecurity, to ensure workplace health and safety.

Objective – SAC

- To ensure a robust system is in place for relevant audits to be performed by SAC-accredited AOs, which provides confidence in the safety and security of BSL 3 facilities in Singapore.

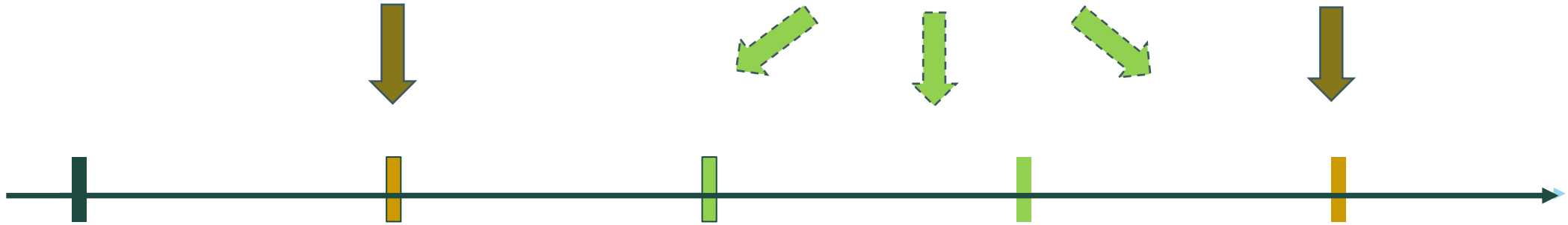
- To build a network of recognised 3rd party AOs that provide assurance that BSL 3 AOs will audit with professionalism and integrity in accordance with SAC and relevant regulatory criteria. The programme will enhance the rigour and veracity of audit outcomes delivered by recognised AOs.

TIMELINE

SS 696: 2023
Designing, construction/ retrofitting of BSL3 facility

Certification:
MOH BSL3 certification checklist
SS 696: 2023 (voluntary)

Certification:
SS 696:2023



SEP 23	FEB 24	MAR 24	SEP 24	MAR 25
Release of SS 696:2023	Launch of SS 696:2023	Launch of the SAC Accreditation Programme for BRM Audits under the AOs Scheme	SAC accreditation of AOs for BSL3 facility All MOH-AFCs must be SAC-accredited	Complete replacement of MOH BSL3 facility certification checklist with SS696:2023

THANK YOU

After the Break…

- SS 696:2023 — Enhancements in Design and Engineering
- SS 696:2023 — Administrative, Operational, and Performance Requirements for BSL-3 Facilities

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Presentation

SS 696:2023 Enhancements in Design and Engineering

Mr Dan Yoong

Managing Director, World BioHazTec Asia Pacific

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

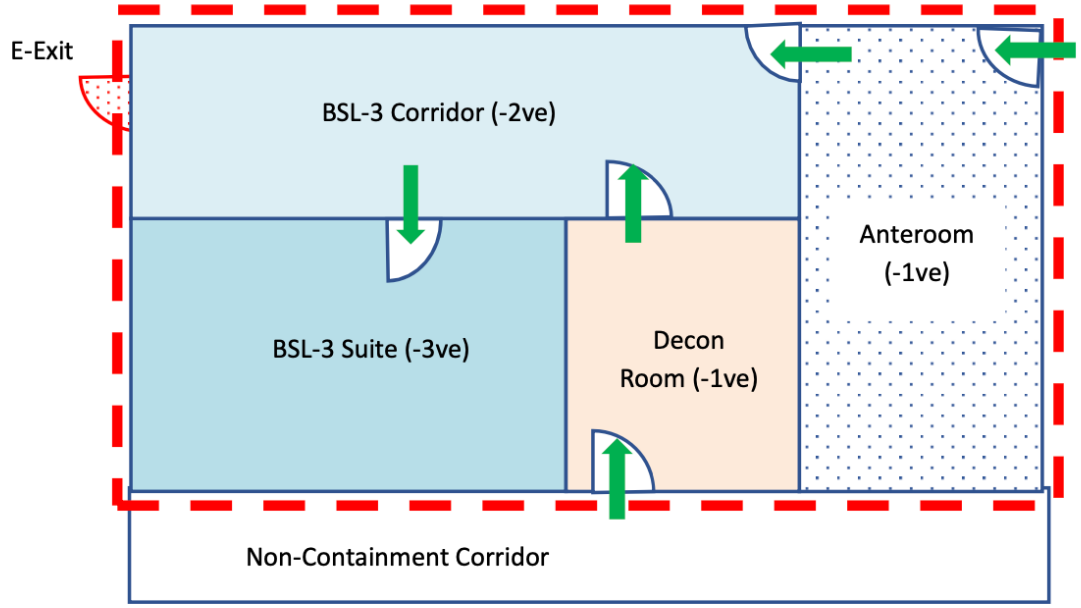
Launch of SS696:2023

Enhancements in Design and Engineering

20 February 2024

Design & Engineering

Bio-containment principles were not changed, the Standard has enhanced it by highlighting some additional features to address Biorisks via Design and Engineering



←	Airflow direction
- - -	CZ perimeter
(-ve)	pressure differential in relation to the external of the CZ

SS696:2023

Design & Engineering

Anteroom is still an Anteroom. With additional features if it is being used for changing of PPE.

4.5.2.4 If the anteroom is also serving as a PPE change room, it shall be further separated into "clean" (for donning of clean PPE) and "dirty" (for doffing of PPE) change rooms or areas (see Figure 2(a) and Figure 2(b)). If there is an interconnection between "clean" and "dirty" change, the pressure differential in the dirty change room (or area) such as in Figure 2(b), shall be more negative than the clean change room (or area). Space shall be provided for the storage of PPE in use.

Principle: if there are 'clean' and 'dirty' change room(s), the dirty change zone shall be more negative than the clean change.

Design & Engineering

In the new standard, a mock-up of the BSL-3 is recommended.

4.2.2.2 Resources should be factored in for a mock-up during the construction stage of the project. This helps to prevent misinterpretation of design features. The mock-up which serves to provide the anticipated standard of finishes for the entire project, may include the following features:

(a) Architectural interfaces (e.g. floor to wall, wall to ceiling, wall to door frame);

(b) Installation method (e.g. gas lines, electrical sockets, plumbing and sanitation (sink, discharge connections));

(c) Sealing method and material of services penetration on the wall and ceiling;

(d) Architectural layout marking;

(e) Laboratory furniture finishing;

(f) Mechanical and engineering services interface and finishing (e.g. diffusers, alarms, sprinklers);

(g) Building management system display (e.g. temperature, pressure differentials, room humidity, etc.); and

(h) Any other critical services installation.

Design & Engineering

Although not spelt out in detail in the Standard, there are requirements from PUB for BSL3 facilities. As such, seeking in-principle approval with PUB is necessary for effluent monitoring or treatment prior to designing.

PUB SINGAPORE'S NATIONAL WATER AGENCY

Design & Engineering

GREEN!

4.2.1.5 Green building designs including energy saving features can be incorporated into the design of the facility, and this shall be done in a manner that does not compromise the safety and security of the facility.

4.7.4.2 Recirculation of HEPA-filtered air back to the facility is not encouraged. If this is to be attempted, risk assessment shall be conducted, and mitigation measures shall be in place to minimise the risks of cross contamination. HEPA-filtered air can only be recirculated to areas of the same containment level and shall never be recirculated to an area of lower containment level.

Design & Engineering

Other Enhancements:

Arthropod Containment:
- Requirements for cabinets, furniture, finishing
- Air Conditioning and Mechanical Ventilation
- Layout considerations
- Plumbing

SS696:2023

Design & Engineering

ABSL3 with loose pen housing:

- Airtight Doors = Airtight rooms = Pressure Decay Test

4.12.2.2 Airtight doors shall be provided at the point(s) of the anteroom (or the Dirty Change, in the context of Figure 3), and the animal (and/or material) transfer. A shower room shall be provided at the point of exit (or within the Dirty Change). See Figure 3 for a simple illustration of the containment principles and room relationships, and requirements of airtight doors for a facility designed for loose pen animal work. Alternate design without airtight doors may be considered for animal work involving indigenous human pathogens, and this shall require a thorough risk assessment.

Appendix C

(b) Pressure decay test on AC room (where the room is used as primary containment for open cages animal work);

NOTE – Acceptance criteria include two consecutive tests with a maximum of 250 Pa loss of pressure from an initial 500 Pa over a 20-minute period).

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Design & Engineering

ABSL3 with loose pen housing:

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Provision of an Effluent Decontamination System (EDS)
Requirements of EDS
Requirements of the EDS room

Design & Engineering

HEPA Housing Requirements (4.7.4.3):

- (d) designed with:
  - bubble-tight or gas-tight isolation dampers (both upstream and downstream);
  - decontamination ports;
  - provision to validate the efficacy of the decontamination process for HEPA filters;
  - an introduction port for poly alpha olefin, at 8 duct diameter length upstream;
  - HEPA scanning ports (scanning of filters is preferred over single point sampling);
  - ability to test each HEPA filter individually if the housing consists of multiple HEPA filters; and
  - bag-in/bag-out feature which is optional depending on risk assessment.

Design & Engineering

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Design & Engineering

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Rooftop view of a BSL-3 Lab in Singapore

Thank You!

Presentation

SS 696:2023 Administrative, Operational, and Performance Requirements for BSL-3 Facilities

Dr Sabai Phyu

Director, Laboratory Biorisk Consultancy & Training Pte Ltd

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

LBCT
Laboratory Biorisk Consultancy & Training Pte. Ltd.

SS 696: 2023 – Administrative, operational, and performance requirements for BSL-3 facilities

Dr. Sabai Phyu
Director – Laboratory Biorisk Consultancy & Training Pte. Ltd.

The Robertson House by The Crest Collection
SS 696:2023 Launch event

20.02.2024
SINGAPORE

Disclaimers

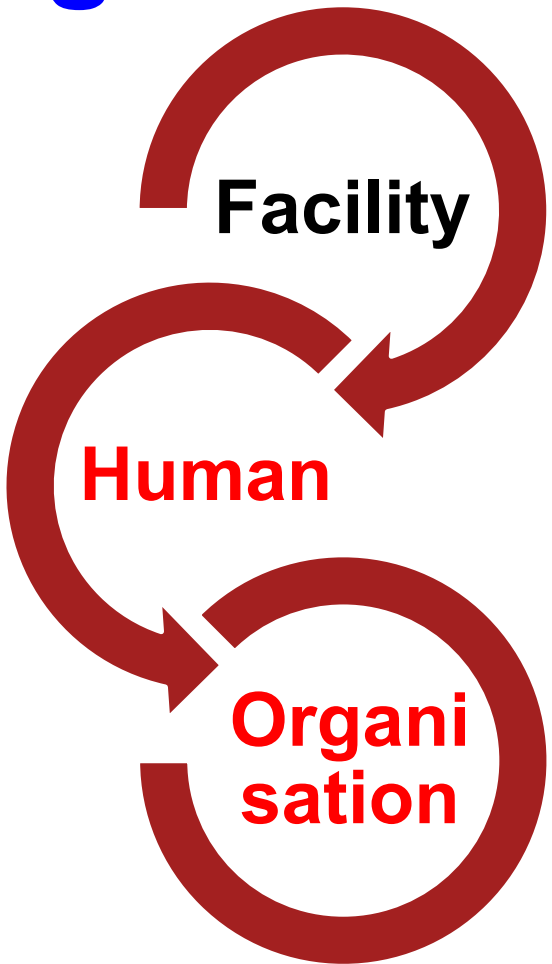
The opinions expressed in this presentation are solely those of the presenter.

This presentation is prepared in my own personal capacity and the opinions are not necessarily reflecting any other organizations' views.

Goals

To share SS 696:2023 requirements in terms of administrative, operational, and performance for BSL-3 facilities

Components involved in managing and operating of high containment (BSL-3) facility



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Index

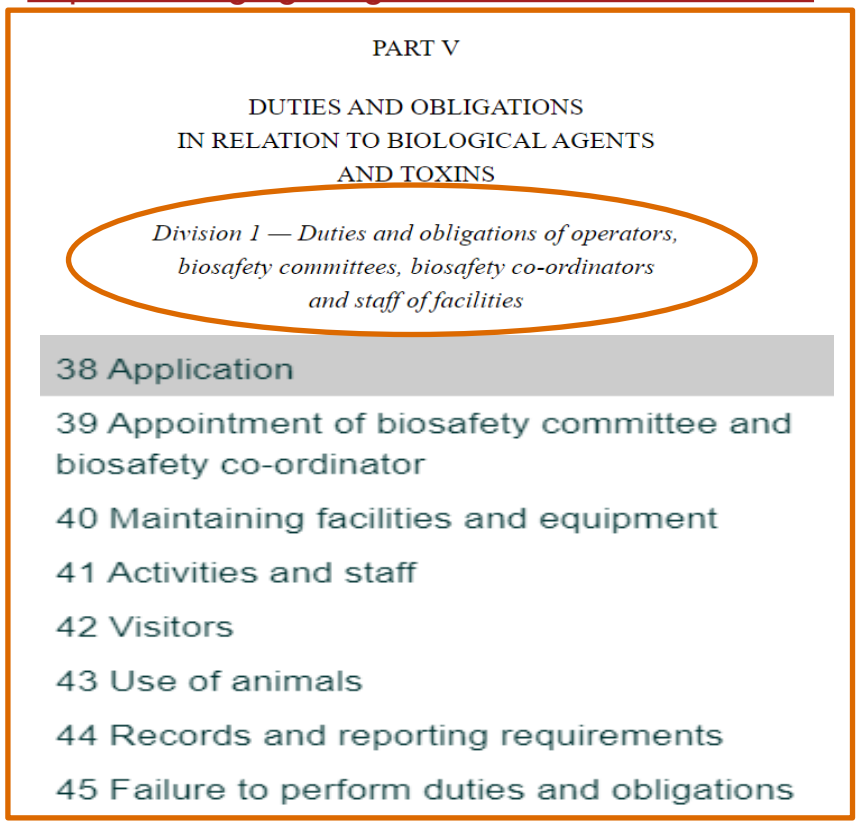
5.5 Risk assessment and management planning

Facility operator – *Duties and obligations (BATA)*

For 1st, 2nd, 3rd and 5th Schedule biological agents (BAs) and toxins

- **Duties** of the operator, BSC members, personnel and visitors.
- **Operator:** A person **who operates** the facility **or who has the management or control** of the facility.
- Appointing the "Facility Operator" varies among the BSL-3 labs e.g., some appoint CEO/ GM of the organization, some appoint a Facility director/ Head of the laboratory etc.

Source: https://sso.agc.gov.sg/Act/BATA2005#P1V-P21-



PART V

DUTIES AND OBLIGATIONS IN RELATION TO BIOLOGICAL AGENTS AND TOXINS

Division 1 — Duties and obligations of operators, biosafety committees, biosafety co-ordinators and staff of facilities

38 Application

39 Appointment of biosafety committee and biosafety co-ordinator

40 Maintaining facilities and equipment

41 Activities and staff

42 Visitors

43 Use of animals

44 Records and reporting requirements

45 Failure to perform duties and obligations

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Refer to 5.2, 5.3, 5.4, and 5.5

❖Additional information to be taken into account while appointing the FO:

- Responsibilities of **organisations**
- Responsibilities of **Top Management and Management (Management)**
- **Other critical personnel involved** in managing BSL-3 facilities (e.g., BRM advisor, scientific director/ programme management)
- Define the layout of the **reporting line** for critical personnel involved in managing/ operating the laboratory
- Define who should be **held accountable for implementing and managing laboratory BRM**

5.2 BRM system

5.2.1 The organization shall

- **establish a <u>sustainable BRM system</u>*** that incorporates appropriate administrative controls and operational framework,
- **align** the BRM system with **<u>organizational</u>** policies and standards of health, safety, security, and business management processes,
- **ensure** the BRM system **<u>complies</u> with applicable statutory and regulatory requirements.**

*It is a systematic way of addressing and controlling biorisks encountered in labs.

BRM system

Assessment (A)	+	Mitigation (M)	+	Performance (P)
•Hazard/ Threat identification •Risk assessment		•Biorisk control measures		•Monitoring & Evaluating •Reviewing

5.3 BRM policy

- **Organisation's Top Management** shall develop, authorize, and sign a BRM policy.
- **Policy** shall be appropriate to the nature and scale of the risks associated with the facility and associated activities and commit to :

(a) protect staff, contractors, visitors, community and environment from biological agents, toxins and biological materials that are stored or handled within the facility;

(b) reduce the risk of unintentional release of, or exposure to biological agents, toxins and biological materials;

(c) reduce the risk to an acceptable level of unauthorised intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures;

(d) comply with all legal requirements applicable to the biological agents and toxins that are handled or possessed, and with the requirements of this standard;

(e) ensure the need for effective BRM shall take precedence over all non "health and safety" operational requirements;

(f) inform all employees and relevant third parties and communicate individual obligations effectively with regards to biorisk to those groups; and

(g) improve BRM performance continually.

(The policy shall be reviewed every ≤2 years)

Roles and responsibilities

Top management and Management

Top Management
A person or group of people who directs and controls an organisation at the **highest level**, and who holds **authority, resources and decision-making power** regarding changes at the organisation (3.64).

Management
A person who **operates the facility**, or who has the **management or control** of a facility (3.54).

5.4.1 Organisation and leadership

Ensure to

- ❖align with national legislations, regulations, national and international standards
- ❖align and compatible with the strategic direction of the organisation and achieve the intended outcome
- ❖develop a BRM policy
- ❖inform the importance of an effective BRM and conform to BRM requirements
- ❖provide sufficient resources (human, budget)
- ❖assign the representative of the Top Management to oversee the performance of BRM
- ❖promote **a strong organisational safety and security culture** and **continual improvement** of the BRM

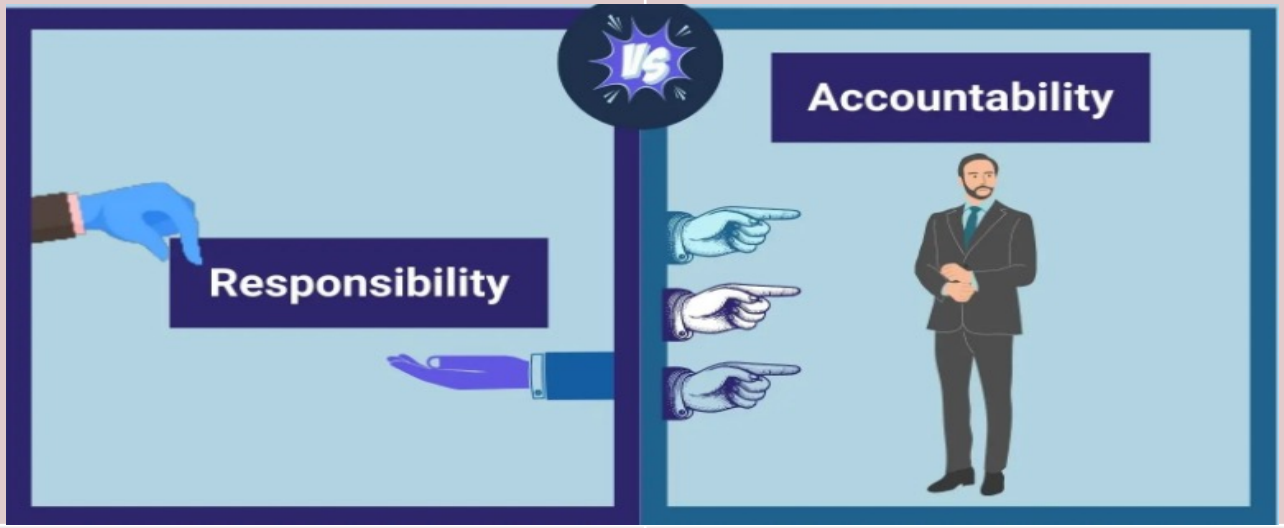
5.4.2 Top Management/ Management

❖ Maintain **oversight**, be **responsible and accountable** for **implementing and managing** all national, organizational, and facility requirements.

❖ The Top management
- can **delegate** day-to-day management to suitable personnel who are competent and possess the necessary qualifications **but not accountability**.
- all delegation shall be properly documented.
- shall take into account the potential areas with conflict of interest when assigning critical roles and responsibilities.

Responsibility vs. Accountability

Responsibility	Accountability
- He/She **is assigned** to do tasks.	- He/She is assigned as **a task owner.** - Thus, he/she **is responsible and answerable** for the task **outcome**.
- Responsibility **can be delegated**. Proper recording of the delegation.	- Accountability **cannot be delegated.**



https://www.edstellar.com/blog/accountability-vs-responsibility

5.4.3 BRM Committee & lab personnel

5.4.3.1 The responsibilities of BRM committee shall include, but not limited to the following:

(a) Formulate laboratory biorisk policies, devise appropriate risk mitigation programmes including training, risk assessment and occupational health programmes, and codes of practice.

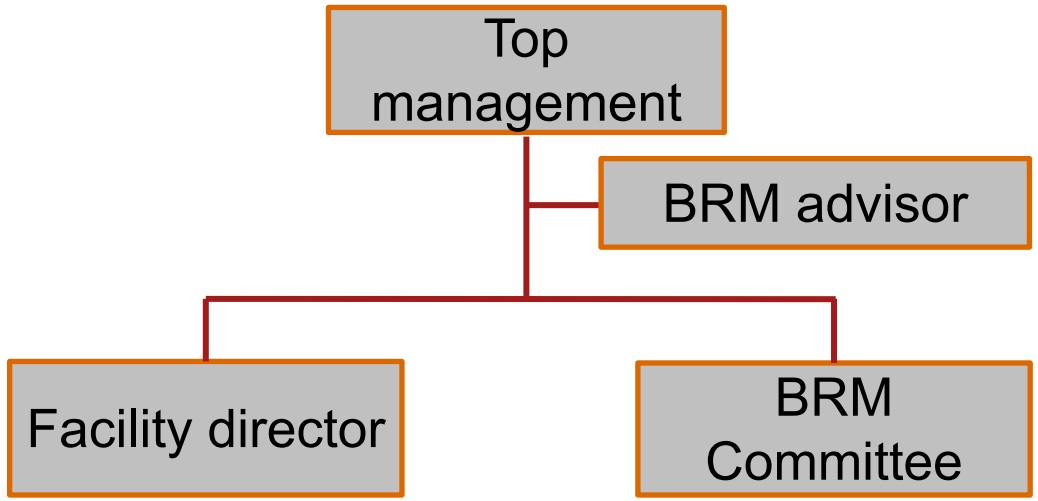
(b) Review all submitted laboratory project proposals, laboratory safety, security and response procedures, experimental protocols including risk assessments, risk mitigation measures, policies, work procedures and practices, and provide feedback to the relevant personnel or parties. The documents shall be reviewed every two years or earlier.

(c) Oversee other relevant activities such as importing and shipping biological agents, toxins and biological materials, inactivating biological agents, incident investigating, occupational health related issues, and policy changes, etc.

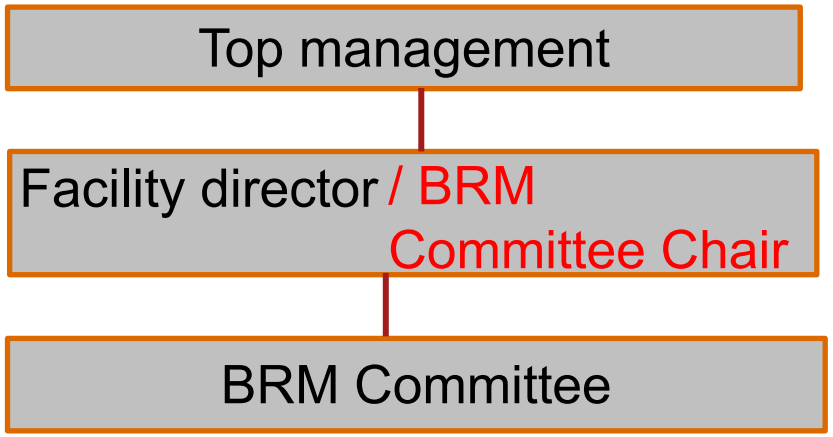
5.4.3 BRM committee & lab personnel

5.4.3.3 The governance structure, the roles and responsibilities of BRM committee members, and the reporting lines shall be explicitly described and documented, e.g. in the BRM manual. Refer to Annex D for more details regarding compositions and potential responsibilities of BRM committee.

Reporting line example



Reporting line with potential conflict of interest examples



Risk assessment and management

5.5 Risk assessment and management planning

5.5.3 New or review of risk assessment

5.5.3.1 The following situations shall trigger either a new risk assessment or review of an existing one:

(a) Commencement of new work or changes to the programme of work, including the introduction of new biological agents, toxins, biological materials, new equipment, or alterations to workflow or volume;

(b) New construction or modifications to the facility, and equipment or its operation;

(c) Introduction of altered or unplanned staffing arrangements, including contractors, visitors, and other non-core personnel;

(d) Significant alterations to SOPs or working practices (e.g. disinfection or waste management methodologies, PPE provision, entry or exit protocols);

(e) When unexpected events that may have relevance for the management of biorisks are observed, such as accidents, near misses or changes in the security threat environment;

(f) When actual or potential noncompliance with regulations or nonconformity with internal or external rules is identified (e.g. introduction of new legislation or major accident exposure);

(g) When there are emergency response and contingency planning requirements; and/or

(h) As part of the existing management system review process (also refer to 5.5.3.2).

Annexes in SS 696

Annex E: Risk assessment and mitigations

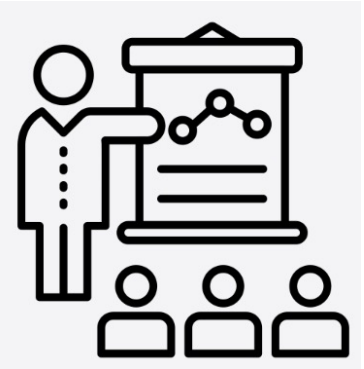
Some examples can be found

- **Biosafety and biosecurity risk assessment methodology**
- **References for biosecurity risk assessment including dual-use research**
- **Biosafety risk mitigation** strategies and measures
- **Biosecurity risk mitigation** strategies and measures
  - Facility access control
  - Biological agents/ toxins/ material access control
  - Handling security-sensitive information

Personnel training and management

5.8 Personnel training

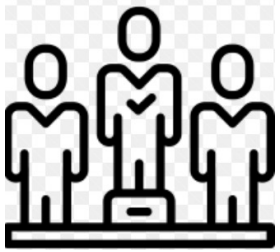
Both internal and external personnel including suppliers/ out-sourced service providers/ collaborators, researchers, and students



5.8.2 Personnel training and competency programme (the Management assisted by BRM Committee)

- Develop a **competency training programme - Define competency level** and **training topics for each level**
- Assess **competency** (different methods) at the end of the training
- Review **the competency of personnel** at least every 2 years or earlier
- Provide **appropriate refresher training** whenever needed.
- Define **trainers' qualification personnel**

5.8 Personnel management



5.8.3 Personnel suitability and reliability

- **Recruit suitable** lab personnel and inform their roles & responsibilities
- **Monitor them periodically** if they are suitable/ reliable with their tasks
- **Re-evaluate contracts** from time to time

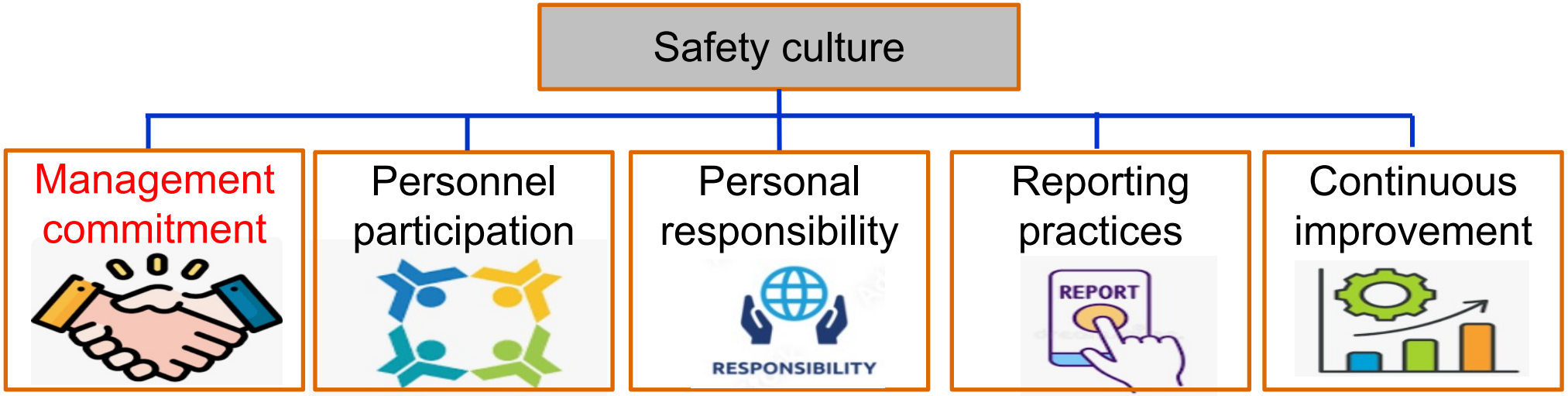
5.8.4 Personnel control access to the facility

- **Define requirements of authorized personnel:** Competent (Trained) + Security clear (background screened) personnel –for accessing the gazetted facility.
- **Complimented with implementing other access control methods** (e.g., engineering, admin, SOP) for facility, BA agent/material/ toxin inventory, and sensitive info

5.8 Personnel management

5.8.5 Naturing safety and security culture and motivating personnel

- Promote a safety/ security culture i.e. the set of **values, beliefs, and behaviours shared by everyone** in an organisation, that determine how people are expected to think about and approach safety and security.



- Motivate personnel to keep learning in biosafety and biosecurity

5.8.6 Termination of service

- Withdraw all access to the facility and assets

Emergency response plan and readiness

5.14 Emergency response plan and readiness

5.14.2 Emergency scenarios

- Generation or discoveries of an unexpected virulent BAs
- Breach of security
- Potential loss of BAs, toxins, chemicals, radioactive or other hazardous materials through theft or any other reasons
- Act of terrorism or deliberate vandalization
- Utility failure
- Loss of others supporting service, e.g., communication systems
- Natural disaster
- Intense media attention
- ----------

5.14 Emergency response plan and readiness

5.14.3 Emergency response plans (ERP) and procedures

- Develop ERP for potential emergency scenarios to **effectively manage medical and /or environmental consequences.**

- **Components of ERP:**
  - **Develop SOPs** for each scenario,
  - **Coordinate:** Emergency Response Team **(ERT)** personnel, organization personnel and externals
  - **Define the roles and responsibilities** for ERT
  - **Assign ERT personnel**

5.14 Emergency response plan and readiness

5.14.3 ERP procedures

- **Necessary tools/equipment and supporting documents such as** SOPs, contact numbers of internals, externals, maps, drawings etc.
- **Emergency preparedness and readiness: Training and practicing simulation exercises**, sharing with laboratory personnel about lessons learned from the simulation exercises
- **Contingency plans:** Adequate contingency measures should be in place to ensure safety and security of continued operations, or that normal operations can be resumed ASAP with minimum losses. (e.g., power failure, security breach etc.)
- **Back-up** location, equipment, consumables, and personnel ----------

5.16 Whistleblowing provision

Organisation shall establish

5.16.1 A policy and procedures to provide **confidential channels of communication** for any party to report, **without fear of retaliation or victimisation, legitimate concerns or incidents, whether actual or suspected, on any of the matters below**:

(a)Academic, research or other professional misconduct;
(b)Breach the organisation's policies, rules and procedures
(c)Assisting any breach of, or misconduct against policies, rules, regulations, and laws
(d)Concealing information about any malpractice or misconduct
(e)Unsafe work practices that can endanger the health or safety of persons or the environment
(f)Harassment including bullying, stalking and sexual harassment
(g) Any breach of applicable laws or regulations

5.16.2 Confidential reporting directly to: Top management, the management, scientific director, supervisor, regulators

5.16.3 Establish an internal escalation process and **reporting procedures** when nefarious activities are observed

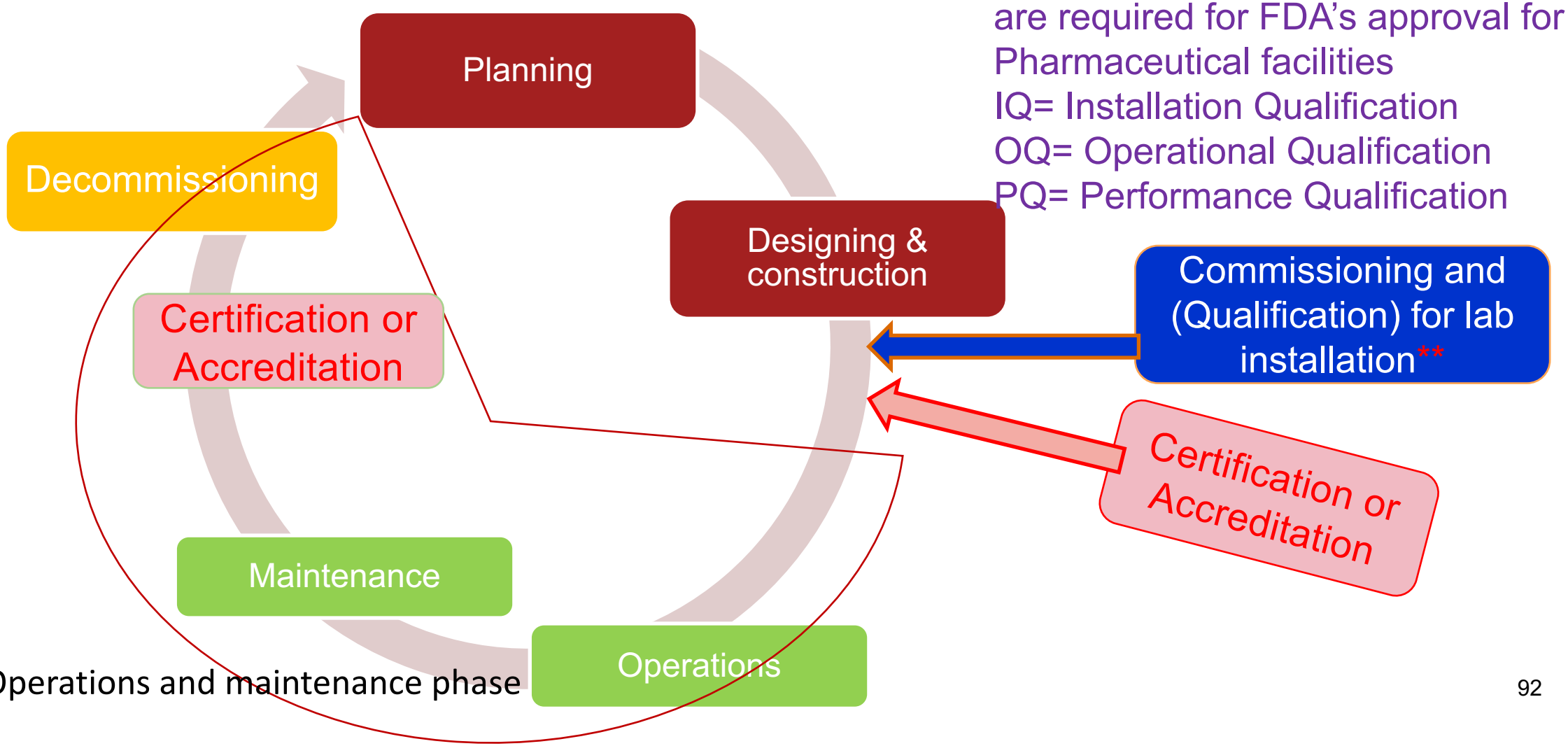
5.18 Continual improvement

5.18 Continual improvement

- **Management's responsibilities** to establish a system to assess continuously and **to ensure effective and sustainable improvement** of the implemented **BRM**
- A system should have
  - objectives
  - targets (Human, facility, and organisation)
  - indicators (compliance, conformities)
  - strategies/ methods (internal review process, internal audit, external certification/ audit)
  - assurance (Regularly monitoring BRM system implementation – at least alternate year)

6. Performance verification requirements and recommendations

Laboratory life cycle



**Qualification Processes (IQ,OQ, PQ) for facility & equipment are required for FDA's approval for Pharmaceutical facilities
IQ= Installation Qualification
OQ= Operational Qualification
PQ= Performance Qualification

Operations and maintenance phase

6.3 Certification

- Certification is a legal requirement for the operation of BSL-3 facilities.
- Carried out by an independent accredited or approved qualified party.
- Aim is to attest and to **provide assurance** that a facility is meeting the requirements **set in this standard and the regulatory requirements,** whenever appropriate.

Ministry of Health Singapore
Certification Checklist for High Containment Facilities

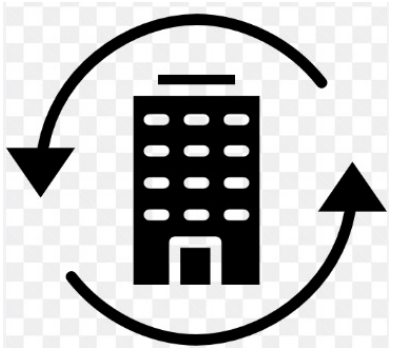
6.5 Decommissioning

6.5.1 General

- When a facility is intended for **repurposing and renovation.**
- Comply with applicable **statutory and regulatory requirements.**

6.5.2 Decommissioning process shall entail:

- **Notification to the Authority**
- Disposal or transfer of BAs and toxins
- Decontamination of equipment
- Decontamination of facility
- Retention of the record



Conclusions

- SS 696 - more **detailed instructions** on the implementation of a biorisk management (BRM) system in laboratories.
- A positive safety and security outcome in the laboratory relies on the strong commitment of multi-level management, laboratory personnel, and independent certifiers/ auditors to **implement effective BRM** and **continuously monitor the performance** of the **BSL-3 facility, its equipment, and personnel.**
- Safety and security in laboratories are **everyone's responsibilities**.

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After the Break…

- Q&A

Complete event survey via the QR code
(also available on the back of your badge)

For discussion

Q&A

Dr Adrian Yeo (Moderator)

Chair, Technical Committee for Biotechnology and Laboratory Testing

A/Prof Raymond Lin

Dr Se Thoe Su Yun

Mr Dan Yoong

Dr Sabai Phyu

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THANK YOU