THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

TÜBA Turkish Academy of Sciences

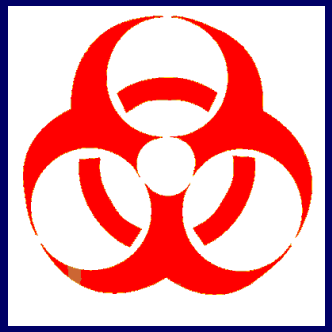
BIOSECURITY ENGAGEMENT PROGRAM

Anticipating Biosecurity Challenges of the Global Expansion of High Containment Biological Laboratories
Istanbul, Turkey
10-13 July 2011

High Containment Laboratories
- Current Thinking and Trends Ahead -

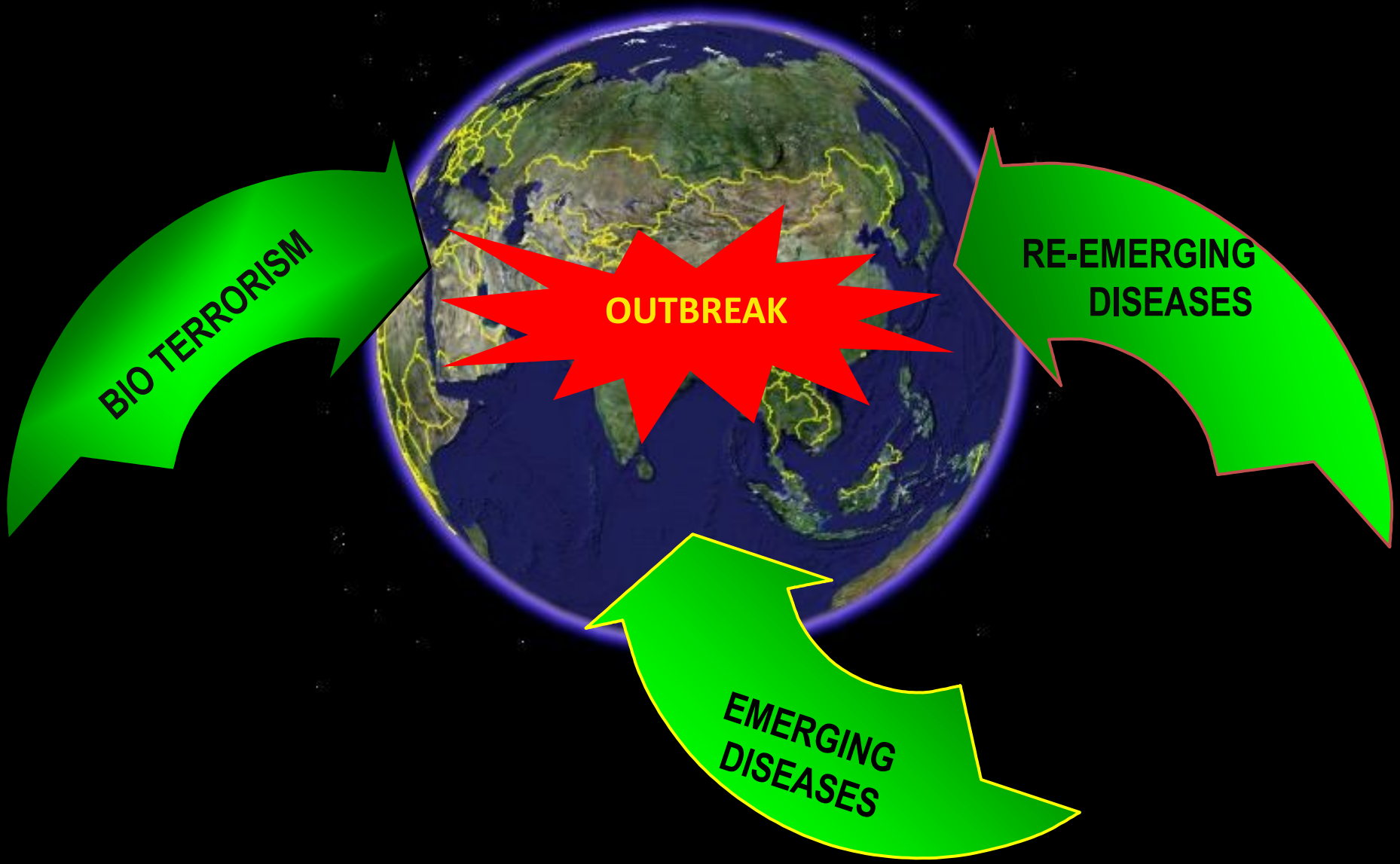
Dr Teck-Mean Chua
A-PBA

BIOSAFETY & BIOSECURITY

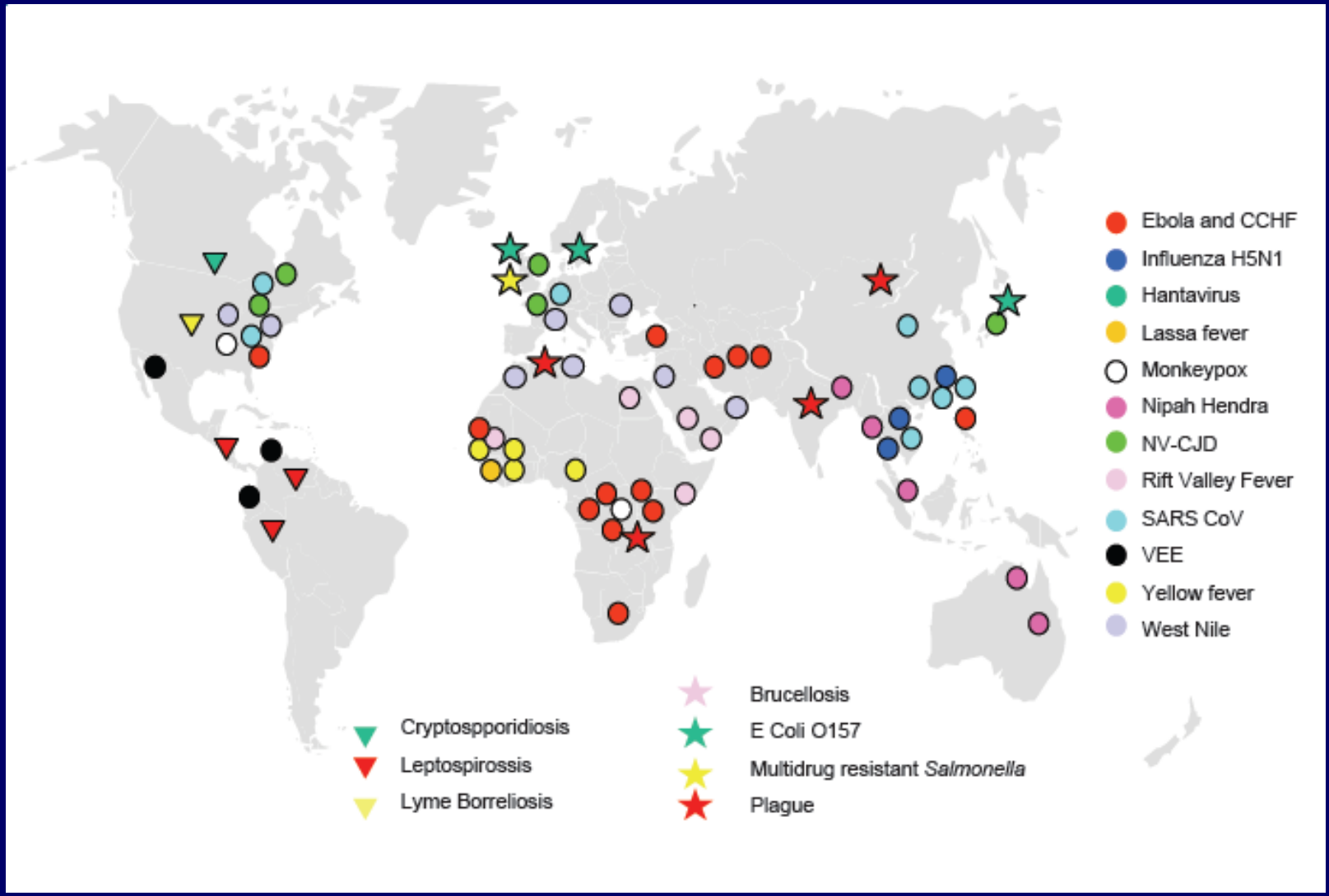


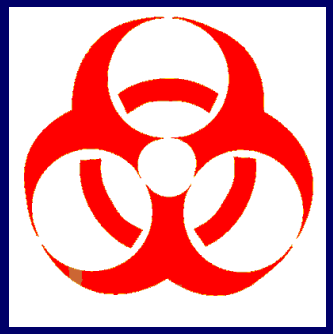
What are the Factors That Shape Our Current Thinking ?

Global Threats



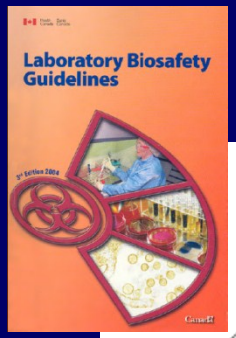
Outbreak of diseases is a global problem…

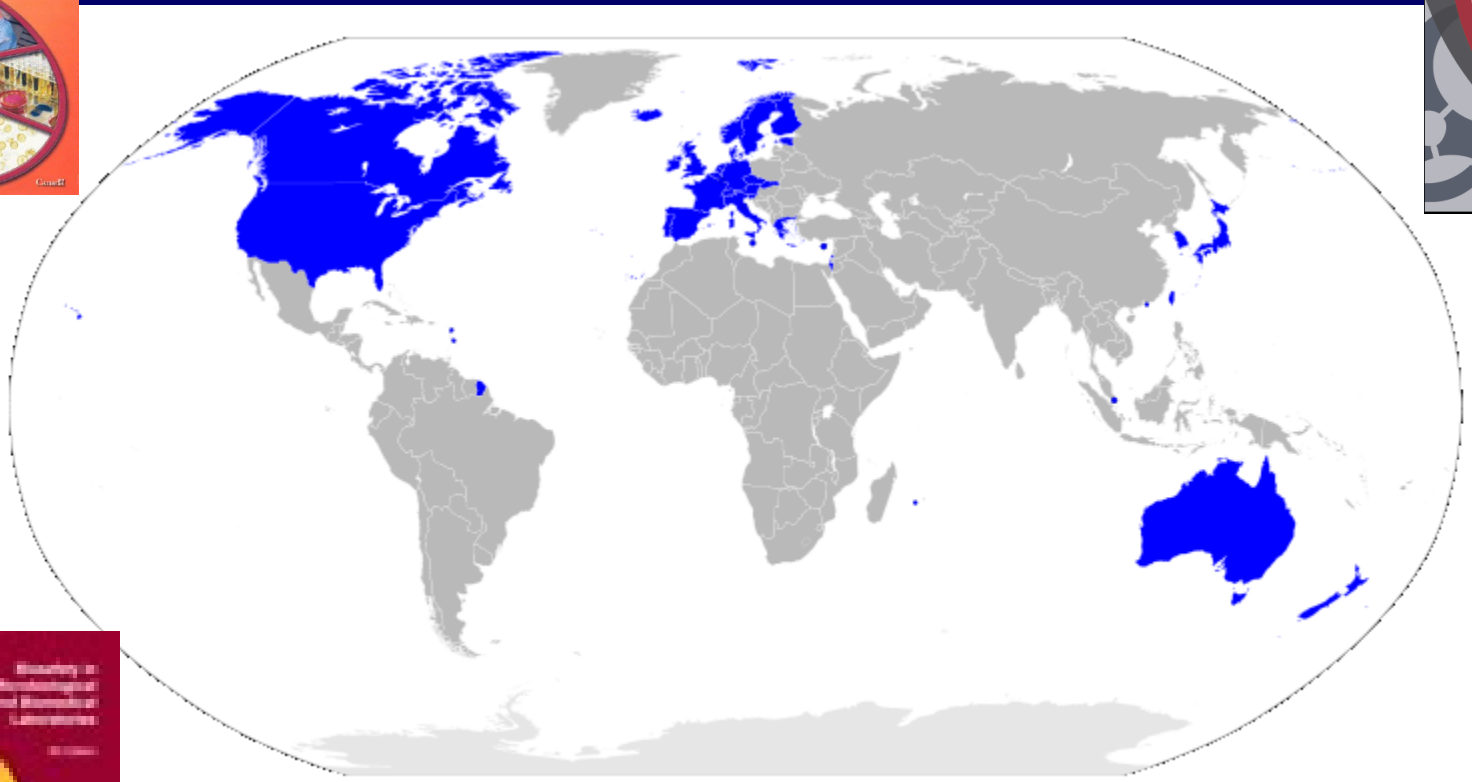




Who Takes The Lead in Legislation, Regulations & Guidelines ?

IMF Advanced Economies 2008

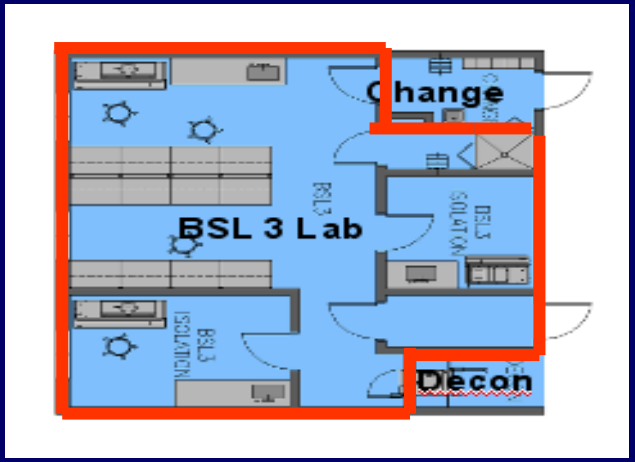




AS/NZS 2243.3:2010 Safety in Laboratories
Part 3: Microbiological safety and containment.

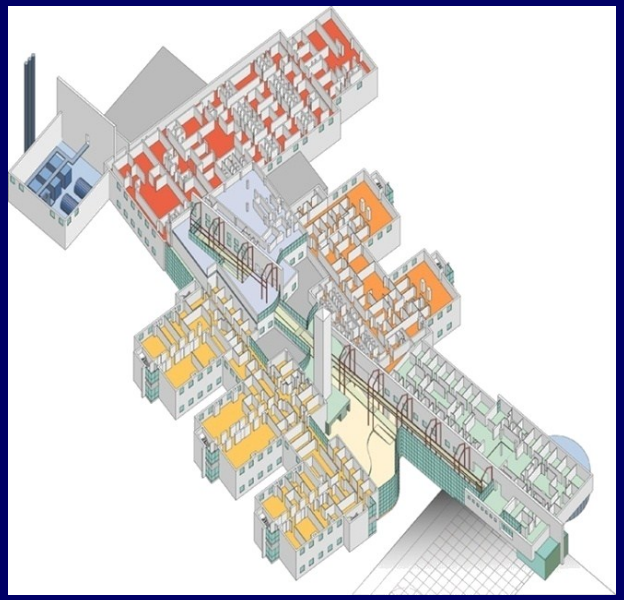
What is a high containment facility?

- Facility where there is high risk of infection (animals or man) or release of microbiological organism
- May needed:
  - Increased protective equipment (PPE)
  - Increased use of safety equipment (BSC, IVC, etc)
  - Increased facility containment features



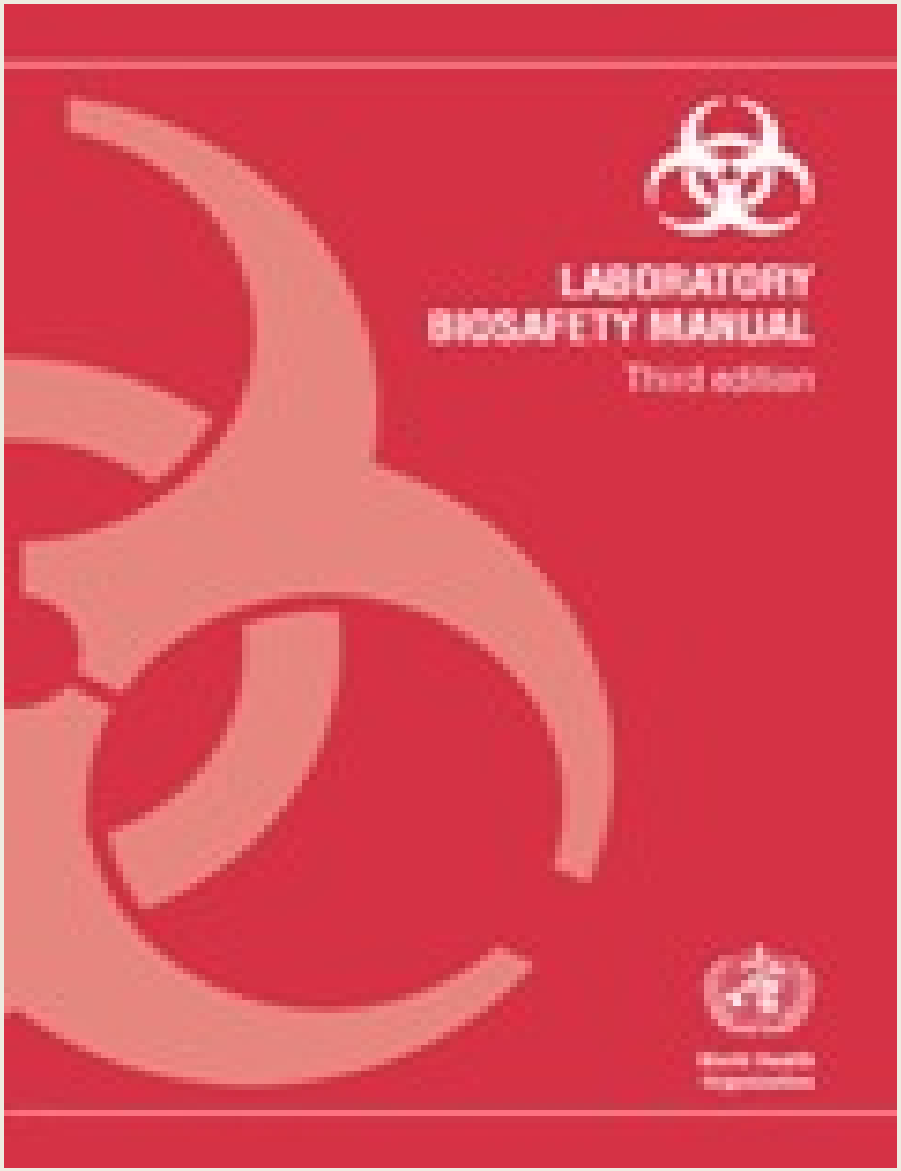
Hallmarks of high containment facility design in developed countries

- Double door entry
- Directional airflow
- Negative pressure gradients
- Single pass air
- High air changes per hours
- Autoclave in or very near
- Operates 24/7
- Redundancies, BAS, etc



World Health Organization

ONE WORLD
ONE HEALTH


LABORATORY
BIOSAFETY MANUAL
Third edition

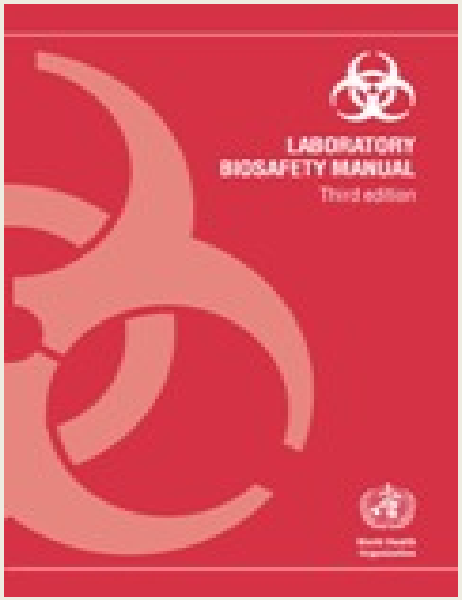
4. The containment laboratory – Biosafety Level 3

The containment laboratory – Biosafety Level 3 is designed and provided for work with Risk Group 3 microorganisms and with large volumes or high concentrations of Risk Group 2 microorganisms that pose an increased risk of aerosol spread. Biosafety Level 3 containment requires the strengthening of the operational and safety programmes over and above those for basic laboratories – Biosafety Levels 1 and 2 (set out in Chapter 3).

The guidelines given in this chapter are presented in the form of additions to those for basic laboratories – Biosafety Levels 1 and 2, which must therefore be applied before those specific for the containment laboratory – Biosafety Level 3. The major additions and changes are in:

1. Code of practice
2. Laboratory design and facilities
3. Health and medical surveillance.

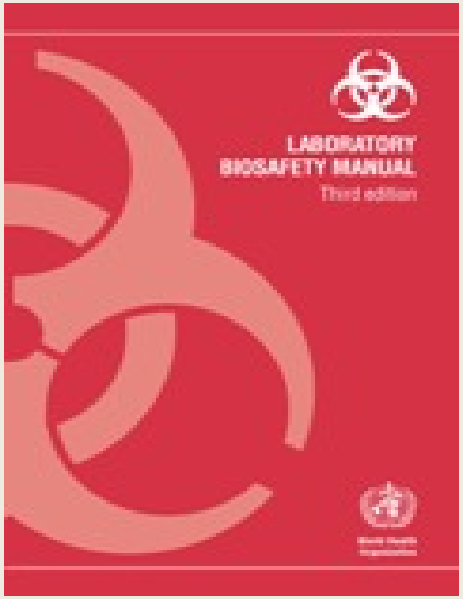
Laboratories in this category should be registered or listed with the national or other appropriate health authorities.



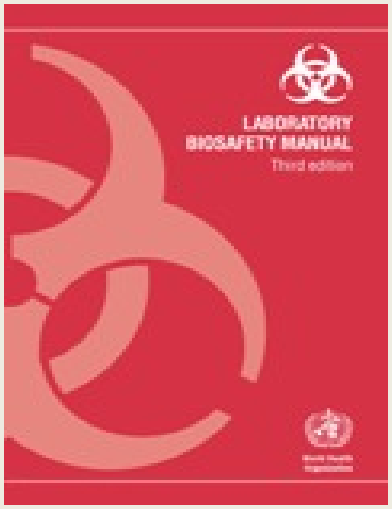
Laboratory design and facilities

The laboratory design and facilities for basic laboratories – Biosafety Levels 1 and 2 apply except where modified as follows:

1. The laboratory must be separated from the areas that are open to unrestricted traffic flow within the building. Additional separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom (e.g. a double-door entry or basic laboratory – Biosafety Level 2), describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space. The anteroom should have facilities for separating clean and dirty clothing and a shower may also be necessary.
2. Anteroom doors may be self-closing and interlocking so that only one door is open at a time. A break-through panel may be provided for emergency exit use.
3. Surfaces of walls, floors and ceilings should be water-resistant and easy to clean. Openings through these surfaces (e.g. for service pipes) should be sealed to facilitate decontamination of the room(s).
4. The laboratory room must be sealable for decontamination. Air-ducting systems must be constructed to permit gaseous decontamination.
5. Windows must be closed, sealed and break-resistant.
6. A hand-washing station with hands-free controls should be provided near each exit door.
7. There must be a controlled ventilation system that maintains a directional airflow into the laboratory room. A visual monitoring device with or without alarm(s) should be installed so that staff can at all times ensure that proper directional airflow into the laboratory room is maintained.
8. The building ventilation system must be so constructed that air from the containment laboratory – Biosafety Level 3 is not recirculated to other areas within the building. Air may be high-efficiency particulate air (HEPA) filtered, reconditioned and recirculated within that laboratory. When exhaust air from the laboratory (other than from biological safety cabinets) is discharged to the outside of the building, it must be dispersed away from occupied buildings and air intakes. Depending on the agents in use, this air may be discharged through HEPA filters. A heating, ventilation and air-conditioning (HVAC) control system may be installed to prevent sustained positive pressurization of the laboratory. Consideration should be given to the installation of audible or clearly visible alarms to notify personnel of HVAC system failure.



7. There must be a controlled ventilation system that maintains a directional airflow into the laboratory room. A visual monitoring device with or without alarm(s) should be installed so that staff can at all times ensure that proper directional airflow into the laboratory room is maintained.



8. The building ventilation system must be so constructed that air from the containment laboratory – Biosafety Level 3 is not recirculated to other areas within the building. Air may be high-efficiency particulate air (HEPA) filtered, reconditioned and recirculated within that laboratory. When exhaust air from the laboratory (other than from biological safety cabinets) is discharged to the outside of the building, it must be dispersed away from occupied buildings and air intakes. Depending on the agents in use, this air may be discharged through HEPA filters. A heating, ventilation and air-conditioning (HVAC) control system may be installed to prevent sustained positive pressurization of the laboratory. Consideration should be given to the installation of audible or clearly visible alarms to notify personnel of HVAC system failure.

What is practical ?

Based on the Risk Assessment of the Agents and Type of Scientific Activities in the Containment Lab, can the following be considered ?

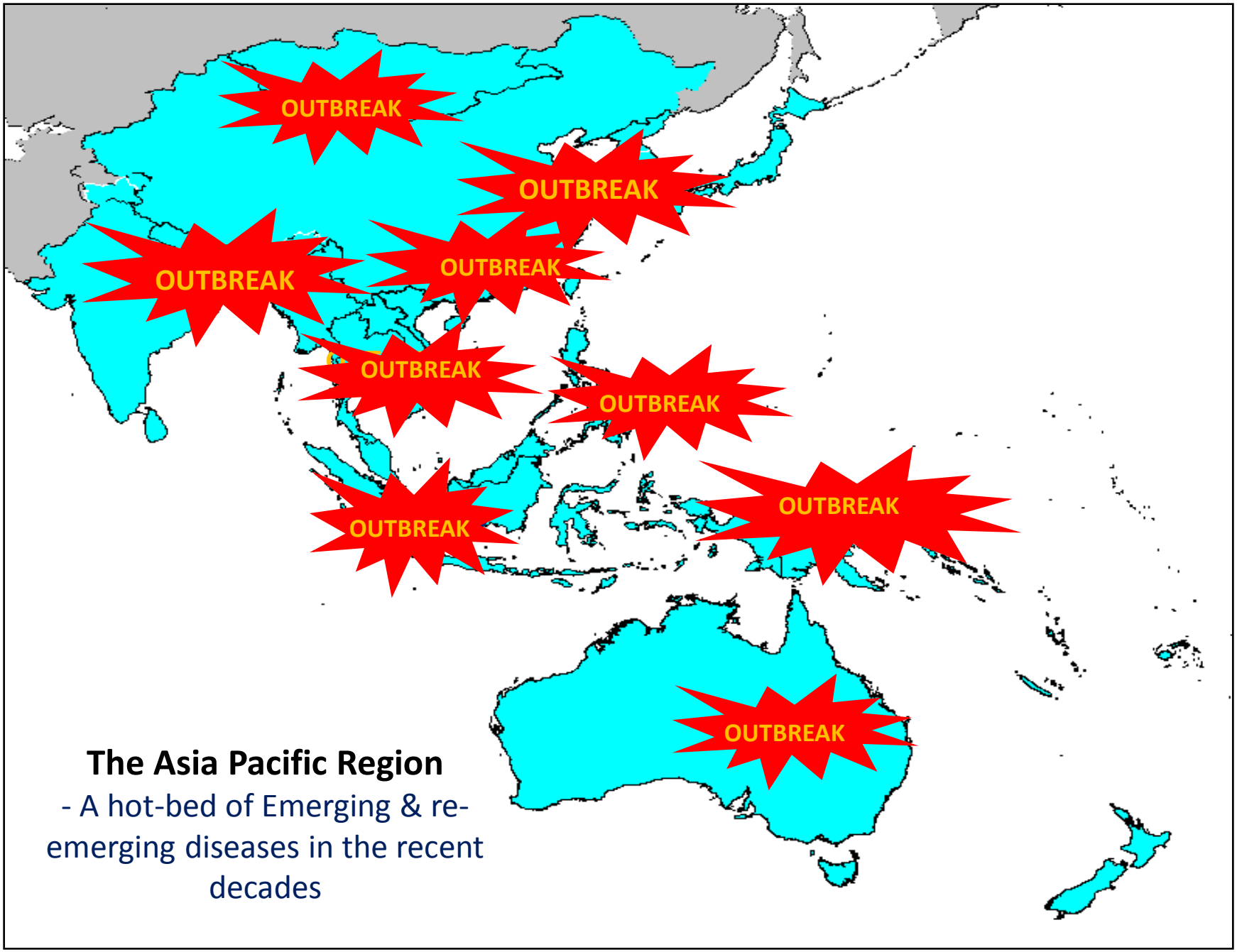
- Create directional airflow only when lab in use
  - Why run labs when not in use?
  - Can you turn them off at night?
  - Can you turn them down (sleep mode)?
- Reduce air changes per hour
  - Less air being moved = less energy used
  - What would be the acceptable minimum ACH ?
- Recycle air after HEPA filtering
  - WHO guidelines

High Containment Lab - What is Practical for Developing Countries?

- The FAO-APBA Experience –

Considerations
towards a practical approach in high containment for developing countries

Dr Pawin Padungtod
Dr. Robert A. Heckert
Dr Teck Mean Chua


OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
OUTBREAK
The Asia Pacific Region
- A hot-bed of Emerging & re-emerging diseases in the recent decades

General Observation – BSL3

- Designed incorrectly,
- Not operating correctly,
- Not being used correctly, or
- All of the above.


M25
PMD1179
M76 IPH
PMD3850

IV. Challenges

- Existing structure of veterinary services constrains direct management by a central veterinary authority of all activities needed for animal disease control
- Poverty and belief system inhibit adoption of prevention measures to protect poultry

BIOSAFETY CABINET CERTIFICATION

[redacted]

Class	Class II Type A2		
Model	EQU/03-EBC-2A	Serial No	2001-1920
Location	Vaccine Research	Test Report No	BSC-2502110Y
Test Date	25 Feb 11	Due Date	
NSF 49 ☒	EN 12469 ☐	Others ☐	

Tests performed to manufacturer's specification, NSF 49 or other international guideline	Pass	Fail
Primary Test		
Inflow Velocity		/
Downflow Velocity		/
Airflow Smoke Patterns		/
Supply HEPA Filter Leakage	/	
Exhaust HEPA Filter Leakage	/	
Site Installation Assessment	/	
Secondary Test		
Lighting Intensity		/
UV Intensity	/	
Certification Result		

Remarks: Motor speed controller not work & require repair. Smoke pattern fail at sash window.

Certified By: Chan Chun Kwong Certificate No.: 0R050-02

Signature _____ Email: c8c8k8@hotmail.com

[redacted]

[redacted]

Email: bryanopk@singnet.com.sg

Laminar Air Flow Services

EXTRACT FROM TEST AND VERIFICATION CERTIFICATE

Certificate No : IS1122/0110 Date of Test : 13/1/2010

Equip. Brand : ESCO Type : Class II

Model : EQU/03-EBC-2A Serial No : 2001-1920

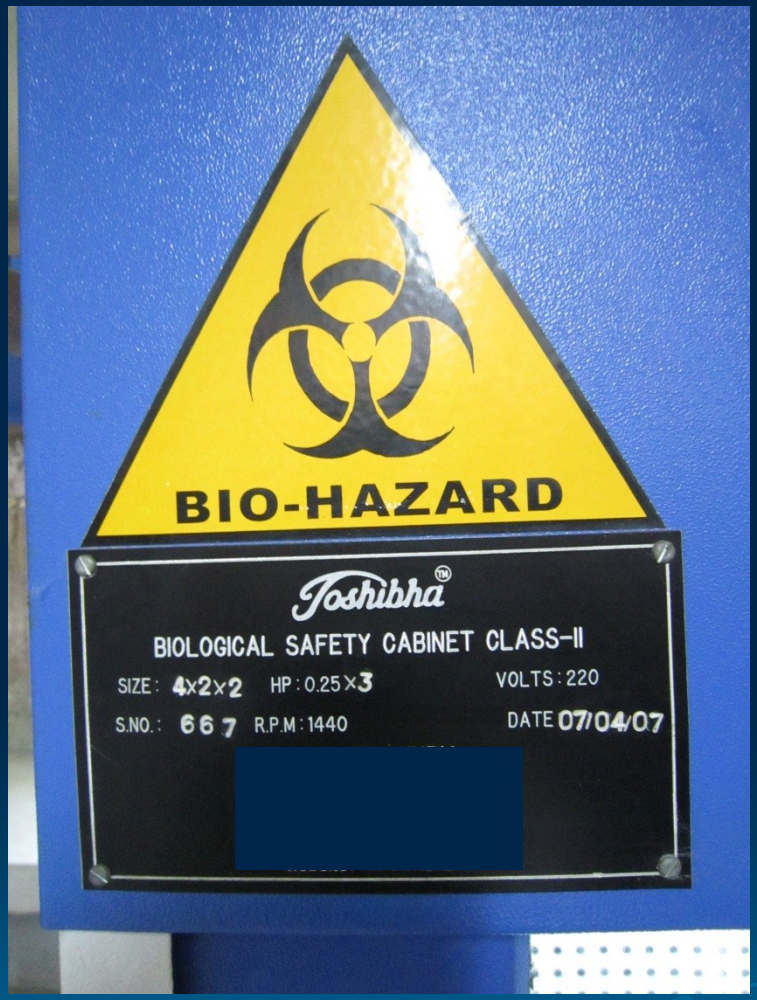
The test results reported have been obtained using methods in accordance with the Australian NSF 49 or EN Standards.
This document shall not be reproducted except in full.

This equipment was tested to one or more of the Australian Standard. As 1807 or NSF49 test methods as indicated.

☐ AS1807 ☑ EN 12469:2000
☐ NSF49

	PASS	FAIL	NOT TESTED
Air velocity and uniformity	☑	☐	☐
Work zone integrity	☐	☐	☑
HEPA filter installation integrity	☑	☐	☐
Particle count in work zone	☐	☐	☑
Illuminance	☐	☐	☑
Sound level	☐	☐	☑
Vibration	☐	☐	☑
Inward air velocity	☑	☐	☐
Air barrier containment	☐	☐	☑
UV intensity	☐	☑	☐
Smoke Pattern	☑	☐	☐
Others _____	☐	☐	☐

Date next test due : 13/1/2011 Signed : [redacted]


BIO-HAZARD
Toshibha
BIOLOGICAL SAFETY CABINET CLASS-II
SIZE : 4x2x2
HP : 0.25x3
VOLTS : 220
S.NO. : 667
R.P.M : 1440
DATE 07/04/07


BIO-HAZARD

FUTURE TRENDS IN BIOCONTAINMENT ?

The goals are not about closing gaps between developed and developing countries but to provide :

- ✓ Practical solutions to effective biocontainment in countries that have limited resources.
- ✓ The effects of global warming and higher energy cost will demand a more “green technology approach” towards the design and operation of high containment facility
- ✓ Threats of bioterrorism, emerging and re-emerging diseases will continue to drive further the integration of national communities to a global biosafety community

Biosafety & Biosecurity Program

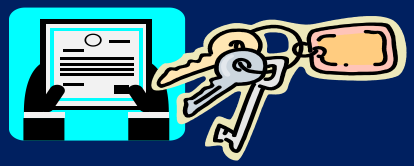
Multi-discipline Approach

STRIVE FOR A GOOD BALANCE WITH ALL RELEVANT DISCIPLINES

Management
Administrative Controls

Effective Biorisk Management

Science
Risk Assessment,
SOPs, etc



Engineering
Facility design, HVAC,
Equipments, BSCs, etc

What is practical ?

Based on the Risk Assessment of the Agents and Type of Scientific Activities in the Containment Lab, can the following be considered ?

- Create directional airflow only when lab in use
  - Why run labs when not in use?
  - Can you turn them off at night?
  - Can you turn them down (sleep mode)?
- Reduce air changes per hour
  - Less air being moved = less energy used
  - What would be the acceptable minimum ACH ?
- Recycle air after HEPA filtering
  - WHO guidelines

Some Considerations for Future Development in Biocontainment

Background : Not all BSL-3 labs have the same scientific activities and faces the same biorisk

Question : **Can BSL3 Laboratory be further classified ?**

- in accordance to the design approach that provides the necessary containment based on the risk assessment of the intended activities of the lab

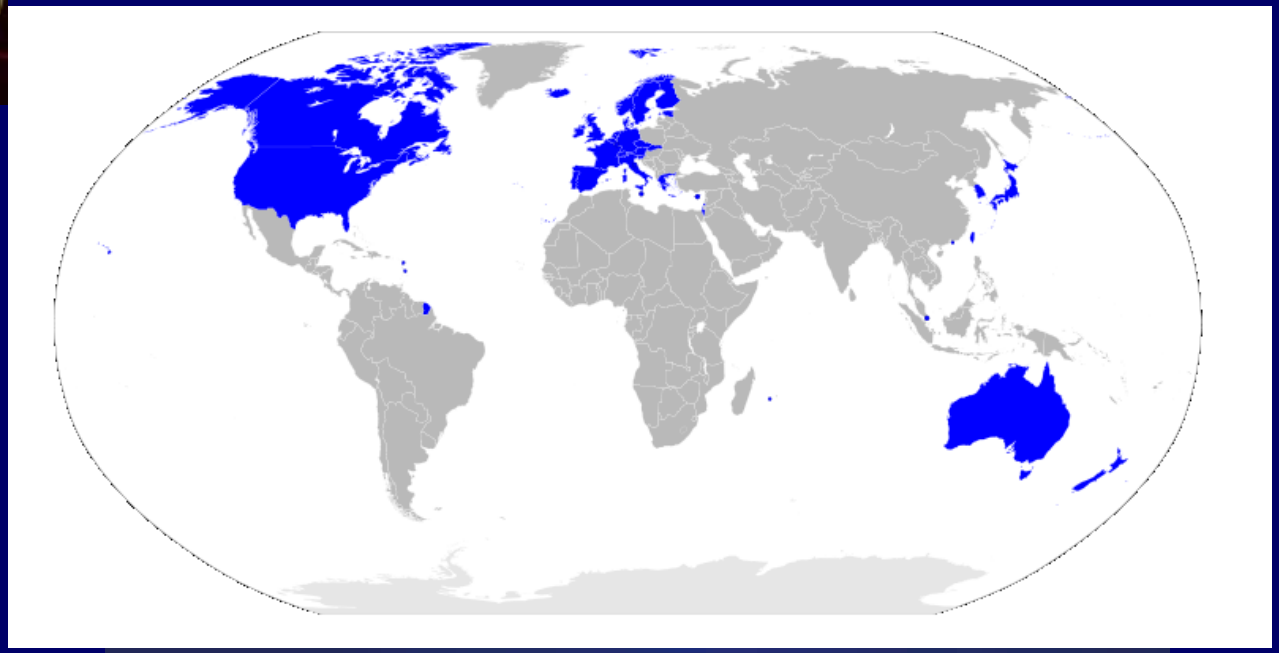
Biosecurity Challenges

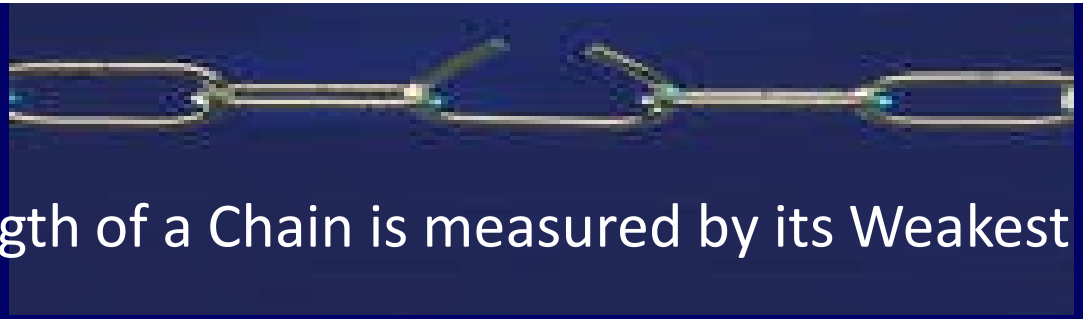
- In many developing countries, the focus could still be on the fundamentals of biosafety as many of the facilities handling infectious agents were built more than 10 or 20 years ago with little or limited provision for biosafety and biosecurity measures in their design and practices.

"Physical security to reduce the risk of unauthorized access to a laboratory is relatively weak in nearly every region".

Survey of Bioscience Research and Biosafety and Biosecurity Practices in Asia, Eastern Europe, Latin America, and the Middle East. *Applied Biosafety*. 2009

Biorisk Assessment





Strength of a Chain is measured by its Weakest Link

- Developing countries can pose as the weakest link in that chain of control in biosecurity against the misuse of biological agents to inflict harm.

World Health Organization

ONE WORLD

ONE HEALTH

Thank You

tmchua@tll.org.sg