Biosecurity Planning and Prevention

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Biosecurity

Biosafety Breaches

2007 - Institute for Animal Health, Pirbright, UK

- Leakage of FMDV was a result of “biosecurity lapses”

2004 - National Institute of Virology, Beijing, China

- SARS outbreak – 9 infected, 1 died

2003 – Plum Island Animal Disease Laboratory, NY

- Containment/security failure – 3 hour power failure

Biosecurity Breaches

Intentional release

- 2001 anthrax attacks, 5 died

Biosafety vs Biosecurity

- Laboratory Biosafety

  Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins or their accidental release.

- Laboratory Biosecurity

  Institutional and personal **security measures** designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

International Participation

UNSC Resolution 1540 (2004)

- All UN member states to take and enforce effective measures against the proliferation of weapons of mass destruction, their means of delivery and related materials

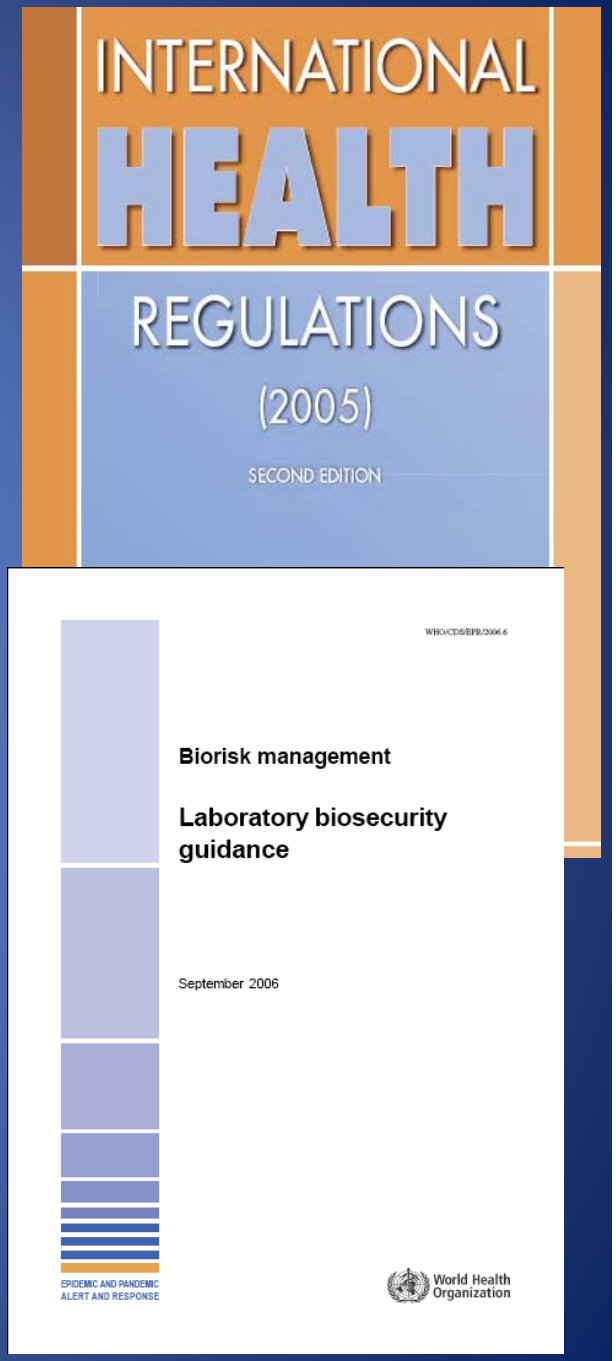
- In real terms it engages “countries to secure biological materials in production, use, storage and transport and implement physical protection measures, border controls, other law enforcement efforts and end-user controls”

World Health Assembly Resolution 58.29 (2005)

- Urged member states of WHO to “implement an integrated approach to laboratory biosafety including containment of microbiological agents and toxins.

International consensus

- WHO Lab Biosafety Manual
- WHO Laboratory Biosecurity Guidelines
- OECD Best Practice Guidelines on Biosecurity for Biological Resource Centres (2007)



National Level Participation
United States of America

- Prior to 2001
  - US instituted regulations regarding the acquisition, transfer, packaging, labeling and handling of biological select agents and toxins (BSATs or Select Agents)
- 2001 - USA PATRIOT Act
  - Tighter regulations on BSATs
  - Criminal and civil penalties
- 2002 - Public Health Security Bioterrorism Preparedness Act
  - Research institutions to report work on BSATs and provide names to government authorities of employees who work with the organisms/agents

National Participation - Australia

- 2002 – COAG review of hazardous materials

  Regulation, reporting and security relating to storage, sale, handling, transfer and disposal of hazardous materials

- 2006 COAG Report

  Recommending a national regulatory scheme for biological agents. Based on risk management approach.

- *National Health Security Act 2007*
  - Surveillance and response to national and international health emergencies
  - Establishment of a national scheme for the registration and regulation of security-sensitive biological agents (SSBAs)

SSBA Regulatory Scheme

Security Sensitive Biological Agents - SSBA

Tier 1	Tier 2
Abrin	African swine fever
Bacillus anthracis	Capripox virus
Botulinum toxin	Classical swine fever virus
Ebolavirus	*Clostridium botulinum*
Foot and mouth disease virus	*Francisella tularensis*
Highly pathogenic Influenza A virus, infecting humans (including Avian Influenza H5N1)	Lumpy skin disease virus
Marburgvirus	Peste des petits ruminants virus
Ricin	*Salmonella* Typhi
Rinderpest	*Vibrio cholerae* (O1 and O139)
SARS coronavirus	Yellow fever virus
Variola virus	
Yersinia pestis	

Derived using intelligence information and analysis of impact and feasibility of using the agents in a terrorist act

SSBA Standards

Outline requirements for

- Physical security
- Information management
- Personnel security
- Deactivation and disposal of SSBA
- Transport security

Physical Security

- Perimeter
  - non-opening windows, locked doors, solid construction
- Physical access controls
  - only authorised or approved persons have access to areas containing SSBAs
  - prevention of tailgating
- Storage of SSBAs

Information Management

- Record keeping
  - maintain records of all activities relating to SSBAs
- Information security
  - Internal and external communication such as email, phone communication, data storage
  - controlled access
- Inventory
  - Must have and maintain accurate and up to date inventory of all SSBAs, which ones and where.
  - Maintain records of receipt, holding, transport and disposal of SSBAs
- Disposal of records

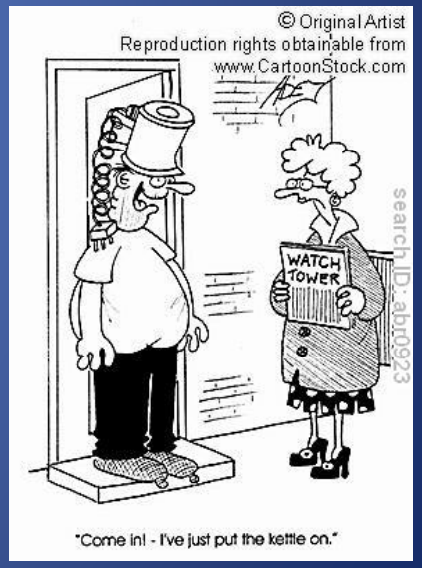
Personnel Security

Ensure that individuals who work in life science laboratories are properly screened, qualified and trained.

- Responsible officers
  - head honcho
- Authorised persons
  - people doing the real work, handling the SSBAs
- Approved person
  - contractors, visitors, suppliers etc.
  - escorted (tier 1) or supervised (tier 2) by authorised person

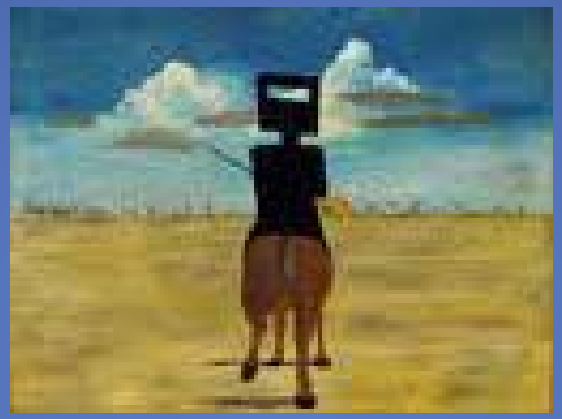
Personnel Security

- Training and competency
  - Ensure that staff have the required education, training and experience
  - Ensure they are provided with up-to-date information pertaining to the risks
- Recruitment - factors to consider
  - Screening of employees; integrity, identity and credentials
  - Technical qualifications and expertise
  - Medical clearance and mental health checks

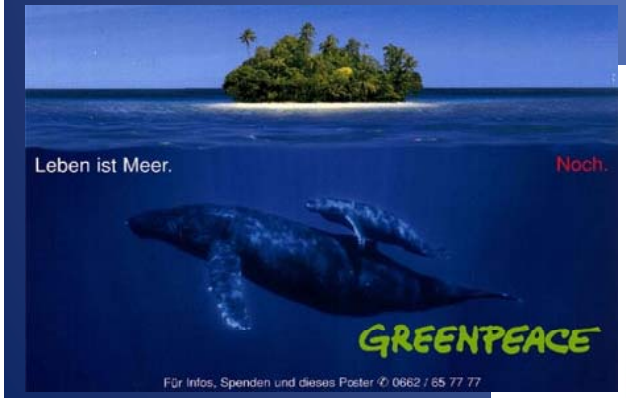


Personnel Handling Tier 1 Agents

- National Criminal History Check (AFP)



- Politically Motivated Violence Check (ASIO)



Personnel Security

- Behaviour – “the trusted insider”
- Suspicious behaviour
  - Reliability – unexplained periods of absenteeism
  - Working alone or outside regular working hours
  - Dramatic change in appearance
  - Withdrawn, unwilling to socialise
  - Becoming furtive, secretive or excessively anxious or suspicious
  - Interactions with other workers.

Personnel Management

Personnel are a key factor in controlling biorisks

- Ensure that individuals working with or handling agents of concern are properly screened, qualified and trained for use of that particular agent.

Shipment and Transport

- Screening of biosecurity aspects of transporters, recipients and transfer process
- Compliance with national regulations for transport by rail, road and air of dangerous goods
- Identify vulnerabilities in transport chain
- Documentation by sender and receiver
  - notification by sending facility of shipment and
  - verification of receiving facility of receipt

WHO Shipping Guidelines

WHO/HSE/EPR/2008.10

Guidance on regulations for the
Transport of Infectious Substances
2009–2010

Applicable as from 1 January 2009

EPIDEMIC AND PANDEMIC ALERT AND RESPONSE

World Health Organization

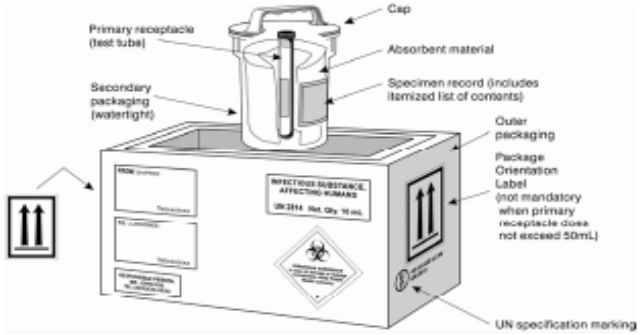


Figure 1. Example of triple packaging system for the packaging and labelling of Category A infectious substances (Figure kindly provided by IATA, Montreal, Canada)

Category A

Inactivation and decontamination

Making it safe

SSBA Guidelines

- Loss of agents
- Reportable events - theft, infection, release
- Reporting to law enforcement and national security agencies
- Transportation processes
- Handling samples from a person or animal with an SSBA
- SSBAs in the natural environment

Components of a Biosecurity Framework

- Physical security - environment
- Personnel management

] Accessibility

- Accountability and oversight - material control
  - Incident or misuse reporting
  - Information security
- Program management practices
- Transport security
- Training
- Raising awareness

Life Scientist

Obligations

- Animal and plant health
- Food safety
- Ethics
- Intellectual property
- Trade
- Human health

Regulation

- Animal and human ethics
- IBC
- OGTR
- AQIS
- SSBA

Challenges for Biosecurity

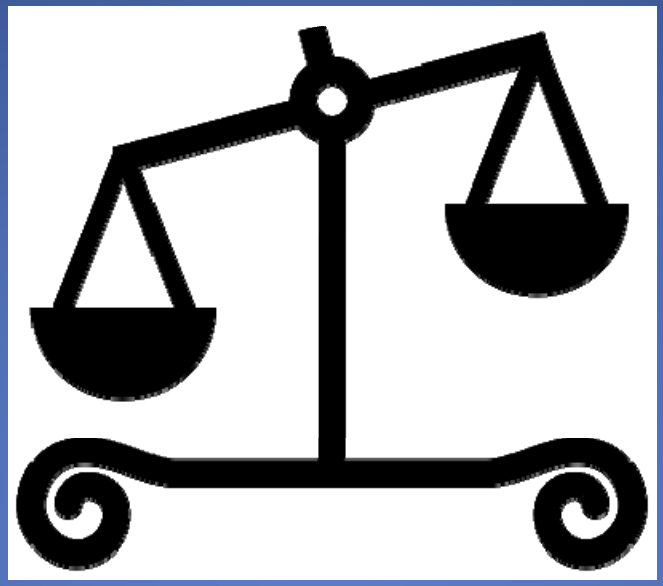
- Personnel screening

  As an increasing number of individuals enter the life sciences the odds of a worker becoming a terrorist or an individual with an agenda to cause harm increase.

- Ensuring that proper risk management programs are implemented.

- Understanding and managing the advances in life sciences to ensure adequate control of dual-use pathogens, equipment and expertise.

At what cost?



Biosecurity must be instituted to maintain preservation and legitimate research freedom with respect to microbiological research, diagnosis and disease control