Basic biorisk management terminology and concepts

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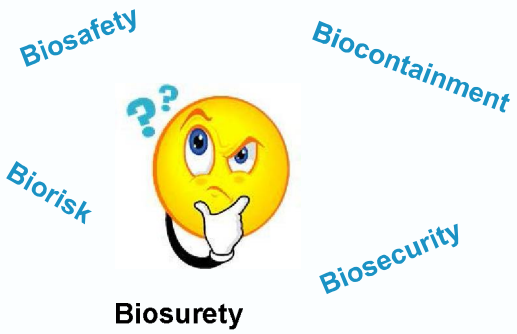
Training Course April 2015

AUSTRALIAN ANIMAL HEALTH LABORATORY
www.csiro.au

NCRIS
National Research Infrastructure for Australia
An Australian Government initiative

What's in a word?



Biosurety

What is biosecurity?

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- **Oxford Dictionary:** '*Procedures or measures designed to protect the population against harmful biological or biochemical substances*
- **Merriam-Webster:** not
- **Wikipedia:** '*Preventive measures designed to reduce the risk of transmission of infectious diseases in crops and livestock, quarantined pests, invasive alien species, and living modified organisms*
- **CWA 15793:** 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

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What is biosafety?

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- **WHO:** the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to

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What is biocontainment?

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- WHO: Not defined

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What is biosurety?

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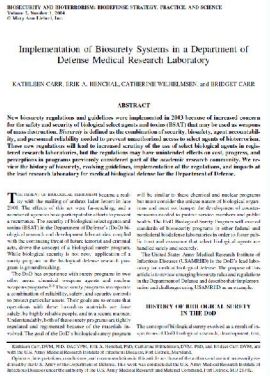

Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory

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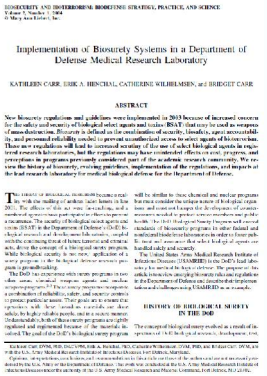

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ABSTRACT

In Simple Terms

- **Biosafety – Keeping bad ‘bugs’ away from people**
- **Biosecurity – Keeping bad people away from ‘bugs’**
- **Biocontainment – Keeping bad bugs away from people, the environment and community**

BioSafety

BioSecurity

Laboratory Biorisk Management

The CEN Workshop Agreement (CWA 15793) September 2011

- 76 participants from 24 countries
- Applies Internationally but does not have the force of regulation - conformity is voluntary
- Adopts a 'management system approach' similar to that adopted by the International Organisation for Standardization (ISO)
- Based on continual improvement

Certified System Quality ISO 9001

ISO

CEN EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

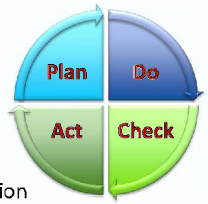
Laboratory Biorisk Management

PLAN Planning, including identification of hazard and risk and establishing goals

DO Implementing, including training and operational issues

CHECK Checking, including monitoring and corrective action

ACT Reviewing, including process innovation and acting to make needed changes to management system



ISO

Laboratory Biorisk Management

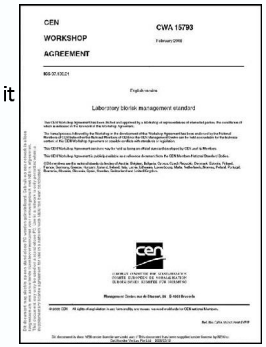
- Sets the requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.
- Based on;
  - WHO biosafety manual, third edition, 2004, WHO/CDS/CSR/LYO/2004.11
  - Biosecurity Guidance, 2006,

Both of these are on your USB Stick !

CEN EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

Laboratory Biorisk Management

- Biorisk includes 'biosafety' and 'biosecurity'
- CWA 15793 is not a technical document it is a performance based approach
  (ie., It describes what needs to be achieved not how to do it)


CEN
WORKSHOP
AGREEMENT
CWA 15793
Laboratory biorisk management standard

Laboratory Biorisk Management

- Biorisk Management Policy
- Hazard Identification, risk assessment, and risk control
- Roles, responsibilities, and authorities
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review

What is a hazard?

- Hazard is a source that has the potential for causing harm
- Risk is the likelihood that the harm from a hazard will be realised

What is a threat?

- Threat is a person or thing likely to cause harm – intentionally or unintentionally –

What is risk?

- Risk can be based on either a hazard and or a threat
- It is the combination of the likelihood and the consequence of

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Laboratory Biorisk Management

Biorisk Assessment

Biorisk Mitigation

Biorisk Performance Monitoring

Biorisk Improvement

Laboratory Biorisk Management

Biorisk Assessment

PLAN

- Big teeth
- Big claws
-

Laboratory Biorisk Management

Biorisk Mitigation

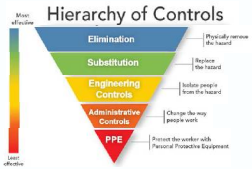
DO


Elimination


Substitution


Engineering Controls

Administrative Control



Laboratory Biorisk Management

Biorisk Performance Monitoring **CHECK**



- Audits
-

Laboratory Biorisk Management

Biorisk Improvement **ACT**

Reduce bar spacing

Laboratory Biorisk Management

During the next five days;

- You should be able to better identify and understand biorisks in your work environment
- Understand how to perform risk assessments
- Understand what controls can be implemented to mitigate some of those risks to yourself and others
- Apply what you have learnt in a laboratory environment

Any Questions?



Thank you

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WHO Biosafety Manual requirements and box-within-box concept

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April 2015

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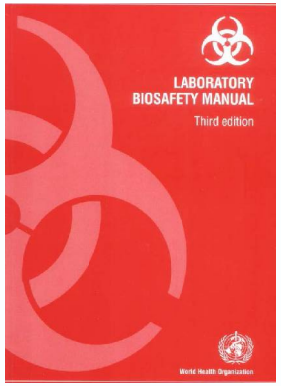
WHO Laboratory Biosafety Manual



- The WHO guidelines provide a frame work for countries which do not have their own specific guideline
- Most countries now have Biosecurity regulations (UN resolution 1540)
- Most countries now have regulations controlling work with genetically modified organisms
- Australian Standards (2243.3) and regulatory standards (OGTR, DAFF) are closely aligned with WHO

WHO Laboratory Biosafety Manual

- Sets out requirements, responsibilities and guidelines for safe
- **WHO suggest that each country classify microorganisms into risk groups depending on degree of risk and whether they are endemic or exotic**
- AS/NZ 2243.3 is similar to WHO:ie Risk group based on pathogenicity; mode of transmission; host range and available

Risk Classification

Risk Group 1 – *Low*
Unlikely to cause human or animal disease

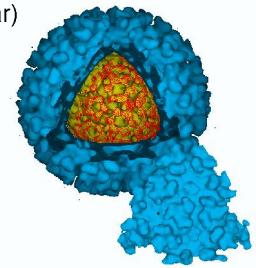
Risk Group 2 – *Moderate*
Lab exposures may cause infection, preventative measures and treatment available. Not a significant risk to community

Risk Group 3 – *High individual Moderate*
Cause serious human and animal disease, significant risk to lab worker and moderate risk if spread in community usually treatments or preventative measures

Risk Group 4 – *High*
Produce life-threatening illness, significant risk to lab worker, readily transmissible, no treatment or preventative measure

Quick Quiz: Guess the BSL level

Rabies (99.9%, >50K/year)
Hendra virus (67%, 4 deaths)
Lassa fever (1%, 300K-500K /year)
HIV (>95%, >34M)
Dengue Fever (<1%, >58K)



Which are RG4 ?

Rabies (99.9%, >50K/year)
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SARS (9.5%, 775)

Which are RG3 ?

Rabies (99.9%, >50K/year)

~~Hendra virus (67%, 4 deaths)~~

~~Lassa fever (1%, 300K-500K /year)~~

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Which are RG3 ?

Rabies (99.9%, >50K/year)

~~Lassa fever (1%, 300K-~~

HIV (>95%, >36M)

SARS (9.5%, 775)

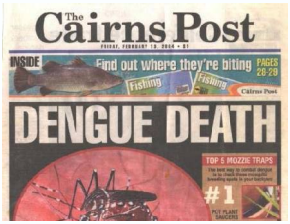
Dengue is RG2

~~Hendra virus (67%, 4 deaths)~~

~~Lassa fever (1%, 300K-500K /year)~~

~~HIV (>95%, >36M)~~

Dengue Fever (<1%, >58K)



RG2 microorganisms can still kill you and others!

Biosafety Level (BSL)

BSL level 'roughly' corresponds to risk group level

ie BSL 3 for risk group 3 / BSL 4 for risk group 4 but depends on risk assessment

Large volumes of risk group 2 pathogens that are respiratory spread may require BSL3

BSL Level includes specific requirements relating to;

1. Code of Practices
2. Lab design & facilities
3. Laboratory Equipment
4. Health and Medical Surveillance

Having a building that is constructed to BSL3 or BSL4 standard does not mean it is a BSL3 or BSL4 containment equipment is present and the appropriate work practices

Biosafety Level (BSL)

- BSL Levels are cumulative;
- Everything that is required of a BSL1 laboratory is also required of a BSL 2 laboratory but there are additional requirements
- Everything that is required of a BSL2 laboratory is also required of a BSL 3 laboratory but there are additional requirements
- Everything that is required of a BSL3 laboratory is also required of a BSL 4 laboratory but there are additional requirements

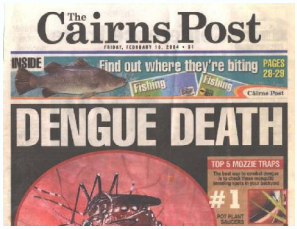
Laboratory Certification

Regular Laboratory Certification

1. Proper engineering controls are being used & functioning
2. Appropriate site and administrative controls are in place
3. PPE is appropriate for task being performed
4. Decontamination of Waste and materials has been adequately considered & proper waste management procedures are in place
5. Proper procedures for general laboratory safety, including

Risk Group 2 organisms

Influenza*
Dengue
Herpes Simplex
Rhinoviruses
Measles
Ross River
Rubella



(Risk group 3 in Singapore)

Hepatitis E
Bluetongue
Leptospira interrogans
Salmonella *(Risk group 3 in Singapore)*

BSL 2

Personal protection

1. Lab coveralls, gowns or uniforms worn at all times
2. Gloves worn for direct /indirect contact with blood, bodily fluids
3. Wash hands after work & when leaving
4. Safety glasses/visors worn when necessary
5. No protective lab clothing outside of lab (in canteens, offices)
6. No open-toed footwear worn in labs
7. Eating, drinking, applying cosmetics or contact lenses prohibited
8. Storing human food or drink in lab is prohibited
9. Protective lab clothing must not be stored with street

BSL2

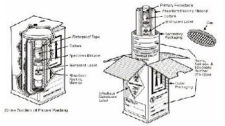
Procedures

1. No mouth pipetting
2. Nothing placed in mouth (no licking labels)
3. Procedures to minimise aerosols
4. Use of needles and syringes is minimised & only used for injection or aspiration from animals
5.
6. Written procedure for spills clean-up developed & followed
7. Contaminated fluids decontaminated before discharge to sewer – effluent treatment may be required
8. Written documents which may be removed from lab

BSL2

Laboratory Working Areas

1. Kept clean & neat and free of irrelevant material
2. Work surfaces decontaminated after spill & at end of day
3. All contaminated material must be decontaminated before disposal, cleaning for reuse
4. Packing & transport follow national & IATA regulations
5.



BSL2

Biosafety management

1. Director must ensure the development and adoption of a biosafety management plan and operations manual
2. Laboratory supervisor regular biosafety training is provided
3. Staff must read manual and follow procedures outlined, lab manual to be available in lab. Supervisor must make sure staff understand requirements
4. Should be an arthropod & rodent control programme in place
5. medical evaluation, surveillance & treatment should be provided to staff where required. Medical records

BSL2

Laboratory Design features (1 of 3)

1. Ample space for work, cleaning and maintenance
2. Walls, ceilings and floors smooth, impermeable to liquids and easy to clean
3. Bench tops smooth, impermeable to liquids and easy to clean
4. Illumination adequate for all activities
5. Open spaces between and under benches & cabinets & equipment accessible to cleaning
6. Storage space adequate to hold immediate supplies without clutter
7. Space & facilities for safe storage of solvents, radioactive,

BSL2

Laboratory Design features (2 of 3)

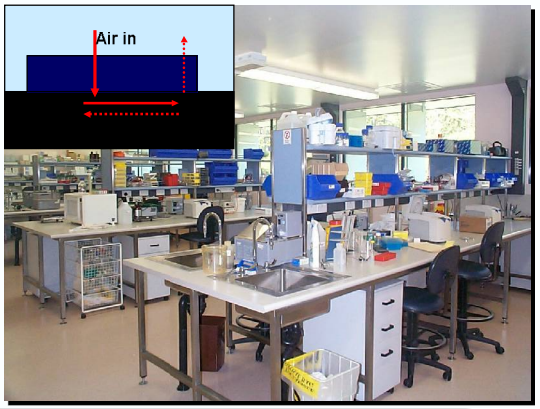
8. Facilities for storing personal clothing provided outside of lab working areas.
9. Facilities for eating, drinking & rest provided outside of lab working areas
10. Hand washing basins (dedicated) provided near door
11. Doors have windows, fire rating & be self closing
12. An autoclave or other means of decontamination be available in close proximity
13. Safety system for fire, electrical emergencies. Eyewash & safety shower
14. Equipped First-

BSL2

Laboratory Design features (3 of 3)

15. New facilities should have an inward flow of air without recirculation
16. Dependable supply of water, backflow prevention
17. Reliable & adequate electricity supply, emergency lighting. A standby generator is desirable
18. Reliable and adequate supply of gas
19. Physical & fire security must be considered, Strong doors &

BSL 2



BSL2

Essential Biosafety Equipment

1. Pipetting aids to avoid mouth pipetting
2. Biological Safety Cabinets used for procedures with a high potential for aerosols (centrifugation, blending, shaking, mixing, sonication, inoculating & harvesting from animals, eggs or infectious tissue
3. Plastic disposable transfer loops
4. Screw capped tubes and bottles
5. Autoclaves or other means to decontaminate infectious material
6. Plastic disposable Pasteur pipettes to avoid glass
7. BSCs & Autoclaves validated before being commissioned &

BSL2

Health & medical surveillance

1. Provision of active or passive immunization
2. Facilitation of early detection of laboratory-acquired infections
3. Exclusion of highly susceptible individuals (pregnant women & immunocompromised) from highly hazardous areas
4. [illegible] equipment & p ocedu es

Covered in More detail in *Medical Surveillance training module*

BSL2

Training

Managers must ensure safe laboratory practices and procedures are an integral part of new employees introduction to lab.

1. Inhalation risks when using loops, pipetting, making smears opening cultures
2. Ingestion risks when handling specimens, smears & cultures
3. Risk of exposures when using needles /syringes
4. Bites & scratches from animals
5. Handling of blood & other potential biohazardous pathology samples
6. [illegible]

BSL2

Waste Handling

All infectious material should be decontaminated, autoclaved or incinerated within the laboratory

1. Have objects or material been decontaminated or disinfected by approved procedure?
2. If not, have they been packaged in an approved manner for immediate onsite or transport to off-site incineration
3. Does disposal of decontaminated objects or material pose [illegible]

Autoclaving is preferred method of decontamination

Risk Group 3 organisms

Australia

Yellow Fever
Rabies virus
Japanese Encephalitis virus
HIV
West Nile virus
Brucella sp.
Rickettsia

Singapore

(RG2 Australia)
Rabies virus
Japanese B encephalitis virus
HIV
West Nile virus
Brucella—all species
Rickettsia—

Summary of biosafety level requirements

	BSL2	BSL3	BSL4
Isolation of Lab	No	Yes	Yes
Room Sealable for Decontamination	No	Yes	Yes
Ventilation- Inward airflow	Desirable	Yes	Yes
Ventilation—Controlled system	Desirable	Yes	Yes
Ventilation—HEPA-Filtered air exhaust	No	Yes	Yes
Double—door entry	No	Yes	Yes
Airlock with shower	No	No	Yes
Anteroom with Shower	No	Yes/No	No
Effluent Treatment	No	Yes/No	Yes
Autoclave-onsite	Desirable	Yes	Yes
Autoclave—in laboratory	No	Desirable	Yes
Autoclave - double sided	No	Desirable	Yes
Biological Safety Cabinets	Desirable	Yes	Yes
Personnel safety monitoring	No	Desirable	[illegible]

BSL 3

Construction Requirements

All requirements of BSL1 & 2 plus additional requirements relating to;

1. Code of Practice
2. Laboratory Design & facilities
3. Health and medical surveillance

BSL3 Laboratories should be registered or listed with the national or other

BSL3

Laboratory design and facilities

All requirements of BSL1 & 2 except where modified below;

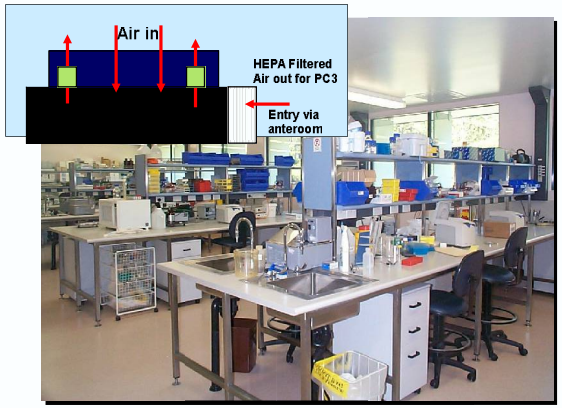
1. Physically separated from other areas, including offices by **airlock/anteroom** which may need to include a change room and shower
2. Anteroom door interlocked
3. decontamination of facility
4. Windows closed, sealed and break resistant (ventilation)
5. Hand- **hands-free operation**
6. Directional air flow into lab –

BSL3

Laboratory Design and facilities

7. Separate HVAC - no recirculation of air to non-PC3 areas
8. Exhaust air is HEPA filtered and HEPA filters sealed to allow gaseous decontamination & testing
9. Exhaust air from BSC should not air balance of cabinet or room ventilation
10. An autoclave should be available inside containment laboratory
11. Backflow prevention on water (RPZ or break tank) and HEPA filters on vacuum lines
12.

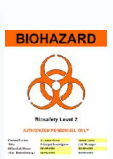
BSL3



BSL3

All requirements of BSL1 & 2 except where modified below;

1.
2.
3.
4. All work with infectious material must be conducted in Biological
5.



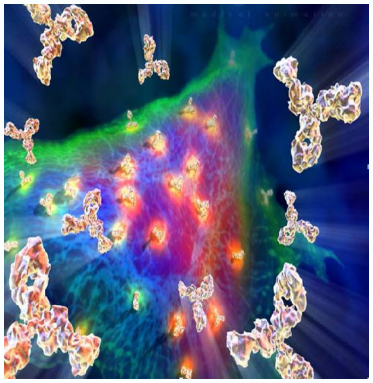
BSL3

Laboratory Equipment

1. Manipulation of all potentially infectious material must be conducted in a Biological safety cabinet
2.

Risk Group 4 organisms

Hendra virus
Nipah virus
Smallpox
Ebola
Marburg
Lassa Fever
Junin
Sabia
Kyasanur



BSL4

Laboratory design and facilities

— Class III cabinet laboratory.

- *Passage through a minimum of two doors prior to* entering the rooms containing the Class III BSC (cabinet room).
- Class III is primary containment
- A personnel shower with inner and outer changing rooms is necessary
-

BSL4

Laboratory design and facilities

— Suit laboratory.

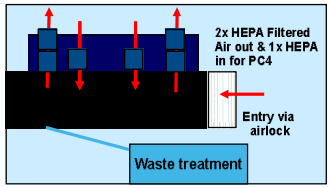
- A suit decontamination shower must be used by personnel leaving the containment laboratory area.
- A separate personnel shower with inner and outer changing rooms
- Personnel who enter the suit area are required to don a one-piece, positively pressurized, HEPA-filtered, supplied-air suit.
- Air to the suit must be provided by a system that has a 100% redundant capability with an independent source of air
- Entry into the suit laboratory is through an airlock fitted with airtight doors.
- An appropriate warning system for personnel working in the suit laboratory

BSL4

Controlled Access

- The Lab must be located in a separate building or in a clearly delineated zone within a secure building.
- Entry and exit of personnel and supplies must be through an airlock or pass-through system.
- On entering, personnel must put on a complete change of clothing;
- Before leaving, they should shower before putting on their street

BSL4



Controlled Air System

- Negative pressure must be maintained
- Both supply and exhaust air must be HEPA-filtered.
- Dedicated room air supply and exhaust systems are required.
- The supply and exhaust provide directional airflow within the suit area from the area of least hazard to the area(s) of greatest potential hazard.
- Redundant exhaust fans are required to ensure that the facility remains under negative pressure at all times.
- HEPA-filtered supply air must be provided to the suit area, decontamination shower and decontamination airlocks or chambers
- Double HEPA filtered exhaust air and all those being Category

BSL4

Decontamination of Effluents

- All effluents must be decontaminated before final discharge. Heat treatment is the preferred method.
- Water from the personnel shower and toilet may be discharged directly to the sanitary sewer without treatment.

Sterilization of waste and materials.

- A double-door, pass-through autoclave must be available in the laboratory area.
- Other methods of decontamination must be available for equipment and [illegible]

The AAHL Facility: quick overview

Planning Commenced 1972
Opened in 1985 (27 years)
100 year life span
$200M to build
Replacement cost $700-850
35 hectares
Building 2 Ha
6 Floors
65,000 m^2
15,000m^2 *'lab'*

Lab Space
BSL2 = 2600 m2 2x Labs
BSL4 = 400m^2

Animal Facility
BSL3 = 955 m^2 26x
BSL4 = 127m^2 2x

Containment Philosophy

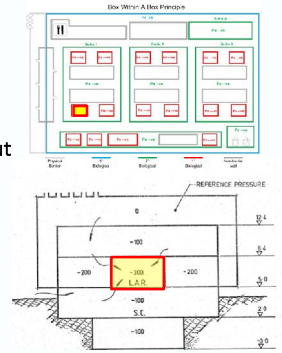
*In order that micro-organisms cannot escape in infective amounts the escape of pathogens during any malfunction period must not exceed one infective dose**

For the purposes of calculation a malfunction period of one hour is assumed and for results in this paper to be achieved, management of the laboratory must ensure that this malfunction period is not exceeded.

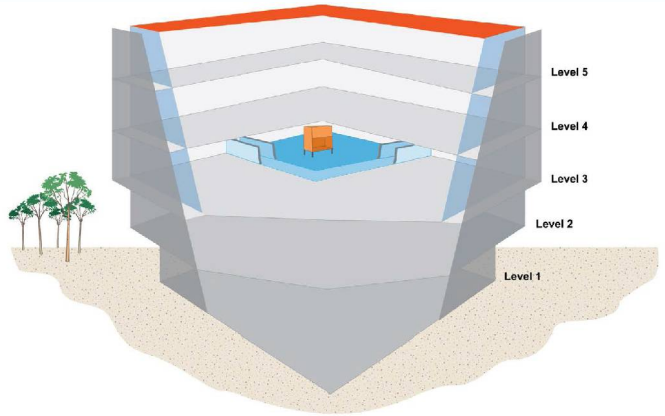
* 30 pigs each excreting $10^{5.7}$ infective doses FMDV per hour=$10^{7.2}$

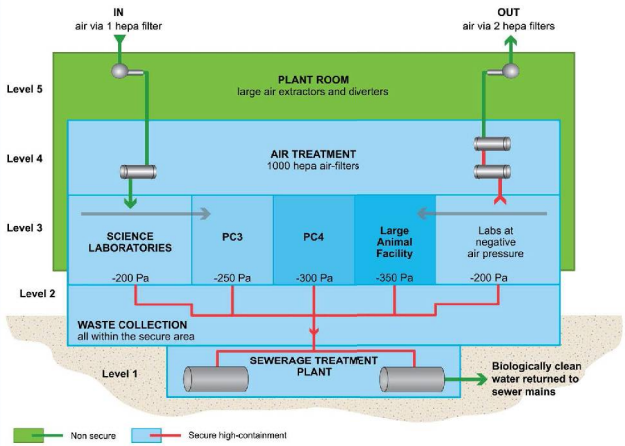
Design Principals

- Accepted that all buildings will leak to some degree
- Under normal operation directional airflow and pressure gradient would ensure leaks would be into and not out of hazardous areas
- **Box within a box**" means any leak must pass through two barriers or
- though one barrier and the air filtration system of the adjoining area
- Methods of control of differential air pressure were complex and expensive in 1974



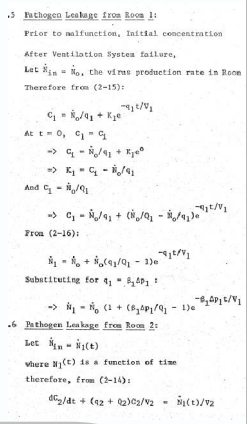
Box within a Box





Design Principals

- Accepted that it is impossible to build an air handling system that could be guaranteed to never fail
- Assumed worse case - dual system failure leading to loss of negative pressure for one hour
- Facility had to be sufficiently air tight to prevent egress of $10^{7.2}$ virus from animal room containing 30 FMDV infected pigs
- Graham Pickering *Analysis of Containment*



.5 Pathogen Leakage from Room 1:

Prior to malfunction, initial concentration

After Ventilation System failure,

Let $\dot{N}_{in} = \dot{N}_o$, the virus production rate in Room

Therefore from (2-15):

$$C_1 = \dot{N}_o/q_1 + K_1 e^{-q_1 t/V_1}$$

At $t = 0$, $C_1 = C_i$

$$\Rightarrow C_1 = \dot{N}_o/q_1 + K_1 e^0$$

$$\Rightarrow K_1 = C_i - \dot{N}_o/q_1$$

And $C_i = \dot{N}_o/q_1$

$$\Rightarrow C_1 = \dot{N}_o/q_1 + (\dot{N}_o/q_1 - \dot{N}_o/q_1)e^{-q_1 t/V_1}$$

From (2-16):

$$\dot{N}_1 = \dot{N}_o + \dot{N}_o(q_1/Q_1 - 1)e^{-q_1 t/V_1}$$

Substituting for $q_1 = \beta_1 \Delta p_1$:

$$\Rightarrow \dot{N}_1 = \dot{N}_o\,(1 + (\beta_1 \Delta p_1/Q_1 - 1)e^{-\beta_1 \Delta p_1 t/V_1}$$

.6 Pathogen Leakage from Room 2:

Let $\dot{N}_{in} = \dot{N}_1(t)$

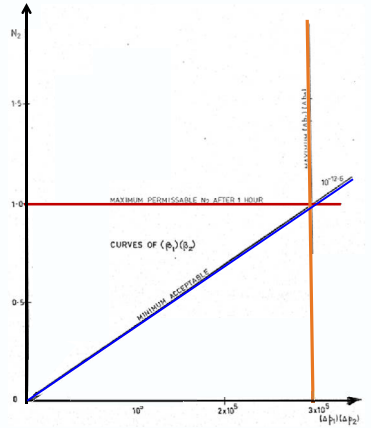
where $N_1(t)$ is a function of time

therefore, from (2-14):

$$dC_2/dt + (q_2 + Q_2)C_2/V_2 = \dot{N}_1(t)/v_2$$

Design Principals

Examine the worst of the numerous possible failure scenarios from which to develop acceptance criteria for leak testing all of the important elements of this complex construction.



Design Principals

- Doors with inflatable seals
- Patented penetrations

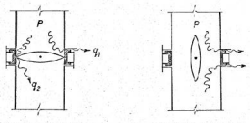


Figure 8. Valve Closed

Figure 9. Valve Open

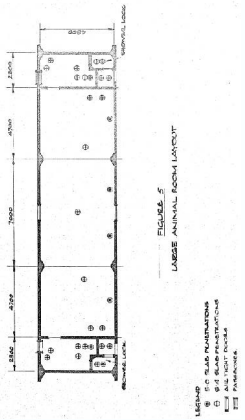


FIGURE 6 LARGE ANIMAL ROOM LAYOUT

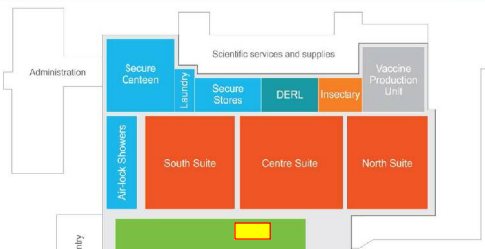
The total k value may be found from the constituent k values as follows:

$$1/k_{total} = \Sigma 1/k_{penetrations} + \Sigma 1/k_{a.t.doors} + 1/k_{struct}$$

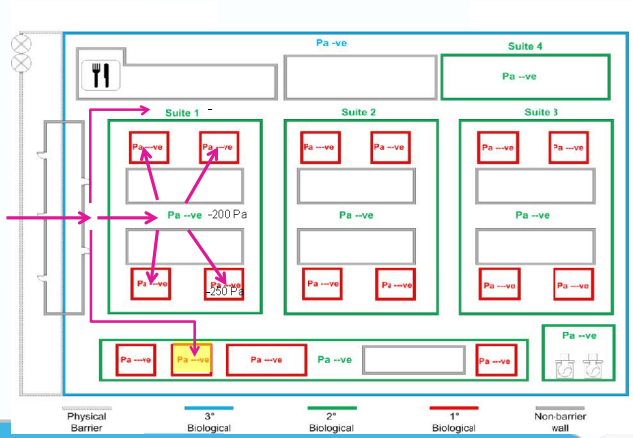
(2-

The k values for each component group will obviously differ and, to assist in deriving acceptable values, a typical Large Animal Room will be considered as an example.

Box within a box floor Plan

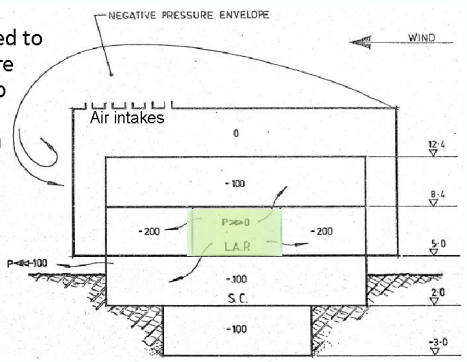


Box within a Box (horizontal)



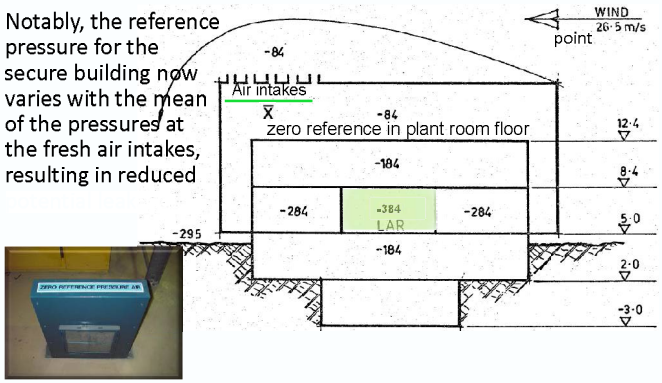
Effect of Wind Speed and direction

Traditionally room pressures were fixed to barometric pressure which could lead to reduced pressure gradients and even pressure reversals



Effect of Wind Speed and direction

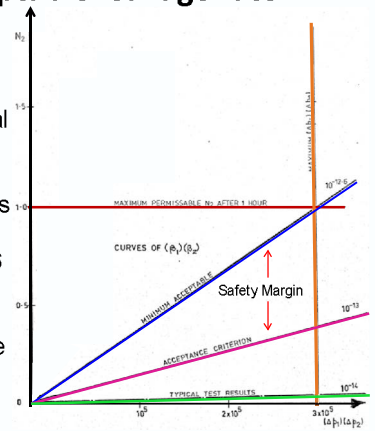
Notably, the reference pressure for the secure building now varies with the mean of the pressures at the fresh air intakes, resulting in reduced



Build to an acceptable leakage rate

Room pressure decay test conducted for every animal room. An acceptable leakage rate based on Pickering's calculations was 20 L/min at 1000Pa
Mean leakage rate was 4.6 L/min

AS/NZ 2243.3:2010 require

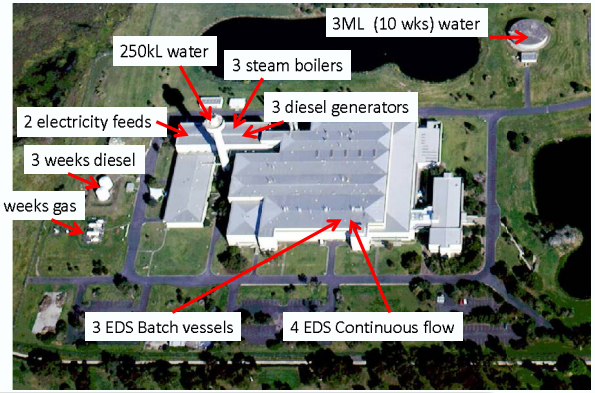


Design Principal 2: Redundancy

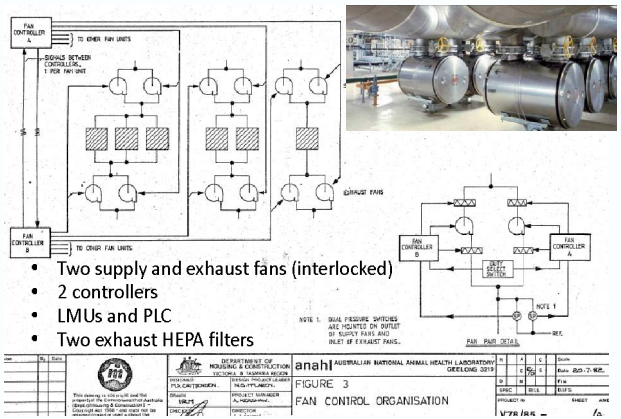
- Redundancy to reduce chance of failure.
- Many critical systems in triplicate
  - 1x in service
  - 1x in maintenance
  -

Redundancy to reduce failure risk

(No single point of failure)

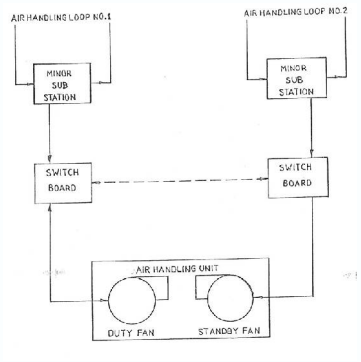


Redundancy in Air Handling

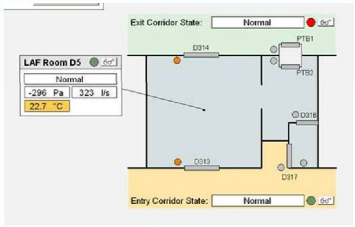


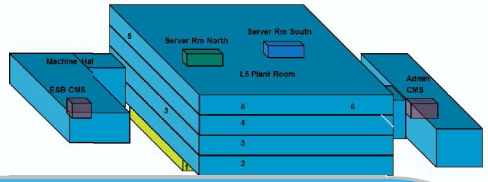
- Two supply and exhaust fans (interlocked)
- 2 controllers
- LMUs and PLC
- Two exhaust HEPA filters

Redundancy Air Handling Power Supply



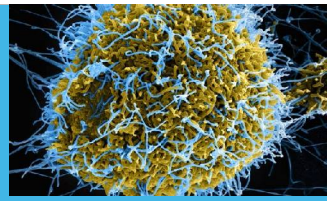
Redundancy in controllers





Questions

MSG



Thank you

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Biosecurity Awareness

Greg Smith| Microbiological Security Manager
On Line Training Module 6 October 2012 (MS-TRN-10-H)

AUSTRALIAN ANIMAL HEALTH LABORATORY
www.csiro.au

NCRIS
National Research Infrastructure for Australia
An Australian Government Initiative

Background

Background: Trends in illegal bioagent use

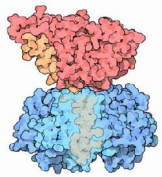
Year	Terrorist	Criminal	Uncertain	Total
1990-1999	19	40	94	**153**
1980-1989	3	6	0	**9**
1970-1979	3	2	3	**8**
1960-1969	0	1	0	**1**
1950-1959	1	0	0	**1**
1940-1949	1	0	0	**1**
1930-1939	0	3	0	**3**
1920-1929	0	0	0	**0**
1910-1919	0	3	0	**3**
1900-1909	0	1	0	**1**
Total	**27**	**56**	**97**	**180**

From W. Seth Carus Working paper; Bioterrorism and Biocrimes ; The Illicit Use of Biological

Agents involved in bioterrorism/crime

Type	Terrorist	Criminal	Uncertain	Total
Pathogen	15	38	83	**136**
Toxin	9	15	2	**26**
Unknown	4	1	1	**6**

In only 33 instances was an agent actually acquired



From W. Seth Carus Working paper; Bioterrorism and Biocrimes ; The Illicit Use of Biological

Source of Agent

Type	Terrorist	Criminal	Uncertain	Total
Legitimate Supplier	1	9	1	**11**
Theft	1	3	0	**4**
Self-manufactured	1	4	1	**6**
Natural Source	2	4	0	**6**
Unknown	2	3	0	**6**
Total instances	**8**	**23**	**2**	**33**

ATCC
The Global Bioresource Center™

From W. Seth Carus Working paper; Bioterrorism and Biocrimes ; The Illicit Use of Biological Agents

Scientific and Technical Expertise background

Type	Terrorist	Criminal	Uncertain	Total
Medical & Scientific Expertise	4	17	2	**23**
No Known Expertise	6	24	6	**36**
Unknown	17	15	89	**121**
Total	**27**	**56**	**97**	**180**

40% of terrorist acts involved medical/scientific trained perpetrators

41% of criminal acts involved medical/scientific trained perpetrators

Size of Perpetrating Groups

Size of Group	Terrorist	Criminal	Uncertain	Total
Lone	0	37	6	**43**
Small Group (2-4)	5	12	2	**19**
Large Group (5+	3	0	0	**3**
Unknown	19	7	89	**115**
Totals	**27**	**56**	**97**	**180**

The lone perpetrator:
was responsible for 43 cases
•successfully acquired biological agents in 19 of
•Used the agent in 12 of these

From W. Seth Carus Working paper; Bioterrorism and Biocrimes; The Illicit Use of Biological Agents Since

Casualties from use of bioagents

Type	Total Casualties	Deaths
Bioterrorism	751	0
Biocrimes	130	10
Totals	**881**	**10**

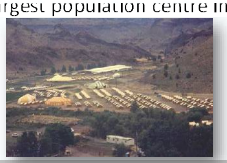
From W. Seth Carus Working paper; Bioterrorism and Biocrimes; The Illicit Use of Biological Agents Since

Some Examples

North America

Rajneeshee 1984 - background

- Followers of Bhagwan Shree Rajneesh had settled in Wasco county Oregon and established *Rajneeshpuram*
- City denied building permits to prevent further expansion
- Decided to influence council elections in Nov 1984 & gain political influence
- Sought to gain two of three seats on Wasco Country Circuit Court
- The Dalles largest population centre in county



Rajneeshee 1984 – the Attack

- Chose *Salmonella enterica* Typhimurium
- Delivered to two city councilors in a glass of water Aug 29th
- A plastic bag containing contaminated liquid "salsa" was spread over food or added to salad dressing
- 10 Local salad bars were contaminated
- Planned to also introduce into towns water supply
- Cultures were purchased from ATCC and grown in the Sects medical

Rajneeshee 1984 – results of attack

- Salmonellosis in 751 individuals
- Diarrhea, fever, chills, nausea, vomiting, headaches, abdominal pain and bloody stools
- 45 hospitalized – no deaths
- Victims ranged in age from 2 days old (5% chance of survival) to 87 years old)
- Remains largest bioterroism act in US history
- Local residents turned out in force on election day
- Only 239 of 7,000 Rajnesshees voted – they lost election
- [illegible]


Rajneeshee 1984 - background

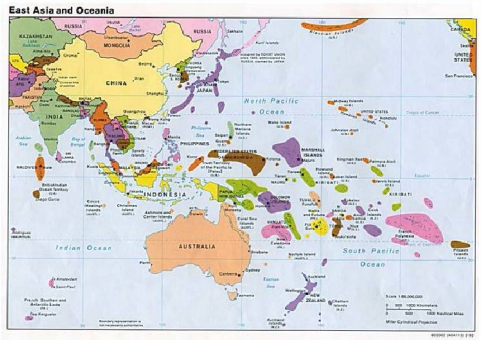
- Investigation by public health officials concluded outbreak due to food handler's poor personal hygiene as many had fallen ill before most patrons
- Congressman Weaver did not believe the conclusion and gave speech on floor of congress
- FBI investigation linked Salmonella strain obtained from cult lab to strains isolated from outbreak
- Former Rashneeshpuram mayor turns state evidence
- At least 19 involved
- Only two individual eventually charged both

Aum Shinrikyo

Infamous for Sarin gas attack on Japanese subway on Japanese subway attack in 1995 – killed 13 and injured over 1000 (17 critically)

Between 1990 and 1995 launched 17 biological and chemical [illegible]


ASIA Pacific



Aum Shinrikyo

The Aum cult was established in 1987 by Shoko Asahara,

- After losing a parliamentary election bid in February, 1990, Shoko Asahara ordered his deputies to obtain some *Clostridium botulinum* – 5 field strains isolated

Had between $300M to $1B in assets. Actively recruited microbiologists, physicists, chemists and engineers

- Attempted to harvest the bacterium from soil and propagate it. (possibly 450 tonnes) 3x 9,000L fermenters


Shoko A


Seiichi Endo

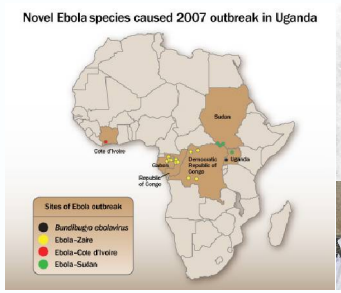
Aum Shinrikyo: *botulinum*

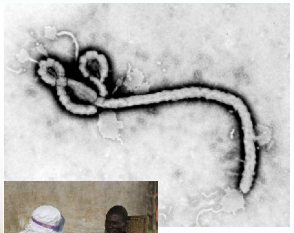
- March-
  - [illegible]
  - [illegible]
  - [illegible]
  - [illegible]
  - the headquarters of a rival group

- 10 to 20 separate attacks in Tokyo
- Nov 1993 20 litres of it sprayed from a car targeting a 'rival' Buddhist movement's (Soka Gokkai) leader
- 1994 Attempted to poison lawyer with spiked drink
- [illegible]

Aum Shinrikyo: Ebola

- In October 1992 40 cult members travelled to Africa to 'provide aid' during Ebola outbreak (and to acquire Ebola strain). Authorities remain uncertain if

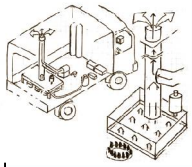




Aum Shinrikyo: Anthrax

- In 1992 turned to *Bacillus anthracis*
- Obtained strain from Obihiro University considered buying from ATCC
- Established research facility on top floor of building in Kameido
- Attempted to spray anthrax from roof of laboratory complex 20 metric tonnes sprayed
- July 1 1993 residents in the neighborhood reported a "gelatin-like, oily, gray-to-black" fluid from the mist from the cooling towers.
- 118 complaints lodged - foul smelling
- Forced to cease on July 2nd

Aum Shinrikyo: Anthrax



- July –Aug 1993 Tokyo
- Disseminated 20 tonnes of 'Anthrax' using a homemade sprayer in a van in 10 to 20 individual
- **Spectacular failure**
- Anthrax vaccine strain (Sterne strain)
- Botulinum strain low toxin producer and possibly a

Aum Shinrikyo: Chemical Attacks

- Chemical program much more successful
- Used Australia property (*Banjawarn Station)* in WA to test some agents on sheep
- Produced and used Sarin, VX, Zyklon and phosgene gases
- On 10 October 1995, Aum Shinrikyo was ordered to be stripped of its official status as a "religious legal entity" and was declared bankrupt in early 1996.
- Death sentence for Endo and Shoko Asahara and other senior

Unrealised potential

- 100 Kgs of Anthrax spread over Washington DC under ideal conditions would kill 1-3 million people
- One megaton Nuclear warhead would kill 0.75-1.9 million people

Sverdlovsk could produce 300 tons in 220 days

>

Unrealised potential: Agriculture

Australian Productivity Commission Report 2002

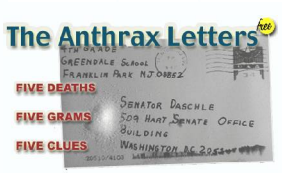
- **Short Outbreak** - $2-3B export losses
  - $30M for control
- **12 month** - $8-13B
  - $450M for control & compensation

A strong case before 2001

- Bioagents (microbes or toxins) had been used or were planning to be used for crime or terror on 180 occasions
  - 881 casualties
  - 10 deaths
- Global in nature
- Scientists and medically trained individuals involved in 40% of cases
- Spectacular in their failure – much greater potential harm could have occurred

Amerithrax: A much stronger case

- Commenced 1 week after 9/11 attack in 2001
- **Killed 5** (half as many as were killed in preceding 100 years
- **infected 17 others**
- A lab worker at Ft Detrick was charged
- Another letter was mailed to a paediatrician in Chile from a [illegible]

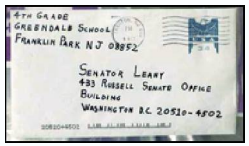


Amerithrax: the attack

- Attack came in two waves
- The first set of letters had a Trenton, New Jersey postmark dated September 18, 2001.
- Five letters are believed to have been mailed at this time to: ABC News, CBS News, NBC News and the *New York Post*, all located in New York City
- The fifth letter was sent to the *National Enquirer* at American Media, [illegible]

Amerithrax: the attack

- 63 year old photo editor Robert Stevens worked for Sun Tabloid at AMI in Baca Raton died 5 October
- Only the *New York Post* and NBC News letters were found
- Two more anthrax letters, bearing the same Trenton postmark, were dated October 9, three weeks after the first mailing.
- Letters were addressed to two Democratic Senators, Tom Daschle of [illegible]



Amerithrax: the attack

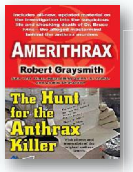
- The Daschle letter opened by an aide on October 15, and the government mail service was shut down.
- The unopened Leahy letter was discovered in an impounded mail bag on November 16 – it had been misdirected to mail annex in Sterling, Virginia
- A postal worker at Steriling mail annex, David Hose, contracted [illegible]

Amerithrax: The death toll

- A 63 year old photo editor Robert Stevens died 5 October
- 2 employees of Brentwood mail facility in Washington, D.C.
- 2 others, (source of exposure is still unknown)
  - a Vietnamese immigrant resident in the borough of the Bronx who worked in New York City
  - A 94-year old widow of a prominent judge from Oxford, [illegible]

Amerithrax: The global impact

- Focused world attention on bioterrorist potential of biological agents
- Immediately strengthened US legislation that had been introduced in 1996 – US Patriot Act 2001
- *UK 2001 Anti-*


Part I: SSBA Bio-Security Awareness

Legislation Background

- **Resolution 1540**
- This resolution requires all states to implement measures aimed at preventing non-state actors from acquiring NBC weapons, related materials, and their means of delivery
- **resolution is legally binding on all UN members.**
- Requires states implement domestic legislation to prevent non-state actors from manufacturing, acquiring, or transporting NBC weapons within or from their territory.

Singapore was among the first in S.E. Asia

The Singapore Government (Ministry of Health) introduces Biological Agents and Toxins Act (BATA) on 3 January

CEN CWA 15793:2008

- In 2008 the European Committee for Standardisation held an international workshop (CEN **CWA 15793** Workshop Agreement: *Laboratory Biorisk Management Standard* to assist countries formulate Domestic legislation to address requirements of UN

Security Sensitive Biological Agents Regulatory Scheme

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

ISO 9001 Management Approach – PDCA

The CWA management system is based on the Plan, Do ,Check, Act

PLAN:

DO:

CHECK:

ACT: Reviewing, including process innovation & acting to make

Risk Assessment and continuous improvement

Scope of CWA 15793

- The scope of this laboratory biorisk management system standard is to set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.
- Two central guidance documents for biorisk management and the development of this standard are:

  WHO Laboratory biosafety manual, third edition, 2004

  WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006

National Health Security ACT

- **The National Health Security (NHS) Act** introduced in Australia in 2009 enables regulations to provide further specific detail for the SSBA regulatory scheme

Singapore **Biological Agents and Toxins Bill** regulates the possession, use, import, transfer, transportation of biological agents and

What legislation addresses UN resolution 1540 in your country?

Elements

There are six elements to SSBA legislation:

1. Personnel Policies and Procedures including training -competency
2. Physical Security & Access controls
3. Information Management
4. Transport
5. Inactivation and Decontamination

SSBA Scheme

- Principles behind selection of SSBA List:
- Intelligence
  - what microorganisms and toxins are the terrorists interested in using
- Impact
  - what would be the impact to Australia if that microorganism is released
- Feasibility
  - how easy is it to acquire, grow & deliver the microorganism or

Different horses for different courses!

What agents are controlled in your country?

Tier 1 Organisms

More tightly controlled / higher security concern than Tier 2 agents

Bacillus anthracis (Anthrax-virulent strains)

Ebolavirus

Foot-and-mouth disease virus

Highly pathogenic influenza virus, infecting humans

Marburgvirus

Rinderpest virus

SARS coronavirus

Variola virus (Smallpox)

Yersinia pestis

Tier 2 Organisms

African swine fever virus

Capripoxvirus(Sheep pox virus and Goat pox virus)

Classical swine fever virus

Clostriduim botulinum(Botulism: toxin-producing strains)

Francisella tularensis (Tularaemia)

Lumpy skin disease virus

Peste-des-petits-ruminants virus

Salmonella typhi (Typhoid)

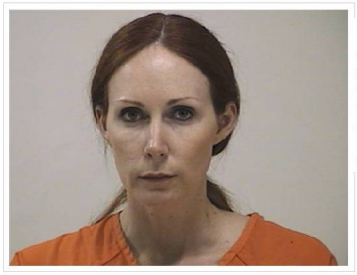
Vibrio cholerae (Cholera)(serotypes O1 and O139)

Yellow fever virus (non-

Attacks continue 2012

Attacks continue 2013

Texas woman indicted over ricin letters sent to Obama, Bloomberg



Titus County Sheriff's Office via Reuters

Booking photo of Shannon Richardson

In a new twist, the woman who blamed her husband for sending ricin-laced letters to President Obama and New York City Mayor Michael Bloomberg was charged Friday with sending the letters herself, NBC's Anne Thompson reports.

By Pete Williams and Matthew DeLuca, NBC News

A Texas woman has been arrested in connection with the mailing of three letters containing a form of the poison ricin to President Obama, New York City Mayor Mike Bloomberg and the director of Mayors Against Illegal Guns, federal authorities said.

Shannon Rogers Guess Richardson of New Boston, Texas, originally called the Federal Bureau of Investigation claiming that her husband had sent the letters, officials said. The investigators found that she had sent the letters herself, they said.

Richardson is an actress with minor roles on television shows like The Walking Dead and the Vampire Diaries, and was arrested in Arkansas on charges that will be filed Friday afternoon, the authorities said. She has flu ever, according to the New York Times.

Thank you

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