Summary of HKU Biosafety Management and Arrangements

Biological Safety arrangements in HKU

Biosafety Policy

Biosafety Committee

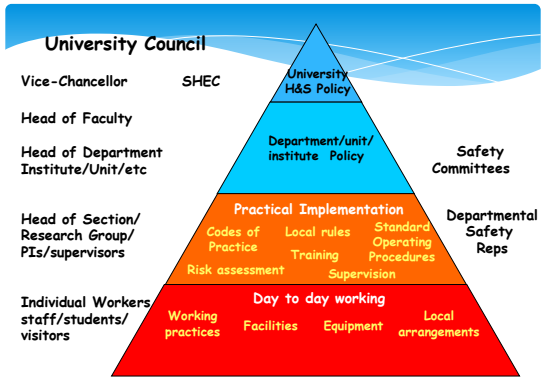
Biological Safety Officer

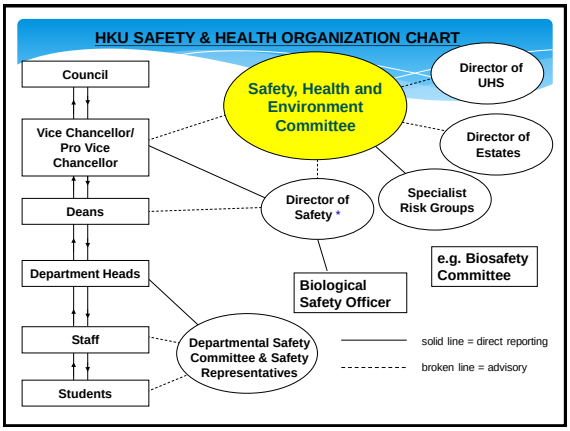
Safe Systems of Work

Information -Instruction –Training

Biosafety "Manual" – guidance on virus vectors, clinical samples, disinfection etc.

Audit/Inspection (internal and external)





Biosafety Policy

1. INTRODUCTION
2. BIOLOGICAL HAZARDS AND THE LAW
3. ADMINISTRATIVE PROCEDURES
4. REQUIREMENTS FOR THE DIFFERENT TYPES OF BIOLOGICAL WORK
5. SAFE SYSTEMS OF WORK
6. EQUIPMENT
7. DISINFECTION AND WASTE DISPOSAL
8. TRANSPORT OF BIOLOGICAL MATERIALS
9. TRAINING AND SUPERVISION
10. ACCIDENTS AND INCIDENTS
11. OCCUPATIONAL HEALTH
12. ACCESS TO BIOLOGICAL LABORATORIES BY NON-LABORATORY PERSONNEL
13. MONITORING, INSPECTION, AUDIT AND REVIEW

Biosafety Committee

Role is:-

To oversee work in the University that might present a biological hazard

To prescribe conditions for containment, housing, storage, transportation and procedures under which biohazardous research may proceed

To report on a regular basis to the Safety Health and Environment Committee

To collect and disseminate information and guidance on biohazards and biosecurity

Biological Safety Officer – role & duties

To provide competent advice and guidance

Conduct biosafety audits

Give appropriate training – postgraduate & staff

Investigating accidents/ incidents

Review risk assessments - to ensure they are made and consistent

Information gathering

Safe Systems of Work

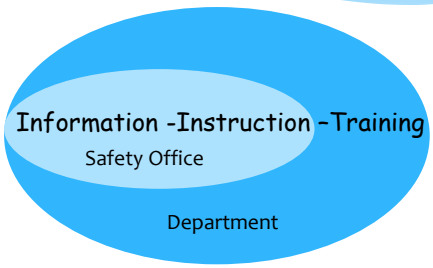
1) Controlling the routes of potential infection

2) Good microbiological practice, including techniques and administrative procedures

3) Agent Classification - Hazard (Risk) Class1-4

4) Biosafety Levels 1-4

Biosafety competence



Inspection & "Intelligence"

Review of CULATR applications for animal holding

Review of Risk Assessments

Regular inspection of all facilities and departments – full reports to HoD.

Focused inspections start shortly.

General issues for organisations and HKU

How to ensure risk assessment of experimental work is carried out and appropriate controls instituted

A consistent and thorough approval process for projects

How to provide training and competency testing and how to evaluate its effectiveness

How to promote/encourage a culture of safe working.

Risk Assessment

The importance of Risk Assessment

Risk Assessment establishes a containment/biosafety level and leads to risk management

Risk Management includes all the practices and procedures established to mitigate risk and minimise exposure

-administrative controls

-engineering controls

-training

-medical intervention and surveillance

Please see Guidelines and Risk Assessment forms on Safety Office Website

Hazard

"The potential to cause harm"

Risk

"The likelihood (probability) of that harm actually occurring *and the severity of its consequences*"

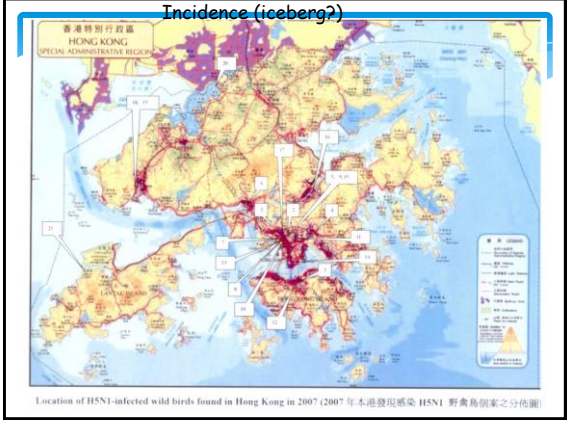
Question from Estates Office to Safety Office:-

If our staff find a dead bird on Campus what should we do? (By implication what precautions should we take?)

Safety Office:- Talk to the BSO. So what would you say if you were me? Don't worry about it?

Risk assessment (also need to ask what government want)

Incidence (iceberg?)



Location of H5N1-infected wild birds found in Hong Kong in 2007 (2007 年本港發現感染 H5N1 野禽鳥個案之分佈圖)

Is this the way we should go?

This is more about an entrepreneurs response to seeing an opportunity!

Basic Risk Assessment

Identification of the hazard.

Identification of those who might be affected.

Evaluation of the steps to be taken to achieve and maintain adequate control;

Recording findings

Review at regular intervals and revise if necessary

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P.S. Biosafety Committee requires all projects to be risk assessed and if Class 2 or above or viral vector work approval by the committee is required before work starts

What are the major biological hazards in laboratories? (Hazard Identification)

Potential Infection can arise from:-

Deliberate culture of various agents
Virus vector work – e.g. AAV, Adenoviruses, Retroviruses
Clinical Samples, bloods, histology specimens, FACS etc
Zoonosis (agents that can infect animals and humans)
Cell culture – risk mainly from adventitious agents that may be present in primary cultures
Clinical waste including sharps

(Risks may be altered by Genetic Modification)

Biological experiments with Carcinogenic, Teratogenic or Toxic chemicals/agents

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Risk Assessment

Identify Hazard
H5N1 infection and death?

Identify who might be harmed:-
Handler of carcass> General passer-by

Evaluate the risk (likelihood that harm will occur)
·Bird dies, virus dies (hours)
·No previous evidence of human infection from wild birds.
·Virus titre low (<<poultry)
·Main route of infection respiratory
·**NOTE MANY UNKNOWNS**
(What changes with alert level?)

Establish containment conditions (PPE) etc

Five Steps to RISK ASSESSMENT (HSE UK)

·Identify Hazard (anything that can cause harm)
·Identify who might be harmed
·Evaluate the risk (likelihood that harm will occur) and the proposed controls
·Record the findings
·Review assessment regularly

IND6163(rev1)

Australian OGTR risk analysis framework

Risk Analysis → **Risk Assessment** + **Risk Management** + **Risk Communication**

Risk Assessment: What might happen? How might it happen? Will it be serious if it happens? How likely is it to happen? What is the risk?

Risk Communication: Requires interactive dialogue between, risk assessors, risk managers and stakeholders

Difficulties with risk assessing biosafety, particularly GM work

1. Societal concerns, GM crops etc

2. Vast majority of work is inherently safe

3. GM technology is able to create hazards, which are difficult to assess and/or identify

4. Quantitative risk assessment unreliable

5. Many assessments involve incomplete data i.e. unknowns

Risk assessment (from CDC)

-Identifying risk factors
- Agent hazards
- Protocol hazards
- GM alterations
- susceptibility of at risk persons

-evaluating likelihood and consequence of exposure

-evaluating the capability of safeguards to control risk

Agent Hazards

Pathogenicity
- Virulence
- Infectious Dose
- Route of transmission
- Stability
- Host Range

Protocol Hazards

Agent concentration

Manipulations that produce droplets and aerosols

Manipulations involving sharps

Manipulations with high potential for spills and splashes

Animal work

Exposure to zoonotic diseases of experimental animals

Hazards arising directly from the inserted gene (i.e. from donor organism)

- Toxins
- Cytokines
- Hormones
- Gene expression regulators
- Virulence factors or enhancers
- Oncogenic gene sequences
- Antibiotic resistance
- Allergens.

Risk control strategy

Hierarchy of control

Most Effective

Elimination

Substitution

Isolation

Engineering controls

Information, training & procedures

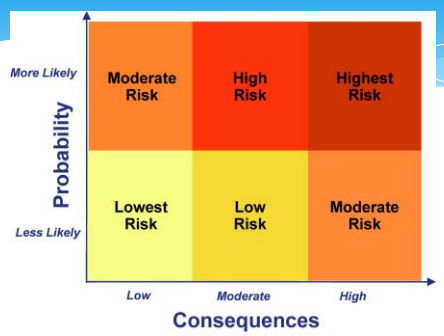
Personal protective equipment

Least Effective

Example of risk assessment

- Studies of the natural transmission of very high virulence influenza in a range of animals (animals not in isolators)
- Consequence of infection
  - Serious respiratory infection or death (H5N1- high mortality)
  - Serious community consequence (next pandemic of influenza?)
- Probability of infection
  - Without any respiratory protection, very high
- On risk matrix this work would fall in the very high zone and would need to have controls

Risk Matrix



Controls to reduce risk to acceptable level

- Physical containment (P3 animal room)
  - HEPA filtered exhaust air
  - Negative air pressure (-250Pa) and contained
  - Air flow
  - Sewage treatment
  - Shower out
- PPE
  - Tyvec coverall, boots and gloves
  - Racal half suits with P3 filter to provide respiratory protection
- Work practices
  - Animals constrained when being worked on
  - Air shower in work room after leaving animal room (to remove virus from air – about 60 air changes per hour)
  - Decontamination of respirator and coverall with glutaraldehyde before removal 3 minutes after entering work room
  - Shower out of facility
- Risk now reduced to low level acceptable for work to proceed

DNV

Organizational Risk matrix with acceptability levels

Likelihood	Consequence				
	Insignificant	Minor	Moderate	Major	Catastrophic
Certain	Moderate	Moderate	High	High	High
Common	Low	Moderate	Moderate	High	High
Possible	Low	Low	Moderate	Moderate	High
Unlikely	Low	Low	Low	Moderate	Moderate
Rare	Low	Low	Low	Low	Moderate

Rare– Very Unusual requires freak combination < 1 in 100 years
Unlikely – Could occur at some time. Rare mix of factors for 1 in 30 years
Possible – The event does occur. At least 1 in 10 years
Common – Has happened here or similar institute At least 1 per year
Certain – Almost inevitable. Once per month

Consequence Category Descriptions

Performance/Facilities

Image/Reputation

Health and Safety

Environment

Legal/Regulatory

Financial

Security

Task analysis and risk assessment

Procedure	Likely Hazards	Likelihood of infection		
		Outside BSC		Inside BSC
		Wearing PPE		
		No	Yes	
Growth of Virus in Eggs	Eggs smash on transfer to cabinet or incubator	H	U	EU
Titration of virus in microtitre plates	Dropping plates Spillage of virus Leak from a plate	H H P	U	EU
Virus Neutralisation	Dropping of microtitre plates Spillage of virus Leak from a plate	H H P	U	EU
Plaque reduction assays	Dropping plates Spillage of virus Leak from a plate	H H P	U	EU
Tissue culture Amplification	Dropping tubes/flasks Spillage of virus Leak from a tubes/flasks	H H P	U	EU
Preparation of antigen for ELISA	Aerosols produced during sonication Spillage of virus Leak from tubes, flasks	VH H P	U	EU
Centrifugation of Allontic Fluid	Break of tubes during centrifugation and opened inadvertently	VH	P	N/A
Centrifugation of Virus	Break of tubes during centrifugation and opened inadvertently	VH	P	N/A
Animal experiments	Infected ferret with flu like symptoms sneezes on your face	VH	P	N/A

Risk assessment in action?

University Risk Assessment forms and Guidance Documents (please e-mail to ask for what you need)

RA1 Risk assessment form for deliberate work with infectious agents
RA2 Obsolete
Guidance document on work with adeno-associated virus (AAV) vectors
RA3 Risk assessment form for working with retroviruses
Guidance document on working with retroviruses
RA4 Risk assessment form for work with Adenovirus
Guidance document on working with adenoviruses
RA5 Risk assessment form for work with poxviruses
Guidance document on work with poxviruses

Guidance on Risk Assessment

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2859 2404

http://www.hku.hk/safety

Five steps to risk assessment

http://www.hse.gov.uk/pubns/indg163.pdf

(UK Health and Safety Executive booklet)

A series of examples using this process can be found at:-
http://www.hse.gov.uk/risk/casestudies/index.htm
A standard template can also be found at this URL

University Risk Assessment guidance
http://www.safety.hku.hk/homepage/pdf/BSRA2014.pdf

PROFESSIONAL BIOSAFETY ORGANISATIONS etc

American Biological Safety Association
http://www.absa.org/
http://www.absa.org/resbslinks.html - extensive list of useful links

European Biological Safety Association
http://www.ebsaweb.eu/

Asia-Pacific Biosafety Association
http://www.a-pba.org/

International Federation of Biosafety Associations (IFBA)
http://www.internationalbiosafety.org/english/index.asp

Others biosafety groupings have been formed including national organisations in Belgium, Japan, Kazakhstan, Taiwan, The Netherlands, The Philippines and Thailand.

WHO Global Response and Alert section
http://www.who.int/csr/resources/publications/csrpublications/en/index2.html

WHO Laboratory Biosafety Manual - Third Edition (2004)
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition (2007) http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm

Laboratory Biosafety Guidelines 3rd Edition - 2004
http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index-eng.php

Biological Agents – Managing the Risk (ADCP) - 2006
http://www.hse.gov.uk/biosafety/biologagents.pdf

Scientific Advisory Committee on Genetic Modification – compendium of advice
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

AS/NZS Safety in Laboratories *(part 3, Microbiological Aspects and Containment Facilities)* -2002

CEN Workshop 31 - Laboratory Biosafety and Biosecurity (2007/8)
http://www.cen.eu/cenorm/businessdomains/sectors/isss/cen+workshop+agreements/cwasnon-ict.asp