

# 生物安全概論

## Basic Principle of Biosafety

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# 報告內容綱要

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- ✦ 簡介
- ✦ 國際發展沿革
- ✦ 生物安全預防控制原則
- ✦ 風險與危害分析評估
- ✦ 設施設備安全簡介

# 生物安全(Biosafety)

## -全球永續發展議題

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聯合國環境發展會議 (United Nations Conference on Environment and Development, UNCED )

1992年6月簽定「生物多樣性公約」(Convention on Biological Diversity)，主要目的在保存及自然資源永續利用，及公平共享基因資源。

2001年1月「卡塔赫納生物安全議定書」( **Cartagena Protocol on Biosafety to the Convention on biodiversity** )，規定會員國對於基因改良活生物體 (living modified organisms, LMOs) 之跨境運輸、過境、處理和使用，確保生態保育與生物多樣性之永續使用。

# 全球暖化 熱帶昆蟲恐絕跡 惡化糧食危機

中國時報 2008.05.07 鍾玉珏／綜合六日外電報導



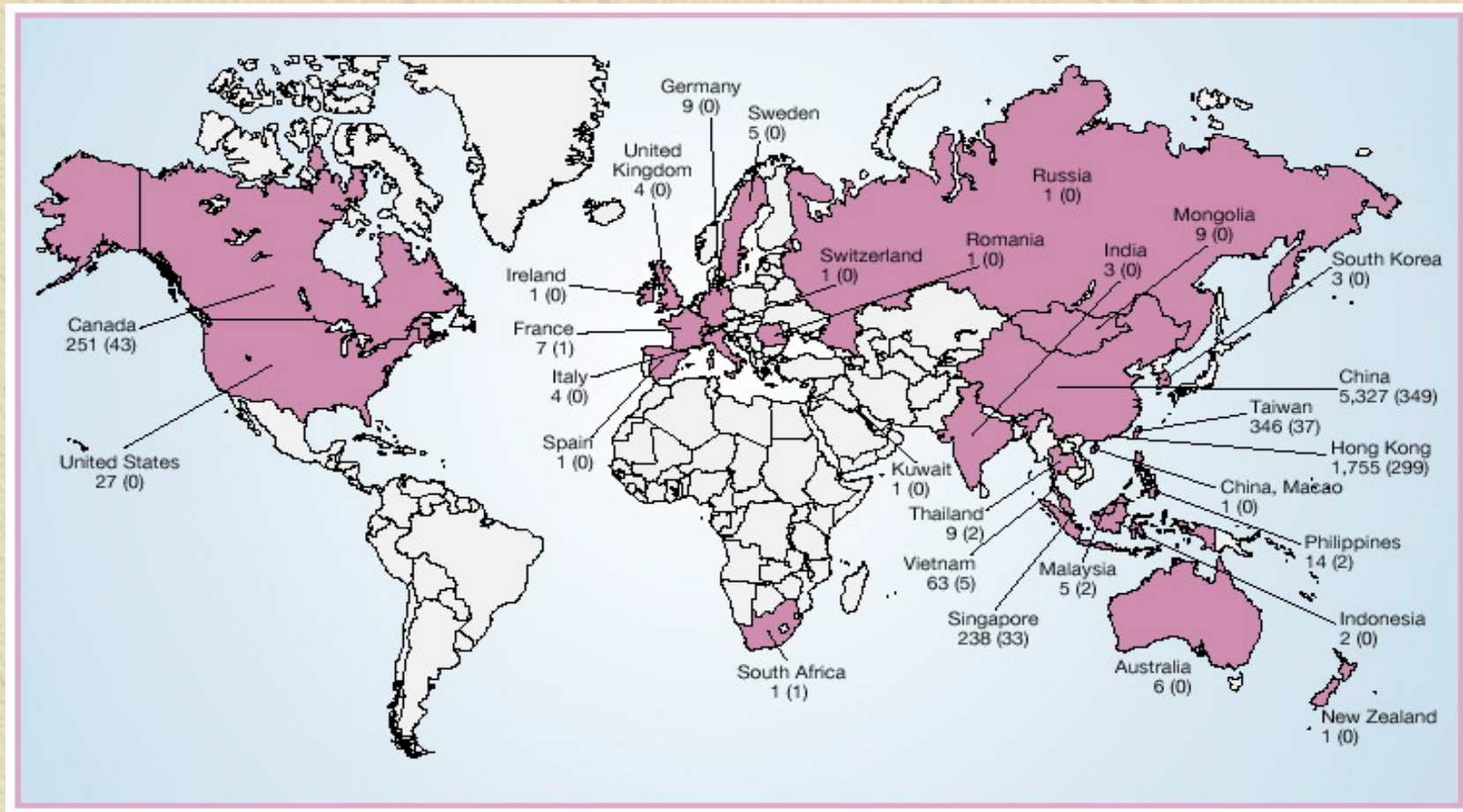
美國華盛頓大學最新研究指出，熱帶昆蟲若無法適應全球暖化所造成的環境變化，數量可能銳減，最快可能在本世紀結束之前絕種。反之，生活在較高緯度的寒帶昆蟲或溫帶昆蟲數量可能暴增。

華大生物系助理教授涂斯貝利主持的研究指出，熱帶昆蟲受氣溫變化的影響高於其他地區昆蟲，若無法順利進化，適應外在環境變化，恐有絕跡之虞。該研究結果刊登在最新一期的《美國國家科學院刊》。昆蟲數量銳減，將影響農作物授粉，讓食物供應出現問題，進一步惡化糧食危機。

# 全球糧食危機 比戰爭、環保危機更嚴重

中時電子報 2008/04/28

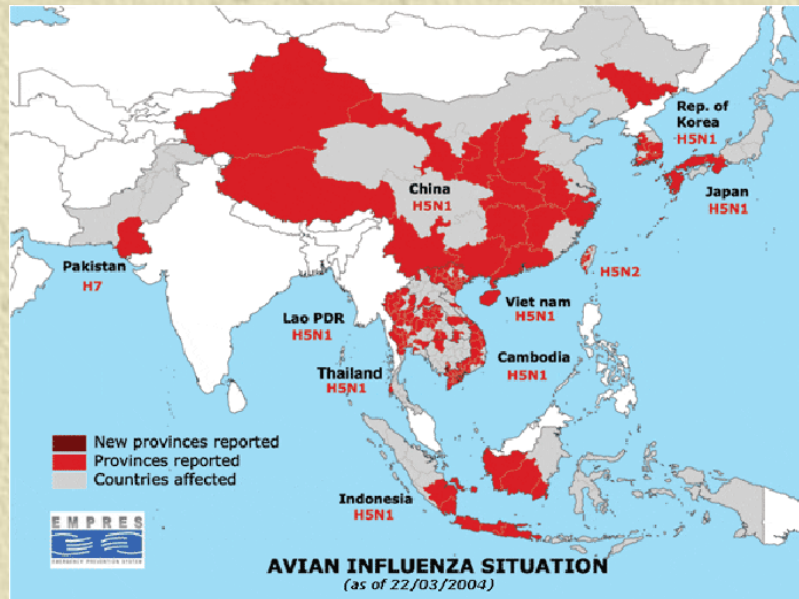
- 
- ✦ 從海地到辛巴威，北韓到阿富汗，摩多瓦到車臣，數以千萬計的貧苦人民已經買不起維持活命最低需要的玉米粉、糙米、或雜糧，正在飢餓邊緣掙扎。原物料與石油價格飛漲導致的糧食危機，比發生戰爭、全球暖化或環保失控的危機更加嚴重。
  - ✦ 世界銀行和國際貨幣基金在華盛頓聯合發出警訊，呼籲工業化國家和各國的主權財富基金（sovereign wealth funds）要出錢出力，支持曾任美國副國務卿的世銀總裁佐立克提議的「全球糧食政策新政」（New Deal on Global Food Policy）。
  - ✦ 糧食供應與全球人口總數、農業生產技術乃至環保危機環環相扣，牽一髮而動全身。地球只有這麼大，170年前，馬爾薩斯（Thomas Malthus, 1766-1834）已經提出人口論，預言糧食生產永遠趕不上人口增加率。



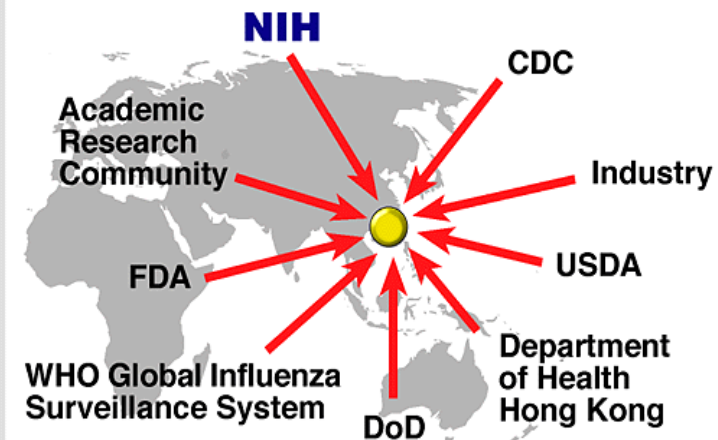
**Figure 3 Probable cases of severe acute respiratory syndrome (SARS) with onset of illness from 1 November 2002 to 31 July 2003. Cases are given by country. SARS-related deaths are indicated in parentheses. A total of **8,096 cases (and 774 deaths)** are presented. Figures published by the World Health Organization (see <http://www.who.int/csr/sars/country/en> ).  
**From: Morens: Nature, Volume 430(6996).July 8, 2004.242-249****

# 禽流感 Avian influenza

## What is the Current Situation of AI Since 1997?



### Response to H5N1 Avian Influenza Outbreak in Hong Kong



禽流感全球擴散趨勢 2003年底在東南亞再度發現H5N1高病原性的禽流感疫至今，高病原性的H5N1禽流感已近乎席捲全球世界衛生組織指出，從2003年以來，全球感染禽流感病毒有130人，至少已有68人死亡，其中還未包括中國最近通報的病例。

# 英國口蹄疫疫情震動歐洲

## 英口蹄疫 元凶是實驗室

【聯合報／編譯朱小明、王麗娟／綜合報導】

- ✦ 英國爆發自二〇〇一年以來首次口蹄疫疫情，英國環境食品與農村事務部（DEFRA）已迅速追查出病毒來源可能是一所疫苗實驗室。英國已主動停止出口肉品和乳製品，歐盟、美國、日本、新加坡等國也已暫停自英國進口肉品。
- ✦ DEFRA表示，英國南部薩里郡病牛的病毒株和動物身上的一般病毒不同，類似一九六七年英國口蹄疫流行時分離出來的病毒株，用於疫苗製造，來源可能是附近的裴布萊特實驗室。這所實驗室由政府的動物衛生研究所和美國最大動物保健藥廠梅里亞（Merial）共用，病毒株和梅里亞上個月中旬用來生產一批疫苗的病毒株相同。
- ✦ 梅里亞已立即停止生產疫苗。梅里亞是由美國默克大藥廠與歐洲賽諾飛安萬特旗下的動物保健部門合併成立。



# 英國口蹄疫疫情震動歐洲

2007年08月05日 來源：北京晚報

## ✦ 病毒從實驗室漏出？

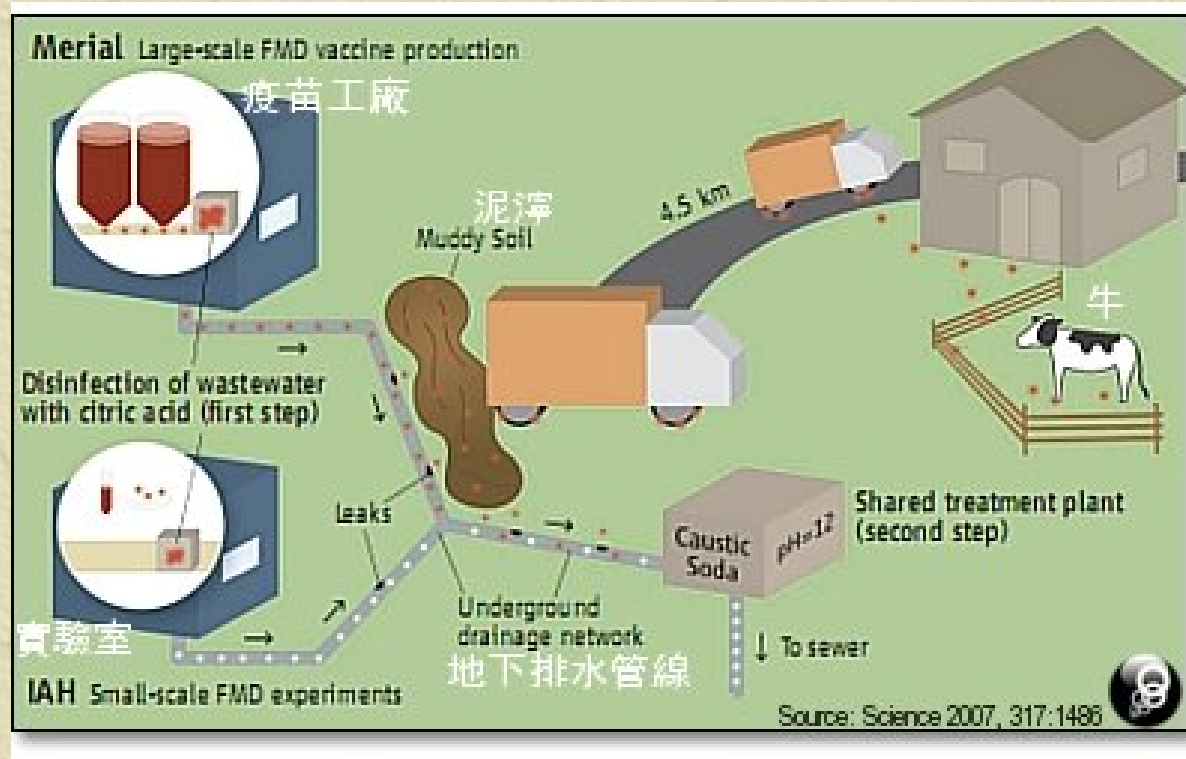
✦ 英國首相戈登·布朗在4日主持“內閣應急委員會”第二次會議後說：“我向人民保證……我們將竭盡所能蒐集科學證據，查出疫情根源，並根除疫情。”

✦ 英國政府首席獸醫官戴比·雷諾茲同日說，目前推斷這次疫情出現的原因為時尚早。不過她在新聞發佈會上指出，研究口蹄疫的英國皮爾布賴特動物衛生研究所正位於疫情監控區，距出現疫情的農場不到6公里，英國政府已要求研究所徹查實驗室各項程式是否符合生物安全標準。

✦ “重點在於，不能排除任何可能。”雷諾茲說。科學家正在進行各項測試，以確定這次口蹄疫病發源頭，並探討能否借助接種疫苗有效遏制疫情蔓延。雷諾茲說，政府已從其他農場接到“少量”牲畜出現不良徵兆的報告，不過至今尚未有新的病例被證實為口蹄疫。

✦ 而法新社報道說，由於口蹄疫一般在患病3天到6天后才會表現出症狀，英國農民擔憂，口蹄疫恐怕已經擴散。

# Biorisk-人為的口蹄疫



全世界聞名的口蹄疫研究機構栽進年久失修，但維修權責卻疊床架屋多頭馬車的排水管線，成了口蹄疫疫情的元兇。

# 人畜共通傳染病

## 獼猴帶原B病毒7成感染者會喪命

【中國時報 沈揮勝／南投報導】2008.07.15

- ✦ **美國**在一九八七年到一九八九年間，發生過B病毒透過外露傷口及針筒誤刺或口沫感染，導致四十七名**醫療**和相關研究人員死亡。
- ✦ **臺灣**有許多獼猴為B病毒（B Virus）帶原者，若不慎被牠們抓咬感染，致死率超過七成，倖存者也會終生癱瘓，這種人畜共通的傳染病，在猴子身上症狀並不明顯，除了口腔泡疹，頂多是帶有神經質，而神經質的猴子通常比較容易咬人。換句話說，會咬人或搶人食物的猴子，往往是B病毒高危險群。
- ✦ 農委會對這種現今國內**醫療**機構毫無操作能力的人猴共通傳染病如臨大敵，通令各單位萬不得已須接觸獼猴時，必須小心。
- ✦ 農委會指出臺灣中寮鄉的南投縣野生動物收容所內的**十六隻台灣獼猴**中，有**四隻B病毒檢驗呈陽性**；之後國姓鄉李姓民眾飼養的**廿三隻獼猴**中，亦發現**十七隻帶原**。高雄市柴山送驗的**五十隻**更高達**廿九隻抗體為陽性反應**。

# 生物安全(Biosafety)

-職業安全衛生的觀點

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What is biological safety or “biosafety”?

- Anticipation,
- Recognition,
- Evaluation, and
- Control of agents of known or suspected pathogenicity in man, animal, or plants  
(*also known as biohazard control or infection control*)

✚ 經由安全防護技術及管理以預防病原微生物或其毒素對人員產生傷害。

# 實驗室感染案例

## Laboratory-Acquired SARS in Taiwan, Dec. 2003

Waste Package  
inside the Isolator



The 75%  
Alcohol Sprayer



Power Switch of  
the Isolator



為了清除傾倒出來的廢液，先以酒精噴灑消毒，十分鐘後，打開負壓艙門，手伸入亦無法碰到，故將上半身亦探入，這時研究人員只帶手術口罩及手套。

# Laboratory-Acquired Infection

## 共同性缺失事項

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### ✧ 實驗室

- 缺乏標示生物危害標識
- 缺乏進入管制、每日進入操作記錄
- 無可目視的負壓表
- 第三級實驗室內無冷凍冰櫃，導致檢體必須送到第二級實驗室貯存、無病原體貯存記錄、無冰箱維護記錄
- 更新HEPA 濾網前無燻蒸消毒
- 啟用前徹底消毒、檢查設施、設備、操作

### ✧ 人員 - 缺乏生物安全訓練及持續教育

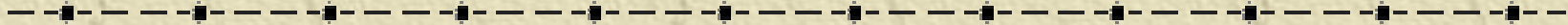
- 缺乏個人防護裝備
- 缺乏緊急應變演練

### ✧ 健康監督

- 缺乏人員健康管理及安全文件
- 缺乏強制性醫療監測計畫
- 先行施打疫苗(日本腦炎、黃熱病、B型肝炎)

# NIH Guidelines

## Recombinant DNA and Gene Transfer



### Guidelines for Research Involving Recombinant DNA Molecules

**April 2002** Effective June 24, 1994, Published in Federal Register, July 5, 1994 ([59 FR 34496](#))

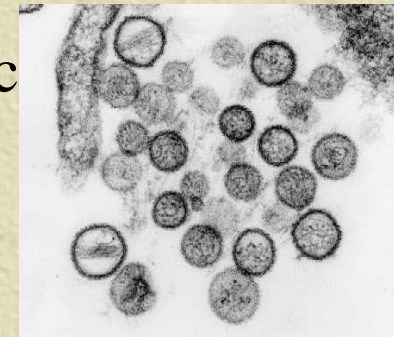
Amendment Effective January 24, 2002 Federal Register, November 19, 2001 ([66 FR 57970](#))

NATIONAL INSTITUTES OF HEALTH  
**Office of Extramural Research**

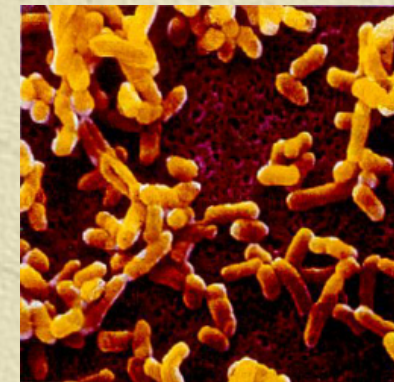
# Risk Group (RG):

- ❑ RG1: not known to cause disease (E. coli engineered lab strains like K12)
- ❑ RG2: rarely serious disease, with therapeutic intervention often available (adenoviruses, Hepatitis A, B & C, Influenza, Measles, Neisseria gonorrhoeae, Treponema pallidum, Rhinoviruses - all types)
- ❑ RG3: serious, lethal disease for which preventive or therapeutic interventions may be available (Bacillus anthracis, mycobacterium tuberculosis, Hantaan virus, HIV, Yellow fever virus, Yersinia pestis)
- ❑ RG4: serious, lethal disease with no therapeutic intervention (Lassa virus, Ebola virus, Marburg virus)

**Hanta Virus**



**Yersinia pestis**





# Classification of Biohazards



BSL 4

BSL 3

BSL 2

BSL 1

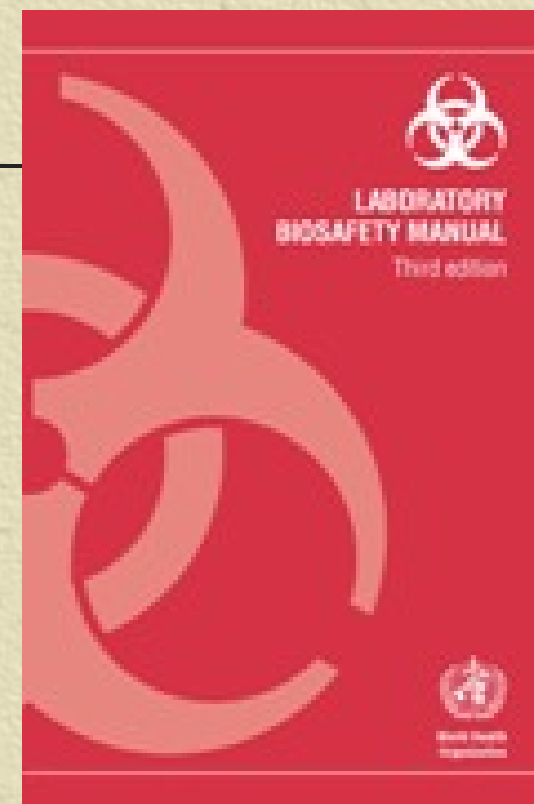
As the level ↑ so does ;

- the risk of the organism to humans, animals, plants and/or the environment
- the procedural and facility requirements
- the level of containment required
- the degree of protection for personnel, the environment and the community.

## 世界衛生組織實驗室生物安全手冊

For more than 20 years, since it was first published in 1983, the *Laboratory Biosafety Manual* has provided practical guidance on biosafety techniques for use in laboratories at all levels.

For this new edition, the manual has been extensively revised and expanded. The manual now covers risk assessment and safe use of **recombinant DNA technology**, and provides guidelines for the **comissioning** and **cetification** of laboratories. Laboratory biosecurity concepts are introduced, and the latest regulations for the transport of infectious substances are reflected. **Material on safety in health-care laboratories, previously published elsewhere by WHO, has also been incorporated.**



WHO

1<sup>st</sup> Edition 1983

2<sup>nd</sup> Edition 1993

3<sup>rd</sup> Edition 2004

# 危險群感染性微生物分類

*Table 1. Classification of infective microorganisms by risk group*

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**Risk Group 1** (*no or low individual and community risk*)

A microorganism that is unlikely to cause human or animal disease.

**Risk Group 2** (*moderate individual risk, low community risk*)

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

**Risk Group 3** (*high individual risk, low community risk*)

A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

**Risk Group 4** (*high individual and community risk*)

A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

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## 各等級危險群微生物相對生物安全等級操作實務與設備

*Table 2. Relation of risk groups to biosafety levels, practices and equipment*

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

## 動物設施防護等級：安全設備與操作實務摘要

*Table 4. Animal facility containment levels: summary of practices and safety equipment*

RISK GROUP	CONTAINMENT LEVEL	LABORATORY PRACTICES AND SAFETY EQUIPMENT
1	ABSL-1	Limited access, protective clothing and gloves.
2	ABSL-2	ABSL-1 practices plus: hazard warning signs. Class I or II BSCs for activities that produce aerosols. Decontamination of waste and cages before washing.
3	ABSL-3	ABSL-2 practices plus: controlled access. BSCs and special protective clothing for all activities.
4	ABSL-4	ABSL-3 plus: strictly limited access. Clothing change before entering. Class III BSCs or positive pressure suits. Shower on exit. Decontamination of all wastes before removal from facility.

ABSL, animal facility Biosafety Level; BSCs, biological safety cabinets

# 生物安全各等級設施防護需求摘要

Table 3. Summary of biosafety level requirements

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation <sup>a</sup> of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No <sup>b</sup>	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No <sup>c</sup>	No
Effluent treatment	No	No	Yes/No <sup>c</sup>	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability <sup>d</sup>	No	No	Desirable	Yes

<sup>a</sup> Environmental and functional isolation from general traffic.

<sup>b</sup> Dependent on location of exhaust (see Chapter 4).

<sup>c</sup> Dependent on agent(s) used in the laboratory.

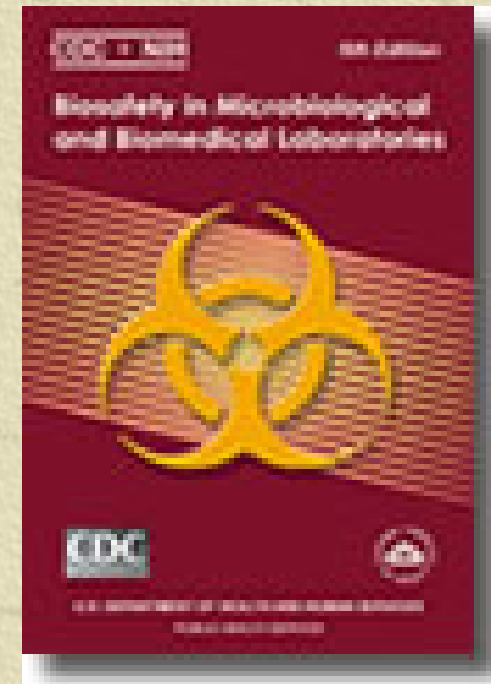
<sup>d</sup> For example, window, closed-circuit television, two-way communication.

# 微生物及生物醫學實驗室生物安全 Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

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**U.S. Department of Health and  
Human Services  
Centers for Disease Control and  
Prevention and  
National Institutes of Health  
Fifth Edition, Feb 2007**

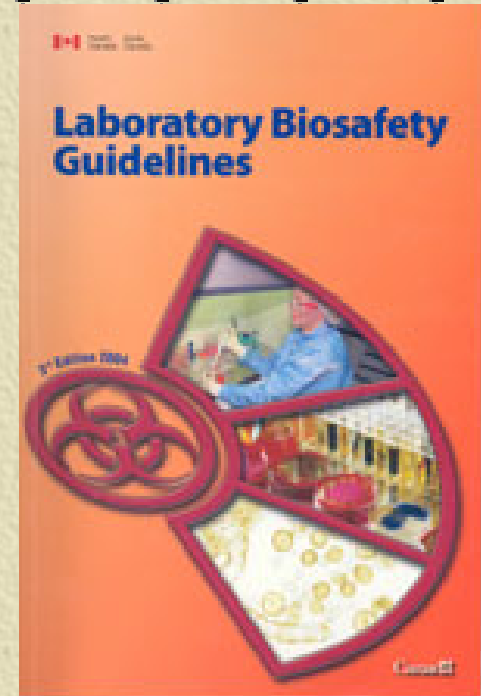
**US Government Printing Office  
Washington: 2007**



# 實驗室生物安全指引

## Laboratory Biosafety Guidelines

This 3rd edition has been updated to reflect current biosafety and biocontainment principles and practices. The document has been written with a performance-based approach, which not only accommodates contemporary state-of-the-art technologies and ever-changing approaches to achieving containment but provides simple and sensible solutions as well. Additions include sections on nonhuman primates, biomedical facilities using sheep as research animals, arthropods, and toxins. A separate section dedicated specifically to work with mycobacteria has also been included to reflect an ongoing area of concern to biosafety professionals and to outline a stratified approach to containment according to the type of procedures used.



**CSCHAH, Canada**

2<sup>nd</sup> Edition 1996

3<sup>rd</sup> Edition 2004

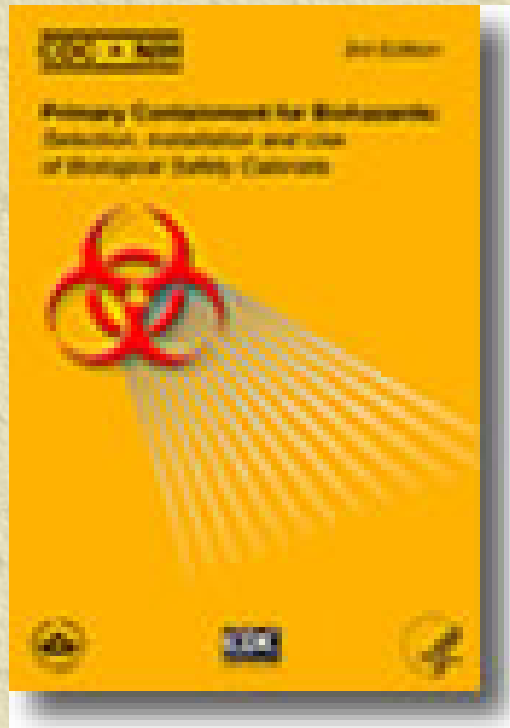
**3<sup>rd</sup> Edition 2004**



# 生物危害：基本防護生物安全櫃選擇安裝及使用 Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets

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**3rd Edition**



**Primary Containment for Biohazards:**

**Selection, Installation and  
Use of Biological Safety Cabinets**

**U.S. Department of Health and Human  
Services**

**Public Health Service  
Centers for Disease Control and Prevention  
*and***

**National Institutes of Health  
September 2007**

# 美國國家衛生基金會



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- ✦ 1944年，一群美國科學家為了回應社會的需求，成立了一個以科學研究為基礎的非營利民間組織——「美國國家衛生基金會（National Sanitation Foundation）。經過60年的發展，美國國家衛生基金會已成為一個具有國際影響力和公信力的機構，並更名為「NSF International」，或簡稱NSF。
  - ✦ NSF的創立宣言，可以讓我們了解NSF的主要工作內容和使命：  
NSF是一個非營利性質的獨立組織，透過標準的制定、教育培訓，及評估檢測的服務，以達到促進公眾健康安全與保護環境的目的

# 美國國家衛生基金會



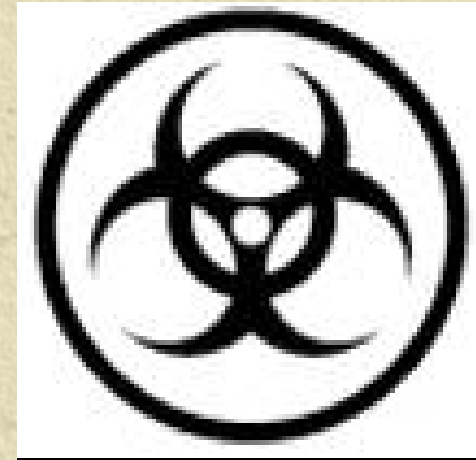
- ✦ NSF 為一非營利性、非政府機關組織，在標準開發、產品認證、教育及公共健康及安全之風險管理等領域扮演著世界領先者的角色。成立的六十年來，NSF 致力於維護公共健康安全和環境保護。
- ✦ NSF 開發食物、水、室內空氣以及環境等國家認證標準，並透過其公眾健康教育中心提供學習機會；同時也是第三公正檢測服務單位。合作對象包括工業界、政府管理機構及消費者。
- ✦ NSF 於健康及環境科學的科學及技術專業受到廣大的肯定。其專業技術人員均來自公、私立機關具有相關經驗背景的工程師、化學家、毒理學家、衛生保健專家。
- ✦ NSF 的專業形象及技術受到全世界的認同，也成為世界衛生組織 (WHO) 在食品及水安全、室內環境健康合作中心。
- ✦ NSF 的服務範圍遍及世界 80 餘國，其總部於 1944 年成立於美國密西根州安娜堡市。NSF 商標在全世界受到肯定並受到各層級政府管理機構的信賴。

# 生物危害物之分類

## Classification of Biohazards

---

- ✦ Conventional Agents
- ✦ Unconventional Agents
- ✦ Recombinant DNA
- ✦ Tissue Culture
- ✦ Animal Work
- ✦ Anatomical Specimens



# 如何達生物安全

## What is Biosafety

---

✦ Measures employed when handling biohazardous materials to avoid infecting oneself, others or the environment.

✦ Achieved through

- Engineering Controls
- Administrative Controls
- Practices and Procedures
- Personal Protective Equipment

# 工程控制 Engineering Controls

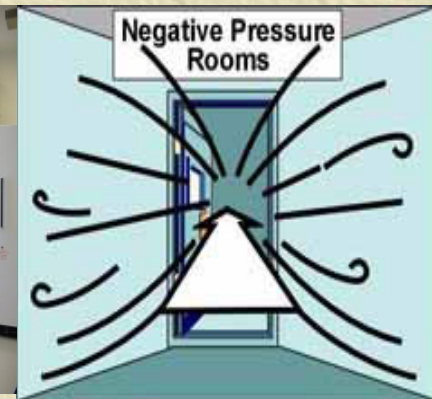
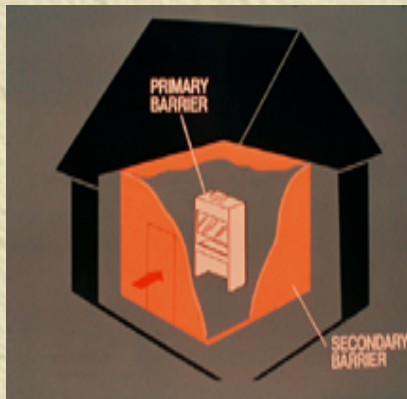
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- ✦ Consist of substitution, isolation, ventilation, and equipment modification.
- ✦ These controls focus on the source of the hazard, unlike other types of controls that generally focus on the employee exposed to the hazard.
- ✦ The basic concept behind engineering controls is that, to the extent feasible, the work environment and the job itself should be designed to eliminate hazards or reduce exposure to hazards

# 暴露預防 Preventing Exposures – Engineering Controls

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- ✦ Ventilation and Exhaust
- ✦ Directional Air Flow
- ✦ Air Filtration
- ✦ Biological Safety Cabinets



# 管理控制

## Management Controls

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- ✦ Management controls may result in a reduction of exposure through such methods as changing work habits, improving sanitation and hygiene practices, or making other changes in the way the employee performs the job.



# 個人防護具

## Personal Protective Equipment

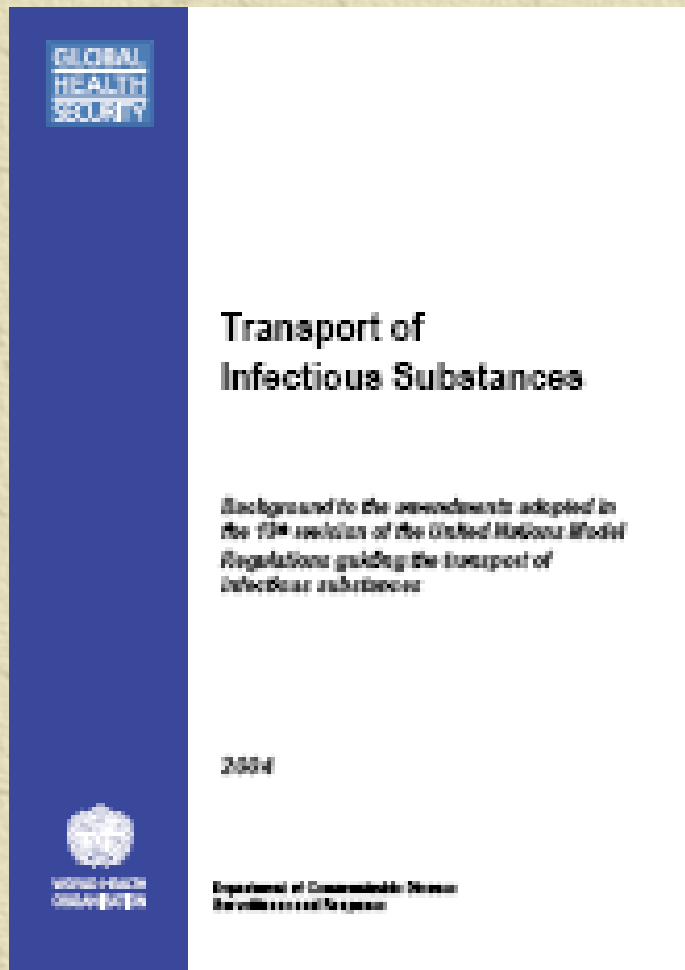
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- ✦ When exposure to hazards cannot be engineered completely out of normal operations or maintenance work, and when safe work practices and administrative controls cannot provide sufficient additional protection from exposure, personal protective clothing and/or equipment may be required.

# 感染性物質傳輸

## Transport of Infectious Substances

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- Transport of Infectious Substances**  
**PART I - BACKGROUND**
- Foreword
  - Introduction
  - Aim of this document
  - Rationale for changes in the United Nations Model Regulations
  - Transmission of infection and risks in transport of infectious substances
  - References
- PART II - UNITED NATIONS MODEL REGULATIONS**
- Key text of 13th edition of the United Nations Model Regulations with explanatory comments
  - Annex 1
  - Annex 2

# Proper packing and labeling of the secondary container for shipping of diagnostic

- ✦ 所有運送的檢體(UN 3373、UN 2900 或 UN 2814 類運輸)都必須遵照危險品一覽表(Dangerous Goods Index) 規定，以三層容器作三層包裝。



# 實驗室生物安全

## Biosafety in Laboratory

---

### 引發動物或人類疾病

天花病毒(Small pox virus)、炭疽桿菌(*Bacillus anthrax*)、口蹄疫病毒(FMD virus)、肺結核桿菌(*Mycobacterium tuberculosis*)

### 與外界病毒產生核酸重組

流感病毒(Influenza virus)、輪狀病毒(Rotavirus)、Norovirus

### 與外界細菌交換遺傳物質

抗藥性或毒素基因

# 感染性廢棄物處理

## Managing infectious waste

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- ✦ The safe disposal of infectious waste is essential to control the risk of cross-infection.
- ✦ Guidelines provided by your employer should always be adhered to when dealing with waste disposal.

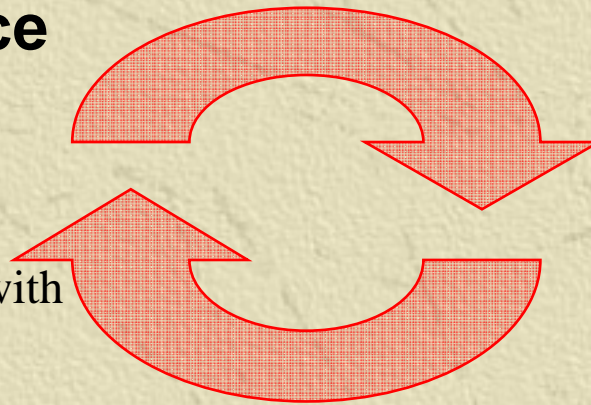
# 實驗室感染

## Laboratory Acquired Infections

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### Infection Source

- ✦ Cultures and stocks
- ✦ Research animals
- ✦ Specimens
- ✦ Items contaminated with above



### Susceptible Host

- ✦ Immune system
- ✦ Vaccination status
- ✦ Age

### Route of Transmission

- ✦ Percutaneous inoculation
- ✦ Inhalation of aerosols
- ✦ Contact of mucous membranes
- ✦ Ingestion

# 風險評估

## Risk assessment

---

**The IBC shall examine agent use and will examine factors such as:**

- ✦ Virulence/pathogenicity/infectious dose**
- ✦ Environmental stability of the agent**
- ✦ Route of spread, communicability**
- ✦ Quantity/concentration/volume of agent used**
- ✦ Vaccine/Treatment availability**
- ✦ Allergenicity.**

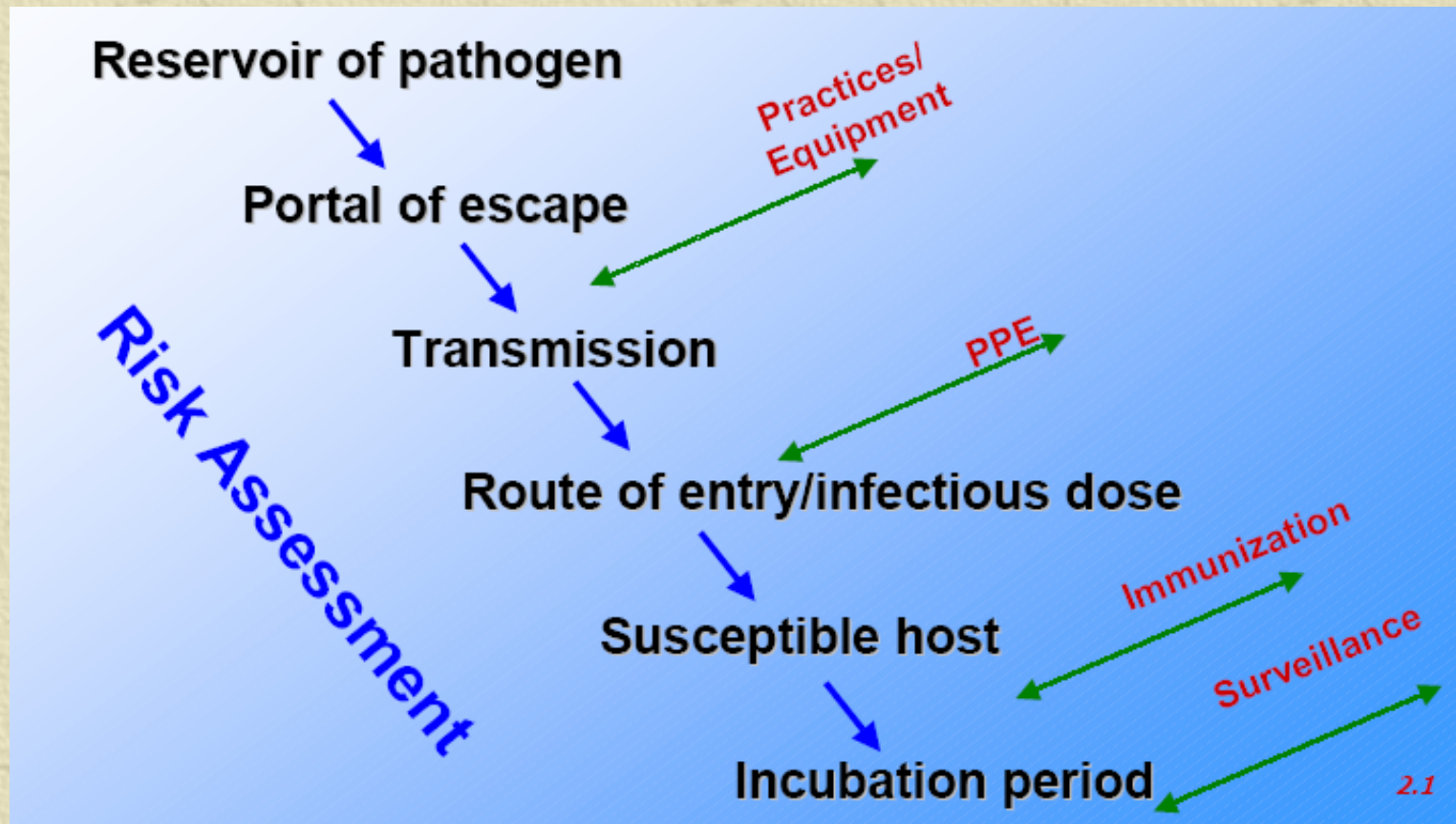
# 風險評估

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1. 評估實驗室個人及個人安全需求
2. 評估適當的防護等級及操作需求
3. 決定個人防護裝備
4. 決定訓練需求
5. 決定設置機構之責任義務
6. 決定生物保全需求
7. 符合法規需求



The backbone of practice of biosafety is risk assessment.



# 病原特性

## Pathogen Characteristics

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We must think of the characteristics of a pathogen in order to determine how best to contain it.

- ✦ Ecotropic pathogens are less risk than amphotropic pathogens because **amphotropic** can infect humans.
- ✦ Some pathogens are carried by **vectors** (e.g., mosquitoes and malaria).
- ✦ **Survivability in the environment** varies greatly among pathogens, from minutes to years.
- ✦ Virulence can also vary greatly, even among different **strains** of the same microbe.
- ✦ Some pathogens produce **toxins**, many do not.
- ✦ Whether a pathogen **stays local** in the host or goes systemic (**spreads to other organs**) greatly affects virulence and host survival.

# 宿主 Host Susceptibility

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- ✦ Age
- ✦ Immune Competence
- ✦ Medication (Illness or disease present)
- ✦ Nutritional Status
- ✦ Pregnancy
- ✦ Metabolic Disorders
- ✦ Malignancy
- ✦ Allergies
- ✦ Inherited genetic factors

# 傳輸途徑

## Routes of Transmission

- 
- ✦ Fecal - oral
  - ✦ Vector – e.g., mosquito
  - ✦ Mucosal (splash)
  - ✦ Cuts, scratches, bites
  - ✦ Aerosol, inhalation \*\*

\*\* Aerosol transmission tends to be the most hazardous and hardest to contain. We will give these some additional consideration

# 環境因素

## Environmental Factors

---

### ✦ 操作病原體的量

> 10 litres usually requires large scale containment

### ✦ 病原體濃度

臨床檢體- less concentrated

培養 – may contain very high numbers of agent

### ✦ 檢體來源

內在 found naturally in environment

外來 not naturally present in environment

外洩危害 Risk to environment if accidentally released

# 可能產生生物氣懸膠的操作

## Some Common Activities That Generate Aerosols

---

- ✦ Vortexing
- ✦ Pipetting
- ✦ Sonication
- ✦ Electroporation
- ✦ Popping tube caps
- ✦ Flame sterilizing tools
- ✦ Flow cytometry
- ✦ Centrifugation
- ✦ Infected animals

# 生物實驗室其他危害項目

## Some Other Hazards

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- ✦ Bloodborne Pathogens – for those working with human blood or tissue
- ✦ Mixed Hazards – for those who use chemical and biological materials combined
- ✦ Physical Sharps Hazard – for needles and broken glass

# 血媒傳染病原微生物

## Bloodborne Pathogens

---

**Occupational Exposure to Bloodborne Pathogens**  
**Occupational Safety & Health Administration (OSHA)**  
29 CFR 1910.1030

- ✦ Universal Precautions – handle human blood, body fluids and tissues as if they harbor pathogens like HIV, Hep B, etc
- ✦ Use BSL 2 containment:
  - ◆ Protect against cuts, needle stick injuries
  - ◆ **Use a BSC for aerosol control**
  - ◆ Hepatitis B **vaccine** recommended
  - ◆ Wear gloves, lab coat, safety glasses, etc
  - ◆ **Decontaminate spills with approved disinfectant**



# 人體細胞組織

## Human Tissue and Fluid

- 
- ✦ Use BSL 2 work practices and procedures.
  - ✦ Additional requirements for HIV work.
  - ✦ Everyone needs to be offered the Hepatitis B vaccine.
  - ✦ Develop specific exposure plan SOPs.
  - ✦ Specific training is required.
  - ✦ Review needle/syringe use and replace with “safe” devices.
  - ✦ Exposure incidents must be followed up.

國內主管機關訂定「人體細胞組織優良操作規範」適用於人體細胞組織物，其製造所使用之方法、設施及管制措施，包括人體細胞組織提供者之篩檢與檢驗、人體細胞組織物之採集、處理、貯存、標示、包裝及配送等過程。

# 複合性危害 Mixed Hazards

## Chemical and Biological

### – Some Lab Practices

---

- ✦ Door closed: negative air pressure 負壓
- ✦ Limit/Restrict access to lab 門禁
- ✦ Use of signs/labels 標識
- ✦ **Minimize aerosol production 減少氣霧產生**
- ✦ Containment: fume hoods for chemicals 排煙櫃
- ✦ PPE required: gloves, lab coats, safety glasses, respirators in some cases 個人防護具
- ✦ High degree of caution with sharps 尖銳物使用
- ✦ Decontaminate surfaces and equipment 設備清消

# Decontaminants and Their Use in Laboratories

## 消毒滅菌

Decontaminant	Active Ingredient/ Concentration	Temp (°C)	Contact time (min.)	Vegetative bacteria	Lipo viruses	Tubercle bacilli	Hydrophilic viruses	Bacterial spores
Autoclave	Steam	121	50-90	+	+	+	+	+
Incinerator	Heat	649-929	1-60	+	+	+	+	+
Phenolic compounds	0.2-3%		10-30	+	+	+	±	-
Chlorine compounds	0.01-5%		10-30	+	+	+	+	±
Alcohol (ethyl or isopropyl)	70-85%		10-30	+	+	+	+	+
*Formaldehyde	4-8%		10-30	+	+	+	+	+
*Glutaraldehyde	2%		10-600	+	+	+	+	±
Hydrogen peroxide	6%		10-600	+	+	+	+	+

# 動物實驗生物安全

## Biosafety Hazards when Working with Laboratory Animals

---

- ✦ **Sharps**: claws, teeth, surgical instruments, edges on animal cages
- ✦ **Zoonoses**: human pathogens which are often asymptomatic in the animal
- ✦ **Surface Contact**: blood, body fluids
- ✦ **Allergens**: dander, fur, dust, bedding
- ✦ **Vectors**: insects, parasites

# 機構內生物安全委員會考量事項

## IBC Considerations in the Review of Animal/Biohazard Experiments

---

- ✦ **Risk Determination** 判斷風險
- ✦ **Routes of Transmission** 傳輸途徑
- ✦ **Medical Surveillance** 醫學監督
- ✦ **Engineering Controls** 工程控制方法
- ✦ **Personal Protective Equipment Use** 使用個人防護具
- ✦ **Facility Design, both laboratory and vivaria** 設施安全設計
- ✦ **Zoonoses** 人畜共通傳染病
- ✦ **Vectors** 病媒

# 動物實驗暴露途徑

## Routes of Exposure in Animal rocedures

- 
- ✦ Parenteral Inoculation (needle stick)
  - ✦ Subcutaneous wound (bite or scratch)
  - ✦ Surface Contact (contaminated work area)
  - ✦ Ingestion (hand to mouth, food in lab)
  - ✦ Inhalation (aerosol-generating procedures)
  - ✦ Ocular (hand to eye, cleaning infected bedding)
  - ✦ Mucous Membrane (aerosol droplets in face)

## Some Zoonotic Agents Associated with Animal Usage 人畜共通傳染病

---

The IBC should become familiar with zoonotic organisms often associated with specific animal subjects.

### TYPE

### EXAMPLE

✳ Bacteria

*Salmonella typhi*(dogs)

✳ Virus

*Herpes B Virus* (macaques)

✳ Fungi

*Histoplasma capsulatum*(birds)

✳ Parasites

*Toxoplasma gondii*(cats)

✳ Rickettsia

*Coxiella burnetti*(sheep)

# 接觸動物血液注意事項

## Contact With Animal Blood

-----  
The IBC must review procedures that may involve release of blood or body fluids, such as necropsy:

- ✦ The body fluids of infected animals may be a potential source of disease.

被感染的動物血液潛藏致病原

- ✦ Wild or feral animals may not be screened for all potential diseases and many organisms are asymptomatic in animals.

無法全部篩選全部疾病且許多致病原在動物是無症狀的

- ✦ Therefore, handle animal blood as if it were infectious, similar to the approach taken with human specimens (Universal Precautions).



# 過敏原 Allergens

---

The IBC should work with the Occupational Health Physician on assessing the following risks:

- ✦ Animals shed hair and fur which may exacerbate existing allergies.
- ✦ Animal bedding may also be a potential source of allergens and must be handled in a manner to minimize aerosols.
- ✦ Animal urine may have proteins that cause allergies in humans.
- ✦ Animals may also track dirt or dust from outside that can cause discomfort.

# 病媒與中間宿主

## Vectors and Possible Intermediate Hosts

---

The IBC must be cognizant of vector borne illnesses:

### **Wild and Feral Animals...**

- ✦ may have biting insects such as **fleas or ticks** that may carry disease

### **All Animals may:**

- ✦ attract **flies** that are around feces or food/water
- ✦ attract **mosquitoes** that can also harbor disease (if work is conducted outside)

The IBC must determine if the animal experiment will be conducted with an intermediate host as part of an evaluation of the life cycle, such as with snails and *Schistosoma mansoni*.

# 危害分析評估

## Job Hazard Analysis

---

- ✦ 發展或更新標準實驗步驟 Developing or updating Standard Operating Procedures (SOP)
- ✦ 訓練操作者 Training employee: training directed to most hazardous operations
- ✦ 查核 Conducting inspections: to identify hazard
- ✦ 意外事件調查 Investigating accidents: comparison in procedures performed to determine if employee training had been adequate
- ✦ 觀察及評量操作情況 Observe and verify employee performance (as in containment laboratory operations)

# 職務危害評估

## Job Hazard Analysis

Job on Operation title

日期Date Performed

地點Job Location

操作者Title of Employee Doing Job

危害Special or Primary Hazard

個人防護裝備Personal Protective Equipment required or recommended

**實驗步驟Basic Job Steps**

**可能的危害Existing and potential hazard**

**建議Recommended Corrective Measures**

細胞繼代

1. 打開瓶蓋  
Remove tube cap

1. 手接觸瓶蓋  
Hand touch tube cap

戴手套Wear latex disposable gloves for Handling culture

2. 吸取培養基  
remove media from plate

2. 液滴掉落  
Dropping culture

全面罩防護潑濺Full face shield required to protect against splash

更新細胞計數器Replace of an old cell counter generating aerosol with a new one

病毒濃縮.....

萬一離心管破裂What if the centrifuge tube broke while spinning?

萬一停電What if the power supply is interrupted?

# 緊急應變 Emergencies

---

✦ Develop and practice plans for:

- ✦ Spills: large spills, spills inside BSC 洩漏
- ✦ Accidental exposures: needlesticks, eye/mucous membrane splash, breathing aerosols 意外事件
- ✦ Power/Utility failures: BSC, freezers, ventilation, lights, water 停電
- ✦ Fires 火災
- ✦ Medical emergencies 急救

# Facility Design and Construction:

## Engineering Design Issues

BSL Laboratories

Guidelines, Standards, Codes and Regulations

Cotainment Barriers

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Architectural Design Issues

Commissioning

Mechanical Design Issues

Other Engineering Design Consideration

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# Facility Design and Construction: Engineering Design Issues

## Mechanical design issues

HVAC system, air  
flow, diffuser, HEPA, damper, BSC, plumbing  
systems, drainage, autoclave, decontamination  
ports, other critical components

---

## Other engineering design consideration

space pressure control, control system, space  
pressure control, flow  
tracking, alarm, monitor, sensor, electrical  
issues, phone/intercom, door  
interlock, penetration, security/entry control

# 圍阻體(Containment)

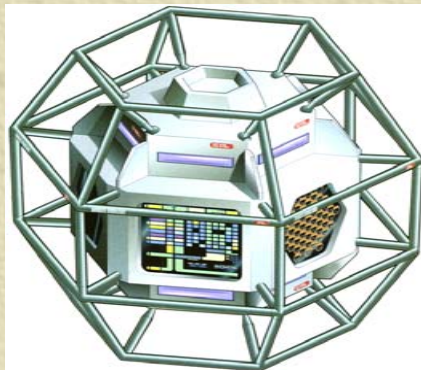
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## Containment:Definition

Term used for describing safe methods for managing infectious agents in the laboratory

## Containment:Purpose

Reduce or eliminate exposure of laboratory workers and outside environments to potentially hazardous agents

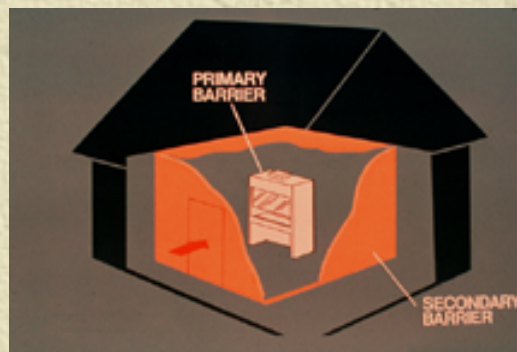




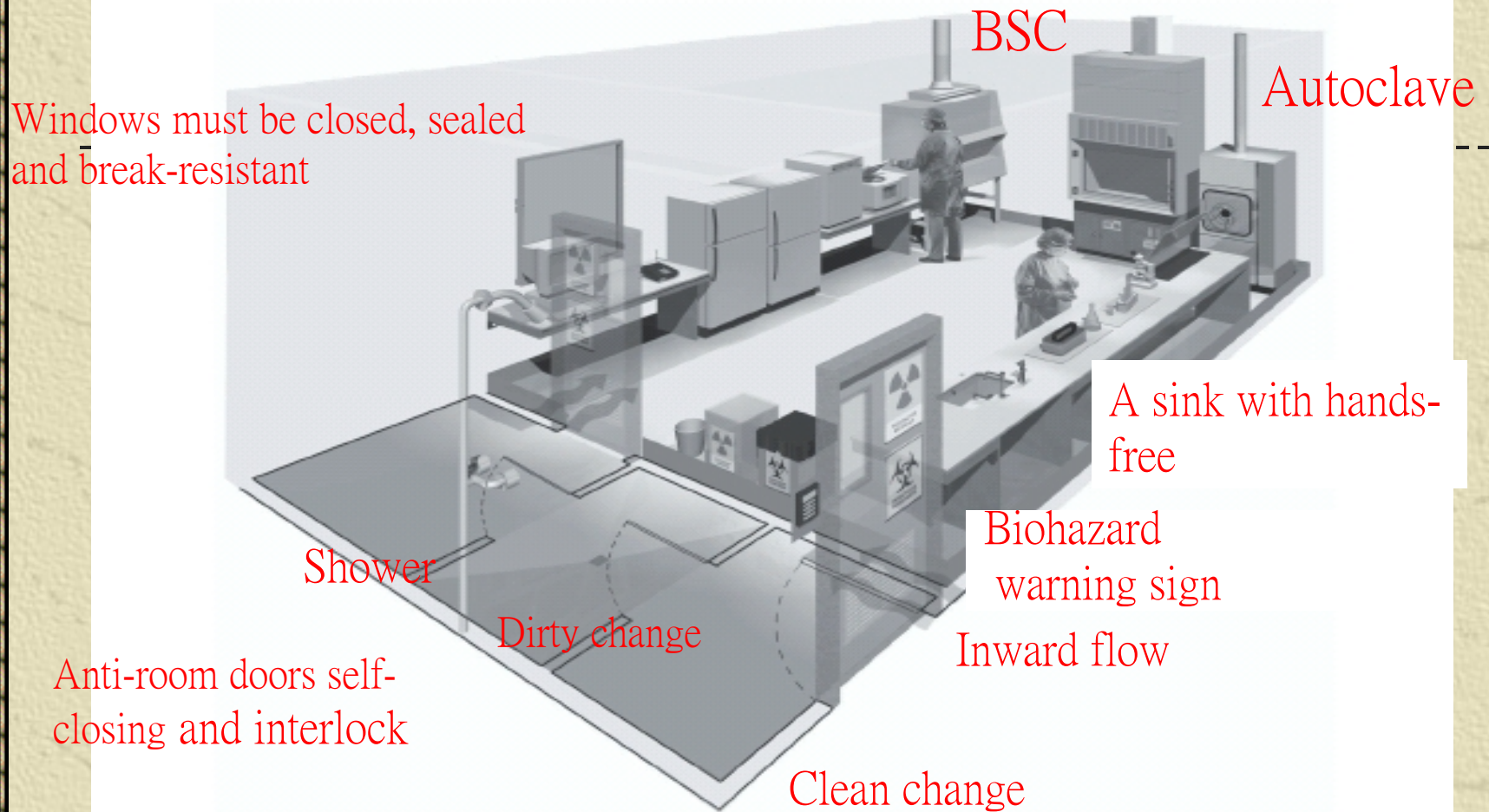
# 安全防護基本原則

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- ✦ Containments based on the combination of:
  - Work practices and techniques
  - Safety equipment
  - Laboratory facilities



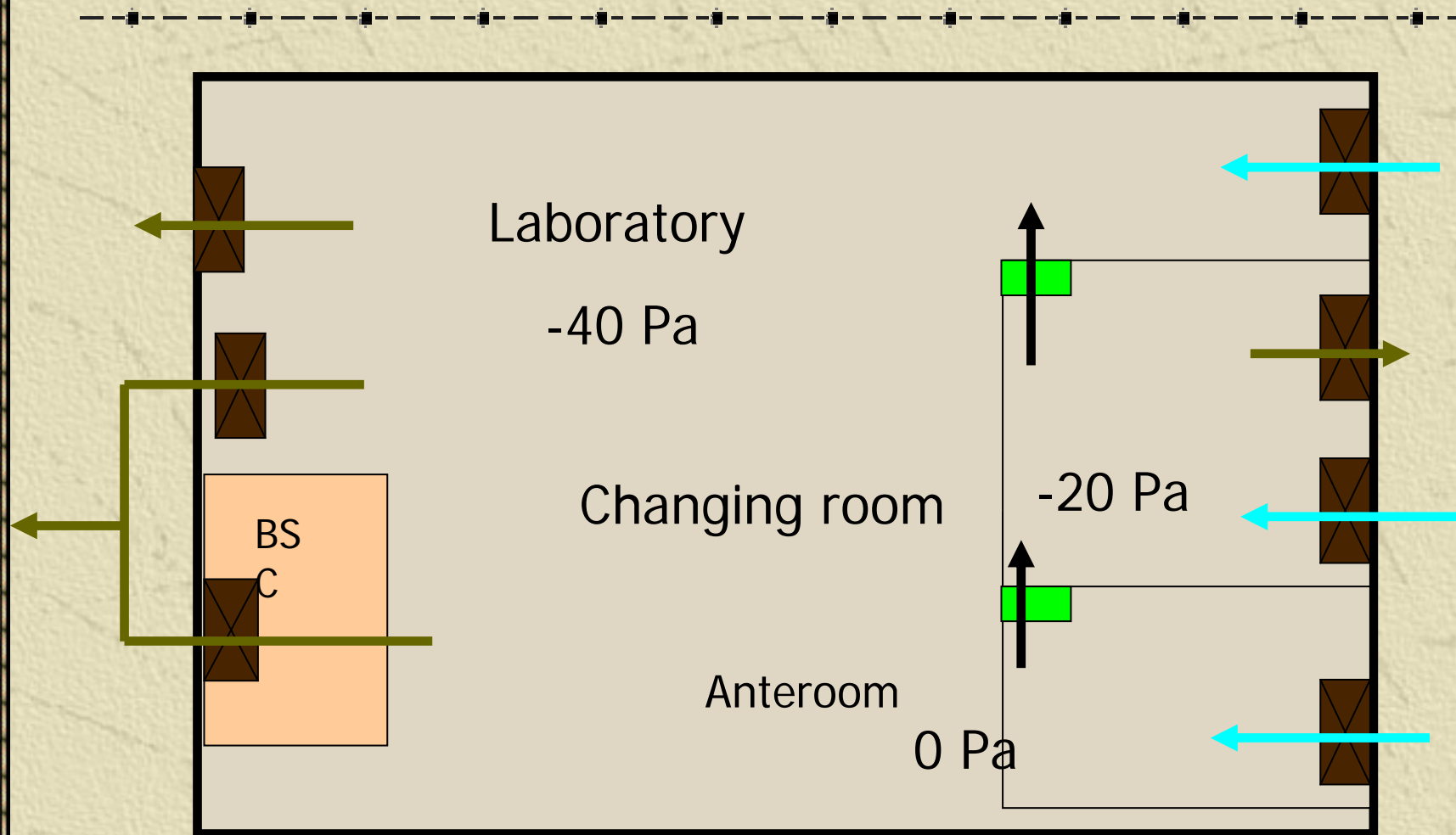
#### 4. THE CONTAINMENT LABORATORY – BIOSAFETY LEVEL 3



**Figure 4. A typical Biosafety Level 3 laboratory**

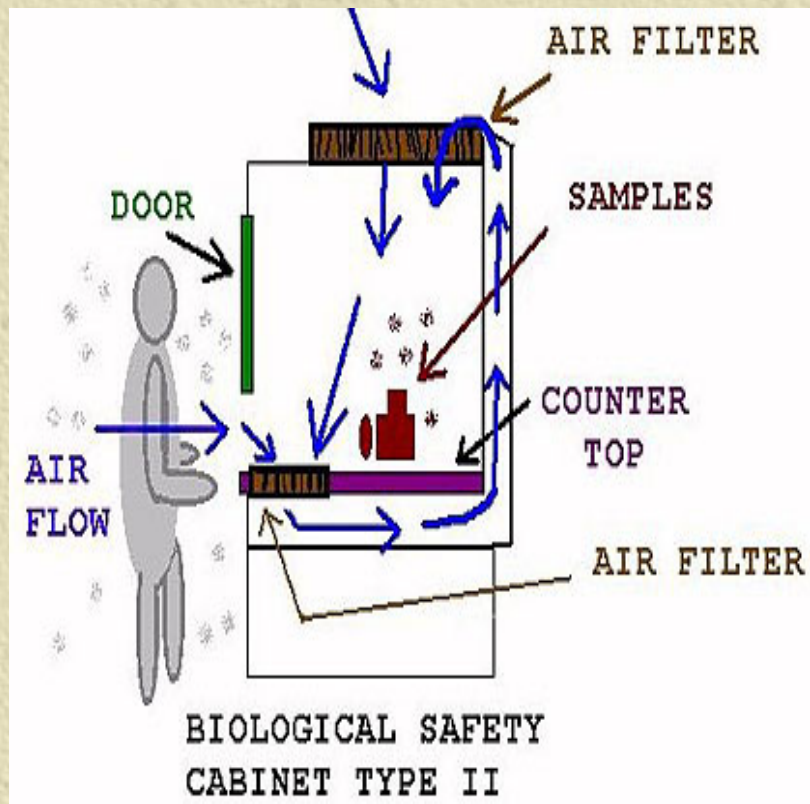
(graphics kindly provided by CUH2A, Princeton, NJ, USA). The laboratory is separated from general traffic flow and accessed through an anteroom (double door entry or basic laboratory – Biosafety Level 2) or an airlock. An autoclave is available within the facility for decontamination of wastes prior to disposal. A sink with hands-free operation is available. Inward directional airflow is established and all work with infectious materials is conducted within a biological safety cabinet.

# 排氣系統定向氣流分佈



# 生物安全櫃

## Biological Safety Cabinets (BSCs)



- ✦ BSCs work to protect workers and material from microbes.
- ✦ Avoid working with volatile chemicals in a BSC.

# 生物安全櫃(Biological Safety Cabinet ) International Standardization

---

## ✦ National Sanitation Foundation

-NSF/ANSI 49

## ✦ European Standard

-EN12469

## ✦ Australian Standard

-AS2252.2 AS1807

# 生物安全櫃種類與氣流分佈

*Table 9. Differences between Class I, II and III biological safety cabinets (BSCs)*

BSC	FACE VELOCITY (m/s)	AIRFLOW (%)		EXHAUST SYSTEM
		RECIRCULATED	EXHAUSTED	
Class I <sup>a</sup>	0.36	0	100	Hard duct
Class IIA1	0.38–0.51	70	30	Exhaust to room or thimble connection
Class IIA2 vented to the outside <sup>a</sup>	0.51	70	30	Exhaust to room or thimble connection
Class IIB1 <sup>a</sup>	0.51	30	70	Hard duct
Class IIB2 <sup>a</sup>	0.51	0	100	Hard duct
Class III <sup>a</sup>	NA	0	100	Hard duct

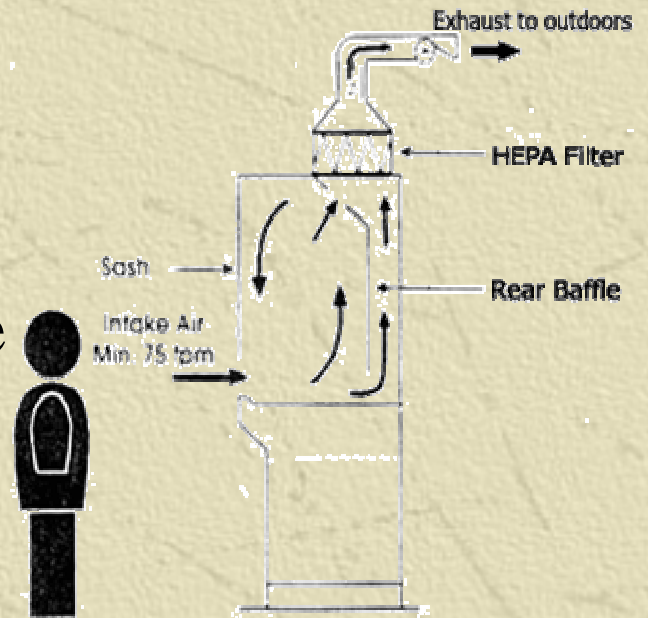
NA, not applicable.

<sup>a</sup> All biologically contaminated ducts are under negative pressure or are surrounded by negative pressure ducts and plenums.

# Fielding Testing and Certification Biological Safety Cabinet

---

- ✦ Downing velocity profile test
- ✦ Inflow velocity test
- ✦ Airflow smoke patterns
- ✦ Cabinet leak test for Class 2 Type A1
- ✦ Site installation assessment Test
- ✦ HEPA filter leak test



# 生物安全計畫

## Biosafety Programs

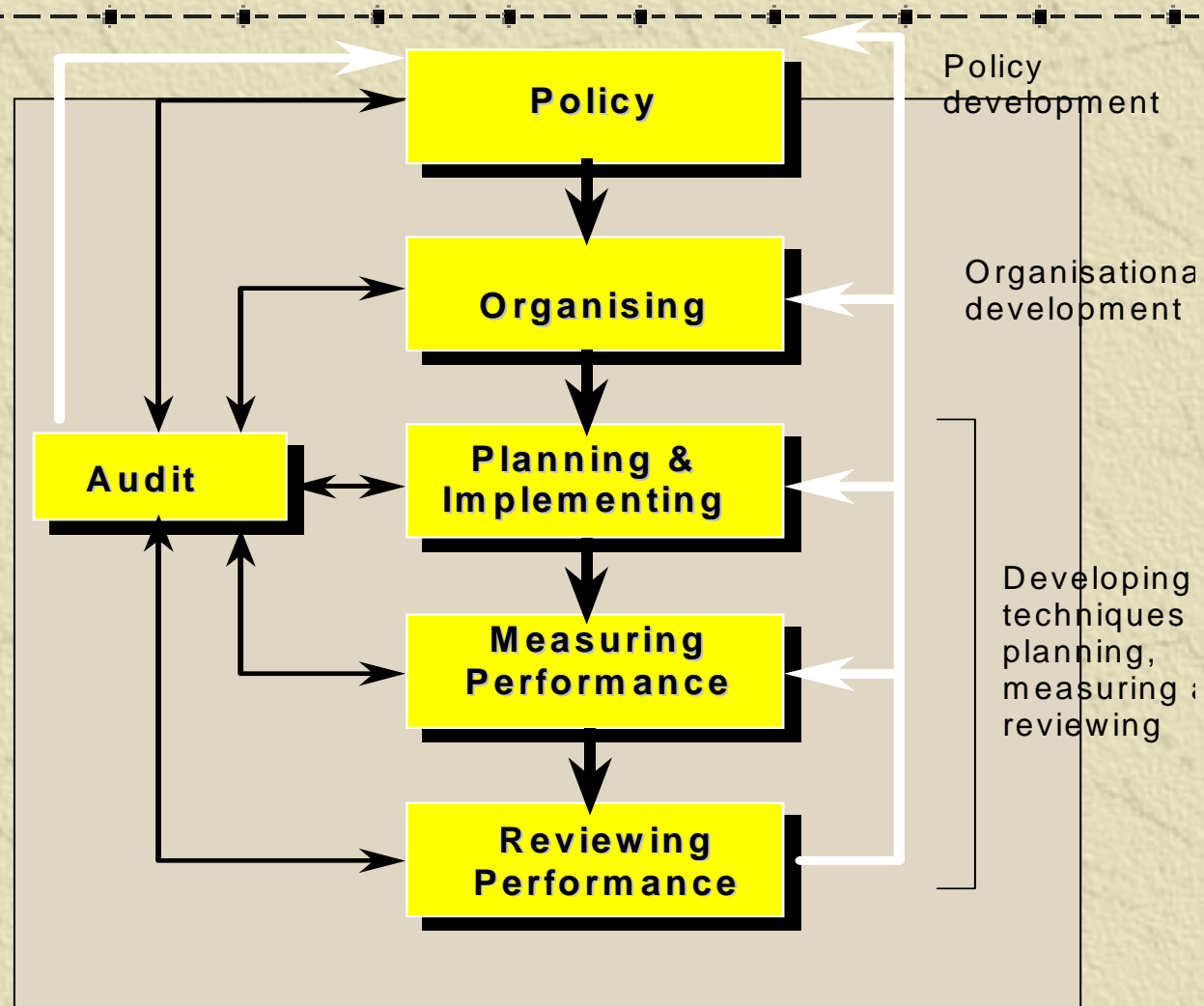
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- ✦ 組織(Organization)
- ✦ 風險評估(Risk assessment)
- ✦ 危害清單(Inventory and registration)
- ✦ 生物安全(Biosecurity)
- ✦ 標準作業程序( SOPs)
- ✦ 管制措施(Control measures)
- ✦ 教育訓練(Training)
- ✦ 緊急應變程序(Emergency procedures)
- ✦ 醫護管理(Medical management)
- ✦ 保持文件與記錄(Documentation & record keeping)
- ✦ 檢體傳輸與接受(Transportation & Receipt)
- ✦ 廢棄物管理(Waste Management)



# 生物風險管理系統

## Biorisk Management System



# Summary

## Basic Principle of Biosafety

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BSL 1 = Practice + Safety equipment + PPE + P1

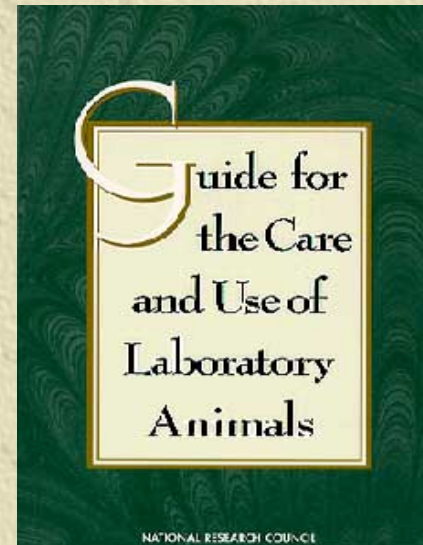
BSL 2 = Practice + Safety equipment + PPE + P2

BSL 3 = Practice + Safety equipment + PPE + P3

BSL 4 = Practice + Safety equipment + PPE + P4

# Thank You For Your Attention

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