出國報告（出國類別：研究）

參加第 53 屆美國生物安全研討會暨訓練課程

服務機關：行政院衛生局疾病管制局

姓名職稱：第 五 組　副組長 曾淑慧

疫苗中心　科長　　李政道

派赴國家：美國

出國期間：99 年 09 月 30 日至 10 月 08 日

報告日期：99 年 12 月 06 日

摘　　要

美國生物安全協會（American Biosafety Association；ABSA）成立於1984年，爲一具國際性生物安全專家代表之民間組織，以協助當地政府建立有關生物安全政策及制度。該協會每年於世界各地舉辦相關生物安全教育訓練、研討會及生物安全年會，並於每年年會前舉辦會前生物安全研習課程，以增進生物安全之提升與新知分享，今年爲第53屆。來自世界各地的的國家或與多生物安全感相關領域之政府及美國官方單位（包括美國疾病管局及美國國家衛生院）官員、學者專家、廠商代表等均齊聚一堂，分享生物安全最新研發成果及策略。

今(2010)年10月，第53屆美國生物安全年會（52nd Annual Biological Safety Conference）在美國科羅拉多州丹佛市凱悅飯店（Hyatt Regency Denver）舉行，本次課程共有30種與生物安全相關之會前課程，可供不同領域及需求的專業人士選擇，其中「BSL-3實驗室之操作與管理（BSL3 Operations and Management）」、「商業模式之實驗室管理規範及認證檢定（A Business Model for Managing Lab Regulatory and Accreditation Inspections）」及「美國國家衛生研究院先進生物醫學研究設施之設計要求（New NIH Design Requirements Manual for State-of-the-Art Biomedical Research Facilities）」等三場課程與個人業務較爲相關，且在台灣，生物安全專家們之間對部份生物安全的軟硬體規範，並無共識。因此希望藉由此次的研習，能了解先進國家的相關規範。以作爲台灣生物安全的軟硬體規範的參考。

藉由此次ABSA及IFBA年會機會，學習並交換國際間生物安全最新資訊及經驗，並取得相關生物安全訓練研習課程之訓練證明，同時建立美國CDC及學術研究機構等與我方之聯繫管道，以擴展國際生物安全技術交流，希望未來能加強與國際間生物安全組織合作關係，達到積極參與國際生物安全事務之目標。以提升台灣的實驗室生物安全且將實驗室生物安全事件的可能性降到最低。

生物安全、生物保全及緊急應變計畫的都必需經由生物風險評估的過程，才得以有效的被建立。執行生物風險的目的最主要的目的是降低風險及使工作者與環境或得最大保護。並且必須有一個觀念就是”風險永遠不可能是零”。 執行生物風險的目的最主要的目的是降低風險及使工作者與環境或得最大保護。風險評估是一個群策群力共同合作的過程，參與的對象包括生物安全委員會成員、實驗室PI、保安人員、法規部門人員等等。評估的範圍除了是微生物學領域還有分子生物學領域、獸醫學領域、環境保護、工程等等….風險評估常須依循病原生物特性、宿主及環境等三個因素間的相互作用進行考慮。

目　　次

目　　的

美國自 1984 年成立美國生物安全協會，即不斷致力於實驗室生物安全事項的提升，由早期的生物安全(Biosafety)演進到注重到生物保全(Biosecurity)，美國生物安全協會所舉辦之年會今年也進入第 53 屆，雖然 GMP 的藥廠有 GMP 法規規範，但作爲疫苗的生產的疫苗株，其本質都是馴化後病原體，因此此行目的主要藉由參加國際生物安全訓練課程，汲取最新國際生安資訊及觀摩學習以瞭解在不與 GMP 法規衝突下，如何執行生物安全與生物保全事項的知識與技能。並且經由該協會所舉辦的生物風險評估訓練課程，了解如何建立風險評估的模式和方法，如何透過科學方法建立生物保存及生物安全管理及緊急應變程序，以作爲本局生物安全作爲施行的參考與改進的方向。

美國生物安全協會是目前國際上最具規模之生物安全民間組織，我國疾病管制局爲全國實驗室生物安全管理之主管機關，爲提升我國實驗室生物安全水準，自2005年起每年派員參與ABSA年會，以獲取各國生物安全最新發展動態，藉以提升我國實驗室生物安全管理制度。

「實驗室生物安全」用來敘述於實驗室環境內，處理生物性危害時所應注意及採取的防範措施、安全程序與方法。對於含有生物性危害的作業場所，如生物實驗室、醫療檢驗室，隔離病房等，世界衛生組織（World Health Organization,WHO）與美國疾病管制局（Center of Diseases Control, CDC,USA）等單位建議採用四個等級的管制層面，並定名爲生物安全等級(Biological Safety Level, BSL)第一至第四等級，其各等級均對應有不同的設施設計、防護設備、人員管制、標準操作程序。然而我國對於有關病原微生物實驗室設施設計、管理與查核各方專家仍存有不同看法，藉由此次第53屆美國生物安全協會年會及第21次國際生物安全協會年會之參與，目的在了解並交換國際間對生物安全第三等級實驗室相關問題之政策與管理。

過　　程

一、行程摘要

自 09 月 30 日（週四）自桃園機場搭機出發後，於舊金山轉機飛抵美國科羅拉多州丹佛市。詳細行程如下表：

日期	工作日誌	地　　點	行　程　內　容
99/09/30	啓程	台北→美國丹佛市	路程（舊金山轉機）；抵達
99/10/01 99/10/03	報到	丹佛市	第 53 屆生物安全年會訓練程 第 21 次國際生物安全協會
99/10/04 99/10/06	開會	丹佛市	第 53 屆生物安全年會
99/10/06 99/10/07	返程	丹佛市	第 53 屆生物安全年會 路程（洛杉磯轉機）
99/10/07	返程	丹佛市	洛杉磯飛台北
99/10/08	抵達	台北	抵達

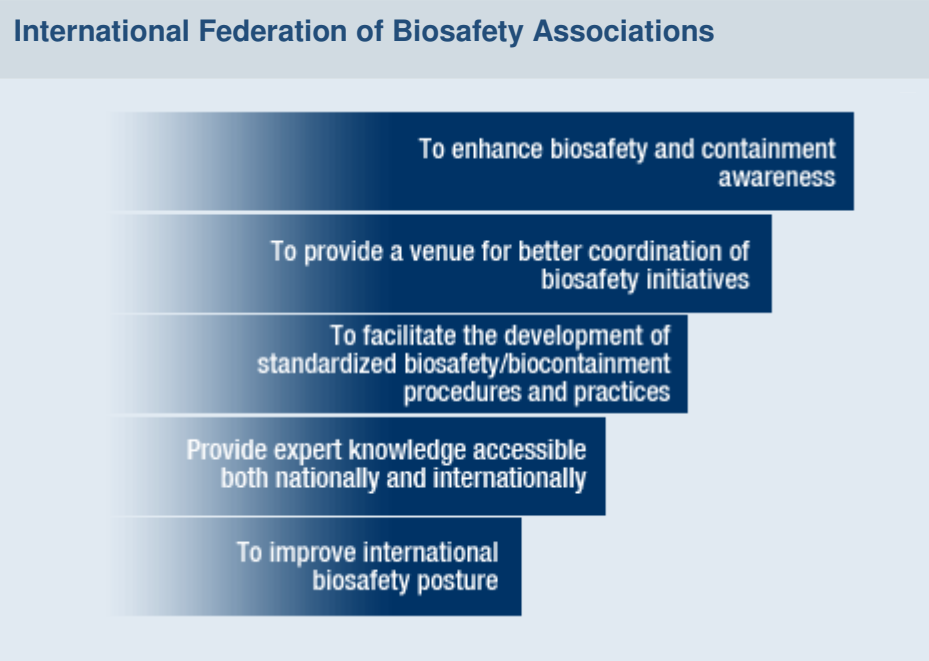
二、美國生物安全協會（American Biosafety Association；ABSA）簡介

美國生物安全協會（American Biosafety Association；ABSA）成立於1984年，爲一具國際性生物安全專家代表之民間組織，以協助當地政府建立有關生物安全政策及制度。該協會每年於世界各地舉辦相關生物安全教育訓練、研討會及生物安全年會，並於每年年會前舉辦會前生物安全研習課程，以增進生物安全之提升與新知分享。ABSA下設有6個工作小組，包括專家研發小組、專業鑑定小組、管理小組、聯盟小組、法規及技術事務小組、會議諮詢小組等，負責生物安全相關事務。

Ben Fontes, ABSA president

三、國際生物安全協會 (International Federation of Biosafety Associations; (IFBA)簡介

國際生物安全協會(International Federation of Biosafety Associations ；IFBA）的前身是國際生物安全工作小組（International Biosafety Working Group；IBWG）秘書處。目前 IFBA 有 13 個會員組織及 9 個觀察員組織（包括 10 個國家屬性或區域性之生物安全協會，共 45 個國家）。我國衛生署疾病管制局(Taiwan CDC)， 於今年申請加入爲觀察員，並獲得大會同意 。參加今年之第 21 次國際生物安全協會年會，爲我國第一次參加國際生物安全協會年會，對台灣生物安全的發展有重要的意義。國際生物安全工作小組（IBWG）開始於 2001 年秋季，這是一個針對生物安全問題廣泛討論的國際論壇，提供一個獨特的平台，使來自不同國家的生物安全專業人士，協同合作發展一個全球生物安全網，其宗旨是透過國家或區域生物安全組織之合作，支援並促進世界各國生物安全政策與制度之能力。



國際生物安全協會（IFBA）成立於 2001 年，成立的宗旨是透過生物安全組織之、政府及專家之合作，支援並促進一個國家或國際間之生物安全。IFBA 成員包括國家及區域性生物安全協會（包括非洲、亞太、中亞及高加索地區、巴基斯坦、日本、韓國、泰國、歐洲、北美洲、墨西哥及南美洲）；非政府組織 （包括國際獸醫生物安全工作小組、藥物生物安全小組、國際第 4 級使用人小組、國際生物安全研究協會、國際生命科學理事會）；政府（美國疾病控制中心、加拿大公共衛生署、全球 G8 夥伴關係計劃、全球 G7 衛生保全行動小組）及其他。

透過成員組織及資源之攜手合作及運用，IFBA 就能有效的持續的對世界各國提供建構生物安全和生物保全之能力方案。

四、全球生物保全和生物安全會議

Biosafety and Biosecurity are central to the global fight against emerging生物安全與生物保全是全球打擊新興infectious disease傳染疾病之關鍵，缺乏可靠的生物安全的實驗室， 其處理危險病原體，不僅對accidental laboratory release or deliberate theft and subsequent實驗人員存在感染的風險，甚至危險病原體之意外釋出、被竊或延伸出之生物恐怖事件都對國家社會產生重大影響。 Further, states lacking adequate laboratory capacity此外，國家如果缺乏能夠勝任生物安全與生物保全重大責任的實驗室，將 無法發現新興infectious disease傳染疾病並對之做出及時反應。This is a global problem that requires a global solution. 生物安全與生物保全是一個全球性之問題，需要全球性之解決策略，由於新興infectious disease傳染疾病之持續發生，這個全球互助合作之呼籲有其深遠之意義。目前生物安全與生物保全在世界各國仍然是一個急迫性、持續性發展之重要議題。爲了這個目的，美國生物安全協會(ABSA)，國際生物安全協會International Federation of Biosafety Associations (IFBA) will host（IFBA）舉辦這次 國際會議，提供這個被忽視的議題一個更大視野的關注平台，並作爲建設長期性全球生物安全與biosecurity capacity building.生物安全能力之行動催化劑。

2004 年 4 月 28 日，聯合國安理會一致根據聯合國憲章第七章之第 1540 號決議案，責成各國建立生物安全措施和防止生物武器擴散機制。2005 年 5 月，世界衛生大會通過第 WHA58.29 號決議案，加強實驗室生物安全，該決議案是一種動員國際資源加強全球生物安全的計畫。 第 58 屆世界衛生大會認識到一些會員國家可能沒有足夠的管控機制，因此大會敦促這些國家動員該國人力與財力資源以提高實驗室生物安全。從 2004 及 2005 年之聯合國有關生物安全決議以來，目前雖然已經取得一些進展， 仍有許多工作有待完成， 因此密集的行動是必需的，運用 IFBA 平台資源協助世界各國建立國家級生物安全及生物保全方案。

基於上述之背景，ABSA 與IFBA會議內容以「全球生物安全與生物保全」之議題進行全球性對話。

五、第21次國際生物安全年會會議記錄

1、主辦：美國生物安全協會(American Biological Safety Association；ABSA)
時間：2010年10月3日13時
地點：美國科羅拉多州丹佛市 Hyatt Regency Denver Hotel 之 Mineral Hall

2、紀錄摘要

2-1.IFBA 共同主席 Maureen Ellis 致歡迎詞。並特別歡迎台灣 CDC 以觀察員身分第一次參加 IFBA 會議。 Maureen Ellis 也介绍「2011 國際生物安全社區建設年」議題內容，IFBA 及 the Elizabeth R. Griffin Research Foundation 將參加該活動。她也感謝 Ben Fontes 及 ABSA 主持第 21 次 IFBA 會議，並感謝秘書處的支持 IFBA 共同主席 Steven Theriault 也發言致詞，並高興看到 IFBA 在過去幾年努力所獲得的成果。ABSA 會長 Ben Fontes 除致詞感謝外並介紹下屆新會長 Karen Byers 的簡歷。

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台灣 CDC 第一次以觀察員身分參加 IFBA 會議

2-2.大會審查第 20 次 IFBA 會議記錄(23 June 2010: Ljubljana, Slovenia)， 摩洛哥生物研究安全協會(Temsamani of the Moroccan Biosafety Association ；MOBSA)的與會代表 Khalid Temsamani 要求秘書處查核非洲生物安全協會(African Biological Safety Association ；AfBSA)爲何否決他們的表決權。 秘書處將與 AfBSA 主席 Willy Tonui 一同討論該案，如果結果有所變更，將公告之，大會期間任何被批准的提案將做成記錄。

2-3.依照議程，大會將回顧審視第 21 次會議目標及宗旨、對會員或觀察員的申請案進行表決、對國際生物安全社區建設年之議題提出說明、提出 2011 年 IFBA 會議案、討論一些新的世界衛生組織將啓動的議題。
秘書處同事Craig Reed則分別對會員及觀察員之出席人員做了介紹。在第21次會議，有3個組織申請會員身份，包括中亞暨高加索生物安全協會（the Biosafety Association for Central Asia and the Caucasus；BACAC）、台灣生物安全協會（Taiwan Biological Safety Association）及阿富汗生物安全暨生物保全協會（Afghan Biosafety and Biosecurity Association），其中秘書處只接受BACAC的組織章程，其他申請人因未遞交申請書及組織章程故未被考慮，BACAC已經投票並接受該組織爲會員身份。另外，申請觀察員身份有4個組織，包括區域新興疾病干預中心（The Regional Emerging Diseases Intervention Center； REDI Center）、加勒比海醫學實驗室基金會（Caribbean Med Labs Foundation）、意大利Landau Network Centro Volta及美國實驗動物科學協會（The American Association of Laboratory Animal Sciences）
。經分開表決後，所有觀察員申請案都被接受了，秘書處歡迎這些組織成爲 IFBA 的新成員，IFBA 主席 Maureen Ellis 也宣示新成員將獲得美國生物保全計畫（the US Biosecurity Engagement Program）之支援，同時表示 ABSA 將與阿富汗生物安全暨生物保全協會共同制訂他們的組織章程。

表決以後， Maureen Ellis 簡單介紹了 IFBA 之組織架構， IFBA 成立於十年前，爲一個非盈利性機構，主席任期二年。十年來 IFBA 組織與運作未有明顯變動，但 IFBA 對會員及活動之發展，有賴 IFBA 執行部門之持續性作爲，以確保會員在授權下達成 IFBA 之任務與願景，因此 IFBA 將參考商業機構之模式，以期更容易獲得資金與合同，也許 IFBA 將在下次會議上公布新的組織架構。

六、第53屆美國生物安全年會會議摘要

1、此次 ABSA 年會議對政策制定者、各國政府、國際援助方案、國際創新解決發展方案利益相關者提供一個全球性論壇，以實現聯合國和世界衛生大會的目標，論壇上與會各國專注於開發方案及方案持續的方式。會議將同時確定緊急風險、重要資源類別並提高對現存全球性生物安全及生物保全差距的承諾與保證，以強化生物安全及生物保全工作並有助於全球對抗新興傳染性疾病，因此會議目的包括：

- 討論全球區域性生物安全缺失及優先事項
- 探討生物安全成本效益及持續性之方案。
- 促進對話並充分運用資源以共同提升區域生物安全能力。
- 強化各國生物安全策略、政策及方案
- 增進各生物安全協會及個人新的視野

今(2010)年10月，第53屆美國生物安全年會（52nd Annual Biological Safety Conference）在美國科羅拉多州丹佛市凱悅飯店（Hyatt Regency Denver）舉行，本次課程共有30種與生物安全相關之會前課程，可供不同領域及需求的專業人士選擇，其中「BSL-3實驗室之操作與管理（BSL3 Operations and Management）」、「商業模式之實驗室管理規範及認證檢定（A Business Model for Managing Lab Regulatory and Accreditation Inspections）」及「美國國家衛生研究院先進生物醫學研究設施之設計要求（New NIH Design Requirements Manual for State-of-the-Art Biomedical Research Facilities）」等三場課程與個人業務較爲相關，且在台灣，生物安全專家們之間對部份生物安全的軟硬體規範，並無共識。因此希望藉由此次的研習，能了解先進國家的相關規範。以作爲台灣生物安全的軟硬體規範的參考。

General session

本次會議報告議題包括「最新生物安全之立法」、「生物保全」、「動物/節肢動物生物安全及分子設計」、「動物房」、「去活化及除污」、「實驗室及操作與除污設計」、「實驗室及工程與建構設計」及「管理方面及職業健康」等，共計 50 場次之演講及報告。會議進行期間約有 75 家廠商參展，並且會場張貼 70 餘篇壁報論文。

藉由此次ABSA及IFBA年會機會，學習並交換國際間生物安全最新資訊及經驗，並取得相關生物安全訓練研習課程之訓練證明，同時建立美國CDC及學術研究機構等與我方之聯繫管道，以擴展國際生物安全技術交流，希望未來能加強與國際間生物安全組織合作關係，達到積極參與國際生物安全事務之目標。以提升台灣的實驗室生物安全且將實驗室生物安全事件的可能性降到最低。

心得及建議

一、 第53屆美國生物安全年會會議心得

綜觀此次三天次大會的內容其會議重心主軸圍繞著教育訓練、生物保全及職業健康。愈來愈多的資訊顯示爲由透過完善與良好的教育訓練才能達到降低生物危害與風險的的機會，生物安全觀念在組織內化的過程，必須對員工不斷施以教育訓練，使其真正明瞭生物安全的意義，主動遵行並嚴格恪守各項準則。根據研究百分之八十的生物危害事件均是人爲因素造成，因此對於如何將生物安全觀念深植而成爲組織文化生物安全是重要的發展方向。對於標準作業程序必須被確實執行與定期評估。人員教育訓練制度必須建立並被嚴格執行，將生物安全觀念內化落實於組織文化內。

二、 BSL-3實驗室之操作與管理（BSL3 Operations and Management）心得

1、本課程將從實驗室操作與管理這二個觀點，說明BSL – 3實驗室日常運作時之重要面向，這對已獲授權的實驗室有幫助。本課程涵蓋操作BSL - 3設施之所有知識，例如核准工作人員、培訓工作人員、職業衛生問題、廢棄物管理、空調及硬體設施維護、設施定期檢查及不同類型的突發事件。

課程也包括操作BSL – 3時其他應注意事項，包括了解何時可以安全進入、何時撤離實驗室、通風失效時該如何處置、進入與離開程序演練、個人防護裝備之選用、實驗標準操作程序範圍內的安全考量、廢棄物處理、清洗設施以及設備如何維修或維護。

本課程以互動方式進行，讓參與者和講師經驗交流，因此不包括特定區域的管理。本課程讓學員掌握基本的風險評估及生物安全的原則。

2、課程目標：

2-1. 確定BSL-3方案之要素及方案評估之方法

2-2. 了解從管理者至使用者之責任

2-3. 對操作手冊、標準作業程序及訓練進行文字說明

2-4. 對年度驗證、緊急反應等闡明其要點

三、 商業模式之實驗室管理規範及認證檢定（A Business Model for Managing Lab Regulatory and Accreditation Inspections）心得

1、本課程在講解實驗室如何進行管理及認證檢定，這個課程在講師帶領下研習驗證程序。

課程目標：

1-1. 學習認證法規及類型

1-2. 認證單位學習如何準備認證規範及認證檢定

1-3. 協助認證單位建立最佳演練清單共享全體性之生物安全

1-4. 收集相關方案與意見並爲未來的認證做好準備

四、美國國家衛生研究院生物醫學研究機構設計新版指引（New NIH Design Requirements Manual for State-of-the-Art Biomedical Research Facilities）心得

1、2008年美國國家衛生研究院出版生物醫學研究機構設計新版指引（Design Requirements Manual；DRM）- 即先前出版的國家衛生研究院設計政策與準則（NIH Design Policy and Guidelines），是唯一對生物醫學實驗室及動物研究機構之相關設計需求提出詳盡解說之著作，它提供該類機構於計畫、程序及設計上之許多方案、策略、指引及其他相關資訊。

DRM 包括 NIH 自己擁有或租用場所之最低設計標準，遵守國家衛生研究的 DRM 以確保這些場所設施品質能支持生物醫學之研究。本課程針對生物醫學或動物研究機構之計畫、程序及設計，提供各類方案、策略、指引及衛生與安全資訊， 特別是生物、阻隔及安全等議題。

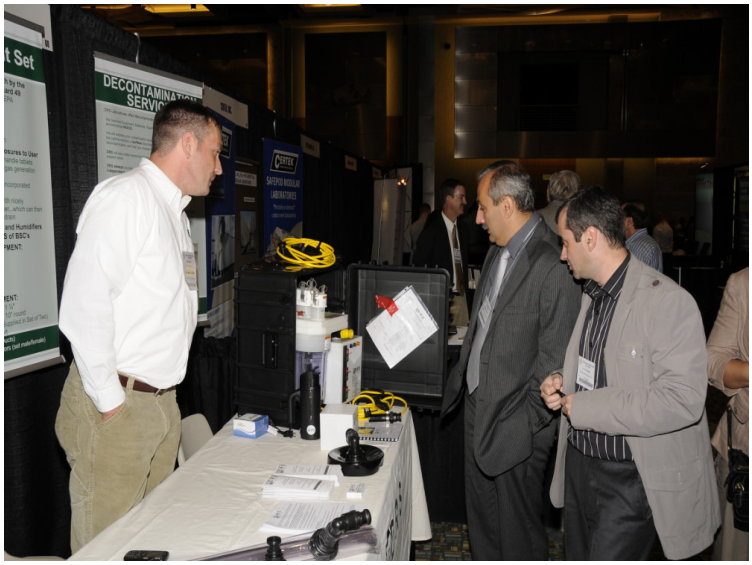
2、課程目標：

2-1. 了解如何設計與建構BSL3 實驗室，以符合生物醫學或動物研究機構、高性能設備設計者、工程師、所有者與實驗室管理者之特殊需求。

2-2. 提供明確的要求、建議、更新資訊和指引

2-3. 確認文件製作及管理

ABSA council and Dr.shu-hui Tseng 2009-2010



ABSA exhibitors in 53rd annual biological safety conference

五、生物安全第三等級實驗室安全認證要求（Biosafety Level 3-Laboratory Certification Requirements）心得

美國國家衛生研究院（National Institutes of Health）生物安全第三等級實驗室安全認證要求（Biosafety Level 3-Laboratory Certification Requirements）與動物實驗和研究有關之生物安全第三等級實驗室（BSL-3 /ABSL-3）是所有實驗室系統設計及操作中，用於生物性危害物質較難以控制之實驗設施。這類實驗室可能影響實驗環境，因此系統設施在初始啓用前、年度計畫或計畫變更、裝修或更換關鍵性的暖氣空調/排氣系統部件（特別是風扇，空氣閥，或風扇電機）時需先通過認證許可。

實驗室認證是系統性的審查所有與實驗室有關的安全功能及程序與制度（如工程控制、個人防護設備、建築及系統的完整性、標準作業程序（SOPs）及文件和記錄保存方法等之行政管理），這種驗證可以確保實驗室所有設施運作及措施謹慎之合理性與安全性，並能將與實驗室操作及使用生物性危害物質有關之風險暴露降至最低。生物安全第三等級實驗室設施之初始標準化及年度認證程序目的在建立生物安全第三等級實驗室之責任制，以確保實驗設施進行適當且定期之維護作爲，並驗證標準操作程序之規範，以保護人、動物、環境和研究的完整性。 因此，管制實驗室之認證有助於：

1. 確保實驗室設施、行政管理及控制工程之正常運作。
2. 確保個人防護裝備（Personal protective equipment ；PPE）之完整及正常，以維護工作時之人身安全。
3. 確保處理廢棄物及其他潛在性感染性材料之去污系統（Decontamination systems）及洩漏管理（spill management）具備適當的程序，以降低環境和人員的污染。
4. 建立第三等級實驗室之標準作業程序（SOP），以確保實驗室之安全與保全，包括物理，電機，生物及化學控制機制之完整性。

在美國，高防護實驗室之認證，由具備工程、生物安全及職業安全與衛生之專業人士來執行。國家衛生研究院之職業衛生與安全部門（Division of Occupational Health and Safety ；DOHS）負責管理及執行國家衛生研究院院內實驗室及其他高防護設施之認證事宜，必要時，DOHS 可委託提供實驗

室或設施認證的第三者來進行。部分實驗室之認證，其所附之查核清單內容必需完成，並保存此記錄文件，請參閱附錄二。

實驗室設施之重新認證，若以年度認證計畫執行時視爲最低之要求，其比較基準線在於初始之認證，因此需詳細記錄認證過程及測試結果，以提供正確的實驗室操作歷程。

在爲特殊建築物發展認證標準過程中，DOHS 或職司政策與方案評估（Division of Policy and Program Assessment；DPPA）的機關得提出變更設計，以符合現有建物的限制或條件。DOHS 也可徵求其他具相同功能的設計，此設計可能不符合 BSL – 3 的認證要求，但提供實驗室生物安全第三等級的能力，符合實驗室設施的指定用途。

六、實驗室生物保全心得

1、全球生物保全及生物風險管理之背景與現況

2001 年美國發生炭疽桿菌郵件事件後，實驗室生物保全逐漸受到全球矚目，對於惡意使用生物材料之事件，世界衛生組織也於 2002 年第 55 屆世界衛生大會提出呼籲，要求各會員國應提高警覺做好感染性生物材料之管控，並以生物風險管理概念提升實驗室生物保全水準。

2003 至 2004 年間在新加坡、台北及北京所發生之感染 SARS 事件，不但使上述國家提高生物安全意識，生物安全政策得以改善，甚至其他國家也受到影響。世界衛生組織會員國於 2005 年第 58 屆世界衛生大會決議促使各國加強實驗室生物安全防護政策。

全球每天都有有關疾病診斷、人類或動物檢體分析、流行病學研究、科學研究及藥物開發的實驗在生物實驗室中進行，這些實驗室皆與具有危險性之病原體或其產品有著密切的接觸。因此實驗室工作人員必需遵守生物安全相關規定並依循生物倫理規範，使內緣性的生物風險在適當防護措施下可以被控制，以確保工作與材料之安全。但人爲疏失仍是實驗室意外發生最重要的因素，例如不夠專心、迴避責任、不適當之責任歸屬、不完整的記錄、不充足之實驗室基礎設備、拒絕考量倫理規範、缺乏行爲規範等等，都可能造成實驗室感染、生物材料遺失、不當操作，甚至可能出現蓄意破壞意圖之惡意行爲。

病原體及毒素從過去到現在都曾被用來威脅或傷害民眾、擾亂社會、經濟及政治現況，例如天花及小兒麻痺病毒、炭疽郵件之生物恐怖攻擊事件。現今國際社會響應生物安全暨實驗室生物保全之議題，紛紛制訂併施行相關法律規範，包括實驗室生物保全的立法，限制生物材料之持有、使用及取得，以建立全球性之生物風險管理文化與機制。

生物風險管理是一種新的觀念，由生物安全、實驗室生物保全及倫理責任三個要素所組成，以減少或預防實驗室內人爲疏失的發生及其所產生之負面影響。但目前世界各國對有價生物材料必須妥善保護之觀念已經廣爲接受，但各國對實驗室生物保全之原則及執行則尚未獲得共識，使得國際社會要辨識什麼是應該解決並回應的問題成爲一項艱鉅的任務。在公共衛生

的結構裡，世界衛生組織、聯合國糧農組織及世界衛生動物組織所面臨的挑戰，則是如何提出適當的、永續的實驗室生物材料保全建議擴大至生物保全。但生物保全這個名詞在國際組織或國際協議中有許多不同之背景與意義，聯合國糧農組織及世界衛生動物組織將它界定爲食物、農林漁業相關之生物或環境之風險。在生物保全方面，由於 911 的陰影仍壟罩在美國，因此他們對於病原體的管制仍非常重視，生物安全的管制不僅重視病原體的被竊、遺失或遭惡意誤用，更重視病原體相關知識的保全，例如病原體的生物特性、培養方式、保存條件、大量繁殖方式、甚至包括疫苗製造等相關知識，均是列爲生物安全的範圍。

2、實驗室生物安全與實驗室生物保全之名詞意義及關係

實驗室生物安全與實驗室生物保全的目的在於降低不同之風險，但卻有一個共同的目標就是確保有價生物材料的安全。

實驗室生物安全（Biosafety）主要是敘述防護的原則，並說明爲預防非預期性的暴露或病原體及毒素的蓄意釋出，所需之技術及操作層面細節。

實驗室生物保全（Biosecurity）主要是描述實驗室中有價生物材料的保護、控管及責任歸屬，以防止它們未經授權而被取用、遺失、偷竊、誤用、挪移或蓄意釋出。

實驗室生物安全與實驗室生物保全具有互補關係，某些特定生物安全措施的執行就已經涵蓋了部分生物保全的觀點。系統性的執行生物安全規範與操作，可以減少人員意外暴露之風險，同時也可以減少因處理不當、權責不清、保護不週所造成之有價生物材料之遺失、失竊或物用之風險。實驗室生物安全須建立在穩定的、良好的實驗室生物安全之基礎上。

3、物保全之構成要素

生物保全之系統包括環境保全（Physical security）、人員保全（Personnel security）、材料管控措施（Material handling control measures）、運輸保全（Transport security）、資訊保全（Information security）、計畫管理與執行（program management practices）等 5 種要素。

3-1.環境保全（Physical security）

環境保全（Physical security）之主要範圍包括分級保護（Graded protection）、門禁管制（Access control）、入侵偵測（Intrusion detection）及反應系統（Response force）。生物保全與生物安全在環境保全之意義有所不同，生物保全中的環境保全例如門禁管制、入侵偵測，係指對優先保護區（Property Protection Area）、限制區（Limited Area）或清消區（Exclusion Area）之不同等級的生物危險事件施以不同等級的分級保護措施；而生物安全的環境保全是指排氣櫃（Laboratory Hoods）、生物安全櫃（Biological Safety Cabinets）、特定空間之負壓條件（Negative air pressure ），係指強化BSL-1、BSL-2、BSL-3及BSL-4等實驗環境之阻隔能力，以防止危險生物製劑釋出事件之發生。

環境保全的內容必須考慮分級的保護(Graded protection)、門禁管制

(Access control)、侵入偵測(Intrusion Detection)、反應力(Response force)幾個方面。必須針對不同的生物安全等級進行分級的保護(Graded protection)，例如在不同等級的生物危險條件下必須採取不同的措施，不同等級的病原體就必須使用不同等級的的個人防護裝備，或者採行不同的保安措施，其目的是要資源能獲得合理利用。

門禁管制(Access control)是另一項考慮因素，僅有獲得授權的人員才能進入管制區域或存取變原體的權限，可同時採取多項措施已達到管制目的，例如鑰匙、卡片、個人識別碼、密碼或是生物性特徵(指印或眼底掃描)侵入偵測(Intrusion Detection)與反應力(Response force)，雖然一般實驗室都有安全警衛守護，但是在偵測侵入方面顯然是不夠，因此閉路監視系統、磁簧開關、紅外線警報系統均可做爲防止入侵的偵測系統，在獲得入侵的訊息以後，必須採行適當反應措施排除入侵，如防止入侵保全系統與警局連線等。

3-2.人員保全（Personnel security）

生物保全之人員保全係指人員之背景及保證人的查核，以確保人員之誠實與信賴，並禁止未經授權之人員進入保全區。

生物安全之人員保全則指生物安全之人員保全係指人員之背景及保證人的查核，確保人員具有處理危險生物材料之適當證件，並禁止未經培訓之人員操作有生物安全風險之材料。

在人員保全方面必須注意管訪客管制、人員篩選、警衛人員等幾個方面訪客進到管制區內是必須被限制的，而且必須有留存到訪紀錄及離開時間，以利日後追蹤；對於新聘進人員必須經過身家調查再給予其可信任度的工作及門禁管制權限；安全警衛人員是必需的，除了是排除入侵的反應武力，通常他們也是生物保全的第一線。

3-3.材料管控措施（Material handling control measures）

生物保全之材料管控措施係指實驗室有清楚確切之生物材料之存放地點、知悉其用途，以利生物材料遺失或被竊之調查，並指定實驗室工作人員對特殊材料之權限及責任。

實驗室內必須確切明瞭有哪些生物材料的存在?這些生物材料存在哪些地方?有多少的數量?誰擁有權限可以存取這些材料?盤點的時間間隔是多久?做這些管控的目的不是爲了查明生物材料是否遺失，而是爲了營造一個環境，強調這是一個被管控的物質以防止有心人的偷竊與故意的誤用。

生物安全之材料管控措施係指個人防護裝備之使用及預防操作程序偶發之感染。

3-4.運輸保全（Transport security）

生物保全之運輸保全係指生物材料在設施內部或設施之間最妥善之保全運送，且任何一處連結都須有完備之監視。生物安全之運輸保全係指生物材料在實驗室內運送之安全要求，且當感染性材料運出離開實驗室時，也應受國家相關法律規範。

3-5.資訊保全（Information security）

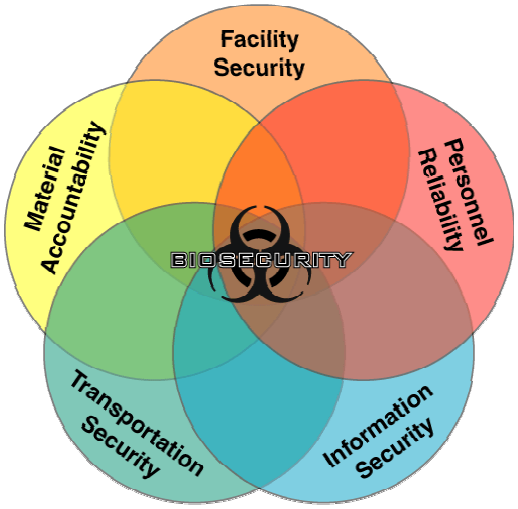
生物保全之資訊保全係指所有與實驗室設施相關之資訊，並採取適當步驟予以保護(例如密碼管制)，以避免第 3 級以上材料失竊之風險。

生物安全之資訊保全係指生物材料所含之資訊，例如對環境的耐受性、培養方式以及基因序列等等。

資訊保全首先要思考哪些資訊室需要被保密，理由是什麼?通常對於資訊的散佈會使大眾具敏感性的資訊是被考慮需要限制資訊的要素。例如病原體生物特性資料、大量培植病原體的技術、疫苗製造技術等資訊都必須被高度保全。

3-6.計畫管理與執行（program management practices）

計畫管理與執行包括實驗室意外事件應變計畫、人員訓練、發展生物安全與生物保全文化、生物風險評估及生物保全風險評估、有價生物材料的辨識等



七、生物風險評估心得

風險評估可包括實驗室風險評估、設施風險評估、生物保全風險評估。生物風險評估就是利用一定的程序來辨識可接受或不可接受之風險，並評估這些風險可能帶來的影響，因此基於實驗室生物安全、實驗室生物保全及預防措施的決擇，實驗室必須進行風險評估。

1、生物風險評估與生物風險管理

生物實驗室是微生物及其組成或衍生物之收集、存放、處理的場所，因此意外感染或未經授權使用、遺失、偷竊、誤用、挪移或蓄意釋出具有風險的生物材料，可能造成危害。生物風險評估是一種過程，用來識別一個已

知或潛在的傳染性病原體或生物材料之危害特徵、或識別造成人員對物質暴露之活動、或識別與實驗室相關感染（laboratory -associated infections；LAI）之暴露或用來辨識某種感染的可能後果，簡言之，生物風險評估就是利用一定的程序來辨識可接受不可接受之風險，並評估這些風險可能帶來的影響，而生物風險管理即是分析並發展可以降低生物風險事件發生的方法及策略。

2、生物性危害風險分類

生物性之危害特性是：它有能力對易感性人類或動物宿主造成感染或引起疾病，其疾病嚴重程度與致病力、有用的預防措施、 有效的治療方法有關。世界衛生組織依據病原體之主要特徵及傳染路徑，將實驗室病原體之風險分成 4 種群組，而美國國家衛生研究院則依病因學也將人類病原體之危害分成 4 種群組，如下表所示：

Table 1: Classification of Infectious Microorganisms by Risk Group

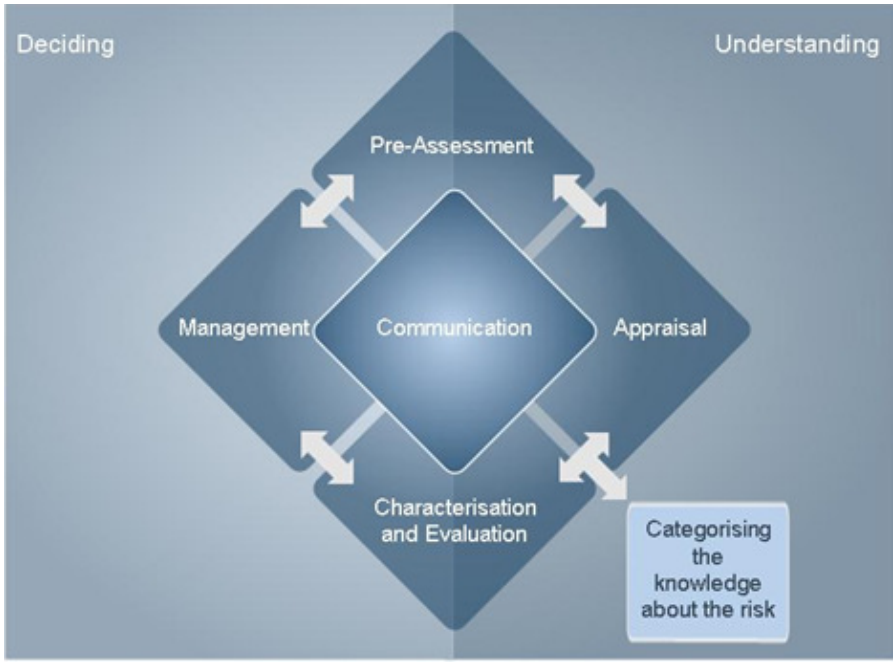
Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules 2002[2]	World Health Organization Laboratory Biosafety Manual 3rd Edition 2004[1]
Risk Group 1	Agents not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism unlikely to cause human or animal disease.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	(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	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(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	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.[3]

3、生物風險評估程序

生物風險評估是一個主觀的過程，判斷通常基於不完整的資訊，也無標準程序來進行生物風險評估，一般根據生物性因素的危害和所需控制措施進行分級，評估各生物性危害級別對健康的影響，並減低工作人員因暴露於有害生物因素而對健康造成的影響，最後採取特別控制措施，包括在研究

或實驗室等工作方面的安全措施，以控制暴露程度。進行生物性危害風險評估時，可根據英國「控制健康危害物質」（Control of Substances Hazardous to Health — COSHH）規列及「危險病原體諮詢委員會」（Advisory Committee on Dangerous Pathogens — ACDP）對生物性危害及所需控制措施的分級作爲參考，藉以確定控制暴露於每一危害級別的最低安全預防措施的要求。下列 5 個原則可幫助我們進行生物風險評估：

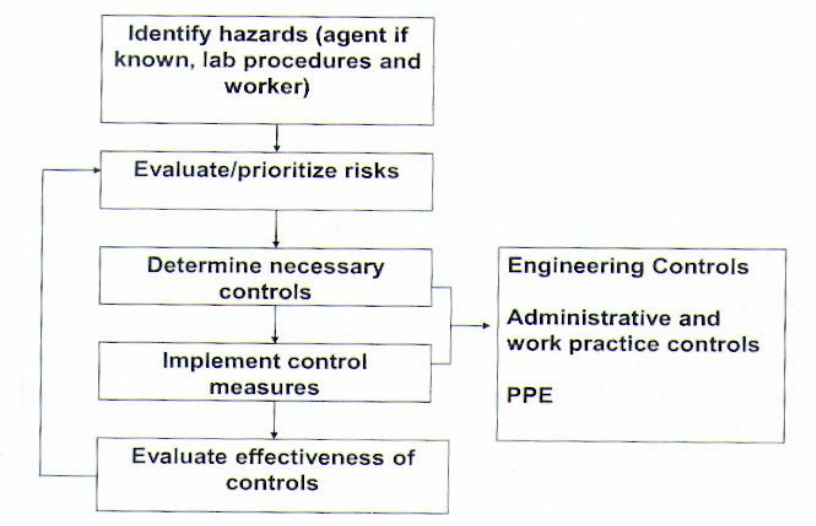
- ●定義危害之性質，確定病原體的危害，並執行初步風險評估
- ●風險評估方法儘可能簡單，對不確定因素之風險評估應該明確，風險評估方法可以合併多種策略
- ●確定病原體的危害，鑑別實驗步驟的危害，並執行初步風險評估
- ●作出適當的生物安全等級的決策，並選擇預防措施
- ●評估工作人員安全操作的熟練度及防護裝備之完整性
- ●邀集生物安全專家、主題專家及國際生物倫理委員會檢討風險評估



4、生物風險評估(Biorisk Assessment)

生物安全、生物保全及緊急應變計畫的都必需經由生物風險評估的過程，才得以有效的被建立。執行生物風險的目的最主要的目的是降低風險及使工作者與環境或得最大保護。

4-1.生物風險評估流程



4-2.什麼是危害(Hazard)?

在進行風險評估之前必需界定什麼危害?它將會發生什麼事?如何發生?有多少發生的機會?嚴重性如何?這些都必需被評估。風險的接受程度是依據危害的可容度而定並非絕對，對危害容忍度愈低相對而言風險指數就愈高，並且必須有一個觀念就是”風險永遠不可能是零”。因此我們必須時時做最好的準備、最高的保護和最少的暴露。

4-3.風險評估

在考慮生物風險時必須考慮病原的存在與否、環境中的安定性、毒性或感染劑量、傳播途徑與積轉、進入人體途徑、它的次宿主、是否產生外毒素、有無疫苗可供預防、是否具傳染性及菌種血清學差異等參數。

多久進行一次風險評估?風險發生的頻率、當改變發生是否進行評估(如新進人員、新的感染性物質、新的設備或技術被使用或新的資訊被運用。

4-4.風險評估的範圍

風險評估是一個群策群力共同合作的過程，參與的對象包括生物安全委員會成員、實驗室 PI、保安人員、法規部門人員等等。評估的範圍除了是微生物學領域還有分子生物學領域、獸醫學領域、環境保護、工程等等….風險評估常須依循病原生物特性、宿主及環境等三個因素間的相互作用進行考慮。

4-5.生物風險評估方式

進行生物風險評估必須評估暴露後可能的不良作用、結果的嚴重度和影響範圍，一樣從病原生物特性、宿主及環境等三個因素進行評估，例如從宿主影響有是不是有致癌性、生殖毒性、感染後有無症狀、急性或慢性、嚴重程度或致死率；環境因素則是考慮有環境汙染問題、對經濟的衝擊程度等等，因此必須套用公式推論可能性與結果之間的關係。

5.生物風險評估方法與模式：

風險是可能（Likelihood）和後果（Consequence）的交集結果，風險評估是指什麼是可接受、能忍受和難容的？標準化的生物風險評估允許評估重複及量化。 可能性是指感染病原體或暴露於感染路徑，後果是指疾病意外暴露。

（1）. 實驗室風險暴露路徑：

Likelihood of infection（based on the routes of infection of the agent）

- Inhalation：Aerosol generating procedures、Accidental aerosol release、Animals、Aerosolization experiments
- Ingestion：Splashes、Waste handling、Contaminated items with potential to enter mouth
- Contact：Splash、Spill、Contaminated surfaces、Animals、Waste
- Percutaneous；Animals、Sharps、Waste
- Vector-Borne

Likelihood of exposure (based on the routes of infection)

- Potential of inhalation exposure
- Potential of ingestion exposure
- Potential of percutaneous exposure
- Potential of contact exposure

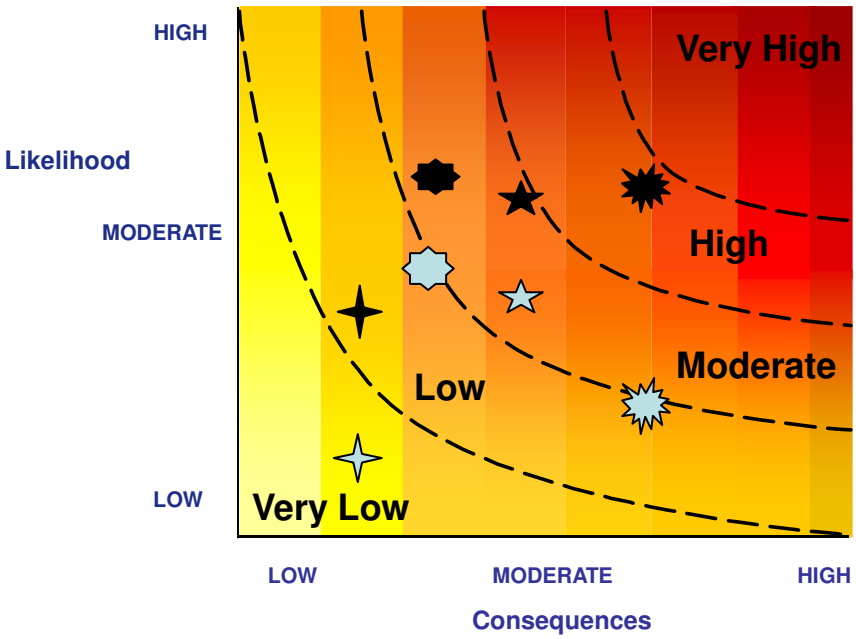
（2）. Biosafety Risk Assessment Methodology （Biosafety RAM）

這是評估風險等級的一種標準化、系統化的風險評估方法，包括：

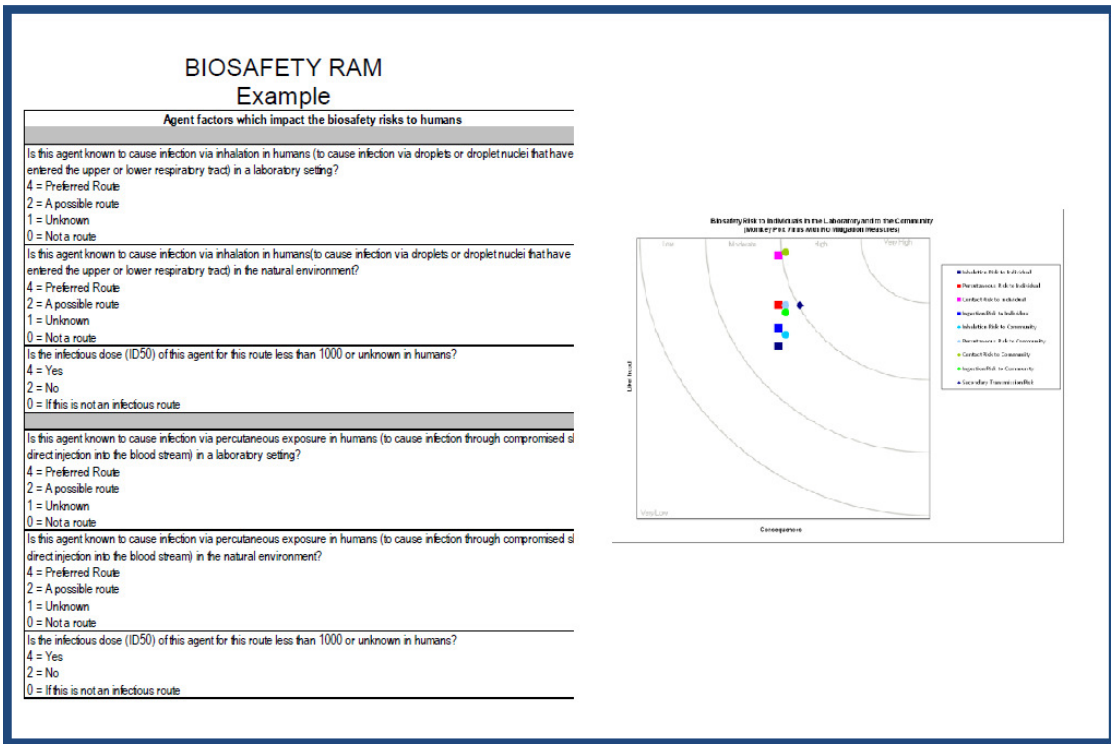
- 以共同認可的標準來評估風險
- 以“得分制” 評估風險情況
- 將風險評級分等
- 鑑別驅動風險因素，並採取有效之緩解措施
- 風險溝通，有助於確定什麼是可以接受的風險

（3）Biosafety RAM 風險評估模式係以 Biosafety RAM Software 執行 BioRAMSoftware.exe program.程式分析風險等級，如下圖所示。

Risk Evaluation: What is acceptable, tolerable, and intolerable?



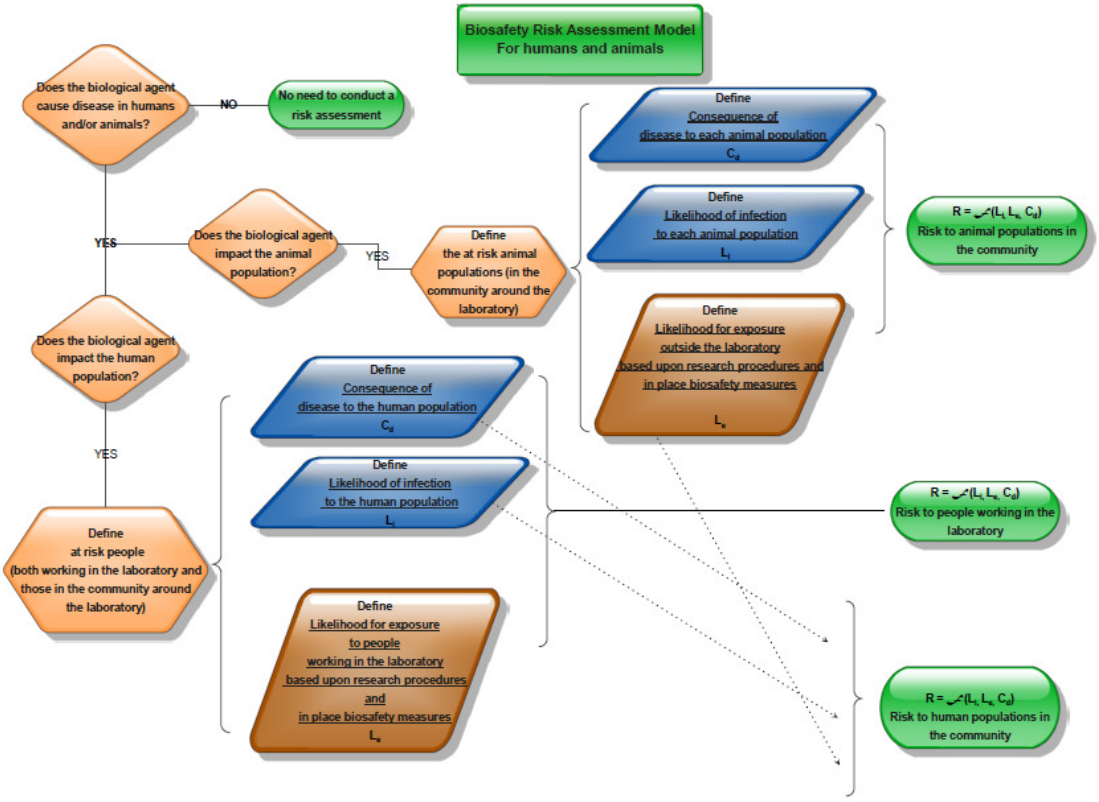
（4）下列圖示是以 Biosafety RAM 軟體分析病原因子對人類生物安全風險影響評估之實例



BIOSAFETY RAM
Example

Agent factors which impact the biosafety risks to humans
Is this agent known to cause infection via inhalation in humans (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in a laboratory setting? 4 = Preferred Route 2 = A possible route 1 = Unknown 0 = Not a route
Is this agent known to cause infection via inhalation in humans(to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in the natural environment? 4 = Preferred Route 2 = A possible route 1 = Unknown 0 = Not a route
Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans? 4 = Yes 2 = No 0 = If this is not an infectious route
Is this agent known to cause infection via percutaneous exposure in humans (to cause infection through compromised sl direct injection into the blood stream) in a laboratory setting? 4 = Preferred Route 2 = A possible route 1 = Unknown 0 = Not a route
Is this agent known to cause infection via percutaneous exposure in humans (to cause infection through compromised sl direct injection into the blood stream) in the natural environment? 4 = Preferred Route 2 = A possible route 1 = Unknown 0 = Not a route
Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans? 4 = Yes 2 = No 0 = If this is not an infectious route

（4）. 人類及動物生物安全風險評估流程模式
（ http://www.biosecurity.sandia.gov/subpages/pastConf/20082009/absa09/methodmodel.pdf ）



八、建議事項

1、美國生物安全協會（American Biological Safety Association）所辦理之生物安全年會爲生物安全領域中重要的一項國際會議，全球所有許多生物安全感相關領域之政府及美國官方單位（包括美國疾病管局及美國國家衛生院）官員、學者專家、廠商代表等均齊聚一堂，分享生物安全最新研發成果及防治策略。其每年大會前所舉辦的教育訓練課程也很精采，今(2010)年10月，第53屆美國生物安全年會（52nd Annual Biological Safety Conference）在美國科羅拉多州丹佛市凱悅飯店（Hyatt Regency Denver）舉行，會前會所安排之課程多樣且精采，從管理的角度，我選擇的「BSL-3實驗室之操作與管理（BSL3 Operations and Management）」、「商業模式之實驗室管理規範及認證檢定（A Business Model for Managing Lab Regulatory and Accreditation Inspections）」及「美國國家衛生研究院先進生物醫學研究設施之設計要求（New NIH Design Requirements Manual for State-of-the-Art Biomedical Research Facilities）」等三場課程帶給個人在BSL3設計、管理與查核等方面新的觀念及完整的認知。隨形同仁則選修「Risk Assessment：A Basic Course」、「Developing Biorisk Assessment Method and Models」及「Introduction to Laboratory Biosecurity」等三項課程，由於其課程有基礎與進階，因此建議有計劃安排相同人員前往受訓，如兩年乙次有計畫的上課，才能使課程有所連貫。

2、生物安全認知內化於組織文化內，如何將生物安全觀念深植而成爲組織文化，也是生物安全是重要的發展方向。此次會議與訓練課程都一再重複強調合作參與、溝通協調及教育的重要性、除了標準作業程序必須被確實執行與定期評估、人員教育訓練制度必須建立並被嚴格執行，也一再強調風險評估必須定期的被重新檢視。因此對於相關的標準作業程序及風險評估都應有計畫定期的被重新檢視。

3、感染性生物材料及防疫檢體涵蓋範圍及危險等級界定，應就實際執行面明確界定其危險等級。依據 WHO 於 2004 年出版第 3 版「實驗室生物安全手冊」之說明，感染性生物材料之 RG 等級並非「對等於」其操作所需之實驗室生物安全等級，而必須根據風險評估結果來指定感染性生物材料或臨床檢體應於何種等級之生物安全實驗室進行。

4、在職業健康方面延續著生物安全的觀念，再次要求透過完善教育訓練，使員工了解其職業風險，恪守實驗室相關規範，減少職業災害發生機率，並須有醫師提供足夠的諮詢與健康監視。另外也必須有適當的緊急應變計畫，使員工降低在職災現場暴露於污染的風險與暴露時間，良好的溝通、員工的參與，適當的訓練也是減少員工暴露於職業風險的最佳工具。

5、生物安全(Biosafety)與優良藥品製造規範(GMP)

雖然本局疫苗中心疫苗廠內，做爲疫苗生產用疫苗株對人體傷害性低且具又相當高的安全性，在生物安全的風險的評估上並不特別危險，但負責疫苗生產人員常需接觸高濃度的疫苗原液或動物血漿，因此在不違反 GMP 法規的原則下，仍應依循生物安全要求，穿戴適合的個人防護具(PPE)，在生物保全分面，該疫苗株的生物特性，大量繁殖技術、純化製造過程均被應視爲高度生物機密保全資料獲得嚴密保管，目前本中心所使用疫苗株除依據 GMP 疫苗株保存及使用的要求，由專人管理並依實造冊登錄取用數量與明細，更應加強在相關生產文件上做好生物保全工作。雖然在 GMP 的管理上，在某些方面對於安全的要求比生物安全法規要求的多更多，但在生物保全的方面上不能因疫苗株是安全的、低風險的，而對於生物保全要求的事項有所遲疑。

6、生物安全與生物保全是協同或對立?

生物安全與生物保全在許多方面是有著相同的組成，比方說同樣要求門禁管制，同樣要求列出感染性病原清單，但是在本質精神上卻是不同，例如同樣是門禁管制，在生物安全觀念是限制非相關人員進入以減少暴露於病原的機會，維護健康爲首要；而在生物保全卻是爲排除有心人士心懷不軌，避免病原遭到偷竊或刻意誤用。

有時候生物安全與生物保全在某些作爲上卻是對立的，比如生物安全要求列清所有病原體清單，並清楚標示位址，以警示其他人能立即察覺他正身楚感染性的環境避免接觸，而生物保全卻要求不可以將病原體所在位置清楚標示，以避免又心人士覬覦。

但不論如何，當在生物安全與生物保全發生衝突時，不應犧牲安全而缺就於保全，應以生物安全事項爲優先考量。在衡量生物安全或生物保全孰者爲重時，最好的方法仍應該透過風險評估的過程，經由風險評估結果以後再採取適當的方法。

7、強化國內民間生物安全組織，協助政府推廣生物安全教育，落實生物安全組織之運作及功能，提升國內生物安全自主管理能力，全方位推展我國與國際間實驗室生物安全及生物保全交流。

附　錄

附錄一

第 53 屆美國生物安全年會前會課程

Preconference Courses

Please visit our web site for course availability.
www.ABSAconference.org

Thursday, September 30, 2010

8:00 am - 12:00 pm

1. Preventing Zoonotic Disease Transmission in the Vivarium

Robert Heckert, DVM, PhD, CBSP, Robert Heckert Consulting, Bowie, MD
Joseph Kozlovac, RBP, CBSP, United States Department of Agriculture, Beltsville, MD

Working with animals in the vivarium presents a risk of zoonotic diseases transmission to people (animal care takers, laboratory technicians, principle investigators, etc.) who come in contact with animals (large and small). This course will provide an overview of zoonotic disease transmission routes and will provide descriptions of biosafety practices, equipment, and facilities design that mitigate the risk of becoming infected. The course provides a practical method for conducting a risk assessment in the vivarium, which then forms the basis for selecting risk mitigation strategies. The instructors will go in-depth on the routes of zoonotic disease transmission and will then focus on means by which these routes of transmission can be interrupted using animal biosafety practices, animal biosafety equipment (animal containment caging, bedding change equipment, etc.) and facility design features, to mitigate the risk. The program will describe the various features of each animal biosafety level (ABSL-1, ABSL-2, ABSL-3, and ABSL-4), but put into context how these need to be tailored to the facility, based on the risk assessment. The students will learn how to (using assessment documents) determine if their facility is providing enough biosafety risk reduction required to work safely with the zoonotic pathogens being used. The course will be presented as a combination of lectures, case studies, videos, and interactive exercises.

Objectives:

- Understand communicable disease risks of working with animals in the vivarium
- Recognize the ways in which people working with animals can be exposed to zoonotic infectious diseases
- Understand the principles and practices, safety equipment, and facilities design that mitigate the risk of zoonotic disease transmission in the vivarium

Suggested Background: Fundamentals of Biosafety
Target Audience: Animal caretakers, new biosafety professionals
Audience Level: Basic

1:00 pm - 5:00 pm

2. Hands-on Aseptic Technique & Equipment Training When Working with Animals Infected with BSL-2 & BSL-3 Agents

Michael Sidelsky, Sr., Allentown, Inc., Allentown, NJ

A hands-on demonstration of aseptic technique for the safe handling of rodents with infectious agents on-board using IVC systems, BSC, ATS, and high-level disinfectants, as well as methods of decontamination of that equipment using VHP, ClO_2 gas, and steam autoclaving. Attendees will have the opportunity to use the caging and biosafety equipment, as well as setting-up an aseptic field for rodent manipulation and cage changing. This workshop will prepare individuals for the challenges of containment of animals infected with BSL-2 and BSL-3 agents, as well as the containment of the dispersal of the agents into the environment from the animals.

Objectives:

- Biosafety when working with animals
- Seeing and handling equipment that will protect personnel, environment, and animals from cross-contamination
- Application of aeptic techniques for the containment of BSL-2 and BSL-3 agents in animals

Suggested Background: Fundamentals of Biosafety, Biosafety Level 3 Design and Operations
Target Audience: Animal caretakers, new biosafety professionals, experienced biosafety professionals, and anyone interested in applying safe handling and manipulation of animals infected with BSL-2 and BSL-3 agents
Audience Level: Basic, Intermediate, Advanced

8:00 am - 5:00 pm

3. Carriage of Infectious & Diagnostic Substances by Air—IATA Accredited

Nicholas Mohr, MBA, Peter East Associates Ltd., London, England
Joyce Beerbower, MBA, Safety & Compliance Services, Inc., Reston, VA

This course will enable delegates to ship infectious and biological samples by air in compliance with international regulations for the transport of hazardous materials (dangerous goods). The course covers the classification of pathogens, the UN numbering system, packaging, labeling, and the prepararion of shipping papers. Based on the ICAO regulations as amended by 49 CFR and using the IATA Dangerous Goods Regulations (2010 edition) as source material, delegates will learn how to navigate their way through the regulations, so they leave with a complete understanding of the sections relevant to their products. The course concludes with an open-book exam—successful candidates receive an IATA certificate, which valid for two years. The course is delivered through formal presentation, exercises, and discussion. Every participant receives a comprehensive course manual and a copy of the IATA Dangerious Goods Regulations (2010 edition). The material is also linked to U.S. hazmat regulations (49 CFR), so delegates understand how international regulations and national regulations apply.

Objectives:

- To classify infectious substances and clinical samples in compliance with the regulations
- To ensure that infectious samples and related material (dry ice) are packaged in accordance with the regulations
- To label packages and prepare shipping papers in accordance with the regulations

Suggested Background: Involvement with or responsibility for the dispatch of infectious substances and/or clinical or biological samples by air
Target Audience: All safety professionals
Audience Level: Basic, Intermediate, Advanced

8:00 am - 5:00 pm

4. Employing Principles of Adult Learning in the Development and Implementation of Case Studies

Tanya Dvorak, PhD, Kansas State University, Manhattan, KS
K. Patrick McKinney, RBP, U.S. Army Garrison, Fort Detrick, MD

Developing and altering biosafety trainings for learning effectiveness is a constant. Taking adult learning principles into consideration when developing biosafety trainings is essential. Teaching through case studies is one method of educating adults to cause them to think critically and make learning situations more realistic and memorable. Case studies offer an interactive approach for teaching and assessing biosafety comprehension. This course is designed for trainers and trainees to learn more about principles of adult learning, how adults prefer to learn, developing effective case studies, and utilizing case studies in current biosafety trainings for adults. This course is limited to 25 participants to encourage group engagement and involvement.

Objectives:

- Explain principles of adult learning
- Discuss the history of case studies
- Develop effective case studies
- Apply case studies effectively to biosafety training while acknowledging adult learning principles

Suggested Background: None
Target Audience: Biological safety professionals, safety and occupational health professionals
Audience Level: Basic

Friday, October 1, 2010

8:00 am - 12:00 pm

5. Process Biosafety

Brian Petuch, RBP, CBSP, Merck, West Point, PA

This course will provide information for the biosafety professional involved in the scale-up of a biological manufacturing process. Information will be applicable to production of natural products, recombinant proteins and recombinant virus. Topics include: NIH Appendix K Guidelines, Bioprocess technologies (such as Fermentation/Cell Culture, Centrifugation, Filtration, Chromatography), Basics of Process Hazard Analysis, Waste Handling, Equipment Safety Inspections, and Risk Assessment. Hands-on activities include evaluating a model production processes to develop a biosafety risk assessment.

Objectives:

- Understand how Appendix K of the NIH rDNA guidelines is applied to large-scale processing
- Recognize the various large-scale technologies used in bioprocessing
- Gain awareness (but not formal training) of the various process hazard analysis techniques

Suggested Background: Fundamentals of Biosafety
Target Audience: All safety professionals, new and experienced
Audience Level: Basic

8:00 am - 5:00 pm

12. Biosafety Management Techniques for Improving Organization Program Understanding and Support

Bob Emery, DrPH, CHP, RBP, University of Texas Health Science Center at Houston, Houston, TX
Bruce Brown, MPH, CBSP, University of Texas Health Science Center at Houston, Houston, TX

A recurrent challenge for biosafety professionals is the garnering of necessary program resources. This task is difficult because, on a good day in the world of biosafety, nothing happens, so upper management may not fully appreciate or understand all of the effort that went into making nothing happen. Biosafety professionals in particular experience difficulty in this regard because many in the profession have received intensive training in the biological sciences, but little or no training in the area of program management. This course will focus on some key management techniques that can be used within biosafety programs to help improve stakeholder understanding of the program and its activities, which in turn can result in the provision of necessary programmatic resources. Numerous real world examples of successful applications of the techniques discussed will be displayed for review and discussion. Ample time will be provided throughout the course for participant inquiries.

Objectives:

- Identify various biosafety programmatic measures and metrics that can be easily captured and communicated
- Understand the techniques that can be used for displaying biosafety data in ways that others can readily understand and appreciate it
- Describe how biosafety programs can assist with other basic safety program needs to help avoid the notion of program duplication of efforts and to improve safety and client satisfaction levels
- Employ various commonly used sales methods to improve the visibly and support for their biosafety programs

Suggested Background: Basic exposure to biosafety
Target Audience: All safety professionals
Audience Level: Basic, Intermediate

8:00 am - 5:00 pm

13. Basic Virology and Virus-Based Gene Vectors

Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, NC

The first section of this course will introduce some concepts of gene expression, and then review basic virology with a focus on characteristics of viral families, viral replication strategies, pathogenesis and persistence, and anti-viral intervention. The second section will examine gene expression technology and principles of viral vector use before exploring characteristics of viral systems that are commonly used as gene delivery vectors in biomedical research. The material is targeted for the biosafety professional who does not actively conduct laboratory research, yet wishes to acquire a basic knowledge of virology and recombinant viral vectors.

Objectives:

- Be familiar with the molecules, and understand the basic processes involved in recombinant gene expression
- Understand basic concepts of virology
- Understand the characteristics of viral systems that are used as gene delivery vehicles
- Apply the knowledge of basic virology and characteristics of viral vector systems to risk assessment of recombinant viruses and protocols involving them

Suggested Background: None
Target Audience: All biosafety professionals
Audience Level: Intermediate

8:00 am - 5:00 pm

14. Introduction to Biofilms: Culture, Counting, Antimicrobial Resistance, In vitro Biofilm Assays and Animal Models of Infection

Jeff Leid, PhD, Northern Arizona University, Flagstaff, AZ
Mark Shirtliff, MD, University of Maryland, Baltimore, MD

The course will be a mix of lecture and hands-on experimental demonstrations of how biofilm organisms are cultured, monitored, and assayed. The participants will also get an introduction to the antimicrobial resistant properties of biofilm organisms as well as some common animal models of infection. All the while, the course will be linked back to basic biosafety and the challenges that biofilm organisms create. The course will also introduce current molecular approaches to biofilm study, including genomics and proteomics.

various factors used in assessing risk are related to each other and their overall importance in assessing risk. This workshop will include presentations and discussions on methodologies and models for standardizing biorisk assessments and the differences between actual risk and concern (or perception). Workshop attendees will have a chance to review and conduct biorisk assessments.

Objectives:

- Understand the principle of AMP and specifically the value of assessment
- Define risk
- Develop a risk model for biosafety and/or biosecurity
- Compare the differences between technical assessments and concern assessments

Suggested Background: Fundamentals of Biosafety
Target Audience: All safety professionals
Audience Level: Basic, Intermediate

8:00 am - 5:00 pm

18. Fundamentals of the Class III Biosafety Cabinet

Dave Bressler, CBSP, Centers for Disease Control and Prevention, Atlanta, GA
Bob Hawley, PhD, RBP, CBSP, Midwest Research Institute, Frederick, MD

This course is designed to provide an overview of the history, function, design, maintenance, and operational safety considerations of Class III Biosafety Cabinets. Class III Biosafety Cabinets have found new relevance as a tool for public health and other microbiological laboratories in an era of all-hazards preparedness, bioterrorism and pharmaceutical production capacity. These types of biological safety cabinets provide a controlled environment for working with high hazard chemical and biological materials as well as the maximum amount of personnel and environmental protection—if they are used and maintained properly.

Objectives:

- Ability to describe the basic function of a Class III Biosafety Cabinet
- Able to describe the type of materials worked with in a Class III Biosafety Cabinet
- Able to discuss at least two components of a Class III Biosafety Cabinet
- Able to discuss the major differences between a Class II and III Biosafety Cabinet

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Biosafety Level 3 Design and Operations, Principles and Practices of Biosafety, Fundamentals of Biosafety Level 4 Containment
Target Audience: Biosafety officers, potential BSL-4 project officers, facility engineers, researchers, animal caretakers, new and experienced biosafety professionals laboratory personnel, response personnel, and others affiliated with high and maximum containment laboratory operations
Audience Level: Intermediate

8:00 am - 5:00 pm

19. Laboratory Biosafety Training for BSL-3 Biosafety Professional: What They Need to Know Before Starting

Anne-Sophie Brocard, PhD, RBP, University of Texas Medical Branch, Galveston, TX

This course was developed for BSL-3 researchers and is offered through our National Biocontainment Training Center to give them the necessary tools and knowledge to work safely and produce good scientific data in a BSL-3 environment. The course is to introduce biosafety professionals to the world of research, giving them the opportunity to better understand the challenges faced by researchers in containment. The course will emphasize biosafety levels, personal protective equipment, and proper use of biosafety cabinets, aerosol procedures, emergency procedures, decontamination and waste management as it pertains to the BSL-3 research environment. This hands-on training will apply the theoretical portion of this course through demonstrations and exercises using laboratory equipment such as pipetters, tips, centrifuges, performing serial dilutions, plating out biological on cell culture or agar plate, using BSL-3 PPE. This course has been modified to address the some of the facility and country differences for ABSA members.

Objectives:

- Become familiar with common practices and techniques for BSL-3 work
- Be able to assess situations and understand what is requested from their scientist
- Learn the basics of proper use of BSC and how to minimize and contain aerosol
- Experience benchwork first-hand
- Interact with an experienced BSL-3 scientist and safety profesional

Suggested Background: BSL-3 Operations and Management
Target Audience: All safety professionals
Audience Level: Basic

8:00 am - 12:00 pm

20. Waste Water Management for High Containment Laboratories

Becky Langer, PhD, Bayer Crop Science, Morrisville, NC
Chris Kiley, PE, Merrick, Duluth, GA
Gilles Tremblay, CET, Merick, Atlanta, GA

This course will focus on the critical aspects of waste water (wH_2O) management with respect to high containment facilities. The course will begin with a focus on wH_2O risk assessment, demonstrating the numerous items that should be taken into account when considering options for wH_2O management (guidelines, agent summaries, etc.). Management options will vary greatly depending on the composition (minerals, organics, solids) of the effluent to be treated and local and state laws for water discharge. The instructors will provide an in depth overview of the types of treatment options, which can vary widely from batch or constant flow, large- or small-scale, and heat and/or chemical treatment. Once a wH_2O management system is chosen, it is critical that the system be commissioned and validated to assure proper treatment of the wH_2O. Many factors can cause treatment system failure, even if the unit is operating to manufacturer's specifications and commissioning is successfully completed. Thus, the final step in implementing any wH_2O management system is to assure that any pathogens expected to be present are successfully inactivated by the system parameters that have been implemented.

Objectives:

- Perform wH_2O risk assessments/identify management options
- Recognize how design issues affect wH_2O management options
- Understand commissioning procedures for wH_2O systems
- Develop biological validation schemes for wH_2O systems

Suggested Background: None
Target Audience: New and experienced biosafety professionals, laboratory workers, all safety professionals
Audience Level: Basic, Intermediate, Advanced

Sunday, October 3, 2010

8:00 am - 12:00 pm

21. Working Safely in a Biosafety Cabinet

Felix Gmuender, RBP, Basler & Hofmann Singapore Pte Ltd., Singapore

The biosafety cabinet (class II) is the most important and most widely used primary barrier found in the microbiological and biomedical laboratory (BSL-2, BSL-3, and BSL-4). Biosafety cabinets protect against aerosol exposure and to a lesser degree against small droplets. The protection of the operator depends on the selection of appropriate types and size of the cabinet, proper function, correct placement of the cabinet in the laboratory, and how the work is organized and carried out. Biosafety cabinets need appropriate maintenance and annual certification. The user (or BSO) should be able to identify malfunctioning cabinets. The course starts with the technical background of the types of biosafety cabinets available on the market, and their strengths and limitations. Video demonstrations are used to illustrate airflow, sample procedures with varying quality and perfection, as well as management of small and large spills. Participants work in groups to analyze, discuss, and comment the procedures shown and suggest improvements and alternatives.

Objectives:

- Understand different types of BSCs, laminar flow hoods and their applications
- Understand function of BSC (video-supported) and what that means for organzing your work
- Learn how to place and operate biosafety cabinets from the user's and BSO's perspective. Simple performance tests. Certification requirements (manufacturer and installation)
- Learn how to organize your work in the cabinet (set-up until conclusion of work)
- Learn how to manage small and large spills
- Group exercises—analyze and comment several examples of procedures and workflows presented in video clips

Suggested Background: Fundamentals of Biosafety, Principles and Practices of Biosafety
Target Audience: All safety professionals, laboratory workers, new biosafety professionals
Audience Level: Intermediate

1:00 pm - 5:00 pm

22. Biological Safety in *Mycobacterium Tuberculosis* Research

Noman Siddiqi, RBP, Harvard School of Public Health, Boston, MA

Participants will be introduced to the bacterial pathogen *Mycobacterium Tuberculosis* (MTB) and the intrinsic properties that make it a BSL-3 pathogen (e.g., transmission, epidemiology, clinical presentation and therapy, drug

resistance, hot areas of research, etc.). MTB will be used as a typical agent for discussion of the basic principles of biosafety. Risk-identification, assessment, and control needed in conducting safe research on MTB will be covered. Basic concept of risk-based grouping of pathogens in general and as applied to MTB will be discussed. In a general introduction to BSL-3 design, participants we be familiarized with engineering controls and primary barriers (equipment and personal protective equipment). We will also discuss waste management, decontamination, decommissioning, administrative controls (such as biosafety program management and occupational health). Interactive exercises in drafting standard operating procedures, BSL-3 specific protocols for equipment use, spill control, etc., will be conducted. Participants will be challenged with case studies to understand and act on real-life scenarios.

Objectives:

- Working knowledge of MTB
- Identify what is important in determining risk associated with pathogen research
- Set-up a robust biosafety program for managing the research
- Identify engineering controls, PPE, and equipment needed for conducting safe research

Suggested Background: Fundamentals of Biosafety
Target Audience: All safety professionals
Audience Level: Intermediate, Advanced

8:00 am - 5:00 pm

23. Responding to Laboratory Emergencies and Conducting Mishap Investigations

Melina Kinsey, RBP, CBSP, Midwest Research Institute, Frederick, MD
K. Patrick McKinney, RBP, U.S. Army Garrison, Fort Detrick, MD

The course will go will discuss who your responders are and what you need to provide to assist them. This course will also provide an overview of the various levels of clinical and research biological laboratories; what should be incorporated in a pre-plan for your facility; how individuals should respond to a person down, hazmat spill, and other emergencies within your facility; as well as decontamination procedures. Discussions will include types and levels of personnel protective equipment, sampling detectors, and sampling methods.

Objectives:

- Participants will be able to recognize an overview of the National Information Management System
- Participants will be able to caculate what your facility's emergency response limitations are and what you need to do to address them

Suggested Background: None
Target Audience: Biological safety professionals, safety and occupational health professionals
Audience Level: Basic

8:00 am - 5:00 pm

24. The Role of Threat Assessment in Laboratory Biosecurity Programs

Ben Perman, PhD, RBP, Booz Allen Hamilton, McLean, VA
Jason Griffeth, Booz Allen Hamilton, McLean, VA
Dan Apple, Booz Allen Hamilton, McLean, VA
Lindsey Odell, Booz Allen Hamilton, McLean, VA

This course will teach administration, management, and researchers the basic principles of threat assessment and introduce students to the role of threat assessment in a laboratory biosecurity programs. The course will follow established criminal psychology techniques in the personal protection field that are used to identify, assess and manage dangerous threats. Students will be presented with relevant case studies in order to learn about basic threat indicators, approaches to make threats and threatening behaviors. Through an analysis of relevant case studies, students will learn how to recognize specific personal security vulnerabilities and how to link these vulnerabilities to threats. The course will focus on the purposes and requirements of biosecurity programs and the role of threat assessment in the management of effective personal security and personal reliability components of biosecurity programs. Regulatory issues relevant to threat assessment and to the implementation of reliability programs will also be discussed. The course will include a tabletop exercise devised around a realistic laboratory security problem that draws on the material presented in the lecture and case studies.

Objectives:

- Understand the purpose and requirements of basic reliability programs and the role of threat assessment in such programs
- Understand the purpose and requirements of a suitability investigation and the role of threat assessment in personnel management
- Identify resources and legal/regulatory controls relevant to threat assessment and the implementation of reliability programs, and personnel management programs

Suggested Background: None
Target Audience: All safety professionals
Audience Level: Basic, Intermediate, Advanced

8:00 am - 5:00 pm

25. Risk Assessment: A Basic Course

Elizabeth Weirich, CBSP, Centers for Disease Control and Prevention, Atlanta, GA
Esmeralda Prat, RBP, Bayer Crop Science, Gent, Belgium
Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, ND
Anne-Sophie Brocard, PhD, RBP, University of Texas Medical Branch, Galveston, TX

Rapid scientific and technological advances continue to challenge the biosafety community in determining and establishing the appropriate practices and containment necessary to avoid exposure to the wide array of hazardous biological agents and materials found in the laboratory today. This interactive course will provide an opportunity to incorporate the basic knowledge and skills necessary to perform risk assessments for working safely with human, animal, and plant pathogens; rDNA, genetically modified organisms, and viral vectors. Using case studies, participants will work together in groups to conduct risk assessments by determining the hazards involved; the appropriate questions to address the potential risks associated with the intended activities; and making recommendations for containment and practices in order to work safely. Group conclusions will be evaluated.

Objectives:

- Identify procedures and equipment that may be a source of potential exposure or may result in an accident or incident
- Critique containment conditions determined in a group exercise from information provided in a series of case studies
- Determine what information you need to perform your own risk assessment and where to find it

Suggested Background: Basic knowledge of microbiology, molecular biology, biohazardous materials and agents, biosafety procedures, containment facilities and practices
Target Audience: All safety professionals, laboratory workers
Audience Level: Basic

8:00 am - 12:00 pm

26. New NIH Design Requirements Manual for State-of-the-Art Biomedical Research Facilities

Alamelu Ramesh, Antonio Ramis, Gabor Konkoly-Thege, National Institutes of Health, Bethesda, MD

The 2008 National Institutes of Health (NIH) Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), formerly called the NIH Design Policy and Guidelines, is the only detailed design requirements and guidance manual for biomedical research laboratory and animal research facilities in the U.S. It provides the tools, direction, guidance, and additional information for the planning, programming, and design of Biomedical or Animal Research Facilities. The DRM promulgates minimum performance design standards for NIH owned and leased facilities (new and renovated). Compliance with the DRM ensures that all NIH owned and leased facilities will be of the highest quality to support biomedical research. This course will provide tools, direction, guidance, health and safety information for the planning, programming and design of Biomedical or Animal Research Facilities and will also address some of their biological, containment, and safety issues.

Objectives:

- Recognize how to design and construct facilities that meet the special needs of biomedical, animal research laboratory, and high performance facility designers, engineers, owners and facility managers
- Provide clear requirements, recommendations, up-to-date information, and guidance
- Identify minimum documentation requirements

Suggested Background: None
Target Audience: Architects and engineers (seasoned professionals or new to the industry), biological safety officers, laboratory, construction, and facility managers
Audience Level: Intermediate

1:00 pm - 5:00 pm

27. All You Ever Wanted to Know About OSHA

Nancy Hauter, Occupational Safety and Health Administration, Washington, DC

What does your facility need to do in order to be incompliance with OSHA? What happens if an OSHA inspector shows up at your door? In this informative session, hear directly from OSHA personnel on what hazards they find most frequently in health care and research laboratory facilities. We will look at ways to assist you in the recognizing and evaluating of these hazards. More importantly, we will explore methods for you to correct these dangerous conditions thereby preventing worker injuries, illnesses, and possibly deaths.

Objectives:

- Become familiar with the OSHA inspection process
- Recognize hazards in health care and research laboratory facilities
- Develop methods to correct the most common hazards in health care and research laboratory facilities
- List the most frequently cited OSHA violations

Suggested Background: None
Target Audience: Safety and health professionals, laboratory managers, researchers, and laboratory workers who want to know how to protect themselves and their staff from occupational injuries and illness
Audience Level: Basic

8:00 am - 5:00 pm
28. Biosafety Training
Per Staugaard, Biosafety Training and Consultancy, Utrecht, Netherlands
Vibeke Halkjaer-Knudsen, PhD, Statens Serum Insitute, Copenhagen, Denmark
This workshop is intended to provide a basis to set-up a training and qualification program in connection with activities involving biohazards. After an introduction to training in general about qualification, and more specifically to education, knowledge, and experience, the trainees will breakout into small groups to discuss real-life topics and present the results. Emphasis is of choosing the optimal training tool for the specific training. A practical session on giving feedback with the aid of photos and videos is part of the workshop. Specific attention is paid to evaluation of training. The trainees should be able to design a training program for their institution after this course.
Objectives:
- Make a training program
- Do an evaluation of a training
- The use of appropriate training methods

Suggested Background: None
Target Audience: All safety professionals, new biosafety professionals
Audience Level: Basic, Intermediate, Advanced

8:00 am - 5:00 pm
29. Complying With U.S. Export Controls
Deborah Howard, CBSP, University of North Carolina, Chapel Hill, NC
You've been trained to ship hazardous materials according to the IATA/DOT regulations; but did you know many viruses, bacteria, and genetic elements of these pathogens require you to apply for an export control license through the Department of Commerce? All Select Agents and their genetic elements as well as several other recognized pathogens require a license to export. Did you know that items shipped out of the U.S. costing more than $2500 need to be filed with the U.S. Census Bureau? This class is intended for professionals who manage the shipping program at their university. There is more to shipping than classification, labeling, and marking; there are licensing, under-invoicing, and ITN numbers from the U.S. Census Bureau to consider when shipping anywhere outside the U.S. including Puerto Rico. Join us to learn about the SNAP-R program, Visual Compliance and how the International Traffic and Arms (ITAR) regulations fit into exporting. Troublesome clauses in contracts will also be covered. The class will discuss which pathogens and lab equipment require a license when exporting, how to obtain a license, Census Bureau requirements, recordkeeping, and much more.
Objectives:
- Upon completing this course participants should be able to classify biologicals that need to be exported
- Participants will know how to apply for a license
- Participants will receive a basic understanding of the various regulations for exporting
- Attendees will understand the penalties for exporting illegally

Suggested Background: Experience in exporting biological
Target Audience: All safety professionals, experienced biosafety professionals
Audience Level: Intermediate

8:00 am - 5:00 pm
30. Occupational Health and Surveillance and Monitoring in Biological Labs and Animal Facilities
Gary Fujimoto, MD, Palo Alto Medical Foundation, Palo Alto, CA
This seminar will review the following critical elements of an occupational health and medical surveillance program for employees with potential exposures to biohazards: preplacement and periodic medical evaluations; serum banking; immunizations (including Hepatitis A, B, Rabies, and Vaccinia); animal facility issues including animal allergy assessments; baseline and periodic screening; reproductive hazards and evaluations; recommendations for immunocompromised staff; post-exposure prophylaxis and medical management of infections (including tuberculosis); non-human primate exposures and internal blood donor programs.
Objectives: TBD
Suggested Background: None
Target Audience: All safety professionals, occupational health professionals
Audience Level: Basic, Intermediate, Advanced

Informational Session
1:00 – 3:00 pm
Open Forum Discussion
Next steps in the implementation of CWA 15793: Laboratory Biorisk Management Standard
Open to all participants. Space is limited.

6:30 pm - 8:00 pm
Opening Reception

附錄二

BSL - 3 實驗室認證準則清單（Basis of BSL-3 Laboratory Certification Checklist）

以下是 BSL - 3 實驗室開始運作前重要之查核驗證清單，檢測記錄應保存在實驗室安全操作文件裡，保存期限需符合職業衛生與安全法規。

1. 行政管理和設施維護與操作能力之評價，確保人員安全及設施的完整性

(1). 審查影響維護操作之背景資料：

- 索取並審查權限委託書
- 審查建築及機械設計圖，以釐清設計意圖
- 審查實驗室之生物安全政策及標準作業程序(包括實驗人員及維修人員之培訓)
- 評估工程管理與技術程序，以確定這些程序是否符合該方案的需要
- 審查危險（感染性）廢棄物管理程序
- 審查實驗室事故反應議定書
- 審查正在實行或預期執行之去污程序議定書
- 審查蟲害綜合管理方案
- 審查文件保存、實驗室維護及實驗程序之標準作業程序

(2). 查核及評價：

- 建物之門、天花板、照明燈具、電器設備等之表面處理、穿透或嵌縫完整性需在防害範圍內，以滿足：
  - ⇨ 包括家具在內之所有表面的清潔能力
  - ⇨ 所有表面的光滑性
  - ⇨ 密封接縫和穿透
  - ⇨ 大的防滑地板
  - ⇨ 表面抗滲透
  - ⇨ 表面抗化學消毒劑（有機溶劑、酸、鹼）及適度之高溫
  - ⇨ 氣密性去污
  - ⇨ 蟲害管理需求
  - ⇨ 不可開啓之窗戶
  - ⇨ 生物性密合

(3). 檢查實驗室空間的規劃、設備的安置及設備的狀況

- 評估高壓滅菌器驗證測試程序、檢查儀器使用及維修記錄

- 評估進入及退出之程序
- 其他可用性之評估：
  - ⇨ 緊急設備
  - ⇨ 緊急雙向通信系統
  - ⇨ 實驗室訊息對外電子傳輸系統
  - ⇨ 緊急照明系統
  - ⇨ 滅火器
  - ⇨ 化學品洩漏清消套組

- 評估特定設施之備援系統，例如空氣處理組件、排氣扇、淨化系統組件（如泵和高效能過濾器）
- 評估 BSL - 3 實驗室與 BSL - 2 支援實驗室、辦公室、聯誼室、電梯、裝卸區、門等空間之關聯性，些空間會影響實驗室之壓力及氣流狀況。
- 淋浴室
  - ⇨ 存儲提供清潔防護衣物及安全設備（如:PAPR）
- 靠近實驗室出口的免手動水槽
- 辦公地點以外的清消
- 檢查張貼告示之適當性，包括
  - ⇨ 生物危害標誌
  - ⇨ 替代使用
  - ⇨ 實驗室管理人員之姓名及電話號碼
  - ⇨ 特別要求，如個人防護裝備（personal protective equipment；PPE）之使用、人員進出
  - ⇨ 審查所有機電控制及其所在位置的清單
  - ⇨ 查核在緊急情況下，實驗室啓動和關閉程序

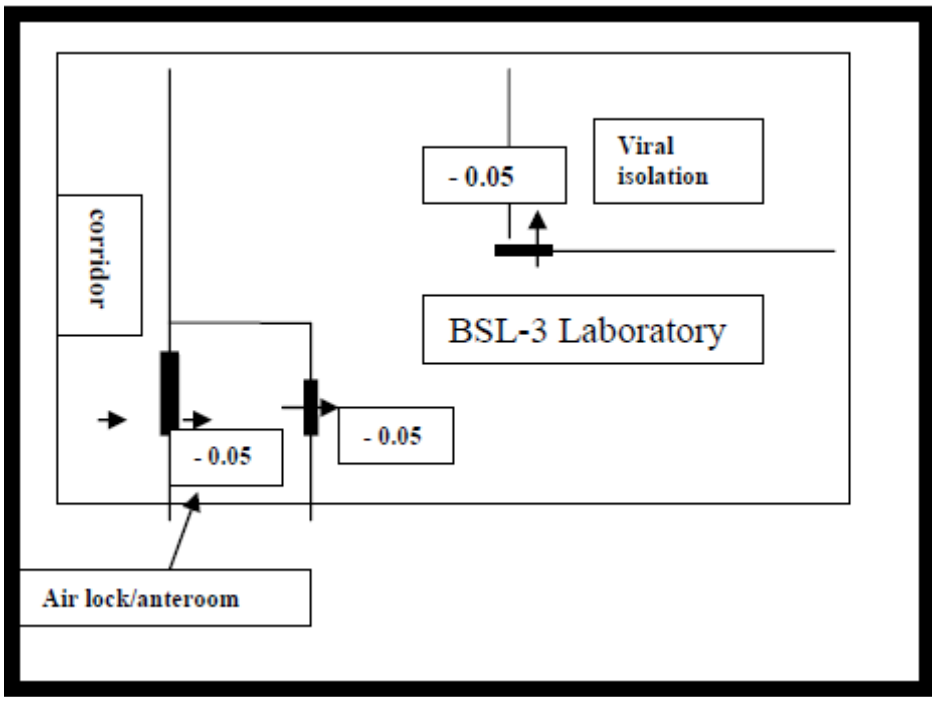
(4). 評估審查實驗室維修頻率及日誌

- 高溫高壓滅菌器
- 生物安全櫃濾網
- 離心機
- 門/鎖
- 空調平衡
- 空調皮帶

- 空調機電/皮帶輪
- 燈具
- 配管系統

(三). 工程控制之驗證

1. 供給及排氣系統額外負載容量之評估，估計並量化備用容量
2. 確認氣流單一方向之通過
3. 測量氣流量及方向、壓力關係、空氣變化及記錄測量資料
4. 氣流流動方向必須是從潔淨區進入污染區，如果在多個相關污染區內時，則必需建立連續性的負壓差，使受污染的空間維持在負壓環境裡，以減少受污染的區域。 壓差量測結果需隨時顯示於實驗室門口，壓差量測儀器也必需經標準設備校正，理想情況下，從潔淨區到多污染區內，其壓差至少需保持在-0.05 每英吋水柱（in. WG），相當於-12.5 帕（Pa）。在無任何污染情況下實驗室關門時，壓差維持在小於-0.03 每英吋水柱（相當於-7.6 帕）即可。



5. 中央空調系統及電力系統之故障測試，使之符合實驗室設計參數，進行測試並記錄數據。爲驗證正確之操作，確保實驗室維持在負壓狀態以減少污染，故障測試至少應包括：

- 正常運作 ➔ 緊急電源
- 緊急電源 ➔ 正常操作
- 供氣風扇故障（單一和全部）

- 排氣風扇故障（單一和全部）
- 設置自動化系統(BAS :building automation system）以維持或回復實驗室所有設定點之操作功能
- 自動化系統重新啓動時，必須包含所有操作之設定點
- 實驗室如安裝不斷電供應器（UPS: uninterrupted power supply），則驗證 UPS 之接續操作
- 提供 UPS 給 BAS
- 評估 UPS 運作狀況

6. 評估中央空調設備之性能

- 目視檢查
  - ⇨ 皮帶
  - ⇨ 皮帶保護
  - ⇨ 線路
  - ⇨ 輸送管及連接管
  - ⇨ 導引線（如須要）
  - ⇨ 空氣調節閥（如需要）
  - ⇨ 軸承（噪音）
  - ⇨ 管路系統之裝配或損壞等
- 確保機電運行的溫度保持在設施所訂之規格
- 確保供氣及排氣之間的聯結正常
- 確認生物安全櫃安置於正確位置，使供氣及排氣之擴散器、安全門及動線達到要求使用煙霧測試，需確保生物安全櫃之供氣及排氣裝置未被阻礙影響氣流流向。

7. 於不同位置進行煙霧測試，驗證氣流

- 門
- 通風口
- 窗
- 高溫高壓滅菌器
- 其他通風區

8. 檢查並確認門互鎖系統及自動關門裝置

- 自動關門裝置是必備項目

⇨ 確保門自動關閉和閂鎖

⇨ 連鎖需求

⇨ 檢查操作性能

- 打開及關閉出入門之所有可能的順序
- 確保具有足夠時間排除錯誤的連鎖

9. 測試所有的報警系統

- 空調故障報警系統
- 有效的氣流警示系統，能顯示實驗室在正常條件下呈現正壓或者門打開超過 20 秒之異常現象
- 有效的視覺指示器，使人員在進入實驗室之前就能得知實驗室內處於正壓或負壓的狀態
- 查核火災報警系統之年度文件
- 查核保全報警系統之年度文件

10. 廢氣排放評估（當作執行手段）

- 檢查屋頂環境避免使廢氣重新被吸入的機會

⇨ 排氣口與進氣口至少具 25 英尺、排氣口與鍋爐排氣管口至少 40 英尺、排氣口與建物排氣管口至少 15 英尺

- 實驗室排氣管口至少高於屋頂最高點 3 公尺
- 檢查排氣管位置及廢氣排放速度
- 排氣速度= 15-20 公尺/秒或 3000-4000 fpm
- 是否所有會產生氣霧之設施皆具有經認證之 HEPA 過濾設備 ？

⇨ 確保離心機或其他可能產生氣霧之設備，其氣流在進入實驗室之前已經 HEPA 過濾

- 確保排風設備（local exhaust ventilation；LEV）能防止廢氣回流
- 考慮各空調設備正常運作

11. 防護區（containment spaces）換氣率（air change rates；ACR）之驗證

- ACR 的設計是根據防護區之熱能負載量、污染物、氣味而制訂
- 每年使用經校準之儀器設備測量供氣及排氣之風量
- 估算 ACR 及監測氣流方向
- 在任何情況下實驗室換氣率不得小於 6 次/hr、動物房則不得小於 10 次/hr

12. 查核生物安全櫃（biological safety cabinet ；BSC）的認證資料，包括驗證序號

- BSC 必須每年列入認證計劃
- 驗證的 BSC 需遠離門窗及通風口
- 驗證 BSC 所安裝之適用操作櫃型式
- 檢查 HEPA 過濾裝置
- 審查所有空調高效排氣 HEPA 過濾裝置之證明文件
- 確認 HEPA 濾網在攜帶式空氣真空系統使用時的時機及限制
- 目測檢查
  - ⇨ 除污隔離閥
  - ⇨ 除污及測試部位
  - ⇨ 掃描 BSC 的氣流路徑

13. 查核機電及配管(Mechanical-electrical and plumbing (MEP) systems)系統以符合 NIH 設計政策

- 檢查是否有足夠的照明
- 確認阻隔區外部電路阻斷器
- 預防實驗室供水系統之回流
- 清楚標識水槽及排水渠設施
- 有效的應急供電系統
- 有效的緊急洗眼用水
- 可用的緊急淋浴設備
- 可用的嵌縫密封必需品，電氣設備如線路管道、電氣箱、照明設備等
- 專用真空泵之確效驗證，如有此設備時
- 查核污水淨化系統，如有此設備時

14. 高溫高壓蒸氣滅菌鍋之驗證：包括有效性、操作、生物指示帶

- 內控鎖測試
- 流程確認及負載測試
- 生物指示帶檢測
- 煙霧測試生物指示帶 I
- 維持滅菌條件 121℃度 60 分鐘之測試。

- 高溫高壓蒸氣滅菌鍋在 BSL - 3 新設施中爲必需之設備，維持其運作功能以阻絕生物危險性物質
- 其他環境保護措施（例如個人淋浴器、HEPA、污水排放管線設施）

(四). 審查標準作業程序

1. 高溫高壓蒸氣滅菌鍋及去污淨化

- 去污前先將廢棄物從生物安全櫃移出
- 如果高溫高壓蒸氣滅菌鍋可用但不在 BSL - 3 設施範圍內，則須確保有完整的消毒的程序
- 評估最近的輸送路線，避免公共通道
- 評估使用和處置個人防護裝備的程序
- 去污設備維修或停止使用之評估程序
- 查核生物危害材料之儲存與和運輸
- 評估消毒劑使用類型
- 驗證更換空調過濾器之時間表及頻率

2. 安全標準操作程序

- 確定 BSL – 3 實驗室之負責人
- 對使用防護區之人員進行認證
- 個人防護裝備之使用、存放及處理
- 人員進入設施之限制與記錄
- 進入維修設施維修之程序
- 完備之洗手程序
- 使用機械式吸取裝置，嚴禁用口吸取
- 禁止使用尖銳物件，除非絕對必要，使用時必需遵照說明書指示
- 操作過程必需嚴謹，以減低氣霧產生
- 去污淨化程序必需確實
- 訓練計劃必需完整，包括有助人員訓練之相關文件及進修課程
- 採集並儲存所有實驗室及其他高危險群人員之血清樣品
- 制訂實驗室生物安全手冊
- 標準作業程序需納入生物安全的預防措施
- 如果實驗動物被安置在 BSL - 3 條件下，則所有動物必需遵守特定的規定和程序

3. 職業衛生監護（政策及執行）

- 血液/血清保儲
- 疫苗
- 高風險之個人（免疫抑制、懷孕等）
- 健康檢查
- 實驗室所有使用或貯存生物危害性材料或替代品的地方，其記錄文件及每年暴露控制計劃資料的更新

4. 生物危害性材料的使用授權（例如，人類病原體登錄、重組 DNA 登錄、替代品等）

- 現今生物危害性材料授權狀況
- 症狀記錄
- 檢體接收程序
- 查核最新動物科學委員會批准的文件（如果該設施需使用動物）

附錄三

IFBA(international federation of biosafety associations) 會議議程

AGENDA

21st Meeting of the International Federation of Biosafety Associations

Room: Mineral Hall
Snacks and beverages will be provided

Sunday, October 3, 2010

13:00 – 17:00

Time	Event
13:00	**Topic:** *Welcome Address and Introductions* **IFBA Co-Chairs: Maureen Ellis and Steven Theriault** **ABSA President: Benjamin Fontes** **Members and Observers**
13:15	**Topic:** *Meeting Objectives, Members/Observers, IFBA Structure* Approval Minutes 20th Meeting Goals/Objectives 21st Meeting Approval of Member and Observer Applications IFBA Structure **M. Ellis, K. Johnston, C. Reed**
13:45	**Topic: Year of Building International Biosafety Communities** Biosafety Heroes Biosafety Professional Accreditation Biosafety Academic Program Website of Resources **M. Ellis, J. Welch, B. Goble, B. Fontes**
14:30	**Health Break**
14:45	**Topic: IFBA International Conference** *"Global Biosafety and Biosecurity: Taking Action"* **M. Ellis, B. Johnson, K. Johnston**
15:15	**Topic:** *IFBA Mentoring Program* **M. Ellis, Ed Styger**
15:30	**Topic:** *Selection of New Co-Chair* **S. Theriault, Members**
15:40	**Topic:** *Other Business* Compendium Update Biocontainment Engineers Network **All**
16:10	**Topic:** *Next Meeting and Closing Remarks* **All**

附錄四

IFBA(international federation of biosafety associations)與會貴賓：

會員(Member Organizations Present)

Maureen Ellis, Co-Chair, Asia-Pacific Biosafety Association

Steven Theriault – Co-Chair – Canadian Association of Biological Safety

Heather Sheeley, Past Co-Chair, IFBA – European Biological Safety Association

Martin Kuster – President, European Biological Safety Association

Karen Byers – President, American Biological Safety Association

Benjamin Fontes –Past-President, American Biological Safety Association

Ed Styger, American Biological Safety Association Secretariat

Willy Tonui – President, African Biological Safety Association

Shahida Qureshi – Pakistan Biological Safety Association

Maqboola Dojki – Pakistan Biological Safety Association

Erum Khan – Pakistan Biological Safety Association

Katsuaki Shinohara – Japanese Biological Safety Association

Keigo Kambayashi – Japanese Biological Safety Association

Tech Mean Chua – President, Asia-Pacific Biosafety Association

Lela Bakanidze – Georgian Biosafety Association/BACAC

Alberto Diaz-Quinonez – Mexican Biosafety Association

Edgar Sevilla-Reyes – Mexican Biosafety Association

Bill Gaylord – Pharmaceutical Biosafety Group

觀察員(Observer Organizations Present)

Brad Goble – Global Health Security Action Group, Laboratory Network/IFBA Secretariat

Jennifer Gaudioso – Sandia National Laboratory

Jim Welch – Elizabeth R. Griffin Research Foundation

Caryl Griffin – Elizabeth R. Griffin Research Foundation

Susan Caskey – Sandia National Laboratory

Shanna Nesby-O'Dell – US Centers for Disease Control (CDC)

Shu-Hui Tseng – Taiwan CDC

Chan-Wha Kim – Korean Biological Safety Association

Ryvichi Komatsu – Korean Biological Safety Association

秘書處(Representatives of the Secretariat Present)

Kelly Johnston – Canada, International Centre for Infectious Diseases

Craig Reed – Canada, International Centre for Infectious Diseases

受邀組織(Guests Present)

Ash Randev – Ardesco

Michelle McKinney – ABSA/BTRP-CBEP

Jonathan Richmond – ABSA/JRS Associates

Rosamond Rutledge-Burns – ABSA

Jairo Betancourt – University of Miami

Debra Sharpe – SRI/Biosafety Solution

Susan Weekly – ABSA

Valerie Wilson – Caribbean Med Labs Foundation

Wendy Kitson-Piggott – Caribbean Med Labs Foundation

Richard Rebar – ABSA/PBG

Paul Langevin – Merrick

Barbara Johnson – ABSA/IFBA

Jose Casquero Cavero – ABSA/Instituto Nacional de Salud, Peru

視訊會員(Members by Teleconference)

Khalid Temsamani – Moroccan Biosafety Association

視訊觀察員(Observers by Teleconference)

Terry Taylor – International Council for the Life Sciences