

管制性病原管理的內部威脅分析

國防醫學院預防醫學研究所

高治華

USAMRIID Temporarily Halts Activity at BSL-3 and BSL-4 Laboratories

by **Stephanie Lizotte** June 2, 2018, 9:07 am

 12.3k Vi



Old



New



An explosion rocked a Russian research facility known for housing the smallpox virus

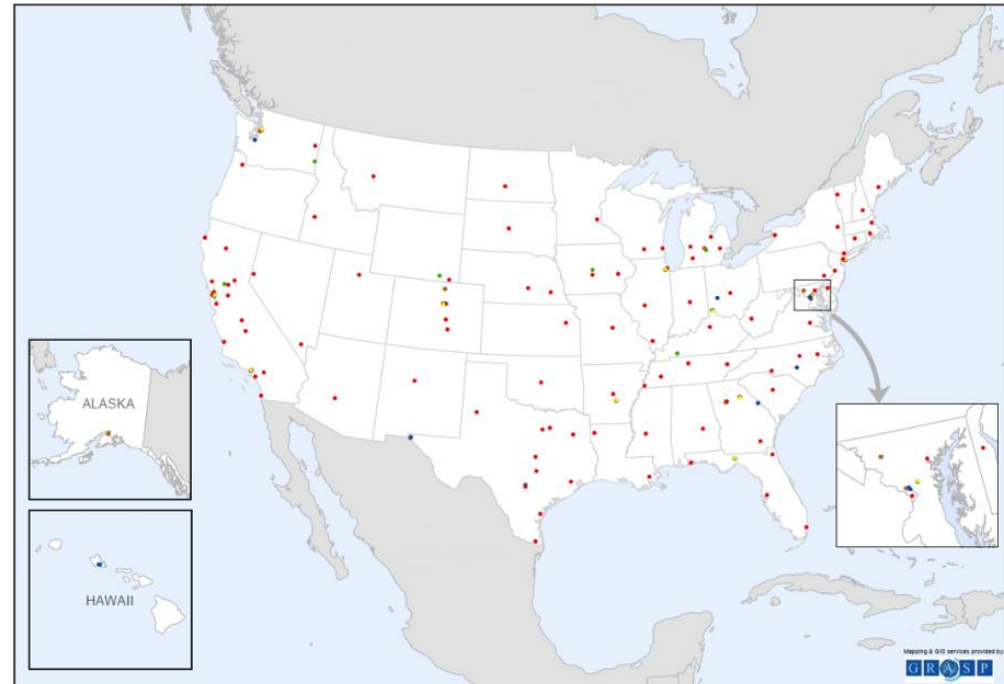
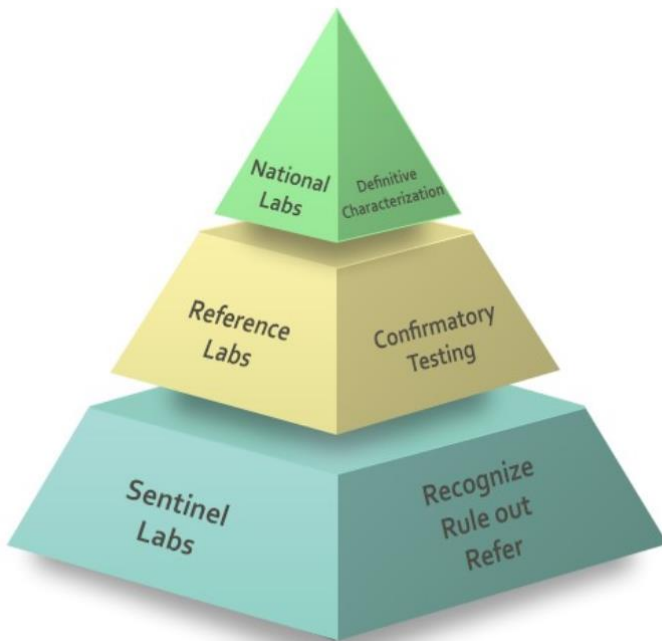
By Matt Field, September 16, 2019



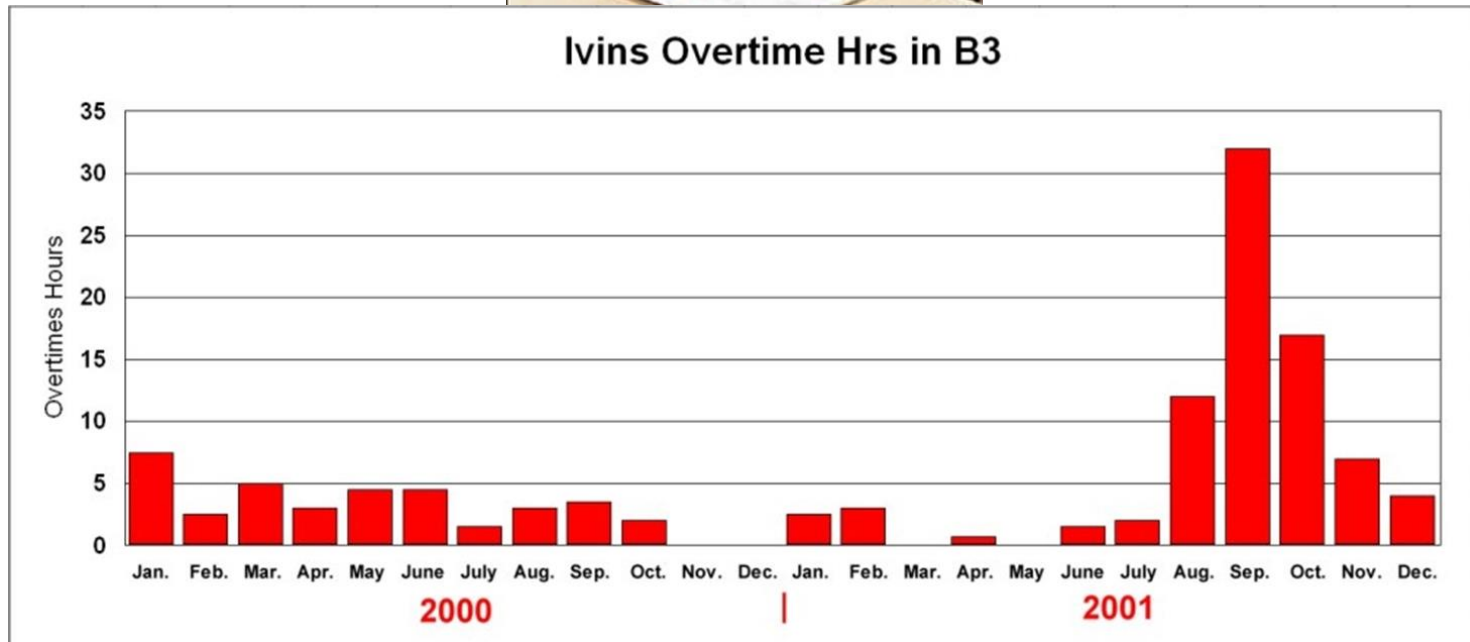
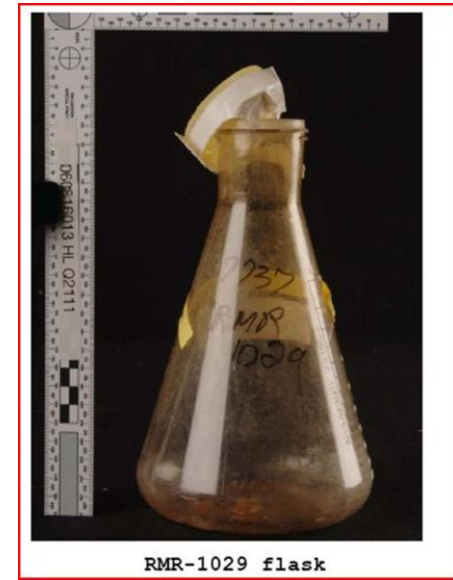
Smallpox virus virions. Credit: Fred Murphy / Sylvia Whitfield / CDC.

HEALTH SECURITY PREPAREDNESS

How Does USAMRIID Shut Down Impact Nation's Bioterrorism Laboratory Response Network?



2001 Anthrax incident





外部威脅?!



傷你最深的其實是內部威脅

- **Insider threat.** The *potential* for a current or former employee, contractor, or business partner to accidentally or maliciously misuse their trusted insider access to harm the organization's employees and customers, assets, partners, or reputation.

From Intel Document



內部威脅大綱

- 我的team members OK嗎？
- 我有確認病原（包含是否去活）的機制嗎？
- 病原標示及保存的方式明確嗎？
- 防護設備是否品質保證？
- 有動物逃離實驗室或操作的風險嗎？



**RISK
MANAGEMENT
PLAN**





國家地理頻道



韋德卡特博士

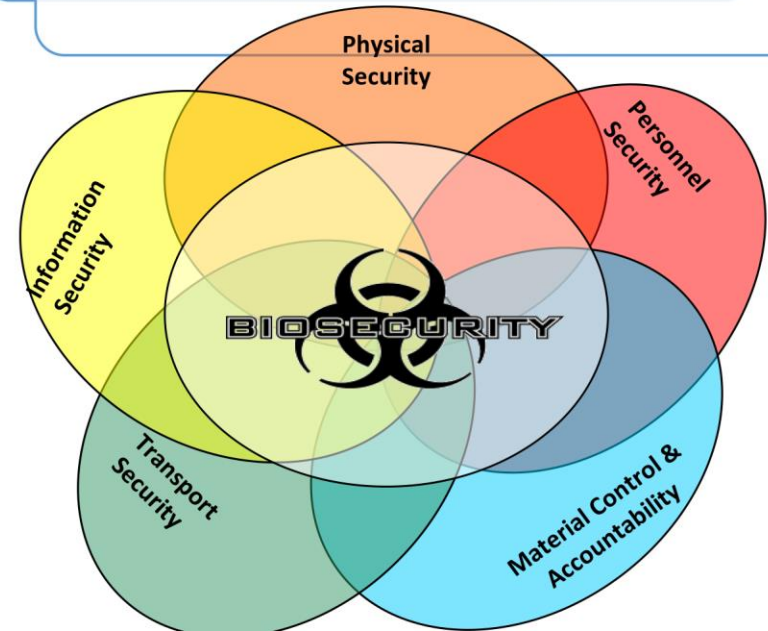
南希賈克斯上校

Identification of Biorisks

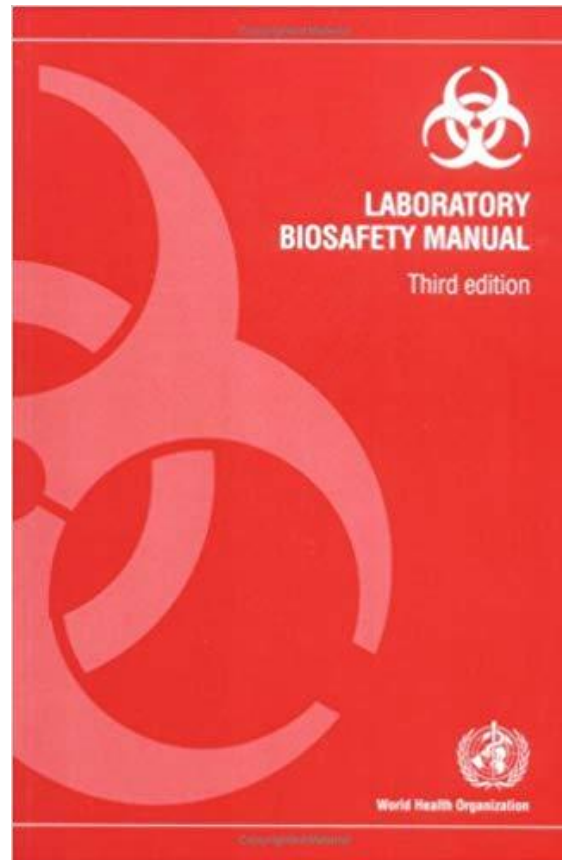
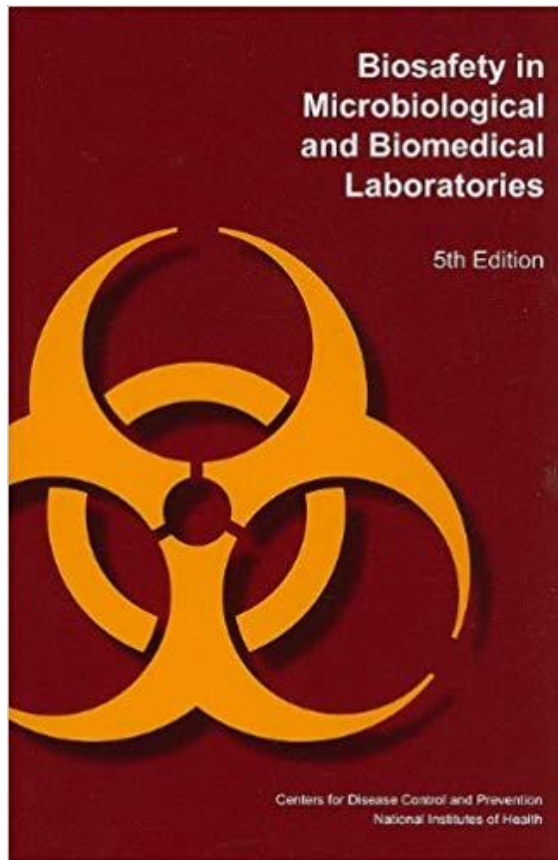
Biosafety Risk Assessment



Biosecurity Risk Assessment



Biosafety Guidelines



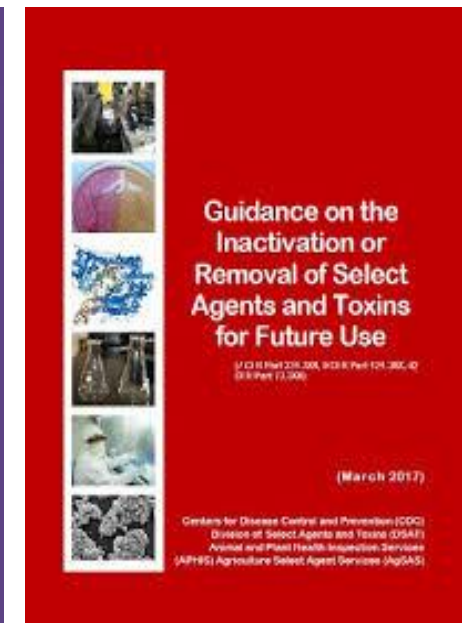
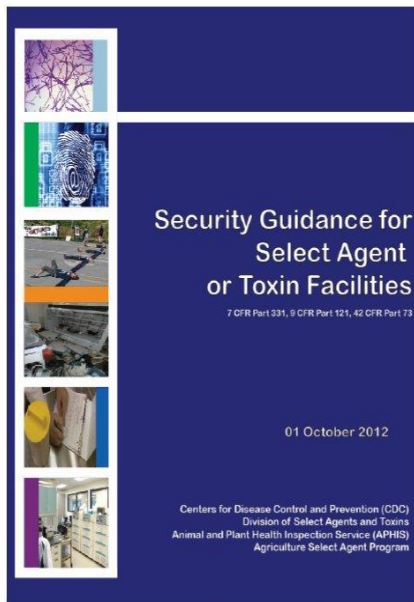
動物生物安全
第一等級至第三等級實驗室安全規範
(第一版)

Safety Guidelines for Animal Biosafety
Level 1 to Level 3 Laboratory
(v.1)



衛生福利部疾病管制署

Select Agents管理



管制性病原及毒素保全計畫指引

- 內部威脅

- 內部威脅來自單位內部的人員，這些人員瞭解單位保全相關之內部資訊、管制性病原及毒素庫存資料、進入生物防護區域和電腦。此類威脅的目標通常涉及詐欺、竊取資訊、竊取智慧財產、偷竊和/或濫用管制性病原及毒素以及破壞電腦系統。

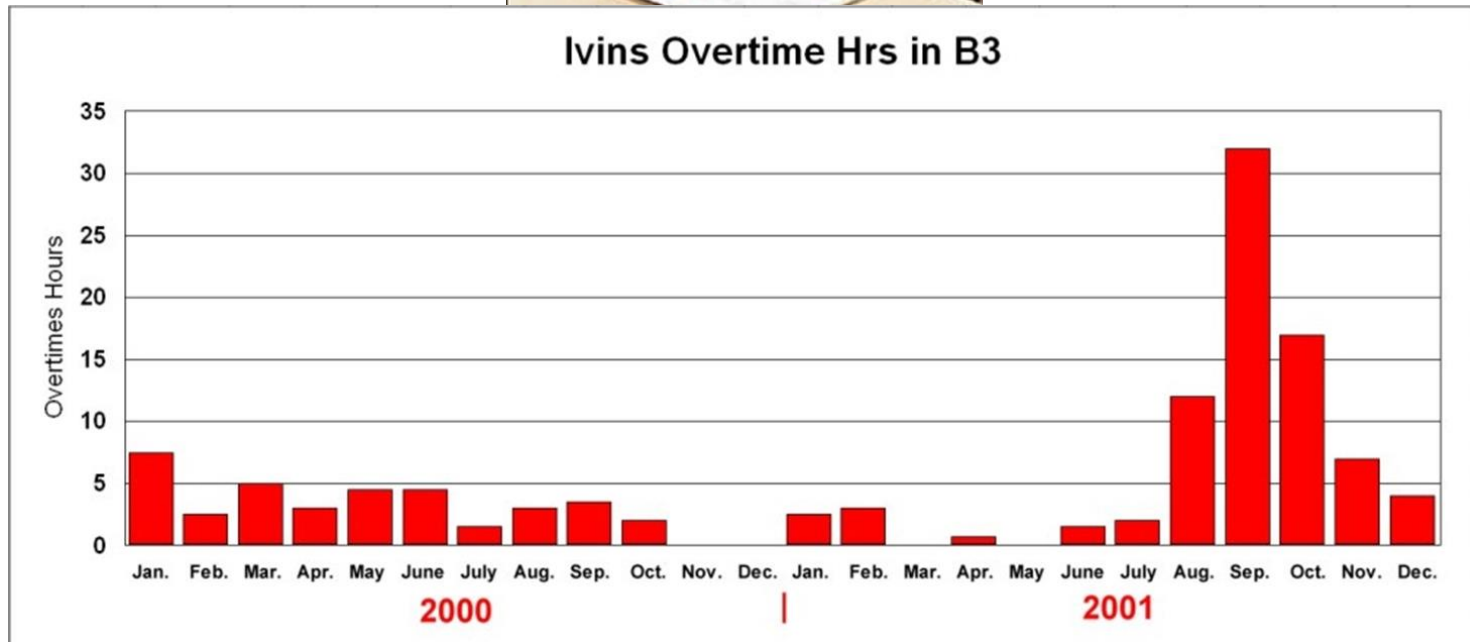
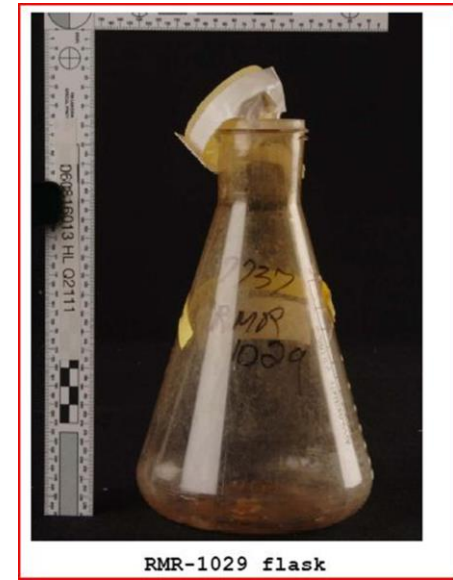
- 外部威脅

- 外部威脅來自單位以外。這些威脅可能包括駭客、運作中斷和其他緊急情況。

Select Agents 管理

- 2001 Anthrax 事件
- 2003 SARS 事件
- 2012 Genetically Manipulated Organisms :
 - Dual Use
- 2014 奇蹟年
- 2015 USA Today Investigation

2001 Anthrax incident




2003 SARS

Laboratory Acquired Infection

- Singapore
- Taiwan
- USA


Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets

BY SANDER HERFST, EEFJE J. A. SCHRAUWEN, MARTIN LINSTER, SALIN CHUTINIMITKUL, EMMIE DE WIT, VINCENT J. MUNSTER, ERIN M. SORRELL, THEO M. BESTEBROER, DAVID F. BURKE, DEREK J. SMITH, GUUS F. RIMMELZWAAN, ALBERT D. M. E. OSTERHAUS, RON A. M. FOUCHIER
SCIENCE | 22 JUN 2012 : 1534-1541 | 


Avian flu can acquire the capacity for airborne transmission between mammals without recombination in an intermediate host.

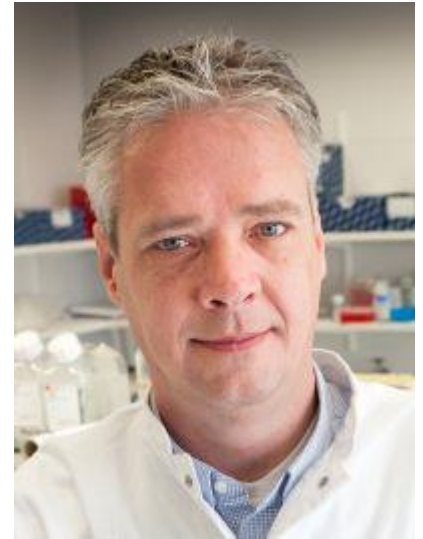
[Abstract](#) [Full Text](#)  [PDF](#)

The Potential for Respiratory Droplet-Transmissible A/H5N1 Influenza Virus to Evolve in a Mammalian Host

BY COLIN A. RUSSELL, JUDITH M. FONVILLE, ANDRÉ E. X. BROWN, DAVID F. BURKE, DAVID L. SMITH, SARAH L. JAMES, SANDER HERFST, SANDER VAN BOHEEMEN, MARTIN LINSTER, EEFJE J. SCHRAUWEN, LEAH KATZELNICK, ANA MOSTERÍN, THIJS KUIKEN, EILEEN MAHER, GABRIELE NEUMANN, ALBERT D. M. E. OSTERHAUS, YOSHIHIRO KAWAOKA, RON A. M. FOUCHIER, DEREK J. SMITH
SCIENCE | 22 JUN 2012 : 1541-1547 | 

Some natural influenza viruses need only three amino acid substitutions to acquire airborne transmissibility between mammals.

[Abstract](#) [Full Text](#)  [PDF](#)



河岡義裕

Pause on Avian Flu Transmission Research

Ron A. M. Fouchier,^{1*} Adolfo García-Sastre,² Yoshihiro Kawaoka,³ Wendy S. Barclay,⁴ Nicole M. Bouvier,⁵ Ian H. Brown,⁶ Ilaria Capua,⁷ Hualan Chen,⁸ Richard W. Compans,⁹ Robert B. Couch,¹⁰ Nancy J. Cox,¹¹ Peter C. Doherty,¹² Ruben O. Donis,¹³ Heinz Feldmann,¹⁴ Yi Guan,¹⁵ Jaqueline Katz,¹⁶ H. D. Klenk,¹⁷ Gary Kobinger,¹⁸ Jinhua Liu,¹⁹ Xiufan Liu,²⁰ Anice Lowen,²¹ Thomas C. Mettenleiter,²² Albert D. M. E. Osterhaus,²³ Peter Palese,²⁴ J. S. Malik Peiris,²⁵ Daniel R. Perez,²⁶ Jürgen A. Richt,²⁷ Stacey Schultz-Cherry,²⁸ John Steel,²⁹ Kanta Subbarao,³⁰ David E. Swayne,³¹ Toru Takimoto,³² Masato Tashiro,³³ Jeffery K. Taubenberger,³⁴ Paul G. Thomas,³⁵ Ralph A. Tripp,³⁶ Terrence M. Tumpey,³⁷ Richard J. Webby,³⁸ Robert G. Webster³⁹

¹Department of Virology, Erasmus MC, 3000CA Rotterdam, 3015GE Rotterdam, Netherlands. ²Department of Microbiology, Mount Sinai School of Medicine, New York, NY 10029, USA. ³Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison, Madison, WI 53711, USA. ⁴Department of Medicine, Imperial College, London, UK. ⁵Division of Infectious Diseases and Department of Microbiology, Mount Sinai School of Medicine, New York, NY 10029, USA. ⁶Virology Department, Animal Health and Veterinary Laboratories Agency, Addlestone, KT15, UK. ⁷Istituto Zooprofilattico Sperimentale delle Venezie, 35020, Padova, Italy. ⁸Harbin Veterinary Research Institute, CAAS, Harbin 150001, China. ⁹Influenza Pathogenesis and Immunology Research Center, Emory University, School of Medicine, Atlanta, GA 30322, USA. ¹⁰Department of Molecular Virology and Microbiology, Baylor College of Medicine, Houston, TX 77030, USA. ¹¹Centers for Disease Control and Prevention, Influenza Division, Atlanta, GA 30333, USA. ¹²Department of Immunology, St. Jude Children's Research Hospital, Memphis TN 38105, USA. ¹³Molecular Virology and Vaccines Branch, Influenza Division, Centers for Disease Control and Prevention, Atlanta, GA 30333, USA. ¹⁴Laboratory of Virology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Rocky Mountain Laboratories, Hamilton, MT 59840, USA. ¹⁵State Key Laboratory of Emerging Infectious Diseases, The University of Hong Kong, Hong Kong SAR. ¹⁶Immunology and Pathogenesis Branch, Influenza Division, Centers for Disease Control and Prevention, Atlanta, GA 30333, USA. ¹⁷Institut für Virologie, 35043 Marburg, Germany. ¹⁸National Microbiology Laboratory, Public Health Agency of Canada, Winnipeg, Manitoba R3E 3R2, Canada. ¹⁹Department of Preventative Veterinary Medicine, China Agricultural University, Beijing, China. ²⁰Animal Infectious Disease Laboratory, School of Veterinary Medicine, Yangzhou University, Yangzhou, Jiangsu 225009, China. ²¹Department of Microbiology and Immunology, Emory University School of Medicine, Atlanta, GA 30322, USA. ²²Friedrich-Loeffler-Institut, D-17493 Greifswald-Insel Riems, Germany. ²³Department of Virology, Erasmus MC, Rotterdam, Netherlands. ²⁴Department of Microbiology, Mount Sinai School of Medicine, New York, NY 10029-6574, USA. ²⁵Department of Microbiology and HKU-Pasteur Research Centre, The University of Hong Kong, Pokfulam, Hong Kong SAR. ²⁶Department of Veterinary Medicine, University of Maryland, College Park, College Park, MD 20742, USA. ²⁷College of Veterinary Medicine, Kansas State University, Manhattan, KS 66506, USA. ²⁸Department of Infectious Diseases, St. Jude Children's Research Hospital, Memphis, TN 38105, USA. ²⁹Department of Microbiology and Immunology, Emory University, School of Medicine, Atlanta, GA 30322, USA. ³⁰Emerging Respiratory Viruses Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 20892-3203, USA. ³¹Southeast Poultry Research Laboratory, USDA/Agricultural Research Service, Athens, GA 30605, USA. ³²Department of Microbiology and Immunology, University of Rochester Medical Center, Rochester, NY 14642, USA. ³³National Institute of Infectious Diseases, Influenza Virus Research Center, Tokyo, 208-001, Japan. ³⁴Viral Pathogenesis and Evolution Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 20892-3203 USA. ³⁵Department of Immunology, St. Jude Children's Research Hospital, Memphis, TN 38105-3678, USA. ³⁶Department of Infectious Diseases, College of Veterinary Medicine, University of Georgia, Athens, GA 30602, USA. ³⁷Influenza Division, Centers for Disease Control and Prevention, Atlanta, GA 30333, USA. ³⁸Department of Infectious Diseases, St. Jude Children's Research Hospital, Memphis, TN 38105-3678, USA. ³⁹Division of Virology, Department of Infectious Diseases, St. Jude Children's Research Hospital, Memphis, TN 38105, USA.



Editorial | Published: 22 February 2012

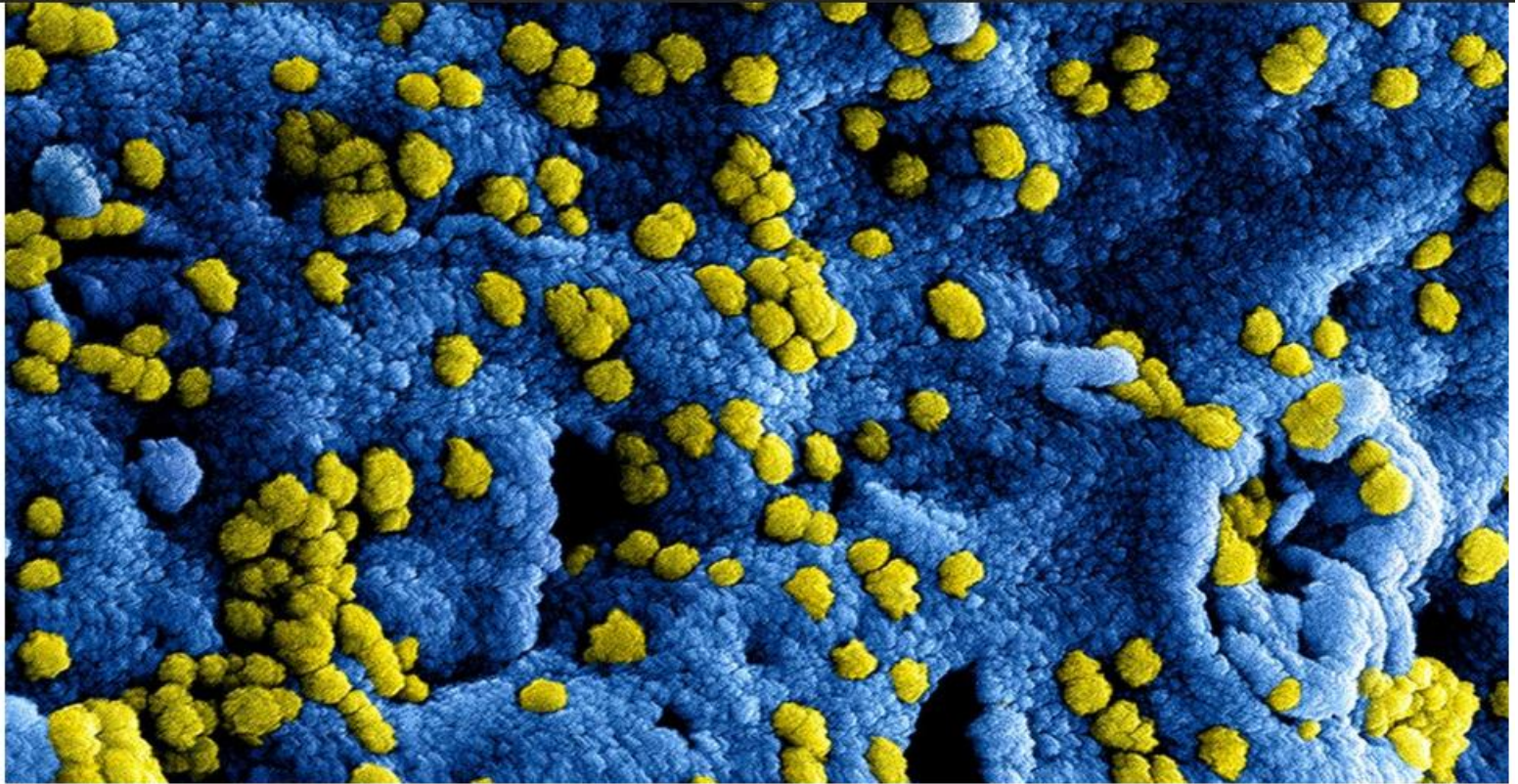
Flu papers warrant full publication

Nature **482**, 439 (23 February 2012) | [Download Citation](#) ↓

Although more debate is needed, the benefits of publishing sensitive data outweigh the risks that have so far been made public.

《自然》期刊：目前對生物安全的關注「太空泛而且是假設性的。」

《科學》的主編艾柏特博士（Bruce Alberts）認為，發表在兩期刊的研究報告，比起淪為恐怖分子的不當使用，更能有效讓需要這些資訊的正派科學家們使用，可說是一把「雙面刃」（Dual Use Research of Concern, DURC）



MERS coronavirus particles NIAID/Flickr (CC BY 2.0)

U.S. halts funding for new risky virus studies, calls for voluntary moratorium

By Jocelyn Kaiser, David Malakoff | Oct. 17, 2014, 5:45 PM

美國暫停資助新的高風險病毒研究，並呼籲自願暫停



A worker at a Centers for Disease Control and Prevention laboratory harvests avian flu viruses for sharing with other laboratories in 2013. JAMES GATHANY/CDC

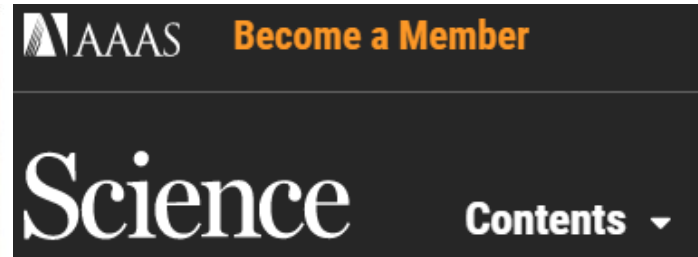
EXCLUSIVE: Controversial experiments that could make bird flu more risky poised to resume

By Jocelyn Kaiser | Feb. 8, 2019, 8:45 PM

Posted in: [Science and Policy](#)

doi:[10.1126/science.aaw9566](https://doi.org/10.1126/science.aaw9566)

準備恢復可能使禽流感風險更大的有爭議實驗



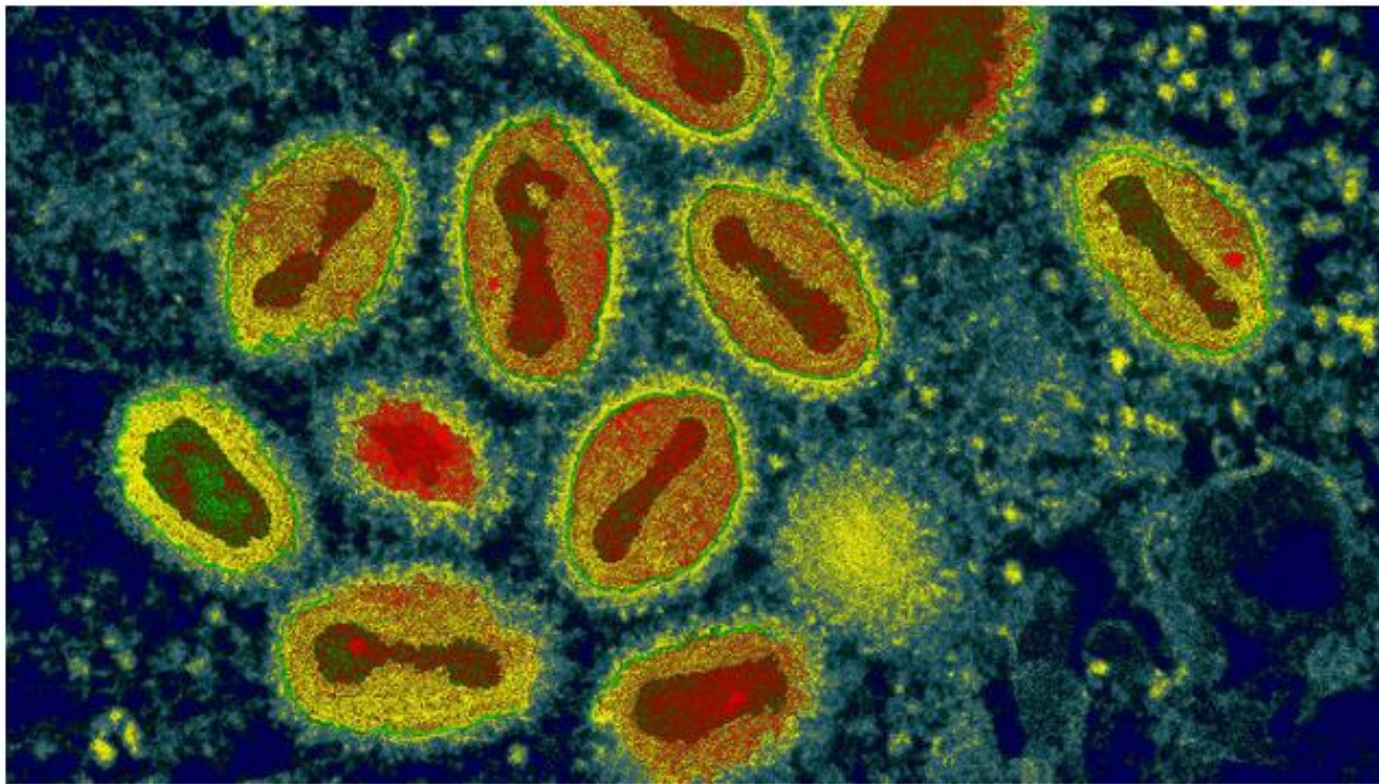
Yoshihiro Kawaoka (left) and Ron Fouchier (right) in 2012, after their work with H5N1 bird flu virus sparked a global controversy over research that can potentially make pathogens more dangerous to humans. MARTIN ENSERINK/SCIENCE

BIOSECURITY SNIPPETS + SPILLOVER

BWC: 禁止生物武器公約

Is There a Role For the BWC in Oversight of Lab-Created Potential Pandemic Pathogens?

by Global Biodefense September 8, 2019



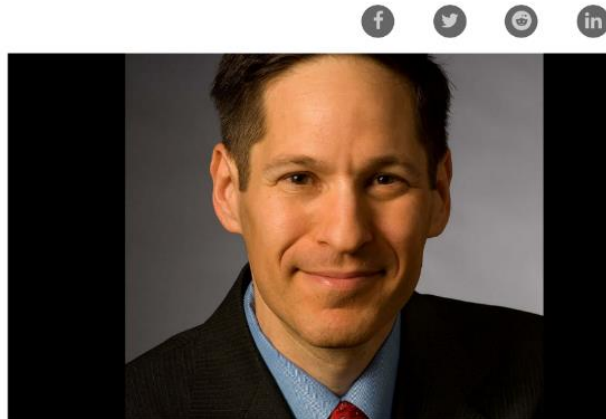
An unpublished study suggests that making variola, the virus that causes smallpox, is neither expensive nor difficult.

Eye of Science/Science
Source

How Canadian researchers reconstituted an extinct poxvirus for \$100,000 using mail-order DNA

By Kai Kupferschmidt | Jul. 6, 2017, 5:00 PM

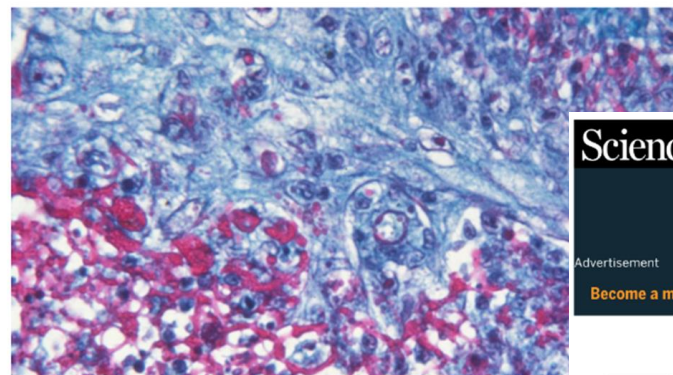
2014生物安全奇蹟年？



CDC Director Thomas Frieden Canlan Control/Wikimedia

Lab incidents lead to safety crackdown at CDC

By Jocelyn Kaiser | Jul. 11, 2014, 4:15 PM



Human skin infected with the smallpox virus. U.S. Center

Six vials of smallpox discovered in U.S. lab

By Jocelyn Kaiser | Jul. 8, 2014, 4:45 PM



A vial of the smallpox found earlier this month at NIH. CDC

Congress asks why CDC safety problems persist

By Jocelyn Kaiser | Jul. 16, 2014, 4:15 PM



Anthrax colonies growing in a dish. Centers for Disease Control & Prevention

CDC says 75 workers may have been exposed to anthrax

By David Malachuk | Jun 10, 2014, 6:00 PM

NEWS

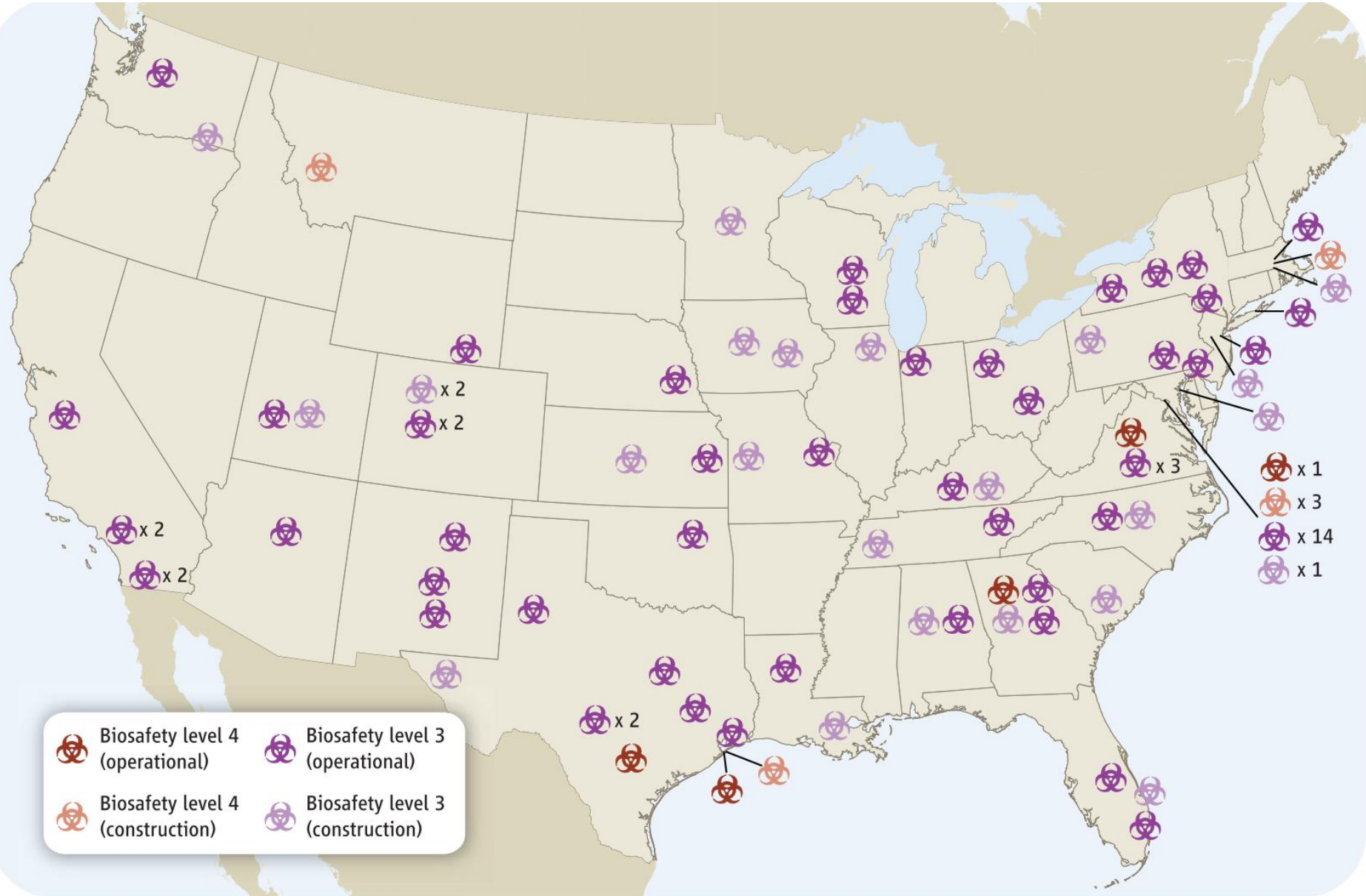
A USA TODAY
NETWORK
INVESTIGATION





Inside America's secretive biolabs

➔ Read Story

Alison Young and Nick Penzenstadler, USA TODAY

A USA TODAY Network investigation last year revealed hundreds of safety accidents at corporate, university, government and military labs nationwide. It also exposed a system of fragmented federal oversight and pervasive secrecy that obscures failings by facilities and regulators. 《今日美國》去年進行的一項網路調查顯示，美國各地的企業、大學、政府和軍方實驗室發生了數百起安全事故。它還暴露了一個分散的聯邦監管體系和無處不在的保密制度，這些制度掩蓋了設施和監管機構的缺陷。



 Biosafety level 4 (operational)	 Biosafety level 3 (operational)
 Biosafety level 4 (construction)	 Biosafety level 3 (construction)

 x 1
 x 3
 x 14
 x 1

x 2

x 2

x 2

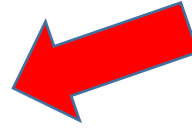
x 2

x 2

x 3



BIOLABS
IN YOUR
BACKYARD



Looking for a cure

DAILY HANDLING OF DEADLY PATHOGENS LIKE
EBOLA, PLAGUE, ANTHRAX



Spreading into the community

WHILE RARE, AN ACCIDENTAL RELEASE COULD
BE A DISASTER



Limitations of self-policing

SOME RESEARCHERS IGNORE BIOSAFETY RULES



Congress gets limited, wrong information

A \$425,000 FINE THAT DISAPPEARED

Lab failures kept hidden

KEY DETAILS OF ENFORCEMENT ACTIONS ARE
SECRET

2002年《公共衛生安全和生物恐怖主義防範與應變法》

CDC officials were unavailable for interviews and officials with the select agent program declined to provide additional information. The USDA said in a statement Friday that all of the information is protected under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

CDC官員無法接受採訪，參與select agent專案的官員拒絕提供更多資訊。美國農業部星期五在一份聲明中說，所有這些資訊都受到2002年《公共衛生安全和生物恐怖主義防範與應變法》的保護。

CDC keeps secret its mishaps with deadly germs

Alison Young, USA TODAY

Published 11:18 a.m. ET Jan. 4, 2017 | Updated 7:11 p.m. ET Jan. 4, 2017

The CDC had previously cited the 2002 bioterrorism law to keep secret the names of government, public and private labs including its own that have been suspended or that have faced enforcement actions for violating safety and security regulations in their work with potential bioterror pathogens.

CDC此前曾援引2002年的《**生物恐怖主義法**》(bioterrorism law)，對政府、公共和私人實驗室(包括CDC自己的實驗室)的名稱保密，這些實驗室在處理潛在的生物恐怖病原體時，因違反安全和安保規定而被暫停或面臨執法行動。

Federal Select Agent Program (2003, 2009, 2010, 2012)

In an effort to determine the extent of the CDC's lab-safety problems, **USA TODAY** filed a request on Jan. 6, 2015 under **the Freedom of Information Act** (FOIA 訊息自由法) seeking copies of lab incident reports for the previous two years .

Newly disclosed CDC biolab failures 'like a screenplay for a disaster movie'

Alison Young, USA TODAY

Published 12:01 p.m. ET June 2, 2016 | Updated 5:43 p.m. ET June 2, 2016

2013 December Influenza Incident Heavily Redacted 15 00302 A Young OADS From T113016 1109am

Stevens, James (CDC/OID/NCIRD)

From: (b)(6) (CDC/OID/NCIRD) (CTR)
Sent: Monday, December 16, 2013 10:06 AM
To: Brykailo Pearce, Melissa (CDC/OID/NCIRD)
Cc: Tumpey, Terrence (CDC/OID/NCIRD); Katz, Jackie M. (CDC/OID/NCIRD); Shaw, Michael (CDC/OID/OD); Zambuto, Laura R. (CDC/OID/NCIRD)
Subject: RE: followup
Attachments: Accident report.docx

Hi,

I am really sorry for what have happened, and I will

(b)(3); 42 U.S.C. § 262a(h)

Thanks,

(b)(6)

From: Brykailo Pearce, Melissa (CDC/OID/NCIRD)
Sent: Friday, December 13, 2013 3:30 PM
To: (b)(6) (CDC/OID/NCIRD) (CTR)
Cc: Tumpey, Terrence (CDC/OID/NCIRD); Katz, Jackie M. (CDC/OID/NCIRD); Shaw, Michael (CDC/OID/NCIRD); Zambuto, Laura R. (CDC/OID/NCIRD)
Subject: followup

H (b)(6)

Please write up a description of what happened

(b)(3); 42 U.S.C. § 262a(h)

(b)(3); 42 U.S.C. § 262a
(h)

Send it to all those that are listed on this email please.

August 2014 CDC lab incident email

(b)(3)-42 U.S.C. § 262a(h) (CDC/OID/NCEZID)

From: (b)(3)-42 U.S.C. § 262a(h) (CDC/OID/NCEZID)
Sent: Friday, June 26, 2015 12:07 PM
To: (b)(3)-42 U.S.C. § 262a(h) (CDC/OID/NCEZID)
Subject: FW: Lab Incident

What we have for (b)(6) incident.

From: (b)(3)-42 U.S.C. § 262a(h) (CDC/OID/NCEZID)
Sent: Friday, August 01, 2014 11:26 AM
To: (b)(3)-42 U.S.C. § 262a(h) Reynolds, Mary (CDC/OID/NCEZID)
Cc: (b)(6) CDC/OID/NCEZID
Subject: Lab Incident

Hi,

When I came in this morning,

(b)(3)-42 U.S.C. § 262a(h)

☺ Please let me know if you have any questions.

Kind regards,

Congressional watchdogs demand names, details of sanctioned bioterror labs

[Alison Young](#), USA TODAY Published 3:33 p.m. ET July 6, 2015 | Updated 5:57 p.m. ET July 6, 2015

Senators, health experts demand action to address biolab accidents

[Alison Young](#), USA TODAY Published 6:00 a.m. ET June 29, 2015

Sep 2016: Congressional Hearing on Inactivation Procedures for Dangerous Pathogens

The Subcommittee on Oversight and Investigations held a hearing on 27 Sep 2016 entitled “Bioresearch Labs and Inactivation of Dangerous Pathogens.”



Emergency trainees mistakenly exposed to deadly ricin

[Alison Young](#), USA TODAY Published 3:14 p.m. ET Dec. 15, 2016 | Updated 7:37 p.m. ET Dec. 15, 2016



The Center for Domestic Preparedness reportedly made the discovery recently and found it had been using the deadly strand for five years. Video provided by Newsy Newslook

Labs cited for 'serious' security failures in research with bioterror germs

Alison Young, USA TODAY Published 4:17 p.m. ET Aug. 28, 2015

Among the ways a lab worker could pose a threat, federal officials say:

A person with ill intent infiltrates a research facility under the guise of a researcher to steal, release or divert dangerous pathogens.

A person working at the facility is coerced or manipulated into providing access or expertise to people intending harm.

A person legitimately working with pathogens who experiences a significant life changing event that prompts misuse, release or diversion of pathogens.

美國聯邦官員表示，實驗室工作人員構成威脅的方式包括：

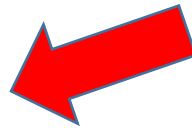
- 一個懷有惡意的人假借研究人員之名潛入研究機構，竊取、釋放或轉移危險的病原體。
- 在該設施工作人員受到脅迫或操縱，向有意傷害別人的人提供專業知識。
- 與病原體有機會接觸的工作人員，經歷了重大的生命轉折事件，引起了病原體的濫用、釋放或轉移。

適任性評估

- 適任性評估程序之目的為降低“內部威脅”。“內部威脅”通常是指個人在其工作職權範圍內可取得高危險管制性病原及毒素，可能濫用該等病原及毒素。“內部威脅”之例子如下：
 - 具有惡意企圖之人員，以合法研究人員身份滲透研究機構，藉以竊取、釋出或移轉高危險管制性病原或毒素；
 - 可取得高危險管制性病原及毒素之人員遭受脅迫或操縱，將該等病原及毒素或其專業知識，提供具有惡意企圖之未被指定人員；
 - 個人因工作需要可合法取得高危險管制性病原及毒素，惟因人生發生重大變故，導致可能濫用、釋出或移轉高危險管制性病原或毒素。



BIOLABS
IN YOUR
BACKYARD



Looking for a cure

DAILY HANDLING OF DEADLY PATHOGENS LIKE
EBOLA, PLAGUE, ANTHRAX



Spreading into the community

WHILE RARE, AN ACCIDENTAL RELEASE COULD
BE A DISASTER



Limitations of self-policing

SOME RESEARCHERS IGNORE BIOSAFETY RULES

Lab failures kept hidden

KEY DETAILS OF ENFORCEMENT ACTIONS ARE
SECRET



Congress gets limited, wrong information

A \$425,000 FINE THAT DISAPPEARED

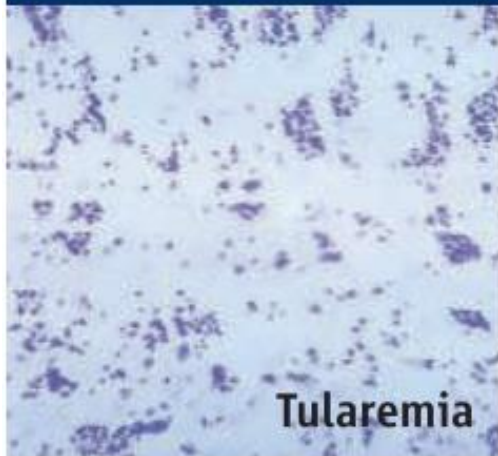


BIOSAFETY BREACHES

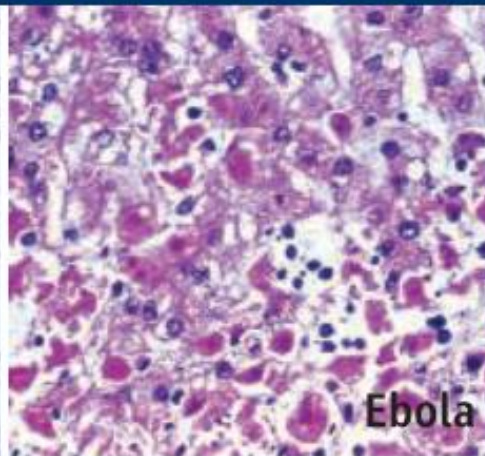
Accidents Spur a Closer Look at Risks at Biodefense Labs

Failure to report a *Brucella* infection and other problems at a Texas university have microbiologists searching for ways to ensure safety and public trust

Some Recent Exposures in U.S. Biodefense Labs



Tularemia



Ebola



Brucellosis

2002, 2003: *E. coli* 0157:H7 infections in two USDA labs

2004: Three workers infected with tularemia, Boston University **OSHA fine: US\$8100**

2004: Ebola needle stick (no infection), USAMRIID

2004: Anthrax exposure (no infection), Children's Hospital, Oakland, CA

2004: Valley fever (*C. immitis*) infection, Medical College of Ohio

2005: Potential Q fever exposure, Rocky Mountain Labs, Hamilton, MT

2006: Brucellosis infection, Texas A&M **CDC fine: US\$1 million**

Texas Tech University

Who: Thomas Butler

Agent: *Yersinia pestis*

What: Apparent loss of 30 vials containing bacteria

69 counts including illegal transportation, tax fraud, embezzlement, fraud, lying to federal officials

Outcomes: **2 years jail time & US\$38,000 fine**





2003-2009

Report: 395 mishaps at US labs risked releasing select agents

Filed Under: [Bioterrorism](#); [Ebola](#); [Tularemia](#)

By: Robert Roos | Sep 28, 2011



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Print & PDF

- animal bites and scratches, 11 cases
- needle stick or sharps injuries, 46
- equipment mechanical failure, 23
- personal protective equipment failure, 12
- procedural issues, 30

Tulane accident



聯邦官員調查名為伯克霍德爾氏假單胞菌(*Burkholderia pseudomallei*)的致命外來細菌，如何從占地500英畝的靈長類動物研究中心(primate center campus)的高等級安全實驗室裡逃出來，導致三隻沒有參與任何實驗的猴子患病。美國CDC調查人員最終得出結論，細菌很可能是藉由草率的生物安全措施，由工作人員的衣服帶出實驗室。



Professor's wrongful termination lawsuit against University of Pittsburgh includes an escaped monkey

By [Nicholas Malfitano](#) | [Jan 29, 2018](#)



2 died in Soviet Ebola weapons lab



**Soviet Union
"Vector"**

**1996
2004**





Lessons Learned

- ✓ 風險評估
- ✓ 標準流程建立
- ✓ 打疫苗
- ✓ 教育訓練
- ✓ 強化管理模式及防護設施設備
- ✓ 瞭解傳染病特徵及症狀
- ✓ 立即通報實驗室所發生的意外事件

通報管制性病原主管

- 可疑活動

- 保全計畫應規範如何向管制性病原主管通報可疑活動、可能與工作人員或其涉及管制性病原及毒素有關之犯罪，並規範設置單位如何通報相關主管機關之程序以及適合負責處置之人員。

- 可疑活動包括：

- 在特定場域進行保全風險評估，以鑑別可疑活動。

- 內部人員：

- 企圖增加未經授權或非需要之管制性病原及毒素之庫存。
- 企圖隱匿及不通報管制性病原及毒素庫存差異。
- 企圖未經授權移除管制性病原及毒素之庫存。
- 企圖讓被限制人員(例如：經警察機關依司法或軍法機關判定、執行刑事犯罪紀錄之人員)進入存在管制性病原及毒素之管制區域。

訓練

- 保全計畫之持續評估程序應涵蓋人員教育訓練，內容包含從事高危險**管制性病原及毒素通報政策及程序、人員適任性評估及其矯正措施**。
- 依管制性病原及毒素管理法規規定，保存、使用高危險管制性病原之設置單位，每年應辦理內部威脅意識教育，教育員工**如何識別可疑行為及通報相關主管**。
- 內部威脅意識教育可與**生物安全、保全、事故應變及特定工作職務**等教育訓練合辦，以節省資源及時間。高危險管制性病原及毒素內部特殊教育訓練之主要重點是（1）提升內部威脅意識，（2）告知高危險管制性病原被指定人員，有關設置單位適任性評估計畫之政策及程序。此訓練至少包含下列內容：

訓練至少包含下列內容：

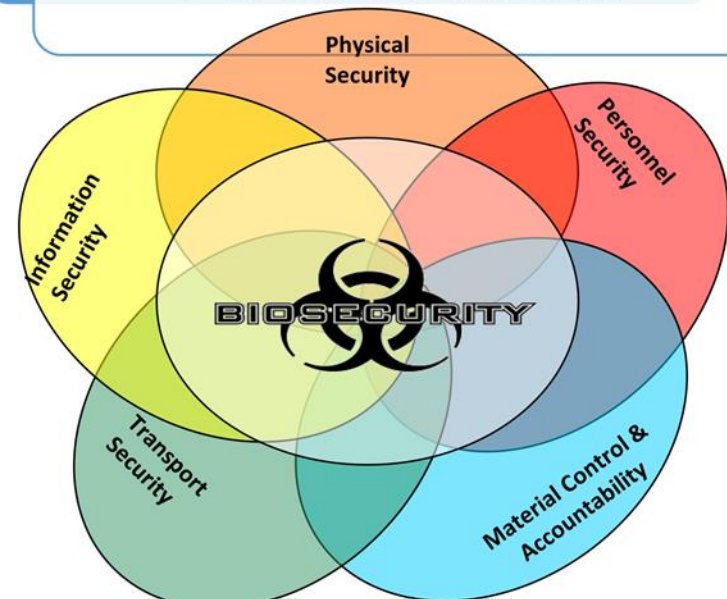
- 內部威脅意識。
- 應被注意的行為。
- 設置單位對於高危險管制性病原之職前適任性政策。
- 自我及同儕通報程序。
- 高危險管制性病原及毒素使用者評估流程。
- 設置單位持續適任性評估程序之政策。
- 設置單位持續適任性監督程序之政策。
- 矯正措施、程序及政策。
- 自願及非自願取消可取得高危險管制性病原及毒素之程序。
- 資訊保全。

Identification of Biorisks

Biosafety Risk Assessment



Biosecurity Risk Assessment

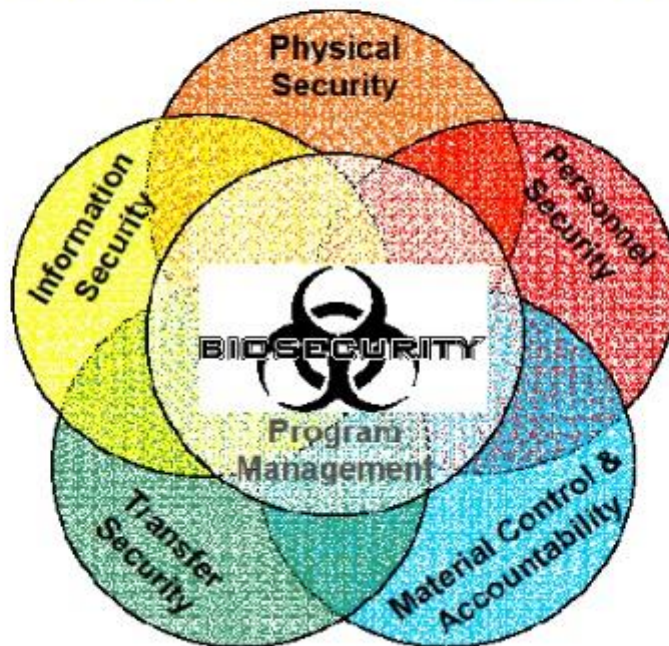


Biosecurity 生物保全

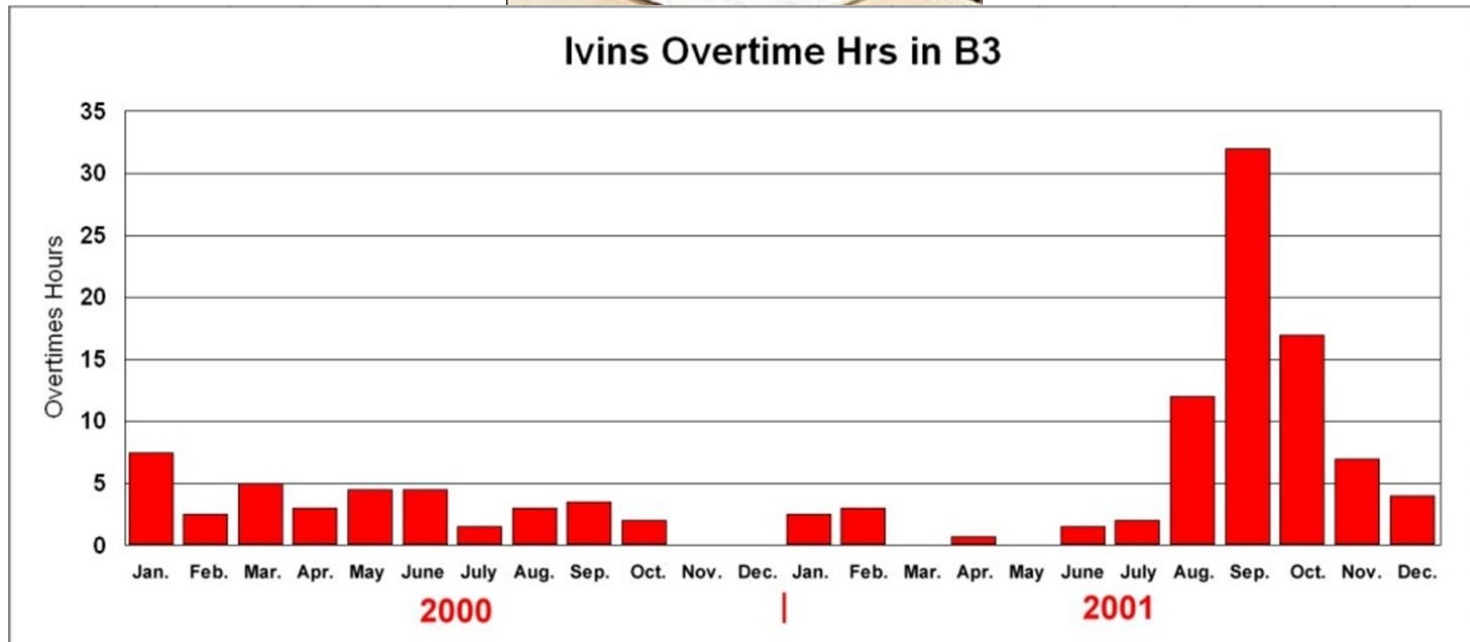
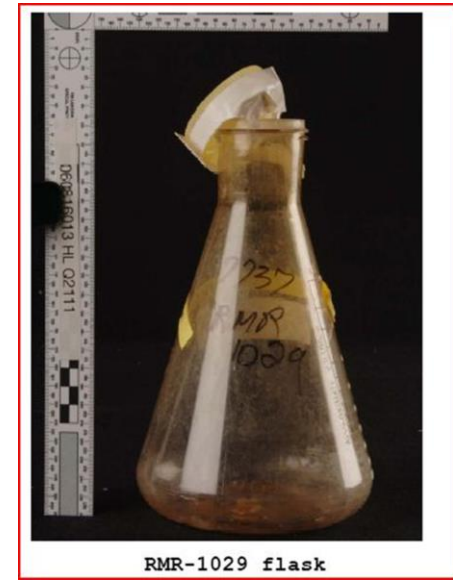
- 目的在於避免（管制性）病原及毒素遺失、被偷、濫用及故意流出等。



COMPONENTS OF LABORATORY BIOSECURITY



2001 Anthrax incident



生物保全規劃

• 物理性保全

- Review of building ,laboratories, and storage areas
- Limit access

• 人員管理

- Proper identification of personnel and visitors



• 病原可靠性

- Identify agents and their location

• 資訊安全

- Establish polices for handling sensitive information
- Ensure confidentiality



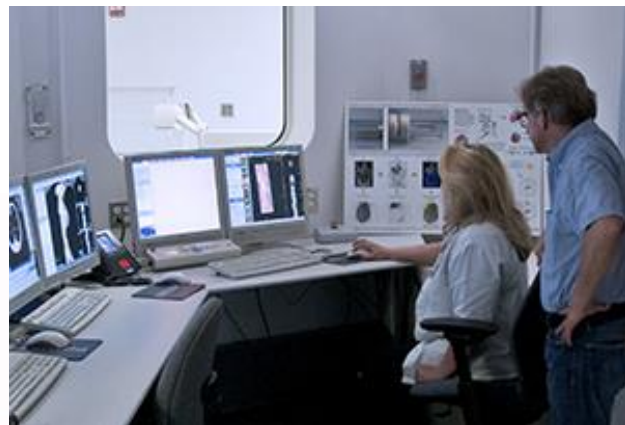
門禁管制



冰箱密碼（取材自伊波拉浩劫）



監視系統



Biosafety?



Biosecurity?

智能移動追蹤網路攝影機

守護寶-IP04

Full HD
1080

智能
跟蹤

遠端
監控

移動
偵測

多人
連線

1080P 超高畫質

物體移動自動追蹤

A white smart camera with a lens and a microphone, positioned in a room. In the background, there are two people wearing black balaclavas and holding a laptop, suggesting a security or surveillance context. The camera is the central focus of the advertisement.

內部威脅大綱

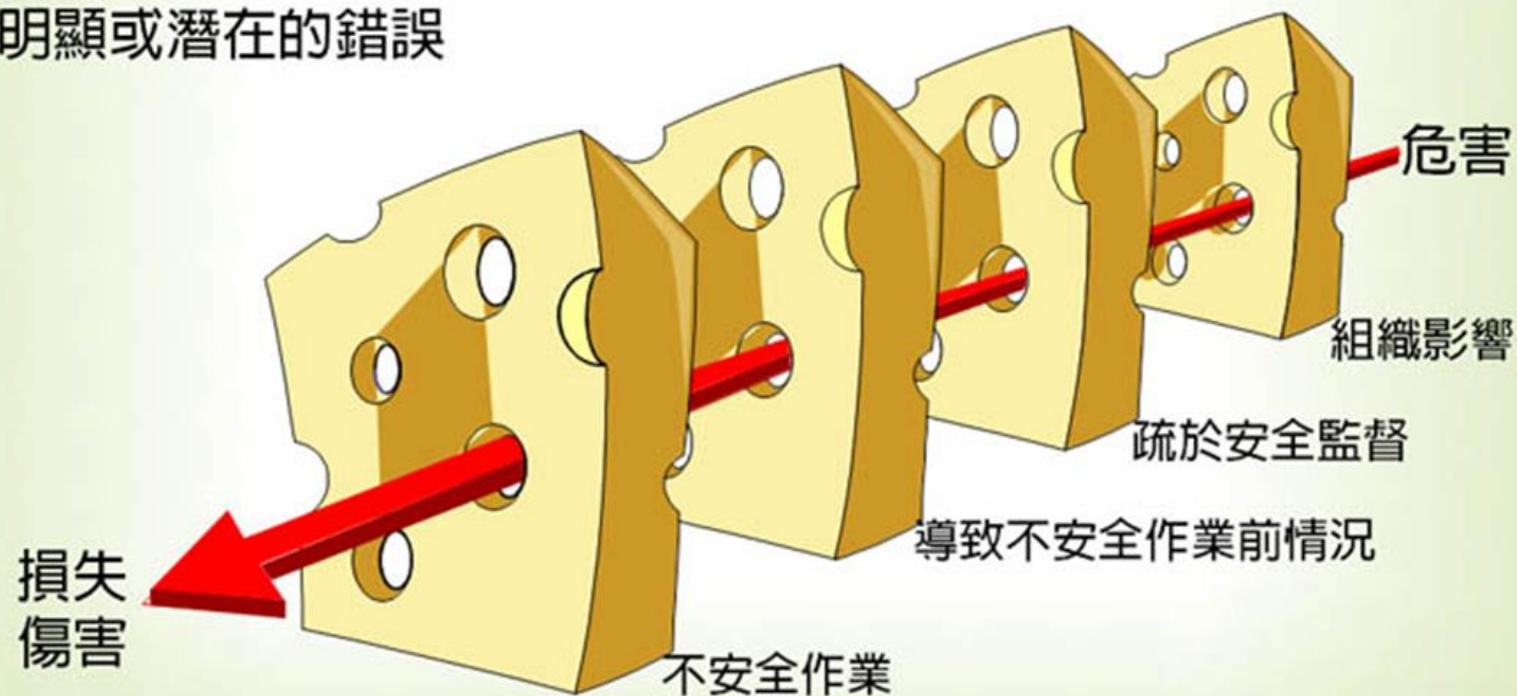
- 我的team members OK嗎？
- 我有確認病原的機制嗎？
- 病原標示及保存的方式明確嗎？
- 防護設備是否品質保證？
- 有動物逃離實驗室的風險嗎？

內部威脅 vs 外部威脅

- 人的威脅：適任性評估、設備維護失當
- 病原的威脅：管理失當、意外或刻意流出
- 法令完備性
- 建構更好的實驗室事故回報系統
 - 人們需要從錯誤中吸取教訓，但首先要瞭解已經犯下的錯誤，如果從未聽說過這些錯誤，又怎能從中學習。

瑞士乳酪模式

一片乳酪：一道防禦機制
洞：明顯或潛在的錯誤



若乳酪上的空洞連成一線，代表事件發生。

Question?



Thank You!

