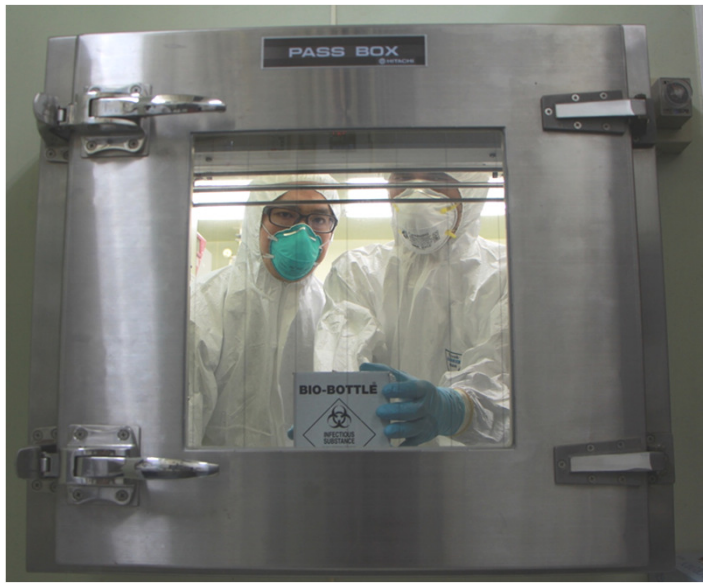
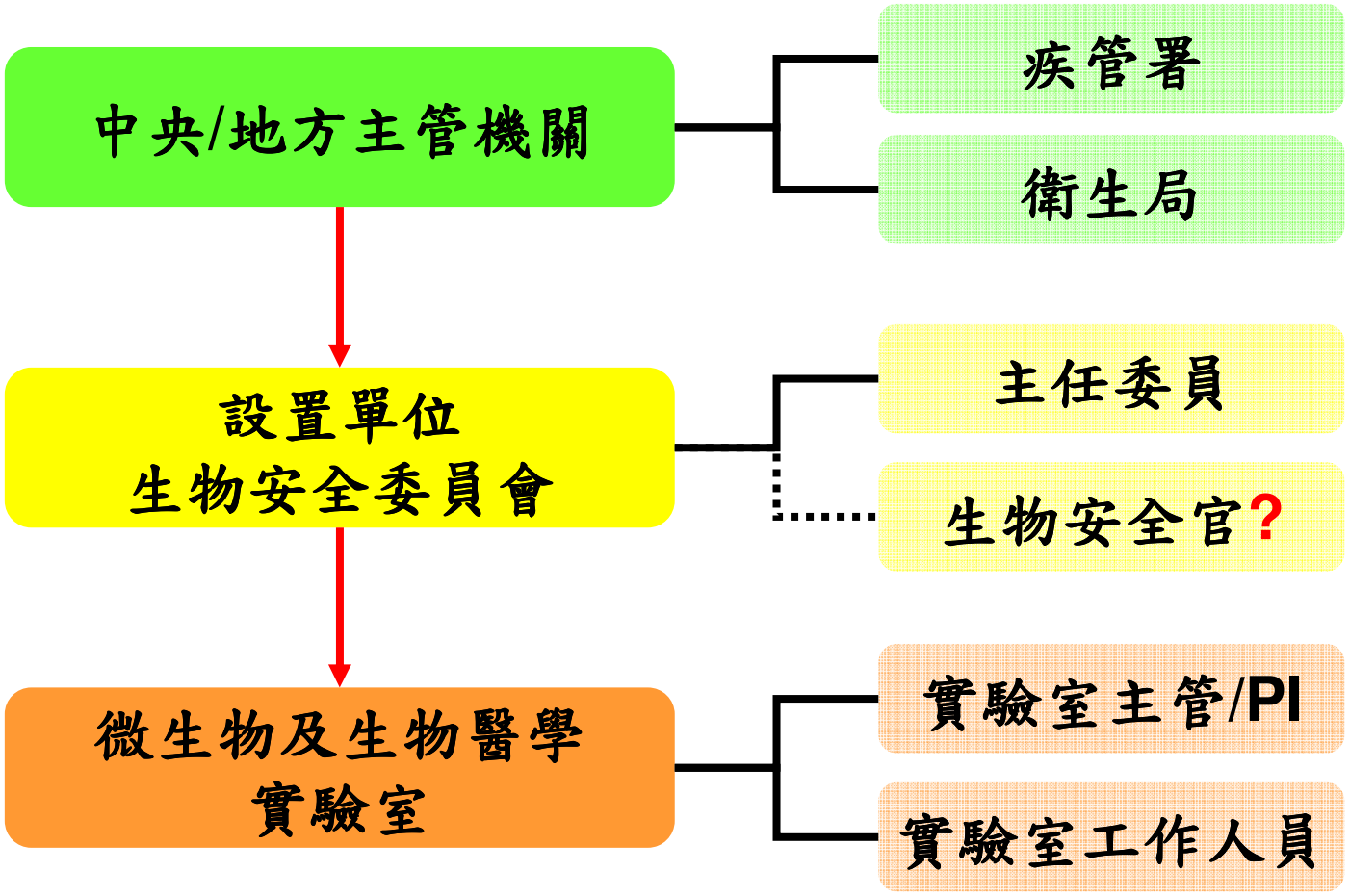
102年我國實驗室生物安全相關議題

- 中國大陸發生人類感染H7N9流感疫情
- 我國發生鼬獾感染狂犬病疫情



我國實驗室生物安全之核心



實驗室生安管理對策_管理系統

- 推動國內微生物及生物醫學實驗室導入「CWA 15793:2011實驗室生物風險管理」標準，建立「實驗室生物風險管理系統」；
- 以「持續改善」為基礎，採取PDCA(規劃-執行-查核-行動）循環流程，促使實驗室主動、有效之鑑別與監控生物安全及保全各方面之活動。

CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2008

CEN

WORKSHOP

AGREEMENT

CWA 15793

September 2011

S 07.100.01

English version

Laboratory biorisk management

CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of
is indicated in the foreword of this Workshop Agreement.

ormal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National

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WORKSHOP

AGREEMENT

CWA 16393

January 2012

ICS 07.100.01

English version

Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

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Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accoun
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This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodie

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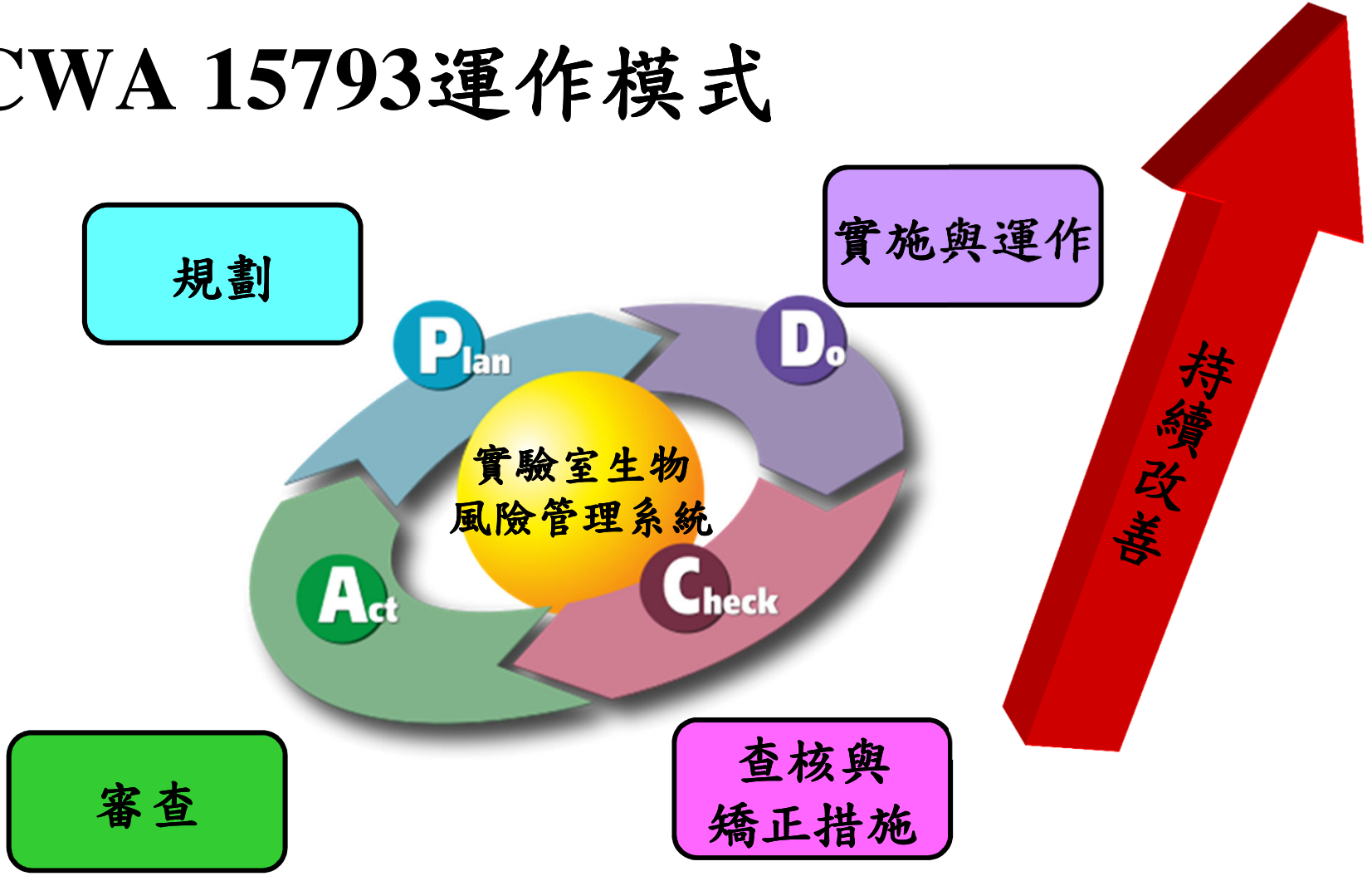
Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway,
Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CWA 15793運作模式



實驗室生安管理對策_管理組織

- 設置單位：提升「生物安全委員會」實質監督及管理功能。
- 衛生主管機關
  - 疾管署：主管RG3以上病原體、管制性生物毒素、BSL-3以上實驗室等督導及查核工作；
  - 地方衛生局：主管RG2以下病原體、一般性生物毒素、BSL-2以下實驗室等督導及查核工作。
- 各目的事業主管機關：加強跨部會主管機關就全國實驗室生物安全管理事務，進行分工及整合。

實驗室生安管理對策_人員知能

- 建立我國實驗室生物安全
  - 初階、中階及高階等三階人員
  - 潛在危害、危害控制、行政管控、緊急應變等四項知能評核
- 確保各階人員具備應有之生物安全知能。

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Supplement / Vol. 60
April 15, 2011

Guidelines for Biosafety Laboratory Competency

CDC and the Association of Public Health Laboratories

實驗室生安管理對策_實驗室評核

- 依據WHO於2004年出版「Laboratory biosafety manual」指出，診斷及衛生保健實驗室（包括公衛、臨床或醫院為基礎）必須是BSL-2以上實驗室。
- WHO於2005年出版「International Health Regulations」之核心能力，要求在健康照護體系下，診斷實驗室應為經authorized或certified之BSL-2以上實驗室。
- 評核基準：生物安全第一等級至第三等級實驗室安全規範。

實驗室生安管理對策_PSDS

- 建立我國已登錄158種(RG2=139種；RG3=19種)「病原體安全資料表（Pathogen safety data sheet，PSDS）」。
- 提供實驗室工作人員、運送人員及救災人員使用。

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Pathogen Safety Data Sheets and Risk Assessment

Pathogen Safety Data Sheets (PSDSs) (previously titled Material Safety Data Sheets for infectious substances) are technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting. These documents have been produced by the Public Health Agency of Canada as educational and informational resources for laboratory personnel working with these infectious substances. Please note that work involving pathogens in Canada may require compliance with International, National, and Provincial laws and guidelines.

For those working with animal pathogens, your will find more information on the Canadian Food Inspection Agency's Disease Agent Information page.

Please note that although the information, opinions, and recommendations contained in these documents are compiled from peer-reviewed literature sources believed to be reliable, PHAC accepts no responsibility for the accuracy, sufficiency, or reliability of the PSDSs, nor for any loss or injury resulting from the use of the information contained within them. Newly discovered hazards are frequent and this information may not be completely up to date.

PSDS by Pathogen Name

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

A

http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

新修正辦法之主要差異

- 辦法名稱：感染性生物材料管理辦法（草案）
- 修正生物安全委員會（或專責人員）之成立條件及組成；
- 新增「生物毒素」之管制；
- 感染性生物材料之異動管理，限定於「RG2以上病原體及生物毒素」，「陽性檢體」排除；

新修正辦法之主要差異_續

- 感染性生物材料之運送包裝規定；
- 新增RG2以上病原體及生物毒素之定期盤點及異常通報等保全規定；
- 新增地方衛生主管機關之權責；
- 修正實驗室工作人員基礎血清保存規定；
- 明定實驗室生物安全教育訓練之對象及訓練時數