BIOSECURITY CHALLENGES OF THE GLOBAL EXPANSION OF HIGH-CONTAINMENT BIOLOGICAL LABORATORIES

Report Release and Summary of a Workshop

9:00 in **Salle XXIII** on

Thursday, 15 December 2011

BIOSECURITY ENGAGEMENT PROGRAM

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

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Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories

Introduction

- Sponsored by the U.S. Department of State Biosecurity Engagement Program
- Project by Policy and Global Affairs Division and Board on Life Sciences at the U.S. National Academy of Sciences
  - Workshop summary produced by Alison Hottes, Benjamin Rusek, and Fran Sharples
- *Panel:*
  - **Benjamin Rusek**, U.S. National Academy of Sciences
  - **Alison Hottes**, U.S. National Academy of Sciences (Consultant)
  - **James Le Duc**, University of Texas Medical Branch
  - **Serhiy Komisarenko**, Head, Commission on Biological Safety of National Security and Defense Council of Ukraine

Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories

Workshop Advisory Committee

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PETER PALESE, Mount Sinai School of Medicine
J. CRAIG REED, Inspirion Biosciences
WILLY TONUI, Kenya Medical Research Institute

Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories

Project Background

- Many countries considering establishing or expanding their high containment biological research laboratories
  - –Combat emerging or endemic infectious diseases
  - –Produce human and livestock vaccines
  - –Assist in disease surveillance
  - –Promote growth in biotechnology sector
  - –Increase safety compared to existing facilities
- Laboratories are complex systems with inherent risks
  - –Many factors influence the risks associated with each lab including laboratory maintenance, personnel training, and security precautions

Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories

Project Components

- **International Workshop**
  - 10-13 July 2011 in Istanbul, Turkey
  - Partnered with Turkish Academy of Sciences
  - 68 participants from 32 countries
    - Laboratory directors, scientists, engineers, and members of governmental and non-governmental organizations
    - Experts in biosafety, biosecurity, scientific research, disease surveillance, and public health
- Country and Region Overviews
  - Partners described their country's high-containment biological facilities, capabilities, and regulations as well as past accidents, safety and security issues, and lessons learned.
  - Report contains overviews for Brazil, the European Union, Pakistan, Russia, Sweden, Turkey, Ukraine, the United Kingdom, and the United States

Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories

Workshop Agenda and Goals

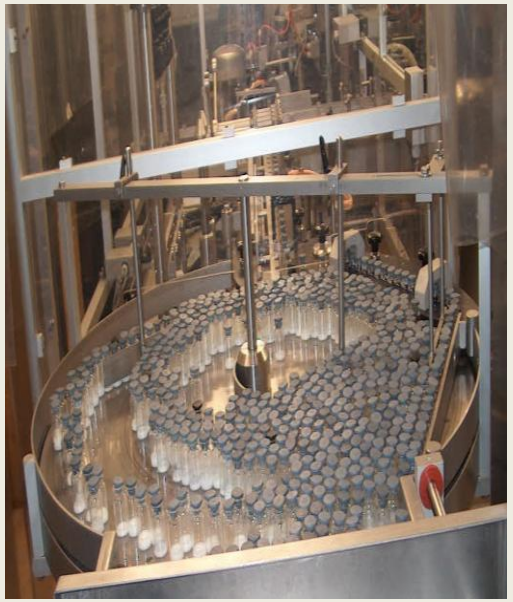
- Description of current norms
  - –Past and current challenges faced by attendees in their laboratories
  - –Steps taken to improve safety and security including training programs, personnel reliability measures, physical security, access controls, and monitoring pathogen inventories.
- Discussion topics
  - –Technological options to meet diagnostic, research, and other goals
  - –Laboratory construction and commissioning
  - –Maintenance to provide sustainable capabilities, safety, and security
  - –Measures for encouraging a culture of responsible conduct
  - –Strategies for enhancing biological safety and security worldwide
  - –Tensions in the field of biosafety and possible areas for local, regional and international action

Chulalongkorn University
Bangkok, Thailand
Photo: Sunee Sirivichayakul

Report Overview

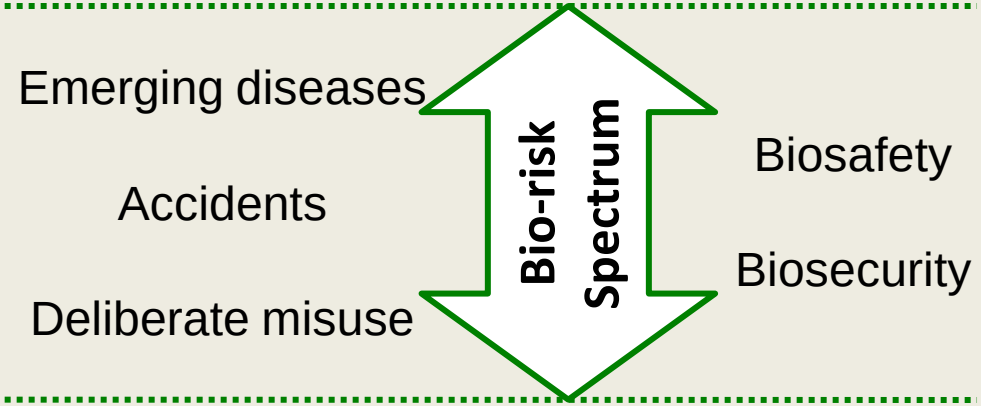
High Security Animal Disease Laboratory
Bhopal, India
Photo: Gaya Prasad

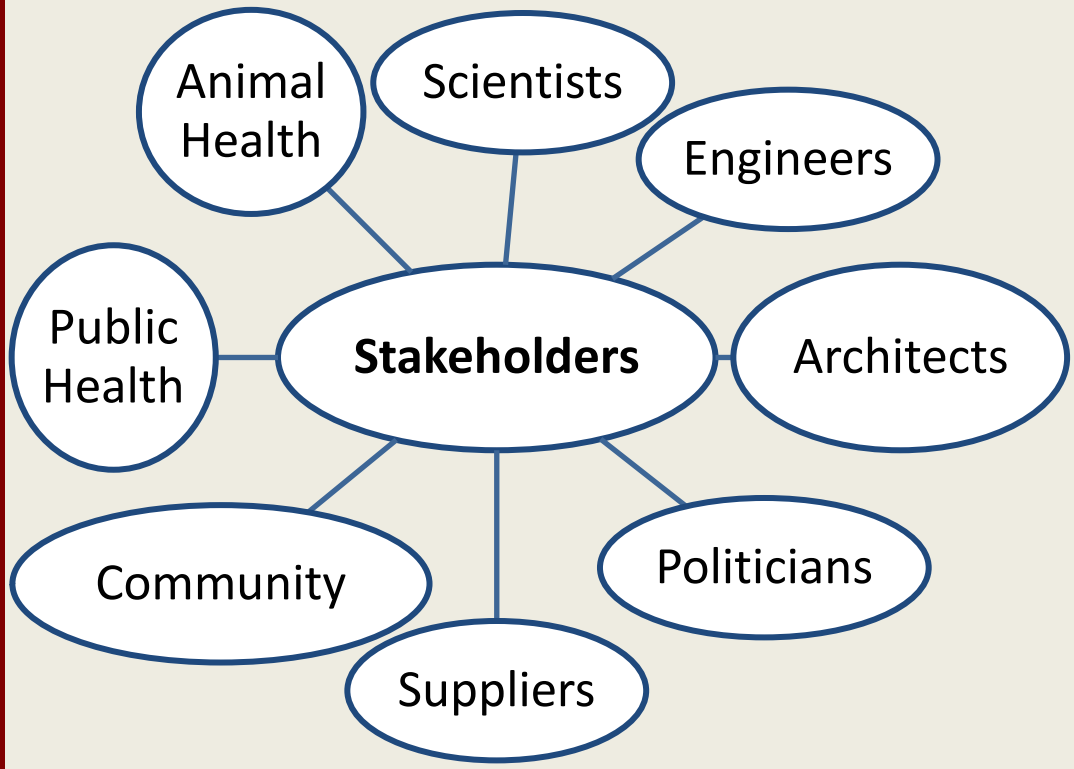
International Centre of Medical Research
of Franceville; Gabon
Photo: Jean-Paul Gonzalez

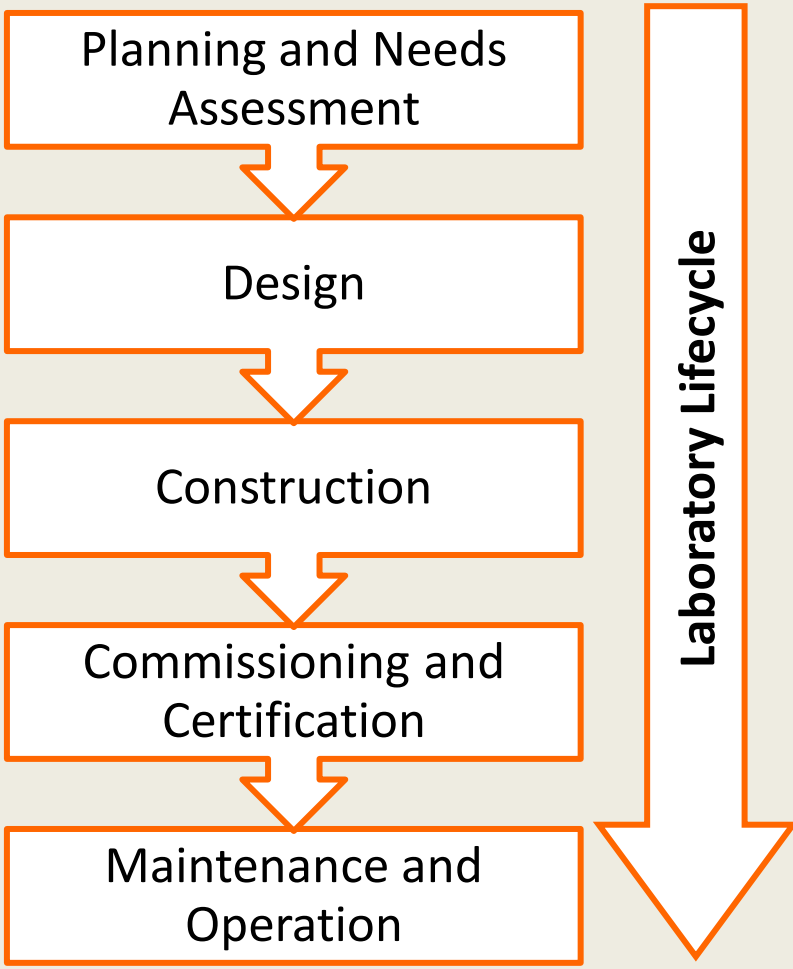


Veterinary Serum and Vaccine
Research Institute; Cairo, Egypt
Photo: Seham El-Zeedy

Scope of Discussions



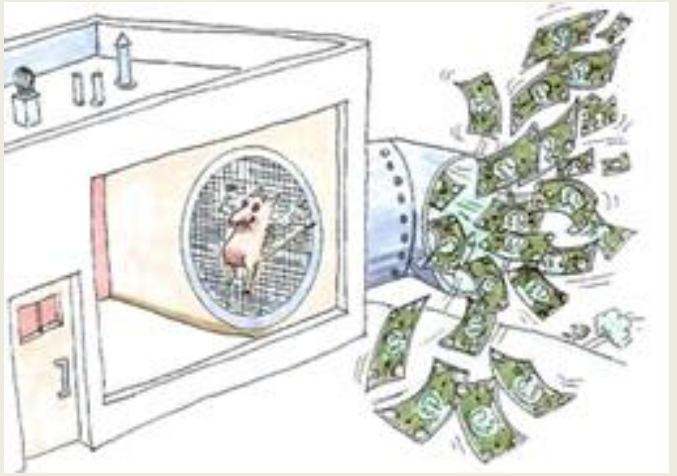




Matching Precautions to Risks

- Many examples of precautions not proportional to risk
- Suggestions:
  - Use situation-specific risk analyses instead of pre-defined biosafety levels
  - Increase applied biosafety research to determine what works

Credit: Teck-Mean Chua



Credit: Ken Ugwu

Practical Suggestions for Building and Improving Labs

- Include all stakeholders from the beginning
- Seek outside advice, but make own decisions
- Define needs and avoid overdesign
- Plan for maintenance and operational costs
- Use local suppliers and workers, but ensure quality of work and materials
- Use contractors with biocontainment lab experience
- Tailor solutions to the situation

Options for Enhancing Biosafety and Biosecurity Worldwide

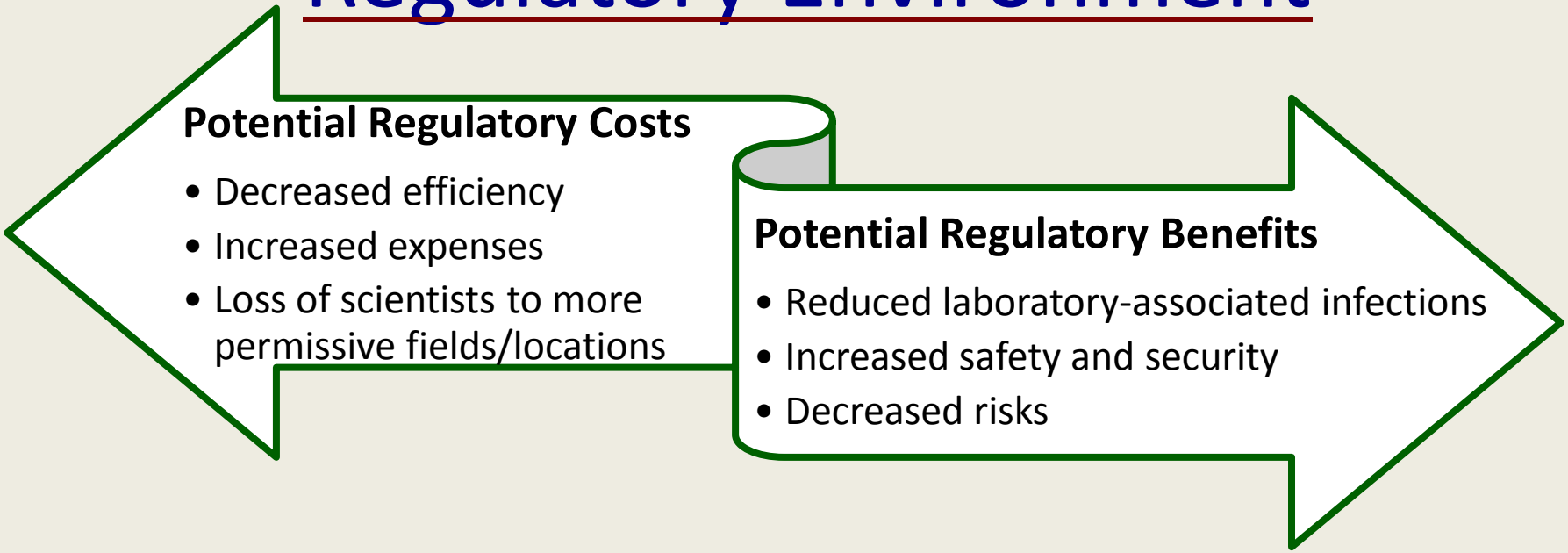
- Biological safety associations should focus and direct action at national, regional, and international levels
- Other suggestions

Validated, accurate point-of-care tests for medical and veterinary practices

International mechanism for recognizing qualified laboratory certifiers

Voluntary, international system for reporting laboratory-associated infections

Regulatory Environment



- High variability among labs and countries
- Many countries deciding whether to increase regulation
- Attendees suggested examining the full cost and value of proposed regulatory solutions

Sample and Specimen Transport

Concerns	Possible Benefits
Loss of intellectual property	Increased collaboration
Accidents	Fewer biocontainment labs and pathogen collections
Theft	

- Continue engaging the International Air Transport Association (IATA), the U.N. Committee on Dangerous Goods Transport, and national governments
  - Characterize risks accurately
  - Define requirements for safe transport

IATA

BSL4 Laboratories
Challenges and Opportunities

Challenges

- Most dangerous pathogens with no vaccines or effective treatments; strong biosafety program essential
- Community concerns of safety and security
- Facilities involve complex engineering; are **expensive** to maintain and operate
- Pathogens are of significant security concern; often heavily regulated (Select Agents)
- Clinical management of lab infections

BSL4 Laboratories
Challenges and Opportunities

Opportunities

- Regionally important human and animal pathogens
- Exciting scientific challenges
- Great need for improved diagnostics, treatments, vaccines
- Important needs for defense against threats as bioterror weapons

BSL4 Laboratories Discussion Topics

- Community Relations and Perceived Risks
  - Sentiments from pride to apathy to opposition
  - Local support is essential for successful operations
- Current BSL4 needs—adequate or more needed?
  - Highlights need for international cooperation and collaborations;
  - Need for rational regulations and specimen shipment

BSL4 Laboratories Discussion Topics

- Personnel Reliability
  - Reduce the “insider threat”, including activists
  - Peer responsibilities; opt out options; psych tests?
- Critical needs for training
  - High standards of biosafety oversight and training
  - Specialized training for building maintenance and safe operations
  - Unique demands for safe handling of laboratory animals