SAND2012-1156C

Iraq Biosafety and Laboratory Biosecurity Workshop

Wednesday, February 1, 2012

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Jordan

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Agenda Overview

Day 1

- Introduction to basic concepts and terminology
- Discussion of the benefits of biosafety and biosecurity
- Objectives of a National Biosafety Committee
- International Reporting requirements
- Discussion of Topical Areas I

Day 2

- Discussion of Topical Areas 2
- Summary of international non-proliferation obligations
- Open Discussion, Conclusions, and Next Steps

US Regulations that Impact Biosafety / Biosecurity

- Roles and responsibilities of a Biosafety Officer (or BRMA)
- OSHA
- BMBL
- NIH rDNA Guidelines
- Dangerous Goods Transportation Regulations
- Import / Export rules
- Select Agent Rule
- DURC
- Public Health and Sanitation rules
- Waste Disposal rules

Roles and Responsibilities of a Biosafety Officer

a) verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed;

b) advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / biorisk management committee;

c) ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other personnel as necessary;

d) advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security);

e) contributing to the development and / or delivery of biorisk training activities;

f) ensuring that all relevant activities are performed in compliance with biorisk regulations and that required biorisk authorizations for work are in place.

OSHA

Department of Labor

- **General duty clause:**

  Each employer shall furnish to each of his employees a place of employment free from recognized hazards that are causing or are likely to cause death or serious physical harm

- **OHSA Bloodborne Pathogen Standard**

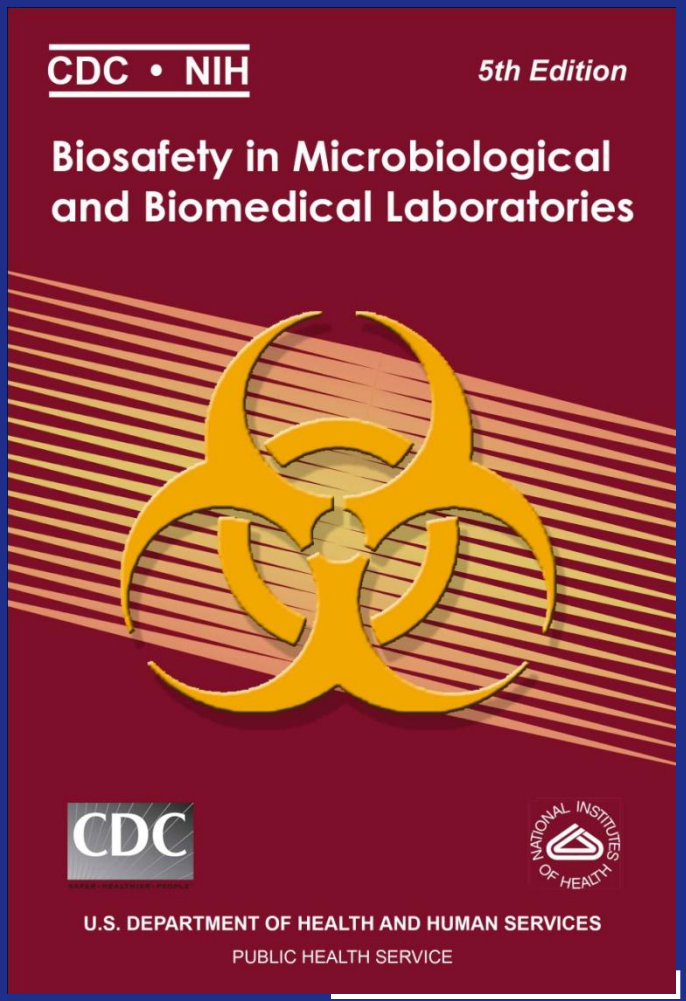
BMBL

Biosafety in Microbiological and Biomedical Laboratories

Department of Health and Human Services

Center for Disease Control (CDC) and the National Institutes of Health (NIH)

“Guidelines” for biosafety practices in research labs



NIH Recombinant DNA Guidelines

National Institutes of Health
Office of Biotechnology Activities

- **Recombinant DNA Advisory Committee**

  The NIH established the Recombinant DNA Advisory Committee (RAC) on October 7, 1974 in response to public concerns regarding the safety of manipulating genetic material through the use of recombinant DNA techniques.

- **Institutional Biological Safety Committees**

- **“Guidelines” vs. Regulations**

- **Human Gene Transfer Studies**

- **Five tiered approach: Major Actions, RAC review, IBC approval, IBC review, Exempt experiments**

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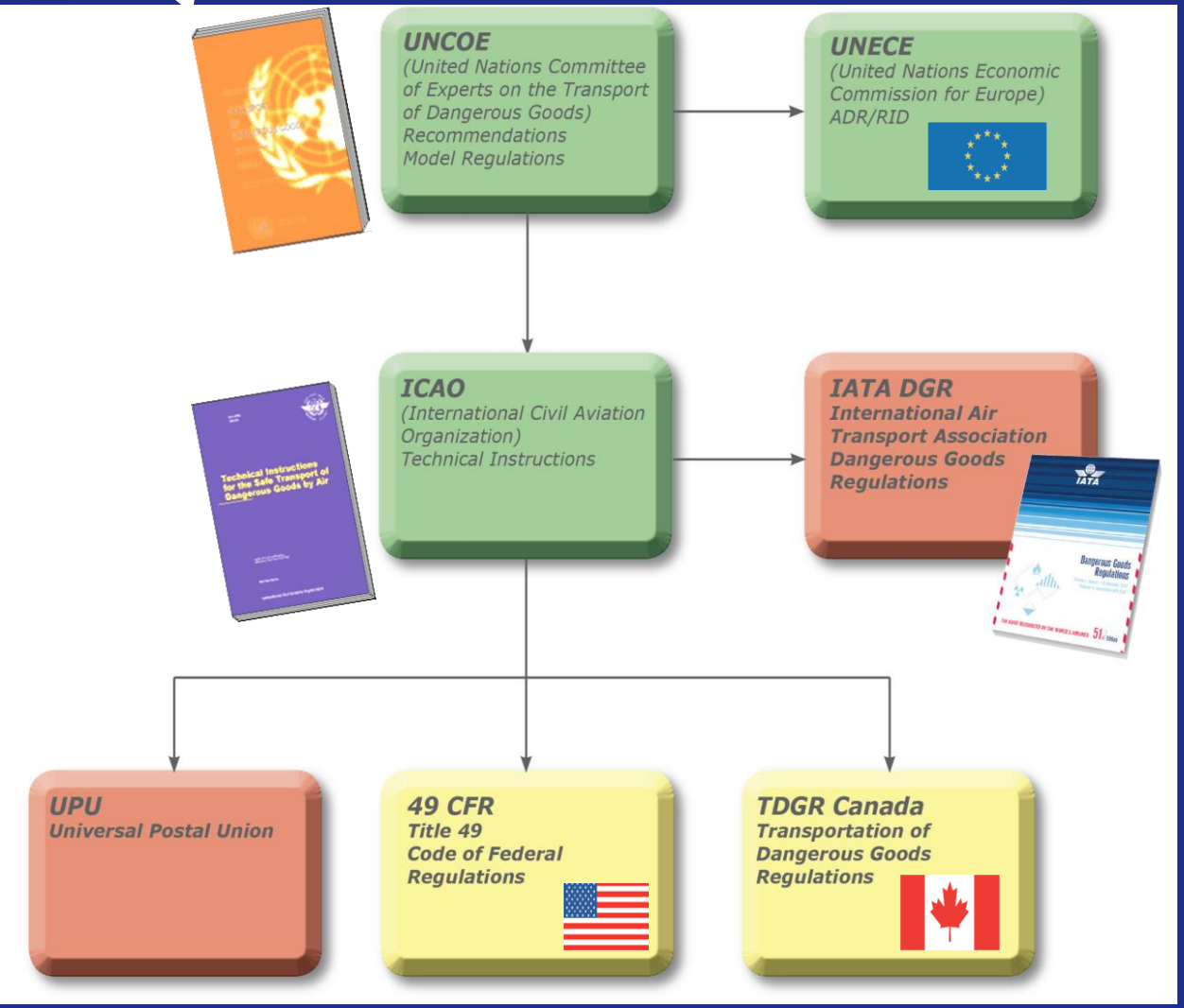
Dangerous Goods Shipping Regulations



- ✓ International
- ✓ Regional
- ✓ National
- ✓ Industry
- ✓ Postal regulations
- ✓ Mode requirements (Air, Road, Rail, Sea)
- ✓ Carrier requirements
- ✓ Import/Export

What requires an import permit into the US?

- Etiologic agents (human pathogens)
- Human and animal specimens with a suspected human pathogen
- Host & Vectors of human disease
- Non-Human Primates

- Infectious agents of livestock
- Biological materials containing animal material
- Tissue culture containing growth stimulants of bovine or other livestock origins
- Any animal source material

Select Agent Rule

- US Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS) and the CDC (Dept of Health and Human Services, HHS)
- "Public Health Security and Bioterrorism Preparedness Response Act of 2002"
- Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121) became effective on April 18, 2005.
- All persons possessing, using or transferring “select” biological agents or toxins must register with HHS and meet biosafety and security procedures established by the HHS Secretary.

National Science Advisory Board for Biosecurity (NSABB)

Areas of expertise/perspectives to be represented on the NSABB, include inter alia:

- Molecular Biology/Genomics
- Microbiology (Bacteriology)
- Microbiology (Virology)
- Clinical Infectious Diseases/Diagnostics
- Laboratory Biosafety and Biosecurity
- Public Health/Epidemiology
- Health Physicist/Radiation Safety
- Pharmaceutical Production
- Veterinary Medicine
- Plant Health
- Food Production
- Bioethics
- National Security
- Military Biodefense Programs and Military Medicine
- Intelligence
- Biodefense
- Law
- Law Enforcement
- Academia
- Scientific Publishing
- Industry Perspective
- NIH RAC Experience/Perspective
- Public Perspective
- IBC Perspective
- Export Controls

- **25 voting members appointed by Secretary, HHS, after consultation with other Federal Agencies**
- **Meets quarterly and as needed**
- **Meetings open to public, unless otherwise determined by the Secretary, HHS**

17. NSABB ex officios

- Exec. Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veteran's Affairs
- Department of Defense
- Environmental Protection Agency
- United States Department of Agriculture
- Department of Interior
- National Sciences Foundation
- Department of Justice
- Department of State
- Department of Commerce
- National Aeronautics and Space Administration
- Intelligence community














Public Health and Sanitation Laws

- Vary state by state and even by municipality
- Vary according to the activity: eg. Day Care centers, Restaurants, Hospitals, etc.
- Medical and Biohazardous Waste treatment and disposal
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Food and Drug Safety Regulations (FDA, USDA)

Recycling of medical waste causes deadly virus outbreak in Gujarat, India

Shaikh Azizur Rahman

Mar 12, 2009

- an outbreak of hepatitis B killed at least 70 people and left about 240 others infected with the deadly virus.
- officials discovered makeshift packaging units where recycled needles, syringes, pediatric droppers, intravenous drips and other equipment were being sorted, simply washed and neatly repackaged for sale
- Scientists from Pune's National Institute of Virology identified the killer virus as a "dangerously mutated strain" of hepatitis B that can kill its victims in an unusually short time.
- "The situation turned worse because private doctors and hospitals are not under a regulatory mechanism. In the absence of any legal obligation and related punitive measures of dereliction, the private medical practitioners use substandard facilities and equipments,"

Topical Areas II
Topic 3: Occupational Health

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Benefits of Occupational Health Programs

- **Occupational health ensures that employees are as effective as possible in their work and that their health is maintained.**

- **Key benefits include:**
  - Reduces personal and business costs of sickness, lost production, and personal injury or illness
  - Ensure that employees are fit to do their job
  - Identifies and protects people who cannot adequately or safely perform their job duties
  - Improves staff motivation and performance – ultimately increases productivity

Occupational Health Questions

- **What kinds of risks does an employee face in a laboratory?**

- **How does Iraq currently handle laboratory acquired infections?**

Examples of Occupational Lab Biorisks

Examples of Occupational Lab Biorisks

Topical Areas II
Topic 4: Hospital Infection Control

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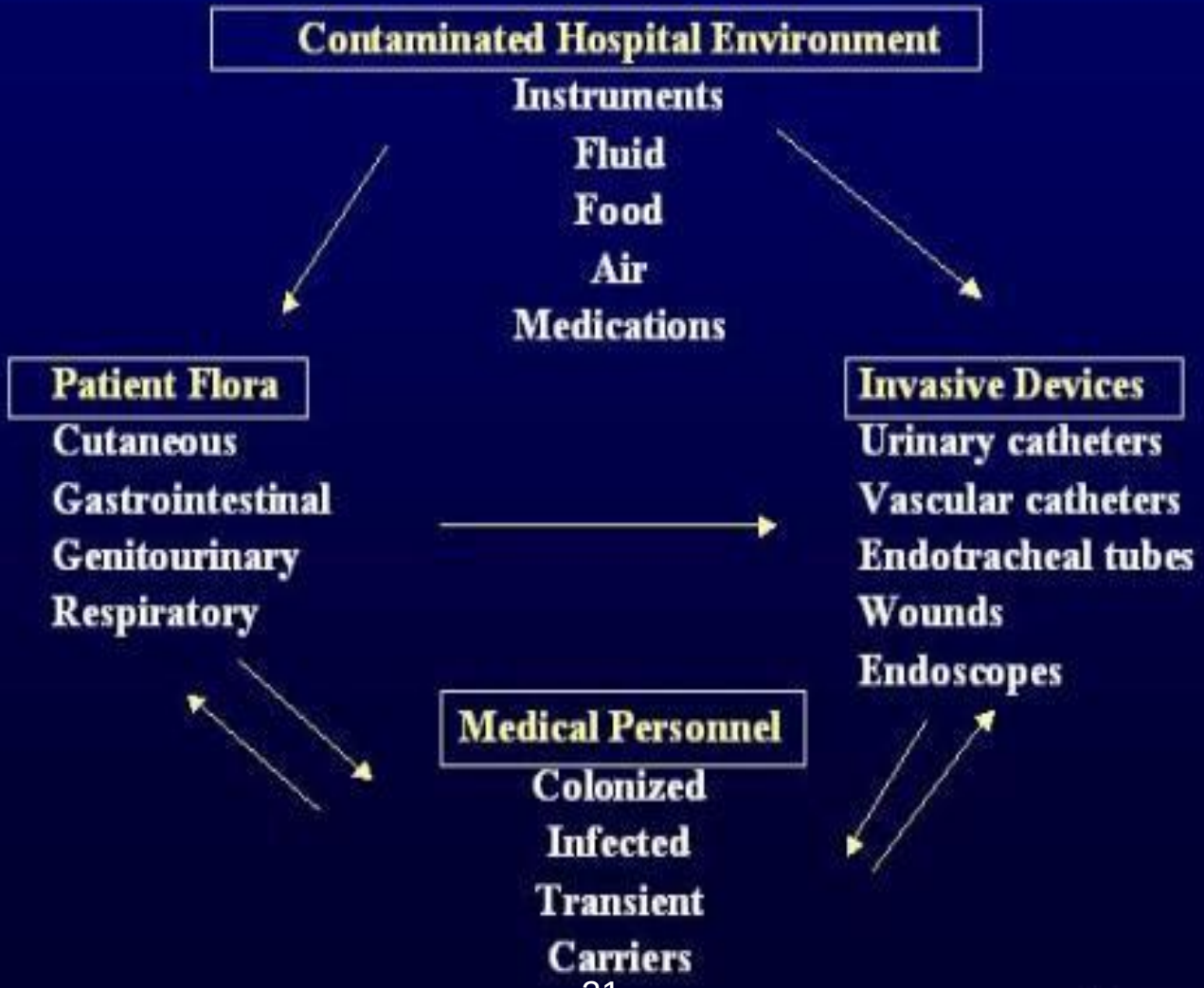
Hospital Acquired Infection

- **Hospital acquired infections (HAI) are any infections that are not present or incubating at the time the patient is admitted to the hospital.**

- **Consequences of HAI**
  - Additional morbidity, possible mortality
  - Prolonged hospitalization
  - Increased costs

- **HAI take up scarce health sector resources by prolonging hospital patient's stay**

Sources of Hospital-Acquired Infections



Statistical Brief on US HAI

- **HAI affect 2 million patients each year in the United States**
- **HAI cost the US between $28 and $33 billion per year**
  - One patient with HAI cost nearly $47,000 more to treat than non-infected patients
- **Hospital patients with infections due to medical care had an average length of stay 19.2 days longer than patients without infections.**
- **HAI are responsible for 90,000 deaths each year**

Source: Lucado J and others. Adult hospital stays with infections due to medical care, 2007. HCUP Statistical Brief [Healthcare Cost and Utilization Project/Agency for Healthcare Research and Quality] #94, Aug. 2010.

Benefits of Hospital Infection Control Programs

- **Hospital infection control is the discipline concerned with preventing health-care associated infections, and addresses factors related to the spread of infections within a health-care setting**

- **Key benefits include:**
  - Reduced patient morbidity and mortality
  - Net cost savings to institution, society, and patient
  - Improved patient satisfaction

Topical Areas II
Topic 5: Waste Management

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Benefits of Waste Management Programs

- **Waste management ensures that employees are as effective as possible in their work and that their health is maintained.**

- **A comprehensive waste management program is critical to both safety and compliance**

- **Key benefits include:**
  - Minimizes adverse impacts to laboratory employees, and the community
  - Significantly reduces environmental pollution impact
    - Air
    - Land
    - Water
    - Animals

Waste Questions

- What types of waste exist in a laboratory?

- How does Iraq currently manage their waste?

Examples of Poor Lab Waste Handling Practices

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Conclusions and Next Steps

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Conclusions

- The terms biosafety and biosecurity have various meanings
- There are a number of benefits associated with biosafety and biosecurity
- Biosafety and biosecurity are integrated concepts
- Biosafety and biosecurity programs mitigate infectious disease risks in a variety of environments
- A national biosafety committee is critical in reducing a country's biorisks and in establishing international confidence-building measures

Next Steps

- Assess needs
- Identify additional players in Iraq
- Establish an internal working group to discuss objectives and goals of an potential biosafety committee in Iraq
- Develop a timeline for future meetings