-Biosafety Standards

-International Biosafety guidelines & legislatives

- In 1949, Sulkin and Pike published the first research

studies on Laboratory Acquired In fection (LAI)

- 222 cases of viral infections (21 fatality)
- Only 27% were related to known accidents (e.g. needle stick, spill, broken glass etc)

- More studies were done in 1951, 1965 and 1976
  - 3921 cases from more than 5,000 labs in US
- Fewer than 20% of these cases were related to known accidents
  - Majority of the cases acquired unknowingly

Exposure to aerosols was possible means of transmission (although unconfirmed) for more than 80% of the reported cases

Formation of biosafety standard guideline

In 1979, knowledge, safety techniques and safety equipment were available
The book " Classification of Etiologic Agents on the Basis of Hazard" became the model for the development of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines

Today's Challenges

- Explosion in research interest in Life Sciences
  - Recombinant DNA, GMO, etc
  - Challenging of animal with antibiotic, agents, Using GMO, etc

- Outbreak of Emerging & re-emerging diseases: Nipah, SARS, Avian Flu

- Biosecurity

Purposes of forming Biosafety Standards

- Safeguard life, property and the environment from biological risks
  - Through adaption of recognised stahdards
  - In the area of management of biological materials or organisms primarily within the laboratory environment

Objective of Biosafety Standards

1. Provide a unifrom biosafety principles, practices
2. Allow peer re view and dedvelopment of current best practice
3. Provide legislator a reference and to ensure standards are kept
4. Enable certification of laboratories to a single standard
5. Provide lab personnel/management in countries that do not have their own standards and guidelines to adopt an internationally guideline as reference

Harmonization of Standards

1. Organizations located in one country may seek specialized biosafety guidance from international and national guidelines and regulations
2. Multi national institutions may consult international and national guidelines and regulations when their biosafety programmes cross national borders

Global Perspectives

1. Guidelines on biosafety may differ from country to country

    -There may be conflicts, and lapses in coverage

2. May lead to confusion among stakeholders when international boundaries are crossed

    -may cause inadvertent (or intentional) lack of compliance

3. Multi-national institutions may face amplified challenges when they develop and maintain their biosafety programmes

    -because they need to address national and local expectations in multiple countries

Regulations and Guidelines

1. Regulations set common standards of practice
   -less flexible by design and validate the practice of biosafety
   -providing mechanisms for enforcement
2. Guidelines also set common standard of practice
   -tend to be more performance-oriented
   -more easily updated than regulations
   -may from the basis for future regulations
3. Guidelines traditionally viewed as voluntary
   -but may be enforced indirectly by measures such as withholding or withdrawal of funding
4. Regulatory agencies may enforce guidelines if they are considered to be an industry standard of practice
   -may be referenced by regulations to allow flexibility for future technological advances and still retasin enforcement capabilities

Overview of World Biosafety Standards

Differentiation in approach:

1. Performance based: -allow more thatn one way to meet the same objectives. If do not dictate how it must be done (e.g WHO)
2. Perspectives[outlines very specific requirements that must be able to achieve (eg. Canadian Guideline)

All with the common guideline

-Safeguard safety of worker, public & environment

Current Guidelines & Standards Available

- Australian/NZ standard
- USA-CDC/NIH Guidelines:BMBL
- WHO: Laboratory Biosafety Manual
- Canadian-PHAC: Laboratory Biosafety Guidelines
- European Directives

PHAC-Canadian

- PHAC: “ Developed to guide govt, industry, university, hospital, and other public health and microbiological labs in their development of biosafety policies and programs
- Serve as a technical document providing info and recommendations on the design, construction and commissioning of containment facilities”

BMBL (CDC/NIH)

Biosafety for Microbiological and Biomedical Lab

- Advisory recommendations
- Providing a voluntary guide or code of practice as well as goals for upgrading operations
- Describes general and special microbiological practices, safety equipment and facilities constituting
- Guide and reference in the construction/ renovation of new lab facilities
- Addresses issue of bio-terrorism and biosecurity

WHO

- Practical guidance on biosafety techniques for use in laboratories at all levels
- Addresses risk assessment and the safe of recombinant DNA technology
- Guidelines for the commisioning and certification of laboratories
- Biosecurity concepts are introduced
- International regulations for transport of infectious materials
- Safety in health care labs

Australian/NZ Std

- Requirementsd for labs dealing with infectious diseases and the classifications of micro-organisms into the 4 risk groups
- 4 levels of physical containment for microbiology labs and labs working with genetically modified organisms
- Addresses obligations of employers and employees under occupational health and safety legislation
- Not required by law, but may specifically incorporated by an Act or Regulation in whole, or in part

Limitations of these documents

- No internationally recognised standard for safety/ security for laboratories
- Wide range of regional/national legislation and guidance documents
- No one clearly driving the process
- Little involvement from major certification organizations
- Perception that there is a significant and growing demand for more formal certification
    - including measures to address management system issues as well as facility design and construction

Biosafety legislation

-USA- PATRIOT ACT

-Biosafety Legislation-Singapore

-Singapore-Biological Agents and Toxins Act: BATA

International Collaboration in Biosafety

- International Collaboration
  - Benefit from others experiences to prevent similar, potentially fatal mistakes
  - Exchange information on new starins, mutating strains, or new outbreaks
- Professional Project Team with containment Specialists
  - Certification & validation, Microbiological practices & SOP development etc

The World Biosafety Framework

International Biosafety Framework

-WHO Biosafety Program

- International Biosafety Associations and Working Groups

National Biosafety Framework

-Australia/New Zealand, Canada UK, US

-Singapore

Integration of National and International approaches to meet the challenges

In Summary

- Knowing the difference between regulations, guidelines and standard
- Overview of international guideline available and their differentiation
- Can be performance or perspective

Choice of guideline adopted depending on the national regulations and needs

Reference:
Dr. TM Chua

Thank you