

Overview of Global Biosafety Tools

(Regulations, Guidelines, Assessment Tools)



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Global Need

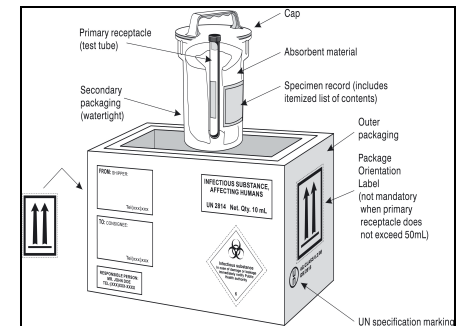
- Safety Support for Biological Labs & Hospital Facilities with.....



Waste Management



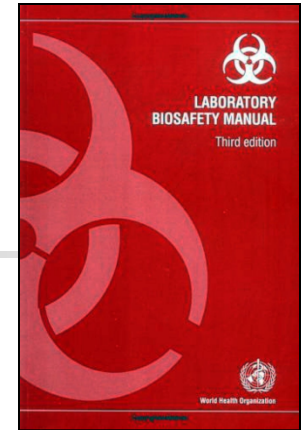
Chemical Management



Specimen Transport



WHO Guidance



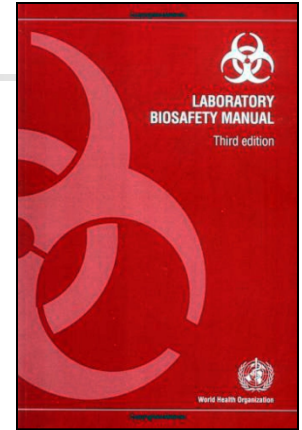
Established the:

- **WHO- Laboratory Biosafety Manual (LBM), 3rd Edition, 2004**
 - International consensus process
- **WHO-Biosafety Advisory Group (BAG)**
 - Collaboration of WHO-HQ
 - WHO Biosafety Collaborating Centers

WHO Laboratory Biosafety Manual (LBM)

Goals:

- Served as initial standardized - global biosafety guidance.
- Provided guidance on several facets of Lab Safety (addressed several safety programs)
- Standardization allows everyone to speak the same language & confidence in minimal criteria.



Need for additional Profession Specific Guidance

- To address unique needs of various professional organizations
- Results - **Embedded** biosafety guidance



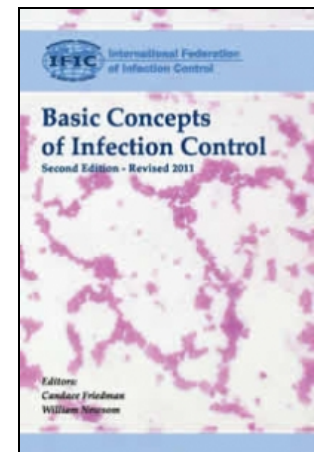
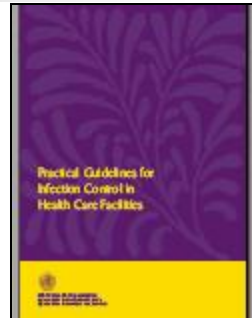


Embedded Biosafety Guidance

- Unmet needs resulted in Professional Organizations developing additional guidance to address their unique needs.
 - Located (embedded) in several additional professional documents
 - Guidelines, Assessment Tools, & Regulations

Examples - Embedded Biosafety Guidance

- WHO Practical Guidelines for Infection Control in HealthCare Facilities, 2003
- International Federation of Infection Control (IFIC), 2011
 - Risk Management
 - Occ. Risk for Health care Workers
 - PPE, Sharps, Waste
 - Facility design, ventilation, containment, etc.



Examples - Embedded Biosafety Guidance

- ISO Quality Management Systems & Safety for Medical Labs
 - Ex: ISO-15189 & 15190

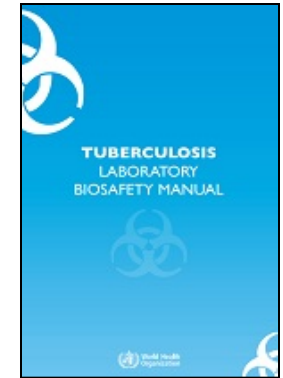


- International Federation of Biomedical Laboratory Science (IFBLS)
 - Workplace safety, PPE, Waste, etc.



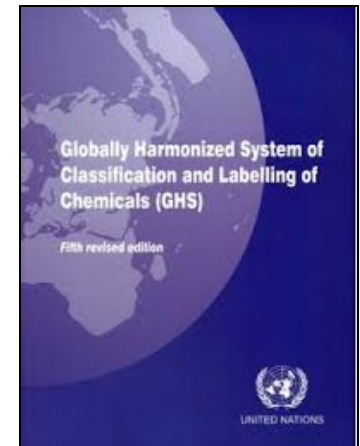
Examples - Embedded Biosafety Guidance

- WHO – Tuberculosis Laboratory Biosafety Manual, 2012
- OIE – Biosafety and Biosecurity in the Veterinary Microbiology Laboratory & Animal Facilities



Examples - Embedded Biosafety Guidance

- UN - Globally Harmonized System of Classification & Labeling of Chemicals
 - Safety handling & storage of hazardous chemicals

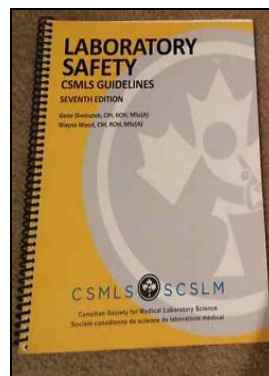
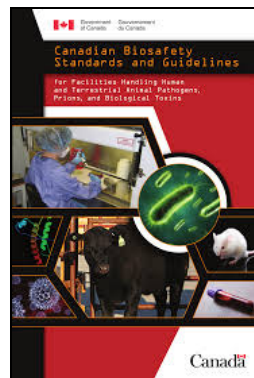
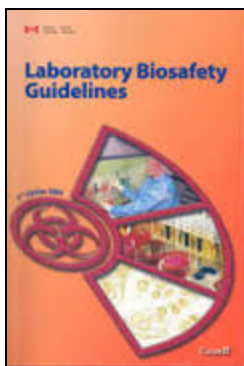
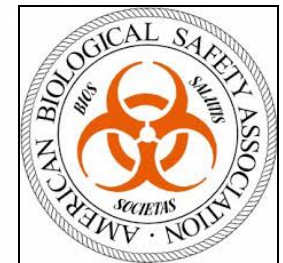
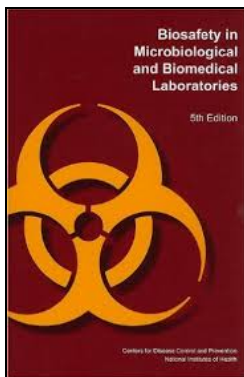


- American National Standards Institute (ANSI)
 - Hazardous Chemical & Environmental guidance



Examples - Embedded Biosafety Guidance

- National & Region specific guidance





Results:



Multiple guidance sources & confusion:

- Where is guidance located.
- What's applicable & when to use.
- Qualifications of technical staff to understand & correctly interpret guidance.
- Understanding one's limitations & recognizing when to seek additional technical assistance.

Need to Update WHO – Lab Biosafety Guidance


New Guidance & Activities:

- CWA – 15793 & 16393:
Lab Biorisk Management

**CWA 15793 laboratory
biorisk management
system certification**

Laboratory Biorisk Management Standard

- System or process to control safety and security risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities



- CWA 15793:2008

- Guidance for Implementing CWA-15793
 - *new* Biosafety Professional Exam. & Certificate

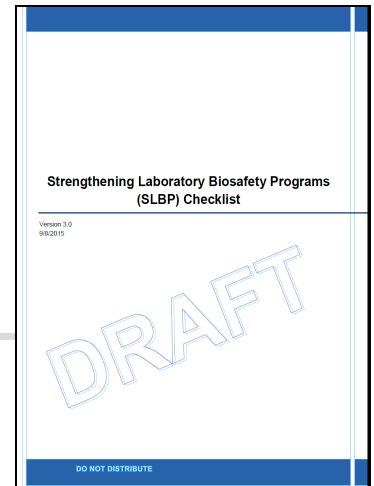


Need for additional Lab Safety tools:

New (draft)

Strengthening of Lab Biosafety Program (SLBP) Checklist

- Organizes safety guidance into individual categories (**13-safety programs**)
 - Target audience Safety officers, Lab staff, Facility engineers
 - All must receive training on consistent interpretation.



New (draft) Strengthening of Lab Biosafety Program (SLBP) checklist



Goals- SLBP:

- Provide basic guidance on the minimal content of each safety program (**minimal Core Competencies**)
- Serve as a training outline (**step-by-step guidance**) to enable Labs to budget and build their safety programs.
- Serve as a **standardized assessment tool** that's endorsed by the international user community (WHO, QMS, IFIC, OIE, etc).

Group Questions



Content of SLBP:

- **Lengthy tool:**
Should tool contain minimal essential program elements (**minimal *core competencies***) for each of the 13-safety program? ...Result in **lengthy tool.**
- **Shorter tool:**
Should tool be **condensed to a subset of competences** that allows us to assume that minimal safety requirements are being implemented for each of the 13-safety programs?
- **Discussion items for break-out sessions**

Considerations to move forward



Requires:

- Standardization of minimal Core Competencies for each 13-safety programs (with international endorsement).
- Funding to enable implementation
 - Teach programs how to develop budgets & seek annual funding.
- Train staff
 - On technical requirements for each of the 13-programs.
- Implement sustainable programs, that undergo continual improvement.



Options for moving forward:

Tiered Approach

Introduce 13-programs in tiered fashion to:

- Prioritize based on community needs
- Gain momentum
- Management buy-in (endorsement)
- Allocate funding

Options for moving forward:



Piggy-Back Approach

Piggy-Back existing safety efforts, to maximize on available funding:

- QMS & Equipment Maintenance programs;
- Biosecurity & Hazard Assessment Process;
- Hospital Infection Control & Employee Health Programs;
- Waste Management programs, etc.

Options for moving forward:



Choose Piece-of-Pie

Each Partner select a Piece-of-Pie to move forward (example):

- Biosafety community – develop staff Training Modules.
- Biosecurity partners – move Hazard Assessment process forward.
- ASLM & Canada – move Equipment Maintenance forward;
- IFIC & QMS partners – move Employee IC & Occupational Health forward, etc.

Need for high-level Champions / Advocates

- Introduce needs & Raise Awareness (*Health Marketing*)
- Solicit Buy-In
- Advocate for funding
- Increase public importance & appreciation



Public / Government Advocate



Private / Recognizable Advocate

Conclusion & Goals

Building sustainable safety programs requires:

- Safety - Champions/Advocates
- Standardized criteria (minimal core competencies)
- Management endorsement (buy-in)
- Funding
- Local - Regional Training
- Local – Assessments & Implementation
- Annual **budget** forecasting & continual improvement

