Development of a New Laboratory Safety Evaluation Tool to Build Robust Safety Programs and Achieve QMS Accreditation

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Define

The **laboratory safety evaluation tool** is a checklist used to identify potential hazards, evaluate risks in laboratory settings, and build sustainable biosafety programs.

Goal

To create an assessment tool that will help countries evaluate biosafety programs, identify safety gaps, and develop strategies to strengthen biosafety programs, policies, and practices

Objectives

- Implement a tool that countries can use to evaluate biosafety gaps and build sustainable biosafety programs
- Assist the MOH with strengthening laboratory capacity, health systems, and biosafety programs
- Integrate biosafety with the QMS / laboratory accreditation process

Reference Documents and Guidelines

- CWA 15793 - Laboratory Biorisk Management Standard
- CWA 16393 - Laboratory Biorisk Management Guidelines for the Implementation of CWA 15793:2008
- ISO 15190 - Medical Laboratories-Requirements for Safety
- ISO 15189 - Medical Laboratories-Particular requirements for quality and competence)
- WHO AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) Checklist
- WHO Laboratory Biosafety Manual, 3rd edition
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition
- Others

Biosafety and Biosecurity

Biosafety is the prevention of employee exposures, occupationally acquired infections, and release of organisms to the environment through the combination of appropriate safety measures:

- Laboratory facilities
  - Facility design and construction
- Safety equipment
  - Lab equipment and Personal Protective Equipment (PPE)
- Work practices and policies
  - Microbiological practices and established SOPs

Biosecurity is the protection of biological agents from loss, theft, or misuse. (Non-intentional or Intentional)

The 14 Core Biosafety Elements

- Management's Oversight & Responsibilities
- Safety Business and Administrative Programs
- Review Laboratory & Biosafety Programs
- Equipment Evaluation - Maintenance, Calibration, & Certification
- Review Building & Facility Safety Programs
- Employee Occupational Health/ Medical Program
- Chemical Management and Industrial Hygiene Programs
- Waste Management & Environmental Safety Programs
- Emergency Preparedness & Response Programs
- Biosecurity
- Transport of Biological Agents
- Employee Training & Outreach Activities
- Radiation Safety Programs (if applicable)
- Field Activities

The 14 Core Biosafety Elements

Management's Responsibility

- Delegate safety responsibility and oversight
- Provide appropriate resources for staffing and funding
- Ensure implementation of the program

Safety Business and Administrative Programs

- Ensure national, international, and regulatory requirements are met
- Ensure written biosafety manuals, policies, SOPs are in place
- Ensure a comprehensive biosafety program has been implemented

The 14 Core Biosafety Elements

Laboratory and Biosafety Programs Review

- Conduct biosafety assessments on work activities, procedures, agents in use, safety equipment and programs

Equipment Evaluation

- Review appropriate PPE usage and laboratory equipment to include BSC, fume hoods, autoclaves, centrifuges, incinerators
- Review maintenance and calibration records

The 14 Core Biosafety Elements

Building and Facility Safety Review

- Review facility design and operations, and establish a preventive maintenance programs

Occupational Health Program

- Review occupational hazards and a conduct risk assessment
- Develop and implement pre- and post-exposure plans, medical surveillance, employee evaluation, respiratory protection program

Chemical Management and Industrial Hygiene Programs

- Provide policies/procedures for the segregation, storage and remediation of chemicals

The 14 Core Biosafety Elements

Waste Management and Environmental Safety Programs

- Ensure the segregation and decontamination of waste and the proper usage of autoclaves, incinerators, etc.

Emergency Preparedness and Response Programs

- Implement an action plan to deal with scenarios such as fire, breach of security, bomb threats, natural disasters, utility failure, release of an agent

Biosecurity

- Protect agents from theft or misuse and limit access to laboratories that contain certain biological agents

The 14 Core Biosafety Elements

Transport of Biological Agents

- Review regulatory requirements for packaging, shipping, labeling of biological agents

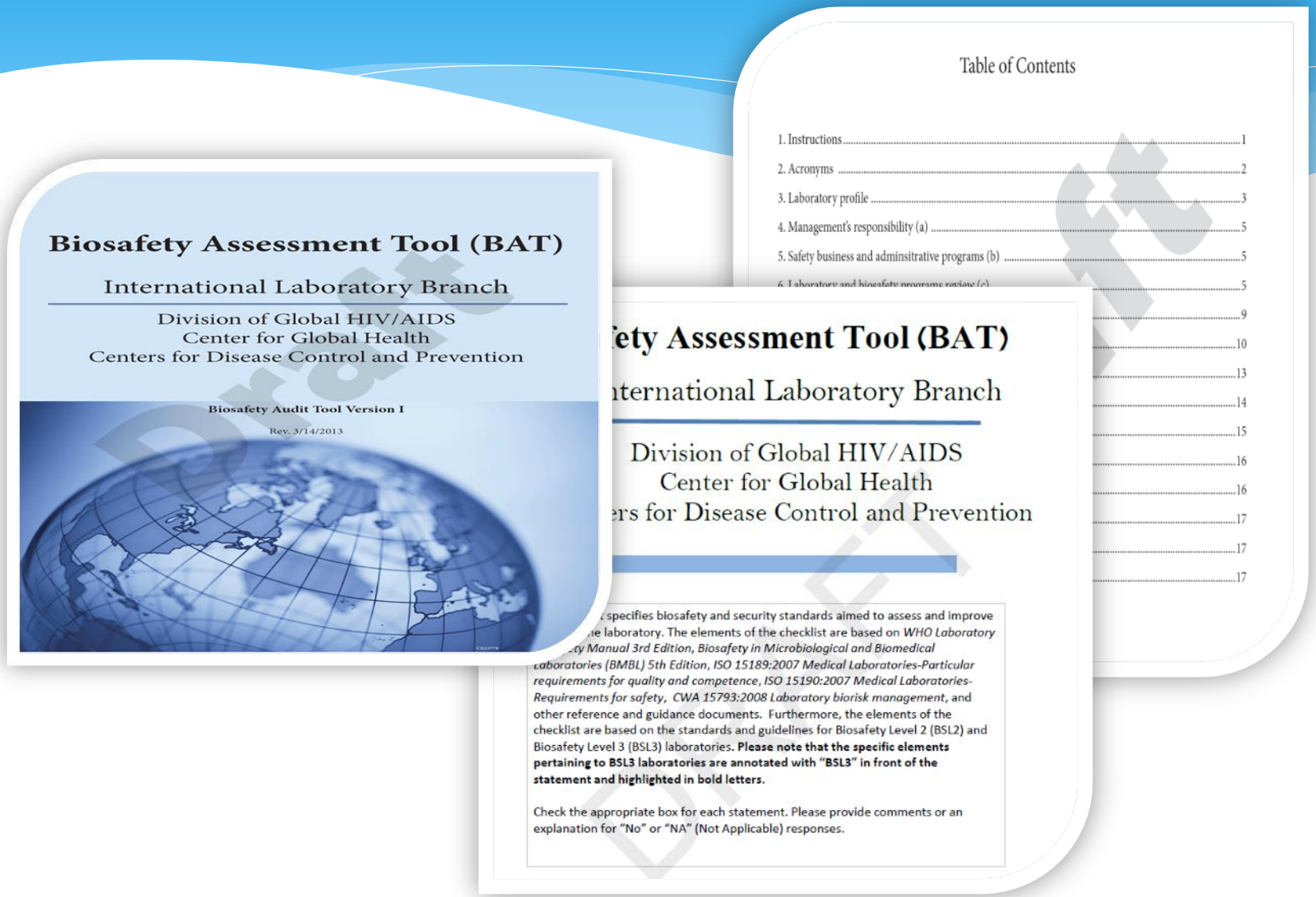
Training

- Establish training programs for laboratorians

Radiation Safety Program

- Ensure radiation compliance

Laboratory Safety Evaluation Tool Overview



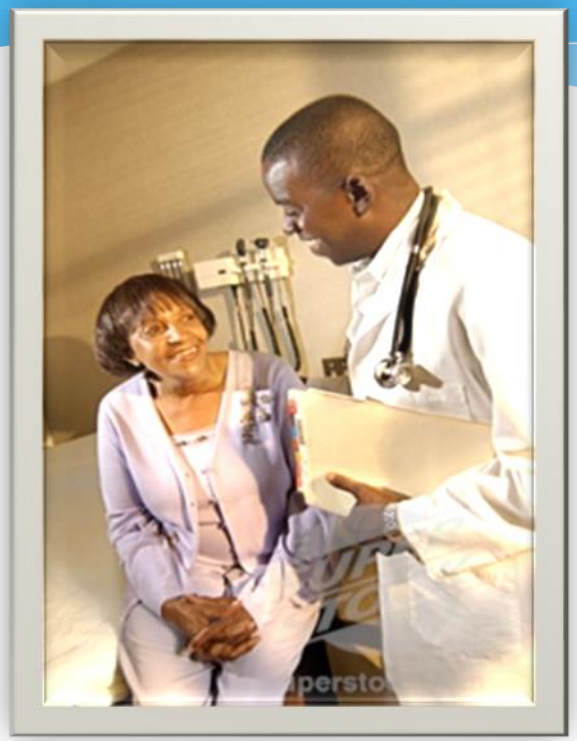
Building and Facility Safety Review Highlights

Building and Facility Safety Review Highlights

- Review facility design and operational procedures
- Review mechanical systems (i.e. ventilation, electrical, plumbing)
- Review safety systems to include water, gas, electrical supply
- Review HEPA filters and housings
- Walls, ceilings and floors should be smooth, easy to clean, and impermeable
- Access to the laboratory is restricted entry and unauthorized persons are not allowed.

BUILDING AND FACILITY SAFETY REVIEW (E)					
		Yes	No	N/A	Comments
E1	Laboratory doors should be kept closed.				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2), BMBL Section IV-Laboratory Biosafety Levels D1				
E2	Doors should have vision panels, appropriate fire ratings, and preferably be self-closing. BSL3: Laboratory doors must be self-closing and have locks in accordance with the institutional policies				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2), WHO LBM Chapter 4- The Containment Laboratory (Biosafety Level 3), BMBL Section IV-Laboratory Biosafety Levels D1				
E3	Unauthorized persons should not be allowed to enter the laboratory working areas. BSL3: The laboratory must be separated from the areas that are open to unrestricted traffic flow within the building.				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2), WHO LBM Chapter 4- The Containment Laboratory (Biosafety Level 3), BMBL Section IV-Laboratory Biosafety Levels D1				
E4	BSL3: Access to the laboratory is restricted to entry by a series of two self-				

Occupational Health Program Highlights



OH&S

OCCUPATIONAL HEALTH & SAFETY

Occupational Health Program Highlights

- Implement a Occupational Health Program and Medical Surveillance Program
- Conduct pre-placement medical evaluations and hazard assessments
- Policies to define and address incidents and accidents
- Vaccination policies are established and also based on a risk assessment
- Pre- and post-exposure protocols and procedures are established

OCCUPATIONAL HEALTH PROGRAM (F)					
		Yes	No	N/A	Comments
F1	The institution/facility has an Occupational Health Program and Medical Surveillance Program and a written description of the program and all associated policies.				
	CEN #15793-4.4.1.6 Occupational health, 4.4.4.6 Worker health programme; ISO 15190-7.2 Procedures; WHO LBM, Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2), Health and medical surveillance, Safety Checklist:#1				
F2	The following hazards were considered for inclusion in the Occupational Health/Medical Surveillance Program: Hazard communication, respiratory protection, hearing conservation, formaldehyde monitoring, ethylene oxide monitoring, anesthetic gas monitoring, chemical Exposures, ergonomics, and infectious agents' exposure.				
	WHO LBM, Chapter 8-Guidelines for Laboratory/Facility Certification, Table 5, Occupational health and safety programmes available				
F3	A preplacement medical evaluation is performed for workers who may be exposed to human pathogens to include: previous and ongoing medical problems, current medications, allergies to medicines, animals, and other environmental proteins, sensitivities to chemicals or other substances, prior immunizations, the need for updated/additional immunizations, medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility / dexterity), the requirement for and ability to use appropriate PPE safely, factors affecting general well-being (e.g. diabetes, immune deficiency, cancer, donor organ receipt, stress, depression, pregnancy, immune status, etc.), and factors affecting susceptibility to biological agents/ toxins (e.g. pregnancy, immunosuppression).				
	CEN #15793-4.4.4.6 Worker health programme; ISO 15190-11.3 Immunization status; WHO-Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level 1; WHO LBM Chapter 4, The Containment Laboratory– Biosafety Level 3, Health and medical surveillance, Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level 2, BMBL Section VII-Occupational Health and Immunoprophylaxis, Preplacement Medical Evaluations				
F4	Policies been set in place to define what constitutes an accident or incident,				

Chemical Management and Industrial Hygiene Programs

Chemical Management and Industrial Hygiene Programs Highlights

- Develop and implement provisions for a written chemical hygiene plan
- Establish procedures for the disposal of chemicals in accordance to national or international regulations
- Establish procedures for the safe remedial, decontamination of contaminated waste
- Establish procedures for storing, labeling, and securing chemicals
- Develop chemical disposal policies to address unused and outdated chemicals/products
- Ensure the proper storage of flammable chemicals

CHEMICAL MANAGEMENT AND INDUSTRIAL HYGIENCE PROGRAMS (G)					
		Yes	No	N/A	Comments
G1	Where hazardous chemicals are used in the workplace, an institution/facility shall develop and implement the provisions of a written chemical hygiene plan, which should be reviewed annually and revised as necessary				
G2	An institution/facility shall maintain any Material Safety Data Sheets (MSDS) that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to the laboratory employees.				
G3	Standard operating procedures (SOP) relevant to safety and health consider-ation should be followed when laboratory work involves the use of hazard-ous chemicals				
G4	Implementation of an emergency response plan, to include a chemical spill clean-up plan				
G5	Chemicals are disposed of in accordance to applicable national and/or inter-				

Waste Management and Industrial Hygiene Programs Highlights

Waste Management and Industrial Hygiene Programs Highlights

- Ensure the availability of autoclaves or other means of decontamination for contaminated waste
- Ensure the segregation of contaminated waste
- Establish procedures for sharps disposal
- Review procedures for the placement of contaminated waste and the transport of this waste to the incinerator
- Incineration of waste must meet the approval of air pollution authorities and regulations

WASTE MANAGEMENT AND INDUSTRIAL HYGIENE PROGRAMS (H)					
		Yes	No	N/A	Comments
H1	An autoclave or other means of decontamination should be available in appropriate proximity, preferably in the laboratory, to the laboratory. BSL3: An autoclave for the decontamination of contaminated waste material should be available in the containment laboratory.				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2), WHO LBM Chapter 4- The Containment Laboratory (Biosafety Level 3), BMBL Section IV-Laboratory Biosafety Levels D11				
H2	Laboratory waste should be identified and segregated into appropriate categories: • Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste • Contaminated (infectious) waste, which should be decontaminated by autoclaving, chemical disinfection, or incineration • Contaminated "sharps" – hypodermic needles, scalpels, knives and broken glass, which should always be collected in puncture-proof containers • Hazardous chemicals and liquids				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2)				
H3	Disposable syringes, used alone or with needles, should be placed in sharps disposal containers and incinerated, with prior autoclaving if required. Sharps disposal containers must not be discarded in landfills.				
	WHO LBM Chapter 3-Basic Laboratories (Biosafety Levels 1 and 2)				

Next Steps

- Request assistance from countries to test the tool in laboratories seeking accreditation
- Tool will be sent to biosafety officers to conduct a pre-assessment
- CDC (ILB) will follow-up and conduct on-site evaluations of the laboratories
- Training and guidance will be provided to the biosafety officers
- Receive feedback/comments from the countries (e.g., biosafety officers) about gaps, ease, and use of the tool

SLIPTA

- The tool will serve as an appendix to the SLIPTA framework
  - The tool will supplement the SLIPTA process and support the accreditation process
- Biosafety officers will be identified and trained on the tool and assist with SLIPTA assessments (focusing on biosafety)
- Develop training products for each of the 14 safety products, based on minimal core competencies
- Request partner support to help administer these training activities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Thank you !