A Multilingual Tool for Standardized Laboratory Biosafety and Safety Assessment and Monitoring

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ABSTRACT

The Biosafety and Biosecurity Laboratory Assessment Tool (BSS-LAT) was first employed in Burkina Faso in collaboration with the African Society for Laboratory Medicine (ASLM) and the US Centers for Disease Control and Prevention (CDC) to support the country in strengthening their biorisk management system. Since then, it has been successfully used in other countries (Armenia, Burundi, Cameroon, Ghana, Guinea, Liberia and Kazakhstan), various settings (medical and veterinary laboratories), and developed in different languages (including French, English and Russian). The BSS-LAT is a multipurpose tool helping to standardize the biosafety requirement for both medical and animal health laboratories, serve as a self-assessment guide for laboratories to develop improvement plans and reinforce their biosafety capacities, and a training tool for individual laboratories, network of laboratories, or at the country level. The BSS-LAT can also be used as a monitoring tool for the accurate assessment and standardized of laboratory biosafety, biosecurity and safety at local, regional or national levels across all laboratories working with infectious materials.

ORIGIN and DEVELOPMENT

The BSS-LAT was originally developed by IQLS in 2017 to perform assessments in Burkina Faso for the ASLM as part of the CDC-led efforts under the GHSA.

This BSS-LAT was built using:

i) The main available international references and standards:

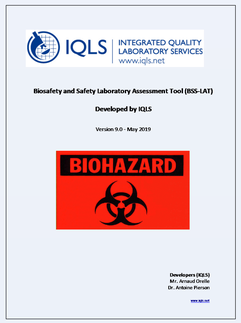
- 3rd edition of the **WHO Biosafety manual**[1]
- **WHO Biorisk management**: laboratory biosecurity guidance[2]
- **OIE Manual of diagnostic tests and vaccines for terrestrial animal**[3]
- 5th edition of the biosafety in microbiological and biomedical laboratories (**BMBL**)[4]
- **ISO15190**:2003[5], **ISO45001**:2018[6] and **ISO35001**:2019[7]
- **CWA 15793**[8] supplemented by the CWA16393
- Various resources from **National Institute of Health** (NIH)[9,10]

ii) IQLS knowledge and experiences from the fields and from various general assessments the team performed worldwide.

Since 2017, the BSS-LAT has been field-tested, revised and supplemented:

- In 8 countries (Burkina Faso, Ghana, Armenia, Cameroun, Burundi, Guinea, Liberia and Kazakhstan)
- In medical and veterinary laboratories with very different levels of biosafety implementation,
- By different experts and evaluators from different backgrounds and with different specializations.

Through this iterative process the BSS-LAT has reached version 9.0 and is highly comprehensive, interactive and robust:

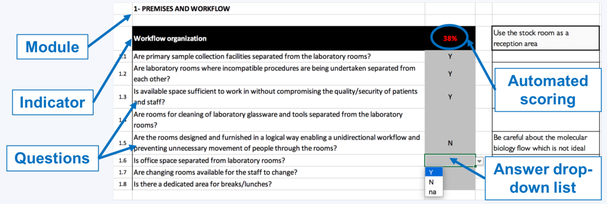


The BSS-LAT will be freely accessible following publication (submitted)

TOOL PRESENTATION

The BSS-LAT is based on **Microsoft Excel** and consists of a **standardized questionnaire, organized into modules:**

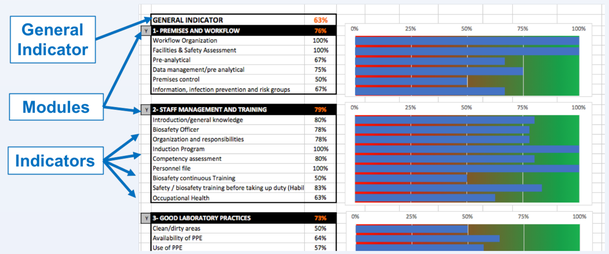
- Each module is made of several indicators
- Each indicators is made of several questions (closed questions)
- Questions are to be answered from a drop-down list (Mostly “Yes” or “No” or “not applicable”) to facilitate the collection of information
- Each question and indicator can be complemented by an open comment cell, to provide more details



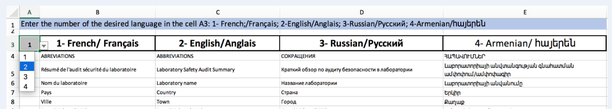
Automated scoring :

- Each question will automatically generate a score (0% if the answer is unsatisfactory and 100% if the answer is satisfactory)
- Indicator scores will automatically generate (average from questions)
- Module scores will automatically generate (average from indicators)
- Laboratory general indicator (average from applicable modules)

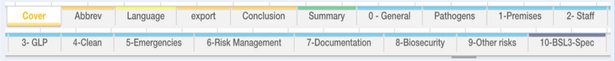
A Summary page is generated (by indicator and module) with a graphic depiction:



The BSS-LAT is **multi-lingual**, currently* available in **English**, **French**, **Russian** and **Armenian**, all embedded into the same file (one button click to switch from one language to another)



Translation to other languages can be performed and included upon request or upon needs.



User-friendliness navigation through MS Excel Tabs; **exportable data**

TOOL MODULES AND CONTENT

The BSS-LAT consists of **10 modules**, and includes a total of **538 questions** (+ 108 for a specific biosafety level 3 Laboratory module)

Associated number of question per indicator and module				Number of Questions
1- PREMISES AND WORKFLOW				42
Workflow organization	8	Data management/ pre-analytical	4	
Facilities & Safety Assessment	5	Premises control	6	
Pre-analytical	16	Information, infection prevention and risk groups	3	
2- STAFF MANAGEMENT AND TRAINING				66
Introduction/general knowledge	7	Personnel file	4	
Biosafety Officer	9	Biosafety continuous Training	4	
Organization and responsibilities	9	Safety / biosafety training before taking up duty (Habilitation)	13	
Induction Program	7	Occupational Health	8	
Competency assessment	5			
3- GOOD LABORATORY PRACTICES				93
Clean/dirty areas	9	Biosafety cabinet management	16	
Availability of PPE	7	General behavior/ Good laboratory practices	8	
Use of PPE	7	Sample preparation	6	
Hand washing	6	Reuse of single use consumables	6	
Equipment	7	Specimen referral system	5	
Aerosol management	4	Specimen transportation	5	
Dangerous pathogen management	7			
4- CLEANING, DISINFECTING, STERILIZATION, WASTE MANAGEMENT				61
Cleaning and Disinfecting	9	Sterilization in general	8	
Disinfectants, scope, use and control	9	Sterilization Management and control (including autoclaving)	10	
Cleaning staff	8	Waste management	7	
Antiseptics	3	Waste elimination	7	
5- EMERGENCIES				60
General emergency equipment	7	Biological Spill kit	8	
Biosecurity emergency equipment	6	Chemical Spill kit	8	
Emergency management	9	First-aid kit	6	
Fire prevention	10	Chemical safety	6	
6- RISK MANAGEMENT				20
Risk Assessment training	5	Analysis and implementation of corrective measures	5	
Risk assessment performance	6	Audits, Monitoring, Follow-up	4	
7- DOCUMENTATION AND REGULATIONS				103
Relationships of the laboratory with International Health Regulations	6	Pre-sampling and sampling SOP/guideline	11	
National Regulations	6	Availability of procedures	14	
Biosafety Manual	9	Procedure availability (good laboratory practices)	20	
Cleanliness and biosafety	7	Availability of procedures (Emergency)	19	
Product insert and safety sheets	5	Availability of forms/ checklist	6	
8- BIOSECURITY				48
Laboratory access and evacuation	12	Management of Pathogen	9	
Signage and Warnings	9	IT security protection and back-up	10	
Theft protection	8			
9- OTHER RISKS				45
Chemical Risks	13	Gas-related Risks	6	
Electrical Risks	9	Radiological Risks	7	
Physical Risks	10			
10- BIOSAFETY LABORATORY LEVEL 3 SPECIFIC				108
Organization, Design and Architecture	9	Maintenance and Calibration	8	
Laboratory finishes, Sealability and Equipment	12	Training	4	
HVAC and General Airflow System	7	Occupational Health	4	
Practices and Procedures	14	Emergencies	14	
Signage	6	Waste Management and Disinfection	8	
Workflow	5	Human Resources	5	
Autoclave	5	Documentation and Roles	7	

CONCLUSIONS

The developed and presented BSS-LAT:

- **Simple to use**, can be filled in a step-by-step approach
- With **automated calculations**, and provide **automated summary** by topic, module, and/or graphic depictions
- **Available in four languages**, including three UN languages (all integrated into the same file), and other languages can easily be added.
- Relies on widely known software (**MS Excel**) and is shared in an open format to ease any adaptation or update
- Successfully tested eight countries to date, at central and regional levels, in medical and veterinary laboratories, and even in a specialized pathogen-specific laboratory (HIV).
- The BSS-LAT was designed so that it can be used in any infectious disease laboratory at national or regional level
- Allow **standardization** of the assessment process
- Allow laboratory to rely on objective assessment, that is self explanatory and transparent
- Can be used as a **self-assessment tool**
- Can be used as a **monitoring tool** for follow-up over time

Lastly, the BSS-LAT can be used as:

- A **guiding tool** and as an opportunity to sensitize laboratory staff to biosafety concepts, knowledge and practices
- A major asset for countries or laboratory networks that would like to enhance or develop their biosafety capabilities.
- A basis and **backbone to develop national biosafety standards** (The BSS-LAT served to this end in Kazakhstan to develop a national biosafety and safety checklist).

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ACKNOWLEDGMENTS and CONTACT

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