



International Federation of
Biosafety Associations

IFBA Sample Policy and Procedures

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Laboratory Inspection Policies and Procedures

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1.0 PURPOSE & SCOPE

This purpose of this Standard Operating Procedure (SOP) is to describe the procedures for inspecting *Laboratory ABC* for compliance to the requirements and guidelines as outlined by the World Health Organization's Laboratory Biosafety Manual.

2.0 REFERENCES

Laboratory ABC Biosafety Manual Section 8.2

WHO Laboratory Biosafety Manual

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

3.0 RESPONSIBILITY

It is the responsibility of the Laboratory Supervisor to ensure the laboratory is inspected at least annually, to ensure identified deficiencies are corrected as soon as possible, and to further investigate any underlying causes or problems.

It is the responsibility of the Biosafety Officer to conduct periodic safety and security inspections, and advise *Laboratory ABC* management on any matters requiring their attention.

It is the responsibility of all employees to participate in laboratory inspections, to inspect their workplaces daily to identify and correct hazardous conditions, and to report them to the Biosafety Officer and/or Laboratory Supervisor.

4.0 Glossary of TERMS and DEFINITIONS

“Conformance (C)”: based on the evidence, the laboratory has demonstrated full implementation of the required criteria.

“Non-Conformance (NC)”: based on the evidence, the laboratory has not fully or effectively implemented the required criteria. Corrective action must be undertaken to safeguard the safety and security of the staff and/or surrounding community. Minor NC's

are issued where there are isolated instances of failures to meet the required criteria resulting in minimal risk to the safety and security of the staff and surrounding community. Major NC's are issued where there is an absence of meeting critical safety and security requirements and/or systemic failures to meet the required criteria.

“Not-Verified (NV)”: the inspector could not confirm conformance because evidence could not be provided, or the activity has not yet occurred.

“Not-Applicable (NA)”: the inspector did not confirm conformance because this requirement is not relevant to the laboratory.

“Recommendations”: recommendations have been provided that may assist the laboratory to achieve continual improvement by ensuring more efficient implementation of the requirements. The laboratory is conformant with required criteria, and the recommendations are opportunities for improvement.

5.0 PROCEDURES

5.1 Introduction

The inspection process involves gathering objective evidence through asking questions to laboratory employees about what they are doing, observing how employees are carrying out laboratory activities, examining the laboratory facility and equipment, and examining records (e.g. training records, biological agent inventories, and accident & incident reports). In addition to the formal annual inspection, all employees working in the laboratory are responsible for ongoing day-to-day inspections of their work areas to identify and correct hazardous conditions, and to report them to the Biosafety Officer and/or Laboratory Supervisor. Special inspections may also be conducted as a result of changes in laboratory operations, the introduction of new equipment, or after a laboratory accident or incident.

Any identified deficiencies are rectified as soon as reasonably possible, and further investigated to identify any underlying causes or problems. In cases where identified deficiencies present an unacceptable risk to employees, the public, the environment, the property, security and/or gross disregard to health and safety, *Laboratory ABC* management will take immediate action to rectify the situation. Action may include the immediate suspension of the laboratory activity of concern, prohibited entry to the laboratory, and/or removal of hazardous material from the premises until such time as the deficiency is corrected. Records are maintained of all laboratory inspection findings, including the action taken to address any deficiencies and opportunities for improvement.

5.2 Biosafety Evaluation Checklist

The laboratory inspection team utilizes a Biosafety Evaluation Checklist (*see Appendix A*) based on the requirements of the WHO Laboratory Biosafety Manual for a Biosafety Level 2 laboratory as the minimum criteria to determine compliance. The inspection activities encompass the gathering of objective evidence through a combination of examining documentation and inspecting the laboratory. A key first step of the process is information gathering and conducting a detailed risk assessment. This assessment will gather a

thorough understanding of the nature of the current laboratory operations, pathogens worked with, equipment, and physical facilities. Consultations with a cross-section of stakeholders are used to garner valuable insight in identifying gaps, challenges, and opportunities for improvement. Both administrative (biosafety program management, occupational health, pathogen inventories, training, laboratory SOPs, personal protective equipment, emergency response) and engineering controls (physical facility design, biosafety cabinets and equipment) are evaluated by the inspection team.

Planning & Preparation

In order to adequately prepare for and plan the inspection, and to gather information, the inspection team will carry out the following tasks:

- Conduct meaningful consultations with relevant facility authorities, which may include: biosafety coordinator, laboratory supervisor, technicians and scientists, facility and equipment maintenance technicians)
- Conduct risk assessment on the activities carried out within the laboratory
- Review documentation related to the operation of the laboratory (e.g. biosafety manual, standard operating practices, biosafety management program, training records, occupational health & safety program, facility maintenance program)
- Review past inspection reports (to determine if any trends or systemic problems are occurring)

On-site Inspection

In order to evaluate the physical laboratory facilities and equipment, the inspection team will carry out the following tasks:

- Gather objective data by physically inspecting laboratories/supporting infrastructure/equipment, observing activities and practices, and asking questions about said inspection.

Inspection Findings & Follow-Up

In order to follow-up on the inspection outcomes, the inspection team will carry out the following tasks:

- Compile inspection observations and conclusions into compliant and non-compliant findings (including both minor and major deficiencies)
- Provide an action plan and prioritized list of recommendations for compliance
- Follow-up action items, verify for compliance, and track to closure

APPENDIX A – Biosafety Evaluation Checklist

(Based on requirements for BSL 2 laboratory, WHO Laboratory Biosafety Manual)

1. Facility Information

Date:	
Inspectors:	
Organization Name:	
Contact Person (s):	
Address:	Telephone:
	Fax:
	Email:
Room (s):	
Brief Description of Laboratory Activities, Samples Handled, Pathogens:	

2. Biosafety Program and Facility Management

Statement <i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>	C	NC	NA	Comments
A detailed risk assessment is regularly conducted of the planned work.				
A biosafety program is in place with appropriate roles & responsibilities to manage biological risks (e.g. biosafety coordinator, biosafety committee)				
A biosafety manual, commensurate with the risks, is developed, is accessible, implemented and regularly updated.				
Where needed, there is an occupational health and medical surveillance program.				
Where needed, there is a respiratory protection program in place including training and fit-testing.				
A facility maintenance program is in place with appropriate roles and responsibilities to maintain critical containment equipment and proper functioning of the laboratory.				

3. Biosecurity

Statement <i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>	C	NC	NA	Comments
A biosecurity plan is in placed as may be required by the risk assessment (i.e. threats, vulnerabilities).				
The biosecurity plan is sufficient to safeguard against unauthorized access, theft, loss, or release of infectious materials and describes procedures for physical security, inventory control, personnel reliability and emergency procedures (e.g. reporting of unauthorized persons, loss or theft, inventory discrepancies, failure of physical security).				

There is a proper inventory control system for all infectious substances including record keeping of quantities received, transferred or destroyed.				
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4. Physical Laboratory Facility

Statement <i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>	C	NC	NA	Comments
Ample space is provided for the safe conduct of laboratory work, and for cleaning and maintenance.				
Ample space is provided for the storage of supplies for immediate use in the laboratory to avoid clutter on benchtops and floors.				
Appropriate space and equipment has been provided for the safe storage of chemical solvents & flammables.				
Offices are located outside of the laboratory. Paperwork stations and report writing areas within the laboratory are away from areas where infectious materials are manipulated.				
The laboratory is separated from areas accessible to the general public and access is restricted to authorized personnel only (e.g. locked door).				
Laboratory doors have appropriate signage (e.g. biohazard sign, contact information, entry requirements).				
Openable windows to the exterior are provided with appropriate pest control (e.g. screens) and security features as may be required by the risk assessment.				
Adequate illumination has been provided to work safely in the laboratory.				
Space has been provided at the laboratory entry area for the storage of laboratory coats and personal protective equipment.				

Space has been provided outside the laboratory area for the storage of outer garments and personal items.				
BSCs are located away from high traffic areas, doors, ventilation grilles, and air-conditioning systems and other equipment that may interfere with the BSCs proper functioning.				
BSCs are certified by qualified individuals using calibrated equipment after installation, at least annually and after being moved or repaired.				
The laboratory is equipped with a handwashing sink, located near the exit.				
An emergency eye wash station is available within the laboratory or in close proximity to the laboratory as may be required by the risk assessment.				
An emergency shower is located in close proximity to the laboratory as may be required by the risk assessment.				
Working surfaces, bench-tops and chairs are non-absorptive and compatible with the laboratory function, disinfectants, other chemicals used. Surfaces that have been compromised (e.g. cracked, chipped) are regularly repaired or replaced.				
Interior wall, floor, and ceiling coatings are compatible with laboratory function and decontamination methods. Floors are slip resistant.				
Vacuum systems, if present, are fitted with a device to protect internal contamination (e.g. liquid disinfectant traps).				
The water supply system to the laboratory is designed to reduce the risk of backflow and contamination of drinking water systems.				
As may be required by the risk assessment, the laboratory is equipped with a mechanical ventilation system to provide inward directional airflow.				

As may be required by the risk assessment, emergency lighting is provided for safe egress and emergency back-up power is provided for essential equipment. If an emergency generator is present, load testing is carried out and test results verify that the generator can pick up and carry the load if required.				
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5. Laboratory Entry/Exit & Protective Clothing

Statement	C	NC	NA	Comments
<i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>				
Laboratory doors are kept closed at all times.				
Access is restricted to authorized personnel only who have been advised of potential hazards.				
There is a procedure/area (e.g. coat hooks) for personnel to don laboratory coats when entering the laboratory and removing laboratory coats when leaving the laboratory.				
Personnel wear suitable footwear with closed toes and heels in the laboratory area.				
Eye and face protection is worn when there is a chance of splashing.				
Gloves are worn for all procedures that might involve direct skin contact with infectious materials. Alternatives to latex are provided.				
If a known or suspected exposure occurs, contaminated laboratory coats are decontaminated before laundering.				

6. Handling Infectious Substances

Statement	C	NC	NA	Comments
<i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>				
Staff have demonstrated skills and competency in microbiological practices and technique and				

for the minimization of infectious aerosols.				
It is forbidden to eat, drink, smoke, and store food, personnel belongings and utensils in the laboratory.				
It is forbidden to apply cosmetics or insert/remove contact lenses in the laboratory.				
It is forbidden to wear jewelry in the laboratory.				
Long hair is tied back so it cannot come into contact with infectious materials.				
Open wounds, cut, scratches are covered with waterproof dressings.				
Oral pipetting of any substance is prohibited in the laboratory.				
The use of needles and sharps is restricted. Needles are not bent, sheared or recapped.				
Activities with the potential for generating infectious aerosols are performed within the BSC in accordance with the risk assessment for the activity being performed.				
Proper procedures are followed when using the BSC for start-up of procedures, safe operation and closing down of operations. Open flames are not used in the BSC.				
Hands are washed after gloves are removed, after handling infectious materials, and before leaving the lab.				
Office activities are conducted outside of the laboratory. Paperwork stations and report writing areas within the laboratory are away from areas where infectious materials are manipulated.				
The laboratory is kept neat and tidy.				
There is an insect and rodent control program.				

Animals and plants not associated with the work are kept outside of the laboratory.				
There is an appropriate program in place for cleaning of the laboratory by trained staff.				
Samples are transported internally and externally using appropriate labelling, packaging, and documentation.				

7. Disinfection, Decontamination, Waste Handling & Disposal

Statement <i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>	C	NC	NA	Comments
A waste management and disposal policy is in place in accordance with applicable local and national requirements.				
All potentially contaminated materials are decontaminated before disposal, re-use or removal from the laboratory.				
Needles and sharps are disposed of in puncture-resistant sharps containers.				
Methods for decontamination and disinfection of equipment, surfaces, spills, wastes are effective against the microorganism of concern based on the risk assessment.				
An autoclave is available either within the laboratory or within the facility.				
Efficacy monitoring of autoclaves is done at regular intervals using appropriate biological indicators (with positive controls).				
Autoclave cycle logs and results of efficacy tests are kept on file.				
Laboratory bench tops and working surfaces are decontaminated at the end of each working session/day and after any spill of potentially infectious materials.				
Potentially contaminated equipment is decontaminated and appropriately labeled as				

such prior to servicing or disposal.				
It is forbidden to dispose of infectious materials directly into the sink without prior treatment.				

8. Spills, Incidents and Emergencies

Statement	C	NC	NA	Comments
<i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>				
Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other incidents established, followed and practiced regularly.				
Spill, accidents, potential exposures and other incidents are reported immediately to the laboratory supervisor.				
A mechanism is in place to investigate all spills, incidents and other emergencies. Results are used for continued improvement, to mitigate future risks, and for education and training.				
Written records of these incidents and the results of subsequent investigations are kept.				

9. Training

Statement	C	NC	NA	Comments
<i>C- Conformant</i> <i>N- Non-conformant (Major, Minor)</i> <i>NA - Not Applicable</i>				
Before working in the laboratory, personnel receive training and understand the potential hazards of the work, and the necessary procedures to prevent potential exposures and releases of infectious materials from the lab.				
Personnel have received training and understand the roles & responsibilities and requirements of biosafety and biosecurity program for the facility.				
Maintenance, support staff and visitors have received training appropriate to their specific				

activities in the laboratory.				
Training records are maintained and kept on file.				