World Health Organization
REGIONAL OFFICE FOR Europe

Tuberculosis Laboratory Maintenance Plan (LMP) for preventive and routine maintenance of laboratory equipment

Expert opinion of the European Tuberculosis Laboratory Initiative 2017

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Acknowledgements

This technical document was developed as a collaborative product by core group members of the European Tuberculosis Laboratory Initiative (ELI). Document development was guided by Masoud Dara (WHO Regional Office for Europe) and led by Soudeh Ehsani (WHO Regional Office for Europe) and ELI core group members Natalia Shubladze (National Centre of Tuberculosis and Lung Diseases and the National Reference Mycobacteriology Laboratory Tbilisi, Georgia), Evgeni Sahalchyk (IML red GmbH, Institute of Microbiology and Laboratory Medicine, Supranational Reference Laboratory (SRL) for TB, Gauting, Germany), Rasim Tahirli (WHO Collaborating Centre on Prevention and Control of Tuberculosis in the Penitentiary System, Baku, Azerbaijan) and Sven Hoffner (Department of Microbiology, Tumor and Cell Biology Karolinska Institutet, Stockholm, Sweden). The document was reviewed and technical inputs were provided by ELI core group members Francis Drobniewski (Imperial College London, United Kingdom), Irina Felker (Novosibirsk Tuberculosis Research Institute, WHO National Centre of Excellence, Russian Federation), Gulmira I. Kalmambetova (National Reference Laboratory, Bishkek, Kyrgyzstan), Hasmik Margaryan (Laboratory quality manager, Médecins Sans Frontières , Nukus, Uzbekistan), Elina V. Sevastyanova (Central Tuberculosis Research Institute, WHO National Centre of Excellence, Moscow, Russian Federation), Nukra Sinavbarova (National Public Health Laboratory, Dushanbe, Tajikistan), and Alena Skrahina (Republican Research and Practical Centre for Pulmonology and Tuberculosis, Minsk, Belarus). Additional review and/or technical inputs were provided by Paul Jensen (Lead for TB Infection Control and Biosafety CDC Atlanta, USA), and the external reviewers Grigory Volchenkov (Infection Control specialists, Vladimir Regional TB Control Center, Vladimir, Russia), Riccardo Alagna (TB laboratory specialist, WHO Collaborating Centre in Tuberculosis Laboratory Strengthening - SRL for TB, San Raffaele Scientific Institute, Milan, Italy), Joerg Weber (engineer), Svenja Schneider (engineer, third party certifier of biosafety cabinets), and Kathleen England (Senior TB Diagnostics Advisor. Médecins Sans Frontières International, Geneva).

ELI has been partly supported by funds from the United States Agency for International Development.

Publication of this document was made possible with financial support from the Government of Germany.

About this document

This technical guiding document has been developed by core group members of the European TB Laboratory Initiative to provide practical guidance for planning and implementing equipment maintenance in tuberculosis laboratories in the WHO European Region. It will help to ensure accurate and uninterrupted laboratory services, cost-efficient use and extended lifetime of equipment, and increased laboratory safety. Correct functioning of (bio)safety equipment is important for ensuring the safe handling and manipulation of infectious or chemical materials. Therefore, the calibration, certification and regular maintenance of laboratory equipment is essential.

The tuberculosis laboratory maintenance plan provides a table for each key piece of laboratory equipment for use in organizing regular maintenance and providing answers to the four following questions:

- who is responsible?
- when should it be done?
- what activity is necessary?
- which laboratory equipment?

The "who" category helps to identify the responsible person and indicates whether the maintenance activity can be done by a laboratory worker or whether a certified and specialized engineer is needed. The time interval between each maintenance activity is described under the "when" category for each piece of equipment. The "what" and "which" categories describe the necessary maintenance activities needed for each item of equipment.

Target audience

This expert opinion is intended for use as a bench aid in the WHO European Region for equipment maintenance organization in the laboratory and to help laboratory managers, programme managers, implementing partners and donors in planning and calculating the necessary budgets for equipment routine maintenance, regular service and spare parts and human resources.

Abbreviations

BI	biological indicator
BSC	biological safety cabinet
ELI	European TB Laboratory Initiative
HEPA	high-efficiency particulate air
LMP	laboratory maintenance plan
MGIT	Mycobacteria growth indicator tube
SOP	standard operating procedure
SRL	Supranational Reference Laboratory
TB	tuberculosis
UV	ultraviolet
UVGI	ultraviolet germicidal irradiation
WHO	World Health Organization

Background

Equipment management is an essential element of a quality management system programme for any laboratory. Routine maintenance, calibration and repairs require formal documentation and regular monitoring to ensure quality performance and optimize the lifespan of each piece of equipment *(1–4)*. In addition, proper equipment installation, verification and validation will ensure that routine test results produced for patient management are reliable, accurate and timely.

A number of documents provide a detailed description of the different steps necessary for facility and equipment maintenance *(1-7)*. This document describes the roles of the four key personnel groups within a tuberculosis (TB) programme required to design and enforce proper strategies and protocols necessary to sustain equipment performance:

- the National TB Programme manager
- the laboratory manager
- laboratory technical staff
- the biomedical engineer.

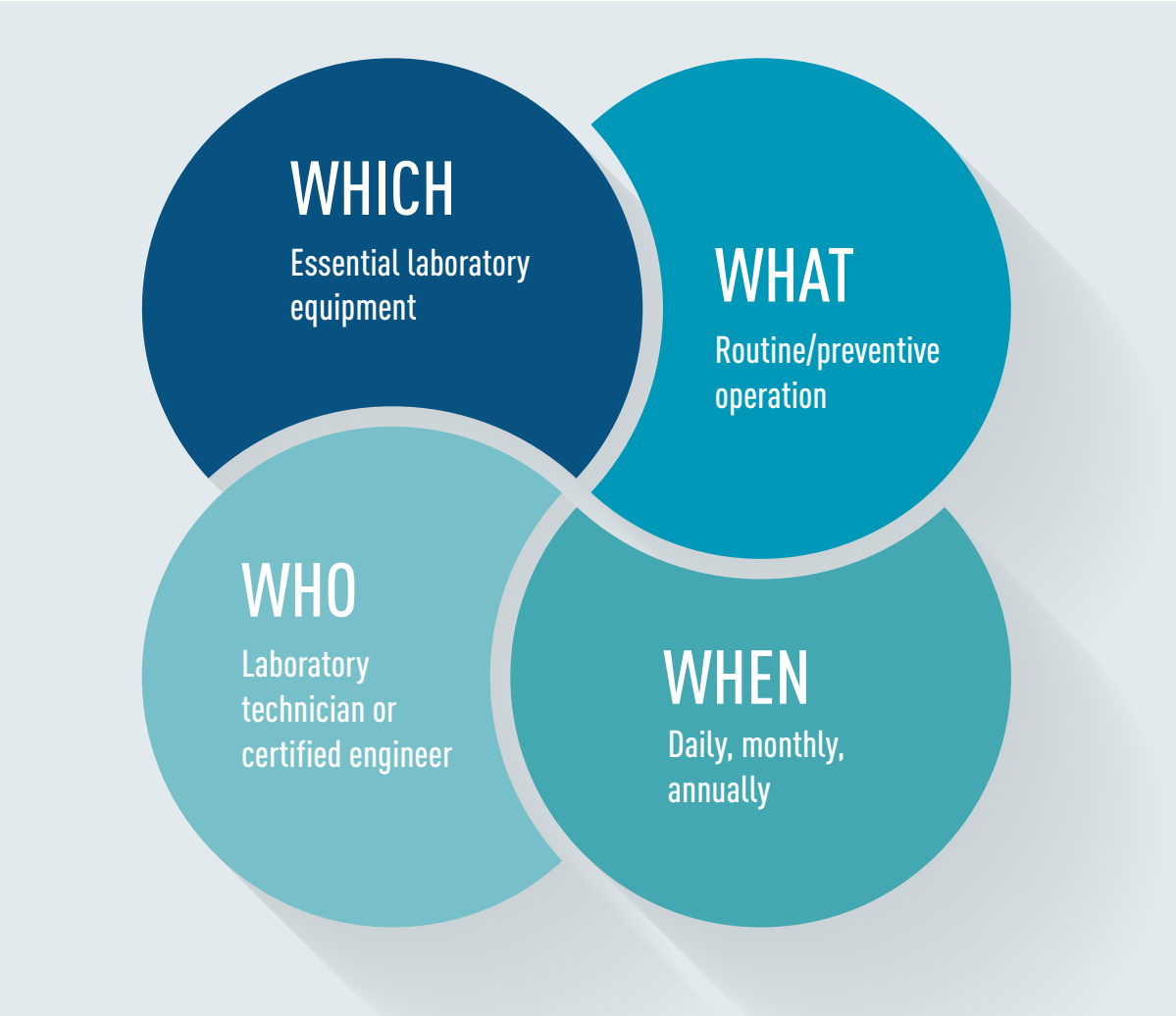
These groups are responsible for systematically organizing and managing the proper maintenance of all key laboratory equipment used in a TB clinical laboratory in a cost-efficient and sustainable manner. This is achieved by addressing four major questions (Figure 1):

1. which pieces of equipment need to be maintained?
2. when or how frequently (time interval) is the maintenance to be done?
3. who is responsible for maintenance (i.e. most qualified and most appropriate)?
4. what type of maintenance task or work is to be completed?

This document outlines two approaches to designing a proper laboratory maintenance plan (LMP). The plan illustrated in Fig. 2 covers areas of maintenance which include both equipment and infrastructure (*y*-axis) with regard to frequency (time interval; *x*-axis) and the person responsible for completing the task (indicated by colour coding). This outline provides a quick overview of staff workload, the involvement of specialists or certified engineers, and the involvement of National Tuberculosis Programme and National TB Reference Laboratory managers. From this LMP, the level of additional budget necessary to sustain maintenance practices (i.e. whether and how often a certified engineer is needed) can be inferred.

The second version of the LMP is shown in Fig. 3. This detailed plan may be used to provide laboratory technicians and qualified engineers with an overview of the necessary procedures and relevant time intervals required to maintain each piece of equipment.

FIG. 1. Rationale for the laboratory maintenance plan, as proposed by the European Tuberculosis Laboratory Initiative



The second LMP template (Fig. 3) can be used to provide the equipment officer (Equipment Officer; or laboratory staff member responsible for overseeing the maintenance of all equipment) with an overview of the tasks to be done and the person responsible for reporting the regular completion of such tasks to the laboratory manager. For maintenance procedures and specific pieces of equipment that could directly affect the quality assurance of results or laboratory bio/safety measures, three personnel (the Equipment Officer, quality officer and biosafety officer) are responsible for ensuring that such tasks are performed and well documented. These officers typically form part of the organizational structure of larger laboratories such as national reference laboratories. Depending on the laboratory size and its workload and human resources capacity, a single individual may perform more than one role provided that she or he has the necessary knowledge and skills. Further, such individuals may also support other regional reference laboratories in the same role. By serving as monitors for other facilities or mentoring other staff, their operational function could be extended throughout the reference laboratory network. This would depend on the extent of the reference laboratory network within the country programme.

FIG. 2. First version of the LMP, as proposed by the European Tuberculosis Laboratory Initiative

Area of Maintenance		Laboratory Maintenance Plan						
		Time table and responsible person						
		Equipment	Daily/per procedure	Weekly	Monthly	Every 6 months	Yearly	As needed
	Equipment							
	Infrastructure							

Laboratory worker	Qualified engineer/technician

FIG. 3. Second version of the LMP, including the role of the coordinating officer (equipment, laboratory safety and/or quality)

Which	What	When	Who
Equipment	Procedure	Time interval	Responsible person

Laboratory worker	Qualified engineer/technician

The implementation tools of laboratory quality management systems provide a stepwise approach to equipment management *(1–3,5)*. The main steps of equipment management procedures include equipment selection and placement, installation and validation, preventive maintenance, procedures for troubleshooting and basic repairs, as well as relevant standard operating procedures (SOPs). A good equipment maintenance programme can help the laboratory to achieve a high level of performance, lengthen instrument life, reduce service interruption due to breakdowns and failures, reduce variations in results, forecast budgetary needs for planning high expenditure on maintenance, and improve customer satisfaction and instrument utilization, as well as ensuring a safe working environment *(4)*.

The first step in an equipment management programme is to assign responsibilities for all activities and train personnel in operating various pieces of equipment. It is recommended that at least one Equipment Officer who will have oversight of all laboratory equipment management tasks should be identified. The biosafety officer should be responsible for maintenance tasks for equipment with direct biosafety implications, such as biosafety cabinets, ventilation systems, ultraviolet (UV) lamps and autoclaves. The Equipment Officer should work closely with the biosafety officer to coordinate monitoring and supervision of the necessary procedures for use and maintenance, routine documentation (record and logbook reviews), and routine updating of SOPs as needed.

Implementing a maintenance programme for laboratory equipment requires the following steps *(1–4)*:

- assigning responsibility based on the LMP;
- ensuring that manufacturer's instructions and operations manuals are on site;
- developing a verification and validation protocol (for use after installation or repair);
- calibrating equipment (as recommended by the manufacturer);
- developing a written protocol to ensure proper equipment calibration, inspection or troubleshooting, and routine performance checks;
- creating recording and reporting templates, logs or registers;
- archiving documentation; and
- providing well-documented staff training and refresher training programmes.

All laboratories should have an inventory logbook created for all equipment (large and small) in the laboratory in which the following parameters should be recorded *(1–4)*:

- the equipment name and manufacturer
- the instrument type and/or model number
- the serial number
- important specifications (e.g. voltage, hertz, capacity, size)
- the location in the laboratory
- the laboratory inventory number

- the date of purchase and date received
- the date of installation
- the date of calibration
- the date of validation
- the date of entry into routine service
- contact information for the manufacturer and vendor
- verification that the manufacturer's operating instructions or manual are available on site
- the warranty (note expiration date)
- a list of spare parts included in shipment (and their location).

A SOP should be developed for each piece of equipment. SOPs may be based on templates recommended by World Health Organization (WHO) *(5)*, but should be customized according to the manufacturer's instruction for each piece of equipment and include:

- a general procedure for routine use
- routine maintenance activities (based on the LMP)
- function and safety checks
- a calibration protocol
- troubleshooting information
- the manufacturer's service information.

Each piece of equipment should have a dedicated folder containing the manufacturer's instruction guide or manual, an SOP on its use and maintenance, concise operator instructions (quick guide), and a logbook for recording data on routine calibrations, maintenance activities, error reports, service and repairs, and function checks.. These records must be kept for the lifespan of the equipment; hence, they comprise the so-called "book of life" for each piece of equipment.

All problems in equipment function should be recorded in the dedicated logbook, including:

- the date the problem occurred
- the date the equipment was removed from service
- the reason for the breakdown or failure (error codes or a description of what occurred when the equipment stopped normal operations, i.e. sounds, leaks, vibrations)
- a troubleshooting report
- whether decontamination was needed
- the date the service provider was contacted (if needed)
- the date the service provider responded
- the corrective actions taken
- the date of return to use
- changes to maintenance or function checks.

Development of a LMP

The LMP template can be used to develop a laboratory-specific LMP providing an overview of all key laboratory equipment, the routine maintenance schedules and the responsible person for performing maintenance tasks. All redundant equipment should be removed from the laboratory. Laboratories should adapt the LMP based on the existing laboratory equipment inventory and availability of appropriate laboratory and engineering staff.

The laboratory manager should be assisted by the Equipment Officer and biosafety officer to plan and apply for the necessary budget and for appropriately qualified laboratory and engineering staff required to implement the LMP.

Preventive maintenance plan for laboratory equipment

General laboratory equipment

Autoclaves

Autoclaves play a key role in sterilizing and decontaminating infectious materials (e.g. objects, media, waste) in laboratories. Maintenance of this equipment involves seven daily and weekly procedures that can be done by operating laboratory technicians, three monthly procedures that need the involvement or supervision of the biosafety officer, and seven annual or biannual procedures that can only be done by a qualified engineer.

The sterilization process should be routinely monitored using mechanical, chemical and biological indicators.

Mechanical indicators. For monitoring sterilization, the cycle time, temperature and pressure of sterilization equipment are recorded daily in the logbook by the instrument operator.

Chemical indicators (internal and external). Sensitive chemicals are used to assess physical conditions such as temperature (autoclave tape, steam chemical process indicators) or steam penetration (Bowie–Dick test) during the sterilization process. Chemical indicators are heat sensitive (i.e. temperature-dependent colour change). An internal chemical indicator should be placed in every sterilization package, and external indicator should be used when the internal indicator cannot be seen from outside the package. Single-parameter internal indicators provide information on only one sterilization parameter; multiparameter internal indicators measure two to three parameters and can provide a more reliable indication that sterilization conditions have been met (e.g. autoclave test strips with time, steam and temperature control). Consult the manufacturer's instructions for the proper use and placement of chemical indicators.

Biological indicators (BIs). BIs are the most accepted method of monitoring the sterilization process because they directly determine whether the most resistant endospore-forming microorganisms (i.e. *Geobacillus* or *Bacillus* species) are viable after the sterilization cycle. Correct functioning of sterilization cycles should be verified for each sterilizer via the periodic (at least weekly) use of BIs. Follow the manufacturer's instructions on the most appropriate placement of the BI in the sterilizer.

TABLE 1. Maintenance plan for autoclaves

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Autoclave	1. Temperature control for each sterilization cycle (autoclave tape test and sterilization report printout check)	Daily	Responsible lab staff
	2. Bowie–Dick testing (air removal inside chamber control)	Daily	Responsible lab staff
	3. Cleaning the front of the autoclave, controls, indicators and handles with a damp cloth	Daily	Responsible lab staff
	4. Cleaning the sterilization chamber and drainage filter with non-chlorine/non-corrosive disinfectants	Weekly	Responsible lab staff
	5. Cleaning external rust-proof surfaces with a mild detergent	Weekly	Responsible lab staff
	6. Lubricating the rubber O-ring	Weekly	Responsible lab staff
	7. Draining the vapour generator	Weekly	Responsible lab staff
	8. Replacing paper in the printer and checking ink levels in the recorder	As needed	Responsible lab staff
	9. Checking for adequate functioning using a biological or chemical indicator	Weekly	Responsible lab staff
	10. Checking the temperature using chemical test strips	Weekly	Responsible lab staff
	11. Checking indicator lights; comparing temperature & pressure gauges with recordings	Monthly	Responsible lab staff
	12. Checking the function of manometers	Every 6 months	Qualified engineer/ technician
	13. Manually activating the safety valves	Every 6 months	Qualified engineer/ technician
	14. Lubricating the door gasket	Every 6 months	Qualified engineer/ technician
	15. Checking the seals of safety valves	Every 6 months	Qualified engineer/ technician
	16. Calibrating the control unit	Annually	Qualified engineer/ technician
	17. Maintaining and/or replacing filters	As needed	Qualified engineer/ technician
	18. Maintaining solenoid valves	As needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

As well as in routine monitoring, BIs should be used under the following conditions*:

- whenever a new type of packaging material or tray is used
- after training new sterilization personnel
- after a sterilizer has been repaired
- after any change in sterilizer loading procedures.

Procedures 1–8 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedures 9–11 should be performed by the biosafety officer or by operating laboratory technicians under the direct supervision of the biosafety officer in coordination with the Equipment Officer.

Procedures 12–18 can be performed only by a qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable. The Equipment Officer should ensure that the engineer is certified according to international or national standards and that the utilized equipment is calibrated by an ISO 17025 accredited entity.

For general maintenance information, consult Chapter 12, Autoclave (pp. 81–92), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 11: use and maintenance of an autoclave *(5)*.

For information on safe management of waste from health-care activities, consult the second the WHO document on safe management of wastes from health-care activities *(6)*.

* More information can be obtained from the Centers for Disease Control and Prevention (https://www.cdc.gov/oralhealth/infectioncontrol/questions/sterilization/monitoring.html).

Air displacement pipettes

Pipettes are devices used for measuring or transferring small volumes of liquid with great precision. Pipettes are widely used in most TB laboratory tests and their functionality is very important. A dedicated logbook for leakage control and calibration of pipettes should contain records of these parameters. Four maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer and quality officer and three procedures should be done only by the Equipment Officer.

TABLE 2. Maintenance plan for air displacement pipettes

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Air displacement pipettes	1. Inspecting the integrity and adjusting the mechanism	Daily or per procedure	Responsible lab staff
	2. Testing leakage control by putting on a tip and filling it with distilled water	Daily or per procedure	Responsible lab staff
	3. Disassembling and cleaning all pipette parts	Biannually	Equipment Officer
Air displacement pipettes	4. Calibrating pipette using a standardized procedure	Biannually	Equipment Officer
	5. External cleaning and decontamination with a mild detergent	As needed	Responsible lab staff
	6. Sterilizing the pipette according to the manufacturer's instructions	As needed	Equipment Officer
	7. After using harmful substances, complete decontamination is needed	As needed	Equipment Officer

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1, 2 and 5 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedures 3, 4 and 6 can be performed by a trained Equipment Officer using the relevant procedure.

Procedure 7 should be performed by the biosafety officer or by an operating laboratory technician under the direct supervision of the biosafety officer in coordination with the Equipment Officer.

For general maintenance information, consult Chapter 16, Pipettes (pp. 119–26), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*.

Biological safety cabinet

Biological safety cabinets (BSCs) are the most important items of safety equipment for working with air-born infectious substances. The proper functioning of BSCs ensures safety for workers, so this equipment should be monitored and maintained

TABLE 3. Maintenance plan for class II biosafety cabinets

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Class II BSC	1. Disinfecting internal working parts with 70% alcohol or adequate before and after use	Daily (before and after usage)	Responsible lab staff
	2. Checking the airflow conditions on the display and checking the inward air velocity using a vaneometer	Daily (before usage)	Responsible lab staff
	3. Switching on the built-in UV lamp (if installed) after use	Daily (after usage for 30 min if the time is not regulated automatically by the BSC)	Responsible lab staff
	4. Air sampling on agar plates for BSC product protection testing	Every 6 months	Responsible lab staff
	5. Visually examining airflow (inflow and downflow) using smoke test tubes	Monthly	Responsible lab staff
	6. Disinfecting and cleaning external parts with a general cleaner	Monthly	Responsible lab staff
	7. Disinfecting and cleaning internal parts with a general cleaner after removing the working surface	Quarterly	Responsible lab staff
	8. Installation testing	At installation and relocation, before beginning of operation	Qualified engineer/ technician
	9. Field testing and certifying each BSC as per corresponding standard (EN 12469, NSF/ANSI 49 or other)	Annually	Qualified engineer/ technician
	10. Replacing HEPA filters (with recalibration and recertification)	As needed according to the engineer's report	Qualified engineer/ technician
BSC maintenance equipment	1. Calibration	Annually	Qualified body (ISO 17025 accredited)

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

regularly. A dedicated logbook should be created for recording maintenance procedures. Most maintenance procedures can be done by the responsible laboratory technician; however, annual certification and if necessary changing the high-efficiency particulate air (HEPA) filters (and subsequent recertification) must be performed only by authorized engineers based on the corresponding standards (EN 12469, NSF 49 or others).

Class II *bsc*: procedures 1–7 can be performed by an operating laboratory technician under the supervision of the Equipment Officer and safety officer.

- Daily airflow readings (of actual values or signals) of the *BSC* display and measured values using a vaneometer (for qualitative indication of velocity, containment and turbulence) should be recorded in the daily *BSC* check-off form. If the reading is below the threshold based on the manufacturer's manual or shows a warn signal, the *BSC* should not be used and the head of the laboratory alerted to initiate the testing of the *BSC* by a qualified engineer/technician.
- Qualitative checks across the entire width of the *BSC* opening should be performed with a smoke generator. The smoke test is an indicator of airflow direction, not of velocity.
- Air sampling (passive) is used to check for product protection only. This test cannot be used to assess personal protection provided by the *BSC* and it does not replace the annual field testing and certification by a specialist. A negative air sampling result (no growth on the test plates and negative control) cannot lead to the conclusion that the *BSC* is functioning properly. The annual *BSC* field testing needs to be performed on schedule.

  In this test (in accordance to EN 12469, NSF/ANSI 49 standard or equivalent) the entire *BSC* work space is covered with agar plates during laboratory operating times. All test agar plates should be exposed without lids for 30 min in the *BSC*. In addition 2 agar plates are used for the negative control, the first one incubated without any exposure and the second one handled equally as the test plates with the difference, that during exposure in the *BSC* the lid is not removed. The agar plate for the positive control should be exposed to laboratory air (outside the *BSC*) for the settlement of bioaerosols or if available exposed to environmental microbes. Subsequently all plates, including the positive and negative controls are incubated at 36± 1°C for 24h and 48h. Results should be recorded at 24h and 48h incubation time.

  Any growth on the test plates (with absence of growth on the negative controls) should be recorded, the *BSC* thoroughly cleaned and the test repeated. If comparable growth is observed as a result of the repeated test, the *BSC* should not be used and be checked by a qualified engineer/technician."

Class II *bsc*: procedures 8 and 10 can be only performed by an authorized engineer in the presence of the Equipment Officer and safety officer. Obligatory annual certification of each *BSC* unit should be performed in accordance with the corresponding standard (EN 12469, NSF/ANSI 49 or other).

- All internal and external surfaces of the safety cabinet should be visually examined to ensure that there are no surface defects or other damage.
- Smoke test for down flow and inflow visualization should be performed based on the corresponding Standard.
- The downflow and inflow air velocity must be checked in accordance with the manufacturer's requirements and adjusted if necessary.
- An aerosol leakage test should be performed for the HEPA filters using a particle counter or photometer. Each filter should be tested independently.
- The alarm indicators should be checked according to the manufacturer's specifications. The alarm device should be calibrated, if necessary.
- The extraction duct system should be visually inspected to ensure that it is free from defects, cracks and other damage, and that it is clearly labelled.

A spare set of suitable HEPA filters should be available in laboratory in case the filter leaks.

For general maintenance information, consult Chapter 6, Biological safety cabinet (pp. 35–44), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 10: use and maintenance of class I and class II biological safety cabinets *(5)*.

***BSC* maintenance equipment: procedure 1** should ideally be done yearly by an ISO 17025 accredited body.

Centrifuge

The centrifuge is used for concentrating specimens after decontamination procedures. Centrifugation at the correct speed and temperature is important for preserving viable mycobacteria in the sample. These parameters should be recorded in a dedicated logbook for each procedure and use.

TABLE 4. Maintenance plan for table centrifuges

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Centrifuge	1. Drying condensed water in the rotor chamber after use	Daily	Responsible lab staff
	2. Balancing buckets before spinning	Per procedure	Responsible lab staff
	3. Disinfecting the centrifuge chamber and rotor buckets	Weekly	Responsible lab staff
	4. Lubricating rotor trunnions	Monthly	Responsible lab staff
	5. Cleaning external surfaces with a general purpose cleaner	Monthly	Responsible lab staff
	6. Disinfecting after spillage	As needed	Responsible lab staff
	7. Checking and calibration	Annually	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–5 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 6 can be performed by an operating laboratory technician under the supervision of the Equipment Officer and safety officer.

Procedure 7 should be performed only by a qualified engineer under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 7, Centrifuge (pp. 45–52), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 13: use and maintenance of a centrifuge *(5)*.

Drying oven

In the laboratory, drying ovens (also known as hot air ovens) are used for drying and sterilizing glass and metal containers. The operating temperature is between room temperature and 350°C.

TABLE 5. Maintenance plan for drying ovens

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Drying oven	1. Checking temperature	Per procedure	Responsible lab staff
	2. Cleaning surfaces with 70% alcohol	Weekly	Responsible lab staff
	3. Servicing	Annually or as needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1 and 2 can be performed by an operating laboratory technician.

Procedure 3 can be performed only by a qualified engineer in the presence of the Equipment Officer.

For general maintenance information, consult Chapter 13, Drying oven (pp. 93–8), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*.

Freezer/refrigerator/ultralow freezer

Refrigerators and freezers are among the most important pieces of laboratory equipment. They maintain a temperature controlled (refrigerated) environment for storing various liquids, reagents and samples. Different kinds of refrigerators and freezers are used in the laboratory, and temperature logs should be kept for each. Maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer and quality officer. One of the procedures for the ultralow freezer should only be performed by a qualified engineer.

TABLE 6. Maintenance plan for freezers/refrigerators

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Freezer/refrigerator	1. Checking temperature control (display and thermometer)	Daily	Responsible lab staff
	2. Cleaning internal and external surfaces	Monthly	Responsible lab staff
	3. Checking gasket seals	Monthly	Responsible lab staff
	4. Checking blower fan for proper operation	Monthly	Responsible lab staff
	5. Checking hot air vents with cooling fans near the bottom, cleaning with vacuum	Monthly	Responsible lab staff
	6. Cleaning filters, washing with general purpose disinfectant	Monthly	Responsible lab staff
	7. Defrosting	Every 6 months	Responsible lab staff
	8. Cleaning the condenser	Every 6 months	Responsible lab staff
	9. Verifying the door gasket is functional	Every 6 months	Responsible lab staff
	10. Clearing out expired reagents	Quarterly	Responsible lab staff
Ultralow freezer	11. Maintaining the alarm system battery	Biannually	Qualified engineer/ technician
	12. If the frost thickness is → 8 mm, defrosting and cleaning/disinfecting	As needed	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–9 and 12 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 10 can be performed by an operating laboratory technician under the supervision of the quality officer

Procedure 11 can be performed only by a qualified engineer under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 18, Refrigerators and freezers (pp. 131–42), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, SOP module 14: use and maintenance of a freezer and module 15: use and maintenance of a refrigerator *(5)*.

Incubator

An incubator is a chamber with controlled temperature, atmosphere and humidity; it is used for maintaining live organisms in a suitable growth environment. Some incubators have CO_2 injection for achieving specific atmospheric conditions to support the growth of *Mycobacterium tuberculosis* in specific medium. Temperature logs should be updated daily for each incubator. All maintenance procedures except for servicing can be performed by the responsible laboratory technician under the supervision of the Equipment Officer.

TABLE 7. Maintenance plan for incubators

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Incubator	1. Checking temperature controls (display and thermometer)	Daily	Responsible lab staff
	2. Disinfecting internal and external surfaces	Monthly	Responsible lab staff
	3. Full cleaning, removing old cultures, disinfecting internal surfaces and cleaning fan filter vents (if present)	Annually	Responsible lab staff
	4. Servicing	As needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–3 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 4 can be performed only by a qualified engineer under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 14, Incubator (pp. 99–104), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 16: use and maintenance of an incubator *(5)*.

Microscope

In TB laboratories, microscopes are used for sputum smear acid-fast bacilli microscopy. Two types of microscopes are used for TB diagnostics: clear field optical microscopes and fluorescence optical microscopes. Routine maintenance can be performed by responsible laboratory staff under the supervision of the Equipment Officer. Basic adjustments and cleaning can be done by Equipment Officer. Specialized servicing tasks should be done only by a qualified engineer.

TABLE 8. Maintenance plan for microscopes

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Microscope	1. Cleaning the objective lens, removing residual oil	Daily	Responsible lab staff
	2. Covering the microscope with a dust cover	Daily	Responsible lab staff
	3. Removing dust particles from eyepieces, objectives and condenser with a rubber bulb air blower	Monthly	Responsible lab staff
	4. Removing the slide holder mechanism, cleaning carefully and reinstalling	Monthly	Responsible lab staff
	5. Verifying that good ventilation conditions, temperature and humidity control are in place	Every 6 months	Responsible lab staff
	6. Testing the quality of the electrical system of the microscope	Every 6 months	Responsible lab staff
	7. Servicing	As needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–6 can be performed by an operating laboratory technician under the supervision of the Equipment Officer. All troubleshooting procedures described in the manufacturer's manual should be performed by the Equipment Officer.

Procedure 7 can be performed only by a qualified engineer in presence of the Equipment Officer

For general maintenance information, consult Chapter 15, Microscope (pp. 105–18), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 18: use and maintenance of a light microscope *(5)*.

pH meter

The pH meter is used to determine the concentration of hydrogen ions, [H^+], in a solution by measuring the difference in electrical potential between the pH electrode and a reference electrode. pH meters are also called pH analysers, pH monitors or potentiometers. All maintenance procedures can be done by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 9. Maintenance plan for pH meters

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
pH meter	1. Rinsing and drying the electrode with deionized water and clean paper towels	Daily	Responsible lab staff
	2. Calibrating before each use	Daily	Responsible lab staff
	3. Maintaining and cleaning of the electrode	Every 4 months or as needed	Responsible lab staff
	4. Evaluating the general physical condition of the parts: cables, connections, controls, meter, electrode	Every 6 months	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 3, pH meter (pp. 13–20), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 20: use and maintenance of a pH meter *(5)*.

Precision and analytical balances

Precision and analytical balances are important for preparing media and reagents. These very sensitive instruments need regular maintenance and periodic calibration. All procedures can be performed by laboratory staff under the supervision of the Equipment Officer or quality officer.

TABLE 10. Maintenance plan for the balance

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Balance (precision or analytical)	1. Cleaning the weighing chamber, externally and internally	Daily or per procedure	Responsible lab staff
	2. Verifying the adjustment mechanisms on the front door	Monthly	Responsible lab staff
	3. Accuracy checking with external certified reference weights	Every 6 months	Responsible lab staff
	4. Internal calibration: - drift check - performance check - measurement uncertainty check	After maintenance, relocation, power failure	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1 and 2 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedures 3 and 4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer and quality officer.

Reference weights

Reference weights are calibrated as indicated by the manufacturer. The weight tolerance is equal to ANSI/ASTM E617 Class 0 and exceeds OIML R 111 Class E2. This class is used as a reference standard for calibrating other reference standards and weights, and is appropriate for calibrating high-precision analytical balances with scale readability of as low as 0.01 mg *(9)*.

Drift check

For calculating the drift, 10 measurements for the 10 mg weight should be noted in the performance check log. Variation in the observed weight from the mean value should not exceed ± 0.2 mg. The 10 mg weight should meet the performance check

criteria of the mass value (i.e. 0.1% of actual mass value). For example, for all the 10 measurements of the 10 mg weight, the variation at weighing cannot exceed 0.01 mg.

Performance check

After autocalibration, add 1 mg, 2 mg, 5 mg, 10 mg and 20 mg weights individually. The measurement should be within the 0.1% of actual mass value of the individual weight as given in the performance check log.

Measurement uncertainty check

The measurement uncertainty should be calculated by first determining the mean and standard deviation of 10 measurements of the 10 mg weight and then inserting these values into the following equation:

The measurement uncertainty should not be more than 0.001 *(10)*.

For general maintenance information, consult Chapter 4, Balances (pp. 21–30), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 12: use and maintenance of an electromagnetic balance *(5)*.

Thermal cycler

The thermal cycler is used for amplifying DNA from samples in the line probe assay. All maintenance procedures, except for servicing, can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 11. Maintenance plan for thermal cyclers

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Thermal cycler	1. Removing dust from external surfaces with a lint-free cloth and distilled water	Weekly	Responsible lab staff
	2. Cleaning the heated lid with a mild detergent	Weekly	Responsible lab staff
	3. Checking the temperature inside the heated lid	As needed	Responsible lab staff
	4. Cleaning the sealing tape and unit frame with 70% alcohol	Weekly	Responsible lab staff
	5. Servicing	Annually or as needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 5 can be performed only by a qualified engineer under the supervision of the Equipment Officer.

For more information, consult the manufacturer's manual *(13)*.

Water-bath and heat block

In the TB laboratory, the water-bath is used for inactivating TB cultures before DNA extraction for the line probe assay or genome sequencing. Water-baths are normally used at between room temperature and 100°C. Water-bath chambers have a capacity of 2–30 l.

Heat blocks are used for a range of procedures, including heat killing mycobacteria during specimen processing for molecular analyses.

Routine maintenance procedures can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 12. Maintenance plan for water-baths

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Water-bath	1. Lubricating (for water-baths with agitating or circulator unit)	Daily	Responsible lab staff
	2. Cleaning the tank interior and exterior with a mild detergent and rinsing with clean water	Monthly	Responsible lab staff
	3. Periodic inspection: checking the thermometer or temperature controls, recording results in the logbook	Quarterly	Responsible lab staff
Heat block	4. Cleaning the unit and heating blocks with a mild detergent	Weekly or as needed	Responsible lab staff
	5. Calibrating	Every 6 months	Responsible lab staff
	6. Servicing	As needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–5 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 6 can be performed only by a qualified engineer.

For general maintenance information, consult Chapter 5, Water bath (pp. 31–4), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, the generic WHO SOP for water-bath use and maintenance *(16)*.

Water distiller

The laboratory water distiller (also called the distillation unit or water still) purifies mains water via controlled vaporization and cooling processes. Distilled water is used for preparing culture medium and other reagents. All routine maintenance procedures can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 13. Maintenance plan for water distillers

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Water distiller	1. Inspecting and cleaning the vapour generator tank	Monthly	Responsible lab staff
	2. Changing the activated carbon filter	Quarterly	Responsible lab staff
	3. Cleaning the condenser	Annually	Responsible lab staff
	4. Sterilizing the distilled water storage tank using a chemical process with chlorine-based bleach	As needed	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 8, Water distiller (pp. 53–8), in the *Maintenance manual for laboratory equipment, 2nd edition (7)*, and SOP module 21: use and maintenance of a water distiller *(5)*.

Specialized instruments

BACTEC MGIT 960 TB system

The BACTEC MGIT 960 TB system is an automated system for growing *Mycobacterium tuberculosis* in liquid medium (Middlebrook 7H9 modified broth) using mycobacteria growth indicator tubes (MGIT). This instrument ensures better recovery and faster growth of mycobacteria. Six maintenance procedures can be done by the responsible laboratory technician under the supervision of the Equipment Officer and quality officer, and one procedure (annual servicing) should only be done by a Becton Dickinson engineer.

TABLE 14. Maintenance plan for the BACTEC MGIT 960

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
BACTEC MGIT 960	1. Temperature control and recording	Daily	Responsible lab staff
	2. Checking drawer and section light indicators	Daily	Responsible lab staff
	3. Cleaning external surfaces with a general purpose cleaner	Weekly	Responsible lab staff
	4. Replacing dust filters	Monthly	Responsible lab staff
	5. Archiving the results and saving onto an external hard disk	Monthly	Responsible lab staff
	6. Changing calibrators	As needed	Responsible lab staff
	7. Service maintenance	Annually	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedures 5 and 6 should be performed by an operating laboratory technician under the direct supervision of the quality officer in coordination with the Equipment Officer.

Procedure 7 can be performed only by an authorized engineer in the presence of the quality officer and Equipment Officer.

For more information, consult the BACTEC MGIT 960 manufacturer's manual *(8)*.

GeneXpert Dx system

The GeneXpert Dx system is a fully integrated and automated on-demand molecular diagnostic system with a mini-polymerase chain reaction laboratory enclosed within each module. All maintenance procedures can be performed by the responsible laboratory technician under the supervision of Equipment Officer.

TABLE 15. Maintenance plan for the GeneXpert Dx system

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
GeneXpert Dx system	1. Discarding used cartridges	Daily	Responsible lab staff
	2. Cleaning the cartridge bay interior	Weekly	Responsible lab staff
	3. Restarting the system (GeneXpert and computer)	Weekly	Responsible lab staff
	4. Cleaning the syringe plunger rod	Monthly	Responsible lab staff
	5. Cleaning instrument surfaces	Monthly	Responsible lab staff
	6. Cleaning the optics inside the PCR tube slot with a dry brush	Monthly[a]	Responsible lab staff
	7. Cleaning the fan filters with a mild detergent	Monthly	Responsible lab staff
	8. Archiving and saving data to an external drive	Monthly	Responsible lab staff
	9. Checking the calibration of all modules using manufacturer's procedures (and replacing if necessary)	Annually or after 2000 tests/module	Responsible lab staff or service engineer

Laboratory worker | Qualified engineer/technician

Lab: laboratory; PCR: polymerase chain reaction.
Note: All maintenance and service procedures must be recorded in the respective logs.
[a] Depending on placement – if there are high levels of humidity and dust, this should be performed weekly.

Procedures 1–9 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

For more information, consult the Cepheid GeneXpert maintenance module *(11)*.

GT-Blot

The GT-Blot is one of the instruments used for the line probe assay. All maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer.

TABLE 16. Maintenance plan for the GT-Blot

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
GT-Blot	1. Cleaning the GT-Blot trays	Per procedure	Responsible lab staff
	2. Cleaning the insert for the internal tray with 70% ethanol and a cotton-tipped applicator stick	Weekly	Responsible lab staff
	3. Washing and rinsing the delivery pipes	Weekly	Responsible lab staff
	4. Cleaning the outside of the instrument with a moist, lint-free cloth	Monthly	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–4 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

For more information, consult the manufacturer's manual *(12)*.

TwinCubator

The TwinCubator is used for DNA hybridization in the line probe assay. All maintenance procedures, except of servicing, can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 17. Maintenance plan for the Twincubator

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Twincubator	1. Wiping the Plexiglas lid regularly during operation to remove condensation	Daily or per procedure	Responsible lab staff
	2. Cleaning with 1% bleach and rinsing with water	Weekly	Responsible lab staff
	3. Cleaning the unit frame with 70% ethanol	Weekly	Responsible lab staff
	4. Cleaning the wells of the hybridization block after spillage	As needed	Responsible lab staff
	5. Rinsing the plastic trays used for hybridization reactions with distilled water and UV exposure (may be reused several times)	As needed	Responsible lab staff
	6. Prior to each service, cleaning and decontaminating the case (70% ethanol) and wells (1.5% bleach)	As needed	Responsible lab staff
	7. Servicing	Annually or as needed	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1–6 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 7 can be performed only by a qualified engineer under the supervision of the Equipment Officer.

For more information, consult the manufacturer's reference manual *(14)* or the SOP *(15)*.

Laboratory facility

Fire extinguisher

Fire extinguishers should be in good working condition and regularly checked for functionality by safety officer.

TABLE 18. Maintenance plan for fire extinguishers

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Fire extinguisher	1. Checking gauge or pressure indicator for the correct pressure	Monthly	Safety officer
	2. Checking the site and accessibility	Monthly	Safety officer
	3. Examining thoroughly and repairing, recharging or replacing as necessary (this might reveal the need for hydrostatic testing)	Annually	Service engineer
	4. Completely discharging, cleaning, inspecting and recharging after each use	As needed	Service engineer

Laboratory worker | Qualified engineer/technician

Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1 and 2 can be performed by the safety officer.

Procedures 3 and 4 can be performed only by a service engineer under the supervision of the safety officer*.

* More information can be obtained from the Fire Equipment Manufacturers' Association (http://www.femalifesafety.org/types-of-extinguishers.html) and Fire Extinguisher Training.com (http://www.fireextinguishertraining.com/).

Uninterruptable power (UPS) supply

An uninterruptable power supply is used to support equipment in case of power failure. It should be serviced annually by a qualified engineer.

TABLE 19. Maintenance plan for uninterruptable power supply

Which	What	When	Who
UPS	1. Preventive maintenance	Annually	Qualified engineer/ technician

Laboratory worker | Qualified engineer/technician

UPS: uninterruptable power supply.
Note: All maintenance and service procedures must be recorded in the respective logs.

For more information, consult the accompanying manufacturer's manual.

Upper-room UV germicidal irradiation and UV AirClean workstations

Upper-room UV germicidal irradiation (UVGI) lamps are used for room air disinfection. UVGI destroys infectious agents in the air: exposure to UV radiation damages the nucleic acid of bacteria and viruses, including *M. tuberculosis*, thereby preventing replication. UVGI generally uses a UV wavelength of 253.7 nm (within the UVC, 100 - 280 nm). The lamps should be checked for emission of the appropriate wavelength at least once every 6 months by a qualified specialist. Other maintenance procedures should be done by responsible laboratory staff under the supervision of the Equipment Officer.

TABLE 20. Maintenance plan for upper-room UVGI and UV AirClean workstations

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
UV Airclean workstation	1. Checking the operation of UV lamps: both external and inside the recirculator	Daily	Responsible lab staff
	2. Cleaning the workstation surface with 70% alcohol, chlorine-based bleach solution or DNA/RNA-removing solution	Daily	Responsible lab staff
	3. Checking the dust filter at both ends of the UV recirculator with the internal UV lamp; cleaning filters by unclipping the covers, rinsing filters in water, drying and reinstalling in reverse sequence	Monthly	Responsible lab staff
Upper-room UVGI	4. Cleaning with 70% alcohol	Every 2–3 months	Responsible lab staff
	5. Checking irradiance effectiveness and safety using a calibrated UV meter	Every 6 months	Qualified engineer/ technician
	6. Changing the lamp	As needed, according to hours of use	Responsible lab staff

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.

Procedures 1-4 and 6 can be performed by an operating laboratory technician under the supervision of the Equipment Officer.

Procedure 5 can be performed only by a qualified engineer under the supervision of the Equipment Officer.

For more information, see Memarzadeh et al. *(17)* and Kizer *(18)*.

Ventilation system

In addition to biosafety cabinets, the ventilation system is one of the most important systems for providing biosafety in TB (and other airborne disease) laboratories undertaking manipulation of infectious material. To ensure safety for laboratory workers, the ventilation system should be properly maintained and serviced. Routine maintenance procedures are performed by the safety officer, Equipment Officer and responsible laboratory staff. Servicing, calibration, filter replacement and disinfection should be performed only by a qualified engineer.

TABLE 21. Maintenance plan for ventilation systems

Which	What	When	Who
Equipment	**Procedure**	**Time interval**	**Responsible person**
Ventilation system	1. Monitoring and recording air pressure	Daily	Responsible lab staff
	2. Measuring air direction (exhaust and supply) using a smoke test	Weekly	Responsible lab staff
	3. Checking *BSC* exhaust air if a thimble connection is present	Weekly	Responsible lab staff
	4. Sampling air on agar dishes during and after use	Monthly	Responsible lab staff
	5. Checking the filter	Monthly	Responsible lab staff
	6. Changing prefilters at the air intake point	Quarterly[a]	Responsible lab staff
	7. Maintaining and servicing the entire ventilation system (checking function, air volume, pressure, filters, control system, safety devices, cooling/heating/electrical supply system)	Every 6 months	Qualified engineer/technician
	8. Servicing and calibrating the ventilation system after maintenance	Annually	Qualified engineer/technician
	9. Replacing filter if the pressure drops below the critical value	As needed	Qualified engineer/technician
	10. Cleaning and disinfecting	As needed	Qualified engineer/technician

Laboratory worker | Qualified engineer/technician

Lab: laboratory.
Note: All maintenance and service procedures must be recorded in the respective logs.
[a] Depending on the setting and air quality.

Procedures 1–6 can be performed by an operating laboratory technician under the supervision of the equipment and safety officer.

Procedures 7–10 can be performed only by a qualified engineer under the supervision of the Equipment Officer and safety officer.

The following recommendations are aimed to minimize dust pollution in the laboratory and prolong the life of *BSC* HEPA filters.

1. Incoming air should be pre-filtered through G1 (EU1) and G4 (EU4) type filters for coarse dust and an F9 (EU9) type filter for fine dust. Filters need to be replaced when the pressure drops below the critical value (as specified by the ventilation engineer for each ventilation system). The pressure should be monitored using an inclined tube manometer and documented each month.
2. The pipes of the ventilation system should be cleaned (after each prefilter replacement).
3. The control unit should be calibrated annually by a qualified engineer.
4. Wet cleaning of the laboratory and surrounding rooms should be done every day.
5. The windows must be always closed in the biosafety level 3 area. Doors and transfer hatches should have airtight seals.

For more information, consult the *Tuberculosis Laboratory Biosafety Manual (19)*; Chapter 7, Tuberculosis infection control, in the *Core curriculum on tuberculosis: what the clinician should know (20)*; and Kizer *(18)*.

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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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