

DRAFT (version oct 2013 – after expert meeting)

GENERIC FACILITY TUBERCULOSIS INFECTION CONTROL PLAN
TEMPLATES

draft

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FOREWORD

The Plan was developed as activity of the project “Technical assistance for Romania to strengthen TB infection control in specialized health facilities 2013/S 049-078785” funded by the European Center for Disease Control (ECDC) and implemented by TBC consult as a request of the National Program for TB surveillance, prevention and control in Romania (NTP). The content of the document is based on WHO guidelines. The material was revised by a group of experts – local coordinators of the TB program, lung disease specialists, epidemiologists.

The authors are grateful to all who contributed to the elaboration, revision and framing of the document.

The authors are also grateful beforehand to all that will use the model and will send us suggestions and recommendations regarding any problems appeared during its implementation.

The Purpose of the Facility Tuberculosis Infection Control Plan

The Facility Tuberculosis (TB) infection control plan is aimed to establish procedures for identifying and reducing the risk for transmission of tuberculosis among patients, healthcare workers, and/or visitors during the time spent at the facility.

In Romania, health care workers and other staff in TB facilities are at particularly high risk of infection with TB because of the frequent exposure to patients with infectious TB disease. Nosocomial transmission of *M tuberculosis*, including resistant strains to health care workers and visitors, and transmission of drug resistant strains to hospitalised patients with drug susceptible TB is of concern, given the burden of disease in TB hospitals, increased prevalence of multidrug (MDR) and extremely drug resistant (XDR) TB.

Audience

The generic facility TB infection control (IC) plan template is designed as a tool to be used by TB IC responsible persons or commissions at TB facilities in Romania in creating their own TB IC plans, reflecting their own specific situations and priorities.

Facility TB IC plan, prepared based on this template by TB-IC responsible person(s), has to be updated at least once every year and is to be adhered to by all staff of the facility.

Organization of the documents

The document consists of 9 chapters for each part of the facility TB-IC plan. Each chapter is organized in:

(a) Background information - for each template section, containing tools, rationales, definitions and references;

(b) Accompanying instructions - for each template section, outlining how to fill in the template sections;

(c) Template section - the actual building block of the TB IC plan.

All template sections combined result in a Facility TB IC plan (Annex 1).

All templates are a recommendation only and each facility should feel free to adjust their TB infection control plans to best fit their own circumstances.

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1. INFECTION CONTROL COMMISSION

a) Background

Infection control is the responsibility of every person working in a health facility and requires teamwork. To ensure that TB IC measures are successful, commitment from health managers is necessary.

The manager/head of the facility should establish the IC commission and provide adequate resources for effective functioning of the IC program.

The facility manager and the managers of different sections of the facility should be made aware of the risks of TB transmission to themselves, their staff, visitors and patients, and how it can be prevented. A copy of the facility IC plan should be available for staff reference in each department of the facility.

The TB Infection Control commission

A TB IC commission should be formed to coordinate TB-IC activities of the different sections of the facility. This commission should be integrated in the Nosocomial Infection Commission. TB IC commission is a multidisciplinary group which consists of the epidemiologist, the coordinator of TB activities in the facility, the head of each department, and professional nurses from each clinic section. Including in the TB IC commission of the facility manager and representatives of the administrative and accountability services, the authority of the commission is increasing, as its chances to monitor and to contribute to budget elaboration.

If the health facility has a general plan for nosocomial infections, TB IC plan will be integrated in it.

The responsibilities of the IC commission can include, but are not limited to:

- To produce and update, at least yearly, the facility TB IC plan.
- To review own surveillance data and identify areas for intervention.
- To develop facility policies for the prevention and control of infection.
- To assess and promote improved practice at all levels of the health care facility.
- To meet regularly (at least quarterly) to monitor the implementation of the TB IC plan and to suggest modifications if needed. To keep minutes of the meetings.
- To ensure continuous TB IC training for all staff.
- To ensure budget for IC activities.
- To ensure provision of protective equipment.

These responsibilities should be extended if necessary.

b) Instruction

1. Develop terms of reference (TOR), including the role and responsibilities of TB-IC commission for your facility

2. The facility manager nominates TB-IC commission members, including the Chairperson and TB-IC Responsible officer, who will be the primary contact point for TB-IC at the facility
3. Make sure TB-IC commission members understand and follow their role and responsibilities

c) Template 1: Infection control commission

Facility name Date Approved by

Terms of reference for TB-IC commission

Responsibilities	List responsibilities Specify the responsibilities of the Chairperson and TB-IC responsible officer
Authority	List rights and authority Specify the authority of the Chairperson and TB-IC responsible officer
Reporting to	Indicate whom the TB-IC commission reports to, in what form and how often
Commission members	In a separate annex list the names, positions and contact information of TB-IC commission members
Meetings	Indicate the frequency of TB-IC commission meetings, location and where documentation of the TB-IC commission will be stored

2. TB RISK ASSESSMENT IN THE FACILITY

a) Background

Risk assessment includes analysis, collection and review of surveillance data and in-depth facility description, including:

- incidence of TB in the community during the year, TB evolution during last 5 years
- the number of infectious TB patients who presented at the health care facility, number of patients with symptoms of infectious TB who were identified or treated in the facility
- the types of patients investigated/treated in the health care facility (immunosuppressed, comorbidities)

Risk assessment determine the types of interventions that will help form the TB-IC plan for the facility. The risk in different departments of the health care facility may differ, according to the procedures performed, number and type of patients, number of visitors. Other risk factors are the type of clinical focus (TB, M/XDR-TB, HIV, general services, etc.), the number of beds, the number of employees and disease prevalence in the community.

After the baseline risk assessment, risk should be reassessed at least annually because of the possible changes in services and procedures, the use of spaces, and the epidemiologic situation.

Any epidemiologic event (outbreak, TB case identified in staff, increase of TB incidence in the population) requires reassessment of the measures included in the IC plan or of their implementation, including risk assessment of the facility.

TB infection risk map

The TB Infection Risk Map for Health Care Facilities (Fig. 1) focuses on a typical patient's experience on his or her road to recovery as a hospitalized patient and highlights potential infection risks at the various stages of his or her stay. The map can be helpful to the management of health care facilities, as it provides a quick reference guide to IC measures, allowing assessment of those already in place and opportunities to investigate areas for improvement, as well as enabling them to identify existing problems. (Source including figure 1: Risk reduction and inter-professional collaboration for TB IC by International Council of Nurses, 2011, p. 16)

Figure 1. TB IC risk map for health facilities

General risk factors which apply to all steps									
• Patients uninformed of IC measures may spread or catch infection. • Lack of proper ventilation (open window policy) increases risk of infection in all areas. • Lack or misuse of protective equipment poses a risk. • Incorrect application of IC measures increases risk of transmission. • Overcrowding and poor spacing of facilities lead to increased waiting times which in turn increase both closeness and duration of exposure. • UVGI lights must be installed and used properly, but are an addition, and not a substitute for other IC measures. • Nurses, doctors, and other members of staff may be unknowingly infected and put patients and visitors at risk.									
1. Patient arrives at facility.	1. Patient in waiting area	3. Patient sees nurse	4. Patient undergoes diagnostic TB tests.	5. Sputum sample reaches the lab.	6. Patient with suspected TB is admitted to ward.	7. Patient with confirmed smear positive TB starts DOT.	8. Patient stays on the ward to continue treatment (intensive	9. Patient's sputum converts to smear negative.	10. Patient enters continuation phase

						phase).		
Receptionist is at risk due to frequency of exposure.	Patients with symptoms, suggesting active TB pose a risk to others and must be separated and diagnosed promptly.	All risk factors from previous stages apply.	Returning to the community may lead to stigmatisation and discrimination. Patients may also return to their previous life-style (e.g. alcohol abuse, homelessness, malnutrition).					
Undiagnosed patients with no knowledge of TB or IC measures pose the greatest risk.	Patients with smear positive sputum, cavities on chest X-ray and forceful, frequent coughing are the most infectious.	Inadequate bed spacing may contribute to cross infection between different strains.	Once the patient feels better they may discontinue the treatment without ongoing education and support. As the patient recovers, other priorities may distract them from their treatment (Williams et al, 2007).					
Infections can spread between patients, visitors and staff, due to undiagnosed cases, lack of IC measures and overcrowding.	Patient not adhering to IC measures may infect nurse.	Improper separation of patients groups (HIV/smear positive/DR status). Rooms that host infectious patients (especially DR cases) should not be located in areas that others may have to pass through.	Observation of treatment is more difficult at the community.					
Patients not properly educated about IC practices may spread infection.	Sputum collection poses a great risk and thus must be performed properly (e.g. outdoors, not facing anyone, in a cough booth).	Patients and staff may lower their level of adherence to IC measures over time, putting others at risk.	The insurgence of side effects may go unnoticed and lead to interruption of treatment.					
	Incorrectly produced samples may be wrongly diagnosed, putting others at risk.	Improper treatment (e.g. not observed, wrong dosage, irregular administration, wrong drugs) hinders recovery and creates risk of developing DR-TB. Delay in diagnosing DR-TB leads to further spread of resistance.						
	Radiology rooms are usually enclosed and poorly ventilated.	Side effects from treatment increase the risk of treatment interruption.						
	The samples may be stored inadequately or kept for too long before they reach the lab, especially in facilities which have to outsource some tests.	Improper monitoring of patients' treatment regime and IC adherence may lead to reinfection.						
	Incorrect handling of specimens and equipment puts lab staff at risk.	Inadequate hand washing facilities and practices.						
		Patients moving around the ward without surgical masks, using lifts and sharing toilets.						
		Visitors may not be aware of risks and IC procedures.						

TB risk categories

Classification of the areas or procedures according to the risk of transmission of TB infection is based on the probability to encounter/produce aerosols containing *M tuberculosis* in the area or during the procedure. The risk of infection depends also on the infection control measures in place.

World Health Organization (WHO) has the following risk classification:

Low risk

An area or procedure within the health facility, which has a limited likelihood of exposing staff to TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. The primary risk in this area is a rare and occasional exposure to a staff, patient or visitor with TB.

Medium risk

An area or procedure in the health facility which has a moderate likelihood of exposing staff, patients and visitors to TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. The medium risk TB cases or procedures may be present in these settings but for short durations or by accidents.

High risk

An area or procedure within the health facility, which has a high likelihood of exposing staff to TB suspects or patients or to TB droplet nuclei from infectious TB patients or biologic products of these patients. High-risk areas settings and procedures are where many infectious TB suspects (undetected) or many known infectious TB patients may be present or subject to high-risk procedures. These settings may also have high concentrated numbers of MDR-TB / XDR-TB suspects or patients.

Very high risk

An area or procedure within the health facility, which has a very high likelihood of exposing staff to TB suspects or patients or to TB droplet nuclei from infectious TB patients or biologic specimens from these patients. Very high-risk areas and procedures are where many infectious TB suspects (undetected) or many known infectious TB patients may be present or subject to high-risk procedures. These settings may also have high concentrated numbers of XDR-TB or MDR-TB suspects or patients.

The classification gives only rough estimation; it is based only on the probability to encounter TB infectious sources in an area, the risk may vary after implementing of different interventions; as an example, the risk in the MDR ward, classified as very high, may decrease after implementing TB IC measures (administrative, ventilation, UV).

Table 1: Classification of health units/departments based on risk category¹

Area within the health unit	Low risk	Medium risk	High risk	Very high risk
Administrative areas (no patient or suspect contact – e.g. separate buildings from those for patients)				
Administrative areas (with limited patient or suspect contact or air exchange from				

¹ The risk for same facility may vary implementing different controls; in the table is only a classification based on the “native” risk, disregarding the possible interventions in the facility. For example, the risk into a MDR TB facility (that normal falls to “very high risk”) may decrease to high, moderate or low risk, regarding to the IC measures implemented.

patients)				
Maternities, pediatric departments				
Ambulatory centers for the HIV patients				
Outpatient department (waiting rooms and consultation rooms)				
Emergency rooms				
Intensive care or Internal medicine wards				
TB dispensaries				
TB inpatient wards				
MDR-TB wards				

XDR-TB wards				
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Table 2: Classification of procedures based on the risk category

Procedure done within the health unit	Low risk	Medium risk	High risk	Very high risk
Microscopy				
Surgery (on non-TB patients)				
X-Ray				
Spirometry, respiratory therapy				
Oro-tracheal intubation				
Bronchology procedures				
Culture and DST for Mycobacterium tuberculosis				
Molecular testing with live Mycobacterium specimen				
Sputum collection				
Sputum induction				

It is possible to make quantitative evaluations of the risk. CDC recommends risk assessment in the health-care facility based on the number of TB patients that may be encountered in the facility:

-for a health-care facility with more than 200 beds, where less than 6 TB cases were treated last year, the risk is considered as low; if the number of TB cases was higher than 6, the facility is classified as medium risk.

-for a health-care facility with less than 200 beds, where less than 3 TB cases were treated last year, the risk is considered as low; if the number of TB cases was higher than 3, the facility is classified as medium risk.

-for an outpatient health-care facility where less than 3 TB patients were encountered in the last year, the facility is classified as low risk for TB; more than 3 TB patients classifies it as medium risk.

-The prove of TB transmission in the health-care facility or a new TB case in the staff classifies the facility as “ongoing risk for TB transmission”

b) Instruction

TB-IC commission or, in its absence, a TB-IC responsible officer conducts the baseline risk assessment in order to develop the initial facility TB-IC plan. Thereafter TB-IC commission needs to conduct risk assessment for the entire facility including each department or clinical setting once a year.

1. Coordinate with the management of the facility the assessment
2. Update your information about TB in HCWs at the facility related to the TB incidence in general population – relative risk for the staff for each category of employer
3. Prepare equipment to be used during the assessment. If your facility uses ultraviolet germicidal irradiation (UVGI) it is advisable to have a UV meter, calibrate it. If your facility uses mechanical ventilation it is advisable to check if it works and to calculate air changes in the rooms/wards. You will need an anemometer and a tape measure.
4. Make sure you have been fit tested recently and have a properly fitting respirator to be used in high-risk areas.
5. Make risk assessment using the facility/department/lab floor plan. If a detailed plan is not available, you can use the emergency evacuation plan.
6. Identify the chart / flow of the TB patient and risk areas. Draw the flow of the patient (specimen for laboratories) on the floor plan.
7. Use the classification of health units/departments based on risk category and the classification of procedures based on the risk category to identify additional risk areas and procedures.
8. If there is a change in the risk level of a facility area/department or a procedure, update the relevant controls: administrative, environmental and the use of personal protective equipment for this facility area/department or a procedure.

c) Template 2: TB risk assessment

TB Infection Control Plan

FACILITY NAME (TB HOSPITAL – WARD/ AMBULATORY/ LAB)

Date of elaboration.....

Date of revision.....

The baseline risk assessment in the facility was performed in: (month, year).

By: (person or team nominated to conduct baseline risk assessment)

Floor plan with indication of patients or specimens flow:

(here)

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According to the results of the baseline risk assessment, in the facility the following areas and procedures were identified and grouped according to different risk of TB transmission: (In the table below record the results of the baseline risk assessment)

level of risk	list facility areas according to level of risk	list procedures that increase the risk of TB transmission
low risk		
medium risk		
high risk		
very high risk		

Date of subsequent risk assessment (month, year).

By: (person or team nominated to conduct baseline risk assessment)

In table record any changes in facility areas or procedures which result in the changed level of risk

level of risk	list facility areas according to level of risk	list procedures that increase the risk of TB transmission
low risk		
medium risk		
high risk		
very high risk		

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3. MANAGERIAL ACTIVITIES

a) Background

Facility area and procedure-specific TB infection control activities are to minimize, reduce or eliminate the risks of TB transmission, identified in the previous section.

There is a set of managerial activities, and three levels of controls: administrative, engineering and personal respiratory protection.

Managerial activities are used by facility managers to support and facilitate the implementation, operation, maintenance and evaluation of TB infection control at the facility.

Three levels of controls:

(1) Administrative control measures intend to reduce the risk or exposure to persons with infectious TB. They are considered as high efficacy and low cost interventions.

(2) Environmental control measures are aimed to reduce the concentration of *M. tuberculosis* droplet nuclei in the air.

(3) Personal respiratory protection is the procedure applied to persons in settings where administrative and environmental controls may not protect them from airborne TB infection.

Managerial activities – coordination and organization at the facility level

1. Identification and strengthening TB infection control responsible person(s)
2. TB infection risk assessment within the facility and separately for each area/department
3. Development and updating the TB Infection Control Plan, with budget included.
4. Reorganization or rehabilitation of facility areas based on the risk assessment, if needed.
5. TB-IC staff training
6. Advocacy, Communication and Social Mobilization ACSM and Collaboration with the Public Health Directorate and other institutions
7. Surveillance of TB cases among staff
8. Participation in research activities
9. Monitoring and evaluation of TB-IC activities

1. **Identification and strengthening TB infection control responsible person(s)**

In inpatient TB facilities, assign TB specific responsibilities to the service/department of nosocomial infections prevention and control.

Train at least two persons in each facility on TB infection control.

Involvement in the TB infection control shall not be limited to health care workers; it is recommended to include the accountable, administrative and technical departments.

Involvement of each category of staff should be reflected in their job descriptions, for examples see Annex 2 - Staff TB-IC Roles and Responsibilities.

2. TB infection risk assessment within the facility and separately for each section/department

Risk assessments of the whole facility, including all departments, are done periodically - yearly after the baseline risk assessment and the initial planning for TB-IC. Risk assessments should always be carried out at the time of changing the activities or procedures, changing the use of spaces or in case of an epidemiological event such as discovering nosocomial TB infection - contracting TB infection within the facility.

3. Development and updating of a budget included Facility TB Infection Control Plan

Development of the TB-IC plan or integration of the TB infection control measures in the plan existing in the facility is among the responsibilities of the nosocomial infections commission/TB-IC commission.

TB-IC plan needs to be updated at least once yearly or anytime is needed, based on the yearly facility TB-IC assessment. Updating of the TB-IC plan is another responsibility of the facility TB-IC commission. Copies of the updated TB-IC plan need to be made available to all staff through the management of their departments.

Development of the budget for the TB-IC plan should be done in collaboration with the Finance & Planning staff of the facility, after the interventions are drafted and prioritized; If the facility currently does not have extra funds to allocate for TB-IC, the budget needs to be developed nonetheless, and the budgeted TB-IC plan can be used by the facility management for advocacy to secure the funds, when such an opportunity is present.

4. Reorganization or rehabilitation of the facility areas

Rethink the use of available spaces and consider renovation of existing facilities or construction of new ones to optimize implementation of controls. For example:

- Select existing building for converting into TB ward/clinic on site where there is a good cross breeze.
- Separate staff areas from patient areas with additional doors in the halls as needed and reallocate the different sections within the building.
- Create anterooms before entering high risk areas, i.e. isolation wards, laboratories, sputum collection points indoor, between staff and patients areas.
- Create multiple separate waiting areas for different patients; big waiting areas can be subdivided for the separation of different groups of patients. Construct open-air sheltered or half-open spaces – with a roof to protect patients from sun – and ~~and~~ ^{and} ~~function~~ - during the appropriate spring and summer months as waiting areas, sputum production & collection points and daytime recreational areas. (TB-IC Implementation Framework, p. 33)

- The laboratory should be divided into “functionally clean” and “potentially contaminated” areas, with the clean areas reserved for administrative and preparatory work. (Tuberculosis Laboratory Biosafety Manual, WHO, 2012)

5. TB-IC staff training

All staff of health care workers (clinical, paramedical staff, administrative staff and others like drivers, cleaners, cooks etc.) must receive training on transmission, prevention, signs and symptoms of TB, as well as on the facility’s infection prevention and control plan. Students and residents will be included in the training program.

Facility TB-IC training should reflect the recommendations in the national policies and guidelines for TB-IC. At the same time, in order to result in behavioral change, training should be:

- adjusted to the training needs to different cadres.
- based on adult learning principle.
- reinforced in the workplace.

Training needs assessment

- Analyze tasks of each cadre of employees in relation to TB-IC.
- Identify required employees’ knowledge, relevant skills and desired behavior targets which will reduce risks of transmission and infection at your facility.
- Identify the current level of knowledge and skills among the employees and identify behavior that needs to be modified.
- Translate required improvements in knowledge, skills and behavior into concrete training objectives.

Adult learning principles mean that the training should:

- Build on existing knowledge and experience of the training participants, already identified during training needs assessment.
- Relate training to concrete examples and situations/cases from your facility/department.
- Motivate by explaining how the learning will improve participants’ concrete life situations in relation to personal health and safety.
- Involve participants actively, use different methods - discussions, small groups work, let employees participate in parts of actual IC assessment or risks assessment. Training can be given in short sessions over a number of days. Participants have the opportunity use new skills and apply new knowledge step-by-step. Before the next session feedback from their practice can be asked and any arising questions addressed.
- Provide safe learning environment, especially to cadres of employees who have less experience participating in trainings and seminars or have lower knowledge in the topic.
- Try to accommodate the training within normal working hours, suitable for the schedules of different cadres of employees.

- Reinforce training in the workplace
- Training participants should understand clearly what would be expected from them in terms of application of TB-IC training in practice in their workplace. Most skills or information without being put to practice in the first 6 weeks following the training are forgotten.
- Actual change of behavior and application of new skills and knowledge by employees should be rewarded. There are many ways to reward employees, which include encouragement and positive feedback from supervisors, contests for an 'infection control champion' of the month at a facility or a department, management letters of appreciation, encourage inter and intra-departmental gatherings and sharing of experiences.

6. ACSM and Collaboration with the Public Health Directorate and other institutions

Advocacy, communication and social mobilization - ACSM:

Advocacy at facility level seeks to ensure that local authorities, decision-makers and opinion leaders in the community remain strongly committed to implementing TB control policies. Examples:

- Sensitize decision makers - National Insurance House representatives, local authorities - about the importance of TB infection control in your community.
- Conduct events around the World TB Day and invite local mass media to attend and cover them.

Behaviour-change communication aims to change knowledge, attitudes and practices among various groups of people. It frequently informs the public of the services that exist for diagnosis and treatment and relays a series of messages about the disease. Examples:

- Distribute print materials at community meetings or events.
- Organize interpersonal communication and counseling training for health workers.

It is important to take into consideration personal perceptions, motivation and people's beliefs and modify them if necessary, because otherwise they can derail the best intentions of an Infection Control Plan.

Social mobilization brings together community members and other stakeholders to strengthen community participation for sustainability and self-reliance. At the heart of social mobilization is the need to involve people who are either living with active TB or have suffered from it at some time in the past (ACSM for Tuberculosis Control: A Handbook for Country Programmes, p. 2). Example:

- Cooperate with local civil society organizations to strengthen their outreach to vulnerable populations (e.g. ethnic minorities, children, PLHIV) in the area of TB-IC at community level.

7. Staff TB surveillance

Collaboration with the contracting labor medicine provider for the surveillance of the TB spreading among the personnel of the facility

- TB screening of all staff is done routinely (annually).

- In case there were registered TB cases among the members of the staff, the personnel screening shall be repeated after 6 months.
- Consider developing specific questionnaires to staff screening.

8. Participation in research efforts

Operational research efforts are usually planned, prioritised and budgeted within the national TB-IC plan. Facility's participation in research can help:

- Evaluate the effectiveness of specific IC measures at your facility.
- Assess the impact (for example, by detecting TB infection or disease in health care workers).
- Identify problem areas to be addressed and find possible solutions.

9. Monitoring and evaluation of TB-IC activities

Monitoring -

- Routinely collecting and interpreting information, using TB-IC indicators, to be aware of the TB-IC situation at the facility and to take corrective steps, if required.
- Usually done by the IC commission or delegated to facility departments' TB-IC responsible persons.
- Performed on a continuous basis.

Evaluation -

- Systematically determining if TB-IC at the facility - including managerial activities, administrative and environmental controls and personal respiratory protection - minimizes the risk of infection in an effective and efficient way.
- Used to inform decision making; adjust TB-IC plan, policies and activities; provide feedback to stakeholders.
- More time consuming than routine monitoring, more comprehensive, also evaluating the effectiveness of the facility TB-IC plan and policies.
- Can be done by IC commission or external parties at least once a year.

TB-IC indicators are measures of process, outcomes, and/or impacts for TB-IC activities. Some examples of indicators are included into this template, see Chapter Monitoring and Evaluation (M&E), but specific indicators must be established in each facility, based on risk and the specific activities of the facility.

Responsibility of the facility management and the IC commission is to make sure the TB-IC activities are regularly monitored and evaluated by

- Establishing a system for monitoring and evaluation describing methods and tools, frequency, reporting format and how results of M&E will be used for decision making.
- Developing TB-IC indicators.

b) Instruction

1. List a number of managerial activities that apply to the facility in general.
2. Describe managerial activities in details.
3. Outline time frames for each activity; indicate regularly repeated or continuous activities.
4. Assign a relevant performance indicator
5. Estimate the required budget, in collaboration with staff from the finance & planning of your facility.

c) Template 3: Managerial activities

Managerial activities	Description of activities	When to implement	Performance Indicator (target)	Budget (short- and long-term)
Identification and strengthening TB infection control responsible person(s)				
Evaluation the TB infection risk within the facility and separately for each area/departement				
Development and updating of a costed Facility TB-IC Plan				
Reorganization or rehabilitation of facility areas				
TB-IC staff training				

ACSM and Collaboration with the Public Health Directorate and other institutions				
Staff TB surveillance				
Participation in research efforts				
Monitoring and evaluation of TB-IC activities				

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4. ADMINISTRATIVE CONTROLS

a) Background

Administrative controls are measures that are intended to reduce the risk or exposure to persons with infectious TB.

1. Triage, which means to promptly identify, separate and fast-track people with TB suggestive symptoms includes:
 - Training the staff in the ambulatories and emergency rooms to check for and recognize TB symptoms:
 - a. cough longer than two weeks;
 - b. fever;
 - c. night sweats;
 - d. weight loss.
 - Reducing to the minimum time spent in the areas (waiting areas, admissions, wards) used by TB suspects and infectious patients known to have TB.
 - Placing the TB suspects or infectious patients known to have TB in well-ventilated spaces.
2. Cough hygiene
 - Training and reminders (posters, leaflets) for visitors, TB suspects and TB patients concerning cough etiquette
 - Insuring means to contain the infectious aerosols (surgical masks, paper napkins)
 - Placing in high visibility places educational materials about cough hygiene.
3. Establishing the infectious patient circuit in the facility
 - The TB suspect or infectious TB patient shall wear a surgical mask while being transferred from one department to the other and during the medical investigations and hospitalization formalities.
 - The movement of the patient shall be limited, avoiding the crowded spaces or spaces, populated with persons receptive to TB infection.
4. Reduction of diagnostic delay
 - Carrying out investigations in parallel rather than in sequence.
 - Minimizing the time of obtaining the bacteriological results, including communication of the sputum smear result in maximum 24-48 hours, preferably on the same day.
 - It is preferable to obtain the sputum smear result before patient's hospitalization.
 - It is recommended to implement rapid diagnostic methods (genetic tests, liquid media culture) and to follow the algorithm of rapid testing use, recommended by the national guidelines.
5. Sputum collection
 - Collecting sputum in specially designed well-ventilated rooms.
 - Instructing the patient how to collect sputum.
 - Presenting the sputum collection procedure – a poster with steps/instructions - in the sputum collection room/area.
 - Training the staff supervising the collection to follow the respiratory protection measures.
 - Limiting the sputum induction procedures due to the production of infected aerosols and cough persistence after the procedure. If these cannot be avoided, they shall be done in specially designed well-ventilated place, while applying supplementary measures (respiratory protection for staff, UV light).

- Using special disposable containers, with filleted lid and large enough opening for sputum collection.
- Using special transport containers, with lid and handle, easy to disinfect, in order to store and transport products to the laboratory.

6. Patients' isolation and separation in wards

- A patient with TB suspicion, in need of hospitalization, shall be placed into an isolator until establishing their bacteriologic status; each ward shall have at least one space of this type (isolation room), preferably with only one bed.
- Within the wards, TB patients shall be placed in separate rooms from those having other diseases.
- The extra-pulmonary TB cases and those with sputum smear negative results do not need isolation.
- Patients with positive sputum smear results shall be placed separately (separate rooms, preferably with own lavatory) from those with negative sputum smear results.
- Patients suspect of or confirmed to have drug-resistance (mono-resistance, poly-resistance, MDR, XDR) shall be hospitalized in separate spaces, according to the resistance range, in order to avoid nosocomial cross-transmission of the stains.
- TB patients with positive sputum smear results shall be served their meals inside the rooms and will not be allowed in the common areas.
- Patients with positive smear results, MDR-TB patients and XDR-TB patients shall be placed in rooms with as few beds as possible; studies showed that the reduction of the number of beds in the room represents the most efficient administrative infection control measure of nosocomial TB transmission.
- The movement of the infectious patients within the health facility shall be limited.
- Isolation shall be stopped:
 - After at least 3 weeks (according to the proposed national policy and national TB-IC plan), for patients with positive evolution, in the absence of any resistance suspicion;
 - After the sputum smear becomes negative, for the patients with suspicion of drug-resistance or with confirmed resistances (including MDR-TB and XDR-TB)
- Patients with HIV/TB co-infection who are smear positive shall be hospitalized and treated in TB sections/wards, not in the infectious diseases sections/wards, as the risk to infect susceptible person in these departments is high, and the isolation is usually not possible.
- TB treatment has priority compared to the antiretroviral (ARV) treatment.

7. Infectious patients' transportation

The transportation of smear positive TB patients or TB suspects shall be done in ambulances equipped with supplementary infection control measures (increased ventilation, separate place for the patient, respirators for the other persons, surgical mask for the patient).

- Infectious TB patients shall be transported individually, wearing a surgical mask, and not together with patients with other diseases.
- Inform the staff in case of transportation or interdisciplinary consult of the infectiousness of the patient, in order for the staff to apply respirator protection measures.
- Contagious patients shall walk outside their rooms, inside the health facility or in other departments only if needed and only wearing a surgical mask.

8. Rapid initiation of treatment

- It is preferable to obtain the sputum smear result before patient's hospitalization.
- Anti TB treatment shall start as soon as possible after hospitalization.
- Anti TB treatment shall begin with at least four anti-TB medicines.

- Resistance spectrum will be determined as soon as possible after initiation of the investigations.
 - In case of known drug-resistances from previous investigations, the treatment shall be initiated based on the sensitivity spectrum.
 - For the known multidrug-resistant cases it is recommended to consult the MDR consilium before admitting the patient for treatment.
9. Reducing the time within the health facilities
- Ambulatory treatment is recommended to patients with negative sputum smear results or extra-pulmonary TB.
 - Duration of children's hospitalization shall be limited to the period necessary to establish the diagnostic and treatment initiation.
 - Reduction of the period spent in the TB facilities should be backed up by optimum organization of the ambulatory treatment – directly observed treatment (DOT).
10. Infectious TB cases without therapeutic resources (palliative care)
- TB patients with limited therapeutic resources (wide drug-resistance spectrum, severe co-morbidities, and chronic cases with negative therapeutic prognostic) preferably shall be isolated at their place of residence.
 - These patients and their families need to be educated about TB, TB transmission and infection control at home and in the community.
 - In case there are contacts with increased receptivity (children, immunosuppressed, PLHIV) and the isolation at the place of residence cannot be ensured, it is recommended to hospitalize the patient.
 - It is recommended to identify health facilities with beds, fulfilling the isolation conditions and insuring the TB infection control for the palliative care of patients without therapeutic resources.
11. Visitors' access in the wards with TB patients
- There shall be limited visitor access in the wards with sputum smear positive TB patients and MDR TB.
 - It is forbidden for children, immunosuppressed visitors or immunosuppressed staff to access the wards treating TB patients.
 - If the visitors' access to TB wards is absolutely necessary, they shall be informed about TB transmission and will wear fitting respiratory masks, the windows of the rooms shall be open and the patients shall wear surgical masks.
 - Visits shall take place according to an established visiting policy, preferably in designated areas (outdoors or well-ventilated places).
 - Visitors (as well as staff and patients) shall be informed by means of signage – printed information and signs, placed where they can be easily seen, with information about the risk to contract the disease, restricted areas and protection measures.
12. Ensuring cleaning and disinfection of surfaces
- Cleaning and disinfection of surfaces - if absent - may favor TB transmission.
 - Select and use disinfectant with known efficacy for *Mycobacterium tuberculosis*.
 - Create and following standard operating procedures (SOP) outlining a disinfection program in the high-risk departments/areas.

b) Instruction

1. For each facility area/department and procedure, according to their level of risk, identified during risk assessment, select a number of administrative controls.
2. Remember that administrative controls are the most important and often least costly to implement.
3. Describe the administrative controls in details by breaking them down into a number of activities.
4. Indicate regularly repeated or continuous activities and other timeframes for implementation of activities.
5. Assign performance indicators to be used to monitor implementation of the administrative controls.
6. Estimate the required budget, in collaboration with staff from the finance & planning of your facility (See Chapter Budget)
7. Repeat for each facility area/department or procedure, identified during risk assessment

c) Template 4: administrative controls

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
administrative			

5. ENVIRONMENTAL CONTROLS

a) Background

1. Ventilation

Ventilation is the process of air movement and is preferably done in a controlled manner; insuring adequate space ventilation is essential for airborne infections prevention. The World Health Organization recommends adequate ventilation implementation as a TB infection control measure with proven efficacy.

Objective of ventilation is to ensure sufficient air changes per hour (ACH) and control airflow direction to reduce the risk of TB exposure.

In the medical practice there are used the following ventilation types:

- Natural ventilation
- Mixed-mode ventilation
- Mechanical ventilation

In choosing a ventilation system (i.e. natural, mechanical, or mixed-mode) for healthcare facilities, it is important to consider local conditions, such as building structure, climate, building byelaws and regulations, culture, cost and outdoor air quality. Any ventilation system must be monitored on a regular basis/schedule and maintained in the case of mixed mode or mechanical ventilation. Adequate resources (budget and staffing) for maintenance are critical. The current WHO ventilation standard for an airborne precaution room is at least 6ACH for the existing buildings and 12 ACH for the new constructed.

a) Natural ventilation

Represents the ventilation created by means of natural conditions (wind, temperature); it is done using doors, windows and ventilation apertures.

In a good scenario, natural ventilation can insure a high number of air changes per hour and an efficient dilution of the infecting particles, at low costs.

Disadvantages of natural ventilation are that it is difficult to forecast and control and even impossible to use during the cold season.

In healthcare facilities effective natural ventilation should be achieved by proper and systematic operation:

- Maximize natural ventilation by increasing the size of the opening of windows and locating them on opposing walls.
- Use natural ventilation as much as possible in all health care facilities that are not provided with mechanical ventilation.
- In order to create airflow, it is recommended to fix some ventilation grills on the wall opposite to the window (above the door or at the inferior part of it).
- In case of using thermopane windows, it is compulsory to design them such the opening to be large enough.

- Ventilation of each space has to be periodically monitored and evaluated; to measure the ventilation there are used special equipment: smoke tube (watching the smoke column one can establish the air flows direction), vaneometers (mechanical devices measuring air speed), meters (in order to establish the openings and room)
- A space with good enough ventilation is defined by²:
 - o A number of air changes higher than 12 ACH
 - o 160l/s/patient for airborne precaution rooms
 - o 80l/s/patient for new health care facilities and renovations
 - o 60l/s/ patient for general wards and outpatient departments
 - o 2,5l/s/m² for corridors and other transient spaces without a fixed number of patients.

Some buildings are foreseen from the design phase with passive ventilation systems (pipes in the walls reaching the roof of the building) which insure supplementary ventilation; these systems can be dangerous by moving the contaminated air from one room to some other space, from one floor to another.

b) Mixed ventilation

Mixed ventilation refers to improving natural ventilation by use of mechanical ventilation.

Use mixed mode ventilation:

- In health facilities where natural ventilation can't achieve an optimal air change/hour (6 ACH);
- In high risk areas for TB transmission (emergency rooms, isolation rooms for TB suspects, rooms for smear positive TB patients, isolation rooms for MDR TB suspects, spaces for procedures that can induce aerosols in TB patients – sputum collection rooms, bronchoscopy rooms, spirometry).

The placement of the fans should take into account what the specific rooms are used for and the need to create negative (in “contaminated” areas, with patients or infecting pathological products) or positive pressure (in spaces destined for the staff).

Use of fans is compulsory when the windows are closed (during the night and the cold season), in crowded spaces or with multiple sources of bacilli.

c) Mechanical ventilation

Mechanic ventilation implies the use of some complex devices (ventilation systems) controlling the air inside the building or in different parts of it. It functions by generating positive or negative pressure, the airflow being directed from the area with positive pressure to that with negative pressure.

² According to Natural Ventilation for Infection Control in Health-Care Settings, Annex B, recommendation #2

It is recommended in areas with high risk of TB transmission, where the natural or mixed ventilation does not insure an optimum air changes rate (rooms with MDR or XDR TB patients, laboratories for cultures and DSTs).

Advantages of mechanical ventilation consist in the efficient control of air direction and temperature within the room, may be used in all types of climate and also insures a constant number of air changes.

The disadvantages of mechanical ventilation consist of increased construction and maintenance costs, the need of good technical expertise from design to using phase, difficult acceptance by patients.

During the functioning of the mechanical ventilation, it is compulsory that the doors and windows to be closed.

Ventilation in the room can be determined:

-measuring the dilution of a gas (requires special equipment)

-dividing the flow of air in the room (air velocity at the level of the openings multiplied by the section of the opening – window, grille) to the volume of the room; the report between the flow of the air and volume of the room is the number of airchanges per hour (ACH)

ACH=flow of air exchanged per hour / volume of the room

ACH= (air velocity at the level of openings x opening section) / volume of the room

2. Ultraviolet germicidal irradiation

UV radiation with 254 nm wavelength has bactericide action upon microorganisms, including *Mycobacterium tuberculosis*. It is used as additional environmental measure when ventilation is not enough for TB infection control. The medical devices generating this type of radiation have the generic name of UV lights or bactericide lights. In practice, there are used several types of UV lamps in order to air decontamination and rooms and surfaces sterilization.

- UV lamps with direct radiation (unshielded), used inside rooms for air disinfection, outside the working hours and in the absence of people.
- UV lamps with radiation directed to the upper area of the room (upper room UV GI), which thanks to a protection shield reflects the UV radiation towards the ceiling, where it creates a decontaminating layer. By the natural movement of the air towards the ceiling, the entire air volume within the rooms is decontaminated. This type of devices can be used in the presence of people in the room.
- Mobile UV lamps, which can be placed in different points of the rooms, according to the existing needs.
- UV lamps used inside biosecurity cabinets.
- UV lamps used in ducts for air decontamination inside the ventilation systems.
- Air cleaning devices using the UV light in an enclosed system ("air purifiers")
- The use of UV radiation needs technical expertise for purchase, installation and monitoring the functioning.

Shielded UV radiation is used in spaces with high risk of TB transmission (waiting rooms, the emergency room, crowded hallways, rooms with contagious patients, spaces with insufficient ventilation) and has to function permanently (24 hours/day).

In case of UV use in the presence of humans, it is compulsory to measure the irradiation level with an UV-meter; the maximum admitted dose for the 254nm UV radiation is 6000uJ/cm² for 8 hours (0,2uJ/cm²/s).

UV lamps maintenance consists of:

- Measure of intensity of UV radiation with an UV-meter if this is available (an efficient lamp shall produce an UV radiation with the intensity of 100uJ/cm²/s at one meter away from the source);
- Cleaning of the UV lamp with water with detergent at least every two months (cleaning with alcohol only can lead to the formation of one layer on the surface of the lamp, decreasing its efficiency).
- Change the UV light after the number of hours recommended by the producer.

Efficiency of UV radiation increases with the adequate ventilation of the space (air mixing) and decreases in humidity conditions.

In order to establish the number of UV lamps needed, the surface of the rooms shall be taken into account, one lamp covering 20m².

Monitoring the unshielded lamps use shall be done by an hourly chart, which includes also the date of lamp cleaning. UV lamps shall be included in the equipment service contract.

Specifications for the acquisition of the UV lamps:

- to generate UV light with the wavelength of 254 (253,7)nm
- to be provided with a shield or with a guide system of the UV radiation designed to provide a level of radiation less than 0,2uJ/cm²/s in the lower part of the room (under 1,80m, permitting the presence of the people inside the room) and a high level of radiation in the higher part of the room (over 1,80m), for an efficient germicidal effect.
- for each 20m² of the room is needed one 30W UV lamp

3. Devices for air disinfection ("air purifiers")

Air disinfection devices ("air purifiers") function on the principle of air decontamination while inside, where it is heavily radiated with a high dose of UV radiation or is filtered with HEPA filters; their efficiency is usually limited by the reduced air volume which can be filtered and especially by the impossibility of mixing the entire air volume in the room. Usually, the air around the device is re-circulated, and the air from the remote areas of the room, less ventilated, is not decontaminated.

b) Instruction

1. For each facility area/department and procedure, according to their level of risk, identified during risk assessment, select a number of environmental controls.
2. Describe the environmental controls in details by breaking them down into a number of activities.
3. Indicate regularly repeated or continuous activities and other timeframes for implementation of activities.

4. Assign performance indicators to be used to monitor implementation of the environmental controls.
5. Estimate the required budget, in collaboration with staff from the finance & planning of your facility (See Chapter Budget)
6. Repeat for each facility area/department or procedure, identified during risk assessment

c) Template 5: environmental controls

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
environmental			

6. PERSONAL RESPIRATORY PROTECTION

a) Background

The objective of personal respiratory protection is to minimize the entrance of potentially infecting particles in the respiratory ways, using mechanical barriers in the way of the airflow.

The respiratory protection represents one of the most efficient prevention measures of TB infection control among the staff. The respiratory control measures consist of:

- Use of respirators (FFP2 or FFP3) by the persons entering the infected environment (protects the person wearing the mask);
- Use of surgical masks by patients, in order to limit the dispersing of infectious aerosols (protects family and friends, other patients and visitors, medical personnel, the community).

The infection control plan should contain a respiratory protection program, specific for the degree of risk. Recommended elements of a respiratory protection program:

1. The use of respirators.

Respirators should be used:

- By the medical staff (nurses, doctors), caretaking staff, technical staff, ambulance drivers, the visitors and anyone else entering the environment with high TB infection risk.
- In the emergency rooms, the consultation cabinets, radiology department, functional investigations, in the presence of potentially infectious patients;
- In the TB laboratories it is recommended to wear respirators in case all the other TB infection control measures are not ensured.

2. The spaces where wearing a respirator is compulsory shall be marked with attention signs; these spaces are the rooms of the TB suspects and sputum smear positive patients, M/XDR-TB wards, bronchology department, triages.

3. Technical specifications of the equipment:

- Classification of respirators is done according to their capacity to efficiently filter the particles with the dimension of 0.3 microns (particles of these dimension having the highest capacity to pass the filter).
- The respiratory protection masks accepted for TB infection control must fulfill FFP2 and FFP3 standards (EC benchmarks) equivalent to N95 and N98 respectively (US benchmarks).
- Respirators fulfilling standards lower than FFP1 / N90 are not efficient against TB infection.

4. Mode of use:

- Application and use of respirators shall be done according to manufacturer's recommendations.
- It is important to ensure good respirator fitting, because the air entering between the face and the respirator leads to the respirator's inefficiency.

5. Checking the respirator efficiency:

- Checking a respirator's efficiency shall be done by determining the fitting it ensures (performing a fit-test).
- The fit test can be done by either quantitative fit testing (hard to perform, requiring special equipment – particle counter) or by qualitative fit tests.
- In practice qualitative fit tests are used (Bitrex test or sucrose test). The principle of a qualitative fit tests is: in case of respirator inefficiency the subject will taste the bitter (Bitrex) or sweet (sucrose) taste depending on the substance used.

- Factors, which can influence the fitting of the respirator and lead to the respirator efficiency, are: incorrect use, face form and dimensions, facial features (e.g. beard, scars, excessive use of make-up and foundation).
 - Before the first use, every person using a respirator should be fit tested, and then re-tested periodically (annually), after the appearance of facial changes (scarring, substantial weight gain or loss) or after changing the type of a respirator used. Each TB facility has to have access to the fit test.
6. Duration of use:
- Although the manufacturer's technical specifications foresees that the respirators are disposable, for TB reuse by the same persons is accepted, because TB is exclusively airborne and is not transmitted by direct contact.
 - If the respirator is intact, filter efficiency is not affected by a high number of uses, it is the decreasing of the fit which is the primary factor limiting the number of uses.
7. Storage of respirators:
- It is recommended to store respirators together with the rest of the equipment (gowns) in a well-ventilated space, in low humidity conditions.
 - When not in use, a respirator could be covered in a paper napkin.
 - In order to keep the filter intact, the respirator may not be bent/punctured/soiled.
8. Equipment life expectancy:
- Normally, an average duration of respirator usage of two weeks is accepted, but in case of intensive use, this duration can be shorter. For staff using the respirator every day, 2-3 respirators /month are needed.
9. The use of surgical masks:
- Surgical masks shall be used by pulmonary TB suspects, sputum smear positive patients, MDR-TB or XDR-TB patients, when these are indoors and in the presence of other persons (patients, medical staff, visitors).
 - Outside the buildings wearing of surgical masks by patients is not compulsory, except during the transportation in an ambulance or in other means of transportation.
 - Enough surgical mask are to be provided for the patients (average 10 masks during the hospitalization period)
10. Training in the area of respiratory protection:
- Healthcare workers and patients as well should be trained in the correct use of the respiratory protection equipment.
 - The patients shall be explained the reason for using the respiratory protective equipment.
11. The waste management for the respirators
- Waste management for the respiratory equipment is done according to the rules of the facility for infectious waste management. However, the respirators or surgical masks used for TB are not dangerous for the TB transmission.
12. It is recommended to continuously monitor the implementation of the personal respiratory protection program in each department/area of the facility:
- Number of respirators for each employer per month
 - Number of fit tests performed per year
 - Number of trained person on TB IC

b) Instruction

1. For each facility area/department and procedure, according to their level of risk, identified during risk assessment, select a number of personal respiratory protection measures and activities.
2. Describe the personal respiratory protection in details by breaking them down into a number of activities.
3. Indicate regularly repeated or continuous activities and other timeframes for implementation of activities.
4. Assign performance indicators to be used to monitor implementation of the personal respiratory protection measures and activities.
5. Estimate the required budget, in collaboration with staff from the finance & planning of your facility (See Chapter Budget)
6. Repeat for each facility area/department or procedure, identified during risk assessment
7. Compile all parts: administrative controls, environmental controls and personal respiratory protection measures for each facility area/department or procedure). **These together with the facility managerial activities comprise your Facility TB-IC Plan.**

c) Template 6: personal respiratory protection

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
personal respiratory protection			

7. TB infection control in TB laboratories

a) Background:

The risk of TB in the staff that manipulates or processes products potentially contaminated with mycobacterium tuberculosis is 3 to 9 times higher than in people who do not work with such products. Infection occurs in most cases through the uncontrolled production of aerosols containing *mycobacterium tuberculosis* and their inhalation; only by exception, infection can occur through direct contact, through solutions of continuity in the skin or accidental aspiration. Drug resistant mycobacterium tuberculosis (MDR or XDR) have the same way of transmission and it was not proved that they have a different pathogenesis of sensitive strains. However, because the consequences of infection/illness with a resistant germ are far more severe, tuberculosis transmission control in laboratories that process products with resistant microbes must be applied strictly.

TB infection control in TB laboratories consists in a combination of using the best work practices with administrative measures, optimum utilization of appropriate equipment and infrastructure and individual protection in order to protect the staff from infection with pathogenic microorganisms.

Risk assessment is specific to each laboratory, varying with:

- the number, type and concentration of the bacilli in processed products
- the procedures that are performed in the lab
- work practices and infection control measures in place
- access to infrastructure and equipment maintenance.

Continuous training of personnel of laboratory is essential to lower the risk of transmission of TB infection, as well as assuming the responsibilities for each member of the team working in the laboratory. Laboratory staff must have the ability to react proper in case of emergency situations in the laboratory (biohazard).

Mycobacterium tuberculosis is classified (according to the Directive 2000/54/EC) as a pathogen requesting level 3 of biosecurity. According to the procedures performed, the laboratories are classified as level I (microscopy), level II (microscopy and cultures) and level III (microscopy, cultures and drug susceptibility tests); the level of laboratory is an indicator of the risk. Depending on the risk of generating infective aerosol, WHO classified TB laboratories into three categories: laboratories with low, moderate and high risk the factors taken into consideration for the classification of a laboratory and the minimum requirements of each type of laboratory are presented in table:

	Low risk	Moderate risk	High risk
<i>The type of procedure practiced</i>	-direct microscopy -preparation of the products for use in automatic devices for amplification of nucleic acids (GeneXpert)	-growing Mycobacteria (performing cultures) -direct sensitivity testing through phenotypic methods (MODS-Microscopic observation Drug Susceptibility, NRA - the Nitrate Reductase Method) -performing genetic tests for sensitivity carried out directly from the sputum-	-handling of cultures for identification of m. tuberculosis -indirect susceptibility tests (drug sensitivity tests on liquid or solid media) -Molecular tests (line probe assay)

		direct line probe assay	
<i>Minimum technical requirements</i>	- proper working techniques	- proper working techniques	-proper working techniques
<i>Minimum requirements for protective equipment</i>	-the procedures may be carried out outside the biosafety cabinet (on bench) -necessary gloves, gown	-the procedures are performed in biosafety cabinet -gloves, gown; -respiratory protection is not mandatory but may be used in certain procedures	-the procedures are performed in biosafety cabinet -gloves, long gown, eventually protection for head (caps), shoes; -respirators are recommended for high risk procedures (manipulation of liquid cultures for sensitivity tests)
<i>Minimum infrastructure requirements</i>	-room with adequate ventilation (natural ventilation is sufficient)	-unidirectional ventilation in the laboratory, with the assurance of 6-12 air changes per hour (ACH)	-laboratory with adequate biosafety level: entrance with double doors, -ventilation is recommended with assurance of unidirectional 6-12 air changes per hour (ACH), negative pressure ventilation

Table : classification of mycobacteriology laboratories according to the risk of TB infection

Measures to prevent TB transmission control in the Laboratories of mycobacteriology – background information:

Assuming the responsibilities by each member of the staff of the laboratory is essential. Head of the laboratory will ensure availability of a biosafety system (TB infection control) based on a manual of procedures. The adherence of each laboratory worker to the TB IC procedures is essential; heating systems, ventilation, etc. should be monitored and checked periodically in accordance with the maintenance plan.

Sputum collection is done only outside of the laboratory; sputum is the most usual clinical sample used for the identification of *mycobacterium tuberculosis*; due to viscosity and relatively small concentration in bacilli, the possibility of generating infective aerosols from sputum already harvested is small; however, sputum collection is a procedure with high risk of producing aerosols; it will be done only in special places - outdoors or in cabins specially designed for sputum collection, under the supervision of specially trained staff, who will wear the respirators if exposed to potential infectious aerosols.

Access to the work area of the laboratory is allowed only to authorized persons; at the entrance of lab is mandatory posted the international symbol of biohazard. Access will be restricted in the laboratory by blocking access roads and allowing selective access only for personal use.

Handling of sputum or other clinical samples with potential content of mycobacterium tuberculosis is done only by authorized, trained personnel. Personnel will wear gloves when handling containers. Sputum collection recipients will be transparent and will have the lid screwed with a diameter large enough to allow harvesting. Transport of containers from the place of collection to the lab is made in

closed boxes with lid, which will allow for storage and transport containers for harvesting in a vertical position. Containers are not opened during carriage.

Reception of products in laboratory and releasing results: the reception is done in specially designed space, at the entrance of the laboratory. Containers with biological product are opened only at the place of processing. The release of results and their communication to the applicant is done in the shortest time.

Individual protection equipment will be used only inside the laboratory; it has to be adapted the procedures performed, it is forbidden to wear individual protection equipment outside the laboratory (e.g. offices, canteens, toilets). Laboratory equipment is kept separate from personal clothes. Washing equipment that is not disposable is done in the hospital.

- *Laboratory coats (gowns)* to be used in spaces where there is increased risk of infection.
- *Disposable Gloves* to be used for all procedures involving direct contact with sputum, blood, or other fluids or materials with potential of contagiousness. After use, gloves are thrown, according to the procedure for destruction of contaminated materials.
- *Respirators* are not required to be used routinely in the lab if the procedures are followed and proper equipment are available; however, they can be used as an additional measure if it considers that there is a potential risk of aerosol inhalation with mycobacterium tuberculosis; FFP2 or FFP3 standards (N95 or N98 - USA) are required. Respirators do not replace defective functioning of a biosafety cabinet or the absence of other measures to control the TB transmission; in the case of work which is carried out in biosafety cabinets, respirators are not mandatory; however, we strongly recommend wearing them at least by people at high risk of falling ill with tuberculosis (immune deficiencies, immunosuppressive medication, other conditions favoring the disease development) on the handling in open spaces of products containing mycobacterium tuberculosis or in any situation in which personal risk of infection is increased. For tuberculosis, respirators can be reused by the same person more than once, as long as they ensure fit. Masks do not wash or disinfects; they may be stored in dry spaces, outdoor or wrapped in a paper towel (not plastic bag); their destruction is carried out in accordance with the rules of contaminated waste destruction.

Biosafety Cabinets represents the equipment which limits movement of aerosols produced in working space within them, the air discharged into the environment being decontaminated through retention of infectious particles from the HEPA filters. Any procedure involving environmental hazard or increased production of aerosols containing mycobacterium tuberculosis must be done inside the biosafety cabinet. For TB laboratories (performing cultures and DST) it is recommended the level II class A2 biosafety cabinet, as it protects the worker, the specimen and the environment. Smear preparation can be performed in a hood, evacuating the air to outside or in a biosafety cabinet class I. Equipment must be maintained and periodically tested;

Biosafety cabinet testing is done:

- At install it, once a year or at any time when the equipment is moved or its destination is changed, the procedure of maintenance is provided by a specialized firm;
- at the beginning of each work session, the operator working at the booth of biosafety will check the direction and speed of movement of the air currents at the entrance of

the cabinet (normally it must be 0, 2 m/s, oriented towards the inside of the cabinet biosafety).

- *Placing biosafety cabinet in the room* is done in such a way that the flow of air at the entrance of the booth does not interfere with other air currents in the room (the streams produced by opening doors, air conditioning, centralized ventilation, passage of people near the cabinet). Behind and above the cabinet, a space of at least 30-35 cm is needed to ensure air flow circulation.

After finishing work, before being stopped, biosafety cabinet will be left to work at least 15 minutes to ensure "cleaning" of indoor air.

Recommendations concerning the working procedures:

- any procedure must be performed in such manner to prevent the formation of aerosols
- It is forbidden mouth pipetting
- It is forbidden contact of the mouth with laboratory materials; self-adhesive labels will be used for labeling
- avoid the use of needles in the laboratory,
- centrifugation of products with potential to contain mycobacterium tuberculosis will be done only in centrifuges, with cap; pathological products will be centrifuged only after they have been placed in special, closed containers. At the end of the centrifugation, opening the containers is performed only inside the biosafety cabinet, after at least 10 minutes after turning off the centrifuge.
- all materials contaminated with mycobacterium tuberculosis will be decontaminated before being destroyed (possibly cleaned and reused in the case of materials)
- Tubes of culture will be manipulated only screwed with lid

Molecular biology procedures: PCR involves in terms of infection control two phases that need different work areas:

- processing of biological material with alive mycobacterium tuberculosis (before inactivation) needs biosafety conditions with negative pressure
- DNA extraction, amplification and analysis is done in separate work areas, preferably with positive pressure in order to avoid contamination.

GeneXpert method doesn't require special precautions in terms of infection control. The machines must be placed in dry, cool space and the technique doesn't involve higher risk than microscopy.

Biohazards: In case of incidents with potential of producing aerosols containing mycobacterium tuberculosis (breaking or leaking from a container), the **emergency procedure** must be known and applied by all employees; the emergency procedure must be displayed in a visible place in the laboratory.

b) Instruction

1. According to the procedures performed into the laboratory, classify the laboratory in one of the 3 risk groups

2. Describe TB IC controls in details for each activity developed in the lab, following the flow of the specimen, starting from the specimen collection and handling to the waste management.
3. Establish procedures for equipment use and maintenance (biosafety cabinets, centrifuges...)
4. Establish policies for personal respiratory protection in the laboratory
5. Improve the ventilation in the laboratory, according to the risk
6. Establish procedure for emergency situations in the laboratory (biohazard).

c) Template 7: TB IC in the laboratory

According to the risk assessment performed on...dd//mm//yyyy.... by....., the laboratory was classified as (high/medium/low) risk, based on the procedures performed (...)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
Managerial activities (responsibilities, work practices, training, monitoring TB disease in staff, research, etc.)			
Administrative activities (product collection and handling, access into the laboratory, reception of specimen, delivery of results, equipment use and maintenance, biohazards, waste management, etc.)			
Environmental (ventilation, eventually UV)			
Personal respiratory protection			

8. MONITORING AND EVALUATION

a) Background

Internal routine monitoring of the infection control's plan implementation is carried out by the nosocomial infections commission or is delegated to the IC responsible person(s). During the routine monitoring activities are observed and compared to the activities of the TB-IC plan, time frames or frequency are checked, as well as relevant quantitative and qualitative indicators, recorded in TB-IC plan.

During the supervision visits, each TB facility is subject to external monitoring and evaluation, sometimes in form of TB-IC assessments. TB-IC assessment is the responsibility of the supervisor together with the facility, performed during supervision visits at least one time a year. Annex 3 contains a TB infection control data collection form, recommended for the external assessment during the supervision visits. This tool can also be used by the facilities to assess their IC activities.

Some examples of indicators for monitoring and evaluation of the TB infection control plan's implementation include:

Implementation of the separation policies:

- Number of infectious TB patients separated according to the policy out of total number of infectious TB patients identified in the facility (target=100%)
- Time from arrival into the unit until identification of smear positivity for smear positive TB patients (target <48 hours)
- Time from arrival into the unit until identification of drug resistances for the MDR TB target <24 hours for GeneXpert, 3-4 weeks for liquid media DST, 3 months for solid media DST)
- Time from arrival into the facility until proper isolation of MDR TB patients (target <24 hours)

Access of TB diagnostics and follow up:

- Number of TB patients with DST out of confirmed TB patients (target 100%)
- Percentage of patients benefiting of rapid testing of Mycobacterium tuberculosis resistance identification out of MDR TB patients identified in the facility (target 100%)

Training process and educational activities:

- Number of staff members trained on TB IC in the last year out of the total number of staff (target 100%)
- Number of patients that received information about TB transmission and cough hygiene among the number of patients registered in the facility (target 100%)

The risk of TB disease among staff

- Number of TB cases among the health care workers of the facility (target 0)

- Index of TB cases among the medical (defined as the report between the number of cases among the health staff reported to the total number of staff and the number of cases in the general population reported to the population number) (target <1)
- Number of employees screened for TB last year out of the total number of employees (target 100%)

Implementation of environmental IC measures

- Percentage of the areas with high and very high risk with efficient ventilation (over 12 ACH) (target 100%)
- Percentage of the areas with high and very high risk equipped with shielded UV lamps, which can be used in the presence of people (target 100%)

Proper maintenance of equipment:

- Percentage of equipment with service and maintenance contracts established (target 100%)

Personal respiratory protection:

- Number of health care workers running procedures with risk of TB transmission receiving one respirator each 2 weeks among the total number of health care workers running procedures with risk of TB transmission (target 100%)
- Percent of staff fit tested among the total number of staff (target 100%)
- Number of surgical masks used for contagious TB patients in last month reported, to the number of contagious TB patients registered in the facility

b) Instructions

1. Identify the responsible for TB-IC routine monitoring at your facility.
2. For large facilities, identify responsible for TB-IC routine monitoring at each department.
3. Identify how often routine monitoring will take place.
4. Decide when/how often your facility will evaluate its TB-IC activities and plan's implementation and what tools you will use (you can use TB infection control data collection form in Annex 3).

c) Template 8: monitoring and evaluation

Facility:

Date:

Department:

Monitoring by:

Infection controls	Description of activities	When to implement	Performance Indicator (target)	activity observed/implemented	on time/ regularly	Performance Indicator (actual)

administrative	(from TB-IC plan)	(from TB-IC plan)	(from TB-IC plan)	yes no if no, why:	yes no if no, why:	
environmental						
personal respiratory protection						

Date for next monitoring (set a tentative date for next monitoring)

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9. BUDGET

a) Background

Infection control activities require financial resources that need to be budgeted. Equipment maintenance always has to be considered, as it usually represents each year about 5-10% of the cost of equipment. Usually, environmental controls (mechanical ventilation, UV lights) and personal respiratory protection are considered to be expensive. However sometimes managerial or administrative controls may involve important costs such as building reconstructions, space reorganization, human resources, educational materials, training.

As the financing of the TB facilities is complex, infection control activities are budgeted from different sources: TB Programme (funded by the MOH through two budget lines – material expenses and transfers), local authorities (for the health units that belong to them) or own revenues. Sometimes, IC activities must be budgeted from other sources: projects, private programs, sponsorships, donations.

Each time when the budget of the facility for next year is established, all infection control expenses must be included in the financial forecast and this is the responsibility of the IC responsible officer, together with the manager of the facility.

In the table below, there are examples of the most important activities and procedures to be included into the facility budget; each facility will identify their own activities according to the risk assessment and taking into account the IC measures already implemented.

Activity (Budget category)	Budget sub-categories	Estimated cost	Potential source of financing
I. Managerial (programmatic) activities			
a. Conducting situational analysis	Consultancy for situational analysis (risk assessment, IC assessment) if it was not done and if no internal technical resources are available		e.g. NTP (MOH), local authorities, own revenues, sponsorships, donations
b. Policy/plan development	Consultations and/or meetings for development of IC plan (if it was not done)		
c. Advocacy and sensitization meetings	Consultative meetings, media activities		

d. Trainings	Training materials, organization of the trainings		
e. Patient education materials	Elaboration and printing of educational materials (pamphlets, posters, flyers)		
f. Monitoring TB in staff	Develop questionnaires, procedures (X Ray, bacteriological investigations, TST)		
g. Human resources	Fees for the Infection control team members, Fees for trainers involved in trainings		
II. Administrative measures			
Triage of TB suspects, patient separation	-organizing proper waiting areas -organizing triage areas -optimizing flow of the patients		
Upgrade/Renovate existing infrastructure to create isolation rooms	-isolation rooms for TB suspects, smear positive and MDR TB patients		
Create safe sputum collection rooms	-creating proper sputum collection booths or rooms or organizing special spaces outside		
Cough etiquette	-other items beside the list below includes poster and		

	patient education which were included in the programmatic measure – surgical mask, tissues		
Signage in the facility	-improve signage in the facility; mark all medium/high/very high risk areas and procedures		
III. Environmental measures			
Infrastructure changes to implement natural ventilation, mixed-mode ventilation or mechanical ventilation	-Acquisition of monitoring tools: velocimeters, vaneometers, smoke tubes, -cost of mechanical ventilation devices (fans, mechanical ventilation systems, HEPA filters) -cost of maintenance; cost of exploitation (power supply)		
UV light	-Acquisition of measuring devices (UV meter) -acquisition of shielded UV lamps -modification of unshielded UV lamps -cost of maintenance; cost of exploitation (power supply)		
g. Equipment maintenance	Cost of the service for the equipment (lab, ventilation, UV)		
IV. Personal protection			

Assurance of respirators for the staff	-assure at least one FFP2 respirator for each staff member exposed to TB risk / 2 weeks -assure FFP3 respirators for high risk procedures and areas		
Fit testing kits for the staff	-each facility to have access to fit test for each employee (at least one test per year)		
V. Other IC activities			
Ensuring infection control in TB laboratories			

b) **Instruction**

1. TB-IC responsible or the nosocomial infections commission together with Finance and planning staff review managerial activities at facility level and administrative, environmental and PPE related activities of all departments, which together constitute the facility TB-IC plan.
2. Compile activities, translated into budget categories and sub-categories.
3. Estimate and costs.
4. Identify the potential sources of financing, such as the NTP (MOH), local authorities, own revenues, sponsorships and donations.

c) **Template 9: Budget**

Period: from (dd/mm/yyyy) to (dd/mm/yyyy)

Activity (Budget category)	Budget sub-categories	Estimated cost	Potential source of financing

I. Managerial (programmatic) activities			
- (from TB-IC plan)			
-			
-			
Sub-total			
II. Administrative measures			
- (from TB-IC plan)			
-			
-			
Sub-total			
III. Environmental measures			
- (from TB-IC plan)			
-			
-			
Sub-total			
IV. Personal protection			
- (from TB-IC plan)			
-			

-			
Sub-total			
V. Other IC activities			
- (from TB-IC plan)			
-			
-			
Sub-total			
Grand Total			

Submitted by:

Date:

Approved by:

Date:

REFERENCES

ACSM for Tuberculosis Control: A Handbook for Country Programmes, 2007

WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households - 2009

Implementing the WHO Policy on TB Infection Control - A framework to plan, implement and scale-up TB infection control activities at country, facility and community levels.

Tuberculosis laboratory biosafety manual – World Health Organization, 2012

Biosafety Recommendations for the Contained Use of Mycobacterium tuberculosis Complex Isolates in Industrialized Countries – Philippe Herman, Maryse Fauvile-Dufaux & colab, 2006

Practices and procedures for the tuberculosis aerosol challenge facility – Immunology group international Centre for Genetic Engineering & Biotechnology – New Delhi, 2008

CDC/NIH biosafety in Microbiological and Biomedical Laboratories, 5th Edition (2007)

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ANNEX 1 FACILITY TB-IC PLAN TEMPLATES

Template 1: Infection control commission

Facility name Date Approved by

Terms of reference for TB-IC commission

Responsibilities	List responsibilities Specify the responsibilities of the Chairperson and TB-IC responsible officer
Authority	List rights and authority Specify the authority of the Chairperson and TB-IC responsible officer
Reporting to	Indicate whom the TB-IC commission reports to, in what form and how often
Commission members	In a separate annex list the names, positions and contact information of TB-IC commission members
Meetings	Indicate the frequency of TB-IC commission meetings, location and where documentation of the TB-IC commission will be stored

TB Infection Control Plan

Template 2: TB risk assessment

FACILITY NAME (TB HOSPITAL – WARD/ AMBULATORY/ LAB)

Date of elaboration.....

Date of revision.....

The baseline risk assessment in the facility was performed on: (month, year).

By: (person or team nominated to conduct baseline risk assessment)

Floor plan with indication of patients or specimens flow:

(here)

According to the results of the baseline risk assessment, in the facility the following areas and procedures were identified and grouped according to different risk of TB transmission: (In the table below record the results of the baseline risk assessment)

level of risk	list facility areas according to level of risk	list procedures that increase the risk of TB transmission
low risk		
medium risk		
high risk		
very high risk		

Date of subsequent risk assessment (month, year).

By: (person or team nominated to conduct baseline risk assessment)

In table record any changes in facility areas or procedures which result in the changed level of risk

level of risk	list facility areas according to level of risk	list procedures that increase the risk of TB transmission
low risk		
medium risk		
high risk		

very high risk		
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Template 3: Managerial activities

Managerial activities	Description of activities	When to implement	Performance Indicator (target)	Budget (short- and long-term)
Identification and strengthening TB infection control responsible person(s)				
Evaluation the TB infection risk within the facility and separately for each area/department				
Development and updating of a costed Facility TB-IC Plan				
Reorganization or rehabilitation of facility areas				
TB-IC staff training				
ACSM and Collaboration with the Public Health Directorate and other institutions				
Staff TB surveillance				
Participation in research efforts				

Monitoring and evaluation of TB-IC activities				
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Template 4: administrative controls

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
administrative			

Template 5: environmental controls

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
environmental			

Template 6: personal respiratory protection

Facility area/department/procedure: (indicate)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
personal respiratory protection			

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Template 7: TB IC in the laboratory

According to the risk assessment performed on...dd//mm//yyyy....

by.....

the laboratory was classified as (high/medium/low) risk, based on the procedures performed (list the procedures)

Infection controls	Description of activities	When to implement	Performance Indicators (target)
Managerial activities (responsibilities, work practices, training, monitoring TB disease in staff, research, etc)			
Administrative activities (product collection and handling, access into the laboratory, reception of specimen, delivery of results, equipment use and maintenance, biohazards, waste management, etc.)			
Environmental (ventilation, eventually UV)			
Personal respiratory protection			

Template 8: monitoring and evaluation

Date:

Department:

Monitoring by:

Infection controls	Description of activities	When to implement	Performance Indicator (target)	activity observed/implemented	on time/regularly	Performance Indicator (actual)
administrative	(from TB-IC plan)	(from TB-IC plan)	(from TB-IC plan)	yes no if no, why:	yes no if no, why:	
environmental						
personal respiratory protection						

Date for next monitoring (set a tentative date for next monitoring)

Template 9: Budget

Period: from (dd/mm/yyyy) to (dd/mm/yyyy)

Activity (Budget category)	Budget sub-categories	Estimated cost	Potential source of financing
I. Managerial (programmatic) activities			
- (from TB-IC plan)			
-			
-			

Sub-total			
II. Administrative measures			
- (from TB-IC plan)			
-			
-			
Sub-total			
III. Environmental measures			
- (from TB-IC plan)			
-			
-			
Sub-total			
IV. Personal protection			
- (from TB-IC plan)			
-			
-			
Sub-total			
V. Other IC activities			

- (from TB-IC plan)			
-			
-			
Sub-total			
Grand Total			

Submitted by:

Date:

Approved by:

Date:

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ANNEX 2 STAFF TB-IC ROLES AND RESPONSIBILITIES

Background

In accordance with the Romania's National TB Infection Control Plan, here are the roles and responsibilities of the health care workers in TB infection control.

Role of individual staff members

- Employees must understand their legal duty to take reasonable care of their health, safety and security and that of other persons who may be affected by their actions and for reporting untoward incidents and areas of concern.
- Healthcare workers are responsible for identifying infectious conditions and circumstances that may lead to outbreaks of infection that require specific controls to protect themselves, their patients or others.
- They are responsible for notifying the Infection Control Team of such circumstances and it is the responsibility of healthcare workers to ensure that they utilize safe working practices as outlined in Infection Control policies.
- Any breach in Infection Control Policies or Practice will place staff, patients and visitors at risk

Responsibilities to the Public

- Provision of appropriate patient information leaflets regarding TB
- Disseminating information regarding any measures to control the spread of infection by appropriate signage at key entry points to the hospital and individual clinical areas or by verbal guidance from staff

Doctor:

- To identify the TB suspects (persons coughing for more than 3 weeks, fever, weight loss, haemoptysis, TB in antecedents)
- To refer the TB suspects to the TB specialist for diagnostic confirmation
- To educate the TB suspects on TB transmission, cough etiquette
- To know and adhere to the IC practices of the facility

Pneumologist:

- To assure rapid diagnosis (best procedures and practices available for the bacteriological diagnosis, rapid find out of the results) and initiate the proper treatment as soon as possible
- To place infectious TB patients and the high TB suspects in separate areas (patients and suspects triage)
- To educate patients on TB (transmission, pathogenesis, treatment, complications)
- To train staff (nurses, other healthcare workers) on TB infection control activities

- To inform families of patients about the TB transmission and infection control
- To adhere to Infection control measures (administrative, environmental and respiratory protection) imposed in the health facility
- To use a respirator during the contact with infectious TB patients, MDR or XDR TB patients or during procedures with high risk of transmission performed on TB suspects or TB patients
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Laboratory manager

- to ensure that a biosafety management system is developed and adopted
- to ensure that a laboratory biosafety manual and a set of standard operating procedures are developed and adopted
- to ensure that laboratory staff are trained in TB-IC
- to ensure that systems for heating, ventilation, air and containment (directional airflow) have a permanent maintenance plan and are maintained

Laboratory technician

- To minimize or prevent the formation of aerosols and droplets during procedures
- To report all accidents, spills and potential exposures to infectious materials to the laboratory manager
- To participate in trainings on TB infection control
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Nurse in TB diagnosis and treatment facilities:

- To identify patients with high TB suspicion in the waiting areas, to isolate them from other patients (especially children), to fast track them – give them priority in line for consultation
- To participate to the isolation of the infectious TB patients in dedicated spaces
- To educate patients on cough etiquette
- To assure the minimum spread of bacilli for the infectious patients (giving surgical masks to the patients during the transportation or waiting in indoor closed areas)
- To assure good natural ventilation of patient rooms, consultation rooms, waiting areas, procedure rooms opening the windows
- To use a respirator during the contact with infectious TB patients, MDR or XDR TB patients or during procedures with high risk of transmission performed to the TB suspects or TB patients

- To participate in trainings on TB infection control
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Cleaning personnel, hospital attendants:

- To assure good ventilation of the spaces, opening the windows as per facility TB-IC plan
- To use a respirator while being in wards of and/or during any contact including transportation of the infectious TB patients, MDR or XDR-TB patients
- To ensure the use of surgical masks by patients during transportation outside the wards, in spaces with limited ventilation and during contacts with staff, visitors or patients from other wards
- To know and adhere to the IC practices of the facility

Administrative staff:

- To minimize the exposure to the infectious aerosols, avoiding areas with infectious TB patients or
- To use a respirator during the access in the spaces with potential transmission of TB
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Technical staff:

- To assess periodically and to assure a good maintenance of the devices related to infection control (windows, mechanical ventilation systems, UV devices, air purifiers)
- To use respirators during the access in the spaces with potential transmission of TB
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Hospital epidemiologist:

- To be in charge of the development and implementation of the infection control plan
- To implement the isolation of infectious TB patients
- To participate to the trainings on infection control for staff and education for the patients and visitors
- To report TB cases among the healthcare workers to the National TB infection control team
- To participate in regular respirator fit-testing
- To know and adhere to the IC practices of the facility

Instruction

1. Together with the human resources department of the facility review the current job descriptions of staff, in relation to TB infection control, to make sure that IC responsibilities are included in the updated job descriptions of staff.

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Annex 3 TB infection control data collection form

Facility, location _____

Level: ☐ country ☐ regional ☐ county ☐ municipal
☐ inpatient ☐ outpatient ☐ both ☐ laboratory

TB Infection Control Body ☐ committee ☐ authorized person ☐ No

General IC plan ☐ officially approved ☐ revised annually ☐ No

Airborne TB infection control components incorporated into General IC plan ☐ Yes ☐ No

Key IC staff members trained on airborne TB IC ☐ Yes ☐ No

Facility educational program on airborne TB IC ☐ Yes ☐ No

Average incidence of occupational TB among staff for last 10 years (per 100K), if available

Triage of coughers, TB suspects and patients ☐ Yes ☐ No

Separation of TB patients and suspects ☐ Yes ☐ No

- based on

☐ smear microscopy

☐ culture

☐ DST

☐ HIV – status

☐ treatment regimen

Separation provided ☐ in patient rooms ☐ separate floors ☐ separate buildings

Zoning of the facility into high, medium, low risk areas ☐ Yes ☐ No

TB transmission risk signage in medium and high risk zones ☐ Yes ☐ No

Ventilation in the patient floors (departments) ☐ natural ☐ mechanical ☐ local

Year and cost of mechanical ventilation installation _____ ☐ N/A

Actual air controlled flow direction pattern in relation to zoning of the floor, if detectable:

☐ from low risk to high risk area ☐ from high risk to low risk area ☐ unstable ☐ No

Ventilation in the laboratory ☐ natural ☐ mechanical ☐ local

Year and cost of mechanical ventilation installation _____ ☐ N/A

Actual air flow direction pattern in relation to zoning of the laboratory, if detectable:

☐ from low risk to high risk area ☐ from high risk to low risk area ☐ unstable ☐ No

Maintenance budget _____ USD per year and **availability of valid current contract** for ventilation system maintenance ☐ Yes ☐ No

No

Staff responsible for ventilation system exploitation and monitoring ☐ Yes ☐ No

UVGI fixtures installed in high risk areas ☐ Upper room ☐ Whole room ☐ No

UVGI fixtures cleaning and lamp replacement protocol ☐ Yes ☐ No

UVGI lamps ☐ clean ☐ dirty

UV-C radiometer available ☐ Yes ☐ No

UV-C irradiance readings: in upper room space @ 1m _____ $\mu\text{W}/\text{cm}^2$

in occupied space maximal _____ $\mu\text{W}/\text{cm}^2$

Availability and installation year of laboratory biological safety equipment:

Biosafety centrifuges _____

Biosafety cabinets Class I _____

Biosafety cabinets Class II Type A2 _____

Maintenance of laboratory biological safety equipment:

Annual maintenance budget _____ Certified contractor ☐ Yes ☐ No

Last BSC certification date _____ Last HEPA filter replacement date _____

Laboratory staff trained on biological safety in TB laboratories ☐ Yes ☐ No

Sputum collection site

☐ outdoors ☐ outdoor booth ☐ Yes ☐ No

☐ indoor booth ☐ room - mechanically ventilated ☐ Yes ☐ No

other _____

☐ Negative pressure ☐ UVGI in the sputum collection booth/room

Facility respiratory protection program regulations (SOPs) ☐ Yes ☐ No

Respirators ☐ available for high risk staff ☐ used

Surgical masks ☐ available for patients ☐ used

Annual budget for respirators _____

High risk staff ☐ trained on respiratory protection ☐ appropriately use respirators

Respirators class of protection ☐ FFP1 ☐ FFP2 ☐ FFP3 ☐ Not certified

Fit test kit available ☐ Yes ☐ No

Fit testing records available ☐ Yes ☐ No

Cough etiquette education program ☐ Yes ☐ No

Real practice of cough etiquette ☐ Yes ☐ No

Remarks _____

Date _____

Name _____