TUBERCULOSIS
LABORATORY BIOSAFETY MANUAL

World Health Organization

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Executive summary

Following a technical consultation held between the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (CDC) in Atlanta, GA, in September 2008 on strategies, approaches and partnerships that could be implemented to improve laboratory biosafety worldwide, an Expert Group meeting was convened at WHO's Headquarters in Geneva, Switzerland, in April 2009 to elaborate guidance on biosafety related to laboratory procedures for diagnosing tuberculosis (TB). Members of the Expert Group submitted Declarations of Interest. These were reviewed by WHO's legal department prior to the meeting. The purpose of the meeting was to reach consensus on the basic principles of laboratory practices and design necessary to establish minimum criteria to ensure biosafety during TB microscopy, culture, drug-susceptibility testing (DST) and molecular testing in different countries and epidemiological settings.

This manual was developed from the Expert Group meeting. The recommendations are based on assessments of the risks associated with different technical procedures performed in different types of TB laboratories; the manual describes the basic requirements for facilities and practices, which can be adapted to follow local or national regulations or as the result of a risk assessment. Risk assessments require careful judgement: on the one hand, underestimating risks may lead to laboratory staff being exposed to biological hazards but, on the other hand, implementing more rigorous risk mitigation measures than are needed may result in an unnecessary burden on laboratory staff and higher costs to establish and maintain the laboratory's infrastructure. Risk assessments should consider the bacterial load of materials (such as specimens and cultures), the viability of the bacilli, whether the material handled is prone to generate aerosols during the activity being assessed, the laboratory's workload, the epidemiology of the disease, and the health of laboratory workers; assessments should also consider other factors that may influence the likelihood or the consequence of exposure to TB.

The intended audience for these recommendations are directors and managers of laboratories and TB programmes as well as the laboratory technicians who test for TB, especially in high-burden, low-resource settings. In this document, the laboratory or section of the laboratory conducting TB testing is referred to as the TB laboratory.

The recommendations are specific to laboratories that follow well defined procedures to test samples potentially containing *Mycobacterium tuberculosis*. For any other combination of pathogen and procedures, a process similar to the one used here could be used to define biosafety precautions.

This manual was approved by WHO's Guidelines Review Committee[1] in May 2012, and explanations are provided throughout the manual where it differs from WHO's *Laboratory biosafety manual*, 3rd edition.[2] It is intended to inform rather than replace country-level requirements and standards for biosafety. The recommendations do not supersede any local or national rules or regulations.

Review by date: 2017

Participants in the guideline development process

The following contributed to the writing of this manual:

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The following were part of the technical review panel convened at WHO's Headquarters, 22–23 August 2011, Geneva, Switzerland:

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The writers also wish to acknowledge the original contributions of the many professionals who worked on WHO's *Laboratory biosafety manual, 3rd edition, from which portions of this document have been adapted*.

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Abbreviations

ACH	Air exchanges per hour
AFB	Acid-fast bacilli
BSC	Biological safety cabinet
DST	Drug-susceptibility testing
HEPA	High-efficiency particulate air
MDR-TB	Multidrug-resistant tuberculosis
XDR-TB	Extensively drug-resistant tuberculosis

Definitions of terms

Aerosol-generating procedure	High-risk procedures that may increase the potential for generating droplet nuclei as a result of the mechanical force of the procedure (for example, pipetting, vortexing, centrifuging or mixing).
Airborne transmission	The transmission of disease caused by dissemination of droplet nuclei that remain infectious when suspended in air.
Air changes per hour (ACH)	The number of laboratory room volumes of air expelled per hour and replaced with clean air.
Anteroom	A small room leading from one part of a laboratory into another part (for example, leading into a TB-containment laboratory).
Biosafety management plan	The use of a combination of administrative controls, containment principles, laboratory practices and procedures, safety equipment, emergency preparedness, and laboratory facilities to enable laboratory staff to work safely with infectious microorganisms.