

TUBERCULOSIS LABORATORY BIOSAFETY MANUAL





TUBERCULOSIS LABORATORY BIOSAFETY MANUAL





WHO Library Cataloguing-in-Publication Data

Tuberculosis laboratory biosafety manual.

1.Laboratories – standards. 2.Laboratory infection – prevention and control. 3.Tuberculosis – diagnosis. 4.Containment of biohazards. 5.Laboratory manuals. 6.Guideline. I.World Health Organization.

ISBN 978 92 4 150463 8

(NLM classification: WF 220)

© World Health Organization 2012

All rights reserved. Publications of the World Health Organization are available on the WHO web site (<u>www.who.int</u>)orcanbepurchasedfromWHOPress, WorldHealthOrganization, 20AvenueAppia, 1211 Geneva 27, Switzerland (tel.:+41227913264; fax:+41227914857; e-mail: <u>bookorders@who.int</u>). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press through the WHO web site (<u>http://www.who.int/about/licensing/copyright_form/en/index.html</u>).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Designed by GPS Publishing Printed in Italy WHO/HTM/TB/2012.11

Contents

| EXECUTIVE SUMMARY | | V |
|---|--|----|
| PARTICIPANTS IN THE GUIDELINE DEVELOPMENT PROCESS | | VI |
| ABBREVIATIONS | | |
| | | |
| | 1.1 Risk assessment for TB laboratories: what is it? | 5 |
| | 1.2 Hazard identification | 6 |
| | 1.3 Determining risks | 6 |
| | 1.4 Monitoring risks and mitigation measures | 10 |
| | 1.5 Employee occupational health programme | 11 |
| | 1.6 Classification of TB laboratories | 11 |
| 2. | ESSENTIAL BIOSAFETY MEASURES FOR TB LABORATORIES | 13 |
| | 2.1 Codes of practice | 13 |
| | 2.2 Equipment | 16 |
| | 2.3 Design and facilities | 16 |
| | 2.4 Training | 17 |
| | 2.5 Waste handling | 17 |
| | 2.6 Disposal procedures for contaminated materials | 19 |
| 3. | LOW-RISK TB LABORATORIES | 20 |
| | 3.1 Factors that increase the risk of infection | 20 |
| | 3.2 Specific features and essential minimum biosafety measures | 20 |
| 4. | MODERATE-RISK TB LABORATORIES | 24 |
| | 4.1 Factors that increase the risk of infection | 24 |
| | 4.2 Specific features and essential minimum biosafety measures | 24 |

| 5. | HIGH-RISK TB LABORATORIES (TB-CONTAINMENT LABORATORIES) | 28 |
|-----|---|----|
| | 5.1 Factors that increase the risk of infection | 28 |
| | 5.2 Specific features and required biosafety measures | 28 |
| 6. | SAFETY EQUIPMENT | 30 |
| | 6.1 Biological safety cabinets | 30 |
| | 6.2 Centrifuges with safety buckets | 36 |
| | 6.3 Autoclaves | 36 |
| 7. | PERSONAL PROTECTIVE EQUIPMENT AND CLOTHING | 39 |
| | 7.1 LABORATORY GOWINS | 39 |
| | 7.2 Respirators | 40 |
| | 7.3 Gloves | 40 |
| 8. | PLANS FOR EMERGENCY PREPAREDNESS AND RESPONSE | 42 |
| | 8.1 Emergency preparedness plan | 42 |
| | 8.2 Emergency response procedures for TB laboratories | 42 |
| | 8.3 Spill Clean-up kit | 43 |
| 9. | REFERENCES | 44 |
| 10. | ANNEX | 46 |
| | Annex 1: Meeting participants | 46 |
| | Annex 2: Declarations of Interest | 49 |
| | Annex 3: Peer review panel | 50 |

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 Committee¹ 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

V

Participants in the guideline development process

The following contributed to the writing of this manual:

Christopher Gilpin (Lead), Jean Iragena, Fuad Mirzayev, Wayne van Gemert, Karin Weyer

The following participated in the joint CDC–WHO International Technical Consultation on Laboratory Biosafety, 2–4 September 2008, Atlanta, GA, USA:

May Chu, Daniela Cirillo, Philippe Dubois, Christopher Gilpin, Paul Jensen, Shanna Nesby, Nicoletta Previsani, John Ridderhof, Thomas M Shinnick, Veronique Vincent, Karin Weyer.

The following were members of the Expert Group convened at WHO's Headquarters, 8–9 April 2009, Geneva, Switzerland:

Jenny Allen, May Chu, Daniela Cirillo, Sébastien Cognat, Philippe Dubois, Knut Feldmann, Christopher Gilpin, Jean Iragena, Paul Jensen, Moses Joloba, Jean Joly, Sang Jae Kim, Scott Kreitlein, Shanna Nesby, CN Paramasivan, Nicoletta Previsani, John Ridderhof, Thomas M Shinnick, Andrew Ramsay, Peter van't Erve, Veronique Vincent, Karin Weyer.

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

Heather Alexander, Pawan Angra, Daniela Cirillo, Gerrit Coetzee, Edward Desmond, Maria Alice da Silva Telles, Sara Irène Eyangoh, Knut Feldmann, Christopher Gilpin, Rumina Hasan, Jean Iragena, Moses Joloba, Fuad Mirzayev, Satoshi Mitarai, Richard O'Brien, Daniel Orozco, CN Paramasivan, Nicoletta Previsani, Leen Rigouts, Thomas M Shinnick, Akos Somoskovi, Magdi Samaan, Wayne van Gemert, Elsie Van Schalkwyk.

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.

Development and publication of this document have been made possible with financial support from the United States Agency for International Development (USAID) and the United States Centers for Disease Control and Prevention.

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. |

预览已结束, 完整报告链接利

https://www.yunbaogao.cn/report/index/report