

TOBACCO PRODUCT REGULATION

Building laboratory testing capacity



World Health
Organization



#beatNCDs

TOGETHER
LET'S BEAT
TOBACCO

TOBACCO PRODUCT REGULATION

Building laboratory testing capacity



World Health
Organization



#beatNCDs

TOGETHER
LET'S BEAT
TOBACCO

Tobacco product regulation: building laboratory testing capacity.

ISBN 978-92-4-155024-6

© **World Health Organization 2018**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Tobacco product regulation: building laboratory testing capacity. Geneva: World Health Organization; 2018. Licence: [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. 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 WHO 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 and dashed 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 WHO 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 WHO 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 WHO be liable for damages arising from its use.

Printed in Switzerland

CONTENTS

Preface	v
Acknowledgements	vi
Glossary	vii
Chapter 1:	
Testing in the context of a country's regulatory authority	1
1.1 Initial considerations	2
1.1.1 Reason for the regulatory authority	2
1.1.2 Scientific basis of the legislation	3
1.1.3 Public health concerns	3
1.1.4 Resonance with the public and decision-makers	4
1.1.5 Legal requirements	4
1.2 How data can be used	4
1.2.1 Product standards	5
1.2.2 Marketing/Advertising restrictions	5
1.2.3 Public education	6
1.2.4 Informing future legislation	6
1.2.5 Notification or marketing authorization	7
1.2.6 Developing scientific information	7
1.2.7 Manufacturing standards	8
1.3 Identifying tobacco products to test	8
1.3.1 Types of tobacco products most prevalent in the market	8
1.3.2 Types of tobacco products most harmful to users	9
1.3.3 Tobacco products most feasible to regulate	9
1.4 Analytes to test	9
1.5 How the tests are to be conducted	11
1.6 Communicating data to regulators	11
1.7 Covering costs	13
1.8 Implementation	14
Chapter 2:	
Introduction to three possible routes to a testing laboratory	15
2.1 Contracting with an external laboratory	15
2.2 Using an existing internal laboratory	17
2.3 Developing a dedicated laboratory	18
Chapter 3:	
Contracting with an external testing laboratory	21
3.1 Laboratory selection criteria	21
3.1.1 Experience in tobacco analyses	21
3.1.2 Equipment capabilities	21
3.1.3 Staff qualifications	22
3.1.4 Breadth of capabilities	22
3.1.5 Excess capacity	22
3.1.6 Proven track record	23

3.1.7 Accreditation	23
3.1.8 Ability to add new methodologies	23
3.1.9 Information technology systems	23
3.1.10 Quality assurance programme	24
3.1.11 Participation in inter-laboratory validation	24
3.1.12 Cost of analyses	24
3.1.13 Other customers	24
3.1.14 Location	25
3.2 WHO TobLabNet	27
3.3 Agreements and legal/ethical issues	31
3.4 Sample load estimates	33
3.5 Costs	33
3.6 Case study - Canada	34
3.7 Step-by-step process	35
Chapter 4:	
Using an existing internal testing laboratory	36
4.1 Requirements (laboratory equipment, staff, overall cost)	
- how to identify the right laboratory	38
4.2 Accreditation	40
4.3 Case study - Singapore	40
4.4 Step-by-step process	41
Chapter 5:	
Developing a tobacco-exclusive testing laboratory	42
5.1 Requirements (infrastructure, laboratory equipment, staff, overall cost)	42
5.2 Information technology (IT) systems	44
5.3 Data verification	45
5.3.1 Analysis of quality control materials	45
5.3.2 Systematic checks of accuracy and reproducibility	45
5.3.3 Long-term trend analysis	45
5.4 Case study - CDC	45
5.5 Step-by-step process	47
Chapter 6:	
Resources: WHO TobLabNet Membership (criteria, advantages, and procedures)	48
Summary	51
References	52
Appendix 1.	
Intra- and inter-laboratory validation	53
A1.1 Intra-laboratory method validation	53
A1.2 Inter-laboratory method validation	54
References	55

PREFACE

It is well established that tobacco use is a major public health problem. However, tobacco products are one of the few openly available consumer products that are virtually unregulated in terms of contents, design features and emissions. The majority of countries hesitate to implement regulations in this area, partly due to the technical complexity associated with tobacco product regulation. There has been a high demand from WHO Member States for resources consolidating information on tobacco testing and building laboratory capacity for countries, especially to facilitate the implementation of Articles 9 and 10 of the WHO FCTC¹. This is to provide a useful, comprehensible and easy guide for regulators and policymakers on how to test tobacco products, what products to test, and how to use testing data in a meaningful way to support regulation.

The importance of laboratory testing is reflected in the WHO Framework Convention on Tobacco Control (WHO FCTC). Article 9 of the WHO FCTC defines obligations for Parties with respect to the testing of tobacco products, while Article 10 deals with the disclosure of information on the contents and emissions of tobacco products. The disclosure of product information takes two forms: 1) the disclosure of information by manufacturers to regulators, and 2) the disclosure of information from regulators to the public. Tobacco product testing is used to generate data necessary to support both forms of disclosure.

In 2006, the first Conference of the Parties (COP) to the WHO FCTC established a working group to elaborate guidelines and recommendations for the implementation of Articles 9 and 10 of the Treaty (Decision FCTC/COP1(15)). COP 2 extended the mandate of the working group and encouraged WHO's Tobacco Free Initiative (WHO TFI) to continue its work on tobacco product regulation (Decision FCTC/COP2(14)). In 2010, the partial guidelines submitted at COP4 were adopted. The partial guidelines currently contain recommendations for regulation to reduce the attractiveness of tobacco products. Recommendations to reduce the addictiveness and toxicity of tobacco products will be developed later. The working group was requested by the COP to continue its work to elaborate the guidelines in a step-by-step process, with updates on addictiveness and toxicity requested to be submitted to future sessions of the COP for consideration.

It is important to note that, contrary to claims by the tobacco industry, these guidelines are final and in effect. The regulatory measures advocated by the partial guidelines are to be treated as minimum requirements and do not prevent Parties from adopting more comprehensive measures.

¹ Participants of a WHO workshop on the How-to's of Establishing a Testing Laboratory in (April 2016, New Delhi, India) requested WHO to prepare a handbook on building laboratory capacity. Additionally, the WHO Tobacco Laboratory Network's sixth meeting (Maastricht, Netherlands, 9-11 May 2016) recommended the development of a primer informing governments and the public of WHO TobLabNet's activities in order to expand membership and build testing capacity globally.

WHO has continually supported Member States in developing laboratory capacity. In 2004, WHO TFI published a recommendation from the WHO Study Group on Tobacco Product Regulation (TobReg) on ‘guiding principles to increase laboratory capacity to facilitate the implementation of Articles 9 and 10 of the WHO FCTC and to guide the initiation of tobacco product testing’. (1) The guiding principles provided advice to countries intending to develop such capacity and help in realising this objective. Over the intervening years, new knowledge has developed and progress has been made to support these efforts; these include establishing the WHO Tobacco Laboratory Network (TobLabNet) in 2005 and the Global Tobacco Regulators Forum (GTRF) in 2016. Therefore, it is appropriate to update the previous document and provide a practical guide for countries interested in developing or accessing tobacco product testing capacity to support their regulatory authority.

This document provides options for building laboratory capacity, which include developing a testing laboratory, using an existing internal laboratory, contracting an external laboratory, and making use of the support mechanisms available, including but not restricted to WHO TobLabNet. Finally, it provides practical, step-by-step approaches to implementing tobacco testing and is relevant even to countries with inadequate resources to establish a testing facility.

ACKNOWLEDGEMENTS

Main contributors to development: David L. Ashley, Ph.D (RADM (retired), US Public Health Service, Limited-Term Professor, Division of Environmental Health, School of Public Health, Georgia State University), and staff from WHO Department of Prevention of Noncommunicable Diseases.

Thanks to Nuan Ping Cheah, Ph.D (Director, Pharmaceutical, Cosmetics and Cigarette Testing Laboratory, Health Sciences Authority, Singapore/Chair, WHO Tobacco Laboratory Network), Dr. Ghazi Zaatari, (Professor & Chair, Department of Pathology & Laboratory Medicine, American University of Beirut, Lebanon/Chair, WHO Study Group on Tobacco Product Regulation), and the WHO FCTC Secretariat, for reviewing the text and providing useful comments.

Funding for this publication was made possible, in part, by the Food and Drug Administration through grant RFA-FD-13-032.

GLOSSARY

Accreditation — the documentation by an independent body that a laboratory has the systems in place that should enable them to produce reliable results that have been adequately tracked and verified.

Accuracy — the nearness of a measurement of a quantity to the quantity's true value

CDC — U.S. Centers for Disease Control and Prevention

DAD — diode array detector

FID — flame ionization detection

Firewall — a system to ensure that data and information are protected so that public health and commercial interests are separate and not accessible to each other

GC — gas chromatography

HPLC — high-performance liquid chromatography

Labstat — a private commercial tobacco analysis laboratory, Labstat Incorporated, in Kitchener, Ontario, Canada

LC — liquid chromatography

MS — mass spectrometry

MS/MS — tandem mass spectrometry

Precision — a determination of how close measurement results are to each other if a measurement is made repeatedly on the same sample, typically using the same method

Quality control — a process which evaluates whether systems are operating within standard parameters on an ongoing basis

Ruggedness — ability of an analytical system to withstand deviations from the defined analytical method.

Selectivity — the ability to correctly identify that a substance is not present when it is indeed not present.

Sensitivity — the ability of a measurement to make accurate and precise determinations at low levels.

TCD — thermal conductivity detector

TFI — Tobacco Free Initiative of the World Health Organization

TobLabNet — WHO Tobacco Laboratory Network

TobReg — WHO Study Group on Tobacco Product Regulation

TSNAs — tobacco-specific nitrosamines

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_25976

