WHO TobLabNet
Official Method
SOP 02

Standard Operating Procedure for Validation of Analytical Methods of Tobacco Product Contents and Emissions

Tobacco Free Initiative
Tobacco Laboratory Network (TobLabNet)

World Health Organization

WHO TobLabNet
Official Method

SOP 02

Standard operating procedure for validation of analytical methods of tobacco product contents and emissions

Standard operating procedure for validation of analytical methods of tobacco product contents and emissions, WHO TobLabNet Official Method SOP02
ISBN 978-92-4-151206-0

Suggested citation. Standard operating procedure for validation of analytical methods of tobacco product contents and emissions, WHO TobLabNet Official Method SOP02. Geneva: World Health Organization; 2017. Licence: CC 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

No.: SOP 02
Date: November 2016

World Health Organization

World Health Organization Tobacco Laboratory Network

Standard operating procedure for method

Validation of analytical methods of tobacco product contents and emissions

Method:	Standard operating procedures for validation of analytical methods of tobacco contents and emissions
Analytes:	Not applicable
Matrix:	Tobacco cigarette mainstream smoke and tobacco filler contents
Last update:	November 2016

No.: SOP 02
Date: November 2016

No machine smoking regimen can represent all human smoking behaviour: machine smoking testing is useful for characterizing cigarette emissions for design and regulatory purposes, but communication of machine measurements to smokers can result in misunderstanding about differences between brands in exposure and risk. Data on smoke emissions from machine measurements may be used as inputs for product hazard assessment, but they are not intended to be nor are they valid as measures of human exposure or risks. Representing differences in machine measurements as differences in exposure or risk is a misuse of testing with WHO TobLabNet standards.

No.: SOP 02
Date: November 2016

FOREWORD

This document was prepared by members of the World Health Organization (WHO) Tobacco Laboratory Network (TobLabNet) as a standard operating procedure (SOP) for the validation of analytical methods of tobacco cigarette mainstream smoke contents and cigarette tobacco filler contents.

INTRODUCTION

In order to establish comparable measurements for testing tobacco products globally, consensus methods are required for measuring specific contents and emissions of cigarettes. The Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) at its third session in Durban, South Africa, in November 2008, recalling decisions FCTC/COP1(15) and FCTC/COP2(14) on the elaboration of guidelines for implementation of Articles 9 (*Regulation of the contents of tobacco product*s) and 10 *(Regulation of tobacco product disclosure*s) of the WHO FCTC, noting the information contained in the report of the working group to the third session of the Conference of the Parties on the progress of its work ... requested the Convention Secretariat to invite WHO's Tobacco Free Initiative to ... validate, within five years, the analytical chemical methods for testing and measuring cigarette contents and emissions (FCTC/COP/3/REC/1).

Using the criteria for prioritization set at its third meeting in Ottawa, Canada, in October 2006, the working group on Articles 9 and 10 identified the following contents for which methods for testing and measurement (analytical chemistry) should be validated as a priority:

- nicotine
- ammonia
- humectants (propane-1,2-diol, glycerol (propane-1,2,3-triol) and triethylene glycol (2,2-ethylenedioxybis(ethanol)).

Measurement of these contents will require validation of three methods: one for nicotine, one for ammonia and one for humectants.

Using the criteria for prioritization set at the meeting in Ottawa mentioned above, the working group identified the following emissions in mainstream smoke for which methods for testing and measurement (analytical chemistry) should be validated as a priority:

- 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)
- *N*-nitrosonornicotine (NNN)

- acetaldehyde
- acrylaldehyde (acrolein)
- benzene
- benzo[*a*]pyrene
- 1,3-butadiene
- carbon monoxide
- formaldehyde

Measurement of these emissions with the two smoking regimens described below will require validation of five methods: one for tobacco-specific nitrosamines (NNK and NNN), one for benzo[*a*]pyrene, one for aldehydes (acetaldehyde, acrolein and formaldehyde), one for volatile organic compounds (benzene, 1,3-butadiene) and one for carbon monoxide).

The table below sets out the two smoking regimens for validation of the test methods referred to above.

Smoking regimen	Puff volume (mL)	Puff frequency	Filter ventilation holes
ISO regimen: ISO 3308; *Routine analytical cigarette smoking machine — definitions and standard conditions*	35	Once every 60 s	No modifications
Intense regimen: Same as ISO 3308, but modified as indicated	55	Once every 30 s	All ventilation holes must be blocked 100% as described in WHO TobLabNet SOP 01.

This method SOP was prepared to describe the procedure for the determination of nicotine and carbon monoxide in mainstream cigarette smoke under intense