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ISO and Health Canada intense smoking parameters —

Part 2:

Examination of factors contributing to variability in the routine measurement of TPM, water and NFDPM smoke yields of cigarettes

Paramètres de fumage ISO et Santé Canada Intense —

*Partie 2: Examen des facteurs contribuant à la variabilité des mesures
de routine de MPT, d'eau et de MPAEN dans la fumée de cigarette*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 126, *Tobacco and tobacco products*.

ISO/TR 19478 consists of the following parts, under the general title *ISO and Health Canada intense smoking parameters*:

- *Part 1: Results of an international machine smoking study*
- *Part 2: Examination of factors contributing to variability in the routine measurement of TPM, water and NFDPM smoke yields of cigarettes*

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Introduction

ISO/TC 126 Working Group 10 (WG 10) was established by ISO/TC 126 in 2007 in response to a New Work Item Proposal by the British Standards Institution (BSI) for the development of a new regime for the machine smoking of cigarettes that was more intense than the then current ISO 3308:2000, and a subsequent questionnaire sent to TC 126 members. Twenty out of 26 members of ISO/TC 126 voted in favour of the following option:

“to install a Working Group 10 dealing with an ‘Intense Smoking Regime’ which shall start with the preparatory work. WHO is invited to participate with their technical experts. No draft Standard is expected to be presented by this group until the future method proposal of WHO has been taken into consideration”.

The third session of the Conference of the Parties (COP) to the World Health Organization (WHO) Framework Convention on Tobacco Control Durban, South Africa, 17 to 22 November 2008, requested the Convention Secretariat to invite the WHO’s Tobacco Free Initiative (TFI) to undertake the following task:

“validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report of the working group 1 using the two smoking regimens set out in paragraph 18 of that report, and inform the Conference of the Parties through the Convention Secretariat on a regular basis of the progress made.”

The two smoking regimens were specified in paragraph 18 of the report of the COP working group (FCTC/COP/3/6) as follows:

Smoking regimen	Puff volume (ml)	Puff frequency	Ventilation holes
ISO 3308:2000, Routine analytical cigarette-smoking machine — Definitions and standard conditions	35	Once every 60 s	No modifications
Same as ISO 3308:2000 but modified as indicated.	55	Once every 30 s	All ventilation holes must be blocked with Mylar adhesive tape.

The two regimes were those specified in ISO 3308 and by Health Canada in Method T-115. At the early meetings of WG 10, some new human smoking studies were presented and are included in [Annex A](#) for completeness of reporting, but WG 10 never considered the correlation with machine smoking regimes in detail as this brief had previously been given to ISO/TC 126/WG 9 and WG 9 had produced a comprehensive report, ISO/TR 17219:2013.

The WHO TFI requested the WHO Tobacco Laboratory Network (TobLabNet) to carry out the practical work of validating the two smoking regimes. In 2008, TobLabNet organized and carried out a collaborative test to measure the tar, nicotine and carbon monoxide yields of cigarettes when using the Health Canada Intense (HCI) regime. The collaborative test involved 14 laboratories smoking five products (three reference cigarettes/monitor test pieces and two commercial products). Details of this collaborative were supplied to ISO/TC 126/WG 10.

WG 10 had expressed a willingness from its inception to participate with the WHO groups in the development of an intense smoking regime but had not been invited to do so. It, therefore, decided at its fifth meeting in December 2009 to undertake a collaborative study to measure the tar, nicotine and carbon monoxide yields of cigarettes using both the ISO 3308:2000 and Health Canada intense smoking regimes. A steering group was established and the laboratory work was carried out in 2010 involving 35 laboratories smoking 10 products (eight commercial and two reference cigarettes/monitor test piece). A final report on the study was approved by WG 10 and subsequently converted to a Technical Report, ISO/TR 19478-1. ISO/TR 19478-1 provided a basic analysis of the study data, drawing conclusions about the possible sources of the increased variability associated with the HCI regime.

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These conclusions provided the basis for the additional studies reported here and instigated to provide a more complete understanding of how the smoke yield changes with increasing smoking intensity.