



BSI Standards Publication

**Review of human
smoking behaviour and
recommendations for a new
ISO standard for the machine
smoking of cigarettes**

National foreword

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**Review of human smoking behaviour
and recommendations for a new ISO
standard for the machine smoking of
cigarettes**

*Évaluation des données relatives au comportement du fumeur et
recommandations relatives à une nouvelle norme ISO concernant le
fumage mécanique de cigarettes*





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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art" for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 17219 was prepared by Technical Committee ISO/TC 126, *Tobacco and tobacco products*.

0 Introduction

0.1 Editorial comments

This Technical Report is based on the report of the ad hoc Smoking Behaviour Review Team to ISO/TC 126. To meet ISO Central Secretariat requirements for Technical Reports the following editorial changes have been necessary.

- The Executive Summary has been made into a Conclusion.
- ‘Scope’ and ‘Abbreviated terms’ clauses have been added.
- The Bibliographies that appeared at the end of each chapter in the original report have been combined at the end of the Technical Report. Some footnotes have been replaced by notes in the text or by reference to the Bibliography.
- ISO Technical Reports are a work product of an ISO Technical Committee and as such do not have named authors.
- In the Introduction some repetition has been removed (two paragraphs describing the preparation of the report have been combined) and one paragraph was moved as a consequence.

0.2 Background

Smoking machines for measuring cigarette smoke yields were initially developed in the 1930s. The 35 ml puff volume currently used in both the International Organization for Standardization (ISO) and US Federal Trade Commission (FTC) methods was originally proposed by Bradford in 1936. Throughout the 1950s and early part of the 1960s various smoking machines were developed each using a set of parameters to define how the cigarette was smoked. Examination of the data showed that smoke yields were dependent on the smoking parameters used in the methodologies.

In 1966 the FTC in the US proposed a standardised machine smoking method with a smoking regime of 35 ml puff volume, 2 s puff duration and one puff per min. The rationale for adopting a standardised smoking regime was outlined in an FTC press release issued in 1967. The FTC stated that the method enabled products to be ranked in terms of their tar and nicotine yields. They also claimed that the yields obtained using their method would not provide individuals or groups of smokers with the precise amounts of tar or nicotine they would obtain from cigarettes. This limitation of the FTC method arises because smokers exhibit a wide range of smoking behaviour characteristics while the smoking machine uses a fixed standardised smoking regime.

Other national standards institutes had developed machine smoking methods in parallel to the activities in the US. Most of these adopted the 35 ml puff volume, 2 s duration and 1 puff per min regime, but there were differences between the various methods in factors such as butt lengths, type of smoking machine used, and the method of collecting smoke.

By the end of the 1980s a number of standardised machine smoking methods were in use worldwide. These included FTC, ISO and CORESTA methods, and methods used by the standards authorities in the UK, Germany, Canada, Australia, New Zealand and Japan. In 1988 ISO recommended that a standard worldwide smoking method was needed and they asked CORESTA to conduct the experimental work necessary to produce and validate a revised standard method. A comprehensive series of studies were subsequently conducted by CORESTA and a revised ISO method was introduced in 1991.

The ISO standard method is now used worldwide with the exception of the US and Japan. However, both the FTC method in the US and the Japanese standard method are very similar to the ISO method.

Periodically, the parameters used in the standardised machine smoking methods have been criticized for not being representative of the behaviour parameters produced by smokers. Critics have raised the following points.

- Many human smoking behaviour studies show that many smokers take larger and more frequent puffs than the standardised smoking machine.

- As a result of their more intensive puffing behaviour smokers may obtain higher smoke yields than those reported using standard methods.
- Some smokers have been observed to alter their smoking behaviour when switching to a lower yield cigarette e.g. increasing puff volume. This phenomenon is frequently referred to as “compensation”. All cigarettes are tested using the same parameters under the ISO/FTC method. Consequently, declared ISO/FTC yields would provide misleading information to smokers on the ranking of brands by smoke yields if they compensate to such an extent that rank order of yields is no longer maintained.
- The filter ventilation zones are unblocked when cigarettes are smoked using the ISO and FTC methods. However smokers may block some of the ventilation holes with their fingers or lips when smoking. Ventilation hole blocking may result in increases in smoke yields.

The WHO formed a group called the “WHO Study Group on Tobacco Product Regulation” (TobReg). During the first meeting of the TobReg group in October 2004 there was a discussion between TobReg members and representatives of ISO including the Secretariat of ISO/TC 126. TobReg expressed its view that *“the current ISO standard for machine measurement of cigarette emissions is not a valid means of comparing different brands of cigarettes relative to their emissions, human exposures that result from their use, or for purposes of regulation”*. TobReg requested that ISO modify the ISO machine standard for measuring cigarette emissions.

Representatives from the WHO Tobacco Free Initiative and TobReg were invited to present their views on the ISO method at the annual meeting of ISO/TC 126 in Geneva in 2004. It was decided that the following actions should be taken:

- 1) To consider an amendment to the scope of ISO 4387.
- 2) To review worldwide human smoking behaviour, uptake studies, and smoking methods in order to advise ISO/TC 126.
- 3) Based on the review outline in 2) to consider the development of a robust and practical smoking regime that as far as possible is representative of smokers’ behaviour and that has acceptable reproducibility and variability.
- 4) To report back to ISO/TC 126 with any proposals for a new work item.

0.3 Mandates

ISO/TC 126 proposed the formation and approved the membership of the present ad hoc group and prepared a detailed statement of work for that group. The purpose of the work was defined as:

- Identify one or more sets of values for smoking machine parameters for additional method(s).
- Propose machine smoking methods(s) more relevant to smoking behaviour which could reflect maximum yields.
- The existing ISO methods should be retained and evaluated as giving lower yields.

The ad hoc Smoking Behaviour Review Team was established with the following terms of reference.

- 1) To review worldwide human smoking behaviour documentation, uptake studies and smoking methods to advise ISO/TC 126.
- 2) To report maximum and minimum values for puff volume, puff duration, puff frequency, ventilation blocking, butt lengths and other parameters.
- 3) To recommend one or more sets of parameters for potential new practical machine smoking regimes in addition to the existing ISO standard (ISO 3308).
- 4) To identify gaps in existing knowledge.

0.4 Ad hoc Smoking Behaviour Review Team, ISO/TC 126

This report is the joint effort of the Smoking Behaviour Review Team members. The report begins with an Executive Summary outlining the recommendations of the ad hoc group. The Executive Summary was authored collectively by the ad hoc group. Each member of the ad hoc group prepared a chapter that addresses the issues named in the mandate.

The Executive Summary includes:

- a history and overview of machine smoking protocols;
- a review and summary of the published literature and some recent unpublished data on smoking topography, including a summary of puff volumes, puff durations, puff frequencies and puff numbers grouped according to ISO/FTC tar yields, geographical location and date of data collection;
- literature on filter ventilation and ventilation hole blocking;
- a review of the literature and a clause on butt length;
- an overview of studies that address the issue of cigarette smoking and nicotine intake and uptake.

0.5 Limitations

In the following clauses each of the main parameters of machine smoking are discussed. It is acknowledged that there are limitations to the use and the interpretation of smoking machine yields. Most important among the limitations of the machine smoking methods is the recognition that no machine standard can truly reflect the wide range of human smoking behaviour. People smoke cigarettes differently. The variability between smokers can be due to pharmacological as well as social, economic, and cultural differences. Furthermore smoking topography in the same person varies as a function of the time of day, social circumstance, time since the last cigarette, and the number of cigarettes smoked among other possible influences. Finally, puffing parameters differ over the course of a single cigarette. For example smokers may take larger and more frequent puffs at the beginning of a cigarette and smaller and less frequent puffs toward the end of the cigarette. It is also possible that blocking of filter ventilation holes differs over the course of smoking a single cigarette. Specifically, vent blocking may occur when some puffs are taken but not others. Thus the provisions of machine standards where all puffs are identical through the entire cigarette rod, the intervals between puffs are identical, the vent blocking is constant and the inter-puff interval is constant, does not reflect the large diversity in smoking behaviour.

In spite of these limitations the use of machine smoking represents a tenable solution to the complex problem of assigning and studying yields of commercially available cigarettes. The results of such tests are useful for the assessment of the delivery of components of tobacco smoke and for comparisons of cigarettes on the delivery of nicotine tar, carbon monoxide and other components of tobacco smoke. The consideration of new parameters for the machine smoking regimen is appropriate because of changes in cigarettes and the consumption patterns of smokers.

Review of human smoking behaviour and recommendations for a new ISO standard for the machine smoking of cigarettes

1 Scope

This Technical Report was prepared by an ad hoc Smoking Behaviour Review Team to address the following terms of reference:

- a) to review worldwide human smoking behaviour documentation, uptake studies and smoking methods;
- b) to report maximum and minimum values for puff volume, puff duration, puff frequency, ventilation blocking, butt lengths and other parameters;
- c) to recommend one or more sets of parameters for potential new practical machine smoking regimes in addition to the existing ISO standard (ISO 3308);
- d) to identify gaps in existing knowledge.

2 Abbreviated terms

Avg	Average
CORESTA	Centre de Coopération pour les Recherches Scientifiques Relative au Tabac
DoH	Department of Health (formerly known as DHSS)
DHSS	Department of Health and Social Security
FTC	Federal Trade Commission
Ind.	Individual
RH	Relative Humidity
Run	The smoking run that the cigarette was smoked in
Tar	Nicotine Free Dry Particulate Matter (NFDPM)
Tipping	Overwrap - i.e. the wrapping material applied to the mouth end of the cigarette
TNCO	Tar, nicotine and carbon monoxide
TSNAs	Tobacco specific nitrosamines
UKAS	United Kingdom Accreditation Service
USPO	United States Patent Office
Yield	The concentration of analyte measured in the smoke (normally per cigarette) when smoked in a prescribed manner