INTERNATIONAL STANDARD

First edition 2003-02-01

Tobacco and tobacco products — Monitor test piece — Requirements and use

Tabac et produits du tabac — Éprouvette de contrôle — Exigences et utilisation

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>ISO 16055:2003</u> https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-902ce9886dea/iso-16055-2003



Reference number ISO 16055:2003(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>ISO 16055:2003</u> https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-902ce9886dea/iso-16055-2003

© ISO 2003

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org Published in Switzerland

Contents

Page

Forev	vord	iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	2
5	Testing	2
6	Data sheet information	2
7	Use	3
Anne	x A (informative) Control charts	6
Bibliography		13

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>ISO 16055:2003</u> https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-902ce9886dea/iso-16055-2003

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.

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 16055 was prepared by Technical Committee ISO/TC 126, Tobacco and tobacco products.

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>ISO 16055:2003</u> https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-902ce9886dea/iso-16055-2003

Tobacco and tobacco products — Monitor test piece — Requirements and use

1 Scope

This International Standard describes the requirements for a monitor test piece as well as its use.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3308, Routine analytical cigarette-smoking machine — Definitions and standard conditions

ISO 4387, Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine (standards.iteh.ai)

ISO 5725-2, Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method

https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-ISO 7870, Control charts — General guide and introduction₃₋₂₀₀₃

ISO 7873, Control charts for arithmetic average with warning limits

ISO 8258:1991, Shewhart control charts

ISO 10315, Cigarettes — Determination of nicotine in smoke condensates — Gas-chromatographic method

ISO 10362-1, Cigarettes — Determination of water in smoke condensates — Part 1: Gas-chromatographic method

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

monitor test piece

a cigarette taken from a batch produced under particularly strictly controlled manufacturing conditions

NOTE The cigarettes in such a batch show the greatest possible homogeneity with regard to their physical, chemical and smoke yield characteristics.

3.2

analysis value

the result, based on the testing of 5 or 20 items (depending on the type of smoking machine used), of a smoking test and analysis carried out in accordance with ISO 4387, ISO 10315 and ISO 10362-1

4 Requirements

4.1 The monitor test pieces shall be produced from one production batch.

4.2 The number of monitor test pieces produced shall be sufficient to cover the needs of a period of at least 2 years.

4.3 For reasons of homogeneity, the cut tobacco used shall be taken from one well-mixed batch (if possible, it is advisable to use a single grade of tobacco with no addition of further materials, such as stems, humectants or flavours, to avoid unnecessary heterogeneity of the blend).

4.4 The non-tobacco materials used, such as cigarette paper and filters, shall be taken from one production batch and strict quality-control measures shall be applied during the production of the filters.

4.5 Specifications for the length and diameter of the monitor test piece, and for its filter length, tipping length and filter material, shall be set before production. If the design of the product includes filter ventilation, this shall also be specified prior to production.

4.6 The production tolerances on tobacco mass, circumference and draw resistance of the monitor test piece shall be controlled as precisely as possible. It will normally be necessary to increase the quality-control measures and to decrease the production machine speed to obtain the required consistency in physical, chemical and smoke yields of the monitor test pieces.

4.7 The monitor test pieces in a lot shall show consistent values for the content of nicotine-free dry particulate matter and for nicotine in their smoke. This consistency shall be assessed by means of a comparative study of sufficient size, the size chosen depending on whether the monitor is for local or broader use (see ISO 5725-2).

(standards.iteh.ai)

4.8 The packaged monitor test pieces shall be stored at a temperature below +4 °C until they are to be used. ISO 16055:2003

https://standards.iteh.ai/catalog/standards/sist/b1995a51-53af-4c61-83a2-

NOTE Other reference standards in the tobacco field require a storage temperature below -16 °C for reasons of hygiene. Normally, a storage temperature of +4 °C is sufficient for monitor test pieces.

5 Testing

Testing of the lot, including determination of the values for nicotine-free dry particulate matter and nicotine in the smoke, shall be carried out in accordance with ISO 4387, ISO 10315 and ISO 10362-1 in the form of an inter-laboratory trial run in accordance with ISO 5725-2. The study shall be performed by using the butt length given in the data sheet accompanying the monitor test piece.

Monitor test pieces for daily routine use may be produced by the individual company for its own purposes. However, for the purposes of inter-laboratory comparisons or for comparison of analytical consistency between laboratories, it is advised to use monitor test pieces from a common source. At present, a monitor test piece is available from CORESTA¹). The CORESTA monitor test piece is tested annually for consistent smoke yields in an international comparative study in accordance with ISO 5725-2.

6 Data sheet information

6.1 General

A data sheet from the source of supply of the monitor test piece shall be included. It shall contain the information set out in 6.2 and 6.3.

¹⁾ Address: CORESTA, 11, rue du Quatre-Septembre, F-75002 Paris.

6.2 General production specifications

The specifications for length, diameter, filter length, tipping length and filter material.

6.3 Analysis values from inter-laboratory testing

The results from the inter-laboratory testing of the monitor test piece, comprising:

- the butt length used;
- the type of smoking machine used;
- the average and standard deviation of the results for nicotine in the smoke;
- the average and standard deviation of the results for nicotine-free dry particulate matter;
- the two-sided confidence interval for the mean values, with a confidence level of 95 %.

7 Use

7.1 General

Monitor test pieces are used to monitor the stability of the analytical processes involved when using a cigarette-smoking machine for routine analyses in accordance with ISO 3308. In particular, they are used to assess whether the analytical process related to the machine-smoking of cigarettes (described in ISO 4387, ISO 10315 and ISO 10362-1) is "in statistical control" (see ISO 7870).

NOTE 1 As monitor test pieces are produced to process-control purposes, the product design is chosen to give smoke yields which are well suited to these purposes and thus may well not conform to official declaration restrictions. In this context, it should be understood that the monitor test piece is not to be regarded as a commercial cigarette.

The routine use of monitor test pieces may vary from laboratory to laboratory and between the two commonly used types of analytical smoking machine. The general principle is to evaluate the consistency of the values of the essential parameters (such as puff number, total particulate matter, nicotine and water in smoke condensate and nicotine-free dry particulate matter) by using control charts.

Monitor test pieces are not to be used for calibration purposes, and the results obtained with monitor test pieces shall not be used for correcting or calculating analytical data from investigation samples.

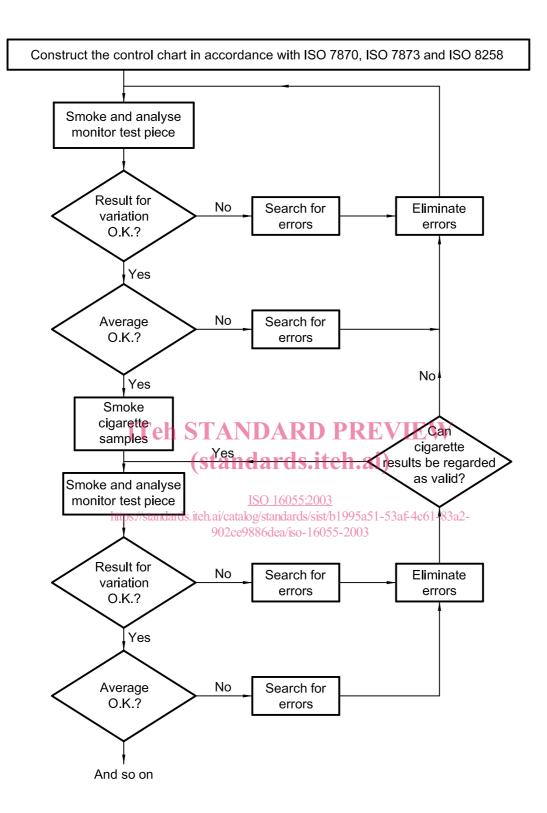
The smoke yields will normally be based upon the smoking of at least 20 cigarettes as described in ISO 4387.

The smoking of 20 cigarettes will give one average result from a rotary smoking machine whereas a linear smoking machine will give 4 average results from smoking 5 cigarettes in each of 4 channels. This means that the variation in the smoking process has to be determined by different methods for the two smoking machines. For the rotary machine, the variation may be determined as a "between smoke runs" variation whereas the variation for the linear machine may be determined from the 4 individual results from the 4 channels. In other words, the process variation from the rotary smoking machine is based on "independent" single results while the variation from the linear smoking machine can be based on 4 results from one smoke run but from 4 "independent" channels.

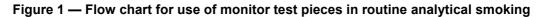
This means that different types of control chart have to be used for the two smoking machines. The actual choice shall be made according to the actual demands and cannot be specified to fit all needs. Annex A gives advice on, and examples of, the practical use of control charts.

NOTE 2 This advice is based on the statistical theory described in ISO 7870, ISO 7873 and ISO 8258 combined with practical experience from daily use.

Figure 1 illustrates the use of monitor test pieces in routine smoking analysis.



IMPORTANT: When analysing the control chart, always test for assignable causes in accordance with ISO 8258 and ISO 7873.



7.2 Practical procedures for the use of monitor test pieces

The practical procedures for use of monitor test pieces are based upon the condition that the consistency of a process can be evaluated by analysing control samples at chosen intervals, and comparison of the test results graphically in a control chart (see ISO 7870).

The frequency at which the monitor test pieces shall be analysed cannot be specified. It depends on the local need. But the following considerations describe the importance of a practical choice (see also ISO 8258:1991, 10.4).

Under the condition that the analytical process is consistent (stable), it is assumed that all the analytical results obtained between two valid results from the monitor test pieces are also valid. In contrast, results obtained during a period which begins with a valid check result and ends with a non-valid check result must be regarded as non-valid until further investigations have indicated their validity. Thus there is a risk of having to reject these results and having to repeat the analysis. To avoid the loss of large numbers of results, it is important to analyse the monitor test piece at intervals which are not "too great". It becomes a balance between analytical capacity and need for confirmation of consistency.

The procedure for the two types of smoking machine will be different but based, of course, upon the same principle — sequential smoking and confirmation of the validity of the smoking results.

The following procedure can be recommended:

For the rotary smoking machine: At the beginning of a series of smoking analyses, a smoking run and an analysis is performed with the monitor test piece. At practical intervals (for example for each 10 to 15 smoke runs), this procedure should be repeated, ending the day with smoking of the monitor test piece.

For the linear smoking machine: At the beginning of a series of smoking analyses, the monitor test piece is smoked on a selection of channels (4 would normally fit into a smoking plan). During the daily smoking, this could be repeated at a practical frequency, with test pieces being smoked on 4 channels for every 2 or 3 smoke runs. To secure the best information, it is important that smoking of the monitor test piece is evenly distributed on all 20 channels over a period of time.

7.3 Practical use of control charts

The analysis values from smoking and analysis of monitor test pieces are plotted on the appropriate control charts (see Annex A and ISO 7870, ISO 7873 and ISO 8258) so that the results for average and for variation can be evaluated.

It is possible to use control charts where standard values are given, but also where the standard values are not given (see ISO 8258:1991, 4.1, 4.2 and Clause 12). This means that control charts can be constructed for the individual laboratory without knowledge of the official target values for the test piece, but the control chart can also be constructed with reference to target values.

The control charts may have both warning and action limits (see ISO 7873) or have only one set of control limits (see ISO 8258). Either kind of control chart can be used, but for the correct evaluation of the consistency of the analytical process it is very important that the rules for testing for assignable causes (see ISO 8258:1991, introduction and Clause 7) are followed.

It is a matter of choice whether to use control charts with or without target values combined with one set or two sets of control limits. It depends on the actual needs. It may be practical to combine the target values from the inter-laboratory testing with the results from the individual laboratory's own routine check. On the other hand, this may be impractical for laboratories which have analytical averages which differ from the target values. In these cases, the consistency check will be affected by the obstruction of the control limits by the official target values, and it may be better to determine any difference between the local average and the official average by other statistical methods for differences between variances and between averages.