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

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

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

This third edition cancels and replaces the second edition (ISO 16055:2012), which has been technically revised. The main changes compared to the previous edition are as follows:

— to align with the more intensive smoking regimes used in ISO 20778 and ISO 20779.

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

1 Scope

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

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*

ISO 7870-2:2013, *Control charts — Part 2: Shewhart control charts*

ISO 8454, *Cigarettes — Determination of carbon monoxide in the vapour phase of cigarette smoke — NDIR method*

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*

ISO 10362-2, *Cigarettes — Determination of water in smoke condensates — Part 2: Karl Fischer method*

ISO 20778, *Cigarettes — Routine analytical cigarette smoking machine — Definitions and standard conditions with an intense smoking regime*

ISO 20779, *Cigarettes — Generation and collection of total particulate matter using a routine analytical smoking machine with an intense smoking regime*

ISO 22947, *Cigarettes — Determination of carbon monoxide in the vapour phase of cigarette smoke with an intense smoking regime — NDIR method*

ISO 22253, *Cigarettes — Determination of nicotine in smoke condensates with an intense smoking regime— Gas-chromatographic method*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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3.1
monitor test piece
sample produced for a specific test purpose, validated to fulfil requirements within specified tolerances and intended to be used for laboratory purposes only and labelled to clearly indicate that it is not for human use

Note 1 to entry: A monitor test piece is a sample taken from a batch of cigarettes that show the greatest homogeneity with regard to their physical, chemical and smoke yield characteristics.

3.2
analysis value
result of a smoking test and analysis carried out in accordance with ISO 4387, ISO 8454, ISO 10315 and ISO 10362-1 (or ISO 10362-2) or for intense smoking in accordance with ISO 20779, ISO 22947 and ISO 22253 respectively

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 two 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.

Recommended specifications for the production of the monitor test piece are to be found in Annex B.

The requirements shall now include a stable yield for carbon monoxide which is best obtained with a non-ventilated filter. Therefore, the recommendation is that the monitor test piece is unventilated.

If it is necessary to use humectants for the tobacco, only glycerol is allowed. Propylene glycol cannot be used due to its high vapour pressure, which may lead to uncontrolled (undetected) loss of mass during conditioning.

4.5 The production tolerances on tobacco mass, circumference and draw resistance of the monitor test piece shall be controlled as precisely as possible. It is often 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. Mass control is critical in the production of a reliable monitor test piece. Excessive mass variation contributes to unacceptable variation in smoke yields. The standard deviation of mass of individual monitor test piece shall be controlled to below 16 mg.

4.6 The monitor test pieces in a lot shall show consistent values for the content of nicotine-free dry particulate matter, nicotine and carbon monoxide in their smoke yields under the use of the smoking regime specified in ISO 3308 and for the content of nicotine and carbon monoxide under the use of smoking regime specified in ISO 20778. 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).

4.7 The packaged monitor test pieces shall be stored at a temperature below or equal to +4 °C until they are to be used.

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.

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4.8 The product design shall ensure that the smoke yields (nicotine-free dry particulate matter, nicotine and carbon monoxide) are sufficiently high per monitor test piece (approximately 14 mg NFDPM and carbon monoxide, approximately 1,4 mg nicotine under the use of the smoking regime specified in ISO 3308) so that the influence from a possible offset in the smoking machine settings can be distinguished from the normal variation of the smoke yields.

NOTE Under the use of the intense smoking regime as specified in ISO 20778, much higher yields are expected. A study carried out in 2010 has shown that the yields for products as described above will increase to approximately 26 mg carbon monoxide and 2,7 mg nicotine.

4.9 It is essential to make the monitor test piece clearly distinguishable from commercial cigarettes. The monitor test pieces shall be packed in hard boxes of 20 which should be carrying a text.

EXAMPLE CORESTA approved, Monitor No. X, for non-consumer laboratory purposes only. Not a commercial product [date of production].

5 Testing

Testing of the lot, including determination of the values for carbon monoxide, nicotine-free dry particulate matter and nicotine in the smoke, shall be carried out in accordance with ISO 8454, ISO 4387, ISO 10315 and ISO 10362-1 or ISO 10362-2 in the form of an inter-laboratory trial run in accordance with ISO 5725-2. For the intense smoking regime, the test for carbon monoxide and nicotine shall be performed in accordance with ISO 20779, ISO 22947 and ISO 22253. 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 interlaboratory 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 CORESTA[6].

The CORESTA monitor test piece is tested annually for consistent smoke yields in an interlaboratory study in accordance with ISO 5725-2.

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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.

6.2 General production specifications

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

6.3 Analysis values from interlaboratory testing

The results from the interlaboratory testing of the monitor test piece, comprising:

— the smoking regime being used;

— 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, if applicable;

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— the average and standard deviation of the results for carbon monoxide in the smoke;

— 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 or ISO 20778. In particular, they are used to assess whether the analytical process related to the machine-smoking of cigarettes is “in statistical control” (see ISO 7870-1).

As monitor test pieces are produced for 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, carbon monoxide in the vapour phase, total particulate matter and nicotine as well as water in smoke condensate and nicotine-free dry particulate matter, if applicable) by using control charts.

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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.

NOTE 1 The monitor test piece cannot control the process of vent blocking required by the smoking regime specified in ISO 20778.

The smoke yields will normally be based upon the smoking of at least 20 monitor test pieces/cigarettes as described in ISO 4387 or in ISO 20779.

The smoking of 20 cigarettes under ISO 3308 conditions or 10 cigarettes under ISO 20778 conditions 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 under ISO 3308 conditions or 3 cigarettes in each of 4 channels under ISO 20778 conditions. 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 7870-1, ISO 7870-2 and ISO 7873 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 7870-2.

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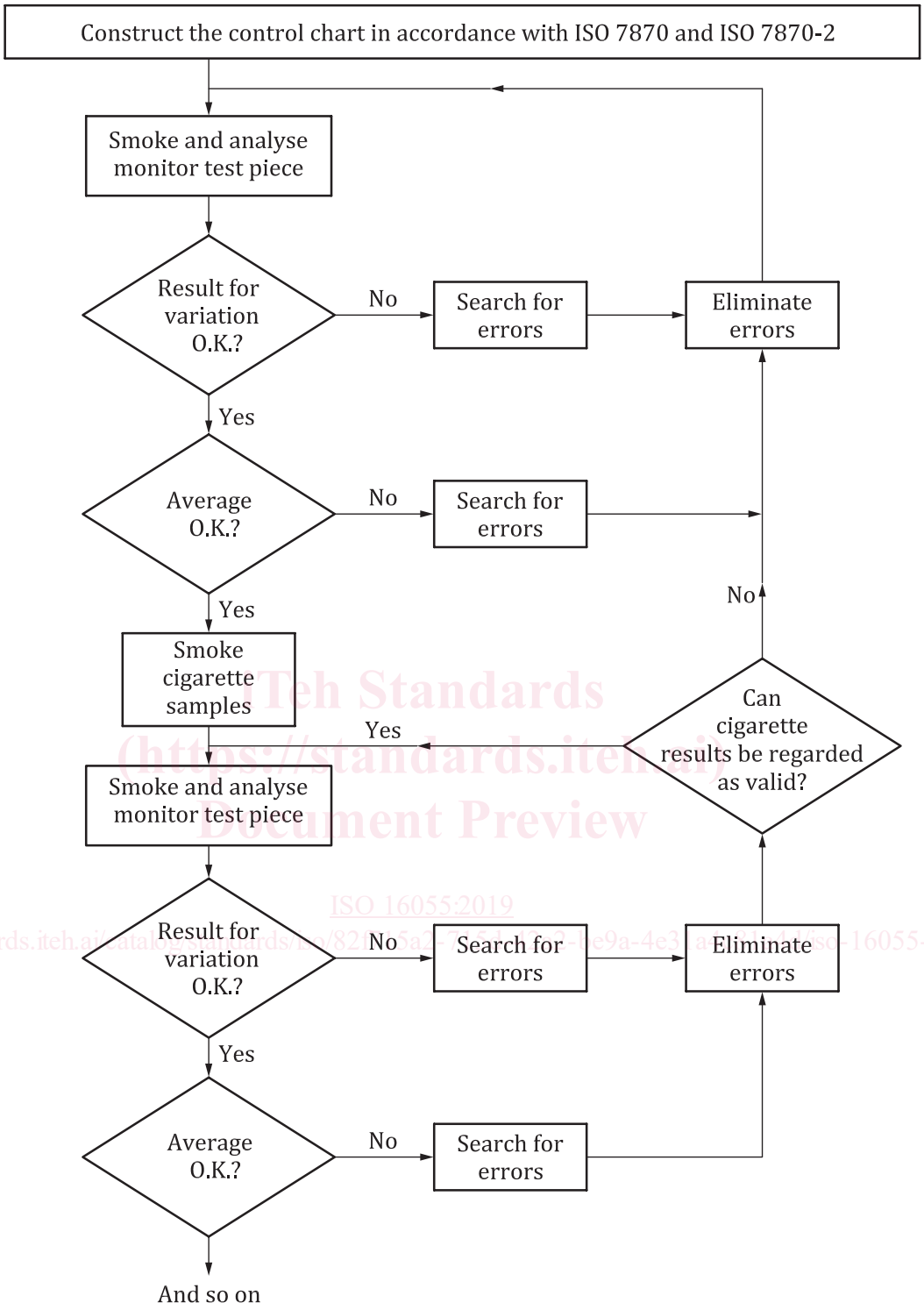

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Figure 1 — Flow chart for use of monitor test pieces in routine analytical smoking

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 7870-1).

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The frequency at which the monitor test pieces shall be analysed cannot be specified. It depends on the local need. However, the following considerations describe the importance of a practical choice (see also ISO 7870-2:2013, 11.4).

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 shall 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 sufficient intervals to reduce this risk. 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.

a) 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.

b) 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 channels over a period of time.

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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 as well as ISO 7870-1, ISO 7870-2 and ISO 7873) 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 7870-2:2013, 5.1, 5.2 and Annex A). 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 only one set of control limits (see ISO 7870-2). 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 7870-2:2013, Introduction and Clause 8) 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 interlaboratory 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.

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