BS ISO 16055:2012

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

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National foreword

This British Standard is the UK implementation of ISO 16055:2012. It supersedes BS ISO 16055:2003 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee AW/40, Tobacco and tobacco products.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

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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.

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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*.

This second edition cancels and replaces the first edition (ISO 16055:2003), which has been technically revised.

INTERNATIONAL STANDARD **ISO 16055:2012(E)**

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*

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 7870-1, *Control charts — General guide and introduction*

ISO 7873, *Control charts for arithmetic average with warning limits*

ISO 8258:1991, *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*

3 Terms and definitions

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

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, 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 8454, ISO 10315 and ISO 10362-1 (or ISO 10362-2)

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 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. 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 must 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. 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.

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) so that the influence from a possible offset in the smoking machine settings can be distinguished from the normal variation of the smoke yields.

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. 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 CORESTA[1)]. 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.

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 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. In particular, they are used to assess whether the analytical process related to the machine-smoking of cigarettes [described in ISO 3402, ISO 4387, ISO 8454, ISO 10315 and ISO 10362-1 (or ISO 10362-2)] is “in statistical control” (see ISO 7870-1).

NOTE 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,

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

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 monitor test pieces/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 7870-1, 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.

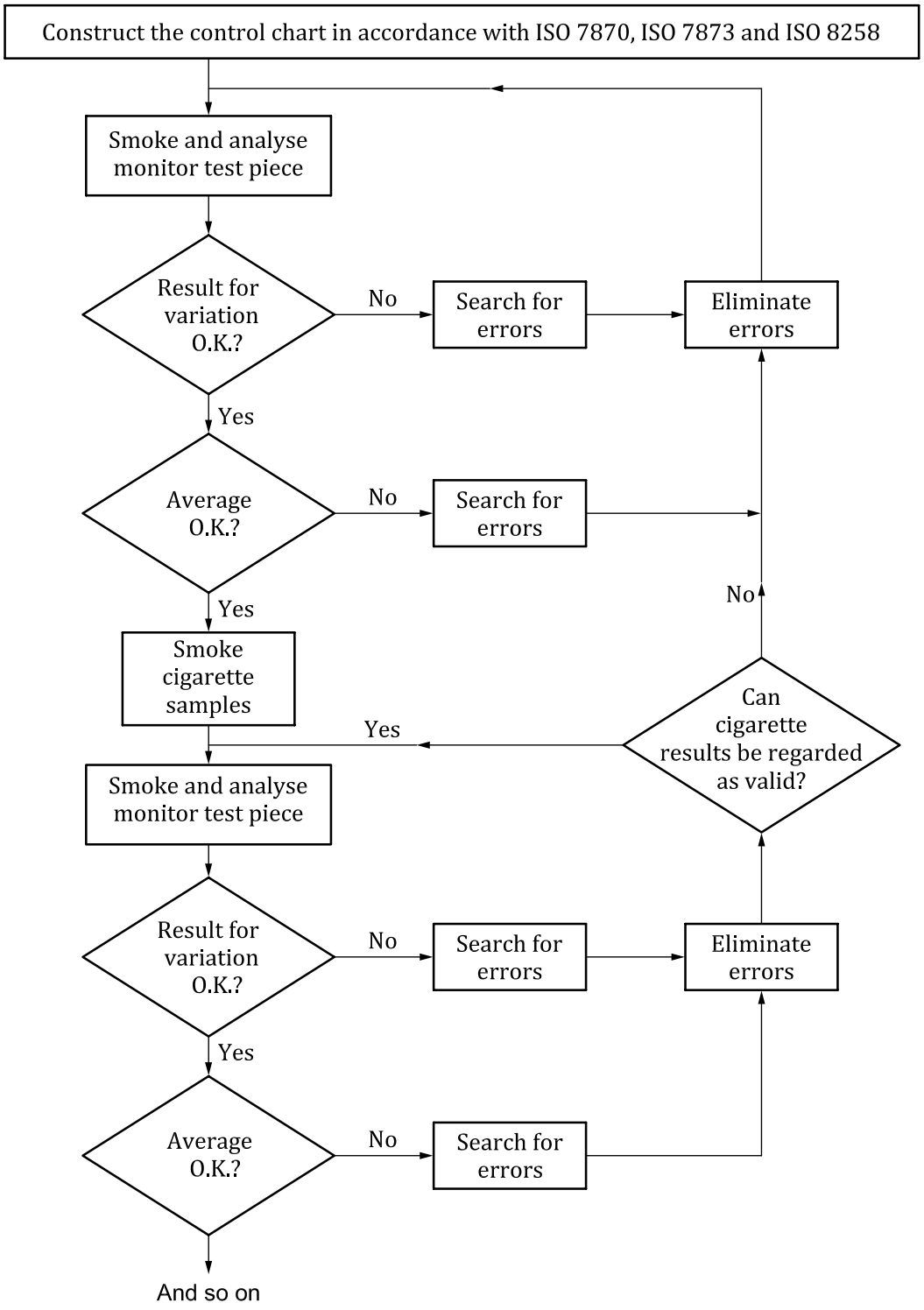


Figure 1 — Flow chart for use of monitor test pieces in routine analytical smoking

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).

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 7870-1, 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.

Annex A
(informative)

Control charts

A.1 General

The choice of control charts for plotting results from smoking and analysis of the monitor test piece is illustrated below by three examples which are by no means mandatory or complete. (For further information, see e.g. ISO 8258, ISO 7870-1 and ISO 7873 which describe the theory and use of control charts. ISO 8258 also includes information about the eight tests necessary for interpreting patterns in the control charts, tests which are vital before the decision is made that a control chart is "in control".) The first two examples describe different types of control chart: one for smoking processes which give more than one result per smoke run (typically smoking on several channels on linear smoking machines) and the other for smoking processes which give only one result per smoke run (typically smoking on a rotary smoking machine). The third example is a control chart with standard values given and may be used in cases where smoking analysis is not performed continuously.

A.2 Calculation of control chart limits

A.2.1 Examples 1 and 2

A.2.1.1 General

A suitable control chart for linear machines can be a "mean and standard deviation" chart (or a "mean and range" chart). For the rotary smoking machine, an "individuals" chart (also known as a "mean and moving range" chart) is described.

Two sets of results for calculation of control limits for nicotine-free dry particulate matter (NFDPM) are given in Table A.1, in which the subgroup averages in Example 1 and the results in Example 2 have been chosen so that they are identical. The examples are chosen to be as realistic as possible and in fact could be seen as practical laboratory results. The calculations are performed as described in ISO 8258. The control charts are shown in Figures A.1 and A.2. Please note that in Figure A.1 the 12th result in the mean chart is "out of control" which ought, of course, to have prompted deliberations concerning the actual consistency of the smoke analysis immediately after the analysis.

The examples given are control charts without warning limits. Should warning limits be required, they can be calculated at a distance from the central line equal to 2σ.

NOTE The number of subgroups necessary for the construction of a control chart is important. ISO 8258 recommends in the text that 20 to 25 subgroups should be obtained but the examples go as low as 15. No safe number can be given, but care should be exercised that the analytical process during the initial collection of data is not influenced intermittently by extraneous changes such as in machine settings or other external factors.

Table A.1 — Examples of the calculation of control chart limits

EXAMPLE 1				**EXAMPLE 2**		
Linear smoking machine (smoking on 4 channels)				**Rotary smoking machine**		
Mean and standard deviation chart				**Mean and moving range chart**		
Subgroup number	**Subgroup average**	**Subgroup standard deviation**		**Subgroup number**	**Result**	**Moving range** R
	mg NFDPM	mg NFDPM			mg NFDPM	mg NFDPM
1	15,0	0,52		1	15,0	—
2	15,2	0,54		2	15,2	0,2
3	15,2	0,24		3	15,2	0,0
4	15,8	0,22		4	15,8	0,6
5	15,6	0,47		5	15,6	0,2
6	15,7	0,69		6	15,7	0,1
7	15,1	0,57		7	15,1	0,6
8	16,0	0,29		8	16,0	0,9
9	14,9	0,12		9	14,9	1,1
10	14,9	0,55		10	14,9	0,0
11	15,4	0,67		11	15,4	0,5
12	14,5	0,63		12	14,5	0,9
13	15,6	0,56		13	15,6	1,1
14	15,1	0,33		14	15,1	0,5
15	15,5	0,43		15	15,5	0,4
Mean	$\overline{\overline{x}}$ = 15,30	$\overline{s}$ = 0,455		Mean	$\overline{x}$ = 15,30	$\overline{R}$ = 0,51
UCL	16,04	1,03		UCL	16,20	1,67
LCL	14,56	0		LCL	14,40	0
NOTE UCL = Upper control limit; LCL = Lower control limit.						

A.2.1.2 Formulae for the calculation of UCL and LCL in the mean and standard deviation chart (Example 1)

$UCL_{\overline{x}}$ and $LCL_{\overline{x}}$, expressed in mg of NFDPM, are given by the equations:

$$UCL_{\overline{x}} = \overline{\overline{x}} + 1{,}628 \times \overline{s}$$

$$LCL_{\overline{x}} = \overline{\overline{x}} - 1{,}628 \times \overline{s}$$

where

1,628 is the factor for the control limits (see ISO 8258:1991, Table 2, A_3 for $n = 4$);

UCL_s and LCL_s, expressed in mg of NFDPM, are given by the equations:

$$UCL_s = 2{,}266 \times \overline{s}$$

2,266 being the factor for the control limits (see ISO 8258:1991, Table 2, B_4 for $n = 4$),

$$LCL_s = 0 \times \overline{s}$$

0 being the factor for the control limits (see ISO 8258:1991, Table 2, B_3 for $n = 4$).

A.2.2 Formulae for the calculation of UCL and LCL in the mean and range chart (Example 2)

UCL_x and LCL_x, expressed in mg of NFDPM, are given by the equations:

$$UCL_x = \overline{x} + \frac{2}{1{,}128} \times \overline{R}$$

$$LCL_x = \overline{x} - \frac{2}{1{,}128} \times \overline{R}$$

where

$\frac{2}{1{,}128}$ is the factor for the control limits (see ISO 8258:1991, Table 3, $E_2 = \frac{3}{d_2}$ and Table 2, $d_2 = 1{,}128$ for $n = 2$).

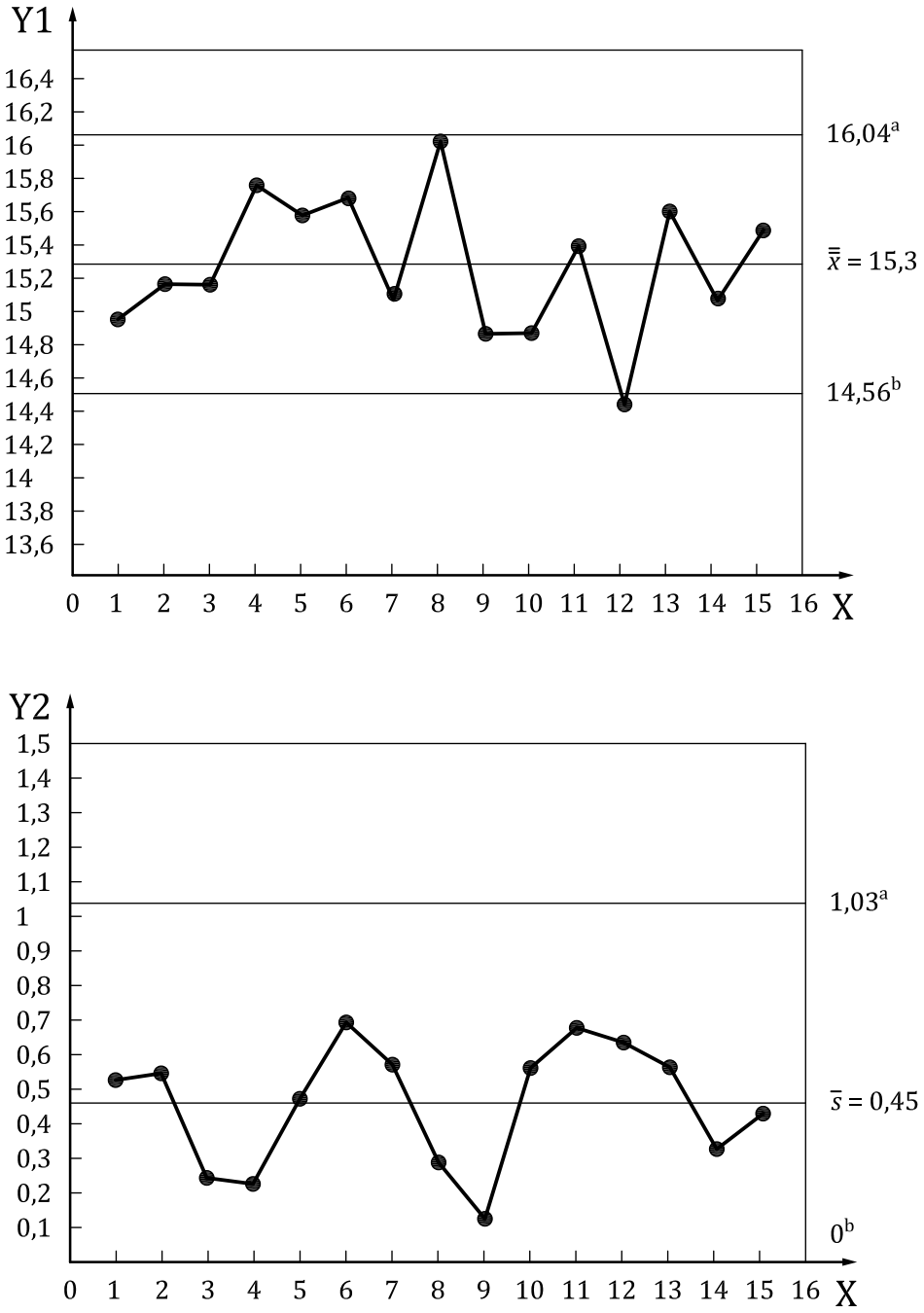
UCL_R and LCL_R, expressed in mg of NFDPM, are given by the equations:

$$UCL_R = 3{,}267 \times \overline{R}$$

3,267 being the factor for the control limits (see ISO 8258:1991, Table 2, D_4 for $n = 2$),

$$LCL_R = 0 \times \overline{R}$$

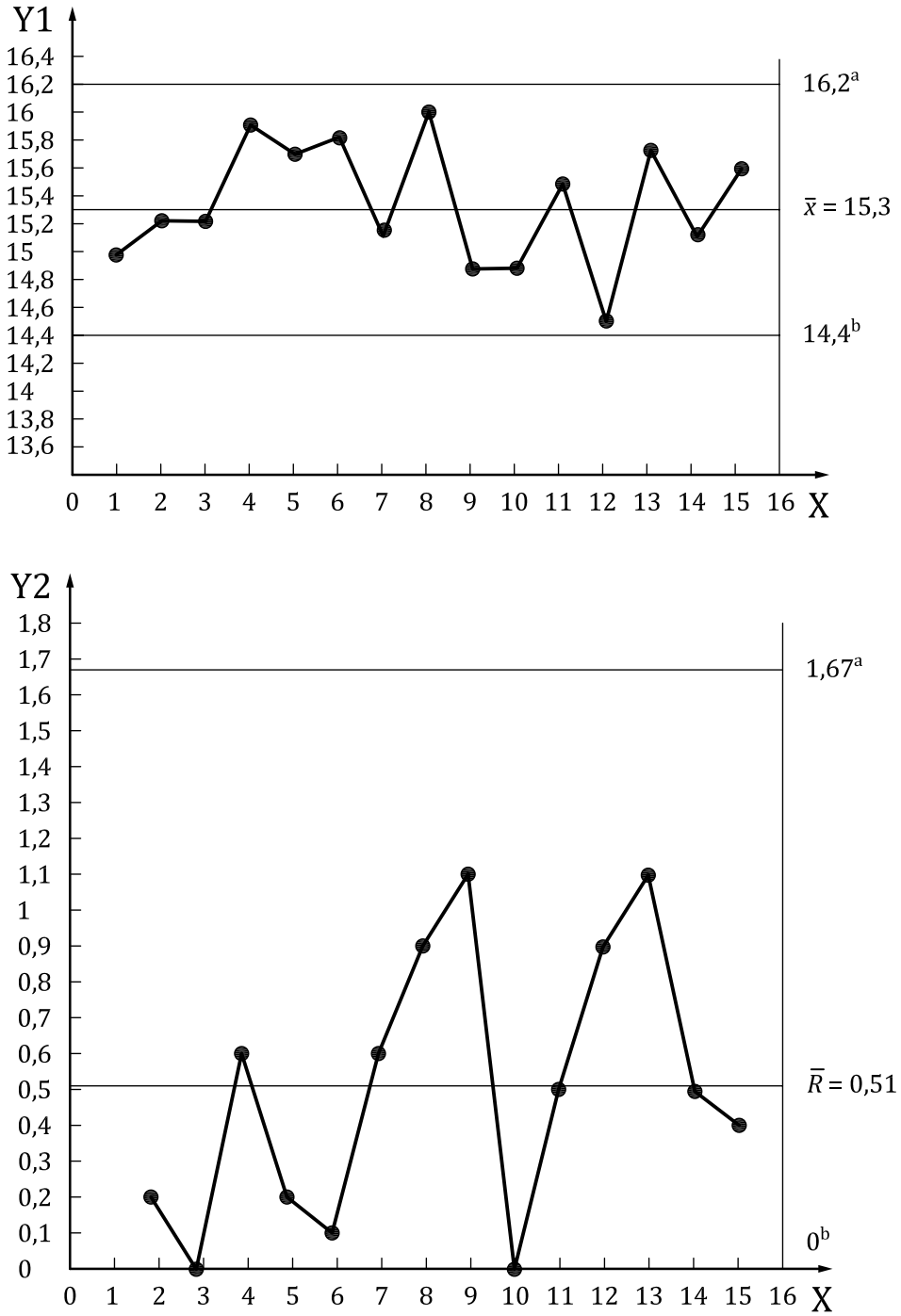
0 being the factor for the control limits (see ISO 8258:1991, Table 2, D_3 for $n = 2$).



Key

X subgroup no.
Y1 NFDPM (mg)
Y2 standard deviation
a UCL.
b LCL.

Figure A.1 — Mean and standard deviation chart



Key

X subgroup no.
Y1 NFDPM (mg)
Y2 moving range
a UCL.
b LCL.

Figure A.2 — Mean and moving range chart

A.2.3 Example 3

A.2.3.1 General

Control charts with standard values may be used in cases where a laboratory does not perform smoking analysis continuously. The control charts are intended for use only as an internal control of the consistency of the smoking analysis within the laboratory.

In contrast to Examples 1 and 2, no explicit data are given for this example, only a raw control chart being shown in Figure A.3. The standard values for this control chart should be taken from an inter-laboratory trial (see NOTE) in which the smoke yields between individual laboratories may exhibit greater scatter than the smoke yields within an individual laboratory. Thus it is necessary to assume that not every individual laboratory will obtain results which approximate to the mean values from the inter-laboratory trial. This means that the individual laboratory can have mean smoke yields which differ from the standard values and at the same time still be regarded as smoking correctly as long as the control chart is in control and the smoke yields are within the variation over time to be expected from the inter-laboratory trial.

If smoke yields deviate systematically from the standard values (i.e. their scatter has e.g. a high variation over the whole range), it is advisable for the laboratory to try to detect and correct the possible causes of this deviation, but under no circumstances should the laboratory correct the level-of-smoke results by taking any non-scientific measures or by making any arithmetic calculations.

NOTE At the time of publication of this International Standard, the only international inter-laboratory smoking trial which exists is the annual smoking trial with the CORESTA monitor test piece which is performed by the CORESTA Routine Analytical Chemistry Sub-Group. Results from this trial can be obtained from the Secretary-General of CORESTA.

A.2.3.2 Formulae for the mean chart

The mean value (x_0) and standard deviation (σ_0) for NFDPM are taken from the CORESTA annual smoking trial using the CORESTA CM 3 monitor test piece (1999). LCL_x and UCL_x are given by the following equations:

$$LCL_x = x_0 - 3\sigma_0 = 13{,}71$$

$$UCL_x = x_0 + 3\sigma_0 = 16{,}55$$

where

x_0 is the mean of the subgroup measurements $x_0 \triangleq (\bar{x} = 15{,}13)$;

σ_0 is the standard variation of the laboratory mean values in the inter-laboratory study ($\sigma_0 = s = 0{,}473$).

A.2.3.3 Formulae for moving range chart

For control of the intra-laboratory variation, the mean value of the intra-laboratory variation ($\sigma_1 = 0{,}275$) is used for the moving range chart. The central line (CL), LCL_R and UCL_R are given by the following equations:

$$CL = 1{,}128 \times \sigma_1 = 0{,}310$$

$$LCL_R = 0 \times \sigma_1$$

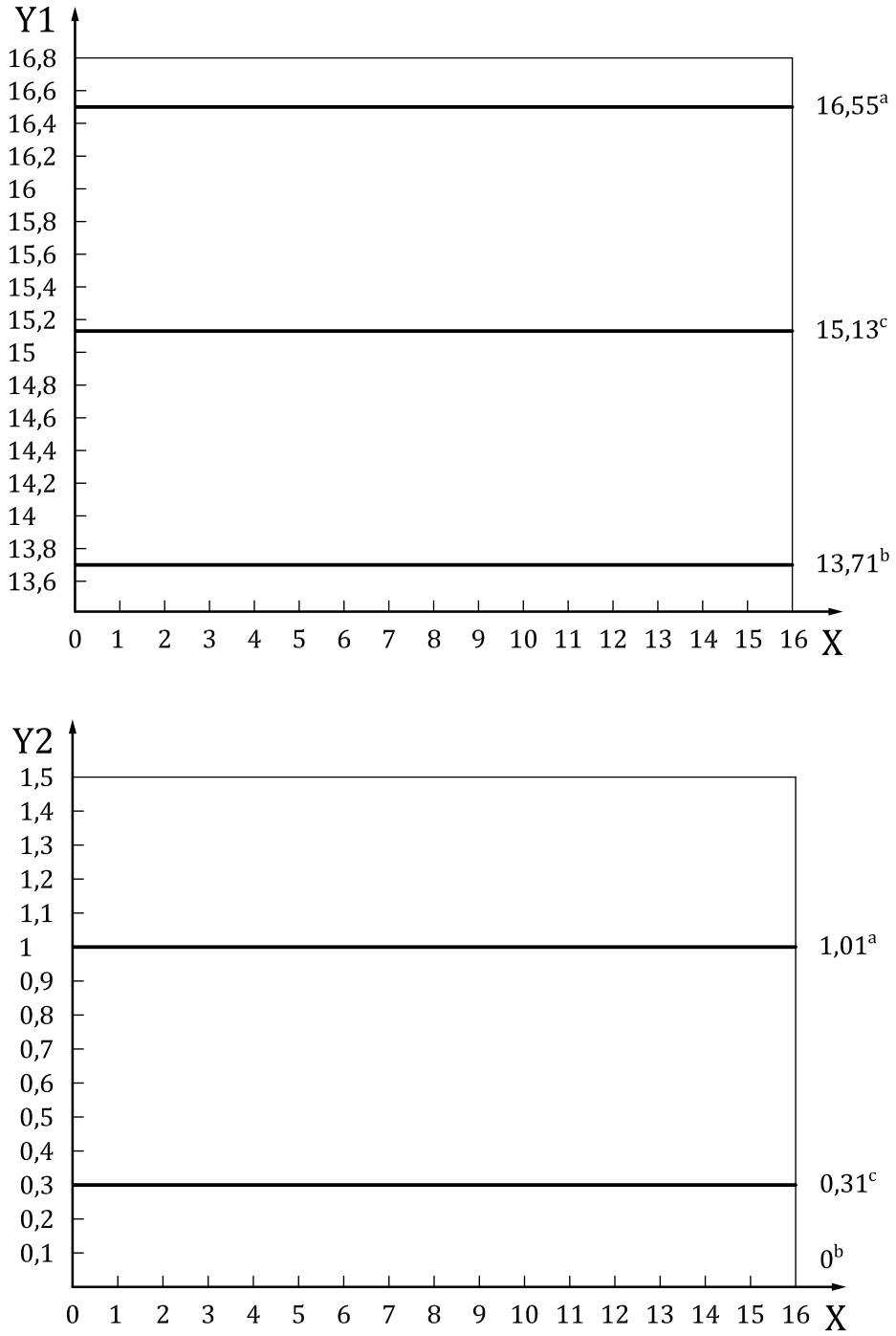
$$UCL_R = 3{,}686 \times \sigma_1$$

where

1,128 is the factor for the control limits (see ISO 8258:1991, Table 3 and Table 2, d_2 for $n = 2$);

0 is the factor for the control limits (see ISO 8258:1991, Table 3 and Table 2, D_1 for $n = 2$);

3,686 is the factor for the control limits (see ISO 8258:1991, Table 3 and Table 2, D_2 for $n = 2$).



Key

X subgroup no.
Y1 NFDPM (mg)
Y2 moving range
a UCL.
b LCL.
c Central line.

Figure A.3 — Mean and moving range chart

Annex B
(informative)

Monitor test piece — Specification

It is recommended that the following specifications be met for CORESTA monitor test piece production:

Table B.1 — Tobacco blend and cut rag

Parameter	Description
Type of tobacco	Flue cured lamina without stems
Additives	Preferably none, but absolutely no more than 2 % glycerol
Cut width	≈ 0,9 mm

Table B.2 — Monitor test piece dimensions

Parameter	Value
Test piece length	≈ 83 mm (king size)
Test piece diameter	≈ 7,8 mm
Test piece mass	≈ 980 mg
Test piece pressure drop	≈ 1,4 kPa[a]
Rod length	≈ 62 mm
Rod mass	≈ 820 mg
Tobacco mass	≈ 780 mg
Tobacco density	≈ 260 mg/cm^3
Tobacco moisture	≈ 12,0 %

[a] Pressure drop may also be expressed in millimetres water gauge (mmWG). 1,4 kPa ≈ 140 mmWG.

Table B.3 — Monitor test piece non-tobacco materials

Parameter	Value
Filter rod diameter	≈ 7,8 mm
Tow specification	High-crimp cellulose acetate tow of type 2,8Y36HK (dtex units) (in denier units 2,5Y32HK) or similar
Filter pressure drop	In the range 0,75 kPa to 0,8 kPa[a]
Plasticiser	≈ 7 % triacetin
Plug wrap	Non-porous
Filter length	≈ 21 mm
Tipping	Distinguishable from commercial products (i.e. grey tipping) with CM logo, no perforation preferable
Tipping width	≈ 29 mm
Test piece paper	Wood pulp, filler precipitated calcium carbonate ≈ 30 %, air permeability ≈ (40 to 50) $cm^3\ min^{-1}\ cm^{-2}$ at a pressure differential of 1 kPa[b], citrate (expressed as anhydrous citric acid) ≈ 0,7 %
Paper width	≈ 26 mm

[a] Pressure drop may also be expressed in millimetres water gauge (mmWG). 0,75 kPa to 0,8 kPa ≈ 75 to 80 mmWG.

[b] Air permeability may also be expressed in CORESTA units (CU). 1 CU = 1 $cm^3\ min^{-1}\ cm^{-2}$.

Table B.4 — Smoke yields

Parameter	Value
NFDPM	≈ 14 mg/monitor test piece
Nicotine	≈ 1,4 mg/monitor test piece
CO	≈ 14 mg/monitor test piece
Puff number	≈ 9

Bibliography

[1] ISO 3400, *Cigarettes — Determination of alkaloids in smoke condensates — Spectrometric method*

[2] ISO 3402, *Tobacco and tobacco products — Atmosphere for conditioning and testing*

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