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ISO and Health Canada intense smoking parameters

Part 1: Results of an international machine smoking study

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National foreword

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TECHNICAL REPORT

ISO/TR 19478-1

First edition
2014-11-01

ISO and Health Canada intense smoking parameters —

Part 1: Results of an international machine smoking study

Paramètres de fumage ISO et Santé Canada Intense —

Partie 1: Résultats d'une étude internationale de fumage sur machine

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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 Institute for the development of 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 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."

At its fifth meeting, in December 2009, WG 10 decided to undertake a collaborative study using both ISO 3308 and Health Canada Intense smoking regimes. A steering group was established and the laboratory work was carried out in 2010. A final report on the study was approved by WG 10 and this ISO Technical Report has been prepared at the request of WG 10 at its tenth meeting, in June 2012.

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ISO and Health Canada intense smoking parameters —

Part 1: Results of an international machine smoking study

1 Scope

This part of ISO/TR 19478 comprises a description of the collaborative study undertaken by WG 10 during 2010 and 2011 and an analysis of the data generated in the study.

2 Abbreviated terms

C	Cochran
cig	Cigarette
CM	CORESTA monitor test piece
CO	Carbon monoxide
CORESTA	Centre de Coopération pour les Recherches Scientifiques Relative au Tabac
DG	Double Grubbs
FTC	Federal Trade Commission
G	Grubbs
HCI	Health Canada Intense (smoking machine regime)
NFDPM	Nicotine-free dry particulate matter
r	Repeatability
R	Reproducibility
SD	Standard deviation
TPM	Total particulate matter
Yield	Concentration of analyte measured in the smoke (normally per cigarette) when smoked in a prescribed manner

3 Objectives

The objectives of the collaborative study organized by WG 10 are the following:

— To measure the mainstream smoke yields of nicotine-free dry particulate matter (NFDPM), nicotine and carbon monoxide (CO) from eight commercial cigarette products of different types, and two reference cigarettes/monitor test pieces (test articles) when smoked under both the ISO 3308 and the Health Canada Intense (HCI) (Health Canada, 1999) machine smoking regimes.

— To determine intra-laboratory and inter-laboratory variability for the measured smoke yields.

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4 Test protocol

The protocol was agreed by WG 10 at its meeting on 30th April 2010 and is summarized here.

— Participants and test results were coded by the ISO/TC 126 Secretariat to make them anonymous.

— Ten test articles were used: 8 commercial cigarettes of different designs, one reference cigarette, one monitor test piece, with ISO NFDPM yields ranging from 1 mg to 14 mg per test article.

— The following test parameters were measured and recorded: total particulate matter (TPM), nicotine, water, nicotine-free dry particulate matter (NFDPM), carbon monoxide (CO), puff count, and cigarette mass.

— Comparison of data from the two smoking regimes (ISO and HCI).

— The design was based on a set number of smoked test articles and smoking runs.

— Both linear and rotary smoking machines were used in the study.

The protocol was sent to the participants in May 2010. All test results were reported between July and September 2010 to the ISO/TC 126 Secretariat and compiled for evaluation.

5 Participants

Thirty-five participants from 21 countries took part in the study with six laboratories contributing two data sets for each smoking regime (ISO and HCI). The participating laboratories, sorted by country, are listed in Table 1.

Table 1 — List of participants

Company or Institute	Country
Japan Tobacco International/Ökolab	Austria
Papierfabrik Wattens GmbH & Co KG	Austria
Souza Cruz S.A.	Brazil
Labstat International ULC	Canada
China National Tobacco Corporation (2 laboratories)	China
Laboratoire National de Métrologie et d'Essais	France
Imperial Tobacco Group	France
British American Tobacco Germany	Germany
Borgwaldt KC GmbH	Germany
Chemisches und Veterinäruntersuchungsamt Sigmaringen	Germany
Japan Tobacco International Germany GmbH	Germany
Reemtsma/Imperial Tobacco	Germany
General State Laboratory of Greece, Department of Serres	Greece
Tobacco Institute of Greece	Greece
Central Tobacco Research Institute	India
Godfrey Philips India Limited	India
Indian Tobacco Company Limited	India
Vazir Sulton Tobacco Company India	India
PT HM Sampoerna Tbk	Indonesia
Japan Tobacco Inc.	Japan

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Table 1 *(continued)*

Company or Institute	Country
Heintz van Landewyck	Luxembourg
Testing Laboratory of Tobacco and Tobacco Products, Tututn CTC S.A.	Moldova
Food and Consumer Product Safety Authority	Netherlands
British American Tobacco Polska S.A.	Poland
Russian Research Institute of Tobacco and Tobacco Products	Russia
British American Tobacco South Africa	South Africa
Korea Tobacco & Ginseng Central Research Institute	South Korea
Centro de Investigación y Control de la Calidad	Spain
Philip Morris International	Switzerland
Arista Laboratories Europe	United Kingdom
British American Tobacco GR&D	United Kingdom
Filtrona Technology Centre	United Kingdom
Altria Client Services	USA
Lancaster Laboratories	USA
Lorillard Tobacco Company	USA

6 Test articles

Eight commercial cigarettes, the CORESTA monitor test piece (CM6), and the University of Kentucky reference cigarette 1R5F were used in this study (Table 2). Every participant received 20 packs of each of the eight commercial cigarettes from the coordinators, coded A to H, per smoking machine. Some laboratories used more than one smoking machine and required additional batches for each machine. Test articles I and J were purchased by the participants themselves. However, not all participants were able to smoke all the 10 test articles for the reasons described in Clause 8.

Table 2 — Test articles

Code	Name	Nominal ISO NFDPM yield (mg/cig)	Filter/Product style	Filter ventilation %	Blend style	Supplier
A	L&M One	1	Monoacetate King Size (83 to 84) mm	76	US Blended	Philip Morris International
B	Gold Coast	5	Monoacetate King Size (83 to 84) mm	52	US Blended	Japan Tobacco International
C	Fortuna	10	Monoacetate King Size (83 to 84 mm)	26	US Blended	Imperial Tobacco Group
D	Players Smooth KS	10	Monoacetate King Size (83 to 84) mm	34	Virginia	Imperial Tobacco Canada
E	Gitanes	10	Plain (no filter)	—	Dark Tobacco	Imperial Tobacco Group
F	Misty FSC Blue Lights	10	Slim (22 mm circumference)	42	US Blended	R J Reynolds Tobacco

[a] The yield was determined by the method described by the Federal Trade Commission (FTC) later known as the Cambridge Filter Pad method (Cigarette: testing for tar and nicotine content: Federal Register 1967; 32, 11178).

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Table 2 *(continued)*

Code	Name	Nominal ISO NFDPM yield (mg/cig)	Filter/Product style	Filter ventilation %	Blend style	Supplier
G	Mild Seven	10	Carbon filter (dual)	18	US Blended	Japan Tobacco Inc.
H	L&M 100	10	Long (100 to 120) mm	22	US Blended	Altria Client Services
I	1R5F	1,7 (FTC[a])	Reference product	71	US Blended	University of Kentucky
J	CM6	14	Monitor test piece	0	US Blended	Borgwaldt/Cerulean

[a] The yield was determined by the method described by the Federal Trade Commission (FTC) later known as the Cambridge Filter Pad method (Cigarette: testing for tar and nicotine content: Federal Register 1967; 32, 11178).

Filter ventilation was measured on unconditioned cigarettes in the laboratory of one of the organizers.

7 Test methods and smoking conditions

Each laboratory was requested to measure TPM, nicotine, water, NFDPM, CO, puff count, and cigarette mass (only for ISO) using a routine analytical smoking machine under both ISO and HCI smoking regimes.

As a general guide, experiments conducted under each smoking regime followed the ISO standard requirements. The relevant ISO standards are the following:

— ISO 3308:2000 + ISO 3308/Amd.1:2009[1];

— ISO 3402:1999[2];

— ISO 4387:2000 + ISO 4387/Amd.1:2008[3];

— ISO 8454:2007 + ISO 8454/Amd.1:2009[4];

— ISO 10315:2000 + ISO 10315/Amd.1:2011[5];

— ISO 10362-1:1999[6].

For HCI smoking, in addition to the ISO standards listed above, the puffing parameters and filter ventilation characteristics were modified from those described in ISO 3308 according to those described in the Health Canada method:

Health Canada Method T-115.[7]

Data were analysed according to ISO 5725 (all parts).[8]

Puffing parameters and vent blocking conditions for each puffing regime are summarized in Table 3.

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Table 3 — Comparison of ISO and HCI smoking methods

Smoking regime	Puff volume	Puff interval[a]	Puff duration	Ventilation zone blocking	Number of test articles per pad
	(ml)	(s)	(s)	(%)	
ISO	35 ± 0,3	60 ± 0,5	2 ± 0,2	0	5 (linear) 20 (rotary)
HCI	55 ± 0,5	30 ± 0,5	2 ± 0,2	100	3 (linear) 10 (rotary)

[a] Time from the start of one puff to the start of the next puff.

The total number of test articles which had to be smoked under each smoking regime for the two types of smoking machines (rotary and linear) is shown in Table 4.

Table 4 — Test articles to be smoked for different types of smoking machine

	Rotary machine				Linear machine			
	Test articles per pad	Pads	Days	Total test articles	Test articles per pad	Pads	Days	Total test articles
ISO	20	1	5	100	5	4	5	100
HCI	10	2	5	100	3	7	5	105

For ISO smoking, one test result was defined as the mean yield obtained from smoking 20 test articles in a single smoking machine run; therefore, from a rotary machine, it is the result from one run smoking 20 test articles and from a linear machine, it is the mean of four ports/channels, smoking five test articles per port/channel. This was repeated on five separate days resulting in 100 test articles being smoked on both rotary and linear machines.

For HCI smoking, the number of test articles smoked per Cambridge filter pad was reduced to avoid overloading the pad. Thus, one test result from a rotary machine was the mean of two runs smoking 10 test articles each and from a linear machine, it was the mean of seven ports/channels, smoking three test articles per port/channel. This was repeated on five separate days resulting in 100 test articles being smoked on a rotary machine and 105 on a linear machine.

A summary of the different types of smoking machines is given in Table 5.

Table 5 — Smoking machines used by participants

Linear machines		Rotary machines	
Type	Number	Type	Number
SM 450	17	RM 200	4
LM20X	2	RM 200A	3
MBC 2000	2	RM 20	6
		RM 20H	7
		RM 20D	1
		RM 20CSR	1
		CR 20	1
	21 (20[a])		23 (22[a])

[a] Number of smoking machines relevant for statistical evaluation.

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In total, 21 linear and 23 rotary smoking machines were included in this study (giving a total of 44 smoking machines). However, two participants used two different smoking machines for ISO and HCI smoking, so that the actual number for the statistical evaluation was 42.

The very similar number of the two different types of smoking machine allows a formal statistical analysis of the results from different machine types (see 10.2).

8 Handling of basic data sets

This clause describes the initial assessment by the organizing group of the basic measurement values provided by the participating laboratories.

For the 42 smoking machines, 35 complete data sets were received.

Five participants carried out a reduced smoking program due to technical problems, lack of time, or delivery problems:

— No. 3: Test article I not smoked due to non-availability of 1R5F

— No. 7: Test article A not smoked under ISO smoking conditions

— No. 10: Test article D not smoked under ISO or HCI machine smoking conditions

— No. 12: Test article A not smoked under ISO or HCI machine smoking conditions

— No. 15: Test article E not smoked under ISO or HCI machine smoking conditions

After reviewing the data sets No. 35 and No. 44, the following were realized by the statisticians:

— No. 35: HCI smoking performed under ISO regime, therefore results were not included in the evaluation

— No. 44: The wrong test article was used as test article I under ISO conditions, therefore results were not included in the evaluation.

Furthermore, several data reports of the laboratories for the 10 test articles were not completed:

— No. 6: Cigarette mass: Error comment in test article G was corrected by the statisticians.

— No. 16: Calculation in some cells of the data sheet was carried out incorrectly. Errors were corrected by the statisticians.

— No. 22: ISO smoking regime: Blank cells for test articles A, B, and I which correspond to values below the limit of quantification (LOQ) were reported by the participant. The mean was calculated by the statisticians based on the supplied number of data points.

— No. 26: Incorrect value for CO in test article mentioned by the authors and removed by the statisticians.

— No. 29: Data transfer into the data sheets not correctly carried out. It was corrected by the statisticians.

— No. 30: ISO smoking regime: In test article A of the original data set, one water value was below the LOQ. This value was treated as zero by the statisticians.

— No. 31: ISO smoking regime: In test article A, a water value was below the LOQ. This value was treated as zero by the statisticians.

— No. 37: ISO smoking regime: Missing data in the test articles A to E and H to J for all parameters.

— No. 44: HCI smoking regime: Missing values in test article B.

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— No. 50: HCI smoking regime: Missing values in test articles C and E. Data mistake of temperature and relative humidity in ISO table.

The basic measurement data returned by the participants had different formats for rotary and linear smoking machines and were dependent on the smoking regime.

For ISO 3308 smoking, the reported mean of five cigarettes per channel/pad from the linear machines was aggregated to represent a mean for 20 cigarettes to make the values from the different smoking machine types comparable. The basic data sets for the evaluation then consisted of five data points each representing a mean for 20 cigarettes from both types of smoking machines. The statistical analysis was based on these mean values.

For HCI smoking, the reported mean values of 10 cigarettes per pad from rotary machines and three cigarettes per channel/pad from the linear machines had to be aggregated to represent mean values for 20 cigarettes (rotary) and 21 cigarettes (linear machines) to make the values from the different smoking machine types comparable. The statistical analysis was based on these means.

An overview of the number of data points of both smoking regimes included in the evaluation is shown in Tables 6 and 7.

Under ISO smoking conditions (Table 6), a maximum of 210 data points for each test article and each of the smoke parameters TPM, nicotine, water, NFDPM, and CO was possible. However, due to missing data sets or runs (described above), this was not achieved for all test articles and a total of 10 342 data points was available for the statistical analysis of the ISO smoking results.

For HCI smoking (Table 7), a maximum of 205 data points for each test article and for each of the five smoke parameters could be reached. However, due to missing data sets or runs (described above), for example, the exclusion of data set 35, a maximum of 1 025 data points was achieved for a test article and a total of 10 150 data points was available for the statistical analysis of the HCI smoking results.

Table 6 — ISO smoking — Number of data points (before outlier removal)

Test article	NFDPM (Number)	Nicotine (Number)	CO (Number)	TPM (Number)	Water (Number)	Total number of data points
A	199	200	200	200	199	998
B	210	210	210	210	210	1 050
C	210	210	210	210	210	1 050
D	205	205	205	205	205	1 025
E	205	205	205	205	205	1 025
F	210	210	210	210	210	1 050
G	210	210	210	210	210	1 050
H	210	210	210	210	210	1 050
I	197	200	200	200	197	994
J	210	210	210	210	210	1 050
Total number	**2 066**	**2 070**	**2 070**	**2 070**	**2 066**	**10 342**

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Table 7 — HCI smoking — Number of data points (before outlier removal)

Test article	NFDPM (Number)	Nicotine (Number)	CO (Number)	TPM (Number)	Water (Number)	Total number of data points
A	200	200	200	200	200	1 000
B	205	205	205	205	205	1 025
C	205	205	205	205	205	1 025
D	200	200	200	200	200	1 000
E	200	200	200	200	200	1 000
F	205	205	205	205	205	1 025
G	205	205	205	205	205	1 025
H	205	205	205	205	205	1 025
I	200	200	200	200	200	1 000
J	205	205	205	205	205	1 025
Total number	**2 030**	**2 030**	**2 030**	**2 030**	**2 030**	**10 150**

9 Results

9.1 Raw smoke yield data

The statistical data analysis is based on ISO 5725 and the Grubbs and Cochran methods have been used for outlier testing. As the study size was determined by the 42 smoking machines (corresponding to "number of laboratories" in ISO 5725), the ISO 5725 tables for these different outlier tests had to be enlarged to the appropriate size in evaluating the relative test statistics.

The mean values for the five runs per test article per data set were used as the basis for calculating the internal variances of the laboratories and, after exclusion of laboratories with outliers, also for the overall mean per test article.

Examples of the raw data for TPM, nicotine, water, NFDPM, and CO, together with the overall mean and the relevant ±2 × standard deviation (SD), are shown in scatter plots of the data for each variable for ISO and HCI smoking for test articles I and J to provide a general overview of the measurement distributions.

TPM yields are shown in Figures 1 to 4 and nicotine yields in Figures 5 to 8. Water yields are given in Figures 9 to 12. Test results below zero were reported in data set 31 for test article A under ISO smoking conditions. This result was treated as zero in the tables and figures. For HCI smoking, no values below zero were reported. NFDPM and CO yields are shown in Figures 13 to 16 and Figures 17 to 20 respectively.

The distributions of the puff counts for all test articles around the mean values were nearly homogeneous for ISO, as well as for the HCI smoking procedure. However, a few data sets (No. 17 test article A, B, and C – ISO, test article D and G – HCI; No. 3 test article F, H, and J – ISO, test article G and H – HCI; No. 15 test article F – HCI and test article I ISO) showed a clear deviation from the overall mean for some of the test articles.

Cigarette masses for all data sets were in good agreement with the exception of slightly lower cigarette mass measurements of data set 4 in test articles E and G, the higher values of data set 17 in test article I, and the deviating results of data set 27 in the test articles H and I.

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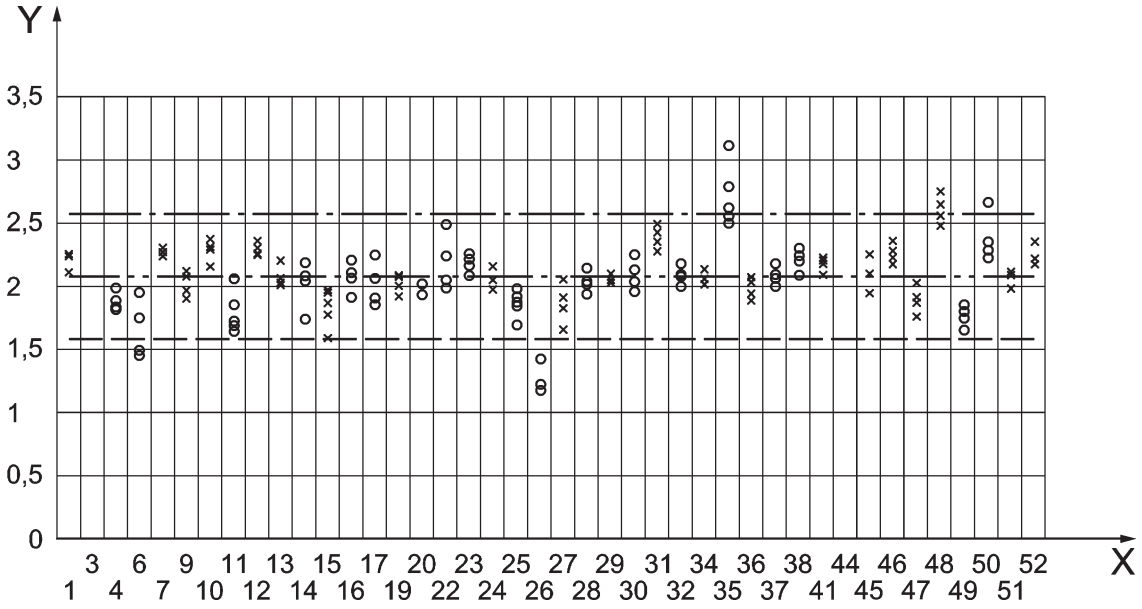
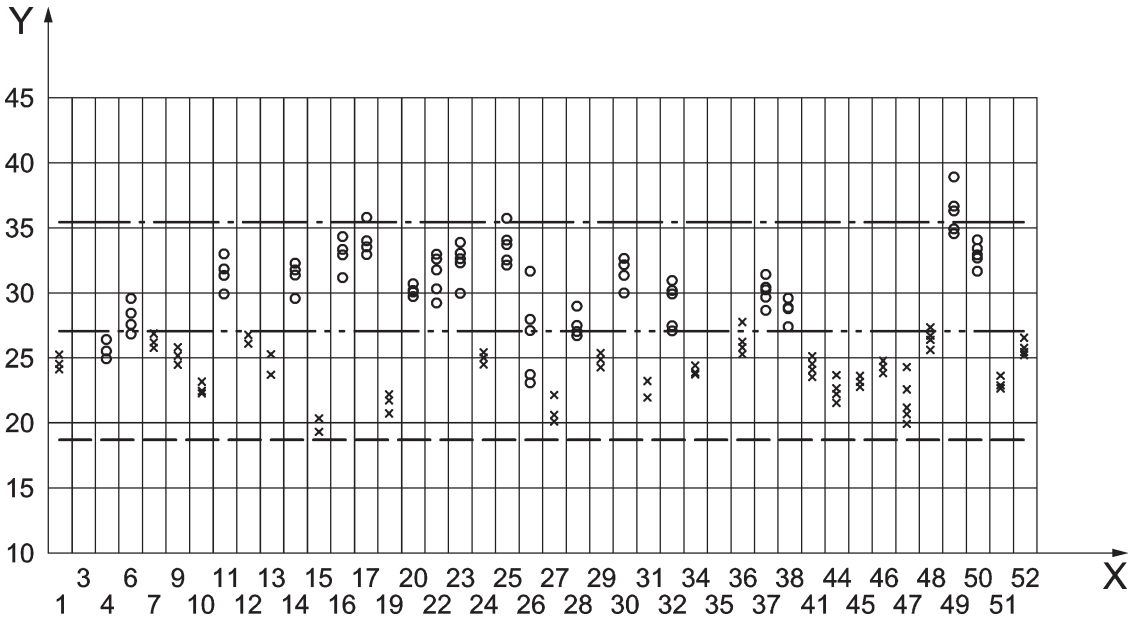


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	TPM (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 1 — TPM yields under the ISO smoking regime for test article I



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	TPM (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 2 — TPM yields under the HCI smoking regime for test article I

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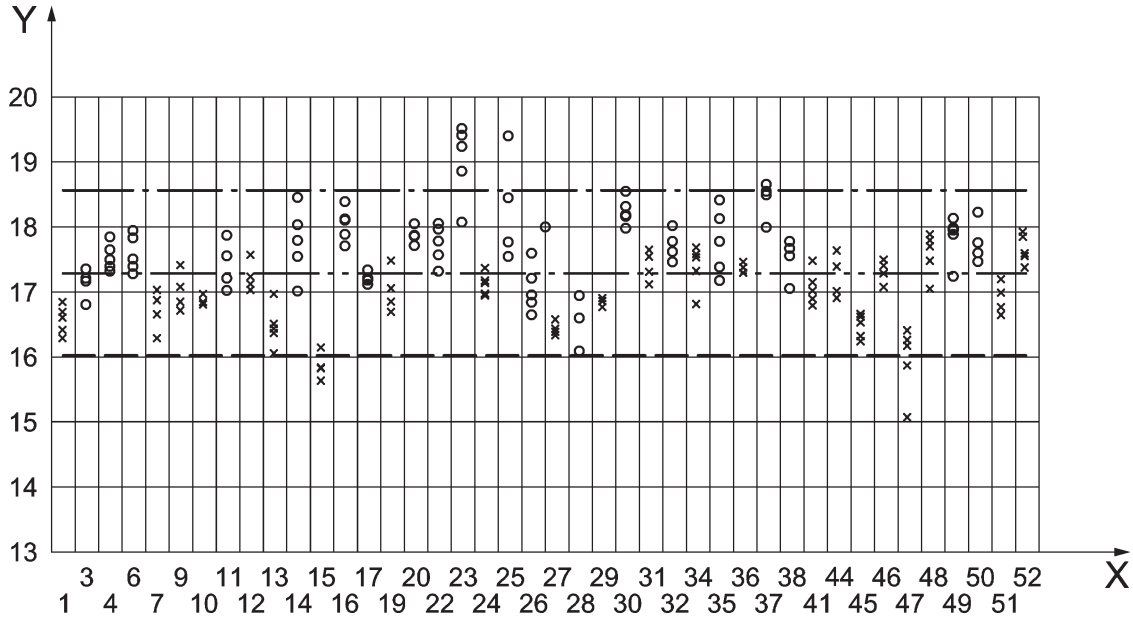
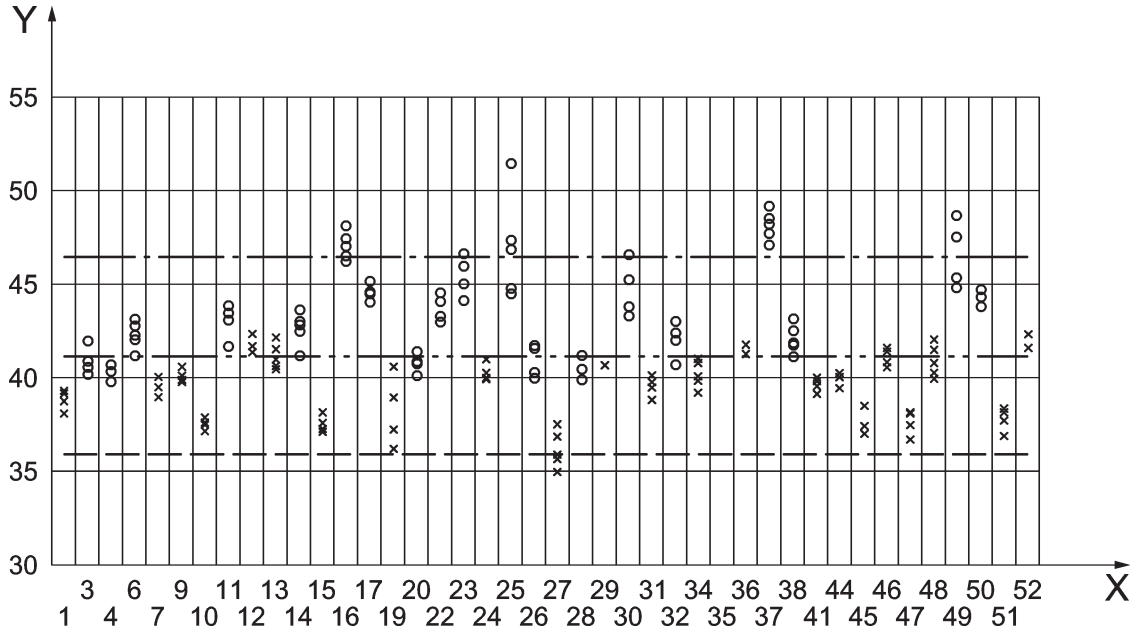


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	TPM (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 3 — TPM yields under the ISO smoking regime for test article J



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	TPM (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 4 — TPM yields under the HCI smoking regime for test article J

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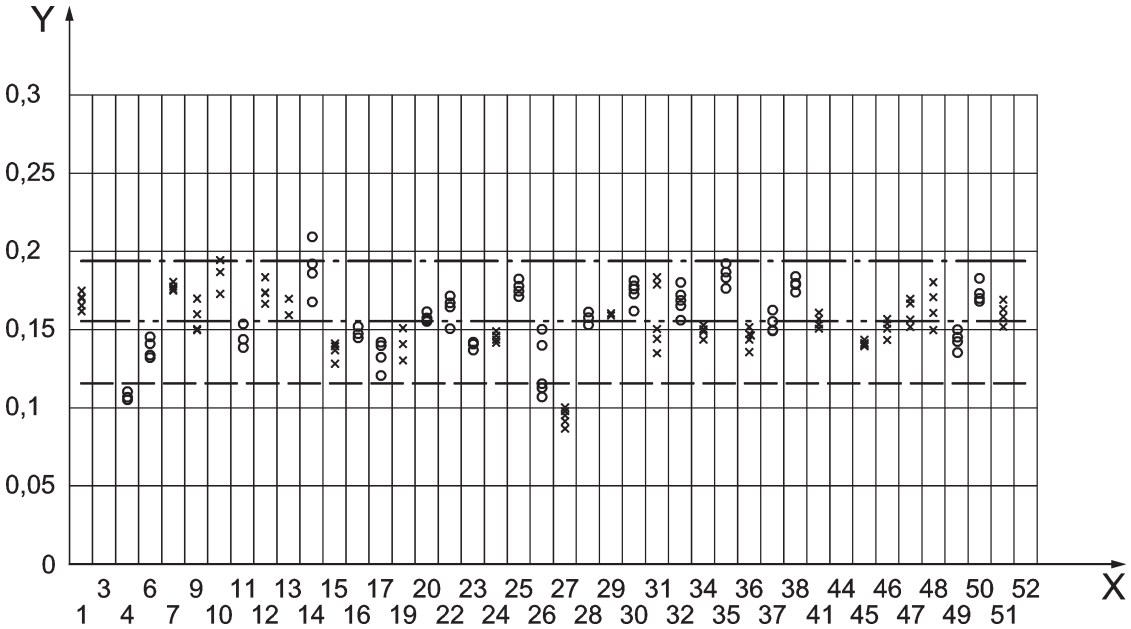
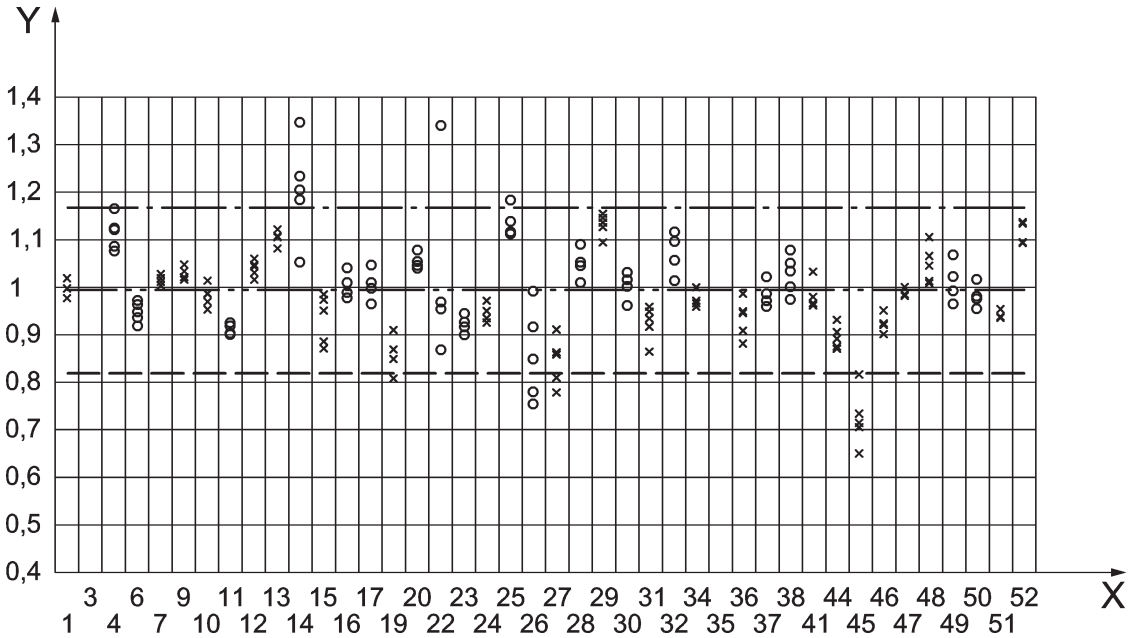


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	nicotine (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 5 — Nicotine yields under the ISO smoking regime for test article I



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	nicotine (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 6 — Nicotine yields under the HCI smoking regime for test article I

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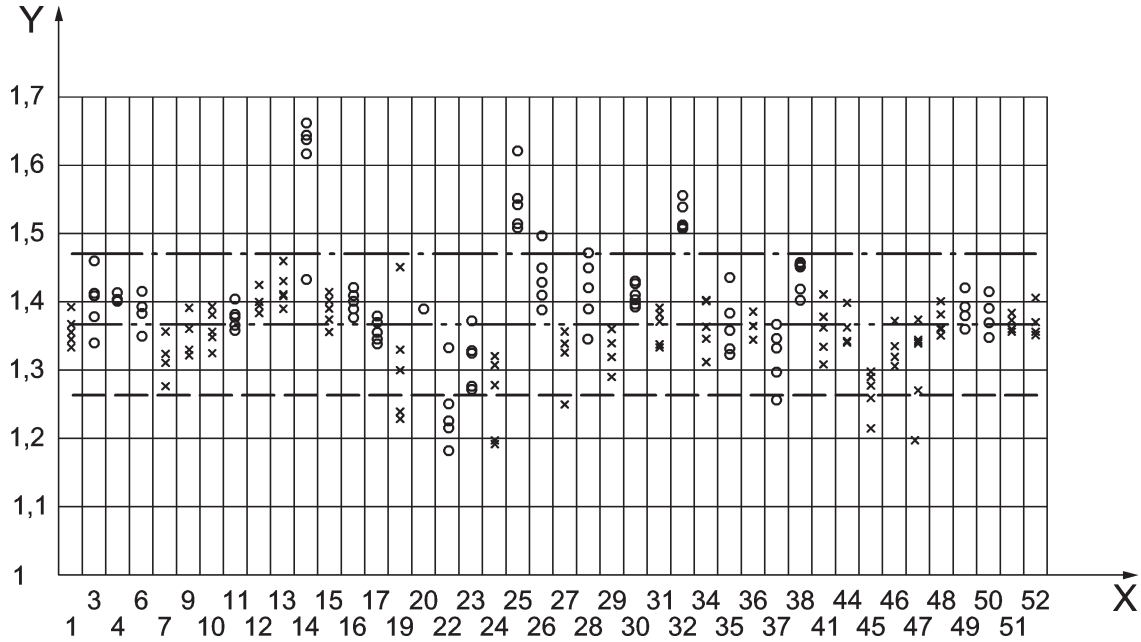
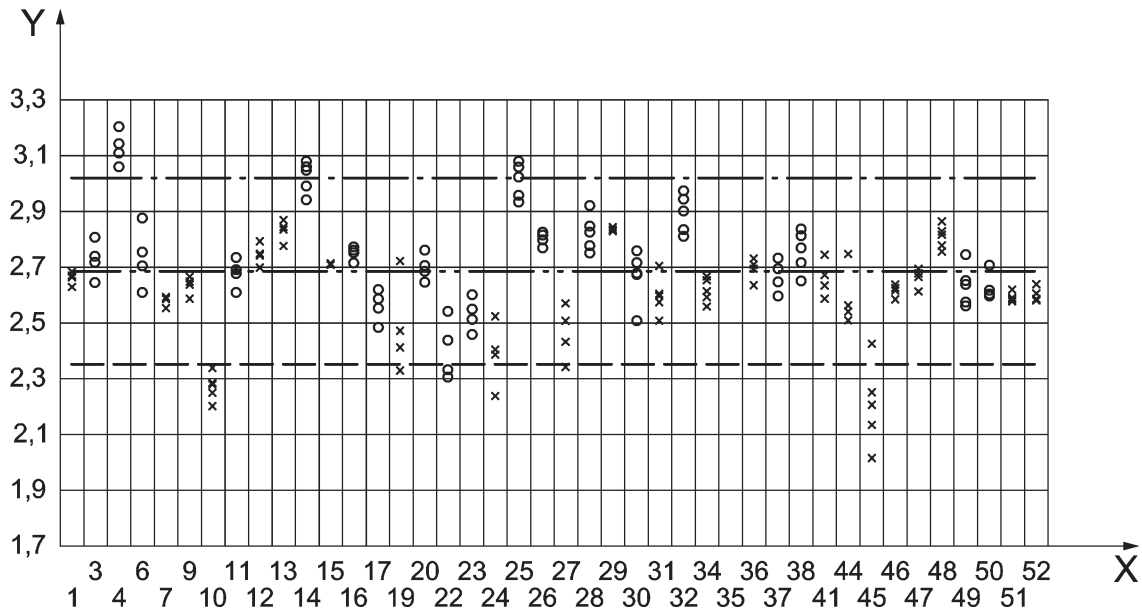


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	nicotine (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 7 — Nicotine yields under the ISO smoking regime for test article J



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	nicotine (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 8 — Nicotine yields under the HCI smoking regime for test article J

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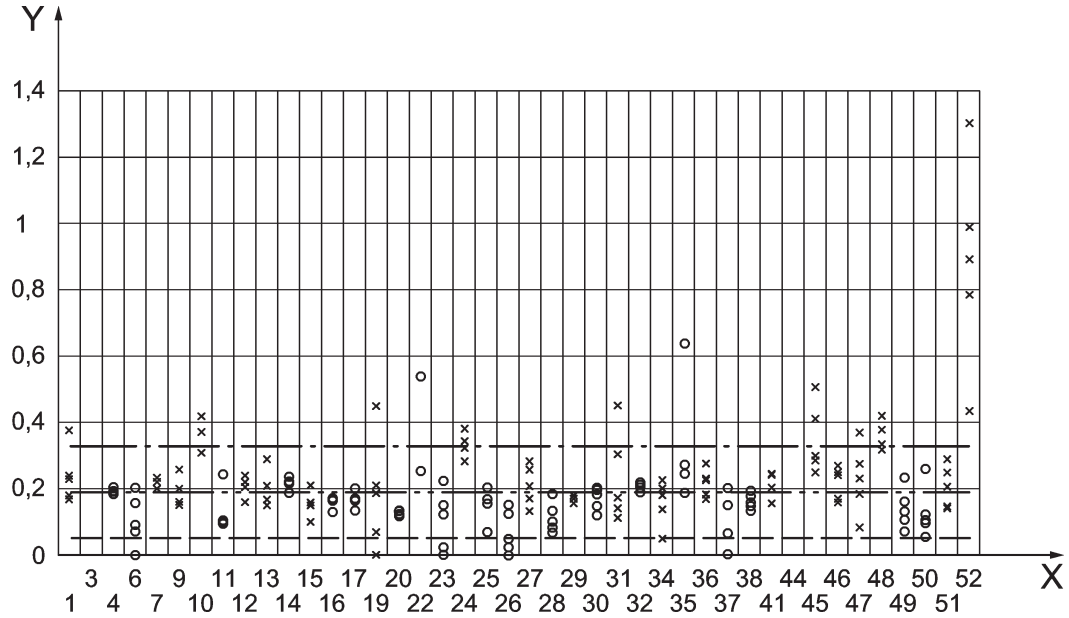
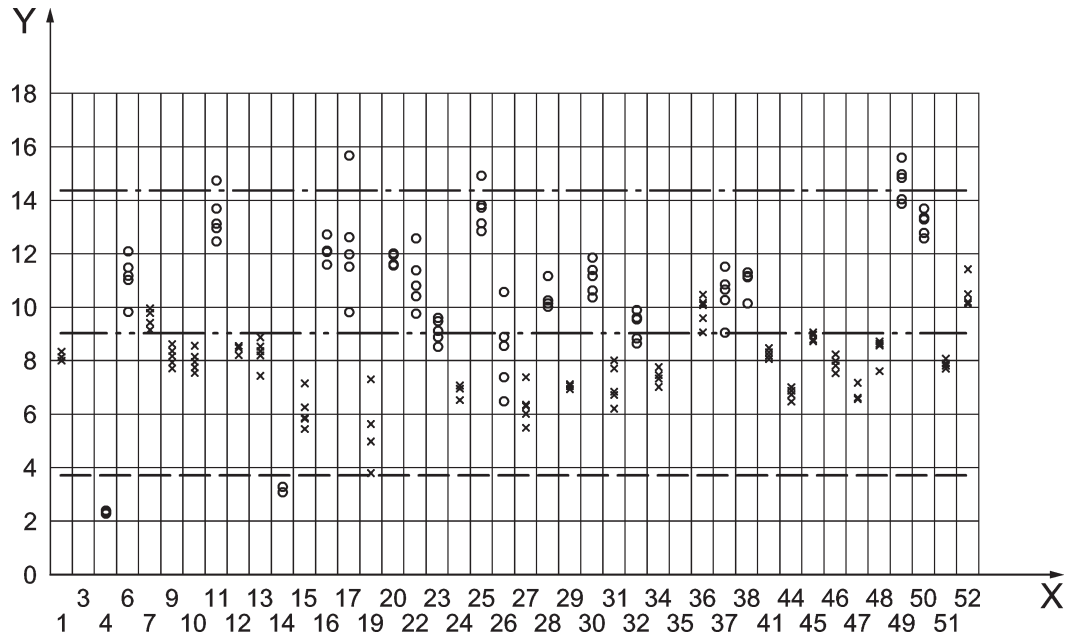


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	water (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 9 — Water yields under the ISO smoking regime for test article I



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	water (mg/cig)	— · · —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 10 — Water yields under the HCI smoking regime for test article I

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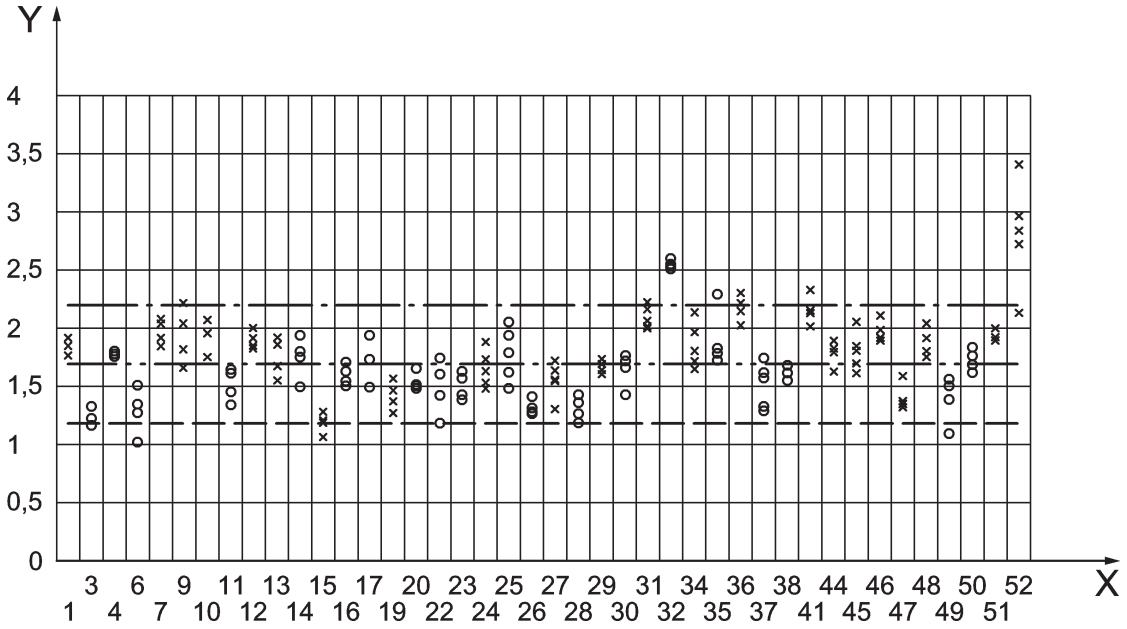
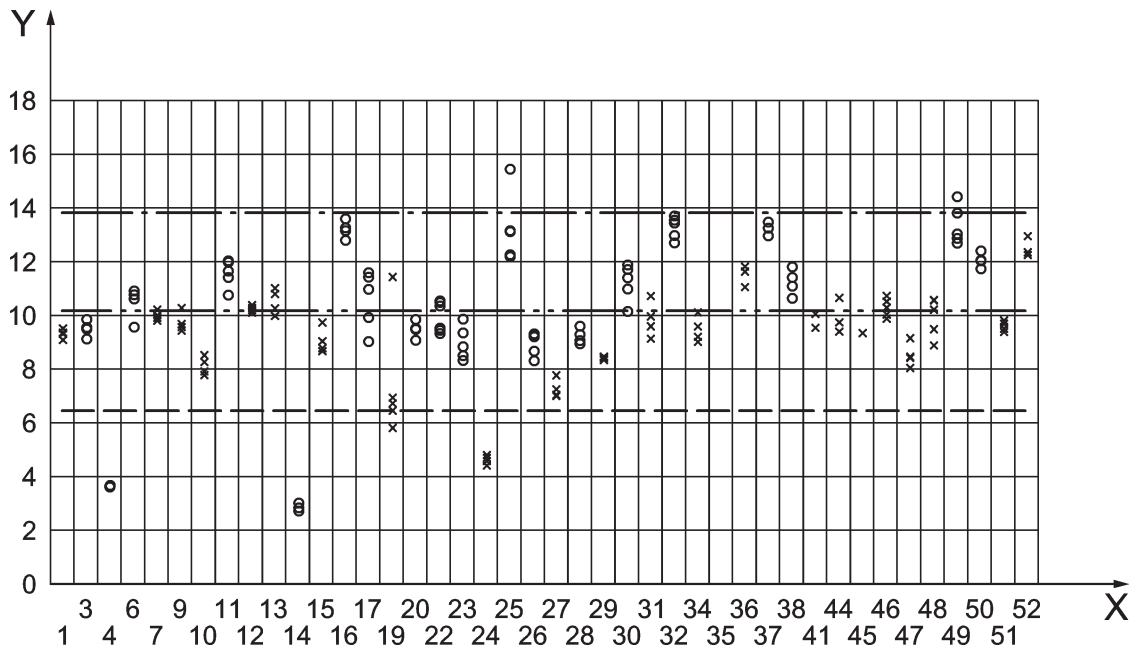


Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	water (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 11 — Water yields under the ISO smoking regime for test article J



Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	water (mg/cig)	— · · —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

Figure 12 — Water yields under the HCI smoking regime for test article J

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