TECHNICAL REPORT

ISO/TR 19478-1

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*

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.

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.

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 <u>Table 1</u>.

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

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).

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.

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.			

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.

— 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

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.
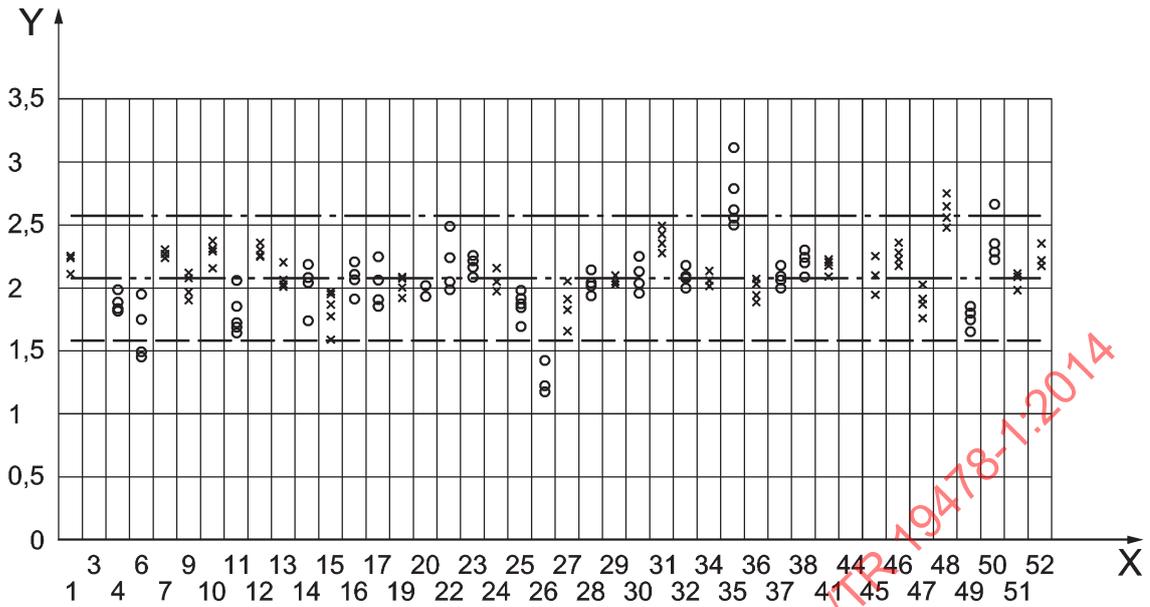
Key

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
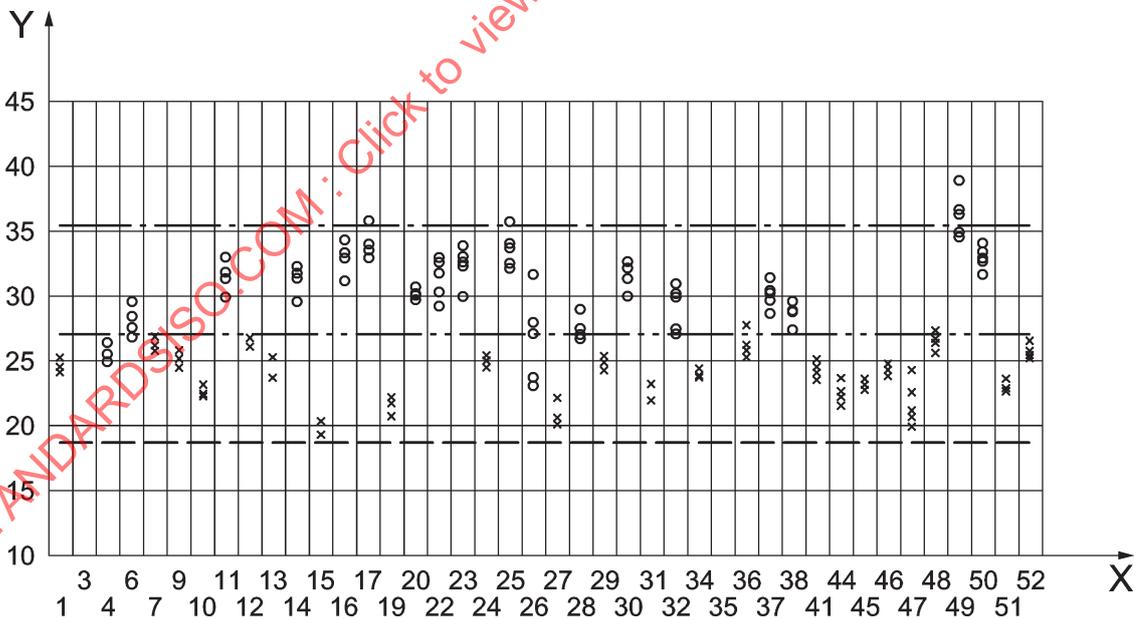
Key

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
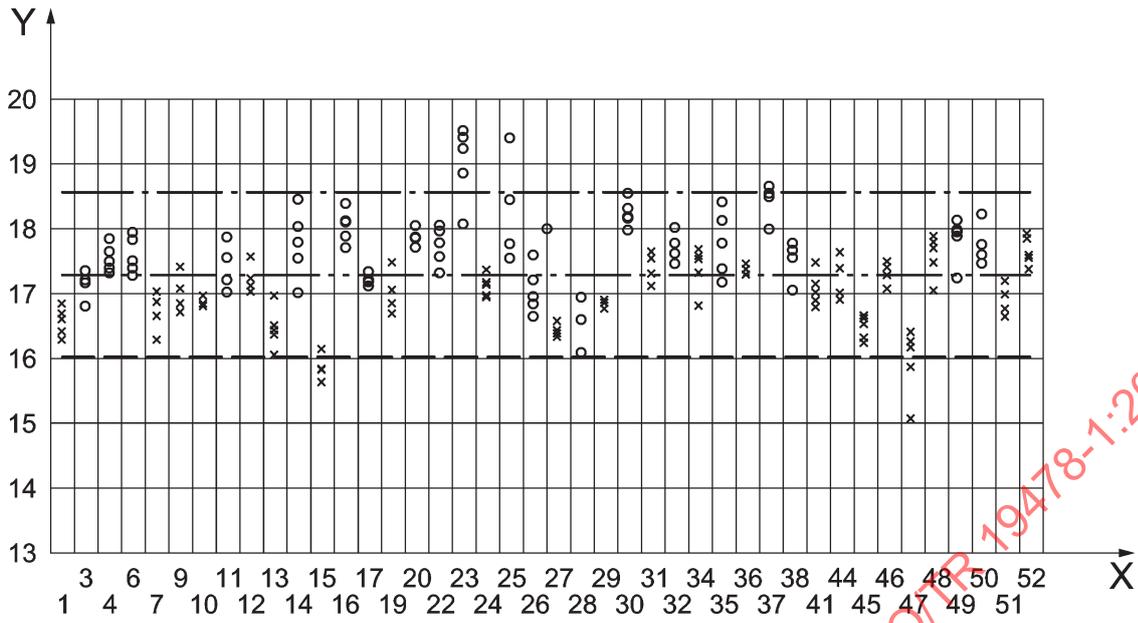
9

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
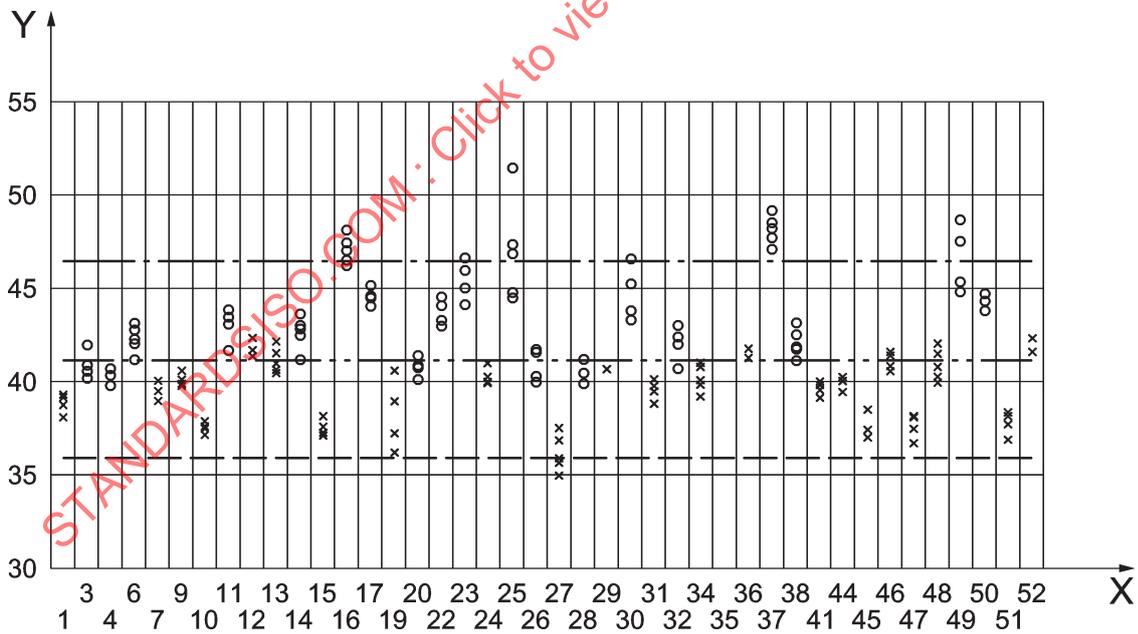
Key

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		

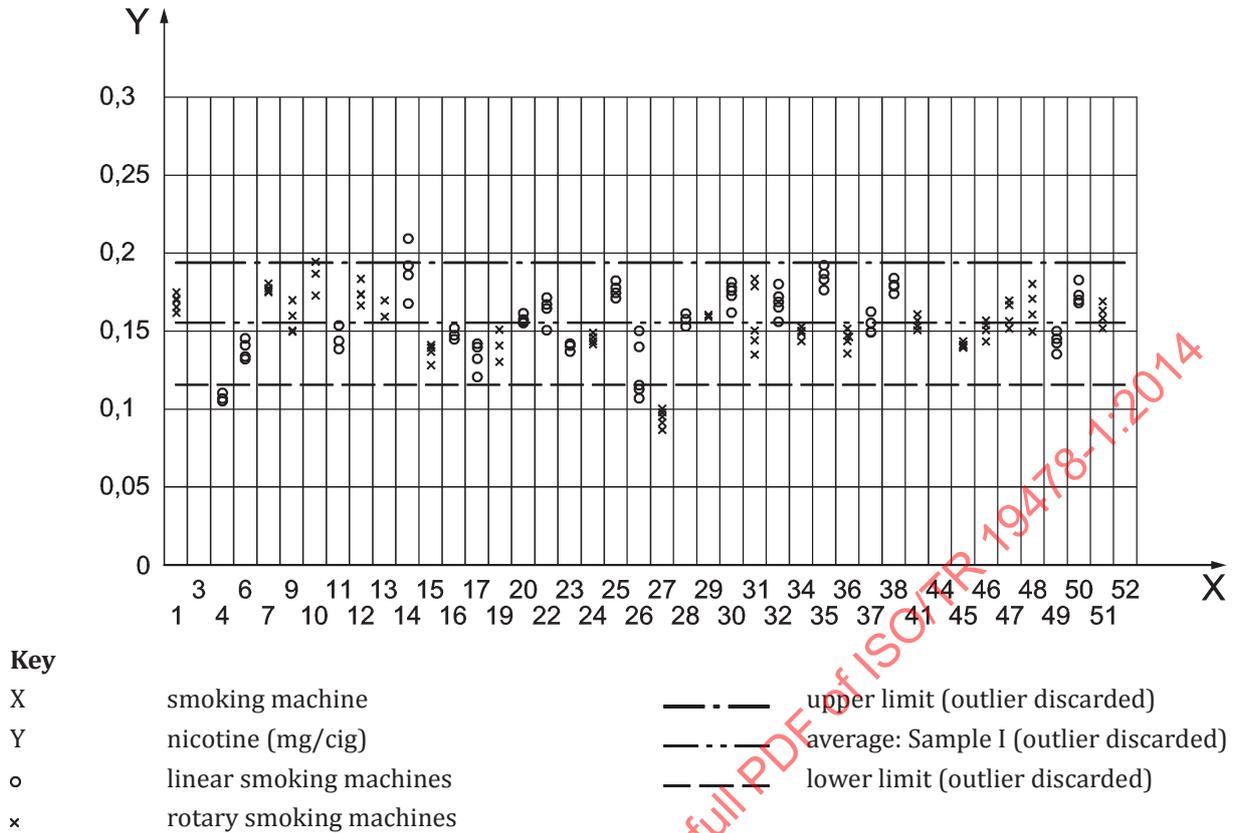**Figure 4 — TPM yields under the HCI smoking regime for test article J**

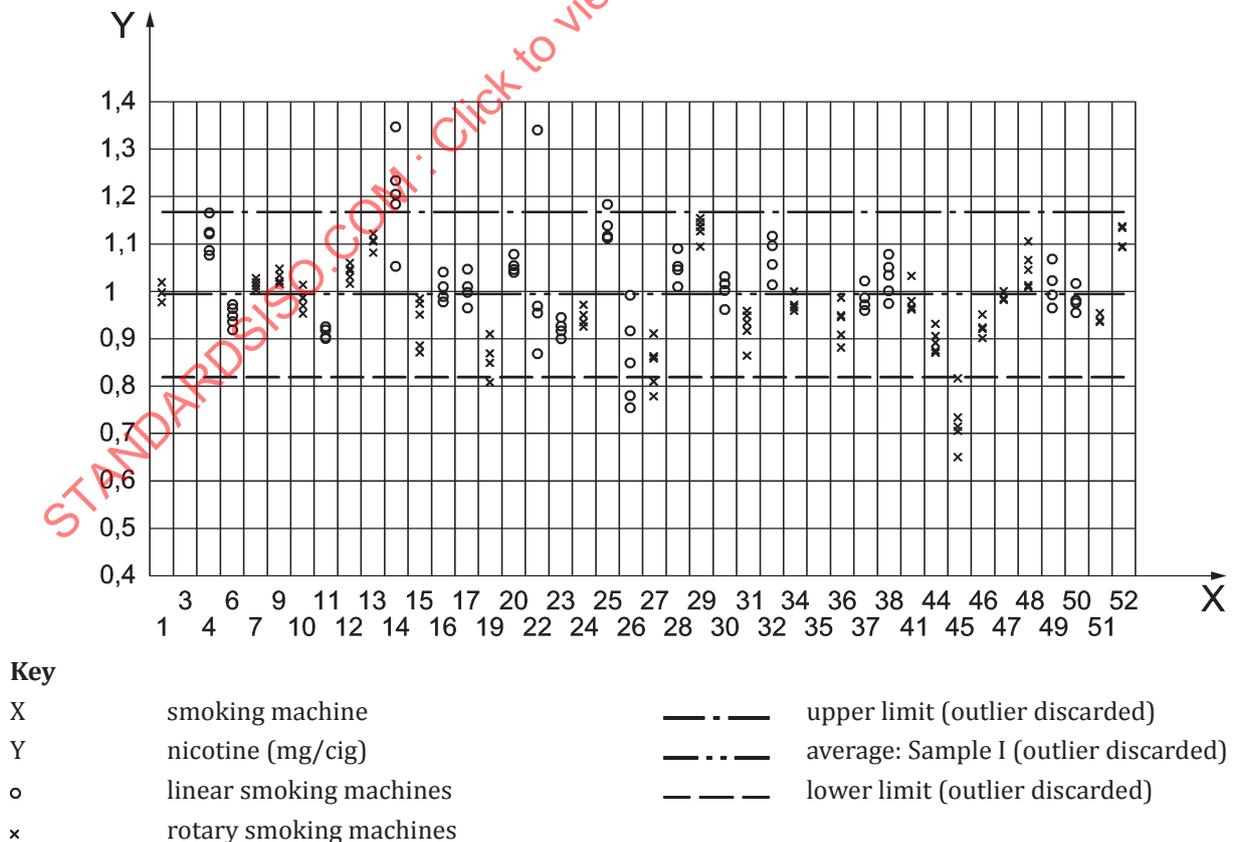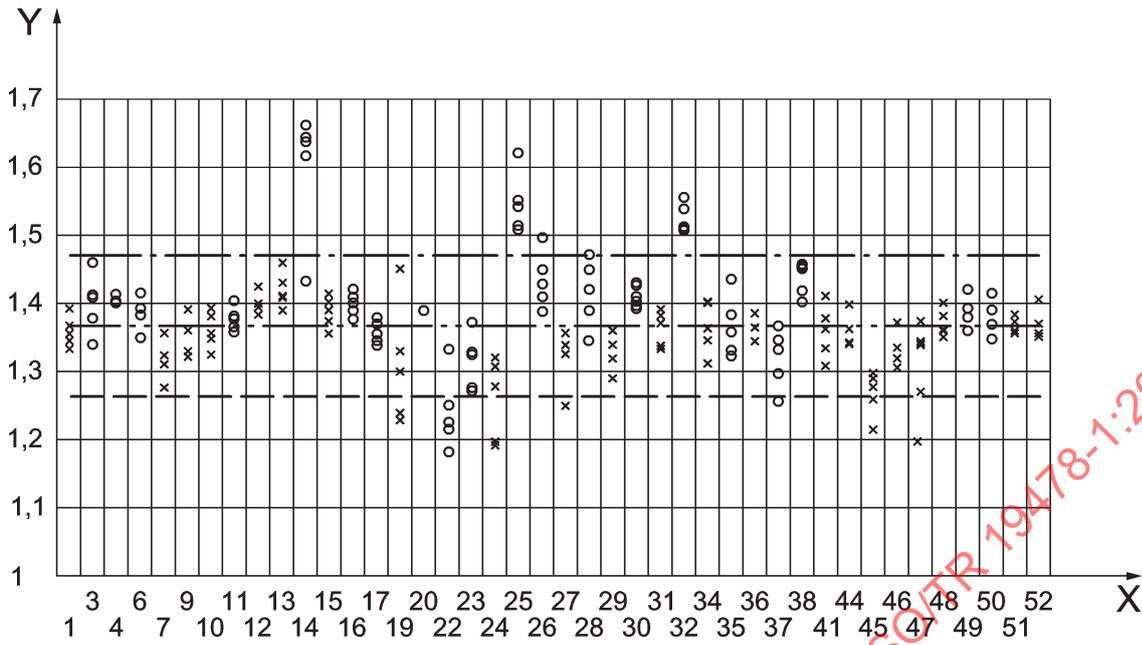**Figure 5 — Nicotine yields under the ISO smoking regime for test article I**

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		

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

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
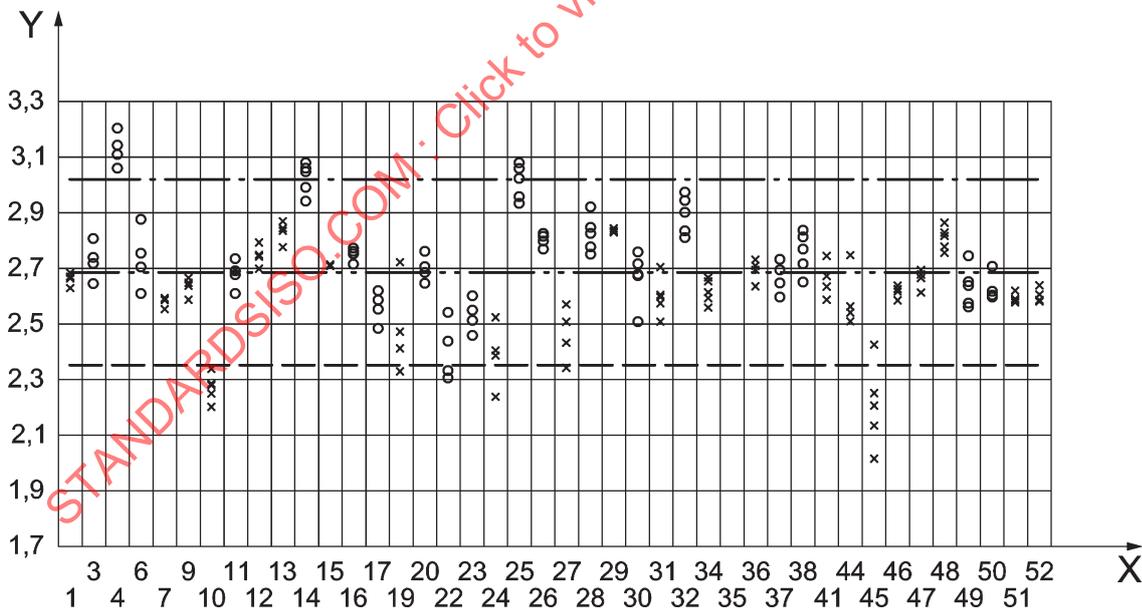
Key

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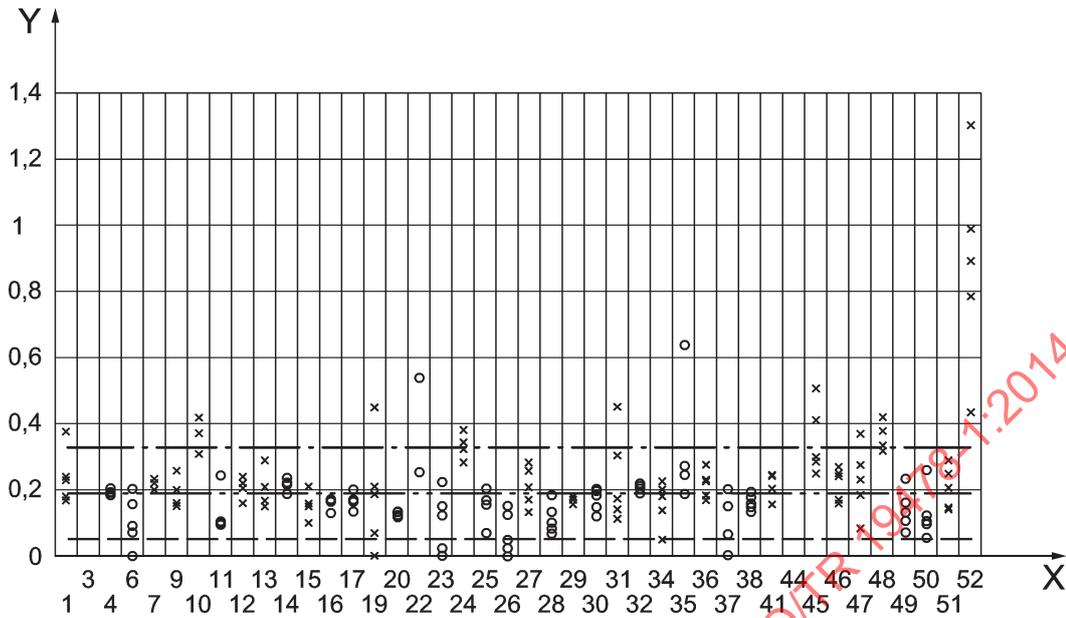
Figure 9 — Water yields under the ISO smoking regime for test article I
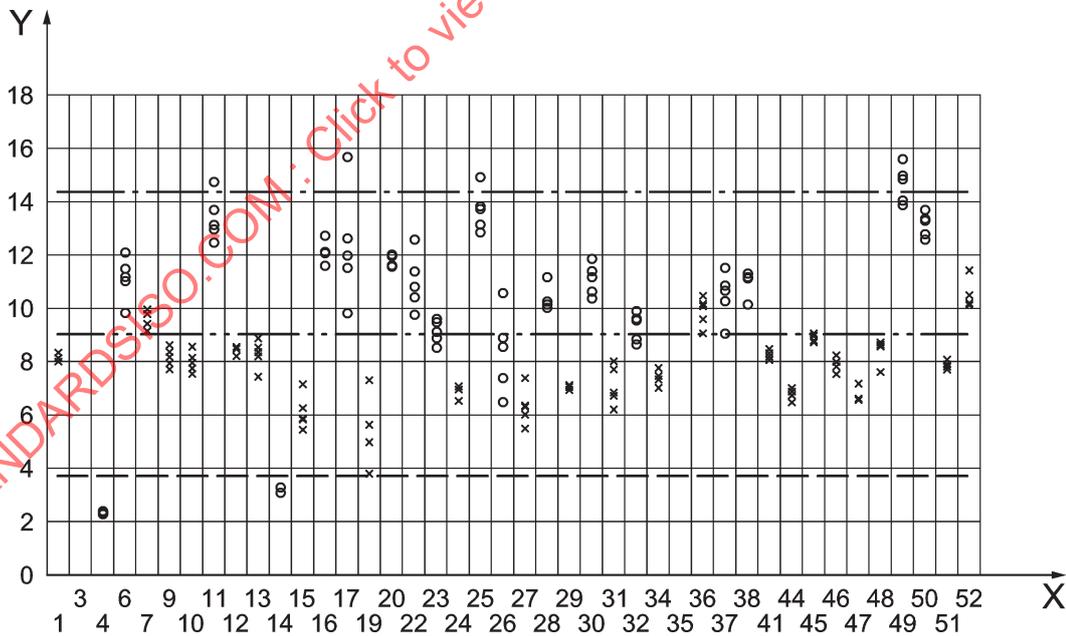
Key

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

Key

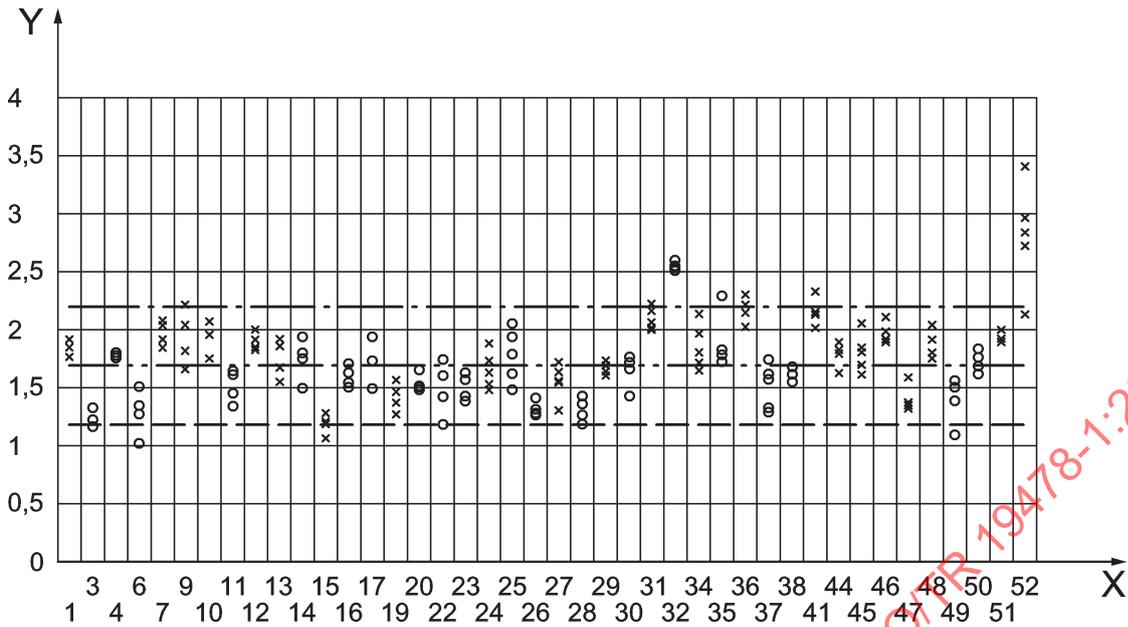|			
X	smoking machine	— . —	upper limit (outlier discarded)
Y	water (mg/cig)	— .. —	average: Sample I (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		

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

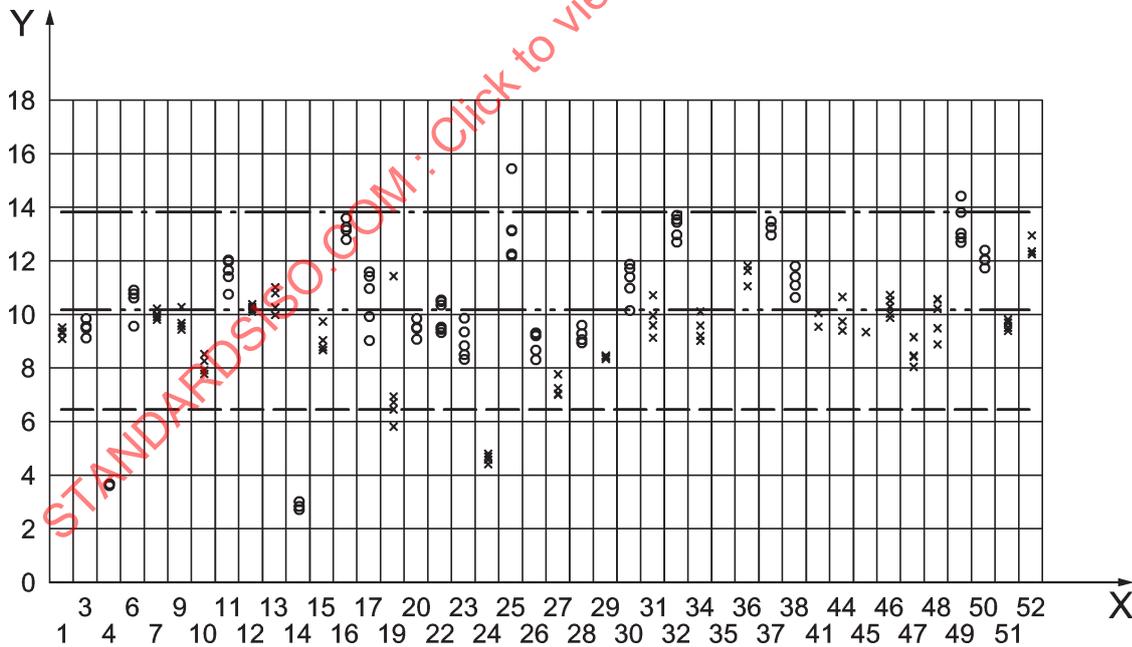|			
X	smoking machine	—·—	upper limit (outlier discarded)
Y	water (mg/cig)	—··—	average: Sample J (outlier discarded)
o	linear smoking machines	— —	lower limit (outlier discarded)
×	rotary smoking machines		

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

Key

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

Figure 13 — NFDPM yields under the ISO smoking regime for test article I

Key

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

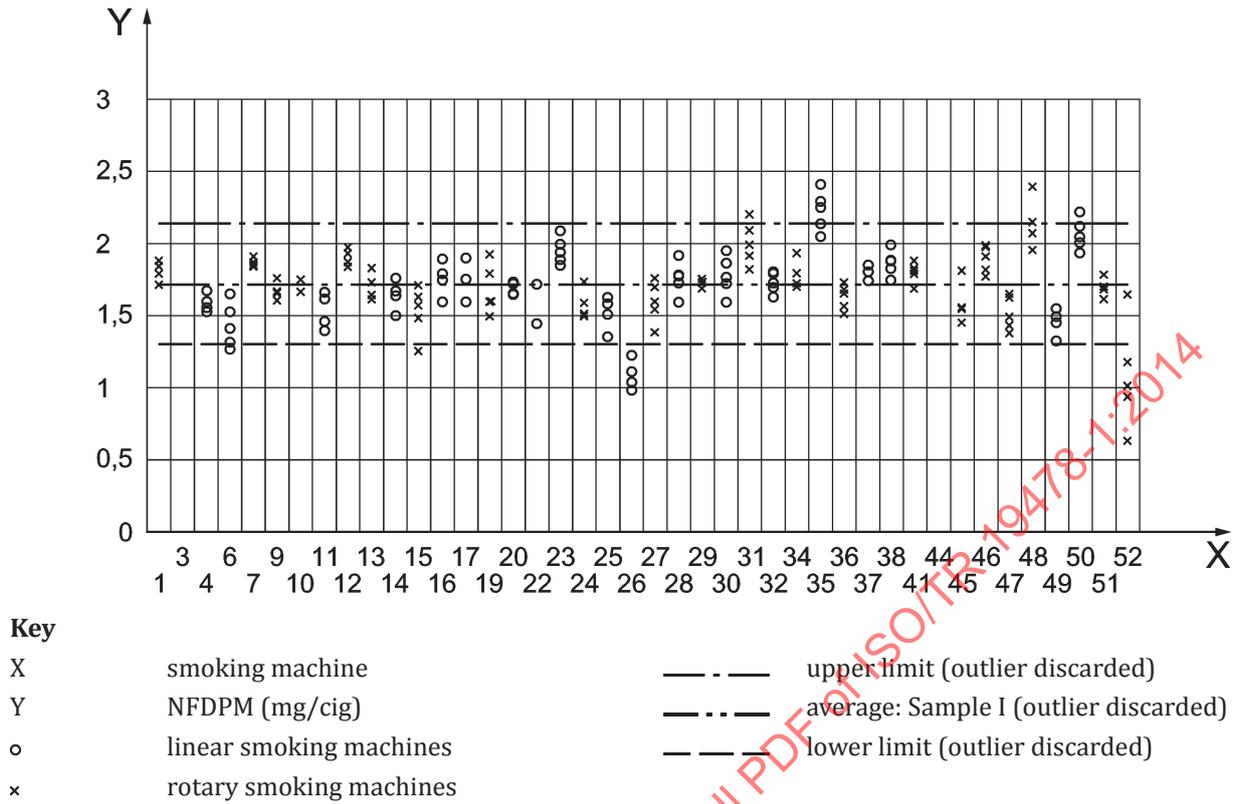**Figure 14 — NFDPM yields under the HCI smoking regime for test article I**

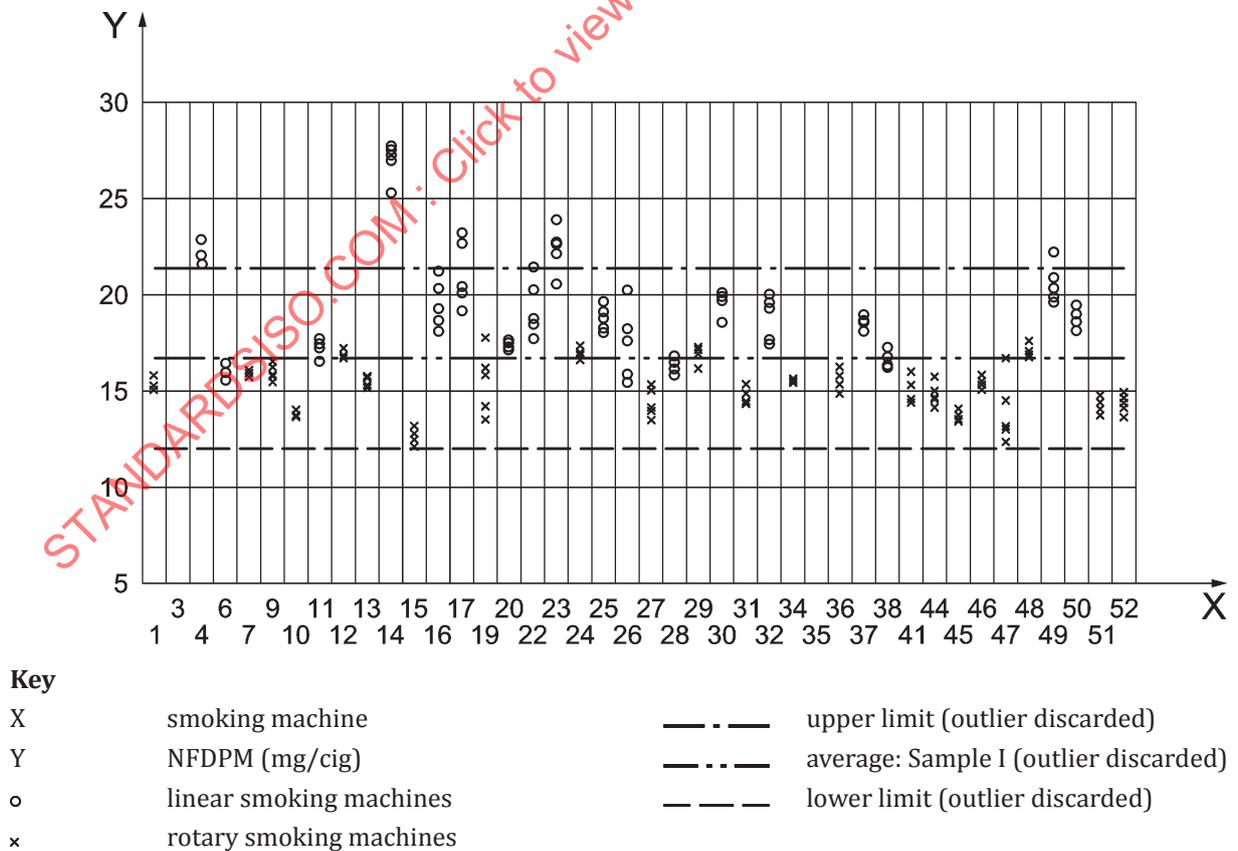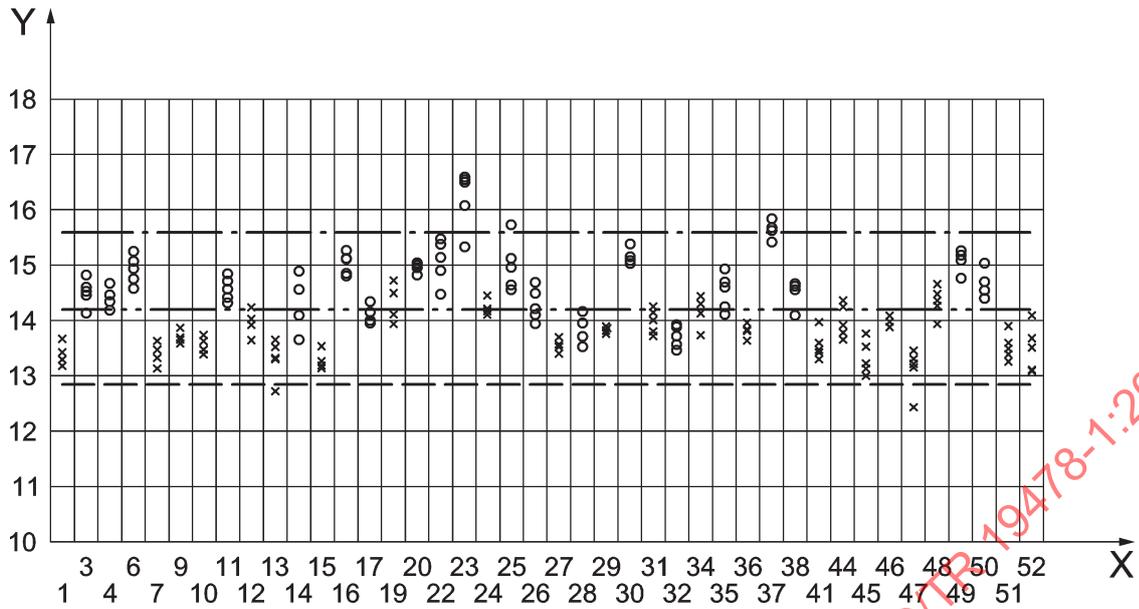**Figure 15 — NFDPM yields under the ISO smoking regime for test article J**
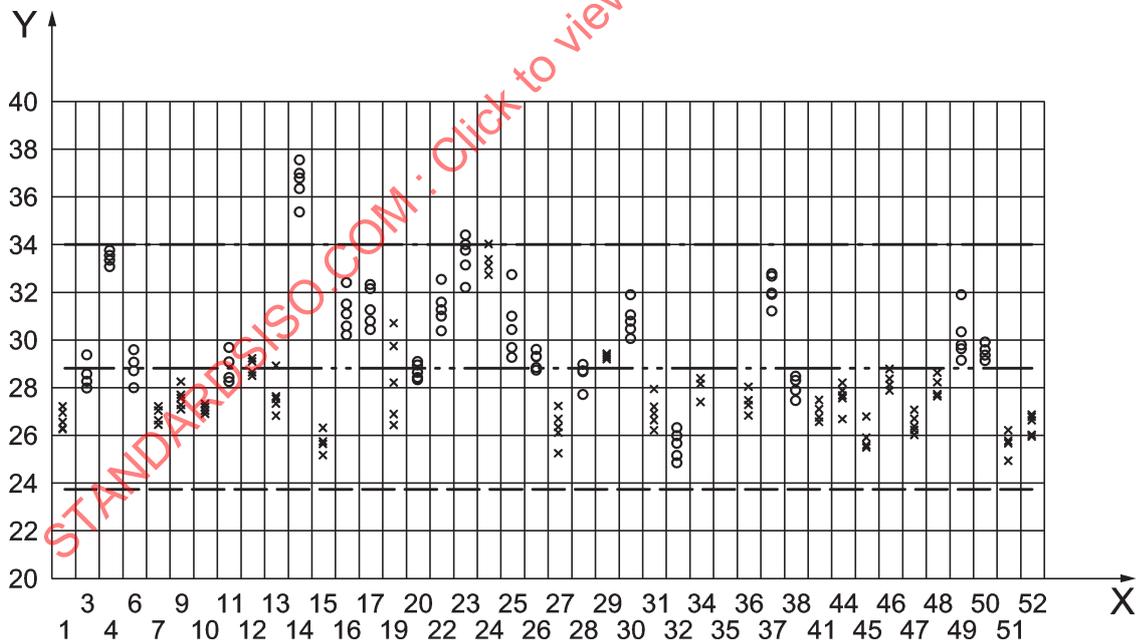
Key

X	smoking machine
Y	NFDPM (mg/cig)
o	linear smoking machines
×	rotary smoking machines

— · — upper limit (outlier discarded)

— ·· — average: Sample J (outlier discarded)

— — — lower limit (outlier discarded)

Figure 16 — NFDPM yields under the HCI smoking regime for test article J

Key

X	smoking machine
Y	NFDPM (mg/cig)
o	linear smoking machines
×	rotary smoking machines

— · — upper limit (outlier discarded)

— ·· — average: Sample J (outlier discarded)
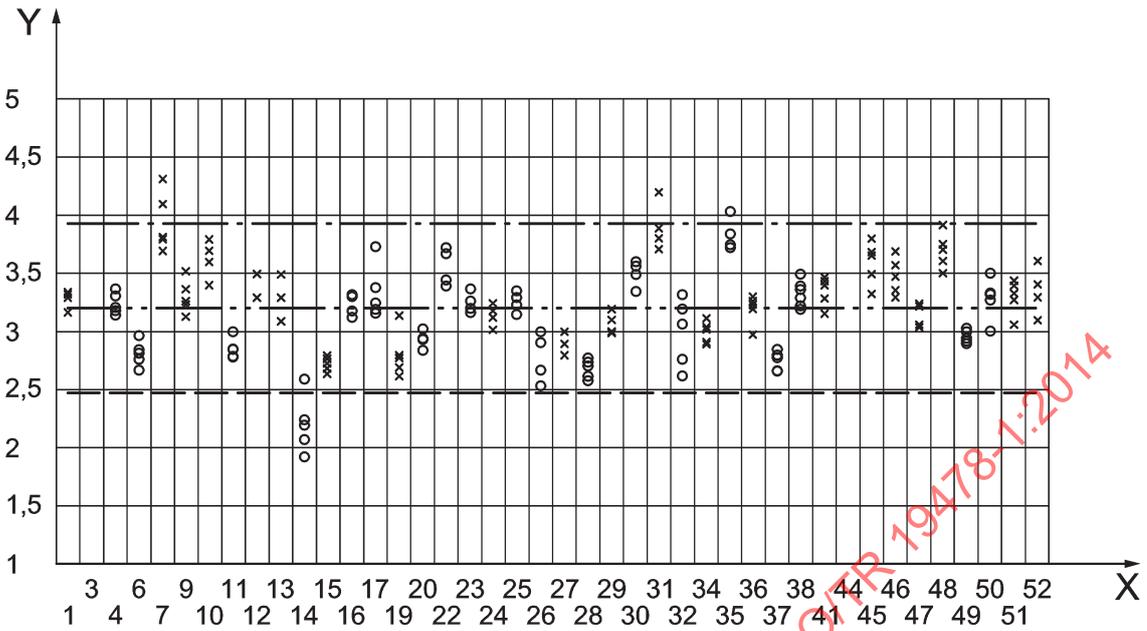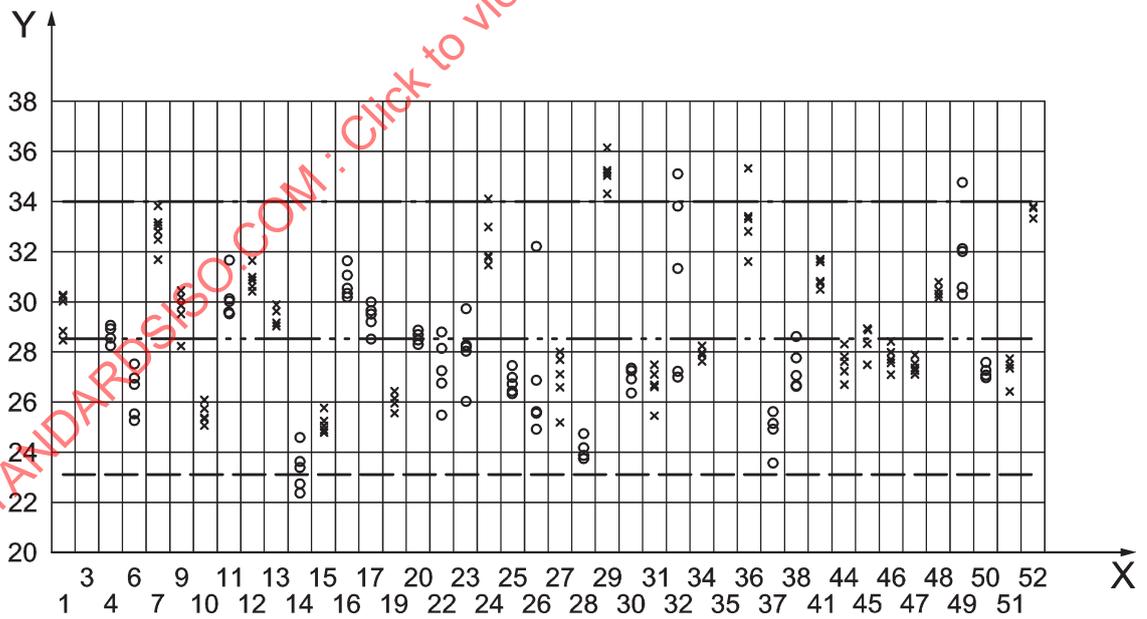
— — — lower limit (outlier discarded)

Key

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

Figure 17 — CO yields under the ISO smoking regime for test article I

Key

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

Figure 18 — CO yields under the HCI smoking regime for test article I
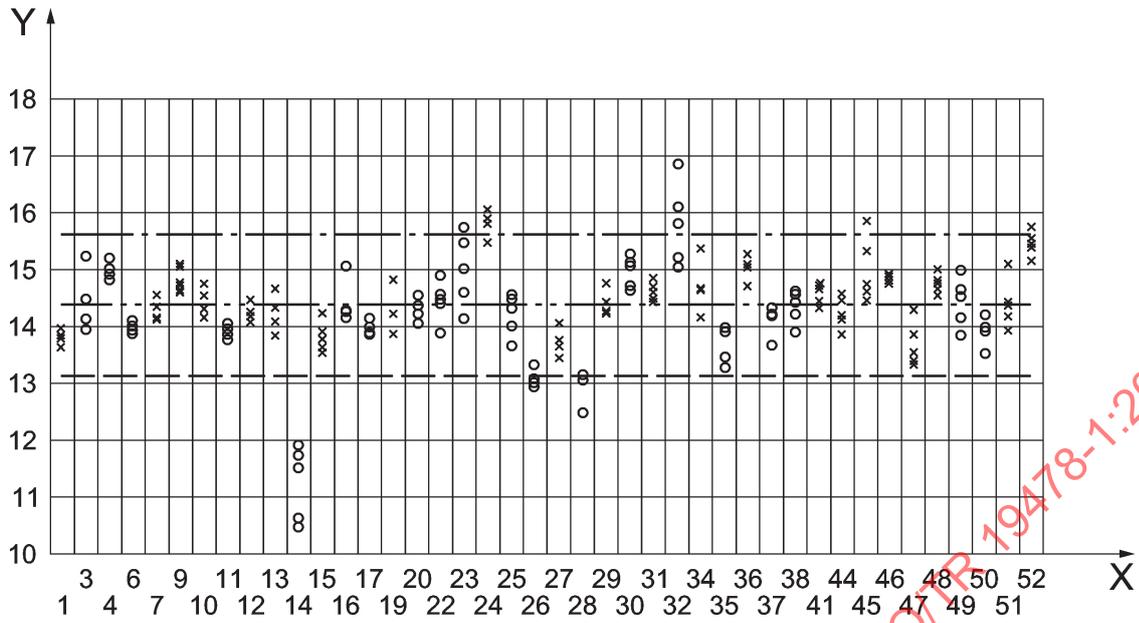
Key

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

Figure 19 — CO yields under the ISO smoking regime for test article J
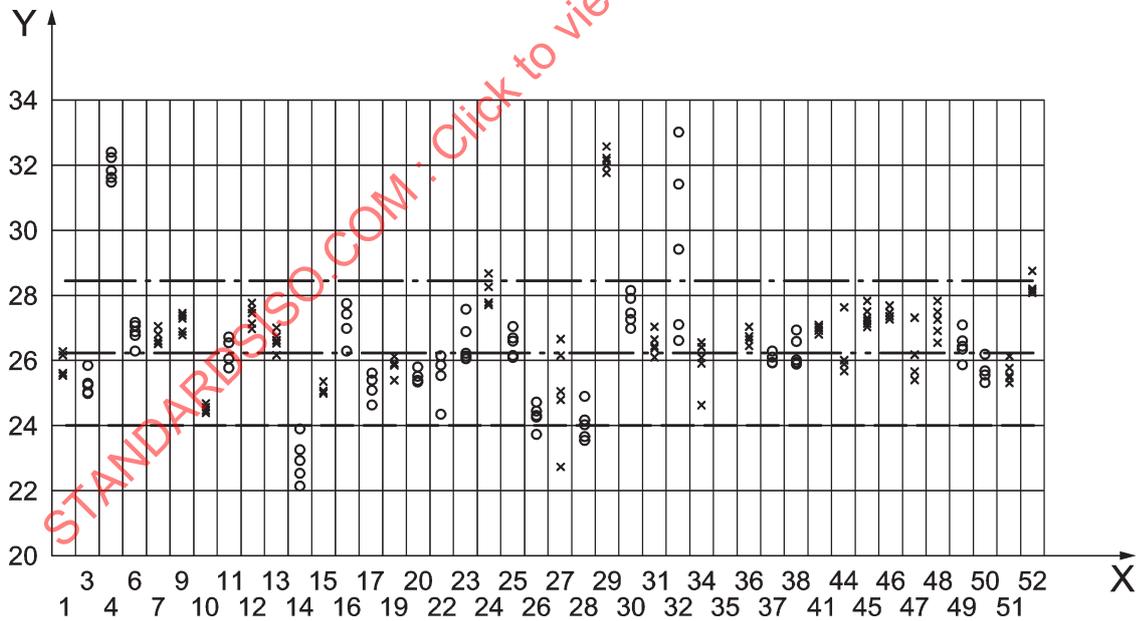
Key

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

Figure 20 — CO yields under the HCI smoking regime for test article J

9.2 Outliers

9.2.1 Treatment of outliers

In accordance with ISO 5725, if the significance value of the outlier test ("p-value") was ≤1 %, the data set was judged to be an outlier and excluded from further statistical evaluation. When the significance value was between 1 % and 5 % in the outlier test, the data set was identified as a straggler. Stragglers were not excluded from the analysis.

The data sets were tested for outlying values for the five parameters TPM, nicotine, water, NFDPM, and CO on a test article by test article basis. After outlier removal, the repeatability (r) and reproducibility (R) statistics for each of the 10 test articles under both the ISO and HCI smoking regimes were calculated.

The Cochran test was used to assess the within-laboratory variability and the Grubbs test was used to detect whether the largest (or smallest) measurements within replicate sets were outliers. The Cochran and Grubbs tests were applied simultaneously. The Grubbs test was also used to examine the overall means for data sets with outliers due to their "location". Single Grubbs, as well as double Grubbs, statistical analysis was performed.

In addition, where Cochran's testing had shown the replicate SD to be suspect, the Grubbs test was also applied to the individual values within the replicates. If the Grubbs test was positive, then the outlying value was discarded for this parameter. A new mean and SD with 4 replicates (data points) was calculated and included in the calculation of r and R.

Detailed results of the outlier testing are given in Annex A along with a description of the outliers for each test parameter.

9.2.2 Outlier overview

In total, 73 outliers were found under ISO smoking conditions (23 Grubbs = 32 % and 50 Cochran = 68 %). In contrast, HCI machine smoking resulted in 118 outliers (19 Grubbs = 16 % and 99 Cochran = 84 %).

Tables 8 and 9 show an overview of the number of data sets which were used for the calculation of r and R for each of the smoke parameters NFDPM, nicotine, CO, TPM, and water, for each of the 10 test articles. A maximum of 42 data sets was possible for each test article but, due to missing data sets or positive outlier testing where data sets with outliers were discarded, the number of data sets varied, either for the test articles or for the different measured parameters. For ISO smoking, there were most outliers for water and nicotine where 24 (5,79 %) and 20 (4,83 %) data sets respectively had to be removed prior to the calculation of r and R. Under HCI smoking conditions, more data sets were removed for each measured smoke parameter than ISO smoking. Most of the discarded data sets can be attributed to NFDPM (30; 7,38 %), water (27; 6,65 %), and CO (25; 6,15 %).

Table 8 — Number of data sets obtained under ISO smoking considered for the calculation of r and R after outlier removal

Test article	Total number of data sets available	TPM	Nicotine	Water	NFDPM	CO
A	40	40	38	36	39	39
B	42	42	41	39	42	41
C	42	42	41	40	42	42
D	41	40	40	38	41	40
E	41	41	40	39	41	38
F	42	42	40	41	42	41

a   This is the number of data sets removed, expressed as a proportion of the total number of data sets considered, to enable comparison where the total differs.

Table 8 *(continued)*

Test article	Total number of data sets available	TPM	Nicotine	Water	NFDPM	CO
G	42	42	38	41	42	41
H	42	42	41	41	42	41
I	40	40	36	35	39	40
J	42	41	39	40	42	41
Total considered	414	412	394	390	412	404
Removed data sets		2 (0,48 %[a])	20 (4,83 %[a])	24 (5,79 %[a])	2 (0,48 %[a])	10 (2,14 %[a])
[a] This is the number of data sets removed, expressed as a proportion of the total number of data sets considered, to enable comparison where the total differs.						

Table 9 — Number of data sets obtained under HCI smoking considered for the calculation of r and R after outlier removal

Test article	Total number of data sets available	TPM	Nicotine	Water	NFDPM	CO
A	40	40	38	40	37	37
B	41	39	39	38	36	38
C	41	40	40	40	38	38
D	40	37	39	36	38	39
E	40	40	39	38	39	39
F	41	38	39	35	37	37
G	41	41	39	39	38	39
H	41	41	39	40	40	40
I	40	39	36	37	34	37
J	41	38	39	36	39	37
Total considered	406	393	387	379	376	381
Removed data sets		13 (3,20 %[a])	19 (4,68 %[a])	27 (6,65 %[a])	30 (7,38 %[a])	25 (6,15 %[a])
[a] This is the number of data sets removed, expressed as a proportion of the total number of data sets considered, to enable comparison where the total differs.						

9.3   Mean smoke yields after outlier removal

The mean values (calculated after outlier removal) and the standard deviations for all test articles at both smoking regimes are presented in Tables 10 and 11. In 10.2, the linear and rotary smoking machine data are analysed separately.

Table 10 — Mean and SD values of smoke yields under the ISO smoking regime

Test article	TPM (mg/cig)		Nicotine (mg/cig)		Water (mg/cig)		NFDPM (mg/cig)		CO (mg/cig)	
	Total mean	±SD	Total mean	±SD	Total mean	±SD	Total mean	±SD	Total mean	±SD
A	1,279	0,175	0,108	0,014	0,096	0,042	1,050	0,186	1,321	0,138
B	5,209	0,266	0,389	0,028	0,397	0,105	4,401	0,284	5,154	0,452
C	10,809	0,592	0,677	0,041	1,255	0,198	8,846	0,531	7,786	0,615
D	10,032	0,435	0,816	0,040	0,926	0,205	8,262	0,405	9,335	0,508
E	11,539	0,688	0,663	0,035	1,099	0,165	9,750	0,747	9,075	0,440
F	10,649	0,371	0,752	0,041	1,117	0,186	8,748	0,364	9,884	0,473
G	12,052	0,503	0,830	0,041	1,510	0,280	9,683	0,443	10,956	0,635
H	11,076	0,418	0,665	0,040	1,064	0,185	9,315	0,372	13,614	0,706
I	2,082	0,246	0,154	0,019	0,190	0,068	1,724	0,206	3,204	0,364
J	17,296	0,639	1,366	0,051	1,685	0,254	14,213	0,690	14,435	0,622

Table 11 — Mean and SD values of smoke yields under the HCI smoking regime

Test article	TPM (mg/cig)		Nicotine (mg/cig)		Water (mg/cig)		NFDPM (mg/cig)		CO (mg/cig)	
	Total mean	±SD	Total mean	±SD	Total mean	±SD	Total mean	±SD	Total mean	±SD
A	25,410	2,708	1,267	0,066	7,348	1,988	16,479	1,430	20,182	1,075
B	31,255	4,040	1,342	0,072	9,389	2,796	20,175	1,921	22,885	1,193
C	39,841	4,806	1,789	0,118	11,869	3,327	25,815	2,515	22,250	1,186
D	39,069	5,019	2,106	0,135	11,190	3,298	25,446	2,675	27,017	1,456
E	29,705	3,212	1,407	0,120	6,061	1,755	22,033	2,362	19,712	1,453
F	43,688	4,014	2,069	0,125	13,419	2,243	28,190	2,467	28,976	1,492
G	43,427	5,116	2,086	0,110	14,164	3,746	26,732	2,777	26,969	1,617
H	40,092	4,191	1,681	0,101	11,469	2,980	26,603	2,388	33,543	1,673
I	27,052	4,183	0,994	0,084	9,031	2,673	16,689	2,337	28,532	2,710
J	41,178	2,636	2,683	0,167	10,106	1,788	28,880	2,546	26,212	1,118

9.4 Repeatability (r) and reproducibility (R) of smoke yields

In Figures 21 to 30 and Tables 12 to 16, the r and R estimates for ISO and HCI smoking are shown for all test articles for TPM, nicotine, water, NFDPM, and CO yields. Linear regressions for each set of r and R data have been calculated and are included in Figures 21 to 30.

For both smoking regimes, the r and R values generally lay close to the relevant regression lines, while the R values are more scattered around their regression lines than the r values. For ISO smoking, R is a factor of two times higher than r with the exception of some cases (i.e. nicotine test article I) where R is around three times higher.

The factor between r and R is clearly higher with the intense smoking regime: for TPM and water, R is five to six times higher than r; for nicotine, R is up to three times higher; for NFDPM, R is three to four times higher than r; and for CO, this factor is around three.

Key
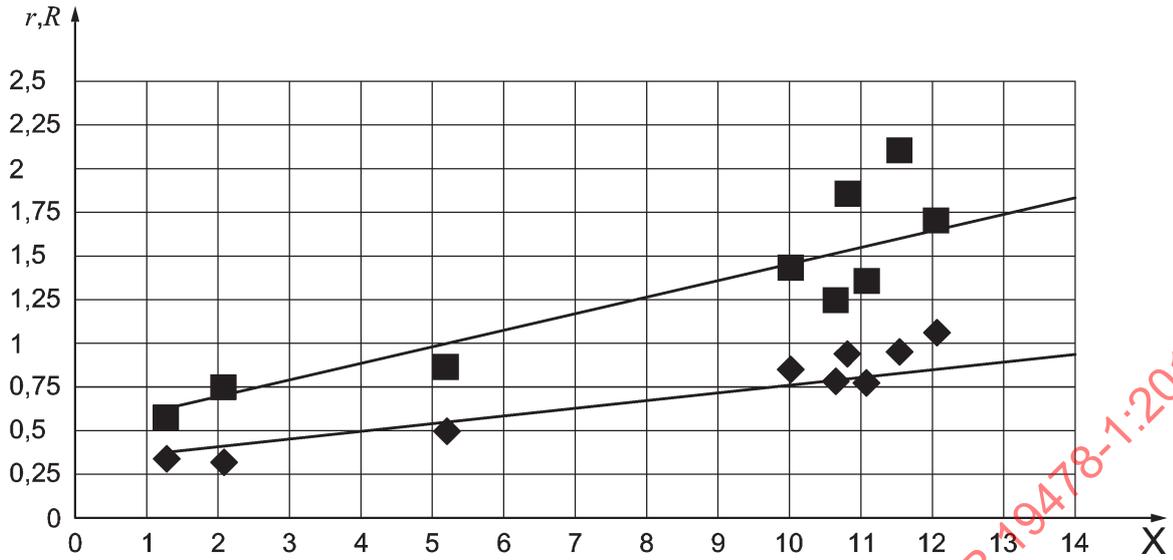
X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 21 — Relationship between mean TPM yield and *r/R* values under ISO smoking

Key
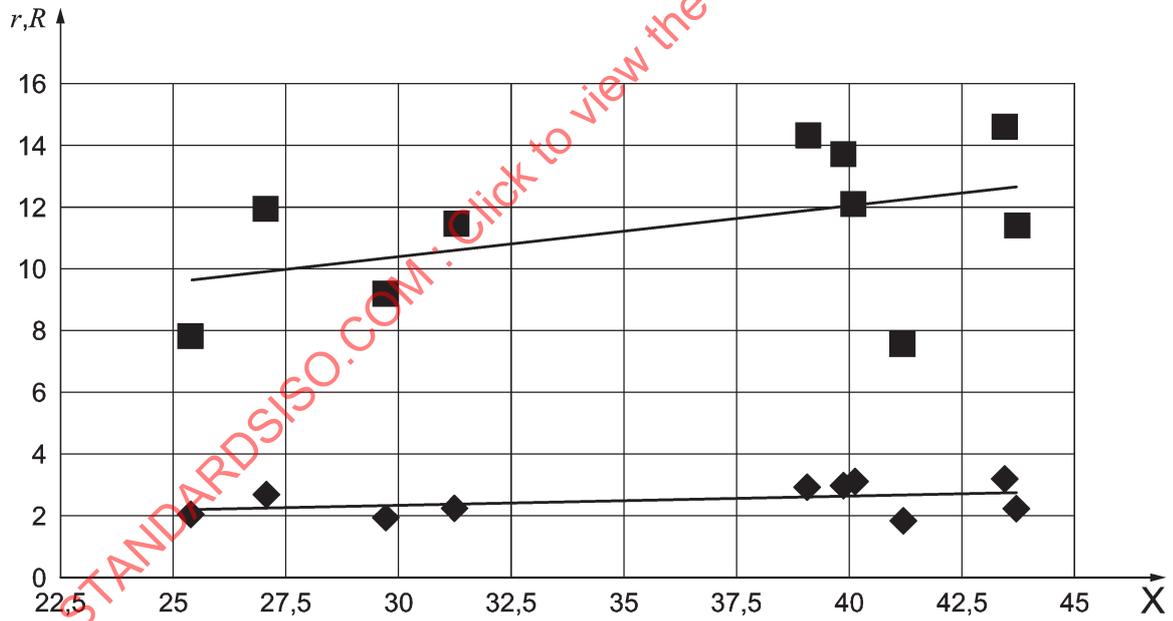
X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 22 — Relationship between mean TPM yield and *r/R* values under HCI smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded
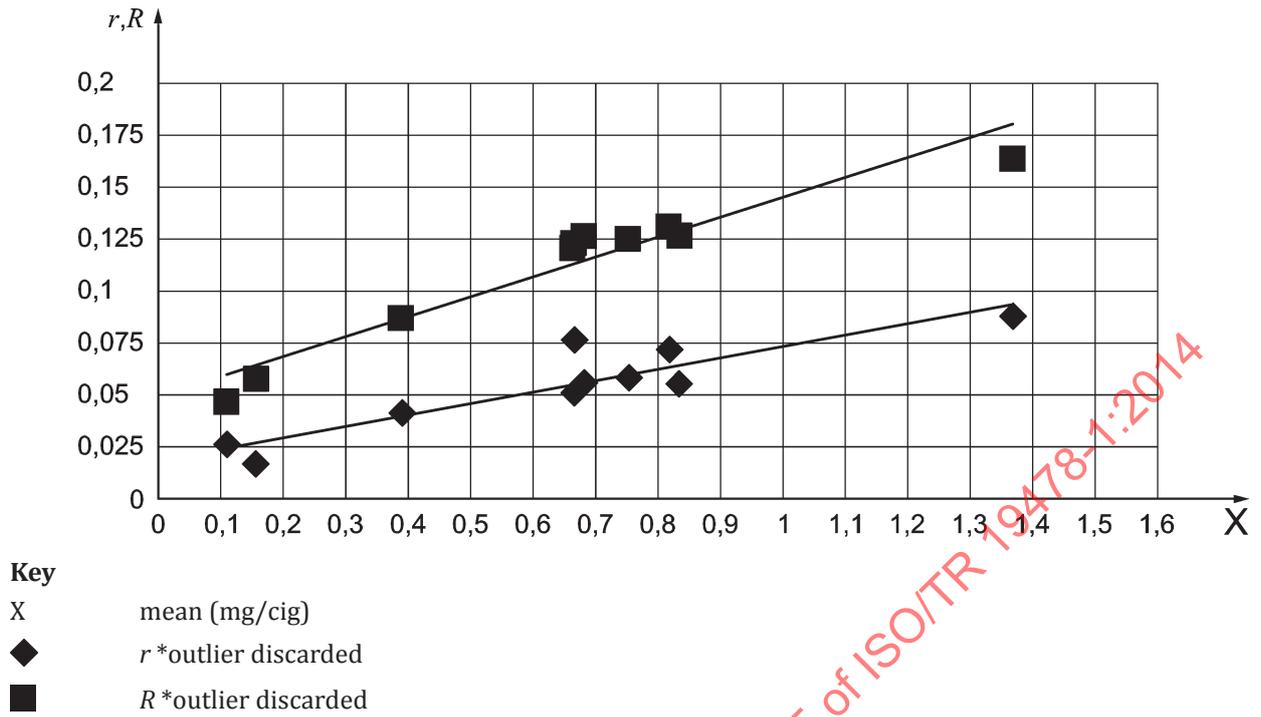
■   *R* *outlier discarded

Figure 23 — Relationship between mean nicotine yield and *r/R* values under ISO smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

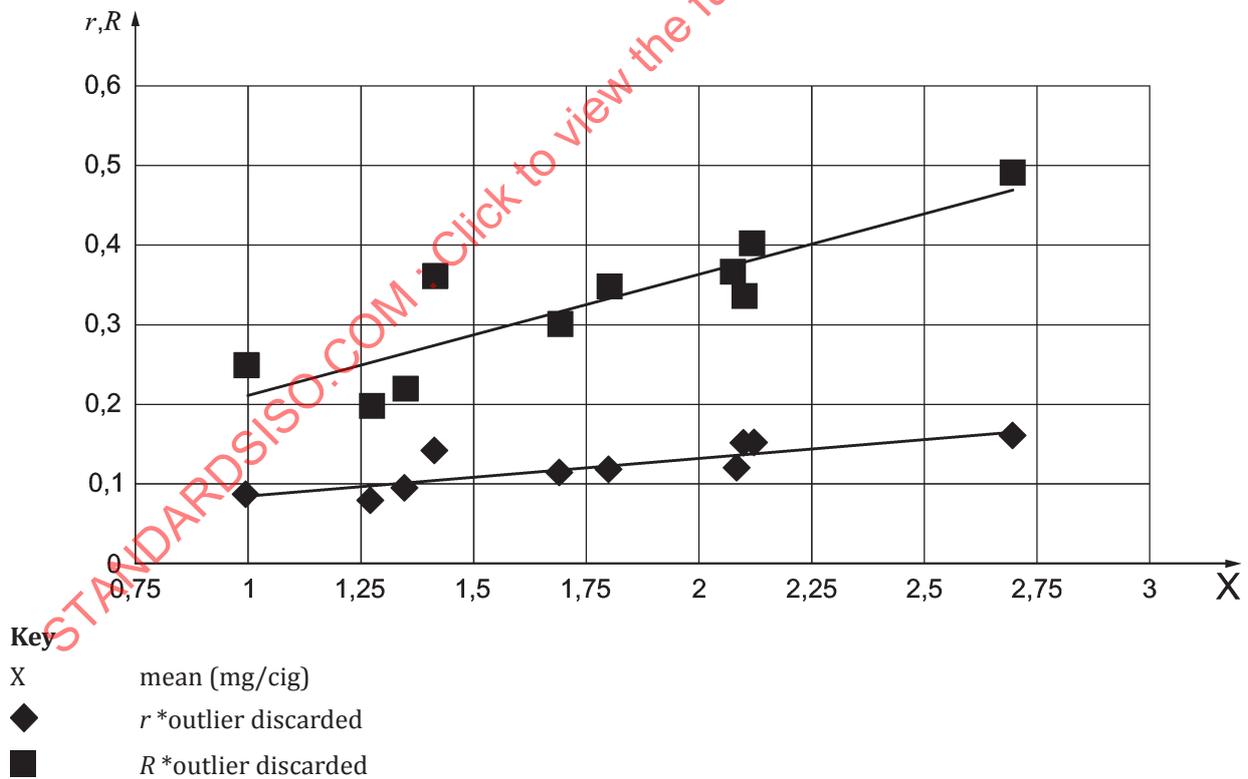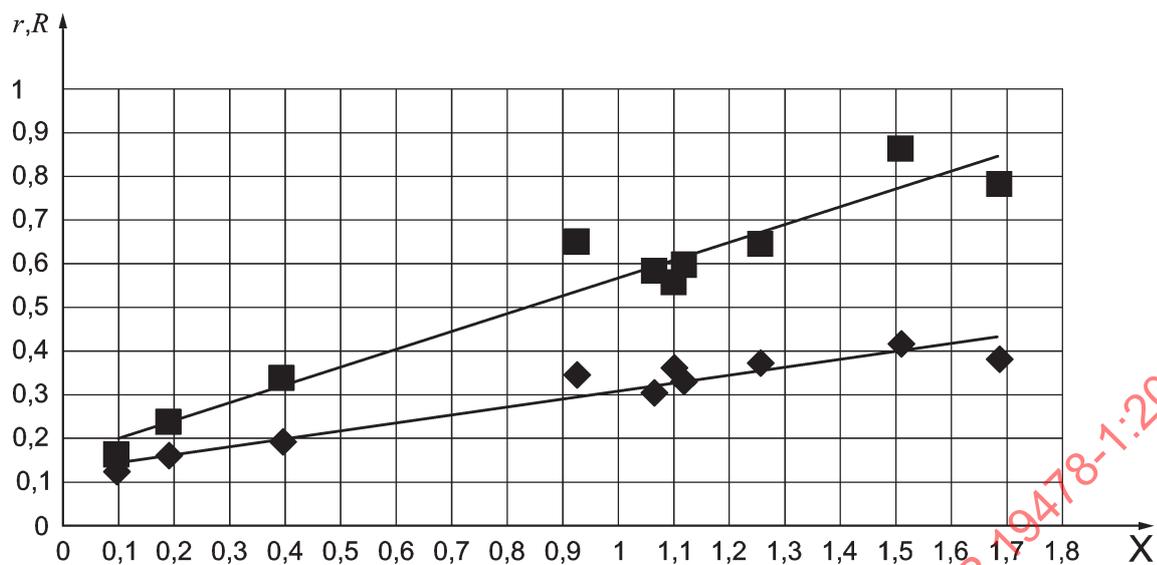■   *R* *outlier discarded
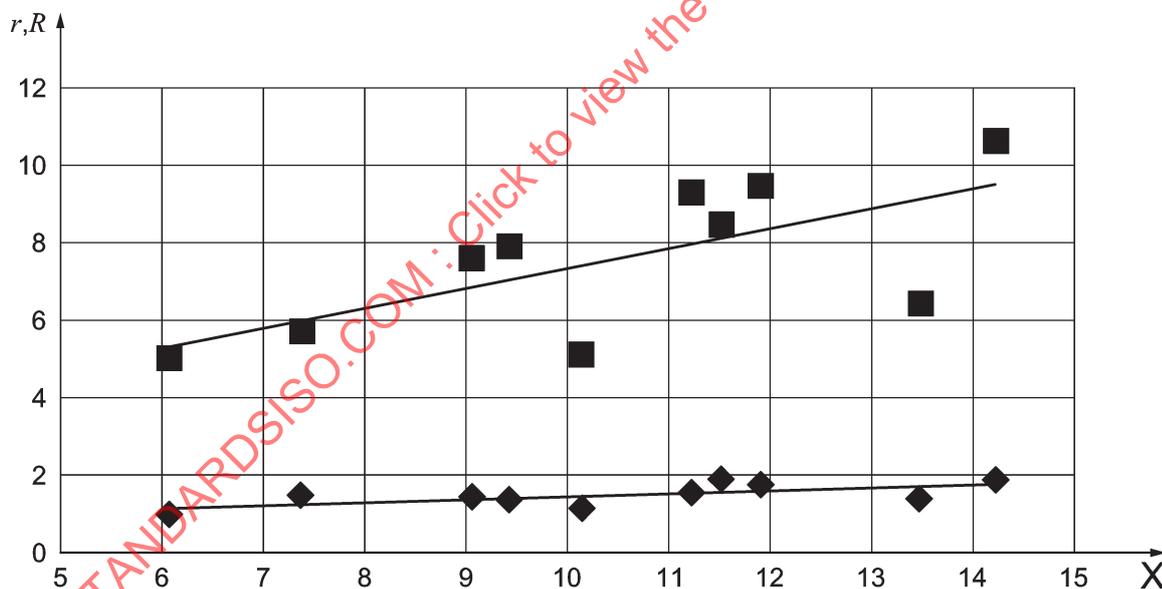
Figure 24 — Relationship between mean nicotine yield and *r/R* values under HCI smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 25 — Relationship between mean water yield and *r/R* values under ISO smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 26 — Relationship between mean water yield and *r/R* values under HCI smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 27 — Relationship between mean NFDPM yield and *r/R* values under ISO smoking

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded

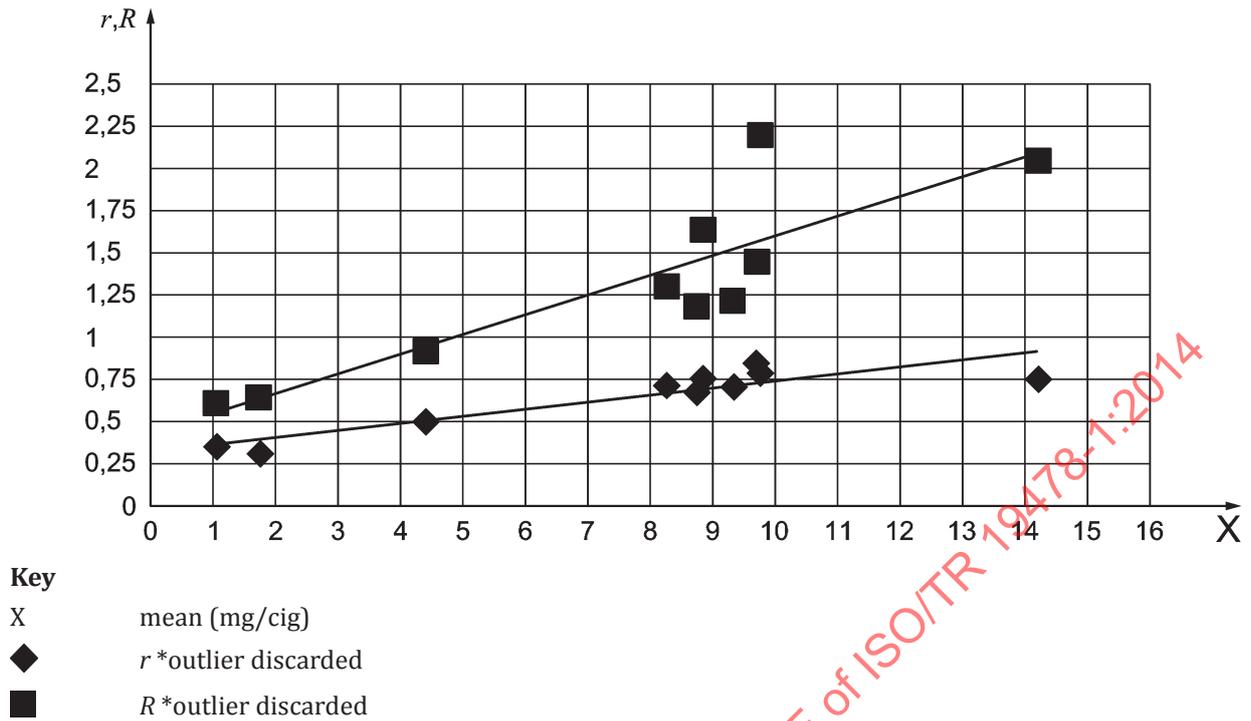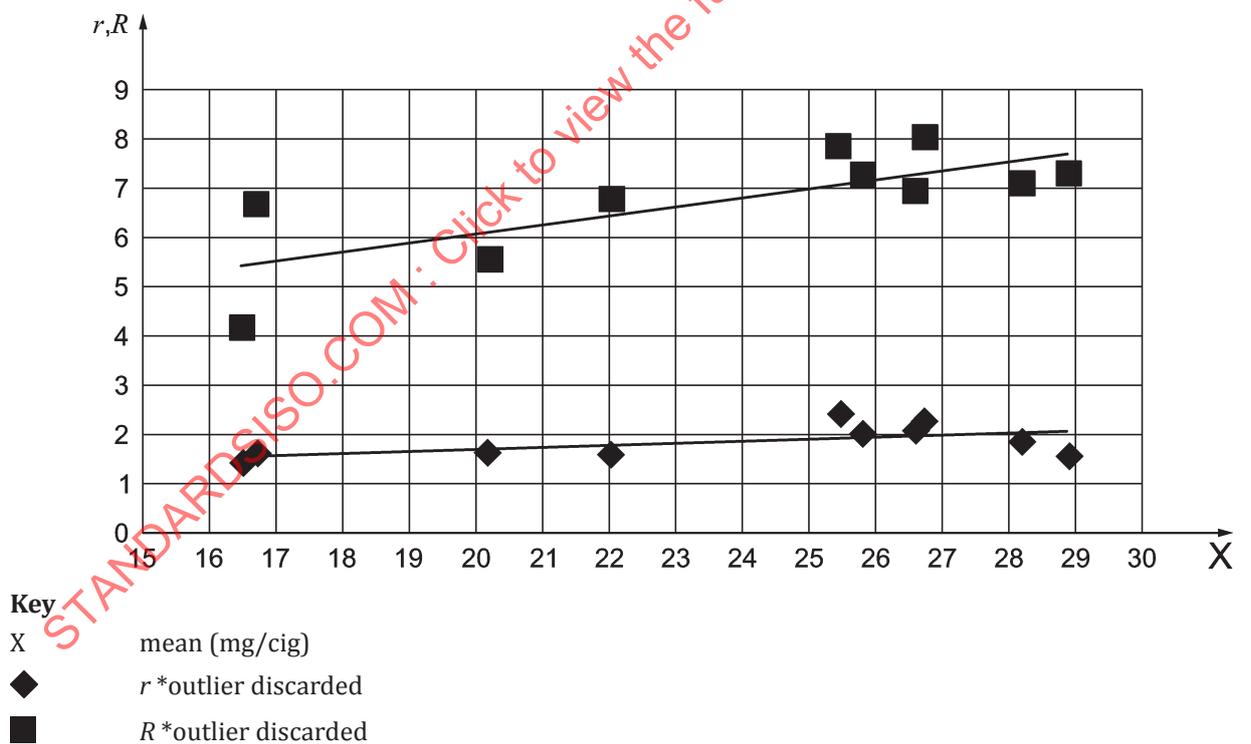**Figure 28 — Relationship between mean NFDPM yield and *r/R* values under HCI smoking**

Key

X   mean (mg/cig)

◆   *r* *outlier discarded

■   *R* *outlier discarded
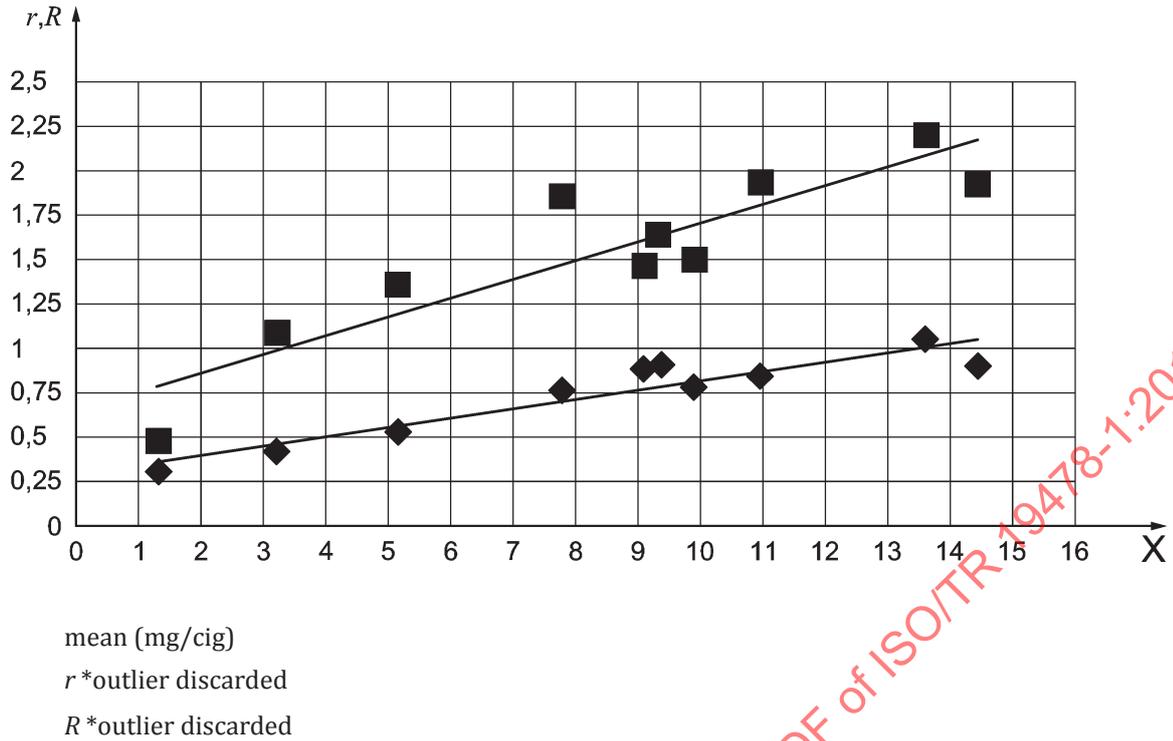
Figure 29 — Relationship between mean CO yield and *r/R* values under ISO smoking

Key

X   mean (mg/cig)

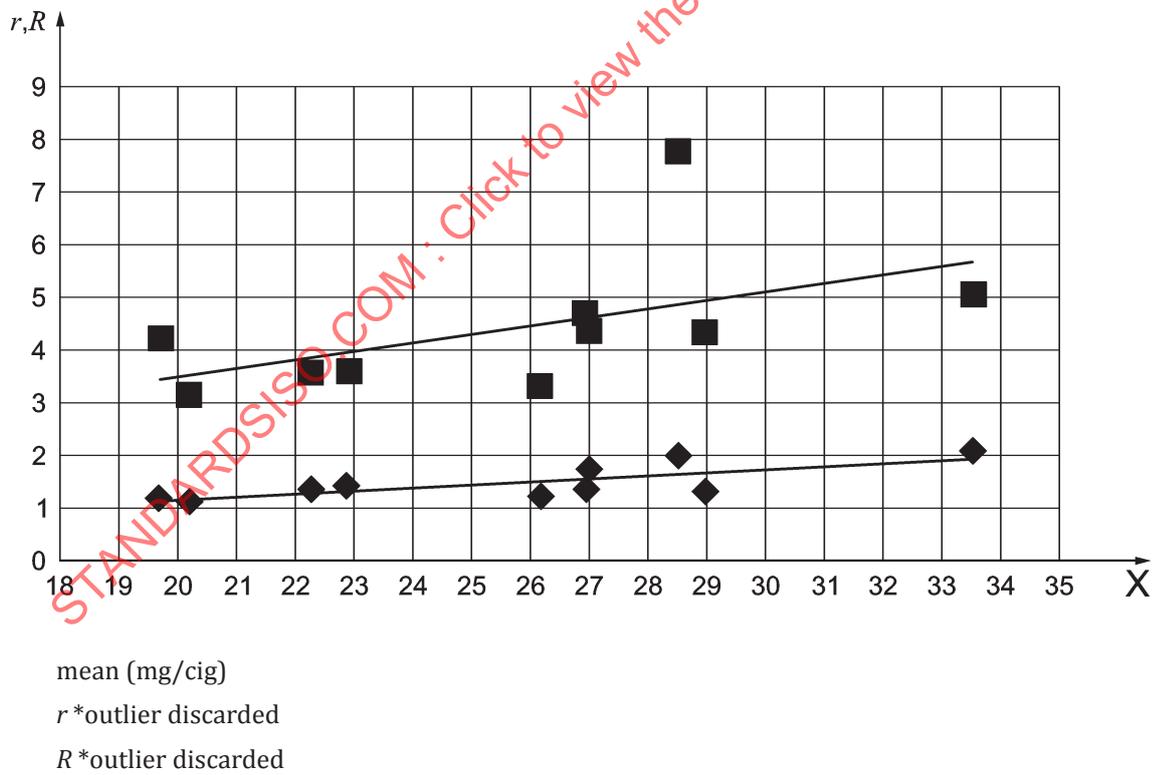◆   *r* *outlier discarded

■   *R* *outlier discarded

Figure 30 — Relationship between mean CO yield and *r/R* values under HCI smoking

Table 12 — TPM repeatability (*r*) and reproducibility (*R*)

Test articles	ISO					HCI				
	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)
A	1,279	0,333	0,575	26	45	25,410	2,034	7,800	8	31
B	5,209	0,491	0,866	9	17	31,255	2,225	11,486	7	37
C	10,809	0,941	1,861	9	17	39,841	2,942	13,713	7	34
D	10,032	0,851	1,436	8	14	39,069	2,922	14,296	7	37
E	11,539	0,950	2,106	8	18	29,705	1,968	9,166	7	31
F	10,649	0,780	1,251	7	12	43,688	2,204	11,411	5	26
G	12,052	1,061	1,698	9	14	43,427	3,173	14,603	7	34
H	11,076	0,773	1,361	7	12	40,092	3,117	12,062	8	30
I	2,082	0,318	0,746	15	36	27,052	2,635	11,947	10	44
J	17,296	0,814	1,933	5	11	41,178	1,838	7,562	4	18

Table 13 — Nicotine repeatability (*r*) and reproducibility (*R*)

Test articles	ISO					HCI				
	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)
A	0,108	0,025	0,046	24	43	1,267	0,079	0,199	6	16
B	0,389	0,040	0,087	11	22	1,342	0,092	0,218	7	16
C	0,677	0,054	0,126	8	19	1,789	0,116	0,348	7	19
D	0,816	0,072	0,130	9	16	2,106	0,151	0,401	7	19
E	0,663	0,076	0,120	11	18	1,407	0,139	0,359	10	26
F	0,752	0,058	0,126	8	17	2,069	0,120	0,366	6	18
G	0,830	0,055	0,126	7	15	2,086	0,151	0,338	7	16
H	0,665	0,051	0,123	8	19	1,681	0,116	0,301	7	18
I	0,154	0,016	0,057	11	37	0,994	0,084	0,249	8	25
J	1,366	0,088	0,164	6	12	2,683	0,160	0,490	6	18

Table 14 — Water repeatability (*r*) and reproducibility (*R*)

Test articles	ISO					HCI				
	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)	Mean (mg/cig)	*r*	*R*	*r* (%)	*R* (%)
A	0,096	0,124	0,162	129	169	7,348	1,454	5,718	20	78
B	0,397	0,190	0,340	48	86	9,389	1,385	7,927	15	84
C	1,255	0,375	0,648	30	52	11,869	1,723	9,444	15	80
D	0,926	0,345	0,653	37	70	11,190	1,526	9,336	14	83
E	1,099	0,359	0,565	33	51	6,061	0,954	4,987	16	82
F	1,117	0,331	0,600	30	54	13,419	1,377	6,401	10	48
G	1,510	0,416	0,867	28	57	14,164	1,865	10,622	13	75
H	1,064	0,307	0,587	29	55	11,469	1,879	8,512	16	74

Table 14 *(continued)*

Test articles	ISO					HCI				
	Mean (mg/cig)	r	R	r (%)	R (%)	Mean (mg/cig)	r	R	r (%)	R (%)
I	0,190	0,160	0,239	84	126	9,031	1,419	7,591	16	84
J	1,685	0,381	0,789	23	47	10,106	1,144	5,111	11	51

Table 15 — NFDPM repeatability (*r*) and reproducibility (*R*)

Test articles	ISO					HCI				
	Mean (mg/cig)	r	R	r (%)	R (%)	Mean (mg/cig)	r	R	r (%)	R (%)
A	1,050	0,352	0,609	34	58	16,479	1,384	4,192	8	25
B	4,401	0,502	0,913	11	21	20,175	1,601	5,567	8	28
C	8,846	0,758	1,635	9	18	25,815	2,005	7,268	8	28
D	8,262	0,715	1,302	9	16	25,446	2,420	7,798	10	31
E	9,750	0,795	2,211	8	23	22,033	1,577	6,763	7	31
F	8,748	0,679	1,186	8	14	28,190	1,799	7,095	6	25
G	9,683	0,840	1,450	9	15	26,732	2,242	8,030	8	30
H	9,315	0,705	1,219	8	13	26,603	2,063	6,937	8	26
I	1,724	0,308	0,640	18	37	16,689	1,584	6,697	9	40
J	14,213	0,751	2,048	5	14	28,880	1,559	7,265	5	25

Table 16 — CO repeatability (*r*) and reproducibility (*R*)

Test articles	ISO					HCI				
	Mean (mg/cig)	r	R	r (%)	R (%)	Mean (mg/cig)	r	R	r (%)	R (%)
A	1,321	0,309	0,477	23	36	20,182	1,134	3,177	6	16
B	5,154	0,525	1,351	10	26	22,885	1,419	3,574	6	16
C	7,786	0,764	1,854	10	24	22,250	1,380	3,543	6	16
D	9,335	0,914	1,641	10	18	27,017	1,737	4,365	6	16
E	9,075	0,875	1,461	10	16	19,712	1,197	4,209	6	21
F	9,884	0,785	1,499	8	15	28,976	1,335	4,345	5	15
G	10,956	0,845	1,932	8	18	26,969	1,329	4,682	5	17
H	13,614	1,047	2,190	8	16	33,543	2,072	5,038	6	15
I	3,204	0,413	1,085	13	34	28,532	1,973	7,791	7	27
J	14,435	0,901	1,921	6	13	26,212	1,216	3,316	5	13

10 Discussion

10.1 Comparison of data from ISO and HCI smoking regimes

10.1.1 Ratio of mean yields

The basic data evaluation provided clear evidence for much higher measured values for TPM, nicotine, water, NFDPM, and CO under HCI smoking conditions than ISO (Table 17) with the highest increases at low ISO NFDPM yields (test articles A and I).

Table 17 — HCI/ISO ratio of mean yields per test article

Test article	NFDPM	Nicotine	CO	TPM	Water
A	15,6	12,6	15,2	20,0	81,5
B	4,5	3,5	4,4	6,0	24,0
C	2,9	2,6	2,8	3,6	9,3
D	3,0	2,5	2,8	3,8	12,1
E	2,2	2,1	2,1	2,5	5,5
F	3,2	2,7	2,9	4,1	12,0
G	2,7	2,5	2,4	3,6	9,3
H	2,8	2,5	2,4	3,6	10,8
I	9,6	6,6	8,9	13,0	47,5
J	2,0	1,9	1,8	2,3	6,0

10.1.2 Ranking of test articles

The relative ranking of smoke yields generated by the two smoking regimes was investigated for the different test articles. Figures 31 to 35 rank the test articles based on ISO smoking conditions from rank 1 with the lowest overall mean yield to rank 10 with the highest overall mean. The yield rankings under HCI conditions for the test parameter TPM, nicotine, water, NFDPM, and CO are shown alongside the ISO rankings.

— TPM: In general, the ranking of the test articles are comparable for the two smoking regimes with the exception of the test articles E and F (plain and slim test articles respectively).

— Nicotine: The two different smoking regimes result in nearly identical ranking of the test articles.

— Water: The greatest differences in ranking can be seen for test article E (plain test article) followed by test article J (CM6).

— NFDPM: The ranking for NFDPM mainly reflects the ranking of TPM.

— CO: For this parameter, the ranking under HCI conditions shows mainly differences for test articles E, I, and J (plain, 1R5F, and CM6 respectively), compared with ISO.
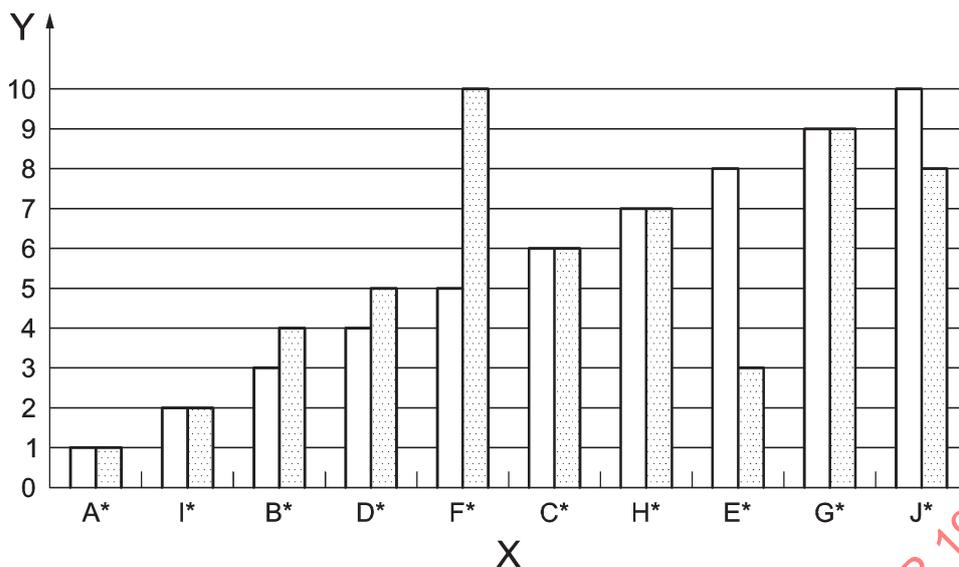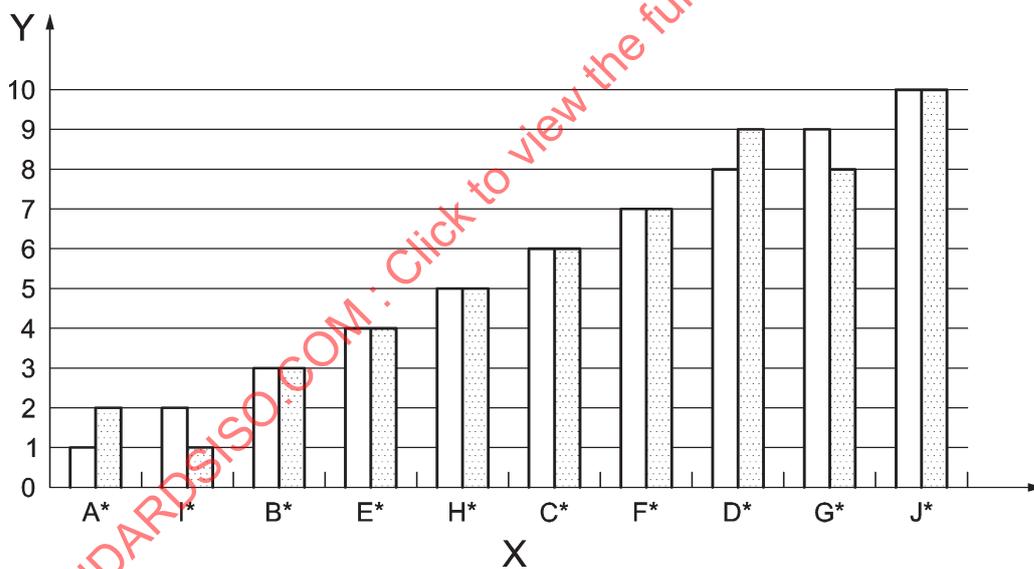
Figure 31 — Comparison of the ranking of NFDPM yields between ISO and HCI regimes

Figure 32 — Comparison of the ranking of nicotine yields between ISO and HCI regimes

Key

X   test article   Rank: ISO

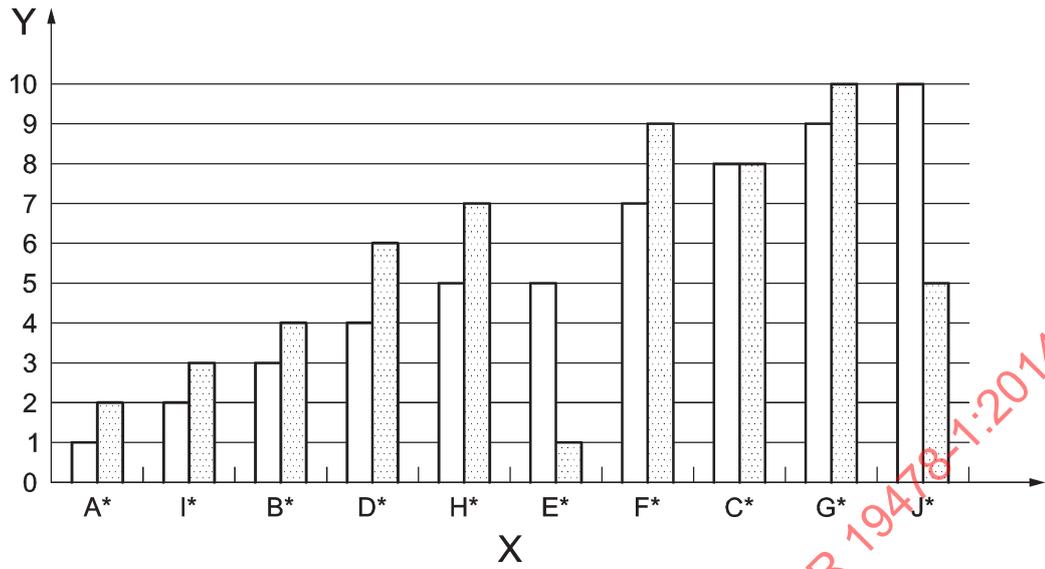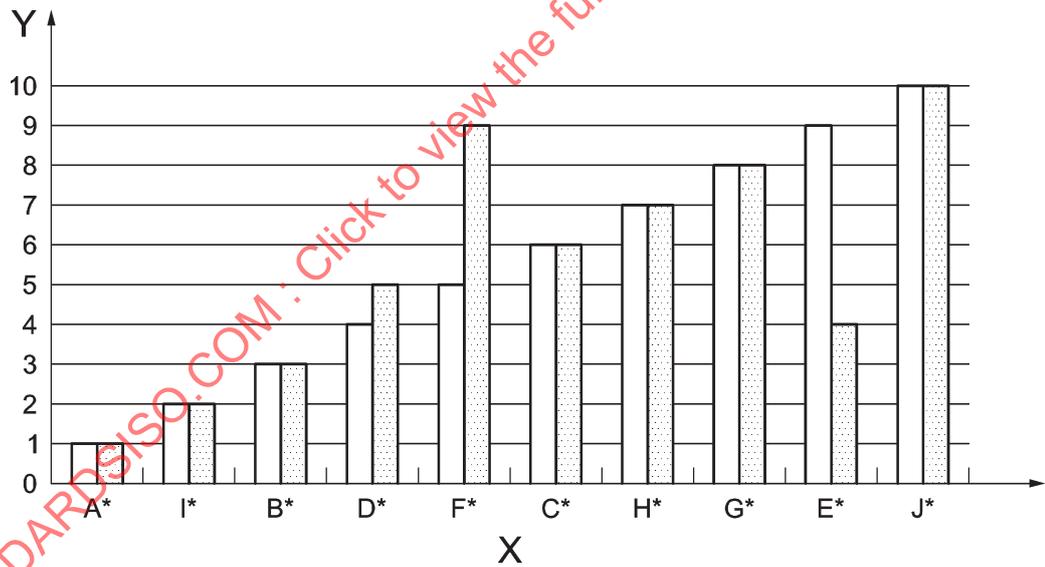Y   rank   Rank: HCI

Figure 33 — Comparison of the ranking of water yields between ISO and HCI regimes
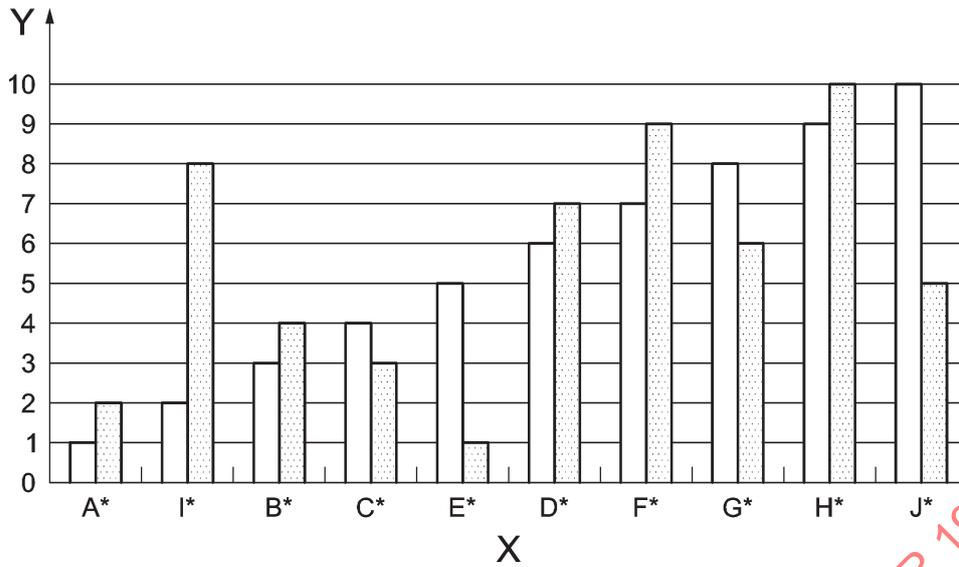

Key

X   test article   Rank: ISO

Y   rank   Rank: HCI

Figure 34 — Comparison of the ranking of NFDPM yields between ISO and HCI regimes

Key

X	test article	☐	Rank: ISO
Y	rank	▨	Rank: HCI

Figure 35 — Comparison of the ranking of CO yields between ISO and HCI regimes

### 10.1.3 Comparison of repeatability and reproducibility of yields

Comparisons of the *r* and *R* variability for each smoke parameter and each test article under the two smoking regimes are shown in Figures 36 to 45, expressed as a percentage of the mean value for that smoke parameter and test article. A line of identity has been included to aid interpretation. Points that are close to the line of identity have similar variability whereas points to either side indicate higher variability for that regime.

Test articles with a low ISO NFDPM yield (test article A and, in some cases, test article I) show strong deviations from the line of identity for several smoke parameters (NFDPM, nicotine, CO, and water). This is apparent for *r*, as well as for *R*. The percentage of *r* and *R* values for test article A are higher under ISO smoking conditions than all other test articles due to the low yields.
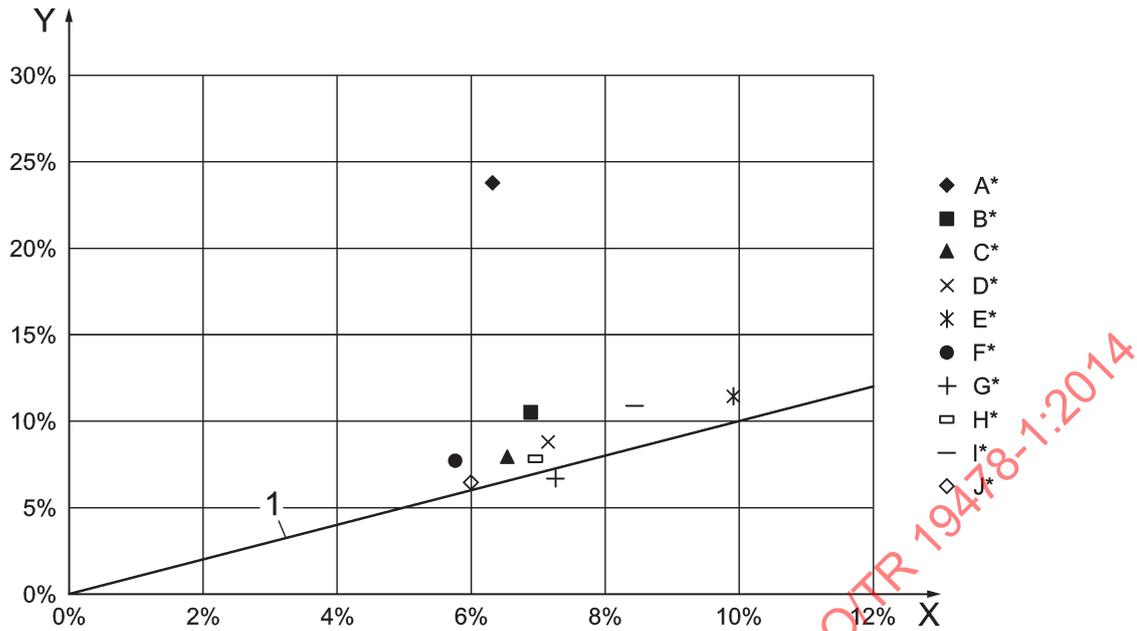
Key

X   HCI
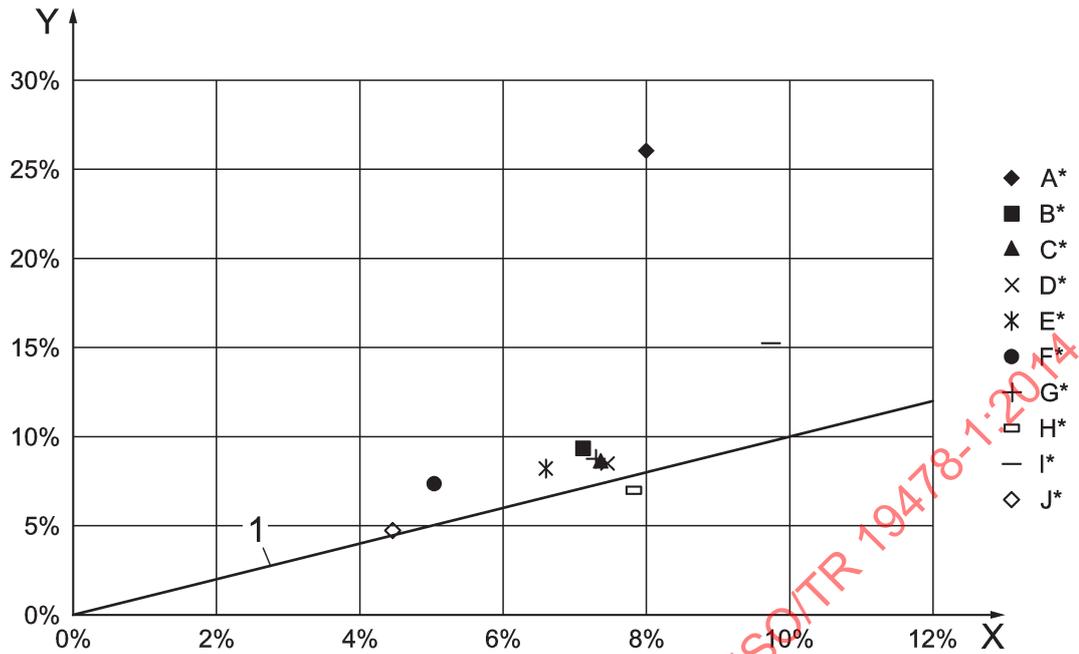
Y   ISO

1   line of identity

Figure 36 — Relationship of % repeatability of TPM between yields obtained under ISO and HCI smoking regimes
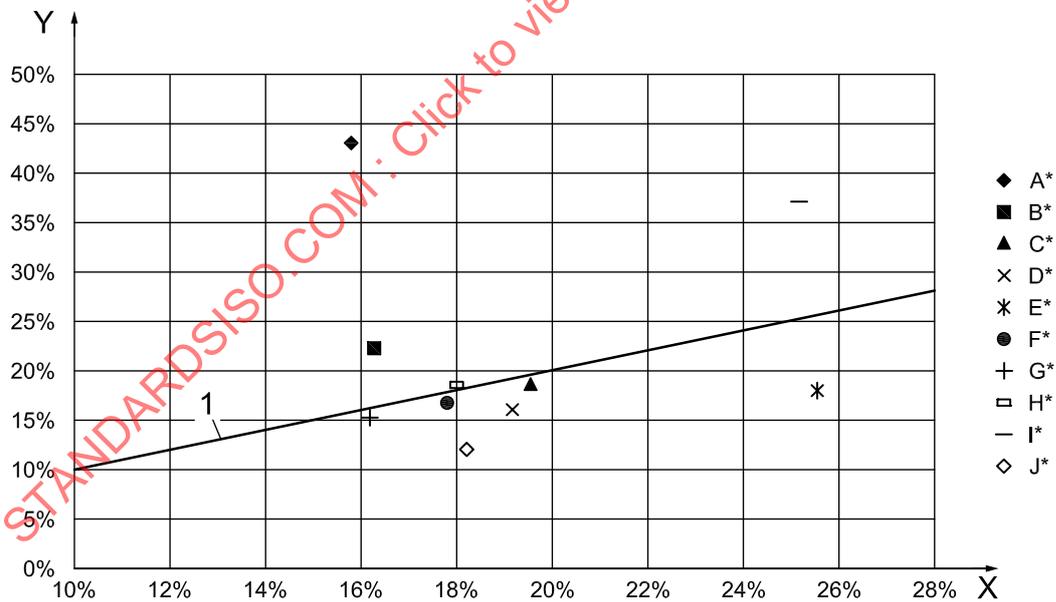

Key

X   HCI
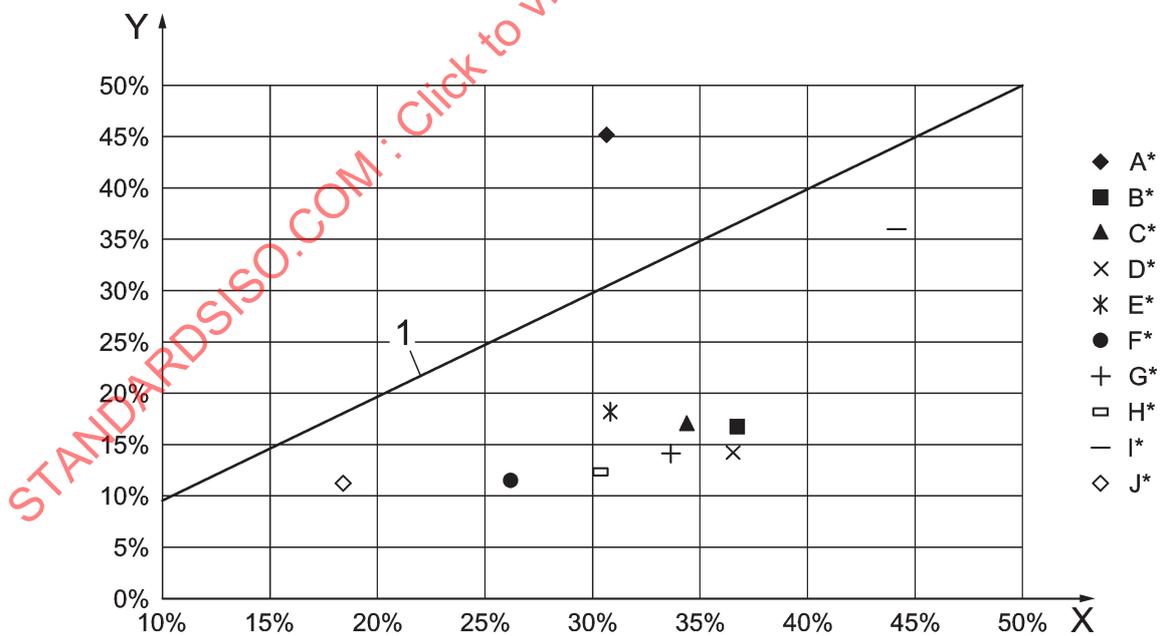
Y   ISO

1   line of identity

Figure 37 — Relationship of % reproducibility of TPM between yields obtained under ISO and HCI smoking regimes

Key

X   HCI

Y   ISO

1   line of identity

Figure 38 — Relationship of % repeatability of nicotine between yields obtained under ISO and HCI smoking regimes

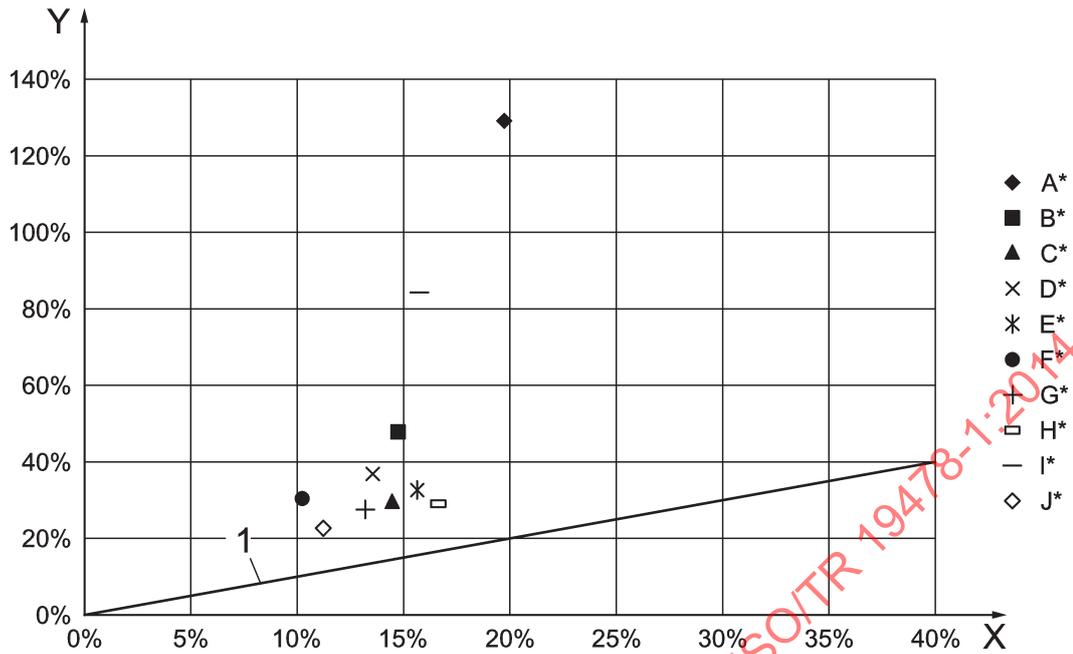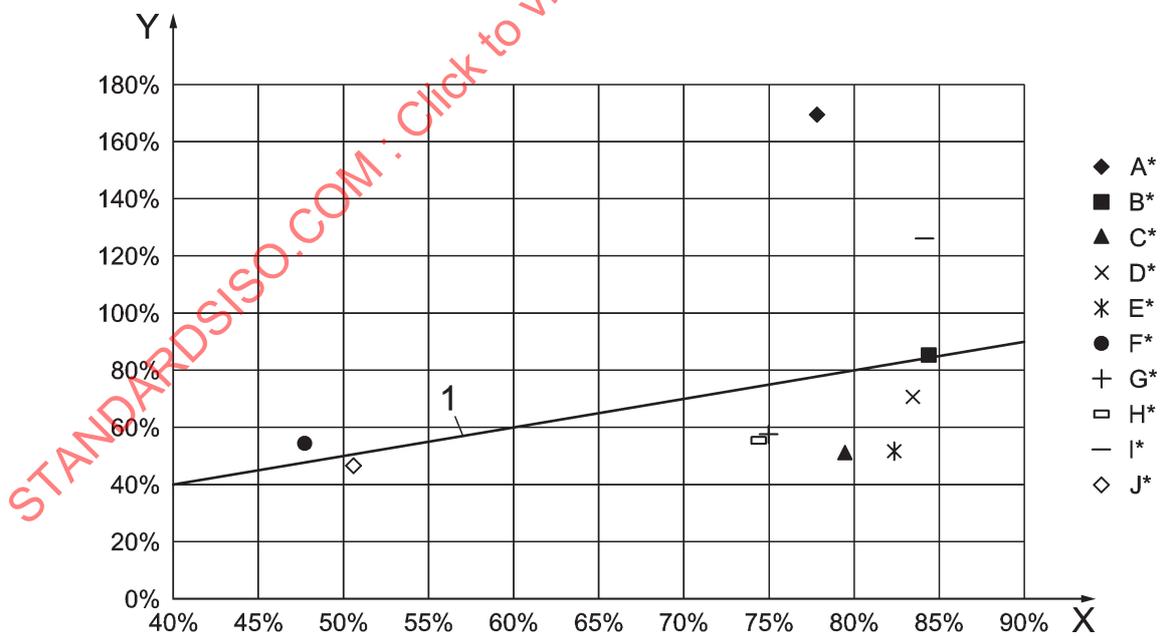**Key**

X   HCI

Y   ISO

1   line of identity

Figure 39 — Relationship of % reproducibility of nicotine between yields obtained under ISO and HCI smoking regimes

Key

X   HCI

Y   ISO

1   line of identity

Figure 40 — Relationship of % repeatability of water between yields obtained under ISO and HCI smoking regimes

Key

X   HCI

Y   ISO

1   line of identity

Figure 41 — Relationship of % reproducibility of water between yields obtained under ISO and HCI smoking regimes

Key

X   HCI

Y   ISO

1   line of identity

Figure 42 — Relationship of % repeatability of NFDPM between yields obtained under ISO and HCI smoking regimes

Key

X   HCI

Y   ISO

1   line of identity

Figure 43 — Relationship of % reproducibility of NFDPM between yields obtained under ISO and HCI smoking regimes

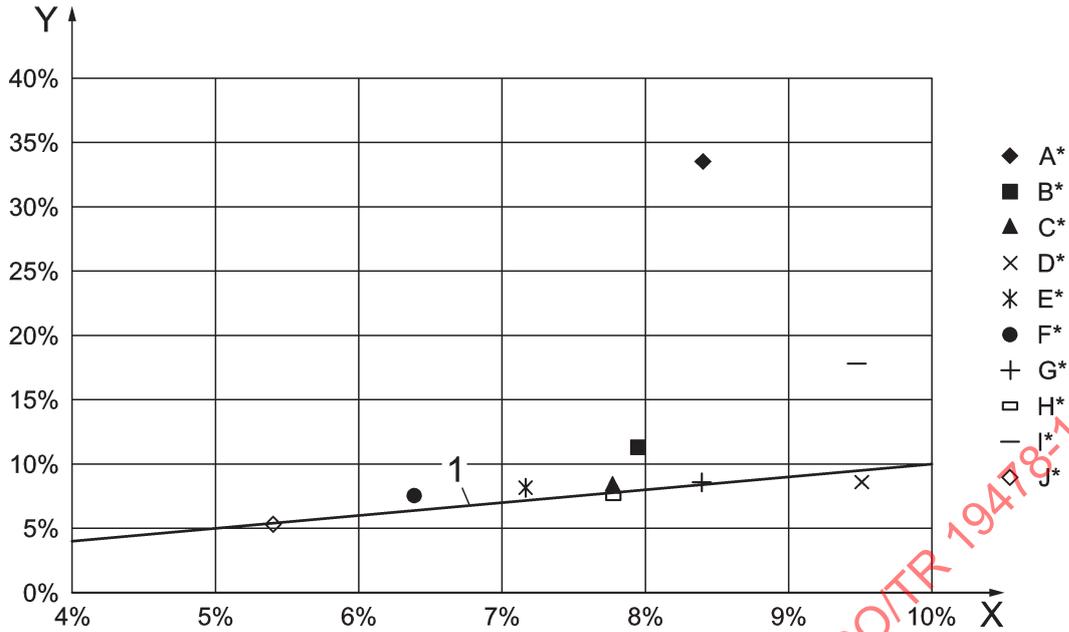**Key**

X   HCI

Y   ISO

1   line of identity

Figure 44 — Relationship of % repeatability of CO between yields obtained under ISO and HCI smoking regimes
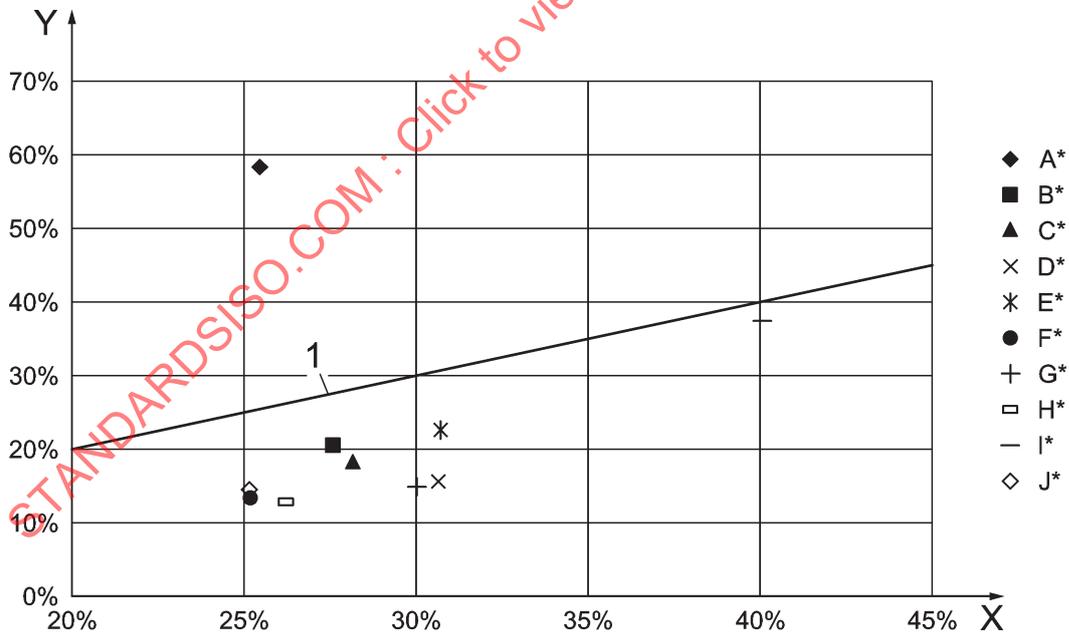

Key

X   HCI

Y   ISO

1   line of identity

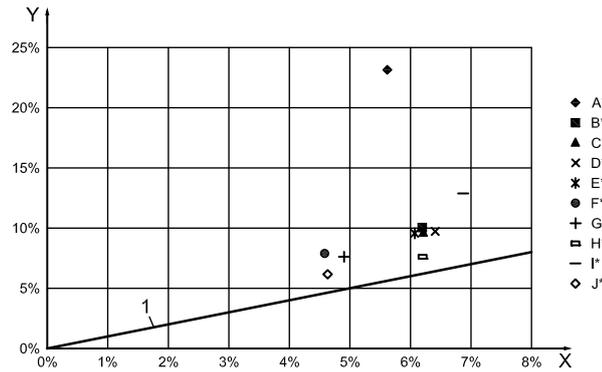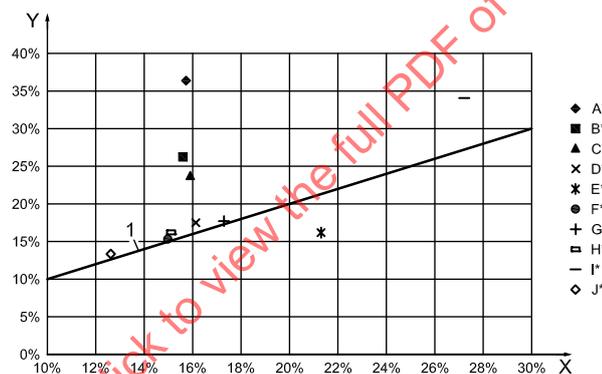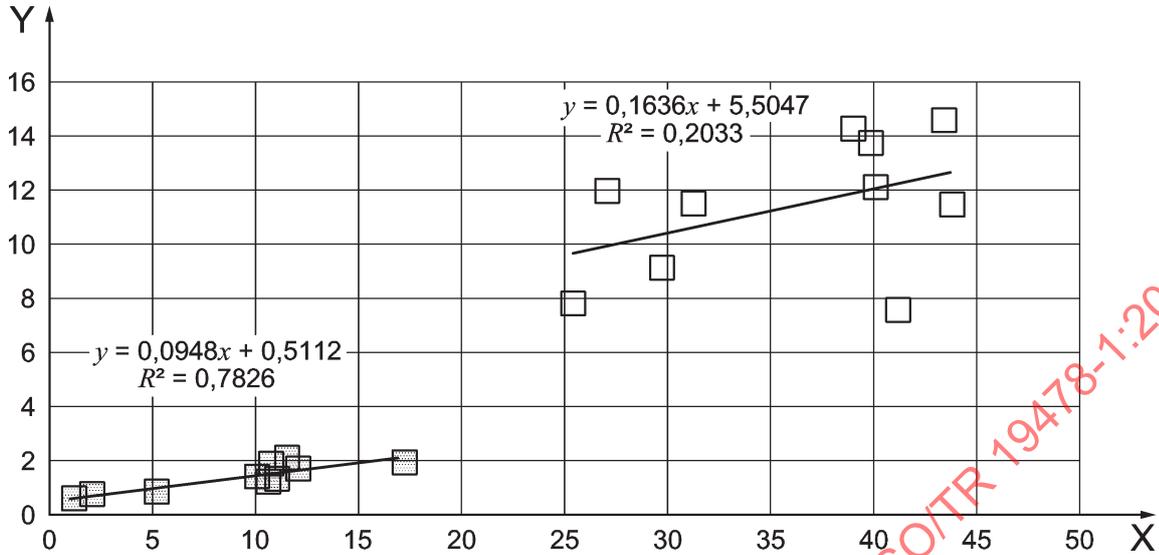**Figure 45 — Relationship of % reproducibility of CO between yields obtained under ISO and HCI smoking regimes**

A comparison of R variability between the two smoking regimes is depicted in Figures 46 to 50 with separate regression models given for each regime. These figures compare the absolute values of R between the two smoking regimes, as well as the scatter around the regression lines.

For TPM (Figure 46), the correlation of the R to mean yield is much weaker with a more dispersed distribution for HCI than ISO smoking. For nicotine, the correlation of these data (Figure 47) reveals a more dispersed distribution for the HCI regime, compared with the ISO smoking regime. Compared with TPM, a slightly better correlation can be seen for water under ISO, as well as under HCI conditions (Figure 48).

The linear regression of the 10 test articles for NFDPM revealed a more dispersed distribution of the mean/R values for HCI, compared with the ISO smoking regime. A similar distribution of the mean/R values in comparison with nicotine can be found for NFDPM (Figure 49). However, the correlation coefficients (R^2 values) for both regimes are clearly lower than the values for nicotine. For CO (Figure 50), the low R^2 value of the HCI smoking regime can be related to the high R value of only one test article (test article I).

     37

In summary, a higher correlation is observed for all smoke parameters under ISO smoking conditions, as well as less scatter of data points around the regression lines.

$y = 0,1636x + 5,5047$
$R^2 = 0,2033$

$y = 0,0948x + 0,5112$
$R^2 = 0,7826$

Key

X	mean (mg/cig)		R-ISO
Y	R		R-HCI

Figure 46 — Relationship of reproducibility and mean for TPM yields obtained under both ISO and HCI smoking

$y = 0,1526x + 0,0616$
$R^2 = 0,7619$

$y = 0,0958x + 0,0494$
$R^2 = 0,9291$

Key
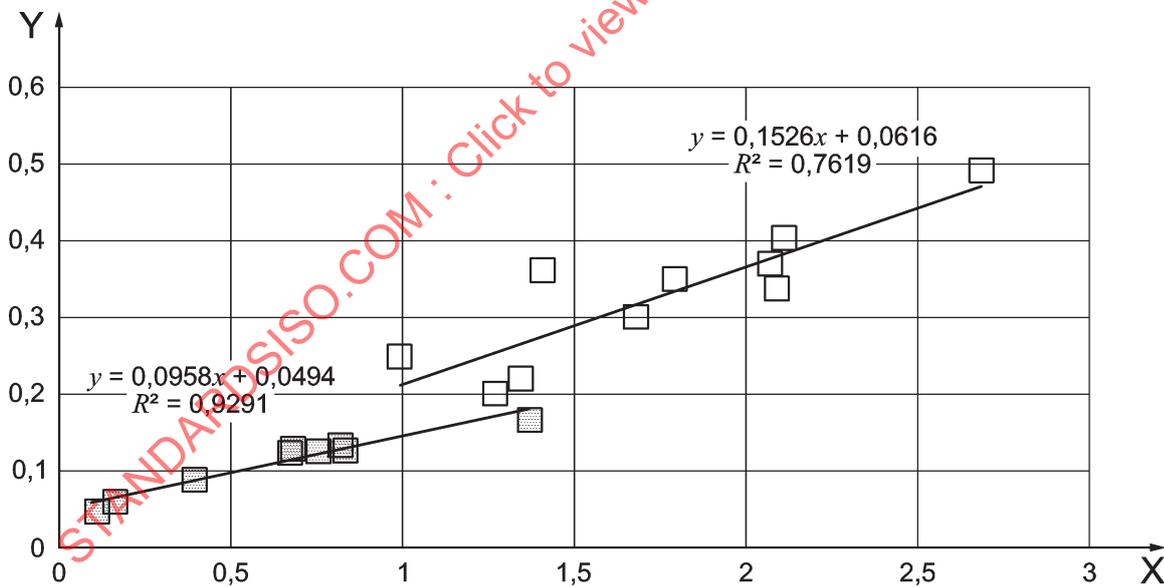
X	mean (mg/cig)		R-ISO
Y	R		R-HCI

Figure 47 — Relationship of reproducibility and mean for nicotine yields obtained under both ISO and HCI smoking

Key

X	mean (mg/cig)		R-ISO
Y	R		R-HCI
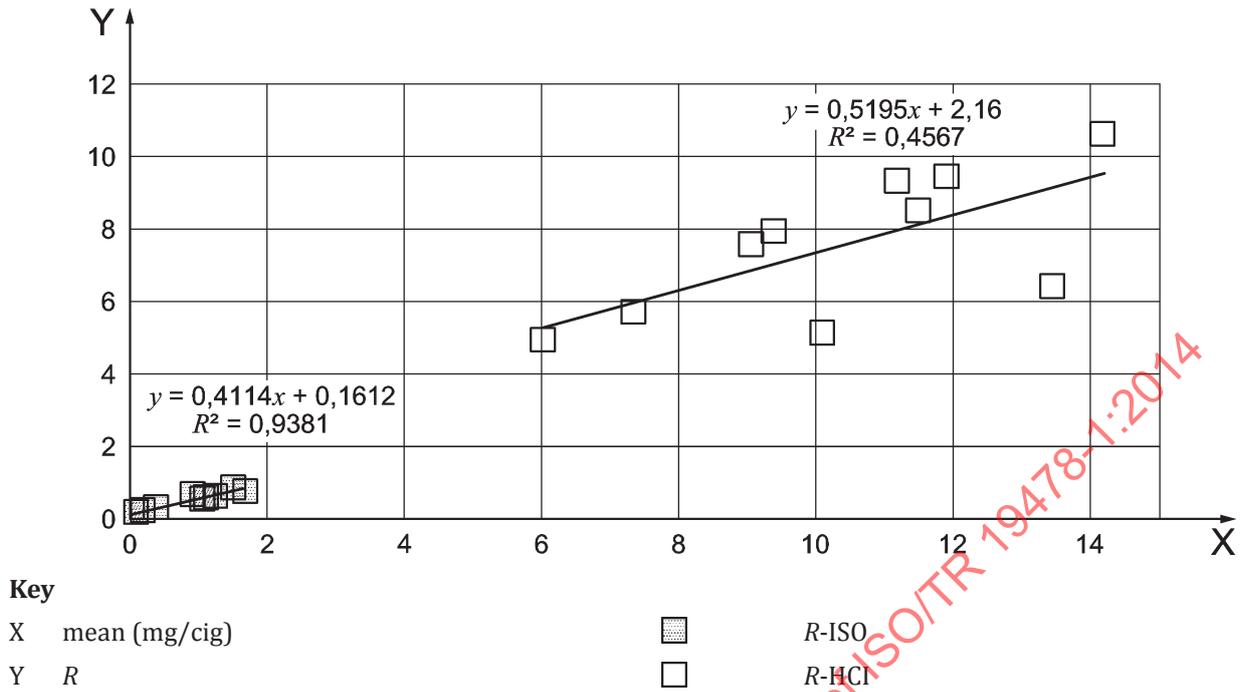
Figure 48 — Relationship of reproducibility and mean for water yields obtained under both ISO and HCI smoking

Key

X	mean (mg/cig)		R-ISO
Y	R		R-HCI
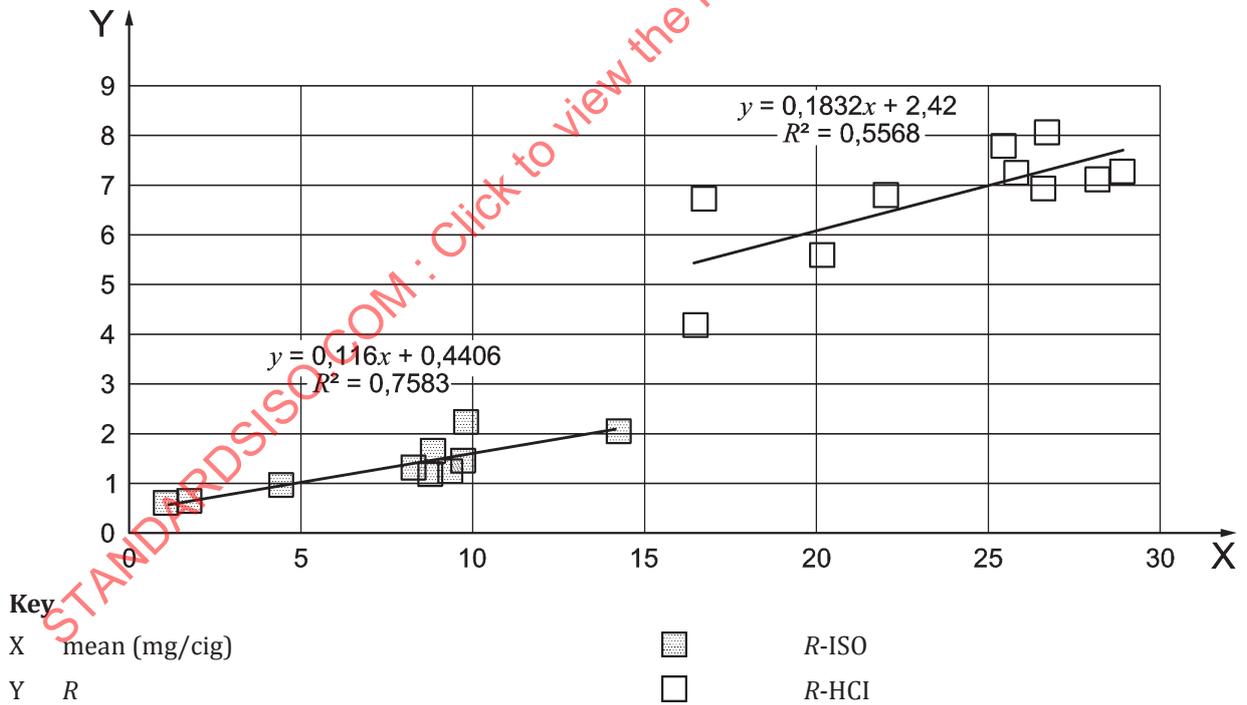
Figure 49 — Relationship of reproducibility and mean for NFDPM yields obtained under both ISO and HCI smoking

Key
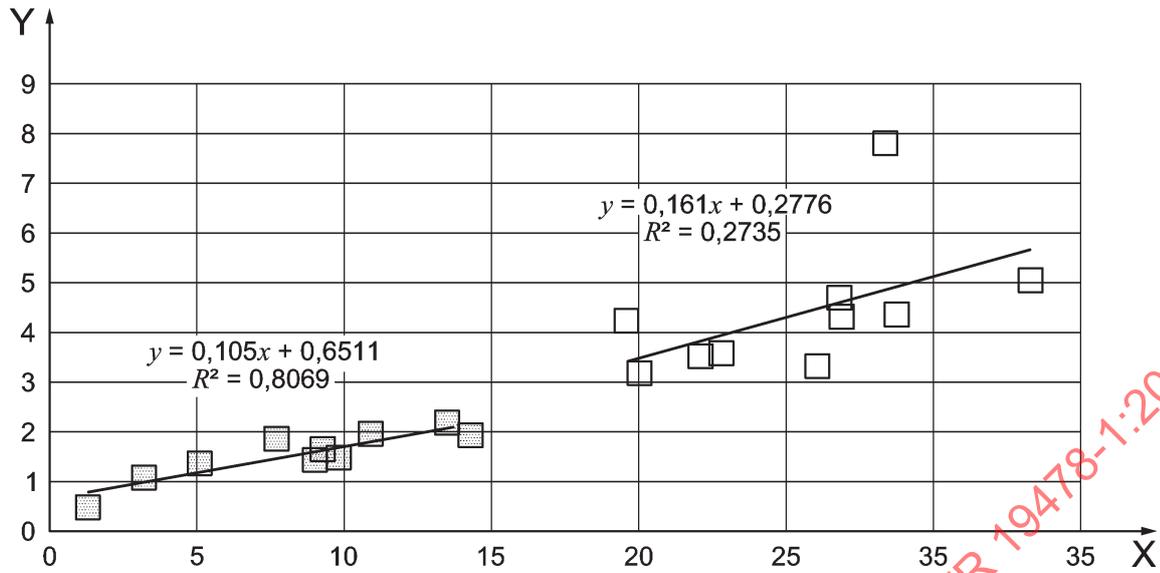
X	mean (mg/cig)	▨	R-ISO
Y	R	☐	R-HCI

Figure 50 — Relationship of reproducibility and mean for CO yields obtained under both ISO and HCI smoking

10.2 Comparison of linear and rotary smoking machines

10.2.1 Outliers

The similar number of linear and rotary smoking machines (20 and 22 respectively, Table 5) allowed an evaluation of the two different types of smoking machines. An analysis of the outliers (see Annex A) suggested considerable differences between linear and rotary smoking machines for all the measured parameters. A condensed summary of these outlier results is shown in Table 18.

Under ISO smoking conditions, the total number of outliers was very similar for both smoking regimes [linear (35) versus rotary (38)]. However, this changes for the different smoke parameters. For nicotine and CO, more outliers were found for the linear smoking machines. In contrast, for water, many more outliers were detected for rotary smoking machines (linear: 9 versus rotary: 25). Also, it was evident that the high numbers of outliers were related to data inconsistencies in only a few data sets. In particular, all 10 CO outliers from the laboratories using linear machines were attributed to one data set.

Considerably, more outliers (79) were produced under HCI smoking conditions by the linear smoking machines, whereas that for rotary smoking machines remained nearly constant (39) (Table 18). With the exception of nicotine, more outliers were found in data sets using linear smoking machines for all other smoke parameters, especially for water (22) and NFDPM (25). In contrast, HCI smoking nearly doubled the amount of nicotine (17) outliers for the rotary machines but decreased significantly the number of outliers for water (5).

Despite this increase in outliers under HCI smoking conditions, the number of data sets responsible was limited. For example, the 17 nicotine outliers from rotary machines under this regime (see Table 18) were found in only two data sets.

Table 18 — Outlier comparison between data collected on rotary and linear smoking machines

	Total number of outliers				Number of data sets with outliers			
	ISO smoking		HCI smoking		ISO smoking		HCI smoking	
	Linear	Rotary	Linear	Rotary	Linear	Rotary	Linear	Rotary
NFDPM	1	1	25	7	1	1	8	2
Nicotine	14	8	4	17	4	5	4	2
CO	10	3	17	8	1	2	7	3
TPM	1	1	11	2	1	1	6	2
Water	9	25	22	5	5	5	10	1
Total	35	38	79	39	12	14	35	10
	73		118		26		45	

10.2.2 Test parameters

Tables 19 and 20 show the mean yields for TPM, nicotine, water, NFDPM, and CO for the whole data set and separated by smoking machine type. As an example for sample J, Figures 46 to 51 show the reported data for NFDPM, nicotine, and CO (after outlier removal) separated by machine type, with the mean and ±2 SD limits.

Table 19 — Mean yields derived under ISO smoking separated by smoking machine type

Test article	TPM mean (mg/cig)			Nicotine mean (mg/cig)			Water mean (mg/cig)			NFDPM mean (mg/cig)			CO mean (mg/cig)		
	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary
A	1,27	1,22	1,33	0,10	0,11	0,10	0,09	0,08	0,10	1,05	1,01	1,08	1,32	1,32	1,32
B	5,20	5,13	5,28	0,38	0,38	0,38	0,39	0,34	0,44	4,40	4,38	4,41	5,15	4,87	5,41
C	10,80	10,97	10,65	0,67	0,67	0,68	1,25	1,15	1,34	8,84	9,12	8,58	7,78	7,48	8,06
D	10,03	10,11	9,94	0,81	0,81	0,81	0,92	0,81	1,06	8,26	8,48	8,05	9,33	9,17	9,46
E	11,53	12,05	11,13	0,66	0,66	0,66	1,09	1,00	1,20	9,75	10,38	9,21	9,07	8,98	9,23
F	10,64	10,68	10,61	0,75	0,76	0,73	1,11	0,96	1,25	8,74	8,94	8,56	9,88	9,75	9,99
G	12,05	12,06	12,02	0,83	0,83	0,83	1,51	1,30	1,70	9,68	9,82	9,46	10,95	10,71	11,16
H	11,07	11,09	11,05	0,66	0,67	0,65	1,06	0,93	1,18	9,31	9,48	9,16	13,61	13,19	13,97
I	2,08	2,01	2,13	0,15	0,15	0,15	0,19	0,14	0,23	1,72	1,69	1,74	3,20	3,09	3,30
J	17,29	17,74	16,93	1,36	1,39	1,34	1,68	1,55	1,80	14,21	14,74	13,73	14,43	14,14	14,55

Table 20 — Mean yields derived under HCI smoking separated by smoking machine type

Test article	TPM mean (mg/cig)			Nicotine mean (mg/cig)			Water mean (mg/cig)			NFDPM mean (mg/cig)			CO mean (mg/cig)		
	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary
A	25,41	27,62	23,40	1,26	1,28	1,23	7,34	8,89	6,63	16,47	17,78	15,60	20,18	19,68	20,65
B	31,25	35,27	28,33	1,34	1,36	1,32	9,38	11,98	8,09	20,17	22,39	18,89	22,88	22,34	23,36
C	39,84	44,24	36,23	1,78	1,83	1,76	11,86	15,11	10,35	25,81	27,83	24,22	22,25	21,88	22,54
D	39,06	43,78	35,20	2,10	2,15	2,07	11,19	14,46	9,68	25,44	27,77	23,58	27,01	26,36	27,57
E	29,70	32,24	27,40	1,40	1,44	1,37	6,06	6,81	5,42	22,03	23,83	20,46	19,71	19,45	19,93
F	43,68	47,49	40,68	2,06	2,13	2,03	13,41	15,62	11,94	28,19	30,21	26,64	28,97	28,56	29,29
G	43,42	48,05	39,43	2,08	2,12	2,04	14,16	17,61	12,50	26,73	28,87	24,64	26,96	26,37	27,47
H	40,09	43,74	36,94	1,68	1,71	1,65	11,46	13,98	10,30	26,60	28,52	25,03	33,54	33,09	34,04

Table 20 *(continued)*

Test article	TPM mean (mg/cig)			Nicotine mean (mg/cig)			Water mean (mg/cig)			NFDPM mean (mg/cig)			CO mean (mg/cig)		
	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary	Total	Linear	Rotary
I	27,05	31,02	24,09	0,99	1,01	0,97	9,03	11,57	7,93	16,68	19,31	15,23	28,53	27,63	29,33
J	41,17	43,31	39,59	2,68	2,74	2,62	10,10	11,04	9,43	28,88	30,45	27,25	26,21	25,77	26,58

Key

X	smoking machine	— · —	upper limit (outlier discarded)
Y	NFDPM (mg/cig)	— ·· —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		
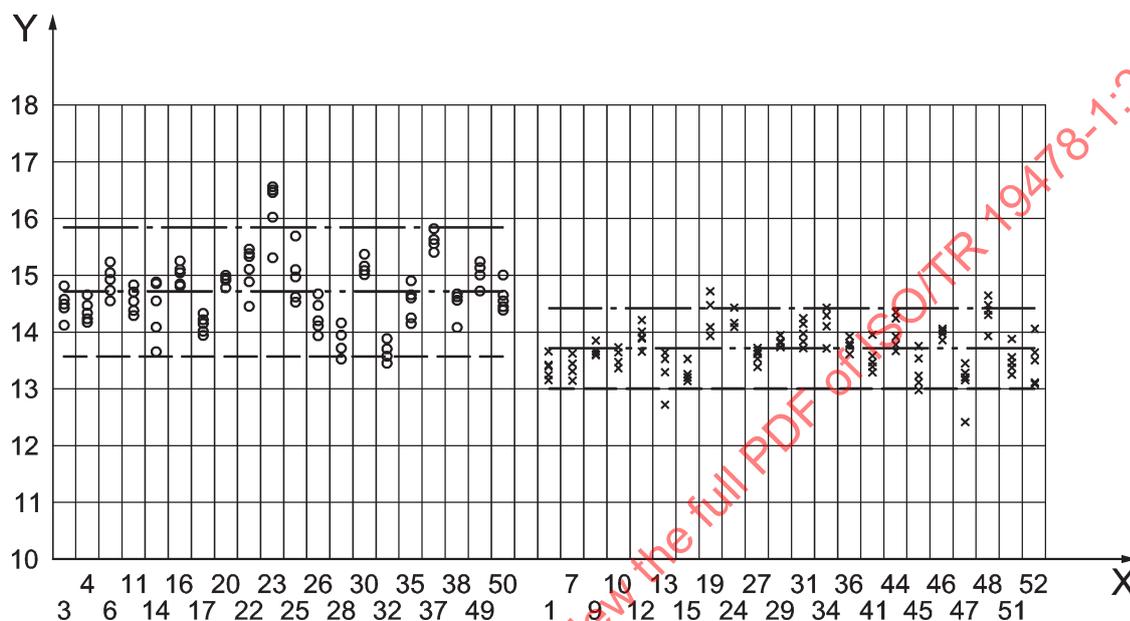
Figure 51 — NFDPM yields obtained under ISO smoking separated by smoking machine type for test article J

Key

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

Figure 52 — NFDPM yields obtained under HCI smoking separated by smoking machine type for test article J

Key

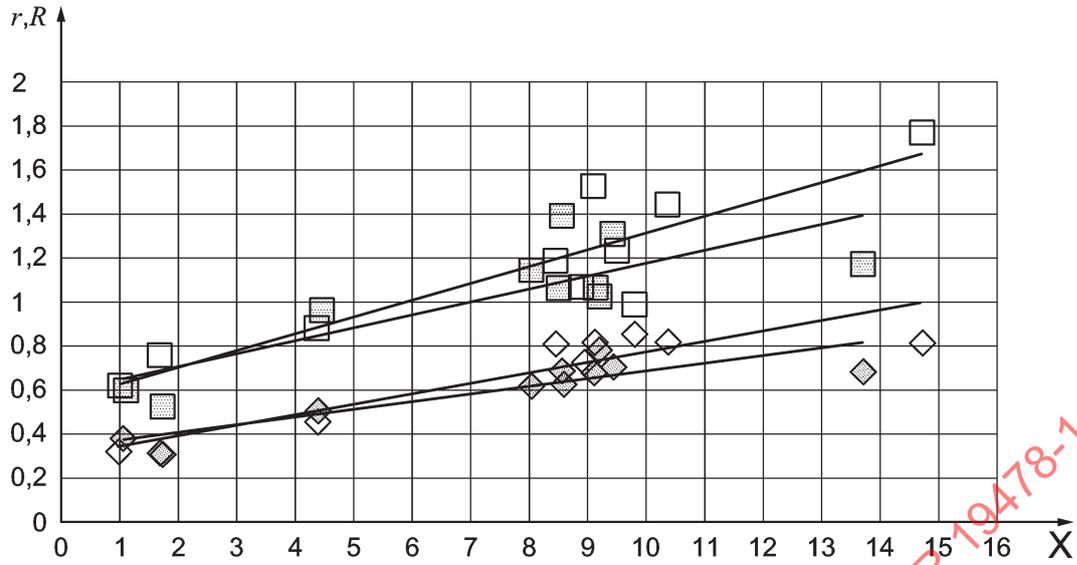|			
X	smoking machine	— . —	upper limit (outlier discarded)
Y	nicotine (mg/cig)	— . . —	average: Sample J (outlier discarded)
o	linear smoking machines	— — —	lower limit (outlier discarded)
×	rotary smoking machines		
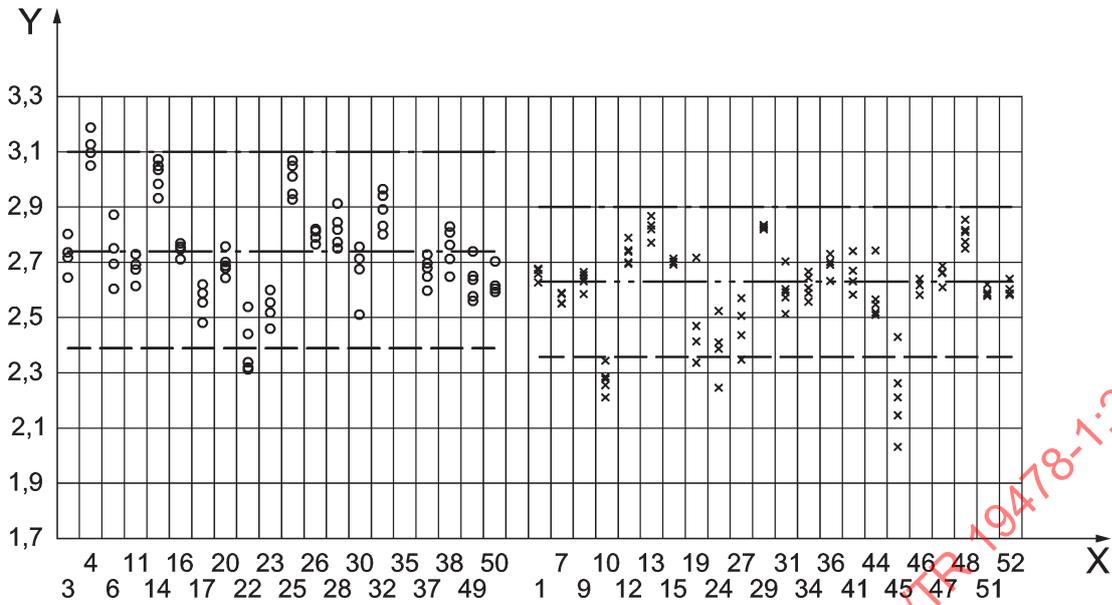
Figure 53 — Nicotine yields obtained under ISO smoking separated by smoking machine type for test article J

Figure 54 — Nicotine yields obtained under HCI smoking separated by smoking machine type for test article J
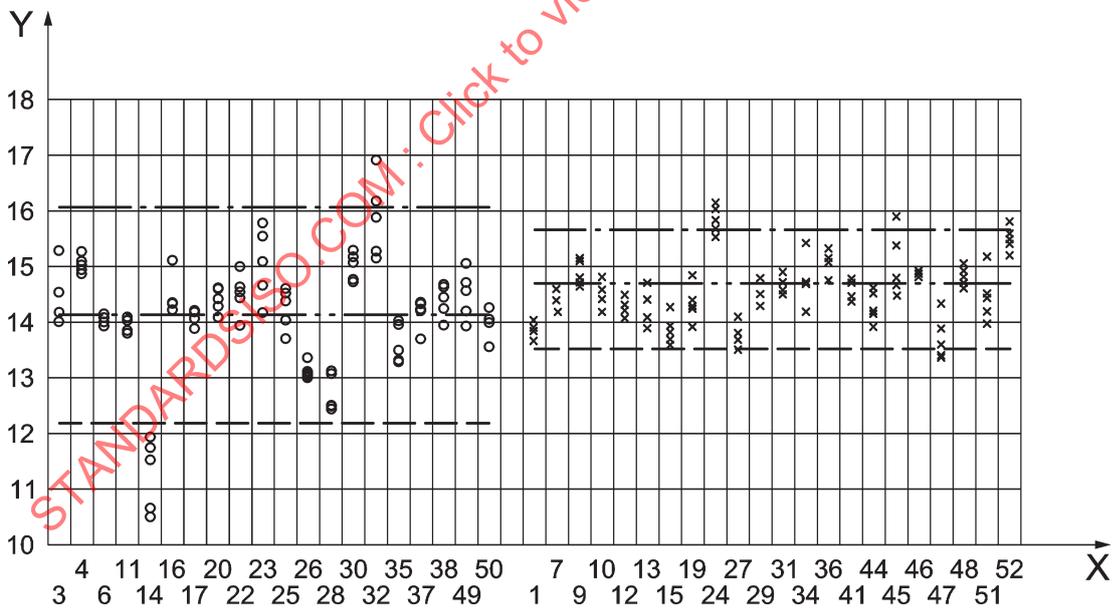
Figure 55 — CO yields obtained under ISO smoking separated by smoking machine type for test article J

Key

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

Figure 56 — CO yields obtained under HCI smoking separated by smoking machine type for test article J

10.2.3 Repeatability (*r*) and reproducibility (*R*)

Repeatability (*r*) and reproducibility (*R*) values for linear and rotary machines were calculated separately for each smoking regime and smoke parameter and are presented in Figures 57 to 62 (with linear regressions shown) and in Tables 21 to 25.

Key

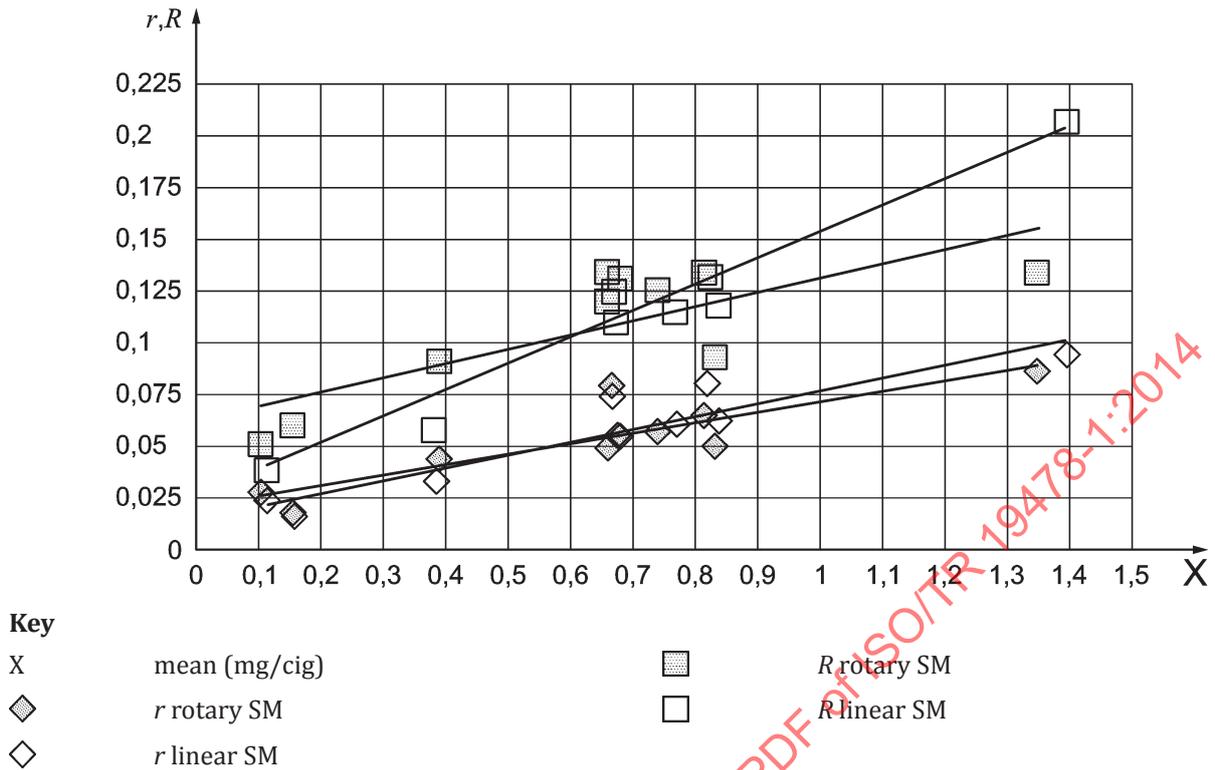|			
X	mean (mg/cig)	▨	*R* rotary SM
◈	*r* rotary SM	☐	*R* linear SM
◇	*r* linear SM		

Figure 57 — Relationship between mean NFDPM yield and *r/R* values under ISO smoking separated by smoking machine type

Key
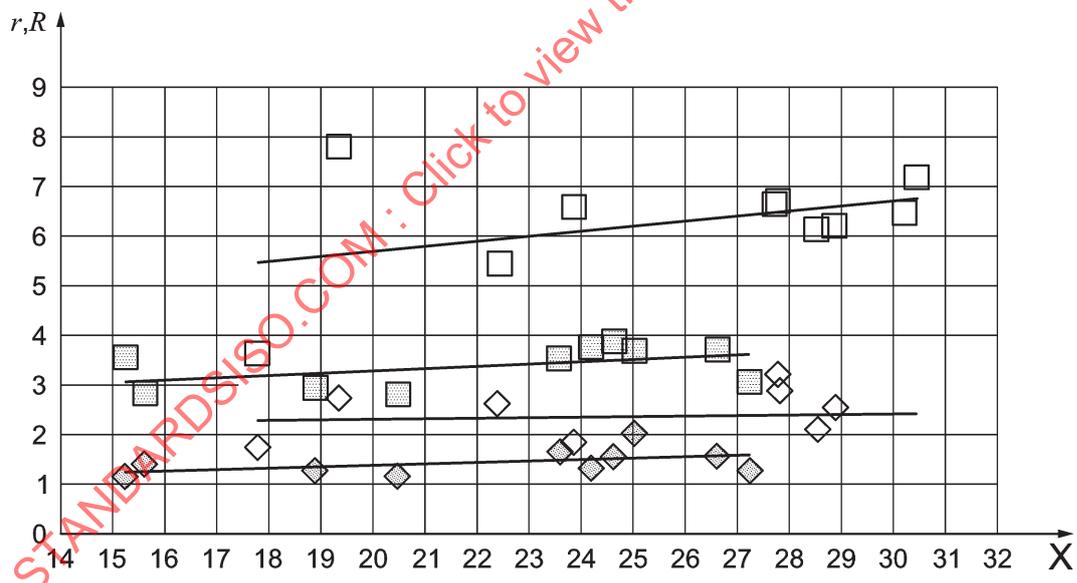
X	mean (mg/cig)	▨	*R* rotary SM
◈	*r* rotary SM	☐	*R* linear SM
◇	*r* linear SM		

Figure 58 — Relationship between mean NFDPM yield and *r/R* values under HCI smoking separated by smoking machine type

Key

X	mean (mg/cig)	▨	*R* rotary SM
◈	*r* rotary SM	☐	*R* linear SM
◇	*r* linear SM		

Figure 59 — Relationship between mean nicotine yield and *r/R* values under ISO smoking separated by smoking machine type

Key

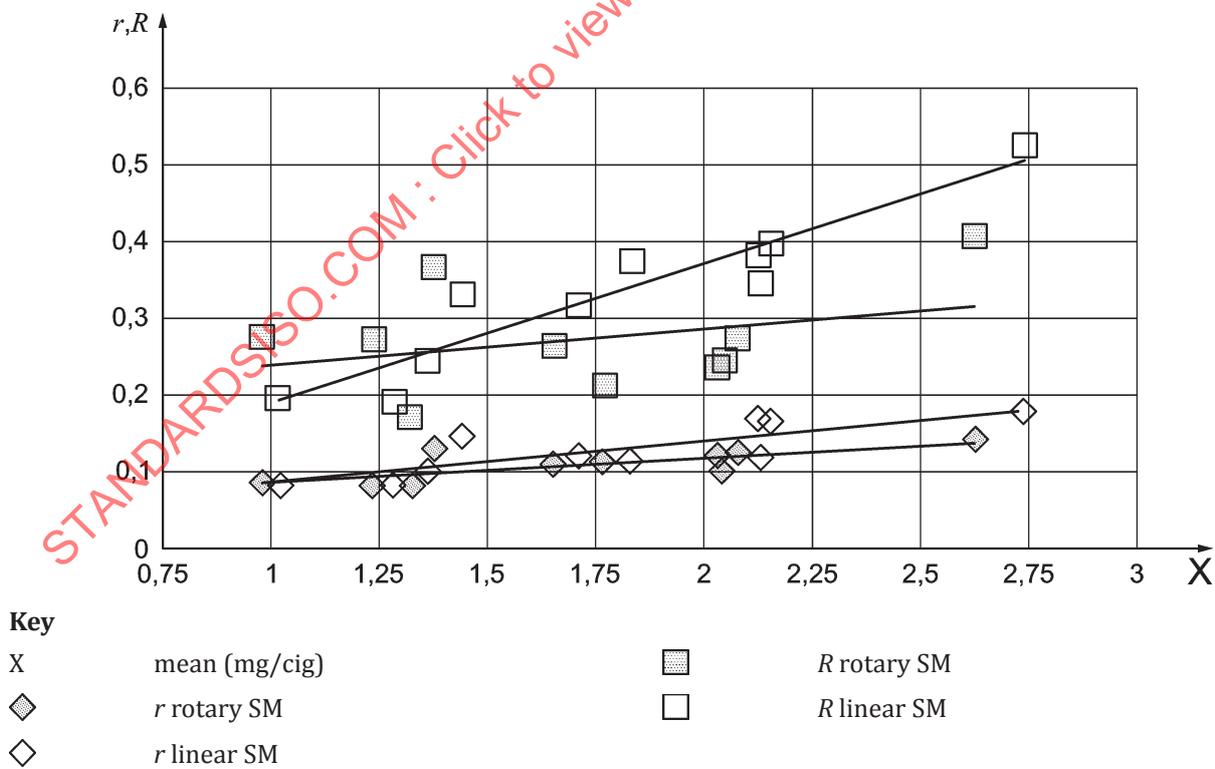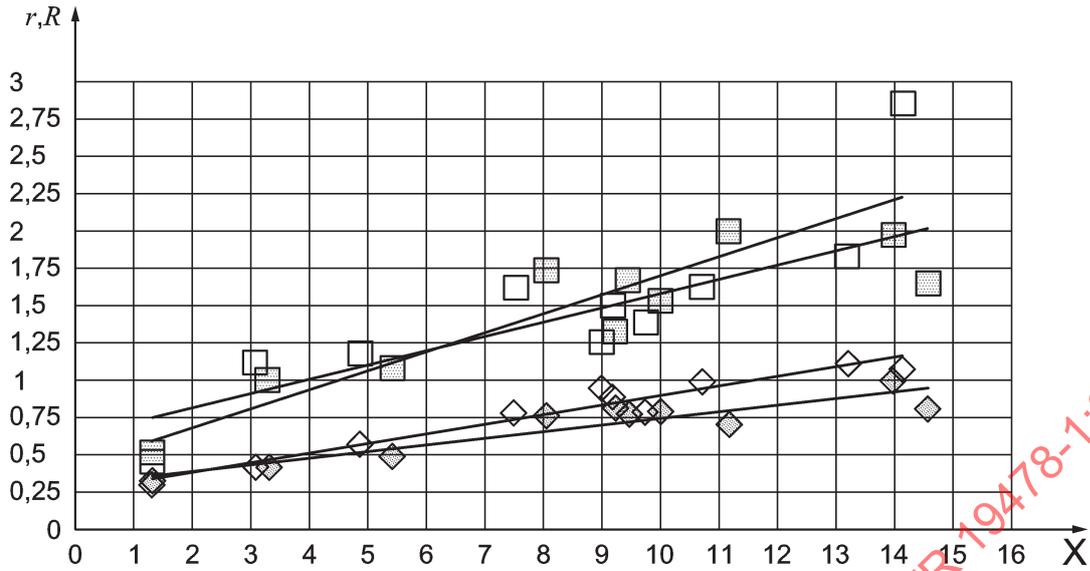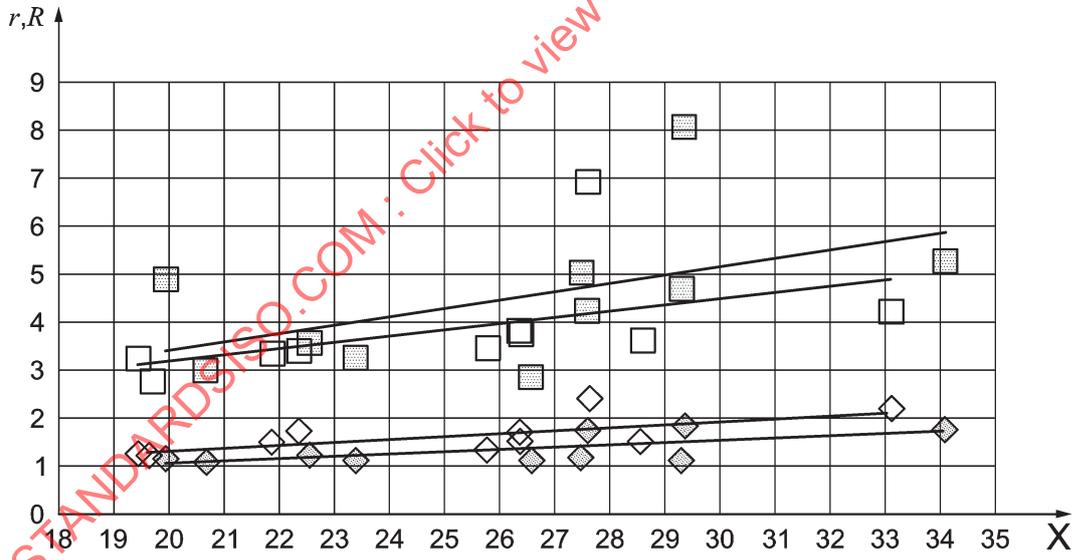|			
X	mean (mg/cig)	▨	*R* rotary SM
◈	*r* rotary SM	☐	*R* linear SM
◇	*r* linear SM		

Figure 60 — Relationship between mean nicotine yield and *r/R* values under HCI smoking separated by smoking machine type

Figure 61 — Relationship between mean CO yield and *r/R* values under ISO smoking separated by smoking machine type

Figure 62 — Relationship between mean CO yield and *r/R* values under HCI smoking separated by smoking machine type