
Gradbeni proizvodi – Ocenjevanje sproščanja nevarnih snovi - Navodilo za statistično ocenjevanje deklariranih vrednosti - 2. del: Tehnično in statistično ozadje

Construction products: Assessment of release of dangerous substances - Guidance on the statistical assessment of declared values - Part 2: Technical and statistical background

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Produits de construction - Evaluation de l'émission de substances dangereuses - Guide pour l'évaluation de la performance et la vérification de sa constance - Partie 2 : Données techniques et statistiques

Ta slovenski standard je istoveten z: CEN/TR 16797-2:2015

ICS:

13.020.99	Drugi standardi v zvezi z varstvom okolja	Other standards related to environmental protection
91.100.01	Gradbeni materiali na splošno	Construction materials in general

SIST-TP CEN/TR 16797-2:2015 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST-TP CEN/TR 16797-2:2015](https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015)

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015>

TECHNICAL REPORT
RAPPORT TECHNIQUE
TECHNISCHER BERICHT

CEN/TR 16797-2

August 2015

ICS 03.120.20; 91.100.01

English Version

Construction products: Assessment of release of dangerous substances - Guidance on the statistical assessment of declared values - Part 2: Technical and statistical background

Produits de construction - Evaluation de l'émission de substances dangereuses - Guide pour l'évaluation de la performance et la vérification de sa constance - Partie 2 : Données techniques et statistiques

This Technical Report was approved by CEN on 16 January 2015. It has been drawn up by the Technical Committee CEN/TC 351.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST-TP CEN/TR 16797-2:2015](https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015)

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	4
0 Introduction.....	5
0.1 General	5
0.2 Background.....	5
0.3 Assessment of construction products.....	6
0.4 Reading guide to CEN/TR 16797-2.....	9
0.4.1 General introduction	9
0.4.2 Rules of application	9
0.4.3 Statistical background	9
0.4.4 Annexes.....	9
1 Scope	10
2 Terms, definitions, abbreviations and symbols	10
2.1 Terms and definitions	10
2.2 Abbreviations and symbols	14
3 Context	16
4 Quality level of performance with respect to the release, emission or content of RDS	17
5 Methods for statistical assessment of declared values for RDS	17
5.1 Goal of the assessment	17
5.2 Assessment of the production.....	17
5.3 Assessment of clusters	19
5.4 Assessment of no-further-testing	20
5.5 Methods of assessment.....	23
5.5.1 Introduction.....	23
5.5.2 Assessment by variables	23
5.5.3 Assessment by attributes.....	24
5.6 Description of the assessment procedure	24
5.6.1 Type testing	24
5.6.2 Further-testing	25
5.6.3 Clusters	26
5.6.4 No-further-testing	29
5.7 Banned substances.....	29
6 Assessment by variables	30
6.1 Single production units	30
6.1.1 Type testing	30
6.1.2 Further-testing	31
6.1.3 Rule of application for products where the test values are significantly below the declared value (Gamma rule)	33
6.1.4 Rule of application for products where a small number of test results may be expected	33
6.2 Cluster of production units	34
6.2.1 Type testing	34
6.2.2 Further-testing	36
6.2.3 Rule of application for cluster products where the test values are significantly below the declared value (Gamma rule).....	37
6.3 No-further-testing	37
6.4 Handling values lower than the detection limit.....	38
6.5 Identifying outliers	38

6.6	Choosing a declared value	39
7	Assessment by attributes	40
7.1	Single production units	40
7.1.1	Type testing	40
7.1.2	Further-testing	41
7.2	Cluster of production units	42
7.2.1	Type testing	42
7.2.2	Further-testing	43
7.3	No-further-testing	44
7.4	Handling values lower than the detection limit	44
7.5	Identifying outliers	44
7.6	Choosing a declared value	45
8	Statistical principles of the rules of application	45
8.1	Introduction	45
8.2	Assessment of a production part	45
8.3	Test error	50
8.4	Assessment by variables	51
8.4.1	Type testing and further-testing	51
8.4.2	Test frequency for further-testing	52
8.4.3	Gamma rule	56
8.4.4	No-further-testing	56
8.5	Assessment by attributes	57
8.5.1	Type testing and further-testing	57
8.5.2	No-further-testing	59
8.6	Consumer's and producer's risk	60
8.6.1	Acceptance and non-acceptance of batches that exceed the declared value	60
8.6.2	Estimation of the consumer's risk	63
8.6.3	Practical approach	64
9	Additional sampling requirements	65
9.1	General	65
9.2	Probabilistic sampling	66
9.3	Judgemental sampling	68
10	Indirect tests	68
10.1	General	68
10.2	Correlation	69
10.3	No correlation	70
	Annex A Examples of the rules of application	71
	Annex B Distribution of test values	87
	Annex C Checklist for Technical Committees	90
	Annex D Model clauses for product standards	92
	Annex E Critical values for assessment by variables	113
	Annex F Gamma factor	117
	Bibliography	120

CEN/TR 16797-2:2015 (E)**European foreword**

This document (CEN/TR 16797-2:2015) has been prepared by Technical Committee CEN/TC 351 “Construction products: Assessment of release of dangerous substances”, the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

CEN/TR 16797, *Construction products: Assessment of release of dangerous substances — Guidance on the statistical assessment of declared values*, comprises the following two parts:

- *Part 1: Principles and rules of application;*
- *Part 2: Technical and statistical background* [the present document].

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

[SIST-TP CEN/TR 16797-2:2015](https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015)

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015>

0 Introduction

0.1 General

CEN/TR 16797-1 [1] provides a brief introduction to declaring performance for the potential release, emission and/or content of dangerous substances from or in construction products and gives the principles which underpin the assessment and verification of constancy of performance (AVCP) of the product in respect of such declarations. The main rules of application are introduced, all of which satisfy the given principles.

CEN/TR 16797-2 provides a more detailed background and technical explanation together with examples and the statistical justification for the rules of application. The definitions and abbreviations listed in Clause 2 also apply to CEN/TR 16797-1. Annex D contains a model clause and the rules of application as normative text that may be copied into or cited by product standards. A recommended solution is to copy the model clause into the product standard and specify the 'rule of application given in CEN/TR 16797-2:2015, Annex D' to be used.

This Technical Report was developed on the basis of experience with the control of release into soil and water. As it is an assessment of data against a declared value regardless of the source of the data, it is the technical view of CEN/TC 351 that these procedures are also valid for the assessment of emission from construction products into indoor air and assessment of gamma radiation from construction products.

It is suggested that all product technical committees follow the principles set out in this CEN/TR and it is hoped that all regulators will accept that these principles achieve their objectives with respect to an acceptable AVCP procedure. The rules of application are examples of the ways in which these principles may be applied. There is no obligation on a product technical committee to adopt these rules of application and they are free to determine their own rules of application. The given rules of application may also be used as a benchmark for assessing alternative rules of application.

If product technical committees and producers could streamline their approaches in a way that could be accepted by all regulators, it might support a common understanding on the European market and it might encourage regulators to harmonize their existing different approaches and requirements on reliability and meaning of performance declarations in legislation and enforcement.

0.2 Background

CEN/TC 351 in its Resolution 162 (Milan 2011) has allocated to its TG 7 the task of drafting a technical report with the following content:

'This technical report provides guidance to Technical Committees on the evaluation of conformity of test results with regard to dangerous substances from or in construction products. Where further testing is required, methods for assessing whether the product conforms to the information provided on the potential release of dangerous substances is described and justified. This technical report also describes the conditions and assumptions under which the proposals are given.'

In undertaking this task, TG 7 reviewed existing systems that are accepted by regulators. In practice these were the Dutch Soil Quality Decree system, a statistically based system where the rate of testing is a function of the closeness of the measured values to the regulatory limit value, and the German technical approval system. Technical Approvals normally apply to products not covered by CEN standards, but in Germany they are also being applied to the characteristic of release of dangerous substances, as this characteristic is not yet covered by CEN procedures. The German Technical Approval defines a rate of routine testing for release (not a constant between different products) and the product needs to achieve a release not greater than the defined value. The simplicity of this pass/fail criterion has merit, but there is no possibility of reducing the rate of testing (or incentive to the producer to achieve the lowest possible values of potential release) and when used

CEN/TR 16797-2:2015 (E)

in a CEN system, the declaration of non-conformity over a period of months would have disproportionate consequences.

After reviewing the options, CEN/TC 351 is proposing a single statistically based system that includes the concept of a producer being able to reach a point where no-further-testing is required and a system that is applicable to a wide range of construction products, allowing a uniform assessment of release or emission which is not dependent of the type of construction product.

The objective of this CEN/TR is to provide guidance to product technical committees and information to regulators on the statistical assessment of declared values/classes for release, emission or content of dangerous substances.

0.3 Assessment of construction products

CEN/TR 15858 [2] describes three procedures for classifying the potential release of RDS: without-testing, without-further-testing and further-testing. Without-testing (WT) is a generic procedure where a comprehensive dossier of information containing information and previous test data on release from a product is prepared and submitted to the European Commission. The Commission appoints an expert group that includes regulators and product experts to review the dossier of information. If approved by the expert group and endorsed by the Commission, the product standard may include generic procedures for declaring classes of release based on composition, without the need for type testing and further-testing by the producer. Document DS 129 [4], however, describes this procedure as WFT on the basis that a dossier will not be approved without test data.

In this technical report, only the term WFT will be used, following the way it is used in DS 129.

Where a WFT procedure is not provided in the product standard or not selected by the producer, the producer undertakes type testing (TT) to determine the initial rate of further testing. Further-testing usually follows type testing and this is where every batch (called 'batch testing') or more usually a random batch selected from a defined period of production is tested (called 'random testing') and this test result is used with previous test data to show the consistency of production and to determine the frequency of testing. Further-testing by the producer (FT) and the assessment as to whether the declared value is validated using these test data is fully described in this CEN/TR.

If the FT (and rarely the TT) shows the product is consistently safe and the distance between the measured values and declared values is large, FT may end provided certain other requirements are met (essentially to ensure the composition of the product or the process is not changed significantly) and with the involvement of an independent third party. The criteria for no-further-testing (NFT) are defined in this technical report. This technical report recommends that any NFT decision is approved and audited by an independent third party.

NOTE CEN/TR 15858 [2] described this end to FT as 'without-further-testing', but this term is used in DS 129 [4] and in this technical report to mean something else; see text above.

All methods of verifying the declared value/class have equal status and validity. Figure 1 shows the outline procedure for these options.

The conditions under which the statistical assessment of declared values/classes described in this CEN/TR applies are:

- the product is covered by a harmonized European product standard requiring information on the potential release, emission or content of RDS or the contract of supply requires the provision of information on the potential release of RDS;
- there is one or more RDS that require FT to confirm the technical class or value declared by the producer;

- the FPC system has specifically addressed the control of RDS.

This CEN/TR provides guidance on the statistical assessment of declared values where type testing followed by further testing is required with respect to RDS for:

- potential release into soil, groundwater and surface water;
- potential emission into indoor air;
- content;
- potential gamma radiation or emission (exhalation) of radon gas into indoor air

to support:

- declarations of performance made under CE-marking;
- for showing conformity of RDS restricted at the Community level;
- for showing conformity of RDS restricted by provisions valid in the place of use;
- for showing conformity to limits for RDS specified in the contract of supply.

In all four cases the procedure for the statistical assessment of the declared value is the same.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

[SIST-TP CEN/TR 16797-2:2015](https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015)

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015>

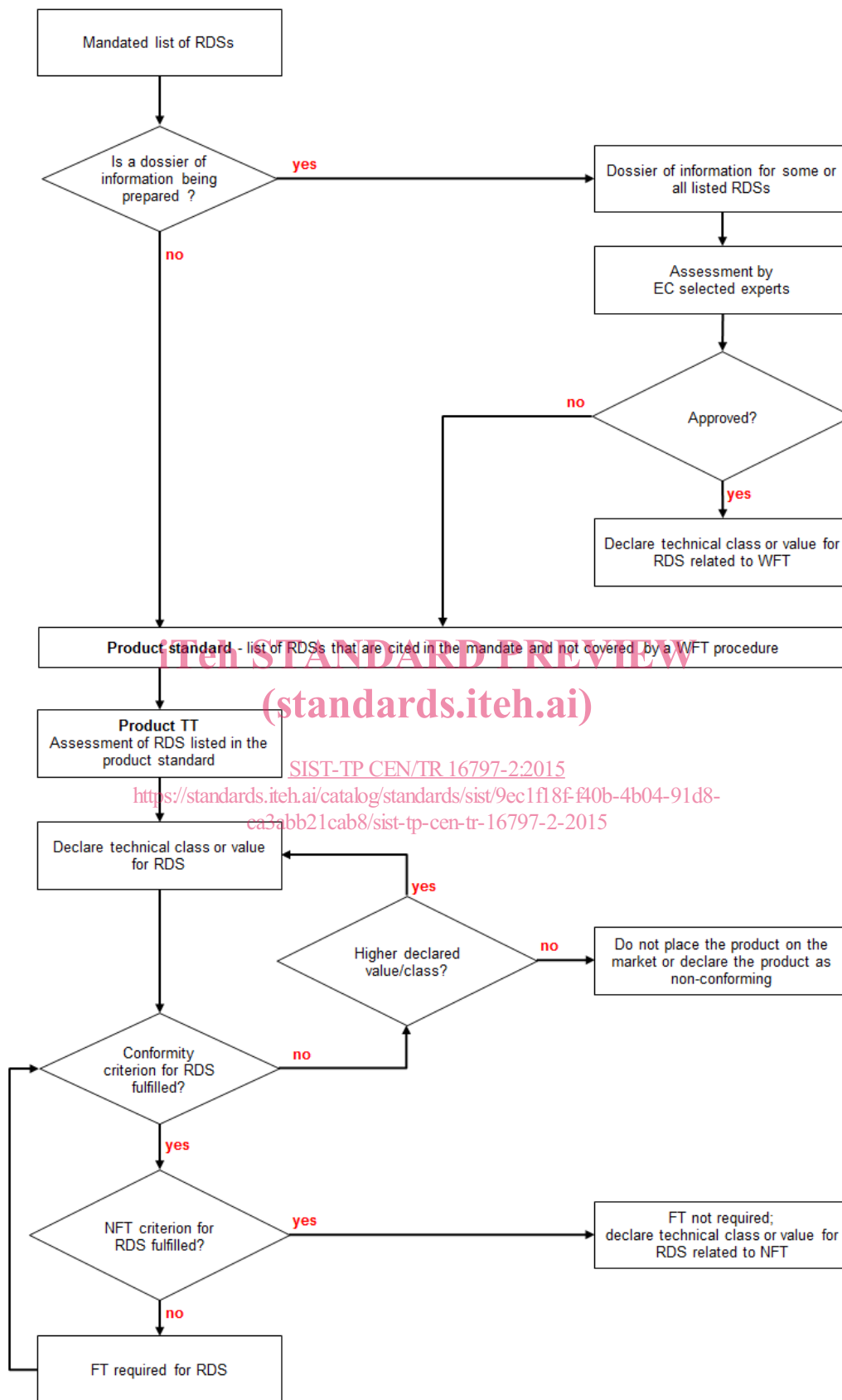


Figure 1 — Possibilities of WFT, FT and NFT for construction products

0.4 Reading guide to CEN/TR 16797-2

0.4.1 General introduction

A general introduction to the statistical assessment of declared values for the release, emission or content of RDS from or in construction products is given in Clauses 0, 1, 2 and 3. Terms and definitions are given in Clause 2 and Clause 3 puts CEN/TR 16797-2 into its context and identifies the tasks that need to be undertaken by CEN Technical Committees.

0.4.2 Rules of application

The rules of application are explained in Clauses 4 to 7. In Clause 4 the quality level of performance of the rules of application are defined. The methods and basic rules for the statistical assessment of declared values are described in Clause 5 followed by a technical description of the rules of application for assessment by variables (Clause 6) and assessment by attributes (Clause 7), all of which satisfy the given principles.

0.4.3 Statistical background

The statistical background of the rules of application is described in Clause 8. Clause 9 contains additional sampling requirements not addressed in CEN/TR 16220 [3], while Clause 10 gives guidance on the use of alternative, indirect test methods.

0.4.4 Annexes

Annex A contains examples of the rules of application described in this CEN/TR. Background information on the statistical distribution of RDS are given in Annex B. Annex C contains a checklist for technical aspects related to RDS that need to be addressed in product standards. In Annex D examples of model text are given on how to include normative requirements for statistical assessment of declared values. Annex E gives an extensive table with values for some of the statistical parameters used in this CEN/TR. Annex F gives values for the factor of a specific tool called the gamma rule.

CEN/TR 16797-2:2015 (E)**1 Scope**

This Technical Report provides guidance on the statistical assessment of declared values with respect to the release, emission and/or content of dangerous substances. This report provides statistically-based criteria for type-testing (TT), further-testing (FT) and where a product has been shown to be consistent with measured values for the release, emission or content that are significantly below the declared values, the point where no-further-testing (NFT) is permitted.

A series of fundamental principles are defined in CEN/TR 16797-1 and two statistical approaches are defined. The first approach is to use assessment by variables and this approach requires the data to be normally or log-normally distributed. This approach is recommended as the default option. The alternative approach based on assessment by attributes is appropriate for data sets that are not normally or log-normally distributed. The downside to this form of assessment is that more test data are needed for the same level of reliability. CEN/TR 16797-1 introduces these assessment procedures and CEN/TR 16797-2 provides more detail and the statistical proof that they satisfy the principles defined in CEN/TR 16797-1. With both of these approaches the minimum frequency of testing is a function of the distance between the mean value and declared value and the variability of the data set, i.e. the sample standard deviation.

To reduce the costs of testing, production plants producing a similar product may share data, e.g. be grouping the product into clusters for statistical assessment of declared values. Rules for the use of clusters are given in this document.

This document also contains rules for identifying outliers within a data set and guidance on using tests other than the reference method for FT.

A list of tasks for product technical committees is given in this document as is a model clause for including in product standards and rules of applications that may be cited in the product standard or copied into product standards.

2 Terms, definitions, abbreviations and symbols**2.1 Terms and definitions**

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

NOTE The following definitions are used in this document for the purposes of using and explaining the system of assessment. These definitions align with those given in EN 16687 [6], ISO 3534-1 [10] and ISO 3534-2 [11].

2.1.1**assessment by attributes**

assessment by noting the presence (or absence) of one or more particular characteristic(s) in each of the items in the group under consideration, and counting how many items do, or do not, possess the characteristic(s)

[SOURCE: [11] (adapted)]

Note 1 to entry: With respect to the assessment of the release, emission and/or content of RDS 'presence' or 'possessing the characteristic' means that the test result is greater than the declared value and 'absence' or 'not possessing the characteristic' means that the test results is equal to or lower than the declared value.

2.1.2**assessment by variables**

assessment by measuring the magnitude(s) of the characteristic(s) of an item

[SOURCE: [11] (adapted)]

Note 1 to entry: With respect to the assessment of the release, emission or content of RDS 'magnitude of the characteristic' means the test result.

2.1.3

batch

amount of *construction product* at which *conformity* is established

Note 1 to entry: Within this document the size of a batch is undefined. The batch size should be defined in the product standard.

2.1.4

batch testing

procedure where every *batch* is tested prior to it being placed on the market

2.1.5

cluster

group of *production units* that are considered as one with respect to type testing and routine control of RDS

2.1.6

coefficient of variation

standard deviation divided by the *mean*

[SOURCE: [10]]

2.1.7

conformity

fulfilment of a requirement

iTeh STANDARD PREVIEW
(standards.iteh.ai)

2.1.8

construction product

product which is produced for incorporation in a permanent manner in construction works and placed as such on the market

SIST-TP CEN/TR 16797-2:2015

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-40b-4b04-91d8-ca9abb21cab0/sist-tp-cen-tr-16797-2-2015>

[SOURCE [6]]

2.1.9

consumer's risk

probability of accepting a *batch* that has a release greater than the *declared value*

[SOURCE [11] (adapted)]

2.1.10

continuous random variable

random variable having a continuous distribution

[SOURCE [10]]

2.1.11

declared value

level, expressed as a numerical value, declared by the producer, having a very low probability of being exceeded in the production

Note 1 to entry: Where the term 'declared value' is used in this document, it may be interchanged with the terms 'regulatory class limit' or 'technical class limit'.

CEN/TR 16797-2:2015 (E)**2.1.12****discrete random variable**

random variable having a discrete distribution

[SOURCE [10]]

Note 1 to entry: The value of a discrete random variable is not expressed as a number but as a non-arithmetical expression, e.g. yes/no, pass/fail.

2.1.13**further-testing (FT)**

assessment procedure where the AVCP requires routine testing by the manufacturer to verify that the *declared value* is being achieved

[SOURCE: [2] (adapted)]

Note 1 to entry: Further-testing is applied when the type assessment shows there is a risk that the declared value may be exceeded.

2.1.14**mean**

sum of the test values divided by the number of test values

[SOURCE: [10] (adapted)]

Note 1 to entry: For a series of n random test results, i.e. $\{x_1, x_2, \dots, x_n\}$, the **sample mean** \bar{x} is:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

(standards.iteh.ai)

(1)

SIST-TP CEN/TR 16797-2:2015

<https://standards.iteh.ai/catalog/standards/sist/9ec1f18f-f40b-4b04-91d8-ca3abb21cab8/sist-tp-cen-tr-16797-2-2015>

2.1.15**no-further-testing (NFT)**

deemed-to-conform assessment procedure for determining the *declared value* based on type assessment, type testing and routine testing where at some point it is shown that there is a very low risk that the *declared value* may be exceeded

2.1.16**non-conformity**

non-fulfilment of a requirement

[SOURCE: [11]]

2.1.17**operation characteristic curve (OC-curve)**

curve showing the relationship between the probability of acceptance of a *batch* and the percentage of the *production* that has a release greater than the *declared value* and the incoming quality level for a given assessment scheme

[SOURCE: [11] (adapted)]

2.1.18**outlier**

member of a set of values which is inconsistent with the other members of that set

[SOURCE: [10]]

2.1.19**process**

set of interrelated or interacting activities which transform inputs into outputs

[SOURCE: [11]]

2.1.20**producer's risk**

probability of rejecting a *batch* that has a release equal to or lower than the *declared value*

[SOURCE: [11] (adapted)]

2.1.21**product**

result of a *process*

[SOURCE: [11]]

2.1.22**production**

entire (statistically assumed to be infinite) amount of *construction product* that has been and will be produced, that is divided into batches of equal size for testing purposes and that may be defined as the amount represented by:

- one type of construction product as defined in the product standard from one *production unit*; or
- a group of construction products with similar properties from one *production unit*; or
- one type of construction product as defined in the product standard that is grouped into a *cluster* for AVCP; or
- a group of construction products with similar properties from a *cluster*

Note 1 to entry: In the case of RDS, the declaration of performance (covered by CE-marking) is based on the properties of the production and not on the properties of single *batches* except when testing every batch.

2.1.23**production unit**

location where a construction product is manufactured

2.1.24**random testing**

procedure where a limited number of randomly selected *batches* is tested

2.1.25**sample**

representative portion of material selected from a *batch* and which reflects the average properties of that *batch* as much as possible

[SOURCE: [6] (adapted)]

2.1.26**standard deviation**

non-negative square root of the *variance*

[SOURCE: [10] (adapted)]

Note 1 to entry: This is a measure of the spread of results around their *mean*.