GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 19.040

N 61

GB/T 29252-2012

Rule of the Quality Inspection of Laboratory Instruments and Equipment

实验室仪器和设备质量检验规则

Issued on: December 31, 2012 **Implemented on: June 1, 2013**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine;

Standardization Administration of the People's Republic of China.

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Rule of the Quality Inspection of Laboratory Instruments and Equipment

1 Scope

This Standard specifies the terms and definitions, inspection classification and inspection items, inspection conditions, nonconformity classification, exit-factory inspection, periodic inspection and type inspection of the quality of laboratory instruments and equipment.

This Standard is applicable to the exit-factory inspection, periodic inspection and type inspection of laboratory instruments and equipment.

2 Normative References

The following documents are indispensable to the application of this Document. In terms of references with a specified date, only versions with a specified date are applicable to this Document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this Document.

GB/T 2828.1-2003 Sampling Procedures for Inspection by Attribute - Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection

GB/T 2829-2002 Sampling Procedures and Tables for Periodic Inspection by Attributes (apply to inspection of process stability)

GB/T 13264 Sampling Procedures and Tables for Small Lot Inspection by Attributes for Percent Nonconforming Items

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Item

Item is a basic unit divided for the demand of carrying out sampling inspection.

[GB/T 2829-2002, Definition 3.1.1]

Example: a single product, a pair of products, a group of products, a component, or a part of a certain length, a certain area, a certain volume and a certain weight.

3.2 Lot

Requirement refers to a demand or expectation that is explicitly expressed, usually implied, or must be fulfilled.

[GB/T 19000-2008, Definition 3.1.2]

NOTE 1: "usually implied" refers to the routine or general practice of an organization, customer and other interested parties where the demands or expectations under consideration are self-evident.

NOTE 2: specific requirements may be expressed with modifying words, such as: product requirements, quality management requirements and customer requirements.

NOTE 3: specified requirements are explicitly expressed requirements.

NOTE 4: requirements may be proposed by different interested parties.

3.9 Quality Characteristic

Quality characteristic refers to an inherent characteristic of a product, process or system related to a requirement.

[GB/T 19000-2008, Definition 3.5.2]

NOTE 1: "inherent" refers to something inherent in some object, especially a permanent character.

NOTE 2: the characteristics (such as: the price of a product and the owner of a product) endowed to a product, process or system are not its quality characteristics.

3.10 Conformity

Conformity refers to the satisfaction of a requirement.

[GB/T 19000-2008, Definition 3.6.1]

3.11 Nonconformity

Nonconformity refers to the failure to satisfy a requirement.

[GB/T 19000-2008, Definition 3.6.2]

NOTE: nonconformity is classified in accordance with the importance of quality indicated by quality characteristic, or the severity of nonconformity of quality characteristic. Generally, nonconformity is divided into nonconformity type A, nonconformity type B and nonconformity type C.

3.12 Nonconformity Type A

Nonconformity type A means that an extremely important quality characteristic of an item fails to satisfy a requirement, or the quality characteristic of an item extremely severely fails to

satisfy a requirement.

NOTE: GB/T 2829-2002, Definition 3.1.8 is modified.

3.13 Nonconformity Type B

Nonconformity type B means that an important quality characteristic of an item fails to satisfy a requirement, or the quality characteristic of an item severely fails to satisfy a requirement.

NOTE: GB/T 2829-2002, Definition 3.1.9 is modified.

3.14 Nonconformity Type C

Nonconformity type C means that a general quality characteristic of an item fails to satisfy a requirement, or the quality characteristic of an item slightly fails to satisfy a requirement.

NOTE: GB/T 2829-2002, Definition 3.1.10 is modified.

3.15 Nonconforming Item

Nonconforming item refers to an item with one or more nonconformities.

NOTE 1: in accordance with the severity of nonconformity, nonconforming item is usually divided into nonconforming item type A, nonconforming item type B and nonconforming item type C.

NOTE 2: GB/T 2828.1-2003, Definition 3.1.7 is modified.

3.16 Nonconforming Item Type A

Nonconforming item type A refers to an item with one or more nonconformities type A, and probably nonconformity type B and (or) nonconformity type C.

[GB/T 2829-2002, Definition 3.1.12]

3.17 Nonconforming Item Type B

Nonconforming item type B refers to an item with one or more nonconformities type B, and probably nonconformity type C, but no nonconformity type A.

[GB/T 2829-2002, Definition 3.1.13]

3.18 Nonconforming Item Type C

Nonconforming item type C refers to an item with one or more nonconformities type C, but no nonconformity type A or nonconformity type B.

[GB/T 2829-2002, Definition 3.1.14]

3.19 Percent Nonconforming (in a sample)

Example: rework and degradation.

3.25 Rework

Rework refers to measures taken to bring nonconforming products into compliance.

[GB/T 19000-2008, Definition 3.6.7]

3.26 Inspection

Inspection refers to an activity of determining, inspecting, testing or measuring one or more characteristics of a product, and comparing them with specified requirements in order to determine whether the various characteristics of a product are conforming.

[GB/T 2828.1-2003, Definition 3.1.1]

3.27 Test

Test refers to the determination of one or more characteristics in accordance with a procedure.

[GB/T 19000-2008, Definition 3.8.3]

3.28 Acceptance Inspection

Exit-factory inspection

Acceptance inspection refers to an inspection carried out to determine whether the submitted product or lot is acceptable.

NOTE: GB/T 3358.2-1993, Definition 3.13 is modified.

3.29 Periodic Inspection

Quality conformance inspection

Periodic inspection refers to an inspection, in which, samples are taken from a certain lot or several lots that have passed lot-by-lot inspection to determine whether the stability of the production process complies with the specified requirement within a specified period (as specified by time, or specified by the number of items manufactured).

[GB/T 2829-2002, Definition 3.1.22]

3.30 Type Inspection

Type inspection refers to a periodic and lot-by-lot inspection carried out to determine whether a certain production line allows manufacturing by lots that complies with the specified quality requirement.

[GB/T 2829-2002, Definition 3.1.23]

3.31 Inspection by Attributes

Inspection by attributes refers to an inspection with respect to a specified requirement or a set of requirements that merely classifies an item as conforming or nonconforming, or merely counts the number of nonconformities in items.

[GB/T 2828.1-2003, Definition 3.1.3]

NOTE: inspection by attributes includes both the inspection of product conformity and the inspection of nonconformities per 100 items.

3.32 Lot-by-lot Inspection

Lot-by-lot inspection means each lot in the series of lots is inspected.

[GB/T 3358.2-1993, Definition 3.14]

3.33 100% Inspection

Complete inspection

100% inspection refers to an inspection of each product within a specific range.

NOTE: GB/T 3358.2-1993, Definition 3.15 is modified.

3.34 Sampling Inspection

Sampling inspection refers to an inspection of a product or process using the samples taken.

[GB/T 3358.2-1993, Definition 4.1]

3.35 Sampling Scheme

Sampling scheme refers to a combination of sampling plan and the rule of changing from one sampling plan to another.

[GB/T 2828.1-2003, Definition 3.1.18]

3.36 Sampling Plan

Sampling plan refers to a combination of sample size used and relevant lot acceptance criteria.

[GB/T 2828.1-2003, Definition 3.1.17]

NOTE: sampling plan does not include the rules on how to take samples.

3.37 Single Sampling Plan

Single sampling plan refers to a sampling plan consisting of a combination of sample size and determination array [Ac, Re].

Distinguish level refers to the level of capability to distinguish the stability of production process that does not comply with the specified requirement.

[GB/T 2829-2002, Definition 3.1.33]

3.43 Acceptance Number

Ac

Acceptance number refers to the maximum number of nonconformities or nonconforming items allowed in the sample of a conforming lot in the sampling of inspection by attributes.

[GB/T 2829-2002, Definition 3.1.25]

3.44 Non-acceptance Number

Rejection number

Re

Non-acceptance number refers to the minimum number of nonconformities or nonconforming items allowed in the sample of a nonconforming lot in the sampling of inspection by attributes.

[GB/T 2829-2002, Definition 3.1.26]

3.45 Determination Array

Determination array refers to a combination of acceptance number and non-acceptance number, or acceptance number series and non-acceptance number series.

[GB/T 2829-2002, Definition 3.1.27]

3.46 Simple Random Sampling

Simple random sampling refers to a sampling method, in which, the probability of any n samples being taken is equal when n samples are taken from a lot of N by sampling without replacement.

[GB/T 3358.1-1993, Definition 5.7]

4 Inspection Classification and Inspection Items

4.1 Inspection Classification

The inspection of laboratory instruments and equipment is divided into:

a) exit-factory inspection;

b) periodic inspection;

c) type inspection.

4.2 Exit-factory Inspection

4.2.1 Exit-factory inspection shall be carried out when products are delivered, so as to determine whether the submitted products comply with the specified quality requirements.

4.2.2 Exit-factory inspection is carried out by the manufacturer's quality inspection department, and a quality certification document is issued. If necessary, the ordering side may send representatives to participate.

4.2.3 Exit-factory inspection is an inspection of some quality characteristics of the product. The product standard shall specify the items of exit-factory inspection, and if necessary, the sequence of the inspection items of the exit-factory inspection. Generally, exit-factory inspection shall adopt a non-destructive test mode.

4.2.4 In exit-factory inspection, the inspection shall be carried out lot by lot. All exit-factory inspection items may be subject to 100% inspection, or some of the items may be subject to 100% inspection, while the other items are subject to sampling inspection.

4.2.4.1 Under one of the following circumstances, 100% inspection shall be adopted:

a) Quality characteristics that are significantly affected by changes in production process or production skills;

b) Quality characteristics that are crucial to reaching the pre-determined requirements;

c) Basic safety test items;

d) Items with a simple inspection method, a low inspection cost and not much time required for inspection.

4.2.4.2 Under one of the following circumstances, sampling inspection may be adopted:

a) Quality characteristics that are significantly affected by the quality of parts or equipment, but less affected by production process and production skills;

b) Quality characteristics determined by the design structure;

c) Items with a complex inspection method, a high inspection cost and excessive time required for inspection;

d) Safety test items that may lead to sample destruction.

4.3 Periodic Inspection

4.3.1 Products that are in normal production shall be subject to periodic inspection on a regular basis or when a certain amount of output is accumulated, so as to determine whether the products can guarantee continuous and stable quality during the production process.

---the AC power supply frequency deviates from the rated value by not more than ± 1%;

---the total distortion of the AC power supply waveform does not exceed 5%;

---the external magnetic field interference is less than twice the interference caused by the earth's magnetic field.

5.2.3 For inspection items that have special requirements for factors, such as: vibration, noise, cleanliness, radiation from cold or heat sources, electromagnetic radiation and airflow in the test environment, the specific requirements shall be clearly specified in the product standard.

6 Nonconformity Classification

6.1 When multiple quality characteristics are involved, and they are of different levels of importance in terms of quality and / or economic effects, they should be classified into nonconformity type A, nonconformity type B and nonconformity type C in accordance with the severity of nonconformity. For simple products, two types of nonconformity may be distinguished, and even the types of nonconformity may be exempt from distinguishing.

6.2 The following conditions shall be determined as nonconformity type A:

---posing a danger to personal safety or public safety;

---serious damage to the basic functions of the instrument;

---extremely important quality characteristics fail to comply with the stipulations;

---quality characteristics extremely severely fail to comply with the stipulations.

6.3 The following conditions shall be determined as nonconformity type B:

---important quality characteristics fail to comply with the stipulations;

---quality characteristics severely fail to comply with the stipulations;

---sudden electrical failure or structural failure (such as: rupture of structural components and obvious deformation, etc.);

---looseness, displacement and falling off of mechanical connections or components, which lead to failure of components and the instrument's failure of properly functioning;

---performance degradation, which leads to failure of reaching the pre-determined requirements;

---changes of the performance of components as a result of corrosion, peeling and damage, etc., which hinders normal operation and use;

---other failures that cannot satisfy the requirements specified in the product standard.

6.4 The following conditions shall be determined as nonconformity type C:

---general quality characteristics fail to comply with the stipulations;

---quality characteristics slightly fail to comply with the stipulations.

6.5 If necessary, the conversion factors among the various types of nonconformities shall also be specified.

7 Exit-factory Inspection

7.1 100% Inspection

7.1.1 In the exit-factory inspection where 100% inspection is adopted for all items, each unit of product in the inspection lot shall be inspected for all items in accordance with the inspection sequence specified in the product standard.

7.1.2 When all inspection items are qualified, the unit of product shall be determined as conforming. When any item is disqualified, the unit of product shall be determined as nonconforming, and at this moment, the inspection of the unit of product shall usually be suspended.

7.1.3 When multiple quality characteristics are involved, and the product standard or technical protocol classifies the nonconformities and specifies the allowable number of nonconformities per unit of product, the cumulative number of the various types of nonconformities shall be counted after inspection. When the cumulative number of the various types of nonconformities is less than or equal to the allowable number of nonconformities, the unit of product shall be determined as conforming, otherwise, it shall be determined as nonconforming.

7.1.4 After rework, the nonconforming products may be re-submitted for inspection. During re-inspection, whether all items shall be inspected or only the nonconforming items shall be inspected shall be specified in the product standard.

7.2 Sampling Inspection

7.2.1 Acceptance quality limit

7.2.1.1 The sampling inspection in exit-factory inspection uses the acceptance quality limit (AQL) and sample size code to retrieve the required sampling scheme and sampling plan.

The product standard or technical protocol shall specify the AQL. Different AQLs may be specified for nonconforming groups or for individual nonconformities. The division of nonconforming groups shall be adapted to the quality requirements of specific occasions. When the quality level is expressed in percent nonconforming, the AQL value shall not exceed 10% of the nonconforming items; when the quality level is expressed in nonconformities per 100 items, the AQL value that can be used can be up to 1,000 nonconformities per 100 items.

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