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An American National Standard

Standard Terminology Relating to Conformity Assessment[1]

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1. Scope

1.1 This standard defines terms related to conformity assessment.[2] It includes terms used in those standards under the jurisdiction of ASTM Committee E-36. When definitions are those used by other ASTM committees, the committee designation is given in parentheses after the definition. When definitions are based on those used by other organizations, the symbol or abbreviation of the name of the organization is given. In either case, a postscript letter is used to indicate the degree of correspondence between the definition given herein and that in the citation. Postscript "*A*" indicates the definition is identical to the definition cited by the organization indicated. Postscript " *B*" indicates the given definition is a modification of that cited, though the essential meaning differs little. Postscript " *C*" indicates the given definition differs substantially from the one cited.

1.2 Since conformity assessment is being carried out by many accrediting bodies in several fields of testing and numerous product areas, usage of descriptive terms varies considerably. There is no attempt to include all conformity assessment terms in this standard, but to concentrate on those most commonly encountered.

2. Referenced Documents

2.1 *ASTM Standards:*

E 10 Test Method for Brinell Hardness of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 92 Test Method for Vickers Hardness of Metallic Materials[3]

E 384 Test Method for Microhardness of Materials[3]

E 699 Practice for Criteria for Evaluation of Agencies Involved in Testing, Quality Assurance, and Evaluating Building Components in Accordance with Test Methods Promulgated by ASTM Committee E-16[4]

E 1267 Guide for ASTM Standard Specification Quality Statements[5]

2.2 *ANSI Standard:*

A3-1987 Quality Systems Terminology[6]

2.3 *ISO Standard:*

ISO/Guide 2 General Terms and Their Definitions Concerning Standardization, Certification and Testing Laboratory Accreditation[7]

2.4 *Other Document:*

Laboratory Accreditation—Principles and Practice, Collected Reports 1979-1983 (ILAC Task Force C Reports)[8]

3. Terminology : Terms and Their Definitions

accreditation—procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks, (ISO Guide 2).

accreditation criteria, *for laboratory accreditation, n*—set of requirements used by an accrediting body which a testing laboratory must meet to be accredited, (ISO Guide 2, *A*).

accredited laboratory—testing laboratory to which accreditation has been granted, (ISO Guide 2, *A*).

accredited laboratory test report—test report that includes a statement by the testing laboratory that it is accredited for the test reported and that the test has been performed in accordance with the conditions prescribed by the accrediting body, (ISO Guide 2, *A*).

accrediting body—governmental or non-governmental body that conducts and administers a laboratory accreditation system and grants accreditation, (ISO Guide 2, *A*).

assessment, *of a laboratory*—the activity of evaluating a laboratory's compliance with accreditation criteria.

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[1] This terminology is under the jurisdiction of ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies and is the direct responsibility of Subcommittee E36.50 on Support Operations.

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[2] There were numerous other sources consulted, but not specifically used, to formulate definitions for the above terms.

[3] *Annual Book of ASTM Standards,* Vol 03.01.

[4] *Annual Book of ASTM Standards,* Vol 04.07.

[5] *Annual Book of ASTM Standards,* Vol 14.02.

[6] Available from American National Standards Institute, 1430 Broadway, NY, NY 10018.

[7] Available from ISO, 1 rue de Varembé, Case Postale 56, Crt 1221. Geneve 20, Switzerland.

[8] Available from American Association for Laboratory Accreditation, 656 Quince Orchard Rd.-704, Gaithersburg, MD 20878.

assessor, *of a laboratory*—an individual who carries out some or all functions related to laboratory assessment, (ISO Guide 2, *B*).

assurance of conformity—procedure resulting in a statement giving confidence that a product, process or service fulfills specified requirements, (ISO Guide 2).

DISCUSSION—for a product, the statement may be in the form of a document, a label or other equivalent means. It may also be printed in or applied on a communication, a catalog, an invoice, a user instructions manual, etc. relating to the product.

authority—body that has legal powers and rights, (EN 45020).

bilateral agreement—recognition arrangement that covers acceptance of each other's results by two parties, (ISO Guide 2).

calibration—the set of operations that establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of measurement, (ISO Guide 25).

calibration laboratory—laboratory that performs calibration, (ISO Guide 25).

calibration method—defined technical procedure for performing a calibration, (ISO Guide 25).

certificate of competence—document issued under the rules of a certification system indicating that adequate confidence is provided that the named person is competent in performing specific services, (EN 45020).

certificate of conformity—document issued under the rules of a certification system, indicating that adequate confidence is provided that a duty identified product, process or service is in conformity with a specific standard or other normative document, (ISO Guide 2).

certification body—body that conducts certification of conformity, (ISO Guide 2).

DISCUSSION—A certification body may operate its own testing and inspection activities or oversee these activities carried out on its behalf by other bodies, (ISO Guide 2).

certification scheme—certification system as related to specified products, processes or services to which the same particular standards and rules, and the same procedure, apply, (ISO Guide 2).

certification system—system that has its own rules of procedure and management for carrying out certification of conformity, (ISO Guide 2).

conformity—fulfillment by a product, process or service of specified requirements, (ISO Guide 2).

conformity surveillance—evaluation for conformity to determine the continuing conformity with specified requirements, (ISO Guide 2).

conformity testing—evaluation for conformity by means of testing, (EN 45020).

consensus—general agreement, characterized by the absence of substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments, (ISO Guide 2).

deficiency—departure from, or noncompliance with, specified accreditation criteria.

entity—that which can be individually described and considered.

DISCUSSION—An entity may be, for example: an activity or process, a product, an organization, a system or a person, or any combination thereof.

field of testing—broad sphere of science, engineering, or technology used to describe a general area of testing for classification purposes only. (For accreditation purposes, fields of testing are subdivided into specific tests, groups of tests, or product areas.)

generic criteria, *for laboratory accreditation***,** *n*—accreditation criteria expressed in general terms which address organization, human and material resources, operating procedures, calibration and quality assurance practices of a laboratory.

inspection—process of measuring, examining, testing, gaging, or using other procedures to ascertain the quality or state, detect errors or defects, or otherwise appraise materials, products, services, systems, or environments to a preestablished standard.

inspection agency—see *inspection body*, (ISO Guide 2).

inspection body—body that performs inspection services on behalf of a certification body, (ISO Guide 2).

interlaboratory test comparison—organization, performance and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions, (ISO Guide 2).

laboratory accreditation—formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests, (ISO Guide 2, *B*).

laboratory accreditation system—system having its own rules of procedure and management, for carrying out laboratory accreditation, (ISO Guide 2, *A*).

laboratory assessor—person who carries out some or all functions related to laboratory assessment, (ISO Guide 2).

mark of conformity, (*for certification***)**—protected mark, applied or issued under the rules of a certification system, indicating that adequate confidence is provided that the relevant product, process or service is in conformity with a specific standard or other normative document, (ISO Guide 2).

multilateral arrangement—recognition arrangement that covers the acceptance of each other's results by more than two parties, (ISO Guide 2)

nonconformity—the nonfulfillment of specified requirements, (ISO 8402).

proficiency testing—determination of laboratory testing performance by means of interlaboratory test comparisons, (ISO Guide 2).

quality—totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs.

DISCUSSION—In a contractual environment, or in a regulated environment, such as the nuclear safety field, needs are specified, whereas in other environments, implied needs should be identified and defined.

In many instances, needs can change with time; this implies a periodic review of requirements for quality.

Needs are usually translated into characteristics with specified criteria. Needs may include, for example, aspects of performance, usability, dependability (availability, reliability, maintainability).

quality assurance—all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

DISCUSSION—There are both internal and external purposes for quality assurance: internal quality assurance: within an organization, quality assurance provides confidence to the management; external quality assurance: in contractual or other situations, quality assurance provides confidence to the customers or others.

Some quality control and quality assurance actions are interrelated.

Unless requirements for quality fully reflect the needs of the user, quality assurance may not provide adequate confidence.

quality audit—systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

DISCUSSION—The quality audit typically applies to, but is not limited to, a quality system or elements thereof, to processes, to products or to services. Such audits are often called "quality system audit,"" process quality audit," "product quality audit" or" service quality audit."

Quality audits are carried out by staff not having direct responsibility in the areas being audited but, preferably, working in cooperation with the relevant personnel.

One purpose of a quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with quality surveillance or inspection activities performed for the purpose of process control or product acceptance.

Quality audits can be conducted for internal or external purposes.

quality control—operational techniques and activities that are used to fulfill requirements of quality.

DISCUSSION—Quality control involves operational techniques and activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at all stages of the quality loop in order to achieve economic effectiveness.

Some quality control and quality assurance actions are interrelated.

quality management—all activities of the overall management function that determine the quality policy objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

DISCUSSION—Quality management is the responsibility of all levels of management but must be led by top management. Its implementation involves all members of the organization.

In quality management, consideration is given to economic aspects.

quality manual—a document stating the quality policy, quality system and quality practices of an organization, (ISO Guide 25).

quality plan—a document setting out the specific quality practices, resource and sequence of activities relevant to a particular product, service, contract or project, (ISO 8402).

quality policy—overall intentions and direction of an organization with regards quality, as formally expressed by top management.

DISCUSSION—The quality policy forms one element of the corporate policy and is authorized by top management.

quality surveillance—continual monitoring and verification of the status of an entity and analysis of records to ensure that specified requirements are being fulfilled.

DISCUSSION—Quality surveillance may be carried out by, or on behalf of, the customer.

Quality surveillance may include observing and monitoring controls which can prevent the deterioration or degradation of an entity with time.

"Continual" may mean either constant or frequent.

quality system—organizational structure, procedures, processes and resources needed to implement quality management.

DISCUSSION—The quality system should be as comprehensive as needed to meet the quality objectives.

The quality system of an organization is designed primarily to satisfy the internal managerial needs of the organization. It is broader than the requirements of a particular customer, who evaluates only the relevant part of the quality system.

reciprocity—bilateral relationship where both parties have the same rights and obligations towards each other, (ISO Guide 2).

recognition agreement—agreement that is based on the acceptance by one party of results, presented by another party, from implementation of one or more designated functional elements of a certification system, (ISO Guide 2).

DISCUSSION—Typical examples of recognition arrangements are testing arrangements, inspection arrangements and certification arrangements.

reference material—material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials, (ISO Guide 2, *A*).

registration—procedure by which a body indicates relevant characteristics of a product, process or service, or particulars of a body or person, in an appropriate, publicly available list, (ISO Guide 2).

requirement—a translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination, (ISO Guide 25).

specific criteria , *n*—accreditation criteria related to the ability of a laboratory to conduct specific tests or specific types of tests.

standardization—correlation of an instrument response to a standard of known accuracy.

supplier—the party that is responsible for the product, process or service and is able to ensure that quality assurance is

exercised. The definition may apply to manufacturers, distributors, importers, assembles, service organizations, etc., (EN 45020).

supplier declaration—procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements, (ISO Guide 2).

DISCUSSION—In order to avoid any confusion, the expression "self-certification" should not be used.

test—technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure, (ISO Guide 2).

testing agency—see *testing laboratory*.

test method—defined technical procedure to determine one or more specified characteristics of a material or product, (ISO Guide 2, *A*).

test report—document that presents test results and other information relevant to a test, (ISO Guide 2, *A*).

testing—action of carrying out one or more tests, (ISO Guide 2).

testing laboratory—laboratory that measures, examines, tests, calibrates, or otherwise determines the characteristics or performance of materials or products, (ISO Guide 2, *A*).

third party—person or body that is recognized as being independent of the parties involved, as concerns the issue in question, (ISO Guide 2).

traceability—the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparison, (ISO Guide 2).

traceability, *n*—the ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded identification. (ANSI/ASQC-1987, *A*)

DISCUSSION—Traceability requirements should be specified for some stated period of history or some point of origin.

DISCUSSION—Traceability may be used in three major senses: (*1*) in a distribution sense relating to components and materials used in making a product or providing a service, (*2*) in a calibration sense relating measuring equipment to national or international standards, primary standards, or basic physical constants or properties, (*3*) in a data sense relating to operational, computational and recording steps of a measurement or evaluation of a product, process, or service.

unilateral arrangement—recognition arrangement that covers the acceptance of one party's results by another party, (ISO Guide 2).

verification—checking or testing to assure conformance with the specification, (Test Method E 384, Committee E-4; Test Method E 10, Committee E-28; Test method E 18, Committee E-28; Test Method E 92, Committee E-28).

verification of conformity—confirmation by examination of evidence, that a product, process or service fulfills specified requirements, (ISO Guide 2).