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# FINAL DRAFT BAHAMAS NATIONAL STANDARD

# CONFORMITY ASSESSMENT -- GUIDANCE FOR DRAFTING NORMATIVE DOCUMENTS SUITABLE FOR USE FOR CONFORMITY ASSESSMENT

**FDBNS X:20XX**

**ISO/IEC 17007:2009**

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# Contents

## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO/IEC 17007 was prepared by the ISO *Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17007 cancels and replaces ISO/IEC Guide 7:1994, of which it constitutes a technical revision.

National Foreword

## Introduction

This International Standard provides principles and guidance on how to write normative documents, such as standards, technical specifications, codes of practice and regulations, such that they are concise and clear, especially in the context of any subsequent conformity assessment activity.

Conformity assessment activities include testing, inspection and various forms of certification. These activities can result in attestations such as declarations, reports, certificates, marks of conformity or the granting of permissions and licences (see also ISO/IEC 17000:2004).

This International Standard is intended for the following users:

— standards developers not applying the ISO/IEC Directives;

— industry associations and consortia;

— purchasers;

— regulators;

— consumers and non-government groups;

— accreditation bodies;

— conformity assessment bodies;

— conformity assessment scheme owners; and

— other interested parties, e.g. insurance organizations.

This International Standard is intended to assist the above users in developing specific normative documents at national, regional or international levels, both in regulated or non-regulated applications.

Users of this International Standard may also find useful the good standardization practices defined in the ISO/IEC Directives (which specify the requirements for ISO and IEC normative documents containing specified requirements) and the WTO Agreement on Technical Barriers to Trade, Annex 3, *Code of Good Practice for the Preparation, Adoption and Application of Standards*. The ISO/IEC Directives, Part 2, 2004, 6.7, also covers aspects for conformity assessment.

This International Standard also includes guidance on specialized International Standards and Guides in the domain of conformity assessment, known as the conformity assessment toolbox. These are principally the work of CASCO in cooperation with IEC. Reference to these generic publications is included to emphasise that they contain internationally agreed provisions covering conformity assessment activities. Reliance on such publications facilitates reproducibility and mutual acceptance of conformity assessment results around the world.

To make this International Standard easy to follow, technical terminology has been avoided as much as possible. However, in some cases, the use of some technical terminology has been unavoidable. For example, the requirements in normative documents can relate to many different areas, e.g. a particular material, product, service, installation, process, system, person or body. In a conformity assessment context, these are all examples of an "object of conformity assessment". To avoid repeating a list of the examples throughout the text, the term "object of conformity assessment" is used, for which a definition is provided in Clause 3.

The guidance in this International Standard is subdivided into three clauses, as follows:

— Clause 4 specifies five principles as the basis for the subsequent guidance;

— Clause 5 provides guidance for the preparation of normative documents that specify requirements for characteristics of objects of conformity assessment;

— Clause 6 provides guidance for the preparation of normative documents specifying requirements for conformity assessment systems.

# Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment



## 1 Scope

This International Standard provides principles and guidance for developing normative documents that contain:

— specified requirements for objects of conformity assessment to fulfil;

— specified requirements for conformity assessment systems that can be employed when demonstrating whether an object of conformity assessment fulfils specified requirements.

This International Standard is intended for use by standards developers not applying the ISO/IEC Directives, industry associations and consortia, purchasers, regulators, consumers and non-government groups, accreditation bodies, conformity assessment bodies, conformity assessment scheme owners, and other interested parties, such as insurance organizations.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000:2004 and the following apply. For convenience of use, the following definitions are repeated.

**3.1**
**conformity assessment system**
rules, procedures and management for carrying out conformity assessment

NOTE Conformity assessment systems may be operated at international, regional, national or sub-national level.

[ISO/IEC 17000:2004, 2.7]

**3.2**
**conformity assessment scheme**
**conformity assessment programme**
conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply

NOTE Conformity assessment schemes may be operated at international, regional, national or sub-national level.

[ISO/IEC 17000:2004, 2.8]

**3.3**
**object of conformity assessment**
particular material, product (including services), installation, process, system, person or body to which conformity assessment is applied

NOTE Adapted from ISO/IEC 17000:2004, 2.1, Note 2.

**3.4**
**specified requirement**
need or expectation that is stated

NOTE Specified requirements may be stated in normative documents such as regulations, standards and technical specifications.

[ISO/IEC 17000:2004, 3.1]

**3.5**
**surveillance**
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[ISO/IEC 17000:2004, 6.1]

# 4 Principles

## 4.1 General

The principles listed below are the basis for the subsequent guidance in this International Standard. This International Standard does not give specific guidance for all situations that can occur. Therefore, the following principles may provide guidance for such situations:

— principle 1: separation of specified requirements for the object of conformity assessment from specified requirements related to conformity assessment activities (see 4.2);

— principle 2: neutrality towards parties performing conformity assessment activities (see 4.3);

— principle 3: functional approach to conformity assessment (see 4.4);

— principle 4: comparability of conformity assessment results (see 4.5);

— principle 5: good practice in conformity assessment (see 4.6).

Principles 1 and 2 are primarily directed towards the preparation of normative documents that contain specifications for objects of conformity assessment (Clause 5 provides further information). Principle 3 is directed towards the preparation of separate normative documents that contain specifications for how conformity assessment systems are structured and carried out. However, the functional approach can assist the developer of normative documents for characteristics of the object of conformity assessment to anticipate and formulate requirements that can be used in the subsequent conformity assessment activities.

## 4.2 Principle 1: separation of specified requirements for the object of conformity assessment from specified requirements related to conformity assessment activities

Normative documents that contain specified requirements for objects of conformity assessment, i.e. characteristics for an object of conformity assessment, should not contain provisions related to conformity assessment activities, except sampling and testing methods related to the specified characteristics. Normative documents that specify requirements for conformity assessment activities should be established separately.

Examples of conformity assessment provisions that should not be contained in normative documents for objects of conformity assessment are requirements or recommendations concerning:

— specific conformity assessment systems or schemes to be applied;

— who should undertake conformity assessment activities, such as a first, second, or third party;

— the type of conformity assessment body to be involved (e.g. testing laboratory, inspection body); or

— specific indications of conformity, such as marks of conformity.

The benefits of separating specified requirements for objects of conformity assessment from specified requirements related to conformity assessment activities include the following:

a) more rigorous consideration of the characteristics of the object and conformity assessment aspects in their proper contexts;

b) greater use of the normative document for the object by parties not pursuing conformity assessment;

c) easier reference to specified characteristics of the object and/or conformity assessment requirements by authorities such as regulators.

### 4.3 Principle 2: neutrality towards parties performing conformity assessment activities

Normative documents for objects of conformity assessment should be written so that conformity of the objects to the specifications can be assessed by any interested party. Interested parties can be:

— a manufacturer or supplier of the object (first party);

— a user or purchaser of the object (second party);

— an independent body (third party).

NOTE Users of the normative documents that contain specifications for objects of conformity assessment can select the parties that are acceptable. Examples of this include:

— regulators regulating the use of the first-party supplier's declarations of conformity (SDoC);

— purchasing organizations specifying specific acceptance criteria and performing tests in their own laboratories for purchased goods (second party);

— regulators requiring product certification by a recognized independent body (third party) before a product enters the market;

— purchasing organizations or regulators requiring certification of the supplier's quality management system as a prerequisite to supply goods or services.

### 4.4 Principle 3: functional approach to conformity assessment

Further information regarding principle 3 is provided in Clause 6.

In accordance with principle 3, normative documents that specify conformity assessment activities should consider the "functional approach to conformity assessment", consisting of the following functions:

— selection;

— determination;

— review and attestation; and

— surveillance (if needed).

These conformity assessment functions are described more fully in 6.4, as well as in ISO/IEC 17000:2004, Annex A.

Each of the various kinds of users of conformity assessment has specific needs. As a result, there is much variety in the way conformity assessment is performed. However, all types of conformity assessment follow the same general approach, characterized by the functions listed above.

The benefits of the functional approach include the following:

a) thorough consideration of all functions of conformity assessment, including clear interfaces between conformity assessment functions;

b) greater substance and credibility that aims of conformity assessment functions are fulfilled;

c) greater consistency and possibility of harmonization among national, regional and international conformity assessment activities, thus facilitating mutual recognition and trade.

### 4.5 Principle 4: comparability of conformity assessment results

The requirements for the objects of conformity assessment (Clause 5) and the requirements for the conformity assessment activities (Clause 6) should be specified in a clear and unambiguous manner, with sufficient detail to ensure that conformity assessment results will be comparable and reproducible.

An important outcome of standardization and of conformity assessment activities is confidence in the objects' fulfilment of specified requirements and the realization of the intended benefits (e.g. interoperability with other products or reduction of safety risks). If different parties (i.e. people, bodies and/or organizations) are applying the specified requirements to produce the object of conformity assessment, the resultant objects should all be comparable with respect to fulfilment of the requirements specified. If conformity with the specified requirements is assessed by different parties, the results of the conformity assessment should be comparable.

### 4.6 Principle 5: good practice in conformity assessment

Developers of normative documents for conformity assessment activities should consider International Standards and Guides as a source of good practice in conformity assessment.

ISO and IEC have developed a series of International Standards and Guides to promote the international comparability and credibility of conformity assessment activities, known as the conformity assessment toolbox. The criteria contained in these documents represent an international consensus on what constitutes good practice in conformity assessment. Using these documents fosters international compatibility and may avoid technical barriers to trade. Annex A lists all the documents that constitute the conformity assessment toolbox.

## 5 Guidance for the preparation of normative documents that specify requirements for objects of conformity assessment

### 5.1 General

**5.1.1** Objects of conformity assessment may be products (including services), materials, installations, processes, systems, persons or bodies. Although the guidance in this clause may appear to be biased towards tangible products, developers of normative documents should interpret this guidance to apply to other objects of conformity assessment. Some examples are provided in 5.2.5.

**5.1.2** This clause does not apply to conformity assessment systems and bodies as objects of conformity assessment.

## 5.2 Drafting specified requirements

**5.2.1** Specified requirements relating to the characteristics of the object of conformity assessment should be stated in the clauses that form the normative parts of the document.

**5.2.2** Specified requirements should be written in such a way that they are clear, direct and precise and will result in accurate and uniform interpretation, so that parties making use of the normative document are able to derive from the contents of the normative document a common understanding of its meaning and intent.

**5.2.3** Normative documents for objects of conformity assessment should focus only on the criteria or performance characteristics of the object.

**5.2.4** Normative documents may specify test methods for determining that the criteria or characteristics have been met. They should be expressed in such a way that any interested party may carry out the testing. It should be left to the users of the normative document to decide what conformity assessment activity (if any) will be utilized, who will carry out the conformity assessment and under what conditions.

**5.2.5** Specified requirements should be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent, and the methods of determination, such as test methods or inspection, in order to verify the specified characteristics. Examples of results or outcomes for a variety of objects of conformity assessment include:

— a manufactured component specified in terms of durability and interoperability within an assembly;

— market research service requirements in terms of defining market composition and reliability of data;

— process requirements for organic agriculture to ensure that production and supply result in food products free of inorganic contaminants;

— a security management system specified in terms of effectiveness of the security environment and continual improvement;

— requirements for personal financial planners in terms of the body of knowledge and experience necessary to demonstrate competence.

**5.2.6** Specified requirements should be written in such a way that they facilitate the development of technology. In general, this is accomplished by:

— specifying requirements in terms of performance, rather than design or descriptive characteristics;

— specifying requirements related to the object, and not to the production process for the object.

**5.2.7** Specified requirements should be divided into distinct, consistent and easily identifiable sections, in order to permit their incorporation by reference in codes, regulations and other standards. This structure permits selected clauses to be identified separately in a code or regulation when only part of the normative document is referenced.

**5.2.8** If a set of specified requirements incorporates requirements stated in another document, the incorporation should be by specific reference and clearly indicate the referenced version, usually by the date (year) of publication. If the version of the referenced document is not specified, the conventional understanding is that the latest version of the document applies, including all amendments and revisions. The use of the term "latest issue" in conjunction with an undated reference should be avoided.

If the referenced document is not dated, it is possible that the format and content of the referenced requirements could change over time. The consequences of changes to the referenced requirements should be considered.

**5.2.9** Specified requirements should be stated unambiguously using wording that is objective, logical, valid and specific. In particular,

— terms such as "adequate", "adversely affected", "sufficiently strong" and "extreme conditions" are subjective and should be avoided;

— qualitative nouns and adjectives that could be taken as absolute, e.g. "waterproof", "unbreakable", "flat", and "safe", should not be used unless defined;

— qualitative nouns and adjectives that describe a measurable property, e.g. "high", "strong", "transparent", and "accurate", should not be used unless defined;

— the term "unless otherwise specified" should not be used, except when the "other specification" is clearly identified in the requirements.

**5.2.10** Specified requirements may contain more than one category, type, class or grade within the same normative documents, or in separate documents, if necessary. Where multiple types, classes, grades, etc. are permitted, the document should specify how these are to be identified to the user.

**5.2.11** All measurement values should be expressed in SI units (International System of Units).

**5.2.12** Specified requirements established by purchasers should follow the principles and practices of this International Standard. This is notably the case for government purchasers and other organizations that may be subject to international trade agreements.

## 5.3 Sampling

**5.3.1** The developer of normative documents for characteristics of the object of conformity assessment should anticipate that specified test methods and related sampling requirements may be selected for use in subsequent conformity assessment activities. Guidance on specifying test methods is given in 5.4.

**5.3.2** Sampling requirements may relate to specified test methods or to acceptance criteria in a conformity assessment system. The developer of normative documents for characteristics of the object should be careful to restrict any sampling requirements to specified test methods for characteristics of the object.

**5.3.3** To gain consistent and reproducible results, sampling methods should be based, whenever possible, on statistical methods provided in International Standards, e.g. ISO 10725 and ISO 11648-1.

## 5.4 Test methods

**5.4.1** As far as practicable, test methods should describe clearly how the test is to be performed, e.g.

— the choice and preparation of samples,

— the use of testing equipment,

— the data to be recorded,

— the acceptance criteria,

— the limits to be used for accepting or rejecting the result, and

— (if relevant) what is acceptable in terms of uncertainty of measurement, accuracy, reproducibility and repeatability.

Specific related International Standards include ISO/IEC 17025 and ISO 5725-1.

**5.4.2** Test methods should focus on the specified requirements of the object of conformity assessment and should avoid stating requirements not directly related to the object's performance.

**5.4.3** Test methods should be selected bearing in mind their effectiveness, economy and practical application.

**5.4.4** Non-destructive test methods should be chosen whenever they provide the same level of confidence as destructive test methods.

**5.4.5** The normative document should specify the sequence of tests when the sequence can influence the results.

**5.4.6** If necessary, alternative test methods or test equipment should be included in the normative document. The equivalence or any advantage or disadvantage when compared with the primary test method should be explained. If equal tests are provided, it should be specified which one will be used in case of dispute.

**5.4.7** If different test methods are permitted from those that are specified, it should be required to maintain a documented correlation of the test results with the specified test methods.

**5.4.8** Specified test methods should follow the metrological principles concerning validation, measurement traceability and estimation of measurement uncertainty described in ISO/IEC 17025:2005, Clause 5. Specific guidance in this respect is provided by ISO/IEC Guide 99 (vocabulary in metrology), and ISO/IEC Guide 98-3, (measurement of uncertainty).

**5.4.9** When specifying requirements of the object of conformity assessment, it is good practice to investigate whether the test methods referred to specify requirements related to testing equipment. If this is not the case, such requirements should be considered for inclusion in the normative document. Requirements related to testing equipment should follow the provisions concerning accuracy and calibration described in ISO/IEC 17025:2005, Clause 5. Other considerations include safety provisions and other requirements relevant to the installation and operation of testing equipment.

## 6 Guidance for the preparation of normative documents that specify requirements for conformity assessment systems

### 6.1 General

Conformity assessment systems which demonstrate that objects of conformity assessment meet specified requirements are developed by:

— industry associations and consortia,

— purchasers,

— regulators,

— consumers and non-government groups,

— accreditation bodies,

— conformity assessment bodies,

— conformity assessment scheme owners, and

— other interested parties, e.g. insurance organizations.

ISO/IEC Guide 60 provides a code of good practice for conformity assessment activities. Other relevant publications are listed in Annex A.

## 6.2 Identifying the need for conformity assessment systems

**6.2.1** The decision to develop a conformity assessment system should be taken after consideration of a number of factors, including the following:

— the societal or economic need or demand for demonstration that an object of conformity assessment meets specified requirements;

— the balance between the potential advantages (e.g. helping to enhance confidence in objects of conformity assessment, improving quality and facilitating trade) and the potential disadvantages (e.g. adding costs, distorting market access and setting up technical barriers to trade);

— the impact of the proposed conformity assessment system on affected parties;

— the party or parties that would be most effective and efficient to perform conformity assessment; and

— the existence of conformity assessment systems that could fulfil the need or demand, or serve as a model for a new conformity assessment system.

**6.2.2** Developers of conformity assessment systems should be aware that ISO and IEC have developed International Standards and Guides which can form the basis for a range of conformity assessment systems that fulfil societal, government and industry interests.

Table B.1 provides a schematic overview of the main conformity assessment activities and their results related to conformity assessment systems and processes, based upon the functional approach and in combination with the parties performing the conformity assessment activity.

## 6.3 Risk assessment

**6.3.1** The choice of conformity assessment system should be based upon risk assessment. Before deciding whether to develop a conformity assessment system or to use an existing one, a risk assessment should be undertaken by those who have an interest in the resulting objects of conformity assessment.

**6.3.2** Once the risks have been identified, the developer and/or user of the conformity assessment system will be in a better position to select which conformity assessment activities to use (e.g. testing, inspection, declaration of conformity or certification) and who should perform it (e.g. a first, second or third party).

## 6.4 Designing conformity assessment systems

**6.4.1** Developers of conformity assessment systems should involve the affected parties in the design of the systems.

**6.4.2** Developers of conformity assessment systems should follow the functional approach to conformity assessment, which provides a framework of basic conformity assessment functions and their relationships.

**6.4.3** The functional approach identifies the following generic functions or elements that are normally present in any conformity assessment system:

— **selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;

— **determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample;

— **review and attestation**, including the review of evidence from the determination stage, and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls; and

— **surveillance** (if needed), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfil the specified requirements.

See ISO/IEC 17000:2004, Annex A.

## 6.5 Specifying requirements for conformity assessment systems

**6.5.1** ISO and IEC have developed a range of International Standards and Guides – known as the conformity assessment toolbox – that are adopted worldwide into conformity assessment systems. These International Standards and Guides incorporate good conformity assessment practices established by international consensus.

**6.5.2** Developers of a conformity assessment system might identify additional requirements to those contained in the selected International Standards and Guides. Any additional requirements should be specified in a separate document, which permits users to identify such additional requirements of a system under development from the requirements of selected International Standards and Guides.

## 6.6 Accreditation, peer assessment and other forms of recognition

**6.6.1** In some cases, normative documents (e.g. regulations) might require an independent attestation of the competence of conformity assessment bodies participating in a conformity assessment system. This might include the requirement that the bodies carrying out the conformity assessment be assessed themselves for competence to carry out their nominated conformity assessment activities. Such forms of recognition can be obtained through accreditation by an accreditation body and/or acceptance in a peer assessment grouping, or through being involved in proficiency testing, or they can have some other form of recognition from an industry or government body.

**6.6.2** Examples of International Standards and Guides that deal with these forms of recognition include ISO/IEC 17011 (accreditation), ISO/IEC 17040 (peer assessment) and ISO/IEC 17043 (proficiency testing).

## 6.7 Mutual recognition of conformity assessment results

**6.7.1** Mutual recognition can occur when interested parties have confidence in the results of each other's conformity assessment system.

EXAMPLE Such mutual recognition can occur between regulators, accreditation bodies or certification bodies.

When such mutual recognition occurs, it facilitates trade between markets and reduces costs of conformity assessment.

**6.7.2** The developers of normative documents on conformity assessment should also consider the likelihood that conformity to their requirements will be carried out, demonstrated and accepted by parties outside of their area of operations. ISO/IEC Guide 68 provides guidance on establishing mutual recognition arrangements (MRAs).

# Annex A
(informative)

## The conformity assessment toolbox

Table A.1 lists the documents that constitute the conformity assessment toolbox.

**Table A.1 — The conformity assessment toolbox**

| Subject | Document | Title |
|---|---|---|
| Vocabulary, principles and common elements of conformity assessment | ISO/IEC 17000:2004 | *Conformity assessment — Vocabulary and general principles* |
| Code of good practice for conformity assessment | ISO/IEC Guide 60:2004 | *Conformity assessment — Code of good practice* |
| Drafting normative documents for use in conformity assessment | ISO/IEC 17007:2009 | *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment* |
| Testing/calibration | ISO/IEC 17025:2005 | *General requirements for the competence of testing and calibration laboratories* |
| | ISO/IEC 17043:— [a] | *Conformity assessment — General requirements for proficiency testing* |
| Inspection | ISO/IEC 17020:1998 [b] | *General criteria for the operation of various types of bodies performing inspection* |
| Supplier's Declaration of Conformity (SDoC) | ISO/IEC 17050-1:2004 | *Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements* |
| | ISO/IEC 17050-2:2004 | *Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation* |
| Product certification | ISO/IEC Guide 23:1982 [b] | *Methods of indicating conformity with standards for third-party certification systems* |
| | ISO/IEC Guide 28:2004 [b] | *Conformity assessment — Guidance on a third-party certification system for products* |
| | ISO/IEC Guide 53:2005 [b] | *Conformity assessment — Guidance on the use of an organization's quality management system in product certification* |
| | ISO/IEC Guide 65:1996 [b] | *General requirements for bodies operating product certification systems* |
| | ISO/IEC Guide 67:2004 [b] | *Conformity assessment — Fundamentals of product certification* |
| Management system certification | ISO/IEC 17021:2006 | *Conformity assessment — Requirements for bodies providing audit and certification of management systems* |
| Certification of persons | ISO/IEC 17024:2003 [b] | *Conformity assessment — General requirements for bodies operating certification of persons* |
| Marks of conformity | ISO Guide 27:1983 [b] | *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity* |
| | ISO/IEC 17030:2003 | *Conformity assessment — General requirements for third-party marks of conformity* |
| Accreditation | ISO/IEC 17011:2004 | *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies* |
| Mutual Recognition Arrangements (MRAs) | ISO/IEC Guide 68:2002 | *Arrangements for the recognition and acceptance of conformity assessment results* |
| Peer assessment | ISO/IEC 17040:2005 | *Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies* |

[a] To be published in 2010.
[b] Currently under revision.

# Annex B
(informative)

## Overview of conformity assessment activities

Table B.1 provides a schematic overview of conformity assessment activities.

**Table B.1 — Overview of conformity assessment activities**

| Conformity assessment system or scheme | Document | Party performing conformity assessment | | | Functional approach | | | Surveillance (when needed) [b] | Result |
|---|---|---|---|---|---|---|---|---|---|
| | | First party | Second party [a] | Third party | Selection stage | Determination stage | Review and attestation stage | | |
| Supplier's declaration of conformity | ISO/IEC 17050 | ✓ | — | — | ✓ | ✓ | ✓ | — | Declaration |
| Certification of products | ISO/IEC Guide 65 | — | — | ✓ | ✓ | ✓ | ✓ | ✓ | Certificate |
| Certification of management systems | ISO/IEC 17021 | — | — | ✓ | ✓ | ✓ | ✓ | ✓ | Certificate |
| Certification of persons | ISO/IEC 17024 | — | — | ✓ | ✓ | ✓ | ✓ | ✓ | Certificate |
| Inspection | ISO/IEC 17020 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | — | Report |
| Testing | ISO/IEC 17025 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | — | Report |

[a] At present, ISO and IEC do not have specific International Standards or Guides for second-party conformity assessment systems. Second-party conformity assessment systems can be developed to rely on first-party declarations, third-party attestations and certification, or second-party acceptance criteria.

[b] **Surveillance** (3.5) is part of the conformity assessment system and not an external market surveillance activity.

# Bibliography


[1] ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[2] ISO 9001, *Quality management systems — Requirements*

[3] ISO 10725, *Acceptance sampling plans and procedures for the inspection of bulk materials*

[4] ISO 11648-1, *Statistical aspects of sampling from bulk materials — Part 1: General principles*

[5] ISO 14001, *Environmental management systems — Requirements with guidance for use*

[6] ISO 14065, *Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition*

[7] ISO/IEC 17011:2004, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

[8] ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

[9] ISO/IEC 17021:2006, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

[10] ISO/IEC 17024:2003, *Conformity assessment — General requirements for bodies operating certification of persons*

[11] ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

[12] ISO/IEC 17030:2003, *Conformity assessment — General requirements for third-party marks of conformity*

[13] ISO/IEC 17040:2005, *Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies*

[14] ISO/IEC 17043:—[1)], *Conformity assessment — General requirements for proficiency testing*

[15] ISO/IEC 17050:2004 (all parts), *Conformity assessment — Supplier's declaration of conformity*

[16] ISO 19011, *Guidelines for quality and/or environmental management systems auditing*

[17] ISO/TS 22003, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*

[18] ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems*

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The Bahamas Bureau of Standards & Quality

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The main objective of the BBSQ is to improve industry competitiveness in the domestic and export markets, facilitate trade by reducing technical barrier to trade, and strengthen consumer and environmental protection against unsafe products or services being placed on the market. This is accomplished through the formulation, adoption and /or adaption of standards as national instruments of socio-economic development. Additionally through offering metrology, inspection, testing and certification services, the latter three being collectively termed conformity assessment.

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1. The preparation of standards documents is undertaken upon the Standards Council's authorization. This may arise out of representations from national organizations or existing Bureau of Standards' Committees or Bureau staff. If the project is approved it is referred to the appropriate sectional committee, or if none exists a new committee is formed, or the project is allotted to Bureau staff.

2. If necessary, when the final draft of a standard is ready, the Council authorizes an approach to the Minister in order to obtain the formal concurrence of any other Minister who may be responsible for any area which the standard affects.

3. With the approval of the Standards Council, the draft document is made available for general public comments. All interested parties, by means of notice in the Press, are invited to comment. In addition copies are forwarded to those known to be interested in the subject.

4. The Committee considers all the comments received and recommends the final document to the Standards Council.

5. The Standards Council recommends the document to the Minister for publication.

6. The Minister approves the recommendation of the Standards Council.

7. The declaration of the standard is gazzetted and copies placed for sale.

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