BAHAMAS BUREAU OF STANDARDS AND QUALITY

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FINAL DRAFT BAHAMAS NATIONAL STANDARD

CONFORMITY ASSESSMENT -- FUNDAMENTALS OF PRODUCT CERTIFICATION AND GUIDELINES FOR PRODUCT CERTIFICATION SCHEMES

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ISO/IEC 17067:2013

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National Foreword

Introduction

This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to the term "product" can also be read to mean "services" or "processes".

As products are designed, produced, distributed, used and ultimately disposed of, they can give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions.

Generally, these concerns are addressed by specifying the required product attributes in a normative document such as a standard.

The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the normative document.

It might be sufficient for the supplier to assess and declare its product's conformity, but in other cases the user or a regulatory authority might require that conformity be assessed by a competent and impartial third party.

Assessment and impartial third party attestation that fulfilment of specified requirements has been demonstrated for the product is referred to as product certification.

This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.

This International Standard is intended for use by those involved with product certification, particularly those who are, or who are considering becoming, product certification scheme owners. Product certification scheme owners can include:

a) product certification bodies;

b) government and regulators;

c) purchasing agencies;

d) non-government organizations;

e) industry and retail associations; and

f) consumer organizations.

This International Standard provides only guidance and does not contain requirements. It is compatible with ISO/IEC 17065, which specifies requirements for product certification bodies.

In this International Standard, the following verbal forms are used:

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

The modal verb "shall", which indicates a requirement, is not used because this International Standard only provides guidelines.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

1 Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification, and especially by certification scheme owners.

NOTE 1 In this International Standard the term "product" can also be read as "process" or "service", except in those instances where separate provisions are stated for "processes" or "services". Definitions of product, process and service are given in ISO/IEC 17065.

NOTE 2 The certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000) carried out by product certification bodies. The requirements for product certification bodies are specified in ISO/IEC 17065.

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*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 and the following apply.

3.1
certification system
rules, procedures and management for carrying out certification

[SOURCE: ISO/IEC 17000:2004, 2.7, modified]

3.2
certification scheme
certification system (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply

Note 1 to entry: The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

[SOURCE: ISO/IEC 17065:2012, 3.9, modified]

— **decision** on certification;

— **attestation**, which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated (see ISO/IEC 17000:2004, 5.2);

— **surveillance** (where needed), which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (see ISO/IEC 17000:2004, 6.1).

NOTE 1 Further information about the functions is given in ISO/IEC 17000.

NOTE 2 In ISO/IEC 17065, the functions of "selection" and "determination" have been combined and are referred to as "evaluation".

NOTE 3 In ISO/IEC 17065, the function of "attestation" is related to the subclause on "certification documentation" (see ISO/IEC 17065:2012, 7.7).

5.1.2 Whenever product certification is performed, a certification scheme (see 3.2) is in place.

5.2 Functions and activities in product certification schemes

5.2.1 Product certification schemes are developed by defining specific activities for each of the applicable functions described in 5.1.1. Table 1 shows how to build a product certification scheme by using these functions, and outlines some of the combinations of activities in use in the wide range of fields where product certification is employed. The types of product certification schemes in Table 1 are further described in 5.3.

5.2.2 Clause 6 describes the process for deciding which activities to use for a given situation and the factors to be taken into account in making the decision.

are carried out. For scheme types 1a and 1b, no surveillance is required since the attestation relates only to the product items which have been subjected to the determination activities. For the other scheme types, 5.3.4 to 5.3.8 outline the way in which the different surveillance activities can be used and the circumstances to which they could be applicable.

5.3.2 Scheme type 1a

In this scheme, one or more samples of the product are subjected to the determination activities. A certificate of conformity or other statement of conformity (e.g. a letter) is issued for the product type, the characteristics of which are detailed in the certificate or a document referred to in the certificate. Subsequent production items are not covered by the certification body's attestation of conformity.

The samples are representative of subsequent production items which could be referred to by the manufacturer as being manufactured in accordance with the certified type.

The certification body may grant to the manufacturer the right to use the type certificate or other statement of conformity (e.g. letter) as a basis for the manufacturer to declare that subsequent production items conform to the specified requirements.

5.3.3 Scheme type 1b

This scheme type involves the certification of a whole batch of products, following selection and determination as specified in the scheme. The proportion to be tested, which can include testing of all the units in the batch (100% testing), would be based, for example, on the homogeneity of the items in the batch and the application of a sampling plan, where appropriate. If the outcome of the determination, review and decision is positive, all items in the batch may be described as certified and may have a mark of conformity affixed, if that is included in the scheme.

5.3.4 Scheme type 2

The surveillance part of this scheme involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements.

While this scheme may identify the impact of the distribution channel on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective corrective measures may be limited since the product has already been distributed to the market.

5.3.5 Scheme type 3

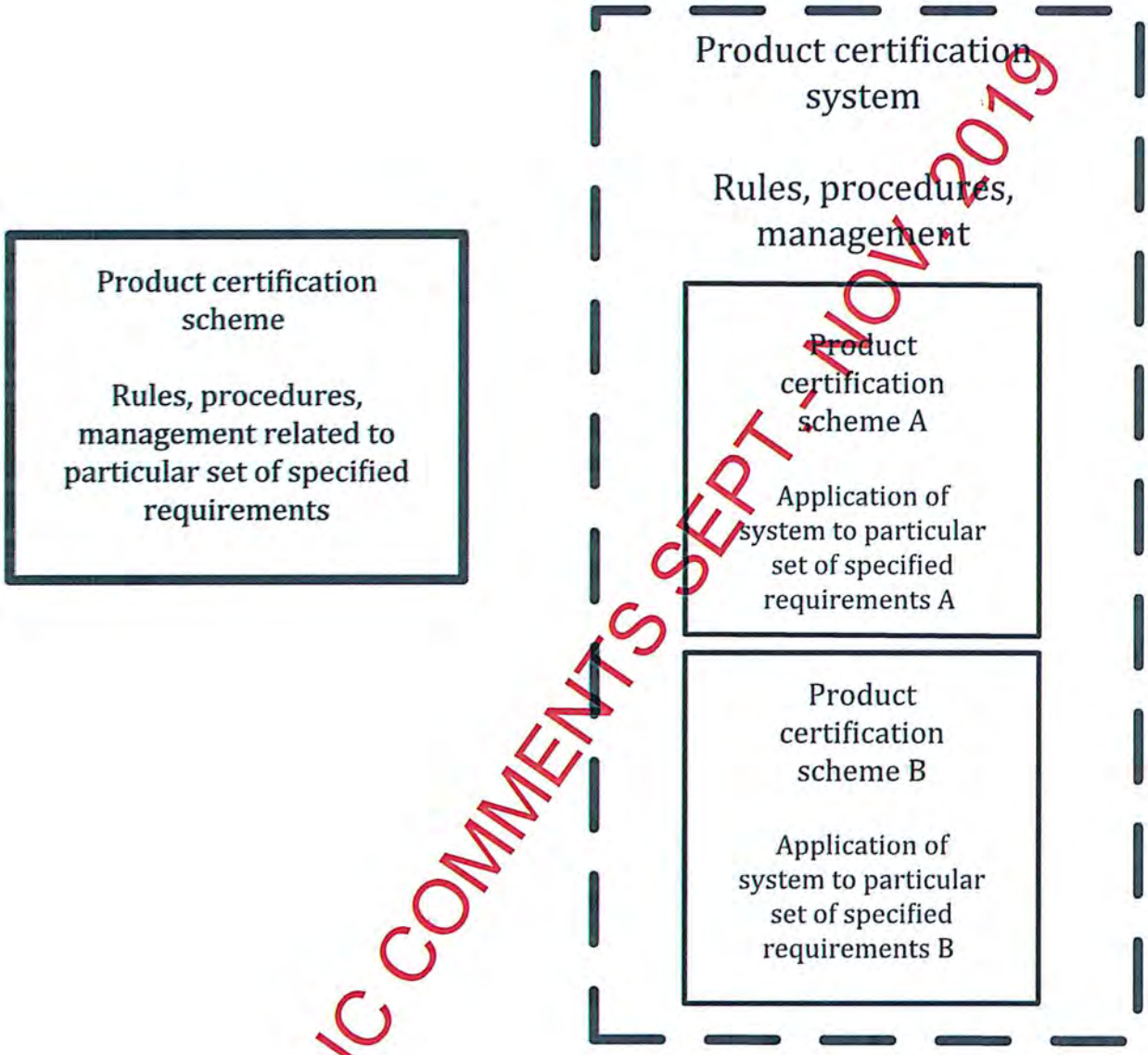
The surveillance part of this scheme involves periodically taking samples of the product from the point of production and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution occurs.

5.3.6 Scheme type 4

The surveillance part of this scheme allows for the choice between periodically taking samples of the product from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.



a) Unique product certification scheme

b) Product certification system relating to several schemes

Figure 1 — Relationship between product certification scheme and product certification system

6.3 Scheme owner

6.3.1 The following main types of scheme owners can be identified:

a) certification bodies which develop a product certification scheme for the sole use of their clients;

b) organizations such as a regulatory body or a trade association not being a certification body, which develop a product certification scheme in which one or more certification bodies participate.

NOTE A group of certification bodies, perhaps in different countries, can together set up a certification scheme. In that case, it would be necessary for the certification bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating certification bodies.

6.4.5 Once developed, the scheme owner should ensure that information about the scheme is made publicly available to ensure transparency, understanding and acceptance. The scheme owner should ensure that the scheme is regularly reviewed, including confirmation that it is fulfilling its objectives, in accordance with a process that includes stakeholders.

6.5 Content of a scheme

6.5.1 General

A product certification scheme should specify the following elements:

a) the scope of the scheme, including the type of products covered;

b) the requirements against which the products are evaluated, by reference to standards or other normative documents; where it is necessary to elaborate upon the requirements to remove ambiguity, the explanations should be formulated by competent people and should be made available to all interested parties;

NOTE Further guidance on how to formulate specified requirements is provided in ISO/IEC 17007.

c) the selection of the activities (see Table 1) appropriate to the purpose and the scope of the scheme; as a minimum, a certification scheme should include the functions and activities I, II, III, IV and V a);

d) other requirements to be met by the client, e.g. the operation of a management system or process control activities to assure the demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products;

e) the requirements for certification bodies and other conformity assessment bodies involved in the certification process; these requirements should not be in contradiction to the requirements of the applicable standards for conformity assessment bodies;

f) whether conformity assessment bodies involved in the scheme (e.g. testing laboratories, inspection bodies, product certification bodies, bodies auditing manufacturers' management systems) are to be accredited, participate in peer assessment or qualified in another manner; if the scheme is to require that conformity assessment bodies are accredited, the appropriate references should be specified, e.g. that the accreditation body is a member of a mutual recognition arrangement between accreditation bodies;

g) the methods and procedures to be used by the conformity assessment bodies and other organizations involved in the certification process, so as to assure the integrity and consistency of the outcome of the conformity assessment process;

h) the information to be supplied to the certification body by an applicant for certification;

i) the content of the statement of conformity (e.g. certificate) which unambiguously identifies the product to which it applies;

j) the conditions under which the client may use the statement of conformity or marks of conformity;

k) where marks of conformity may be used, the ownership, use and control of the marks; the requirements of ISO/IEC 17030 should be applied;

l) the resources required for the operation of the scheme, including impartiality and competence of the personnel (internal and external), the evaluation resources, and the use of subcontractors;

m) how the results of the determination (evaluation) and surveillance stages are to be reported and used by the certification body and the scheme owner;

n) the question of how non-conformities with the certification requirements, which include product requirements, are to be dealt with and resolved;

Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.

6.5.6 Licensing and control of the mark

Where the scheme provides for the use of certificates, marks or other statements of conformity, there should be a license or other form of enforceable agreement to control such use. Licenses can include provisions related to use of the certificate, mark or other statement of conformity in communications about the certified product, and requirements to be fulfilled when certification is no longer valid. Such licenses may be between two or more of the following:

— scheme owner;

— certification body;

— client of the certification body.

6.5.7 Surveillance

If surveillance is included, the scheme should define the set of activities (see function 6 in Table 1) that make up the surveillance functions. When deciding upon the appropriate surveillance activities, the scheme owner should consider the nature of the product, the consequences and probability of non-conforming products and the frequency of the activities.

6.5.8 Non-conforming products

The scheme should define requirements that apply when a product no longer fulfils certification requirements, such as product recall or providing information to the market.

NOTE See also ISO Guide 27.

6.5.9 Reporting to the scheme owner

When reporting to the scheme owner is required, the content and frequency of reporting should be defined. Such reporting may be for the purpose of scheme improvement, for control purposes and for monitoring the extent of conformity by clients.

6.5.10 Subcontracting of the operation of the scheme

If the scheme owner subcontracts all or part of the operation of the scheme to another party, it should have a legally binding contract defining the duties and responsibilities of both parties. A governmental scheme owner can subcontract operation of the scheme by regulatory provisions.

6.5.11 Marketing

The scheme should define the policies and procedures related to marketing, including the extent to which certification bodies and clients can make reference to the scheme.

6.5.12 Fraudulent claim of certification

Actions and responsibilities for situations where certification under the scheme is being claimed fraudulently should be described.

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[1] ISO 2859-10, *Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*

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[3] ISO 10576-1, *Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles*

[4] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

[5] ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[6] ISO/IEC 17021 (all parts), *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

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

[9] ISO 22514-1, *Statistical methods in process management — Capability and performance — Part 1: General principles and concepts*

[10] ISO 31000, *Risk management — Principles and guidelines*

[11] ISO Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

[12] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[13] ISO/IEC Guide 53, *Conformity assessment — Guidance on the use of an organization's quality management system in product certification*

[14] ISO/IEC Guide 68, *Arrangements for the recognition and acceptance of conformity assessment results*

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