AFSEC

GUIDE FOR CONFORMITY ASSESSMENT

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First edition

The project leader, Kuta Omar – AFSEC 2nd Vice President & ACAC Chair, appreciates the contributions made by all and the final editing team with support from PTB and Leon Drotsche (PTB Expert) to create this AFSEC CONFORMITY ASSESSMENT guide.

Final editing team:
Dr Lemba Nyirenda
Hanan Mohamed
Assane Mbengue
Irene Njine

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PART ONE

GUIDE FOR DEVELOPMENT OF CONFORMITY ASSESSMENT IN THE AFRICAN ELECTRO-TECHNICAL SECTOR

Contents

Acronyms and Abbreviations

Certification body	Third-party conformity assessment body operating certification schemes. A certification body can be non-governmental or governmental (with or without regulatory authority).
Client	Organization or person responsible for ensuring that certification requirements including product requirements are fulfilled.
Product	Result of a process, there are four generic product categories are noted in ISO 9000: • Services (e.g. transport); • Software (e.g. computer program, dictionary); • Hardware (e.g. engine, mechanical part); • Processed materials (e.g. lubricant).

Preamble

International Standard ISO/IEC 17000 defines conformity assessment as a "Demonstration that specified requirements are fulfilled". Conformity assessment (CA) is specific to the object being assessed as listed – product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof. For example; it may be the first party, such as the manufacturer of a product, which is making a supplier's declaration of conformity using its own internal testing system or a third-party certification or inspection, undertaken by an independent service provider. The service provider could be a government agency or a private company.

The AFSEC CA program is associated with International Electrotechnical Commission (IEC) and African Organisation for Standardisation (ARSO) with International Organization for Standardization (ISO).

Conformity Assessment (CA) is any activity which results in determining whether a product or other object meets requirements contained in a specification. A specification, typically but not exclusively a standard, is a technical description of the characteristics which are required to be fulfilled by some object.

In its simplest form, conformity assessment is determining (directly or indirectly) if a process, product, materials, services, systems or people meet the specifications of a relevant standard.

Conformity assessment can involve one or more of the following:

- Testing and/or calibration of a product or service to determine if it meets specified requirements or performs in accordance with them;
- Inspection of the manufacturing process of a product to ensure that it is produced or assembled in an appropriate manner with regards to health and safety, especially according to any health, safety or environmental regulations;
- Certification to a management system to ensure that a product or service is produced in a consistent manner and will satisfy the purpose for which it is intended;

- Accreditation of a product certification body to demonstrate its competence to carry out third party attestations.

There are **three types** of conformity assessment that are widely used:

First Party – The manufacturer or supplier declares that tests and other conformity assessment activities required to show that the product conforms has been successfully completed. In many cases manufacturers will self-perform testing and evaluation and provide a Supplier's Declaration of Conformity (SDoC). This type of conformity assessment is used where the product does not represent great danger, a critical reliability risk or large economic impact. It is furnished information by the supplier.

Some national regulations will accept SDoC for low risk products. This is the easiest and cheapest form of conformity assessment.

Second Party – This type of conformity assessment is typically performed by a person or organization that has a purchaser or user interest in the product or service. A very large important or demanding customer (e.g. government or major manufacturer) will put in place its own conformity assessment for the products and services it purchases. This may include test facilities and special assessment procedures that are conducted to guarantee the quality of the purchased goods and fitness for purpose. The aim is typically to obtain better assurance that the supplier has carried out their first-party conformity assessment. This is sometimes performed by an independent engineer or an owner's representative and in many cases this is being replaced by third party conformity assessment.

Third Party – This is a conformity assessment activity that is performed by a person, organization or body that is independent from the manufacturer and the buyer. In most cases the organization or body's prime focus of work is testing and conformity assessment. It is sometimes called certification and provides the highest level of confidence. Certification is an independently unbiased assurance of the safety of the product or service. It is applied where a major market makes it cost effective or where it is mandated by legislation. These activities is performed by certification bodies (CBs), which are usually for-profit companies, and is more expensive than first party conformity assessment.

1 Introduction

1.1 The African Electrotechnical Standardization Commission (AFSEC)

The African Electrotechnical Standardization Commission (AFSEC) was established on 28th February 2008 by the Association of Power Utilities of Africa (APUA) at the request of Africa Ministers of Energy, as a subsidiary of African Energy Commission (AFREC) under the auspices of the African Union Commission. AFSEC was established as the continental body in Africa that focuses on the harmonization/development of electrotechnical standards and conformity processes in order to improve access to electricity and hence the wellbeing of the African population in support of the Sustainable Development Goals (SDGs) and Agenda 2063 of the African Union.

AFSEC through the harmonization of standards and conformity assessment procedures contribute to the broad ambitions of the Africa Free Continental Trade Area (AfCFTA) with its role mentioned in Annex 6 of the AfCFTA agreement on Technical Barriers to Trade (TBT) to overcome the technical barriers between African countries.

Up to August 2019, 17 Countries out of 54 had established National Electrotechnical Committees (NECs) and became statutory members of AFSEC (Cote d'Ivoire, Democratic Republic of Congo (DRC), Egypt, Ethiopia, Ghana, Guinea, Kenya, Namibia, Nigeria, Rwanda, Senegal, South Africa, Sudan, Tunisia, Uganda, Zambia, Zimbabwe).

The Affiliate members are APUA, Representative of African Energy Commission (AFREC), Representative of the African Union Commission (AUC) Commission and the African Power Pools.

In 2014 AFSEC established a Standards Management Committee (ASMC) for the management of the AFSEC Technical Committees (ATCs) and a Conformity Assessment Committee (ACAC).

1.2 AFSEC Conformity Assessment Committee (ACAC)

The ACAC has the task of guiding conformity assessment activities of products or services in accordance and in liaison with other international bodies or possibly partner organizations for matters of Conformity assessment (CA).

The ACAC takes all the measures deemed necessary to promote and facilitate the activities of AFSEC in the field of Conformity Assessment, included in their Action Plan for 2020-2021 is the development of a Conformity Assessment Guide.

1.3 Scope of the guide

The scope of work in developing the AFSEC CA application guide will cover Renewable Energy Systems -Wind, Solar PV & Marine Energy (RE), Electrotechnical/Electronic Equipment and Components (EE), Explosive Atmospheres (Ex) and Electronic Components (CQ).

This guide aims at assisting AFSEC members in supporting the development of an electrotechnical CA strategy in their countries and also support the AfCFTA (TBT) in the field of electrical/electronic equipment traded in Africa.

1.4 Objectives of the guide

The part 1 of the guide serves as a framework to harmonize initiatives by various countries and ARSO for conformity assessment (CA) systems in the Africa Continent. Other parts of the guide will focus on specific use cases and CA Systems.

This AFSEC CA application guide aims to assist to develop good regulatory practices in conformity assessment activities for those that the economic impact in Africa is vital.

The guide will map various processes that can be introduced in an African Country whereby conformance/quality control can assist to have:

- Verification of certification certificates (authentication) to manage the products that are important against false certificates.
- Identifying what are the main areas of substandard electrotechnical equipment in a country e.g. how is it tested/ not tested.
- Guide countries to optimally use the IEC CA as an IEC member or participate in an AFSEC CA program, etc.

The guide will also assist to identify how to Harmonise Electrotechnical CA with related Quality Infrastructures in Africa.

1.5 International Trade and Conformance Assessment

Conformity Assessment provides tangible benefits to the Governments and it helps reduce trade barriers caused by different certification criteria in various countries and helps countries meet their obligations as stipulated in World Trade Organization Agreement (WTO) on Technical Barriers to Trade as well as for African Continental Free Trade Area Agreement on Technical Barriers to Trade – *Annex 6*.

1.6 African Conformance Assessment (CA) Situation Analysis (Status Quo)

1.6.1 Status of needs for electrotechnical CA in Africa

The most commonly used Conformity assessment schemes in Africa are IECEE and IECEx. The uptake of CA activities in Africa is low due to lack of awareness of CA activities and schemes. In order to improve CA activities in Africa, there is need to:

- Create awareness on CA activities and schemes.
- Develop policies and regulatory framework on CA activities.
- Harmonise standards.
- Enhance testing capability.
- Provide adequate resources to undertake CA activities.

1.6.2 Existing test laboratories and their scope of activities

Referring to AFSEC Database, only 10 countries out of 17 have Testing labs registered and the max number of Labs is available in South Africa. Available Labs are most commonly for testing Electricity Metering Standards and there are also labs for testing the standards of Communication networks, Low-voltage electrical installations, Electrical installations of buildings, Recommendations for Renewable energy, etc. with a total number of 176 International Labs covering 102 Standards recommended for adoption by AFSEC.

1.6.3 A survey with AFSEC members about their Status of CA was conducted in 2020

One of the objectives of the survey questionnaire was to share experiences. Topics were related to the issues affecting development of standardization and conformity assessment in AFSEC Member States.

The questionnaire included enquiries about the status of the NSB/NEC in a Country and what dedicated institutions for Standardization and Conformity Assessment was in place. It also enquired if they have Legal, Regulatory and Institutional frameworks. It included if the country had a Policy/Documented Procedure/Process of Importing and the Approval of Electrotechnical Goods and services.

The questionnaire also focused on the availability of IEC Conformity Assessment Schemes, how was the Conformity Assessment activities funded, challenges faced and the level of awareness with the concept of Conformity Assessment in the Country.

Annex A: Questionnaire brief analysis of the collected data from Seven Member States

2 Conformity Assessment

When products are traded between willing suppliers and willing consumers within a free market system where there are no price controls the "laws" of supply and demand usually take precedence. Suppliers have an interest in efficiently providing as many products as possible in order to remain in business and grow. Consumers, on the other hand, have a need to buy products but seek to obtain them at the best price possible.

Somewhere in the negotiations that follow the issue of product quality comes up. Consumers require a level of quality that equates to their perception of fitness for purpose and safety or else they will not buy the product. It is thus in the interest of suppliers to meet the requirements of consumers to guarantee repeat business.

The answer to the definition of that level of fitness for purpose and safety is usually provided by standards.

When products are involved that can have an effect on health or safety, the environment, or that might encourage deceptive practices, consumers need protection from faulty or dangerous products or from the unscrupulous behavior of suppliers. This is where governments need to step in and introduce legislation in the form of technical regulations to assure a reasonable level of customer protection. Without some form of enforcement of regulations there will be little compliance and therefore governments need to establish one or more technical regulatory systems.

Since a product will be certified once by an accredited single Certification Body and that Certification will be accepted by others all over the world, normally without the need to assess the product or system again, products can get to the market more quickly with less expense and have access to a larger market.

2.1 Standards and Conformance Assessment

Conformity assessment enables buyers, sellers, consumers and regulators to have confidence that products sourced in a global market meet specific requirements. It is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

Conformity assessment procedures includes:

- supplier's declaration of conformity,
- sampling and testing,
- inspection,
- certification,
- management system assessment and registration,
- the accreditation of the competence of those activities,
- recognition of an accreditation program's capability.

Standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment scheme or program. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements) and the products themselves.

Together standards and conformity assessment activities affect almost every aspect of life – they are the two sides of a coin.

2.2 Certification

A Certification Body is responsible for carrying out audits or conformity assessments for Trust Service Providers (TSPs). Each Certification Body must carry out audits in accordance with the regulations applicable in the sector.

The audit process is carried out in the following three phases:

1. Planning and programming: The audits are carried out with an Audit Plan which will be carried out by the audit team each year and the Technical Committee will review and approve the audit plan.

2. Execution: Considering the Audit Plan as a work guide there are two steps at this point.

   a) Documentary review: by verifying the conformity of the system (documents, records) through compliance with the points of the standards / laws of reference.

   b) On-site inspection: verifications of compliance with the established controls is carried out. A sampling inspection of the objective evidences is carried out to prove the correct functioning of the technical and organizational processes related to the scope of the audit.

3. Audit report: Once the audit is completed the audit team will write a results report, clearly and definitively identifying the detected nonconformities. Product Conformity Assessment (PCA) is a solution designed to ensure that specific products meet the requirements of the technical regulations and standards set by a regulatory authority in the importing country.

2.3 Product Compliance Schemes

Schemes for product compliance can be structured and managed by identifying common assessment techniques that are used as a basis for product certification such as product testing, inspection, auditing e.g.

- Accepting / authentication of conformance certificates
- Verifying / sample testing
- A recognition system, etc.

2.4 Technical Regulation

A generic technical regulatory system consists of five elements:

- A regulator, in the form of a public body identified to administer technical regulations
- A suite of technical regulations, that normally include both administrative and technical provisions
- A supplier of the product (designer, manufacturer, importer, distributor, retailer) which is responsible for marketing safe products and monitoring their products in the marketplace
- A conformity assessment infrastructure to enable the regulator to make decisions about compliance or noncompliance
- A range of sanctions that can be applied by the regulator in the event of proven noncompliance

Regulators and suppliers have the duty to monitor products coming onto the market to ensure that they conform to relevant technical regulations. This is the essence of market surveillance and is either carried out by the regulator itself or by a market surveillance authority appointed. Market surveillance may be carried out after the product is placed on the market.

2.4.1 Conformity assessment of locally produced products

For those products that are produced within their own territory regulators have available to them a variety of approaches including carrying out inspections, the sampling and testing of products and others. Regulators can undertake these activities themselves or use recognized conformity assessment bodies to undertake the task on their behalf. They need to work closely with manufacturers and suppliers and may take samples from production runs or even test pre-production prototypes as part of their duties. They can typically carry out both scheduled and random visits to premises and can obtain and test samples of products already placed on the market from retail outlets, etc.

There are also market surveillance systems where suppliers are obliged to monitor the market and report defects and incidents with products. Both pre-market and post-market surveillance activities are useful to protect consumer safety and ensure product quality. Proper pre-market surveillance can help ensure the conformity of products entering the market and alleviate the pressure on post-market surveillance. The manufacturer or supplier has a liability for any nonconforming product.

2.4.2 Conformity assessment of imported products

With products imported from other countries, although the applicable technical regulations do not change, regulators in an importing country can use pre-shipment inspection as a tool to prevent nonconforming products entering the market and will have to work in close cooperation with customs authorities.

Regulators or market surveillance authorities should become involved in the investigation of incidents that are notified to them and when required initiate nonconforming of products including the follow-up of any corrective actions. They have a duty, together with suppliers, to keep the public informed of dangers as they arise. The emphasis should not just be on punishing those economic operators who break the rules but in providing information to them to enable corrective actions to be taken in order to ensure future compliance.

2.5 Conformity Assessment Systems

IEC runs four global Conformity Assessment Systems which operate schemes and programs based on third party testing and certification and mutual recognition agreements. Laboratories and certification bodies test and certify products, equipment, services and personnel competency against IEC/ International Standards to ensure their reliability, interoperability with other products, services and installations that the relevant safety standards have been applied.

2.5.1 IECRE

IECRE is the IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications. RE (Renewable Energy) Sectors are known by different names such as Marine Energy, Solar PV Energy and Wind Energy.

2.5.2 IECEE

IECEE is the worldwide system of conformity assessment schemes for electrotechnical equipment and components. The CB Scheme covers a wide range of products and services, for safety, performance and electromagnetic compatibility e.g. Information technology (IT) and office equipment, Electronics, Electrical equipment for medical use, Installation accessories and connection devices, Lighting, Switches and automatic controls for electrical household appliances, Portable tools, Photovoltaic, Low voltage, high power switching equipment, Batteries, Cables and cords, etc.

2.5.3 IECEx

IECEx is the worldwide system for certification to standards relating to equipment for use in explosive atmospheres (“Ex equipment”), Ex equipment is frequently found in locations such as e.g. Oil refineries, rigs and processing plants, Chemical processing plants, Hospital operating theatres, Off-shore oil platforms, Underground coal mines, Grain handling and storage installations, Sugar refineries, etc.

2.5.4 IECQ

IECQ is the worldwide quality assessment system for electronic components. Electronic components represent a wide range of products such as e.g. Active components, including integrated circuits, Electromagnetic components, Hybrid integrated circuits, electromechanical components, Wires and cables, etc.

2.6 Benefits of Conformity Assessment

Conformity assessment process has a number of benefits among which are the following:

- It provides consumers and other stakeholders with added confidence
- It gives a company a competitive edge
- It helps regulators ensure that health, safety or environmental conditions are met
- Improved quality of products in the country
- Reduced consumer complaints
- Improved customer satisfaction
- Fair competition among traders in the market

3 Requirements for Conformity Assessment

3.1 Quality Management System (QMS)

QMS is essential for improving business operations and enabling them to meet the requirements of customers. Many types of quality management systems are built around ISO 9000 series, a framework requiring all business processes to be documented and for people to follow closely, which allows the organization to remain compatible with the latest standards and regulations.

Once an organization is ISO 9001 certified, implementing Total Quality Management (TQM), it will allow them to evaluate all processes, improve efficiency and reduce waste.

Annex B – ISO, the International Organization for Standardization

3.2 Requirements for test laboratories

ISO/IEC17025 – General requirements for the competence of testing and calibration laboratories.

This standard is applicable to all organizations performing tests and/or calibrations including first, second and third party laboratories. Such tests are required to demonstrate the fulfillment of regulatory safety or contractual requirements. It addresses both management system elements and technical competence in a systemic and consistent way. There are two main requirements: management requirements and technical requirements.

Annex C – Criteria to establish accreditation bodies and test laboratories. (CASCO toolbox)

3.2.1 Opportunities for test laboratories (Labs)

An increasingly educated public demands to know what standards have been set, what limits are safe and what assurances are being provided. Suspicion of dumping of sub-standard products in the market place which have failed testing in other countries is a cause of concern as is the importation and deployment of counterfeits products.

A key component of the answer to such concerns is to have a robust approval regime and test labs working from a set of technical standards, a testing regime and testing capability to approve and monitor electrotechnical technologies which are being deployed on the market place backed by surveillance, audits and enforcement. If there are no established technical requirements, type approval regimes and test labs available to a country or region then the market place is left largely unprotected.

A positive is that there are standards available or under development to define the technical requirements for products legitimately deployed in the market place. However adopting and adapting these standards for national systems requires a depth of expertise that many countries do not presently have but AFSEC can support these interim deficiencies.

Furthermore institutional arrangements, legislation and regulatory regimes need to be established to give force to mandatory requirements and to provide the authorizations needed for market place intervention, surveillance and enforcement.

3.3 Requirements for accreditation bodies

ISO/IEC17011 – Conformity assessment–General requirement for accreditation bodies accrediting conformity assessment bodies.

The accreditation body shall exist as a legal entity. It will have a structure, a management system, qualified human resource and a documented accreditation process.

3.4 Training by IEC for Affiliated Countries

IEC Webinar on Affiliated Countries CA: https://etech.iec.ch/issue/2021-02/helping-developing-countries-understand-the-advantages-of-conformity-assessment

4 Conclusion

The AFSEC Conformity Assessment Committee (CAC) has no legal authority over any country or entity. It serves to put forward a platform that can be adopted by AFSEC member countries through their National Committees (NC's) and implemented to improve the safety of electrical equipment used in each country by ensuring the conformity of products and services with recognized and accepted standards.

Inter-Country trade in such products should be made easier when conformity with the recognized and accepted standards can be proved.

The platform provided by the AFSEC Conformity Assessment Committee (CAC) and this guide is intended to provide a path for regulators to institute minimum requirements for electrotechnical products used in AFSEC member countries.

AFSEC member countries and their regulators are able to enforce (through regulation) compliance of products and services with the standards recommended for adoption by AFSEC and demonstrate compliance with these standards through conformity assessment activities.

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3. Conformity assessment for developing countries, guidelines, International Electrotechnical Commission IEC, Edition 3.0 2008-10

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Annex A
Analysis of the Feedback on the Questionnaire Received from Seven Member States

- Most of the Countries have dedicated institutions for Standardization, Standards Compliance & Conformity Assessment, Legal, Scientific & Industrial Metrology and Power/ Energy/ Renewables Regulation.
- Less than 200 up to 1298 IEC standards are adopted from the Standards Bodies in concert with the Country IEC/NEC.
- Most of the Countries supports that an "Electrotechnical Standards Compliance (SC) and Conformity Assessment (CA) Guide for Africa" will assist in improving the country's Quality of Products and Services, Commerce/Trade/Industry Quality Infrastructure, Science/Technology/Innovation Harmonized Policies, Fit-for-Purpose AfCFTA (SC/CA) Ecosystem and Technical/Socio-Economic Productivity between SC and CA Providers and Stakeholders.
- The level of awareness of IEC Conformity Assessment Schemes appears to be on medium scale.
- The level of awareness of Standards Conformity Assessment activities on a medium scale.

Detail on the questionnaire is available on the AFSEC website.

Annex B
ISO, the International Organization for Standardization

ISO is an independent, non-governmental international organization with a membership of 165 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

The ISO 9000 family provides a model to follow when setting up and operating a management system. It is for organizations seeking the improvement of the quality of their products and services and consistently meets their customers' expectations.

ISO 9001 sets out the criteria for a quality management system and is the only standard It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.

- **ISO 9000 – Quality Management Systems – Fundamentals and Vocabulary**
  The ISO 9000 family of standards and has two main purposes. Firstly, it is used to define the many terms that are used throughout the quality management system standards. Secondly, it describes the fundamental quality management principles that are behind the ISO 9001 standard for implementing a quality management system.
  It is not, however, a document containing requirements against which a company can certify its quality management system; this is available through the ISO 9001 standard.

- **ISO 9001 – Quality Management Systems**
  The ISO 9000 family is the world's most best known quality management standards for companies and organizations of any size
  The ISO 9001: Provides the information necessary for a company to implement a quality management system, and a **QMS certification** against ISO 9001 is recognized worldwide.

- **ISO 9004 – Quality Management: Quality of an organization – Guidance to achieve sustained success**
  The ISO 9004: Provide guidance to any organization on ways to make their quality management system more successful. Unlike ISO 9001, ISO 9004 is not intended for certification, regulatory or contractual use. This means that you cannot certify your quality management system to ISO 9004. It also means that the use of ISO 9004 is not intended to be mandated as a legal or contract requirement. The standard is, however, a good reference to turn to for ideas in how to make your implementation of ISO 9001 more effective and successful.

Annex C
Criteria to establish accreditation bodies and test labs (CASCO toolbox)

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardisation. 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.

ISO/IEC 17040 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.

The following CASCO toolbox standards and guides are important in the establishment of accreditation bodies and test labs:

For the most current version, please visit:
https://www.iso.org/committee/54998/x/catalogue/p/1/u/1/w/0/d/0

ISO/IEC17000 – Conformity assessment – Vocabulary and general principles.

ISO/IEC17011 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

ISO/IEC17020 – General criteria for the operation of various types of bodies performing inspection.

ISO/IEC17021 – Conformity assessment – Requirements for bodies providing audit and certification of management systems.

ISO/IEC17024 – Conformity assessment – General requirements for bodies operating certification of persons.

ISO/IEC17025 – General requirements for the competence of testing and calibration laboratories.

ISO/IEC17030 – Conformity assessment – General requirements for third-party marks of conformity.

ISO/IEC17040 – Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation.

ISO/IEC17043 – Conformity assessment – General requirements for proficiency testing.

ISO/IEC17050 – Conformity assessment – Supplier's declaration of conformity.

ISO/IECGuide65 – General requirements for bodies operating product certification systems.

ISO/IECGuide67 – Conformity assessment – Fundamentals of product certification.

ISO/IECGuide68 – Arrangements for the recognition and acceptance of conformity assessment results.