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INDEPENDENT COMMUNICATIONS AUTHORITY OF SOUTH AFRICA

NO. 1381 **13 DECEMBER 2018**

INDEPENDENT COMMUNICATIONS AUTHORITY OF SOUTH AFRICA

THE DRAFT CONFORMITY ASSESSMENT FRAMEWORK FOR EQUIPMENT AUTHORIZATION

The Independent Communications Authority of South Africa ("the Authority") hereby publishes the Draft Conformity Assessment Framework for Equipment Authorization ("Draft Framework") in terms of section 8.4 of the position paper on Equipment Type Approval Exemption ("the Position") as published in Notice 248 of 2017 Government Gazette 40733.

A copy of the proposed Draft Framework is available on the Authority's website (www.icasa.org.za) and in the ICASA Library at 350 Witch-Hazel Avenue, Eco Point Office Park, Eco Park, Centurion, Highveld Park 0169, Block C during the Authority's office hours.

Interested parties are hereby invited to submit written representations with regards to the proposed Draft Framework. Written representations must be submitted to the Authority within thirty (30) working days from the date of the publication of this notice by post or hand delivery or email as follows:

Independent Communications Authority of South Africa

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Written representations received by the Authority pursuant to this notice, will be made available for inspection by interested persons at the Authority's library and such copies will be obtainable upon payment of the prescribed fee.

When a person submits information to the Authority, such person may request that specific information be treated as confidential information in terms of section 4D of the Independent Communications Authority of South Africa Act, 2000 (Act No. 13 of 2000) ("ICASA Act"). The request for confidentiality must be accompanied by a written statement explaining why the specific information should be treated as confidential in terms of section 4D(4)(a) to (e) thereof. The Authority may determine that such representations or any portion thereof is to be treated as confidential in terms of section 4D of the ICASA Act. Where the request for confidentiality is refused, the person who made the request will be granted an opportunity to withdraw such representations or portion(s) thereof.

Persons submitting written representations are further invited to indicate, as part of their submissions, whether they require an opportunity to make oral presentations.

Rubben Mohlaloga
Chairperson

Date: 11 / 12 /2018

DRAFT CONFORMITY ASSESSMENT FRAMEWORK FOR EQUIPMENT AUTHORISATION

Executive Summary

The objective of this document is to propose a more robust multilateral Conformity Assessment Framework with relevant criteria, that is responsive and adaptive to advancing information, communication and technology (ICT) developments, and achieving regulatory objectives in line with the Electronic Communications Act, 2005 (Act No. 36 of 2005), as amended (ECA).

Conformity assessment is a process used to obtain evidence and proof that equipment and systems conform to the appropriate standards and specifications, and that they interoperate with each other as specified. Regulators, service providers and operators along with the users of equipment and systems require such evidence and proof for compliance, quality management when making informed purchasing decisions.

There are various Conformity Assessment Schemes that can be used to determine whether specified requirements are fulfilled, they include but are not limited to: type or periodic testing, inspection, audit of management system, assessment, calibration, evaluation, and examination.

There are also various schemes to attest to conformity: Supplier's Declaration of Conformity (SDoC), Second Party Assessment, Third Party Certification or Inspection, Accreditation and Peer Assessment.

The current Type Approval Framework used by the Independent Communications Authority of South Africa ("the Authority") was last revised and published in 2013 in accordance with section 35 of the ECA. Generally, amongst other supporting documents, upon receipt of Type Approval applications for Radio Frequency and Telecommunication Terminal Equipment, are test reports from any accredited test laboratory/ies that will be evaluated. Type Approval is a special kind of certification, which means that the equipment is certified to meet specific

requirements for its type. Compliance with Type Approval requirements is denoted by a marking/labelling of the equipment and the packaging.

Manufacturers, distributors and suppliers consider this process in relation to placing ICT equipment in the market to be too long. This is largely since the same Type Approval framework is applied throughout all types of equipment and technologies.

The international trends in Europe and the United States of America (USA) for an example have shown that different conformity assessment regimes may be applied for various devices and conformity assessment is more dependent on the risk profile of the device category.

Considering the maturing production processes in the ICT sector, certification may not be a sustainable process. Testing laboratories play a very important role in the effective operation of conformity assessment schemes including certification and the SDoC.

The Authority's Type Approval Regulations, 2013[1] ("2013 Regulations") prescribe that only test reports produced by an ISO/IEC 17025 compliant test laboratories are acceptable. ISO/IEC 17025 compliant testing laboratories operate a management system, are technically competent and able to generate technically valid results. Test reports prepared by testing laboratories are necessary information to support both certification and SDoC.

[1] *Type Approval Regulations, 2013: Regulations for the Type Approval of Electronic Communications Equipment and Electronic Communications Facilities and the Certification of Type Approved Equipment; GG 36785*

Abbreviations and Definitions

"Accreditation" means third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks;

"Certification" means a process involving initial testing of equipment, including an initial assessment of the manufacturer's premises and manufacturing practices and continuous equipment surveillance;

"Conformity Assessment" means a process that is used to demonstrate that specified requirements relating to a product, process, system, person or body are fulfilled;

"European Telecommunications Standards Institute or ETSI" mean a non-profit organization that establishes telecommunications standards for Europe;

"European Union or EU" mean a political and economic union of 28 member states that are located primarily in Europe;

"Federal Communications Commission or FCC" means an independent agency of the United States government that regulates interstate communications by radio, television, wire, satellite, and cable;

"**ICASA**" means the Independent Communications Authority of South Africa established in terms of the Independent Communications Authority of South Africa Act, 2000 (Act No.13 of 2000);

"ICT" means information, communications and technology;

"International Electrotechnical Commission or IEC" means the international standards and conformity assessment body for all fields of electrotechnology;

"IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components or IECEE" means a multilateral certification system based on IEC International Standards;

"**International Laboratory Accreditation Co-operation or ILAC**" means the international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020);

"International Organization for Standardization or ISO" means an international organization for standardization that develops and publishes international standards;

"ISO/CASCO or CASCO" means Conformity Assessment Committee, which is the ISO committee that develops policy and publishes standards related to conformity assessment;

"Market Surveillance" means the process or activities carried out and measures taken by public authorities of ensuring that products that are already in the market still comply with minimum technical requirements of the prescribed standards;

"Notified Bodies or NB" means an organisation designated by a European Union country to assess the conformity of certain products before being placed on the market;

"**NRCS**" means the National Regulatory Compulsory Specifications (NRCS) established in terms of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008);

"Registration" means a process by which the regulatory authority, following an assessment of the documentation submitted by manufacturers and suppliers, lists the product on a register or gazette of approved/recognized products for the purposes of a product to be put onto the market with no need for the issuance of the certificate by the regulatory authority;

"Regulatory Authority" means a government agency responsible for telecommunications systems and products within its territory, and develops and

publishes technical regulations, including conformity assessment requirements, in the public interest;

"SABS" means the South African Bureau of Standards (SABS) as established in terms of the Standards Act, 2008 (Act No. 5 of 2008), as amended;

"**SANAS**" means the South African National Accreditation System (SANAS) established in terms of Section 3(1) of the Accreditation for Conformity Assessment Calibration and Good Laboratory Practice Act, 2006 (Act No. 19 of 2006);

"SI[2] Standard Unit" means a scientific method of expressing the magnitudes or quantities of important natural phenomena;

"Supplier" means manufacturer, importer or distributor of equipment or any person registered with the Authority for the purpose of Type Approval;

"Supplier Declarations of Conformity or SDoC" means a procedure recognized internationally where the supplier or manufacturer tests the product to the applicable technical regulations and labels before it is placed in the market. It is a written undertaking by the manufacturer declaring that equipment conforms to specified technical requirements;

"**Surveillance**" means a systematic iteration of conformity assessment activities as a basis for maintaining the ongoing validity of the statement of conformity;

"Telecommunication Certification Body or TCB" means an accredited product certification body with the authority to issue Grants of Certification for compliance with Federal Communications Commission (FCC) rules and regulations;

"Testing Laboratory or TL" means the testing laboratory responsible to make determination of the applicable test procedures and to properly test to those requirements;

[2] ***Systeme Internationale,*** the French version of the name.

"Type Approval" means certifying that a product meets certain requirement for its type, for example cell phones operating in a certain frequency band. Type approval is granted to a product that meets a minimum set of regulatory, technical and safety requirements by a competent body;

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1 Introduction

The use of conformity assessment in regulatory practice may warrant policy development and the discussion about the design of conformity assessment options to be structured around the functional approach which provides for:

- selection;
- determination;
- review and attestation; and
- surveillance.

The techniques and activities involved in conformity assessment include assessment, auditing, calibration, evaluation, examination, inspection and testing, which can result in an award of a Supplier's Declaration of Conformity certificate or document (SDoC), Certification or Accreditation.

ISO and IEC have published joint International Standards and Guides on conformity assessment[3]. These international standards and guides are the internationally accepted basis for conformity assessment and are used by many regulators around the world.

Statutory standards development bodies prescribe standards and requirements for ICT equipment and systems that will be employed to provide services in the country. Regulators prescribe Regulations, standards and specifications for equipment and systems that are deployed and used in their territories.

However, as South Africa is a signatory to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade ("TBT Agreement"), it is required, through the Secretariat, to give notice of any deviations from technical Regulations and conformity assessment procedures. This is to allow other WTO Members to be aware of new product requirements and to make comments prior to the finalisation of technical requirements and standards as well as where there is non-compliance with the TBT Agreement.

[3] *For further information on international standards and guides please see https://www.iso.org/committee/54998/x/catalogue/*

Conformity assessment accreditation allows accreditation bodies to make informed decisions when selecting an organisation to carry out testing, calibration, or inspection activities, as it demonstrates competence, impartiality and the capability of that organisation. Thus, accreditation helps to underpin the credibility, safety and performance of goods and services.

Accreditation bodies around the world, which have been evaluated by peers as competent, have signed an ILAC Mutual Recognition Arrangement that enhances the acceptance of products and services across national borders which has resulted in the removal of technical barriers to trade.

1.1 The Design of Conformity Assessment Scheme

A conformity assessment scheme (CAS) relates to the degree of risk associated with non-compliance considering aspects such as safety, health or environmental impact, durability, compatibility and suitability for intended use. When consequences are insignificant or not severe, society expects little or no demonstration of conformity of product since the problems generated can be easily addressed and resolved after they occur. In these cases, the supplier's claims may be sufficient, but they may be complemented by third-party product certification on a voluntary basis.

CAS should be designed in such a way that it ensures transparency and neutrality, and that costs are not inflated.

A fully developed regulatory system requires the following components to determine compliance and assessing penalties for non-compliance:

- a trusted and recognized accreditation system;
- testing laboratories;
- certification bodies;
- market surveillance; and
- audit and enforcement capabilities.

1.2 Voluntary and Regulatory Schemes

A CAS can be set up as voluntary (self-regulation/ commercial marketing) or regulatory (mandatory). A voluntary CAS improves market perception for a group of suppliers, to share assessment facilities by a group of purchasers and/or to respond to market needs by a third-party assessment organisation.

There is no legal requirement for suppliers or purchasers to use the voluntary CAS, although there can be strong market and peer pressure to do so. Regulators may even interact with specific sectors to rely on such schemes as a method of allowing the industry to regulate itself as an alternative to formal regulation.

The Regulatory CAS is a mandatory product certification scheme. Regulators can find it useful to introduce specific conformity assessment approaches to enable compliance with legal requirements. The regulator will consider the dangers to workers, consumers, the environment and the economy posed by deficient goods, services or processes. The measures which are adopted will need to be proportional to the risks involved, with statutory inspection or certification schemes being introduced where the risks are highest.

In mandatory conformity assessment, it may be of assistance to developing countries to have a database providing hyperlinks to mandatory conformity assessment data for telecommunication equipment that products must meet to be legally imported and deployed in the marketplace.

For mandatory requirements, the testing laboratory will submit the results of its accreditation along with administrative and other information to its regulator for designation. If the scope of accreditation covers requirements of a foreign country and the regulator is engaged in a mutual recognition agreement/arrangement (MRA) with that foreign country, the regulator after its designation of the testing laboratory will send the same information to the regulator of its MRA partner for recognition.

There are limitations to mandatory conformity assessment as there are no guarantees that products will work properly or interoperate with other systems/networks and it does not help identifying counterfeit equipment.

A closer look at the USA and the European markets has shown that different conformity assessment regimes may be applied for various devices depending on the device category risk profile. Countries benchmarked in this document were selected based on ITU regional segmentation e.g. ITU region 1, ITU region 2 and ITU region 3, with South African located in ITU region 1. Second criteria focused on developed countries with effective equipment authorisation frameworks.

United States of America

The FCC oversees the authorization of equipment using radio frequency spectrum in the USA. The said equipment may not be imported or marketed unless it meets the technical standards specified by the FCC. Depending on its capabilities, equipment may be subjected to the following:

- **verification** *(in which case, the manufacturers test their own device)*;
- **declaration of conformity** *(in which case, requires testing by an accredited test laboratory)*; or
- **certification** (*in which case, is issued by the FCC or a designated Telecommunications Certification Body (TCB) based on test results submitted by the supplier*).

European Union (EU)

The Radio Equipment Directive, which is used in conformity assessment, defines a harmonised regulatory framework for the approval of radio and telecommunications equipment compliant with a single set of requirements that can be placed in the EU market. The following procedures, in table 1, are applicable depending on the type of apparatus and whether harmonised standards are used.

Table 1: Radio and telecommunications equipment compliant procedures

Procedure		**Applicable to apparatus:**		**Role of the notified body (if applicable)**
		Without radio part	**with radio part**	
II	Internal production control	Terminal equipment	Receivers	
III	Internal production control plus specific apparatus tests		Radio equipment including a transmitter complying with harmonised standards	Identification of the essential radio test suites if they are not defined in the harmonised standard
IV	Technical construction file	Terminal Equipment	All radio equipment including a transmitter not complying or only partially complying with harmonised standards	Opinion on the conformity of the equipment based on a review of the technical construction file established by the manufacturer
V	Full quality assurance	All equipment covered by the Radio Equipment Directive		Certification of the manufacturer's quality system

2 Background

2.1 The South African Legislative Framework

The South African conformity assessment regime consists of four areas of responsibilities namely; standard formulations, regulations (authorization), accreditation and testing.

Standard formulations

The mandate of the SABS is to be the national institution for the development, promotion and maintenance of standardisation and quality related to commodities and the rendering of related conformity assessment services[4].

The SABS is responsible for testing, product and system certification and standards development, and also has collaboration with regional and international standardization bodies such as European Telecommunications Standards Institute (ETSI), IEC and ISO.

Regulatory

The NRCS is responsible for the administration and maintenance of compulsory specifications and the implementation of a regulatory and compliance systems for compulsory specifications.

The Authority's mandate is to regulate electronic communications, postal and broadcasting sectors in the public interest. Section 35 of the ECA, prohibits any person to possess, use, supply, sell, offer for sale or lease or hire any type of electronic communications equipment or electronic communications facility, including radio apparatus, used or to be used in connection with the provision of electronic communications, unless such equipment, electronic facility or radio apparatus has been approved by the Authority.

Section 35 (2) of the ECA permits the Authority to prescribe—

[4] *https://www.thedti.gov.za/agencies/sabs.jsp*

(a) the types of equipment, electronic communications facilities and radio apparatus, the use of which does not require approval where such equipment, electronic communications facilities and radio apparatus has been approved for use by the European Telecommunications Standards Associations or other competent standards body where the equipment complies with Type Approval standards prescribed by the Authority; and

(b) circumstances under which the use of equipment, electronic communications facilities, radio apparatus and subscriber equipment does not require approval, including uses for research and development, demonstrations of prototypes and testing.

The objective of this mandate is to ensure that electronic communications equipment conform to relevant technical standards prior to them being used in connection with the provision of electronic communications. Users of such equipment will then acquire quality equipment that ensures that personal safety of end-users is protected; the integrity of electronic communications networks is protected; the interworking of electronic communications networks and ensuring access to emergency call services.

For the equipment and systems to be approved by the Authority, evidence and proof that equipment and systems conform to the appropriate standards and specifications, and that they interoperate with each other as specified, is required. The test reports must contain technically valid results produced by ISO/IEC 17025 compliant test laboratories. The test laboratories are accredited by accreditation bodies. The criteria to be considered in the selection of an accreditation body includes that the accreditation body be a signatory to the ILAC MRA or a member of regional cooperation bodies recognized by ILAC.

Accreditation and testing

SANAS is a local accreditation body responsible for competency assessment and accreditation of testing and calibration laboratories for radio equipment, electronic and electrical equipment in accordance with ISO/IEC 17025 requirements.

SANAS is an ILAC MRA signatory. The SANAS ILAC MRA's scope also covers medical testing: ISO 15189 and inspection: ISO/IEC 17020.

The diagram in figure 1 below illustrate countries that are affiliated with ILAC.

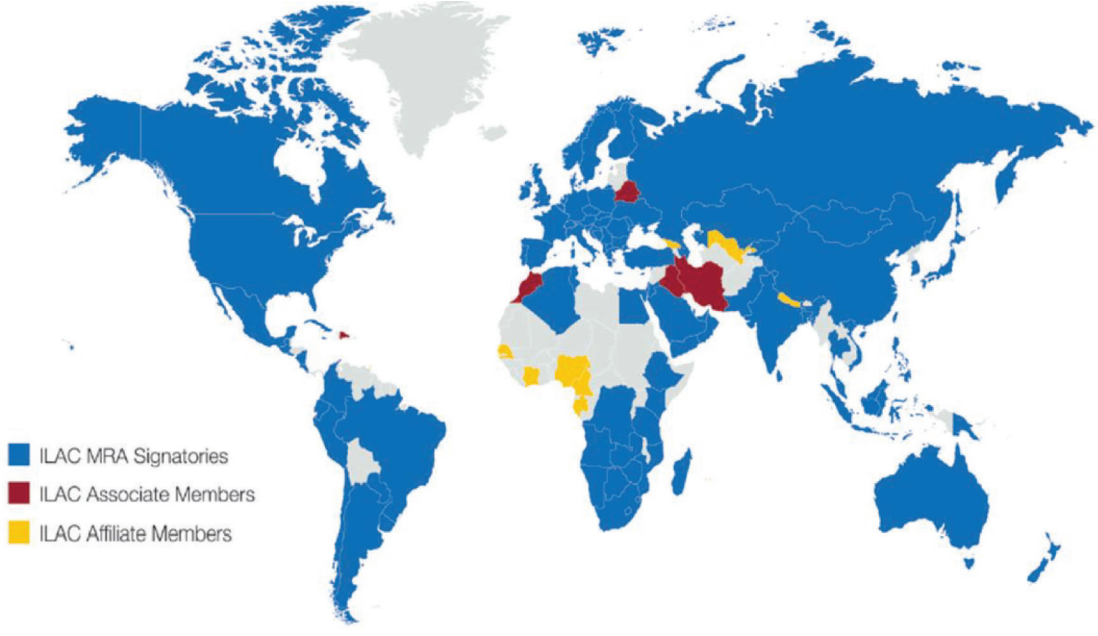

Figure 1: ILAC MRA signatory World Map

2.2 The Authority's Type Approval Framework

The Authority's Type Approval Framework ("Approval Framework") was revised and published in 2013 in accordance with section 35 of the ECA. In general, the Approval Framework calls for the submission of Type Approval applications for Radio Frequency and Telecommunication Terminal Equipment (RTTE) to the Authority for approval. The approval process entails evaluation of test reports from any accredited test laboratory as depicted in figure 2 below.

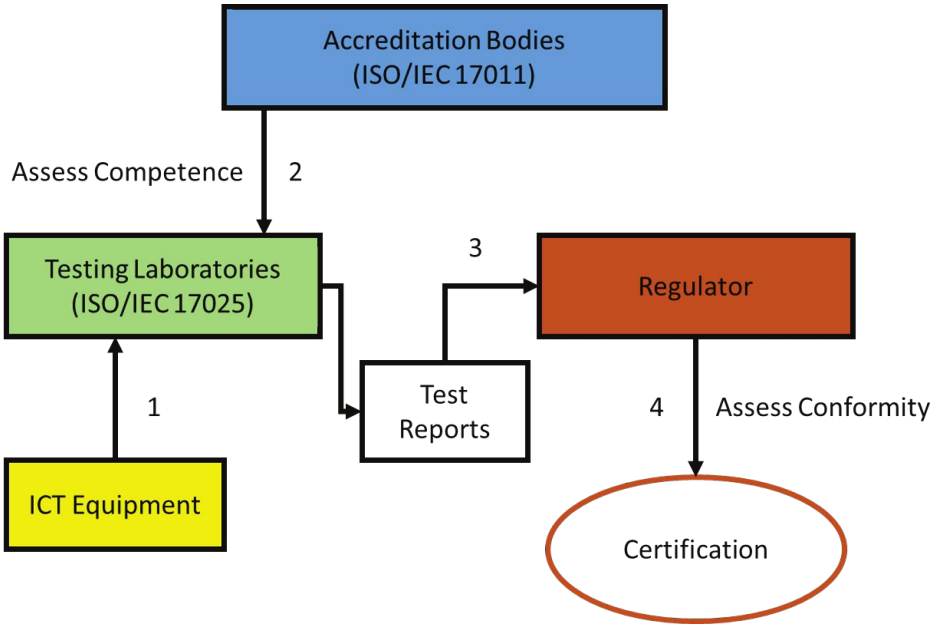

Figure 2: Conformity assessment scheme: ICASA Approval Framework

The first step towards certification is to conduct testing of the equipment by an ISO/IEC 17025 compliant testing laboratory. The test report produced by the testing laboratory along with the appropriate administrative information is then sent to the Authority for assessment and certification.

If the conformity assessment result is positive, the Authority issues a certificate for the equipment or a rejection letter in cases of non-compliance.

The Authority is also mandated by section 36 of the ECA to prescribe standards[5] for the performance and operation of any equipment or electronic communication facility, including radio apparatus. Such standards are aimed at—:

(a) protecting the integrity of the electronic communications network;

(b) ensuring the proper functioning of connected equipment or electronic communications facilities;

(c) ensuring interoperability, interconnectability and harmonisation; and

[5] *the Regulations on the Official List of Regulated Standards for Technical Equipment and Electronic Communications Equipment Regulations, 2015: published in Notice No. 896 under Government Gazette No. 39182*

(d) avoiding harmful interference with the electronic communications network.

The Official List of Regulated Standards for Technical Equipment and Electronic Communications Equipment Regulations ("the Official List") incorporate technical standard by reference to—

(i) the number, title and year of issue of the technical standard; or
(ii) other particulars by which the particular standard can be identified.

The Authority is subject to the Standard Act No. 8 of 2008, when developing these mandatory technical standards. This means the Authority is required to engage the SABS throughout its standard development process.

To satisfy this requirement, the Authority has entered a Memorandum of Understanding (MoU) with the SABS. The MoU, signed in 2004, established an ICASA/SABS Telecommunications Standards Sub-Committee (TC080). Figure 3 below illustrates the process of developing and adopting regulated standards.

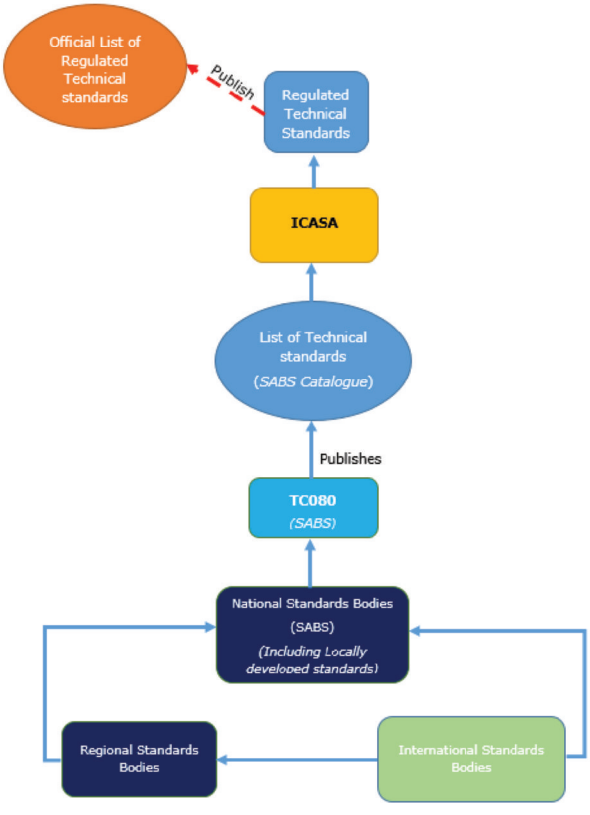

Figure 3: Official List of Regulated Standards development process

The Authority recently entered into a second MoU, signed on 30 March 2016, with the SABS which enable the two entities to collaborate in ensuring compliance of non-telecommunications equipment with EMC/EMI standards. The MoU facilitates a more robust process of issuing EMC/EMI Certificates of Compliance for the non-telecommunications products which include manufacturing plant inspections, witness testing and independent product sampling and testing.

2.3 Benefits of the Approval Framework

One of the benefits to the approval framework is certification, which gives confidence that specific requirements are met by products and systems. The concerns can involve such product attributes such as safety, health or environmental impact, durability, compatibility, suitability for intended purposes or for stated conditions, and similar considerations.

The Type Approval Framework enables consumers to make better purchase decisions about products, allows suppliers' products market acceptance when their products demonstrate conformity, public networks are not compromised with the introduction of sub-standards products or counterfeit products as they maintain interoperability and ensures technical barriers to trade are at a minimum, or eliminated in line with the TBT Agreement.

For equipment designed to meet mandatory standards, the Type Approval certificate indicates to the consumer/end-user that the equipment fulfils the appropriate standards and suppliers can market their equipment better.

2.4 Challenges with the Approval Framework

The current Type Approval process is not robust as it does not categorise equipment. Neither does it have in place risk profiles for different products to develop and implement different mechanisms of conformity assessment.

The validation of the evidence and proof that equipment or systems conform to the appropriate standards and specifications depends on the test facility confirming the authenticity of test reports. The country's mechanism to oblige certification bodies to authenticate test reports along with the results is reactive and ineffective.

There is a lack of post-market surveillance in place to continuously ensure that the equipment and systems placed in the market continue compliance with applicable technical standards.

Manufacturers, distributors and suppliers consider the turnaround time to place ICT equipment in the market to be too long. This is largely because the same Approval Framework used is applied throughout all types of equipment and technologies.

3 Concepts and Discussions on Conformity Assessment Techniques and Schemes in terms of ISO/CASCO

Conformity assessment is the term given to techniques and activities applicable to equipment authorisation that include: assessment; auditing; calibration; evaluation; examination; inspection; and testing which can result in a supplier's declaration of conformity, certification or accreditation.

A basic concept underpinning all conformity assessment is the functional approach[6]. The functional approach can be used as a good starting point when developing conformity assessment frameworks to support regulations.

3.1 The Functional Approach

The functional approach consists of the following sequential functions:

1) Selection – this includes selecting equipment to demonstrate adherence to specified legal requirements;
2) Determination activities are used to gather information regarding the fulfilment of specified requirements of conformity assessment by the object or its sample;
3) Review and attestation are the final stages of the process.
    - Review is the activity of checking before deciding on whether equipment has adequately demonstrated that it conforms and fulfils the specified requirements. Attestation: After the review the final decision will be made on whether compliance with specified requirements was met or not and if so, a statement of conformity, for example a certificate and/or mark of conformity will be issued.
4) Surveillance can be used where there is a need to provide continuing assurance of conformity, although conformity assessment can end when attestation is performed.

[6] *For more information on the functional approach see:* ***Conformity assessment - Functional approach*** *and ISO/IEC 17000:2004, Conformity assessment - Vocabulary and general principles.*

Figure 4 provides the elements of the functional approach, with each element involving certain activities as illustrated:

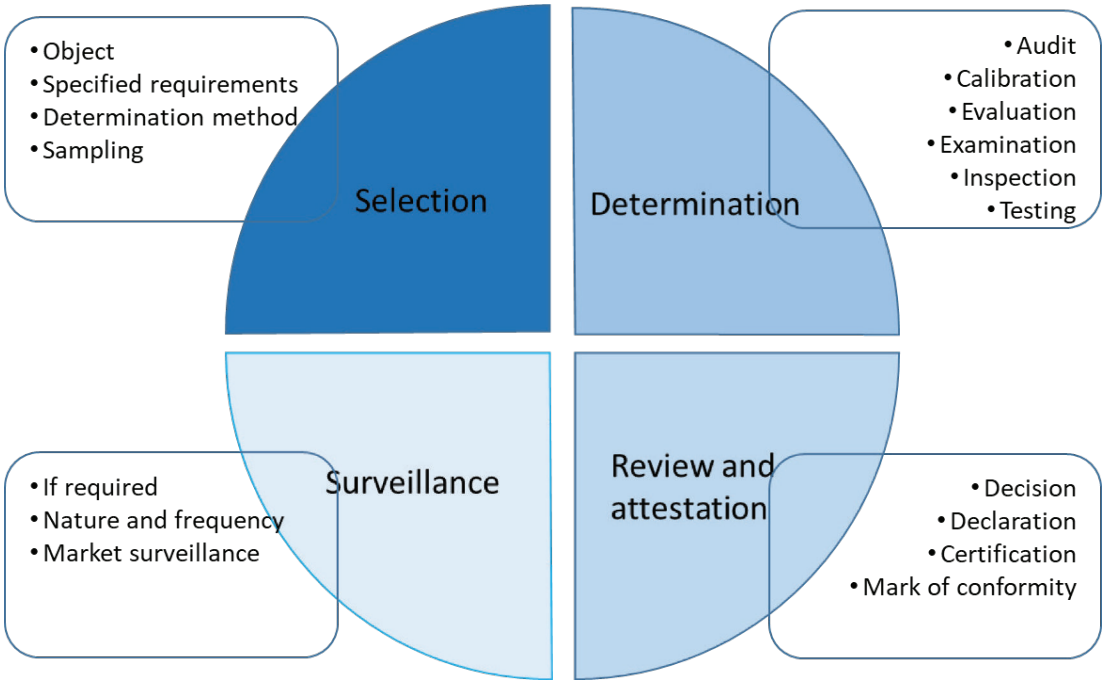

Figure 4: Functional approach to conformity assessment

The above described functional approach works in conjunction with the following key considerations:

- Good Regulatory Practice;
- Identifying controlled products and requirements;
- Conformity Assessment Scheme Design and Ownership;
- Investment and cost associated with conformity assessment;
- Conformity Assessment and Competition;
- Risk Management;
- Access to competent resources; and
- Surveillance.

3.2 Key Considerations in conjunction with Functional Approach

Good Regulatory Practice

The ISO/CASCO toolbox sets out good regulatory practices regarding conformity assessment and it can be supplemented by the WTO agreements listed below:

- TBT Agreement;
- Sanitary and Phytosanitary Measures (SPS Agreement);
- Trade in Services (Services Agreement);
- Pre-shipment Inspection (Pre-shipment Inspection Agreement); and
- Trade Facilitations (Trade Facilitation Agreement).

Investment and cost associated with conformity assessment

It is good practise to be aware of the amount of investment and costs associated with an approach of choice when compared to an alternative approach.

In the undertaking of conformity assessment resources must be committed, whether considered to be 'costs of compliance' or 'investment', in achieving company or public policy outcomes.

Regulators may consider which option meets their needs by considering the following:

- the nature of the risks involved;
- the extent or complexity of the conformity assessment required;
- the ability to practically access the selected conformity assessment option at the domestic level;
- the anticipated costs of each conformity assessment option (both in terms of administrative burden, price and time involved);
- the degree of independence the regulator expects in terms of providing conformity assessment results and statements of conformity; and
- the level of market and political acceptance of the proposed option.

Figure 5 illustrates the impact on cost inflation associated with conformity assessment in regulation.

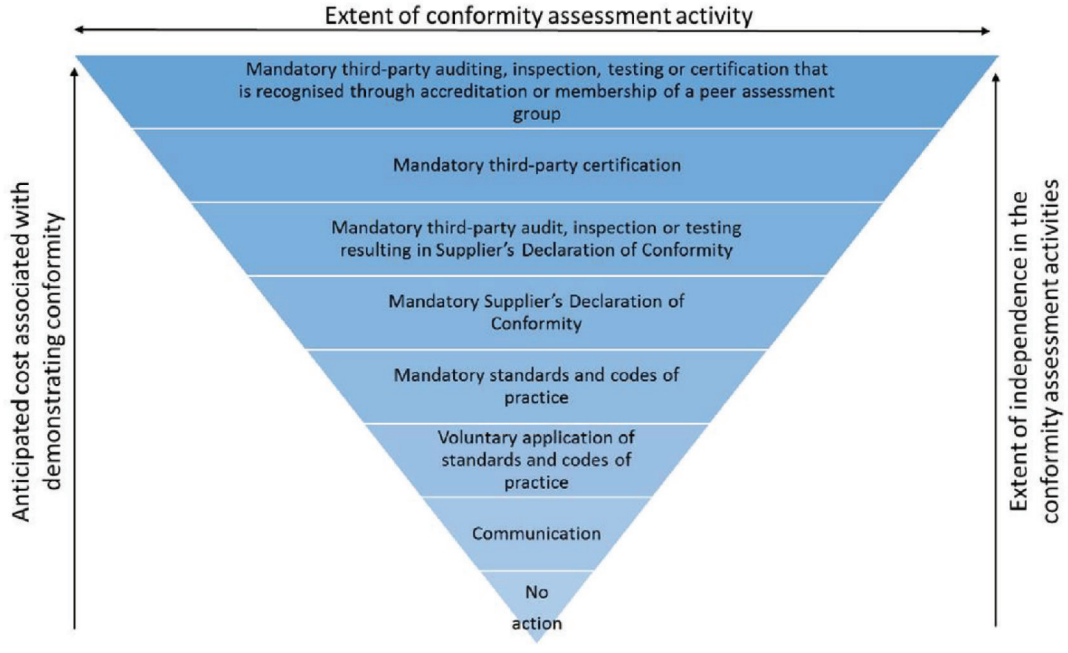

Figure 5: Cost implication for use of conformity assessment in regulation

Conformity assessment and competition

An important aspect of conformity assessment is to consider the impact of competition between Conformity Assessment Bodies (CAB's) and to ensure that the creation of monopolies is avoided. The use of accreditation and peer assessment in deterring a negative impact on competition can be utilised.

Risk Management

Where there is low risk associated with a product the "do nothing" approach is taken or a requirement to supply a first party SDoC. However, if there is high risk associated with a product of a negative effect the SDoC must be complemented with an independent assessment (keep watch).

International Federation of Standards Users has developed a representation conformity scheme matrix, figure 6, illustrates the issue:

Figure 6: Conformity scheme matrix

Surveillance activities

Surveillance can be considered in at least two ways:

- market surveillance activities that the regulator may undertake; and
- surveillance that is associated with the conformity assessment activity undertaken by CABs, TCBs or Notified bodies.

In some case these two forms of surveillance can be combined into the one activity. It is the regulation and the associated conformity assessment scheme that defines what is required in terms of surveillance.

The main conformity assessment techniques[7] and their most common applications can be described as follows:

Assessment of an organisation's technical competence;

Auditing of a management system within an organisation;

[7] *Please see ISO/CASCO standards in regulations.*

Evaluation	of a product, process or service's fulfilment of specified requirements that are set out in a defined conformity assessment scheme;
Examination	of a person's competence;
Inspection	of an installation or of a product or service in use;
Testing	of a product characteristic.

In some instances, one conformity assessment technique may encompass another, for example, an inspection can include a test technique; or a product evaluation may consider a test report or an inspection report. How these conformity assessment techniques are used and interrelated is often prescribed in a specific mandatory or voluntary conformity assessment scheme.

Conformity Assessment Bodies

There are various types of CABs which offer conformity assessment activities. In most cases, CABs can act as a first, second or third party that is making the claim of conformity in accordance with various international standards as outlined in table 2 below.

Table 2: Conformity Assessment Bodies

Type of conformity assessment body (CAB)	International Standard	First party	Second party	Third party
Testing laboratories	ISO/IEC 17025	✓	✓	✓
Inspection bodies	ISO/IEC 17020	✓	✓	✓
Certification body for persons	ISO/IEC 17024			✓
Certification body for products, process and services	ISO/IEC 17065			✓
Certification body for management systems	ISO/IEC 17021			✓

Testing Laboratories

Testing laboratories play a very important role in the operation of CAS, including certification and the SDoC. Testing, measurement and calibration are the most prevalent conformity assessment techniques used.

The relevant International Standard that testing laboratories must comply with ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. Testing laboratories covered by this standard can be owned and operated by government, or industry bodies, or be separate organisations.

Accreditation bodies and Peer assessment

Accreditation is carried out by accreditation bodies, in accordance with the requirements set out in ISO/IEC 17011:2004[8].

In conformity assessment, the process of peer assessment is specified in ISO/IEC 17040:2005[9]. As noted in the title of this international standard, peer assessment can take place amongst groups of CAB's, or amongst groups of accreditation bodies. Accreditation bodies assess and accredit test facilities.

Claims of Conformity

Claims of conformity is the attestation that the object (product, process, service, management system, person or organisational body) fulfils the essential requirements.

ISO/CASCO recognizes the following as claims of conformity:

- "first party – the person or organisation that provides the object and is responsible for that object's fulfilment of specified requirements (e.g. a manufacturer);

[8] ISO/IEC 17011:2004 *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.*
[9] ISO/IEC 17040:2005, *Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies*.

- second party – a person or organisation that has a user interest in the object (e.g. a retail chain that is purchasing the product for subsequent sale);
- third party – a person or body that is independent of the first-party and second-party (e.g. an independent and impartial testing laboratory or certification body)."

First-Party Claims of Conformity

The first-party claims of conformity are self-declaration of conformity, or manufacturers declarations of conformity. The SDoC can reduce regulatory costs, although such scheme may not be appropriate, particularly in developing countries where technical infrastructure is lacking, or health, safety or environmental protections may be compromised. Government institutions, or authorities need to apply caution when adopting SDoCs, as such claims may or may not be based on objective evidence.

The recognised ISO and IEC International Standards for making first-party claims of conformity are:

- ISO/IEC 17050-1:2004, Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements; and
- ISO/IEC 17050-2:2004, Conformity assessment - Supplier's declaration of *conformity - Part 2: Supporting documentation*.

Second-Party Claims of Conformity

The ISO and IEC do not have any specific standard or guide about second party conformity assessment. Second-party claims of conformity relate to supplier and retailers claims of conformity informed by the requirements of a product intended for the market. The second party then makes a claim about the products that they have purchased.

Third-Party Claims of Conformity

Third-party claims of conformity need to be independent of the person or organisation with interest in the object of conformity assessment. Independent

and impartial CABs like, testing laboratories, inspection bodies or certification bodies, make third-party claims of conformity, otherwise known as "Certification".

Below are ISO/IEC standards and guides related to third-party claims of conformity:

- ISO/IEC 17067:2013, Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes;
- ISO/IEC Guide 28:2004, Conformity assessment - Guidance on a third-party certification system for products;
- ISO/IEC Guide 53:2005, Conformity assessment - Guidance on the use of an organisation's quality management system in product certification;
- ISO/IEC 17021:2011, Conformity assessment - Requirements for bodies providing audit and certification of management systems;
- ISO/IEC 17024:2012, Conformity assessment - General requirements for bodies operating certification of persons; and
- ISO/IEC 17065:2012, Conformity assessment - Requirements for bodies certifying products, processes and services.

Mark of Conformity

A mark of conformity relates to statements of conformity and may be associated with placing a mark of conformity on a product where conformance has been met.

The use of a mark of conformity is controlled through a registration or licence issued by the owner of the mark or by an organisation operating on behalf of the owner such as a certification body.

Market surveillance is vital in policing the use of marks of conformity to ensure continuous adherence to marking requirements.

The perceived risk and rigor of conformity assessment determine the requirements for marks of conformity as shown in figure 7.

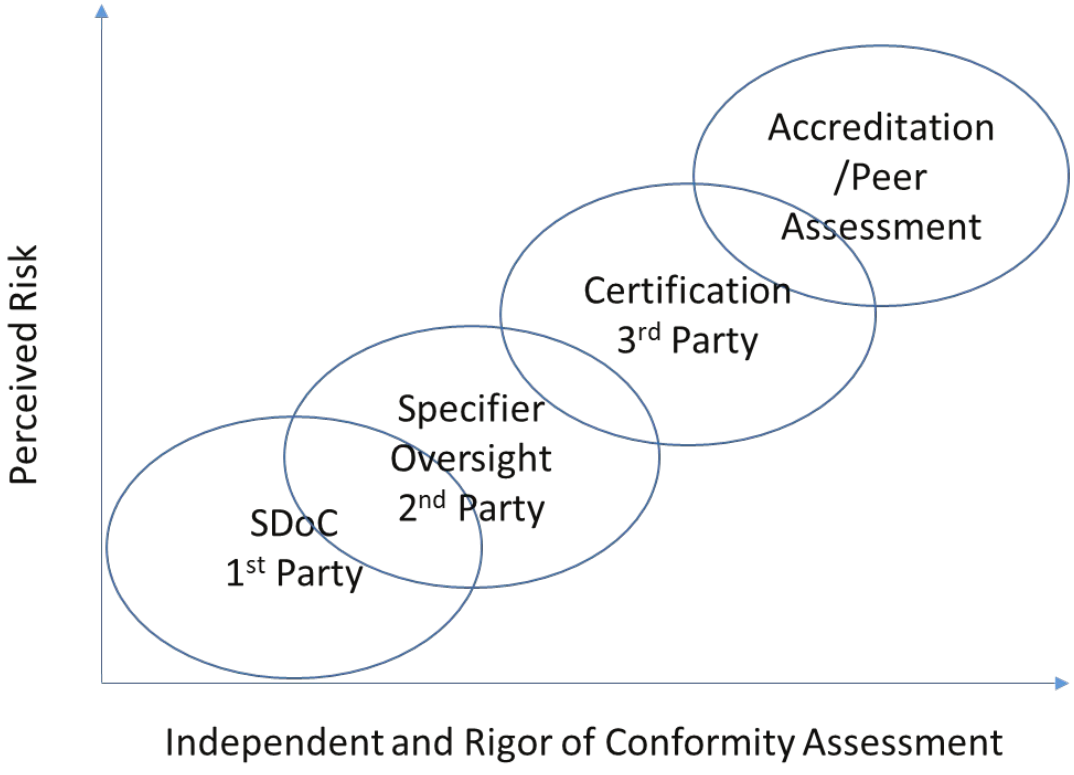

Figure 7: Conformity Assessment with perceived risk

Certification Bodies

Certification bodies are always third-party impartial CABs that can certify products, processes or services, management systems or persons. They can be owned and operated by government, industry bodies, or be separate organisations and have all a set of relevant international standards in place.

Product, process or service certification bodies

The relevant International Standards for product, process or service certification bodies is ISO/IEC 17065:2012, *Conformity assessment - Requirements for bodies certifying products, processes and services*.

It sets out the following requirements:

- general requirements, including legal and contractual matters, management of impartiality, liability and financing, non-discriminatory conditions, confidentiality and publicly available information;
- structural requirements, including organisational structure and top management and a mechanism for safeguarding impartiality;
- resource requirements, including certification body personnel, resources for evaluation activities and outsourcing;
- process requirements, including application, application review, evaluation, review, certification decision, certification documentation, directory of certified products, surveillance, changes affecting certification, termination, reduction, suspension or withdrawal of certification, records, and complaints and appeals; and
- management system requirements.

One of the critical aspects regarding product, process or service certification is that it must take place in the context of a certification scheme. The certification scheme sets out the following parameters:

- product, process or service to be certified;
- the specified requirements (e.g. standards) that the product, process or service must fulfil;
- sampling criteria for the certification if required;
- types and combinations of conformity assessment techniques (e.g. audit, inspection or test) that will be used to evaluate the product, process or service;
- the process to be followed for the evaluation, review and decision;
- the mark of conformity and its control; and
- activities that must be undertaken during surveillance, if any.

Schemes should be developed in accordance with ISO/IEC 17067:2013, *Conformity assessment - Fundamentals of product certification and guidelines for product certification* schemes and ISO/IEC 17026, *Conformity assessment* - Example of a product certification scheme, contain guidance on how to establish and manage certification schemes for products, processes and services.

Inspection Bodies

Inspection is a form of conformity assessment which has a long history. Some inspection activities are closely aligned with testing activities; others may be closely associated with certification activities (and particularly product certification); while other inspection is a stand-alone activity without any relation to testing or certification. One of the key aspects of inspection is that the determination of conformity with specific requirements is made based on professional judgement of the inspection bodies' personnel. This underlines the fact that the competence of inspection bodies is highly dependent on the knowledge, experience and interpretive skills of the inspection bodies' personnel.

Inspection as a conformity assessment technique can include:

- visual examination of physical items;
- measurement or testing of physical items;
- examination of specification documents such as design drawings;
- comparison of the findings with the requirements of specification documents or with generally accepted good practice in the field; and
- drawing up a report on the results of the inspection.

The relevant International Standards for inspection bodies is ISO/IEC 17020:2012, *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*. Inspection bodies covered by this standard can be owned and operated by government or industry bodies or be separate organisations.

ISO/IEC 17020 identified three types of inspection body:

- Type A Inspection Bodies - these bodies provide third-party services and are expected to be independent of the other parties involved;
- Type B Inspection Bodies - provide first-party services to their parent body only; and
- Type C Inspection Bodies - first-party inspection bodies which may also provide inspection services to other organisations.

The requirements contained in the standard apply to all types of inspection bodies, except for special requirements. The general requirements include:

- general requirements, including impartiality, independence and confidentiality;
- structural requirements, including administrative requirements and organisational management;
- resource requirements, including personnel, facilities and equipment, subcontracting;
- process requirements, including inspection methods and procedures, handling inspection items and samples, inspection records, inspection reports and inspection certificates, complaints and appeals; and
- management system requirements.

4 Internationally Accepted Conformity Assessment Schemes

For ICT equipment, including telecommunication equipment, the internationally accepted conformity assessment schemes are certification SDoC as shown in Figure 8 below:

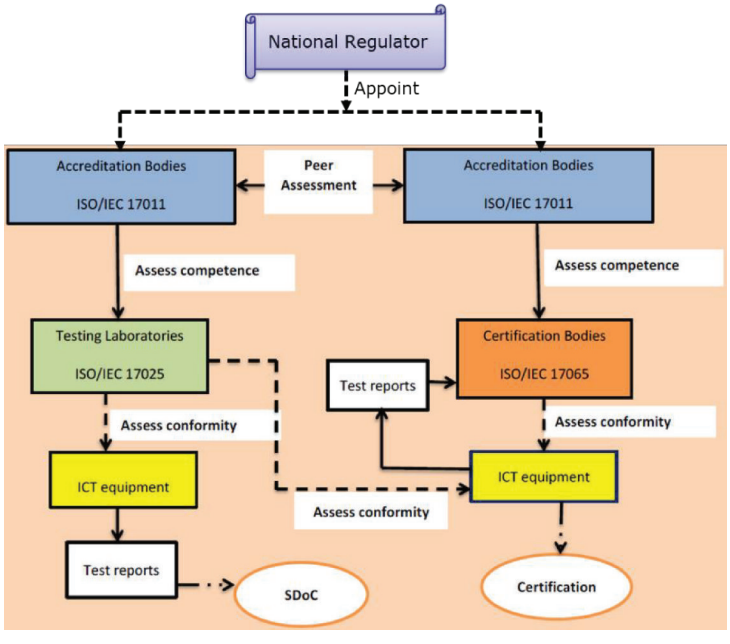

Figure 8: Product Certification and the Supplier Declaration of Conformity

4.1 Product Certification

Certification is a third-party attestation related to products, processes, systems or persons. Certification of equipment is the confirmation that the equipment meets the requisite conditions – normally indicated using documentary evidence such as test reports attesting to this fact.

Certification is the preferred and often recommended CAS for ICT equipment using new technologies and equipment which has safety and health concerns. The rigorous process of certification addresses these concerns. With the maturing of the production process and the technologies, it may not be necessary to maintain the certification process. It is often recommended to change the CAS from certification to SDoC. This would reduce production cost and the time to bring the equipment to market.

Type approval

Type approval is a specific kind of certification. Type approval simply means the equipment is certified to meet certain requirements for its type. Compliance to Type Approval requirements is often denoted by a marking/labelling on the equipment or package.

To ensure a smooth and transparent operation of a type approval system, several procedures and processes must be put in place by the entities which operate with the system. The regulator must specify the regulations and specifications for the ICT equipment which the Type Approval system is required to approve.

Regulatory aspects

It is the responsibility of the regulator to prescribe the regulations and specifications which the ICT equipment should meet within its territory. Similarly, the purchaser or service provider should specify the standards and specifications for the ICT equipment which it intends to purchase.

To demonstrate that the equipment meets its specifications and standard, the regulator also specifies the conformity assessment procedures. The regulator will

also specify procedures and processes to set up a type approval system and procedures and processes to be used in the operation of a type approval system.

The regulator may also prescribe market surveillance procedures to be conducted by a Type Approval system for the equipment it approves.

Organisation structures

The type approval system has two main components, being assessment by a certification body and a testing laboratory. The management and operations of the two entities must be separate to avoid a conflict of interest. The certification body is used to certify equipment when certification is the conformity assessment procedure required by the regulator or purchaser. A certification body shall not provide any other services and products which might compromise the objectivity, confidentiality, impartiality of its certification decisions or processes.

The testing laboratory is used to test the conformity of the equipment in both certification and SDoC.

Accreditation procedures

Accreditation bodies have their own accreditation procedures in which CAB's must follow, and they may include:

- administrative requirements such as information on the applicant and fees;
- scope of accreditation; and
- assessment rating guides which follow the requirements of the appropriate ISO standards, namely ISO/IEC 17025 for testing laboratories and ISO/IEC 17065 for certification bodies. These rating guides are used by assessors to conduct their assessments of the CABs.

Designation procedures

A regulator issues designation procedures which a CAB must complete to be designated by the regulator. Once designated, the CAB will be able to conduct conformity assessment of ICT equipment to be sold and used within the territory of the regulator. The procedures may include:

- criteria for designation;
- scope of accreditation;
- name of accreditation body and expiry date of accreditation; and
- administrative requirements such as information on the applicant and fees.

Recognition procedures

When a regulator has entered into an MoU with another regulator, it will also issue recognition procedures which a foreign CAB must complete to be recognized by that regulator. Once recognized the CAB will be able to conduct conformity assessment of ICT equipment to be sold and used within the territory of the regulator. These procedures may include:

- criteria for recognition;
- scope of accreditation;
- name of accreditation body and expiry date of accreditation; and
- administrative requirements such as information on the applicant and fees;

Requirements for certification bodies

In addition to the requirement that a certification body must be accredited to ISO/IEC 17065, a regulator may issue additional requirements which may include:

- internal audit to be conducted by the certification body including types and number of samples;
- submission of assessment reports;
- subdivision of scope of accreditation into several different scopes in the event the scope is too large or extensive;
- requirements for contracted testing laboratories if there are permitted;
- retention periods for certification results;
- marking and labelling requirements for equipment which the certification body has certified; and
- notification to regulator on the certificates issued by the certification body.

Supplier Declaration of Conformity

The SDoC is the conformity assessment scheme used for low risk and mature products. The manufacturer/supplier that conscientiously undertake SDoC result in better conformity outcomes than independent third-party assessment. This is true if the manufacturer/supplier has invested in its internal quality control activities, such as:

- maintaining a quality management system;
- ongoing production testing and inspection using competent in-house resources that may be accredited and/or participate in proficiency testing;
- undertaking internal audits;
- undertaking corrective and preventive actions; and
- seeking customer feedback and responding to complaints.

Upon meeting a set of conditions, a supplier can self-declare that the equipment conforms to the appropriate requirements (ISO/IEC 17050: *Conformity Assessment – Supplier's Declaration of Conformity*, and the WTO committee on conformity assessment[10]). There are four different schemes of SDoC as indicated in the table 3 below.

[10] *WTO committee on conformity assessment:* *www.wto.org/english/tratop_e/tbt_e/tbt_wrkshop_note_21march05_e.doc*

Table 3: Supplier's Declaration of Conformity

SDoC different schemes	ISO/IEC 17025 compliant (Test Facility)	Test reports must be kept for a **prescribed period**	Supplier must register the declaration with the Regulator
SDoC I *(e.g. Industry Canada (Canada) conformity assessment requirement for CS-03, terminal attachment equipment)*	✓	✓	✓
SDoC II *(e.g. FCC (USA) conformity assessment for Part 15, EMC)*	✓	✓	✗
SDoC III	✗	✓	✓
SDoC IV *(e.g. Industry Canada (Canada) conformity assessment for ICES-003 EMC)*	✗	✓	unspecified

In implementing an SDoC assessment framework, the Authority could impose a variety of requirements as it deems necessary. A sample of requirements is outlined below:

- ✓ testing requirements including the use of accredited/designated/recognized testing laboratories;
- ✓ technical briefs which include test results and test methods used;
- ✓ prescribed marking or labelling requirements for equipment declared under the SDoC procedures;
- ✓ prescribed audit processes including a stipulated retention period for test results; and
- ✓ registration requirements for equipment declared under the SDoC procedures.

5 Recognition of Conformity Assessment Bodies and their Results

CAB's play an important role in the structure and operation of conformity assessment regimes, namely, testing laboratories and certification bodies. In addition, accreditation bodies play an important role in the qualification of testing laboratories and certification bodies.

Governments can recognise CABs in the following ways:

- administrative recognition, where no consideration of technical competence is required; or
- technical recognition, where consideration of technical competence is required.

Consideration of technical competence should be based on the relevant international standards, and the persons making the assessment of the CAB should be competent in the relevant international standard and technical area. Recognition may take the form of a license to operate, admission to an approved list of CABs or a pre-qualification list of suppliers.

Where there is an urgent need for a conformity assessment approach to be set up, regulatory authorities could decide to directly assess and appoint CAB's. However, the basis of the assessment might not be clear, and it could be difficult for the CAB's and their certificates to gain recognition in other countries.

In the hierarchy of conformity assessment entities and functions, CAB's assess conformity of ICT equipment to meet specific requirements. It is recommended that testing laboratories must be ISO/IEC 17025 compliant and certification bodies must be ISO/IEC 17065 compliant. Accreditation bodies assess the competence of CAB's and accredit these bodies if they are compliant with ISO/IEC 17025 for testing laboratories and with ISO/IEC 17065 for certification bodies.

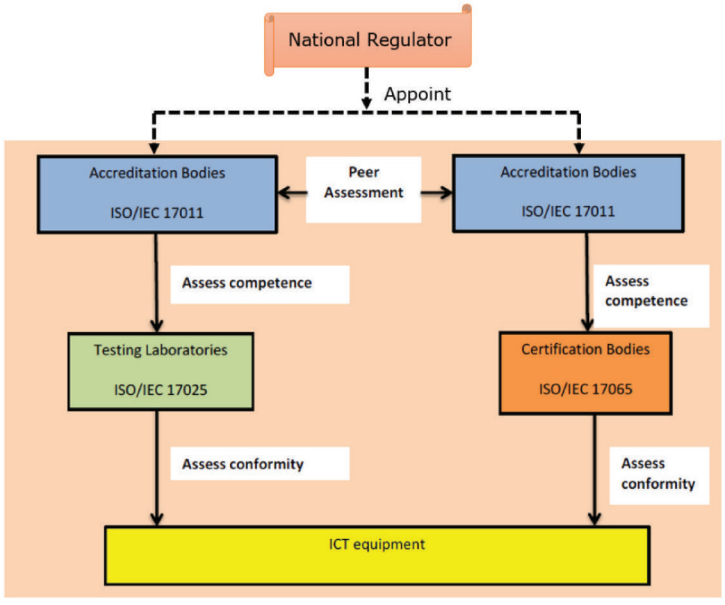

Figure 9: Hierarchy of conformity assessment entities and functions

It is required that the accreditation bodies must be ISO/IEC 17011 compliant. Since there is no entity in this hierarchy higher than the accreditation bodies, the compliance of accreditation bodies with ISO/IEC 17011 is done by peer assessment groups of accreditation bodies. This section describes the qualifications, appointments of these bodies and the inter-relations between these bodies.

There are several ways in which the competence and impartiality of CABs can be recognised, including government recognition, accreditation and peer assessment. Government recognition, accreditation and peer assessment normally utilise specified requirements set out in the following documents as a basis for recognition:

- relevant laws or regulations;
- conformity assessment schemes;
- the relevant International Standards for the type of conformity assessment body; and
- supplementary documents related to the specific technical area being covered.

6 Market surveillance

To support the operation of a Type Approval system and to ensure continued compliance of products and services produced by the Type Approval system, all entities of the Type Approval system including the regulator, CAB's, manufacturers, accreditation bodies must put in place market surveillance procedures to audit, monitor and assess the products and services. Appropriate actions must be taken by these entities to address and correct the problems resulting from the actions of the market surveillance procedures.

Market surveillance by a regulator can be either pre-market, at-the-border, or post-market. It can involve sampling the object of conformity in the above situations and carrying out some form of conformity assessment activity to ensure specified requirements are fulfilled. In this regard inspection and testing are often used to demonstrate an object's conformity with specified requirements.

For some countries, a form of pre-market surveillance especially for imports is pre-shipment verification of conformity (PVOC) which is carried out by an authorised agent of the regulator at the port of origin. Controlled goods that need to meet national standards are inspected and tested by these agents and if found to fulfil specified requirements a pre-shipment certificate of conformity is issued. This certificate then accompanies the shipment of those goods to the destination market and the shipment can be released at the port of arrival and onto the market once that certificate is authenticated. To ensure PVOC does not act as a technical barrier to trade, the specified requirements should also apply to the same goods that are produced domestically.

The advantage of PVOC is that it allows the regulator to outsource the compliance checks associated with imported products, especially where there is a limited capacity to perform these checks within the destination country. It can also speed up delivery of compliant products onto the domestic market without holding up shipments at the border.

6.1 Prerequisites for Good Practice

Empowering legislation for the market surveillance authority/ies must be in place. Governments have the right to introduce technical Regulations in the interests of

protecting consumers from the effects of faulty or unsafe products, deceptive practices, counterfeit goods, etc. In doing so, it is implicit that the authorities establish or appoint to take the responsibility for market surveillance be formally identified, be competent, informed to the public in legislation, and be granted the necessary powers to perform their functions, according to the good practice criteria. For example, powers to enter premises or conduct searches at borders (whether on an ad hoc or regular basis), take samples, demand product safety files or other information, recall or confiscate and, where necessary, dispose of non-conforming goods, order a halt to production, delay or prevent market entry or, in extreme cases, even close down premises, need to be detailed and need to be complete.

There are numerous cases of market surveillance authorities labouring under outdated and incomplete legislation, one example being where they have been given the power to confiscate goods but, by oversight, not the power to dispose of them.

The result can be the unavoidable and costly storage of non-conforming goods for an indefinite period while the legislation is amended (and to do so retrospectively can bring its own problems).

Enforceable technical Regulations and supporting legislation must exist. Whereas standards are, by definition, normative documents with which compliance is voluntary, technical regulations are mandatory.

Market surveillance activities in the public interest need a legal basis for their existence and effective implementation and should, therefore, be supported by:

- technical Regulations that are developed in an open and transparent manner, that provide a measured, risk-based and proportionate solution to a real or potential problem. They should consist of technical, preferably performance-based provisions that meet the regulatory purpose, together with administrative provisions that detail their mode of implementation;
- general product safety legislation;
- product liability legislation (although this can become a controversial issue and whether this is enacted will depend to a great extent on government policy, legal systems, etc.); and

- reference to consumer protection and consumer protection legislation, if it exists in the country.

Transparency in identifying the authorities responsible for enforcing each technical Regulation is essential. Organized industry, commerce and the public have a right to full transparency in the regulatory systems they have to work under, and consumers will only draw real benefits and protection from a system where this is in place. Governments, therefore, have a responsibility to organize their regulatory enforcement agencies in such a way as to minimize conflicts of interest and avoid duplication of responsibilities.

Affected parties need to have the right to challenge decisions or actions taken by market surveillance authorities. Market surveillance authorities must be accountable for their actions and need to be able to demonstrate that their work is carried out independently of any other interested party, with complete impartiality and in a non-discriminatory manner, especially between locally manufactured and imported products.

7 Mutual Recognition of Conformity Assessment

The results of CABs, such as test reports, inspection reports and certificates can be recognised in other jurisdictions and by other bodies if there is confidence that the results have been generated in an appropriate way.

This is often confirmed through MRAs on acceptance of conformity assessment results, especially in the context of international trade and facilitating market access of goods and services. The MRAs normally include reciprocal assessment of each other's facilities and competence to provide confidence in the conformity assessment results.

ISO/IEC Guide 68:2002, *Arrangements for the recognition and acceptance of conformity assessment* results contains guidance for MRAs. The Guide provides information on the elements of an agreement and advice on setting up an agreement group, stressing the importance of using internationally agreed criteria such as those in the ISO/CASCO toolbox. It mentions peer assessment and accreditation as methods for establishing the basis for confidence in the results produced by the members of the group. The Guide also advises that these two techniques can be used in a complementary way as, for example, where accreditation can provide assurance on the organisation and management systems of the members while peer assessment can concentrate on the technical aspects.

7.1 ISO/CASCO Recommended steps for using conformity assessment in Regulations

In many countries, a regulatory impact analysis (RIA) or a socio-economic impact assessment (SEIA) may be required to justify the selected option.

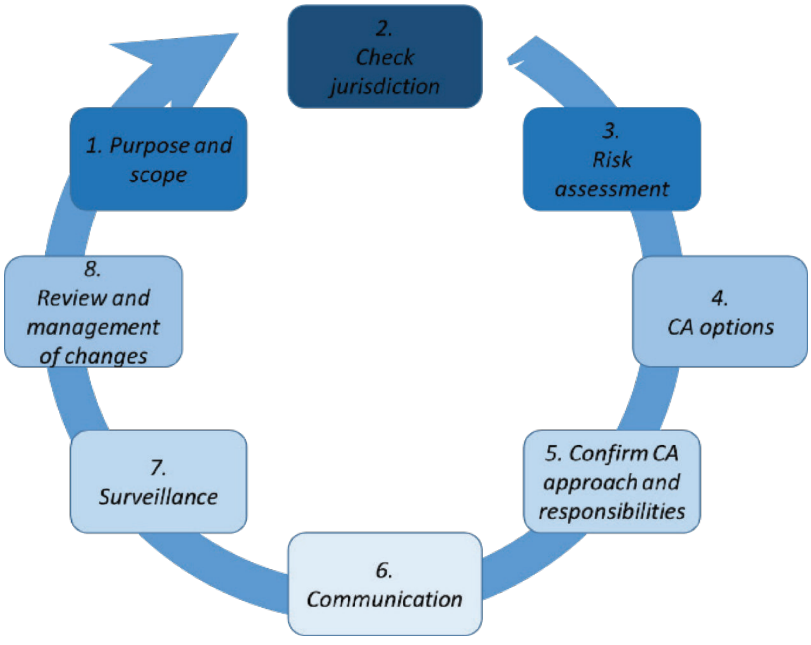

Figure 10: Process used to be considered (these steps are suggestions only)

When considering the use of conformity assessment in Regulations the following suggested steps can be used:

Step 1: Purpose and scope

The purpose for using conformity assessment to support Regulation should be clear and be related to achievement of relevant public policy outcomes and the responsibilities of the regulator.

The scope of the use of the conformity assessment should:

- identify the object of conformity (e.g. the type of product, process, service, management system, person or organisation) being targeted through the Regulation, and in particular what characteristics of that object that need to be controlled;
- the specified requirements that the object must fulfil; and
- identify stakeholders that have the responsibility to comply with the Regulations and demonstrating this compliance through adherence to conformity assessment requirements.

Step 2: Check jurisdiction

From the outset, it is important to ensure the following points are fulfilled:

- The responsibilities and regulatory powers the regulator has and confirm that it has a legal ability to develop and mandate conformity assessment requirements as part of fulfilling its responsibilities.
- It is clear what regulatory controls apply to the object of conformity (e.g. product, process, service, management system, person or organisation), especially if different aspects of the same object are controlled by more than one regulator (e.g. an electrical consumer product that is controlled for electrical safety by one regulator, and energy efficiency by a different regulator). Duplication of conformity assessment requirements should be avoided.
- It is clear which regulators have control over the object of conformity at different stages of the object's 'life cycle' (e.g. at the point of raw material creation, processing, manufacture or fabrication, wholesaling, distribution (including both imports and domestic production), retailing, during the period the product is available for use, during the use of the object by the customer, through to end of life of the object). This is especially true for products that have complex supply chains, or are perishable, or have specific issues in terms of waste and disposal. It is important to know which regulators have jurisdiction at which stages in the life cycle to ensure critical stages are covered. It is also important to coordinate across regulators, if necessary.
- The limits of delegations of any regulatory powers are known and respected, and to avoid situations where conformity assessment activities take on too much responsibility on behalf of the regulator which is not in accordance with the law.
- International obligations (e.g. WTO agreements) and regional commitments, especially for mandatory conformity assessment schemes that need to support and be integrated with any regional regulatory practice are known. In some regions, regional mandatory conformity assessment exists for specific product types, e.g. the Gulf Cooperation Council (GCC) Regulatory System for Control of Products, or the New Legislative

Framework with its association regulations and directives of the European Union.

Step 3: Risk assessment

Having confirmed the scope (including the objects of conformity and specified requirements) in Step 1, a risk assessment should be undertaken to understand the nature of the risks that are trying to be manage through regulation and conformity assessment.

Step 4: Conformity assessment options

The use of conformity assessment represents only a part of the range of options that regulators may choose to facilitate compliance with their Regulations. Practical access to the selected conformity assessment activity is critical if the use of conformity assessment is to be successful.

It is of no benefit to require testing to be carried out in an accredited laboratory if there are no accredited test laboratories that exist, or access to those laboratories is limited (e.g. government laboratories that are prohibited from undertaking testing for private industry clients that require this testing to comply with regulations). In many countries access to appropriate conformity assessment services is enabled through provision of such activities by both, public and private sectors, some of which are multinational conformity assessment companies.

The level of risk determines the adequate methods. For example, it could be a requirement for:

- SDoC based on a test report from an accredited laboratory;
- product certification based on the testing of an initial product type (type-approval) which is then copied for all subsequent units of production without any further involvement of a third-party certifier; and
- a production certification based on testing plus surveillance where a third party takes samples on an ongoing basis by the certification body from the market and testing or inspection to confirm the ongoing conformity.

Step 5: Confirm conformity assessment approach and responsibilities

If a mandatory conformity assessment option is selected, the regulator should develop an appropriate conformity assessment scheme.

Best practice in development of a scheme includes:

- engage a multi-party stakeholder's process;
- involve the sectors that will be required to comply with the regulations;
- provide a level of coverage that reflects domestic circumstances and priorities; and
- manage regulations and associated conformity assessment scheme with transparency and certainty.

Competence can be articulated through carrying out:

- a competence analysis to define the qualification criteria (the person certification standards of ISO/CASCO toolbox could provide you guidance on expected qualifications, work experience and levels of technical competence);
- a prescribed training system;
- qualification process including monitoring the performance; and
- then select the conformity assessment bodies, accreditation and peer assessment, and persons.

Once competence criteria are established, competent persons and organisations need to be appointed. A selection process will help to be consistent on implementing the defined competence criteria. This should also include considerations of independence, impartially and confidentiality.

Step 6: Communication

A specific communication strategy should be established, implemented and maintained, once the conformity assessment scheme is ready for operation. This could include:

- a high-profile launch event;
- distribution of information through various media channels including social networking;
- contact and seminars for those organisations and people that need to comply with the regulation or are involved in the associated conformity assessment activities;
- dedicated website for posting rules and updated scheme details; and
- training courses etc.

Step 7: Surveillance

Irrespective of which form of surveillance (market surveillance or conformity assessment surveillance) it is good practice to take a risk management approach to what is selected for surveillance and the frequency of surveillance. Surveillance provisions should be flexible in order to allow for:

- periodic concentration on aspects of non-compliance that are especially prevalent and that have the highest risk of noncompliance;
- distinguishing between good and bad performers in terms of compliance, especially in terms of frequency of surveillance; and
- the ability to switch focus to novel or emerging risks of non-compliance.

Step 8: Review and management of changes

The regulator in their role as scheme owner should implement a process for reviewing the operation of the conformity assessment scheme on a periodic basis, taking into account feedback from stakeholders. The review should:

- consider whether the conformity assessment scheme is assisting in achieving the relevant public policy and legislative objectives;
- consider whether activities can be undertaken more costs effectively and efficiently; and

- identify aspects requiring improvement.

The regulator, in its role as scheme owner, should monitor and participate in the development of standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the regulator should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the conformity assessment bodies, clients and, where necessary, other stakeholders.

8 Proposed Conformity Assessment Approach

Based on the existing challenges and the experience learned from other jurisdictions, the Authority is of the view that the proposed approaches below can improve the efficiency of the current Type Approval Framework, while ensuring that the conformity assessment of equipment to the specified requirements is not compromised, and the introduction of products in the market is not stifled.

Question 1

In your view, what are the benefits of having conformity assessment to support the regulations?

ICT equipment must be profiled and categorized accordingly based on the level of risk. The proposed conformity assessment regime must be developed in such a way that it can incorporate various conformity assessment approaches to cater for different scenarios relating to the equipment risk profile.

Question 2

Do you see any benefits in risk profiling and the categorization of equipment in carrying out the conformity assessment?

Question 3

With the recommended steps for using conformity assessment in support of the regulations (figure 10), which of the steps would you say are missing in the Approval Framework, and how can they help improve the Approval Framework efficiency?

The Authority proposes to review the coordination with all relevant state organs, by entering into MoUs, in an effort to develop a more robust and dynamic conformity assessment framework. Figure 11 below depicts the proposed process flow for the envisaged conformity assessment framework:

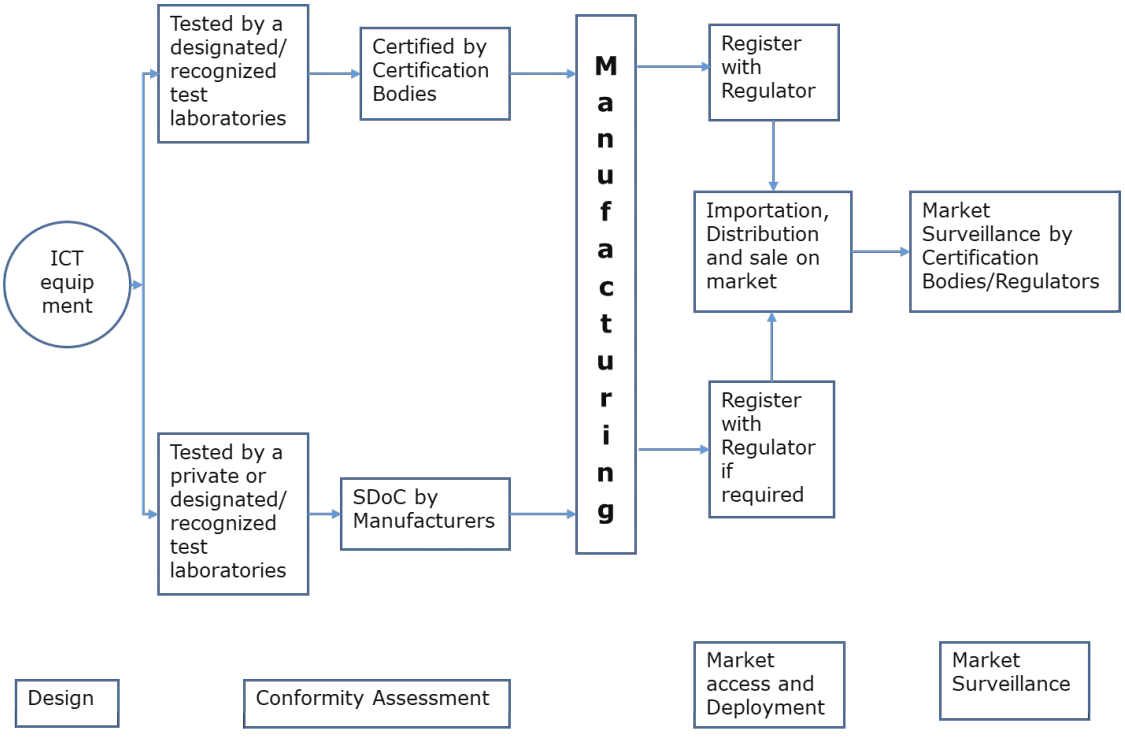

Figure 11: Dynamic conformity assessment scheme

Question 4

Can you suggest an appropriate conformity assessment approach that can address the current Approval Framework challenges?

The Authority shall collaborate with local and international CABs, Accreditation Bodies and Regulatory Authorities. This is essential as it will enable the Authority to appoint Designated Authorities and have recognised accredited test facilities to perform tests and measurements on the Authority's behalf from other jurisdictions.

Question 5

In South African context, what are the benefits for the Authority collaborating with other regulatory institutions/organizations/states?

The Authority proposes a less invasive and more efficient conformity assessment regime such as SDoCs and Equipment Type Approval Exemption where products are considered to have a low level risk.

8.1 Supplier declaration of conformity

Good and effective conditions of a SDoC scheme is the testing of the equipment performed by an ISO/IEC 17025 compliant testing laboratory furthermore, for traceability, the test reports be kept for a prescribed period; and register the statement of conformity or declaration with the relevant national regulator.

Proposed Approach

The Authority proposes allowing SDoCs to be one arm of its conformity assessment framework, specifically in terms of SDoC I as outlined Table 3 above. SDoC I requires that:

1) the product be tested by an accredited test laboratory;
2) the test reports need to be retained by the supplier for a period to be stipulated by the Authority;
3) the supplier registers the declaration with the Authority as prescribed; and
4) the products that are the subject of the SDoC would need to be labelled/marked in line with the Authority's prescripts.

Question 6

Given table 3, which SDoC scheme/s would best suit the South African market, and why?

The SDoC must be registered with the Authority prior to the use, supply, sale, offer for sale, lease, and/or hire of electronic communications equipment that is subject to SDoC within the Republic of South Africa.

The Proposed approach will assist in alleviating the regulatory burden on manufacturers, suppliers, and distributors. This will allow for products to get to market faster and could potentially reduce the cost of devices in the market by reducing the cost of doing business in relation to electronic communications equipment and/or facilities.

It must be noted that in order to effectively implement a robust SDoC assessment framework, it is imperative for the Authority to develop vigorous Post-Market Surveillance. Figure 12 outlines institutional arrangement in support of the SDoC scheme:

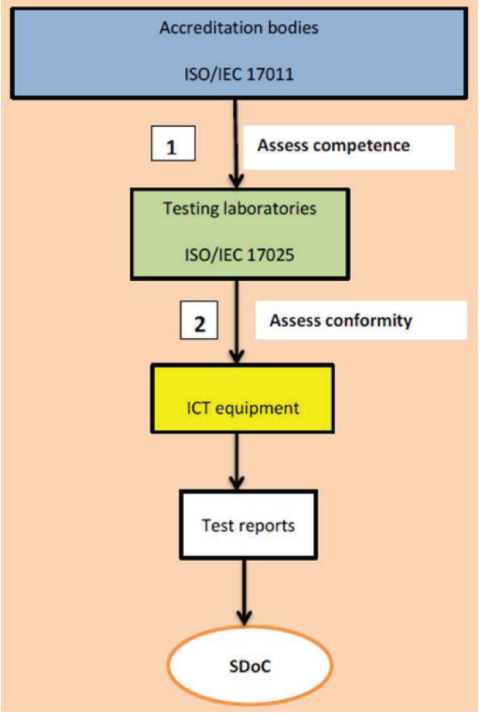

Figure 12: Conformity assessment scheme: Supplier declaration of conformity (SDoC)

8.2 Equipment Type Approval Exemption

Section 35 (2) of the ECA provides that the Authority may prescribe the types of electronic communications equipment/facilities and radio apparatus, the use of which does not require approval and circumstances under which the use of electronic communications equipment/facilities and radio apparatus does not require approval.

In the spirit of section 35(2) of the ECA, read with regulation 3(1) of the 2013 Regulations, the Authority had embarked on the process of exempting certain equipment from the Type Approval process in the 2016/17 Financial Year.

The Authority took a position[11] not to exempt electronic communications equipment/facilities or radio apparatus from type approval as was considered pre-mature at that stage and had potential of yielding irreversible unintended consequences. The position was informed by an international benchmarking study and written, and oral representations received by the Authority from stakeholders. The Authority took a position that it would embark on a process of reviewing the current type approval framework and work towards a multilateral conformity assessment framework based on the relevant criteria to deal with equipment that will be considered for exemption that will be made available.

Proposed Approach

Section 8.4 of the Regulatory Position on Equipment Type Approval Exemption ("the Position"), published in Government 40733 on 31 March 2017, the Authority took a position to develop a framework for the exemption of equipment operating under the circumstances included but not limited to those listed in Table 4 below.

[11] *Equipment Type Approval Exemptions, 2016; as published in Notice 248 0f 2017 Government Gazette 40733*

Table 4: Circumstances under which equipment may be exempted

Equipment Category	Description
Systems and equipment used for the production and distribution of broadcast and content services	All equipment in studios and production facilities that interfaces with the production environment and is under the control and operated by engineering professionals.
Test and measurement equipment	Any test and measurement equipment used by professionals and engineers of a licensed entity in the provision of telecommunications or broadcast services
satellite communications equipment	for temporal and/or limited area use only
Equipment for research and development in a laboratory environment	
Equipment for demonstrations of prototypes and testing	
Equipment for sample testing, demonstrations and field trials.	
Equipment for demonstrations and exhibition.	
Equipment for operations of specialised agencies	
Equipment for maritime or aeronautical operations	
Radio telescope receivers, calibration and test equipment.	
Radio telescope array and radio astronomy facilities	
Amateur radios	Radiocommunication services for the purpose of self-training, intercommunication and technical investigations carried out by amateurs on a non-commercial basis.
Equipment used by Government Services	Used for national security and defence networks.
Equipment produced or imported for the purposes of exporting.	Not for use in South Africa
Spare parts, components to be used for repairs	Provided such part is used in a certified product

Table 4 above serves as a building block towards the Exemption Framework which will be expanded through stakeholder consultations. The Authority retains responsibility for the conformity assessment of high-risk products, whereas medium and low-risk products may be considered for exemptions.

Question 7

In your definition/understanding, what ICT equipment can be classified as low risk and may be considered for equipment authorization exemption?

The Authority proposes a multilateral Conformity Assessment Framework, including MRA's and MoU's with CABs, TCBs and NBs, to alleviate compliance regulatory burden onto the affected stakeholders.

Question 8

What are the risks associated with exempting ICT equipment from Approval Framework, and how can they be mitigated or eliminated?

8.3 Market Surveillance

Good regulatory practice recommends that Regulatory authorities follow pre-market and post-market surveillance in their quest to enhance consumer protection, whilst considering the realities of limited resources and affordability[12].

Regulation 13 of the 2013 Regulations makes provision for market surveillance activities on all equipment that requires Type Approval.

Question 9

What would you propose the Authority do to effectively execute its responsibilities on market surveillance considering the current fiscal challenges?

Question 10

What are the prevalent equipment authorization challenges that may be experienced by manufacturers, distributors, suppliers and retailers post- and pre-market surveillance?

[12] *ISO: Principles and practices in product regulation and in market surveillance*

Proposed Approach

The Authority proposes the following:

1. to conclude MoUs with CABs in realisation of regulation 13 of the 2013 Regulations.

9 Conclusion

Based on the existing challenges and the experience learned from other jurisdictions, the recommendations below are envisaged to improve the current Approval Framework.

The Authority recommends the adoption of SDoCs and Equipment Exemptions within its Approval Framework which will be based on the analysis and considerations from stakeholder submissions and consultations. To complement the adoption of the above mentioned approaches, it is imperative for the Authority to develop a post market surveillance framework which is aligned to the envisaged Conformity Assessment Framework. A periodic review of the efficiency of the proposed approaches will inform the Authority on the need and time to enter into MoUs with CABs that are accredited in accordance with ISO/IEC International Standards and guides and are a member of ILAC MRA signatories.

The current Approval Framework consists of the following Regulations: 2013 Regulations; Labelling Regulations[13]; Official List; and The Position, all of which will need to be reviewed to align with the proposed Conformity Assessment Framework. Based on the outcomes of the submissions and consultations, the Authority will review the current Regulations in the 2019/2020 Financial Year.

[13] *Labelling Regulations, General Notice No. 872 of 2013, Government Gazette 36786*

10 References

[1] International Standards Organisation, "Guide To Good Practice: Principles and Practices in Product Regulation and Market Surveillance," 2013.

[2] International Standards Organisation, *The Conformity Assessment Toolbox: Building Trust,* International Standards Organisation, 2010.

[3] International Telecommunications Union, "Establishing Conformity and Interoperability Regimes: Complete guide," Geneva, 2015.

[4] International Standards Organisation,, "Using ISO/CASCO in standards and regulations".

[5] International Telecommunications Union, "Feasibility Study for a Conformance Testing Centre," Geneva, 2013.

[6] International Telecommunications Union, "Guidelines for developing countries on establishing conformity assessment test labs in different regions," International Telecommunications Union, 2012.

[7] International Electrotechnical Commission, "Taking conformity assessment further," Geneva, 2017.