Conformity Assessment Aspects in Normative Documents
Guidance for IEC standards writers

1 Abreviations

– SD: Standards Development

– CA: Conformity Assessment

2 Introduction

It is said: *"SD and CA are two sides of a coin"*.

This seems to be true since in a lot of cases both sides are not aware of each other as they are on opposite places on the coin.

The goal of this brochure is to improve the understanding of both sides, bringing them together to cooperate more closely, and to benefit from each other to arrive at another picture: *"SD and CA are the two pillars of IEC",* supporting together the demand of the industry, regulators and other actors in the market place.

The purpose of this brochure is to explain the relationship between standardization and conformity assessment to assist IEC/TCs to comply with the requirements of the ISO/IEC Directives Part 2 (in particular clause 33) and the IEC supplement.

The goal of industry and business is to sell their products and services successfully on the market.

For this purpose they have to demonstrate that their products, services and processes comply with the relevant regulations and the requirements of the market place.

The most efficient way to show compliance with regulations is the use of voluntary standards that are in line with the relevant regulations and are recognized by the individual national regulators.

3 World Trade Organization Technical Barrier to Trade agreement

The WTO TBT Agreement encourages its more than 160 signatories to base their technical regulations on International Standards such as IEC standards.

https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
((Currently the provisions of the ISO/IEC Directives and IEC supplement are written in RED, the explanations are written in BLACK. It is up to the designer to find an appropriate layout))
33 Aspects of conformity assessment
33.1 Documents containing requirements for products, processes, services, persons, systems and bodies
All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in accordance with the "neutrality principle", such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party).
NOTE 1 First-party, second-party and third-party conformity assessment activities are defined in ISO/IEC 17000.
NOTE 2 The term "document" is defined in 3.1.1.

3.1 Explanation

Requirements for conformity assessment are in many cases comprehensively fixed in regulations. This means that the relevant regulations set out the way in which suppliers (manufacturers, service providers) are required to demonstrate compliance with the regulations. Suppliers may either have to issue a self-declaration or to use some form of third party attestation.

Third party attestations may include for example test and inspection reports, certificates.

In cases where regulations do not specify the kind of demonstrating conformity it is up to the market partners to decide.

This could include options like:

– supplier's declaration of conformity;
– second party attestation (for example a company wishes to rely on its own testing facilities, even if a supplier's declaration or a certificate has been provided);
– certificate (issued by a third party) on voluntary basis or requested by a user (for example a retailer).

4 ISO/IEC Directives

The ISO/IEC Directives stipulate the so-called "neutrality principle". This principle means that normative documents, such as International Standards, that set out specifications for products, services or processes should be written so that conformity can be assessed by any interested party, whether by a manufacturer or supplier (first party); by a user or purchaser (second party); or by an independent body (third party).

The intent of this principle is to reduce the risk of:

– conflict with regulations;
– restricting the freedom of the market partners (e. g. suppliers, service providers, regulators, retailers, other users of the Standards).

Annex 1 of this brochure provides terms which might give an indication that the neutrality principle is not met.

Such documents shall not include requirements related to conformity assessment other than requirements which are necessary to provide repeatable and reproducible conformity assessment results.

4.1 Explanation

This means that normative documents that contain specifications for products, services and processes are not permitted to contain provisions for conformity assessment activities, except sampling and testing methods.

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

– specific conformity assessment systems or schemes to be applied; (that does not preclude an informative reference to an existing IEC/CA system or scheme);
– who should undertake conformity assessment activities, such as a first, second, or third party;
– the type of conformity assessment body to be involved (e.g. testing laboratory, inspection body); or
– specific indications of conformity, such as marks of conformity.

Wherever necessary and appropriate, each normative requirement for products, services, and processes should be supported by provisions to indicate how compliance with these requirements can be assessed.

To achieve repeatable and reproducible results the compliance provisions (e.g. test methods) should be written in a way that is unambiguous and does not require interpretation.

Committees wishing to specify additional conformity assessment requirements for the product, process, service, persons, systems or bodies may only do so in a separate document or in a separate part of the document provided that the separate parts can be applied independently.

Prior to commencing work on a separate document or separate part, a committee shall seek the approval of the ISO Committee on conformity assessment (ISO/CASCO) or IEC Standardization Management Board (IEC/SMB) or both as applicable.
For particular requirements in IEC, see the ISO/IEC Directives, Supplement – Procedures specific to IEC.

4.2 Explanation

This part of the ISO/IEC Directives has to be read in conjunction with the IEC supplement (see comments on Annex SD of IEC supplement) *((The designer of the brochure is asked to take care on an appropriate link))*

No document containing requirements for products, processes, services, persons, systems and bodies shall make conformity dependent on a quality management systems standard, i.e. it shall not, for example, make normative reference to ISO 9001.

4.3 Explanation

The use of a quality management system standard may be driven by the market place or by regulations.
In certain situations the use of a quality management system can be helpful in demonstrating compliance with requirements of normative documents. However, in the wider market place, normative provisions or references to quality management system standards could restrict the freedom of users of the normative documents to demonstrate compliance.
Another reason for the requirement in the Directives is that it is the regulatory authorities who may choose to mandate the use of a quality management system standard. Therefore, making normative references to a quality management system standard in a normative document could jeopardize the use and acceptance of this normative document by regulators.

For particular requirements in IEC, see the ISO/IEC Directives, Supplement – Procedures specific to IEC.
IEC supplement Annex SD (normative)
Criteria for SMB consideration of requests by technical committees or subcommittees for approval to prepare a separate standard or other document for conformity assessment requirements In accordance with 6.7 of the ISO/IEC Directives, Part 2, 2011, product standards, process standards and service standards shall not include elements related to conformity assessment aspects other than testing provisions (and associated sampling).
However, technical committees or subcommittees may, with the prior approval of the Standardization Management Board based on satisfying all of the criteria below, develop a separate standard specifying additional conformity assessment requirements. The Standardization Management Board shall assess requests from technical committees or subcommittees, to produce a separate standard containing additional conformity assessment requirements, against the following criteria:
a) The product, process or service that is the subject of the principal standard shall not be subject generally to regulation, as in such cases the regulator will specify the relevant conformity assessment requirements.
b) The product, process or service shall be such as to impose significant potential risk to personnel or other equipment or property if it fails to comply in full with the specifications in the standard (e.g. equipment for high voltage live line working).
c) A market need for such a standard shall be identified and there shall be no existing standard that includes the relevant requirements.
d) The technical committee or subcommittee shall outline the conformity assessment requirements it wishes to include in the standard and the justification for such requirements.

4.4 Explanation

The criteria to be fulfilled for getting approval by SMB are very restrictive, and already bullet point a) will in many cases be a reason for rejection as most standards are falling under national regulations, especially safety, EMC or energy efficiency standards.
IEC/TCs should avoid spending resources in specifying CA requirements as in the end the standard will likely fail approval, or the standard may need to be modified when IEC editors become aware of a conflict with the Directives.
Therefore, the IEC/TCs should first consult this document and become aware of what CA aspects are permitted and what are not. They should then consult its Technical Officer and if

necessary then consult SMB before undertaking any further actions towards dealing with CA aspects in their normative documents.
Moreover, IEC/TCs may contact the CAB Secretariat at any time to get additional advice.

Before deciding whether to approve the request, the SMB will first refer it to the CAB for a recommendation.

4.5 Explanation

In order to avoid any conflict of interest, the IEC Statutes and Rules of Procedure have established a separation of powers by entrusting the SMB to manage IEC standards development and the CAB to manage IEC conformity assessment. As the authority for IEC conformity assessment, it is appropriate that the CAB be consulted on any matter pertaining to CA within the IEC. CAB will be able to judge if the proposal is appropriate or if it conflicts, for example with existing activities, and moreover whether the proposal could lead to a new IEC CA service.

33.2 Conformity assessment schemes and systems
Committees shall not develop documents providing general requirements for conformity assessment schemes and systems. Development of such documents is the responsibility of the ISO policy committee ISO/CASCO in liaison with the IEC Conformity Assessment Board (IEC/CAB).

4.6 Explanation

ISO/CASCO together with IEC/CAB has elaborated a broad portfolio on such standards (ISO/IEC 17000 series). These standards are widely used for conformity assessment activities in the market and widely accepted and recognized by regulators.
Therefore, it is necessary to avoid the development of competing standards to the ISO/IEC 17000 series as this would cause confusion in the market place.

Committees wishing
a) to propose the establishment of a conformity assessment scheme or system, or
b) to prepare documents specifying conformity assessment systems or schemes or sector-specific operating procedures for use by conformity assessment bodies and others for conformity assessment purposes, shall consult with the secretariat of ISO/CASCO or IEC/CAB or both as appropriate, prior to commencement of the work to ensure that any documents developed are in line with the conformity assessment policies and rules approved by ISO/CASCO and IEC/CAB as relevant.

4.7 Explanation

All IEC/CA systems fall under the auspices of CAB.
IEC/TCs which identify a need for potential new CA activities are welcomed to contact CAB. CAB has established a specific business developing group for investigating new CA opportunities and, therefore, highly appreciates to take recommendations from IEC/TCs on board.
However, IEC/TCs need to be aware that producing a document(s) addressing Conformity Assessment elements DOES NOT result in an Conformity Assessment Scheme, as defined in ISO/IEC 17000 series. Rather such a document may be used by individual Conformity Assessment Bodies whom act as Scheme owners each with their own set of Conformity Assessment rules and procedures. IEC Central Office may be consulted where there is a need to develop a single International Conformity Assessment Scheme.

33.3 References to ISO/IEC conformity assessment documents
When a committee develops a document relating to conformity assessment systems or schemes, or any other document addressing conformity assessment aspects, the document shall make normative reference to the relevant published ISO/IEC documents for conformity assessment procedures, including ISO/IEC 17000 and ISO/IEC 17025. The committee may include verbatim text from the ISO/IEC documents for conformity assessment procedures but the committee shall not delete, change or interpret them.

4.8 Explanation

This provision of the Directives is not relevant for IEC due to the fact that IEC operates its own CA schemes and systems, and allowing IEC/TCs to develop such documents could

create a conflict of interest. In order to avoid this, IEC does not allow its TCs to develop CA schemes and systems. However, the CAB has established a business development group which is open for ideas from IEC/TCs for new CA activities.

Committees shall consult with the ISO/CASCO or the IEC/CAB secretary or both, as appropriate, for advice on correctly referencing the ISO/IEC conformity assessment documents. Any request for addition, deletion, change or interpretation shall be submitted to the secretariats of ISO/CASCO and IEC/CAB for decision.

4.9 Explanation

Once again, this provision of the Directives is not relevant for IEC for the same reasons as stated for the previous provision, just above.

6.2 Subdivision into documents
Documents are so diverse that no universally acceptable rules can be established for the subdivision of the subject matter. However, as a general principle, an individual document shall be prepared for each subject to be standardized, and published either as a single standard or a single part of a series.

EXAMPLE 1 Examples of reasons for the subdivision into parts under the same number are
– the document is likely to become too long,
– subsequent parts of the content are interlinked,
– portions of the document could be referred to in regulations, and
– portions of the document are intended to serve for certification purposes.
Such subdivision has the advantage that each part can be revised separately as necessary.
In particular, the aspects of a product which will be of separate interest to different parties (e.g. manufacturers, certification bodies, legislative bodies or other users) shall be clearly distinguished, preferably as parts of a document or as individual documents.

4.10 Explanation

Last bullet point in the example is dealing with CA. Although this bullet point is referring to “certification” (third party attestation), it is valid for conformity assessment activities in general.
This bullet point could better be understood if it was rewritten as,
“- portions of the document are intended to describe distinct requirements that can be evaluated separately, eg; safety, EMC, performance, energy efficiency, etc”.
It is good practice to develop different subjects, like safety, EMC, energy efficiency, in separate standards or different parts of a standards series in order to avoid the normative document becoming too voluminous, and making it easier for the user community (including the regulators) to use.

Annex 1 Check List (non exhaustive)

The use of one of the following terms in normative documents might be an indication of potential conflict with the ISO/IEC Directives.
Accredit, accredited, accreditation
Approval
Approving authority
Assessment
Audit
Calibration
Certificate, certification, certify, certified, certifying
Comply, compliant, compliance
Conform, conformity, conformance
Declaration
Designation, designating authority
Evaluation
Inspection
ISO/IEC 17…
Quality
Qualification
Registration
Surveillance
Type test
Validation
Verification

Annex 2 IEC CA systems

The following IEC CA systems are in operation.
IECEE: IEC SYSTEM OF CONFORMITY ASSESSMENT SCHEMES FOR ELECTROTECHNICAL EQUIPMENT AND COMPONENTS
Scope: The IECEE Schemes address the safety, quality, efficiency and overall performance of components, devices and equipment for homes, offices, workshops, health facilities among others. In all, IECEE covers more than 20 categories of electrical and electronic equipment and testing services.
IECEE operates the following two schemes:
a) CB Scheme – Certification Body Scheme
b) FCS – Full Certification Scheme

Explanation:
a) CB Scheme – Certification Body Scheme
The basis of this Scheme is to provide mutual recognition among participating Certification Bodies (NCBs) and Testing Laboratories (CBTLs) to accept testing performed by one body to be accepted by another to prevent repeat testing when seeking national certification or marks. Based on a CB test report issued by a CBTL the NCB will grant an online CB certificate that declares that a type test has been successfully passed.
The manufacturer can use the CB certificate and the CB test report for market access. The manufacturer can also request the NCB to grant its mark under the condition defined by the NCB.
In addition, the holder of CB certificate and the CB test report may request to obtain a mark from other NCB(s). In this case the relevant national differences have to be met.

b) FCS – Full Certification Scheme
The FCS is a full type 5 conformity assessment scheme according to ISO/IEC 17067 and ensures that:

- the national differences of such countries where the manufacturer requires direct entry have been tested by the CBTL and certified by the NCB;
- the initial factory inspection and the inspection of the production line(s) will be recognized by the other NCBs; i. e. they will not carry out their own factory inspections.

For further details see:
www.iecee.org

IECEx: INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES
Scope: The IECEx System comprises the following:
a) The IECEx Certified Equipment Scheme.
b) The IECEx Certified Service Facilities Scheme.
c) The IECEx Conformity Mark Licensing System.
d) The IECEx Certification of Personnel Competencies (CoPC).

Explanation:
a) The IECEx Certified Equipment Scheme
This is a full type 5 CA scheme according to ISO/IEC 17067.
The IECEx Certification Body (ExCB) with its associated Testing Laboratory (ExTL) is carrying out both a type test and an initial inspection of the manufacturer's quality management system (including the production line(s)). If successfully passed, an IECEx test report (ExTR) and an IECEx Quality assessment report (QAR) will be issued. Based on the ExTR and the QAR the ExCB will grant the IECEx Certificate of Conformity via the online IECEx certificate system.
The IECEx Certificate of Conformity remains current while the manufacturer's QM system and their production line(s) satisfactorily passes the periodic assessment and on-site audit conducted by the ExCB.
In some countries (like Australia, Israel, New Zealand, Singapore) IECEx certificates are already directly recognized by the regulators. In the other countries the manufacturer can

request a national ExCB to ensure national approval on basis of the IECEx certificate and supporting test and factory audit reports.
In addition, countries without national Ex regulations are increasingly accepting IECEx Certification as part of contractual requirements. A measure mainly driven by the United Nation's formal endorsement of the IECEx Schemes, via the UNECE Common Regulatory Objective publication.
For further details see:
http://www.iecex.com/unece.htm

b) The IECEx Certified Service Facilities Scheme
Ensuring that Ex equipment is designed and manufactured to comply with International safety Standards such as IEC, is only part way to ensuring overall safe use of Ex equipment in the community.
The way Ex equipment is installed, inspected, maintained and then repaired or overhauled all contribute to the safe use of Ex equipment. IEC have developed Standards addressing each of these important stages with the IECEx Certified Services Scheme aimed at providing independent third party verification that Service Providers to the Ex industries actually conduct their work in accordance with these important safety standards.

c) The IECEx Conformity Mark Licensing System
Provides a licensing system to enable manufacturers of Ex equipment that have achieved an IECEx Certificate of Conformity the ability to clearly display this via the IECEx Mark of Conformity.

d) The IECEx Certification of Personnel Competencies (CoPC)
While both the IECEx Certified Equipment Scheme and the IECEx Certified Services Scheme target the companies and their operations, the IECEx Certification of Personnel Competencies (CoPC) Scheme is dedicated to the individual person and the work they undertake. It is well recognized that Competence is the demonstrated ability to apply knowledge, this IECEx Scheme provides independent verification of a person's competence to be able to apply or work to a specified standard, eg a person being certified as competent to install Ex equipment according to IEC 60079-14.
For further details see:
www.iecex.com

IECQ: INTERNATIONAL ELECTROTECHNICAL COMMISSION QUALITY ASSESSMENT SYSTEM FOR ELECTRONIC COMPONENTS
Scope: Quality assessment system for electronic components (IECQ) to assure quality in the electronics component supply chain industry

Explanation:
The IECQ System is different to other IEC CA Services as it does NOT cover completed or final products but rather provides industry with a valuable Supply Chain Management Tool for Original Equipment Manufacturers (OEMs) to monitor and control suppliers of critical components and assemblies.
An IECQ Certification Body (IECQ CB) will evaluate the supplier's quality management system and grant facility approval for the family (or families) of component(s) concerned.
Suppliers have to show, through testing, that the component conforms to the relevant quality assessment specifications declared by the manufacturers. Some suppliers have their own in-house testing facilities for all of the tests required by the specifications or standards. The IECQ CB will ensure that these testing facilities are adequate. Those who do not have the testing facilities may use external testing laboratories that are accepted by an IECQ CB.

For further details see:
www.iecq.org

IECRE: RENEWABLE ENERGY - IEC SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN RENEWABLE ENERGY APPLICATIONS
Scope:
The IECRE CA System, "IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications", hereinafter referred to as "the IECRE System", is a Renewable Energies Conformity Assessment System which covers the following Sectors:

• Wind Energy (WE);
• Marine Energy (ME);
• Solar PV Energy (PV).

Explanation:
RE (Renewable Energy) Sectors can be known by different names such as “Solar PV Energy”, “Wind Energy”, “Marine Energy”, and the like and relate to areas characterized by systems which generate electricity from renewable natural sources, which consist of complex arrangements of sub-systems including structures, which are installed outside of any protective environment and whose reliability and performance is affected by direct interaction with the natural environment. These areas may include the equipment and processes to produce electricity, as well as the equipment to manufacture, transport and service the electricity-producing equipment. Relevant standards exist for specific industry sectors to which the conformity assessment and certification of the IECRE System is done.
The IECRE System includes conformity assessment of any particular material, product (services, software, hardware or processed materials), installation, process, system, person or body covered by International Standards related to Sectors listed above as proposed by its Management Committee (REMC) and approved by the IEC Conformity Assessment Board (CAB). The IECRE System may also provide for the assessment and certification of competence of persons and bodies working in or conducting work affecting IECRE Sectors.
The IECRE System will not include the conformity assessment covered by the other IEC CA Schemes. However, the IECRE System may select to make use of the deliverables from the other IEC CA Schemes such as certificates and reports for integration in applicable IECRE Schemes.
RE equipment manufacturers and RE service providers, developers, operators and persons can apply to IECRE Certification Bodies (RECBs) and IECRE Test Laboratories (RETLs), in any country.
For further details see:
www.iecre.org