

CONFORMITY ASSESSMENT PUBLICATION

Rules for IEC Systems-approach to CA





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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

The text of this publication is based on the following documents and decisions:

Document(s)	Decision(s)
CAB/1373B/R, CAB/1400/DL	CAB Decisions 37/19, 37/20

INTRODUCTION

The multiplicity of technologies and their convergence in many new and emerging markets, particularly those involving large scale infrastructure, now demand a top down approach to standards development (SD), starting at the system or system architecture rather than at the product level.

System-standards are similar to technical standards in that they both define appropriate requirements; for example, technical system principles, system architectures and roadmaps, etc, for system-standards; safety, energy efficiency, performance requirements, etc, for technical standards.

Such standards have little value if the requirements are not met. Assessment of conformity to the requirements of the standards is where value is created.

To create such value a top down approach is also needed for conformity assessment (CA). A holistic understanding of the system is essential and the appropriate CA needs to be applied at multiple levels. Depending on the needs of the system, those levels may include the component or product level, the system design and integration level, the system realization level, the system maintenance and evolution level, the quality management processes associated with the conception, design, integration, operation and maintenance of the system, and the qualification of suppliers to the system and of people working within the system.

This document provides rules for the management of an IEC systems-approach to CA.

Rules for IEC Systems-approach to CA

1 System – description

Because of the many uses of the term “system” and the confusion that they can cause with respect to the IEC CA activities, this document will consistently and exclusively use the term “IEC CA System(s)” to refer to one or more of the IEC CA System(s). To help avoid confusion when referring to a generic CA system, the term “CA scheme(s) or system(s)” will be used.

The multiplicity of technologies and their convergence in many new and emerging markets, particularly those involving large scale infrastructure, now demand a top down approach to Conformity Assessment, starting at the system or system architecture rather than at the product level. A systems-approach is also increasingly required in sectors such as environment, security, safety and health.

For participation in IEC systems-standardization activities see Annex B.

In the CA context, a “system” is formally defined as:

System

set of interrelated elements considered in a defined context as a whole

NOTE 1 A system is a group of interacting, interrelated, or interdependent elements forming a purposeful whole.

NOTE 2 Conformity assessment activities for a system(s), may require specific structures and work methods to support applications and services relevant to market stakeholders.

[SOURCE: IEV 151-11-27, modified]

2 Establishment of a CA Services Development Group (SDG)

2.1 CA Services Development Group (SDG)

An SDG is an open group drawn from within and beyond the IEC community approved by CAB and led by a CAB designate for the purpose of identifying opportunities for IEC CA through recommendations to the CAB. Its role is to engage the community of experts, identify the relevant stakeholders, define the general architecture and boundaries of the subject to be addressed.

2.2 Establishment of SDGs

SDGs are established and dissolved by the Conformity Assessment Board. They have a limited life, normally of 12 to 24 months and shall not have on-going tasks. They are not entitled to develop standards or IEC CA deliverables.

NOTE 1 If a lack of normative documents is identified, then SMB shall be informed.

A proposal for the establishment of an SDG can be made to the CAB and should include the following information:

- Market needs, market relevance and business drivers;
- Identification of standards, specifications or requirements as a basis for conformity assessment;
- Regulatory demands or other requirements in countries or regions;
- Related work or other valuable information from other organizations or Industries;
- Identification of existing IEC CA schemes (if applicable); Identification of IEC technical committee(s) which should participate;

- Identification of stakeholders, including ISO TC/SCs and ITU SGs, industry sectors, regulators, financiers, insurers, fora and consortia outside of IEC which should be engaged in the work;
- Recommendation of needed expertise and administrative structure of the SDG;
- Proposal for an appropriate name of the SDG;
- Proposal for a convenor.

2.3 Membership of SDGs

The SDG membership should have a strong competence in the issues within the scope of the Group. This may require participation of experts outside the normal IEC community.

There shall be an open call for participation of experts from both within (e.g. IEC National Committees, Member Bodies of the existing IEC CA Systems, and CAB) and outside IEC (such as ISO, ITU and fora / consortia).

The Secretary is provided by the IEC Central Office.

The final membership is approved by the CAB.

2.4 Tasks of SDGs

The principal task of an SDG is to evaluate the CA needs of the market, develop the proposed framework (in accordance with Annex A) and make recommendations to the CAB. This entails the examination of the following factors:

- Proposal of membership to this group, for CAB approval, of participants in the work from inside and outside IEC, members from existing IEC CA Systems, IEC/TCs, ISO/TCs, ITU/SGs, fora, consortia and other groups outside of IEC;
 - Demands/drivers (e.g., regulatory, financial or other requirements) in countries, regions or industries;
 - CA market needs, market relevance and business drivers;
 - identify possible CA services needed,
 - identify the framework in which those services should apply, and
 - identify the operational documents or missing ODs that may be required.
- NOTE It is not the intention of this group to develop such documents.
- Gap analysis of the following
 - appropriate standards or specifications that are suitable for CA,
 - existing IEC CA offerings and needed CA services.
 - An analysis of the Risk Exposure for the IEC (both of taking action and of not taking action).

The following deliverables/outcomes would be expected;

- Creation of a business plan;
- Proposed prioritization of standards and CA service needs;
- Completion of a draft framework.

This group will make regular status reports to the CAB, at least to each of the CAB meetings. CAB shall determine the ongoing activities of the SDG.

Annex A

Conformity Assessment Framework

The CA stakeholders will assist in the framework discussions and will define the CA needs at the various phases of System implementation. Specific items to be considered are:

Conformity Assessment Framework				
System Stage/ Component	Conformity Assessment Needed?	Applicable Standards and CA Needs/ Scope/ Inclusions	Outcomes/ Certifications	Deliverable/ Outputs for Systems Groups

- **System Stages/Component** – This will include an analysis and definition of the various steps in the System implementation which may include a component or sub-assembly of the overall System.
- **Conformity Assessment needed** – This will include a determination of the market needs relative to CA and whether there is a perceived need for CA at the various stages.
- **Applicable Standards and CA Needs/Scope/Inclusions** – This is intended to document the specific market standards (existing or needed) that may be used at the specific stages for the purpose of assessing conformity (if needed).
- **Outcomes/Certifications** – This will include the determination of the specific CA needs and types of CA that the marketplace is seeking, their applicability, whether they exist today and an identification of the specific stakeholder interests.
- **CA Deliverable/Output** – This will included a determination of the specific CA program that may be used and will identify any gaps for the development of necessary rules, guidelines, operational documents, checklists or templates for use in CA activities.
- **Risk Exposure for IEC** – Does this activity expose IEC to a greater level of risk to that which IEC is already exposed and covered.
- **Business case to IEC** – To address issues of costs to IEC and its Members and how costs will be recovered.

Annex B

Participation in IEC systems-standardization activities

The IEC through the SMB has established a process for addressing address complex technical standards at the level above traditional standards for individual products. This document is a supplement to the document produced by the SMB (AC/33/2013) and is intended to be used in conjunction with that document.

The participation of CA experts and stakeholders at the earliest stages in in the SEG, SRG and SyC will enable them to shape the dialog, ensure that practical CA is possible, meets the market (stakeholder) needs and is included in the development of the set of system specifications. The varying customers of the CA services should be able to order a set or combination of CA products, systems and services from multiple vendors to meet the overall System CA needs. All methods of CA should be available depending on the associated risk and business case for IEC.

The participation of CA experts from CAB and the CA Systems also provides an excellent opportunity for the current IEC CA Systems to develop new offerings, adapt or modify current offerings and to continue to provide market relevant solutions. The end CA customer must have confidence that the individual “component level” CA deliverables from multiple CA vendors complies with the system requirements so that when the assembly is connected the amount of unknowns are reduced with the intent that final integration and test times are reduced and the underlying standard features have been proven prior to delivery.

This document outlines how the CA stakeholders can engage in the systems standardization process and subsequently develop and implement CA solutions to meet the system needs.

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