OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

IEC Conformity Assessment Systems
A comparison

OIML Seminar on Conformity to Type
29th to 30th of June, 2011 in Utrecht/NL

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Immediate Passed Chairman IECEx

Who is the IEC ?

- The International Electrotechnical Commission with 60 full members
- Founded in 1906 to promote international co-operation on all questions of standardization and related matters in the field of electrotechnology, including Conformity Assessment.

Relation between ISO and IEC

- The IEC and ISO are twins as international SDOs, located in the same building (Rue de Varembé 3, Geneva, CH)
- IEC full member 60 countries plus 21 associated (ISO: member 108 plus 54 associated)
- Close collaboration:
  - via ISO/IEC Directives and Guides as the procedural rules to be followed for the development and maintenance of international standards
  - on international scenes like WTO, especially for the TBT agreements
  - development of CASCO standards

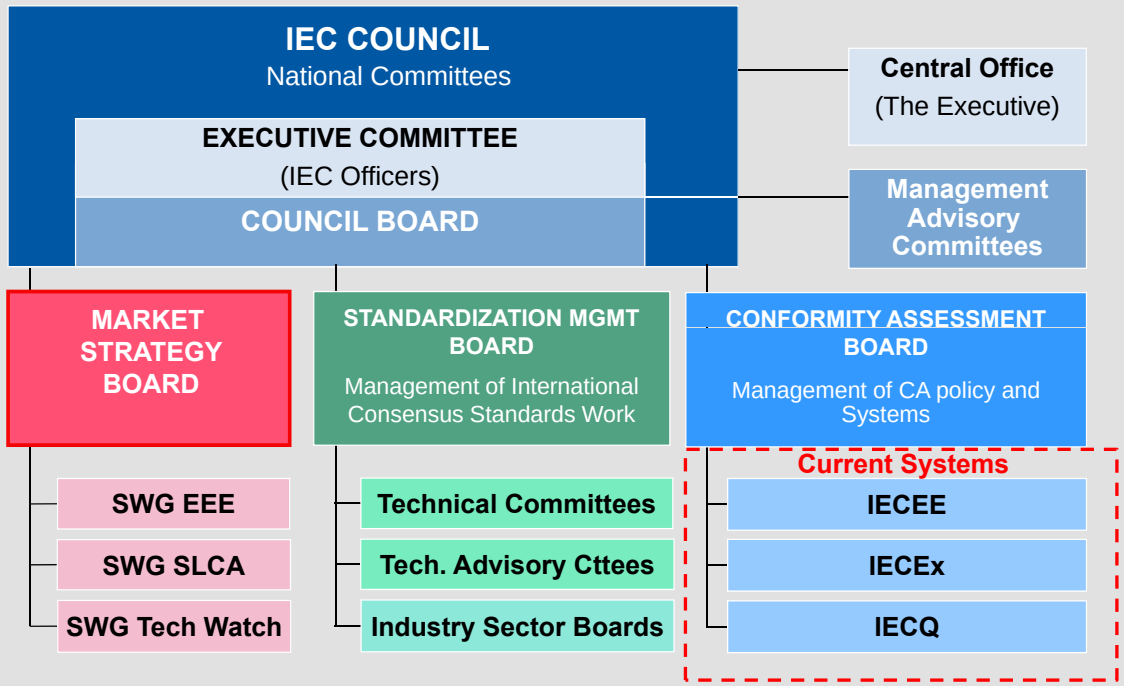
Principles of ISO/IEC for standardization

- Impartiality, stakeholder principle
- Parliamentary process within rectification of standardization documents (comments, voting)
- Integration of regulatory requirements, close contact to regulators and early involvement in the standardization process – see EU New Approach
- Goal: One standard – accepted everywhere and by each stakeholder

Principles of ISO/IEC for conformity assessment (CA)

- Strict separation between standardization and conformity assessment
- Main CASCO standards for certification:
  - ISO/IEC Guide 65 (replaced soon by ISO/IEC 17065) and ISO/IEC Guide 67
- Other CASCO standards:
  - ISO/IEC 17025 Laboratories
  - ISO/IEC 17021 Management systems
  - ISO/IEC 17024 Competence of Persons
- IAF/ILAC accreditation accepted by national regulators as a goal, replacing national accreditation systems
- CA schemes should only driven by market demand or regulators, NOT by commercial interest of CA bodies

General IEC Structure



Principles of IEC systems for conformity assessment (CA)

- Peer assessment of CBs and TLs, usually based on IAF/ILAC accreditation as an add on, conducted with technical assessors, applying CASCO standards plus technical guidance documents (Technical Panel with ILAC/IAF based on a MoU)
- Detailed rules and procedures laid down in SOPs (operational documents – ODs)
- Using test report templates related to the IEC standard requirements
- Conducting proficiency testing programs
- Using a single online certification tool, operated by IEC in the Central Office Geneva for total transparency of the CB activities worldwide

Main benefits of the IEC CA systems

- International independent testing and certification as a basis for global confidence of the stakeholders, esp. consumers and regulators
- Test results recorded in a structured template as a basis for the “Fast track” national certification (time to market in international trade)
- Potential of the IEC CA systems for direct certificate acceptance by national regulations (IECEx in AU and NZ)

Size of the systems

	IECEE	IECEx	IECQ
Member bodies	53	30	17
Certification bodies	71	40	21
Test laboratories	341	43	21

Use of the IECEE Schemes

Use of the Schemes to their fullest extent will promote the exchange of information necessary in assisting Manufacturers around the world to obtain certification or direct acceptance in the global markets

The scope of the CB Scheme

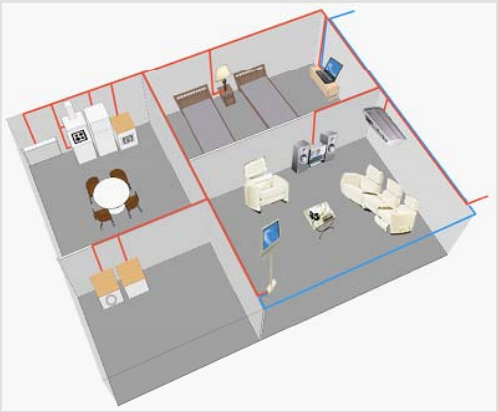
Safety, Performance, Sourcing IECEE

Electrical accessories (TC 23)

Luminaires (TC 34)

Electric cables (TC 20)

Lamps and related equipment (TC 34)



Information Technology (TC 108)

Multimedia (TC 100)

Fibre optics (TC 86)

Cables, wires, waveguides (TC 46)

Household appliances (TCs 59 & 61)

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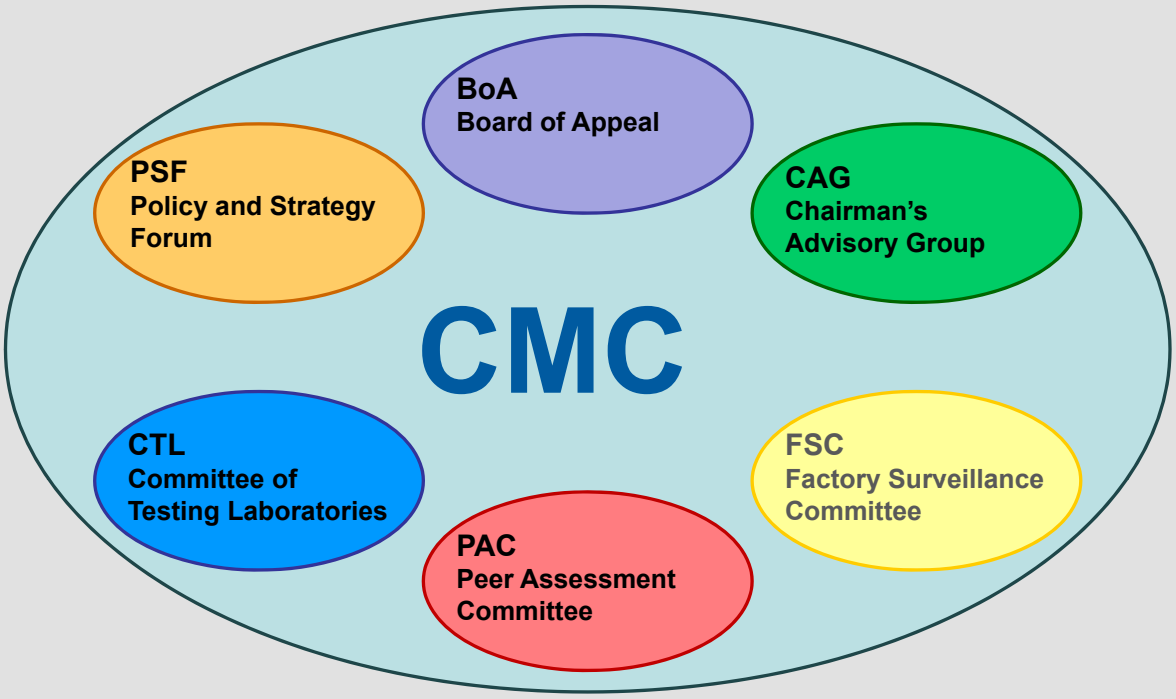
IECEE Organization & Structure



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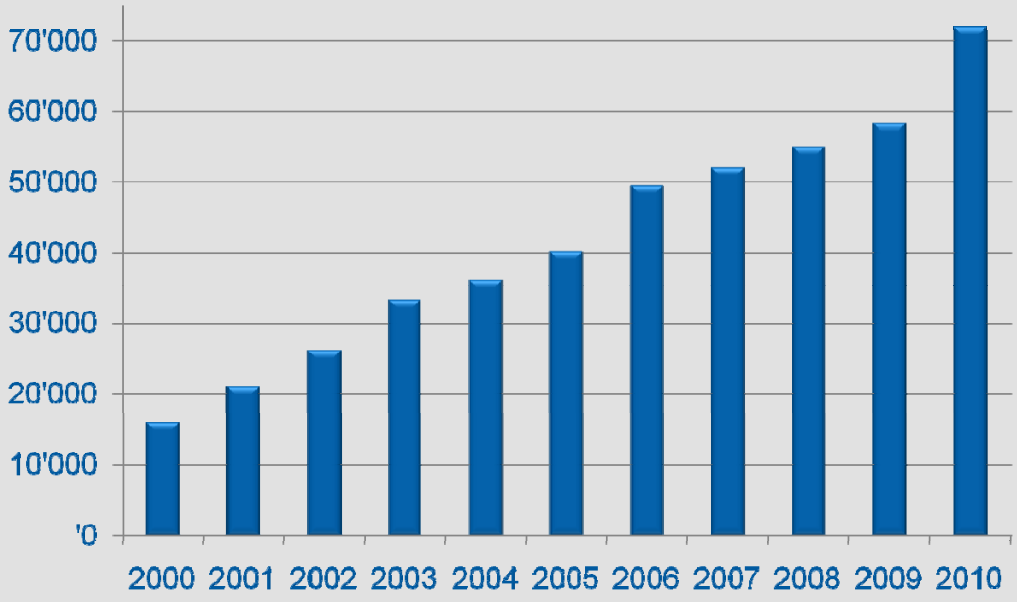
IECEE CB Test Certificates issued



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What is IECEx?

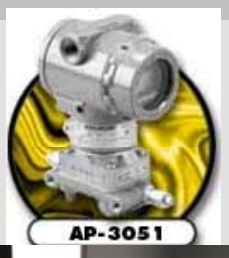
The single International IEC System with Schemes covering Certification to Standards that relate to Equipment and Services in areas relating to Explosive Atmospheres, to provide an Internationally accepted means of *demonstrating claimed compliance with International Standards*

IECEx is a "Conformity Assessment Tool" providing confidence that Products, Services and Personnel covered by an IECEx Certificate meet specified requirements, (International Standards)

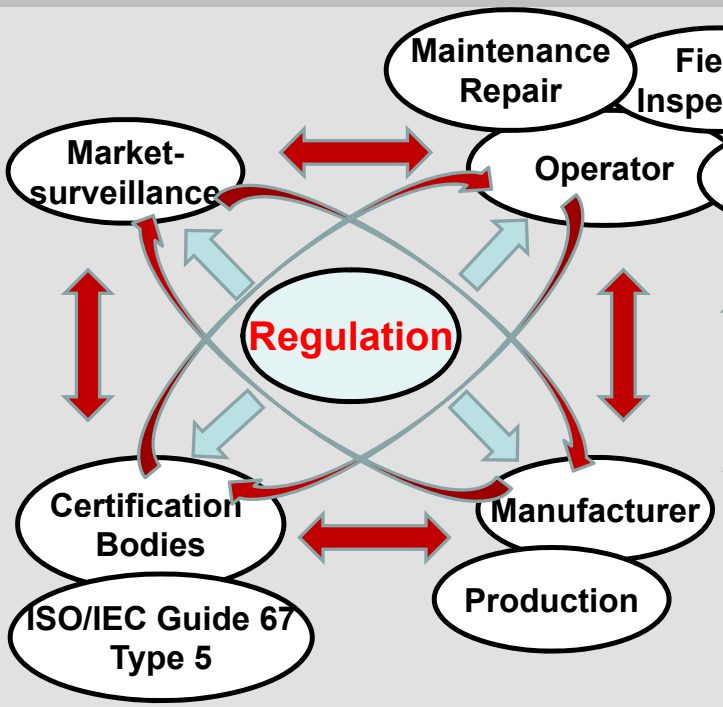
"IECEx is the International Standard way of doing Ex Certification"

Examples of Equipment Covered by IECEx

- Transducers, Sensors etc
- Switchgear
- Control Stations
- Motors
- Luminaries and Lighting
- Underground vehicles
- Radios + Communication
- Junction boxes
- Control Modules
- Control Systems
- Instrumentation
- Analyser houses
- Ventilation Rooms
- Components
  - Terminals
  - Adaptors / Reducers
  - Cable terminations
  - Glands
- Many others



Life Cycle approach within IECEx



1. Definition/Jurisdiction
   a) Market Surveillance
   b) Certification Bodies
   c) Manufacturer
   d) Operator
2. Interaction
   a. Cert. B. ↔ Manu.
   b. Manu. ↔ Oper.
   c. MS ↔ Oper.
   d. MS ↔ Manu.
   e. MS ↔ Insp. B.
   f. Cert. B.↔ Insp. B.

Schemes within the IECEx System

IECEx System
www.iecex.com

IECEx Bodies

ExCBs 39
ExTLs 43

IECEx Equipment Scheme
Certification of Ex Equipment

3 Types:

- IECEx "Certificate of Conformity"
- IECEx "Component Certificate"
- IECEx "Unit Verification" Cert.

ExCBs 14

IECEx Conformity Mark License Scheme

ExCBs 11

IECEx Services Scheme
Certification of Ex Service Providers, eg Repair and overhaul workshops + Install.

ExCBs 3

IECEx Certified Persons Scheme (CoPC)
Competency to work in Ex field (New)

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IECEx Management and Governance Structure as at Jan 2011

Standards Work

STANDARDS MANAGEMENT BOARD (SMB)

IEC TC 31

IEC TC 31 PTs, MTs, SCs

Conformity Assessment work

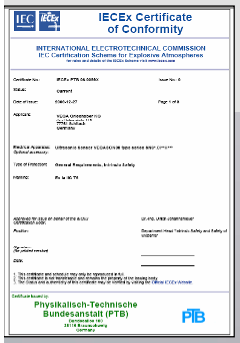
CONFORMITY ASSESSMENT BOARD (CAB) → Set Policy and Oversees Systems

IEC ExMC
Management Committee
Member Countries
→ Coordination Role for day to day Management, finance approves Rules,, CBs, TLs Comprise Industry experts

IECEx ExTAG
all ExCBs and ExTLs represented
→ CB Committee - Ensure common approach to Certification, eg Standard Test Report Forms, ExTRs, Decision Sheets

IECEx Marks Committee
→ Oversee operation of Mark License system Comprise industry experts

IECEx Certificates + Licenses Issued



Ex Equipment, Components + Systems

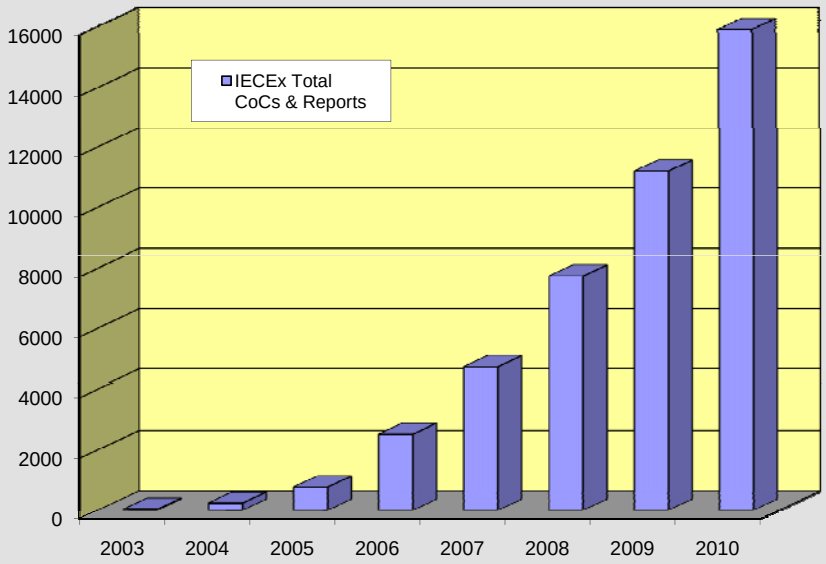
Ex Equipment Unit Verification

Ex Equipment Mark License

Ex Services, eg Repair to IEC 60079-19 + Installation coming

Ex Competent Person

IECEx Statistics to end 2010



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IECEx Key Updates, since Seattle IEC GM
United Nations new Publication, March 2011

New United Nations Publication via UNECE endorsing IEC TC 31 Standards + IECEx as "world's best practice".


UNECE United Nations Economic Commission for Europe

Press Release

Helping smaller countries protect their populations from danger in explosive environments
New UNECE publication offers regulatory framework

Full Text
http://www.unece.org/press/pr2011/11trade_p03e.htm

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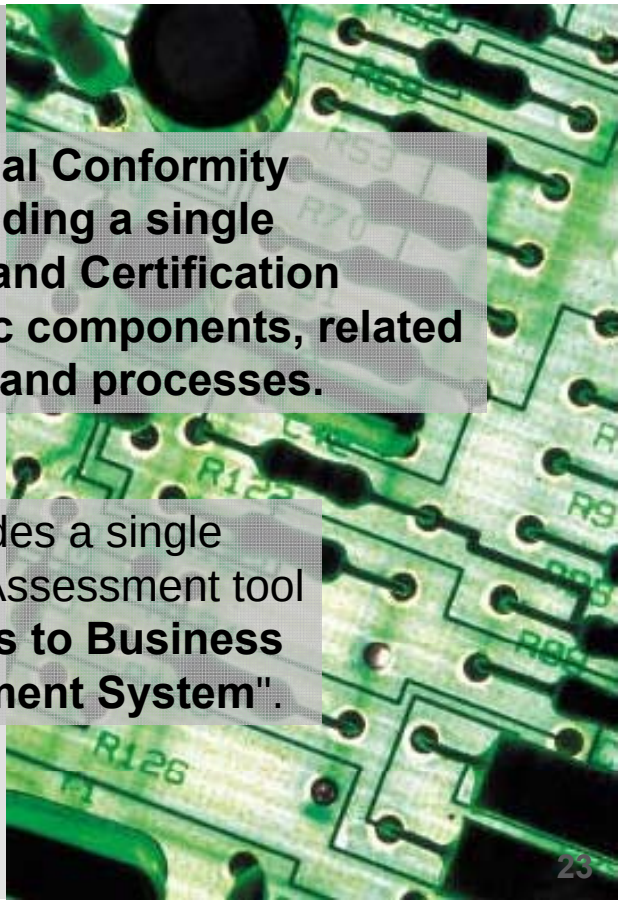
What is IECQ

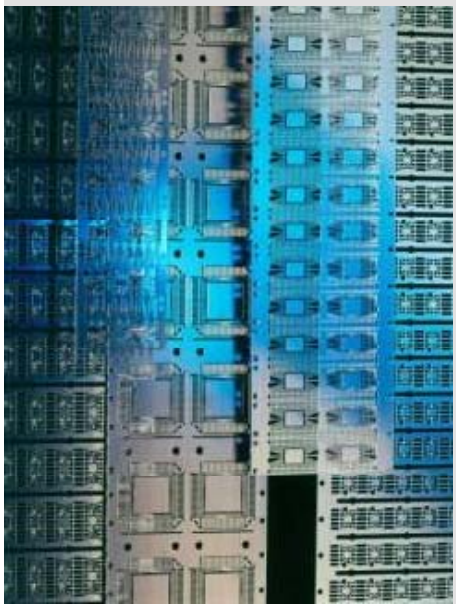
IECQ is the IEC International Conformity Assessment Scheme providing a single International Assessment and Certification System covering electronic components, related materials, sub assemblies and processes.

IECQ therefore provides a single International Conformity Assessment tool to support the **"Business to Business Supply Chain Management System"**.



IECQ System

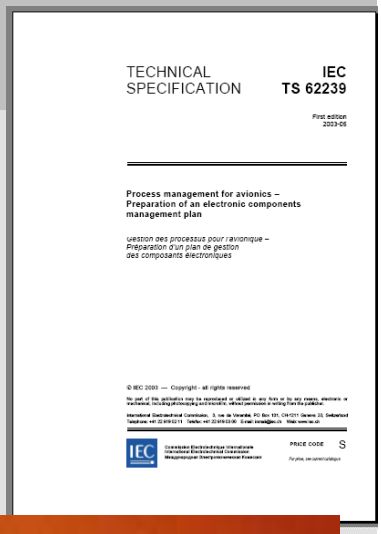
IECQ System
www.iecq.org



- **Process Approvals**
  Eg Electrostatic Discharge Management ESD etc
- **Component Approvals**
  Qualification, Capability (Production of Components +Assemblies)
- **IECQ HSPM QC 080000**
  Hazardous Process Management
- **ECMP**
  Electronic Component Management Plan (Avionics + Others, railways, medical)
- **ITL (Test Laboratories Operating in IECQ)**

What is ECMP (TS 62239)

- IECQ ECMP provides assessment by independent IECQ qualified Certification Bodies that eliminates the need for multiple assessments by different customers of component suppliers, eg Boeing/Airbus and other airframe manufacturers and sub-contractor


TECHNICAL SPECIFICATION

IEC TS 62239

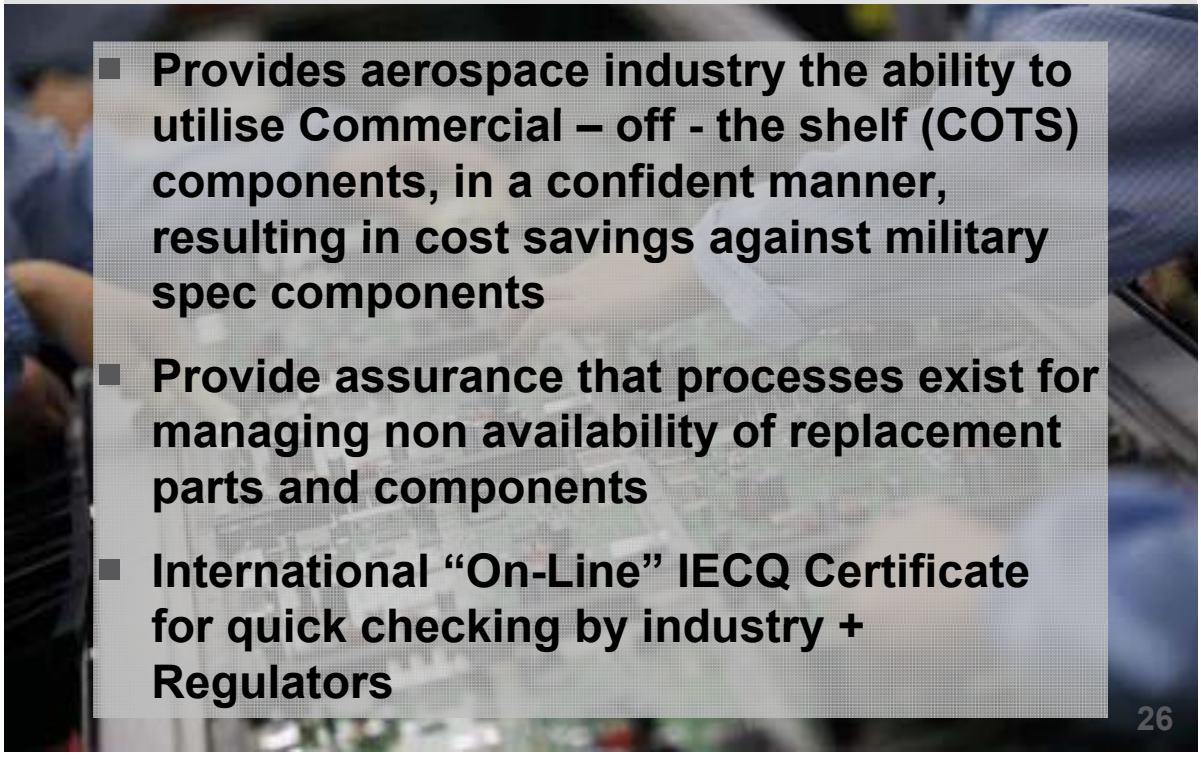
First edition 2003-05

Process management for avionics – Preparation of an electronic components management plan

Gestion des processus pour l'avionique – Préparation d'un plan de gestion des composants électroniques

PRICE CODE S

Benefits of a IECQ ECMP Certification



- Provides aerospace industry the ability to utilise Commercial – off - the shelf (COTS) components, in a confident manner, resulting in cost savings against military spec components
- Provide assurance that processes exist for managing non availability of replacement parts and components
- International "On-Line" IECQ Certificate for quick checking by industry + Regulators

Differences between the systems

- IECEE and IECQ are not so strongly submitted to national regulations like IECEx
- IECEE and IECQ are not structured for the lifecycle approach like IECEx
- IECEE is collaborating with several IEC/TCs, IECEx only with IEC/TC 31
- IECQ serves electronic industry only
- IECEx will get mechanical products under their scope by standards made by IEC/SC 31M
- IECEx accepts tests made at manufacturer's location only by (remote) witnessing of an ExTL

Acceptance of test results not made in an Ex Test Laboratory

- Accreditation bodies worldwide do not tolerate "easy living" in the Ex product certification
- IECEE has developed a sophisticated procedure (TMP, WMP, SMP – OD 2027 to 2030), but this procedure has been declined by regulators
- IECEx is using the OD 024 which allows testing at other locations than the ExTL with "remote witnessing"
  - initial assessment of the test facilities in partial accordance to ISO/IEC 17025
  - full control of each individual test sample by the ExTL (identification, treatment)
  - tests done "remote" under full control of the ExTL via web camera, recorded and archived
  - ongoing surveillance of the location

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Thank You