# OD005 IECEx Quality System Requirements for Manufacturers

## Quality system implementation from a manufacturers' viewpoint

**Evans Massy**

**Rockwell Automation**

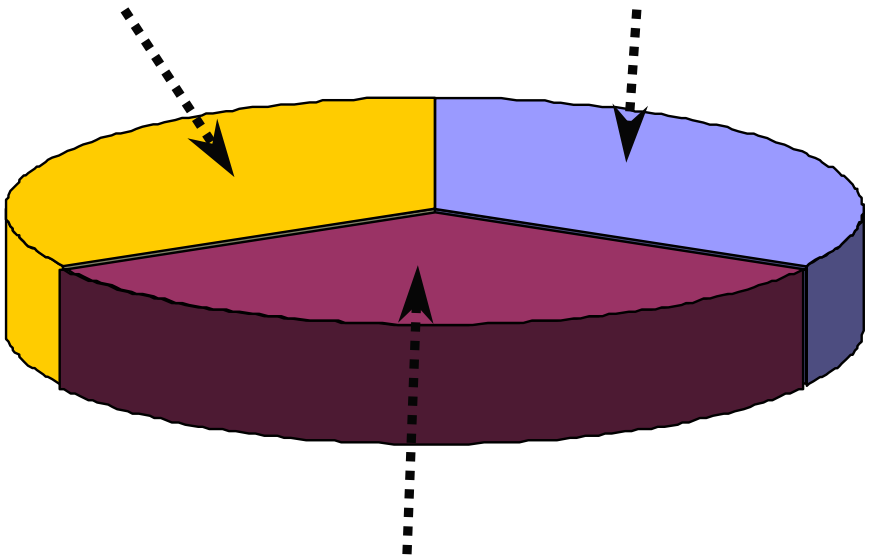
**October 3, 2005**

- **1515 – 1545**
- **Manufacturer's experiences of complying to IECEx quality system requirements (Mr Evans Massey, Rockwell Automation, US)**
  - Changes to base ISO 9001 requirements
  - Experience with audit style
  - Others

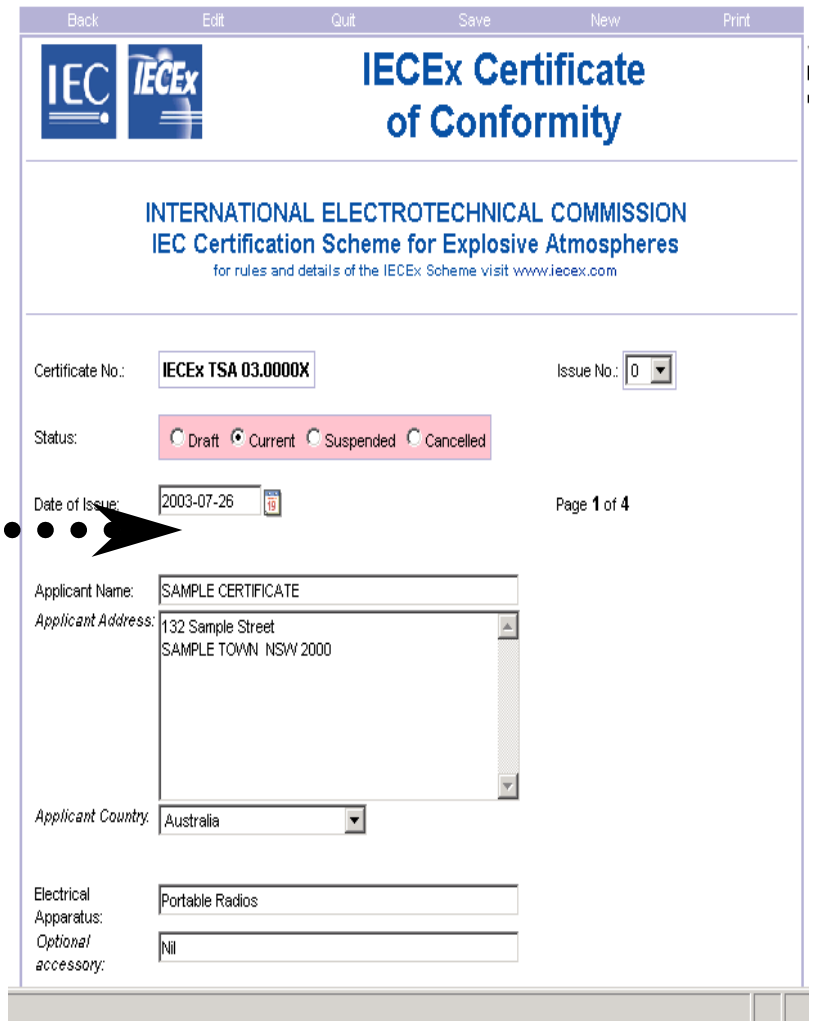
# Core Elements of IECEx Certification

**Testing of Samples (Type Test)**

**Initial Assessment of Manufacturer's Quality System (factory audit)**



**On-going Surveillance (factory audits)**



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IECEx Certificate of Conformity

INTERNATIONAL ELECTROTECHNICAL COMMISSION
IEC Certification Scheme for Explosive Atmospheres
for rules and details of the IECEx Scheme visit www.iecex.com

Certificate No.: IECEx TSA 03.0000X  Issue No.: 0

Status: Draft Current Suspended Cancelled

Date of Issue: 2003-07-26  Page 1 of 4

Applicant Name: SAMPLE CERTIFICATE

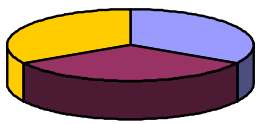
Applicant Address: 132 Sample Street
SAMPLE TOWN NSW 2000

Applicant Country: Australia

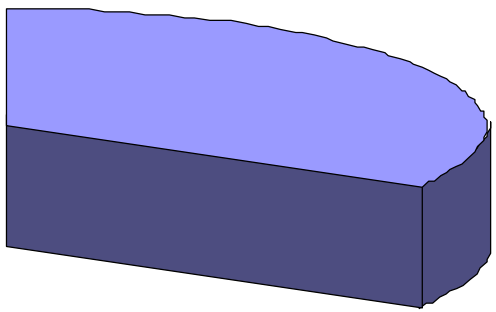
Electrical Apparatus: Portable Radios

Optional accessory: Nil

# Core Elements (2 of 3) of IECEx Certification



## Initial Factory Audit



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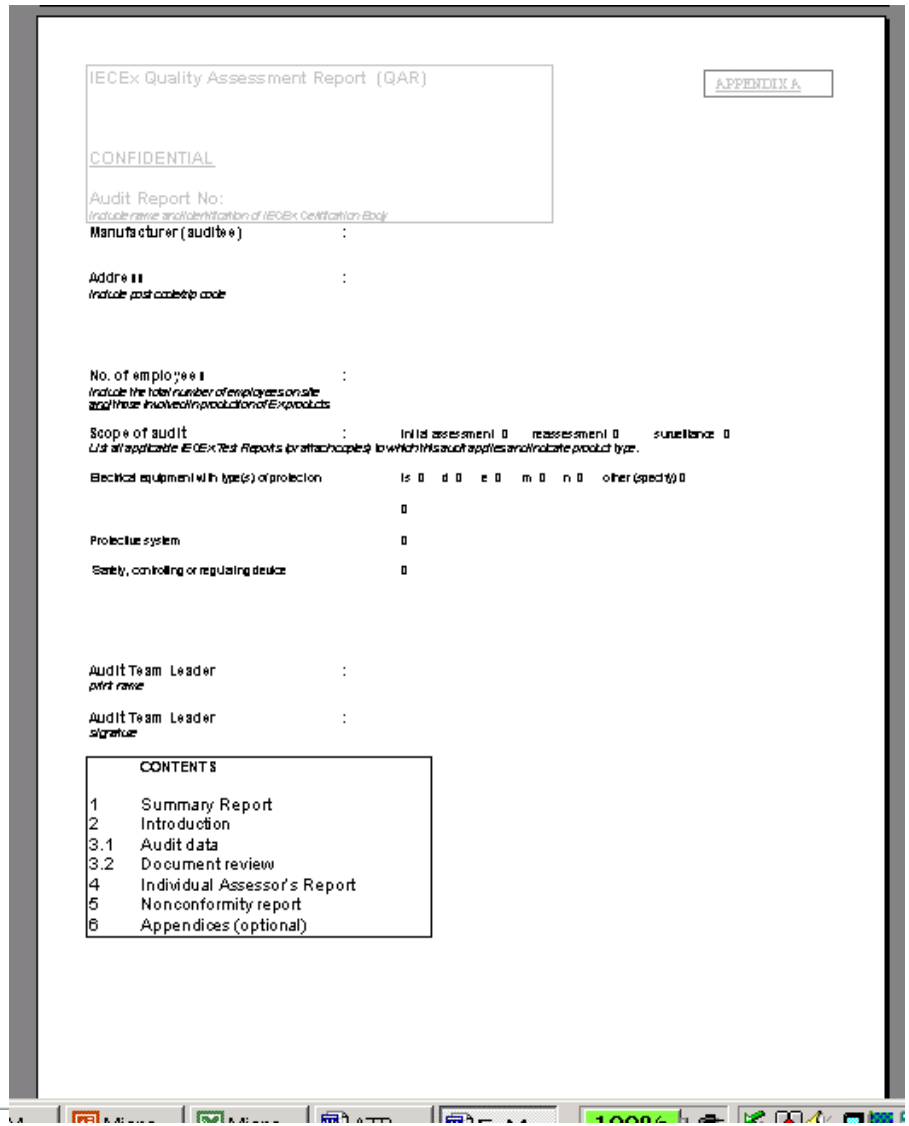
**Document Review and on-site factory audit of manufacturer, by ExCB**

**Provision for previously conducted audits**



IECEx Quality Assessment Report (QAR)

APPENDIX A

CONFIDENTIAL

Audit Report No:
*Include name and identification of IECEx Certification Body*

Manufacturer (auditee) :

Address :
*Include post code/zip code*

No. of employees :
*Include the total number of employees on site and those involved in production of Ex products*

Scope of audit : Initial assessment ☐ reassessment ☐ surveillance ☐
*List all applicable IECEx Test Reports (or attach copies) to which this audit applies and indicate product type.*

Electrical equipment with type(s) of protection Is ☐ d ☐ e ☐ m ☐ n ☐ other (specify) ☐

☐

Protective system ☐

Safety, controlling or regulating device ☐

Audit Team Leader :
*print name*

Audit Team Leader :
*signature*

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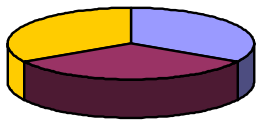
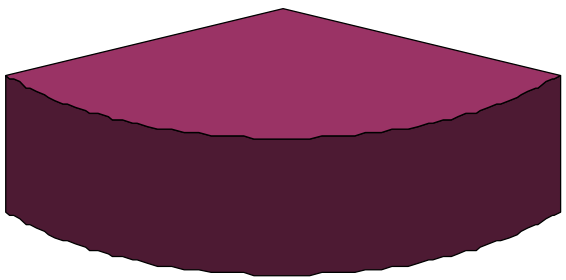
# Core Elements (3 of 3) of IECEx Certification



**Surveillance**
**Factory audit**



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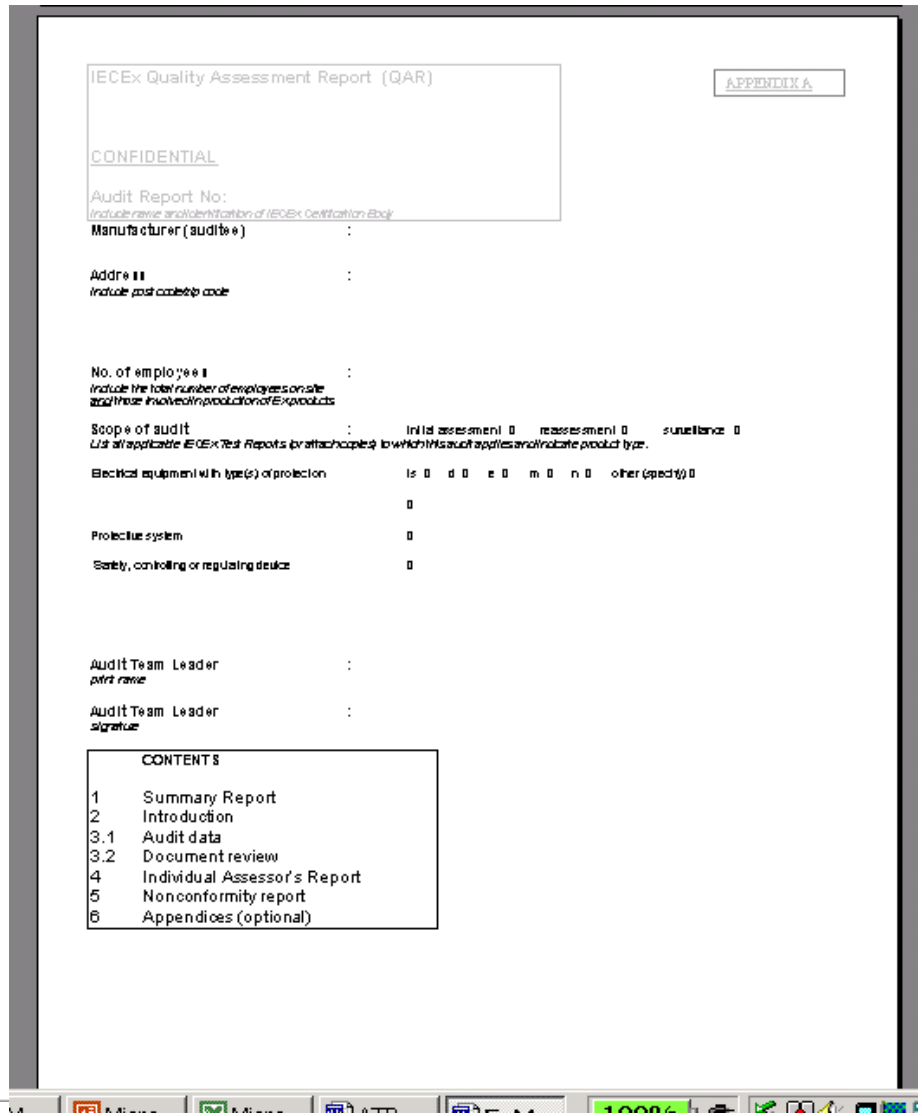
**Review Documentation or other Changes ?????**

**ExCB, IECEx CoC issuer, ensures On-site factory audit is conducted. Other ExCBs may perform**

**Provision for coordination**



IECEx Quality Assessment Report (QAR)

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☐

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*signature*

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1 Summary Report
2 Introduction
3.1 Audit data
3.2 Document review
4 Individual Assessor's Report
5 Nonconformity report
6 Appendices (optional)

# OD/005 Version 2 Notes

- IECEx Certification is an ISO /IEC Guide 67  Type 5 product certification system which includes both type testing and assessment of the quality system
- Most existing manufacturers of Ex equipment already have quality systems in place to assure conformance to certifications.
- Prior to IECEx, other Type 5 programs existed such as those required for national certifications, or ATEX.
- This presentation will include observations of the standard from a manufacturer's viewpoint, addressing key differences from ISO9001.

# OD/005 3 Terms and Definitions

- Clause 3.3 requires tracking of customer complaints which may affect the protection concept.
- Clause 3.5 introduces the concept of Schedule Drawing. (Many manufacturers choose to create special drawings for product certification.)
- Clause 3.6 introduces “related drawings” these can be the actual drawings used to produce the product.
- Clause 3.7 introduces technical documentation. All manufactures of certified product must have some form of this documentation in order to obtain certification.

# OD/005 Quality Management Requirements

- This Operational Document builds on ISO9001:2000
- Often times manufacturers must create additional procedures to insure that their product conforms with their certification and their ExTR.
- Document Control for OD /005 adds the requirement for making sure that related drawings are not changed unless they are in compliance with the certification or schedule drawings

# OD/005 4.2.3 Control of Documents

- Some manufacturers process design changes daily.
- It is necessary in those cases to have procedures in place to assure that no change is processed which would compromise the certification
- An example of how this may be addressed – all new sales orders and any change request for related drawings are reviewed by competent staff and compared with the certification documents to determine whether certificate updates are required.
- Schedule Drawings and Related Drawings must be clearly identified

# OD/005 4.2.3 Control of Documents

- The interrelationship between schedule drawings and related drawings can be by identification by visual marking on the drawings, drawing cross reference indexes etc.
- In this day of electronic bills of material, a possible solution is to refer to the certification and Certificate Number (thereby documenting which ExCB is responsible) on the Bill of Material, and have a verification step in the Engineering Change process for parts to determine the “Where Used” for the part prior to processing the change. This process then let’s the designer know which individual certifications must be reviewed , and which Certifiers must be contacted.

# OD/005 4.2.4 Control of Records

- Manufacturers must maintain adequate records to be able to demonstrate conformity of their product.
- How this is applied may vary from market to market and type of product, but in general, if there is a catastrophic failure, the manufacturer should be able to provide documentation to prove his product met the requirements on the date of manufacturer.
- This document retention may be new for some manufacturer, depending on the product manufactured.

# OD/005 5 Management Responsibility

- In addition to the ISO9001 requirements, it is essential that management of Ex product manufacturing facilities be familiar with the requirements for IECEx.
- 5.4 Planning – Necessitates having production quality plans which address all of the critical features of the certification.
- 5.5 Responsibility and authority – There should be someone with the assigned responsibility to liaise with the ExCB and ExTLs with respect to any change in product or quality systems affecting the certification.

# OD/005 5 Management Responsibility

- Additional procedures may be needed to address:
  - Coordination of activities for Ex products
  - Liaison activity with ExCB and ExTL
  - Review of any Quality System updates
  - Authority to approve changes to related drawings
  - Authority to make concessions
    - Most manufacturers do not authorize concessions which affect protection concepts.
  - Informing customers relative to any X or U conditions on their certificate.

# OD/005 5 Management Responsibility

- Management representative
  - A manufacturer may elect to have one representative for Quality Systems in general, and a more specialized representative for Ex quality systems
  - This management representative must participate in Management Reviews at least every 12 months.
  - Results of internal and external audits relative to Ex products should be presented in the Management Review meetings.

# OD/005 Resource Management

- ISO9001:2000 applies

# OD/005 Product realization

- 7.2.1 Determination of requirements related to the product – the customer must let the manufacturer know what certification is required
- 7.2.2 Review of the requirements – Manufacturers may have procedures to review the customer request and compare with the certification to determine if the customer request can be built as a certified construction.
- 7.4.1 Purchasing- the Ex product manufacturer is ultimately responsible for his product. The manufacturer must have a supplier evaluation process.

# OD/005 Product realization

- 7.4.2 Purchasing Information- the manufacture must clearly identify in his purchasing documents any requirements relating to subcontracted product as required in the ExTR such as process control, inspection or testing.  The manufacturer must have procedures for traceability of specifications back to a specific order. (This could be handled by providing document revision dates for the order specification documents)
- 7.4.3 Verification of purchased products is required if the product can compromise the protection method.

# OD/005 Production and service ops

- 7.5.1 Control of production…may require special inspection plans
- 7.5.3 Identification and traceability- requirements for traceability of Ex products are more rigorous
- 7.5.4 Customer property – if the manufacturer uses customer supplied parts, the manufacture must verify compatibility.
- 7.5.5 Preservation – The manufacturer must provide instructions which include special requirements for maintenance.

# OD/005 Control of monitoring and measurement

- Any instruments used for monitoring or measurement of key protection method  features or determining compliance with routine testing must be calibrated, traceable and be applied appropriately for the application

# OD/005 Measurement, analysis...

- 8.2.1 Customer satisfaction with respect to protection concepts and compliance with the ExTr must be tracked
- 8.2.2 Internal Audits – should normally be 12-14 months, and should address effectiveness of the elements in this quality system. Manufacturers using audit checklists may elect to include these requirements in their checklists.
- 8.2.3 Monitoring and measurement – When routine testing is required by the IECEx CoC, those tests must be performed. Where practical, the Ex Marking label should be applied after passing all requirements

# OD/005 Control of nonconforming product...

- 8.3 The intent is to not ship nonconforming product. The standard requires a method of notifying the customers as well as the ExCB responsible where non-conforming product are found to have been shipped.
- Manufacturers are required to maintain records of all nonconforming product shipped for a period of 10 years.
- 8.3 f) Concessions- Concessions for the product which take it outside the design as defined in the ExTR and technical documentation are not permitted.

# OD/005 Annex A

- Annex A is called up as (informative)
- The best recommendation for manufacturers is to treat this guide as normative, and use the items in this annex as recommended practices.

# Annex B

- Annex B is essential for manufactures utilizing sintered technology.
  - Gives inspection and acceptance criteria for use of sinters.

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

# Closing summary...

In closing, a properly implemented IECEx Quality System, based on OD/ 005 will help improve and control manufacturing processes and help insure product Integrity and safety

Questions?