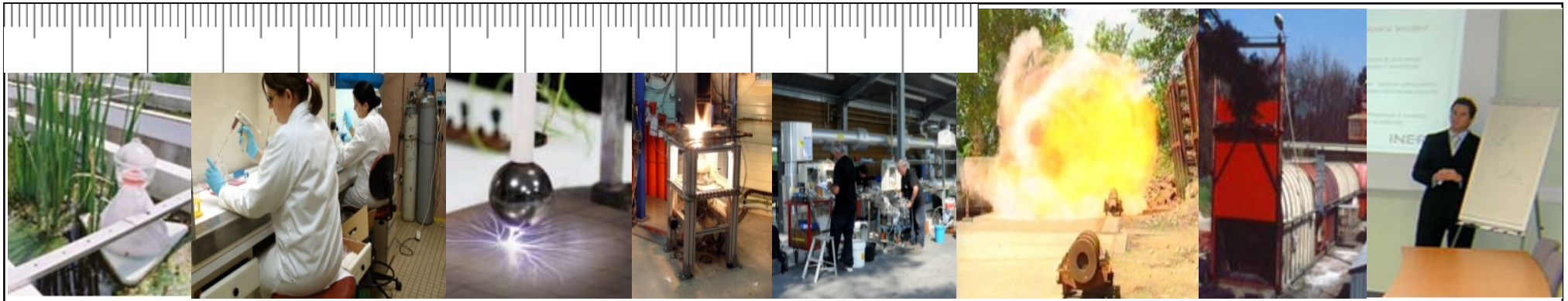

Assessment and Auditing under the IECEx 02 Certified equipment Scheme

Thierry Houeix

Certification Officer & Technical Advisor

IEC IECEx

INERIS

controlling risks for sustainable development

Contents

1. Auditing
2. Issuing QARs,
3. Scheduling of surveillance audits
4. IECEx Mark surveillance
5. Information on the ‘Online’ Certificate of Conformity System (Wal Robson)

Auditing in accordance with the IECEx rules

- Up to now the requirements that the manufacturer has to implement to satisfy the IECEx 02 rules are defined in the Ex OD 005-1.
- In 2007, it was decided to form a new Standard Committee dealing with Non Electrical Equipment and Quality of Equipment Manufacture, named SC31M.
- A Project Team was formed and started the work to write a new ISO/IEC standard based on the EN 13980:2002 standard and the IECEx OD 005.
- In April 2011, the ISO/IEC 80079-34 "Application of quality systems for equipment manufacture" has been published.
- During the last ExMC WG5 in London, it was decided that ISO/IEC 80079-34 is going to replace the OD 005-1.

IEC IECEx

INERIS
controlling risks for sustainable development

Differences between ISO/IEC 80079-34 & OD005-1

The ISO/IEC 80079-34 & OD005-1 have practically the same structure

All specific IECEx terms are replaced by general term, like:

- IECEx Test Report -> test report
- IECEx CoC -> Ex Certificate

The main differences are:

- Clause 2: Reference are made to ISO and IEC standards
- Clause 3: Adding of new definition like Ex equipment, Ex component, Ex Certificate, manufacturer, protective systems, safety devices, body responsible for verification
- Clause 4.2.3 g): Adding of a note to explain that the body responsible for the quality assessment may be different from the body who issued the Ex certificate

IEC IECEx

INERIS controlling risks for sustainable development

Main differences (following)

- Clause 4.2.3 h): Adding of new requirement specifying that the manufacturer shall have a documented process to annually check the validity of all document relating to Ex products
- Clause 4.2.4: The note regarding the fact the manufacturer has to retain adequate quality records to demonstrate conformity of the product is now a requirement.
  A minimum of 10 years for retain records should be applied
  The documents example requiring retention are now given as a requirement of a list of document to retain.
- Clause 5.5.1 g): The responsibilities and authority of the person who reviews the Ex certificate and the technical documentation and who identifies any changes that affect product compliance with the certificate need to be defined.

Main differences (following)

- Clause 6.2.2: All people having an impact on Ex compliance need to receive appropriate training.
- Clause 7.3.7: The Authorised person has to approve any changes that could compromise Ex compliance.
- Clause 7.4.1 f): Move from 5.4.2 the fact that the manufacturer has to facilitate the audit of the supplier if required by the body responsible for the verification of the Ex quality system
- Clause 7.4.3 j): Explanation of what is required for material purchasing (specific analysis certificate or declaration)
- Clause 7.5.2: Move from 8.2.3 of the requirement regarding that special validation need to performed to validate the processes for production

IEC IECEx

INERIS controlling risks for sustainable development

Main differences (following)

- Annex A: Update of the example of what need to be checked for each type of protection
- Addition of example for type of protection ‘t’, gas detectors and flame arrestors
- A.3 Ex d – Flameproof enclosures
  - Castings should be subject to verification that demonstrates conformity, e.g.:
    a) 100 % visual inspection should be done on each part;
    b) wall thickness (including those parts not subject to machining);
    c) flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality).
  - Machining should be subject to verification by either 100 % inspection or statistical techniques as appropriate that demonstrates conformity.

IEC IECEx

INERIS controlling risks for sustainable development

During the audit

The auditor have to perform his assessment by using the following tools:

1. OD 005-1, which define the requirement for IECEx equipment manufacture which will be replaced by ISO/IEC 80079-34 standard.
2. OD 005-2, which give to the auditors some assistance in order to not forget something

These documents are available on:

- http://www.iecex.com/operational.htm

Preparation of the QAR

The QAR prepared by the body responsible for the verification of the quality system shall be based on the F-001 form

The potential NCR shall be based on F-002 form.

All the information required by the F-001 and F-002 forms shall be in the QAR issued.

These forms are available on:

- http://www.iecex.com/QAR_Forms.htm

IEC IECEx

INERIS controlling risks for sustainable development

Issuing of QAR

As the IECEx Certificate of Conformity, the QAR number has to be taken on the "On-Line" Certificate of Conformity System

When the QAR is regarding a Surveillance Assessment or a Re-Assessment:

- Don't take a new number
- Select the QAR that needs to be "Up dated" and select "New Version".
- This is the only way to have an automatic update of the certificate.

➔ See the following presentation of Wal Robson

Scheduling of surveillance audits

As defined in the OD 025, the surveillance audit shall be carried out:

- every 12 months, when the manufacturers is not ISO 9001:2008 certified
- every 18 months, when the manufacturers is ISO 9001:2008 certified

Additional surveillance / assessments may be conducted at the discretion of the IECEx Certification Body based on the manufacturer's performance and results of previous surveillance / audit results.

Scheduling of surveillance audits

Therefore, the ExCB has to plan all surveillance audit:

- to be sure that the audit is performed before the end of the validity date,
- Even if the audit is performed by another ExCB

The validity of the QAR has an incidence on the validity of CoC

- The ExCB who has issued the CoC has to control the validity of the QAR, even it was issued by another body
- In the extreme, the certificate must be suspended

IECEx Mark surveillance

Usually, the initial assessment is performed by correspondence to verify that the manufacturer has to implemented the IECEx 04 rules, as:

- The internal procedure regarding the use, display and control of the IECEx Conformity Mark
- The format of the IECEx Conformity Mark which will be used
- Sign IECEx Conformity Mark the License

After, the surveillance of the IECEx Mark use could be included in the Quality System Audit Surveillance.

IECEx Mark surveillance

What is required to verify during the audit?

Manufacturer's procedures regarding the IECEx Conformity Mark has to be correctly followed, as:

1. The registry of its Ex products carrying the IECEx Conformity Mark exists
2. The IECEx Conformity Mark is only affixed on or in relation to an Ex Product indicates that the Ex Product is covered by an IECEx Certificate of Conformity, listed on the IECEx Conformity Mark Licence.
3. The IECEx Conformity Mark shall not be altered or misused

The result of the IECEx Mark surveillance could be included in the QAR

Thank you very much for your attention!

Thierry Houeix
Certification Officer & Technical Advisor
INERIS French National Institute for Industrial Environment and Risks
BP n°2 Parc technologique ALATA F-60550 Verneuil-en-Halatte
Tel +33 (0)3 44 55 64 88 Fax +33 (0)3 44 55 67 04
http://www.ineris.fr Email : Thierry.Houeix@ineris.fr

IEC IECEx

INERIS
controlling risks for sustainable development