IECEx Auditing Practices for ISO/IEC 80079-34+ISO 9001 coverage

1. Approach when Auditing of both ISO 9001 Certified + Non Certified Companies
2. Planning / Audit conduct / Reporting / Surveillance according to IECEx requirements
3. QAR registration on IECEx website

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ISO/IEC 80079-34 vs OD 005-1

In 2011, Management Committee have determined that the following transition arrangements shall apply to enable smooth transition for the previously used IECEx Operational

1. New Applicants – Until 31 December 2014, Audits may be conducted according to either IECEx OD 005-1 or ISO/IEC 80079-34 but all subsequent audits shall be conducted using ISO/IEC 80079-34.
2. Surveillance audits and re-assessments : From 1 January 2012, the next surveillance audit or re-assessment may be conducted using either IECEx OD 005-1 or ISO/IEC 80079-34. However, after that audit all following surveillance audits shall be conducted using ISO/IEC 80079-34.

Extract ExTAG/247/Inf

How to read ISO/IEC 80079-34?

- The ISO/IEC 80079-34:2011 is based on the same structure as ISO 9001:2008
- In order to not repeat the text of ISO 9001 in ISO/IEC 80079-34, for each clause it was decided to specify that the relating clause of ISO 9001 applies.
- This means that the two standards have to be read jointly, together

Example:

4 Quality management system

4.1 General requirements

Subclause 4.1 of ISO 9001:2008 applies, with the following addition:

The quality system shall ensure that the product conforms to the type described in the Ex certificate and the technical documentation.

ISO 9001 Certified + Non Certified Companies

Four types of manufacturers can be found when the ExCB prepares the quality audits:

1. Manufacturer with quality system, ISO 9001 certified by an ILAC/IAF Certification Body
2. Manufacturer with quality system, ISO 9001 certified by an non ILAC/IAF Certification Body
3. Manufacturer with quality system, non ISO 9001 certified
4. Manufacturer with no quality system

Following these four types what does the ExCB have to consider?

Manufacturer with quality system, ISO 9001 certified by an ILAC/IAF Certification Body

When the ISO 9001 requirements have been already checked by an ILAC/IAF Certification Body and if the certificate or the report and findings are available, the ExCB does not have to check in details the ISO 9001 requirements.

Only the specific Ex requirements written in ISO/IEC 80079-34 have to be checked.

The OD 025 recommends the following time for the audit:

	AUDITOR(s) TIME ON SITE IN PERSON DAYS		
No. OF PROTECTION CONCEPTS LISTED ON THE ON-LINE NOTIFICATION	25 OR LESS Ex PERSONS ON SITE	100 OR LESS Ex PERSONS ON SITE	100 OR MORE Ex PERSONS ON SITE
1	1	1	1 - 2
2-3	1 – 1 1/2	1 – 1 1/2	2
4-5	2	2 - 3	3 - 4
6+	2 - 3	3	3 - 4

Manufacturer with quality system, ISO 9001 certified by an non ILAC/IAF Certification Body

When the ISO 9001 requirements have been already checked but by a non ILAC/IAF Certification Body, it is considered that this certification body is not internationally recognised.

Therefore the report can not be considered, the ExCB have to check all requirements written in ISO/IEC 80079-34 including ISO 9001 requirements

The OD 025 recommends the following time for the audit:

	AUDITOR(s) TIME ON SITE IN PERSON DAYS		
No. OF PROTECTION CONCEPTS LISTED ON THE ON-LINE NOTIFICATION	25 OR LESS Ex PERSONS ON SITE	100 OR LESS Ex PERSONS ON SITE	100 OR MORE Ex PERSONS ON SITE
1	2	2	2 - 3
2-3	2 - 3	2 - 3	3
4-5	2 - 3	3 - 4	3 - 4
6+	3 - 4	4	5

Manufacturer with quality system, non ISO 9001 certified

When the ISO 9001 requirements have not been checked by another Certification Body, the ExCB have to check all requirements written in ISO/IEC 80079-34 including ISO 9001 requirements

The OD 025 recommends the following time for the audit:

	AUDITOR(s) TIME ON SITE IN PERSON DAYS		
No. OF PROTECTION CONCEPTS LISTED ON THE ON-LINE NOTIFICATION	25 OR LESS Ex PERSONS ON SITE	100 OR LESS Ex PERSONS ON SITE	100 OR MORE Ex PERSONS ON SITE
1	2	2	2 - 3
2-3	2 - 3	2 - 3	3
4-5	2 - 3	3 - 4	3 - 4
6+	3 - 4	4	5

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Manufacturer with no quality system

When the manufacturer has no quality system, it is not possible for him to comply with ISO/IEC 80079-34 requirements.

The only possibility for him to have its products certified in accordance with IECEx rules is to apply to the IECEx Unit Verification Certificate:

- Available for a defined number of items under a single production run.
- The routine tests are performed by the ExTL or in his presence (witness testing)

Auditing process

The main steps for an audit according to IECEx requirements are:

- Preparation and Planning
- Audit conduct
- Reporting
- Audit Follow-up
- Surveillance

Planning

An audit plan has to be prepared and communicated to the manufacturer in order to inform him about:

- the audit criteria and any reference documents (such as ISO/IEC 80079-34 and if audited: ISO 9001);
- the dates and places where the on-site audit activities are to be conducted;
- the identification of the organisational and functional units and processes to be audited;
- the expected time and duration for audit on-site activities, including meetings with the auditee's management and audit team meetings;
- the identification of the auditee's key representative participating in the audit;
- the audit report topics (including any methods of nonconformity gradings), format and structure, expected date of issue and distribution;

Audit conduct

It is recommended to conduct an IECEx audit as followed:

- Opening meeting: after introducing the participant, a confirmation of the audit objectives, scope and criteria have to be formulated;
- Collecting and verifying information;
- Communication during the audit: During the audit, the audit team leader should periodically communicate the status of the audit and any concerns to the auditee and audit client, as appropriate.
- Preparation for the closing meeting: review the audit findings and any other appropriate information collected during the audit and prepare a list of audit findings, if appropriate
- Closing meeting

Reporting

The audit team leader is responsible for the preparation and contents of the audit report.

The audit report should provide a complete, accurate, concise and clear record of the audit and should contain audit conclusions on issues such as the following, if within the audit objectives and scope:

- When ISO 9001 has been audited in addition with ISO/IEC 80079-34, this has to be clearly written in the report
- The templates which has to be used are:
  - IECEx_F-001_V1_Audit_Report for the report and
  - IECEx_F-002_V1_NCR_Master for the non-conformities

All shall be made for the audit report to be submitted to the audit client within 1 month from the date of the audit.

Audit follow-up

The ExCB shall review the audit report, any non conformities raised and the manufacturer's responses, and then the ExCB should approve the report.

The IECEx Certification Body should have a unified method of addressing the actions required following an audit.

An accepted method is described in OD025 depending on no non-conformity, minor non-conformities, major non-conformities and many major non-conformities.

Surveillance

Surveillance assessments shall be carried out as follows:

- For manufacturers without a certified ISO 9001:2008 Quality System, surveillance audits should be conducted every 12 months.
- Manufacturers with a Qualified ISO 9001:2008 Quality System, surveillance audits should be carried out every 18 months.

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

QAR registration on IECEx website

ExCB shall register the QAR on the official IECEx Website in accordance with Operational Document OD 011 Part 2.

This On-line registration provides the following summary information, which is publicly available.

- QAR reference number
- ExCB conducting the audit
- Audit Client
- Manufacturer and audit location(s)
- IECEx Certificates of Conformity covered by the audit report
- Details of Major Non-conformances raised (if any)
- Comments of the ExCB if any:
  - A proposal could be to write ISO9001 certificate number and CB issuer
  - A proposal could be to indicate the complete assessment of ISO/IEC 80079-34 including ISO 9001

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Thank you for your attention

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