**INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE
IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

Title: Draft Amendment to IECEx OD 009 - Operational Document - Procedures for the Issuing of IECEx Certificates of Conformity, IECEx Test Reports and IECEx Quality Assessment Reports

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## To: Members of the IECEx Management Committee, ExMC

**Introduction**

This document contains a proposed amendment to Section 4 of IECEx OD 009, as proposed by ExMC WG1 arising from their May 2019 meeting.

The proposed amendment addresses concerns raised over the content of IECEx QARs and that of the QAR Summary shown on the On-Line Certificate system.

This is now submitted for consideration and approval during the 2019 ExMC meeting for publication as Edition 4.3

Proposed changes affect Section 4 and therefore this document only contains those areas affected by these proposed changes, shown using the tracking tools.

**IECEx Secretary**

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**Proposed Revisions of IECEx OD 009, Edition 4.2, Section 4**

| **Step** | **Section 4- Surveillance Audits - Procedures for Maintaining an IECEx Certificate of Conformity - Description of Activity** | **Related Documents** | **By Whom** | **Notes/Comments** |
| --- | --- | --- | --- | --- |
| **1** | IECEx Certificate of Conformity verified as valid by the ExCB that issued the IECEx CoC (ExCB #1) and confirms details on IECEx Certificate website are current and correct, eg manufacturing location(s), product identifier etc.In principle, the procedures detailed in Section 3 apply when conducting surveillance audits of manufacturers with those detailed in this Section 4, providing additional information. | IECEx 02IECEx CoC | ExCB that issued the IECEx CoC (ExCB #1) | The previous OD 005-1, Part 1 has been replaced by ISO/IEC 80079-34However OD 005-2, Part 2 provides a checklist for the requirements listed in ISO/IEC 80079-34ExTAG/247A/Inf sets out the transitional arrangements from OD 005-1 to ISO/IEC 80079-34 |
| **2** | ExCB that issued the IECEx CoC (ExCB #1) shall verify that a surveillance audit has been conducted or shall arrange to conduct the surveillance audit.Where the previously issued QAR, which is linked to the IECEx CoC, was issued by another ExCB (ExCB #2 as an alternative EXCB that issues a supporting QAR Summary), then (ExCB #1) shall verify that a surveillance audit has been conducted or shall request that the other ExCB conducts a surveillance audit. As an alternative, the holder of the IECEx CoC may arrange for another ExCB (ExCB #2 as an alternative ExCB that issues a supporting QAR Summary) to conduct the surveillance audit by informing the ExCB that issued the IECEx CoC (ExCB #1), providing that the scope of the alternative ExCB matches the scope of the IECEx CoC. In such cases changing to another ExCB for the purposes of surveillance audits requires the issue of a new QAR and a Supplementary (New Issue) of the IECEx CoC by the ExCB that issued the original IECEx CoC (ExCB #1), showing the change in ExCB conducting the surveillance audit as the reason for the new Issue of the IECEx CoC. In such instances the new ExCB (ExCB #2) conducting the surveillance visit shall treat the “transfer” as a new/initial assessment.This ensures full traceability of the system | ExCBs own Quality System and OD 025F-001 | ExCB that issued the IECEx CoC (ExCB #1) |  |
| **3** | Review of the manufacturer’s quality documentation to ensure that any changes since the last audit complies with the requirements of ISO/IEC 80079-34. This review of documentation may take place either prior to the site visit or as part of the site visit and audit of the manufacturer’s premises | ISO/IEC 80079-34 OD 025 | ExCB conducting the audit (which may be ExCB #1 or ExCB #2) | In most cases it is more productive to conduct this document review at the manufacturer’s premises as part of the on-site audit |
| **4+8a****4+8b** | Where the document review reveals non-compliance with the requirements of ISO/IEC 80079-34, the ExCB shall determine whether the non-conformance is such that they need correction prior to continuing with the site audit.Corrective action by the manufacturer or audit staff shall be documented. |  ISO/IEC 80079-34 OD 025 | ExCB conducting the audit  |  |
| **5** | Following the document review, the ExCB shall carry out the site audit in accordance with OD 025  | OD 025 ISO/IEC 80079-34  | ExCB conducting the audit  |  |
| **6** | A Quality Assessment Report, QAR shall be completed by the ExCB conducting the audit  | OD 025F-001 | ExCB conducting the audit  | F-002 provides a format for issuing NCRs |
| **7** | Prior to issuing and registering the QAR Summary on the IECEx On-line Certificate System, the ExCB shall conduct an internal independent review of the prepared QAR using a person not involved in the assessment. This review shall verify at least the following items:* That a complete audit as planned had been conducted
* Necessary documentation and records available
* Confirmation that the auditor/team was appropriate.

  | OD 025 ISO/IEC 80079-34 IECEx 02 | ExCB that issues the IECEx QAR Summary  |  |
| **8, 8a, 8b** | Where the review of the QAR reveals that the audit was incomplete, not conducted in accordance with OD 025 or contains errors, the matter is to be raised with the audit staff and applicant listed on the IECEx Certificate of Conformity, as appropriate.The purpose of the QAR review is for the ExCB to be assured that they have sufficient objective evidence that the manufacturer’s quality system and associated quality plans enable Ex products (as listed on the IECEx CoC) to be produced in compliance with the International Standards listed on the IECEx CoC This review may require a revised QAR to be issued or even a subsequent audit of the manufacturer where it is identified that the audit was incomplete or insufficient or unqualified auditor(s) used.  | OD 025IECEx 02ISO/IEC 80079-34  | ExCB conducting the audit | Where a subsequent audit is required due to errors on the part of the ExCB, such audits may need to be conducted at the ExCB’s own expense |
| **9** | QAR may be issued to the applicant listed on the IECEx CoCs. | OD 025 | ExCB conducting the audit |  |
| **10, 11 +12** | The ExCB conducting the audit shall review proposed corrective actions relating to Non Conformance Reports (NCRs) in terms of:* The time to implement such action is appropriate
* Whether a follow up audit is necessary or can verification be handled at the next scheduled surveillance audit

It should be noted that where Major NCRs are raised consideration must be given to the likelihood of non-complying product being released to the market |  ISO/IEC 80079-34 OD 025 | ExCB conducting the audit | Contact the IECEx Secretariat for any questions or concernsIn the situation of a Major NCR being raised it is recommended that the ExCB conducting the audit advise ( for information purposes only at this stage) any other ExCBs that have issued CoCs based on the relevant QARs of the fact that Major NCR has been raised |
| **12a+12b** | The ExCB that issued the IECEx CoC (ExCB #1) will need to determine whether the IECEx CoC needs to be suspended or cancelled. Given the seriousness of the situation, prompt action by the ExCB is required. This includes, notifying the applicant listed on the IECEx CoC in writing and the IECEx Secretariat requesting that the IECEx CoC be suspended or withdrawn  | IECEx 02 | ExCB that issued the IECEx CoC (ExCB #1) | Contact the IECEx Secretariat for any questions or concerns |
| **13** | Where ExCB conducting the assessment is satisfied that a full and complete surveillance assessment/audit has been completed demonstrating compliance with the requirements of ISO/IEC 80079-34 and OD 025, the ExCB that issued the IECEx CoC (ExCB #1) shall confirm that the details as listed on the IECEx website are accurate and up to date.The ExCB that issues and registers the QAR Summary on the IECEx On-line Certificate System shall up-date the QAR registration on the IECEx website. OD 011 Part 2 provides detailed guidance for registering surveillance audits on the IECEx On-Line Certificate System. The ExCB that issued and registered the QAR Summary on the IECEx On-line Certificate System shall then schedule the next surveillance audit visit, in accordance with OD 025. | IECEx 02OD 025OD 011 Part 2 | ExCB conducting the audit | Contact the IECEx Secretariat for any questions or concernsOnly QARs that indicate compliance with IECEx requirements, even if minor NCRs are issued, shall be registered on the IECEx Website.QARs that show Major or significant problems shall NOT be registered on the IECEx website |