Procedures for the issuing of an IECEx Quality Assessment Report (QAR)

A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Nurgül Çınar	02.05.2023

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
2	The references F-012, F-013, OD 204, and OD 205 have been removed. Article 8.2.9 refers to the latest version of OD 060. Removed from 8.1.10 referring to another ExCB conducting the audit. Reference was made to OD 203 by adding clause 8.2.13.	NCR3 and NCR10 in IECEx audit report.	02.05.2023	02.05.2023
1	According to NCR7 in the internal audit performed on 17.03.2023, the procedure has been revised.	Internal audit nonconformity.	28.03.2023	28.03.2023
0	Creation of documentation within the scope of IECEx.	First Publication	16.03.2023	16.03.2023

5. Purpose and Scope

The purpose of this document is to conduct assessment of the conformity of the QMS of manufacturer, surveillance visits and to prepare IECEx quality assessment report (QAR) relating Ex equipment by SZUTEST for compliance with ISO/IEC 80079-34.

According to **Table 1 — Building a product certification scheme** in **ISO/IEC 17067** standard

Table 1 — Building a product certification scheme

Conformity assessment functions and activities (a) within product certification schemes		**Types of product certification schemes (b)**							
		1a	**1b**	**2**	**3**	**4**	**5**	**6**	***N*** **(c) (d)**
I	**Selection**, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	**Determination of characteristics**, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	**Review** Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	**Decision on certification** Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	**Attestation, licensing**								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	b) granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) issuing a certificate of conformity for a batch of products	x							
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.	x	x	x	x	x	x		
VI	**Surveillance**, as applicable (see 5.3.4 to 5.3.8), by:								
	a) testing or inspection of samples from the open market	x	x	x					
	b) testing or inspection of samples from the factory	x	x	x					
	c) assessment of the production, the delivery of the service or the operation of the process	x	x	x	x				
	d) management system audits combined with random tests or inspections	x	x						

(a) Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.
(b) An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.
(c) A product certification scheme includes at least the activities I, II, III, IV and V a).
(d) The symbol *N* has been added to show an undefined number of possible other schemes, which can be based on different activities.

This procedure covers the process shown step by step for the preparation of the relevant IECEx QAR in SZUTEST, in case of no obstacles, errors, or non-conformity related to QAR considering the relevant standards, regulations, and OD documents.

6. Terms and Definition
The following terms and definitions is specified in order to good understanding the procedure.

IECEx: International Electrotechnical Commission Explosive
ISO: International Standard Organization

OD: Operational Document
Ex certification body (ExCB): A body which has been accepted according to these Rules and to issue IECEx CoCs, IECEx QARs and to endorse IECEx test reports Explosive Certification Body
Ex Management Committee (ExMC): The body which administers the operation of the IECEx System and is responsible to the Conformity Assessment Board of the IEC
IECEx certificate of conformity (CoC): Document issued under these Rules that conveys the assurance of the conformity of a product with the specified standard or standards
IECEx test report (ExTR): A document issued by an ExTL that includes a documented record of the obtained test and assessment results for endorsement by an ExCB, associated with the issuing ExTL, demonstrating that the examined product type is in conformity with specified Standards
IECEx quality assessment report (QAR): A document that presents the results of an assessment of the quality management system (QMS) of a manufacturer or manufacturing location by an ExCB, to the requirements of the IECEx Certified Equipment Scheme
Ex testing laboratory (ExTL): A testing laboratory which is accepted according to these Rules, and which performs tests and assessments and compiles IECEx test reports for endorsement by the associated ExCB
Applicant: A manufacturer or a person which acts on behalf of the manufacturer and who applies to an IECEx certification body (ExCB) for obtaining, suspending, or cancelling an IECEx certificate of conformity, or for obtaining an IECEx test report or an IECEx quality assessment report
Manufacturer: An organization, situated at a stated location or stated locations, that carries out or controls such stages in the design, manufacture, assessment, handling, and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection
NCR: A nonconformance report or NCR is a construction-related document that addresses specification deviation or work that fails to meet quality standards.
IAF: The International Accreditation Forum, Inc. is the world association of Conformity Assessment Accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programs of conformity assessment.
Audit: An activity based on a systematic, independent and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.
NOTE: Whilst “audit” applies to management systems, “assessment” applies to conformity assessment bodies as well as more generally. The assessment process includes auditing.
Product Audit: An audit to determine whether the product is in compliance with the type described in the IECEx Assessment and Test Report.
Audit Criteria: Set of policies, procedures or requirements used as a reference.
Audit Evidence: Records, statements of fact or other information, relevant to the audit criteria and which are verifiable.
NOTE: Audit evidence can be qualitative or quantitative.
Audit Finding(s): Result of the evaluation of the collected audit evidence against audit criteria.
NOTE: Audit findings can indicate either conformity or nonconformity with audit criteria.
Audit Conclusion(s): Outcome of an audit, reached by the audit team after consideration of the audit objectives and all audit findings.
Audit Client: Organisation or person requesting an audit.
Auditee: Organisation being audited.
Auditor: Person with the competence to conduct an audit .
Audit Team: One or more auditors conducting an audit.
NOTE 1: One auditor of the audit team is appointed as audit team leader.
NOTE 2: The audit team can include auditors-in-training and, where required, technicalexperts.
NOTE 3: Observers can accompany the audit team but do not act as part of it.
Technical Expert: Person who provides specific knowledge or expertise to the lead auditor with respect to the subject being audited.
NOTE 1: Specific knowledge or expertise includes those on the organisation, process, product, or activity to be audited, as well as language or cultural guidance.
NOTE 2: A technical expert does not act as an auditor in the audit team.
Audit Programme: Set of one or more audits planned for a specific time frame and directed toward a specific purpose.
Audit Plan: Description of the on-site activities and arrangements for an audit.
Audit Scope: Extent and boundaries of an audit.
NOTE: The scope typically includes a description of physical locations, organisational units, activities and processes, as well as the time period covered.
Competence: Demonstrated capability to apply knowledge and skills.
Initial Assessment: Activities related to the notification of a manufacturer to determine whether the manufacturer and applicable manufacturing locations(s) and production sites(s) meet all the requirements of the relevant clauses of the specified standard necessary for granting notification as to whether they have effectively implemented, including documentation review, site audit at the manufacturers’ premises, manufacturing locations(s) and production site(s), preparation and consideration of the audit report and other relevant activities necessary to provide sufficient information to allow a decision to be made as to whether notification shall be granted. Audit results shall be recorded on a Quality Assessment Report (QAR).
Surveillance: Surveillance of a manufacturer’s quality system takes place on a regular basis as defined in this document. The surveillance audit should be product based with audit results being recorded on an approved Surveillance Audit Report. The purpose of surveillance programmes is to:

- Verify that the approved quality system and associated product quality plans, continues to be implemented; and:
- To consider the implications of any changes to the system, initiated as a result of changes in the manufacturers operation; and
- To confirm continued compliance with ISO/IEC 80079-34.

• To evaluate any addition manufacturing, suppliers, sub-suppliers where critical requirements of ISO/IEC 80079-34 are being performed.

Re-Assessment: To verify overall continuing effectiveness of the manufacturer's quality system in its entirety. In most cases it is unlikely that a period greater than three years for periodic re-assessment of the manufacturer's quality system would satisfy this requirement. The re-assessment should provide for a review of past performance of the system over the period of the notification. The re-assessment program shall take into consideration the results of the above review and shall at least include a review of the quality system documents and a site audit (which may replace or extend a regular surveillance audit). It shall at least ensure;

• the effective inter-action between all elements of the system,
• the overall effectiveness of the system in its entirety in the light of changes in operations,
• demonstrated commitment to maintain the effectiveness of the system.

Quality Assessment Report: Upon the acceptance of the assessment, the Certification Body shall. Issue an IECEx Quality Assessment Report (QAR) and have this registered on the official IECEx Website www.iecex.com

7. Responsibilities

This procedure is operated by the authorized person (audit team leader, auditor) who is assigned by SZUTEST according to the PR.EX.01 ExCB Personnel Procedure.

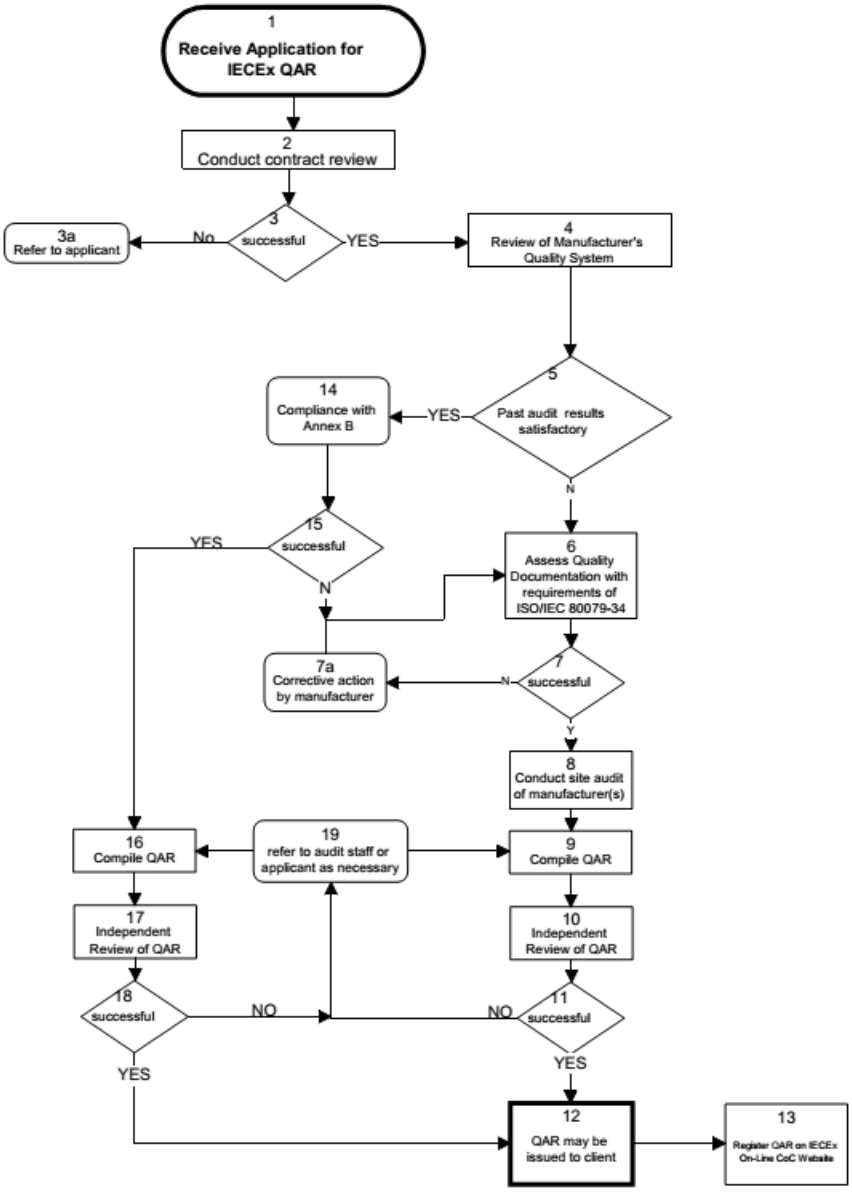
• IECEx Certificate of Conformity
IECEx OD 009 (Procedure)
IECEx-OD-011-1 (Stage 1: General Information Creating IECEx COC From Website)
IECEx-OD-011-2 (Stage 2 : Creating IECEx Equipment COC from Website)
IECEx-OD-209 (Suspension, Cancellation, Reinstatement of COC)
IECEx-02 (Rules of Procedure)
IECEx-OD-210 (Modular Combination)
IECEx-OD-280 (Non-electrical Equipment and Protective System)

• IECEx Test Report (ExTR)
IECEx Form F-005 (IECEx Quality Assessment Attendance List)
IECEx-02 (Rules of Procedure)
IECEx OD 009 (Procedure)
IECEx OD 010-1 (Development and posting of blank)
IECEx OD 010-2 (Procedures and guidance)
IECEx-OD-011-1 (Stage 1: General Information Creating IECEx COC From Website)
IECEx-OD-011-2 (Stage 2 : Creating IECEx Equipment COC from Website)
IECEx OD 017 (Drawing and Documentation)
IECEx OD 019 (Participation and System Fees)

• IECEx Quality Assessment Report (QAR)
IECEx Form F-001 (Audit Form)
IECEx Form F-002 (Non-Conformity Report)
IECEx OD 009 (Procedure)
IECEx-OD-011-1 (Stage 1: General Information Creating IECEx COC From Website)
IECEx-OD-011-2 (Stage 2 : Creating IECEx Equipment COC from Website)
IECEx-OD-025 (Management of Assessment and Surveillance Manufacturer's QS)
IECEx-OD-026 (Qualifying Lead Auditors and Auditors)
IECEx-OD-208 (Audit Checklist for Manufacturer)
IECEx-OD-250 (Management of QAR)
IECEx-02 (Rules of Procedure)
IECEx-OD-005-3 (QS Requirements for Manufacturer)

8. Method

8.1. Method of the issuing of an IECEx Quality Assessment Report (QAR)



8.1.1. Step 1 – Receive Application for IECEx QAR

Application received in accordance with PR.EX.02 Evaluation of the Application and Contract Procedure.
For applications for IECEx Unit Verification Certificates of Conformity, refer to PR.EX.09 Procedures for the issuing of IECEx Unit Verification Certificate.

Application received in accordance with IECEx 02.

Related Documents : IECEx 02
Related Forms : FR.EX.01 Application Form

8.1.2. Step 2 – Conduct Contract Review

Contract review to be conducted by the Technical Manager receiving the application, in accordance with the SZUTEST's own Quality System and as required by ISO/IEC 17065, refer to PR.EX.02 Evaluation of the Application and Contract Procedure.

Contract review shall include:

- A review to ensure that the application is within the scope of acceptance of the SZUTEST and associated ExTL
- Whether the manufacturer has an established quality management system
- Whether a surcharge applies for manufacturers from nonmember countries (Refer to IECEx OD 019)
- Estimation of costs and time to complete project
- Determination of any special requirements, eg travel for site audit etc.
- Agreement on method and system of payment by applicant, in accordance with SZUTEST’s own policy and quality system

The results of the contract review shall be documented and recorded.
Related Documents : SZUTEST Quality System, ISO/IEC 17065
Related Forms : FR.EX.02 Contract Form

8.1.3. Step 3 – Successful?

SZUTEST shall only proceed where the contract review has been successfully completed..

8.1.4. Step 3a – Refer to Applicant & Product Certification Auditor & Open the Project in SZUTEST APP System

Where unsuccessful, SZUTEST shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the SZUTEST's scope of IECEx acceptance does not cover the application.

Also, the Technical Manager assigns the Product certification Auditor to carry out the certification Project.
Related Form: FR.EX.25 Audit Team Certification Committee Assigning Form

8.1.5. Step 4 – Review of Manufacturer's Quality System

The SZUTEST must review the manufacturer's quality management system to ensure compliance with ISO/IEC 80079-34 by either:
1) Conduct a site audit of the manufacturing location(s); or
2) For manufacturers previously audited, conduct a document review of past audits and other documentation to cover new products, review the QAR summary report at the IEC Ex WEB site to ensure, that the product type, type of protection and manufacturing locations and all IECEx CoCs are covered by a valid QAR.

Situation 2) above takes into account where the manufacturer has been previously audited for the purposes of a previous IECEx application. When conducting a review according to situation 2) above, the SZUTEST receiving the application must consider at least the following:

- The scope and product types covered by the previous audit
- The time since the previous audits and where more than 1 year ago should consider that a new audit may be required
- The results of the past audits
- Any changes in management, manufacturing etc since the last audit

For this reason, SZUTEST's Product Certification Auditor as Lead Auditor shall prepare the audit plan and record it to FR.EX.27 Audit Plan. SZUTEST Auditors shall prepare the Audit report according to FR.EX.06 IECEx Quality Assessment Report (QAR) Audit Form (IECEx-F-001).

Related Documents : ISO/IEC 80079-34, IECEx OD 025
Related Forms : FR.EX.27 Audit Plan, FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.6. Step 5 – Past audit result satisfactory

Where an audit of the manufacturer has taken place by the SZUTEST for a related program and within the last 18 months, such results may be used where the applicant wishes to do so.

To rely on past audits, for new applications, it is necessary to demonstrate that the production of equipment, to be covered by new Certificates, was included as part of the previous audit.

Related Documents : IECEx-OD-009 Annex B

8.1.7. Step 6 – Assess Quality Documentation with requirements of ISO/IEC 80079-34

Assessment of the manufacturer's quality management system procedures that relate to the manufacture of Ex products to be covered by new IECEx Certificates of Conformity. Generally this will relate to the detailed product quality plans. The assessment shall ensure that all requirements contained in ISO/IEC 80079-34, as they relate to the product, are adequately addressed by the Manufacturer's quality system procedures and work instructions.

This step may also be termed the "Documentation Review"

The document review may be conducted prior to the on-site audit, at the SZUTEST premises or on-site at the manufacturers premises as part of the on-site audit.

Where different manufacturing sites are involved the SZUTEST should satisfy itself that the same quality plans are used.

If not then each manufacturing location must be treated separately with separate assessments and site audits for each location.

Related Documents : ISO/IEC 80079-34, IECEx OD 025, IECEx OD 026
Related Forms : FR.EX.27, FR.EX.25, FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.8. Step 7+7a – Successful? / Corrective action by manufacturer

Relevant manufacturer's quality system documentation is to be reviewed to verify that documentation complies with the requirements of ISO/IEC 80079-34.

Where serious deficiencies in the manufacturer's documented quality plans may give rise to non-complying product being produced, these shall be raised by the SZUTEST as majör nonconformances and the applicant and manufacturer are required to take action to correct this situation (usually by the introduction or amendment of quality plans), prior to proceeding with the issue of an IECEx Certificate of Conformity.

Where non-compliance with various clauses of ISO/IEC 80079-34 are judged to be of a minor nature by the SZUTEST, the process of on-site auditing may continue.

IECEx OD 025 includes a checklist of ISO/IEC 80079-34's documentation requirements.

Related Documents : ISO/IEC 80079-34, IECEx OD 025, IECEx OD 026
Related Forms: FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.9. Step 8 – Conduct site audit of manufacturer(s)?

The SZUTEST conducts on-site audit with preparing Audit plan FR.EX.27 Audit Plan.

This on-site audit shall seek to verify that relevant quality system procedures and work instructions are in place and that there are records and evidence to demonstrate that the requirements of ISO/IEC 80079-34 are being met by the manufacturer(s).

IECEx OD 025 provides guidance in the management of assessments of manufacture's quality system and shall be used by all ExCBs.

IECEx OD 026 provides guidelines for the qualification of ExCB auditors conducting IECEx audits.

IECEx F-001 and IECEx F-002 are IECEx QAR forms and Nonconformity Report Forms respectively, available from the IECEx website at www.iecex.com/QAR_Forms.htm.

Where the Ex product is manufactured in different locations, especially different countries each location shall be audited.

Related Documents : ISO/IEC 80079-34, IECEx OD 025, IECEx OD 026, IECEx F-001, IECEx F-002
Related Forms : FR.EX.27, FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.10. Step 9 – Compile QAR

A Quality Assessment Report (QAR) of the assessment/audit of the manufacture's quality system, including site audit, shall be compiled by the SZUTEST.

Where serious deficiencies in the manufacturer's documented quality plans may give rise to non-complying product being produced, these shall be raised by the SZUTEST as major onconformances and the applicant and manufacturer are required to take action to correct this situation (usually by the introduction or amendment of quality plans), prior to proceeding with the issue of an IECEx Certificate of Conformity.

Where non-compliance with various clauses of ISO/IEC 80079-34 are judged to be of a minor nature by the SZUTEST, the process may continue.

SZUTEST auditor needs to prepare the FR.EX.29 Final Report.

Related Documents : ISO/IEC 80079-34, IECEx OD 025
Related Forms : FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report, FR.EX.29 Final Report

8.1.11. Steps 10 - Independent review of QAR

An independent review of the QAR shall be conducted within the SZUTEST to whom the original application was made.

The independent review shall be conducted by a staff member of the SZUTEST that is not responsible for the audit

This independent review is to ensure that a complete assessment and audit has taken place and that the recommendations are in line with the audit findings and any NCRs and related corrective actions.

The Technical Manager shall record the result of certification decision in FR.EX.30 Review and Certification Decision Form.

Related Documents : SZUTEST Quality System,
Related Forms : FR.EX.30 Review and Certification Decision Form, FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.12. Step 11 – Successful?

The SZUTEST to which the application for an IECEx CoC or QAR has been made shall determine that the QAR is complete and complies with the following:

- IECEx rules and procedures
- SZUTEST own quality management system
- All NCRs provide a clear description of their nature
- Shows a clear relationship to the products covered by the ExTR(s), which are the subject of the IECEx Certificate of Conformity, where part of the original application

Where discrepancies are identified they shall be immediately raised within the SZUTEST and a further review of steps 14 – 17 are conducted by the SZUTEST to confirm all details remain relevant.

The applicant and or IECEx Secretary may need to be informed where errors or discrepancies are of a major nature, eg incorrect audit personnel conducting the audit or insufficient audit depth revealed.

The review should also ensure that the principles and guidelines of IECEx OD 025 have been followed.

Related Documents :FR.EX.30 Review and Certification Decision Form, ISO/IEC 80079-34, IECEx OD 025, SZUTEST Quality System

8.1.13. Step 12 – QAR may be issued to client

The final Quality Assessment Report (QAR) shall be issued, by the SZUTEST to whom the original application was made, to the applicant and a copy retained on the SZUTEST file.

IECEx F-001 provides the QAR report format while IECEx F-002 provides the format for Non-Conformity Reports.

Related Documents : IECEx F-001
Related Forms : FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.1.14. Step 13 – Register QAR on IECEx On-Line COC Website

SZUTEST to register the QAR on the IECEx On-Line Certificate System on the IECEx Website @ www.iecex.com by creating a QAR Summary Report which is an electronic document that summarises some key elements of information from the QAR.

The publishing of a QAR Summary Report on the On-Line Certificate System creates a reference source for key information such as

- Manufacturer and sites audited
- ExCB performing the site audit
- Protection Techniques
- Ex Performance related standards
- Product Type
- Related CoCs
- Other

This enables the future use of the QAR for the purpose of issuing an IECEx Certificate of Conformity, through a Linked Database with IECEx CoCs and QARs.

Refer to IECEx OD 011-1 and IECEx OD 011-2 for further information.

IECEx OD 011-2 provides a detailed step by step guide to registering a QAR on the IECEx On-Line CoC System by creating a QAR Summary Report.

Contact the Secretariat for any assistance.

Also, the projects will be closed on SZUTEST APP system, and surveillance audits under these projects will be opened based on the assigned surveillance period.

Related Documents : IECEx OD 011-2, IECEx Website
Related Forms : FR.EX.30 Review and Certification Decision Form

8.1.15. Step 14+15 – Compliance with Annex B / Successful?

The SZUTEST shall review past audit / assessment results for compliance with Annex B.

8.1.16. Step 16 – Compile QAR

Where the past audit/assessment results are acceptable the SZUTEST shall compile an IECEx QAR.

Related Documents : IECEx F-001
Related Forms : FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form, FR.EX.30 Review and Certification Decision Form

8.1.17. Step 17+18 – Independent review of QAR / Successful?

The independent review of Step 10 shall be conducted by a staff member of the SZUTEST that has not undertaken the quality assessment and the following items should be considered.

Technical aspects:

- That the information contained within the QAR is sufficient to enable a clear conclusion to be drawn that the manufacturing production procedures are in compliance with ISO/IEC 80079-34 or OD 005

Administrative aspects:

- Use of IECEx Blank QAR Forms
- Evidence that the SZUTEST has taken into account relevant ExTAG Decision Sheets
- Product or Protection Techniques listed on related CoC match those on the QAR
- Manufacturing location(s) listed on the CoC match those on the QAR
- QAR is registered on IECEx Website
- Duration between surveillance audits of the manufacturers complies with IECEx Rules, e.g. maximum 12 month intervals where the manufacturing site(s) does NOT hold ISO 9001 certification and 18 month maximum intervals where the manufacturing site(s) do hold ISO 9001 certification
- All parts and sections of the QAR Blank form have been completed. Noting that clauses of the standard that may not apply to the product have been identified as N/A or by other means and that such exclusions are appropriate
- Persons listed as conducting the audits and completing the QARs are those identified by the ExCB as being competent and or listed on their internal competency matrix.
- Audit report findings and NCRs have been closed out.

Related Documents : IECEx F-001
Related Forms : FR.EX.30**,** FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form

8.1.19. Step 19 – Refer to audit staff or applicant as necessary

Where this review is successful then the procedures according to step 16 or 9, as appropriate, shall be conducted by the SZUTEST issuing the QAR.

Related Documents : SZUTEST internal procedure

8.2. Additional information regarding the QAR
8.2.1. General Information Before AUDIT(QAR)
Before audit of the QAR, preparation and precaution should be done according to the related document.
Related Documents : IECEx-OD-025

8.2.2. Document Refresh Controls
In order to control the QAR audit for re-certification some preparation and precautiin should be done according to related document.

Related Documents : IECEx-OD-250

8.2.3. Suspension of Inspections/Inspections
A QAR has a limited duration (three years) and can be withdrawn or suspended if intermediate follow-up assessments are not satisfactory.
Related Documents : IECEx-02

8.2.4. **Follow-up of Detected Non-conformities**
In order to detect non-conformities regarding the QAR reports the related document should be followed up.
Related Documents : IECEx-OD-025
Related Forms : FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.2.5. Closing Non-conformities with Follow-up
In order to close non-conformities regarding the QAR reports the following document should be followed up.
Related Documents : IECEx-OD-025
Related Forms : FR.EX.07 (IECEx-F-002) IECEx QAR Non-Conformity Report

8.2.6. Certification Change controls
PR.EX.04 Procedures for the Processing of changes to issued IECEx Certificates of Conformity should be followed.

8.2.7. Review and Decision
It is carried out according to the Table 1 — Building a product certification scheme and the following document should be followed .

The Technical Manager should review the lead auditors audit report, any non conformities raised and the manufacturer’s responses, and then the SZUTEST should approve the report. The SZUTEST should have a unified method of addressing the actions required following an audit. The following rating system is provided for guidance.

RATING	DEFINITION	ACTION FOLLOWING AN INITIAL ASSESSMENT OR RE-ASSESSMENT	ACTION FOLLOWING A SURVEILLANCE VISIT
A	Where a quality system fully meets the	Issue new or updated	Issue updated IECEx

RATING	DEFINITION	ACTION FOLLOWING AN INITIAL ASSESSMENT OR RE-ASSESSMENT	ACTION FOLLOWING A SURVEILLANCE VISIT
	requirements or where there are only very few minor nonconformities. Also where compliance of the product is observed during a product audit.	IECEx QAR	QAR
B	Where the quality system has a series of minor nonconformities Also where compliance of the product is observed during a product audit.	Issue new or updated IECEx QAR upon receipt of satisfactory documentary evidence supporting effective corrective action which is then subject to verification at the next surveillance visit	Issue updated IECEx QAR upon receipt of an acceptable corrective action plan, which is subject to verification at the next visit.
C	Where the quality system has major nonconformities and, or there is a non compliant product observed during the product audit.	Issue new or updated IECEx QAR only after a satisfactory follow-up visit has verified that the corrective actions have been effectively documented and implemented.	Issue updated IECEx QAR only after a satisfactory follow-up visit has verified that the corrective actions have been effectively documented and implemented. Should the manufacturer fail to take timely and effective corrective action, then the IECEx Certification Body reserves the right to suspend or cancel the IECEx Certificate of Conformity.
D	Where the quality system has many major nonconformities which may include non compliant product observed during the product audit	Issue new or updated IECEx QAR only after a further complete assessment of the quality system has been satisfactorily completed.	Suspend the IECEx Certificate of Conformity pending a further complete assessment to re-establish the effectiveness of the quality system. This is to be followed by surveillance visits at a frequency which maintains confidence in the effectiveness of the quality system.
E	Where there is no quality system or a system that has serious deficiencies rendering it ineffective	Close the application, no IECEx QAR to be issued or re-issued	Cancel the IECEx Certificate of Conformity and inform other IECEx Certification Bodies

Related Documents : IECEx-OD-025, in ISO/IEC 17067

8.2.8. Reporting and Certification

The audit team leader should be 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:

- extent of conformance of the quality system to the requirements of ISO/IEC 80079-34;
- the effective implementation and maintenance of the quality system, relevant to the requirements of ISO/IEC 80079-34;
- the ability of management review process to ensure the continuing suitability, adequacy, and effectiveness of the quality system, relevant to the requirements of ISO/IEC 80079-34;

The audit report should also include, or make reference to the following:
a) the identification of the organisational and function units or processes audited;
b) the identification of the manufacturer and audit client;
c) the identification of audit team members;
d) the date(s) and place(s) the on-site audit activities were conducted;

e) the audit criteria, and, if applicable, a list of reference documents, against which the audit was conducted, e.g. ISO/IEC 80079-34
f) the audit findings.

The audit report can also include or reference, as appropriate:
g) the agreed audit objectives, scope and plan;
h) the time period covered by the audit;
i) the identification of the auditee's key representatives participating in the audit;
j) a summary of the audit process including any obstacles encountered;
k) a statement of the confidential nature of the contents;
l) a distribution list for the audit report;
m) confirmation that the audit objectives have been accomplished within the audit scope in accordance with the audit plan;
n) any agreed follow-up action plans;
o) any unresolved diverging opinions between the audit team and the auditee;
p) areas not covered, although within the scope.

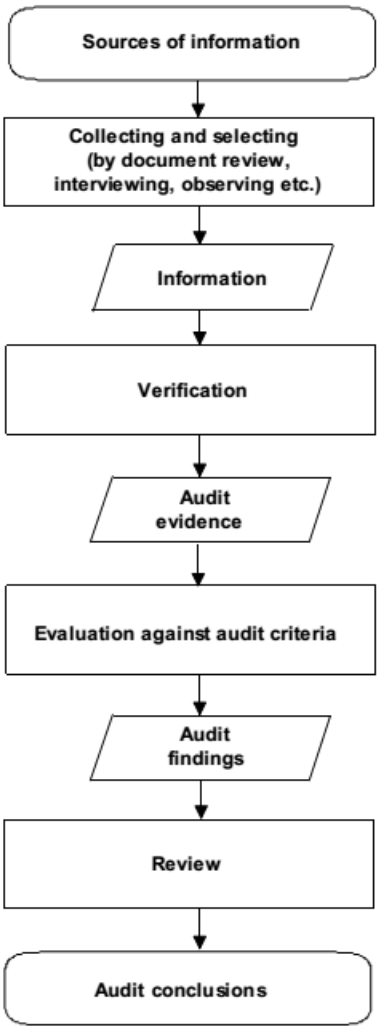
The QAR has a 3-year life and at, or before, the end of the 3 years a full assessment audit is required. Surveillance audits are also conducted during the 3-year period. The frequency of surveillance audits is determined by ISO 9001 and ISO 80079-34 certification status and is specified in OD 025.
Related Documents : IECEx-OD-025, IECEx-OD-0250
Related Forms : FR.EX.06 (IECEx-F-001) IECEx Quality Assessment Report (QAR) Audit Form

8.2.9. Remote Control
Concerning remote audits and possibilities about this matter, complying with requirements and the latest edition of OD 060 available on the IECEx website is required.

8.2.10. Surveillance Inspection
PR.EX.07 Surveillance Audits - Procedures for maintaining an IECEx COC should be followed up.
Related Documents : IECEx-OD-025, IECEx -02

8.2.11. ICT Methods Applicable in Audits (Collecting and verifying information)
In order to carried out ICT Methods Applicable in Audits the PR.EX.06 Procedures for the issuing of an IECEx Quality Assessment Report (QAR) should be followed up.

Figure 3 provides an overview of the process steps from collecting information to reaching audit conclusions.



Information relevant to the audit objectives, scope, and criteria, including information relating to interfaces between functions, activities, and processes should be collected during the audit. It should be verified by the auditor(s) and can then be considered to be audit evidence. Audit evidence should be identified as such and recorded.
NOTE: The audit evidence will inevitably be only samples of the information available, since an audit is conducted during a finite period of time and with limited resources. There is thus an element of uncertainty inherent in all audits, and those acting upon the audit conclusions should be aware of this uncertainty.

The sources of information chosen can vary according to the scope and complexity of the audit and can include:
a) interviews;
b) observations of activities and the surrounding work environment and conditions;
c) documents, including, for example, policy, objectives, plans, procedures, instructions, product certificates and notifications, specifications, drawings, contracts orders;
d) records, such as inspection records, minutes of meetings, reports or logbooks on customer complaints and other relevant communication from external parties, audit reports, monitoring programmes and results of measurements;
e) data summaries, analyses, metrics and performance indicators;
f) records of the basis of relevant auditee's sampling programmes and the procedures for ensuring effective quality control of sampling and measurement processes;
g) reports from other sources, for example, customer feedback, external reports and vendor supplier ratings;
h) computerised data bases and web sites.

Related Documents : IECEx-OD-025

8.2.12. Prohibited Practices
SZUTEST is NOT permitted to issue an IECEx Quality Assessment Report (QAR) until a document review and site assessment have been satisfactorily completed.

8.2.13. Complying with the requirement of the latest edition of OD 203 in case of the below items are required:
- Issue of QAR and IECEx Certificates of Conformity covering a distributor or agent who does not actually manufacture the equipment

- Use of a Local Assembler for final assembly and despatch of a product made from fully defined parts supplied by the manufacturer