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PR.EX.04 Procedures for the issuing of IECEx Certificates of Conformity (ExCoC)

A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Nurgül Çınar	28.04.2023

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
2	Reference has been made to OD 203 by adding article 8.2.7.	NCR10 in IECEx audit report.	28.04.2023	28.04.2023
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	17.03.2023	17.03.2023

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5. Purpose and Scope

The objective of this document is to create IECEx Equipment Certificates of Conformity (ExCoC) based on an ExTR and QAR. The IECEx CoC may be issued for a product with its variety of types, including different processes and electrical connections, different temperature classes, different types of protection, etc.

The IECEx Certified Equipment Scheme provides the means for manufacturers of Ex equipment to obtain CoCs that are intended to be accepted in all participating countries as equivalent to their national certification. An IECEx CoC may also be accepted in other non-participating countries.

The final objective of the IECEx Certified Equipment Scheme is worldwide acceptance of one standard, one certificate, and one mark.

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 ExCoC certificates of Conformity in SZUTEST, in case of no obstacles, errors, or non-conformity related to ExTR and QAR by the manufacturer's quality system, the relevant standards, regulations,

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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 non-conformance 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.

7. Responsibilities

This procedure is operated by the authorized person who is assigned by SZUTEST (ExCBs) according to the PR.EX.01 ExCB Personnel Procedure and IECEx Test Laboratories (ExTLs) to ensure a thorough and consistent assessment of applications for either an:

• IECEx Certificate of Conformity
IECEx-0D-204 (Mid-term Assessment Report Form)
IECEx-0D-205 (Mid-term Assessment Report Form Checklist)
IECEx OD 009 (Procedure)
IECEx-OD-011-2 (Creating IECEx 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-OD-017 (Drawing and Documentation)

• 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-017 (Drawing and Documentation)

• IECEx Quality Assessment Report (QAR)
IECEx Form F-001 (Audit Form)
IECEx Form F-002 (Non-Conformity Report)
IECEx OD 009 (Procedure)
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)
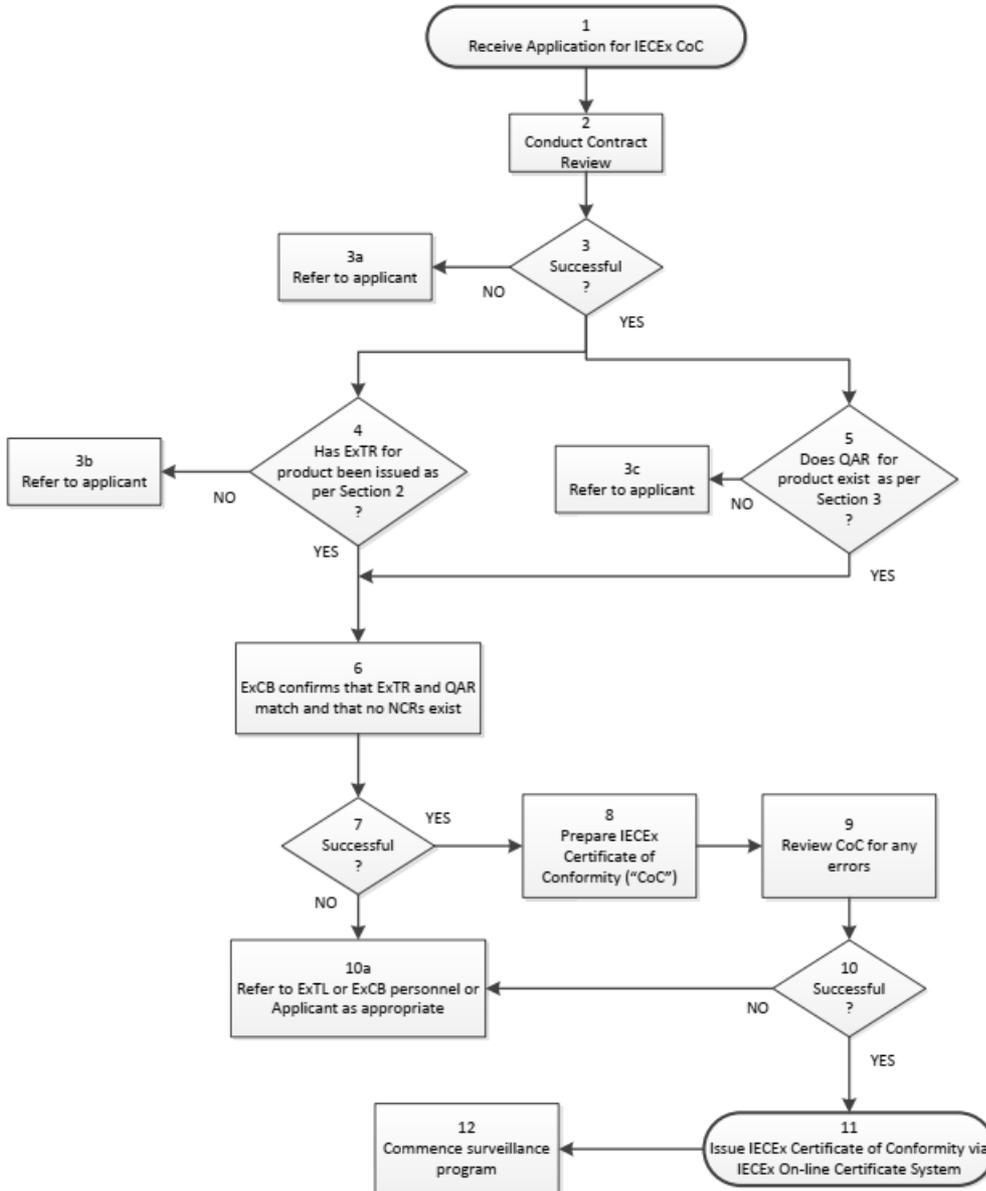**IECEx-OD-250** (Management of QAR)

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IECEx-02 (Rules of Procedure)
IECEx-OD-005-3 (QS Requirements for Manufacturer)
IECEx-OD-017 (Drawing and Documentation)

8. Method

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8.1. Method of the issuing of an IECEx Certificate of Conformity (COC)

8.1.1. Step 1 – Receive Application for IECEx COC

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 .

The SZUTEST shall ensure that the Applicant is aware of and agrees with the Terms and Conditions of the SZUTEST which shall include reference to the current editions of IECEx 02 Scheme Rules and IEC CA 01.

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

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.

• 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

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• Whether a surcharge applies for manufacturers from non member countries (Refer to IECEx OD 019, IECEx System Fees)
• 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

Related Documents: SZUTEST's own Certification procedures as included in their Quality System as required by ISO/IEC 17065, PR.EX.02
Related Form: FR.EX.02

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

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.

8.1.5. Step 3b - Refer to Applicant & Product Certification Auditor & Open the Project in SZUTEST APP System

Where successful, SZUTEST will provide in writing to the applicant an offer describing the scope of work involved, the applicable technical and IECEx system requirements, testing and certification costs, and time until issuing the ExTR and/or CoC, provided all tests passed satisfactorily.PR.EX.05 Procedures for the issuing of an IECEx Test and Assessment Report (ExTR)
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

8.1.6. Step 4 – Has ExTR for the product been issued as per Section 2?
An ExTR(s) covering the product(s) that are to be listed on the CoC must exist and be in the possession of the SZUTEST. Where an ExTR does not exist then the process of PR.EX.05 Procedures for the issuing of an IECEx Test and Assessment Report (ExTR) shall be followed. When completed the IECEx CoC application process may proceed according to this Procedure.
The Product Certification Auditor shall prepare the audit plan and record it to FR.EX.27 Audit Plan.
For Issuing ExTR the client will be referred to the suitable SZUTEST Associate technical laboratory.
And after receiving the Test Report by SZUTEST, it will be evaluated and endorsed.
Related Form: FR.EX.27, FR.EX.08, FR.EX.29

8.1.7. Step 5 – Does QAR for product exist as per Section 3?
A valid (with respect to the "Valid until:" date) IECEx QAR Summary covering the product(s) / technology (for example, Types of Protection and where necessary Ex performance related standards) and the manufacturing locations that are to be listed on the CoC must exist with at least the QAR Summary being in the possession of the SZUTEST. Where a QAR does not exist or does not cover either the Ex protection technique nor any of the manufacturing locations, then the process of PR.EX.06 Procedures for the issuing of an IECEx Quality Assessment Report (QAR)shall be followed. When completed the IECEx CoC application process may proceed according to this procedure.
The Product Certification Auditor shall prepare the audit plan and record it to FR.EX.27 Audit Plan.
Related Form: FR.EX.27, FR.EX.06, FR.EX.29

8.1.8. Step 6 – Szutest confirms that ExTR and QAR match and that no NCRs exist

The SZUTEST shall conduct a certification review accoring in accordance with their quality management system, ensuring among others

• ExTR(s) relate to the same product(s) listed on the Certificate
• Any major Non Conformances have been successfully closed
• All stages of the certification process have been documented and followed, including those contained in this manual
• The SZUTEST has signed a commitment by the applicant to abide by the rules of the IECEx Scheme and SZUTEST's certification conditions
• The applicant and the manufacturer, if different from the applicant, are aware of their obligations under the scheme, including ensuring that any promotional material does not contain misleading information that may infer products NOT covered by IECEx certification

and also ensuring that the person(s) conducting this review of the ExTR have NOT been involved in evaluation work for this particular certification project.

The SZUTEST will review the manufacturer's QAR Summary Report and QAR Summary Report(s)of all Manufacturing Locations and Production Site(s), ensuring that

a) type of protection
b) applicable Ex performance standards
c) product type
d) manufacturing location / production site

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e) validity date
f) issuing ExCB still competent/approved
of the product to be certified are covered and valid.

Related Documents: IECEx 02, ISO/IEC 80079-34, IECEx OD 025, IECEx OD 026, IECEx OD 017
Related Form: FR.EX.30 Review and Certification Decision Form

8.1.9. Step 7 – Successful?

Where Step 6 is not successful then the matter may be referred to the SZUTEST responsible for the ExTR Summary (Associated ExTL) and QAR Summary. Once matters are resolved then the process may continue according to this procedure.

8.1.10. Step 8 – Prepare IECEx Certificate of Confirmity ("COC")

IECEx Certificate of Conformity shall be compiled using the IECEx On-Line Certificate system via the password protected system according to the IECEx OD 011- 2 and also according to PR.EX.03 Certification Operations Procedure.
The IECEx CoC shall contain at least the following information according to Procedure;

- A clear description of the Ex equipment
- Name and address of the applicant
- Name and address of the manufacturer
- Country of manufacturing locations as defined by Clause 3.18
- The Standard and edition, and amendments, if any
- Reference to the supporting ExTR
- In reference to the supporting QAR, except for unit verification
- Ex marking requirements
- Name of the issuing SZUTEST
- Specific conditions of use (if any)
- Schedule of limitations for component certificates
- IS parameters for intrinsic safety, where relevant
- Serial number or other unique identifier when issued for unit verification

Related Documents : IECEx OD 011- 2, IECEx 02

8.1.11. Steps 9+10 - Review COC for any errors / Successful?

A draft of the IECEx Certificate of Conformity is to be reviewed for errors. It may be beneficial to pass a draft copy to the applicant for them to assist in the final review prior to issuing the certificate Every attempt shall be made to correct errors prior to issuing the certificate.

The objective of the review is to check that the information on the sampled certificates is correct and complete.

For certified equipment certificates;

a) Date of issue is appropriate (that is, not showing in the future).
b) A test report number and file reference is included.
c) Manufacturer name detail is consistent with the related ExTR and QAR.
d) Manufacturer's site street (not a PO Box) address is given.
e) Any attached annex has a reference to the CoC number.
f) Referenced annexes are attached.
g) Conditions of certification are listed for "X" type certificates.
h) Equipment description is clear and sufficiently detailed.
i) No major editorial mistakes (including linking to a draft ExTR).
j) Correct links to valid ExTR and QAR.
k) Linked QAR is current. IECEx OD 003-2:2021 © IEC 2021 – 15 –
l) Manufacturer on CoC matches QAR and QAR covers all manufacturing locations.
m) Standards listed on CoC match Standards (including edition #) on ExTR.
n) Scope of certificate matches QAR and ExTR SZUTEST capability.
o) Type of protection concept on CoC matches Standards and QAR.
p) Where more than one issue exists that they are linked and changes explained on CoC.
q) Statement of limitations is included in CoC for component certificates ("U" type).
r) Unit verification certificates have been denoted with "V" and include serial #(s).

Related Documents : Original application form submitted by the applicant

8.1.12. Step 10a – Refer to ExTL or Szutest Personnel or Applicant as appropriate

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Where questions are raised during the final certification review these need to be raised with the relevant ExTL and or relates SZUTEST personnel and resolved prior to issuing the Certificate.

Related Documents: SZUTEST and ExTL internal procedures
Related Form: FR.EX.08

8.1.13. Step 11 – Issue IECEx Certificate of Conformity via IECEx On-Line Certificate System

Once the Certificate is considered correct, a Certification Review record shall be created, signed and dated. The IECEx Certificate is issued by setting status = "Current" on the IECEx On-Line Certificate System when logged in with the Level 2 username and passwords allocated by the IECEx Secretariat (refer to IECEx OD 011-2 for details).

This will be regarded as making the certification decision as defined by ISO/IEC 17065.

The applicant being informed in writing by the SZUTEST, via letter, fax or email.

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.

8.1.14. Step 12 – Commence the surveillance program

Certification Maintenance begins, with SZUTEST according to PR.EX.07 Surveillance Audits – Procedures for maintaining an IECEx Certificate of Conformity
.It shall include:

• Conducting of surveillance assessments / audits is covered by the QAR process.
• Responding to public inquiries regarding the certificate
• Taking necessary action when aware of possible breaches by the applicant, eg claims that product not the subject of IECEx Certificate of Conformity are being claimed as "IECEx Certified"

Where an IECEx CoC is issued, The SZUTEST shall either carry out or ensure that periodic surveillance of certified Ex equipment, including examination of documentation and assessment of the manufacturer's QMS for continued compliance with ISO/IEC 80079-34, is conducted at the manufacturer's premises and all manufacturing locations. For this reason after closing each Project in APP system, follow-up audits as surveillance projects shall be initiated in the system.

The SZUTEST responsible for issuing the CoC may conduct the surveillance activities or arrange for another ExCB to carry out this work according to the PR.EX.07 Surveillance Audits – Procedures for maintaining an IECEx Certificate of Conformity.

Related Documents: IECEx 02, IECEx OD 025, SZUTEST's APP System
Related Form: FR.EX.30 Review and Certification Decision Form

8.2. Additional information regarding the QAR
8.2.1. General Information Before AUDIT(QAR)

Before the audit of the QAR, preparation, and precaution should be done according to the PR.EX.06 Procedures for the issuing of an IECEx Quality Assessment Report (QAR).

8.2.2. Closing Non-conformities with Follow-up
In order to close non-conformities regarding the QAR & ExTL reports the PR.EX.06 Procedures for the issuing of an IECEx Quality Assessment Report (QAR) and PR.EX.05 Procedures for the issuing of an IECEx Test and Assessment Report (ExTR) should be followed up.

8.2.3. Certification Change controls
In order to carry out the control of certification change the PR.EX.08 Procedures for the Processing of changes to issued IECEx Certificates of Conformity should be followed up.

8.2.4. Subcontracting Rules
In order to select an ExTL subcontractor the PR.EX.05 Procedures for the issuing of an IECEx Test and Assessment Report (ExTR) should be followed up.

8.2.5. Remote Control
In order to carry out the remote audit the Risk assessment form shall be completed. This option could be allowed or changed according to the IECEx Secretary. (FR.ATEX.50 Form for Audits to Be Performed Under Temporary Extraordinary Measures Information and Evaluation)

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8.2.6. The Suspension, Cancellation and Reinstatement of Certificates of Conformity

The following steps and the operational documents (IECEx OD 209, IECEx OD 250) should be followed up for suspension, cancellation and reinstatement of Certificates of Conformity.

Actions to be completed before suspension (IECEx OD 209, Clause 5)

- That the person making the request has the authority to do so
- Identify certificate/s to be suspended
- Request list of any linked certificates from the Applicant (IECEx OD 209, Clause 4.3.1 and Clause 5, a))

Actions to be completed as part of the suspension (IECEx OD 209, Clause 6)

- If all Certificates of Conformity on a QAR are suspended, the SZUTEST shall consider if further audits and an update of the QAR Summary is required before the Certificates can be reinstated. Clarity of the status of Certificates linked to the QAR can be provided by insertion (by the issuing ExCB) of explanatory text in the Comment field of the on-line QAR Summary and retained for the period of suspension of the Certificates.
- Check on the Manufacturers marketing material, e.g. website in case they are still advertising that their products are covered by valid IECEx Certificates

Actions to be completed in the event of non-conforming product in the market (IECEx OD 209, Clause 9.3)

- Advice to the market concerning Ex products already in the market prior to the date of suspension or cancellation
- Regulatory/market surveillance authorities informed if necessary

Actions to complete prior to reinstatement (IECEx OD 209, Clause 10.2)

- Removal of any explanatory text about the suspension of linked Certificates from the Comment field of the QAR Summary prior to the reinstated of the certificate
- Applicant is informed of reinstatement progress and any limitations
- IECEx Secretariat is consulted regarding the reinstatement process
- Any issues arisen as a result of the suspension have been addressed (non-conformities have been addressed)

Actions to complete prior to cancellation (IECEx OD 209, Clause 10.3)

- Applicant is informed of intent to cancel, is informed of their obligations and acknowledges the decision
- IECEx Secretariat is consulted regarding the cancellation process
- Any issues arisen as a result of the cancellation and that affect products in the field have been addressed

8.2.7. Complying with the requirement of the latest edition of OD 203 in case of the below items are required:
- Issue of 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