



IECEX OD 009

Edition 2.0 2010-08

IECEX Operational Document

IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEX System)

IECEX Certified Equipment Scheme –

IECEX Certified Equipment Scheme, Procedures for the Issuing of IECEx Certificates of Conformity, IECEx Test Reports and IECEx Quality Assessment Reports



INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX OPERATIONAL DOCUMENT

IECEX Certified Equipment Scheme

Ex OD 009 Edition 2.0

IECEX Operations Manual – IECEX Certified Equipment Scheme - Procedures for the Issuing of IECEX Certificates of Conformity, IECEX Test Reports and IECEX Quality Assessment Reports

This Operational Document, OD 009 sets out the procedures for the processing of applications for IECEX Certificates of Conformity (CoC), IECEX Test Reports (ExTRs), IECEX Quality Assessment Reports (QARs), in accordance with the Rules and Procedures IECEX 02.

Document History

Date	Summary
2003 06	Original Issue (Version 1)
2010 08	Edition 2 includes: <ul style="list-style-type: none">• clarification over the situation of applications for CoCs where manufacturers already hold IECEX Certification for other products and valid QARs• Inclusion of Section 3 "Changes to Certification"• Clarification of IECEX On-Line Registration of ExTRs and QARs

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Introduction

This document is supplementary to the Operational manuals and procedures operated by IECEX Certification Bodies (ExCBs) and IECEX Test Laboratories (ExTLs) for the purpose of ensuring a thorough and consistent assessment of applications for either an:

- IECEX Certificate of Conformity
- IECEX Test Report, ExTR
- IECEX Quality Assessment Report, QAR

The IECEX Certified Equipment Scheme of the IECEX System is modelled on an ISO Type 5 Certification System with the rules, IECEX 02, requiring that both an ExTR (covering product testing) and a QAR, covering the same product, be issued in order that an ExCB may then issue an IECEX Certificate of Conformity. This is shown in the flowchart contained in Section 1.

This IECEX Operational Document comprises 5 Sections:-

- **Section 1** – Procedures for the Issuing of an IECEX Certificate of Conformity
- **Section 2** – Procedures for the Issuing of an IECEX Test and Assessment Report (ExTR)
- **Section 3** – Procedures for the Issuing of an IECEX Quality Assessment Report (QAR)
- **Section 4** – Surveillance Audits - Procedures for maintaining validity of an IECEX Certificate of Conformity
- **Section 5** – Procedures for the processing of changes to issued IECEX Certificates of Conformity

The procedures are set out in table form identifying:

- Step number showing the link between flowcharts and table
- Description of the activity
- Related documents
- Responsible person or party
- Additional comments and remarks where appropriate

This operational document also captures previous decisions of the IECEX Management Committee concerning the use of “previously obtained” test data and the procedures for the compiling and issuing of ExTRs.

The preparation of this document has been done so with the aim of alignment with various ISO/IEC International Standards and Guides, including but not limited to the following:

Guide 28	General rules for a model third-Party certification System for products
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Guide 27	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
Draft Guide 53	Conformity assessment — An approach to the utilization of an organization's quality management system in product certification
Guide 65	General requirements for bodies operating product certification systems
10011 series	Guidelines for auditing quality systems

This Edition 2 is an update of the previous version to take into account industry feedback from experience since introduction of the IECEX Certificate of Conformity in 2003.

Changes incorporated into this revised Edition include:

- Introduction of the “On-Line” facility for the Registration of ExTRs and QARs
- Major re-arrangement of Sections to account for the process of issuing IECEX CoCs where either the ExTR or QAR has already been issued
- Introduction of new Section 5 to cover processing of application for changes in certification
- Other changes aimed at clarifying the requirements and processes of IECEX Certification.

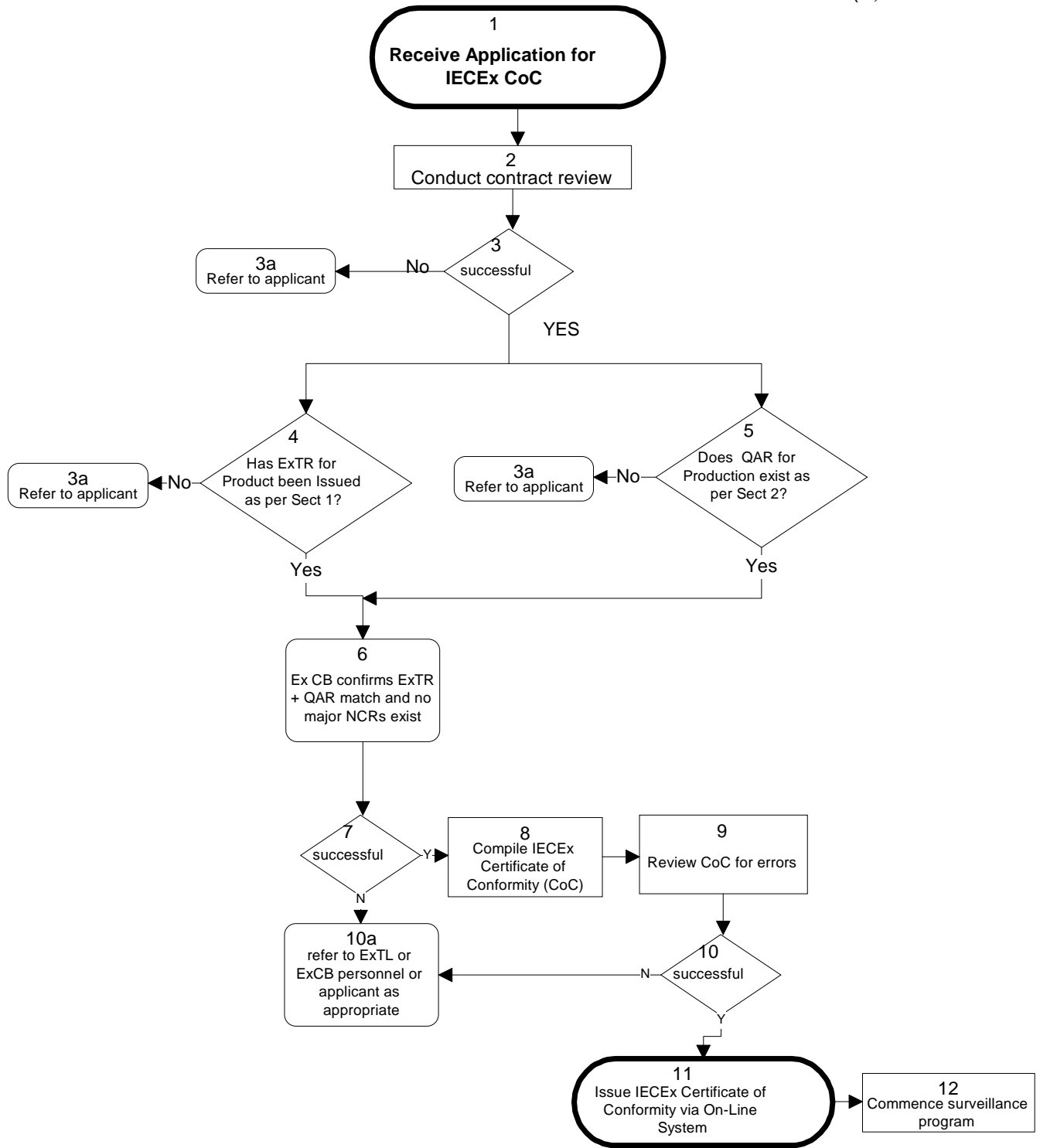
SECTION 1 – Procedures for the Issuing of an IECEX Certificate of Conformity

This Section is to be applied by ExCBs and ExTLs when processing new applications for:

- IECEX Certificate of Conformity

These steps are in line with the requirements of ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEX Scheme rules, IECEX 02.

Section 1 also refers to Annex A for the criteria for use of previous test data and Annex B for criteria concerning the use of quality system assessment and audit results obtained prior to the application for an IECEX Certificate of Conformity being lodged.



Process for Issuing an IECEX Certificate of Conformity

Step	Section 1- Procedures for the Issuing of an IECEX Certificate of Conformity under the Equipment Certification Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
1	Application received in accordance with IECEX 02	IECEX 02	ExCB	Applications for an IECEX Certificate of Conformity can only be made for an IEC Standard.
2	<p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC Guide 65. Contract review shall include:</p> <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether the manufacturer has an established quality management system • Whether a surcharge applies for manufacturers from non member countries • 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 ExCB's own policy and quality system 	ExCBs own Certification procedures as included in their Quality System as required by ISO/IEC Guide 65	ExCB	The results of the contract review shall be documented and recorded.
3	ExCB shall only proceed where the contract review has been successfully completed		ExCB	
3a	Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEX acceptance does not cover the application		ExCB	
3b	Where successful, ExCB shall provide in writing to the applicant an offer describing the scope of work involved, the applicable technical and IECEX system requirements, testing and		ExCB receiving the application	

Step	Section 1- Procedures for the Issuing of an IECEx Certificate of Conformity under the Equipment Certification Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	certification costs and time until issuing the ExTR and/or CoC, provided all tests passed satisfactorily.			
4	An ExTR covering the product(s) that are to be listed on the CoC must exist and be in the possession of the ExCB. Where an ExTR does not exist then the process of Section 2 of this OD 009 shall be followed. When completed the IECEx CoC application process may proceed according to this Section 1			
5	An IECEx QAR covering the product(s)/technology (eg Protection techniques) and the manufacturing locations that are to be listed on the CoC must exist and be in the possession of the ExCB. Where a QAR does not exist or does not cover either the Ex protection technique or any of the manufacturing locations, then the process of Section 3 of this OD 009 shall be followed. When completed the IECEx CoC application process may proceed according to this Section 1			
6	<p>The ExCB to whom the application for an IECEx Certificate of Conformity was made shall conduct a certification review, in accordance with their quality management system, ensuring among others</p> <ul style="list-style-type: none"> • ExTR relate to the same product(s) • 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 ExCB has signed a commitment by the applicant to abide by the rules of the IECEx Scheme and ExCB's certification conditions • The applicant and the manufacturer, if different from the applicant, are aware of their obligations under the scheme, 	IECEX 02 OD 005 OD 025 OD 027	ExCB	

Step	Section 1- Procedures for the Issuing of an IECEX Certificate of Conformity under the Equipment Certification Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	<p>including ensuring that any promotional material does not contain misleading information that may infer products NOT covered by IECEX certification</p> <p>The ExCB has to review the manufacturer's QAR summary report ensuring that</p> <ul style="list-style-type: none"> a) type of protection b) product type c) manufacturing location d) validity date e) issuing ExCB still competent/approved <p>of the certified product are covered.</p>			
7	Where Step 6 is not successful then the matter may be referred to the ExCB responsible for the ExTR and QAR. Once matters are resolved then the process may continue according to this Section 1			
8	<p>IECEX Certificate of Conformity shall be compiled using the IECEX "On-Line" system via the password protected system.</p> <p>OD 011 Part 2 provides step by step guidance on creating a CoC via the On-Line internet system.</p>	Refer IECEX website OD 011 Part 2	The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was made	Contact the IECEX Secretariat for any questions or concerns
9+10	<p>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.</p> <p>Every attempt shall be made to correct errors prior to issuing the certificate</p>	Original application form submitted by the applicant.	The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was	Contact the IECEX Secretariat for any questions or concerns

Step	Section 1- Procedures for the Issuing of an IECEX Certificate of Conformity under the Equipment Certification Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
			made The applicant should also be given the opportunity to review	
10a	Where questions are raised during the final certification review these need to be raised with the relevant ExTL and or ExCB personnel and resolved prior to issuing the Certificate	ExCB and ExTL internal procedures	ExCB staff conducting certification review	
11	Certificate is issued via the IECEX “on-Line” registration system with the applicant being informed in writing by the ExCB, via letter, fax or E-mail		The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was made	Contact the IECEX Secretariat for any questions or concerns
12	<p>Certification Maintenance begins, with the ExCB issuing the IECEX Certificate of Conformity being responsible for the on-going maintenance of the certificate which shall include:-</p> <ul style="list-style-type: none"> • 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” 	IECEX 02 OD 025 ISO/IEC Guide 62 ExCB’s own quality management system	Management of the ExCB that issued the IECEX Certificate of Conformity in coordination with the original ExCB	Contact the IECEX Secretariat for any questions or concerns

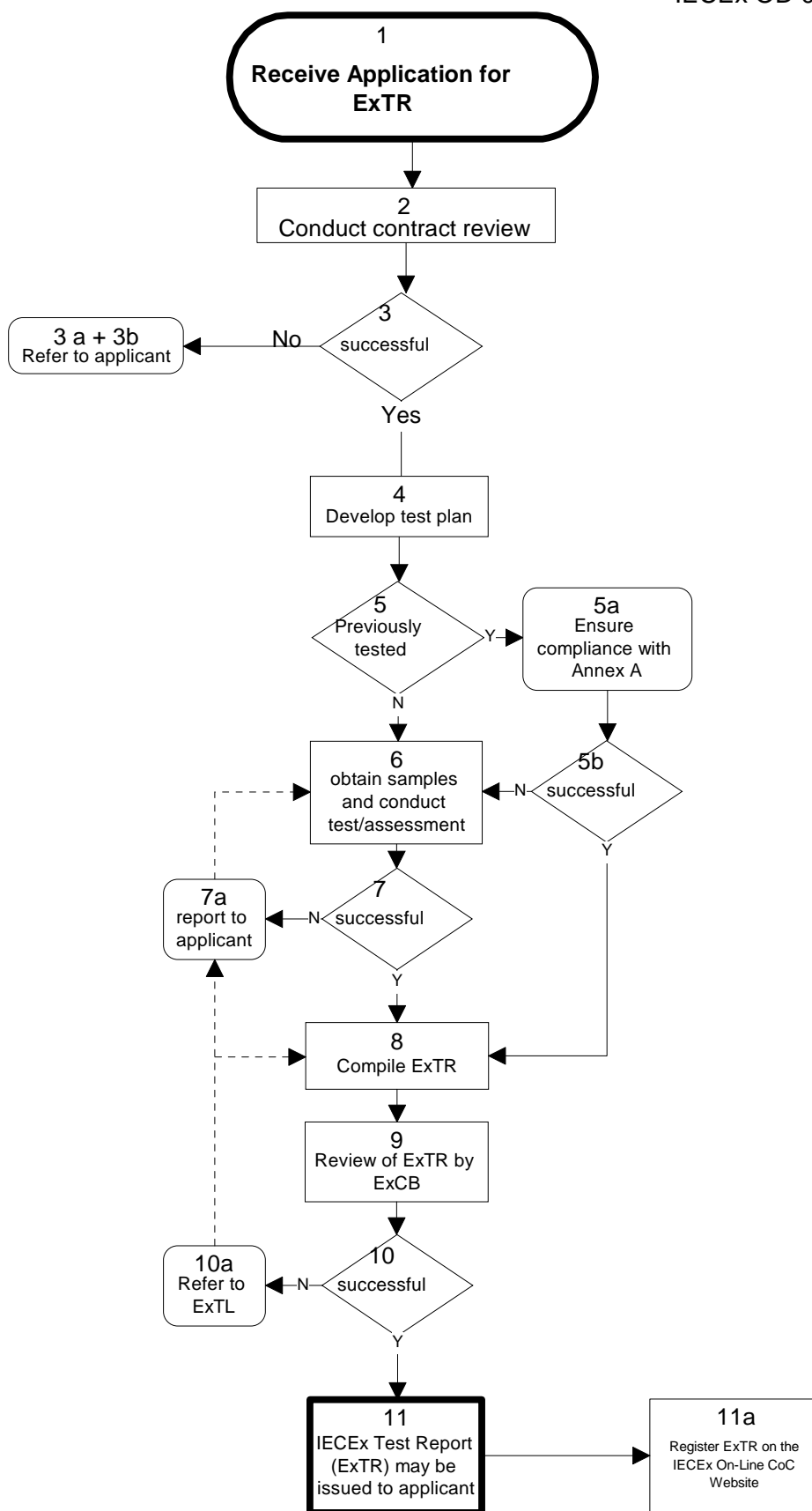
SECTION 2 – Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR)

This Section is to be applied by ExCBs and ExTLs when processing new applications for :

- IECEx ExTR, according to the IECEx 02 Rules

These steps are in line with the requirements of ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02.

This Section 2 also refers to Annex A for the criteria for use of previous test data.



Process for Issuing and IECEX Test and Assessment Report (ExTR)

Step	Section 2- Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
1	Application received in accordance with IECEx 02	IECEX 02	ExCB	Applications for an IECEx Certificate of Conformity can only be made for an IEC Standard.
2	<p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC Guide 65. Contract review shall include:</p> <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether a surcharge applies for manufacturers from non member countries • Estimation of costs and time to complete project • Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and quality system 	ExCBs own Certification procedures as included in their Quality System and required by ISO/IEC Guide 65	ExCB	The results of the contract review shall be documented and reported to the applicant.
3	ExCB shall only proceed where the contract review has been successfully completed		ExCB	
3a	Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEx acceptance does not cover the application		ExCB	
3b	Where successful, ExCB shall provide in writing to the applicant an offer describing the scope of work involved, the applicable technical and IECEx system requirements and certification costs and time until issuing the ExTR and/or CoC, provided all tests passed satisfactorily.		ExCB receiving the application	

Step	Section 2- Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
4	<p>Develop Test and assessment plan, especially where model ranges are involved in the application. The ExCB in conjunction with its associated ExTL need to be satisfied that samples selected for testing are representative of models covered by the application .</p> <p>The ExTL shall take account of any relevant ExTAG Decisions sheet or IECEx Operational Document that apply to the product or Standard applicable to the application</p>		ExCB in conjunction with its associated ExTL	A test plan is required for each application even where it is intended to utilise previously obtained test data to ensure that the original test plan is still relevant for this new application
5	Where products or components covered by the application, have been previously tested without ExTR and the applicant wishes to utilise these tests then steps 5a and 5b may be applied	Annex A to this document	ExCB and ExTL	IECEX OD 010 may also be of assistance
5a	<p>A review of the previous test data shall include:</p> <ul style="list-style-type: none"> • Determination whether the test requirements, methods and pass/fail criteria used previously are the same as those contained in the standard for which application is made • Facilities and methods previously used are still appropriate 	Annex A to this document	ExTL	Note that it is still essential that an ExTR be completed and registered on the IECEx website even when using previously obtained test data
5b	<p>A file note is required to act as a record to demonstrate the outcome of the assessment to Annex A</p> <p>Such file note shall be retained on the ExTL's records for possible review by an IECEx Assessment Team conducting surveillance or re-assessment of the ExTL</p>		ExTL	
6	<p>Samples to be obtained by the ExTL and tests and assessments conducted as required by the Standard.</p> <p>The requirements of both IECEx 02 and IECEx Operational Document OD 010 shall be followed</p>	IECEX 02 IECEX OD 010	ExTL	Note: The ExTL should check the list of ExTAG Decision Sheets to see if there are any that relate to

Step	Section 2- Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
				the product under test.
7 + 7a	Where testing and assessments are unsuccessful, then such results and any non conformances identified during the assessment shall be reported to the applicant, in writing, requesting corrective action. Such action may include modification of the design and provide new samples for testing or amend their original application or withdrawing their application.		ExTL but will need to consult with the ExCB for instances where the original application is amended	
8	<p>The relevant IECEx Test Report (ExTR) blank report forms shall be used to compile an ExTR.</p> <p>An ExTR shall also be compiled when utilising previously obtained test data. This may mean transferring information from a previously issued test report into the ExTR format</p>	IECEX Standard ExTR Blank Forms available from the IECEx Website	ExTL	Note: ExTRs were previously called ATRs. Old ATR blanks can still be used while they are being updated to reflect the new terminology
9	ExTR to be reviewed by the ExCB prior to being issued by the ExCB, with whom the ExTL is associated.		ExCB	
10 + 10a	Where the review by the ExCB is unsuccessful, this shall be referred to the ExTL for correction or may be referred back to the applicant for their action, similar to step 7 and 7a, depending on the nature of the problem detected during the ExCB's review		ExCB The applicant should also be given the opportunity to review	When ExCBs and ExTLs are within the one organisation, the ExTR review shall be conducted by a staff member not involved or responsible for the tests/ assessments
11	<p>The ExTR may now be issued to the applicant or retained for duration of the IECEx CoC procedure.</p> <p>Where the manufacturer is located in a non-IECEX participating country, the ExCB shall, arrange for payment to the IECEx account of the surcharge, refer to OD 019 for Scheme fees</p>		ExCB	Where a valid ExTR already exists, this may be used for the purpose of issuing an IECEx CoC without the repeating the tests.

Step	Section 2- Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
				ExTRs issued prior to the date of application for an IECEx CoC should only be used where it has been confirmed that the testing requirements are the same as those of the Standard for which a CoC is to be issued and that the product has not included any change in design that may affect the Ex protection
11a	<p>ExCB to register the ExTR on the IECEx “On-Line” Certificate of Conformity Internet Website www.iecex.com</p> <p>The On-Line System creates a database entry of key information such as Manufacturer, ExTL, ExTR reference Number, Standards and so on.</p> <p>This enables the future use of the ExTR for the purpose of issuing an IECEx Certificate of Conformity, through a Linked Database with IECEx CoCs and QARs summary,</p> <p>Refer to OD 011 Parts 1 and 2 for further information</p>	<p>OD 011 Part 2</p> <p>IECEX Website</p>	ExCB	Contact the Secretariat for any assistance

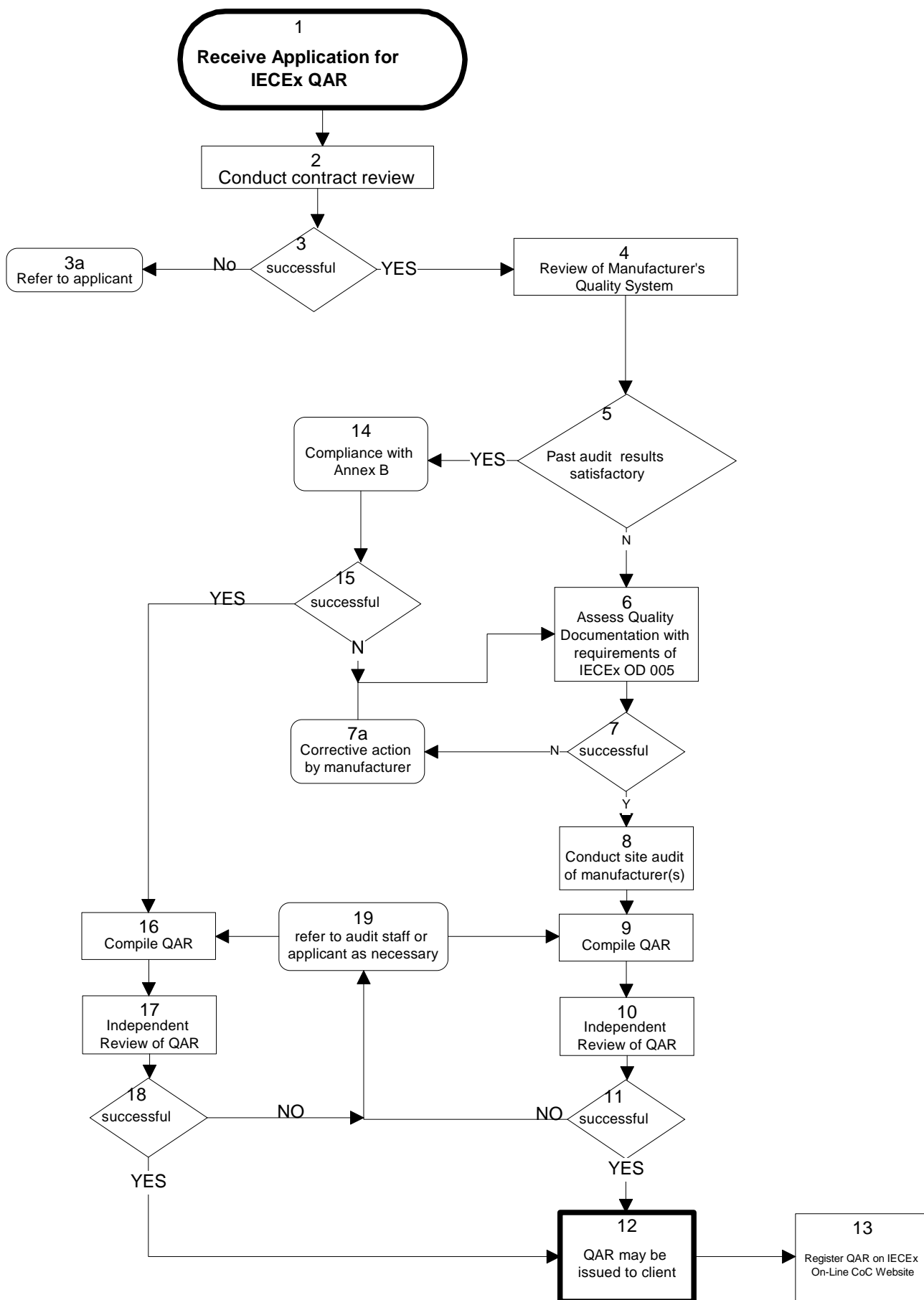
SECTION 3 – Procedures for the Issuing of an IECEx Quality Assessment Report (QAR)

This Section is to be applied by ExCBs when processing new applications for :

- IECEx QAR, according to the IECEx 02 Rules

These steps are in line with the requirements of ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02.

This Section 3 also refers to Annex B for criteria concerning the use of quality system assessment and audit results obtained prior to the application for an IECEx Certificate of Conformity being lodged.



Process for Issuing an IECEX Quality Assessment Report (QAR)

Step	Section 3- Procedures for the Issuing of an IECEX Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
1	Application received in accordance with IECEX 02	IECEX 02	ExCB	Applications for an IECEX Certificate of Conformity can only be made for an IEC Standard.
2	<p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC Guide 65. Contract review shall include:</p> <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether the manufacturer has an established quality management system • Whether a surcharge applies for manufacturers from non member countries • 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 ExCB's own policy and quality system 	ExCBs own Certification procedures as included in their Quality System and ISO/IEC Guide 65	ExCB	The results of the contract review shall be documented and recorded.
3	ExCB shall only proceed where the contract review has been successfully completed		ExCB	
3a	Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEX acceptance does not cover the application		ExCB	
4	The ExCB must review the manufacturer's quality management system to ensure compliance with OD 005-1 by either:	IECEX OD 005-1 OD 025	ExCB	OD 005-1, Part 1 sets out the Quality System requirements while OD

Step	Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	<p>1) Conduct a site audit of the manufacturing location(s); or</p> <p>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.</p> <p>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 ExCB receiving the application must consider at least the following:-</p> <ul style="list-style-type: none"> • 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 			005-2, Part 2 provides a checklist for the requirements listed in Part 1
5	<p>Where an audit of the manufacturer has taken place by the ExCB for a related program and within the last 18 months, such results may be used where the applicant wishes to do so.</p> <p>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</p>	Refer Annex B	ExCB	
6	<p>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.</p> <p>Generally this will relate to the detailed product quality plans. The</p>	OD 005-1 OD 025 OD 026	ExCB or by another ExCB working under direction by the ExCB to which the original	The document review may be conducted prior to the on-site audit, at the ExCB premises or on-site at

Step	Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	<p>assessment shall ensure that all requirements contained in IECEx Operational Document OD 005-1, as they relate to the product, are adequately addressed by the Manufacturer's quality system procedures and work instructions</p> <p>This step may also be termed the "Documentation Review"</p>		application was made.	<p>the manufacturers premises as part of the on-site audit.</p> <p>Where different manufacturing sites are involved the ExCB should satisfy itself that the same quality plans are used.</p> <p>If not then each manufacturing location must be treated separately with separate assessments and site audits for each location.</p>
7 + 7a	<p>Relevant manufacturer's quality system documentation is to be reviewed to verify that documentation complies with the requirements of IECEx OD 005-1.</p> <p>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 ExCB as major non-conformances 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.</p> <p>Where non compliance with various clauses of OD 005-1 are judged to be of a minor nature by the ExCB, the process of on-site auditing may continue</p>	OD 005-1 OD 025 OD 026	ExCB or by another ExCB working under direction by the ExCB to which the original application was made, for manufacturers located in different countries	OD 025 includes a checklist of OD 005 documentation requirements.
8	<p>The ExCB conducts on-site audit</p> <p>This on-site audit shall seek to verify that relevant quality system</p>	OD 005-1 OD 025	ExCB , for manufacturers	Where the Ex product is manufactured in

Step	Section 3- Procedures for the Issuing of an IECEX Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	<p>procedures and work instructions are in place and that there are records and evidence to demonstrate that the requirements of IECEX OD 005-1 are being met by the manufacturer(s)</p> <p>OD 025 provides guidance in the management of assessments of manufacture's quality system and shall be used by all ExCBs</p> <p>OD 026 provides guidelines for the qualification of ExCB auditors conducting IECEX audits.</p> <p>F-001 and F-002 are IECEX QAR forms and Nonconformity Report Forms respectively, available from the IECEX website at http://www.iecex.com/QAR_Forms.htm</p>	<p>OD 026 F-001 F-002</p>	<p>located in different countries</p>	<p>different locations, especially different countries each location shall be audited</p>
<p>9</p>	<p>A Quality Assessment Report (QAR) of the assessment/audit of the manufacture's quality system, including site audit, shall be compiled by the ExCB</p> <p>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 ExCB as major non-conformances 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.</p> <p>Where non compliance with various clauses of OD 005 are judged to be of a minor nature by the ExCB, the process may continue</p>	<p>OD 005-1 OD 025 F-001 F-002</p>	<p>ExCB conducting the audit/assessment</p>	<p>Generally this will be the ExCB to whom the application has been made, but may be compiled by another ExCB requested to conduct the audit</p>
<p>10</p>	<p>An independent review of the QAR shall be conducted within the ExCB to whom the original application was made.</p> <p>The independent review shall be conducted by a staff member of</p>	<p>In accordance with the ExCBs own quality</p>		<p>This independent review is to ensure that a complete assessment and audit</p>

Step	Section 3- Procedures for the Issuing of an IECEX Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	the ExCB that is not responsible for the audit.	management system		has taken place and that the recommendations are in line with the audit findings and any NCRs and related corrective actions
11	<p>The ExCB 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:</p> <ul style="list-style-type: none"> • IECEX rules and procedures • ExCBs 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 <p>Where discrepancies are identified they shall be immediately raised within the ExCB and a further review of steps 14 – 17 are conducted by the ExCB to confirm all details remain relevant.</p> <p>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.</p>	OD 005-1 OD 025 ExCB's own quality management system	Final decision being taken by the ExCB to which the original application has been made	The review should also ensure that the principles and guidelines of OD 025 have been followed
12	The final Quality Assessment Report (QAR) shall be issued, by the ExCB to whom the original application was made, to the applicant and a copy retained on the ExCB file.	F-001	ExCB to whom the original application was made	F-001 provides the QAR report format while F-002 provides the format for Non Conformity Reports
13	ExCB to register the QAR on the IECEX "On-Line" Certificate of Conformity Internet Website www.iecex.com by way of publishing a QAR summary report.	OD 011 Part 2 IECEX	ExCB	Contact the Secretariat for any assistance

Step	Section 3- Procedures for the Issuing of an IECEX Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity	Related Documents	By Whom	Notes/Comments
	<p>The publishing of a summary report on the On-Line System creates a database entry of key information such as</p> <ul style="list-style-type: none"> • Manufacturer and sites audited • ExCB performing the site audit • Protection Techniques • Product Type • Related CoCs • Other. <p>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,</p> <p>Refer to OD 011 Parts 1 and 2 for further information</p>	Website		
14 + 15	The ExCB shall review past audit / assessment results for compliance with Annex B			
16	Where the past audit / assessment results are acceptable the ExCB shall compile an IECEX QAR	F-001		
17 + 18	The independent review of Step 10 shall be conducted by a staff member of the ExCB that has not undertaken the quality assessment.			
19	Where this review is successful then the procedures according to step 16 or 9, as appropriate, shall be conducted by the ExCB issuing the QAR	ExCB's internal procedures	ExCB staff	

SECTION 4 – Surveillance Audits - Procedures for Maintaining an IECEX Certificate of Conformity

This Section is to be applied by ExCBs to ensure that IECEX Certificates of Conformity, issued under the IECEX Equipment Certification Program of the IECEX Scheme remain valid, through surveillance audits according to IECEX 02.

These steps are in line with the requirements of ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEX Scheme rules, IECEX 02.

In addition, they follow the general concepts of Draft revision to ISO/IEC Guide 53 *Conformity assessment — An approach to the utilization of an organization's quality management system in product certification*

Once an ExCB has issued an IECEX CoC they are responsible to ensure that surveillance assessment visits to the manufacturing location(s) are conducted in accordance with IECEX OD 025, either

- By conducting the surveillance visits
- Confirming that surveillance visits have been conducted by another ExCB, by confirming the details on the IECEX QAR registration area of the IECEX CoC website

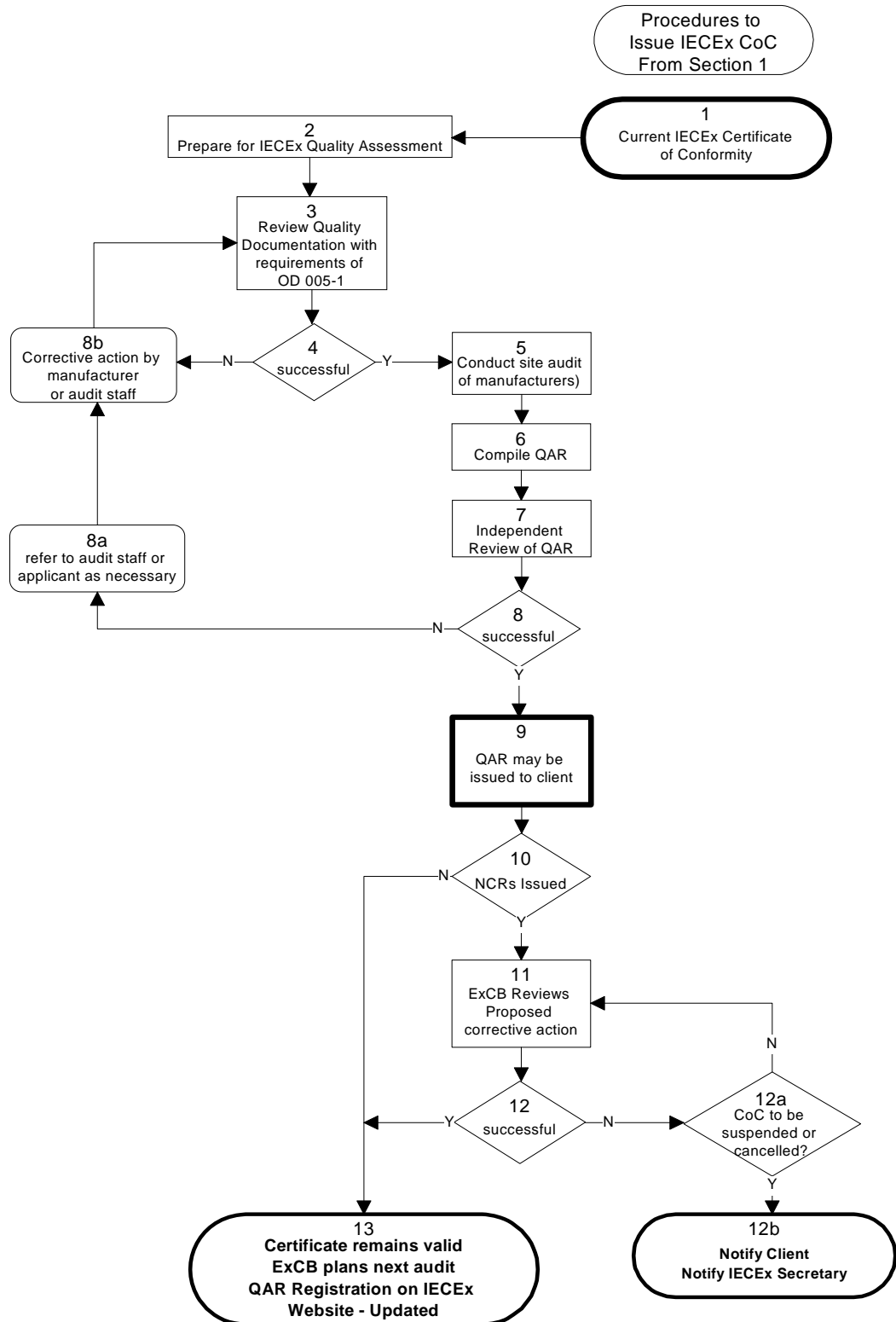
IECEX CoC holders may choose to use the ExCB that issued the IECEX CoC or another ExCB (with the Ex Technique within their IECEX scope) to conduct the surveillance assessment visits.

While this Section provides guidance to ExCBs when arranging for surveillance audits of manufacturers by the QAR issuing ExCB, there may be times where possible non-compliance of Ex products, covered by an IECEX Certificate of Conformity, are suspected not to be in compliance with the IEC Standard nominated on the IECEX Certificate of Conformity. ExCBs have the responsibility to act when this is a likelihood or where IECEX Certificates of Conformity, issued by them, are being misused or misrepresented.

Such action may include conducting unscheduled visits of the manufacturer, “check testing” of samples for serious cases, or even noting such instances on the ExCBs files for raising at the next surveillance audit.

Where a Certificate Holder wishes to transfer their surveillance audits to another ExCB, the new ExCB shall treat such a transfer as a new/initial audit and assessment.

At any time during the maintenance of an IECEX Certificate of Conformity, the IECEX Secretariat, Officers and Management Committee are available to provide assistance with the understanding of the process and expectation of outcomes of such surveillance activity.



IECEX Surveillance Operations - Overview

Step	Section 4- Surveillance Audits - Procedures for Maintaining an IECEX Certificate of Conformity - Description of Activity	Related Documents	By Whom	Notes/Comments
1	<p>IECEX Certificate of Conformity verified as valid by the ExCB that issued the IECEX CoC and confirms details on IECEX Certificate website are current and correct, eg manufacturing location(s), product identifier etc.</p> <p>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.</p>	IECEX 02 IECEX CoC	ExCB that issued the IECEX CoC	
2	<p>ExCB that issued the IECEX CoC (ExCB1) shall arrange to conduct the surveillance audit.</p> <p>Where the previously issued QAR, which is linked to the IECEX CoC , was issued by another ExCB, then (ExCB1) shall request that the other ExCB conducts a surveillance audit.</p> <p>As an alternative, the holder of the IECEX CoC may arrange for another ExCB to conduct the surveillance audit by informing the ExCB that issued the IECEX CoC, 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 require the issue of a new QAR and a Supplementary (New Issue) of the IECEX CoC by the ExCB that issued the original IECEX CoC, 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 conducting the surveillance visit shall treat the “transfer” as a new/initial assessment.</p> <p>This ensures full traceability of the system</p>	ExCBs own Quality System and OD 025 F-001	ExCB that issued the IECEX CoC	

Step	Section 4- Surveillance Audits - Procedures for Maintaining an IECEx Certificate of Conformity - Description of Activity	Related Documents	By Whom	Notes/Comments
3	Review of the manufacturer's quality documentation to ensure that any changes since the last audit complies with the requirements of IECEx OD 005-1. 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	OD 005-1 OD 025	ExCB conducting the audit	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 OD 005-1, 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.	OD 005-1 OD 025	ExCB	
5	Following the document review, the ExCB shall carry out the site audit in accordance with OD 025	OD 025 OD 005-1	ExCB	
6	A Quality Assessment Report, QAR shall be completed by the ExCB conducting the audit	OD 025 F-001	ExCB conducting the audit	F-002 provides a format for issuing NCRs
7	The ExCB that issued the IECEx CoC shall conduct an internal independent review of the prepared QAR by a person not conducting the assessment. This review shall verify among other items: <ul style="list-style-type: none"> • That a complete audit as planned had been conducted • Necessary documentation and records available • Confirmation that the auditor/team was appropriate, 	OD 025 OD 005-1 IECEX 02	ExCB that issued the IECEx CoC	

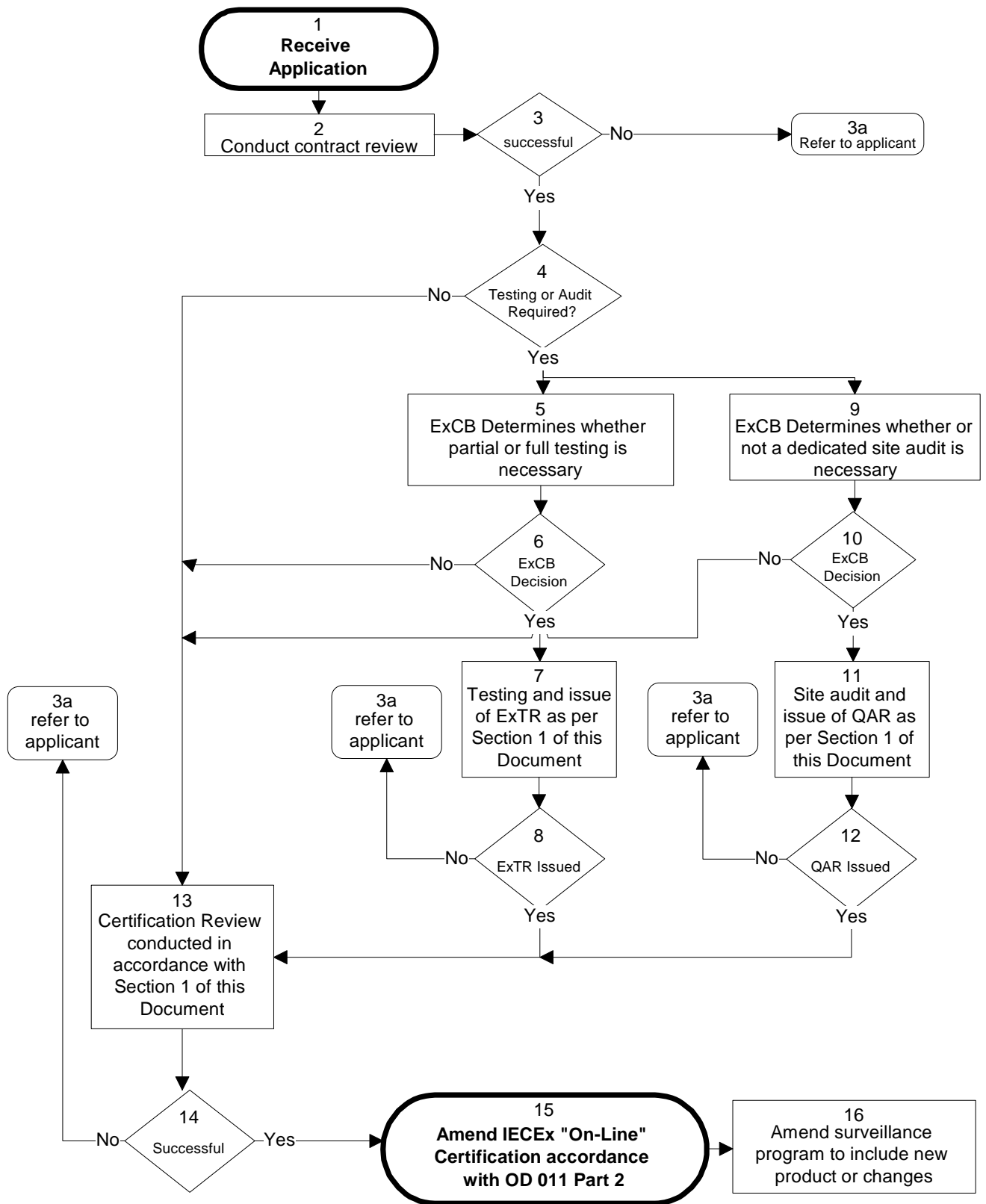
Step	Section 4- Surveillance Audits - Procedures for Maintaining an IECEx Certificate of Conformity - Description of Activity	Related Documents	By Whom	Notes/Comments
	especially where another ExCB is involved in the audit			
8, 8a, 8b	<p>Where the QAR reveals that the audit was incomplete, not conducted 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.</p> <p>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 IEC Standards listed on the IECEx CoC</p> <p>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.</p>	OD 025 IECEX 02 OD 005-1	ExCB that issued the IECEx CoC	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 that issued the IECEx CoC	
10, 11 +12	<p>The ExCB that issued the IECEx CoC shall review proposed corrective actions relating to Non Conformance Reports (NCRs) in terms of:</p> <ul style="list-style-type: none"> • 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 <p>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</p>	OD 005-1 OD 025	ExCB that issued the IECEx CoC	Contact the IECEx Secretariat for any questions or concerns

Step	Section 4- Surveillance Audits - Procedures for Maintaining an IECEX Certificate of Conformity - Description of Activity	Related Documents	By Whom	Notes/Comments
12a+12b	The ExCB that issued the IECEX CoC 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	Contact the IECEX Secretariat for any questions or concerns
13	<p>Where ExCB is satisfied that a full and complete surveillance assessment/audit has been completed demonstrating compliance with the requirements of IECEX OD 005-1 and OD 025, the ExCB that issued the IECEX CoC shall confirm that the details of the IECEX CoC as recorded on the IECEX website are accurate and up to date.</p> <p>The ExCB shall up-date the QAR registration on the IECEX website. The ExCB shall then schedule the next surveillance audit visit, in accordance with OD 025.</p> <p>ExCBs should consult the new Draft ISO/IEC Guide 53</p>	IECEX 02 OD 025 OD 011 Part 2	ExCB that issued the IECEX CoC	<p>Contact the IECEX Secretariat for any questions or concerns</p> <p>Only QARs that indicate compliance with IECEX requirements, even if minor NCRs are issued, shall be registered on the IECEX Website.</p> <p>QARs that show Major or significant problems shall NOT be registered on the IECEX website</p>

SECTION 5 – Procedures for the Processing of changes to issued IECEx Certificates of Conformity

This Section is to be applied by ExCBs when processing applications for changes to IECEx Certificates of Conformity.

These steps are in line with the requirements of ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02



Process for dealing with changes to IECEX Certification - Overview

Step	Section 5- Procedures for Assessing applications for changes to IECEX Certificates of Conformity Description of Activity	Related Documents	By Whom	Notes/Comments
1	Manufacturer lodges an application for Changes to the ExCB responsible for issuing the IECEX Certificate	IECEX 02 Certificate	IECEX Certificate Holder	
2	<p>ExCB that issued the IECEX Certificate shall conduct a contract review to determine, among others, that:</p> <ul style="list-style-type: none"> • The application is within the Scope of the IECEX Scheme • All necessary information has been provided by the applicant • The requested changes, are within the area of operation of the ExCB, eg scope of ExCB acceptance • Whether the requested changes should be treated as a new Certificate, in consultation with the manufacturer 	ExCBs own Quality System and IECEX 02	ExCB that issued the IECEX Certificate	For technical changes that incorporate a significant change to the product, the ExCB may determine that this be best dealt with by a new certificate. Both manufacturer and ExCB may consult with the IECEX Secretariat
3	<p>The ExCB shall inform the applicant of the results and shall record the contract review outcomes within their documented record system</p> <p>Where unsuccessful, the ExCB shall immediately inform the applicant in writing.</p>	IECEX 02 OD 025	ExCB receiving the application	
3a	Where the results of any of the stages are unfavourable to the application, the ExCB must immediately inform such outcome to the applicant who shall decide on whether to proceed by way of correcting any non conformity or to amend or even withdraw their application.	ExCB and Applicant		Where a dispute arises between the ExCB and applicant, the applicant must use the ExCB's internal appeals process before seeking

Step	Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity	Related Documents	By Whom	Notes/Comments
	It is expected that in such situations the ExCB should work with the applicant in the interests of maintaining good customer relations			to use the IECEx Appeals procedure
4	<p>The ExCB receiving the application for change shall determine whether the requested change is of a technical nature or administrative. Examples of administrative changes may be:</p> <ul style="list-style-type: none"> • Change to product identification • Change of company name, with no change to systems or personnel • Model redesignation <p>Even for administrative changes identified above the ExCB shall satisfy itself that changes of company name and ownership and the like ensure that previous controls over production are maintained. This may require the submission of documentation to the ExCB</p> <p>The addition of another manufacturing location is regarded as a technical change and requires an audit of that additional site.</p>	ExCB's own quality procedures	ExCB	
5	The ExCB shall determine the level of testing of samples required where the changes are of a technical nature. The ExCB shall review this situation in light of Section 1 of this Operational Document	Sect 1 of this OD 009 OD 010	ExCB	
6	The decision by the ExCB and it's ExTL on the level of testing or omission of such testing shall be documented and recorded within the ExCB's job files including the reason why any testing or	ExCB's own quality documentation	ExCB and its associated ExTL	

Step	Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity	Related Documents	By Whom	Notes/Comments
	evaluation may have been omitted			
7	On satisfactory completion of testing an ExTR shall be prepared and issued. This ExTR may be issued as an annex to an existing ExTR.	Section 2 of this OD 009 OD 010	ExCB and its associated ExTL	
8	The ExTR shall only be issued where all requirements have successfully met. Where this is not the case the ExCB or its associated ExTL shall notify the applicant as per step 3a The issuing of an ExTR shall only be considered complete once it has been registered on the IECEx website	OD 011 Part 2 Section 2 of this OD 009	ExCB or its associated ExTL	Refer to OD 011 Part 2 for guidance regarding Registration of ExTRs
9	The ExCB shall determine whether or not a dedicated site audit or visit is necessary and the scope of such audit. The ExCB shall review this situation in light of Section 3 of this Operational Document	Section 3 of this OD 009 OD 025	ExCB	
10	The decision by the ExCB whether or not a dedicated site audit or visit is necessary shall be documented and recorded within the ExCB's job files including the reasons why or why not. Refer to step 9 for guidance,	Section 3 of this OD 009 OD 025	ExCB	Contact the IECEx Secretariat for any questions or concerns
11	If a site visit is necessary, a QAR shall be prepared and issued according to Section 3, upon completion.	Section 3 of this OD 009 OD 025	ExCB	

Step	Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity	Related Documents	By Whom	Notes/Comments
12	<p>The QAR shall only be issued where all requirements have successfully met. Where this is not the case the ExCB shall notify the applicant as per step 3a</p> <p>The issuing of a QAR is only considered complete once it is registered on the IECEx website</p>	OD 011 Part 2	ExCB that issued the QAR	Refer to OD 011 Part 2 for guidance regarding Registration of QARs
13	<p>The ExCB responsible for issuing the original IECEx Certificate shall be responsible for conducting a final Certification Review in accordance with Section 1 of this OD and their own quality management system, ensuring among others that:</p> <ul style="list-style-type: none"> • ExTR and QAR relate to the same product(s) • 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 ExCB have a signed commitment by the applicant to abide by the rules of the IECEx Scheme and ExCB's certification conditions, eg agreement to have the ExCB undertake or arrange for surveillance audits • The applicant is aware of his/her obligations under the scheme, including ensuring that any promotional material does not contain misleading information that may infer products NOT covered by IECEx certification are certified 	<p>ExCB own quality system procedures</p> <p>Section 1 of this OD 009</p>	ExCB that issued the original IECEx Certificate	The Certification review step is required even where the application change is of an administrative nature
14	The process to issue a new issue (change to existing CoC), known as Issue 1 or higher, shall only proceed where all requirements have been successfully met. Where this is not the		ExCB that issued the original IECEx Certificate	Note that the first time a certificate is issued is identified as Issue 0,

Step	Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity	Related Documents	By Whom	Notes/Comments
	case the ExCB shall notify the applicant as per step 3a.			otherwise known as Original Issue. Any revisions to that original CoC are known as Issue 1 or higher. See OD 011 Part 1 for further explanations.
15	IECEX Certificate of Conformity shall be compiled using the IECEx "On-Line" system via the password protected system 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	Section 1 of this OD 009 OD 011 Part 2	ExCB that issued the original IECEx Certificate The applicant should also be given the opportunity to review	
16	The ExCB shall review their surveillance program to ensure that the program covers any changes resulting from the new Issues of the certificate, eg the addition of new manufacturing locations for future surveillance visits.		ExCB that issues the IECEx Certificate	

ANNEX A

Acceptance of Test/Assessment Data Obtained prior to the Application for an IECEX Test Report or IECEX Certificate of Conformity

A1 Introduction This Annex sets out the conditions upon which test or assessment data, obtained prior to the ExCB receiving an application for an IECEX Test Report (ExTR) or IECEX Certificate of Conformity (CoC).

A2 Acceptable use

A2.1 Acceptance of test data obtained prior to the acceptance of an ExTL by the IECEX Management Committee

ExTLs may use test or assessment data obtained prior to the ExTL's acceptance into the IECEX Scheme only when ALL of the following criteria have been met, noting that ExCBs receiving ExTRs, may refuse to accept such results where the test were conducted more than 3 years prior to the acceptance of the ExTL:

- a) Data from tests/assessments are not from such test facilities, equipment or processes that were the subject of a Major non-compliance raised at the time of the IECEX Assessment, such that corrective action by way of new/modified test apparatus, test/assessment processes or new personnel were required in order to gain acceptance as an ExTL. Test results falling into this category cannot be used and the test or assessment to be repeated; and
- b) The test parameters, procedures, process used to obtain the previous test or assessment data are the same as those concerning the Standard to which application has been made; and
- c) The previously obtained test or assessment data is from test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEX CoC application.

A2.2 Acceptance of test data obtained after an ExTL has been accepted by the IECEX Management Committee but yet obtained prior to the application for an ExTR or IECEX CoC

ExTLs may use test or assessment data obtained prior to receiving an application for an ExTR only when ALL of the following criteria have been met:

- a) The test parameters, procedures, process used to obtain the previous test or assessment data are the same as those concerning the Standard to which application has been made;
- b) The previously obtained test or assessment data is from test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEX CoC application

A2.3 Manufacturer's test Data

Test results obtained from manufacturer's testing facility are ONLY permissible where such tests have been conducted under the supervision of the ExTL, and in accordance with the ExTL's own quality management system. The requirements of A2.2 above shall also be met.

NOTE: IECEX are currently developing a guide covering the use of manufacturer's test data. Proposals for inclusion in this guide may be submitted by ExCBs, ExTLs, Member Bodies and industry and government stakeholders via their IECEX Member Body or direct to the IECEX Secretariat

A2.4 Method and format for reporting by ExTLs and ExCBs

A2.4.1 Background

As in many cases the ExTR will be used by other Certification and Approval Bodies to issue their own certification/approval, the quality and completeness of the information, such to assist the body receiving an ExTR is most important.

Time and money spent getting the ExTR right, before it is issued, prevents problems for manufacturers and sellers down the track and also possible rejection by bodies receiving ExTRs. The credibility of the issuing ExTL can also be judged on the quality and completeness of the test/assessment information.

The IECEX Management Committee also recognise that the IECEX blank Test Report format requires a greater level of reporting than an ExTL, operating within their own national certification, may normally have been required, as much of the detailed test and assessment data remains on the laboratory's own files. As bodies receiving ExTRs are required to make judgement on the ExTR information alone, the more complete the information and easier to show compliance with each clause of the standard, the smoother will be the acceptance by the body receiving the ExTR and hence their issuing of certification or approval. The end result will be reduced overall costs and quicker time to market for by the seller.

Therefore in light of the above, the IECEX Management Committee have decided on the following requirements when completing and issuing an ExTR using test data from information.

A2.4.2 Reporting requirements

In ALL cases the IECEX Test Report blank forms shall be used (previously known as ATRs). An ExTL is permitted to attach their a complete test report or evaluation record, to an ExTR/ATR format providing the Section 1 of the ExTR provides a clear linkage to the test data and results contained within the attached report.

Copies of related drawings, duly endorsed by the ExTL, shall form part of the overall ExTR.

ExTRs shall clearly identify those test/assessments results that were obtained previously.

ExTRs shall be registered on the IECEX On-Line Certificate of Conformity System. Refer to OD 011 Part 2 for guidance.

ANNEX B**Acceptance of Quality Assessment and Audit Data Obtained prior to the Application for an IECEX Quality assessment Report**

B1 Introduction This Annex sets out the conditions upon which quality assessment data relating to a manufacturer applying for an IECEX Quality Assessment Report (QAR) may be accepted.

B2 Acceptable use**B2.1 Acceptance of quality assessment and audit data obtained prior to the acceptance of an ExCB by the IECEX Management Committee**

ExCBs may use quality assessment or audit data obtained prior to the ExCB's acceptance into the IECEX Scheme only when ALL of the following criteria have been met:

- a) Quality assessments and audits were conducted by the ExCB's personnel with competencies in the Ex field.
- b) No Non-conformances were raised at the time of the IECEX Assessment, such that corrective action by way of new/modified processes or new personnel were required in order to gain acceptance as an ExCB.
- c) The ExCB can demonstrate that the general requirements of IECEX Operational Document OD 005 has been met; and
- d) The previously obtained assessment and audit data are for test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEX CoC application.
- e) The ExCB shall conduct a site visit as part of a surveillance audit, in accordance with OD 025, prior to the issue of a QAR.

B2.2 Acceptance of quality assessment and audit data obtained after an ExCB has been accepted by the IECEX Management Committee but yet obtained prior to the application for an IECEX QAR or IECEX CoC

ExCBs may use quality assessment and audit data obtained prior to receiving an application for a QAR when ALL of the criteria specified in B2.1 above have been met.

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