



IECEX Guide
Guidance for Applicants seeking IECEx
Certification under the
IECEX Certified Equipment Program, IECEx 02

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

**IECEX Guide – Guide for making Applications for IECEx Certificates of
Conformity under the IECEx Certified Equipment Program**

INTRODUCTION

This document provides guidance on the process for applicants seeking IECEx certification of Ex products. It shows the steps and processes required for manufacturers to gain IECEx CoC (Certificate of Conformity).

Note: The details of the process are given on other IECEx documents. These will be referred to in the text.

Document History

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1 Overview

This guide has been prepared to assist manufacturers understand that while technically rigorous, the process of achieving an IECEx Certificate of Conformity is rather straightforward.

Gaining an IECEx Certificate of Conformity for a product provides a manufacturer with an International Statement that:

- The product shown on the certificate is manufactured to meet the listed International IEC Standard; and
- The manufacturer is operating a dedicated quality management system, meeting the specific IECEx requirements; and
- The manufacturer is under on-going surveillance by an Internationally assessed and recognised IECEx Certification Body

As proof of this achievement the International IECEx Certificate of Conformity is on FULL public display via the IECEx Official Internet Website.

1.1 Who do you apply to?

Applications for an IECEx Certificate of Conformity, under the IECEx Certified Equipment Program, are lodged directly with IECEx Certification Bodies (ExCBs) whom themselves have successfully undertaken the IECEx Peer Assessment Program.

A full and up to date listing of ExCBs approved to operate under the IECEx Scheme is maintained on the [IECEx website](http://www.iecex.com) (www.iecex.com).

The screenshot shows the IECEx website interface. A navigation menu on the left includes 'About the IECEx', 'FAQs', 'Countries', 'Officers', 'ExCBs', 'Meeting Schedule', and 'Links'. The 'ExCBs' menu item is highlighted with a red arrow. The main content area displays the 'Approved IECEx Certification Bodies (ExCBs) Certified Equipment Programme' page, which includes a table of approved bodies.

Region	Country	ExCB	Country	ExCB	Country	ExCB	Country	ExCB
AM	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS
CA	USA	SAFARI	SE	SGS	GB	BASESTA	IN	SGS



1.2 Preparing an application

The manufacturer must be able to satisfy the following general requirements. When the manufacturer is confident that the requirements have been met, then application can be made for certification. In readiness for the application, a manufacturer may decide to apply for a “pre-assessment” review with an IECEx Certification Body, prior to the formal application being lodged.

In preparing an application to be submitted to an ExCB, the manufacturer needs to be confident that the following is in place:

- a) Confidence that the product design will meet the specified IEC Ex Standard
- b) Development of QA system covering manufacture of the product (ISO 9001 and IECEx Operational Document OD-005)
- c) Product documentation that meets IECEx Operational Document OD-017 requirements
- d) The relevant application form from the ExCB duly completed

1.3 Making the application

The application for IECEx certification begins with contacting the ExCB, as required by the IECEx Rules, IECEx 02. A special form may not be necessary, but the following information will generally be required by the ExCB.

- a) Letter requesting IECEx Certificate of Conformity or Ex Test Report (ExTR).
- b) Exact details of the product and its manufacturing location(s)
- c) Whether the manufacturer has an established quality management system
- d) List of design standards

The ExCB will estimate the time and cost to complete the certification project.

Refer to the flowchart in this document. It covers the process from the manufacturer’s viewpoint, and shows the typical activities needed to obtain a Certificate of Conformity.

2 Manufacturing Quality Management System (QMS)

The IECEx QMS requirements are modelled on the International Standard ISO 9001, with additional QMS requirements detailed in Item 3 below. This standard needs to be met by a manufacturer applying for IECEx certification of a product. While IECEx does NOT require that a manufacturer separately holds ISO 9001 Certification, this may be beneficial as a culture of QA compliance may exist throughout the manufacturing organisation.

Where ISO 9001 certification is held, some of the ExCBs also hold national accreditation to issue ISO 9001 Certification. This may be more convenient for the manufacturer because all certification work is done by one Certifying Body.

Where ISO 9001 Certification is not held, the ExCB will assess compliance to ISO 9001 as part of their assessment to OD 005

NOTE: The QMS needs to be maintained and audited at regular intervals. See Operational Document OD-025.

3 OD-005 Additional requirements to ISO9001

The requirements of ISO 9001 are generic in nature and apply to any organisation whether manufacturer or service provider. In the IECEx system, there are additional requirements for the QMS (see OD-005). The extra requirements are due to the need to carefully control traceability of material and to ensure that the competence of personnel working on Ex production can be proven.



The additional requirements are intended to ensure that no part of the manufacturing process can lead to a situation where certification is compromised.

For ease of use, OD 005 has been written using the same Clause numbering and headings as the generic ISO 9001 Standard, thereby making it easy to clearly identify the additional and more specific QMS requirements for Ex manufacturing. Annex A of OD 005 provides assistance regarding critical areas of the QMS in relation to the various Ex Types of Protection.

NOTE: All QMS requirements (ISO9001, OD-005) are focussed on assuring that the product is always produced to certification. The QMS system is expected to prevent any deviations in the process which may affect certification of the product.

4 Product documentation

To obtain IECEx certification, the documentation supporting the product must be submitted for review. Product documentation requirements are given in IECEx Operational Document OD-017. Documentation to be provided by the manufacturer covers the life cycle of the product (installation and use instructions, service information, overhaul and repair data and test data for some items).

The manufacturer is responsible for providing the documentation only. The user of a product is responsible for following the manufacturer's instructions and for maintaining the product in compliance with Standards and manufacturer's instructions.

5 Product type testing

Type testing of sample(s) representative of production is conducted by IECEx approved Testing Laboratories (ExTLs), operating under the control of ExCBs. The manufacturer arranges for the product to be tested to the applicable IEC standard by first contacting the ExCB to whom application is made. The ExCB passes the project to the chosen ExTL with any necessary instruction for testing. Refer to the list of approved ExCBs located on the [IECEx website](#).

A product may be covered by one or more IEC Standards. The ExCB will determine the correct standard(s) which apply to a product and will suggest a suitable ExTL (IECEx test laboratory).

Note: IECEx Operational document OD-009 covers this process.

5.1 ExCB and ExTL

ExCBs have a number of associated ExTL Both the ExCB and ExTL must be assessed by the IECEx to operate in the IECEx Scheme.

The Scope of the ExTL must include all standards (including editions) required for certification.

When testing is complete, an ExTR (IECEx Test Report) will be prepared. This is a test report covering the product. OD-009 describes the process of issuing and approving ExTRs.

5.2 Test process

Samples must be prepared by the manufacturer in consultation with the ExTL. These samples may include special modifications to enable tests to be completed.

The ExTL will specify any special requirements for samples.

Testing can take some time and, in some cases, may involve interpretation of a particular clause in a standard. This is why the ExCB remains involved in the test process throughout testing.

Note that some materials require conditioning prior to test, early consultation with the ExCB and ExTL is helpful.

5.3 ExCB Scope

The ExCB can only certify product covered in their IECEx Scope of Acceptance. The Scope is a list of standards where both the certifying body and at least one associated test laboratory have been



assessed as having the competence and correct equipment to test and certify to that standard. In some cases an extension of scope can be made.

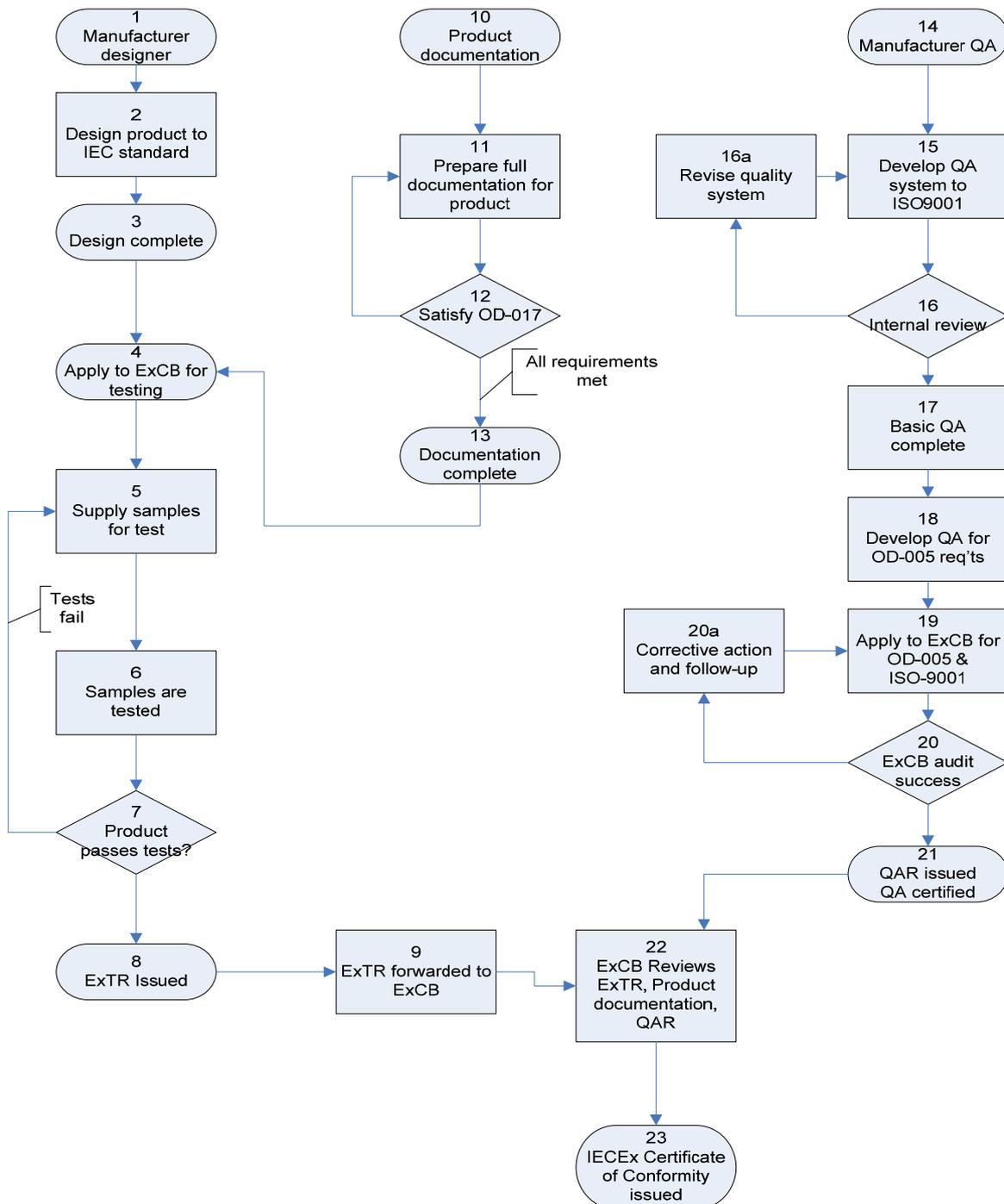
Scope includes the standard itself and the edition of the standard.

6 Application to IECEx for certification

Refer to the following Flowchart and Table of explanatory notes.



Guide to applicants of IECEx product certification





Step	Manufacturer's activities for obtaining an IECEx Certificate of Conformity	Related Documents	By Whom	Notes/Comments
1	The design project is started	Manufacturer's design control procedure	Manufacturer	Manufacturer set the goals for the design.
2	Design standards are decided.. This step will influence design due to need consider testing and what standards will be referenced on IECEx certificate of Conformity	IEC Standards Legislation in target markets	Manufacturer	Latest revision if standards should be used
3	Design complete		Manufacturer	Design review and validation should be clearly documented for review by certification team.
4	Apply to ExCB for testing The ExCB has associated ExTL (test laboratories) The ExCB will suggest an ExTL ExTL agreed between manufacturer and ExCB		Manufacturer	
5	Supply Test Samples		ExCB and ExTL	Samples may need special preparation for testing. Discussions with the ExCB will resolve test and certification issues
6	Testing	IECEX 02 IECEX OD 010	ExTL	The ExTL should check the list of ExTAG Decision Sheets to see if there are any that relate to the product under test.
7	Product passes test		ExTL	Certification data and supporting documents must be available for ExCB prior to issue of certificate.
8	IECEX Test Report (ExTR) is prepared using the appropriate blank report form An ExTR shall also be compiled when utilising previously obtained test data.	See IECEx Website www.iecex.com	ExTL	ExTL may transfer information from previous reports if required



Step	Manufacturer's activities for obtaining an IECEx Certificate of Conformity	Related Documents	By Whom	Notes/Comments
9	<p>ExTR to be reviewed by the ExCB prior to being issued by the ExCB.</p> <p>The endorsement of this ExTR is shown by the ExCB issuing an ExTR Cover Sheet or their own cover page but shall not use the word CERTIFICATE anywhere on the document, as this may give the impression that the endorsement page is a certificate thereby detracting from the real IECEx Certificate of Conformity</p>		ExCB	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
10 to 13	<p>Product documentation</p> <p>The document package can be prepared in parallel with the design activity.</p> <p>Documentation must be reviewed in order to issue a Certificate of Conformity</p>	IECEX OD 017	Manufacturer	The manufacturer should discuss the product documentation requirements with the ExCB as early as possible
14	<p>Preparation for the IECEx Quality Assessment</p> <p>The work on quality assurance can be done in parallel with the design and product documentation work.</p>	ISO 9001 IECEX OD 005	Manufacturer	
15 to 18	<p>QA system development</p> <p>The QA system requires ISO 9001, plus the additional requirements of the IECEx Scheme (OD-005).</p> <p>Relevant manufacturer's quality system documentation is to be reviewed to verify that documentation complies with the requirements of IECEx OD 005 and ISO 9001.</p>	ISO 9001 IECEX OD 005 IECEX OD 025	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.
19 to 20	<p>Application for QA assessment of the manufacturer</p> <p>An application from the manufacturer to the ExCB will result in an audit being scheduled, and the findings collated as a QAR.</p> <p>The ExCB conducts the on-site audit.</p>	IECEX OD 005 IECEX OD 025	See above	Where the Ex product is manufactured in different locations, especially different countries each location shall be audited, prior to the issuing of the IECEx Certificate of Conformity.
21	To issue a Quality Assessment Report (QAR) the following are required:	IECEX OD 005 IECEX OD 025	IECEX auditing body ExCB conducting the	Generally the ExCB to whom the application has been made will audit and



Step	Manufacturer's activities for obtaining an IECEx Certificate of Conformity	Related Documents	By Whom	Notes/Comments
	<p>Auditor's assessment/audit report of the manufacturer's quality system, including site audit.</p> <p>Endorsement by the ExCB to whom the original application was made, once any outstanding matters are dealt with.</p>		audit/assessment	endorse the QAR
22	<p>The ExCB to which the application for an IECEx CoC will need to review the following for the certificate to be issued:</p> <ul style="list-style-type: none"> Manufacturer complies with IECEx rules and procedures Manufacturer's quality system complies with OD-005 ExCBs own quality management system requirements are met and ExTR and QAR relate to the same product(s) Audit NCRs are closed so that the QAR can be issued The ExTR clearly shows that the products covered by the ExTR(s), comply with standards listed on the application. The documentation package complies with OD-017. This ensures that service to the product has sufficient information to keep the product within certification limits. Manufacturer has signed an agreement with the ExCB to maintain the QA system through surveillance audits 	<p>IECEX 02</p> <p>IECEX OD 005</p> <p>IECEX OD 025</p> <p>IECEX OD 017</p> <p>ExCB's own quality management system</p>	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 ExMC/161/CD have been followed
23	<p>IECEX Certificate of Conformity shall be compiled using the IECEx "On-Line" system via the password protected system</p> <p>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</p>	Refer IECEx website	ExCB personnel authorised to issue IECEx Certificates of Conformity (must be ExCB who received the original application)	Contact the IECEx Secretariat for any questions or concerns