



IECEX OPERATIONAL DOCUMENT

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

IECEX Certified Equipment Scheme

IECEX Operations Manual – IECEX Unit Verification Certificates



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Equipment for use in Explosive Atmospheres (IECEX System)**

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IECEX Operations Manual – IECEx Unit Verification Certificates

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IECEX OPERATIONAL DOCUMENT

IECEX Certified Equipment Scheme

Ex OD 033 Edition 1.1

IECEX Operations Manual – IECEX Unit Verification Certificates

This Operational Document, OD 033 is supplementary to the Operational manuals and procedures of the IECEX Certified Equipment Scheme, operated by IECEX Certification Bodies (ExCBs), to enable ExCBs to issue IECEX Certificates of Conformity for individual equipment or apparatus operating in explosive atmospheres.

Document History

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Introduction

A need exists within industry to issue IECEx Certificates that cover a defined number of products/items that are produced under a single production run. This form of Certificate is known as IECEx Unit Verification.

This Operational Document is supplementary to the Operational manuals and procedures of the IECEx Certified Equipment Scheme, operated by IECEx Certification Bodies (ExCBs), to enable ExCBs to issue IECEx Certificates of Conformity for individual equipment or apparatus operating in explosive atmospheres where either explosive gases or combustible dusts may be present.

The following principles, as agreed by ExMC, are applied in the course of issuing IECEx Certificates of Conformity for Unit Verification:

- An IECEx Certificate covering Unit Verification can be issued for a Defined number of items under a single production run. IECEx Unit Verification Certificates do not cover “future’ production runs.
- Certificates shall be the same as the existing CoC BUT listing the serial numbers or other unique identification to be clear which specific items are covered by Certification. To be listed on page 1 of the Certificate, or a reference from page 1.
- A Full and complete ExTR to be issued, according to IECEx 02.
- The ExTL and ExCB are responsible for verifying that all defined units are identical to the items tested / evaluated prior to those shipped by the manufacturer.
- Full requirements of Standards apply. Additional samples/subassemblies may need to be produced to undergo destructive tests.
- Use ISO/IEC Guide 67 as a reference.
- No Quality Assessment or ISO 9001 certification is required or verified at the time of issuing an IECEx Unit Verification Certificate.
- Include “Unit Verification” Text for the QAR field of the Certificate.
- The certificate reference number shall the same as existing CoC system.
- No limit to the number of Units permitted to be covered, BUT all serial numbers or other individual identifications SHALL be listed on the IECEx certificate- (IECEx ExMC will monitor this policy).
- ExCBs/ExTLs currently operating in the IECEx 02 Scheme do not require scope extension applications, however are required to have the requirements of this OD 033 embodied within their internal operating procedures.
- New issues of Issued Unit Verification CoC are NOT permitted.
- Unit Verification may cover repaired items but does not address the repair process.

The purpose of the Operational Document is to ensure that each ExCB, accepted by ExMC for the purposes of issuing IECEx Unit Verification Certificates, processes applications from Ex manufacturers with the same approach and technical rigour, known as “certifying the IECEx way”.

This IECEx Operational Document comprises the following Sections:

Section 1 Procedures for issuing an IECEx Unit Verification Certificate

Section 2 Changes to products covered by IECEx Unit Verification Certificates

Annex A Documentation checklist for applications - IECEx Unit Verification Certificate

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.

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.

Guide 27 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.

ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services

SECTION 1

Procedures for the Issuing of an IECEx Unit Verification Certificate

This Section is to be applied by ExCBs when processing applications for an IECEx Unit Verification Certificate.

These steps are in line with the requirements of ISO/IEC 17065, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02 for certified product.

Annex A contains a checklist of documentation required to fulfil Application and IECEx OD 017 requirements.

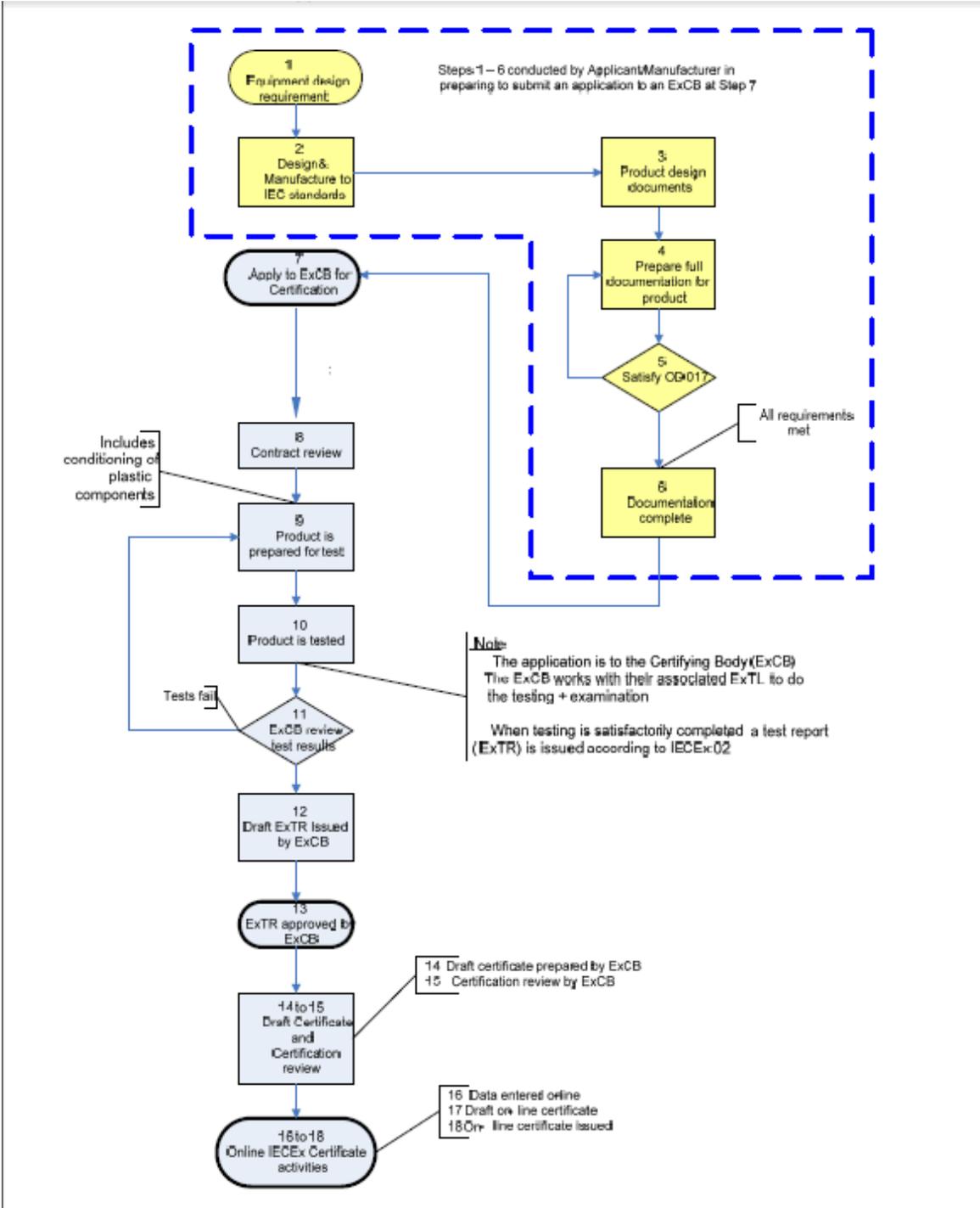
The following is a broad outline of how applications for IECEx Unit Verification Certificates are processed:

- The Applicant/Manufacturer is responsible for ensuring steps 1 - 6 are met.
- The ExCB must review the Application.
- The documentation is reviewed (all the drawings, relevant datasheets and other data).
- A test report (ExTR) is prepared, in accordance with IECEx 02. As testing progresses, the ExTR results are compared with Technical Standards applicable to the equipment described on the Application. On completion of testing, the ExTR is issued.
- An IECEx Unit Verification Certificate is issued via the IECEx “on-line” certificate system.
- The provisions of IECEx OD 024, IECEx Rules of Procedure covering off-site or witness testing at a manufacturer’s, user’s or third party’s facility, concerning testing at other locations may be used for Unit Verification

Marking of products covered by IECEx Unit Verification Certificates

The marking for IECEx Unit Verification Certificates is the same as for conventional IECEx Certificates of Conformity. See OD 011 Parts 1 and 2 for details.

Figure 1 – Applications for IECEx Unit Verification Certificate



Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
1	Ex Manufacturer receives a contract to design and build a “one-off” or limited quantity/batch, usually for a special purpose or application. Standards for design should be specified in the original contract.	IEC Standards National codes for electrical and mechanical safety	The Applicant (or agent).	
2	The design is approved by the Ex Manufacturer. The end user may review and approve the design before applying for IECEx certification.	All design documents	The Applicant (and their customer).	
3	Product design documents are defined as a “package”.	Design	The Applicant.	
4	Documentation covering the design is prepared. This includes datasheets, drawings and Ex approval information for any Ex- certified parts used in the product.	Design	The Applicant.	
5	Ex Manufacturer reviews documents to requirements of IECEx OD 017.	OD 017	The Applicant.	
6	Documentation package has been reviewed by the Applicant as being complete and now prepared for submission with the application to an ExCB.		The Applicant.	The Manufacturer should contact the ExCB once documentation is complete.
7	Application is submitted to an ExCB: The application must be made to an ExCB that has been accepted by the IECEx Management Committee to operate under the IECEx Certified Equipment Scheme, according to IECEx 02. Applicant Ex Manufacturers are encouraged to check the completeness of the application using the checklist in Annex A of this OD 033. The ExCB shall review the application package as part of their contract review. Where the Ex Manufacturer is located in a non-IECEx participating country, the ExCB shall in conjunction with the ExMC Secretary, arrange for payment to the IECEx account of the surcharge, in accordance with OD 019.	IECEx 02 OD 019 (finance)	The Applicant.	Applications for an IECEx Unit Verification Certificate of Conformity will verify compliance with the requirements of the IECEx Scheme and relevant Operational Documents, e.g. OD 009 for the purposes of generating an ExTR.

Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
8	<p>Contract review is conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC 17065. 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, eg protection techniques. • The application package is complete. • Whether a surcharge applies for applicants or Manufacturers from non IECEx member countries. • Estimation of time and costs to complete project. • Determination of any special requirements, eg travel for any assessments or tests to be conducted on site. • Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and quality system. <p>ExCB shall only proceed where the contract review has been successfully completed.</p> <p>Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB.</p> <p>Change of ExCB's may be required if the equipment to be certified is not covered by the ExCB scope of operation.</p>	<p>ExCBs own Certification procedures as included in their Quality System and ISO/IEC 17065.</p>	<p>ExCB</p>	<p>The results of the contract review shall be documented and recorded.</p> <p>Annex A can be used as a summary of the documents supplied.</p>

Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
9	<p>The product (unit) is prepared for testing. The ExCB and their associated ExTL will prepare a Test Plan as required. Use of a Test Plan ensures that all tests performed are logged, and they have the test acceptance criteria. Often, testing will involve a number of ExTR (test reports) due to the need to cover components, and the overall system.</p> <p>NOTE: The Test Plan is a controlled document. Any Plastic components are thermally conditioned before testing, as required by the Standard. Test samples of critical items are submitted for destructive test. Some components which are not certified may need testing.</p>	Test Plan	ExCB ExTL conducts the testing.	A Test Plan may not always be required. Testing may follow the headings given in the ExTR (test report form). Where destructive testing is required additional samples or materials, representative of the completed item(s), may be required to prevent destruction to the completed item(s).
10	<p>The product is tested according to the Test Plan. Testing is be carried out by the ExTL associated with the ExCB. The Test Plan ensures that all tests are agreed and cover all certification issues. A record of all tests performed is kept in the Test Log. The tests performed are listed with pass/fail criteria and have provision for comments on the report.</p>	Test Plan Test Log ExTR	ExTL	
11	<p>The ExTR shall be prepared by the ExTL, using the standard IECEx ExTR blank templates. The ExTR is then reviewed by the ExCB for endorsement. Where the product fails tests listed in the Test Plan, the Ex Applicant/Manufacturer will be notified so that the product may be modified to pass the test which failed. For re-tested items, please refer to step 9 in this document. Failed tests which require correction or further action must be re-tested in full, to obtain a “pass” result in the ExTR.</p>	Test Plan ExTR	ExCB monitors all testing.	Standard ExTR blank templates are available from the IECEx website.
12	<p>A draft of the ExTR maybe issued to the Applicant/Manufacturer for their review prior to being formally issued. This may assist to check for any errors.</p>	Draft ExTR		

Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
13	<p>Upon review and endorsement by the ExCB the ExTR is issued.</p> <p>The ExCB endorsing the ExTR shall “Register” the ExTR on the IECEx “On-Line” Certificate of Conformity System.</p>	ExTR	ExTL issues report ExCB registers the test report “on-line”.	Guidance given in OD 011 Part 2.
14	<p>The draft IECEx Unit Verification Certificate is prepared and may be issued as a draft to the applicant for a review for any errors.</p> <p>All test documents, design data and design drawings are filed.</p> <p>Once satisfied that the test data and the supporting documentation are adequate the Certificate shall be issued, by the ExCB with the original sent to the Applicant and a copy retained on the ExCB file.</p> <p>The registration process provides a database of information such as:</p> <ul style="list-style-type: none"> • Unique Certificate reference number or identifier. • Name and address of Manufacturer of equipment covered by Certificate. • Details of IECEx Unit Verification Certificate such as type of protection. • Any comments that the ExCB feels should be noted. 	IECEx Unit Verification Certificate.	ExCB certification panel reviews the draft certificate.	<p>ExCB shall be assigned a unique password to allow entry of the ExTR and certificate details. The data is entered “On-Line”.</p> <p>Contact the IECEx Secretariat for any questions or concerns.</p> <p>The ExCB MUST maintain security over the passwords provided and notify the Secretariat of any possible breaches of this security, for which new passwords maybe assigned.</p> <p>OD 011 Part 2 provides guidance to ExCBs on the registering of issued ExTR and also the compiling and issuing of On-Line Certificates of Conformity under the IECEx Unit Verification Program.</p>

Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
15	<p>The ExCB to whom the application for an IECEx Unit Verification Certificate was made shall conduct a certification review, in accordance with their quality management system, ensuring among others that:</p> <ul style="list-style-type: none"> • 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. • The Applicant is aware of his/her obligations under the IECEx scheme. 	IECEX 02 ExCB's own quality management system.	The person authorised to conduct such review within the ExCB to whom the original application was made.	Contact the IECEx Secretariat for any questions or concerns.
15a	Where the review undertaken in step 15 is not successful, the ExCB management shall refer the matter to ExCB staff or Applicant personnel as appropriate.		Management of the ExCB to whom the original application was made.	Contact the IECEx Secretariat for any questions or concerns.
16	IECEX Unit Verification Certificate shall be now be completed, taking account of any adjustments arising from the review in step 15 using the IECEx "On-Line" system via the password protected system.	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.
17	<p>Prior to issue a final draft of the IECEx Unit Verification Certificate 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>While the Draft Certificate is created "On-Line" the ExCB may create a protected PDF copy and send this to the Applicant, refer to OD 011 Part 2 for guidance.</p> <p>Every attempt shall be made to correct errors prior to issuing the certificate.</p>	Original application form submitted by the Applicant. OD 011 Part 2	The person authorised to issue IECEx Certificates of Conformity within the ExCB to whom the original application was made. The Applicant.	The Electronic version residing on the IECEx "On-Line" System remains the master version. Any printing or copying is considered an "un-controlled" copy. Contact the IECEx Secretariat for any questions or concerns.

Step	Section 1- Procedures for the Issuing of an IECEx Unit Verification Certificate of Conformity – Description of Activity	Related Documents	By Whom	Notes/Comments
18	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 Unit Verification Certificate within the ExCB to whom the original application was made.	Contact the IECEx Secretariat for any questions or concerns.

SECTION 2

Requirements concerning changes to products covered by IECEx Unit Verification Certificates

As Unit verification certificates covers specific items, any changes to products covered by an IECEx Unit Verification Certificate, that are not already provided for by the certificate, eg additional cable / conduit entries, shall require the issuing of new Unit Verification Certificate.

In such situations, it is recommended that the owner of the equipment, seeking product changes consults the equipment manufacturer, prior to undertaking any such modification.

Annex A

Documentation checklist for applications – IECEX Unit Verification Certificate

The following is a list of specific documentation that an Applicant needs to make available to the ExCB, when seeking IECEX Unit Verification Certification of individual equipment.

1. Applicant Name... Date...	<input type="checkbox"/>
2. Details of Applicant for Ex IECEX Unit Verification... Name, Country, details of design authority Legal status of company	<input type="checkbox"/>
3. Full details of the product/equipment/item to be covered by the IECEX Unit Verification Certificate along with clear and unambiguous identification of the specific units/products to be covered (e.g. by serial Nos)	
4. Formal application to ExCB (and contract for work), including... Description of the product being certified Address where the product was manufactured List of design standards Details of explosion protection technique List of critical Ex certified parts used Ex marking plate information and Equipment Protection Level (EPL)	<input type="checkbox"/>
5. Test reports and final inspection being completed, including: a) test data for critical explosion protection parameters b) functional test results as appropriate	<input type="checkbox"/>
6. Operation and service manuals describing how the product is going to be installed, and safely used.	<input type="checkbox"/>
7. The Applicant confirms that it is in full possession of all necessary rights on the product to be tested (including its components), insofar as testing and/or certification is applied for.	<input type="checkbox"/>
Signed: Dated:	