

IECEX OPERATIONAL DOCUMENT

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

IECEX Operational Document

IECEX Certified Equipment Scheme - Assessment of Ex “s” Equipment





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IECEX Operational Document

**IECEX Certified Equipment Scheme - Assessment of Ex “s”
Equipment**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

IECEX Operational Document 233
IECEX Certified Equipment Scheme
Assessment of Ex “s” Equipment

INTRODUCTION

This IECEX Operational Document OD 233 provides a framework within the IECEX Equipment Certification Scheme for the procedures to be followed when an ExCB receives an application for certification to the requirements of **IEC 60079-33 Explosive atmospheres - Part 33: Equipment Protection by special protection “s”**, through to the point of delivery of the certificate and for subsequent surveillance of the manufacturing process.

Document History

Date	Summary
2015 03	Original Issue (Version 1)
<u>2017 02</u>	<u>Edition 2.0</u> – Removal of previous Annex B and reference to IEC 60079-33 for competence of verifiers and removal of the IECEX Executive from the process according to comments received by close of voting on ExMC/1200/DV

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1. Purpose and Scope

The purpose of this document is to provide a framework within the IECEx Equipment Certification Scheme for the procedures to be followed when an ExCB receives an application for certification to the requirements of IEC 60079-33 *Explosive atmospheres - Part 33: Equipment Protection by special protection "s"*, through to the point of delivery of the certificate and for subsequent surveillance of the manufacturing process.

The Ex "s" Standard IEC 60079-33 was developed by IEC TC31 in response to a request from industry to enable a degree of innovation in the way that products can be designed, whilst still providing a level of protection equivalent to that obtainable from the established types of protection. This issue was raised within the IECEx Management Committee and support for an International Standard conveyed to IEC TC 31.

IEC 60079-33 gives the technical requirements to be met by the equipment to be certified and introduces the notion of more than one ~~Independent Verifier~~ independent verifier responsible for verification of conformity to the standard. It also outlines the role of one or more "independent verifiers" in the conformity assessment process. ~~(The Independent Verifiers~~ The independent verifiers are referenced in IEC 60079-33 as ~~Verifier 1, Verifier 2 and Verifier 3~~ independent verifier (1), independent verifier (2) and independent verifier (3), respectively).

This Operational Document confirms that, for IECEx purposes, an ExCB must identify experts that are classified as ~~"Independent Verifiers"~~ independent verifiers in accordance with and as defined by IEC 60079-33, noting that up to three ~~Independent Verifiers~~ independent verifiers may be required. These independent verifiers ~~maybe may~~ be drawn from experts within or outside both the ExCB and their integral or associated ExTL(s). ExCBs shall have documented procedures of the process to be followed by those verifiers when operating within the IECEx Equipment Certification Scheme.

This document ~~augments and~~ should be read in conjunction with OD 009 as it contains details and requirements additional to those in OD 009.

Annex A to this document provides the procedure to be used when assessing the applications from an ExCB and its associated ExTL to operate to this Operational Document.

~~**Annex B** to this document provides the specific minimum criteria to be used when assessing the competence of an expert person as Independent Verifier 1, Independent Verifier 2 and Independent Verifier 3 to operate to this Operational Document.~~

2. General Principle

Ex "s" standard IEC 60079-33 provides a framework to demonstrate how essential safety requirements can be met by an innovative design. But before proceeding to special protection "s", a manufacturer should consider the possibilities for design of electrical equipment using existing techniques and methods with the following order of preference:

- Recognized types of protection
- Combination of recognized types of protection
- Methods provided by existing standard IEC 60079-26
- Other applicable international standards recognized by the IECEx system

When conditions and/or requirements are not completely met by existing techniques as given above, enough documented analysis, evaluation, testing and verification are

required to demonstrate how the essential safety requirements have been met against the claimed EPL of the equipment under assessment.

According to IEC 60079-33, equipment with special protection “s” shall have levels of protection “sa” (EPL “Ma”, “Ga”, “Da”), or “sb” (EPL “Mb”, “Gb”, “Db”), or “sc” (EPL “Gc”, “Dc”).

The number of ~~i~~Independent ~~v~~Verifiers involved in the conformity assessment process depends on the required level of protection:

- One ~~i~~Independent ~~v~~Verifier for Level “sc”, this means that Verifier (1) shall be involved only.
- Two independent verifiers for Level “sb”, this means that Verifier (1) as well as Verifier (2) shall be involved.
- Three independent verifiers for Level “sa”, this means that Verifier (1), Verifier (2) and Verifier (3) shall be involved.

ExCBs shall maintain a current list of ~~Independent Verifiers~~ independent verifiers as ~~Independent Verifier 1, 2, or 3~~ within their own ~~Training~~ training records as part of a ~~Competency~~ competency or ~~Task Matrix Table~~ task matrix table. This matrix shall be reviewed as part of the IECEx peer assessment process.

According to IEC 60079-33, there shall be ~~a lead~~an independent verifier plus ~~possible~~ additional ~~independent~~ verifiers as follows:

IEC EPL Gc or Dc	Lead Independent independent Verifier verifier (1) only
IEC EPL <u>Mb</u> , Gb or Db	Lead Independent Verifier independent verifier (1) and plus one additional independent verifier (2)
IEC EPL <u>Ma</u> , Ga or Da	Lead Independent Verifier plus two additional independent verifier (1) plus independent verifier (2) plus independent verifier (3)

IEC 60079-33 requires that the independent verifiers shall have ~~had sufficient experience, including access to or involvement~~ in the standards development process, to be aware of any currently discussed issues that might be applicable to the equipment. Familiarity with published standards alone is not considered sufficient.

Accordingly the project shall be allocated for certification management purposes to an individual who has ~~standards development experience~~ access to or involvement in the most applicable ~~standards development for the~~ concept for the equipment. ~~Similar approaches shall be taken for the independent verifiers.~~

~~The appointed ExCB project manager shall ensure that the work of any engineer is closely monitored in line with knowledge of developments in standards and related discussions.~~

~~Where a second or third Independent Verifier is required, the appointed ExCB project manager shall select an individual who is independent but also has standards development experience.~~

3. Procedures for the issuing of an IECEx Test and Assessment Report (ExTR)

The procedure outlined in Section 2 of OD 009 is augmented as follows. The step references are as used in Section 2, with additional steps identified with additional suffix letters. Where only one ~~Independent Verifier~~independent verifier is required (i.e. for level of protection sc), the steps related to the additional independent verifiers shall be ignored. The Steps of Section 2 in IECEx OD 009 shall be varied as follows:

OD 009 Step 1:

The manufacturer's application shall include a draft ignition hazard assessment prepared in accordance with Clause 9 of IEC 60079-33 and a draft assessment and test specification prepared in accordance with Clause 8 of IEC 60079-33 in addition to the data normally required.

OD 009 Step 2:

The contract review shall specifically include an evaluation of the competence of the ExCB and its associated ExTL to complete the work on the specific methods of protection identified by the manufacturer in the draft assessment and test specification (in relation to the ExCB/ExTL scope accepted by IECEx).

The ExCB in conjunction with its ExTL shall review the draft assessment and testing specification and either accept the proposal or initiate communication with the manufacturer to revise the document.

Additional Step 2a:

The ExCB shall determine the required independent verifiers (~~Independent Verifier 2 and Independent Verifier 3~~) to be involved in the process according to the required EPL of Ex "s" equipment, from within its listing of ~~Independent Verifier~~independent verifiers.

The ExCB shall ~~appoint~~nominate to the ExMC Secretary independent ~~verifiers Verifiers 2 and 3~~ from the ExCB's internal ExCB / ExTL list, maintaining a record of providing name, details of experience and how the requirements of Annex B of this document have been met.~~IEC 60079-33 are met.~~

~~The ExMC Secretary shall arrange for the IECEx Executive to review the nominated Independent Verifiers on a project by project basis. The decision of the IECEx Executive shall be arrived by consensus and where full agreement cannot be reached, the IECEx Chairman shall determine the course of action.~~

~~Where the IECEx Executive does not agree with the ExCB nominated Independent Verifiers for a specific project, the ExCB may seek to nominate alternative Verifiers for consideration by the IECEx Executive.~~

~~NOTE: As introduction of Ex s is a new concept for IECEx Certification, assigning the review and approval of Verifiers on a project by project basis is being assigned to the IECEx Executive, however it is envisaged that in the future a dedicated IECEx panel or forum will be established based on experience gained from this process.~~

Additional Step 2b:

Should the ExCB not have the required number of independent ~~Verifiers~~verifiers according to IEC 60079-33 ~~and approved by the IECEx Executive~~, then the ExCB shall inform the applicant and withdraw from the application.

OD 009 Step 4:

This shall be a refinement of the draft plan accepted at Step 2. According to the Category EPL as specified in IEC 60079-33 all ~~Independent Verifiers~~independent verifiers, (1), (2)

and (3) where more than ~~1 one Independent Verifier~~ independent verifier is required, shall agree on the test/assessment plan prior to commencing test and assessment.

OD 009 Step 6:

Once the Test/Assessment Plan has been agreed by all ~~Independent Verifiers~~ independent verifiers the ExTL, associated with the ExCB to whom the application has been made, may then undertake the tests/assessments.

OD 009 Step 7:

A draft ExTR, as prepared by the ExTL shall be reviewed and agreed by all the Independent Verifiers independent verifiers ~~with Verifiers 1, 2 and 3 all reaching agreement~~ (when more than ~~1 Independent Verifier~~ one independent verifier is required by IEC 60079-33) prior to the ExTR being finalised for final endorsement by the ExCB.

Additional Step 9a:

The ExCB shall prepare "QA" requirements as an Annex to the ExTR detailing any specific issues related to quality surveillance of the manufacturing activity for the product. This shall, in principle, stand as an additional part of the Annex to ~~IECEX OD 005-1 or~~ ISO/IEC 80079-34 prescribing the specific additional information necessary to be assessed when completing the QAR activity related to the product. Refer to **Annex B** for an example of the Reporting Form to be attached to the ExTR.

Additional Step 9b:

The ExTR, including the Annex of "QA" requirements, is also to be reviewed and, if acceptable, approved by ~~the additional~~ all independent verifiers.

4. Procedures for the Issuing of an IECEX Certificate of Conformity (IECEX CoC)

According to OD 009 it is possible for an ExCB responsible for the work to issue a new IECEX CoC by using a previous QAR for an Ex "s" product issued within validity date, providing:

- Manufacturing location is the same
- Ex protection techniques that are to be listed on the CoC are the same as covered by the previous audit and QAR
- The product is of a similar general nature of those covered by the previous audit and QAR
- The "QA" requirements annexed to the ExTR covering the product(s) that are to be listed on the CoC are similar to the specific issues covered by the previous audit and QAR
- That the manufacturer commits that the same production management system is being used for the new product

However, as producing product according to Ex "s" IEC 60079-33 requires special attention which would not normally be covered by any previously issued QARs, the ExCB shall assess whether or not an on-site assessment of the manufacturer is required prior to the issue of a new CoC covering Ex "s". The decision taken by the ExCB shall be formally recorded. A possible occasion where this on-site visit may not be necessary is where the

applicant seeks a new Issue of the IECEX CoC to cover changes, of Ex products and where the ExCB determines by assessment of the manufacturer's quality documentation that a site visit is not required

Therefore the procedure outlined in Section 1 of OD 009 is followed, with the addition that the QAR shall make specific reference to each individual product that is to be certified Ex "s" and that this shall be checked before issuing the certificate.

5. Procedures for the Issuing of an IECEX Quality Assessment Report (QAR)

The procedure outlined in Section 3 of OD 009 is followed, with the addition that the ExCB responsible for the work shall take into account the QAR Annex from the ExTR of any Ex "s" equipment that is to be included, and shall specifically include a reference to each Ex "s" certificate in the QAR.

Note that there are no additional competence requirements for an ExCB conducting the QAR assessment as the relevant details to be assessed are included in the QAR Annex to the ExTR. The manufacturer shall be audited only when the ExTR has been issued, and received by the ExCB conducting the IECEX quality assessment of manufacturer.

Readline Version

ANNEX A

Additional Requirements for ExCB and ExTLs to be assigned IEC 60079-33 within their IECEX Scope of Acceptance

(Normative)

This annex is used for assessing the competence of an ExCB and ExTL to hold IEC 60079-33 within their scope within the IECEX Certified Equipment Scheme.

Within the IECEX system, all the candidate bodies must present an application to IECEX secretariat for scope coverage of IEC 60079-33, and should be able to demonstrate the relevant competence of their Staff to undertake assessments according to IEC 60079-33, by an IECEX Assessor.

The application information to be submitted to the IECEX Secretariat by the ExCB shall include:

- a) Completed scope extension Declaration Form (currently ExMC/251B/Q)
- b) Copy of the ExCB's internal procedures (in English) for handling applications for Ex s according to both IEC 60079-33 and this Operational Document
- c) Copy of the ExCB's internal procedure/criteria for appointing experts as ~~Independent Verifier~~independent verifiers according to Annex B of this document
- d) Agreement that the ExCB will ~~appoint~~submit to the IECEX Executive, on a project by project basis, independent verifiers, maintain records of their copies of the list of ExCB's nominated Independent Independent Verifiers, showing name, details of experience and how the requirements of Annex B of this document have been met. competencies in IEC 60079-33 have been met.

The IECEX assessment of the ExCB and ExTL may be undertaken as part of an on-site assessment or via an "off-site" assessment of the ExCBs procedures and interview with staff via Web based Conferencing, arranged and managed by the IECEX Secretary. IECEX Assessors for IEC 60079-33 shall be appointed by the IECEX ~~Executive~~Secretary. The assessments of ExCBs and/or ExTLs are aimed at demonstrating compliance with this document and IEC 60079-33, as well as IECEX 02, ISO/IEC ~~Guide 6517065~~ and/or ISO/IEC 17025, and particularly including verification of the following knowledge, skills and competence:

- A broad knowledge of Ex philosophies, including the principle of explosion prevention, the properties, mechanisms and control of ignition
- Active involvement in IEC or national standardization committees (for example, by participating in document review and commenting processes)

~~The following aspects may also be relevant in a limited number of cases and the ExCB should only accept projects where these are relevant if they have the necessary experience and facilities:-~~

- ~~— In depth knowledge of risk reduction, reliability theory, reliability anticipation, reliability analysis, reliability test as well as calculation of FMEA and PFH **~~
- ~~— Knowledge and experience in evaluation and certification on safety integrity level (SIL) of equipment's hardware and software **~~
- ~~— Having necessary test facilities, equipment (for example, EMC, climate, mechanical), procedures and personnel **~~

- ~~— Having national accreditation on testing and/or evaluation of reliability, functional safety and EMC **~~
- ~~— Having full scope of Ex concepts covered by IEC 60079 and ISO/IEC 80079 series standards within IECEx certified equipment program for both ExCB and its associated ExTL.~~

~~** Note: Where the IECEx Secretariat, in conjunction with the assessment team, believes it appropriate to issue a restricted scope in relation to Ex-s equipment, they may do so.~~

Redline Version

ANNEX B

Requirements for the Competence of Persons declared as Independent Verifiers

(Normative)

~~This annex is to be used by ExCBs for assessing the competence of expert persons being appointed as Independent Verifier 1, Independent Verifier 2 and Independent Verifier 3 of Ex “s” equipment.~~

~~The detailed requirements for a qualified expert person are as follows:~~

- ~~— Employed or under permanent contract by an ExCB and its associated ExTL(s) which is previously accepted within IECEx for the purpose of Ex s certification, according to Annex A of this document~~
- ~~— An experienced member of the ExCB and/or ExTL, deeply involved in the testing and certification of equipment used in hazardous location for ten years at least~~
- ~~— Having additional knowledge and experience on evaluation of risk control, reliability and functional safety~~
- ~~— Active involvement in IEC or national standardization committees, preferably on explosion protection, functional safety and reliability~~
- ~~— Officially nominated for the purpose by the ExCB and/or ExTL,~~
- ~~— Officially registered in the ExCB's internal Competency or Skills matrix Table as an Independent Verifier for the purpose of this operational document~~

Readline Version

Annex CB

QA Related Aspects of IEC 60079-33 Certification

(Informative)

Customer Number:

Customer Name:

Project Number:

Equipment:

ExTR Reference Number:

Basis of Protection (list applicable concepts plus additional details):

Special QA Audit Requirements:

Yes

No

Details:

Prepared by:

Accepted by independent verifier (1):

Accepted ~~by (Independent Verifier 2)~~independent verifier (2):

Accepted by independent verifier (3)~~(Independent Verifier 3):~~

Countersigned (Certification Manager):

Redline Version