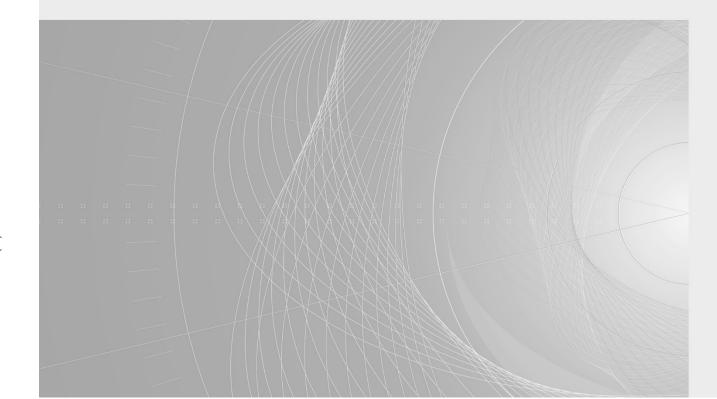


Edition 3.0 2022-10

IECEX OPERATIONAL DOCUMENT

IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System)

IECEx certified equipment scheme – Assessment of Ex "s" equipment





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEx Operational Document OD 233 -

IECEx certified equipment scheme – Assessment of Ex "s" equipment

FOREWORD

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)
2017-02	Edition 2.0 – 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
2022-10	Edition 3.0 – General revision (refer to Redline version for details)

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IECEx certified equipment scheme – Assessment of Ex "s" equipment

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 just evaluation or for evaluation and 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 just a test report or of a test report and certificate, and for subsequent surveillance of the manufacturing process as applicable.

The Ex "s" standard, IEC 60079-33, was developed by IEC TC 31 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 just evaluated or evaluated and certified and introduces the notion of more than one 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 are referenced in IEC 60079-33 as independent verifier (1), independent verifier (2) and independent verifier (3).

This operational document confirms that, for IECEx purposes, an ExCB must identify experts that are classified as independent verifiers in accordance with and as defined by IEC 60079-33, noting that up to three independent verifiers may be required. These independent verifiers 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 independent verifiers when operating within the IECEx equipment certification scheme.

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

2 General principle

The 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 other existing types of protection and methods recognized by the IECEx System with the following order of preference:

- Other existing types of protection recognized by the IECEx System
- Combination of other existing types of protection recognized by the IECEx System
- Methods provided by existing standard IEC 60079-26 as recognized by the IECEx System

When conditions and/or requirements are not completely met by existing types of protection and methods as given above, 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"), "sb" (EPL "Mb", "Gb", "Db"), or "sc" (EPL "Gc", "Dc").

3 Independent verifiers

3.1 Information on independent verifiers from IEC 60079-33

IEC 60079-33 has the following definition of independent verifier:

independent verifier

person or organization, with the appropriate competency in the applied explosion protection methodology, responsible for the verification of design calculations, assessment and testing who are separate and distinct by management and other resources including financial, from the person or organizations responsible for all the activities associated with the design, manufacture or sales of the equipment

Note 1 to entry: This may be a second- or third-party assessor, a test laboratory, a certifying body, etc.

It also includes a note in 5.1:

NOTE An independent verifier may be an individual or an organization.

The number of independent verifiers involved in the conformity assessment process depends on the required level of protection.

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

IEC EPL Gc or Dc	"sc"	independent verifier (1) only
IEC EPL Mb, Gb or Db	"sb"	independent verifier (1) and independent verifier (2)
IEC EPL Ma, Ga or Da	"sa"	independent verifier (1) plus independent verifier (2) plus independent verifier (3)

IEC 60079-33 requires that the independent verifiers shall have 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.

3.2 Application of the independent verifier concept in IECEx

It should be noted that the definition of independent verifier defines the independence in relation to "the design, manufacture or sales of the equipment". It does not define independence within the organization doing the testing, assessment and certification, that is for IECEx, the ExTL and ExCB. For IECEx the normal independence between ExTL and ExCB activities will apply according to ISO/IEC 17065. Hence the activities of the independent verifiers will be regarded as ExTL roles, with the final endorsement done by the ExCB in the normal way.

The independent verifier (1) shall be interpreted as the reviewer of the ExTR for the ExTL. This also relates to the review role relevant to ISO/IEC 17025. This verifier shall be an individual from the same organization as the compiler of the ExTR and shall have been identified as competent to be an independent verifier according to IEC 60079-33.

The independent verifiers (2) and (3) may be from the same organization as the compiler of the ExTR or from another organization and shall have been identified as competent to be an independent verifier according to IEC 60079-33. Where other organizations are used for this

task, they shall be accepted IECEx ExCBs or ExTLs and shall have IEC 60079-33 in their IECEx scope.

ExCBs/ExTLs shall maintain a current list of independent verifiers within their own competency records as part of a competency or task matrix table. This matrix shall be reviewed as part of the IECEx peer assessment process. Where they intend to use other organizations, those organizations shall be clearly identified and there shall be agreements in place for them to undertake the independent verifier role.

The above is summarized in the table below which shows the IECEx application added to the table above:

EPL	Ex "s" marking	No of Independent verifiers required	Application in IECEx
IEC EPL Gc or Dc	"sc"	independent verifier (1) only	Will also be the current ExTL reviewer but performed by someone identified as competent to be an independent verifier
IEC EPL Mb, Gb or Db	"sb"	independent verifier (1) and independent verifier (2)	Independent verifier (2) may be someone from same organization or another organization competent to be an independent verifier
IEC EPL Ma, Ga or Da	"sa"	independent verifier (1) plus independent verifier (2) plus independent verifier (3)	Independent verifiers (2) and (3) may be someone from same organization or another organization competent to be an independent verifier

4 Procedures for the issuing of an IECEx test report (ExTR)

The procedure outlined in Section 2 of IECEx OD 009 is augmented as shown below. The step references are as used in Section 2, with additional steps identified with additional suffix letters. Where only one independent verifier is required (that is for level of protection "sc"), the steps related to the additional independent verifiers shall be ignored.

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). If it is intended to use independent verifiers from other organizations, the competence of the staff of those organizations shall also be evaluated.

The ExCB in conjunction with its ExTL shall review the draft assessment and testing plan and the draft ignition hazard assessment, 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 to be involved in the process according to the required EPL of Ex "s" equipment, from within its listing of independent verifiers and, if used, independent verifiers in other organizations with which they have an agreement.

The ExCB shall appoint independent verifiers, maintaining a record of name, details of experience and how the requirements of IEC 60079-33 are met.

Additional Step 2b:

Should the ExCB not be able to appoint the required number of independent verifiers according to IEC 60079-33, 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 EPL as specified in IEC 60079-33, the compiler and the independent verifier (1), along with independent verifiers (2) and (3) where more than one independent verifier is required, shall agree on the assessment and test plan, based on the ignition hazard assessment, prior to commencing assessment and testing.

OD 009 Step 6:

Once the assessment and testing plan, based on the ignition hazard assessment, has been agreed by the compiler and all independent verifiers, the ExTL associated with the ExCB to whom the application has been made, may undertake the assessment and testing.

Additional Step 8a:

Where a certificate is to be issued, 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 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 8b:

A draft ExTR (including the "QA" requirements as applicable), as prepared by the ExTL, shall be reviewed and agreed by the compiler and all the independent verifiers (when more than one independent verifier is required by IEC 60079-33) prior to the ExTR being finalized for endorsement by the ExCB.

5 Procedures for the Issuing of an IECEx certificate of conformity (IECEx CoC)

According to IECEx 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, provided:

- 1) The manufacturing location is the same
- 2) Ex protection techniques that are to be listed on the CoC are the same as covered by the previous audit and QAR
- 3) The product is of a similar general nature of those covered by the previous audit and QAR
- 4) 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
- 5) 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 IECEx 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.

6 Procedures for the issuing of an IECEx quality assessment report (QAR)

The procedure outlined in Section 3 of IECEx 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.

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.

Annex A

(normative)

Additional requirements for ExCB and ExTLs to be assigned IEC 60079-33 within their IECEx scope of acceptance

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 capability declaration for extension of scope form (IECEx F-011)
- 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 verifiers
- d) Agreement that the ExCB will appoint, on a project by project basis, independent verifiers, maintain records of their name, details of experience and how the 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 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 17065 and/or ISO/IEC 17025, and particularly including verification of the following knowledge, skills and competence:

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

Annex B (informative)

Related aspects of IEC 60079-33 certification

Customer number:	Customer name:	
Project number:	Equipment:	
ExTR reference number:		
Basis of protection (list applicable	concepts plus addition	onal details):
	🗖	🗖
Special QA audit requirements:	Yes	No \square
Details:		
Compiled by:		
Reviewed by independent verifier	(1):	
Reviewed by independent verifier	(2):	
Reviewed by independent verifier	(3):	
Endorsed by certification body off	icer:	

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