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IECEX OPERATIONAL DOCUMENT



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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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)
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- 09	Edition 3.0 - General Revision (refer to Redline Version for details)

This Redline Version is provided to illustrate the differences between this Edition and the previous Edition and displays new text as green underlined text and deleted text as red struckthrough text.

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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 <u>just evaluation or for evaluation and certification</u> to the requirements of IEC 60079-33 Explosive atmospheres - Part 33: Equipment Protection by special protection "s", through to the point of delivery of <u>just a the test report or of a test report and certificate</u>, and for subsequent surveillance of the manufacturing process <u>as applicable</u>.

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 <u>just evaluated or evaluated and certified</u>, 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 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.

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 techniques and methods recogniszed by the IECEx system with the following order of preference:

- Other existing Recognized types of protection recogniszed by the IECEx system.
- —Combination of <u>other existing recognized</u> types of protection <u>recogniszed by the IECEx system</u>
- ——Methods provided by existing standard IEC 60079-26 as recogniszed by the IECEx system
- Other applicable international standards recognized by the IECEx system

When conditions and/or requirements are not completely met by existing types of protection and methods 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").

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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.

- 1) One independent 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.
- 3) Three independent verifiers for Level "sa", this means that Verifier (1), Verifier (2) and Verifier (3) shall be involved.

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 organisation 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 review and 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 only be

an individual, shall be from the same organisation 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 organisation as the compiler of the ExTR or from another organisation, and shall have been identified as competent to be an independent verifier according to IEC 60079-33. Where they are from another organisation, there shall be documented evidence that the person or persons from that organisation doing the review have the appropriate competence to be independent verifiers according to IEC 60079-33. Where other organisations are used for this task, they shall it is expected that they would be accepted IECEx ExCBs or ExTLs and shall a leastly, they should also have IEC 60079-33 in their IECEx scope.

ExCBs/<u>-ExTLs</u> shall maintain a current list of independent verifiers within their own training 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 organisations, those organisations shall be clearly identified and there shall be agreements in place for them to undertake the independent verifier role.

The above is summarised 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	<u>"sb"</u>	independent verifier (1) and independent verifier (2)	Independent verifier (2) may be someone from same organisation or another organisation competent to be an independent verifier
IEC EPL Ma, Ga or Da	<u>"sa"</u>	independent verifier (1) plus independent verifier (2) plus independent verifier (3)	Independent verifiers (2) and (3) may be someone from same organisation or another organisation competent to be an independent verifier

3.4. 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 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 (i.ethat is: 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 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 organisations, the competence of the staff of those organisations shall also be evaluated.

The ExCB in conjunction with its ExTL shall review the draft assessment and testing specification 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 bodies with which they have an agreement.

The ExCB shall appoint independent verifiers from the ExCB's internal ExCB / ExTL list, maintaining a record of name, details of experience and how the requirements of IEC 60079-33 are met.

Additional Step 2b:

Should the ExCB <u>not be able to appoint not have</u> 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 all-independent verifiers (1), along with independent verifiers (2) and (3) where more than one independent verifier is required, shall agree on the assessment and test test/assessment plan, based on the ignition hazard assessment, prior to commencing assessment and testing and assessment.

OD 009 Step 6:

Once the Test/Assessment Planassessment 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 then undertake the assessment and testing tests/assessments.

OD 009 Step 7:

A draft EXTR, as prepared by the EXTL shall be reviewed and agreed by all the independent verifiers (when more than one independent verifier is required by IEC 60079-33) prior to the EXTR being finalised for final endorsement by the EXCB.

Additional Step 89a:

Where a certificate is to be issued, the 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 89b:

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 finalised for final review and endorsement by the ExCB. The review

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



4.5. 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, provideding:

- 1) The mManufacturing 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
- 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 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.

5.6. 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 included and shall specifically include a reference to each Ex "s" certificate in the QAR.

Note that T 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 issued and received by the ExCB conducting the IECEx quality assessment of manufacturer.



Annex AANNEX 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 <u>Ss</u>taff to undertake assessments according to <u>IEC</u> 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 <u>"s"</u> 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
- Active involvement in IEC or national standardization committees (for example, by participating in document review and commenting processes)

Annex A





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Annex B_Q A-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 Requiremen	ts: Yes No No				
Details:					
Compiled Prepared by:					
Accepted Reviewed Agreed by	v independent verifier (1):				
Accepted Reviewed by Agreed					
Accepted Reviewed Agreed by					
Countersigned Endorsed by (Ccertification body officerManager):					