

IECEX OPERATIONAL DOCUMENT

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

**IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations**

Quality Management System requirements for IECEx Service Facilities providing selection of Ex equipment and design of Ex installations related services





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document OD 314-2**IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations****Quality Management System requirements for
IECEX Service Facilities providing selection of Ex equipment and
design of Ex installations related services**

FOREWORD

This Operational Document IECEX OD 314-2 - Quality Management System requirements for the Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations ("IECEX 03-2 Scheme) specifies a mechanism for organizations that provide selection of Ex equipment and design of Ex installations related services meeting the requirements of IEC 60079-14 the ability to obtain IECEX Certification under the IECEX System.

A listing of currently approved ExCBs is maintained on the IECEX website: www.iecex.com.

Document History

Date	Summary
2013-03	This original issue Edition 1.0 of IECEX OD 314-2 supersedes IECEX OD 014 Version 2.0 in part and represents the application of a new numbering system.
2018-10	This Edition 2.0 was approved for publication by the 2018 ExMC Meeting via ExMC Decision 2018/52 and supersedes Edition 1.0 of IECEX OD 314-2 upon publication

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INTRODUCTION

This Operational Document is supplementary to the Operational manuals and procedures operated by IECEX Certification Bodies (ExCBs), approved by the IECEX Management Committee to issue IECEX Certificates of Conformity to Ex Service Facilities providing selection of Ex equipment and design of Ex installation services, according to IEC 60079-14.

The IECEX Certified Service Facilities Scheme is modelled on the IECEX Certificate of Conformity Scheme, which is an ISO Type 5 Certification System.

The purpose of this Operational Document is to ensure that each ExCB, accepted by ExMC for the purposes of issuing IECEX Certified Service Facility Certificates, processes applications from Ex equipment selection and Ex installations design Service Facilities with the same approach and technical or management requirements, known as certifying the IECEX way.

For selection of Ex equipment and design of Ex installations, a certified Ex Service Facility should be capable of selecting equipment and designing an installation of any Ex type of protection. Ex competent personnel for a particular type of protection may need to be engaged for a particular application where such personnel are not permanently employed by the service facility.

The preparation of this IECEX Operational Document has been done so with the aim of alignment with various ISO or IEC International Standards, ISO Guides, and IECEX Rules of Procedures, including but not limited to the following:

NOTE Although this IECEX Operational Document makes reference to IEC 60079-14 and IEC 60079-17, it is also relevant in determining ability to work with other international, national or regional requirements of a similar nature, such as IEC 61892-7 - Mobile and fixed offshore units – electrical installations – Part 7: Hazardous areas.

IECEX 03-0, *IECEX Certified Service Facilities Scheme – Part 0: General Rules of Procedure*

IECEX 03-2, *IECEX Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations – Rules of Procedure*

IEC 60079-14, *Explosive atmospheres – Part 14: Electrical installations design, selection and erection*

IEC 60079 Series *as relevant or as referenced from IEC 60079-14, for example IEC 60079 – Parts 10-1, 10-2, 13, 19, 26, 28, 29-1, 29-4, 30-1, 30-2, 32-1, 43 or 46*

ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*

ISO/IEC 17011, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17020, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021-1, *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*

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

ISO 19011, *Guidelines for auditing management systems*

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

ISO Guide 28, *Conformity assessment – Guidance on a third-party certification system for products*

ISO/IEC Guide 53, *Conformity assessment – Guidance on the use of an organization's quality management system in product certification*

This IECEx OD 314-2 often refers to IECEx OD 025, *Guidelines on the management of assessment and surveillance programs for the assessment of manufacturer's quality system*, in accordance with the IECEx Scheme.

Although this Scheme relates to Service Facilities, many of the elements of IECEx OD 025 are applicable, as such this Operational Document is applicable at a number of steps in this procedure.

Quality Management System requirements for IECEX Service Facilities providing selection of Ex equipment and design of Ex installations services

1 General

This Operational Document sets out the Quality Management System (QMS) requirements that an Ex Service Facility shall conform to in order to gain and maintain IECEX Certification as an IECEX Certified Service Facility, involved in selection of Ex equipment and design of Ex installations.

It also sets out the requirements for IECEX Certification Bodies (ExCBs), approved by the IECEX Management Committee to issue IECEX Certificates of Conformity to Service Facilities concerning the assessment of Service Facilities for their compliance to these requirements.

These requirements also form the basis of surveillance of IECEX Certified Service Facilities by ExCBs.

While certification of the Quality Management System (QMS) to relevant standards is not a requirement of the IECEX Scheme, a Service Facility with a QMS may find it benefits in assisting them to meet the requirements of this Operational Document.

In using ISO 9001 as the basis for this Operational Document, the following requirements replace, add to or are more specific than those required by ISO 9001. The clause references used in this Operational Document have been adopted from ISO 9001:2008.

NOTE Requirements set forth in ISO 9001:2015 and ISO/IEC 80079-34 are under consideration by IECEX ExMC and ExSFC.

2 Definitions

2.1

Ex Service facility

see IECEX 03-2

NOTE 1 Ex Service Facility is a term used by IECEX and in the context of this IECEX OD 314-2 shall apply to an organization that carries out or controls selection of Ex equipment or design of Ex installations, according to IEC 60079-14.

NOTE 2 An Ex Service Facility may have restrictions on the type of Ex equipment, Ex types of protection, ratings and size which will be covered by their limitation of scope.

2.2

Ex equipment

see IECEX 02

3 Application

This IECEX Operational Document shall be applied by ExCBs, approved by the IECEX Management Committee to issue IECEX Service Facility Certificates.

The Quality Management System (QMS) requirements below are based on the relevant requirements of ISO 9001 as amended or added to.

ExCBs shall manage their quality management system auditing, for the IECEX Certified Service Facility Program using IECEX OD 025 as a basis, which covers:

- Audit planning
- Auditor competence
- Duration for surveillance audits
- Audit reporting
- Others

On-going certification maintenance by the ExCB issuing the IECEX Service Facility Certificate shall consist of the following:

- a) **Annual surveillance:** On-site surveillance audits at the location(s) where the Certified Ex Service Facility manages their service activities shall be conducted at not more than 12 monthly intervals, for which a FAR shall be issued in accordance with IECEX OD 313-2; and
- b) **Re-assessment:** Conducted as part of every third annual surveillance audit and shall include the full review of a Service Facility's documented procedures.

3.1 Documentation requirements

3.1.1 General

The Ex Service Facility shall develop a process plan to establish verification of the selection of Ex equipment and design of Ex installations processes to the requirements of IEC 60079-14, other relevant parts of the 60079 series. E.g. 60079-13 and 60079-43 and other relevant standards which may not be part of the IEC 60079 series as applicable to the design e.g. lightning protection and electromagnetic radiation.

All selection of Ex equipment and design of Ex installations performed by the Ex Service Facility require documented procedures and or work instructions and shall be defined in their scope of IECEX Certified Service Facility Certification.

During the surveillance audits, ExCBs are required to assess identified changes.

NOTE National regulations may require certain records to be kept for a minimum period from the date of delivery.

3.1.2 Records

The following requirements are additional to those of ISO 9001, Clause 4.2.4:

Records must be kept of Ex equipment that is selected and Ex installations that are designed in accordance with the requirements of this IECEX OD 314-2 and IEC 60079-14.

Also, records must be kept of Ex equipment that is selected and Ex installations that are designed, even after being selected or designed, do not comply with the requirements of this IECEX OD 314-2 and IEC 60079-14.

As a minimum, records shall be kept for 10 years.

3.2 Management responsibility

The following requirements are additional to those of ISO 9001, Clause 5:

The senior management shall establish a mechanism to ensure that there is at least one person appointed to deputize when necessary for the management representative in matters relating to the scope of work covered by the IECEX Certificate of Conformity for the Ex Service Facility.

The responsibilities and authorities of the management representative and any deputies shall be documented. The ExCB shall be notified of any changes to the personnel appointed as the Responsible Person, according to IEC 60079-14.

NOTE: The term “Management Representative” in ISO 9001 is equivalent to the term “Responsible Person” in IEC 60079-14.

3.3 Resource management

The following requirements are additional to those of ISO 9001, Clause 6:

The Ex Service Facility shall provide for training of all personnel performing activities affecting the selection of Ex equipment and design of Ex installations process. Ex competent persons performing assigned tasks shall be qualified on the basis of appropriate education, training or experience, as defined in IEC 60079-14. Appropriate training and continuing education records shall be maintained.

Ex Competent Persons, including responsible persons and operatives (designers), shall maintain their competence, with ExCBs required to verify the currency of the competence of Ex competent persons as part of the on-going surveillance of the Ex Service Facility.

The Ex Service Facility shall establish and maintain a Competence Management System that includes the evaluation of personnel for compliance with the requirements of IEC 60079-14 for responsible persons and operatives. The Competence Management System shall cover the scope of work undertaken by the Ex Service Facility and geographic application relating to end-user sites.

NOTE 1 Attention is drawn to the requirements that may be applicable relating to different geographic locations and different external influences.

NOTE 2 Evidence of competence can be provided by having personnel certified to the applicable Unit of Competency Ex 009 (Design electrical installations in or associated with explosive atmospheres) of Operational Document IECEX OD 504 (Specification for Units of Competence Assessment Outcomes).

3.4 Product realization

The following requirements are additional to those of ISO 9001, Clause 7:

The Ex Service Facility shall establish specific procedures or work instructions for selection of Ex equipment and design of Ex installations. These procedures or work instructions shall consider each process covered under the scope of the IECEX Service Facility Certificate to the requirements of IEC 60079-14 in accordance with the parameters listed below:

- Type of Ex service offered;
- Verification of designs;
- Details and evidence of Ex competence for responsible persons and operatives, nominated as Ex Competent Persons;
- Details and evidence of other operatives or specialists required to contribute to the design. E.g lightning protection, earthing, corrosion or materials specialists; and.
- Sub-contractor activities, if any.

3.5 Measurement, analysis and improvement

The following requirements are additional to those of ISO 9001, Clause 8.

3.5.1 Planning

Clause 8.1 of ISO 9001 applies with the following exceptions:

Improvements are not within the scope of this IECEX OD 314-2 Operational Document. They may be made at the discretion of the Ex Service Facility, but the provisions of 3.2 shall apply at all times.

3.5.2 Customer satisfaction

Clause 8.2.1 of ISO 9001 is replaced by the following requirement:

For the purpose of this Operational Document, 'customer satisfaction' is in relation to the Ex Service Facilities compliance with the relevant requirements of IEC 60079-14. However additional measures of customer satisfaction according to ISO 9001 are encouraged.

3.5.3 Internal audit

Clause 8.2.2 of ISO 9001 and the following applies:

The audit program shall address the effectiveness of the elements of the Quality Management System (QMS) as described in this document to ensure that the selection of Ex equipment and design of Ex installations processes are in accordance with IEC 60079-14. The period between audits should normally not exceed 12 months.

3.5.4 Monitoring and measurement of processes

Clause 8.2.3 of ISO 9001 applies.

Where a selection of Ex equipment or design of Ex installations process can affect the integrity, safety or functionality of an Ex type of protection or an Ex equipment, that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters.

3.5.5 Monitoring and measurement of product

The following requirement is additional to those of ISO 9001, Clause 8.2.4:

Where tests are required, they shall be performed as specified in IEC 60079-14 with no sampling techniques being permitted, according to IEC 60079-14 provisions and requirements.

The Ex Service Facility shall have an established process for verification of design which is independent of the personnel who carried out the design. Control of non-conforming product

The following requirements are additional to those of ISO 9001, Clause 8.3:

The Ex Service Facility shall take action, appropriate to the degree of significance, associated with selection of Ex equipment or design of Ex installations, which has been found following Ex installation or Ex initial inspection to be non-conforming.

For all non-conforming selection of Ex equipment or design of Ex installations, the Ex Service Facility shall maintain records of:

- Identification of the selection of Ex equipment or Ex installation design;
- The customer who received the Ex installation design;
- The action taken to inform the organization responsible for the selection of Ex equipment or Ex installation design;
- The action taken to implement corrective and preventative action;
- Actions and communications taken with a relevant regulator (whenever applicable).

3.5.6 Analysis of data

Clause 8.4 of ISO 9001 applies.

3.5.7 Improvement

Clause 8.5.1 of ISO 9001 applies.

3.5.8 Corrective action

Clause 8.5.2 of ISO 9001 applies.

3.5.9 Preventive action

Clause 8.5.3 of ISO 9001 applies.

4 Preliminary requirements for ExCB assessment of Ex Service Facilities

As a pre-requisite, it shall be established that the Ex Service Facility satisfies the requirements of IEC 60079-14 in terms of adequate facilities, equipment and competent personnel to perform the scope of work to be covered by the IECEX Certified Service Facility Certificate.

5 Preliminary review (optional)

Prior to an on-site assessment, at the location(s) where the Certified Ex Service Facility manages their service activities, a preliminary review may be conducted by the ExCB, where requested by the Applicant Service Facility. This preliminary review may also serve as a “gap analysis”. Such activity is usually conducted on a fee for service basis.

6 ExCB auditor expertise

The ExCB’s audit of the location(s) where the Certified Ex Service Facility manages their service activities shall be performed by person or persons that have an expertise comparable to the scope of application of the Ex Service Facility, including Quality Management Systems (QMS).

7 On-site assessment

The on-site assessment at the location(s) where the Certified Ex Service Facility manages their service activities will be conducted by an ExCB to verify compliance with IEC 60079-14 and the IECEX Scheme requirements, e.g. this IECEX OD 314-2.

In addition to the general requirements of the IECEX Scheme, the IECEX Service Facility Certificate will be issued subject to the conditions specified on the rules governing this Scheme and based on satisfactory assessment by the ExCB.

Refer to Operational Document IECEX OD 313-2 for further details.

8 Process assessment by ExCBs

This Section identifies the critical areas that ExCBs shall have included in the assessment and surveillance of Ex Service Facilities seeking to obtain and maintain IECEX Service Facility Certification.

8.1 Compliance with IEC 60079-14

ExCBs shall assess the Ex Service Facility's procedures and processes for compliance to be able to meet the relevant requirements to the IEC 60079-14.

This shall include assessment of the Ex Service Facility's selection of Ex equipment or design of Ex installations plans and work procedures for compliance with IEC 60079-14 and verification that such selection of Ex equipment or design of Ex installations plans and work procedures clearly define the method for verification and for pass/fail and acceptance criteria.

8.2 Use of subcontractors

ExCBs shall assess the method of control the Ex Service Facility maintains over any subcontractor used to perform part of the selection of Ex equipment or design of Ex installations process, including testing and calibration activities.

The Ex Service Facility agrees to arrange for the ExCB to evaluate relevant documentation and to arrange a visit to any subcontractor that the ExCB deems warranted. Subcontractors conducting operations that have the potential to impact on compliance with IEC 60079-14 shall be subject to audit by the ExCB.

Subcontracting by Ex Service Facilities shall be clearly defined in agreements between the ExCB and the Service Facility and the ExCB and the Subcontractor or, by delegation of the ExCB, directly between the Ex Service Facility and the Subcontractor.

The scope of activity is an integral part of such agreements as well as evidence of competence of the Subcontractor (e.g. certificates, initial and annual audits by the ExCB). The overall responsibility remains in any case with the ExCB which certified the Service Facility.

Agreements mentioned above shall be registered by the IECEX secretariat.

Subcontracting activities shall be used on a limited basis, mainly in cases where the investments for such activities are rather high and volume for such work at the Ex Service Facility rather low.

Subcontracting activities related to the main scope of selection of Ex equipment and design of Ex installations, indicated in the IECEX Certificate, is not allowed.

8.3 Assessment of competence for operatives and responsible persons

The ExCB shall evaluate the Ex Service Facility's mechanism for verification of current competence of the ExSF nominated Ex Competent Persons, including the responsible person and operatives. Responsible persons and operatives shall satisfy the competence requirements of IEC 60079-14.

For Ex Competent Persons having a Certificate of Personnel Competencies (CoPC) according to IECEX OD 504, Unit of Competence Ex 009 (Design electrical installations in or associated with explosive atmospheres), or having any other evidence of appropriate assessment and demonstration of Competencies based on IEC 60079-14, the ExCB shall verify that the certified or assessed scope of Ex activities covers the actual activities within the Ex Service Facility.

Those qualifying as Ex Competent Persons shall be identified in the Ex Service Facility's documented system, along with their scope of activity.

An Ex Service facility certificate remains valid only while the Competent Persons listed in the facility's documented system, operating as the "Responsible Person" remains engaged in the activity.

Any change that may impact on the Ex Service Facility complying with IECEX Scheme requirements, e.g. change of “Personnel” is required to be notified to the ExCB immediately.

It should be noted that the status of an Ex Competent Person is directly linked to the Ex Service Facility and is therefore not transferable between service facilities without assessment by an ExCB.

Replacement of Ex operatives or responsible Competent Person(s) shall have the evidence of their Ex competence verified by the ExCB.

8.4 Records

Results of the selection of Ex equipment or design of Ex installations conducted by the Ex Service Facility shall be recorded by use of appropriate means that ensure:

- Legibility;
- Traceability of verification; and
- Stored to enable retrieval in accordance with 3.1.2 above.

8.5 Conditions for selection of Ex equipment and design of Ex installations completion

Ex Service Facilities processes and procedures shall comply with the following, concerning selection of Ex equipment and design of Ex installations completion.

Selection of Ex equipment and design of Ex installations shall be considered complete once a complying selection of Ex equipment and design of Ex installations report is issued to show conformance with IEC 60079-14 by the Responsible Person of the Ex Service Facility.

Annex A

Selection of Ex equipment or design of Ex installations service report issued by Ex Service Facilities

A.1 General

This Annex A specifies the minimum content of an Ex Service Report to be prepared, recorded and retained in accordance with their QMS procedures by an organisation certified under the IECEX 03-2 Scheme to provide selection of Ex equipment or design of Ex installations services according to the requirements of IEC 60079-14 and the organisations accepted Scope.

This Ex Service Report shall be prepared following the provision of all Ex services relevant to the organisation's operation as an IECEX Certified Service Facility.

Selection of Ex equipment or design of Ex installations service reports shall be reported taking into account aspects related to Ex equipment, Ex installation and environment (external influences), as required by IEC 60079-14.

A copy of the Ex Service Report, which may be an electronic copy, shall be provided to and approved by the management of the site, system, installation or equipment receiving the Ex service provided.

A.2 Content of selection of Ex equipment or design of Ex installations service provision report form

The Ex Service Report shall contain all relevant details of at least the following content elements:

- Name of IECEX Certified Service Facility Organisation;
- The identifier of the IECEX Certificate held by this organisation as an IECEX Certified Service Facility;
- Name and contact details of personnel from the IECEX certified selection of Ex equipment or design of Ex installations Service Facility that provided the services;
- The name and address of the recipient of the Ex service provided;
- The date that the selection of Ex equipment or design of Ex installations service was provided;
- Ex Report reference number, to be traced in the user verification dossier;
- Reference to IEC 60079-14 for selection of Ex equipment or design of Ex installations services;
- A brief description of the site, system, Ex equipment or Ex assembly applicable to the selection of Ex equipment or design of Ex installations service provided;
- Copies of photographs, measurements and any other relevant artefacts regarding the selection of Ex equipment or design of Ex installations services provided; and
- List and description of any findings, resolutions, actions taken or actions required related to selection of Ex equipment or design of Ex installations services provided, signed by Ex Service Facility Responsible Person, approved and signed by the Ex installation user or responsible person.