



# IECEX OPERATIONAL DOCUMENT

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

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**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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## CONTENTS

FOREWORD.....	3
INTRODUCTION.....	4
1 General .....	5
2 Definitions .....	5
3 Application .....	5
3.1 Documentation requirements .....	6
3.1.1 General .....	6
3.1.2 Records.....	6
3.2 Management responsibility .....	6
3.3 Resource management.....	7
3.4 Product realization .....	7
3.5 Measurement, analysis and improvement .....	7
3.5.1 Planning .....	7
3.5.2 Customer satisfaction .....	8
3.5.3 Internal audit .....	8
3.5.4 Monitoring and measurement of processes .....	8
3.5.5 Monitoring and measurement of product .....	8
3.5.6 Control of non-conforming product.....	8
3.5.7 Analysis of data .....	8
3.5.8 Improvement .....	8
3.5.9 Corrective action .....	9
3.5.10 Preventive action.....	9
4 Preliminary requirements for ExCB assessment of Ex service facilities .....	9
5 Preliminary visit (optional) .....	9
6 ExCB auditor expertise.....	9
7 On-site assessment.....	9
8 Process assessment by ExCBs .....	9
8.1 Compliance with IEC 60079-14.....	9
8.2 Use of subcontractors .....	9
8.3 Assessment of personnel competencies .....	10
8.4 Records .....	10
8.5 Conditions for selection of Ex equipment and design of Ex installations completion.....	11

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**IECEX Operational Document 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 document is the IECEX Operational Document OD 314-2 Quality Management system requirements for the Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations to provide a mechanism for organizations that provide Ex installation 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](http://www.iecex.com).

**Document History**

Date	Summary
2013-03	This original issue Edition 1 of OD 314-2 supersedes OD 014 Version 2 in part and represents the application of a new numbering system.

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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 Service Facilities providing selection of Ex equipment and design of Ex installation services.

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 the 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/management requirements, known as certifying the IECEX way.

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:

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 17021, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

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

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

### **1 General**

This Operational Document sets out the Quality Management System (QMS) requirements that a 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 this may benefit 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 as the most current standard.

### **2 Definitions**

#### **2.1**

##### **Service facility**

see IECEX 03-2

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

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

#### **2.2**

##### **Ex equipment/Ex installation**

see IECEX 02

### **3 Application**

This 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 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 conducted at not more than 12 monthly intervals, for which a FAR shall be issued in accordance with OD 313-2 (this is a shorter duration than specified in OD 025 and considered necessary given the criticality of selection of Ex equipment and design of Ex installations procedures)
- 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 Service Facility shall develop a process plan to establish verification of the design and selection processes to the requirements of IEC 60079-14.

All selection of Ex equipment and design of Ex installations performed by the 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 are selected and Ex installations that are designed in conformity with the requirements of 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 top 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 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.



### 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 design and selection process. Competent Persons performing assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as defined in IEC 60079-14. Appropriate training and refreshment courses records shall be maintained.

Competent Persons, including Responsible Persons and Operatives (designers), shall maintain their competence with ExCBs required to verify the currency of the competency of Competent Persons as part of the on-going surveillance of the service facility.

The 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 and Unit of Competency Ex 009 (Design electrical installations in or associated with explosive atmospheres), in accordance with IECEx OD 504, for Responsible Persons and Operatives (designers). The Competency Management System shall cover the scope of work undertaken by the Service Facility and geographic application relating to sites.

NOTE 1 Attention is drawn to the specific requirements relating to different geographic locations.

NOTE 2 Evidence of competencies 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 Competency Assessment Outcomes).

### 3.4 Product realization

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

The Service Facility shall establish 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 service offered
- Measurement/test/inspection facilities available
- Activities to address any non-conformity of product after release, should the Service Facility become aware of any critical or major defect. Such procedures shall provide for the notification to the ExCB of the problem and to national authorities, e.g. Mining Regulators for Group I
- Details and evidence of competency for responsible persons and operatives, nominated as Competent Persons
- Sub-contractor activities

### 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 Operational Document. They may be made at the discretion of the 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 document 'customer satisfaction' is in relation to the 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 conformity 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.

### **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.

### **3.5.6 Control of non-conforming product**

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

- The Service Facility shall have a process such that the customer or owner can be identified in the event of the Ex installation or equipment later being found not to be complying with IECEx requirements
- The Service Facility shall take action, appropriate to the degree of risk, associated with the non-conforming Ex installation design or Ex equipment selection
- The Service Facility shall liaise with the ExCB responsible for the issue of the IECEx Service Facility Certificate of Conformity

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

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

### **3.5.7 Analysis of data**

Clause 8.4 of ISO 9001 applies.

### **3.5.8 Improvement**

Clause 8.5.1 of ISO 9001 applies.

### **3.5.9 Corrective action**

Clause 8.5.2 of ISO 9001 applies.

### **3.5.10 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 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 visit (optional)**

Prior to an on-site assessment, a preliminary visit may be conducted by the ExCB, where requested by the Applicant Service Facility. This preliminary visit 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 shall be performed by person or persons that have an expertise comparable to the scope of application of the Service Facility, including Quality Management Systems (QMS).

## **7 On-site assessment**

The on-site assessment will be conducted by an ExCB to verify compliance with IEC 60079-14 and the IECEX Scheme requirements, e.g. this 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 on the basis of satisfactory assessment by the ExCB.

Refer to Operational Document 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 Service Facilities seeking to obtain and maintain IECEX Service Facility Certification.

### **8.1 Compliance with IEC 60079-14**

ExCBs shall assess the Service Facility’s procedures and processes for compliance to the IEC 60079-14. This shall include assessment of the Service Facility’s design and selection plans for compliance with IEC 60079-14 and verification that such design and selection plans clearly define the method for pass/fail criteria.

### **8.2 Use of subcontractors**

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

The 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 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 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.

NOTE 1 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 Service Facility rather low.

NOTE 2 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 personnel competencies**

The ExCB shall evaluate the Service Facility's mechanism for verification of current competencies of their nominated Competent Persons, including the Responsible Person and Operatives, as required by IEC 60079-14.

For Competent Persons having a Certificate of Personnel Competencies (CoPC) according to IECEX OD 504, Unit of Competency 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 activities covers the actual activities within the Service Facility.

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

A 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 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 a Competent Person is linked to the Service Facility and is therefore not transferable between service facilities without assessment by an ExCB.

Replacement Competent Person(s) shall have the evidence of their competencies verified by the ExCB.

### **8.4 Records**

Results of the service conducted by the Service Facility shall be recorded by use of appropriate means that ensure:

- Legibility
- Traceability of measured results to calibrated instruments with actual measurements recorded. A tick to just indicate pass is not accepted
- Stored to enable retrieval in accordance with 3.1.2 above

The Ex Service Facility shall retain all design and selection records for a minimum of 10 years from the date the initial design and selection was completed.

#### **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 in accordance with IEC 60079-14 by the Responsible Person of the Ex Service Facility.

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