



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 5: Repair, overhaul and reclamation of Ex equipment –
Quality management system requirements for IECEx Service Facilities
involved in the repair, overhaul and reclamation of Ex equipment

Readline



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Quality management system requirements for IECEx Service Facilities
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document 314-5 –

**IECEX Certified Service Facilities Scheme –
Part 5: Repair, overhaul and reclamation of Ex equipment –
Quality management system requirements for IECEX Service Facilities
involved in the repair, overhaul and reclamation of Ex equipment**

FOREWORD

This operational document OD 314-5 sets out the quality management system (QMS) requirements for service facilities engaged in the repair, overhaul and reclamation of Ex equipment and the guidance on the assessment of a service facility's management system by an ExCB, approved to operate under the IECEX Certified Service Facilities Scheme.

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 OD 314-5 supersedes OD 014 Version 2 in part and represents the application of a new numbering system.
2019-10	Edition 1.1 Revision of Clauses 3 and 3.5.3
2021-01	Edition 1.2 Revision of Clause 8.2, correction of Clause 3.5.3 and update of ISO 9001:2015 Clause references
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INTRODUCTION

This operational document (OD) is supplementary to the operational manuals and procedures operated by IECEx Certification Bodies (ExCBs), approved by the IECEx Management Committee (ExMC) to issue IECEx Certificates of Conformity to service facilities involved in the repair, overhaul and reclamation of Ex equipment.

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 OD is to ensure that each ExCB, accepted by ExMC for the purposes of issuing IECEx Certified Service Facility Certificates, processes applications from Ex equipment repair, overhaul and reclamation service facilities with the same approach and technical/management requirements, known as certifying the IECEx way.

The preparation of this OD has been done so with the aim of alignment with various ISO/IEC International Standards and Guides, including but not limited to the following publications. At the time of publication, the referenced documents were valid and available as published. Where the reference is undated or where no edition for a referenced document is specified, the latest currently published version shall apply. This OD is to be implemented immediately upon publication.

IEC 60079-19:2019 (Edition 4.0), *Explosive atmospheres – Part 19: Equipment repair, overhaul and reclamation*

IEC 60034-23, *Rotating electrical machines – Part 23: Repair, overhaul and reclamation*

ISO 9001:2015 (Edition 5.0), *Quality management systems – requirements*

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*

This procedure often refers to IECEx OD 025, *Guidelines on the management of assessment and surveillance programmes 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 document is applicable at a number of steps in this procedure.

Quality management system requirements for IECEx Service Facilities involved in the repair, overhaul and reclamation of Ex equipment

1. General

This operational document (OD) ~~defines 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 repair, overhaul and reclamation of Ex equipment. It also ~~defines sets out~~ the requirements for IECEx Certification Bodies (ExCBs), approved by the IECEx Management Committee (ExMC) 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 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 OD.

In using ISO 9001:2015 as the basis for this OD, the following requirements replace, add to or are more specific than those required by ISO 9001:2015. The clause references used in this OD have been adopted from ISO 9001:2015 as the most current standard.

2 Definitions

2.1

service facility

refer to IEC 60079-19:2019, Clause 3.20

NOTE 1 to entry: Service facility is a term used by IECEx and in the context of this OD 314-5 shall include an organization that carries out or controls such stages in repair, overhaul and reclamation service facility, as required by IEC 60079-19:2019.

NOTE 2 to entry: 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

refer to IEC 60079-0, Clause 3.37

3 Application

This OD shall be applied by ExCBs, approved by the ExMC to issue IECEx Service Facility Certificates.

The QMS requirements below are based on the relevant requirements of ISO 9001:2015.

ExCBs shall manage their QMS auditing, for the IECEx Certified Service Facilities Programme 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) **Surveillance** – On-site surveillance audits conducted at not more than 12 monthly intervals, for which a FAR shall be issued in accordance with IECEX OD 313-5 (this is a shorter duration than specified in IECEX OD 025 and considered necessary given the criticality of Ex repair, overhaul and reclamation procedures). A longer duration is permitted only if all the criteria of IECEX 03-5, Clause 9.6 are met. The most important of these criteria is that the repair facility is also a manufacturer and is only repairing their own certified products.
- b) **Re-assessment** – Conducted in a period not exceeding 3 years 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 QMS to establish verification of the repair/overhaul processes to the requirements of IEC 60079-19:2019 and IECEX OD 315-5, which includes additional specific information relating to IEC 60079-19:2019. In particular, prior to implementation of any changes to workshop practices, processes or materials, the Ex Service Facility shall assess such changes for on-going compliance with IECEX OD 315-5 and advise the ExCB where such changes may impact on compliance with IECEX OD 315-5.

When the Ex Equipment being overhauled and repaired includes rotating electric machines, the Service Facility shall develop their QMS to establish verification of the repair/overhaul processes to the requirements of IEC 60034-23:2019 as required by IEC 60079-19:2019, Clause 4.3.6.1

The Service Facility shall identify and record the range of test and measurement capabilities and limitations in accordance with IEC 60079-19:2019, Clause 4.3.2.1 c).

Any "off-site" repair or overhaul performed by the Service Facility requires documented procedures and/or work instructions and shall be defined in their scope of IECEX Certified Service Facility Certification in accordance with IEC 60079-19:2019, Clause 4.3.2.1 p).

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 9001:2015, Clause 7.5.3:

- Records must be kept of serviced Ex equipment that are serviced in conformity with the requirements of IEC 60079-19:2019 and IECEX OD 314-5 that are provided with the R-label. Also, records must be kept of Ex equipment that, even after being serviced, do not comply with the requirements of OD 314-5 and IEC 60079-19:2019 and are not marked with the R-label. IEC 60079-19:2019, Clause 4.3.2.4.2 applies.

3.2 Management responsibility

The following requirements are additional to those of ISO 9001:2015, Clauses 5, 6, 7.4 and 9.3:

- The top management shall establish a mechanism to ensure that there is at least one person appointed to deputize, when necessary, for the responsible person 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 responsible person and any deputies shall be documented. The ExCB shall be notified of any changes to the personnel appointed as competent.

3.3 Resource management

The following requirements are additional to those of ISO 9001:2015, Clauses 7.1.1 through 7.1.4, 7.1.6, 7.2 and 7.3:

- The Ex Service Facility shall provide for training of all personnel performing activities affecting the repair, overhaul and reclamation process. Competent persons performing assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as defined in IEC 60079-19:2019, Annex B and IECEx Unit of Competency Ex 005, in accordance with IECEx OD 504. Appropriate training and refreshment course records shall be maintained.
- Competent persons 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 Ex Service Facility.

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 005 (overhaul and repair of explosion-protected equipment) of IECEx OD 504, *Specification for units of competency assessment outcomes*.

3.4 Product realization

The following requirements are additional to those of ISO 9001:2015, Clauses 7.1.5, 8.1 through 8.5:

- The Service Facility shall establish procedures or work instructions for overhaul and repair of Ex Equipment in accordance with IEC 60079-19:2019, Clauses 4.3.2.1 b) and c). These procedures or work instructions shall consider each process covered under the scope of the IECEx Service Facility Certificate to the requirements of IEC 60079-19:2019 and IECEx OD 315-5 in accordance with the parameters listed below:
 - Type of service offered
 - Type of equipment, for example, rotating machines, instruments
 - Types of protection of equipment being serviced, for example, Ex d, Ex e, Ex I, etc.
 - IEC 60079-19:2019, Clause 4.3.2.1 d)
 - IEC 60079-19:2019, Clause 4.3.2.1 k)
 - IEC 60079-19:2019, Clause 4.3.2.2
 - IEC 60079-19:2019, Clause 4.3.2.1 n)
 - IEC 60079-19:2019, Clause 4.3.2.1 o)
 - IEC 60079-19:2019, Clause 4.3.2.1 p)

3.5 Measurement, analysis and improvement

ISO 9001:2015, Clauses 8.6, 8.7, 9.1, 9.2 and 10 apply without additional requirements.

3.5.1 Planning

Clause 8.1 of ISO 9001:2015 applies with the following exceptions:

- Improvements are not within the scope of this OD. 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 9.1.2 of ISO 9001:2015 is replaced by the following requirement:

- For the purpose of this document "customer satisfaction" is in relation to the Ex Service Facilities compliance with the relevant requirements of IEC 60079-19:2019 and information provided by IECEx OD 315-5. However additional measures of customer satisfaction according to ISO 9001:2015 are encouraged.

3.5.3 Internal audit

Clause 9.2 of ISO 9001:2015 and the following applies:

- The audit programme shall address the effectiveness of the elements of the QMS as described in this document to ensure that the repair, overhaul and reclamation processes are in conformity with IEC 60079-19:2019, Clause 4.3.2.1 h) and information provided by IECEx OD 315-5. The period between audits should normally not exceed 12 months.

3.5.4 Monitoring and measurement of processes

The requirements of ISO 9001:2015, Clause 9.1.1 and Clause 4.3.2.1 i) of IEC 60079-19:2019 shall apply.

3.5.5 Monitoring and measurement of product

The following requirement is additional to those of ISO 9001:2015, Clause 8.6 and Clause 4.3.2.1 j) of IEC 60079-19:2019 apply:

- Where tests are required, they shall be performed as specified in IEC 60079-19:2019 and IECEx OD 315-5 or Standards with no sampling techniques being permitted.

3.5.6 Control of non-conforming product

The following requirements are additional to those of ISO 9001:2015, Clauses 8.7 and 10.2 and of IEC 60079-19:2019, Clause 4.3.2.1 k):

- The Service Facility shall maintain a system such that the customer or owner can be identified in the event of repaired, overhauled or reclaimed Ex product later being found not to be complying with IECEx requirements
- The Service Facility shall take action, appropriate to the degree of risk, where non-conforming product has been supplied to a customer
- The Service Facility shall liaise with the ExCB responsible for the issue of the IECEx Service Facility Certificate of Conformity
- For all non-conforming products that have been released, the Service Facility shall maintain records of:
 - Serial numbers or identification of product supplied
 - The customer who received the product
 - The action taken to inform customers 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 9.1 of ISO 9001:2015 applies.

3.5.8 Improvement

Clauses 10.1 and 10.3 of ISO 9001:2015 apply.

3.5.9 Corrective action

Clauses 10.1 and 10.2 of ISO 9001:2015 apply.

4 Preliminary requirements for ExCB assessment of Service Facilities

As a pre-requisite, it shall be established that the Service Facility satisfies the requirements of IEC 60079-19:2019 and IECEX OD 315-5 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 and also comparable to that required to conduct product certification activities for Ex products, including QMS. ~~The ExCB's auditors shall be peer assessed by IECEX.~~

7 On-site assessment

The on-site assessment will be conducted by an ExCB to verify compliance with IEC 60079-19:2019 and the IECEX Scheme requirements, for example, IECEX OD 315-5 and this IECEX OD 314-5. In addition to the general requirements of the IECEX Scheme, the IECEX Service Facility Certificate will be issued subject to the conditions specified in the rules governing this Scheme and on the basis of satisfactory assessment by the ExCB.

Refer to IECEX OD 313-5 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 IECEX OD 315-5

ExCBs shall assess the Service Facility's procedures and processes for compliance to IEC 60079-19:2019 and IECEX OD 315-5. This shall include assessment of the Service Facility's inspection and test plans for compliance with IECEX OD 315-5 and verification that such inspection and test plans clearly define the method for pass/fail criteria.

When the Ex Equipment being overhauled and repaired includes rotating electric machines, the ExCBs shall assess the Service Facility's procedures and processes for compliance to IEC 60034-23:2019 as required by IEC 60079-19:2019, Clause 4.3.6.1.

Where the Service Facility has been third party assessed for compliance with IEC 60034-23 or an equivalent standard this may benefit in assisting them to meet the requirements of this OD.

This requires the ExCB to assess the Service Facility's documented procedures to ensure that the specific requirements of IECEX OD 315-5 have been included or covered by the Service Facility's QMS.

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 repair, overhaul and reclamation processes, 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 the explosion protection technique shall be subject to audit by the ExCB.

Subcontracting by Service Facilities shall be clearly defined by delegation of the ExCB and 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, for example, certificates, initial and annual audits by the ExCB. The overall responsibility remains in any case with the ExCB which certified the Service Facility.

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. Examples are metal spaying techniques, gland openings, grinding of flameproof flanges.

NOTE 2 Subcontracting activities related to the main scope of repair, overhaul or reclamation of Ex equipment, 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 60079-19:2019, Annex B.

For Competent Persons having a Certificate of Personnel Competencies (CoPC) according to IECEx OD 504, Unit of Competency Ex 005 (overhaul and repair of explosion-protected equipment), or having any other evidence of appropriate assessment and demonstration of competencies based on IEC 60079-19:2019, 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 person(s) 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, for example, 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 and tests 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 indicate a pass result is not accepted (see IEC 60079-19:2019, Clause 4.3.2.1 g))
- Stored to enable retrieval in accordance with 3.1.2 above
- The Ex Service Facility shall retain all repair, overhaul and reclamation records for a minimum of 10 years from the date the repaired product was released (see IEC 60079-19:2019, Clause 4.3.2.4.3)

8.5 Marking

Marking shall be in accordance with the requirements of IEC 60079-19:2019. Use of the ExCB's own mark on reports and promotional material may be permitted subject to the agreement of the ExCB.

8.6 Dimensional checks

Ex Service Facilities processes and procedures shall comply with the following, concerning dimensional checks:

IEC 60079-19:2019, Clauses 4.3.2.1 e), f) and g) apply.

8.7 Conditions for Ex equipment release

Ex Service Facilities processes and procedures shall comply with the following, concerning Ex equipment release:

Repaired, overhauled or reclaimed equipment shall be released from the Service Facility's premises only when a Responsible Person (as defined in IEC 60079-19:2019) is satisfied that all the required activities have been undertaken and the Examination Report indicates authorization of results of inspection and tests.

On release of equipment, Service Facilities shall supply a "Job Report for the User" as defined in IEC 60079-19:2019, to cover each item of overhauled or repaired equipment released from the Ex Service Facility with attestation of conformity of the certification status, as agreed with the user, signed by the Responsible Person.
