

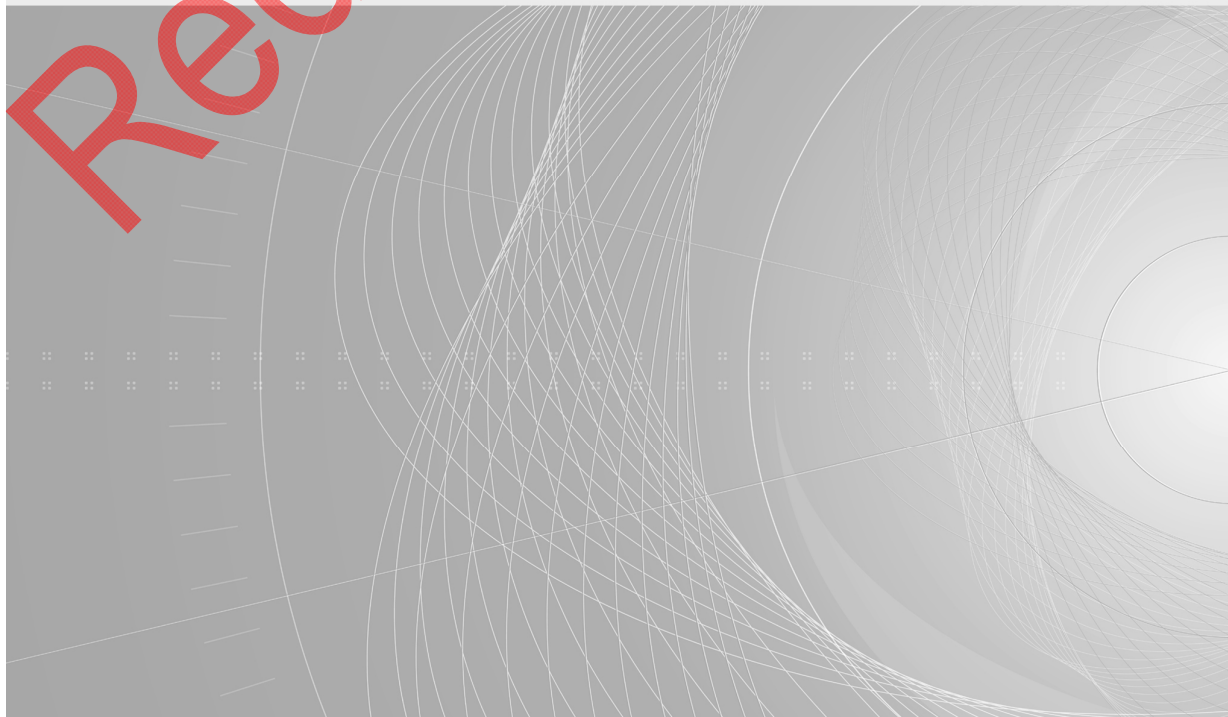


IECEX OPERATIONAL DOCUMENT

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

**IECEX Certified Service Facilities Scheme –
Part 4: Ex inspection and maintenance**

Quality Management System requirements for IECEx Service Facilities providing Ex installations related services





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document 314-4

**IECEX Certified Service Facilities Scheme –
Part 4: Ex inspection and maintenance**

**Quality Management System requirements for
IECEX Service Facilities providing Ex installations related services**

FOREWORD

This document is the IECEx Operational Document OD 314-4 Quality Management system requirements for the Certified Service Facilities Scheme – Part 4: Ex inspection and maintenance (“IECEX 03-4 Scheme”) to provide a mechanism for organizations that provide Ex inspection and maintenance services meeting the requirements of IEC 60079-14 and IEC 60079-17 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 of OD 314-4 supersedes OD 014 Version 2 in part and represents the application of a new numbering system.
2017- 11 ²²	This Edition 2.0 was approved for publication by the 2017 ExMC Meeting via ExMC Decision 2017/55 and supersedes Edition 1.0 of OD 314-4 upon publication
<u>2021-12</u>	<u>Update to align clause references with ISO 9001:2015</u>

This Redline version provides you with a quick and easy way to compare all the changes between this document and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are displayed as green text and deletions are displayed as strikethrough red text.

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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 (ExMC) to issue IECEX Certificates of Conformity to Service Facilities providing an Ex inspection and maintenance service according to IEC 60079-17.

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 inspection and maintenance 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 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 Operational Document is to be implemented immediately upon publication.

NOTE: Although this 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.

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

IEC 60079-17, *Explosive atmospheres – Part 17: Electrical installations inspection and maintenance*

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

IEC 60079 Series Standards as relevant or as referenced from IEC 60079-14 and IEC 60079-17 (for example IEC 60079-13, 28, 29, 32 and 43)

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 17021-1, *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/IEC TR 17026, *Conformity assessment – Example of a certification scheme for tangible products*

~~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 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 document is applicable at a number of steps in this procedure.

Redline Version



Quality Management System requirements for IECEX Service Facilities providing 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 ~~only in~~ inspection and ~~m~~Maintenance of Ex equipment. It also 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 ~~Quality Management System (QMS)~~ to relevant standards is not a requirement of the IECEX Scheme, a Service Facility with this may find it of benefit in assisting them to meet the requirements of this Operational Document.

In using ISO 9001:2015 as the basis for this Operational Document, the following requirements replace, add to or are more specific than those required by ISO 9001:2025. The clause references used in this Operational Document have been adopted from ISO 9001:2015~~08~~ as the most current standard.

NOTE: Requirements specified 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 F~~facility

Refer to IECEX 03-4

NOTE 1 to entry: ~~Ex-Service Facility~~ is a term used by IECEX and in the context of this IECEX OD 314-4 shall apply to an organization that carries out or controls inspections and maintenance, as required by IEC 60079-14 and IEC 60079-17.

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

2.2

Ex equipment

Refer to IEC 60079-0, Clause 3.37~~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 9001:2015, ~~as amended or added to.~~

ExCBs shall manage their quality management system auditing, for the IECEx Certified Service Facilities Scheme 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 conducted at not more than 12 monthly intervals at the location(s) where the Certified 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 OD 313-4
- b) **Re-assessment** – Conducted in a period not exceeding 3 years ~~as part of every third annual surveillance audit~~ and shall include the full review of an Ex Service Facility's documented procedures.

3.1 Documentation requirements

3.1.1 General

The Ex-Service Facility shall develop a quality management system ~~process plan~~ to establish verification of the Ex inspection and maintenance processes to the requirements of IEC 60079-14 and IEC 60079-17.

All Ex inspection and maintenance performed by the Ex-Service Facility requires 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 9001:2015, Clause 7.5.3.4-2.4:

Records must be kept of Ex equipment and Ex installations that are inspected and maintained in conformity with the requirements of this IECEx OD 314-4, IEC 60079-14 and IEC 60079-17.

Also, records must be kept of Ex equipment and Ex installations that, even after inspection and maintenance, do not comply with the requirements of ~~this~~ IECEx OD 314-4, IEC 60079-14 and IEC 60079-17.

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

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 ~~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 ~~responsible person-management representative~~ and any deputies shall be documented. The ExCB shall be notified of any changes to the personnel appointed as ~~competent~~~~the Responsible Person~~, according to IEC 60079-14 and IEC 60079-17.

~~Note: The term Management Representative in ISO 9001 is equivalent to the term Responsible Person in IEC 60079-14 and IEC 60079-17~~

3.3 Resource management

The following requirements are additional to those of ISO 9001:2015, ~~Clauses 6.7.1.1 through 7.1.4, 7.1.6, 7.2 and 7.3:~~

- The ~~Service Facility~~~~organization~~ shall provide for training of all personnel performing activities affecting the inspection and maintenance 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 and IEC 60079-17. Appropriate training records shall be maintained.
- Competent persons, ~~including responsible persons and operatives,~~ shall maintain their competence with ExCBs required to verify the currency of the competence 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 IEC 60079-17 for Responsible Persons and Operatives. The Competence Management System shall cover the scope of work undertaken by the Service Facility and geographic application relating to sites.

NOTE 1 to entry: Attention is drawn to the specific requirements relating to different geographic locations and applicable external influences.

NOTE 2 to entry: Evidence of competence can be provided by having personnel certified to the applicable Units of Competencies Ex 004 (Maintain equipment in explosive atmospheres), Ex 007 (Perform visual & close inspection of electrical installations in or associated with explosive atmospheres) and Ex 008 (Perform detailed inspection of 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 9001:2015, ~~Clause 7.1.5, 8.1 through 8.5:~~

The ~~Ex~~ Service Facility shall establish specific procedures or work instructions for Ex inspection and maintenance. 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 and IEC 60079-17 in accordance with the parameters listed below:

- Type of Ex service offered
- Measurement/test/inspection facilities available
- Details and evidence of Ex competence for responsible persons and operatives, nominated as Ex Competent Persons.

- Sub-contractor activities

3.5 Measurement, analysis and improvement

~~The following requirements are additional to those of 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:~~

3.5.2 Customer satisfaction

Clause ~~8.2.19.1.2~~ 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 60079-14 and IEC 60079-17. However additional measures of customer satisfaction according to ISO 9001:2015 are encouraged.

3.5.3 Internal audit

Clause ~~9.2.8.2.2~~ of ISO 9001:2015 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 Ex inspection and maintenance processes are in conformity with IEC 60079-14 and IEC 60079-17. The period between audits should normally not exceed 12 months.

3.5.4 Monitoring and measurement of processes

The following requirement is additional to those of ISO 9001:2015, Clause ~~8.2.39.1.1~~:

Where a maintenance process can affect the integrity of a type of protection, 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 9001:2015, Clause 8.6~~2.4~~:

Where tests are required they shall be performed as specified in IEC 60079-14 and IEC 60079-17 with sampling techniques being permitted according to IEC 60079-17 provisions and requirements.

3.5.6 Control of non-conforming product

The following requirements are additional to those of ISO 9001:2015, Clause 8.7~~3~~ and 10.2:

- The Ex Service Facility shall take action, appropriate to the degree of significance, associated with Ex equipment or an Ex installation which has been found during inspection or following maintenance to be non-conforming

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

- Identification of the Ex equipment or Ex installation covered by the Ex inspection or maintenance
- The customer who received the Ex inspection or maintenance service



- The action taken to inform the organization responsible for the Ex equipment or Ex installation
- The action taken to implement corrective and preventive action
- Actions and communications taken with a relevant regulator (whenever applicable)

3.5.7 Analysis of data

Clause ~~8.4~~9.1 of ISO 9001:2015 applies.

3.5.8 Improvement

Clauses 10.1 and 10.3~~8.5.4~~ of ISO 9001:2015 apply~~ies~~.

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.

3.5.9 Corrective action

Clauses 10.1 and 10.2~~8.5.2~~ of ISO 9001:2015 apply~~ies~~.

~~3.5.10 Preventive action~~

~~Clause 8.5.3 of ISO 9001 applies.~~

4 Preliminary requirements for ExCB assessment of ~~Ex~~Sservice ~~F~~facilities

As a pre-requisite, it shall be established that the ~~Ex~~ Service Facility satisfies the requirements of IEC 60079-14 and IEC 60079-17 in terms of adequate facilities, equipment and 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 at the location(s) where the Certified Service Facility manages their service activities, 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 of the location(s) where the Certified 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 Service Facility, including quality management systems.

7 On-site assessment

The on-site assessment ~~at the location(s) where the Certified Service Facility manages their service activities~~ will be conducted by an ExCB to verify compliance with IEC 60079-14 and IEC 60079-17 and the IECEX Scheme requirements, for example, e.g. ~~this~~ IECEX OD 314-4. 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~~ IECEx OD 313-4 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 and IEC 60079-17

ExCBs shall assess the ~~Ex~~-Service Facility's procedures and processes for compliance to the relevant requirements of IEC 60079-14 and IEC 60079-17.

This shall include assessment of the ~~Ex~~-Service Facility's inspection, test and maintenance plans for compliance with IEC 60079-14 and IEC 60079-17 and verification that such inspection, test and maintenance plans clearly define the method for pass/fail 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 Ex inspection~~al~~ and maintenance 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 and IEC 60079-17 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 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, 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 to entry: Subcontracting activities should~~al~~ 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 to entry: Subcontracting activities related to the main scope of Ex inspection and maintenance, 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 their nominated Ex Competent Person(s), including the operatives and 'Responsible Person' as required by IEC 60079-14 and IEC 60079-17.

For Ex Competent Persons having a Certificate of Personnel Competencies according to IECEx OD 504, Units of Competency Ex 004 (Maintain equipment in explosive atmospheres), Ex 007 (Perform visual & close inspection of electrical installations in or associated with explosive atmospheres) and Ex 008 (Perform detailed inspection of 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 and IEC 60079-17, the ExCB shall verify that the certified or assessed scope of 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 Ex 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, for example, 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 Ex operatives or responsible Competent Person(s) shall have the evidence of their Ex competencies verified by the ExCB.

8.4 Records

Results of the tests, inspections or maintenance conducted by the ~~Ex~~-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 result is not accepted.
- Stored to enable retrieval in accordance with 3.1.2 above

The ~~Ex~~-Service Facility shall retain all inspection and maintenance records for a minimum of 10 years from the date the initial inspection and maintenance was completed.

The Service Facility shall provide an Ex Service Report to the customer in accordance with the requirements specified in Annex A of this Operational Document.

8.5 Conditions for Ex inspection and maintenance completion

~~Ex Service Facilities processes and procedures shall comply with the following, concerning Ex inspection and maintenance completion.~~

Ex inspection and maintenance shall be considered complete once a complying Ex inspection and maintenance report is issued in accordance with IEC 60079-14 and IEC 60079-17 by the Responsible Person of the Ex Service Facility.

Annex A
Ex inspection and maintenance service report
issued by Ex-Service Facilities (normative)

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 03-4 Scheme to provide Ex inspection and maintenance services according to the requirements of IEC 60079-14 and IEC 60079-17 and the organisations accepted Scope.

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

Ex inspection service reports, including findings and solutions shall be reported taking into account aspects related to Ex equipment (both general and specific), Ex installation and environment (external influences), as required in IEC 60079-17.

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

In cases of Ex inspection services using electronic programs, PDAs and RFIDs, all electronic files generated by the inspection program shall be provided to the management of site, also including complete report in PDF format.

A.2 Content of Ex inspection or maintenance 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 Ex Inspection / Maintenance Service Facility Organisation that provided services;
- The name and address of the recipient of the Ex service provided;
- The date that the Ex inspection or maintenance service was provided;
- Ex Report reference number, ~~to be traced in the user verification dossier;~~
- Reference to IEC 60079-14 and IEC 60079-17 for Ex detailed inspection services;
- For Ex inspection or maintenance services in offshore installations reference also shall be made to IEC 61892-7 - Mobile and fixed offshore units – Electrical installations – Part 7: Hazardous areas;
- Reference to IEC 60079-17 for Ex close or visual inspection services;
- Reference to IEC 60079-17 for Ex maintenance services;



- A brief description of the site, system, Ex installation or Ex equipment receiving the Ex inspection or maintenance service provided;
- The Ex protection techniques employed in the site, system, Ex installation or Ex equipment receiving the Ex inspection or maintenance service provided;
- Copies of photographs, measurements and any other relevant artefacts regarding the Ex inspection or maintenance services provided;
- For visual, close or detailed Ex inspection services, the respective fulfilled Ex checklists specified in IEC 60079-14 (for initial detailed Ex inspection) or IEC 60079-17 (for visual, close or detailed Ex inspection), indicating relevant equipment tags, area classification documents, Ex equipment certificates and findings;
- List and description of any findings, resolutions, actions taken or actions required related to Ex maintenance or Ex inspection services provided, signed by Ex Service Facility Responsible Person, ~~approved and signed by the Ex installation user or responsible person.~~

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