The IECEx Certified Service Facilities Program

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Introduction

Advances in technology along with Globalisation have produced many changes in industries and the field of Explosion Protected Equipment is no exception.

Modern day automation of processes mean more and more specialised equipment are being exposed to the harsh environments, especially those where the presence of flammable gas/vapours or combustible dusts exist or may exist.

The international Ex community (Ex equipment manufacturers, end users and regulators) have worked long and hard at providing standardisation of technical requirements for Ex equipment and systems now reflected in the mature set of Standards; work on standardizing the approaches to testing and certification, is relatively young.

The benefits of publishing international equipment standards can be overshadowed by the application of differing testing and certification practices and systems, resulting in costly re-testing/re-certification and lost time-to-market for manufacturers and down time for plant operators.

While UL, CSA & ATEX has been seen as a solution to a converging common approach the question remains "What about companies and organisations that operate Globally".

IEC

The International Electrotechnical Commission (IEC) is the international organisation responsible for Standardisation in the electrical and electronic fields.

Founded in 1906, IEC was formed as a result of the resolution of the Chamber of Government Delegates at the International Electrical Congress of St Louis, USA, in September 1904.

The object of the Commission is to promote international cooperation on all questions of standardisation and related matters in the electrotechnical fields of electrical and electronic engineering and thus promote international understanding.

In addition to the preparation of International Standards the IEC facilitates the operation of the International Conformity Assessment Schemes which are overseen by the IEC Board on Conformity Assessment (IEC CAB).

In noting that the IEC celebrated 100 years titled as the "Electric Century" a dedication to the success and accomplishments of the IEC have been collated on the IEC Website, www.iec.ch (-About the IEC – History - Electric Century)

ISO 9001
Quality Management System

Whenever the subject of Ex Certification is discussed, the inevitable question arises:

"As a Manufacturer/Supplier we hold ISO 9001 Certification for our QMS why do we need something else"

Although ISO 9001 does provide a heightened level of confidence of a suppliers' overall quality, it does not provide product or component-level quality assurance. ISO 9001 provides an excellent foundation for an organisation's overall Management System.

Those familiar with ISO 9001 will know that Clause 7 and its sub clauses cover "Product Realisation Requirements" and have a major influence on organisations that manufacture and produce product /services. So the immediate question "Who determines which sub clauses of Clause 7 can be "excluded" and how does the customer know which sub clauses have been excluded when looking at an ISO 9001 Certificate especially sub clause 7.4 ***Purchasing*** and how well the Ex Manufacturer/Service Facility manages the supply chain verification of critical components, assemblies and processes all of which result in an ISO 9001 certificate on its own providing limited assurance of final products/services conformity to standards.

IECEx & Quality Assurance

In order to answer the questions raised above the IECEx Scheme has issued a clearly defined set of Quality Management System (QMS) requirements that are in addition to the base line ISO 9001 requirements, applicable to the Ex industry.

Experience with the assessment and auditing of Manufacturer's & Service Facility QMS to date has revealed the need for greater attention to the more technical areas of a QMS such as:

a) Traceability of Measurements
b) Authorising Final Release of Ex Products
c) Purchasing

These are examples of some of the more common areas that Ex Certification Bodies have to address in some detail, even for manufacturers & Service Facilities that hold ISO 9001 Certification.

IECEx Certification Scheme

While 2006 saw IEC enjoying 100 years of operation IECEx itself enjoys a modest 10 years of operation with June 1996 being the first meeting of the IECEx Management Committee in London, where the decision was taken to move ahead and the respective officers appointed and the framework for building Global confidence began.

In just 10 years with an IECEx Management Committee compromising representatives of 26 countries, IECEx has developed a complete suite of Rules, Operational Manuals, Procedures and Standardised Forms to create a single Ex test and certification system with the many IECEx Certification Bodies (ExCBs) operating as IECEx Certification providers.

IECEx 01	IEC Scheme for the Certification to Standards relating to Equipment for use in Explosive Atmospheres - Basic Rules
IECEx 02	IEC Scheme for the Certification to Standards for Electrical Equipment for Explosive Atmospheres – Rules of Procedure
IECEx 03	IEC Scheme for the Certification to Standards relating to equipment for use in Explosive Atmospheres - Certified Service Facility Program

These documents are available for free download from the IECEx website www.iecex.com

It is important to note that the principle aim of the IECEx Scheme is:

To facilitate international trade of Ex equipment and services by eliminating the need for duplication of testing and certification whilst preserving an acceptable level of safety.

One of the core objectives of the IECEx Scheme is:

- Maintaining International Confidence in equipment and services covered by IECEx Certification

The IECEx Scheme comprises the following two Global Certification Programs

1. The IECEx Certified Equipment Program
2. The IECEx Certified Service Facilities Program

IECEx Certified Service Facilities Program

IECEx's latest initiative is the rolling out of its new service offering "IECEx Certified Service Facility Programme" – covering assessment and certification of Ex Repair workshops. This new service has been keenly awaited by both Ex End Users as well as Ex Repair Workshops that wish to differentiate themselves from those operations that may not be complying with minimum Standards e.g. IEC 60079-19.

This IECEx Program is an International Certification Scheme that covers the assessment and the on-site audit of organisations that provide a Repair and Overhaul service to the Ex industry.

Due to the very high capital investment made by industry for most Ex equipment it is much more economical to repair and overhaul equipment rather than replace it with new. This also has obvious environmental benefits.

The challenge to industry is to ensure that all the very unique Ex safety features, included in the design and manufacturing of Ex equipment, are not compromised during the repair process.

Ex Repair and Overhaul Facilities and Workshops certified under the IECEx Certified Service Facilities Program, provide industry with the assurance that repairs and overhauls to Ex equipment will be undertaken according to the strict requirements of the IECEx Scheme and to the International Standard IEC 60079-19:2006

Like the IECEx Certified Equipment Program only "Electronic Certificates" are issued via the "On-Line" system thereby giving industry full access to both the viewing and printing of certificates.

QMS Requirements for IECEx Service Facilities Operational Document 14 (OD 14)

This operational document sets out the quality system requirements that a Service Facility shall conform to in order to gain and maintain IECEx Certification as an IECEx Certified Service Facility. The clause references in this document have been adopted from ISO 9001:2000.

While certification of the QMS to ISO 9001 is not a requirement of the IECEx scheme, a Service Facility with this may benefit in assisting them to meet the requirements of OD 014.

The following requirements are in addition to the requirements of IEC 9001:2000, to clearly identify those additional QMS requirements that bare specific to Ex Repair and Overhaul Industry.

General

The Service Facility shall develop a process plan to establish verification of the Repair/Overhaul processes to the requirement of IEC 60079-19:2006 and OD 015.

Any "Off-Site" repair or overhaul performed by the Service Facility requires documented procedures and or work instructions and shall be defined in the scope of IECEx Certified Service Facility Certification.

Records ISO 9001:2000 Clause 4.2.3

Records must be kept for services Ex equipment that are serviced in conformity to the requirements of IEC 60079-19 /OD 015 and 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 IEC 60079-19/OD 015 and are not marked with the R-label. As a minimum, records shall be kept for 10 years.

Management Responsibility ISO 9001:2000 Clause 5

The top management shall establish a mechanism to ensure there is at least one person appointed to deputise 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 the deputies shall be documented. The IECEx Certification Body (ExCB) shall be notified of any changes to the personnel appointed as competent.

Resource Management IEC 9001:2000 Clause 6

The organisation shall provide for training of all personnel performing activities affecting the repair and overhaul process. Competent personnel performing the assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as defined in IEC 60079-19/OD 015. Appropriate training records shall be maintained.

Competent persons shall maintain their competency with ExCB's required to verify the currency of the competency as part of the on-going surveillance of the Service Facility.

Product Realization ISO 9001:2000 Clause 7

The Service Facility shall establish procedures or work instructions for overhaul and repair of Ex Equipment. These shall consider each process covered under the scope of the IECEx Service Facility Certificate to the requirements of IEC 60079-19/OD 015 in accordance with the parameters listed below:

a) type of service offered
b) type of Ex equipment e.g. rotating machines
c) protection types e.g. Ex d, Ex e, Ex p, etc.
d) test/inspection facilities available
e) recall of product after dispatch should the Service Facility become aware of any critical or major defect after the repaired product has been released
f) details and evidence of competency for persons nominated as Competent Persons
g) sub-contractor activities

Measurement, Analysis & Improvement ISO 9001:2000 Planning Clause 8.1

Improvements are not within the scope of OD 014. They may be made at the discretion of the Service Facility, but the provisions of Management Responsibility above shall apply at all times.

Customer Satisfaction Clause 8.2.1

"Customer Satisfaction" is in relation to the Service Facility's compliance with the relevant requirements of IEC

60079-19/OD 015. However additional measures of customer satisfaction according to ISO 9001:2000 are encouraged.

Internal Audit Clause 8.2.2

The audit program shall address the effectiveness of the elements of the QMS to ensure that the repair and overhaul processes are in conformity with IEC 60079-19/OD 015. The period between audits shall not exceed 12 months.

Monitoring & Measurement of Processes Clause 8.2.1

Where a process can affect the integrity of a type of protection, and where the resulting integrity cannot be verified after manufacture e.g. the environmental conditions required for curing an encapsulant, that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters.

Monitoring & Measurement of Processes Clause 8.2.4

Where tests are required they shall be performed as specified in OD 015 or Standards with no sampling techniques being permitted.

Control of Nonconforming Product Clause 8.3

- The Service Facility shall maintain a system such that the customer or owner can be identified in the event of repaired 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 liaise with the ExCB responsible for the issue of the IECEx Service Facility Certificate of Conformity.

For all non-conforming product that has been released, the Service Facility shall maintain records of—

i. serial numbers or identification of product supplied;
ii. the customer who received the product;
iii. the action taken to inform customers and the relevant ExCB;
iv. the action taken to implement corrective and preventative action.

Analysis of Data Clause 8.4

NOT in the scope of OD 014

Improvement Clause 8.5.1

Not in the scope of OD 014

Corrective Action Clause 8.5.2

Applies

Preventive Action Clause 8.5.3

Applies

Preliminary Requirements

As a pre-requisite the Service Facility shall demonstrate to the ExCB that it satisfies the requirements of IEC6079-19/OD 015 in terms of adequate facilities , equipment and personnel to perform the scope of work to be covered by the IECEx Certified Service Facility Certificate.

Preliminary Visit

A Service Facility can request, as an option, a preliminary visit to serve as a gap analysis on a fee for service basis.

On Site Assessment

The On-site Assessment will be conducted, by an ExCB to verify compliance with IEC 60079-19 / OD 015 and the IECEx scheme requirements. 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 of:

- OD 015 Compliance Assessment Report
- Quality Plan Assessment
- Assessment of Competence of persons nominated as competent by the Service Facility

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 quality management systems.

Process Assessment by ExCBs

This section identifies the critical areas the ExCB shall include in their assessment and surveillance of a Service Facility seeking to obtain and maintain IECEx Service Facility Certification.

Compliance with IEC 60079-19 / OD 015

The Service Facility's procedures and processes for compliance to the requirements of IEC 60079-19 / OD 015 shall be assessed by the ExCB. This shall include assessment of the Service Facility's inspection and test plans for compliance with OD 015 and verification that such inspection and test plans clearly define the method for pass/fail criteria. This requires the ExCB to assess the Service Facility's documented procedures to ensure that the specific requirements of IEC 60079-19 / OD 015 have been included or covered by the Service Facility's QMS.

Use of Sub Contractors

The method of control the Service Facility maintains over any subcontractor used to perform part of the repair and overhaul process, including testing and calibration activities shall be assessed by the ExCB. 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 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 and reviewed by the ExCB.

Note: 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

Assessment of Competencies

The Service Facility's mechanism for verification of current competencies of their nominated Competent Person(s), including the 'Responsible Person' to the requirements of OD 015 shall be evaluated by the ExCB.

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' remain engaged in the activity. Any change that may impact on the Service Facility complying with IECEx Scheme requirements, eg 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.

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 just indicate pass is not accepted.
- Stored to enable retrieval in accordance with Documentation Requirements above.

The service facility shall retain all Repair and Overhaul records for a minimum of 10 years from the date the repaired product was released.

Marking

Marking shall be in accordance with the requirements of OD 015. Use of the ExCBs own Mark on Reports and Promotional Material may be permitted subject to the agreement of the ExCB.

Dimensional Checks

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

When conducting dimensional measurements, the Service Facility shall record “as found” and “as left” values on their Service Facility check sheet or Examination Reports for future reference. A simple “tick” to indicate pass or fail is NOT sufficient on its own. Evidence of compliance will be sampled and reviewed by ExCBs during each audit.

Conditions for Equipment Release

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

Repaired or Overhauled equipment shall be released from the Service Facility’s premises only when a Competent Person (as defined in OD 015) is satisfied that all the required activities have been undertaken and the Examination Report indicates authorisation of results of inspection and tests.

On release of equipment, Service Facilities shall supply a “Service Facilities Report” as defined in OD 015, to cover each item released from the Service Facility.

IECEx Certified Service Facility Program Application Process

A service facility wishing to join the Certified Service Facility Program makes an application, to his local or appropriate IECEx Certification Body (ExCB), who will either have been approved by IECEx for the Certification of Service Facilities or will work through another IECEx ExCB who has been approved by IECEx for the Certification of Service Facilities.

The service facility will review the IECEx requirements as detailed in IEC 60079-19:2006 and IECEx Operating Documents OD 013, OD0 14 & OD 015. Having satisfied itself that it has sufficient evidence to meet the audit requirements of the IECEX ExCB, the service Facility shall submit its QMS & Process Control documentation for review by the ExCB.

The ExCB receiving the application shall conduct a Document Review Assessment of the Service Facility’s quality system procedures to ensure that the Repair, Overhaul and Modification process requirements of IEC 60079-19 / OD 015 have been integrated as part of the Service Facility’s quality system.

Evidence will be required to verify compliance with the demonstration of competency requirements as detailed in Annex B of IECEx 60079-19:2006.

During this document review, the ExCB will take special note of the persons listed as “Competent” by the Service Facility, within their Quality Management System. The ExCB will satisfy itself that the person(s) identified as “Competent” posses the necessary competencies, as defined in OD 015 / IEC 60079-19. This may need an interview by the ExCB to satisfy that the Competent Person meets these requirements.

When the ExCB have verified compliance of the documentation & QMS systems the Service Facility shall be audited by the ExCB

A Facility Audit Report (FAR) in accordance to IECEx OD 013 shall be prepared by the ExCB and only when all non-compliances have been resolved to the satisfaction of the ExCB and the FAR has been independently reviewed by the ExCB shall the FAR be registered on the IECEx “On-Line” Certificate of Conformity System.

Only when a Far has been registered and an ongoing surveillance program agreed is a Certificate of Conformity issued to the Service Facility.

An overview of the application and assessment process is shown in the process flow diagram below:

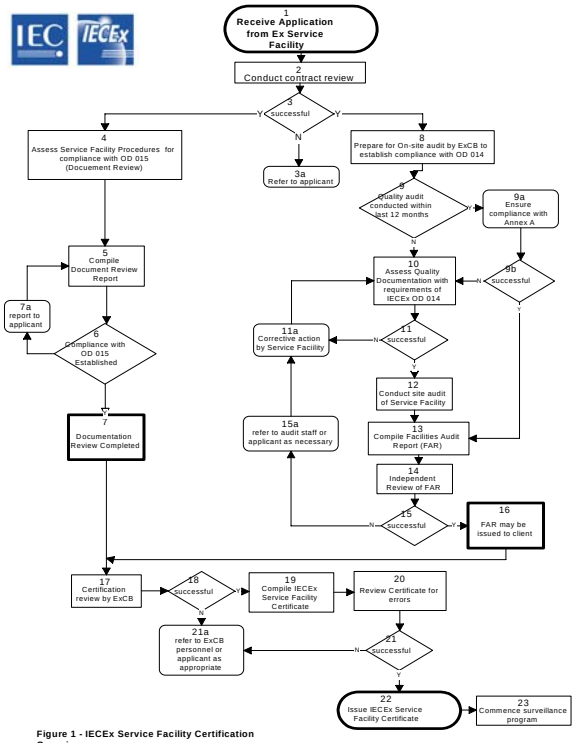

Figure 1 - IECEx Service Facility Certification Overview

IECEx Certified Service Facilities Program Progress to Date

Although the IECEx Service Facility program has only been in operation since October 2006 three applications have been received by the IECEx Secretariat with a further 4 applications being progressed.

IECEx Scheme Success

The IECEx Scheme and its programs continue to enjoy tremendous success with annual increases in the number of issued IECEx On-Line Certificates for Equipment exceeding ambitious predictions in 2006 by 50%.

The key to the IECEx Success lies with the industry experts that serve on the IECEx Management Committee (ExMC), Technical Committee (ExTAG) and the many Specialist Working Groups that all work together to a common goal of the IECEx Vision:

"To be the Global Centre of Excellence in the Highly Specialised Ex Fields"

The network of worldwide experts participating in the management, operation and delivery of IECEx service, e.g. the ExCBs and their IECEx Test Laboratories are supported by a dedicated Technical Secretariat that serve the IECEx and industries as central management centre for the day to day operations of the Scheme.

Acknowledgements:
International IECEx certification Scheme
'IECEx – A Global Solution for the Ex Industry'
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References:

IEC 60079-19 Explosive Atmospheres Part 19: Equipment repair, overhaul and reclamation.
ISO 9001:2000 Quality Management System – Requirements
OD 013 IECEx Operations Manual – Assessment and Certification of Ex Repair and Overhaul Service Facilities
OD 014 IECEx Operational Document: Quality System Requirements for IECEx Service Facilities involved in repair, overhaul and Modification of Ex Equipment
OD 015 IECEx Operational Document: Technical Requirements for IECEx Service Facilities involved in repair, overhaul and modification of Ex equipment.