

IECEX OPERATIONAL DOCUMENT

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

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

**Assessment and Certification of Service Facilities providing selection of
Ex equipment and design of Ex installations related services – Procedures**



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Readline Version

INTERNATIONAL ELECTROTECHNICAL COMMISSION

Operational Document IECEX 313-2 –**IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations****Assessment and Certification of Service Facilities providing selection of
Ex equipment and design of Ex installations related services –
Procedures**

FOREWORD

This Operational Document IECEX OD 313-2 - Operations Manual for the IECEX Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations ~~to~~ providespecifies a mechanism for organizations that provide selection of Ex equipment and design of Ex installations related services meeting the requirements of IEC_60079-14 the ability to obtain IECEX Certification under the IECEX System.

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

Document History

Date	Summary
2013-03	This original issue Edition 1.0 of IECEX OD 313-2 supersedes IECEX OD 013 Version 2.0 in part and represents the application of a new numbering system.
2018-10	This Edition 2.0 was approved for publication by the 2018 ExMC Meeting via ExMC Decision 2018/52 and supersedes Edition 1.0 of IECEX OD 313-2 upon publication

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INTRODUCTION

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

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

The purpose of 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 design and selection Facilities with the same approach and technical or management requirements, known as certifying the IECEX way.

For selection of Ex equipment or design of Ex installations, a certified Ex Service Facility should be capable of selecting equipment or designing installation of any Ex type of protection. If not permanently employed, Ex competent personnel for a particular type of protection may need to be engaged for a particular application.

This IECEX Operational Document comprises the following three 3 Sections:

Section 1:— Procedures for the issuing of an IECEX Service Facilities Certificate

Section 2:— Procedures for maintaining validity of an IECEX Service Facilities Certificate

Section 3:— Procedures for the processing of applications for extension of scope to an IECEX Certified Service Facility

The procedures are set out in table form identifying:

- Step number showing the link between flowcharts and table;
- Description of the activity;
- Related documents;
- Responsible person or party;
- Additional comments and remarks where appropriate.

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

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

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

IECEX 03-3, IECEX Certified Service Facilities Scheme – Part 3: Ex installation and initial inspection – Rules of Procedure

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

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

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

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

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

~~ISO/IEC 17021, Conformity assessment – Requirements for bodies providing audit and certification of management systems~~

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

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

ISO 19011, Guidelines for auditing management systems

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

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

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

This IECEX OD 313-2 often refers to IECEX OD 025, Guidelines on the management of assessment and surveillance programs for the assessment of manufacturer's quality system, in accordance with the IECEX Scheme.

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

Redline Version

Operational Document IECEX OD 313-2 –
IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations

**Assessment and Certification of Ex Service Facilities providing selection of Ex equipment and design of Ex installations related services –
Procedures to be followed by ExCBs**

Section 1 – Procedures for the issuing of an IECEX Service Facilities Certificate

This Section is to be applied by ExCBs when processing new applications for an IECEX Service Facilities Certificate.

These steps are in line with the requirements of ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*, in addition to the requirements as laid down in the IECEX Scheme Rules, IECEX 03-2.

This Section also refers to Annex A for the criteria concerning the use of Quality Management System (QMS) assessment and audit results obtained prior to the application for an IECEX Service Facilities Certificate of Conformity.

Annex B contains a checklist of documentation that an IECEX Certified Service Facility should have in place.

Figure 1 shows a broad outline of the processing of applications from an Ex Service Facilities by an ExCB.

Figure 2 shows a flowchart of the processing of applications from an Ex Service Facilities by an ExCB.

~~The following is a broad outline of the processing of applications from Service Facilities by an ExCB.~~

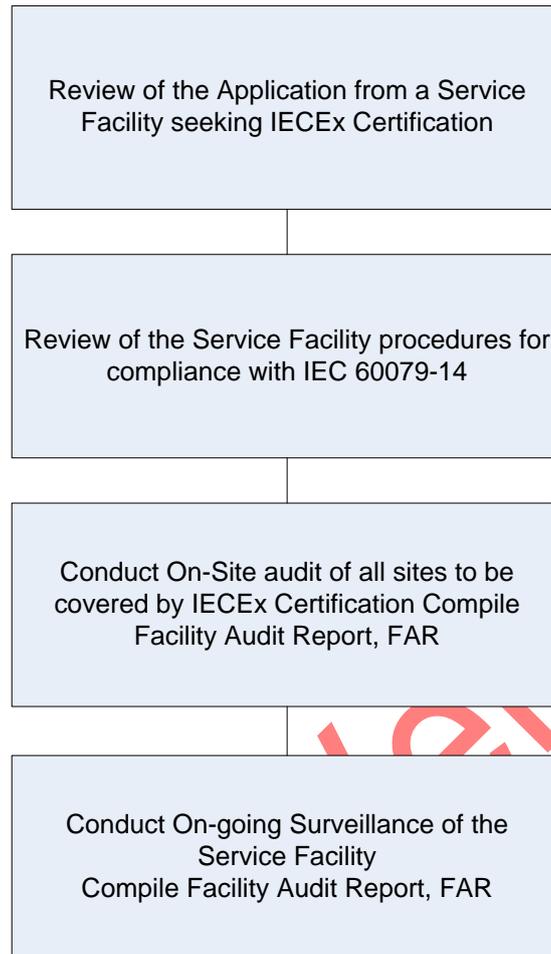
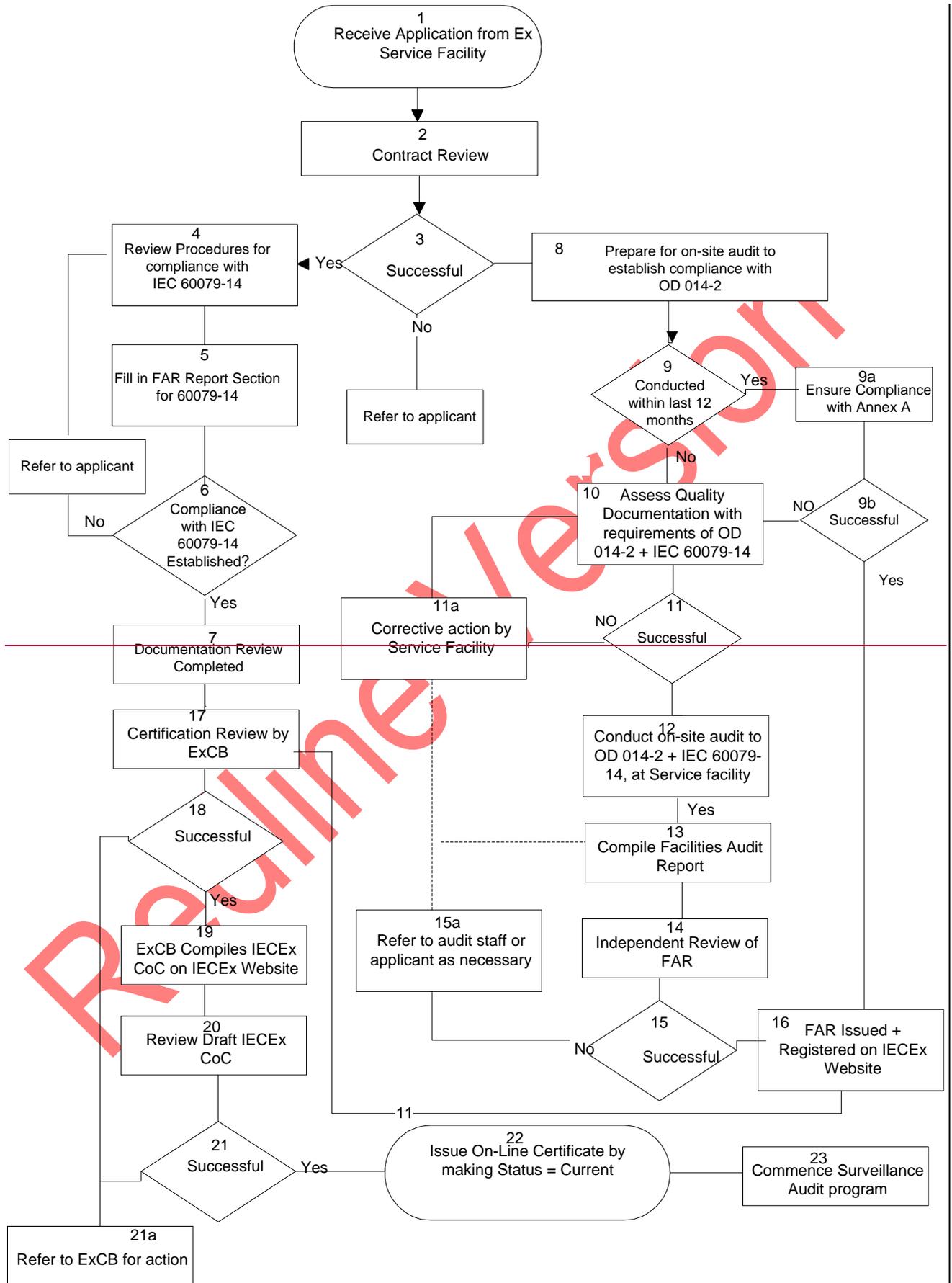


Figure 1 - Outline of the processing of applications from an Ex Service Facilities by an ExCB



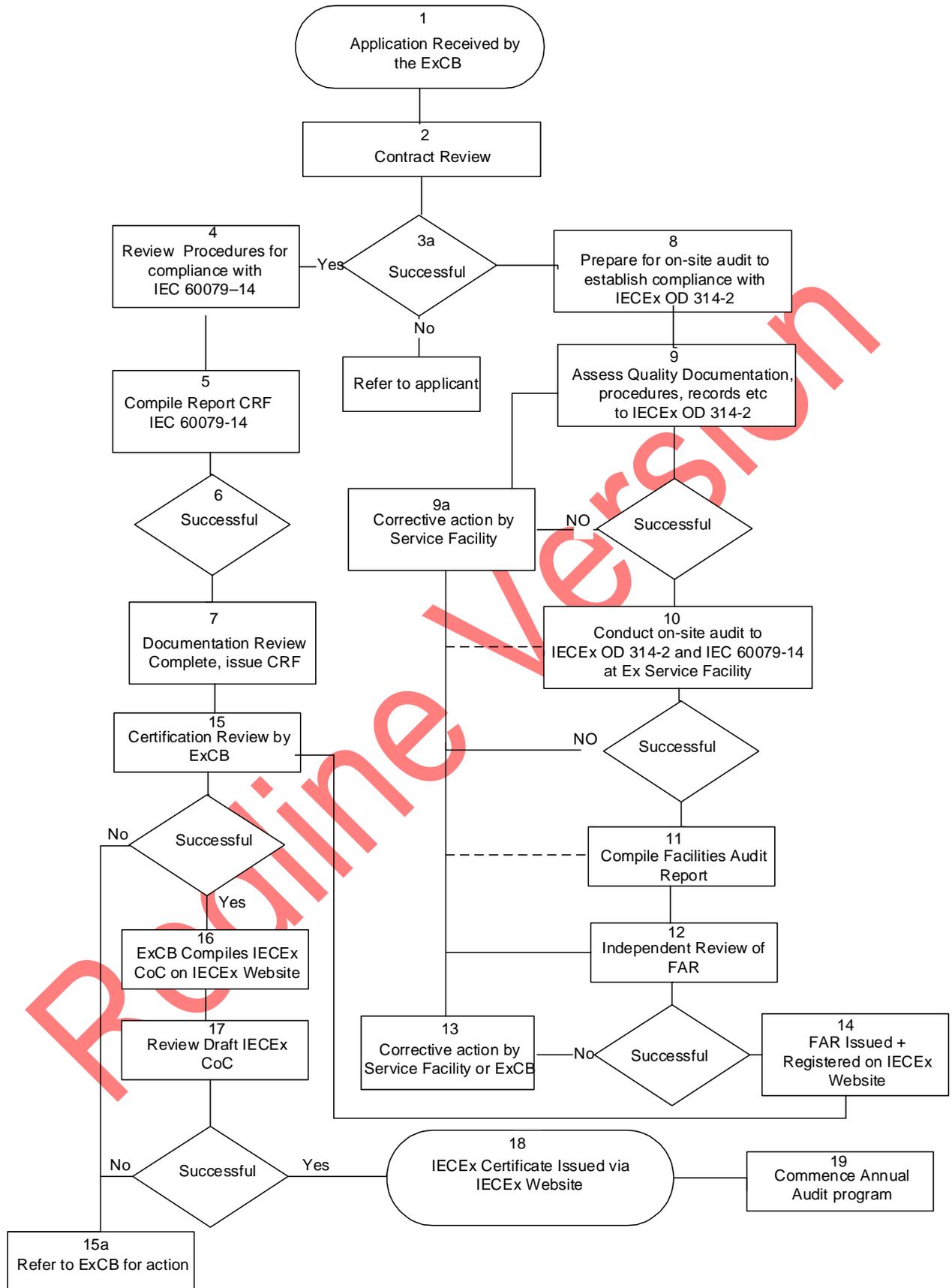


Figure 2 - Flowchart of the processing of applications from an Ex Service Facilities by an ExCB

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
1	<p>Application submitted by an <u>Ex</u>-Service Facility involved in Selection of Ex equipment and design of Ex installations to an ExCB that has been accepted by the IECEx Management Committee as an IECEx Service Facility Certificate issuing ExCB.</p> <p>Applicant <u>Ex</u> Service Facilities are encouraged to check the completeness of the application using the checklist in Annex <u>B</u>.</p> <p>Where the <u>Ex</u> Service Facility is located in a non-IECEx participating country, the ExCB shall in conjunction with the ExMC SecretarySecretariat, arrange for payment to the IECEx account of the surcharge, in accordance with <u>IECEx OD</u> <u>-019</u>.</p>	<p>IECEx 03-2 IECEx OD 019 (IECEx participation and scheme fees)</p>	<p>The Applicant</p>	<p>Applications for an IECEx Service Facility Certificate of Conformity will verify compliance with the requirements of IECEx Scheme and relevant Operational Documents.</p>

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Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
2	<p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC 17065.</p> <p>Contract review shall include:</p> <ul style="list-style-type: none"> • A review to determine whether the Service Facility has had an IECEx Service Facility Certificate of Conformity for design and selection previously issued by other ExCBs, which has since been suspended/cancelled • Whether the <u>Ex</u> Service facility has an established quality management system • Whether a surcharge applies for <u>Ex</u> Service facilities from non IECEx member countries • Estimation of time and costs to complete project • Determination of any special requirements, e.g. travel for site audit etc. • <u>Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and Quality Management System</u> • <u>Confirmation that the application is within the scope of the ExCB</u> 	<p>ExCBs own Certification procedures as included in their Quality Management System (QMS), ISO/IEC 17021-1, ISO/IEC 17065</p>	<p>ExCB</p>	<p>The results of the contract review shall be documented and recorded.</p> <p>Annex B can be used as a summary of the documents supplied.</p>
3	<p>ExCB shall only proceed where the contract review has been successfully completed.</p>		<p>ExCB</p>	
3a	<p>Where the results of the site audits <u>contract results</u> are unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEx acceptance does not cover the application.</p>		<p>ExCB</p>	

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
4	<p>The ExCB receiving the application shall conduct a Document Review Assessment of the <u>Ex</u> Service Facility’s quality system procedures to ensure that the process requirements of IEC_60079-14 have been integrated as part of the <u>Ex</u> Service Facility’s Quality Management System (QMS).</p> <p>The Document Review and subsequent Steps 4 to 7 may be conducted either off-site prior to the on-site assessment or as part of the on-site assessment at the <u>Ex</u> Service Facility’s premises.</p> <p>During this document review, the ExCB should take special note of the persons listed as “Competent” by the <u>Ex</u> Service Facility, within their Quality Management System with the ExCB satisfying itself that the person(s) identified as “Competent” possess the necessary competencies, as defined in IEC 60079-14 and in IECEx_OD_504 (Specification for Units of Competency assessment outcomes):</p> <p>Unit of Competency Ex 009 (Design electrical installations in or associated with explosive atmospheres).</p>	<p>IEC 60079-14 IECEX 03-2 FAR <u>IECEX</u> OD 504</p>	<p>ExCB that received the application</p>	<p>The document review may be conducted at the <u>Ex</u> Service Facility’s site or elsewhere.</p> <p>An IECEx 03-2 FAR provides a mechanism for the reporting of the evaluation of this Document Review and shall be compiled at the end of this document review process.</p> <p>Reference should be made to requirements set forth in IECEx OD 504, Unit of Competency Ex 009 (Design electrical installations in or associated with explosive atmospheres).</p>

Readline Version

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
5	<p>An IECEx 03-2 FAR shall be compiled by the ExCB, provided to the <u>Ex</u> Service Facility and retained on the ExCB files. Where a Service Facility operates multiple sites then each site shall be separately assessed and covered by their own FAR and CoC or combined FAR.</p> <p>A CoC covers one site only.</p>	IECEX 03-2 FAR	ExCB	<p>For <u>selection of Ex equipment and design of Ex installations</u>Ex design and selection Service Facilities <u>with multiple sites, each site shall be inspected. It is permissible for the ExCB to issue one IECEx 03-2 FAR covering all sites. However, each site shall have their own CoC</u>with multiple sites it is not allowed for the ExCB to issue one IECEx 03-2 FAR and CoC to cover all sites, since the scope of each site may be different.</p>
6	<p>The ExCB shall determine whether compliance to IEC 60079-14 has been established. It is necessary that the Service Facility's procedures are fully in line with those requirements specified in IEC 60079-14 before the application for IECEx Service Facility certification can proceed.</p>	IEC 60079-14	ExCB	<p>IECEX 03-2 FAR to record results of assessment <u>against in accordance with</u> IEC 60079-14 requirements and to report on-site audit results.</p>
7	<p>At this stage the documentation review can be considered as complete.</p>			

Ready for Review

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
8	<p>The ExCB prepares for an on-site audit visit of the <u>Ex</u> Service Facility's site to be listed on the Certificate, to determine compliance with the Quality Management System (QMS) requirements of <u>IECEX</u> OD 314-2 and IEC_60079-14.</p> <p>Where the <u>Ex</u> Service Facility has more than one permanent site then the ExCB shall visit each site or arrange to have each independently assessed with each site covered by its own FAR and CoCo <u>or a combined FAR</u>.</p>	<u>IECEX</u> OD 314-2 (Ex QMS) IEC 60079-14	ExCB	<p>Permanent sites are listed on the Certificate, whereas operational <u>or temporary (as non-permanent)</u> sites are not.</p> <p>Permanent sites are subjected to the audit with operational/temporary sites being subjected to a sampling arrangement according to ISO/IEC_-17021-1.</p>
9	<p>Where the ExCB has conducted site audits of the <u>Ex</u> Service Facility prior to an application being lodged, the ExCB may use all or part of the results from that site visit.</p> <p><u>However</u>, in such cases, an IECEx 03-2 FAR shall be compiled and registered on the IECEx On-line Certificate system. <u>Refer to Annex A</u>.</p>		ExCB	
9a 9b	<p>Where full compliance with Annex A of this <u>IECEX</u> OD_-313-2 is not established then a full on site audit visit is required.</p>	<u>IECEX</u> OD 313-2 <u>Annex A</u>	ExCB	
10	<p>An assessment of the <u>Ex</u> Service Facility's Quality Management System (QMS) documents shall be conducted to verify compliance with <u>IECEX</u> OD 314-2 and IEC 60079-14.</p>	<u>IECEX</u> OD 314-2 (Ex QMS) IEC 60079-14	ExCB	
11a	<p><u>If applicable, w</u>here non-compliance is detected ExCB to issue a Non-Conformance Report, in accordance with the guidelines in <u>IECEX</u> OD 025.</p>	<u>IECEX</u> OD 314-2 (Ex QMS) <u>IECEX</u> OD 025	ExCB	

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
12	Preparation for the IECEx <u>On-Site</u> Quality Management System (QMS) Assessment.	<u>IECEx</u> OD 314-2 (Ex QMS) <u>IECEx</u> OD 025	ExCB	Assessment of the competencies of personnel must be done on-site, as well as witnessing of <u>selection of Ex equipment and design of Ex installation testing.</u>
13	<p>The <u>Ex</u> Service Facility audit report (FAR) shall be compiled by the ExCB.</p> <p>Where serious deficiencies in the <u>Ex</u> Service Facility's documented Quality Management System (QMS) plans may give rise to non-complying selection of Ex equipment and design of Ex installations or where <u>there are</u> serious deficiencies in the <u>Ex</u> Service Facility's <u>documented documentation.</u></p> <p>QMS plans may give rise to non-complying Ex product or service being released,</p> <p>These shall be raised by the ExCB as major non-conformances and the applicant and Ex Service Facility required to take action to correct this situation (usually by the introduction or amendment of QMS plans), prior to proceeding with the issue of an IECEx Service Facility Certificate of Conformity.</p> <p>Where non-compliance with various clauses of OD 314-4 is judged to be of a minor nature by the ExCB, the process may continue.</p> <p><u>The process may only continue where ALL Non-conformances have been closed.</u></p>	IECEx 03-2 FAR <u>IECEx</u> OD 314-2 (Ex QMS)	ExCB	
14	<p>An independent review of the Draft <u>Ex</u> Service Facility Audit Report (FAR) shall be conducted, prior to issue, by the ExCB as a requirement of ISO/IEC 17065 and shall be conducted by ExCB staff not involved in the audit.</p> <p><u>Where errors are identified, a revised FAR may need to be prepared.</u></p>	ISO/IEC 17065	ExCB	Should the independent review reveal a major discrepancy or changes in the application a further on site assessment may need to be considered?

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
15 + 15a	Where the Independent review raises questions that need to be resolved, these shall be referred to the ExCB for correction or further action.		ExCB conducting the audit	
16	<p>The final <u>Ex</u> Service Facility Audit Report (FAR) shall be issued, by the ExCB with the original hard copy (master) sent to the applicant and a hard copy (uncontrolled) retained on the ExCB file.</p> <p>The ExCB that received the application for certification shall issue the FAR and register the FAR on the IECEx on-line system. However, where multiple sites exist, it is permissible for an ExCB that received the original application (ExCB A) to arrange for another ExCB (ExCB B, <u>that has been accepted to operate in the IECEx 03-2 Scheme with relevant scope of acceptance</u>) to conduct the site audit of local sites on their behalf; however it is ExCB A that shall issue the final FAR and register this on the On-Line system.</p> <p>The ExCB issuing the FAR shall “Register” the FAR on the IECEx “On-Line” Certificate of Conformity System, in similar fashion as registering a QAR for an IECEx Certificate covering <u>Ex equipment or a PCAR for an IECEx covering Ex Personnel Competence (ExCoPC) products</u>.</p> <p>The registration process provides a database of information such as:</p> <ul style="list-style-type: none"> • Unique FAR reference number or identifier • Name and address of <u>Ex</u> Service Facility covered by FAR • Date of audit completion • Scope of <u>Ex</u> Service Facility and listed type of protection • Any comments that the ExCB feels should be noted 	IECEX OD 314-2 (<u>Ex</u> QMS) <u>IECEX</u> OD 011- <u>Part-3</u>	ExCB that issues the FAR	<p>ExCB shall be assigned a unique password to allow the ExCB to enter the Data “On-Line”.</p> <p>Contact the IECEx Secretariat for any questions or concerns.</p> <p><u>IECEX</u> OD 011-<u>Part-3</u> provides guidance to ExCBs on the registering of issued FARs and also the compiling and issuing of On-Line Certificates of Conformity under the Certified <u>Ex</u> Service Facility Program.</p>

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
17	<p>The ExCB to whom the application for an IECEx Service Facility Certificate was made shall conduct a certification review, in accordance with their quality management system, ensuring among others that:</p> <ul style="list-style-type: none"> Any major non-conformances have been successfully solvedclosed All stages of the certification process have been documented and followed, including those contained in this Operational Document The ExCB have a signed commitment by the applicant to abide by the rules of the IECEx Scheme and ExCB's certification conditions, e.g. agreement to have the ExCB undertake or arrange for surveillance audits The applicant is aware of his/her obligations under the IECEx Scheme, including ensuring that any promotional material does not contain misleading information that may infer products or services NOT covered by IECEx certification are covered 	IECEX 03-2 ExCB's own Quality Management System	The person authorized to conduct such review within the ExCB to whom the original application was made	Contact the IECEx Secretariat for any questions or concerns.
18 + 21a	Where the review undertaken in Step 17 is not successful, the ExCB management shall refer the matter to ExCB staff or applicant <u>Ex</u> Service Facility as appropriate.		Management of the ExCB to whom the original application was made	Contact the IECEx Secretariat for any questions or concerns.
19	IECEX Service Facility Certificate shall be compiled using the IECEx "On-Line" system via the password protected system. http://iecex.iec.ch/iecex/exs.nsf/ex_sf.xsp?v=s	Refer IECEx website www.iecex.com IECEX OD 011- Part-3	The person authorized to issue IECEx Certificates of Conformity within the ExCB to whom the original application was made	Contact the IECEx Secretariat for any questions or concerns.

Step	Section 1 – Procedures for the issuing of an IECEx Service Facility Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
20, 21 + 21a	<p>A draft of the IECEx Service Facility Certificate is to be reviewed for errors. It may be beneficial to pass a draft copy to the applicant for them to assist in the final review prior to issuing the certificate.</p> <p>While the Draft Certificate is created “On-Line” the ExCB may create a protected PDF copy and send this to the Applicant, refer to IECEX OD 011-Part-3 for guidance.</p> <p>Every attempt shall be made to correct errors prior to issuing the certificate.</p>	<p>Original application form submitted by the applicant</p> <p>IECEX OD 011-Part-3</p>	<p>The person authorized to issue IECEx Certificates of Conformity within the ExCB to whom the original application was made</p>	<p>The electronic version residing on the IECEx “On-Line” System remains the master version.</p> <p>Any printing or hard copying is considered “uncontrolled” copies.</p> <p>Contact the IECEx Secretariat for any questions or concerns.</p>
22	<p>Certificate is issued via the IECEx “on-Line” registration system with the applicant being informed in writing by the ExCB, via letter, fax or e-mail.</p>		<p>The person authorized to issue IECEx Service Facility Certificate within the ExCB to whom the original application was made</p>	<p>Contact the IECEx Secretariat for any questions or concerns.</p>
23	<p>Certification Maintenance begins, refer to Section 2 of this Operational Document.</p> <p>The ExCB issuing the IECEx Service Facility Certificate is responsible for the on-going maintenance of the certificate which shall include:</p> <ul style="list-style-type: none"> • Conducting or arranging for surveillance assessments/audits • Responding to public inquiries regarding the certificate • Taking necessary action when aware of possible breaches by the applicant, e.g. claims that product not the subject of IECEx Service Facility Certificate are being claimed as “IECEX Certified” 	<p>IECEX 03-2</p> <p>IECEX OD 025</p> <p>ISO/IEC 17065</p> <p>ExCB’s own Quality Management System (QMS)</p>	<p>Management of the ExCB that issued the IECEx Certificate of Conformity</p>	<p>Contact the IECEx Secretariat for any questions or concerns.</p> <p>Typically, the first surveillance audit begins not more than 12-months from the last audit, unless otherwise justified by the ExCB.</p>

Section 2 – Procedures for maintaining validity of an IECEX Service Facilities Certificate

This Section is to be applied by ExCBs to ensure that IECEX Service Facility Certificate remain valid.

These steps are in line with the requirements of ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*, and ISO/IEC 17021-1, *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*, in addition to the requirements as laid down in the IECEX 03-2 Scheme Rules, ~~IECEX 03-2~~.

While this Section provides guidance to ExCBs when conducting surveillance audits of Service Facilities to ensure the on-going credibility of the Scheme it may be necessary for the ExCB to conduct unscheduled visits of the Ex Service Facility, of sample assessment of selection of Ex equipment and design of Ex installations for serious cases, ~~or even~~ and noting such instances on the ExCBs files for raising at the next surveillance audit.

At any time during the maintenance of an IECEX Service Facility Certificate, the IECEX Secretariat, ~~Officers-Executive~~ and Management Committee are available to provide assistance with the understanding of the process and expectation of outcomes of such surveillance activity.

Certification maintenance comprises the following activities:

- a) **Annual site audits** by the ExCB conducted at no more than 12-month intervals with an FAR up-issued at the end of such audit
- b) **3 Year Re-assessment** by the ExCB involving both a review of the Ex Service Facility's documented quality system procedures and a site audit with the issue of a FAR up-issued at the end of the re-assessment.

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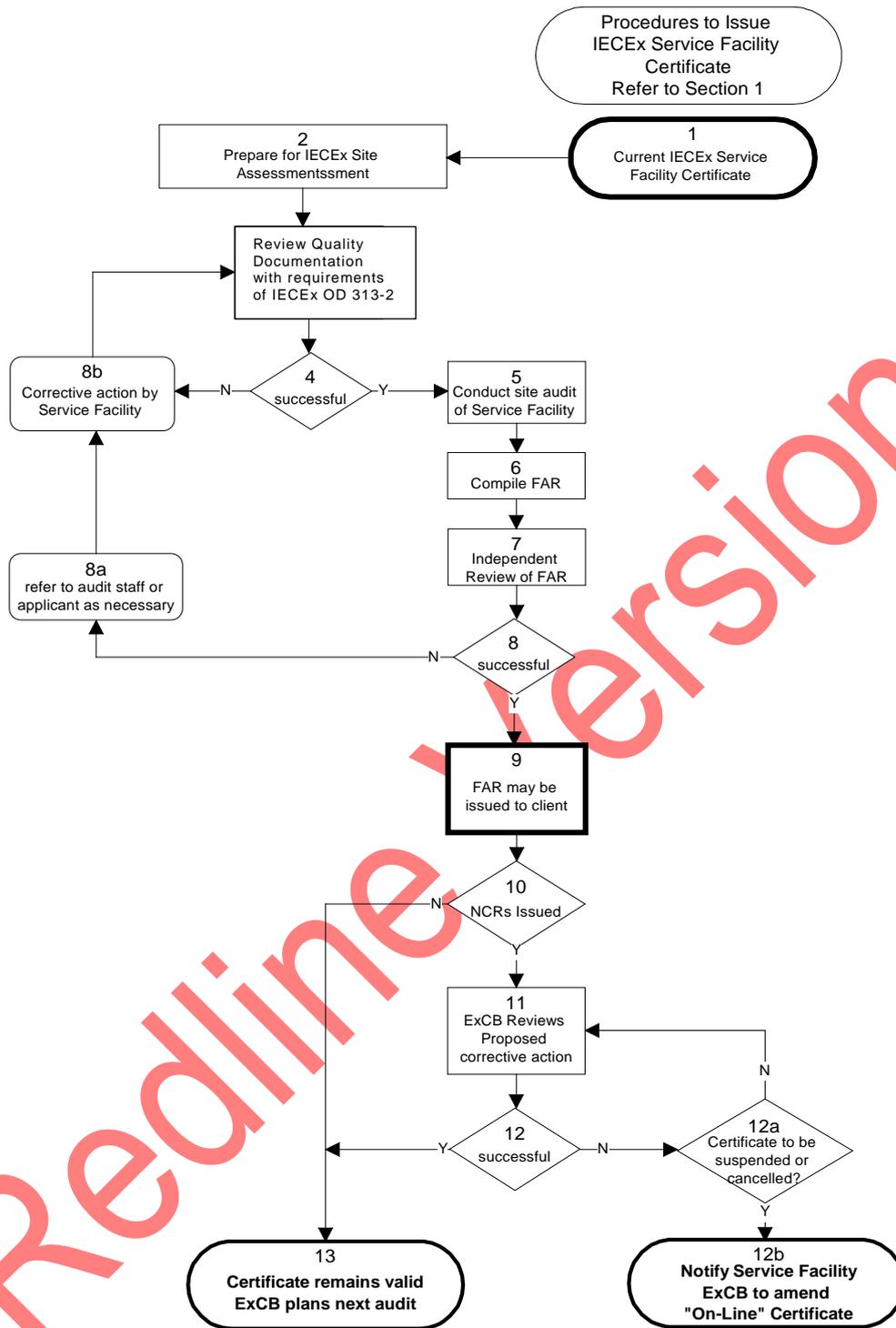


Figure 3 - Procedures to Issue an IECEX Service Facility Certificate (Refer to Section 1)

Step	Section 2 – Procedures for maintaining an IECEx <u>Service Facility</u> Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
1	IECEX Service Facility Certificate verified as valid by the ExCB that issued the Certificate and confirms details on IECEx Certificate website are current and correct, e.g. <u>Ex</u> Service Facility location(s), scope of activities, engagement of Responsible Person(s) and Operatives (designers) satisfying the requirements of IEC 60079-14 and IECEx OD 504, <u>IECEX 03-2</u> , etc.	<u>IEC 60079-14</u> IECEX 03-2 <u>IECEX OD 504</u> IECEX Service Facility Certificate	ExCB that issued the IECEx Service Facility Certificate	<p>Surveillance audits shall be conducted at not more than 12--month intervals for which a Facility Assessment Report (FAR) shall be <u>up</u>-issued.</p> <p>Over the course of a 3- year period a full review of the Quality Management System (QMS) shall be undertaken.</p> <p>This does not prevent an ExCB from conducting a full review of the Quality Management System (QMS) procedures at any surveillance audit where there have been major changes to an organization.</p> <p>Attention is drawn to the IECEx CoPC Scheme and Operational Document <u>IECEX</u> OD 504 (Specification for Units of Competency Assessment Outcomes), Unit of Competency Ex_-009 (Design electrical installations in or associated with explosive atmosphere).</p>

Redline Version

Step	Section 2 – Procedures for maintaining an IECEx <u>Service Facility</u> Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
2	<p>ExCB that issued the IECEx Service Facility Certificate shall conduct the surveillance audit and may utilise resources from other ExCBs within the IECEx 03-2 Scheme for <u>selection of Ex equipment and design of Ex installations</u>design and selection.</p> <p>An audit plan should be prepared especially where more than one <u>Ex</u> Service Facility location is involved.</p>	<p>ExCBs own Quality Management System (QMS) <u>IECEX</u> OD 314-2 <u>IECEX</u> OD 025</p>	<p>ExCB that issued the IECEx Service Facility Certificate</p>	<p>The ExCB should check that the <u>Ex</u> Service Facility conducts work in accordance with the IECEx Scheme for activities within the IECEx Certified scope.</p>
3	<p>Review of the Service Facility's Quality Management System (QMS) documentation to ensure that any changes since the last audit complies with the requirements of IEC_60079-14 and IECEx_OD_314-2. This review of documentation may take place either prior to the site visit or as part of the site visit and audit of the Service Facility's premises. Special attention is drawn to the following:</p> <ul style="list-style-type: none"> • Changes in personnel, especially Responsible Persons and Operatives (designers); • Changes in management and management systems; • Facilities, equipment, software and documentation management system, their availability, maintenance and update; • Calibration of test and measuring equipment; • Records and traceability of completed work; • Customer feedback/complaints; • Others. 	<p>IEC 60079-14 <u>IECEX 03-2</u> <u>IECEX</u> OD 314-2 <u>IECEX 03-2</u> <u>IECEX</u> OD 025</p>	<p>ExCB conducting the audit</p>	
4 + 8a	<p>Where the document review reveals non-compliance with the requirements of IEC 60079-14 or <u>IECEX</u> OD 314-2, the ExCB shall determine whether the non-conformance is such that they need correction prior to continuing with the site audit.</p>	<p>IEC 60079-14 <u>IECEX</u> OD 314-2 <u>IECEX</u> OD 025</p>	<p>ExCB</p>	

Step	Section 2 – Procedures for maintaining an IECEx <u>Service Facility</u> Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
5	Following the document review, the ExCB shall carry out the site audit using <u>IECEX</u> OD 025 for guidance. Site audits shall include site listed on the certificate and a sample of operational sites/locations, using the sampling requirements of ISO/IEC 17021-1 as a guide.	<u>IECEX</u> OD 025 <u>IECEX</u> OD 314-2 <u>ISO/IEC 17021-1</u>	ExCB	
6	A Facility Audit Report (FAR) shall be completed by the ExCB conducting the audit.	IECEX 03-2 FAR <u>IECEX</u> OD 025	ExCB conducting the audit	
7	The ExCB that issued the IECEx Service Facility Certificate shall conduct an independent review of the prepared FAR. This review shall verify among other items: <ul style="list-style-type: none"> • That a complete audit as planned had been conducted; • Necessary documentation and records available; • Confirmation that the auditor/team was appropriate, especially where another ExCB is involved in the audit. 	<u>IECEX</u> OD 025 <u>IECEX</u> OD 314-2 IECEX 03-2	ExCB that issued the IECEx CoC	
8, 8a	Where the FAR reveals that the audit was incomplete, not conducted in accordance with <u>IECEX</u> OD 025 or contains errors the matter is to be raised with the audit staff and applicant listed on the IECEx Service Facility Certificate, as appropriate. The purpose of the FAR review is for the ExCB to be assured that they have sufficient objective evidence that the Service Facility's Quality Management System (<u>Ex</u> QMS) and associated quality plans enable Ex design and selection to be conducted in accordance with the requirements of IEC 60079-14 and <u>IECEX</u> OD 314-2 for the scope listed on the IECEx Service Facility Certificate. This review may require a revised FAR to be issued or even a subsequent audit of the <u>Ex</u> Service Facility where it is identified that the audit was incomplete or insufficient or unqualified auditor(s) used.	IEC 60079-14 <u>IECEX</u> 03-2 <u>IECEX</u> OD 025 <u>IECEX</u> 03-2 IECEX OD 314-2	ExCB that issued the IECEx Service Facility Certificate	Where a subsequent audit is required due to errors on the part of the ExCB, such audits may need to be conducted at the ExCB's own expense.

Step	Section 2 – Procedures for maintaining an IECEX <u>Service Facility</u> Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
9	FAR may now be issued to the applicant listed on the IECEX Service Facility Certificate. The ExCB responsible for conducting the audit shall update the IECEX “On-Line” database registration system for the FAR.	IECEX OD 025 IECEX OD 011- Part 3	ExCB that issued the IECEX Service Facility Certificate	
10, 11 + 12	<p>The ExCB that issued the IECEX Service Facility Certificate shall review proposed corrective actions relating to Non-Conformance Reports (NCRs) in terms of:</p> <ul style="list-style-type: none"> • The time to implement such action is appropriate • Whether a follow up audit is necessary or can verification be handled at the next scheduled surveillance audit <p>It should be noted that where Major NCRs are raised consideration must be given to the likelihood of non-complying installations.</p> <p>ISO/IEC Guide 27 should be consulted by the ExCB issuing the IECEX Service Facility Certificate.</p>	IECEX OD 314-2 IECEX OD 025 ISO/IEC Guide 27	ExCB that issued the IECEX Service Facility Certificate	Contact the IECEX Secretariat for any questions or concerns.
12a + 12b	<p>The ExCB that issued the IECEX Service Facility Certificate will need to determine whether the IECEX <u>Ex</u> Service Facility Certificate needs to be suspended or cancelled. Given the seriousness of the situation, prompt action by the ExCB is required. This includes, notifying the applicant listed on the IECEX Service Facility Certificate in writing and amending the Status of the “On-Line” Service Facility Certificate to reflect either “Suspended” or “Cancelled” as determined by the ExCB responsible for issuing the IECEX Service Facility Certificate.</p> <p>Where disputes arise that cannot be resolved between the ExCB and Service Facility, such matters may be referred to the IECEX Board of Appeal after exhausting the appeal process of the ExCB, via the IECEX Secretariat.</p>	IECEX 03-2	ExCB that issued the IECEX Service Facility Certificate	Contact the IECEX Secretariat for any questions or concerns.

Step	Section 2 – Procedures for maintaining an IECEx <u>Service Facility</u> Certificate of Conformity – Description of activity	Related documents	By whom	Notes/Comments
13	<p>Where ExCB is satisfied that a full and complete surveillance assessment/audit has been completed demonstrating compliance with the requirements of IECEx, <u>IECEX 03-1</u>, IEC 60079-14 and <u>IECEX OD 314-2</u> the ExCB that issued the IECEx Service Facility Certificate shall confirm that the details of the IECEx Service Facility Certificate as recorded on the IECEx website are accurate and up to date.</p> <p>The ExCB shall then schedule the next surveillance audit visit which shall be at intervals not exceeding 12--months and a re-assessment to be conducted as part of the third annual surveillance audit visit.</p>	<p><u>IEC 60079-14</u> IECEX 03-2</p> <p><u>IECEX OD 314-2</u></p>	ExCB that issued the IECEx Service Facility Certificate	Contact the IECEx Secretariat for any questions or concerns.

Readline Version

Annex A

Acceptance of quality assessment and audit data obtained prior to the application for an IECEX Service Facility Certificate for selection of Ex equipment and design of Ex installations

A.1 Introduction

This annex sets out the conditions upon which quality assessment data can be accepted for an Ex Service Facility applying for an IECEX Service Facilities Assessment Report (FAR) or IECEX Service Facility Certificate.

A.2 Acceptable use

A.2.1 Acceptance of quality assessment and audit data obtained prior to the acceptance of an ExCB by the IECEX Management Committee

ExCBs may use quality management assessment or audit data obtained prior to the ExCB's acceptance into the IECEX Scheme only when ALL of the following criteria have been met:

- a) Previous audit covered another appropriate service within the IECEX 03 Service Facility Scheme;
- b) Quality management assessments were conducted by the ExCB's personnel with competences required for the IECEX 03-2;
- c) No non-conformances were raised at the time of the IECEX Assessment, such that corrective actions by way of new/modified processes or new personnel were required in order to gain acceptance as an ExCB;
- d) The ExCB can demonstrate that the general requirements of IECEX Operational Document IECEX OD 314-2 have been met; and
- e) An IECEX Service Facility Certificate shall not be issued where any major non-conformances, as defined in IECEX OD 025 remain outstanding.

Annex B

Documentation checklist for certification of **Ex** Service Facility for selection of **Ex** equipment and design of **Ex** installations

The following is a list of specific documentation that an **Ex** Service Facility should have in place in seeking IECEX Certification as an IECEX Certified Service Facility.

Items 2, 3, 4, should be made available to the ExCB prior to the site audit being undertaken.

1)	Applicant name: <u> </u> Date: <u> </u>	
2)	Ex Service Facility application details as per IECEX 03-2 Clauses 9.2 and 9.4. Name, Country, Contact details Short history, and description of Ex Service Facility Legal status Addresses where Ex Service Facility carries out its operations that are to be covered by IECEX Certification Any other relevant information about the Ex Service Facility	<input type="checkbox"/>
3)	Letter or ExCB application form from applicant Ex Service Facility to ExCB requesting certification under IECEX Service Facility Program Scheme	<input type="checkbox"/>
4)	Declaration of relevant competence/capability as follows: a) competence of responsible persons and operatives b) listing of Ex types of protection and Scope of work to be covered by IECEX Service Facility Certification c) Identification of testing and measurement capabilities	<input type="checkbox"/>
5)	Documentation, such as Quality Management System (QMS) manual, showing compliance with requirements. a) compliance of quality systems to IECEX OD 314-2 b) compliance of Service Facility to technical requirements of IEC 60079-14 This information may be provided during the on-site assessment, however the application should indicate what information is available	<input type="checkbox"/>
6)	Organization charts of the candidate Ex Service Facility Particular attention should be given to those authorized to release completed work	<input type="checkbox"/>
7)	Ex Service Facility procedure for maintaining competence of responsible persons and operatives	<input type="checkbox"/>

Section 3 – Procedures for the processing of applications for extension of scope to an IECEx certified service facility

This Section is to be applied by ExCBs when processing applications for a change to IECEx Service Facility Certification, including extension to the scope of an IECEx Certified Service Facility.

These steps are in line with the requirements of ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*, in addition to the requirements as laid down in the IECEx 03-2 Scheme Rules, ~~IECEX 03-2~~.

Readline Version

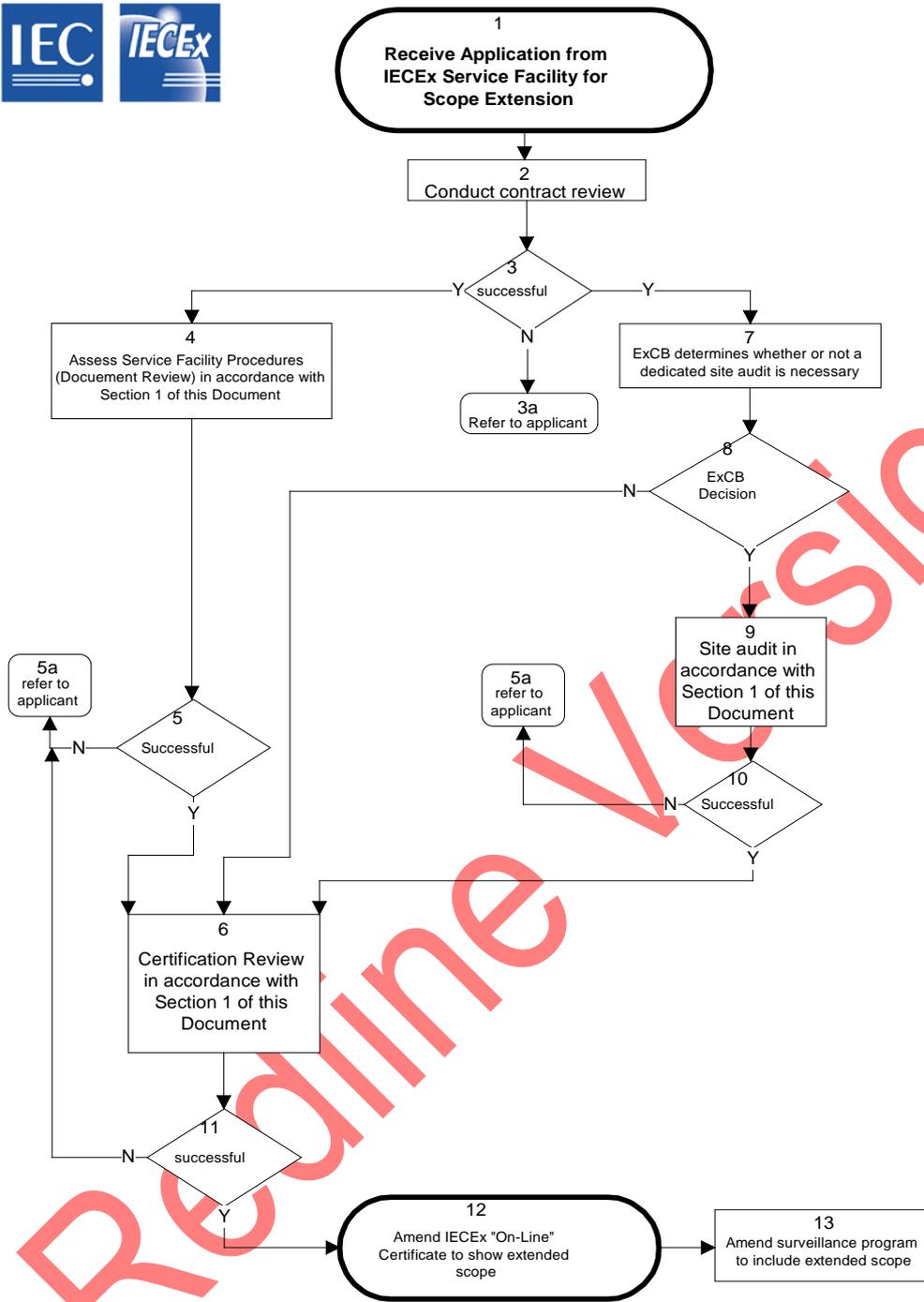


Figure 4 - IECEx Service Facility Certification Changes, including Scope Extension

Step	Section 3 – Procedures for the processing of applications for extension of scope to an IECEx Certified Service Facility – Description of activity	Related documents	By whom	Notes/Comments
1	IECEX Certified Service Facility lodges application for changes to their certification to the ExCB that issued the IECEx Service Facility Certificate.	IECEX 03-2 IECEX Service Facility Certificate	Ex Service Facility holding the IECEx Certificate	
2	<p>ExCB that issued the IECEx Service Facility Certificate shall conduct a contract review to determine, among others, that:</p> <ul style="list-style-type: none"> • The application is within the scope of the IECEx Scheme • All necessary information has been provided by the applicant • The requested changes, including new scope of selection of Ex equipment and design of Ex installations is within the scope of the ExCB • Consideration of sites to be covered 	ExCBs own Quality Management System (QMS) IECEX 03-2	ExCB that issued the IECEx Service Facility Certificate	
3	<p>The ExCB shall inform the applicant of these results and shall record the contract review outcomes within their documented record system.</p> <p>Where unsuccessful, the ExCB shall inform the applicant and the applicant to determine the next course of action if any.</p>	IECEX OD 314-2 (Ex QMS) IECEX 03-2	ExCB receiving the application	
4	<p>A document review shall be conducted by the ExCB receiving the application, in accordance with the procedures detailed in Step 4 of Section 1 of this Operational Document.</p> <p>A FAR shall be compiled where the extension of scope application relates to an Ex protection technique not already covered by the existing IECEx Certification.</p> <p>In such cases, only the section relating to the Ex types of protection, under the scope extension, needs to be completed.</p>	IEC 60079-14 IECEX OD 314-2 (Ex QMS) IEC 60079-14 IECEX OD 025	ExCB	

Step	Section 3 – Procedures for the processing of applications for extension of scope to an IECEX Certified Service Facility – Description of activity	Related documents	By whom	Notes/Comments
5	The findings of this document review shall be retained on the ExCB's documented record system for future reference.	IECEX OD 025 IECEX OD 314-2	ExCB	
6	A final certification review shall be conducted in accordance with the requirements detailed in Section 1 of this IECEX OD 313-2 Operational Document.		ExCB conducting the audit	
7	<p>The ExCB that issued the original IECEX Service Facility Certificate shall determine whether or not a site assessment visit is necessary before issuing a new issue of the IECEX Service Facility Certificate.</p> <p>Such items that influences the ExCB's decision include:</p> <ul style="list-style-type: none"> • Whether the change is regarded as administrative, e.g. name change with no change to the Quality Management System (QMS); • Whether the extension is to cover the installation and initial inspection to activities outside their existing scope covered by the existing IECEX Service Facility Certificate; • Whether the application for scope extension is to include a new or additional location; • Whether the change to certification includes changes to the nominated Responsible Persons and Operatives; • Others. <p>It is expected that where new locations are to be added or an Ex Service Facility has changed their location, that the ExCB conduct a site assessment, to ensure the on-going capabilities of the Ex Service Facility.</p>	IECEX OD 025 IECEX OD 314-2 (Ex QMS) IECEX 03-2	ExCB that issued the IECEX Service Facility Certificate	While the ExCB responsible for the issuing of the original certificate shall make the decision on the extent of assessment required, they may seek guidance from other ExCBs or the IECEX Secretariat.
8	The ExCB shall record the decision from Step 7 in their record document system.		ExCB that issued the IECEX Service Facility Certificate	

Step	Section 3 – Procedures for the processing of applications for extension of scope to an IECEX Certified Service Facility – Description of activity	Related documents	By whom	Notes/Comments
9	Site audit visit in accordance with the procedures and steps detailed in Section 1 of this Operational Document, including the method of reporting.	IECEX OD 314-2 (Ex QMS) IECEX OD 025	ExCB that issued the IECEX Service Facility Certificate	
10	The ExCB shall record the site audit visit in accordance with the requirements of Section 1 of this Operational Document. Where the results of the site audit visit are unsuccessful, the applicant shall determine the next course of action which shall be either the corrective action to address non-conformances or re-submitting an application.	IECEX OD 314-2 (Ex QMS) IECEX OD 025	ExCB that issued the IECEX Service Facility Certificate	Contact the IECEX Secretariat for any questions or concerns.
11	Where the results of the site audit are unsuccessful, the matter shall be reported to the applicant who shall determine the next course of action which shall be either the corrective action to address non-conformances or re-submitting an application.		ExCB and Applicant	
12	A new issue of the certificate is issued by the ExCB responsible for issuing the original certificate, in accordance with the procedures detailed in IECEX OD_011_-Part3 .	IECEX OD 011_-Part3	ExCB that issued the original IECEX Service Facility Certificate	
13	The ExCB shall amend their surveillance program to ensure that the changes covered by the new issue of the IECEX Service Facility Certificate are covered on future surveillance visits.		ExCB that issued the IECEX Service Facility Certificate	