



IECEX OPERATIONAL DOCUMENT

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

IECEX Certified Equipment Scheme

**Guidance on Significant Changes to ExCB
Business Continuity – IECEX Schemes**



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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL
ELECTROTECHNICAL COMMISSION

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IECEX Operational Document OD 255

IECEX Certified Equipment Scheme

**Guidance on Significant Changes to ExCB Business
Continuity – IECEX Schemes**

Introduction

This document has been prepared for application in the IECEX Certified Equipment Scheme however the principles and processes may be applied in other IECEX Schemes in the absence of specific publications on this matter for the other Schemes.

An IECEX Body (Certification Body (ExCB) or Testing Laboratory (ExTL)) may wish to change their organisational structure and this may include an acquisition of another IECEX Body (Body) for strategic reasons or the withdrawal from IECEX Scheme/s. When significant changes to business continuity occur such as acquisitions or withdrawal from IECEX Schemes, it is important that the IECEX Body understand their obligations as per IECEX Rules and ISO/IEC 17065, ISO/IEC 17025 and ISO/IEC 17024.

OD 255 provides a guide to assist IECEX Bodies when significant changes to business continuity occur. This OD provides key considerations on how to best proceed ensuring minimal disruption to all of its key stakeholders, while at the same time seamlessly transitioning its business in an efficient manner while adhering to IECEX Rules.

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Address:

IECEX Secretariat
Australia Square
Level 33, 264 George Street
Sydney NSW 2000 Australia

Contact Details:

Tel: +61 2 4628 4690
Email: info@iecex.com
Web: <http://www.iecex.com>

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Guidance on Significant Changes to ExCB Business Continuity – IECEx Schemes

1.0 Overview

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An IECEx Body (Certification Body (ExCB) or Testing Laboratory (ExTL)) may wish to change their organisational structure and this may include an acquisition of another IECEx Body (Body) for strategic reasons or the withdrawal from IECEx Scheme/s. When significant changes to business continuity occur such as acquisitions or withdrawal from IECEx Schemes, it is important that the IECEx Body understand their obligations as per IECEx Rules and ISO/IEC 17065, ISO/IEC 17025 and ISO/IEC 17024.

The intent of this guide is to assist IECEx Bodies when significant changes to business continuity occur. This guide provides key considerations on how to best proceed ensuring minimal disruption to all of its key stakeholders, while at the same time seamlessly transitioning its business in an efficient manner while adhering to IECEx Rules.

This guide is also provided to assist Bodies in considering their liabilities and obligations within and external to IECEx matters. Any issues relating to legalities should be reviewed by the Bodies' legal departments, especially in regards to liabilities and due diligence in assuming responsibilities of another Body's Certificate of Conformity (CoC), Quality Assessment Reports (QAR) and IECEx Test Reports (ExTR).

1.1 Notification of Key Stakeholders

Should significant business changes occur to an IECEx Body, including acquisitions and withdrawals from an IECEx Scheme, it is the responsibility of the Body to notify the IECEx Secretariat via the Member Body to outline the proposed changes. This step is essential so that the IECEx Secretariat can assist the Body through the process while at the same time ensuring that the IECEx Rules are adhered to and that the impact on key stakeholders is managed through this process.

Key stakeholders need to be informed in advance as per *'IECEx 02 Rules - 11.1.13 Withdrawal'*

An ExCB wishing to withdraw from the IECEx Certified Equipment Scheme shall notify the Secretary of the ExMC via the Member Body of the IECEx Certified Equipment Scheme at least one year in advance and shall indicate the reason for the withdrawal and the date from which the withdrawal will become effective.

The IECEx Secretariat will assist the Body through this 'Management of Change' process. In the IECEx Certified Equipment Scheme this assistance may include:

- Notification to manufacturers that ALL CoCs may need to be cancelled, or implement a transition plan of CoCs, ExTRs and QARs to a new entity that will accept full ownership and responsibility and that the new entity complies with the Conditions of Acceptance as per Section 11.1.1 and 11.2.1 and 11.3.1 of IECEx 02 Rules of Procedure.
- IECEx Secretariat to assist in the transition of withdrawing the Body in the most efficient and timely manner however, the IECEx Secretariat can only assist the process if IECEx 02 Rules are strictly adhered to and a sufficient notice period (a period of one year is recommended however special arrangements may need to be established by the IECEx Secretariat in consultation with the IECEx Executive in the event that an ExCB ceases business 'overnight') is provided so the transition minimizes impacts to its customers and key stakeholders.

A similar approach would be applied to the Certificates and Reports in the other IECEx Schemes.

2.0 IECEx Certification Body responsibility as a result of Significant Changes to ExCB Business Continuity in the IECEx 02 Scheme

A key consideration for an IECEx Body in the IECEx 02 Scheme is its commitment to its customers and the maintenance of QARs and Certificates. Manufacturers have made an investment in obtaining product certification under the IECEx 02 Scheme, therefore IECEx 02 Rules of Procedure ensures that there are obligations by the Body to its customers safeguarding that products and manufacturing facilities can continue to produce and sell IECEx Certified products during the transition phase of significant changes under the IECEx Scheme.

At the same time, there must be a clear path for the Body who may wish to withdraw their Conformity Assessment business or alternatively acquire another IECEx Body that allows it to meet its business objectives. If sufficient notice is not provided, then only the IECEx Executive may grant an exemption to the Body which will consider the necessary resources and time required by the IECEx Secretariat to meet the proposed timeline. The IECEx Secretariat will assist to help facilitate the transition, ensuring minimal disruption to its customers and other key stakeholders.

Scenarios have been provided as part of this Guide to assist Body or Bodies to understand the process required. The scenarios provided do not cover all significant changes but are simply a guide that will assist the Body and also outline the key considerations and obligations associated with each scenario.

A similar approach would be applied to ExTLs and to the Certificates and Reports in the other IECEx Schemes.

3.0 Example Scenarios

The following scenarios are provided as examples to assist Bodies to understand their obligations for each of the example scenarios. By understanding the process, this will allow Bodies to plan its internal Management of Change, while at the same time ensuring the impacts to its key stakeholders are minimized.

3.1 Scenario 1 – Acquisition of ExCB#1 by ExCB#2

ExCB#2 has acquired ExCB#1 and includes existing personnel, facilities, equipment, contracts, accreditations, and all operational preconditions have been directly transferred to ExCB#2. There will be no changes in the commitment and procedures as ExCB#1 is presently an ExCB in the IECEx 02 Equipment Scheme. ExCB#2 must commit to continuing to maintain IECEx Certificates, QARs and ExTRs issued by ExCB#1. This would be the least complicated scenario.

Process Steps:

1. A formal notification in writing to the IECEx Secretariat via the IECEx Member Body as per IECEx 02 Rules of Procedure from ExCB#1 and ExCB#2 (ideally one year prior to the change), so proposed changes can be reviewed by the IECEx Secretariat ensuring the business transition fully complies with IECEx Rules and the transition occurs efficiently. This may include:
 - a. Acceptance of ExCB#2 to continue to manage ExCB#1 issued Certificates, ExTRs and QARs
 - b. ExCB#2 continued acceptance of existing ExCB#1 certificate number marking on products (IECEX ZZZ YY.XXXX)
 - c. IECEx Secretariat recommendation would also include that ExCB#2 continue with ExCB#1 identifier as Certificates originally issued by ExCB#1 are up-issued to reflect technical changes to products, and updates to new editions of standards etc, but without the need for manufacturers to change marking or product series.
 - d. IECEx Secretariat recommendation is that new (Issue 0) IECEx Certificates to be issued only by ExCB#2 and only with an ExCB#2 identifier.
 - e. IECEx Secretariat to assign change of ExCB#1 access passwords to enable only ExCB#2 to up-issue Certificates originally issued by ExCB#2.
 - f. ExCB#2 confirms to the IECEx Secretariat that this is a change in name and ownership ONLY and that it does not affect the current capabilities of the organisation (personnel, equipment, procedures, for certification activities, location etc.) as an IECEx ExCB and as

- IECEX Testing Laboratory. If this is the case, then this may avoid the need for extra formal assessments before the next scheduled surveillance mid-term or reassessment.
- g. If alternatively, there is a potential impact on current capabilities there may be a need to conduct some form of assessment. ExCB#2 shall detail the nature and extent of any changes to current capabilities so the IECEX Secretariat can determine if any additional assessments are required.
 - h. ExCB#2 to advise the IECEX Secretariat of any changes to Accreditations.
 - i. Change of name, Identifier and profile on the IECEX website and On-Line Certification site with updated contact details, email, phone numbers, logo etc.
 - j. IECEX Secretariat to confirm profile for ExCB#1 details so Certificates can be up-issued and managed by ExCB#2 but maintaining ExCB#1 historic CoCs, ExTRs and QARs.
2. ExCB#2 is to provide confirmation to the IECEX Secretariat that, as a new organisation using the previous resources and equipment for ExCB#1, it agrees to abide by IECEX 02 Rules of Procedure and that ExCB#2 will be responsible for maintaining IECEX Certificates issued with ExCB#1 identifiers.
 3. ExCB#1 to notify the IECEX Member Body of the changes as a result of the change including that ExCB#1 and ExCB#2 are in communication with the IECEX Secretariat so an efficient transition can occur. Should the Member Body have any special conditions or objections, then ExCB#2 should communicate these to the IECEX Secretariat so they are on file.

3.2 Scenario 2 – ExCB#1 wishes to withdraw from IECEX Scheme and have an interested party (new applicant ExCB) willing to purchase the business, but the new applicant ExCB is NOT yet accepted as an ExCB in the IECEX 02 Equipment Scheme.

1. Sufficient notification in writing by ExCB#1 to IECEX Secretariat and Member Body so proposed changes can be reviewed and the most efficient transition may occur. This will include:
 - a. Application by new applicant ExCB (ExCB#2) is submitted to the IECEX Secretariat via the Member Body. Conditions of Acceptance as per Section 11.1.1 and 11.1.2 of IECEX 02 Rules of Procedure would be applicable.
 - b. Assessment of the new ExCB (ExCB#2) ensuring that they have qualified personnel, procedures and processes to qualify as an ExCB
 - c. Assessment results with a recommendation by the IECEX Secretariat will be provided as an ExMC document for voting by the IECEX Members
 - d. If the voting results are successful, then the new ExCB (ExCB#2) may proceed with taking over responsibility for the CoCs of ExCB#1.
 2. ExCB#2 confirms to the IECEX Secretariat that, as a new organisation using the previous resources and equipment from ExCB#1, it agrees to abide by IECEX 02 Rules of Procedure and that ExCB#2 will be responsible for maintaining IECEX Certificates issued with ExCB#1 identifiers.
 3. ExCB#1 to notify the IECEX Member Body of the changes as a result of the acquisition by ExCB#2 including that the ExCB#1 and ExCB#2 are in communication with the IECEX Secretariat and Member body so an efficient transition can occur.
- Note: This scenario may be the result of the ExCB#2 management, personnel, equipment and facilities transitioning to a new entity because of the divestment by ExCB#1.

3.3 Scenario 3 – ExCB decides on complete withdrawal from IECEX Schemes

ExCB#1 has made a business decision to withdraw its conformity assessment business. ExCB#1 does not have an interested party to purchase it and assume the conformity assessment responsibilities as per IECEX 02 Rules of Procedure.

Action Items:

1. Sufficient notification in writing to IECEX Secretariat and Member Body so notifications to key stakeholders can be managed properly to allow planning by the ExCB and its customers and other key stakeholders can be managed during this process. This will include:
 - a. Notification by ExCB#1 to all of its customers that it plans to cease its conformity assessment business and will no longer be supporting its QARs, CoCs and ExTRs that it has previously issued, after the designated closure date.
 - b. ExCB#1 to work with a different ExCB (of the customers' choice) to organise a transition of all QARs, CoCs and ExTRs or for ExCB#1 to inform its customers that after the designated closure date, all of the CoCs issued will need to be managed before the QAR validity dates have expired. The option

will exist for the customer to engage other ExCBs to take over re-assessment and surveillance audits however, ALL CoCs would need to be issued as new to the valid QAR. Refer to OD 250 for guidance on this process. The new CoC may reference the previous CoC issued by the ExCB#1 however, the new CoC will require the customer having to change marking on products to display the new CoC number issue 0. ExCB#1 CoCs would be cancelled with the standard Cancellation note that would include:

This Cancellation does NOT affect products manufactured or installed prior to this date and such equipment is not subject to withdrawal from the market or from the installation site.

and, the Cancellation note may also contain a reference to the new ExCB CoC issue 0, therefore ensuring continuity/history of CoCs.

4. In the situation where the CoCs are required to be cancelled, refer to OD 209. ExCB#1 provides a list of all CoCs that are required to be cancelled including the Cancellation date to the IECEx Secretariat.
5. ExCB#1 is to make available to its customer complete ExTRs including supporting documents so these can be provided to new ExCB#2 who will undertake CoC management.

Note: In this scenario, ExCB#2 will not be assuming responsibility for the maintenance of CoCs issued by ExCB#1. It is the preference of the IECEx system that this scenario does not occur and that ExCB#1 is able to find another ExCB to take on responsibility for the maintenance of CoCs issued by ExCB#1 (refer Scenario 2).

3.4 Scenario 4 – ExCB is no longer in business and provides no notification to its Customers the IECEx Secretariat or the Member Body

In the event of the unlikely scenario where an ExCB closes its doors for business and does not provide notice to its Customers, the IECEx Secretariat or the Member Body, the customer will need to engage another ExCB to assume future surveillance or re-assessment audits to maintain its products IECEx certification (as a courtesy to the defunct ExCB's customers, it is recommended that the Member Body attempt to inform the manufacturers if no notification has previously been sent). The manufacturer's existing IECEx certified products will continue to be IECEx certified until the validity date of the QAR surveillance or re-assessment audit is reached.

The options of the manufacturer are:

1. Engage a new ExCB to conduct a re-assessment audit with the intention of continuing to manufacture the product. The new ExCB would inform the IECEx Secretariat and the Member Body of the changes, so the 'management of change' process could be assisted by the IECEx Secretariat, ensuring the IECEx Rules are adhered to.
OR
2. Suspend the product temporarily until it finds a suitable ExCB of its choice to conduct the necessary surveillance or re-assessment audit
OR
3. Cancel the IECEx Certification, noting however the products manufactured prior to this cancellation are still valid (as per note 1b in section 3.3 of this document)

Where the customer engages a new ExCB, it will be necessary to update product labels to reflect the new ExCB Certification number. The ExTR issued by the ExCB that is no longer in business, would remain valid, until any changes to the product occur which require additional testing. The testing would be carried out by the new ExCBs and/or ExTL.

4.0 ExTL Considerations

The ExTL may or may not be included in the proposed merger and acquisition. The following guide provides considerations for each scenario.

If an ExTL previously associated with ExCB#1 will not be acquired by ExCB#2 but wishes to remain as an operating ExTL under the IECEx 02 Scheme, they need to establish a formal association with another ExCB.

Refer to section 11.2 of IECEx 02 Rules of Procedure. Alternatively, they may become an ATF under an existing ExTL.

If an ExTL previously associated with ExCB#1 will be acquired by ExCB#2 they need to establish a formal association with ExCB#2. Refer to section 11.2 of IECEx 02 Rules of Procedure.

If ExCB#1 withdraws from the IECEx system and the ExTL previously associated with ExCB#1 wishes to remain as an operating ExTL under the IECEx 02 Scheme, they need to establish a formal association with another ExCB. Refer to section 11.2 of IECEx 02 Rules of Procedure.

5.0 Summary

Significant changes to business continuity of Bodies operating within the IECEx Schemes may have consequences to its stakeholders. This guide provides considerations and obligations to ensure:

- Minimal disruptions to its customers ensuring that the impact to customer Certificate of Conformity and Quality Assessment Reports are maintained
- Member Body's endorse proposed changes
- The IECEx Secretariat has sufficient notification to assist the Body through significant changes to business continuity ensuring that the interests of the customers are maintained while the IECEx Rules are adhered to

While this guide is not intended to cover every possible scenario, it does highlight areas where changes to business continuity could occur and could have significant impact on customers of the IECEx system.

Where an unforeseen consequence may occur, contact the IECEx Secretariat for further information and direction.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

3, rue de Varembé PO Box 131
CH-1211 Geneva 20 Switzerland

Tel: + 41 22 919 02 11
Fax: + 41 22 919 03 00

info@iec.ch
www.iec.ch