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IECEX OPERATIONAL DOCUMENT

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

**IECEX Guide for Business Continuity –
Management of Extraordinary Circumstances or
Events Affecting IECEx Certification Schemes
and Activities**



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INTERNATIONAL
ELECTROTECHNICAL COMMISSION

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IECEX Operational Document IECEX OD 060

**IECEX Guide for Business Continuity – Management of
Extraordinary Circumstances or Events affecting IECEX
Certification Schemes and Activities**

Foreword

This document has been prepared to provide a uniform approach in dealing with the occurrence of “Extraordinary Circumstances or Events” that may impact on the operation of IECEX certification bodies, testing laboratories, and organizations and personnel holding IECEX Certification.

This Operational Document has been prepared and issued by the IECEX Executive Secretary in consultation with the IECEX Chair and the IECEX Executive and has been updated as Edition 2.0, based on feedback and discussions during the May 2020 IECEX Operational Meetings. This edition applies upon publication, to all schemes and activities of the IECEX System and is implemented due to the current COVID-19 Pandemic in accordance with Clause 0.3.

This OD is to be further reviewed during the 2020 IECEX Management Committee meeting to review its contents and to determine its future. During its application, IECEX Member Bodies are encouraged to submit comments to the IECEX Secretariat via info@iecex.com for discussion during the September 2020 ExMC meeting. Comments from IECEX Member Bodies should be submitted by 31 August 2020.

In line with the Cooperation Agreement between IEC and International Accreditation Forum, Inc (IAF), publication IAF ID 3:2011 has been considered in the preparation of this OD and acknowledgement is made of this assistance

Attention is also drawn to IECEX OD 255 dealing with the situation where an ExCB withdraws from an IECEX Scheme, or has been merged / acquired by another organization.

Document History

Date	Summary
February 2020	Original issue (Edition 1.0) issued by the IECEX Executive Secretary
July 2020	Edition 2.0 issued by the IECEX Executive Secretary, following feedback and discussions during the May 2020 IECEX Operational Meetings and consultation with the IECEX Executive
XXXXX	<u>Edition 2.1 issued by the IECEX Executive Secretary to include minor editorial changes, following feedback and consultation with the IECEX Executive during their March 2021 meeting.</u> This Redline version of Edition 2.1 shows changes to Edition 2.0 with new text displayed as green and deleted text as red strikethrough

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IECEX Guide for Business Continuity – Management of Extraordinary Circumstances or Events affecting IECEX Certification Schemes and Activities

0 Introduction and Application

0.1 Overview

This Operational Document (OD) has been prepared to provide guidance for managing situations arising from Extraordinary Circumstances, or Events, that may impact on IECEX Certification Schemes and activities.

This OD is intended to be used by the IECEX System (e.g. its committees and the IECEX Secretariat), IECEX Certification Bodies (ExCBs) and IECEX Testing Laboratories (ExTLs) as approved to operate in the respective IECEX Schemes according to their Rules of Procedures, e.g. IECEX 02, IECEX 03, IECEX 04, IECEX 05.

This OD is not intended to reduce requirements of the IECEX System or Standards, but to provide guidance for a uniform approach when dealing with extraordinary situations.

0.2 Definition of Extraordinary Circumstances or Events

Situations that are beyond the control of an organisation, commonly referred to as “Force Majeure” or “act of God”.

Note: Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking and other natural or man-made disasters.

0.3 Application of this OD

The application of this OD is intended to apply when such Extraordinary Circumstances or Events present themselves. The decisions to enact this OD and also to end the enactment shall be taken by the IECEX Executive Secretary following consultation with and general agreement of the IECEX Chair and IECEX Executive.

0.4 Summary

Extraordinary Circumstances or Events may have consequences on IECEX stakeholders. This OD provides considerations and obligations to ensure:

1. Minimal disruptions to its customers ensuring that the ~~impact to~~ customer Certificates of Conformity/ Quality Assessment Reports, and Certificates of Personal Competency are maintained;
2. Member Bodies endorse proposed changes; and
3. The IECEX Secretariat has sufficient notification to assist the ExCB / ExTL through significant changes to business continuity ensuring that the interests of the customers are maintained whilst adhering to the IECEX Rules.

Note: since this OD deals with unforeseen circumstances it cannot address every possible scenario. The intent is to highlight typical areas that could have significant impact on customers of the IECEX System.

Where an unforeseen circumstance or event occurs ExCBs, ExTLs or other impacted parties should contact the IECEX Secretariat for further information and guidance.

1 Section 1 - Circumstances affecting normal operation of the IECEx peer assessment program for an IECEx ExCB or IECEx ExTL

1.1 ExCBs and ExTLs operating within the IECEx schemes

For ExCBs and ExTLs located in countries / regions / areas impacted by Extraordinary Circumstances or Events, where travel to that area is restricted thereby preventing a scheduled on-site peer assessment from occurring, the following actions shall occur enabling an “on-site” visit component of peer assessment to be delayed for up to twelve (12) months (or as required by local law), or replaced by other means, e.g. remote assessment.

Acceptance of the principle of risk assessment for deferring scheduled visits associated with surveillance, mid-term or reassessments, using the principles of Clause 6.8 of IECEx OD 025 (refer to IECEx OD 025 for guidance).

A risk assessment shall be conducted by the IECEx Secretariat with issues being considered to include:

- previous assessment reports including the site assessment report (IECEX OD 006) and the Technical Capability Document (TCD)
- requesting the Body to complete a declaration form
- the performance of the body with respect to the IECEx On-Line Certificate System, etc
- the preparation of a desk top review by the IECEx Secretariat as part of the usual preparation of IECEx peer assessments
- a review of any complaints concerning the ExCB or ExTL as recorded on the IECEx Complaints Register

This review shall be conducted by the IECEx Secretariat who may consult with the Convener and Deputy Convener of the IECEx Assessment Group (ExAG) as Officers of the ExAG.

The Secretariat shall report the handling of ExCB and ExTLs assessments according to this OD, to the IECEx Executive and at the next ExMC meeting.

Use of IECEx Assessors located within the same country as the ExCB or ExTL may be accepted on the basis of the Assessors providing a formal declaration of their impartiality for conducting the assessment. This shall be managed by the IECEx Secretariat.

1.2 Applications for scope extensions from ExCBs and ExTLs operating within the IECEx Schemes

For ExCBs and ExTLs located in countries / regions / areas impacted by an Extraordinary Circumstances or Events, where travel to that area is restricted, the processing of scope extensions that normally require a site visit, the following provisions are available, to IECEx Assessment Teams conducting scope extension assessments;

1. In addition to the usual means of communication such as email, use of video communication may be considered as provided in IECEx OD 003-2 for closing out issues raised during a previous site visit associated with the current scope extension.
2. Video Communication may be used for the scope extension application for an ExCB provided the Assessors have availability of and ready access to the ExCB's management documentation and procedures in electronic file format. The use of video conference packages that provide video & voice capabilities and screen sharing may be used.
3. Use of Video communication to replace a site visit, where a site visit would normally be required to verify the correct preparation/operation of a specific test that is not covered within the existing technical scope of an ExTL, may be permitted where the IECEx Assessor and the IECEx Executive Secretary agree that this is appropriate, following consultation with the Officers of the ExAG.
4. Video and remote communication may be used with an assessment plan developed by the IECEx Lead Assessor in consultation with the ExCB / ExTL concerned, as is normal practice.
5. The IECEx Secretariat may be consulted along with the ExAG in developing an assessment plan for this specific situation.
6. The IECEx Executive Secretary shall determine the course of action, following consultation with the IECEx Executive, where an agreement is not reached between the IECEx Assessment Team and ExCB / ExTL.

Use of IECEx Assessors located within the same country as the ExCB or ExTL may be accepted on the basis of the Assessors providing a formal declaration of their impartiality for conducting the assessment. This shall be managed by the IECEx Secretariat.

1.3 New Applicant ExCBs and ExTLs seeking to join IECEx Schemes

The normal IECEx peer assessment program, as reflected in the respective IECEx Rules of Procedures, still apply. An assessment team will be assigned and the usual IECEx peer assessment will take place as per the IECEx Scheme Rules. However, use of remote means for performing an initial assessment may be used but requires agreement from the IECEx Executive Secretary following consultation with the Officers of the ExAG.

Use of IECEx Assessors located within the same country as the applicant ExCB or ExTL may be accepted on the basis of the Assessors providing a formal declaration of their impartiality for conducting the assessment. This shall be managed by the IECEx Secretariat.

Waiting for travel restrictions to ease to enable a normal onsite assessment or the planning of alternative approaches shown above may result in a delay for a Body seeking to become an ExCB or ExTL.

Redline Version

2 Section 2 - Circumstances affecting organizations applying for, or currently holding, IECEx certification in the IECEx 02 Certified Equipment Scheme

2.1 Introduction

The following scenarios are provided as examples of organizations holding IECEx Certification where the rules of the IECEx Certification Scheme require on-going surveillance or re-assessment ~~recertification~~. This section is provided to assist ExCBs to understand their obligations for each of the example scenarios. By understanding the process, this will allow bodies to plan their internal management of change, while at the same time ensuring the impacts to key stakeholders are minimized.

2.2 Provisions

For ExCBs that have issued IECEx certification to organizations (e.g. manufacturers) located in countries / regions / areas impacted by an Extraordinary Circumstance or Event, where travel to that area is restricted, the requirements of Clauses 2.2.1 to 2.2.6 of this OD shall apply:

NOTES:

1. Even during situations arising from Extraordinary Circumstances, it is not acceptable for an ExCB to simply do nothing. It remains the QAR issuing ExCB's responsibility to ensure that QAR's remain in compliance with all applicable IECEx OD's. Although it is possible to delay an audit for up to six months this should be the exception rather than the rule.
2. An ExCB performing an audit by remote means should perform a documented risk assessment in conjunction with the auditee prior to the audit. This documented risk assessment shall be a formal audit record that is included in the audit report.
3. Auditor feedback has shown that the effectiveness of a remote audit is improved if the remote auditor has performed a prior physical audit at the site to be audited.
4. ExCBs are reminded of the provisions for utilizing external auditor resources under contracted arrangements where the evaluation and appointment of these external resources complies with IECEx OD 026.

2.2.1 Scheduled QAR audits of a manufacturer shut-down by an extraordinary event

For manufacturer shut-down by extraordinary events there are several options depending on the status of the QAR and the length of the shutdown.

1. If no audits are missed and the existing ISO 9001 and IEC/ISO 80079-34 QMS remains effective then the next audit shall be performed on-time and onsite in accordance with IECEx OD 025
2. If a scheduled surveillance audit will be missed the manufacturer shall inform the ExCB responsible for the QAR and the ExCB shall notate in the comments section appropriate wording: *ABC Company is currently closed and expects to recommence IECEx manufacturing on YYYY-MM-DD.*
3. If a scheduled ~~recertification~~ reassessment audit will be missed the manufacturer shall inform the ExCB responsible for the QAR and the ExCB shall notate in the comments section of the IECEx online QAR summary, the appropriate wording: *ABC Company is currently closed and expects to recommence IECEx manufacturing on YYYY-MM-DD.*
4. When the manufacturer is ready to resume production, they shall inform the ExCB responsible for the QAR who, depending on the QAR status, shall take the following corrective actions:
 - a) If the surveillance audit has been delayed for six (6) months or less, a surveillance audit shall be performed in accordance with IECEx OD 009 or alternatively, in accordance with Clause 2.2.2 before the manufacturer can resume production of IECEx certified product.
 - b) If the ~~recertification~~ reassessment has been delayed for six (6) months or less a surveillance audit shall be performed in accordance with IECEx OD 009 or alternatively, in accordance with Clause 2.2.3 before the manufacturer can resume production of IECEx certified product.
 - c) In all circumstances if the surveillance or ~~recertification~~ reassessment audits have been delayed longer than six (6) months or if the QAR expiry date has been exceeded, a ~~recertification~~ reassessment audit shall be performed in accordance with IECEx OD 025

2.2.2 Scheduled QAR surveillance audits performed by remote means

The scheduled surveillance audits shall be performed within a two (2) months period prior to the respective one year, two year or eighteen-month due date with the following provisions:

1. In addition to the usual means of communication such as email, use of video communication shall be used (as provided in IECEx OD 003-2) for closing out issues raised during a previous site audit visit associated with the scope of certification.
2. Video communication shall be used to gather the objective evidence required to demonstrate a manufacturer's compliance with the requirements of ISO/IEC 80079-34 to enable the surveillance or re-assessment factory audit to be conducted as required by IECEx 02. The ExCB shall determine the applicability and use of this method.
3. Video Communication shall be used to gather the objective evidence required to demonstrate a manufacturer's compliance with the requirements of ISO/IEC 80079-34 when processing an application for an "up issue" of the certification scope. The ExCB shall determine the applicability and use of this method.
4. The ExCB may require the organization / manufacturer to provide results of the organization's previously conducted internal audit for the ExCB to review and gather sufficient evidence that the requirements of ISO/IEC 80079-34 continue to be met. The ExCB may also require the organization / manufacturer to conduct an internal audit under the instruction of the ExCB, issuing the IECEx CoC or the ExCB that has issued the QAR. Organizations / manufacturers may also be audited by other third-party Ex auditing companies for the purpose of national accreditation schemes. These audit results should also be assessed where they exist.

Following the successful completion of Items 1 to 4 above as applicable, the ExCB shall [add a new version to edit](#) the online QAR Summary to record the date that the surveillance audit was performed using the IECEx "On-Line" Certificate System (as per the requirements of IECEx OD 009, Section 4).

2.2.3 Scheduled QAR ~~recertification~~ reassessment audits performed by remote means

The ~~recertification~~ reassessment audit shall be performed within the two months prior to the QAR expiry date, with the following provisions:

Note: the ideal date is four weeks prior to the QAR's expiry date.

1. As this is a ~~recertification~~ reassessment audit, the use of video communication, in addition to the usual means of communication such as email, shall be employed (as provided in IECEx OD 003-2) for closing out issues raised during a previous site audit visit associated with the scope of certification.
2. Video communication shall demonstrate a manufacturer's compliance with the requirements of ISO/IEC 80079-34 to enable the re- assessment factory audit to be conducted as required by IECEx 02. The ExCB shall determine the applicability and use of this method.
3. Video Communication shall be used to gather objective evidence required to demonstrate a manufacturer's compliance with the requirements of ISO/IEC 80079-34 when processing an application to renew the QAR for a further three-year period.
4. The ExCB may require the organization / manufacturer to provide results of the organization's previously conducted internal audit for the ExCB to review and gather sufficient evidence that the requirements of ISO/IEC 80079-34 continue to be met. The ExCB may also require the organization / manufacturer to conduct an internal audit under the instruction of the ExCB, issuing the IECEx CoC or the ExCB that has issued the QAR. Organizations / manufacturers may also be audited by other third-party Ex auditing companies for the purpose of national accreditation schemes. These audit results should also be assessed where they exist.

Following the successful completion of Items 1 to 4 above as applicable, the ExCB shall up issue their QAR Summary using the IECEx On-Line Certificate System for a further three (3) years (refer to the requirements of IECEx OD 009, Section 4).

2.2.4 Initial Audits performed by remote means

An initial audit is a very important audit as it sets the basis for ongoing compliance with ISO/IEC 80079-34 and therefore the following provisions apply:

1. If this is an initial audit due to the manufacturer moving their QAR to another ExCB the current Ex QMS should be compliant and an online initial audit can be permitted (where the requirements of 2.2.3 shall be applied). An on-site surveillance audit shall be conducted as soon as practicable.

2. If this is an initial audit for a manufacturer that has no previous history of manufacturing Ex equipment an online audit is permitted. This online audit shall validate all applicable clauses of ISO/IEC 80079-34 using video techniques and an on-site surveillance audit shall be conducted as soon as practicable.
3. If following the initial audit, the Ex QMS documentation was found to be effective but there is no Ex production an on-site surveillance audit shall be conducted as soon as practicable.

Following the successful completion of Items 1 to 3 above as applicable, the ExCB shall issue a QAR Summary using the IECEx "On-Line" certificate system for a validity period determined by the ExCB and appropriate to the initial audit results.

2.2.5 ~~New Applicants~~ ~~tions for an IECEx Certificate of Conformity under the IECEx 02 Certified Equipment Scheme~~

In general, the requirements of IECEx 02 and ODs, eg, IECEx OD 009 shall apply. The provisions for new applicants for IECEx 02 Certification are detailed in this Section.

With this in mind, ExCBs are reminded of the provisions of the IECEx Scheme including ISO/IEC 17065 regarding resources and use of:

1. Another ExCB located in the region impacted by any travel ban, to perform the factory audit and issue an IECEx QAR; or
2. The use of contracted resources; i.e. to use auditors located within the country or region that is the subject of travel restrictions. In such situations the ExCB maintains control over the auditor assigned to ensure that they follow the procedures of the ExCB.

An ExCB shall consider these items as part of their "contract review" when considering the acceptance of an application for IECEx 02 certification from organizations. If an ExCB cannot make use of the above then the ExCB may conclude to reject the application from an organization, with the organization free to make application to an alternative ExCB.

2.2.6 IECEx 04 IECEx Conformity Mark Licensing System

The full requirements of IECEx 04 and associated ODs shall apply. There are no special provisions made for new applicants for IECEx 04 Mark Licensing.

With this in mind, ExCBs are reminded of the provisions of the IECEx Scheme including ISO/IEC 17065 regarding resources and use of:

1. Another ExCB located in the region impacted to perform the on-site audit and issue an IECEx QAR; or
2. The use of contracted resources; i.e. to use auditors located within the country or region that is the subject of travel restrictions. In such situations the ExCB maintains control over the auditor assigned to ensure that they follow the procedures of the ExCB.

An ExCB shall consider these items as part of their "contract review" when considering the acceptance of an application for IECEx 04 Licensing from organization. If an ExCB cannot make use of the above, then the ExCB may conclude to reject the application from an organization.

3 Section 3 - Circumstances affecting organizations applying for, or currently holding, IECEx certification in the IECEx 03 Certified Services Scheme

3.1 General

In addition to the general requirements pertaining to the Management of Extraordinary Circumstances or Events the following applies specifically to the IECEx 03 Certified Service Facilities Scheme.

3.2 New Applications for certification as a Certified Service Facility

Ordinarily, new applications for certification should be held in abeyance until it becomes feasible to arrange a visit to the service facility. This does not prevent an initial review of documentation taking place as a desktop exercise. If the ExCB believes that there are additional safeguards in place that would allow the initial certificate to be granted based only on the documentation review and a remote video solution, guidance shall be sought from the IECEx Executive Secretary, who will discuss with other members of the IECEx Executive, including the Chair and Deputy Chair of the ExSFC Committee.

3.3 Surveillance audits of Service Facilities holding IECEx Service Facility Certification

3.3.1 Temporary Closure of Service Facility

Where the extraordinary circumstances or events have resulted in temporary closure of the Service Facility, the surveillance audit should be postponed until the Service Facility is operational and conducted as soon as practical after operations have resumed. The Service Facility shall inform the ExCB that operations have ceased and immediately when operations have resumed. Failure to do so shall be regarded as a non-conformity.

3.3.2 Service Facility is operational but affected

Where the Service Facility remains operational, but the extraordinary circumstance or event prevents the ExCB from visiting the company for the purpose of conducting the surveillance audit, the surveillance activity may be postponed for up to six (6) months subject to the following:

1. There are no outstanding non-conformances
2. The ExCB is not aware of any complaints or concerns that would give rise to the ExCB questioning the ongoing compliance of the Service Facility with IECEx 03 and associated ODs.
3. There is no significant change in personnel at the Service Facility that might reasonably give rise to concerns of loss of competence

Alternatively, a remote audit may take place.

Prior to providing the six-month extension to the current FAR, the ExCB shall obtain a declaration from the Service facility in respect of Items 2 and 3 above.

3.3.3 For Service Facilities with other circumstance

For Service Facilities not meeting the criteria of 3.3.1 or 3.3.2 above OR at the end of any six-month extension, the following apply:

1. The audit shall comprise a desktop documentation review and a remote witnessing of activities via a video conferencing system
2. The documentation review shall include the results of the Service Facility's internal audit, including the minutes of a formal review meeting where the results were evaluated.
3. If there has been no documented internal audit, or formal review, during the last year, the Service Facility shall conduct an audit and review, and shall submit the results to the ExCB. Failure to provide a satisfactory record of an internal audit formal review within one month shall be recorded as a non-conformance and may result in immediate suspension of certification.
4. The video conferencing system shall allow the ExCB to direct the Service Facility in the movement of the camera such that the ExCB can view all aspects of activity that it deems appropriate which includes viewing the workshop. Note that a smart phone or a tablet may be more suitable than a laptop computer for this purpose. The ExCB may record the video conference for the purpose of selecting evidence to retain.

4 Section 4 - Circumstances affecting persons applying for, or currently holding, IECEX certification in the IECEX 05 Certificate of Personal Competence Scheme, CoPC

4.1 General

For ExCBs that have issued IECEX Certification to Persons under the IECEX 05 CoPC Scheme, located in countries / Regions / Areas impacted by an Extraordinary Circumstance or Event, where travel restrictions are imposed, the requirements of this Section shall apply.

4.2 Scheduled re-assessment for re-certification – Postponed for up to 6 months

The scheduled re-assessment for re-certification of personnel holding IECEX CoPC Certification under the IECEX 05 CoPC Scheme may be postponed for a maximum period not exceeding six (6) months on the strict provisions that:

1. there are no outstanding non-conformances; and
2. the ExCB is not aware of any complaints or concerns that could give rise to the ExCB questioning the ongoing compliance of the personnel covered by the IECEX certificate, with the requirements of IECEX 05 and associated ODs.

4.3 Scheduled re-assessment for re-certification – Not meeting Clause 4.2

Where 4.2 is not met or periods beyond six (6) months or for the processing of scope extensions, that normally require a practical assessment, the following provisions apply:

1. Along with other means, eg email communication, use of video communication maybe considered for closing out issues raised during a previous assessment associated with the scope of certification.
2. Video communication may be used to gather the objective evidence required to demonstrate a person's compliance with the IECEX CoPC requirements. The ExCB shall determine the applicability and use of this method.
3. Video Communication may also be used to gather the objective evidence required to demonstrate a person's compliance with the IECEX CoPC requirements when processing an application for an "up issue" of the certification scope to add additional Units. The ExCB shall determine the applicability and use of this method.

Following the successful completion of items 1 to 3 above as applicable, the ExCB shall issue an PCAR and up issue their PCAR Summary using the IECEX On-Line Certificate System.

The main point to stress is that even during situations arising from Extraordinary Circumstances or Events, it is not acceptable for an ExCB to simply do nothing as they are responsible to exercise some level of surveillance over the persons to which they have issued CoPC certificates.

4.4 Processing of New Applications for IECEX 05, CoPC

The full requirements of IECEX 05 and associated ODs shall apply. There are no special provisions made for new applicants for IECEX 05 Certification.

With this in mind, ExCBs are reminded of the provisions of the IECEX Scheme including ISO/IEC 17024 regarding resources and use of:

1. An assessment centre or ExCB located in the region impacted to perform the assessment (eg Practical Assessment); or
2. Use of an assessment centre operating under the strict control of the ExCB located within the country or region that is the subject of travel restrictions.

An ExCB shall consider these items as part of their "contract review" when considering the acceptance of an application for IECEX 05 certification from personnel. If an ExCB cannot make use of them then the ExCB may conclude to reject the application from a person, with the person free to make application to an alternative ExCB.

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