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, including Events Affecting ExCBs, ExTLs and Organizations and Personnel Holding IECEx Certification – All IECEx Certification Schemes and Activities
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Introduction

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

This Interim Operational Document has been prepared and issued by the IECEx Executive Secretary in consultation with the IECEx Chair and the IECEx Executive. It is intended to apply upon publication, to all schemes and activities of the IECEx System.

This Interim OD is to be 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 2020 ExMC Niagara Falls meeting.

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

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IECEx Guide for Business Continuity – Management of Extraordinary Circumstances affecting ExCBs, ExTLs and Organizations and Personnel Holding IECEx Certification – All IECEx Schemes and Activities

1 Overview

This Interim Operational Document (OD) has been prepared to provide guidance for managing situations arising from Extraordinary Circumstances, including Events, that may impact on all IECEx certification schemes and activities.

This Interim 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. It 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 regard 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).

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

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 Guide and acknowledgement is made of this assistance.

1.1 Definition of Extraordinary Circumstances, including 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.

2 Circumstances affecting normal operation of the IECEx peer assessment program for an IECEx ExCB or IECEx ExTL

2.1 ExCBs and ExTLs operating within the IECEx schemes

For ExCBs and ExTLs located in countries / regions / areas impacted by Extraordinary Circumstances, including 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 12 months.

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

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

- previous assessment reports including site assessment report (OD 006) + TCD
- requesting the Body to complete the declaration form (to be prepared by the Secretariat; similar to that used within the IECEx 03 scheme)
- the performance of the body with respect to the On-Line Certificate System, etc
- the preparation of a desk top review, by the 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 Secretariat who may consult with the Convener and Deputy Convener of ExAG.
The Secretariat shall report to the IECEx Executive.

During this interim period the Executive shall decide on acceptance of this deferral or further course of action, based on the report from the Secretariat, eg suspension of the body etc, and shall be reported at the next ExMC Meeting.

2.2 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, including Events, where travel to that area is restricted, the processing of scope extensions that normally require a site visit, the following provisions may be available, to IECEx Assessment Teams conducting scope extension assessments;

1. The use of video communication may be considered as provided in 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 such as “gotomeeting” and “Zoom” etc have video & voice capabilities and screen sharing.

3. Video communication shall not replace a site visit where a site visit is required to verify the correct preparation/operation of a specific test that is not covered within the existing technical scope of an ExTL.

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.

2.3 New Applicant ExCBs and ExTLs seeking to join IECEx Schemes

No provisions exist concerning new applicant ExCBs or ExTLs seeking to join IECEx. The normal IECEx peer assessment program, as reflected in the respective IECEx Rules of Procedures, still apply. No allowance is made for Extraordinary Circumstances, including Events. An assessment team will be assigned and the usual IECEx peer assessment will take place as per the IECEx Scheme Rules.

This may result in a delay for a Body seeking to become an ExCB or ExTL.

3 Circumstances affecting organizations or personnel currently holding IECEx certification

The following scenarios are provided as examples of organizations or Persons holding IECEx Certification where the rules of the Certification Scheme require on-going surveillance or recertification. This section assists bodies 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.

3.1 Organizations holding IECEx certification – IECEx 02 Certified Equipment Scheme

For ExCBs that have issued IECEx certification to organizations (e.g. manufacturers) located in countries / regions / areas impacted by an Extraordinary Circumstances, including Events, where travel to that area is restricted, the requirements of 3.1.1 and 3.1.2 shall apply:

3.1.1 Scheduled surveillance audits – Postponed for up to 6 months

The scheduled surveillance audits of organizations holding IECEx Certification under the IECEx 02 Certified Equipment Scheme may be postponed for a maximum period not exceeding 6 months on the strict provisions of:

1. That there are no outstanding nonconformances; and
2. That the ExCB is not aware of any complaints or concerns that could give rise to the ExCB questioning the on-going compliance of the organization covered by the IECEx certificate, with the requirements of IECEx 02, associated IECEx ODs and ISO/IEC 80079-34.

3.1.2 Scheduled surveillance audits – Not meeting Clause 3.1.1

Where 3.1.1 is not met or for periods beyond 6 months or for the processing of scope extensions, that normally require a site visit, the following provisions apply:

1. The use of video communication maybe considered (as provided in OD 003-2) for closing out issues raised during a previous site audit visit associated with the scope of certification.

2. Video communication may 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 may 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., as applicable, the ExCB shall issue a QAR and up issue their QAR Summary using the IECEx “On-Line” certificate system (re requirements of OD 009 Section 4).

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

3.2 Organisations holding IECEx certification – IECEx 03 Certified Service Facilities Scheme

For ExCBs that have issued IECEx certification to organisations (eg repair workshops, inspection bodies) located in countries / regions / areas impacted by an Extraordinary Circumstances, including Events, where travel to that area is restricted, the requirements of 3.2.1 and 3.2.2 shall apply.

3.2.1 Scheduled surveillance audits – Postponed for up to 6 months

The scheduled surveillance audits of organisations holding IECEx Certification under the IECEx 03 Certified equipment Scheme may be postponed for a maximum period not exceeding 6 months on the strict provisions of:

1. That there are no outstanding nonconformances; and

2. That the ExCB is not aware of any complaints or concerns that could give rise to the ExCB questioning the on-going compliance of the organisation covered by the IECEx certificate, with the requirements of IECEx 03 and associated IECEx ODs.

3.2.2 Scheduled surveillance audits – Not meeting Clause 3.2.1

Where 3.2.1 is not met or for periods beyond 6 months or for the processing of scope extensions, that normally require a site visit, the following provisions apply:

1. Use of video communication may be considered (as provided in OD 003-2) for closing out issues raised during a previous site audit visit associated with the scope of certification.

2. Video communication may be used to gather the objective evidence required to demonstrate an organisation’s compliance with the IECEx Quality Management System requirements for the respective IECEx Service Facilities Scheme rules. 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 an organisation’s compliance with the IECEx Quality Management System requirements for the respective IECEx Service Facilities Scheme rules 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 (eg repair workshop) to provide results of the organization’s previously conducted internal audit for the ExCB to review and gather sufficient evidence that the organization’s compliance with the IECEx Quality Management System requirements for the respective IECEx Service Facilities Scheme rules continue to be met. The ExCB may also require the organization to conduct an internal audit under the instruction of the ExCB, issuing the IECEx CoC or the ExCB that has issued the FAR.

Following the successful completion of Items 1. to 4., as applicable, the ExCB shall issue an FAR and up issue their FAR Summary using the IECEx “On-Line” certificate system.

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

3.3 Persons IECEx certification – IECEx 05 Scheme for Certification of Personnel Competence (CoPC)

For ExCBs that have issued IECEx Certification to Persons under the IECEx 05 CoPC Scheme, located in countries / Regions / Areas impacted by an Extraordinary Circumstances, including Events, where travel restrictions are imposed, the following shall apply.

3.3.1 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 6 months on the strict provisions of:

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

3.3.2 Scheduled re-assessment for re-certification – Not meeting Clause 3.3.1

Where 3.3.1 is not met or periods beyond 6 months or for the processing of scope extensions, that normally require a practical assessment, the following provisions apply:

1. Use of video communication maybe considered (as provided in OD 003-2) 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. 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, including 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 New applications for IECEx certification from organizations and personnel

4.1 IECEx 02 Certified Equipment Scheme

The full requirements of IECEx 02 and ODs, eg OD 009 shall apply. There are no special provisions made for new applicants for IECEx 02 Certification.
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 the travel ban, to perform the factory audit and issue an IECEx QAR; or

2. The use of contracted resources; ie 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.

4.2 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; ie 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.

4.3 IECEx 03 Certified Service Facilities Scheme

The full requirements of IECEx 03 and ODs shall apply. There are no special provisions made for new applicants for IECEx 03 Certification.

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 FAR; or

2. The use of contracted resources; ie 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 03 certification from organizations. If an ExCB cannot make use of them then the ExCB may conclude to reject the application from an organization, with the organization free to make application to an alternative ExCB.

4.4 IECEx 05 Scheme for Certification of Personal Competence (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.
5 Summary

Extraordinary Circumstances, including Events may have consequences to IECEx stakeholders. This Interim 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.

While this Interim OD may not cover every possible scenario, it does highlight areas that could have significant impact on customers of the IECEx System.

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