## 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, 3.1.2, 3.1.3 and 3.1.4 shall apply:

**IMPORTANT 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 the QAR’s remains in compliance with all applicable IECEx OD’s. Although it is possible to delay an audit for up to 6 months this should be the exception rather that the rule.
2. An ExCB performing an audit by remote means shall 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.

### 3.1.1 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 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 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.*
4. When the manufacturer is ready to start manufacturing again they shall inform the ExCB responsible for the QAR who depending on the QAR status shall take the following corrective actions:
5. If the surveillance audit has been delayed for 6 months or less a surveillance audit shall be performed in accordance with 3.1.2 before the manufacturer can recommence IECEx production.
6. If the recertification has been delayed for 6 months or less a surveillance audit shall be performed in accordance with 3.1.3 before the manufacturer can recommence IECEx production.
7. In all circumstances if the surveillance or recertification audits have been delayed longer than 6 months or the QAR expiry date has been exceeded a recertification audit shall be performed in accordance with OD 025

**3.1.2 Scheduled QAR surveillance audits may be performed by remote means.**

The scheduled surveillance audits shall be performed within a two months period prior to the one year, two year or 18 month due date with the following provisions:

1. The use of video communication shall be used (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 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., as applicable, the ExCB shall edit the QAR summary to record the date that the surveillance audit was performed using the IECEx “On-Line” certificate system (re requirements of OD 009 Section 4).

### 3.1.3 Scheduled QAR recertification audits may be performed by remote means.

The recertification audit shall be performed within the two months prior to the QAR expiry date. *Note Ideal date would be 4 weeks prior to the expiry date.*

1. As this is a recertification audit the use of video communication shall be employed (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 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, as applicable, the ExCB shall up issue their QAR Summary using the IECEx “On-Line” certificate system for a further three years (re requirements of OD 009 Section 4).

### 3.1.4 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:

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; the requirements of 3.1.3 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, 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.