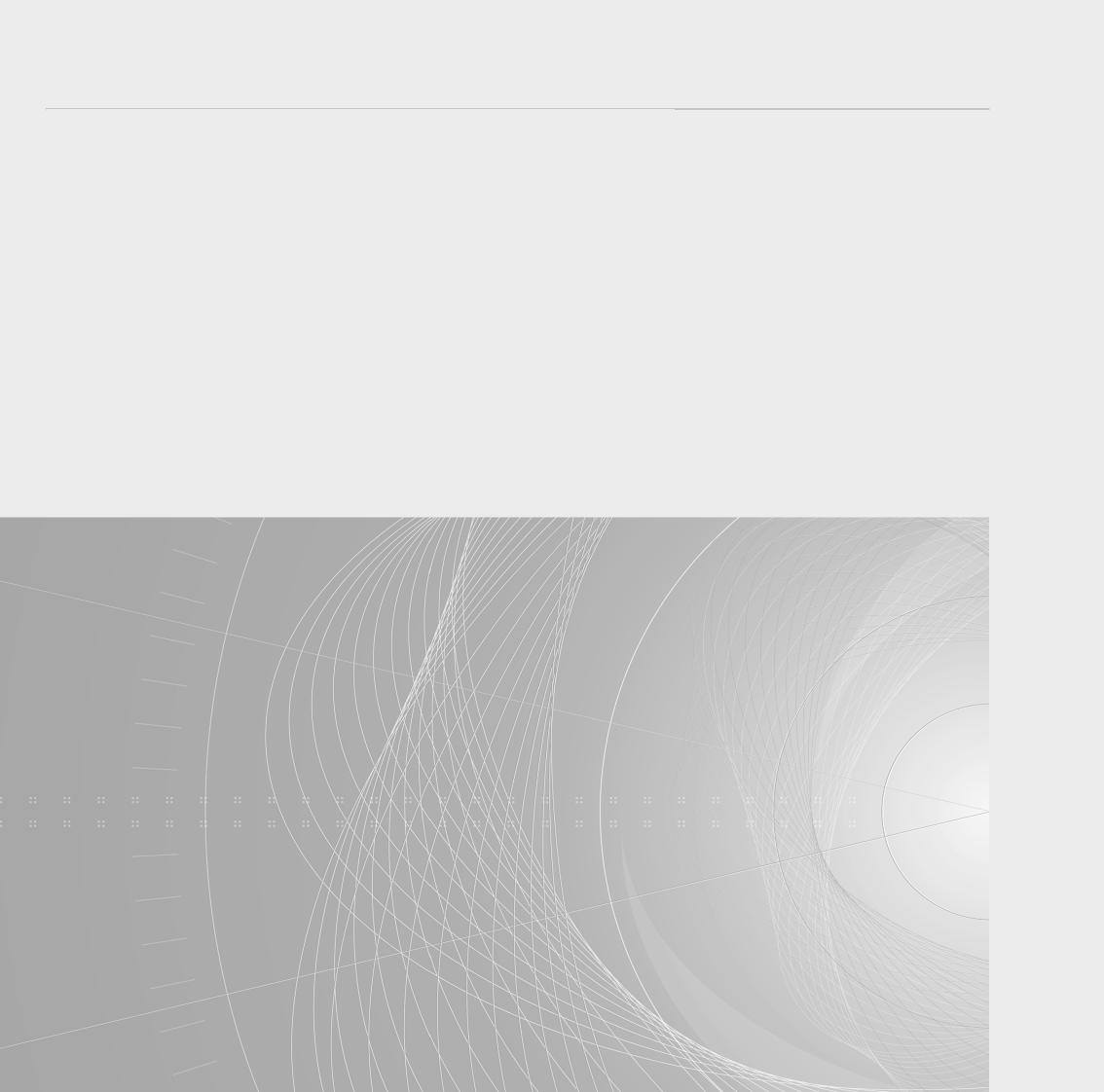
­­

IECEx OD 250:2019(E)



in Explosive Atmospheres (IECEx System)

IECEx Certified Equipment Scheme

|  |  |
| --- | --- |
| Logo IECEx 100px TM | IECEx OD 250 |
| Edition 2.0 2019-09 |

IECEx

OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for use

**Guidance on the Management of IECEx Quality Assessment Reports (QARs)**

|  |  |
| --- | --- |
|  | **THIS PUBLICATION IS COPYRIGHT PROTECTED Copyright © 2019 IEC, Geneva, Switzerland** |

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office Tel.: +41 22 919 02 11

3, rue de Varembé Fax: +41 22 919 03 00

CH-1211 Geneva 20 [info@iec.ch](mailto:info@iec.ch)

Switzerland [www.iec.ch](http://www.iec.ch)

**About the IEC**

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

**About IEC publications**

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

**Useful links:**

IEC publications search - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).

It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [csc@iec.ch](mailto:csc@iec.ch).

|  |  |
| --- | --- |
| Logo IECEx 100px TM | IECEx OD 250 |
| Edition 2.0 2019-09 |

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 the Management of IECEx Quality Assessment Reports (QARs)**

INTERNATIONAL ELECTROTECHNICAL COMMISSION

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**IECEx Operational Document OD 250**

**IECEx Certified Equipment Scheme**

**Guidance on the Management of IECEx Quality Assessment Reports (QARs)**

**Introduction**

This document is supplementary to the IECEx Rules, other IECEx Operational Documents and procedures operated by IECEx Certification Bodies (ExCBs that have been approved by the IECEx Management Committee to issue IECEx Certificates of Conformity (CoCs) for Equipment.

The purpose of IECEx Operational Documents (ODs) is to ensure that each ExCB accepted by the ExMC for the purposes of issuing IECEx CoCs and QARs does so in a consistent manner.

This Operational Document, OD 250 provides guidance on the management of IECEx Quality Assessment Reports (QARS). This Operational Document, OD 250 replaces ExTAG 164Inf and ExTAG 245Inf and is a supporting document to OD 009, OD 025, OD 209 and OD 011-2.

**Document History**

|  |  |
| --- | --- |
| **Date** | **Summary** |
| March 2019 | Original issue (Edition 1.0) |
| September 2019 | Edition 2.0 as a complete revision to reflect the operation, appearance and features of the second generation of IECEx On-line Certificate System (“IECEx OCS – 2nd Generation“) |

**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](mailto:info@iecex.com)

Web: <http://www.iecex.com>

Table of Contents

[**0** **Introduction** 5](#_Toc3536696)

[**1.0**  **IECEx Certifying Body (ExCB) responsibilities of managing QARs** 5](#_Toc3536697)

[**1.1**  **General** 5](#_Toc3536698)

[**1.2**  **Management of QARs** 5](#_Toc3536699)

[**1.2.1**  **Surveillance, re-assessments and registration of QAR Summary** 5](#_Toc3536700)

[**1.2.2**  **The process for managing a change of ExCB for assessments** 5](#_Toc3536701)

[**1.2.3**  **The management of Out of Date QARs and linked Certificates** 6](#_Toc3536702)

[**1.2.4 Management of the auto-linking of CoCs to other ExCBs QARs** 6](#_Toc3536703)

[**2**  **Monitoring and maintenance of QARs and Certificates of Conformity (CoCs)** 7](#_Toc3536704)

[**2.1**  **General** 7](#_Toc3536705)

[**2.2**  **ExCBs Key Responsibilities** 8](#_Toc3536706)

[**3**  **Procedures for typical Scenarios** 2](#_Toc3536707)

[**3.1** **Scenario – *Cancellation of Certificates*** 2](#_Toc3536711)

[**3.2** **Scenario – *Suspension of Certificates*** 4](#_Toc3536712)

[**3.3** **Scenario – *Suspension of Certificates for over one year*** 6](#_Toc3536713)

[**3.4** **Scenario – *Change of auditing and QAR issuing ExCB*** 7](#_Toc3536714)

[**Annex A** 8](#_Toc3536715)

**Guidance on the Management of IECEx Quality Assessment Reports (QARs)**

## **0 Introduction**

The QARs demonstrate that all manufacturing locations where the certified product is manufactured have been audited and have been confirmed as capable of manufacturing product identical in design and performance to the tested sample (ExTR) specified on the Certificate that the QAR Summary and ExTR Summary support. The IECEx Certified Equipment Scheme is a Type 5 Product Certification Scheme (ISO/IEC 17067) that involves surveillance in the form of management system audits.

Therefore, the requirements for Certification Bodies operating in the IECEx Certified Equipment Scheme are based on ISO/IEC 17065 that includes requirements for surveillance. The QARs content provide records of the outcomes of surveillance and assessments. The purpose of the QAR is for the ExCB to attest that they have sufficient objective evidence that the manufacturer’s quality system and associated quality plans enable Ex products as listed in the IECEx Certificate of Conformity (CoC) to be produced in compliance with the International Standards listed in the IECEx CoC.

The QAR has a 3-year life and at, or before, the end of the 3 years a full re-assessment audit is required. Surveillance audits are also conducted during the 3-year period and the frequency of surveillance audits is determined by ISO 9001 and ISO 80079-34 certification status according to IECEx OD 025.

## **IECEx Certifying Body (ExCB) responsibilities of managing QARs**

## **1.1 General**

The above introduction has raised the following four items for which the IECEx Secretariat, in conjunction with IECEx Executive wish to reinforce to all ExCBs.

Note: Throughout this document all references to Scheme are intended to relate to IECEx Certified Equipment Scheme.

1. The need to conduct surveillance assessments and have the QAR Summary from such registered via the IECEx On-Line Certificate System (IECEx OCS)
2. The process for handling the situation where a manufacturer decides to change ExCB for their site assessments resulting in a new QAR
3. The management of QARs and associated CoCs by ExCBs via the IECEx On-Line Certificate System (IECEx OCS) which is assisted by reports showing, ExCBs, ‘QAR out of date’ and ExCBs, ‘CoCs with QAR out of date’.
4. The auto-link feature of CoCs to other ExCBs QARs and what is the process if an ExCBs CoCs is no longer linked to a valid QAR.

These four points are described in detail below and a step by step procedure is provided in Section 3.0 of this document.

## **1.2 Management of QARs**

### 

### **1.2.1 Surveillance, re-assessments and registration of QAR Summary**

While a QAR may be valid for 3 years, this is on the basis that the ExCB (issuing the QAR) conducts surveillance assessments according to 5.2.2.2.2 of IECEx OD 025. This requirement, along with all requirements of IECEx OD 025 has been agreed to by the IECEx Management Committee, ExMC, comprising experts from Manufacturers, End Users, Regulators, ExCBs. The IECEx On-Line Certificate System (IECEx OCS) provides for the mandatory registering of issued QARs and includes the validity date. Subsequent QAR Summary such as surveillance assessment reports should also be registered using the original On-Line QAR Summary registered number with the On-Line System assigning a /01, /02 and so on to the original QAR number. Operational Document IECEx OD 011-2 provides clear instructions to ExCBs on how to register QARs, including reports from Surveillance visits.

### **1.2.2 The process for managing a change of ExCB for assessments**

According to the IECEx 02 Rules of Procedure, the issuing of an IECEx Certificate of Conformity (CoC) for the Equipment Certification Scheme requires that both a successful ExTR Summary and QAR Summary be issued. The QAR Summary may be issued from either the same ExCB that has received the CoC application or any other ExCB (maybe even an ExCB from a different country).

The ExCB that issues the CoC is responsible to check that the QAR Summary is valid and covers the same manufacturing location, Ex protection and product types and so on. Then the ExCB (that has received the CoC application) then issues the CoC by making the CoC current, using the guidelines of OD 011-2. **Under the IECEx Scheme, it is the ExCB that issued the CoC that is responsible to ensure that a valid QAR Summary is in place at all times**. So, the ExCB issuing the CoC must have a mechanism in place to periodically check that the QAR Summary(s) linked to their issued CoCs are valid.

If a manufacturer chooses to use a different ExCB to do surveillance or re-assessment audits and therefore issue a new QAR Summary, the new ExCB must advise the manufacturer to notify the ExCB that issued the original QAR Summary.

The original ExCB must up-issue the CoCs to be linked to the new QAR Summary **and** the "Details of Certificate Changes" field of the CoC must include a statement similar to the following:

*"This new issue of the certificate is issued to show that the ExCB responsible for the QAR has now been changed".* This new issue of the CoC must link to the new QAR.

### **1.2.3 The management of Out of Date QARs and linked Certificates**

IECEx Certification Bodies (ExCBs) are reminded of their obligations according to the IECEx 02 Rules of Procedures to ensure that assessment and surveillance audits of manufacturers are conducted within the maximum duration set by the Rules. ExCBs must maintain their own programme of scheduled surveillance and re-assessment audits and have a system for managing these.

If a manufacturer is no longer under surveillance when the QAR exceeds its assessment expiry date (ie. the *Valid Until date:* specified in the QAR Summary), the CoCs supported by the QAR Summary must be dealt with. This section provides guidance to ExCBs of their responsibilities and actions required ensuring the integrity of the IECEx on-line CoC system is maintained so current CoCs are **always** linked to a valid QAR Summary.

Should the surveillance or re-assessment audit of a manufacturer not occur before the due date, the ExCB has to take immediate action to either:

* bring the manufacturer back under surveillance. Timing is critical so as to not initiate Suspension of the CoC. If reasonable delays occurred due to scheduling and the audit is scheduled and anticipated to be conducted in a few weeks, then Suspension of the CoC may not be necessary. If in doubt, contact the IECEx Secretariat.

OR

* Suspend the CoCs that were previously issued under the QAR, if the ExCB cannot schedule a surveillance or re-assessment audit with the manufacturer. Note that there are many other reasons that ExCB may initiate Suspension of a CoC, and the details of these are provided in OD 209.

OR

* Cancel the CoCs that were previously issued under the QAR. Further detail on Suspend and Cancel can be found in OD 209.

NOTE: Only the IECEx Secretariat can Suspend or Cancel a CoC, therefore it is the responsibility of the ExCB who issued the CoC to notify the IECEx Secretariat and request the appropriate action.

### **1.2.4 Management of the auto-linking of CoCs to other ExCBs QARs**

ExCBs who have CoCs that are showing up on the IECEx On-Line Certificate System (IECEx OCS), under ‘ExCBs, CoCs with QAR out of date’, must understand how the IECEx On-Line auto-link feature of CoCs to QAR Summary(s) works. The auto-link feature of CoCs to a QAR Summary is an integral feature that allows ExCBs to easily link their CoCs to another ExCB’s QAR Summary thereby minimizing duplication of audits and the costs for the manufacturer. Not only is this a front-end feature useful when linking a CoC to a QAR Summary, but there is also a consequence to the use of QAR Summaries issued by other ExCBs – the options for managing these consequences are explained below.

ExCBs may take appropriate action with their issued CoC, such as to up-issue it to be linked to a valid QAR or to cancel the CoC in question, but the CoC still appears on their ‘ExCBs, CoCs with QAR out of date’ list. The reason for this is because the QAR Summary cannot be forced off the out of date list until **ALL** of the CoCs have been dealt with by all ExCBs that have their CoCs linked to this out of date QAR Summary. It is important to note that some QAR Summaries may have many CoCs linked to it, i.e. more than fifty, from a multitude of ExCBs. This can result in delays for the ExCB that issued the QAR Summary to get this invalid QAR Summary forced off their out of date list, and in turn, ExCBs who have dealt with their CoCs, still have them showing up on their ‘ExCB, CoCs with QAR our to date’ list. In such situations, the ExCB should contact the IECEx Secretariat to assist to help facilitate action by all ExCBs so the back-end linkage can be resolved by ensuring all CoCs linked to the out of date QAR Summary have been dealt with appropriately and in a timely manner. Only once this has occurred and the QAR Summary subsequently forced off the out of date list, will the CoCs that were linked to this QAR Summary be automatically removed from the ‘ExCB, CoCs with QAR out of date’ list.

## **2 Monitoring and maintenance of QARs and Certificates of Conformity (CoCs)**

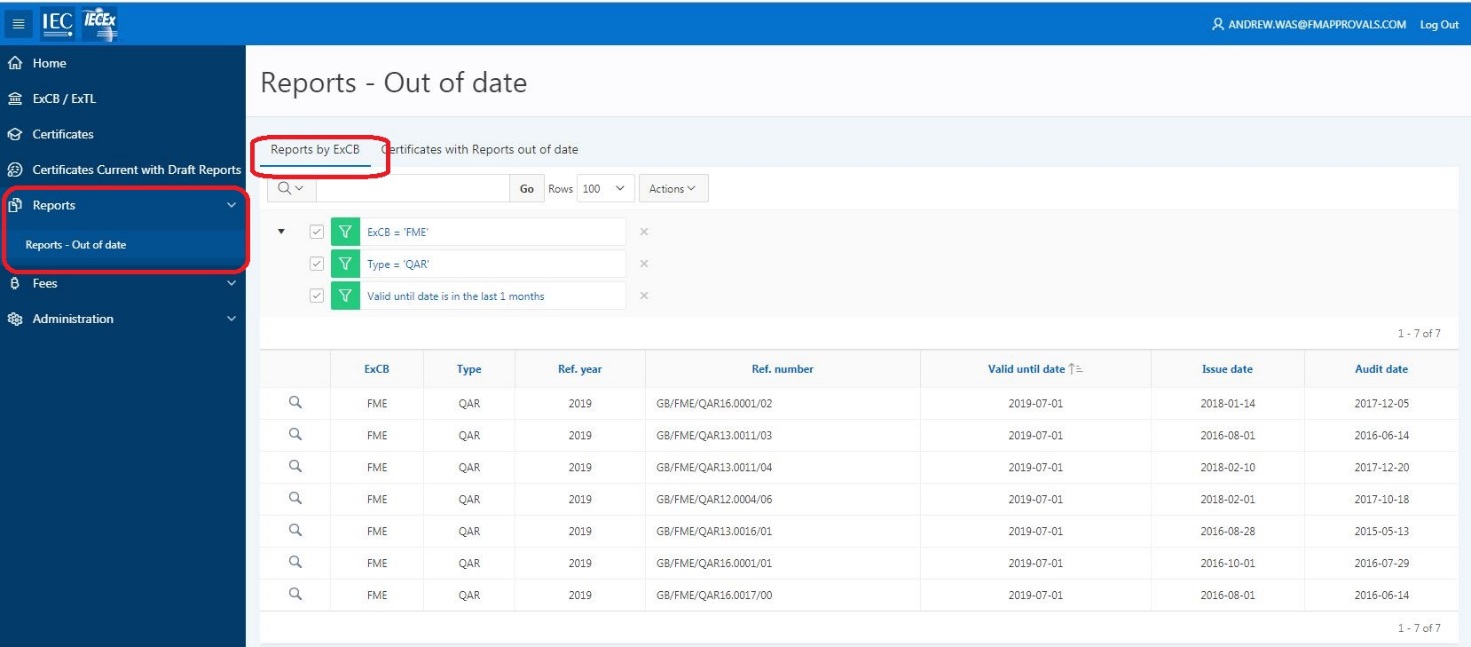
## **2.1 General**

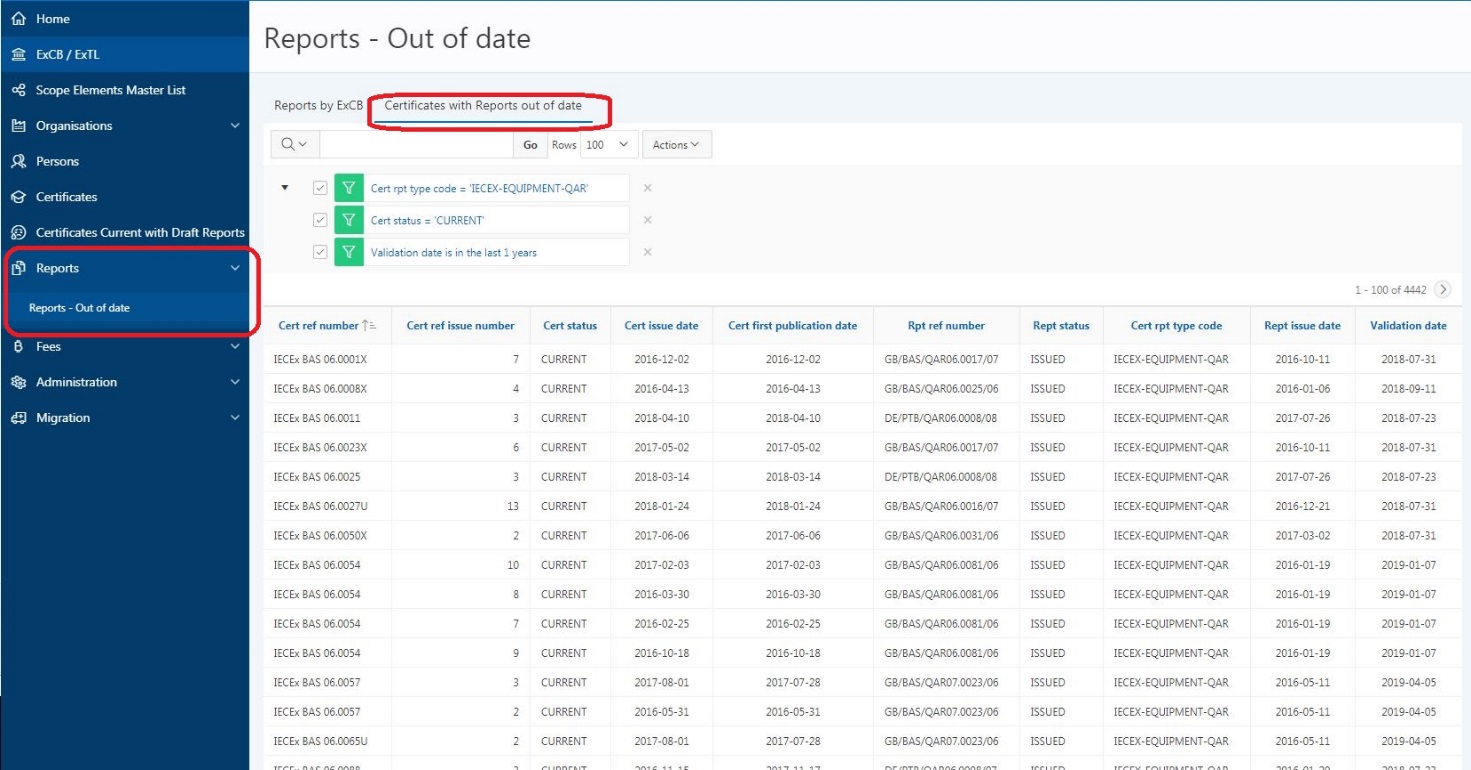
In addition to the basic tools provided for ExCBs for the monitoring and maintenance of QAR Summaries and CoCs, the IECEx On-line Certificate System also provides features to assist the ExCB to monitor out of date QAR Summaries and associated CoCs linked to these QAR Summaries.

To aid in this process the IECEx OCS website provides reports (to ExCBs logged into the IECEx OCS Back Office) on the following:

* ***ExCBs, QARs out of date***
* ***ExCBs, CoCs with QARs out of date***

The following screenshots provide examples of the basic layout of these (noting that facilities for filtering data and also sorting within some columns in the report.





Some key points to note:

* When the QAR is updated to be no longer out of date, it will be removed from the “QAR, out of date” list automatically.
* It is acknowledged that some QAR Summaries will never be updated. The reasons for this include the following:
  + The CoC has been cancelled
  + Another ExCB has taken over the surveillance of the manufacturer
  + The ExCB has raised another QAR Summary to supersede the original QAR Summary
  + or other reasons specific to a unique situation

In such cases the ExCB is requested to advise the IECEx Secretariat and if it can be shown that the QAR Summary will never be updated the IECEx Secretariat can remove it from the “QAR, out of date” list.

* A CoC may have multiple QAR Summaries attached and more than one QAR Summary may need to be updated before the CoC is removed from the list.
* Action must be taken on ALL CoCs linked to an out of date QAR Summary before the Secretariat can force the QAR Summary off the list (refer Clause 1.2.4 above for explanation).

## **2.2 ExCBs Key Responsibilities**

ExCBs to note the following:

* The ExCB that issues a CoC is responsible for maintaining it as valid be being linked to a current and valid QAR Summary – therefore it is the responsibility of the ExCB to monitor ‘QARS out of date’ and ‘CoCs with QARs of date’. The ExCB should have a management process to track QAR Summaries that they have issued so scheduling can be maintained with manufacturers.
* As part of the CoC On-Line Certificate System housekeeping, all ExCBs are requested to routinely review all the QAR Summaries in the listing (section 2.1 of this document) and arrange for the surveillance audits of manufacturers (where these have not been done), as a priority and then update the on-line QAR as soon as possible. In the situation that a QAR Summary will not be updated please contact the IECEx Secretariat and it also suggested the latest QAR Summary in its series be edited to include the following text in the Comment field:

*This QAR series will not be maintained or updated after <date>*

* ExCBs are requested to regularly review the list and arrange for re-assessments or surveillance audits to be conducted as they are due and to ensure that **QAR Summary information is kept updated.**
* If an ExCB takes over the auditing of a manufacturer and a new QAR Summary is issued it is requested that, as a courtesy, that this ExCB inform all ExCBs that issued CoCs with a link to the previous QAR Summary that they need to take action on the CoCs and this will usually involve up-issuing of the CoCs to be linked to the new QAR Summary.
* The Secretariat will provide more detail advice to individual ExCBs, if requested. Any such request may be initially directed to the following:

IECEx Secretariat E-mail: [info@iecex.com](mailto:info@iecex.com)

The IECEx Secretariat routinely reviews ‘Out of date QARs’ and associated CoCs linked to these QAR Summaries and if it is evident that QAR Summary management is poorly managed, then the Secretariat will raise this issue with the ExCB in writing and if necessary, ensure QAR Summary reviews are included as part of audits of ExCBs, which may trigger a non-conformance. In addition, the Secretariat monitors the trend of out of date QAR Summaries and associated CoCs not linked to valid QAR Summaries so they can escalate this matter to the ExCB management.

At any time during the maintenance of an IECEx Certificate of Conformity, the IECEx Secretariat are available to provide assistance to guide the ExCB so they are able to effectively manage the QAR Summaries and CoCs they have issued.

## **3 Procedures for typical Scenarios**



## **Scenario – *Cancellation of Certificates***

The procedure for handling ‘out of date QARs’ where the CoCs are to be Cancelled. If a QAR Summary is escalated to the ‘out of date QARs’ list in the IECEx On-Line Certificate System (IECEx OCS), it may be a result of the manufacturer no longer wishing to be under surveillance as it may no longer produce the Ex product and will never recommence production. In such a situation the following procedure should be followed (IECEx OD 209 and Annex A to this document provide additional guidance).

Note: Cancelled CoCs cannot be restored to status of Current and always remain visible (with status = Cancelled) on the IECEx On-Line Certificate System (IECEx OCS) so that the certification status of product in stock or installed can be determined at any time in the future.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **Section 3.1 – Procedures for the Maintenance of QAR Summaries and CoCs where the CoCs are to be Cancelled** | **Related Documents** | **By Whom** | **Notes/Comments** |
| 1 | ExCB monitors validity of QAR Summaries with their internal DMS and if necessary, verifying using the IECEx on-line admin system tools *(as described above)* | Internal ExCB DMS and IECEx on-line admin tools | ExCB | This is a requirement under ISO/IEC 17065 accreditation |
| 2 | QAR Summary has been identified as no longer valid (expired) |  | ExCB | IECEx Secretariat may flag this with ExCB |
| 3 | ExCB to check with manufacturer and inform them that the QAR has expired and that the products linked to the QAR Summary are no longer IECEx Certified |  | ExCB | Manufacturer products no longer IECEx Certified |
| 4 | If the manufacturer no longer wishes to have their product(s) hold a valid IECEx CoC, then the CoCs linked to the out of date QAR Summary need to be Cancelled   * The Secretariat is to be provided with written confirmation from the ExCB that it wishes to Cancel the CoCs, and * Inform the Secretariat of the date of Cancellation, ensuring that it is not greater than the validity date of the QAR Summary |  | ExCB |  |
| 5 | The ExCB is to notify the Secretariat to Cancel the CoCs that it has linked to the out of date QAR Summary |  | ExCB to notify IECEx Secretariat |  |
| 6 | The Secretariat is to inform other ExCBs that may have CoCs linked to the out of date QAR that they need to formally request in writing from the Secretariat to Cancel their respective CoCs that are linked to the out of date QAR Summary (as per detailed instructions in OD 209) | OD 209 | Secretariat | ExCB may also advise other ExCBs |
| 7 | The Secretariat Cancels the CoCs as per OD 209 and inserts Cancellation text in the Equipment Field of the CoC  ***NOTE: This certificate was CANCELLED on 1st January 20xx at the request of the Manufacturer following their consultation with the Applicant. 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. Any comment may be directed to the Applicant or ExCB.*** | OD 209 | Secretariat under instructions from the ExCB |  |
| 8 | When all of the CoCs are Cancelled that were previously linked to the out of date QAR Summary, then the Secretariat can force the out of date QAR off the ‘out of date list’ |  | Secretariat | ExCB to monitor out of date QAR Summaries |

Note: If the manufacturer does not agree to renew or update the QAR Summary then the ExCB (that issued the CoC) must suspend or cancel the CoC. This is major difference between IECEx and some other systems such as ATEX and why the IECEx On-Line Certificate System (IECEx OCS) has in place a system of linking the CoCs to the QAR Summaries. The ExCB that is to renew the QAR Summary can clearly see all CoCs listed as linked to their QAR Summaryt, (as shown on the QAR Summary page of the IECEx On-Line Certificate System (IECEx OCS) and within the QAR Summary itself). These CoCs must be considered during the ExCBs re-assessment and surveillance assessment visits.

## **Scenario – *Suspension of Certificates***

The process for handling ‘out of date QARs’ where the CoCs are to be Suspended. The suspension of CoC’s may occur for various reasons (refer to OD 209), but in this situation it is assumed that the manufacturer has not yet decided whether it will continue to maintain its QAR Summary and require additional time perhaps to review is business plan and to then remove the Suspension when the matter is resolved. IECEx OD 209 and Annex A provide additional guidance on resolution options.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **Section 3.2 – Procedures for the Maintenance of QAR Summaries and CoCs where the CoCs are to be Suspended** | **Related Documents** | **By Whom** | **Notes/Comments** |
| 1 | If the manufacturer wishes to delay or temporarily halt its IECEx QAR Assessment audits, then the CoCs linked to the out of date QAR Summary must be Suspended until the Assessment audits resume with the manufacturer | OD 209 | ExCB in consultation with the manufacturer | Suspension note inserted in Equip Field of CoC with date of Suspension |
| 2 | If for logistical reasons which are not in the control of the manufacturer or the ExCB, the ExCB should advise the Secretariat that action is being taken |  | ExCB in consultation with the manufacturer | Suspension note may not be inserted if QAR Summary is imminent |
| 3 | The ExCB who is responsible for the ‘out of date’ QAR Summary is to notify the Secretariat in writing that the QAR audit process has not occurred, however it is the intention of the manufacturer to resume the IECEx QAR process in the future (not to exceed one year, as per OD 209) and to temporarily Suspend the CoCs linked to the ‘out of date QAR’ | IECEx 02 Rules | ExCB |  |
| 4 | The Secretariat is to advise other ExCBs who may have their CoCs linked to the out of date QAR Summary that the manufacturer has temporarily Suspended the CoC | OD 209 | Secretariat | ExCB may also inform other ExCBs |
| 5 | The ExCBs are to formally advise the Secretariat to Suspend their CoCs that are linked to the out of date QAR Summary |  | ExCB |  |
| 6 | The Secretariat will Suspend the CoCs, inserting the Suspension standard note in each of the CoCs and their issues when the Suspension was initiated  ***NOTE: This certificate was SUSPENDED on 1st January 20xx at the request of the issuing IECEx Certification Body (ExCB) following their consultation with the Applicant. This suspension 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. Any comment may be directed to the issuing ExCB.*** | OD 209 | Secretariat to Suspend and insert note in Equipment Field of CoC |  |
| 7 | When the ExCB conducts the QAR assessment and the criteria of Section 3 of OD 009 is met, the ExCB is to update the QAR Summary (by preparing a new version) as opposed to the creation of a New QAR Summary, and notify the Secretariat to remove the Suspension and make the CoCs Current and removing the original Suspension note, **but** inserting a new note in the Equipment Field of the CoC, which highlights the period of Suspension during which the product is not IECEx Certified  ***NOTE: This certificate was temporarily SUSPENDED over the period of 1st January 20xx to 20xx-04-21 at the request of the issuing IECEx Certification Body (ExCB) following their consultation with the Applicant. This suspension does NOT affect products manufactured prior to 20xx-01-01 or after 20xx-04-21. Any product manufactured during the suspension period of 20xx-01-01 to 20xx-04-21 cannot be considered to be IECEx Certified under this Certificate. Any comment may be directed to the Applicant or ExCB.*** | OD 009  IECEx 02 Rules | Secretariat to update Suspension note in CoC if Suspension is excessive without good reason | ExCB should inform Manufacturer, that if a Suspension is lengthy, this will result in a statement inserted into the CoC that will remain in the CoC  Suspension should be dealt with within 1 year (see Section 3.3) |
| 8 | The ExCB may need to up-issue the CoC ensuring any technical changes are included (if necessary) and to link the latest version of the QAR Summary to the CoC.  If there are no technical changes to product, it is not necessary to issue a new Issue CoC because the auto tracking feature provides a link from the CoC to the latest QAR Summaries in the series | OD 011-2 | ExCB |  |
| 9 | The Secretariat is to advise other ExCBs who have their CoCs linked to the ‘out of date QAR’ that the manufacturer now has a valid QAR Summary and as per point 7 above and the CoCs can be made Current |  | Secretariat |  |
| 10 | The ExCB would need to formally request the Secretariat to make the CoCs they issued Current and insert the Suspension note as per point 7 above |  | ExCB to inform Secretariat |  |
| 11 | If there are any technical changes from the manufacturer, address, name change etc, then the CoCs will need to up-issued to reflecting key changes. |  | ExCB |  |
| 12 | If there are any product design changes to the CoC, this will trigger the CoC to be up-issued. |  | ExCB |  |

## **Scenario – *Suspension of Certificates for over one year***

The process for handling out of date QARS where the CoCs have been Suspended and the Suspension period has exceeded one year. It should be noted that the ExCB should have an internal document control system to monitor the duration of suspensions. The IECEx On-Line Certificate System (IECEx OCS) will also provide reference as the Suspension of CoCs will not enable the QAR Summary to be forced off the out of date list, so they will still be visible in ‘out of date QARS’

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **Section 3.3 – Procedures for the Maintenance of QARs and CoCs where the CoCs have been Suspended but the Suspension date has exceeded 1 year** | **Related Documents** | **By Whom** | **Notes/Comments** |
| 1 | If after one year, the QAR audit process has not resumed, the ExCB in consultation with the manufacturer must now initiate Cancellation of the CoCs following Suspension | IECEx 02 Rules  OD 209  Internal ExCB DMS and IECEx on-line admin tools | ExCB | CoCs cannot be suspended indefinitely, ExCB should have DMS to inform them that they need to take action |
| 2 | ExCB to notify Secretariat of change of CoC status – Suspend to Cancel | OD 209 | ExCB | Secretariat to change status from Suspend to Cancel and insert note as per section 3.1 step 7 of this document |
| 3 | Secretariat to notify other ExCBs that have Suspended CoCs linked to the out of date QAR Summary, that also need to change status to Cancel |  | Secretariat |  |
| 4 | Other ExCBs to notify Secretariat to formally change status – Suspend to Cancel |  | ExCB | As above |
| 5 | Secretariat to force QAR Summary off out of date list, when all of the CoCs have been linked to it have been Cancelled | OD 025 | Secretariat |  |

## **Scenario – *Change of auditing and QAR Summary issuing ExCB***

The process for handling the situation where a manufacturer changes ExCB for their surveillance or re-assessment resulting in a new issue QAR. The consequence of this is that when such a change is made by the manufacturer, the CoCs that were linked to the old QAR, will need to be up-issued (technical change) to the new QAR. The ExCBs are responsible for their CoCs that they issue, however the ExCB may NOT be aware of manufacturer changes and such, do nothing with the CoCs, resulting in orphan CoCs (old QAR out of date, and CoCs not up-issued). The below procedure addresses this issue and IECEx OD 209 and Annex A to this document also provide additional guidance.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **Section 3.4 – Procedures for the Maintenance of QAR Summaries and CoCs where a manufacturer changes ExCB resulting in a new issue QAR Summary** | **Related Documents** | **By Whom** | **Notes/Comments** |
| 1 | If the manufacturer chooses to use a different ExCB to do the surveillance or re-assessment and issue a new QAR Summary, then the new ExCB is to notify the Secretariat of the change with the new QAR Summary number | OD 009  IECEx 02 Rules | New ExCB |  |
| 2 | In conjunction with the new ExCB, the Secretariat will help facilitate the necessary communication informing the ExCBs who have CoCs linked to the old QAR, to up-issue their CoCs to the new QAR Summary  ExCBs who have issued CoCs to the now discontinued QAR Summary are ultimately responsible to monitor and up-issue their CoCs to the new QAR Summary |  | New ExCB  Secretariat  ExMC CoC holders | Refer to 1.2.4 of this document to understand the auto-link feature of CoCs to QAR Summaries |
| 3 | “Details of Certificate Change” field of the CoC must include a statement or text similar to the following:  ***"This new issue of the certificate is issued to show that the ExCB responsible for the QAR Summary has now been changed"*** |  | ExCB CoC holders |  |
| 4 | The new issue of the CoC must link to the new QAR Summary and the link to the old QAR Summary must be removed |  | ExCB CoC holders |  |
| 5 | The ExCB that issued the CoC are to continue to monitor their CoCs ensuring that it is ALWAYS linked to a valid QAR Summary. The ExCB is responsible for the management of the CoCs it issues. | Internal ExCB DMS and IECEx on-line admin tools | ExCB CoC holders |  |

## **Annex A**

Normative

**Typical Scenarios and Process Outcomes in Managing QARs:**

|  |  |  |
| --- | --- | --- |
| **Scenario #1** | **Action:** | **Comments:** |
| ExCB ‘A’ issues QAR Summary for an applicant or manufacturer (Mfr) | ExCB ‘A’ issues Mfr with CoC Issue 0 that is linked to ExCB ‘A’ QAR Summary | Typical basic application |
| *then* |  |  |
| ExCB ‘A’ up- issues QAR Summary for Mfr | The ExCB ‘A’ issued CoC needs to be maintained as current so the up-issued QAR Summary is reviewed and registered by ExCB ‘A’ and via registration it is automatically linked to the ExCB ‘A’ CoC Issue 0 | No need for ExCB ‘A’ to up-issue CoC to Issue 1 as Issue 0 is automatically linked to up-issued QAR Summary, so there has been no change to the product/manufacturer or other that may trigger a technical change requiring an up-issue of the CoC |
| *subsequently* |  |  |
| The applicant or Mfr decides not to proceed with the 3 year re-assessment and informs ExCB ‘A’ | ExCB ‘A’ notifies the Mfr that products manufactured without a valid QAR Summary are not IECEx Certified and the manufacturer is required to change its product labelling removing reference to IECEx CoC. ExCB ‘A’ notifies the Secretariat to Cancel the CoCs and insert the Cancellation date in the Equipment field of the CoC. | Refer to section 1.1 step 7 of this document to see Cancellation note. |
| **SCENARIO #2** | **Action:** | **Comment:** |
| ExCB ‘A’ issues new QAR Summary for Mfr | ExCB ‘A’ issues Mfr with CoC Issue 0 that is linked to ExCB ‘A’ QAR |  |
| *Subsequently & prior to expiry of 3 year validity of ExCB ‘A’QAR Summary* | | |
| ExCB ‘B’ issues QAR Summary for Mfr in response to request from Mfr for change of auditing ExCB | The ExCB ‘A’ issued CoC needs to be maintained as current so ExCB ‘A’ CoC is ‘up-issued’ as Issue 1 by ExCB ‘A’ and is linked to new ExCB ‘B’ which is considered a technical change | Relationship of CoC with other ExCB’s QAR Summary |
| *Subsequently – years later* |  |  |
| Mfr ceases production of item and informs ExCB ‘B’ that future Surveillance is no longer required | ExCB ‘B’ as good practice, will insert a note in the QAR Summary stating that this QAR Summary will no longer be supported. ExCB ‘B’ notifies Mfr and Secretariat that the CoC previously linked to this QAR Summarywill need to be Cancelled. | Although it is the responsibility of ExCB ‘A’ to monitor their issued CoCs, the Secretariat may also notify ExCB ‘A’ to assist and then acting under the instructions of ExCB ‘B’ Cancel CoC |
| **SCENARIO #3** | **Action:** | **Comment:** |
| ExCB ‘A’ have CoCs on their IECEx admin, out of date list. The CoCs are linked to ExCB ‘B’ QAR Summary which is no longer being maintained | ExCB ‘A’ contacts the Mfr to determine if CoCs are to be maintained and in their current status are not valid. The Mfr informs ExCB ‘A’ that they are reviewing. | ExCB ‘A’ inform Mfr that the CoCs issued will need to be Suspended until they complete their review. |
|  | ExCB ‘A’ informs Secretariat to Suspend CoCs providing a date of Suspension | Under direction of ExCB ‘A’ the Secretariat SUSPENDS CoCs inserting comment in the Equip Field (see section 1.2 step 6 of this document) |
| Suspension has exceeded one year | If after one year and no direction is provided by the Mfr, then ExCB ‘A’ is to contact the Mfr and inform them the CoC will need to be Cancelled | Under direction of ExCB ‘A’ the Secretariat CANCELS CoCs inserting comment in the Equip Field (see section 1.1 step 7 of this document) |
| **SCENARIO #4** | **Action:** | **Comment:** |
| ExCB ‘A’ observes that they have numerous CoCs that are showing up in IECEx Admin ‘ExCBs, CoCs with QAR Summary out of date’ but they have already taken action and have up-issued the CoCs to a valid QAR Summary. | ExCB ‘A’ contacts Secretariat to review previous QAR Summary, as it is likely that the QAR Summary issued by ExCB ‘B’ still have CoC’s linked to it that require action. | A QAR Summary cannot be forced from the out of date list, until ALL CoCs are dealt with (up-issued or Cancelled). |
|  | The Secretariat is to inform other ExCBs that their CoCs require action as they are linked to a out of date QAR Summary. | There could be numerous ExCBs who have their CoCs linked to the out of date QAR Summary. This now requires cooperation by all ExCBs involved to take necessary action to manage their CoCs. |
|  | Only when all the CoCs are dealt with can the Secretariat ‘Force the QAR’ off the out of date list | By forcing or greying out the QAR Summary, (it is not deleted) this removes the CoC – QAR auto-linking feature. This will now resolve ‘ExCBs, CoCs with QAR out of date’ as they will automatically be removed from the list. |

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](mailto:info@iec.ch)

[www.iec.ch](http://www.iec.ch)