

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

ECEX OD 250:2019(E)

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





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

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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.

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Document History

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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 and ExTR support. The IECEx Certified Equipment Scheme is a Type 5 Product Certification Scheme (ISO/IEC 17067) that involves Surveillance. The Surveillance includes 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 assessment audit is required. Surveillance audits are also conducted during the 3-year period. The frequency of surveillance audits is determined by ISO 9001 and ISO 80079-34 certification status and is specified in OD 025.

1.0 IECEx Certifying Body (ExCB) responsibilities of managing QARs

1.1 General

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

Note: Throughout this document all references to Scheme refer 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 System
- 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 System 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 OD 025. This requirement, along with all requirements of OD 025 has been agreed to by the IECEx Management Committee, ExMC, comprising experts from Manufacturers, End Users, Regulators, ExCBs. The IECEx On-Line System provides for the mandatory registering of issued QARs and includes the validity date. Subsequent QA Summary such as surveillance assessment reports should also be registered using the original On-Line QAR Registered number with the On-Line System assigning a /01, /02 and so on to the original QAR number. Operational Document 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, 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 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 is in place at all times**. So, the ExCB issuing the CoC must have a mechanism in place to periodically check that QARs associated with 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, the new ExCB must advise the manufacturer to notify the ExCB that issued the original QAR.

The original ExCB must up-issue the CoCs to be linked to the new QAR **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 and 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, the CoCs supported by the QAR 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.

Should the manufacturer Surveillance or Assessment lapse, then 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 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 System, under 'ExCBs, CoCs with QAR out of date', must understand how the IECEx On-Line auto-link feature of CoCs to QARs works. The auto-link feature of CoCs to QAR is an integral feature that allows ExCBs to easily link their CoCs to another ExCB QAR 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, but there is also a back-end consequence to the use of QARs 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 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. It is important to note that some QARs may have many CoCs linked to it, i.e.: + 50, from a multitude of ExCBs. This can result in delays for the ExCB that issued the QAR to get this invalid QAR 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 have been dealt

with appropriately and in a timely manner. Only once this has occurred and the QAR subsequently forced off the out of date list, will the CoCs that were linked to this QAR 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 QARs and CoCs, the IECEx On-line Certificate System also provides features to assist the ExCB to monitor out of date QARs and associated CoCs linked to these QARs.

To aid in this process the IECEx on-line website provides reports on the following under the **Reports / Reports** – **Out of Date** section of the Back Office of the IECEx OCS (IECEx OD 011-10 provides more details about the IECEx OCS Back Office):

- Reports by ExCB
- ExCBs, CoCs with Reports out of date

These tools include the ability to search and filter search results according to a range of default options as illustrated below (IECEx OD 011-2 provides more detail about the use of the tools illustrated below).

							R nina	KHOSHABA@UL.COM
Ĝ Home								
童 ExCB / ExTL	Repor	rts - Ou	t of date	e				
Certificates	Reports by	ExCR Cortific	ates with Reports	out of data				
) Certificates Current with Draft Reports		EXCB Certific						
Reports 🗸	Q~			Go Rows 100 ~	✓ Actions ✓			
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								1-4
		ExCB	Туре	Ref. year	Ref. number	Valid until date ↑≞	Issue date	Audit date
	Q	UL	QAR	2018	US/UL/QAR15.0021/01	2018-09-03	2017-03-29	2017-02-28
	Q	UL	QAR	2018	US/UL/QAR12.0007/04	2018-09-12	2018-06-20	2018-06-20

🟠 Home	Devente									
盒 ExCB / ExTL	Reports -	Reports - Out of date								
ം Scope Elements Master List										
🖆 Organisations 🛛 🗸 🗸	Reports by ExCB	Certificates with Reports o	o Rows 100	✓ Actions ✓						
R Persons	4.	C	Kows 100	✓ Actions ✓						
→ Certificates	🔻 🗹 🔽 Cert	rpt type code = 'IECEX-EQUI	PMENT-QAR	×						
Certificates Current with Draft Reports	Cert	status = 'CURRENT'		×						
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ju kepons 🗸 🗸										1 - 100 of 4442
Reports - Out of date	Cert ref number ↑=	Cert ref issue number	Cert status	Cert issue date	Cert first publication date	Rpt ref number	Rept status	Cert rpt type code	Rept issue date	Validation dat
Fees ~	IECEx BAS 06.0001X	7	CURRENT	2016-12-02	2016-12-02	GB/BAS/QAR06.0017/07	ISSUED	IECEX-EQUIPMENT-QAR	2016-10-11	2018-07-31
3 Administration 🗸 🗸	IECEx BAS 06.0008X	4	CURRENT	2016-04-13	2016-04-13	GB/BAS/QAR06.0025/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-01-06	2018-09-11
🕽 Migration 🗸 🗸	IECEx BAS 06.0011	3	CURRENT	2018-04-10	2018-04-10	DE/PTB/QAR06.0008/08	ISSUED	IECEX-EQUIPMENT-QAR	2017-07-26	2018-07-23
	IECEx BAS 06.0023X	6	CURRENT	2017-05-02	2017-05-02	GB/BAS/QAR06.0017/07	ISSUED	IECEX-EQUIPMENT-QAR	2016-10-11	2018-07-31
	IECEx BAS 06.0025	3	CURRENT	2018-03-14	2018-03-14	DE/PTB/QAR06.0008/08	ISSUED	IECEX-EQUIPMENT-QAR	2017-07-26	2018-07-23
	IECEx BAS 06.0027U	13	CURRENT	2018-01-24	2018-01-24	GB/BAS/QAR06.0016/07	ISSUED	IECEX-EQUIPMENT-QAR	2016-12-21	2018-07-31
	IECEx BAS 06.0050X	2	CURRENT	2017-06-06	2017-06-06	GB/BAS/QAR06.0031/06	ISSUED	IECEX-EQUIPMENT-QAR	2017-03-02	2018-07-31
	IECEx BAS 06.0054	10	CURRENT	2017-02-03	2017-02-03	GB/BAS/QAR06.0081/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-01-19	2019-01-07
	IECEx BAS 06.0054	8	CURRENT	2016-03-30	2016-03-30	GB/BAS/QAR06.0081/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-01-19	2019-01-07
	IECEx BAS 06.0054	7	CURRENT	2016-02-25	2016-02-25	GB/BAS/QAR06.0081/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-01-19	2019-01-07
	IECEx BAS 06.0054	9	CURRENT	2016-10-18	2016-10-18	GB/BAS/QAR06.0081/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-01-19	2019-01-07
	IECEx BAS 06.0057	3	CURRENT	2017-08-01	2017-07-28	GB/BAS/QAR07.0023/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-05-11	2019-04-05
	IECEx BAS 06.0057	2	CURRENT	2016-05-31	2016-05-31	GB/BAS/QAR07.0023/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-05-11	2019-04-05
	IECEx BAS 06.0065U	2	CURRENT	2017-08-01	2017-07-28	GB/BAS/QAR07.0023/06	ISSUED	IECEX-EQUIPMENT-QAR	2016-05-11	2019-04-05
	1505- BAS AS A000	5	CURRENT	3016 11 15	3617 11 17	DE (DTD /O A DOG 0000/07	TECHTER	IFCEV FOURIENT OAD	2016 01 20	2010 07 22

When the QAR is updated to be no longer out of date, it will be removed from the "QAR, out of date" list automatically.

Note: It is noted that some QARs 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 to supersede the original QAR
- There may be other reasons

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

Again, when the QAR is updated to be no longer out of date, the associated CoC will be removed from the "ExCBs, CoCs with QARs out of date" list automatically.

Note: A CoC may have multiple QARs attached and more than one QAR may need to be updated before the CoC is removed from the list.

Note: Action must be taken on ALL CoCs linked to an out of date QAR before the Secretariat can force the QAR 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 – 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 QARs 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 QARs 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 will not be updated please contact the IECEx Secretariat and it
 also suggested the latest QAR 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 information is kept updated**.
- If an ExCB takes over the auditing of a manufacturer and a new QAR 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 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
- 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

The IECEx Secretariat routinely reviews 'Out of date QARs' and associated CoCs linked to these QARs and if it is evident that QAR management is poorly managed, then the Secretariat will raise this issue with the ExCB in writing and if necessary, ensure QAR 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 QARs and associated CoCs not linked to valid QARs 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 QARs and CoCs they have issued.

3 Procedures for typical Scenarios

3.1 Scenario – Cancellation of Certificates

The procedure for handling 'out of date QARs' where the CoCs are to be Cancelled. If a QAR is escalated to the 'out of date QARs' list in the IECEx On-Line System, 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 System 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 QARs and CoCs where the CoCs	Related	By Whom	Notes/Comments
	are to be Cancelled	Documents		
1	ExCB monitors validity of QARs 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 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 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 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 		ExCB	
5	The ExCB is to notify the Secretariat to Cancel the CoCs that it has linked to the out of date QAR		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 (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 1 st 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	Secretariat	ExCB to monitor out of date
	QAR, then the Secretariat can force the out of date QAR off the 'out of date list'		QARs

Note: If the manufacturer does <u>not</u> agree to renew or update the QAR 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 System has in place a system of linking the CoCs to the QARs. The ExCB that is to renew the QAR can clearly see all CoCs listed as linked to their QAR, (as shown on the QAR Summary page of the IECEx On-Line System and within the QAR itself). These CoCs must be considered during the ExCBs re-assessment and surveillance assessment visits.

3.2 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 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 QARs and CoCs where the CoCs	Related	By Whom	Notes/Comments
	are to be Suspended	Documents		
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 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 is imminent
3	The ExCB who is responsible for the 'out of date' QAR 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' 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		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 <i>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.</i>	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 (by preparing a new version) as opposed to the creation of a New QAR, and notify the Secretariat to remove the Suspension and make the CoCs Current and removing the original Suspension	OD 009 IECEx 02 Rules	Secretariat to update Suspension note in CoC if Suspension is	ExCB should inform Manufacturer, that if a Suspension is lengthy, this will result in a statement inserted into

	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 <u>NOTE: This certificate was temporarily SUSPENDED</u> over the period of <u>1st</u> <u>January 20xx to 20xx-04-21</u> at the request of the issuing IECEx Certification Body (ExCB) following their consultation with the Applicant. This suspension does NOT affect products manufactured <u>prior to</u> 20xx-01-01 or <u>after</u> 20xx-04-21. Any product manufactured during the suspension period of 20xx-01-01 to 20xx-04-21 <u>cannot</u> be considered to be IECEx Certified under this Certificate. Any comment may be directed to the Applicant or ExCB.		excessive without good reason	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 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 QARs 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 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	

3.3 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 System will also provide reference as the Suspension of CoCs will not enable the QAR 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	Related	By Whom	Notes/Comments
	have been Suspended but the Suspension date has exceeded 1 year	Documents		
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	ExCB	CoCs cannot be suspended indefinitely, ExCB should have DMS to inform them that they need to take action
		Internal ExCB DMS and IECEx on-line admin tools		
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, 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 off out of date list, when all of the CoCs have been linked to it have been Cancelled	OD 025	Secretariat	

3.4 Scenario – Change of auditing and QAR 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 QARs and CoCs where a manufacturer changes ExCB resulting in a new issue QAR	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, then the new ExCB is to notify the Secretariat of the change with the new QAR number	OD 009 IECEx 02	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	Rules	New ExCB Secretariat ExMC CoC holders	Refer to 1.2.4 of this document to understand the auto-link feature of CoCs to QARs
	ExCBs who have issued CoCs to the now discontinued QAR are ultimately responsible to monitor and up-issue their CoCs to the new QAR			
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 has now been changed"		ExCB CoC holders	
4	The new issue of the CoC must link to the new QAR and the link to the old QAR 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. 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

	and Process Outcomes in	
Scenario #1	Action:	Comments:
ExCB 'A' issues QAR for an	ExCB 'A' issues Mfr with CoC	Typical basic application
applicant or manufacturer	Issue 0 that is linked to ExCB	
(Mfr)	'A' QAR	
then		
ExCB 'A' up- issues QAR for	The ExCB 'A' issued CoC	No need for ExCB 'A' to up-
Mfr	needs to be maintained as	issue CoC to Issue 1 as Issue 0
	current so the up-issued QAR	is automatically linked to up-
	is reviewed and registered by	issued QAR, so there has been
	ExCB 'A' and via registration	no change to the
	it is automatically linked to	product/manufacturer or
	the ExCB 'A' CoC Issue 0	other that may trigger a
		technical change requiring an
		up-issue of the CoC
subsequently		
The applicant or Mfr decides	ExCB 'A' notifies the Mfr that	Refer to section 1.1 step 7 of
not to proceed with the 3	products manufactured	this document to see
year re-assessment and	without a valid QAR are not	Cancellation note.
informs ExCB 'A'	IECEx Certified and the	cancenation note.
	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	
	Cocs and insert the Cancellation date in the	
	Equipment field of the CoC.	Comment:
SCENARIO #2	Action:	comment:
ExCB 'A' issues new QAR for	ExCB 'A' issues Mfr with CoC	
Mfr	Issue 0 that is linked to ExCB	
	'A' QAR	
	a prior to expiry of 3 year validity	
ExCB 'B' issues QAR for Mfr in	The ExCB 'A' issued CoC	Relationship of CoC with
response to request from Mfr	needs to be maintained as	other ExCB QAR
for change of auditing ExCB	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	
Subsequently – years later		
Mfr ceases production of item	ExCB 'B' as good practice, will	Although it is the
and informs ExCB 'B' that	insert a note in the QAR	responsibility of ExCB 'A' to
future Surveillance is no	stating that this QAR will no	monitor their issued CoCs, the
longer required	longer be supported. ExCB 'B'	Secretariat may also notify
	notifies Mfr and Secretariat	ExCB 'A' to assist and then
	that the CoC previously linked	acting under the instructions
	to this QAR will need to be	of ExCB 'B' Cancel CoC
	Cancelled.	

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