



# **IECEX 02 Scheme – Compliance Reviews**

**IECEX ExTAG Training -  
Assessors  
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# IECEX Equipment Scheme

This system provides an:

- IECEx Technical Report (ExTR)
- IECEx Quality Assessment Report (QAR)
- IECEx Certificate of Conformity (CoC)



- Who is responsible for the management of CoC?
- Who is responsible for the management and monitoring of CoCs linked to another ExCB QAR?
- Who is responsible for informing the ExCB that their CoC is linked to another ExCBs 'Out of date QAR'?



# ExCB Management of QARs

The IECEx Certified Equipment Scheme is a **Type 5** Product Certification Scheme (ISO/IEC 17067) that involves Surveillance including management system audits

- The requirements of ExCBs operating in the IECEx Certified Equipment Scheme are based on ISO/IEC 17065 that includes requirements for **Surveillance**
  - If the QAR summary has expired (validity date) then the manufacturer **cannot** claim that the product listed on the CoC linked to the expired QAR Summary are currently IECEx Certified (post validity date)
  - The manufacturer **MUST** remain under surveillance to maintain the IECEx Certificate of Conformity for the product/s being produced at the manufacturing facility



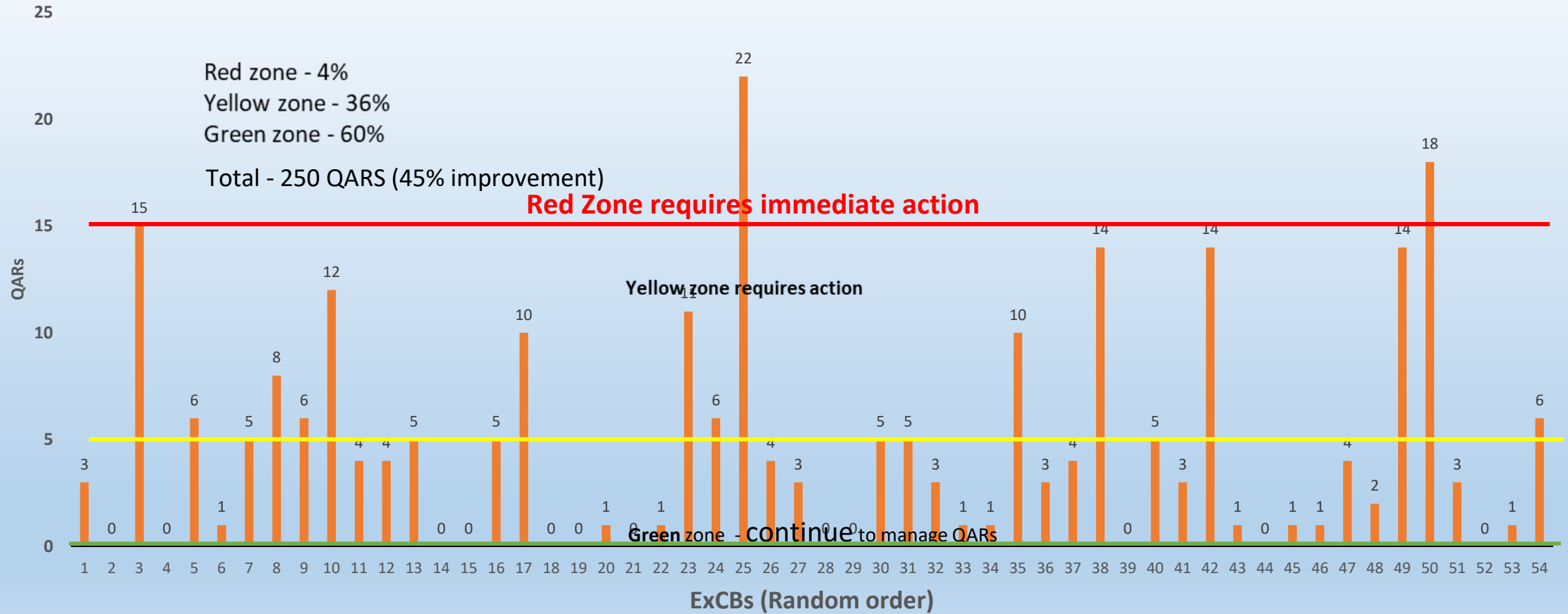
## ExCB Management of QARs – Con't

- The ExCB is to monitor their QARs and CoCs
  - The CoC is the responsibility of the issuing ExCB
  - **Even if linked to another ExCBs QAR**
- Assessors should review how ExCBs monitor/manage QARs and CoCs



# Out of Date QARs - Status

## ExCB Out of Date QARs 2019 YTD





# Key Issues Identified

- ExCBs Internal Processes - Lack of general understanding on the management of the IECEx online system in managing QARs and CoCs
  - The Secretariat reviewed internal ODs and ExTAG documents and have **published OD 250** to simplify and assist ExCBs (one document replaced 3)
  - **Training and guidance** to manage QARs and CoCs, always available
  - Secretariat encouraging **communication between the ExCBs** to resolve CoCs linked to other ExCBs QARs.
  - The Secretariat is working closely with Assessors on reviewing the IECEx online management of QARs, CoCs – **Desktop Review**
- **Auto-linking** of updated QARs to CoCs
- Change of auditing ExCB = Technical Change = CoC up-issue required
- Re-assessments and surveillance audits require emphasis by Assessors on the management of ExCBs internal processes for managing QARS, CoCs – The Secretariat now provides a DTR to the Assessor to highlight issues



## Key Issues Identified – Con't

- Auto linking is a great feature on the front end, BUT on the back end.....
  - Analysis has shown that some ExCBs do not track their CoCs linked to other ExCB QARs
  - The auto link feature is not a set and forget.....CoCs issued by an ExCB are the responsibility of ExCB and must remain linked to a valid QAR to holds it Current status.
  - CoCs that are no longer supported by a valid QAR become orphans and are no longer valid, requiring action (Up-issue, Suspension, Cancellation) **refer to OD 209**
  - Orphan CoCs for ExCB 1 because ExCB 2 is not managing their QAR. Who's fault?
  - ExCBs having to contact their clients and to Suspend the CoCs until the manufacturer is back under Surveillance or a new QAR is issued
  - Manufacturers continuing to produce products and unknowingly thinking their products still hold an IECEx Certificate of Conformity



# Out of Date QARs

- Why do QARs go out of date?
  - Surveillance or re-assessment no longer conducted or delayed by ExCB (internal process non existent or not used) **Assessor to Review CB internal process**
  - Manufacturer may discontinue products **(refer to OD 209 about Cancellation)**
  - Manufacturer selects a different ExCB to conduct the re-assessment, a new QAR is then generated and not all CoCs are up-issued to new QAR
  - Manufacturer does not respond to ExCB to schedule surveillance or re-assessment **(refer to OD 209 about Suspension/Cancellation)**
- Assessors should ask the ExCB ‘How many out of date QARs do you have and how many CoCs do you have linked to out of date QARs, and why these have lapsed?’
- Assessors should ask the ExCB ‘How do they track/manage their CoCs and monitor their QARs’?





# Out of Date QARs

- What happens then?
  - Update the QAR.....auto-linking maintains CoC
  - The CoC may need to be up-issued to a new valid QAR
  - The CoC may need to be **Cancelled** with the following note inserted in the CoC

*NOTE: This certificate was CANCELLED on 18<sup>th</sup> February 2019 at the request of the Manufacturer following their consultation with the IECEx Certification Body (ExCB). 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.*



# Out of Date QARs

- What happens then?

- The CoC may need to be **Suspended** with the following note inserted in the CoC

*NOTE: This certificate was SUSPENDED on 18<sup>th</sup> February 2019 at the request of the Manufacturer following their consultation with the issuing IECEx Certification Body (ExCB). 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.*

REMINDER: the need to manage Suspended Certificates...

Some ExCBs have publicly visible IECEx Certificates that have been SUSPENDED for over **5 years**. Reducing the number of Suspended CoCs in the system will be the next focus by the IECEx Secretariat Compliance Manager. The Secretariat can provide a report of these CoCs and assist with cancellations on request.



# Out of Date QARs - Recap

*It is recognised that some QARs will never be updated. The reasons for this can include:*

- 1. The linked CoC has been cancelled.*
- 2. Another ExCB has taken over the surveillance of the manufacturer.*
- 3. The ExCB has raised another QAR to supersede the original QAR.*

*In such cases ExCBs are requested to advise the IECEx Secretariat and if it can be shown that the QAR will never be updated and that all Current CoCs linked to the now out of date QAR have been updated and linked to a valid QAR, the Secretariat can remove the QAR from the ExCBs “QAR, out of date” list.*

***MORE INFORMATION IN IECEx OD 250***



# DTR – Secretariat Desktop Review

The secretariat has developed the DTR to assist the Assessor when conducting a Surveillance or Re-Assessment audit of an ExCB.

- *The DTR focuses on the **management of the IECEx on-line system**, including :*
  - *Review of the current and previous years generation of CoCs, QARs and ExTRs, including the total number of each generated*
  - *Conclusions based on Secretariat 15% on-line audit review*
  - *Number of out of date QARs*
  - *Number of CoCs linked to out of date QARs*
  - *Any actions from above*
  - *General housekeeping of the IECEx on-line system (as per clause 3.9 OD 003-2)*
- *An Executive Summary of ExTL, ATF, and ExTL applicants on participation in the **Proficiency Testing Scheme** and possible actions, but not divulging ExCB results which are confidential as per OD 202*

➤ ***Operational Document IECEx OD 209***



Requirements and Guidelines for the Suspension, Cancellation and Reinstatement of Certificates of Conformity

➤ ***Operational Document IECEx OD 250***



Guidance on the management of IECEx Quality Assessment Reports

*[NOTE: this replaces ExTAG/164/INF and ExTAG/245/INF]*

***Operational Document IECEx OD 009***

IECEx Certified Equipment Scheme, Procedures for the Issuing of IECEx Certificates of Conformity, IECEx Test Reports and IECEx Quality Assessment Reports

➤ ***Operational Document IECEx OD 011 (Series)***



Guidance on Use of the IECEx Internet based “On-Line” Certificate of Conformity System



# IECEx Compliance Issues 02 Scheme

