Compliance Review of ExCBs Management of CoC and QARs

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Management of IECEx QARs and CoCs

Why is the management of IECEx QARs and CoCs so important and how can we ensure the integrity and confidence of the IECEx Schemes are maintained?

The IECEx Certified Equipment Scheme is a Type 5 Product Certification Scheme modelled on (ISO/IEC 17067) that requires Surveillance and management system audits of manufacturers*.

- IECEx 02 Rules of Procedure for the IECEx Certified Equipment Scheme details requirements for Surveillance including frequency in Section 8.3.7.
  - If the QAR summary has expired (past its validity date) then **the manufacturer cannot claim that the product listed holds a valid IECEx CoC**
  - The manufacturer MUST remain under surveillance to maintain the IECEx Certificate of Conformity for the product/s being produced at the manufacturing facility
- IECEx Certificates linked to 'out of date' QARs need to be dealt with and may include
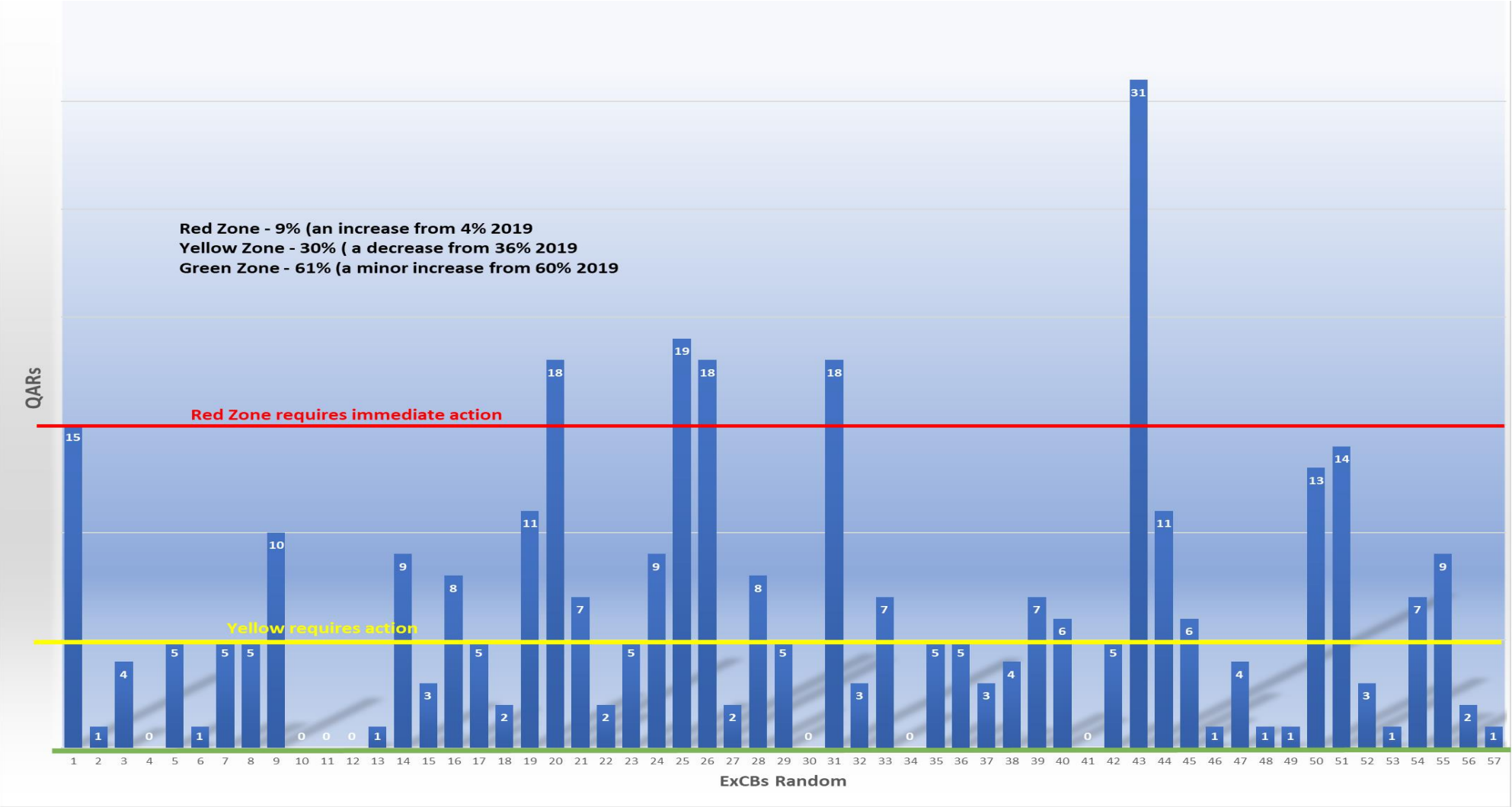 - Organize manufacturer surveillance audit
  - Up-issue to valid QAR
  - Suspension until manufacturer is back under surveillance
  - Cancellation of the CoC

The IECEx OCS back office reports highlight that many ExCBs (est. 20%) do a poor job in managing their CoCs and QARs
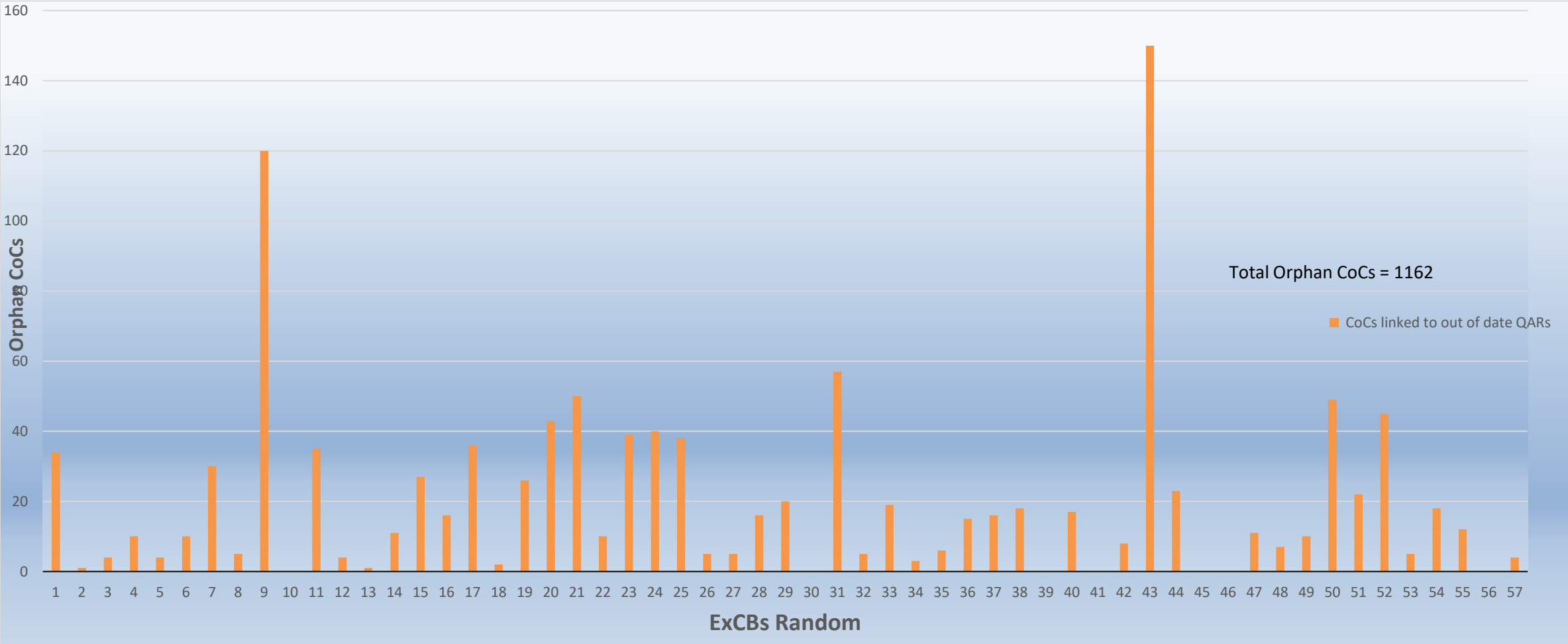
*the certified service facilities scheme IECEx 03 also requires surveillance audits.
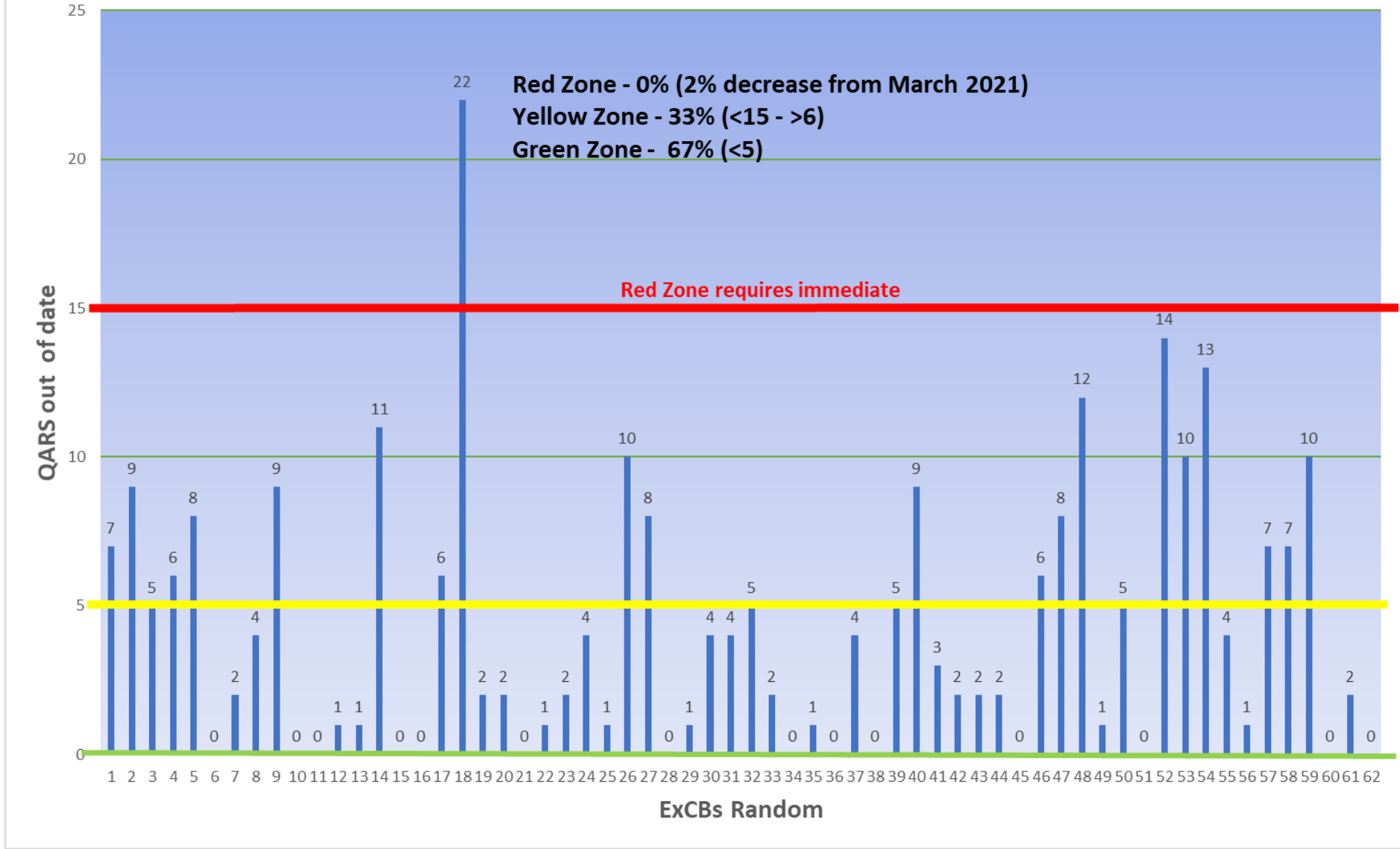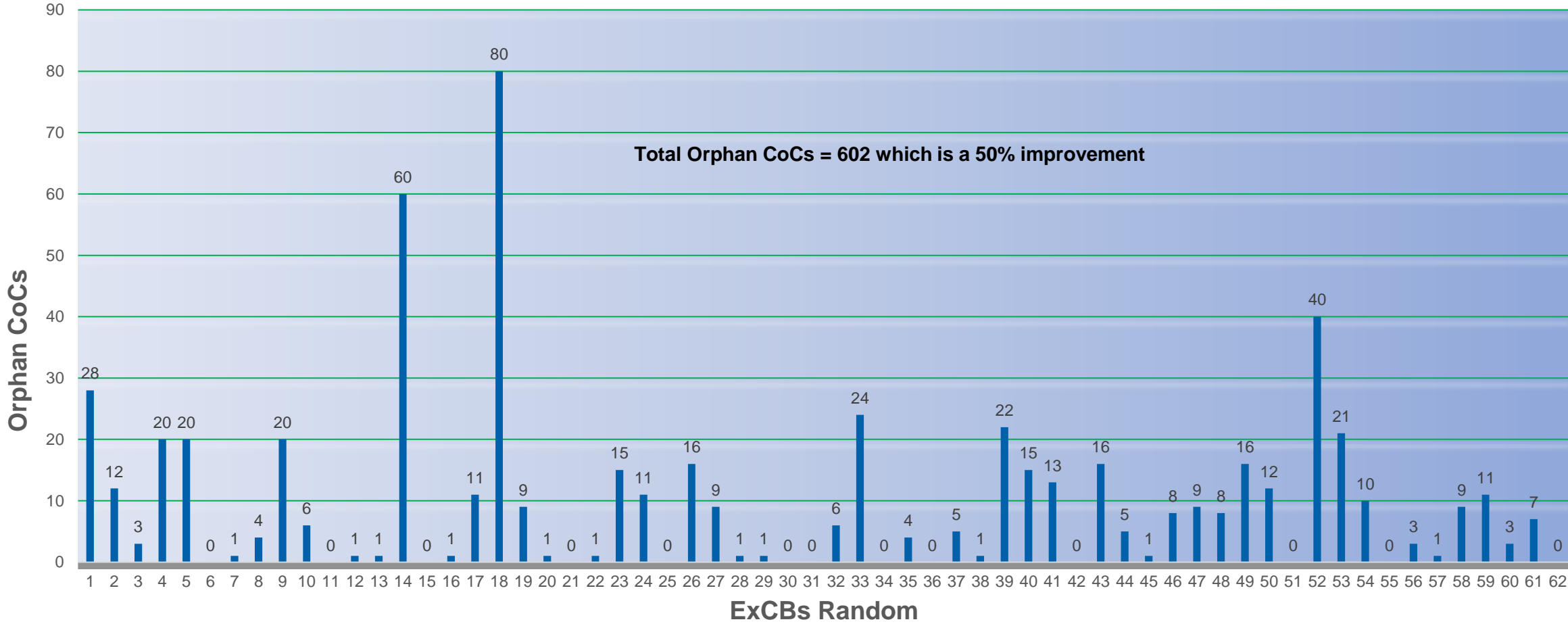
ExCB Out of Date QARs 2020 (Sept)

CoCs linked to out of date QARs 2020 (Sept YTD)

Total Orphan CoCs = 1162

CoCs linked to out of date QARs

Orphan CoCs

ExCBs Random

ExCB – Out of date QAR 2021 (YTD Sept)

Red Zone - 0% (2% decrease from March 2021)
Yellow Zone - 33% (<15 - >6)
Green Zone - 67% (<5)

Red Zone requires immediate

COCs linked to out of date QARs 2021 (YTD Sept)

Total Orphan CoCs = 602 which is a 50% improvement

Y-axis: Orphan CoCs
X-axis: ExCBs Random

ExCB – Out of Date QARs 2022 (April)

CoCs linked to out of date QARs 2022 (April)

Total Orphan CoCs = 572 which is a 5% improvement from 2021

Will focus on the ExCBs with more than 25 CoCs linked to out of date QARs as the new benchmark

Orphan CoCs (y-axis)

ExCBs Random (x-axis)
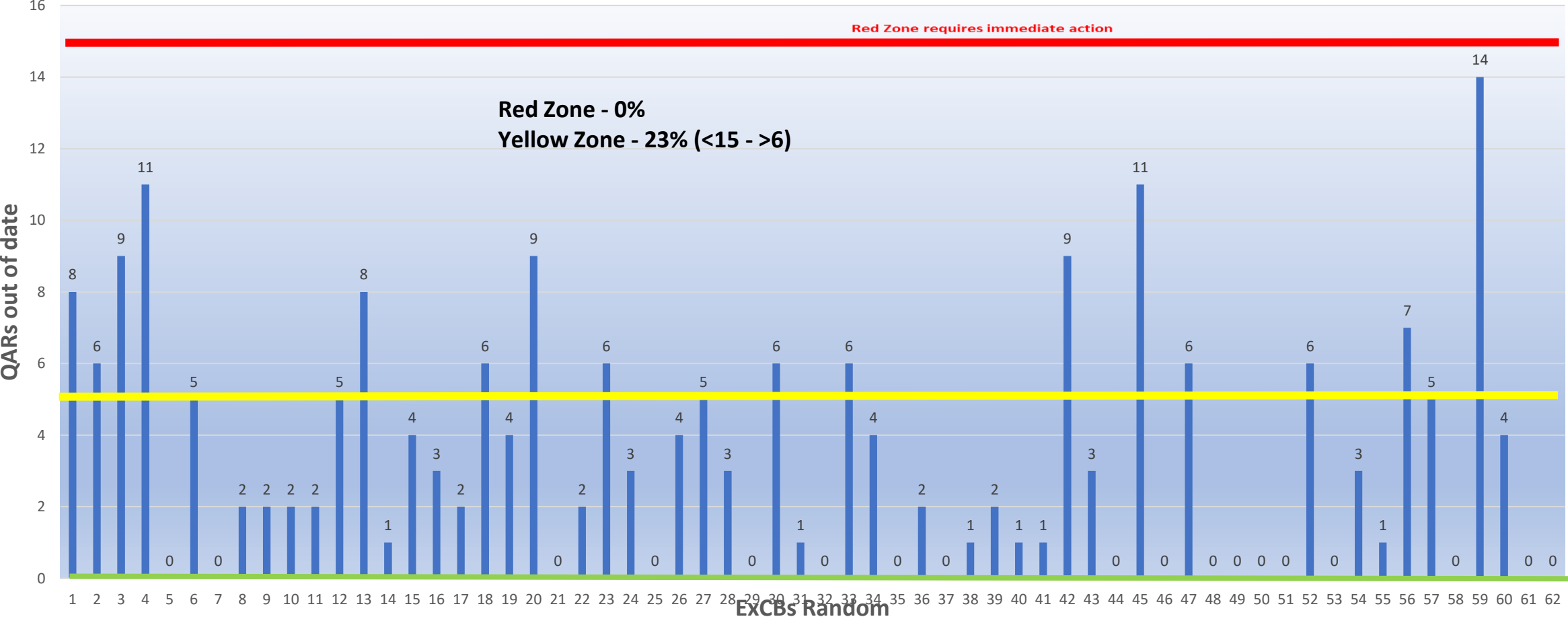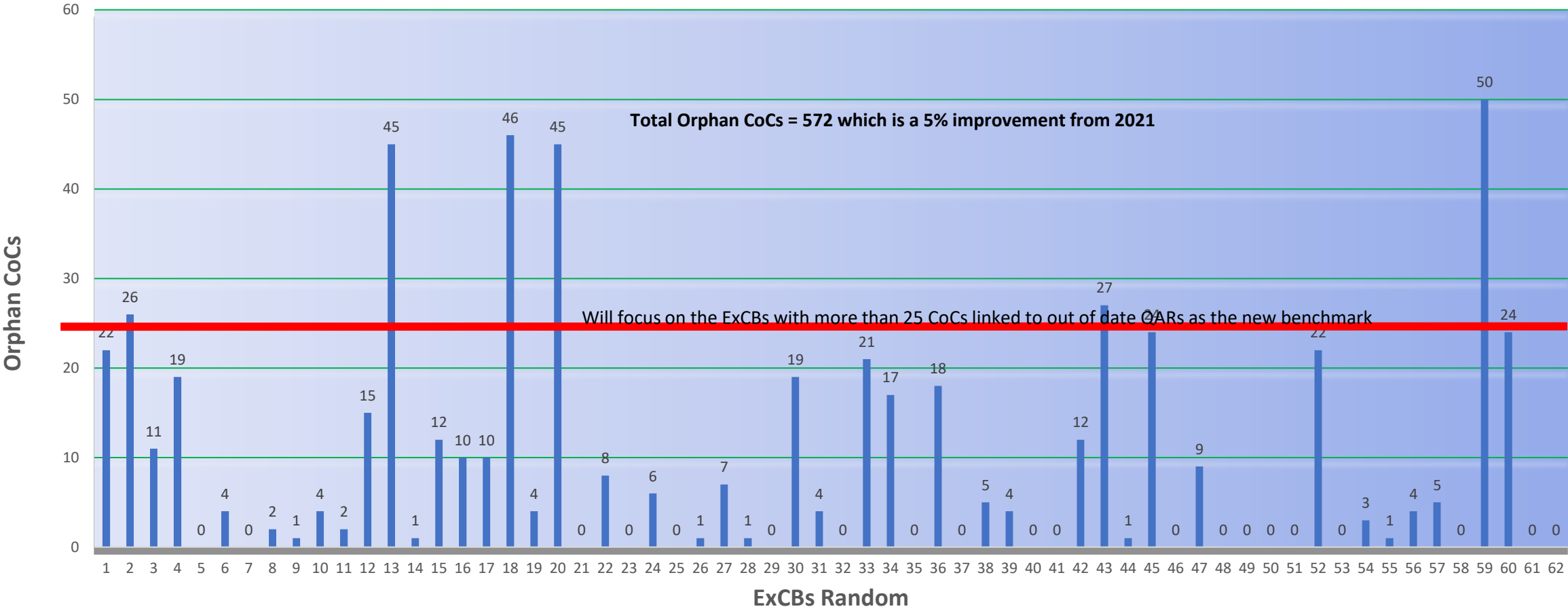
Trends
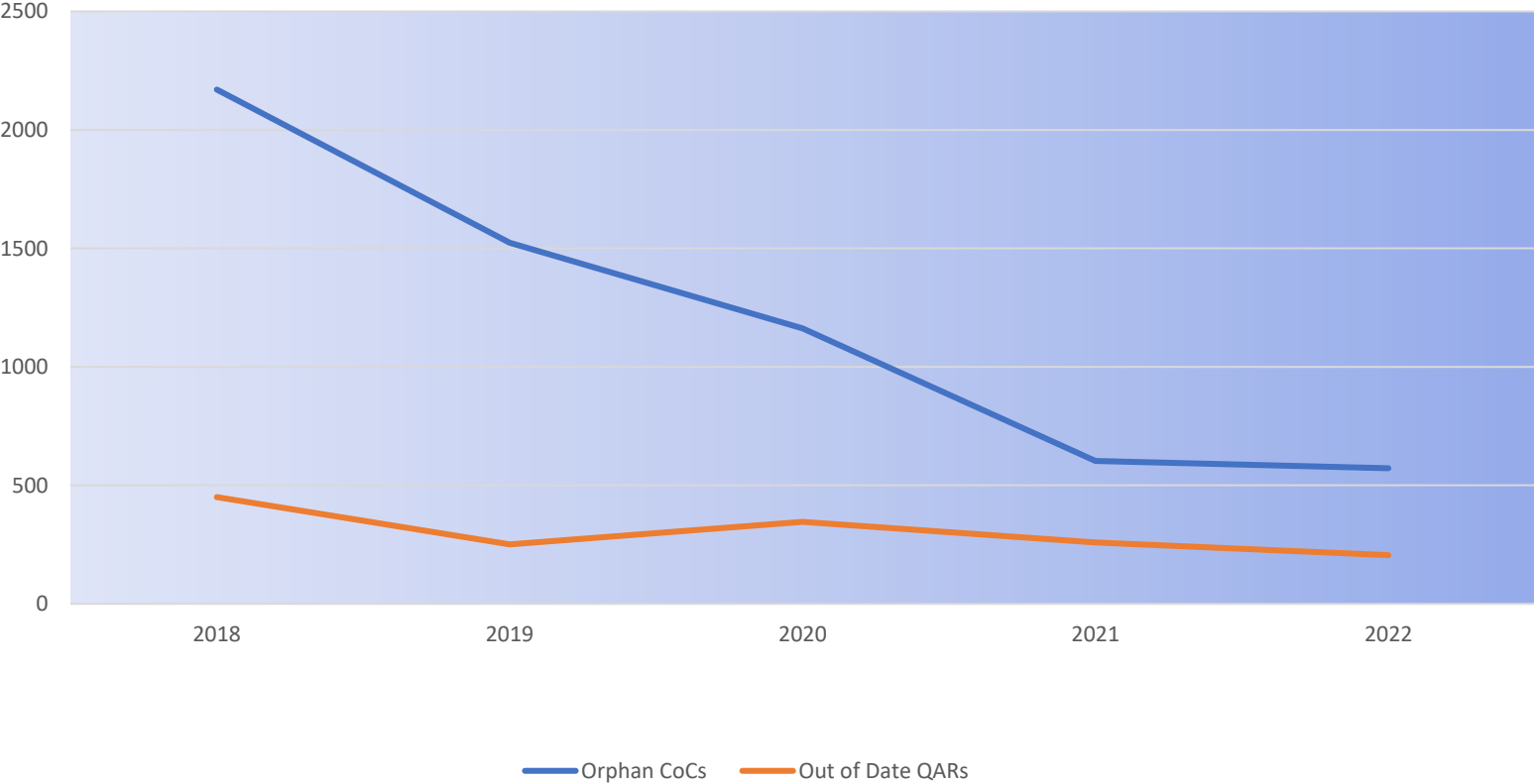
Why do QARs go out of date and what happens to the CoCs?

- Surveillance or re-assessment no longer conducted or delayed by ExCB
- Manufacturer may discontinue products (refer to OD 209 about Cancellation)
- Manufacturer does not respond to ExCB to schedule surveillance or re-assessment (refer to OD 209 and OD 250 about Suspension/Cancellation)
- Manufacturer selects a different ExCB to conduct its IECEx assessment audits, and a new QAR is then generated and not all CoCs are up-issued to new QAR (refer to OD 250 about ExCB actions required)
  - May result in numerous CoCs referencing an invalid out of date QAR.

IECEx OCS Back Office - Reports

- ExCBs can access reports in the IECEx OCS back office that:
  - Provide a list of their QARs 'out of date'
  - Provide a list of CoCs issued by the ExCB that are linked to their QARs and other ExCBs QARs that are 'out of date'
  - These are useful tools for the CB, but in reality as per ISO/IEC 17065 their management system should demonstrate internal tools to manage CoCs issued
  - The Secretariat also provides this information to the Assessor as part of the Desktop Review (DTR) prior to a mid-term or re-assessment
  - The Secretariat has put together an instructional screen sharing video on how ExCBs can access the OCS Back Office – Reports. Knowing how to access these reports is also useful for the Assessor. Link below.

    https://www.iecex.com/assets/Uploads/Video/IECEx-OCS-backoffice-Reports-out-of-date.mp4

Key challenges

- When a CB issues a CoC linked to their QAR, the management of CoCs are straight forward (less of an issue)
- When a CB issues a CoC and they link it to another CBs QAR, then the management of CoCs may be poorly maintained
  - The interdependence of CBs on each other becomes evident
  - The management of the CoCs becomes challenging for CBs
  - The management of the CoCs may be challenging for the manufacturer

- Manufacturers may be unaware of the consequences when they change CB for QAR audits
  - May result in CoCs not being up-issued to the new QAR, or taking months and sometime years to achieve this
  - Should there be a clause in all CBs T&C that if a manufacturer changes CB to continue QAR surveillance, then they must instruct the other CBs to ensure the CoCs previously linked to the old QAR are up-issued to the new QAR (IECEx technical change of CoC) and are aware of the cost implications?
- Assessors ask CBs during the mid-term assessment if they have any CoCs linked to out of date QARs, then have them log into the IECEx back office - Reports and show the assessor if and how many CoCs they have and how many are linked to other CB QARs 'out of date'. If the number is excessive then this is recorded as an action.

Conclusion

- Assessors requested to put more emphasis during the mid-term surveillance or re-assessment to ensure ExCBs are managing their CoCs and QARs

- Secretariat to review IT processes to continue to evolve the IECEx OCS system so the management of CoCs and QARs are more easily managed

- Secretariat compliance role continues to monitor and assist ExCBs ensuring good house keeping of the IECEx OCS

- Hold ExCBs accountable for not meeting a high standard of maintaining the IECEx OCS (CoCs and QARs)

Thank you