INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)

To: Members of the IECEx Management Committee, ExMC

Title: Supplementary Report from the Convener of ExMC WG5, Mr Roy Teather.

<u>Introduction</u>

This document contains supplementary information presented by the Convener of the ExMC WG5 "Manufacturers Quality System Requirements" as presented during the 2020 ExMC Remote meeting.

This document is issued as a Tabled Document, (previously referred to as Green Paper) and is supplementary to the WG5 Report, ExMC/1609/R as tabled for the IECEx Management Committee, ExMC October 2020 meeting under agenda item 8.6 re Agenda ExMC/1614A/DA.

This document is issued for information.

Address:	Contact Details:
Level 33, Australia Square	**Tel: +61 2 46 28 4690**
264 George Street	**Fax: +61 2 46 27 5285**
Sydney NSW 2000	**e-mail: info@iecex.com**
Australia	**http://www.iecex.com**

- The importance of an effective ExQMS cannot be understated, it was once described as the "Crown Jewels" of the IECEx scheme!

- It is currently the only effective control we have to ensure manufacturers ship IECEx compliant equipment and associated user instructions.

- This means we must pay special attention to the training and the performance of auditors and the technical review process performed by the responsible ExCB.

- During the 2020 IECEx Executive and Operational meetings this year we accepted a proposal to update OD-60 to better define the process for remote auditing and allow it to be used for all QAR audits.

- Remote QAR auditing is working in an acceptable manner during this unprecedented pandemic but was always meant to be a temporary option.

- COVID will eventually go away and we should revert to performing QAR audits onsite as soon as possible. There will be some push back from manufacturers, but we are auditing the compliance of critical safety equipment which tends to be a "hand-on" process at multiple levels.

- Also discussed was reformatting the online QAR to allow for more information when multiple sites were listed on the QAR. This remains a work in progress,

QAR Ref. No.:	**NO/PRE/QAR15.0018/02**		Page	1 of ?
QAR Free Ref. No.:	**PRJC-595906-2019-PRC-USA**		Status	*Issued, ~~Expired~~, Cancelled*
Details of change:	*Recertification, Address Change, New Site Added*		Issue Date	YYYY-MM-DD
Audit Schedule	Yearly ☐ 3 Months ☐ Unscheduled ☐		Expiry Date	YYYY-MM-DD

Issuing ExCB:	**PRE - DNV GL Presafe AS**
Manufacturer:	**Emerson - Rosemount, Micro Motion Inc.** **12001 Technology Drive Eden Prairie, MN 55344** **United States of America**
Location of Manufacturer	**United States of America**
Product information:	**Flow Measurement products and systems**
Types of protection:	**Ex d, e, i, n and t.**

Allow as many as needed

Sites Audited:	Manufacturing or Production Sites	Audit Type	Audit report No	Rev.	Audit Date
	Emerson - Rosemount, Micro Motion Inc. **12001 Technology Drive Eden Prairie, MN 55344 United States of America**	Recertification Surveillance 1 Surveillance 2	 *Auto populate from Audit Schedule selection*		 Circa YYYY-MM-DD *Auto populate from Yearly Audit Schedule selection*
	Micro Motion **7070 Winchester Circle Boulder, Co. 80301 United States of America**	Recertification Surveillance 1 Surveillance 2	 *Auto populate from Audit Schedule selection*		 Circa YYYY-MM-DD *Auto populate from Yearly Audit Schedule selection*
	Emerson Process Management Flow B.V **Neonstraat 1** **6718 WX Ede** **Netherlands**	Recertification Surveillance 1 Surveillance 2	 *Auto populate from Audit Schedule selection*		 Circa YYYY-MM-DD *Auto populate from Yearly Audit Schedule selection*

The current linking of a QAR to a C of C can be a burden for the ExCB issuing the C of C as they have to police out of date QAR's, add or subtract QAR's caused by company name changes, scope changes, & new manufacturing sites.

- Recently I "retired" two QARs as the manufacturing sites were being added to a master multi-site QAR at recertification. I added the two sites onto the master QAR but forgot to do anything with the two "retired" QARs as all their C of C's were already listed on the master QAR. Soon emails were arriving stating the two "retired" QARs were no longer valid. Same situation would have happened if the manufacturer had obtained a replacement QAR from another ExCB.

- Current solution is to extend the "retired QAR's" for a further 3 years and add comments that this QAR is now obsolete. A further comment provides the new QAR number and states that any new C of C's should only be added to the new QAR.

- Would it be better if the "retired" QAR could be set to "retired" by the ExCB and this would automatically send an email to the affected ExCB's to move their C of C's to the new valid QAR; the "retired" QAR could retain its original expiry (retirement) date.
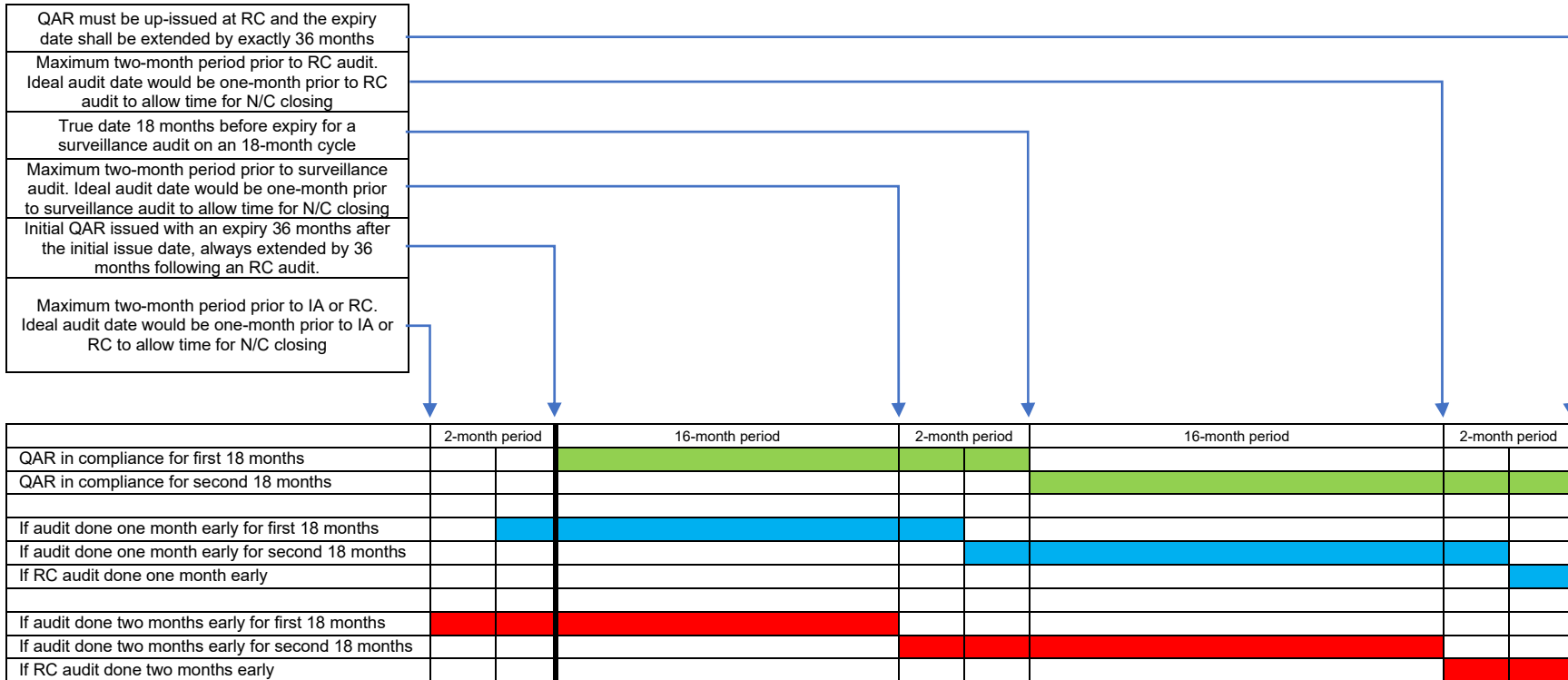
- Is an ISO/IEC 80079-34 audit every 18 months appropriate, ISO 9001 audits are yearly, is that more appropriate?

- Scheduling conflicts can lead to a gap of 20 months or longer between audits, is that acceptable?

- We discussed this at the IECEx Executive and Operational meetings in May 2020 and a solution was proposed and received a positive response but is still a work in progress.

- The purpose of the following flow diagram is to show the relationship between audits on an 18-monthly audit frequency, the same logic can be used for 12 monthly audits. It is based on the expiry date being exactly 36 months after the issue date of the initial QAR with the date being indexed a further 36 months following each recertification audit.

- For a 12-monthly audit cycle, if you always do your audits 2 month early at every audit, within a day or so you will be on a 12-monthly cycle.

- For a 12-monthly audit cycle, if you always do your audits 1 month early at every audit, within a day or so you will be on a 12-monthly cycle.

WG05, 2020 MC Report on Manufacturers Ex QMS

QAR must be up-issued at RC and the expiry date shall be extended by exactly 36 months

Maximum two-month period prior to RC audit. Ideal audit date would be one-month prior to RC audit to allow time for N/C closing

True date 18 months before expiry for a surveillance audit on an 18-month cycle

Maximum two-month period prior to surveillance audit. Ideal audit date would be one-month prior to surveillance audit to allow time for N/C closing

Initial QAR issued with an expiry 36 months after the initial issue date, always extended by 36 months following an RC audit.

Maximum two-month period prior to IA or RC. Ideal audit date would be one-month prior to IA or RC to allow time for N/C closing

	2-month period	16-month period	2-month period	16-month period	2-month period
QAR in compliance for first 18 months		green			
QAR in compliance for second 18 months				green	green
If audit done one month early for first 18 months	blue	blue			
If audit done one month early for second 18 months			blue	blue	blue
If RC audit done one month early					blue
If audit done two months early for first 18 months	red	red			
If audit done two months early for second 18 months			red	red	
If RC audit done two months early					red

Green is what we are trying to achieve, but that is an impossible requirement as that audit would have to be done and completed on the day the QAR was issued and exactly on 18 months thereafter.

Blue color is achievable if we accept that a month early, plus or minus, is OK if it is repeated for every audit.

Red is only acceptable if the ExCB accepts that it can never be more than two months early and this early audit is repeated at all future audits.

Important considerations:

Following satisfactory closing of any initial audit non-conformities the date of issue plus 36 months shall be the expiry date entered on the issue 0 QAR. Thence every three years thereafter the expiry date will shall be updated by 36 months, following a satisfactory recertification audit.

Another important reason for this flexible approach that many companies have five or more manufacturing sites on a single QAR that need to be performed within a 4 to 6 week period in multiple countries.