

ExTAG/164/Inf July 2009

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

REMINDER NOTICE TO ALL EXCBS

Title: Scheduling of Surveillance Assessments + Re-Assessments for the IECEx 02 Certified Equipment Scheme.

Circulation: ExTAG Members, IECEx Officers

IECEX SECRETARIAT NOTICE

As part of the IECEx Secretariat's on-going surveillance checking of the IECEx On-Line Certificate of Conformity System and due to recent inquiries from ExCBs, the Secretariat draws **ALL ExCBs ATTENTION** to the requirements of IECEx Operational Document OD 025, regarding the need to conduct Surveillance assessments of manufacturers within the 3 year validity period of IECEx Quality Assessment Reports (QARs).

OD 025 Clause 5.2.2.2.2 states:

5.2.2.2.2 Surveillance Assessments

Surveillance assessments shall be carried out as follows:-

a) For manufacturers without a certified ISO 9001:2000 Quality System, surveillance audits should be conducted every 12 months.

b) Manufacturers with a Qualified ISO 9001:2000 Quality System, surveillance audits should be carried out every 18 months.

Additional surveillance / assessments may be conducted at the discretion of the IECEx Certification Body based on the manufacturer's performance and results of previous surveillance / audit results. It is recommended that the time frame for audit intervals begin when the initial assessment report is issued.

The above has raised the following two items for which the Secretariat, in conjunction with the IECEx Officers wish to remind all ExCBs:

- 1. The need to conduct surveillance assessments and have the QAR reports 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 and hence new QAR



These two items are described in detail below.

ITEM 1: The need to conduct surveillance assessments and have the QAR reports from such registered via the IECEx on-Line system

Secretariat Note:

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 reports such as surveillance assessment reports can 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 Edition 4.2 available from http://www.iecex.com/operational.htm provides clear instructions to ExCBs on how to register QARs, including reports from Surveuillance visits.

ITEM 2: The process for handling the situation where a manufacturer decides to change ExCB for their site assessments and hence new QAR

Secretariat Note:

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 and QAR be issued, where a QAR may not have already been issued.

The QAR of course 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 is to issue 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 Edition 4.2

The QAR is valid according to the 3 year period as identified on the QAR on-line register but must of course have a surveillance audit at least once in the 3 years, according to OD 025 Clause 5.2.2.2.

After the 3 year QAR validity period, the ExCB that issued the CoC must ensure that the manufacturer has renewed the QAR or obtains a new QAR from another ExCB.

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 when QARs associated with their issued CoCs are to be renewed.



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If the manufacturer does not renew 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 so that the ExCB that is to renew the QAR can clearly see all CoCs listed as linked to their QAR, (as shown on the QAR page of the IECEx On-Line system). These CoCs must be covered during the ExCBs re-assessment and surveillance assessment visits.

So Practically this means that the ExCB that issued the QAR and who is now to re-issue the QAR simply opens the old QAR summary (on the IECEx website using their password) and then selects "New Version" this will then create a new version of the same QAR but the number will be increased by/01 or /02 whichever is the next version number. This way there will be automatic tracking back to the original QAR. See Section 4 of OD 011 Part 2 which can be downloaded from the Operational Documents area of the IECEx website at http://www.iecex.com/operational.htm

Because of this auto tracking of QARs there is NO NEED for the ExCB that issued the CoC to now issue a new Issue CoC. So no adjustment to the existing CoC is necessary.

However, if after the 3 year QAR validity, the manufacturer chooses to use a different ExCB to do the re-assessment and issue a new QAR then the ExCB that issued the CoC MUST be notified and the issued CoC must now be up issued to the next Issue Number. The details "Details of Certificate Changes" 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".

This new issue of the CoC must link to the new QAR.

When changing ExCBs for QARs this is considered a technical change to the certification and for transparency and confidence of industry and regulators the ExCB that issued the CoC must be seen as being aware and in control of the Certification.

We ask all ExCBs to ensure that all personnel within your organisation, associated with IECEx operations and planning are fully aware of the items raised in this Notice.

The Secretariat is continuing with its checking of On-Line CoCs and related QARs and may contact ExCBs where it is not clear that surveillance assessments are being recorded.

IECEx Secretariat On behalf of Michel Brenon, - Secretary ExTAG

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