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

### Title: Report from Dr Jim Munro the Convener of ExAG *– IECEx Assessment Group*

To: Members of the IECEx Management Committee, ExMC

**INTRODUCTION**

This document contains a report from the ExAG Convener, Dr Jim Munro, to the 2020 ExMC online meeting. The meeting will be asked to consider the three Recommendations contained within this report under ExMC Agenda item 7, (ExMC/1614A/DA).

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Report of ExAG – IECEx Assessment Group

# Scope

This ExAG report is for the 12 months since the September 2019 ExMC meeting. It provides a summary of the online meeting held in June 2020 and other actions that have occurred, including appointment of assessments.

# Background to the establishment of ExAG

At the ExMC meeting in Cannes, France 2018, the meeting approved the proposed transformation of ExMC WG4 to the new ExAG (IECEx Assessment Group). The proposal for establishment of the ExAG was considered and approved by CAB, together with the rules document IECEx 06. The following are extracts from IECEx 06.

**Terms of Reference:**

To act as the dedicated IECEx maintenance and consultative group for matters relating to the IECEx Assessment of ExCBs and ExTLs across all IECEx Schemes.

**Responsibilities:**

Responsibilities as directed by the ExMC include but are not limited to the following:

* Ensure on-going alignment with the Peer Assessment fundamentals of CAB (reference is CAB Policy documents, eg IEC CAB-P02)
* Develop and maintain criteria for the qualification of Assessors and Lead Assessors in consultation with the IECEx Scheme Committees
* Review and approval of assessor applications for all schemes, with newly appointed assessors to be reported to ExMC for noting
* Periodic review of existing pool of assessors for all IECEx Schemes
* Maintenance of Assessment Procedures for all IECEx Schemes.
* Maintenance of report forms and records used in assessments
* Maintenance of IECEx Assessors' Guide(s)
* Development and delivery of assessor training
* Provide a consultative forum for recommendations on issues found during assessments
* Development of common interpretations, for example for ISO/IEC 17025
* Maintenance of checklists such as those for ISO/IEC 17024, 17025 and 17065.

Annex A shows the membership of ExAG.

# First meeting of ExAG

The first meeting of ExAG took place in Singapore on Thursday, 9 May 2019. A report of this meeting was provided the September 2019 meeting of ExMC. The following are the outcomes of the ExMC consideration of ExAG recommendations to that meeting:

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| **Recommendation 1:**That ExMC approves the composition of ExAG as shown in Annex A of this report. | Approved |
| **Recommendation 2:**That ExMC approves the implementation of a formal voting system for acceptance of assessor applications by ExAG members.  | Approved  |
| **Recommendation 3:**That ExMC approves that no changes to IECEx06 (formerly EXMC/1376/DV) be recommended to CAB at this time. | Approved |
| **Recommendation 4:**That ExMC provides initial feedback on the proposal to provide further guidance on the use of witnessed assessments for Schemes IECEx02 and 03.  | Noted the current work covered by Recommendation #4 |
| **Recommendation 5:**That ExMC provides initial feedback and in principle support on the proposed implementation of an initial one-off one-year surveillance from date of acceptance for newly accepted ExCBs/ExTLs holding national accreditation, noting the final proposal will come to ExMC for approval as a revision to OD 003-2. | Noted current considerations within ExAG regarding Recommendation #5 and supported further development in this direction |

# Second meeting of ExAG

The second meeting of ExAG was help by Webinar on 15 May 2020. All except one member of ExAG attended the meeting. The major outcomes from the meeting are addressed below.

## Terms of reference

A minor potential change to the Terms of Reference was discussed. However, it was decided to collect a few potential changes before proposing a change to IECEx 06 since any changes will need to be approved by CAB.

## Witnessing of assessments by ExCBs

The witnessing of assessments by ExCBs, which was raised at the last ExMC meeting, was further developed and requirements included in appropriate documents. See Annex B for details.

## Proposed implementation of an initial one-off one-year surveillance from date of acceptance for newly accepted ExCBs/ExTLs holding national accreditation

The ExAG further developed the proposal regarding proposed implementation of an initial one-off one-year surveillance from date of acceptance for newly accepted ExCBs/ExTLs holding national accreditation. Requirements have been included in appropriate documentation. This topic was raised at the last ExMC meeting. See Annex C for details.

NOTE This topic is only applicable to ExCBs/ExTLs with accreditation, as those without accreditation would be subject to an annual surveillance visit.

## Revision of documents

### Revision of F-003 IECEx Assessment Report Form

The following major changes have been made to the report form for ExCBs and ExTLs, F-003:

* It now includes all IECEx Schemes
* It includes additional guidance to assessors and bodies being assessed
* The scope of standards for the IECEx 02 Scheme is now in Appendix A. This will allow the scope to be more readily kept up to date, and the same approach can be used for initial application forms for ExCBs, ExTLs and ATFs. It is proposed that ExAG be authorised to keep this Annex up to date without the need for ExMC approval.

**Recommendation 1:**

That ExMC approve the latest draft revisions of F-003 and to authorise ExAG to keep Annex A up to date with seeking ExMC approval.

### Revision of other documents

The following documents have been revised and are presented to ExMC for approval:

1. Revision of F-004 site assessment report form – brought into line with F-003 to cover all schemes
2. Revision of IECEx OD 003-1 Appointment and surveillance of assessors for IECEx certification schemes
3. Revision of IECEx OD 003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
4. Revision of IECEx F-007 Assessor Application Form
5. Revision of IECEx OD 032 Guidelines and Information for IECEx Assessments

**Recommendation 2:**

That ExMC approve the latest draft revisions of the following documents:

F-004

OD 003-1

OD 003-2

F-007

OD 032

## Others matters discussed by ExAG

The following additional matters were discussed by ExAG.

* Provision of suitably qualified IECEx peer assessors
* Training
* Management of extraordinary circumstances – members reviewed and proposed changes to OD 060 *Management of Extraordinary Circumstances*

Additional agenda items that were not covered have been held over for a later meeting.

# Appointment of new assessors

As noted earlier in the responsibilities, ExAG now approves assessors. Following the approval from the last ExMC, a formal system of online voting by ExTAG members was developed by the IECEx Secretariat in conjunction with the IEC IT staff. Three applicants were received for approval in the past 12 months and these have been appointed based on positive votes from ExAG using the new online voting system.

ExMC is advised of following newly appointed assessors for noting:

* Marco Erdhuizen (NL) – appointed for IECEx 03 Service facilities Scheme and IECEx 05 Certification of Personnel Competencies (CoPC).
* Kavinder Dhillon (CA) – appointed for IECEx 02 Certified Equipment Scheme for both ExCB and ExTL assessments
* Klauspeter Graffi (DE) – appointed for IECEx 02 Certified Equipment Scheme for both ExCB and ExTL assessments, and also as an assessor for IECEx 05 Certification of Personnel Competencies (CoPC).

**Recommendation 3**

It is recommended that ExMC note that appointment of the three assessors since the last ExMC meeting.

# Next Meeting of ExAG

It is anticipated that the ExAG will meet at the next IECEx operational meetings, but may hold an online meeting before then.

# Conclusion

The second meeting of ExAG focussed on the target outcomes of:

* Addressing actions from last ExMC, witnessing of assessment by ExCBs and initial one year surveillance for accepted bodies.
* Revision of documents relevant to assessments for all schemes.

I would like to take this opportunity to thank the deputy convenor of ExAG, Katy Holdredge and the members of ExAG for their support.

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Dr Jim Munro

Convenor of ExAG

6 September 2020

1. Membership of ExAG
	1. Convenors:

Dr Jim Munro (Convenor)

Ms Katy Holdredge (Deputy Convenor)

* 1. Secretariat:

Mr Chris Agius

* 1. Lead assessors (in addition to those above who are all lead assessors):

Mr Ajay Maira

Mr Ralph Wigg

Mr Heinz Berger

Prof Xu Jianping

Mr Thierry Houeix

Mr Bernard Piquette

Mr Ronald Webb

* 1. Other members:

Dr Alexander Zalogin

Mr Michel Brénon

Mr Klauspeter Graffi

Mr John Allen

Mr Julien Gauthier

Ms Yulia Tikhonenko

TOTAL: 16

1. Witnessing of assessments by ExCBs
	1. General

The subject was discussed at the 2019 ExMC and feedback taken into account.

ExAG agreed that the strongest case is for the IECEx 03 schemes because the main focus on acceptance of a body is its ability to determine a body’s capability to assess ExCB applicants’ capabilities to assess practical situations such as repair workshops.

For the IECEx 02 scheme the ability of the applicant ExCB to assess manufacture is only a component of the assessment process related to the issuing of a QAR. The other major component is the assessment of the ability to management the ExTR issuing process. The main input to this process is from the ExTL and it is subject to on-site assessment.

In view of the above it is likely the use of witnessed assessments would be more frequent for IECEx 03 schemes, but it should be possible to develop a common approach. The following approach has been built into the proposed revisions of relevant operational documents and reporting forms.

A witness assessment should be applied in the following situations:

* The applicant ExCB does not hold national accreditation to ISO/IEC 17065 or ISO/IEC 17021; or
* It holds national accreditation, but the national accreditation body does not carry out witness assessments of the ExCB as part of its acceptance process for the above standards
	1. IECEx02 witness assessing

For IECEx02 witness assessing, where applied, would only be used in the following circumstances:

* For initial assessments (but may wait until after acceptance)
* For surveillance or re-assessments, only if issues have arisen from the operation of the body or from those assessments that indicate a witness assessment is desirable

To allow some flexibility, the following text has been included in OD 003-2 “IECEx Secretariat shall, if deemed necessary, …..”

* 1. IECEx03 witness assessing

For IECEx03 witness assessing would be applied as follows:

* For all initial assessments (but may wait until after acceptance)
* Mid-term (mandatory)
	1. Potential issues

Potential issues with carrying out a witnessed assessment include:

* Additional cost
* Language barriers (IECEx assessments are normally carried out in English, but local assessments are normally carried in the local language)
* Additional on-site and probably travelling time for the IECEx assessor
* Difficulties with scheduling convenient dates for all parties
	1. Criteria for assessments

The following proposed criteria was developed:

* Only one IECEx assessor may be used for the witness assessment to reduce complexity and cost.
* The ExCB shall be notified of the witness assessment in a timely manner for scheduling purposes, taking account of the complexity of three parties involved.
* The manufacturer or service facility (as applicable) shall be notified of the IECEx assessor prior to the audit by the ExCB and shall agree to the presence of this external assessor prior to the audit.
* Confidentiality/impartiality concerns with regards to the assessor and the bodies being assessed shall be taken into consideration.
* Local assessors may be used to minimize costs and travel concerns, and to address language issues.
* There shall be no influence or interference with the audit process by the external assessor.  Perhaps guidance from the Clause 9.2.2.2.1 (“Observers”) of ISO/IEC 17021-1:2015 can be used here.  If there is feedback from the external assessor, it should be provided after the audit and not during the audit process.
* The presence of the external assessor shall not extend the time of the audit.
* The use of tele-conferencing facilities such as GoToMeeting or Zoom, may be considered for the IECEx assessor as a means to do the witnessing to reduce travel costs and time.
	1. Application

The witnessed assessment may be applied as follows:

* At the time of the assessment visit if the ExCB is already doing audits that would be appropriate to witness; or
* Sometime after acceptance of the ExCB if audits are only then being implemented.

Later witnessed assessments may be carried out at an appropriate time in the assessment cycle.

* 1. Justification

It is difficult to accurately assess an ExCB’s ability to effectively audit a manufacturer or repair facility based on procedures, interviews and records. Witnessing an audit provides more evidence of competence and compliance with the relevant standards and IECEx requirements. Many bodies are already subject to this process through their national accreditation bodies, but some are not. This would help to improve confidence and provide a more level playing field by witnessing audits for such bodies.

* 1. Approval

ExMC is being requested to approve the revision of OD 003-2 which includes the above approach for the IECEx 02 Scheme.

ExSFC will be asked to approval the revision of OD 316-4 which includes the above approach for the IECEx 03 scheme(s).

1. Possible initial one-off one-year surveillance for newly accepted ExCBs/ExTLs holding national accreditation
	1. Background

The 2019 meeting of ExMC Noted current considerations within ExAG on the subject of a possible initial one-off one-year surveillance for newly accepted IECEx 02 ExCBs/ExTLs holding national accreditation and supported further development in this direction.

* 1. Justification

Five years is a long time between the initial assessment and first re-assessment of a new IECEx ExCB/ExTL body that holds national accreditation. Since a new body is not carrying out IECEx work at the time of the assessment visit, all that can be done at an initial assessment is to make a judgement on their capability to do things the “IECEx way”. For experienced bodies that are operating in a scheme that is very similar to IECEx 02 it might be possible to obtain sufficient evidence of their capability, but that is not the case for most new bodies. A one-off surveillance visit would be very beneficial not only in ensuring work meets the requirements of IECEx but also would present an opportunity to provide constructive feedback to bodies that are struggling to fully understand the rules and procedures for the IECEx 02 Scheme.

* 1. Inclusion in IECEx documentation

A new clause has been included in the draft revision of OD 003-2, Clause 2.2.3:

**2.2.3 Surveillance of newly accepted ExCBs and ExTLs with acceptable national accreditation**

Due to the difficulty of assessing applicant ExCBs and ExTLs when they have not carried out any IECEx work and the time frame of 5 years for the re-assessment, a one-off surveillance site visit **should** be undertaken. The purpose for this visit is to ensure that all relevant IECEx procedures and rules are being followed. This visit will normally take place 12 months after acceptance of the body but may be deferred to a later date if no IECEx work has been undertaken during this period.

Main points:

* Covers both ExCBs and ExTLs
* Not mandatory – on recommendation of the assessment team
* Generally in 12 months – but later if no project available to witness
* Generally expected to be on-site but remote tele-conferencing may be used

A new note is recommended has been included in the draft revision of F-003, Clause 3.16 as follows:

NOTE OD 003-2 makes provision for a possible witness assessment of an ExCB doing an assessment of a manufacturer. Where that has been done, a summary of the outcome of that witness assessment should be provided here, with details to be provided in a separate site assessment report.