New Proposals/Guidelines

Agenda Item 7

# ExAG agenda item 7

The following are new proposals/guidelines that will be included in revised documents, but may need to be presented with supporting justification:

1. Development of proposal on witness assessment of ExCBs
2. Development of guideline on an assessment estimates
3. Development of proposal regarding propose implementation of an initial one-off one-year surveillance from date of acceptance for newly accepted ExCBs/ExTLs holding national accreditation

# Development of proposal on witness assessments of ExCBs

## Background to proposal on witness testing

The following is background information to this topic, including previous discussions:

**ExMC 2018**

UK noted the reference to inclusion of witness assessments of ExCBs while they are conducting on-site audits of manufacturers and noted the challenges that this may present, including issues of timing.”

**ExAG report to 2019 ExMC**

ExAG were advised of a couple of instances where witnessed assessments had been done in the past. The meeting saw merit in the proposal for Schemes IECEx02 and 03, in particular where a body does not hold local accreditation. The option of using a local assessor to help with scheduling and language was also discussed. Appropriate wording will be included in the next editions of OD 003, assessment report F003 and guide OD 032.

**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.

**ExMC 2019**

AU supports all recommendations but suggested that there be an interval under recommendation 5 which should be at the recommendation of the Lead Assessor

US supports 1, 2, 3 and 5 but not with recommendation 4 due to difficulties in scheduling and additional costs and questions the value of this.

UK supports all recommendations but questions Recommendation 4 and whether or not national accreditation also performs witness auditing

Dr Munro responded that Recommendation 4 is aimed at ExCBs where they either do not hold accreditation or the Accreditation body itself does not conduct witness audits. At this point feedback on this idea is being sought prior to developing a proposal further.

ExSFC Chair, Mr Sinclair, raised that witness audits under Recommendation 4 is perhaps more important for ExSFC as all the work is done on site by the ExCB and could be considered similar to the witnessing of tests by an ExTL

In conclusion the Secretary suggested that perhaps Recommendation 4 in its current form could be reviewed by ExAG to take account of the US concerns and any other concerns, with Dr Munro advising that at this point feedback concerning Recommendation 4 is being sought as opposed to specific approval.

Following further discussion the meeting agreed to record the following decision, clarifying that voting with ExAG is a vote by experts and not on behalf of countries which addresses the question from CA.

Decision 2019/16

The meeting

* ..
* noted the current work covered by Recommendation #4
* …

**Feedback from ExSFC members**

Annex A shows the feedback that ExSFC has obtained from its members.

## Possible approach

It appears from the above, 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 is such a recommended approach.

### Premise 1

It is suggested that a witness assessment should not be necessary if the following situation applies:

* The applicant ExCB holds national accreditation to ISO/IEC 17065 or ISO/IEC 17021; and
* The national accreditation body carries out witness assessments of the ExCB as part of its acceptance process for the above standards

### Premise 2

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

### Premise 3

The need for a witnessed assessment is at the discretion of the lead assessor but should be agreed with the IECEx Executive Secretary.

### 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

### Criteria for assessments

The following proposed criteria draws from and enlarges on the criteria provided by Erin le Rocco in Annex A:

1. Only one IECEx assessor may be used for the witness assessment to reduce complexity and cost.
2. 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.
3. 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.
4. Confidentiality/impartiality concerns with regards to the assessor and the bodies being assessed shall be taken into consideration.
5. Local assessors may be used to minimize costs and travel concerns, and to address language issues.
6. 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.
7. The presence of the external assessor shall not extend the time of the audit.
8. 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.

### 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
* Some time after acceptance of the ExCB if audits are only then being implemented

## Justification

It is difficult to properly 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 standard 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 witnesses audits for such bodies.

## Inclusion in IECEx documentation

At this stage none of the above have been implemented in our procedures. For IECEx 02, the most likely procedure if OD 003-2, assessment report F003 and guide OD 032.

# Development of guidelines on an assessment estimates

## Current situation

The following changes have been made to address estimates:

* OD 032 Clause 3.2 *Establishing Dates and Costs*
* OD 003-2 Clause 1.3 Step 10

## Further steps?

Do we need more, for example to address the situation where an application ExTL has not been involved in the proficiency testing program? Perhaps also examples for typical scenarios, especially mid-term assessments and surveillance assessments to define that they should only be one day on site.

# Development of proposal for possible initial one-off one-year surveillance for newly accepted ExCBs/ExTLs holding national accreditation

## Background

**ExAG report to 2019 ExMC**

**12 Monitoring of newly accepted ExCBs/ExTLs**

The meeting agreed that five years seems a long time between the initial assessment and first re-assessment of new IECEx ExCB/ExTL body that holds national accreditation. It was agreed that an appropriate step for such a body would be to implement an initial one-off one-year surveillance from date of acceptance. However, the actual time could be negotiable if no IECEx work has been done after one year. This approach will be included in the revision of OD 003-2. The meeting also suggested that consideration be given to appointing mentors for new bodies from the existing assessor pool.

**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.

**ExMC 2019**

Dr Munro informed of ExAG’s current discussions relating to new ExCBs and new ExTLs and the time frame of 5 years for the re-assessment for bodies with national accreditation suggesting that this is too long and that there is a need to consider a first one off surveillance assessment visit for all new ExTLs and ExCBs, including those holding national accreditation, in order to ensure that all relevant IECEx procedures and rules are being followed.

Decision 2019/16

The meeting

* …
* noted current considerations within ExAG regarding Recommendation #5 and supported further development in this direction

## 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 IECEx02 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.

**Question? Should it be mandatory or optional?**

## Inclusion in IECEx documentation

A new clause is recommended for inclusion in OD 003-2, Clause 2.2.3 as follows:

### 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.

A new note is recommended for inclusion on 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.

1. Proposals for ExFSC

Responses received to email sent to ExSFC members by email on 31st Jan 2020 regarding …..

Dear members of the IECEx ExSFC,

Following discussions at the 2019 ExSFC meeting in Singapore on the concept of witnessed / accompanied assessments during on-site audits of manufacturers and service providers, the IECEx Assessment Group (ExAG) and IECEx Executive subsequently:

1. supported the use of witness / accompanying assessments as a tool for qualifying applicant ExCBs in the IECEx Certified Service Facilities Scheme
2. supported the use of witness / accompanying assessments as a tool for ongoing peer assessments of ExCBs accepted in the IECEx Certified Service Facilities Scheme

and

1. requested that the ExSFC provide ExAG with a list of proposed criteria to be used in assigning assessors and elements of the processes for managing witnessed peer assessments of ExCBs in the IECEx Certified Service Facilities Scheme

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| --- | --- |
| **From**  | **Comments** |
| Geoff Barnier,SIMTARS | My first thoughts on this are that I support the witness assessment. But, only for those ExCBs that don’t have 17065 accreditation or are NOT already being witnessed by their accreditation body. As I understood from our meetings, some ExCBs undergo no witness assessment hence the reason for this.In AU, JAS- ANZ witnesses both our product and service facility audits. The logistics of marrying up an audit while the IECEx auditors are in AU and the additional costs to have IECEx also witness an audit conducted by ExCBs is not insignificant and an added burden. |
| Erin LaRocco,UL LLC | 1. All ExCBs shall participate.
2. ExCB shall be notified of peer assessment in a timely manner for scheduling purposes.  Audits are difficult to schedule with two parties involved and then adding in a third party may make this an even more difficult process.
3. The service facility shall be notified of the assessor/observer prior to the audit by the ExCB and shall agree to the presence of this external assessor prior to the audit.
4. Confidentiality/impartiality concerns with regards to the assessor and the repair facility/ExCB should be taken into consideration.
5. Local assessors shall be used when possible to minimize costs and travel concerns.
6. 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 assessors, it should be provided after the audit and not during the audit process.
7. The presence of the external assessor shall not extend the time of the audit.
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