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IECEx

OPERATIONAL DOCUMENT

IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System)

Guidelines and information for IECEx assessments

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INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEx Operational Document 032 –

Guidelines and information for IECEx assessments

FOREWORD

Document history

Date	Summary
February 2008	Original Issue (Version 1)
January 2009	Edition 2.1 Issued to take into account editorial formatting changes only. No technical changes.
April 2018	Edition 2.2 Updates of the Secretariat contact details, references to ISO/IEC 1700 series and other editorial corrections.
October 2018	Edition 3.0 Updated scope, title and references.
March 2021	Edition 4.0 Updates to provide greater clarity over • Use of video and teleconferencing • Approval of cost estimates and itinerary • Others
October 2024	Edition 5.0 Updates to provide additional information on remote assessments and to update reference to forms used for mid-term assessments.

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Guidelines and information for IECEx assessments

1   Scope

This document provides guidelines and information to IECEx assessors doing assessments of bodies seeking to obtain or continue acceptance as an ExCB, ~~or~~ ExTL or ATF in the IECEx Certified Equipment Scheme, ExCB in the IECEx Certified Service Facilities Scheme, ExCB in the IECEx Certified Conformity Mark Licensing Scheme or ExCB in the IECEx Scheme for Certification of Personnel.

The information here summarizes or supplements the requirements in IECEx OD 003-2. It is intended to assist assessors and help achieve consistency in the assessment process.

~~NOTE   Any suggestions for updates should be directed to the IECEx Secretariat.~~

2   References

a) IECEx 02, *IECEx Scheme Rules of Procedure*

b) IECEx OD 003-2, *IECEx Assessment, surveillance assessment and re-assessment of ExCBs, ~~and~~ ExTLs and ATFs operating in the IECEx 02, IECEx Certified Equipment Scheme*

c) ISO/IEC 80079-34, Explosive atmospheres - Part 34: Application of quality management systems for Ex Product manufacture

~~c)   Quality system requirements for manufacturers~~

d) IECEx OD 009, *Issuing of certificates, ExTRs and QARs*

e) IECEx Document OD 025, *Management of assessment and surveillance programmes for manufacturers*

f) IECEx OD ~~203~~2023, *IECEx Proficiency Testing Scheme~~Programme~~*

g) F-003, *IECEx Assessment Report Form*

h) F-004, *Site Assessment Report Form*

i) ISO/IEC 17065, *Requirements for certification bodies operating product certification*

j) IECEx OD 017, *Drawing and documentation guidance*

k) ISO/IEC 17025, *Requirements for testing laboratories*

l) IECEx Technical capability documents (TCDs)

m) ExTAG decision sheets (DSs)

n) ISO/IEC 17024, *Conformity assessment – General requirements for bodies operating certification of persons*

o) IECEx OD 060, *IECEx Guide for Business Continuity – Management of Extraordinary Circumstances or Events Affecting IECEx Certification Schemes and Activities*

p) IECEx OD 233, *IECEx Certified Equipment Scheme - Assessment of Ex "s" Equipment*

q) *IECEx F-012, Mid-term assessment report form according to Section 3 of IECEx Operational Document OD 003-2*

r) *IECEx F-013, IECEx checklist for the review of IECEx CoCs, ExTRs, QARs*

s) *ISO/IEC TS 17012, Guidelines for the use of remote auditing methods in auditing management systems* (under development)

3   Preparing for assessments

3.1   Defining the assessment team

The initial steps in the assessment process are essentially as shown below.

The process begins with:

- An initial application,

- An application for a scope change that will require an assessment, ~~on-site~~onsite ~~visit,~~ or

- Identification of the need for a surveillance visit or re-assessment.

For initial applications, the IECEx Secretary carries out a review of the application and may require further actions of the applicant.

For re-assessments under the IECEx 02 Scheme, the Secretariat provides a desk top review report (DTR) concerning the activities of ExCBs and ExTLs, including an ExTL's participation in the IECEx Proficiency Testing Programme.

At this stage, the applicant may agree to a pre-assessment visit with one assessor prior to an initial assessment by a team. The reports from the pre-assessment visit are treated as confidential between the assessor and the body, but the knowledge gained can be used by the body to help plan for the initial assessment.

When the application review has been successfully completed, the IECEx Secretary will identify a lead assessor and expert assessor(s). He may also consult with the Convenor of IECEx Assessment Group (ExAG). In some cases, a member of the team may be designated as an "off-site" assessor.

Once the availability of the assessment team has been established, the IECEx Secretary will seek agreement from the body to be assessed.

3.2   Establishing dates and costs

The following actions are carried out prior to the assessment:

- Dates are agreed with the body to be assessed.

- The assessors investigate travel options and potential costs, ensuring that only relevant travel costs are attributed to the bodies that are being subjected to the IECEx assessment.

    NOTE   IECEx OD 003-2 states that "Travel times charged for each assessment visit shall not exceed one day unless there are compelling circumstances and approval is obtained from both the IECEx Secretariat and the applicant."

- In some circumstances it may be possible to do the assessment wholly or partly remotely ~~online~~. Annex E of this OD should be consulted in relation to this.

- The lead assessor puts together a consolidated cost estimate and where necessary consults with the Secretary in its preparation.

- The estimate (including the itinerary) is agreed to between the assessor and the body in the first instance. Although there may need to be some later change (for example in travel costs), a formal acceptance from the body to be assessed is required. A typical cost estimate is shown in Annex A.

- Travel arrangements are finalized and submitted to the Secretariat for review and filing.

- Travel plans should not be finalized until the lead assessor has received agreement from the body and the Secretariat on the cost estimate.

- If circumstances change necessitating a change in assessment dates or travel plans involving additional costs, the following principles will in general apply:

    o If the body to be assessed is primarily responsible for need for change (for example a change in date or increased scope for the assessment), then the body will be responsible for increased cost;

    o If the changes are made by the assessor to suit their personal needs, then the assessor will be responsible for the increased cost; or

    o For less clear scenarios, a decision should be taken in conjunction with the IECEx Executive Secretary.

    NOTE Assessors will often seek cheap deals associated with travel costs to minimise costs to the body to be assessed. However, such cheaper deals often involve penalties if plans change. This situation may lead to costs being incurred and should be taken into account when deciding who should be accountable for the change costs.

3.3   The assessment plan

Generally, in parallel with the actions in Clause 3.2 above, an assessment plan is prepared by the team leader.

This involves:

- Clarifying the scope of Standards to be covered by the assessment as this may impact on the length of the ~~on-site~~onsite visit

- Consultation with fellow assessors to determine the allocation of duties

- Preparation of the plan to provide an indication of the actions to be taken each day and who will be responsible

A typical plan will include:

- The lead assessor's understanding of the scope and any proposed changes or extensions

- An opening meeting

- A brief tour of the facilities

- Allocation of work to the assessment team for the period

- A closing meeting where the findings of the assessment, including draft reports, will be presented

- A list of any tests that the team want to witness

- Clarification of any documentation to be completed by the body prior to the assessment as shown in Clause 3.4

An example of a plan to be carried out by a team is shown in Annex B. An example of a plan that may be used for a surveillance visit is shown in Annex C.

3.4   Prior reading

For the IECEx 02 Certified Equipment Scheme the following documentation should be obtained from the body prior to major assessment visits (initial assessments or re-assessments):

- TCD including for all the relevant Standards listed in scope, a list of the test equipment with photos,

- ISO/IEC 17065 and ISO/IEC 17025 checklists,

- Pre-fill the combined IECEx assessment report form, F-003,

- Staff competence matrix,

- List of subcontractors for testing or auditing of manufacturers,

- ISO/IEC 17065 and ISO/IEC 17025 accreditations, when applicable,

- The quality manual, and

- The body's procedures that are specific to the IECEx Scheme.

Some familiarisation with the above may assist the ~~on-site~~onsite assessment and help assessors better prepare for the assessment.

For the other IECEx Schemes the information sought will vary from that above (refer to IECEx OD 316-* and IECEx OD 501).

3.5 ~~Use of video or teleconferencing~~

~~In noting that an assessment of an ExCB or ExTL encompasses both on-site assessment activities as well as off-site assessment of documentation etc., use of video or teleconferencing facilities can be an effective tool during an assessment, especially when assessing documentation or conducting interviews of key personnel.~~

~~Use of video or teleconferencing may be used across all IECEx Schemes, subject to the guidance contained in this clause.~~

~~However, use of video or teleconferencing cannot be used to prevent at least one member of the assessment team from visiting the site of a new applicant ExCB or ExTL. The following sets some guidance when using video or teleconference facilities:~~

- ~~Dates and timing of video or teleconferencing sessions should always be well planned and coordinated in similar manner to a face-to-face meeting.~~

- ~~Each event should result in the assessor providing a report of the event to the body and for the assessment records, identifying who participated and the conclusions of the session.~~

- ~~Video or teleconferencing can be a most cost effective tool during document reviews and reviews of follow up actions and may help to reduce the level of email communications.~~

- ~~At all times and as part of their overall management of the assessment, it is the IECEx Lead Assessor that shall determine if and how video or teleconferencing shall be used during an IECEx assessment, in their quest for gathering objective evidence to demonstrate compliance with IECEx requirements.~~

- ~~Video communication may be used for the scope extension application for an ExCB provided the assessors have availability of and ready access to the ExCB's management documentation and procedures in electronic file format. The use of video conference packages such as "GoToMeeting" and "Zoom" etc. have video and voice capabilities and screen sharing.~~

- ~~Video communication may be used to verify the correct preparation/operation of a specific test that is not covered within the existing technical scope of an ExTL, subject to the agreement of the lead assessor in consultation with the Executive Secretary. However, a site visit may be required to be conducted by a lead assessor within 12 months of achieving the scope extension, as determined by recommendation of the lead assessor or the Executive Secretary in consultation with the lead assessor. The ExAG Convenor and Deputy Convenor may also be consulted.~~

- ~~The IECEx Secretariat may be consulted along with the ExAG in developing an assessment plan for this specific situation.~~

4   The ~~on-site~~onsite assessment

4.1   The opening meeting

At the opening meeting it is recommended that the following take place:

- Circulate an attendance form

- A "thank-you" to the body visited for their application (where appropriate) and for facilitating the assessment team's visit

- Introductions of the assessment team and personnel present from the body to be assessed

- Agreement on the scope to be addressed during the visit

- Provision for the body to be assessed to describe its operation and any changes that may have taken place since a previous assessment

- Agreement on the schedule for the period of the assessment. This should consider availability of the body's staff over the period of the assessment

- Identification of any information that might be needed during the assessment for the reports, such as accreditation certificates and scopes, and data on certificates and/or test reports issued

- Clarification of the documentation that will be produced during the assessment. This should include an explanation of the reports that will be produced and whether they will be made public or retained by the Secretariat as supporting evidence. Where reports will be subject to voting, the body should be given a summary or how this will occur and possible time frames (for example, the two-month period for voting)

- It may be helpful to point out that the assessment is seeking objective evidence of compliance with the relevant Standards and IECEx requirements, not looking for problems. Further, that it is only a sampling exercise and does not find everything that may need attention

It is helpful to clarify that IECEx scheme assessors are bound by confidentiality agreements. If requested, you should also agree to sign a confidentiality agreement for the body concerned (at least it shows that they are serious about confidentiality).

For multi-day assessments, it is sometimes useful to have a short opening meeting at the beginning of the subsequent days to look at logistics for that day.

4.2   The facility tour

This is particularly important where the assessment is of an ExTL. The idea is to give the assessment team an overview of the facilities. Since the assessment is only a sampling process, it may give the opportunity to see some facilities that may not be examined during the detailed auditing.

However, in-depth discussions or investigations should be avoided during this tour as the time taken will reduce the time available for the rest of the assessment. Some bodies are very proud of the range of their activities and will want to show testing other than that directly relevant to Ex. This may be accommodated provided it does not take up too much time, and it may provide insight into the capability of the organisation to which the Ex part reports.

This tour is also an opportunity to take photographs, but permission must first be asked.

4.3 Getting down to work

4.3.1 Interviewing staff

After the facility tour, it is time for the team to separate (where there is more than one) to undertake their tasks. Generally, this will involve interviewing the relevant staff involved in the area that you are concerned with. Try to target a cross-section of staff, both experienced and newer staff, to get a feeling of the depth of experience, and the effectiveness of training and information dissemination programmes.

4.3.2 Focus of the assessment

It is recommended that a focus of the assessment should be:

- Ensuring that scheme requirements contained in the IECEx rules, operational documents and ExTAG decision sheets are being met and are adequately covered by procedures

- Examining technical aspects of Ex assessment and testing are met. Some accreditation bodies do not consider assessment part of the requirements to be met as an accreditation body and this is a critical area

- Examining common Ex techniques such as Ex d and Ex i in detail, as these are universally applied and provide a good appreciation of the competence of a body in this field

- Ensuring the body has the three elements of adequate facilities, appropriate procedures, and competent staff. The last two will be the most appropriate for an ExCB

4.3.3 Some assessment techniques

Some useful assessment techniques are shown below.

4.3.3.1 Putting people at ease

Try to find ways to put people at ease. You will learn a lot more that way. For example, if casual dress is normal for the body, then look for an opportunity to look less formal by removing a coat or taking off a tie but don't be disrespectful by turning up in casual dress to a body that encourages formal dress. Be aware that dress standards may vary throughout the year or even throughout the week. Depending on your personality, try to strike a lighter note when possible but be careful about any jokes that you may use.

4.3.3.2 Seeking objective evidence

You should seek objective evidence of compliance with the ISO/IEC Standards and IECEx System requirements. This may be found through questions, examining procedures, and looking at actual practice (for example through review of files or examining records). All three should be consistent, and all procedures should be consistent with each other.

One effective approach is to use the "show me" technique. First, ask how they do it, then ask to the see the procedure and finally ask to see an example of how it is done in practice. For example, when examining issues of how confidentiality is ensured, they might say that staff are required to sign confidentiality agreements. Ask to see this in their procedures and then ask them to show you an example of a signed agreement. It is also good to note this in the reports, so it is clear that you have followed the whole process.

4.3.3.3 Following a trail

Often you may need to follow a long paper trail to finally find the evidence you seek. But be persistent. If you have identified a potential area of non-compliance, you should follow it through until you find the evidence that establishes compliance or that identifies an issue. Sometimes you may need to give them time to seek the evidence and move on to something else but don't forget to come back to it. If you find the evidence of compliance, record it in the report or your notes.

4.3.3.4   Types of questions

Be careful about asking questions that can be answered with a simple "yes" or "no". These are commonly called "closed questions"' and will not provide much information. They may even just guess right. Try to use "open questions" that will require them to provide a longer answer and reveal more about their knowledge. Avoid the urge to answer your own questions or to volunteer information about something you want to know their understanding on. Annex D includes some suggestions that have come from an Assessors' Review Day on ways to go about questioning.

4.3.3.5   Cultural issues

Try to be sensitive to cultural issues. For example, if you are doing an assessment in a country where the use of surnames is the norm then be careful about using first names. On the other hand, if you think that you will put people at ease by inviting them to use your first name then certainly do it.

4.3.3.6   Examining records

It is always a good idea to examine records both in the ExCB and ExTL. These will often provide the best evidence of how the body is really operating. For existing bodies in the scheme, look at examples of CoCs, ExTRs and QARs. For new bodies, try to find examples of similar work.

4.4   Witnessing tests

When assessing ExTLs include witnessing some testing. It is recommended that the following approach be taken.

- The tests to be witnessed should be advised in the assessment plan.
- The test artefacts with satisfactory results proved by participating in IECEx proficiency testing programmes in last five years may be excluded as witness test artefacts at the discretion of the assessor.
- Where possible try to get tests conducted using normal procedures, such as using the usual methods of recording results.
- Try to put the operators at ease, as it is a bit scary having an international assessor peering over your shoulder.
- This can be a good opportunity to record and check the calibration of the instruments used.

4.5   Finding issues

Any issues found during the assessment process must have a basis in scheme rules, ISO/IEC 17065, ISO/IEC 17025 or ISO/IEC 17024, or have a technical justification.

If you find issues (non-conformities) that you believe will need addressing, be upfront about it. There should be no surprises at the closing meeting. It is also possible, if they are clear that you are unhappy about something, that they will be able to provide some additional information that will clarify matters immediately.

You should discuss issues you have found as early as possible with your fellow assessors, particularly the lead assessor.

In the unlikely event that major issues have been raised that may prevent the continuation of the assessment, the lead assessor must seek an interview with the senior management representative of the ExTL or ExCB, under assessment, and may require any one of the following:

- Termination of the assessment
- Convert the assessment to a "pre-assessment"

- Seek additional information in order to proceed

- For such an event, the IECEx Secretariat should be immediately informed

4.6   The closing meeting

Over a multi-day assessment, it sometimes helps to have a short closing meeting at the end of the earlier days just to give people an idea of how the assessment is going and how significant any issues are that are being found. This meeting can be quite informal.

On the final day, a formal closing meeting is held. This will be conducted by the lead assessor and should cover:

- Circulate attendance list (may be same form as used for the opening meeting)

- A thank for "enduring"' the assessment and any hospitality provided, such as lunches. It is also a good time to make some positive remarks about the operation

- An indication of what the recommendation will be from the assessment. Don't keep them hanging on until the end because this is what they are really waiting to hear

- A review of the reports and a reminder of what will be open and what confidential. If this review is done using the projector, it is possible to correct any mistakes or take account of feedback during the closing meeting. Make it clear that there will be further opportunities to comment after the closing meeting

- Detailed advice on the issues found. This should seek acceptance of the issues and can include discussions on how they might be resolved

- Any observations or comments about the operation. This is an opportunity to leave them with some ideas of how to improve but in circumstances where action is not necessary to provide a recommendation on acceptance

- For re-assessments or surveillance visits, a commitment to when actions will be taken should be obtained

- Advice on what comes next and an indication of possible time frames (remember that the voting period once everything is right is two months)

- An opportunity for the other assessors to add their comments

- Provision of the reports in draft form

- A final thank you, including one to the rest of the assessment team

5   The reports

5.1   Reports for voting or endorsement

The report shown in form F-003 is used to produce reports on the ExCB, ~~and~~ ExTL and ATF assessments. This form addresses reports for four schemes:

- ExCB for IECEx Certified Equipment Scheme

- ExTL for IECEx Certified Equipment Scheme

- ATF for IECEx Certified Equipment Scheme

- ExCB for IECEx Certified Service Facilities Scheme

- ExCB for IECEx Conformity Mark Licensing Scheme

- ExCB for IECEx Certification of Personnel Competence Scheme

Schemes that are not relevant for an assessment can be deleted and the contents updated to reflect the revised content.

It is important that these reports be completed in their entirety for initial assessments and re-assessments. For scope extensions, only the relevant parts will need to be completed. It is recommended that where feasible these be completed in front of those you are interviewing using a projector or "beamer". This allows them to comment on whether you are getting the information right and contributes to the openness of the process.

When compiling these reports keep in mind that you are trying to convey to the ExMC members what you have found. Try to include sufficient information not only to demonstrate compliance but also to paint a picture of what the operation is like.

At the assessment, these reports will be prepared in draft form and may be subject to several of changes before being issued. The final reports must be at a stage where all issues have been resolved, and both the assessment team and the body under assessment have agreed to the content. Where issues have been found, there should be enough information to indicate what these were, particularly for re-assessments as an indication of how well the body has been operating. There should also be a clear indication that the issues have been resolved but the detail may be shown in the confidential reports.

Once the reports are finalized, they are sent to the IECEx Secretary for final independent review before being sent out for voting (initial assessment or scope change) or endorsement (re-assessment without major scope change).

5.2 Site assessment reports and other confidential information

Typically, the following information, where relevant, may also be completed as part of an assessment process:

- A site assessment report F-004 ~~(formerly IECEx OD 006)~~, which includes records of issues found and how they have been resolved

- Technical capability documents (TCDs)

- Checklist for ISO/IEC 17065 (IECEx OD 107)

- Checklist for ISO/IEC 17025 (IECEx OD 018)

- Checklist for ISO/IEC 17024 (IECEx OD 507)

- Documented records of tests witnessed

- ~~Photos of the facility and tests witnessed when not included in the TCD~~

- Assessors' notes

Generally, the above will form part of the confidential supporting information.

For a surveillance visit, only the site assessment report with the supporting information is required, provided no scope extension has been sought. The final report is retained by the IECEx Secretariat.

5.2.1 Site assessment report

Only one site assessment report is required even if both an ExCB and ExTL is being assessed. This document can provide a convenient way to index all the supporting documentation. The site assessment report contains references to the TCDs and has provision to include annexes that be used to include all the other documentation. It is suggested that as a minimum the site assessment report and the Annex A (ExCB issues and subsequent responses~~/actions~~)), ~~and~~ Annex B (ExTL issues and subsequent responses~~/actions~~) and Annex C (ATF issues and subsequent responses) be completed by the end of the assessment~~.~~, as applicable. Other annexes may be added later.

5.2.2 Technical capability documents

It is difficult to find time to complete the TCDs at the ~~on-site~~onsite assessment, and so it helps to get the body under assessment to complete as much as possible beforehand. In particular it is recommended that the body is requested to insert photographs of all test equipment against each test for a standard. Then any assessor's notes can be added while on site. The format of the TCD for the equipment scheme is in three parts. The first examines the knowledge and competency of the staff. The second contains provision to list any relevant procedures or work instructions. The third identifies the relevant tests and the equipment that is held by the ExTL or ATF being assessed. ~~Both the~~The last two parts can be completed beforehand.

5.2.3 Mid-term assessments

For a mid-term assessment, the following forms should be used, and the site assessment report will not be necessary:

- IECEx ~~OD 204~~F-012 – Mid-term assessment report form according to Section 3 of IECEx Operational Document OD 003-2

- IECEx ~~OD 205~~F-013 – IECEx checklist for the review of IECEx CoCs, ExTRs, QARs

5.2.4 Records of issues found

Annex A for the ExCB be used to record the issues found as shown in F-004. It is preferable that these be recorded at the assessment and discussed at the closing meeting. The second and third columns are generally completed after the assessment. The second and third columns may have more than one entry against an issue if it takes more than one attempt by the body to resolve it.

A similar approach to the above will be used for Annex B for the ExTL.

5.2.5 Checklist for ISO/IEC 17065

It helps to have the second column of the checklist for ISO/IEC 17065 completed beforehand by the body under assessment. This then gives a quick lead into the relevant manuals or procedures to establish compliance with the Standard. A significant number of the requirements of ISO/IEC 17065 will already have been addressed if the ExCB report has been completed beforehand. If a body holds accreditation as a certifying body, not all clauses need to be addressed. However, in some cases, the clauses should be related to the IECEx scheme where there are requirements in the rules.

5.2.6 Checklist for ISO/IEC 17025

For the checklist for ISO/IEC 17025, a similar approach can be taken as for the checklist for ISO/IEC 17065.

5.2.7 Checklist for ISO/IEC 17024

For the checklist for ISO/IEC 17024, a similar approach can be taken as for the checklist for ISO/IEC 17065. Also, IECEx OD 507 may be of use.

5.2.8 Records of tests witnessed

There is provision in F-003 to include a list for all the tests that have been witnessed. It recommended that additional information, including photos, be included in the TCD.

5.2.9 Photos of the facility and tests witnessed

For new ExTL applications, it is recommended that photos of the test facilities be recorded. In all cases, it is useful to take photographs of any tests witnessed to provide a record of what has been seen. These photos will normally be included in the TCD. Always seek permission at the start of the assessment visit to take photos and comply with any conditions provided.

5.2.10 Assessors' notes

It is recommended that any other assessors' notes be attached as annexes to site assessment report.

6 After the ~~on-site~~onsite visit

6.1 Resolving issues

Generally, issues can be resolved by correspondence. However, occasionally if a significant range of issues is found, a follow-up visit may be necessary either by the team or a member of the team. In such a case the follow-up ~~on-site~~onsite visit will take a similar approach to the first visit. Consideration should be given to the alternative approach of doing the follow-up remotely, taking into account the guidance in Annex E.

When resolving issues by correspondence, the first step will normally be receipt of information on actions taken by the body together with any supporting information. It can be useful to get them to complete the second column of Annexes A and B of the site report when submitting actions. These actions should reference the supporting information, including where relevant, the particular parts of documents.

Generally, the lead assessor will review the actions. This can be done using column three of the annexes. This review should then be agreed with the rest of the assessment team. It can then be sent back to the body for comment. The reports may also go through revision at this time.

Depending on how well the actions are done, there may be a need to do this process more than once.

Assessors and bodies are reminded that where matters remain open or unresolved 12 months or more following an assessment, a further additional site visit by one of the IECEx assessors is normally required and at the cost of the body under assessment.

6.2 Finalizing reports

Once all issues have been resolved, it should be possible to finalize the reports. Again, it is recommended that the final reports be agreed with the team before sending to the body for their agreement.

When agreement has been received from the body, the reports can be sent to the IECEx Secretariat for review. This may involve some changes to the reports that depending on their nature may require further agreement from the assessment team and the body under assessment.

When the review is complete, the reports will be subject to the next part of the process that may be voting or endorsement by the ExMC members.

At this stage, the involvement of the team members is generally complete, unless there is a need to answer any questions that coming up during the voting or endorsement process.

Annex A

Example of a cost estimate

NOTE: the daily Rates for Assessors shown below are provided as examples for information only on the required format and content of Cost Estimates.   Refer to the current edition of IECEx OD 019 for the rates applicable at the time of the planned assessment.

Cost estimates for assessment of <body>						
Costs	Lead assessor		Assessor 1		Assessor 2	
Rate in CHF	1 500		1 250		1 250	
Assessment preparation, co-ordination, reporting, post assessment activities (days)	3	4500	2	2500	2	2 500
Travel time (days)	1	1 500	1	1 250	1	1 250
~~On-site~~Onsite assessment (days)	3	4 500	3	3 750	3	3 750
Travel costs (airfare, and ground costs)		1 850		650		600
Totals		12 350		8 150		8 100
Total cost estimate, CHF	28 600					
NOTES:						
1. Accommodation, meals and other living away from home costs are to be covered by the body under assessment and are not covered in above figure.						
2. Estimates of time are based on a successful assessment with a small number of issues requiring resolution. Where a significant number of issues are found, it may be necessary to charge for the additional time taken by the assessors to resolve those issues.						
3. More accurate travel costs are available at the time of booking. Flights are economy and subject to strict change rules.						
4. Payment for the assessment will be made to the assessor(s) by the IECEx S~~c~~cheme which will in turn invoice the body being assessed. This is expected to occur at the end of the assessment visit.						

Annex B

Example of an assessment plan

IECEx scheme, application for ExCB and EXTL
Draft assessment plan for ~~on-site~~onsite visit of \<body\> – \<date\>

Composition of assessment team:

Team Leader	~~On-site~~Onsite
Lead Assessor (LA)	
Expert Assessor	~~On-site~~Onsite
Expert Assessor 1 (EA1)	
Expert Assessor	~~On-site~~Onsite
Expert Assessor 2 (EA2)	

Day:	Activity:	LA	EA1	EA2
1 **\<Day 1 –** **date\>**	Introduction meeting with management	X	X	X
	Facility tour (mainly laboratories)	X	X	X
	Confirmation of scope of Standards of ExCB and ExTL and review of accreditations	X	X	X
	Review of ExCB compliance with ISO/IEC 17065 and IECEx 02 (following ExCB assessment report form)		X	
	Procedures for issuing certificates, ExTRs and QARs (OD 009~~/V1~~)		X	
	Review of ExTL compliance with ISO/IEC 17025 and IECEx 02 (following ExTL assessment report form)	X		
	Review of ExTL compliance according to scope of Standards (work instructions incl. TCDs & decision sheets (DS), equipment and calibration, competence of Ex testing):			
	a) Protection techniques (general requirements and Ex d)			X
	b) Protection techniques (Ex e, n)	X		
	Assessment team internal meeting day 1	X	X	X
	Day 1 wrap-up meeting with management (if required)	X	X	X

Day:	Activity:	LA	EA1	EA2
2 **\<Day 2 –** **date\>**	Kick-off meeting 2nd day	X	X	X
	Continuation of review of ExCB compliance with ISO/IEC 17065 and IECEx 02(following assessment report form)		X	
	Manufacturing assessments covering IECEx OD 025 and ISO/IEC 80079-34, including use of OD 060~~IECEx OD 005 edition 2~~		X	

	Review of ISO/IEC 17065 checklist		X	
	Continuation of review of ExTL compliance with ISO/IEC 17025 and IECEx 02 (following ExTL assessment report form)	X	X	
	Continuation of review of ExTL compliance according to scope of Standards (work instructions incl. TCDs & DS, equipment and calibration, competence of Ex testing):			
	a) Protection techniques (Ex i and related, p)			X
	b) Protection techniques (Ex m, q, o and trace heating)	X		
	Review of ISO/IEC 17025 checklist	X		
	Assessment team internal meeting day 2	X	X	X
	Day 2 wrap-up meeting with management (if required)	X	X	X

3 \<Day 3 – date\>	Kick-off meeting 3rd day	X	X	X
	Continuation of review of compliance with ISO/IEC 17025 and IECEx 02 (following ExTL assessment report form)	X	X	
	Continuation of review of ExTL compliance according to scope of Standards (work instructions incl. TCDs & DS, equipment and calibration, competence of Ex testing):		X	X
	a) Protection techniques (Ex t and other dust techniques)			X
	b) Protection techniques (optical radiation)	X		
	Review of ISO/IEC 17025 checklist	X	X	
	Finalization of ISO 17065 review and draft ExCB assessment report	X	X	X
	Finalization of ISO/IEC 17025 review and draft ExTL assessment report	X	X	X
	Assessment team internal meeting day 3	X	X	X
	Closing meeting with management	X	X	X

Notes:			
1) Draft assessment plan may change during the assessment			
2) The following tests shall be demonstrated during the assessment:			
• Flameproof pressure determination (for any group)	X		X
• Flame transmission using hydrogen			X
• Temperature rise, preferably of a luminaire	X		X
• IP54 test to IEC 60529	X		X
• Use of spark test apparatus, preferably on a power supply			X
• Tests for temperature rise/determination of the maximum short circuit current on a high capacity battery ~~according to 10.5.3 of IEC 60079-11 edition 6~~			X

• From IEC 60079-28 optical radiation: − Measurement of optical power and irradiance − Ignition testing	X		

Proposed scope

Number	Title
IEC 60079-0 edition 7~~6~~.0	Explosive atmospheres – Part 0: Equipment - General requirements
IEC 60079-1 edition 7.0	Explosive atmospheres – Part 1: Equipment protection by flameproof enclosures "d"
IEC 60079-2 edition 6.0	Explosive atmospheres – Part 2: Equipment protection by pressurized enclosure "p"
IEC 60079-5 edition 4.1~~0~~	Explosive atmospheres – Part 5: Equipment protection by powder filling "q"
IEC 60079-6 edition 4.~~0~~1	Explosive atmospheres – Part 6: Equipment protection by ~~oil~~ liquid immersion "o"
IEC 60079-7 edition 5.1~~0~~	Explosive atmospheres – Part 7: Equipment protection by increased safety "e"
IEC 60079-11 edition 7~~6~~.0	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
IEC 60079-15 edition 5~~4~~.0	Explosive atmospheres – Part 15: Equipment protection by type of protection "n"
IEC 60079-18 edition 4.1~~0~~	Explosive atmospheres – Part 18: Equipment protection by encapsulation "m"
IEC 60079-25 edition 3~~2~~.0	Explosive atmospheres – Part 25: Intrinsically safe electrical systems
IEC 60079-26 edition 4~~3~~.0	Explosive atmospheres – Part 26: Equipment with Separation Elements or combined Levels of Protection~~Equipment with equipment protection level (EPL) Ga~~
IEC 60079-28 edition 2.0	Explosive atmospheres – Part 28: Protection of equipment and transmission systems using optical radiation
IEC/IEEE 60079-30-1 edition 1.0	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
IEC 60079-31 edition 3~~2~~.0	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"

Annex C

Example of a surveillance plan

ExCB Assessment Plan – <date>

Based on the existing scope, the following will be the assessment plan for the day (based mainly on <body's> operation as an ExCB):

Action	Assessor notes (to be completed at assessment)
Opening meeting	
Review of actions from the last surveillance visit	
Review of issued or draft certificates, and associated ExTRs and QARS	
Your adoption of IECEx guidance documents Discuss any changes in procedures since last visit IECEx OD 025 – Assessment and surveillance of manufacturers' quality system	
Assessment of selected requirements from ISO/IEC 17065 including: 4.3 Operations 4.9 Records 4.10 Confidentiality 9 Preparation for evaluation 13 Surveillance 15 Complaints to suppliers	
Closing meeting	

<name>
Lead Assessor

Annex D

Questioning techniques

The following are some suggestions that have come from an Assessors' Review Day on ways to go about questioning:

- Introduce yourself first before asking someone questions

- Personalize questions, for example ask "what is your procedure"

- Ask a person what they do – let them tell their story

- When questioning, avoid creating emotional situations. Keep your own emotions in check – be calm. Try starting with introducing positive comments

- Try to put people at ease but always be firm

- Ask a person to carry out a task and look how it is prepared and done. This also gives a chance to look at how test facilities are used

- Try setting a scenario. For example, ask "how would you do …"

- Ask for explanations about a person's responsibilities. Then lead into procedures and then verify how this occurs

- A good test of depth of knowledge could be to ask someone how they would go about selecting appropriate items from a range for assessment and test

Annex E
Guidance for remote auditing methods for assessments

E.1   Scope

This annex provides guidance on the use of remote auditing methods for assessments or where remote auditing methods are used to augment onsite assessments.

An extract from ExMC a decision 2022/09 from the ExMC September 2022 meeting:

> After 1 January 2023, the planning of Peer Assessments shall ensure that the Assessment Team assigned by the IECEx Secretariat conducts the audit in person unless otherwise provided for (for example, in an IECEx OD) or where the IECEx Lead Assessor determines that there are governmental sanctions, restrictions, advice or requirements that impinge such travel and informs the IECEx Secretariat of this determination.

This OD provides information that may be used in the context of that decision.

NOTE ISO/IEC TS 17012, *Guidelines for the use of remote auditing methods in auditing management systems,* which is currently under development may provide useful guidance once published.

E.2   Background

There have been circumstances over many years where remote auditing methods have been accepted for complete assessments or for use in some aspects of an assessment that is mostly onsite. As an example, IECEx OD 233 permits the use of an off-site assessment (remote auditing) for scope extensions for IEC 60079-33. There was also considerable guidance in the previous edition of this OD on their use under the title of "video or teleconferencing". Much of that material is now included in this annex sometimes with a change in terminology.

The use of IECEx OD 060 has provided a significant opportunity to experience the approach of doing assessments completely by remote auditing methods, utilising the provisions in that OD. Feedback from assessors and the results from a survey has enabled that experience to be used as an opportunity to explore how remote assessments, in whole or in-part might be used. There may still be some circumstances where IECEx OD 060 may still be applicable.

This annex provides guidance on when it may be appropriate to use remote assessments or remote auditing tools, and how remote assessments can be carried out.   This guidance is mostly drawn from the presentation made during training at the 2021 IECEx meetings assessor training which also took account of the survey.

At all times, and as part of their overall management of the assessment, it is the IECEx Lead Assessor who determines if remote auditing methods will be used during an IECEx assessment, in their quest for gathering objective evidence to demonstrate compliance with IECEx requirements.

E.3   Deciding on use of a remote ~~n~~assessment

E.3.1   General

Apart from the provisions of IECEx OD 060, the information in this subclause regarding the likelihood of doing an assessment remotely applies to all IECEx Schemes where onsite assessments are normally required.

E.3.2   Key factors to consider

The following key factors may need to be considered by the lead assessor in conjunction with the IECEx Secretariat when considering whether to conduct an assessment completely off-site, noting that onsite assessments remain the preferred method of assessment:

- Does an OD permit the use of a remote or off-site assessment, for example IECEx OD 233?

- Is the cost of travel significant for the time on site (for example if only one day, such as for a mid-term or scope extension assessment)?

- Remote assessments should not be a considered for initial assessments or re-assessments unless IECEx OD 060 is applicable.

E.3.3   Additional factors

If a remote or off-site assessment is being considered, the following additional factors should also be considered as part of a decision to carry out such an assessment to ensure an effective assessment or assessment regime over a longer period of time:

- Is it a type of assessment that can be done effectively remotely?

- Does the body hold relevant national accreditation for the standards being considered?

- Does the body have experience with the testing or certification processes?

- Is there testing that needs to be witnessed?

- How complex is it?

- How many assessors are involved?

- Have any of the assessment team previously visited the facility?

- Was the last assessment remote or onsite?

- Is there likely to be a good internet connection – if in doubt can it be checked beforehand?

- Does the body have its quality documents and records readily available in a form that can be shared remotely?

- Are the quality documents in English or in a form that can be readily translated by computer software?

- Is the English of the people being assessed good enough for online discussion or can the assessor speak the language of the body?

- Is it possible to have one assessor on site and another remote without making things too complex?

E.4   Planning a remote assessment

A greater level of planning is required for a remote assessment compared to one being conducted onsite. The following should be taken into account when planning a remote assessment:

- Planning the assessment time periods for the assessment will be subject to agreement between the assessment team and the body being assessed.

- The length of remote sessions should not be too long but may be over a full day if there are appropriate breaks.

- Dates and timing of remote sessions should always be well planned and coordinated in similar manner to a face-to-face meeting.

- It is best to run the sessions in the time frame of the body being assessed to ensure staff are more likely to be available.

- Once the approach to assessment sessions has been agreed, prepare the assessment plan in the usual way.

- Clearly define in the plan all documentation that needs to be provided before the assessment.

- Define in which form the documentation should be provided, for example in English or in a form that allows easy machine translation.

- Define what documents need to be completed before the assessment (reports and checklists) and provide those documents with the plan or soon afterwards.

- All the above documentation needs to be available in time before the remote assessment to enable a careful review.

- For some bodies that have trouble having trouble committing to a date to provide all the required documentation, it may be necessary to wait until the documentation is available before finalising assessment dates.

- Ensure the body has a device (that can be connected to the meeting) that can be used to display facilities and tests being witnessed.

- The use of a gimbal with above device will provide a steadier picture and less likelihood of motion sickness for the assessor.

- The online platform needs to be agreed by all involved.

- The platform needs to be capable of sharing documents on screen by all parties.

- Consider setting up, or have the body set up, a shared folder for documents. It is a good to check the platform beforehand.

E.5   Partially remote assessments

There may be circumstances where the assessment might be partially remote. These include:

- The use of video or teleconferencing in preparation for an assessment.

- The use of video or teleconferencing after the assessment visit in resolving complex issues raised during the assessment.

- The use of an assessor remotely in addition to the one onsite.

- Contact with staff, or representatives from associated bodies, for personnel who are not available to be onsite during the assessment.

E.6   Carrying out a remote assessment

The following are some recommendations for carrying out a remote assessment:

- Ensure you get complete relevant documentation in time to review it before the opening online meeting.

- If substantial changes are needed, a complete new package may be needed.

- Ensure revised documents show what has been changed.

- Consider having a preliminary meeting before the opening meeting to discuss the approach and to check the technology.

- If warranted, the above meeting could become a pre-assessment.

- Try to keep to some key aspects of onsite assessments, for example having an opening and closing meeting.

- Ensure you still leave first drafts of reports with the body at the end of the closing meeting.

Annex F
Subcontracting of tests within the IECEx Certified Equipment Scheme

The following information comes from ExTAG/662/INF which was discussed in the ExTAG meeting held on 6 and 7 September 2022, with the following decision:

Decision 2022/03

In reviewing the report, members agreed to refer to the ExAG the matter of issuing ExTAG/662/Inf as guidance (possibly as a revision of IECEx OD 032).

1. Background

The subject of "Subcontracting" of tests is certainly not new to IECEx discussions. ExTAG members may recall past ExTAG discussions such as the 2014 ExTAG meeting where document ExTAG/325/CD "use of subcontractors" was discussed with the 2014 ExTAG meeting agreeing to the following resolution {Mins ExTAG/346/R}

"The discussion was then extended to include the definition of minimum test equipment required for a Test Laboratory. The IECEx Secretary suggested that ExMC WG02 includes in the TCD the list of minimum test equipment for each standard. It was also agreed by the members, that even for the tests concerned by these equipment, subcontracting may be possible, for example because of temporary capacity issues."

One of the results from the 2014 ExTAG discussions was the inclusion of "Minimum Testing Capability" in the IECEx Technical Capability Documents (TCDs) used for the IECEx peer assessment of IECEx Testing Laboratories, ExTLs and candidate ExTLs.

Various levels of use of subcontracting by an ExTL is a necessary part of daily business due to either or both:

a) Limitation of resources (equipment/expertise) to undertake specialised tests that may only be conducted very infrequently, for example, CTI (Comparative Tracking Index) testing; or

b) As a result of capacity issues relating to workload or sample size limitation etc.

During early development of the IECEx Certified Equipment Scheme, a key principle established required ExTLs to have and maintain a certain level of testing capability, as determined by the collective IECEx Membership. This principle has been maintained through the years of IECEx's development and continues today. In support of this principle IECEx through its specialist Working Group, ExMC WG2 developed and maintain the IECEx TCD to address each standard used within the IECEx 02 Certified Equipment Scheme. Current editions of TCDs are available from https://www.iecex.com/members-area/documents/tcds/

The TCDs have evolved to be an integral instrument and tool for conducting IECEx assessments of Laboratories seeking to join IECEx and for the 5 year re-assessment of ExTLs.

To be clear subcontracting of tests is still a provision used within the IECEx 02 Certified equipment Scheme, under set guidelines and provisions.

2. "Subcontracting" versus "Contracting"

When discussing the topic of Subcontracting it is important that a distinct separation is made between subcontracting with an organisation versus contracting of persons to support the human resources of an ExTL.

For the purposes of IECEx peer assessments of ExTLs and IECEx Certification Bodies (ExCBs) the clear distinction made has long been that contracted resources, for example, contracted Quality Management System (QMS) auditors, are regarded as a contracting arrangement, similar to an employment contract with staff, as both employees and contracted persons, such as QMS auditors have their training and competence evaluated by the ExTL or ExCB engaging them AND both employees and contracted staff MUST conduct their work in accordance with the procedures and work instructions of the ExTL or ExCB they work for.

When ExTLs and ExCBs are assessed by the IECEx Assessment Teams, both employees and contracted persons are regarded as one in the same with the ExTL and ExCB under assessment needing to demonstrate systems and procedures addressing training and evaluation of ALL persons that perform key tasks within the ExTL or ExCB.

When it comes to "Subcontracting" this is a term used to identify the "Outsourcing" of tasks/work to another organisation, relying on that other organisation's own internal Quality Management System's procedures and systems for having the task/work performed to the satisfaction of the ExTL or ExCB that has engaged the "other organisation".

A quick look at International Standard, ISO/IEC 17021-1 *Conformity assessment —*
Requirements for bodies providing audit and certification of management systems —
Part 1: Requirements, Clause 7.5.1 of "the Outsourcing Clause", extracted below, includes a very useful statement that aligns with the above description.

7.5 Outsourcing {Extract from ISO/IEC 17021-1 Ed 1.0}

> 7.5.1 The certification body shall have a process in which it describes the conditions under which outsourcing (which is subcontracting to another organization to provide part of the certification activities on behalf of the certification body) may take place

While the scope of ISO/IEC 17021-1 applies to Certification Bodies, this principle associated with outsourcing of tasks applies equally to Testing Laboratories, which we will see later in this document.

Regardless of whether subcontracting or contracting is being used by an ExTL or ExCB, IECEx expects that ExTLs or ExCBs have a responsibility towards:

    a) The Tasks/work performed; and

b) Evaluation of the subcontractor or contractor and monitoring of their performance

While in both subcontracting and contracting situations, the ExTL and ExCB takes responsibility for the task/work done by both, control over task/work performed by contracted persons is much simpler as it is the ExTL or ExCB's own procedures and systems that are used hence the level of monitoring and control may be more straightforward.

When using another organisation to perform tasks, such as tests, under a subcontracting arrangement the ExTL or ExCB may need to rely on a number of means to evaluate the competence and overall quality of the Organisation to whom they are subcontracting to. Other means includes use of ISO/IEC 17025 accreditation according to structured approach such as that under the ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum).

3. ISO/IEC 17065 Requirements of ExCBs concerning Subcontracting (Outsourcing)

Apart from specific requirements contained within IECEx rules of procedures and Operational Documents (ODs), the fundamental requirements of ISO/IEC 17065 *Conformity assessment — Requirements for bodies certifying products, processes and services* apply, in particular those of Clause 6.2.2 "External resources (outsourcing)" and its subclauses 6.2.2.1 to 6.2.2.4.

A key requirement of Clause 6.2.2 and its subclauses is that contained under item a) of 6.2.2.4 requiring that the Certification Body to

- *"take responsibility for all activities outsourced to another body"*

- *have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities*

- Others (refer to the text of ISO/IEC 17065)

We are also reminded of the requirements of IECEx 02 regarding the need for the IECEx Management Committee, ExMC to approve the cooperation between ExCBs and ExTLs where they are not part of the same organisation, noting in particular the following extracted bullets from Clause 11.1.1 of IECEx 02:

- The certification body shall have within its organization, or have an agreement to employ, an ExTL accepted by the ExMC according to these Rules for the relevant types of protection
- Where the certification body wishes to cooperate with more than one ExTL, the certification body shall have a separate agreement with each ExTL and such cooperation shall be agreed by ExMC either at a meeting or voting via correspondence.

4. ISO/IEC 17025 Requirements concerning Subcontracting of Tests

In focusing our attention on the subcontracting of tests, we see that previous editions of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* included a

dedicated Clause on the topic of "Subcontracting of Tests", such as Clause 4.5 of Edition 2.0, extracted below

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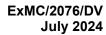**4.5 Subcontracting of tests and calibrations {Extract from ISO/IEC 17025 Edition 2}**

4.5.1 When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.

4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.

A separate Clause, Clause 4.6 *"Purchasing services and supplies"*, to address the control of service providers and suppliers beyond those providing subcontracted testing services was also included in previous editions of ISO/IEC 17025.

During the revision of ISO/IEC 17025 Ed 2.0 both items of Clause 4.5 and 4.6 were somewhat combined and now presented under Clause 6.6 "**Externally provided products and services**", extract below:

6.6 Externally provided products and services {Extract from ISO/IEC 17025 Edition 3}

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services

6.6.2 The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

A common theme that has existed throughout the various editions of ISO/IEC 17025 has been the need for Testing laboratories to have available the necessary personnel, facilities, equipment and systems to perform its testing services. This has now been made very clear via Clause 6.1 Under **Resource Requirements** of the current edition 3 of ISO/IEC 17025, extract below.

6.1 General {Extract from ISO/IEC 17025 Edition 3}

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

A very important message to convey at this point is that in subcontracting to another organisation to provide a service, does not enable one to subcontract its responsibility.

Bottom line, is that Testing Laboratories are responsible for the Test reports they issue and must have processes and procedures for:

- Evaluating;
- Appointing; and
- Monitoring

Of External Service Providers (subcontractors – including subcontracting of tests, where the IECEx TCD permits this) when using such.

5. **IECEx requirements concerning IECEx Testing Laboratories (ExTLs)**

IECEx 02 *IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System) Rules of Procedure* Clause 11.2 and subclauses details the requirements of Organisations seeking acceptance as an ExTL. In particular, the 4th Bullet of subclause 11.2.1 includes the following requirement

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IECEx 02 Ed 7.1 Clause 11.2.1 4th Bullet extract
..........The general competence, efficiency, experience, familiarity with the relevant standards and the types of protection included in those standards as well as compliance with ISO/IEC 17025 and the IECEx Technical Guidance Documents shall be assessed......

In addition, subclause 11.2.2 of IECEx 02 "Application" requires candidate ExTLs to submit information contained in Annex B and C to be provided to the IECEx Secretariat when making application to join the IECEx 02 Certified equipment scheme. Included in the information to be provided by candidate ExTLs is information concerning Subcontracting of tests, re item C.6.2 of IECEx 02, extracted below:

C.6.3 Subcontract work
What type of testing is to be subcontracted in respect of the recognition being sought?

This information assists the IECEx peer Assessment Teams to prepare for the IECEx assessment of candidate ExTLs, whom, as part of the IECEx peer assessment will check and confirm that the candidate ExTL have procedures and systems to address a number of matters such as:

a) Whether the subcontracting of tests is in line with the provisions of the IECEx TCDs;
b) The systems and procedures used by the ExTL for evaluating subcontracted laboratories align with requirements for IECEx requirements associated with
   i. The subcontracted test labs capability for performing the tests;
   ii. Whether or not the subcontracted test lab holds accreditation by an ILAC member accreditation body, or is an Accepted ExTL within IECEx;
   iii. If accredited, are the tests covered by the scope of accreditation and is accreditation current;
   iv. If the test lab is not accredited or the tests are not covered by accreditation, the ExTL must have a procedure for assessing the test lab itself;
   v. Others

c) The systems and procedures used by the ExTL for monitoring subcontracted laboratories align with requirements for IECEx requirements associated with
   i. On-going checking of status of accreditation or IECEx acceptance when using another ExTL;
   ii. On-going assessment by the ExTL itself where the subcontracted test lab does not hold accreditation by an ILAC member accreditation body;
   iii. Others

6. Conclusion
This document does not contain any recommendations, nor propose any changes to the current IECEx rules but rather is presented as a timely reminder for the IECEx community which includes ExTLs and ExCBs, of the IECEx requirements regarding the use of external resources, whether

referred to as Subcontracting / Outsourcing etc for which the starting point of such are the general requirements contained within the ISO/IEC 17000 suite of Standards.