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Guidelines on Auditing Test Bodies

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Abstract
Environmental Technology Verification (ETV) is a new tool enabling the verification of the performance claims put forward by developers of innovative environmental technologies. The EU-ETV programme, launched in 2011 by DG-ENV, is supported by Technical Working Groups (TWGs), one for each technology area active under the Pilot programme. These TWGs are chaired by the JRC and composed by Commission Invited Experts and by Experts representing the Verification Bodies with the overall aim to harmonise and exchange good practices.

Under ETV, verifications are based on tests performed by test bodies. The credibility and reliability of ETV depend, amongst others, on the qualifications of the test body and its ability to perform properly the required tests and generate reliable results. To assess this, verification bodies may have to perform an audit of the test body. This document provides guidance to help Verification Bodies to evaluate whether such audit is needed, what should be the scope, and how to carry out in practice.

This document, adopted on the on the 06/06/2016 by the TWGs, is a guidance document, with the meaning given in the General Verification Protocol of the EU ETV pilot programme (version 1.2), Section A.II.4.3. It has been produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment.
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1 CONTEXT

Environmental Technology Verification (ETV) is a new tool to help innovative environmental technologies reach the market. It consists of the validation of the performance claims put forward by technology manufacturers, on a voluntary basis, by qualified third parties. This should help manufacturers prove the reliability of their claims, and help technology purchasers identify innovations that suit their needs. As a result, technological lock-in is overcome while more effective and cheaper environmental protection measures can emerge.

The EU ETV pilot programme, run by the European Commission on an experimental basis, is implemented by Verification Bodies (VBs) specifically accredited for ETV. The technical reference defining ETV procedures and requirements is the General Verification Protocol (GVP). It ensures that all verifications made in Europe follow the same process and have the same value. VBs are coordinated by thematic Technical Working Groups, providing guidance on the implementation of ETV and ensuring the adequate harmonisation of practices.

2 INTRODUCTION: why an audit?

The credibility and reliability of ETV depend on a well understood and well implemented quality system. The GVP outlines this quality system. Central in this quality system are the qualifications of the Test Body (TB) and its ability to perform properly the required tests and generate reliable results. This depends on the ability of the test body to deploy a test system and a quality management system that are suitable for the tests to be performed. The test system is the system in which the tests are carried out: it covers items like qualification of personal, selection of appropriate test methods, calibration of instruments, sampling procedures, data transmission etc. To ensure the appropriateness of the test system and of the quality management system, the GVP requires the verification body to perform a test system assessment, which is defined as (GVP appendix 1):

> *(23) 'Test system assessment' means determining whether the test system and quality management system applied by a test body to generate data for verification purposes comply with the requirements of the General Verification Protocol and of the specific verification protocol. It includes the review of the relevant accreditations, and may include a test system audit.*

To ensure quality of testing, a specific standard exists: *ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories*. This standard covers both quality management and technical requirements related to the test system.

The existence of an ISO/IEC 17025 accreditation for the tests to be performed is an essential element for the test system assessment: if such accreditation exists, one may assume that the test system the quality management system that are suitable for the tests to be performed.

In the absence of such accreditation, the GVP explicitly requires the verification body to perform a test system audit to assess the suitability of the test system and a quality management system. The test system audit is defined as:

> *(24) 'Test system audit' means the examination of a test system and of a quality management system. It is achieved through the review of relevant procedures, observation of actual practices and evaluation of test performance. Where applicable, it includes the examination of control data for relevant period, participation in proficiency*

testing and/or control of calibration of measurement devices. It is aimed to provide the necessary evidence for the test system assessment.

Test system assessment and the test system audit have thus a broader scope than the test system as such, as they also include the quality management system.

The ISO/IEC 17025 is the reference for the audit, and the GVP specifies that the Verification Body is responsible for deciding which requirements of ISO/IEC 17025 are relevant.

The next section presents the specific requirements of the GVP that organize the quality system outlined above.

3 Overview of the relevant GVP requirements for test bodies

As indicated above, the test body shall have a suitable quality management system and test system for the considered tests. This is expressed in the GVP as "quality management and general test requirements".

GVP section A.II.6.1 specifies the minimal quality requirements for test bodies:

> *Test bodies shall fulfil the relevant requirements described in Part C Quality management, with respect to their role in the verification process (C.I), quality assurance and control for the verification process (C.III), as well as the quality management and general test requirements of the GVP.*
>
> *The quality management and general test requirements of the GVP are those requirements of ISO/IEC Standard 17025 – 'General requirements for the competence of testing and calibration laboratories', that are considered relevant for the tests to be performed. The Verification Body is responsible for deciding which requirements of ISO/IEC 17025 are relevant and these shall be clearly indicated in the specific verification protocol established for the technology to be tested, in application of Chapter B.IV. A list of requirements that need to be considered is provided in Appendix 10.*
>
> *The specific verification protocol may add further requirements on tests when this is necessary to ensure the quality of these tests and test data for the technology in question.*
>
> *Moreover, if tests consist of analyses, the test body performing those analyses shall be accredited to applying ISO/IEC 17025 for the relevant analytical methods. Routine analytical quality control data and participation in proficiency tests for the analysis used and the relevant period shall be made available to the Verification Body upon request.*

Analyses are described in a footnote:

> *Analyses are distinguished from tests when they follow highly standardized methods, independent of the innovation or specific features of the technology at the origin of the test samples. This concerns for example biological or chemical analysis of water samples and other products.*

When referring to analyses the GVP refers thus to tests for which standard methods exist and are appropriate for the verification at hand, and for which suitable ISO/IEC 17025 accredited test

bodies (which may also called be 'laboratories') are available. In this case the GVP requires that the tests are performed by such accredited bodies.

GVP chapter C.I specifies the responsibility of the Verification Body with respect to the test bodies:

> *The Verification Body shall ensure that the test bodies involved in a verification meet the quality management requirements and the general test requirements of the GVP.*

That section of the GVP also indicates measures the verification body had to undertake in order to ensure compliance with GVP requirements:

> *In order to ensure that all quality requirements provided in the GVP are met, the Verification Bodies and the test bodies shall undertake the reviews, assessments and audits provided in the GVP, Chapter C.III on Quality Assurance.*

Tables 2 and 3 in section C.III of the GVP detail the obligations of verification and test bodies.

4 The 'test system assessment'

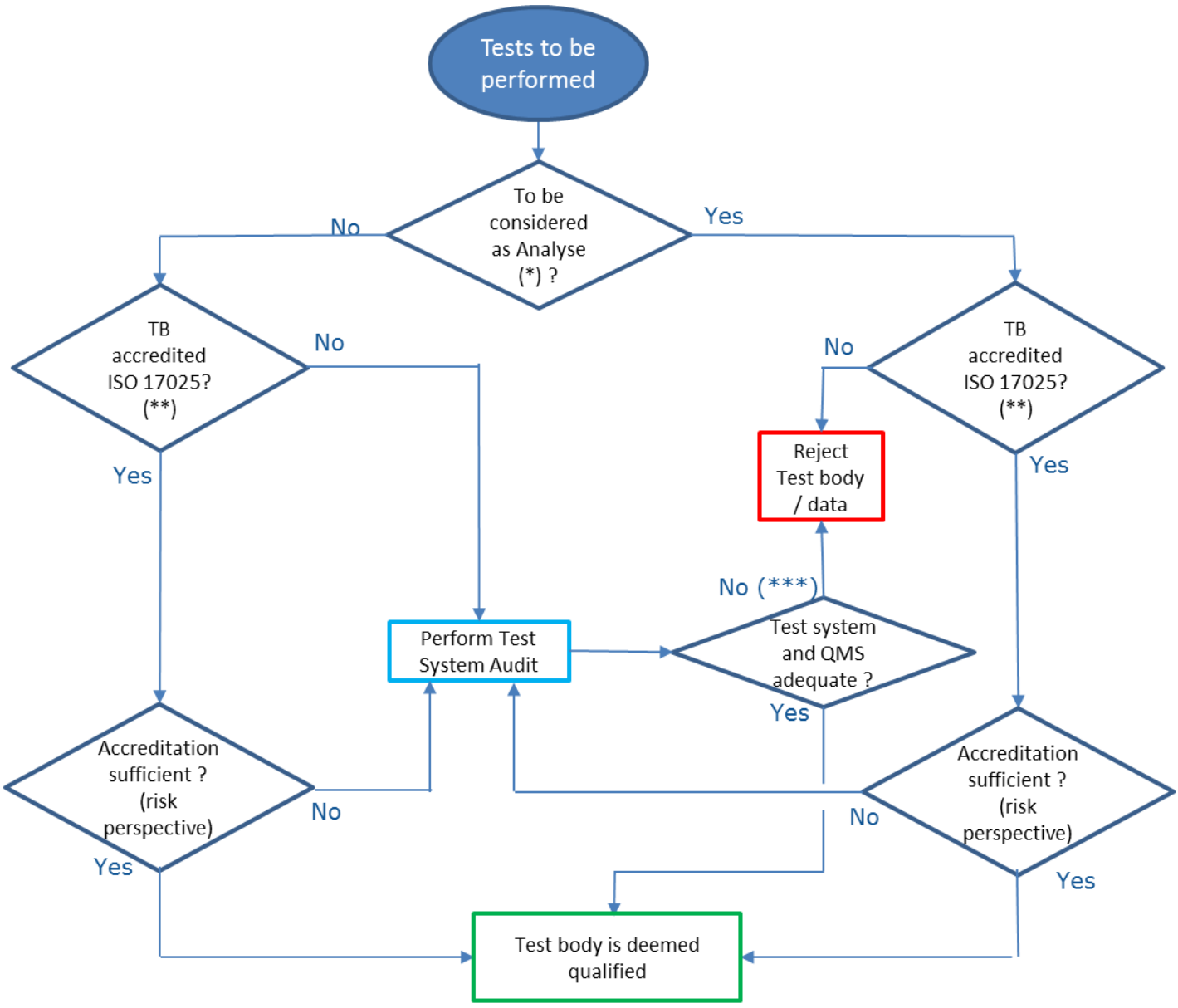
The Verification Body has the duty to assess the capability the TB to perform the tests and produce reliable results by examining the suitability of the quality management system and of the test system. This is achieved through the test system assessment, as indicated above.

The assessment is in fact a risk assessment, trying to identify 'what could go wrong'. The assessment should include any relevant information the VB has at hand. Possible ISO/IEC 17025 accreditation is of course a key element. A key step in the assessment is the decision as of whether to perform a test system audit or not. In the absence of ISO/IEC 17025 accreditation, the audit of the test body is necessary. In case of such accreditation the audit may be omitted, but the verification body may still decide to perform an audit if there is a perceived risk, based on elements like complexity of the tests, reputation of test body, accreditation history, experience with previous testing, etc.

As indicated in the GVP, the possibility to perform an audit should be anticipated in the specific verification protocol.

The audit, if performed is a key input to the test system assessment. The audit results may be complemented by other inputs like the review of the test plan and test report, allowing the verification body to make its final judgment on the suitability of the test system and quality management system.

The following figure illustrates the approach to be followed in the test system assessment:



(*) In the sense of the GVP
(**) for methods in the area of analysis relevant for the verification process
(***) After checking possibilities to improve the situation (possible only in the case of new data yet to be produced)

Figure 1: Logical diagram illustrating the test system assessment

5 The 'test system audit'

The definition of the test system audit is provided above (see also GVP appendix 1):

The purpose of the audit is to collect and evaluate relevant objective evidence allowing to assess the suitability of the quality management system and of the test system. The scope and content of the audit has to be devised in order to provide valuable information for the assessment. The audit shall allow to determine whether the test body meets the requirements of the GVP and the relevant specific verification protocol. The audit shall focus on those requirements of ISO/IEC Standard 17025 - General requirements for the competence of testing and calibration laboratories, that are considered relevant for the tests to be performed. The scope of the audit may be extended to address additional requirements set in the specific verification protocol.

The audit has 3 components:

1. The test system, i.e. the general test requirements of the GVP, covered by the 'Technical requirements' section of ISO/IEC 17025.
2. The quality management system (QMS), i.e. the quality management requirements of the GVP, by the 'Management requirements' section of ISO/IEC 17025.
3. The performance of the tests themselves

This is detailed further in section 11.

The scope and depth of the test system audit has to be decided in a risk-based perspective, in light of the nature complexity of the tests, the experience of the test body, its possible accreditations or certifications. A two-step audit procedure as suggested in the next section will also help to focus on-site observations to the essential elements.

A detailed indicative checklist for the first two components is provided in annex, based ISO 17025 requirements. As indicated in the GVP, the Verification Body is responsible for deciding which requirements of ISO/IEC 17025 are relevant.

The audit may not be required in the following situations:

When the TB is ISO/IEC 17025 accredited for the relevant methods of testing and calibration
When the TB is ISO/IEC 17025 accredited for tests that are very similar to the tests being considered, in that they provide data of the same quality.
When the VB has recently and positively audited the TB for identical or very similar tests, and no significant changes have occurred since that time, that would decrease the quality of the data and the VB has sufficient confidence in the quality of the test system for the tests at hand.

In all these situations (a, b and c), the decision not to perform (parts of) the audit is taken by the VB under its own responsibility, given the overall risk assessment.

6 Audit procedure

It is recommended to perform the test performance audit in several steps:

1. Preliminary assessment, for example through a questionnaire to be filled by the TB. If available, the reviews of the relevant test plan and test report can also provide valuable pre-audit information. Thanks to the preliminary assessment, some potential gaps can be identified, the TB is given a chance to perform corrections, and then the detailed audit can be performed.

2. Desk review: review of the QMS and test procedures. It can be performed remotely (off-site) if all procedures and manuals can be made available to the VB. It can be facilitated using a dedicated check list. This can be seen as the "say what you do" part of the audit.

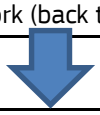
Those two steps could allow to focus the scope of investigations to be performed on-site in the third step, in a risk-based perspective, as explained above.

3. On-site observations: control of the adequate implementation in practice of the QMS and test procedures, performed on-site. This can be seen as the "do what you say" part of the audit. It aims at obtaining confirmation of proper implementation of the procedures that can influence

the outcome of the tests: is there evidence that the TB adequately follows these procedures? It will notably look at the suitability of the measurement method, the test system, and test operators, by examining the test in operation, methods, equipment, data quality control and review, and operator understanding and competence.

A more detailed audit procedure can be recommended as follows:

phase 1: preliminary assessment	1. Test Body fills-in the questionnaire (see annex for typical questions) 2. VB reviews questionnaire (and other relevant material like test plan and test report if available) 3. VB gets further insight via remote phone and/or video conference 4. The VB identifies possible 'gaps' 5. If no significant gaps, the audits can be further carried out (go to step 10) 6. If important gaps are identified, VB discusses with TB how to fill the gaps 7. TB take steps to fill the gaps 8. TB informs VB about steps taken 9. VB approves or requires further work (back to step 5)



Phase 2: detailed assessment	10. In-depth review of quality documentation based on the results of the preliminary assessment 11. Scope of on-site investigations is decided

Phase 3: On-site visit	11. VB goes on-site and performs the necessary observations 12. VB collets test performance data

Audits conclusion	13. VB performs overall assessment based on audit(s) results and other sources of information (documentation) 14. If the outcome is negative then back to step 6, or another TB has to be designated by the proposer (extreme case).

It is advisable that steps 1-11 occur <u>before testing.</u> Step 11 could be performed before or during testing (see section 812 below).

7 How many audits?

As many test system audits have to be carried out as necessary. If there is one test body, then it is expected that in most instances one audit will be enough, but here are instances that can justify carrying additional audits:

- If the verification involves more than one test system. This would be the case for example when different tests are planned at different moments with different personal, different measurement equipment, maybe in different locations. Note that it may be possible to cover several test systems in a single on-site visit, depending on the availability of the test systems at the moment and place of the audit.

- When measurements span over a long period and when there is not sufficient evidence to demonstrate that the quality of data can be maintained (e.g. lack of either internal or external audits).

- When a first audit results in a negative outcome, a second audit may be required in order to control the improvements put in place by the TB as a result of the first audit.

- When there are doubts about the qualifications of a TB[2], the VB may decide to come on site several times to witness the key phases of the testing procedure.

- When time did not allow to collect all required information during a first visit, or when the assessment of collected evidence reveals a need for further on-site investigations.

- When questions/doubts arise as a result of issues found in the test plan and /or report.

Technically, some of these instances can be seen as one audit split in several test site visits. The last instance (questions/doubts as a result of issues found in the test plan and /or report) implies that additional audits may have to be decided even at the end of the verification process.

8 When to conduct an audit?

It is possible to conduct the test system audit before, during or after the tests. The options can be combined.

8.1 Before testing (pre-qualification audit)

Conducting an audit before testing allows identify in advance potential weaknesses in the quality or the test and quality management systems, and could allow to propose possible areas of improvement.
For instance this audit may be relevant when there are doubts about the competence/suitability of a given TB (e.g. TB unknown to the VB, poor reputation, TB has little experience in the domain of the tests to be performed…). In the worst case it could allow to rule out an unqualified TB. If needed, the audit can even be performed before the TB elaborates the test plan, with a view to make sure that the TB does not engage in significant work without then proposer/VB having sufficient evidence about TB suitability. Otherwise it is recommended to wait for the test plan before carrying the audit, as the test plan could contain useful information related to quality assurance issues.

It is advised to complement this audit with an on-site visit during testing, unless the audit findings provide high confidence in the capability of the TB to conduct the considered tests and to produce reliable and reproducible results. However, an audit before testing is not likely to be sufficient if at the time of the audit the TB is not carrying out tests that are similar to the tests planned in the verification. In such case, a second audit during testing is required.

8.2 During testing (standard audit)

Conducting this audit allows to witness to operation of the TB for the specific tests at hand, and therefore to make pertinent observations about the relevant testing and quality management practices. In case of serious concerns, test results already obtained may have to be rejected. It is

[2] E.g. TB unfamiliar with the test at hand, and/or insufficient track record of proven ability to establish and follow sound and robust quality procedures

therefore recommended to perform the audit early in the testing process.

8.3 After testing (ex-post audit)

An ex-post audit comes generally as an additional audit that is supplementary to other audit(s) already performed. It can provide great benefits for example with selective and limited retesting, to determine the reproducibility, and/or parallel tests comparing measurements with those from an accredited test laboratory.

If no other audit is carried, then the ex-post audit should also look at current practices related to similar tests, and include an in-depth auditing of records related the period in which the tests have been carried out. Interview with personnel that was involved in the testing is also useful, if these personnel are still present. The ex-post audit can be used for instance in the case of existing data (data produced before the verification started).

Nb: In case of existing data, the ex-post audit is the normal situation. See the guidance document on existing data for more information.

9 What kind of evidence is needed?

The test system audits should be performed by collecting different types of objective evidence, for instance:

Desk review:

- Questionnaire (check-list)
- Relevant manuals and procedures and other documents
- Previous audit results and recommendations (internal and/or third parties)
- Test performance data: Laboratory control data for relevant period, reports of laboratory participation in proficiency testing etc.

On-site observations

- Examination of records (staff training and qualification, calibration of instruments, measurement and data logs, tractability sheets, non-conformities, method validation reports…)[3]
- Staff interview
- Examination of test equipment and premises
- Observation of practices (e.g. witnessing the tests and other relevant activities such as calibration, filling in of records, sample handling, data handling).

Moreover, the review of the relevant test plan and test report, if available, is expected to deliver useful pre-audit information, e.g.:

- Which tests are covered by a 17025 accreditation?
- Which tests follow recognized methods?
- Are there robust quality assurance measures in place?
- Does the test plan/report refer to internal procedures?
- Does the test plan/report provide the relevant information about staff, measurement devices, test site, calibrations etc. ?

[3] Records that are available under electronic format can be already examined during the desk review

The relevant documents shall be used as main reference against which to make observations: test plan/report, Specific verification protocol, internal quality procedures relevant to the tests at hand, applicable standards and methods etc. ...

It may be useful to let investigations go beyond the tests at hand, in order to obtain confidence that the test body has a proven track record of good practices in various domains of testing. This is particularly true when the TB has little experience in the tests at hand.

The in-depth and exhaustiveness of the audit have to be tailored to each specific situation. In particular if there is satisfactory evidence of sound and robust procedures being well enforced, the number of spot checks can be reduced. In the opposite case, the number of checks has to be increased (e.g. verify that ALL relevant instruments have been properly calibrated).

10 Duration of the audit

The duration of the test system audit will depend on the complexity of the tests and of the test system, the qualifications of the test body and its experience with the considered tests, previous audit experience with the same test body, and VB's own experience with such audits. For a VB's first audits of this kind, 3-days duration for on-site observations is advised, to be progressively reduced according to experience if deemed advisable.

Another element to consider is the duration of the tests themselves. If their duration is limited (e.g. one to two days or less) then it may be worth to include in the audit the witnessing of the whole tests. This is all the more relevant when there is lack of evidence that the test body does have sound, robust and well-enforced quality and test procedures.

The audit involves some preliminary work, as well as an assessment of the collected evidence and the drafting of a report. This does not need to be performed on-site, and is not included in the three days duration mentioned above. The total effort for the audit could therefore be one week, but it could be also less or more, depending on the complexity and other factors highlighted above.

11 What to audit?

As indicated earlier, the test system audit has three components.

a) Quality Management System (QMS) component

In case of ISO 9001 certification, the QMS component of the audit may be simplified: after a satisfactory desk review of QMS procedures and their implementation, the VB may consider that the QMS requirements, or part of them, do not need to be verified on-site.

A detailed audit check list is provided in annex, based on the requirements of ISO 17025 as presented in annex 10 of the GVP.

b) Test system component

The audit shall cover key factors that contribute to measurement reliability. The main question is "what could affect the quality of the result?" The factors to be considered are selected from but not limited to:

- Competence of personnel
- Accommodation and environmental conditions

- Test methods and method validation
- Equipment incl. instrument positioning and condition
- Metrological traceability
- Sampling
- Handling of test and calibration items
- Quality of test and calibration results
- Reporting

The importance of those various factors has to be assessed according to the context, and the focus of the audit has to be adjusted accordingly. For example, is calibration crucial, is the personal quite familiar with those tests, is there a complex data transmission chain, are samples likely to deteriorate etc. ?

When performing the audit, a special attention to the requirements of the Specific Verification protocol and the test plan is needed.

A detailed audit check list is provided in annex, based on the requirements of ISO 17025 as presented in annex 10 of the GVP.

c) Test performance component

The test performance component of the audit aims at answering the following question: is there quantitative evidence of the reliability of the tests? This can be achieved through the review of relevant documentation e.g. calibration data, laboratory control data for relevant period, laboratory participation in proficiency testing, limited retesting to determine the reproducibility, parallel testing for comparing measurements with those from an accredited test laboratory etc. Whether this requires a site visit has to be determined on a case-by-case basis.

12 Outcome of the audit

One important objective of the test system audit is to obtain satisfactory evidence that sound and relevant procedures exist and that they are efficiently enforced. This will give confidence that tests will be performed appropriately even when the auditor has left the test premises. If procedures are poorly designed and/or enforcement level is weak, then the consequences have to be fully evaluated.

Overall, in case of doubtful audit outcomes, at least the following questions need to be addressed:
Are test results already obtained valid?
Is the test body allowed to proceed with testing?
Are improvements required?
Is supplementary testing required?
Is another audit needed?
Is it needed to witness all tests?
How will this be reflected in the outcome of the verification itself (i.e. in the Verification Report and in the Statement of Verification …)?

In the worst case, the TB has to be considered as not qualified and therefore the proposer has to designate another TB.

13 Audit reporting

A summary of collected the evidence and test system audit conclusions shall be compiled in an audit report. The report structure should be in line with the elements audited (e.g. items listed in section 11 above).

The outcome of the audits including possible deviations has to be outlined in the Verification Report (sections 4.2. *Evaluation of test quality*, and 5 *Quality Assurance*), and in the Statement of Verification (section 6 *Quality assurance and deviations*). To provide additional credibility to the verification, the audit report should be attached as an appendix to the verification report.

ANNEX 1 Detailed audit check list

The list may be complemented by specific questions addressing additional requirements set in the specific verification protocol.

To be provided in a later stage (copyright issue pending)

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