

ASSESSMENT OF MINIMALLY STAFFED TEST AND CALIBRATION LABORATORIES: CHALLENGES AND OPPORTUNITIES

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Countries that desire to actively participate in global trade have to ensure that their testing and calibration (T&C) laboratories follow internationally accepted practices. ISO/IEC Standard 17025, *General criteria for the competence of testing and calibration laboratories*, establishes the international norms on accepted practices. The standard stipulates that it is “applicable to all laboratories regardless of the number of personnel”, thus allowing even minimally staffed laboratories (MSLs) to seek accreditation.

MSLs find certain requirements of the standard, such as appointment of deputies to key management personnel, defining the responsibilities of functional personnel, internal auditing, management reviews, providing adequate supervision of staff, etc., difficult to address.

This paper deals with critical issues concerning application of ISO/IEC Standard 17025 to MSLs. Some of the suggestions contained herein may assist in the preparation of international guidelines so as to make the accreditation process for MSLs more uniform, robust and relevant.

1. INTRODUCTION

When it comes to competing in today’s globalized environment, testing and calibration laboratories accredited under ISO/IEC 17025:2005 have a clear advantage. All is well as long as the laboratories are staffed adequately with appropriately qualified personnel having relevant experience and training in their respective areas of testing and calibration (T&C). The documentation, implementation and maintenance requirements of quality systems involving both administrative and technical functions for any testing and/or calibration laboratory are well known and not discussed in this paper.

It is common knowledge in the T&C community that a significant number of testing and calibration laboratories seeking accreditation have a small staff consisting of 1 or 2 test and/or calibration personnel. We will call these laboratories Minimally Staffed Laboratories (MSLs) for the purpose of this paper. It has also been found that many of these laboratories are handling diverse testing and calibration activities involving force, pressure and thermal measurements, electrical and dimensional parameters, mass, balances, etc. Accreditation cannot be denied to such laboratories since

ISO/IEC17025: 2005 explicitly states, "...The standard is applicable to all laboratories regardless of the number of personnel..." However, Accreditation Bodies (ABs) are placed in an awkward situation as regards to some of the requirements of the management and technical systems and also their documentation, implementation and maintenance. Assessors also confront situations during the assessment of the technical competence of MSLs. This is because the wording in some of the requirements of ISO/IEC 17025: 2005 can be fully met only if the laboratory has adequate number of personnel.

This paper attempts to highlight difficult issues in accreditation of MSLs and possible solutions. This paper does not provide solutions, but merely highlights the areas in which assessment and hence accreditation needs to be innovatively practiced. We hope that this paper will stimulate discussion and dialogue in the technical community on the application of ISO/IEC Standard 17025 to MSLs.

2. REQUIREMENTS OF ISO/IEC STANDARD 17025: 2005

ISO/IEC 17025: 2005 contains both quality management and technical requirements for laboratories. The laboratories, irrespective of the number of personnel on their staff, are expected to meet these requirements to earn accreditation. In MSLs, it is not always possible to meet the strict letter of these requirements and during an assessment there are bound to be areas of conflict.

It must be recognized that the core task of any T&C laboratory is highly technical. As such, during assessment of MSLs, rigorous evaluation of the technical requirements is essential. An assessor, perhaps, can be judicious in certain management (or administrative) system requirements. This is because laboratories, basically, are expected to provide technical service to the industry by delivering unambiguous, dependable, and trustworthy results.

3. ASSESSMENT REQUIREMENTS

Whether a laboratory's staff is large or small it is necessary to determine if they meet expertise and competence requirements. It is quite possible that the personnel in larger laboratories complement each other in meeting this requirement. In other words, there may be a certain amount of redundancy in the technical support area. Such a 'complement-each-other' possibility is absent in case of MSLs and any assessment has to take into account this aspect. In any case, even with MSLs, the requirements of competence and expertise cannot be compromised.

An assessor is expected to examine the competence of a laboratory (within its scope of accreditation), and report the findings regarding the fitness of the laboratory for accreditation. His/her job is crucial and should be carried out without any bias. After all, the assessor is physically present on behalf of the AB, as the witness to the demonstration of competence. In case of laboratories with larger staff there may be some noncritical areas where an assessor can suggest opportunities for improvement, where such suggestions might be counter-productive in case of MSLs. This is where detailed records maintained by the MSL could be quite helpful in judging the relevance of some of the decisions taken by management.

As noted earlier, the main task of any T&C laboratory is to generate credible and dependable testing and calibration results. With this as an explicit requirement, it becomes necessary that the person in charge of the MSL be thoroughly knowledgeable in all the areas for which accreditation is sought. The process of assessment of an MSL may need to be more rigorous and, where the scope of accreditation makes it necessary, a number of technical assessors specialized in the respective areas

need to be sent for the assessment. This process can be expensive for a MSL but it cannot be avoided if competence is to be the final aim. There should be absolutely no compromise in judging the competence and expertise of the person handling the T&C assignments.

The areas (cross-referenced to the corresponding ISO/IEC 17025 clauses) where such rigorous and in-depth examination of MSLs needs to be carried out are:

- Adequacy of resources (4.1.5 a)
- Freedom from external and internal pressures (4.1.5 b)
- Impartiality and integrity (4.1.5 d)
- Quality policy and quality objective statements (4.2.2)
- Contract review (4.4)
- Subcontracting, if practiced by the laboratory (4.5)
- Complaints (4.8)
- Technical records (4.13.2)
- Internal audits (4.14) and Management reviews (4.15)
- Competence and skills (5.2.1)
- Educational qualifications and training (5.2.2)
- Inter-laboratory comparison and Proficiency Testing exercises (5.4.5)
- Uncertainty evaluation capability in each of the areas (5.4.6)
- Assuring quality of T&C results (5.9)
- Reporting of results (5.10.1 to 5.10.4)
- Opinions and interpretations (5.10.5)

All the above are a part of the ISO/IEC standard and need to be assessed irrespective of the size of the laboratory. However, during assessments of laboratories with larger staff, it has been experienced that knowledge is more or less distributed and the staff can collectively work towards fulfilling the requirements. As such, some concessions may be accorded to the laboratory, under the assumption that the staff works as a team. This is not possible in the case of MSLs, since the staff is limited which requires that the person in charge to be a “know-all” regarding the requirements of the standard as well as the technical activities. This demands that the assessment be carried out thoroughly to examine each of the requirements in detail and the collection of evidence to ascertain the competency of the MSL. Collection of evidence must be exhaustive and carried out rigorously.

4. ADEQUACY OF RESOURCES (4.1.5 a)

Assessors should carefully examine records as to the quantity of work handled by an MSL. This gives a fair idea about the MSL: if it is too ambitious in accepting the assignments, without commensurate time resources, or is accepting work outside its capacity to deliver. It also helps in understanding how the laboratory goes about handling the assignments. Any test or calibration exercise needs an appropriate amount of time to do a proper job. Experienced assessors can judge if the MSL is accepting assignments within its time-resource capabilities.

5. FREEDOM FROM EXTERNAL AND INTERNAL PRESSURES (4.1.5 b)

This is a difficult area to assess in larger laboratories, but may be even more difficult with MSLs. In a large laboratory or in a laboratory that is a part of a large organization, some documents like general guidelines, standing orders, rules and regulations, etc., of the parent organization mitigate the documentation requirement. But an MSL might not have the appropriate documentation or it may be

impractical to have because the wording of the standard presumes the laboratory has multiple personnel. In an MSL, the same person that has to create the documentation has to follow it as well!

In this case, the least that is expected in an MSL is that the quality policy and quality objectives contain statements about being free from such pressures. It should be insisted that these statements are made as policy statements and the objectives should aim towards following these without compromise. If the policies and objectives do not contain these statements, they should be rewritten to do so.

ISO/IEC 17025: 2005 expects deputies to be appointed for key managerial positions. Such an appointment is possible only in a laboratory with larger staff. Concession on appointment of deputies may be accorded to the MSL.

6. IMPARTIALITY AND INTEGRITY (4.1.5.d)

One of the clauses of ISO/IEC 17025: 2005 requires a demonstration of impartiality and integrity in the operations of a laboratory. In an MSL, this may present a difficult situation, since a single person may be responsible for all of the technical activities as well as the commercial and administrative functions, apart from being the owner of the laboratory.

To provide evidence of the observance of impartiality and integrity, the MSL is expected to record and retain information on the discussions it has had with the customer during the contract review process. Such records could reinforce evidence of the MSL's integrity, particularly if evidence of rejection of T&C assignments by the MSL is found. Rejection of work could be due to technical incapability, lack of infrastructure or lack of expertise needed to handle the assignments or due to conflicts between the needs of the customer and the requirements of the standards.

The reports/certificates generated by the laboratory can, sometimes, serve to draw upon some conclusions on this aspect.

7. CONTRACT REVIEW (4.4)

The process of reviewing the work involved, expertise and facilities available within the MSL has to be rigorously analyzed during contract review. Documentation should exist for the reviews having taken place for each and every assignment handled by the MSL. Exceptions can be only in the case of repeat orders from the same customer. The contract review process must have been carried out even if the job is the same, but with a different customer.

The process of contract review and the documented details of discussions the laboratory has had with the customer will give the assessor some insight into the capabilities of the MSL and the person handling these issues.

8. SUBCONTRACTING (4.5)

Some MSLs may subcontract T&C assignments to other laboratories. When the MSL subcontracts T&C, the laboratory must have observed and documented the requirements of ISO/IEC Standard 17025: 2005. The following requirements and the records need to be thoroughly examined to ensure that the methodologies are being clearly followed by the MSL:

- Reason for subcontracting
- Customer's approval for subcontracting to a particular laboratory
- Accreditation status of the laboratory to which work is subcontracted.
- Capabilities and expertise available within the subcontracted laboratory
- Reports from the subcontracted laboratory

9. COMPLAINTS AND THEIR DISPOSAL (4.8)

The nature of complaints and the way they have been disposed of gives an insight into the working of any laboratory, more so in case of MSLs. As such, the laboratory must keep a record of *all* the complaints received—both valid and invalid. Valid complaints may occur where the laboratory is at fault and the customer demands resolution. Invalid complaints may occur where the laboratory is right and the customer has raised a complaint without either understanding the report or without interpreting it properly. In the first case, the MSL must have resolved the complaint in a professional way and attempted to satisfy the customer. In the second case, the laboratory must have explained its position and must have satisfactorily communicated its position to the customer in a timely manner.

MSLs must document both the types of complaints and the subsequent corrective actions. While the resolution of valid complaints shows how the system is working, resolving invalid complaints can indicate that the laboratory is doing the right thing.

10. TECHNICAL RECORDS (4.13.2)

This requirement of the standard is very important irrespective of the size of the laboratory. Standards are quite expensive and it is possible that some MSLs may avoid procuring a standard purely from the financial point of view. This is to be discouraged and the MSL must be counseled to procure these documents.

In an MSL, since the same person conducting contract review may be the same person handling the assignments, there could be a presumption that documenting processes and procedures is not needed. This presumption is incorrect and the MSL must have documented all the processes and procedures for work carried out by the laboratory. Documentation regarding observations during actual tests or calibrations, raw data sheets, readings obtained, repeated readings, if any, draft reports, basis on which opinions and interpretations are provided, etc., should have been made and should be available for review by the assessor.

Often, documented procedures themselves give an insight into the expertise available within the MSL and the way in which they are written goes a long way in deciding upon the acceptability for accreditation. On-site processes (carried out at the customer's premises) should include checking of the laboratory's own equipment for proper function, before leaving the laboratory, after reaching customer's premises, and on return to the laboratory, apart from addressing the requirements of safe packing and careful transportation.

11. INTERNAL AUDITS (4.14)

Internal audits are powerful tools for identifying potential noncompliance. Normally laboratories carry out internal audits by a staff person not connected with the activity being audited. In case of an MSL, this possibility does not exist and the audit exercise should be carried out by an external auditor. It would be beneficial to the laboratory if internal audits are carried out by an external person who is

technically qualified and experienced in the fields of T&C. Additionally, the individual must have gone through an appropriate training program and conducted several similar audits. Additionally, he/she must be able to carry out both quality system and technical audits.

While it is realized that such an audit is more costly, it adds a lot of value to the process and enhances the quality of the MSL. The MSL should keep documents of the credentials of the auditor, supported by relevant certificates. All nonconformances raised during the audit must be resolved and closed by the same auditor who raised them initially.

If the owner himself has performed the internal audit of the MSL, the results of the audit may require additional verification and laboratory assessors may have to make allowances to spend additional time on this aspect during the assessment

12. MANAGEMENT REVIEWS (4.15)

The management review function is expected to reveal the continuity and effectiveness of the quality system established in a laboratory. Since an MSL has only minimal working staff, it would appear that management review does not serve any useful purpose. This requirement can possibly be minimized, provided the internal audits of both quality management and technical requirements have been carried out thoroughly, all the issues that arose therein have been satisfactorily resolved and the MSL has clear performance goals and measurement tools in place.

13. COMPETENCE AND SKILLS (5.2.1)

The competence and skills of the person handling the T&C assignments need to be examined critically during the assessment of an MSL. A critical and thorough examination is required, because, unlike larger laboratories where redundancy in staff exists allowing other personnel to fill-in, an MSL has no such luxury. In an MSL, the same person has to attend to all the T/C requirements, however diversified they may be. For this reason it is necessary that the person demonstrate how he/she handles the various aspects and various types of T/C exercises. Observation of a valid sampling of tests or calibrations can give an insight into the capabilities, skills, ability to handle equipment and analytical capabilities of the person.

It is beneficial to choose tests and/or calibrations (within the scope of accreditation) in such a way that they are as diverse as possible so that more definitive information about the MSL's capabilities can be obtained.

14. EDUCATIONAL QUALIFICATIONS AND TRAINING (5.2.2)

It is desirable that the person in charge of the MSL has academic qualifications in the respective discipline of work. Academic qualifications provide some assurance that a person has the capacity to establish a management system, write procedures, understand standards, analyze results and give opinions and interpretations. If the person in charge does not have an appropriate academic background, at least he/she must have worked in the area of T&C for a sufficient period to achieve the necessary expertise to carry out the duties.

The person in charge must have undergone training and/or attended refresher courses in *all* fields covered under the scope of accreditation. Documents supporting the qualifications, experience and training must be available for review at the time of assessment.

There should be absolutely no compromise in determining the thoroughness of knowledge of the person in charge within the scope of accreditation. T&C functions are very critical and the consequences of an incorrect report could be far-reaching. A thorough technical interview with the person in charge is necessary to determine expertise.

15. INTER-LABORATORY COMPARISON/PROFICIENCY TESTING (5.4.5)

This is one area wherein an MSL's true capabilities and competence can be judged. The laboratory must have participated in inter-laboratory comparison (ILC) exercises in *all* the fields applied for in the scope (where available). It is also essential that the MSL has carried out these exercises with other accredited laboratories. The exercise is much more meaningful (in calibration labs) if at least one of the participating labs has smaller uncertainties [or better BMCs (best measurement capability)] than the MSL. In such a case, the evaluation of 'E_n' or 'Z' values is more meaningful.

The exercises in ILC could be self-initiated or initiated by other laboratories. Both are acceptable. But, it is essential that the protocols have been documented, methodology for the exercises have been drawn-up and care has been taken to ensure that all participating laboratories have followed the same methodology. The artifact must have been characterized by a higher-level laboratory before the start of the exercise and also characterized at the end of the exercise. 'E_n' numbers or 'Z' scores, as relevant, must have been evaluated and they must be within the permissible (+/- 1 for E_n and 3 for Z) values. In case the values fall outside the permissible limits, root-cause analysis must have been carried out, corrective actions initiated and efforts must have been made to get the value/score within the permissible limits. Documentation for all these actions must be in place and should be presented to the assessors at the time of assessment.

16. UNCERTAINTY EVALUATION (5.4.6)

Evaluation of uncertainties is the heart of any T&C exercise. The person doing the test or calibration, more particularly calibration, should be conversant with the procedure of evaluation, have the necessary knowledge about type 'A' and type 'B' contributions, factors to be considered for evaluation of type 'B' contributions, combined uncertainties, degrees of freedom, coverage factor, etc.

In an MSL, the person in charge should be aware of all the factors above as well as the procedure for evaluation. Also, he should be aware of all these influences in a diversified range of applications. The concepts, theoretical background, factors influencing measurements, etc., should be known to him.

Normally, laboratories use a spreadsheet program for evaluating uncertainties. Use of a spreadsheet does not in any way prove that the user has the theoretical knowledge about the evaluation. Theoretical knowledge is very important and this has to be ensured in an MSL by asking the person to evaluate manually and demonstrate his knowledge about the evaluation. The manual evaluation should be at least for one example in each field of the scope.

17. ASSURING QUALITY OF RESULTS (5.9)

This requirement is important in case of MSLs and an assessor must review the exercises carried out periodically by the laboratory. It is all the more important since only one or two people are handling all the assignments and it gives a reasonable idea of how consistently the person performs the technical work.

Consistent, credible and reliable results can be assured from an MSL only when it does a self-assessment of its own results periodically. The more frequent such periodic checks are conducted, the more confidence will be gained in the MSL by the assessors, the accrediting body and the laboratory's customers. The laboratory must have carried out and documented repeatability and reproducibility exercises periodically. These records should be available for review at the time of assessment.

18. REPORTING OF RESULTS (5.10.1 to 5.10.4)

The T/C reports and certificates are the final products of any laboratory. It is necessary that the reports be critically examined for correctness before they reach the customer. Usually, reports are endorsed by two persons—by the person that creates the report and another higher level person who checks and authorizes it to be issued. This is typical practice in larger laboratories but poses problems in a one-person laboratory. While reports endorsed by only one person can be accepted (for lack of an alternative), it is essential that assessors review typical reports generated by the MSL, to see whether all the reporting requirements are being fulfilled.

19. OPINIONS AND INTERPRETATIONS (5.10.5)

Generally it is the norm that in T&C exercises, particularly in the case of calibration, laboratories do not provide opinions and interpretations unless specifically asked for by the customer. Whenever these are given, they should be handled by experienced personnel having expert knowledge of the subject matter and good analytical skills. Opinions and interpretations given in any of the reports issued by an MSL provides further insight into the person generating the comments and should be carefully reviewed by the assessment team. This is another opportunity to further evaluate the competence of the MSL staff.

20. OTHER AREAS OF RELEVANCE

In addition to the clauses noted above, examining how an MSL handles control of data (5.4.7) provides insight into the competence of an MSL. Having minimal staff may mean that there needs to be experience in the use of computers, data acquisition or other types of automated equipment. Procedures for protecting data, ensuring that software is validated and methods for maintaining confidentiality must be critically assessed.

21. CONCLUSION

In summary, accreditation of all laboratories is a difficult and challenging exercise. Of course, the success of any program depends on the commitment of the people performing the tasks. It is all the more critical in case of MSLs, since it is the responsibility of one or two persons to carry out all that is required to be done and satisfy the requirements of the standard. It should be appreciated that any assessment is only a sampling exercise and that the laboratory needs to be committed in its day-to-day activities if it is to gain the confidence of customers. Assessment and accreditation of MSLs are fraught with ambiguities and awkwardness in applying the clauses of ISO/IEC Standard 17025. This discussion paper is intended to highlight the clauses in the standard that pose particular difficulties for any assessor.