Improving Performance of Testing Laboratories – A Statistical Review and Evaluation

G. I. Anastasopoulos[1(✉)], P. S. Ramakrishnan[1], and I. G. Anastasopoulos[2]

[1] International Accreditation Service, Brea, USA
ganas@checkp.info
[2] School of Letters and Sciences, University of California at Berkeley, Berkeley, USA

Abstract. This paper outlines the most common quality challenges testing laboratories are facing during their accreditation process. Accreditation is the independent evaluation of conformity assessment bodies (i.e. Testing laboratories) against recognized standards to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, government, procurers and consumers can have confidence in the quality of test results, inspection reports and certifications provided.

This study has been performed based on data collected by more than 300 testing laboratories, from 41 countries worldwide, accredited against the requirements of the international standard ISO/IEC 17025-2005 *"General requirements for the competence of testing and calibration laboratories."*

The Non-Conformities were issued during the accreditation process of various testing laboratories specializing in different testing categories (Civil, Geotechnical, Mechanical, Electrical, Chemical, Microbiological, etc.). Findings vary from commonly reported quality management system issues to the most demanding technical challenges faced by testing laboratories.

The identified Non-Conformities were categorized and statistically processed. The trends are identified and analyzed per quality management system or technical category. Under the accreditation process, laboratories are required to respond to any significant findings with a submittal of a corrective action plan containing an analysis of the root cause, details of actions taken to resolve the issue and strategies to prevent reoccurrence. Various responses were analyzed and some suggestions and good practices were gleaned from these submittals. Opportunities for improvement are presented for each corresponding category of findings.

ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification. The standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities.

L. Mohammad and R. Abd El-Hakim (Eds.): GeoMEast 2019, SUCI, pp. 16–34, 2020.
https://doi.org/10.1007/978-3-030-34187-9_2

1 General

ISO/IEC 17025 was first issued in 1999 by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC). It is the single most important standard for calibration and testing laboratories around the world. CASCO is the ISO committee that works on issues relating to conformity assessment. CASCO develops policy and publishes standards related to conformity assessment. CASCO's standards development activities are carried out by working groups made up of experts put forward by the ISO member bodies. The experts are individuals who possess specific knowledge relating to the activities to be undertaken by the working group [1].

The data provided in this paper refers to the ISO/IEC 17025 version 2005 [2]. Since December 2017 the ISO/IEC 17025 version 2017 [3] of the standard is available, with a transition period until December 2020. After that date the 2005 version will not be used anymore and it will be replaced by the 2017 version of the standard. In order to facilitate the reader, at the end of this paper there is a table (see Annex) with corresponding clauses of 2005 and 2017 versions of the standard.

At the International Laboratory Accreditation Cooperation (ILAC) General Assembly in October 2013 the Laboratory Committee (which is composed of stakeholder representatives of accredited testing and calibration) recommended that ILAC request that ISO/CASCO establish a new work item to comprehensively revise ISO/IEC 17025:2005. The 6th ISO/CASCO WG 44 meeting was held on July 10–12, 2017 in ISO Central Secretariat, Geneva. The deliverable of this meeting was the FDIS version of the new ISO/IEC 17025 version. The document was published at November 2017.

Please note that throughout this article the term "the standard" refers to the new ISO/IEC 17025:2005.

2 Scope

According to ISO [4] and ILAC [5] more than 68.000 calibration as well as testing laboratories, worldwide, are accredited to ISO/IEC 17025 standard, from more than 120 Accreditation Bodies, out of which 98 are ILAC MRA signatories. The ILAC Mutual Recognition Arrangement (ILAC MRA) provides significant technical underpinning to the calibration, testing, medical testing and inspection results of the accredited conformity assessment bodies and in turn delivers confidence in the acceptance of results. The ILAC MRA enhances the acceptance of products across national borders. By removing the need for additional calibration, testing, medical testing and/or inspection of imports and exports, technical barriers to trade are reduced. In this way the ILAC MRA promotes international trade and the free-trade goal of "accredited once, accepted everywhere" can be realized [6].

Testing Laboratories are using ISO/IEC 17025 standard to implement a quality system aimed at improving their ability to consistently produce valid results. Since the standard is about competence, accreditation is simply a formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. Regular internal audits are

expected to indicate opportunities to make the test or calibration better than it was. The laboratory is also expected to keep abreast of scientific and technological advances in relevant areas.

This study has been performed based on data collected by more than 300 testing laboratories, from 41 countries worldwide, accredited against the requirements of the international standard ISO/IEC 17025:2005 *"General requirements for the competence of testing and calibration laboratories."*

The Non-Conformities were issued during the accreditation process of various testing laboratories specializing in different testing categories (Mechanical, Electrical, Geotechnical, Chemical, Microbiological, etc.). Findings vary from commonly reported management system issues to the most demanding technical challenges faced by testing laboratories.

The identified Non-Conformities were categorized and statistically processed. The trends are identified and analyzed per management system or technical category. Under the accreditation process, testing laboratories are required to respond to any significant findings with a submittal of a corrective action plan containing an analysis of the root cause, details of actions taken to resolve the issue and strategies to prevent reoccurrence [7]. Various responses were analyzed and suggestions and good practices were gleaned from these submittals. Opportunities for improvement are presented for each corresponding category of findings.

3 Analysis – Results

The non-conformance analysis of data was performed across all countries. Here is the breakdown of number of laboratories per country that was selected for data analysis (Fig. 1).

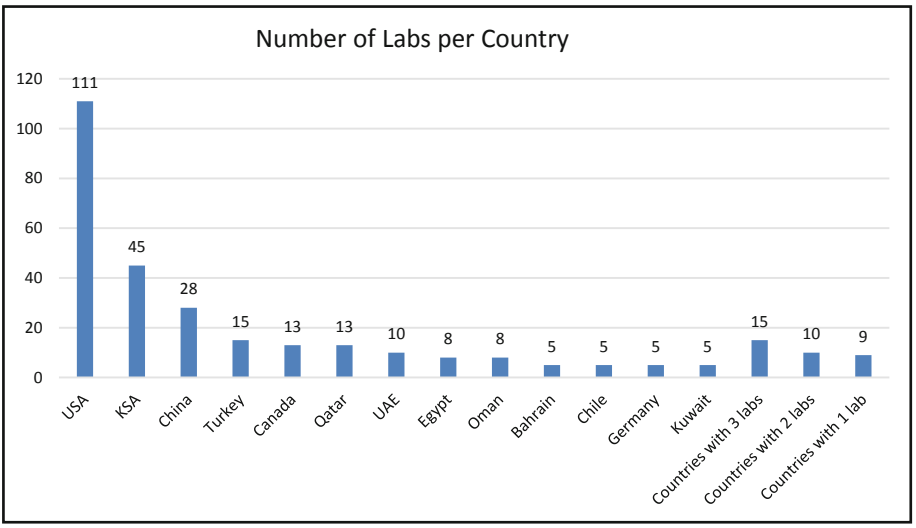

Fig. 1. Number of Labs per Country

Five major fields (scopes of accreditation) were identified and grouped for this analysis:

- Geotechnical
- Mechanical/Physical/Structural
- Electrical/Electronics
- Chemical/Microbiology/Environmental
- Medical

At Fig. 2, below, is the pictorial representation of number of laboratories per scope and number of laboratories identified for this analysis:

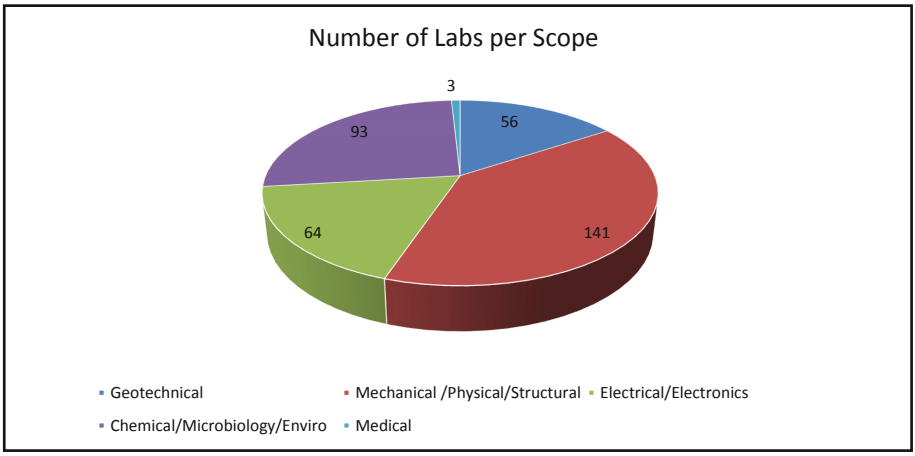

Fig. 2. Number of Labs per Scope

At Fig. 3, below, is the pictorial representation of the number of laboratories per scope and number of laboratories identified of the top five countries with the largest volume of laboratories for this analysis:

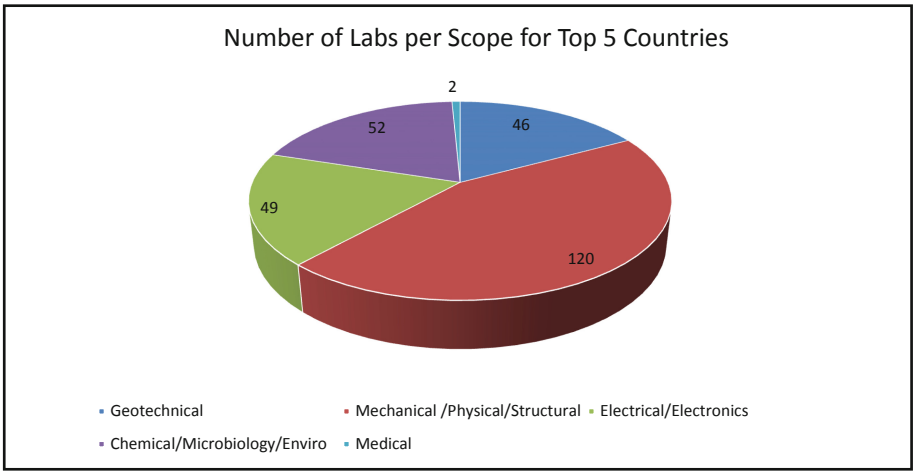

Fig. 3. Number of Labs per Scope for top 5 countries

A total of 1510 non-conformities noted during the assessments that were reviewed. Based on the analysis, the distribution of non-conformities was measured as described in the Fig. 4, below:

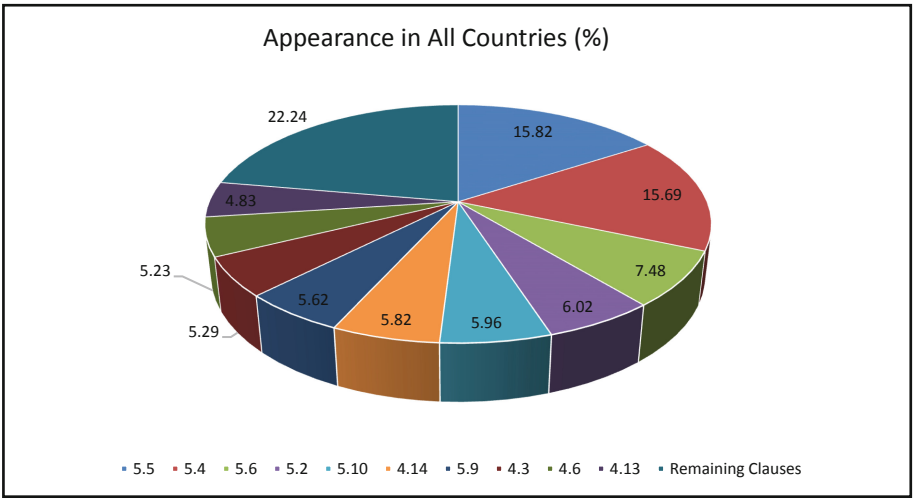

Fig. 4. Appearance in all countries (%)

Upon observation of the chart above, it is noted that the most common of the non-conformities were cited on clauses 5.5 (Equipment) and 5.4 (Test and calibration methods).

The group of clauses 5.6 (Measurement traceability), 5.2 (Personnel), 5.10 (Reporting the results), 4.14 (Internal audits), 5.9 (Assuring the quality of test and calibration results), 4.3 (Document control), 4.6 (Purchasing services and supplies) and 4.13 (Control of records) formed the next layer of non-conformities with similar percentages of findings.

Finally, a series of other clauses were minor ones constituting 22.24% of the non-conformities in the collected data.

The top ten clauses on which the most of non-conformities were cited were:

1. 5.5-Equipment.

This clause refers to the policies and procedures for ensuring equipment used for testing are available, suitable and properly maintained.

2. 5.4-Test and calibration methods.

This clause refers to the policies and procedures for choosing methods of testing and calibration (which covers sampling, transport, storage, uncertainty, control of data etc.).

3. 5.6-Measurement traceability.

This clause refers to the procedure for choosing, using, calibrating, checking and maintaining measurement standards, reference materials used as measurement standards, and equipment used for testing.

4. 5.2-Personnel.

This clause refers to the measures taken to ensure that all laboratory staff is properly skilled and qualified.

5. 5.10-Reporting the results.

This clause refers to the measures taken to ensure that results of testing are reported clearly and objectively.

6. 4.14-Internal audits.

This clause refers to the policies and procedures for conducting internal audits and implementing findings.

7. 5.9-Assuring the quality of test and calibration results.

This clause refers to the procedures for monitoring the validity of testing.

8. 4.3-Document control.

This clause refers to the procedures for:

A. Controlling all documents (internal and external) relating to the QMS – regulations, normative reference documents, drawings, specifications, instructions, manuals etc.
B. Approving and issuing documents (including maintaining a master list).
C. Changing/correcting documents.

9. 4.6-Purchasing services and supplies.

This clause refers to the policies and procedures for choosing and buying services and supplies that, when used, may affect the quality of tests.

10. 4.13-Control of records.

This clause refers to the procedures for controlling records (identification, collection, indexing, access, filling, storage, maintenance and disposal of quality and technical records).

The clauses referred above and all the data provided in this paper refers to the ISO/IEC 17025 version 2005 [2]. Since December 2017 the ISO/IEC 17025 version 2017 [3] of the standard is available, with a transition period until December 2020. After that date the 2005 version will not be used anymore and it will be replaced by the 2017 version of the standard. In order to facilitate the reader, at the end of this paper there is a table (see Annex) with corresponding clauses of 2005 and 2017 versions of the standard.

This standard was developed with the objective of promoting confidence in the operation of laboratories and contains requirements for laboratories to enable them to demonstrate that they operate in a competent and impartial way and that they are able to provide valid results.

It is important to be noted that the new update to ISO/IEC 17025:2017 is introducing greater emphasis on the responsibilities of senior management, risk analysis, impartiality and explicit requirements for continual improvement of the management system itself, and particularly, communication with the customer. Laboratories that use ISO/IEC 17025, version 2005, that have not demonstrated full compliance with new ISO/IEC 17025:2017 international standard by December 1, 2020, are subject to suspension/cancellation of their accreditation status.

Analysis of these top ten clauses across the top five countries with the highest laboratories population was performed and similar trends were observed as presented in Fig. 5, below:

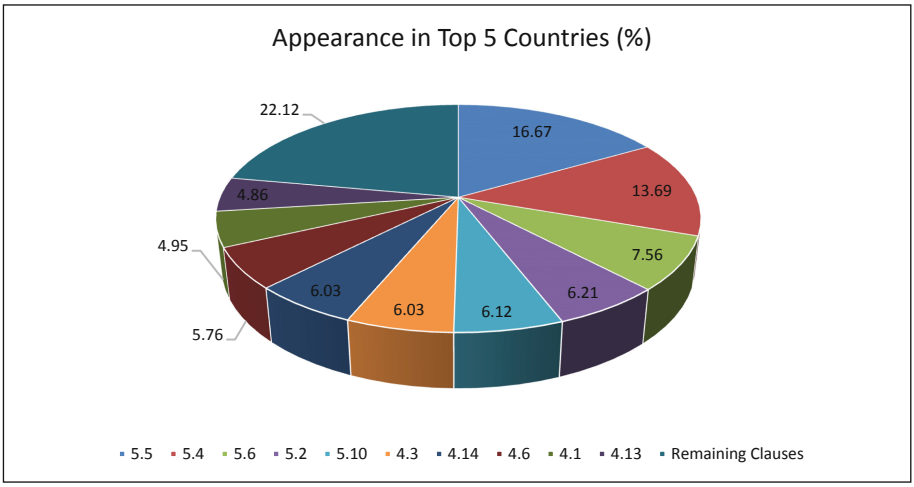

Fig. 5. Appearance in top 5 countries (%)

The top ten clauses on which most non-conformities were cited for the Top 5 Countries, with higher number of laboratories, were:

1. 5.5 (Equipment)
2. 5.4 (Test and calibration methods)
3. 5.6 (Measurement traceability)
4. 5.2 (Personnel)
5. 5.10 (Reporting the results)
6. 4.3 (Document control)
7. 4.14 (Internal audits)
8. 4.6 (Purchasing services and supplies)
9. 4.1 (Organization)
10. 4.13 (Control of records).

The trends between all countries when compared to the ones from the top 5 countries in laboratories population are very similar. It is concluded that the distribution of non-conformities is consistent among the countries with many accredited labs and the ones with less. This is a result of:

- The globalized approach on accreditation rules and guidelines as issued by ILAC and regional ILAC members.
- The harmonized approach on management system documentation in global level, followed by consultants.
- The more homogeneous training programs, facilitating a uniform approach in the design and the implementation of testing laboratory accreditation systems.

A detailed analysis of non-conformities across various scopes of accreditation was also performed and based on that analysis, the following trends were observed (Fig. 6):

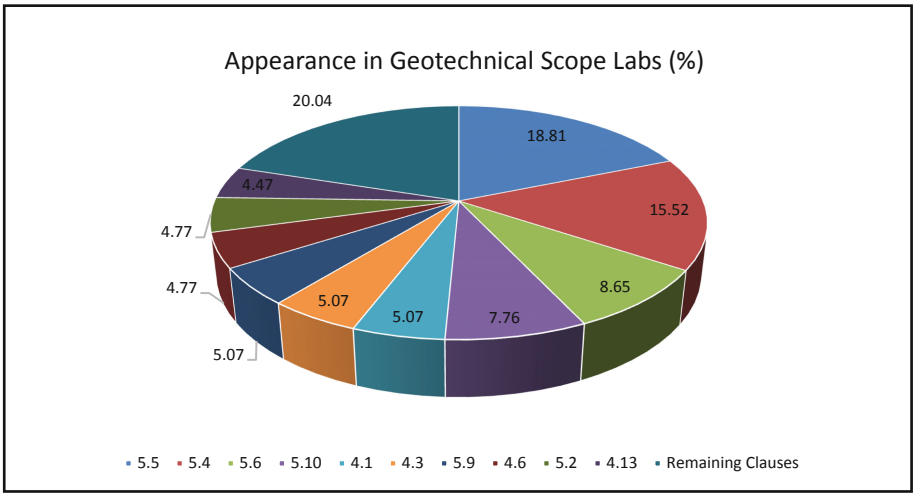

Fig. 6. Appearance in geotechnical scope labs (%)

In the geo-technical scope, most of the non-conformities were cited on the following clauses:

1. 5.5 (Equipment)
2. 5.4 (Test and calibration methods)
3. 5.6 (Measurement traceability)
4. 5.10 (Reporting the results)
5. 4.1 (Organization)
6. 4.3 (Document control)
7. 5.9 (Assuring the quality of test and calibration results)
8. 4.6 (Purchasing)
9. 5.2 (Personnel) and
10. 4.13 (Control of records)

The trends among geo-technical scope are typical to the ones observed among all laboratories. The distribution of non-conformities among labs follows the usual trends. It is interesting though to note the following:

- Technical issues (5.5-Equipment, 5.4-Test and calibration methods, 5.6-Measurement traceability and 5.10-Reporting) produce the majority of non-conformities. Those results remain on the top 4 and constitute more than half of the raised non-conformities.
- Clause 4.1 (Organization) is relatively much higher compared to other types of laboratories. This can be explained due to the nature of geo-technical laboratories, the extended external work performed and the operation of many site laboratories.

The distribution of the non-conformities for mechanical/physical/structural scope was also performed and based on that analysis, the following trends were observed (Fig. 7):

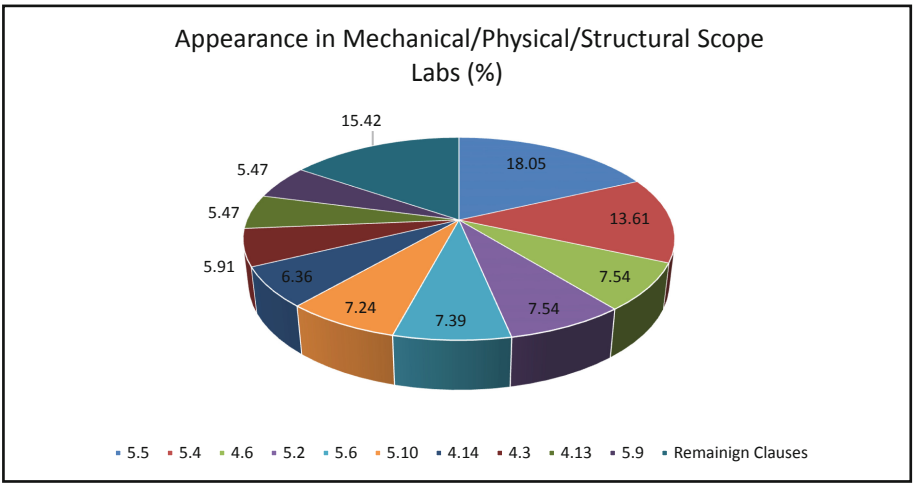

Fig. 7. Appearance in mechanical/physical/structural scope labs (%)

In the mechanical/physical/structural scope, most of the non-conformities were cited on the following clauses:

1. 5.5 (Equipment)
2. 5.4 (Test and calibration methods)
3. 4.6 (Purchasing)
4. 5.2 (Personnel)
5. 5.6 (measurement traceability)
6. 5.10 (Reporting of results)
7. 4.14 (Internal audits)
8. 4.3 (Document control)
9. 4.13 (Control of records) and
10. 5.9 (Assuring the quality of test and calibration results).

The trends among mechanical, physical and structural scope are also typical to the ones observed among all laboratories. The distribution of non-conformities among labs follows the usual trends. It is interesting though to note the following:

- Technical issues (5.5-Equipment, 5.4-Test and calibration methods, 5.6-Measurement traceability, 5.2-Personnel and 5.10-Reporting of results) produce the majority of non-conformities. Those results remain on the top 6 and constitute more than half of the raised non-conformities.
- Clause 4.6 (Purchasing) is relatively much higher (3rd) compared to other types of laboratories. This can be explained as luck of interesting in performing such activities, probably due to sufficient number of complying suppliers.

The distribution of the non-conformities for electrical/electronic was also performed and based on that analysis, the following trends were observed (Fig. 8):

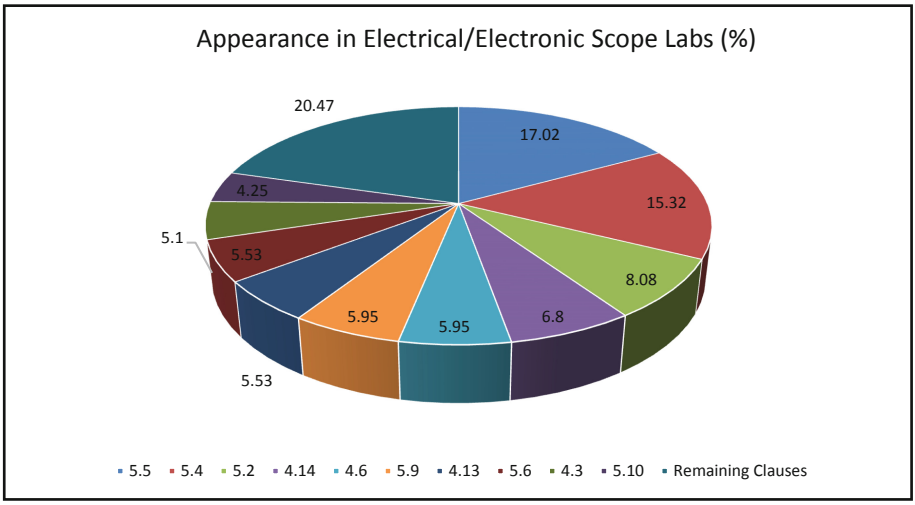

Fig. 8. Appearance in electrical/electronic scope labs (%)

In the electrical/electronic scope, most of the non-conformities were cited on the following clauses:

1. 5.5 (Equipment)
2. 5.4 (Test and calibration methods)
3. 5.2 (Personnel)
4. 4.14 (Internal audits)
5. 4.6 (Purchasing)
6. 5.9 (Assuring the quality of test and calibration results)
7. 4.13 (control of records)
8. 5.6 (Measurement traceability)
9. 4.3 (Document control) and
10. 5.10 (Reporting of results)

The trends among electrical and electronic scope are also typical to the ones observed among all laboratories. The distribution of non-conformities among labs follows similar trends. It is interesting though to note the following:

- Clause 5.10 (Reporting of results) is ranked last at the list of first 10, similarly to 5.6 (measurement traceability) which is no. 10. This indicates a relatively higher level of technical compliance than the rest of the sample.
- Clause 4.14 (Internal audits) is relatively ranked higher (no. 4) than the average of the sample. Similarly clause 4.6 (Purchasing) is relatively higher (5rd) compared to other types of laboratories. This can be explained as luck of interesting in performing such activities, probably due to sufficient number of complying suppliers.

The distribution of the non-conformities for Chemical/Microbiology/Environmental was also performed and based on that analysis, the following trends were observed (Fig. 9):

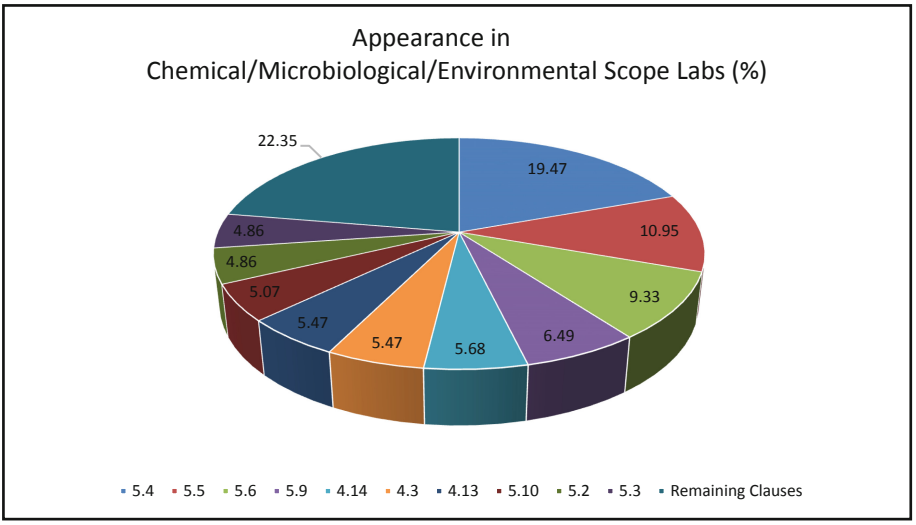

Fig. 9. Appearance in chemical/microbiological/environmental scope labs (%)

In the Chemical/Microbiology/Environmental scope, most of the non-conformities were cited on the following clauses:

1. 5.4 (Test methods)
2. 5.5 (Equipment)
3. 5.6 (Measurement traceability)
4. 5.9 (Assuring the quality of test and calibration results)
5. 4.14 (Internal audits)
6. 4.3 (Document control)

7. 4.13 (Control of records)
8. 5.10 (Test reports and calibration certificates)
9. 5.2 (Personnel) and
10. 5.3 (Accommodation and environmental conditions)

The trends among different fields/scopes, when compared to each other, are also very similar. It is concluded that the distribution of non-conformities among labs of different fields follows the same trends. It is interesting to note the following:

- Clauses 5.4 (Test methods) and clauses 5.5 (Equipment) remain the top sources of non-conformities on all types of testing laboratories.
- Clause 4.14 (Internal audits) is not the top, but it remains a repeated cause of non-conformities throughout all types of testing laboratories.
- Clause 5.3 (Accommodation and environmental conditions) is more common cause of non-conformities in the Chemical/Microbiology/Environmental than the other ones, due to the nature of the tests.

The next task included analysis of data performed in a region-wise approach. The analysis results are presented below (Fig. 10):

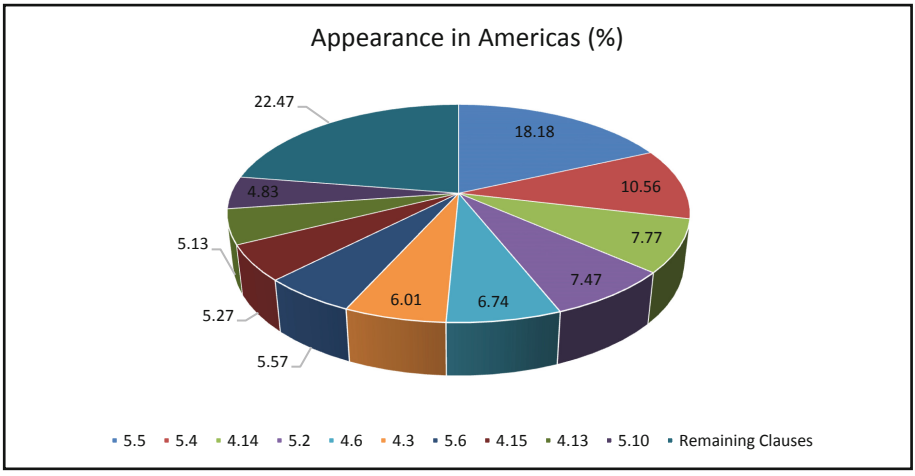

Fig. 10. Appearance in Americas (%)

In the region of North, Central and South America, most of the non-conformities were cited on the following clauses:

1. 5.5 (Equipment)
2. 5.4 (Test and calibration methods)
3. 4.14 (Internal audits)
4. 5.2 (Personnel)
5. 4.6 (Purchasing)
6. 4.3 (Document control)

7. 5.6 (Measurement traceability)
8. 4.15 (Management review)
9. 4.13 (Control of records) and
10. 5.10 (reporting the results)

The trends of North, Central and South America are indicative of the following:

- Clause 5.10 (reporting the results) is last on the list of non-conformities, which makes it the strong point for American labs. The mature market, the litigation risks and the advanced document processing systems are the main drivers for this fact.
- Clause 4.14 (Internal audits) is high for this region. With 4.15 (Management review) they are reaching close to 14% of non-conformities.

The distribution of the non-conformities for Europe, Middle East and Africa was performed and based on that analysis, the following trends were observed (Fig. 11):

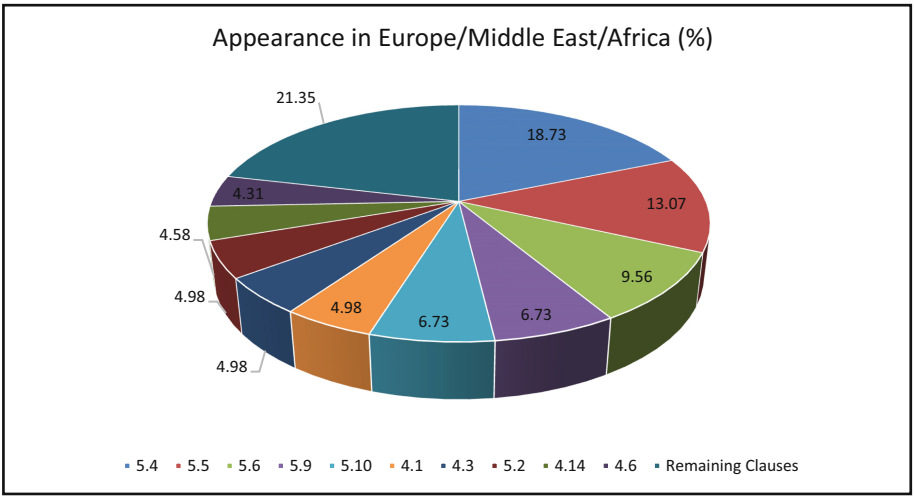

Fig. 11. Appearance in Europe/Middle East/Africa (%)

In the region of Europe, Middle East and Africa, most of the non-conformities were cited on the following clauses:

1. 5.4 (Test and calibration methods)
2. 5.5 (Equipment)
3. 5.6 (Measurement traceability)
4. 5.9 (Assuring the quality of test and calibration results)
5. 5.10 (reporting the results)
6. 4.1 (Organization)
7. 5.3 (Accommodation and environmental conditions)
8. 5.2 (Personnel)
9. 4.14 (Internal audits)
10. 4.6 (Purchasing)

The trends of Europe, Middle East and Africa are characteristic of:

- Strong weakness in evident in Technical issues in that geographical region. Since the majority of the sample comes from Middle-East and Gulf countries, it is evident that the usage of many ex-patriot technicians and the high rates of changing personnel are negatively affecting the lab operation.
- Clause 4.14 (Internal audits) is the strong point for this region. With 4.6 (Purchasing) they are reaching less than 10% of non-conformities.

The distribution of the non-conformities for Asia was also performed and based on that analysis, the following trends were observed (Fig. 12):

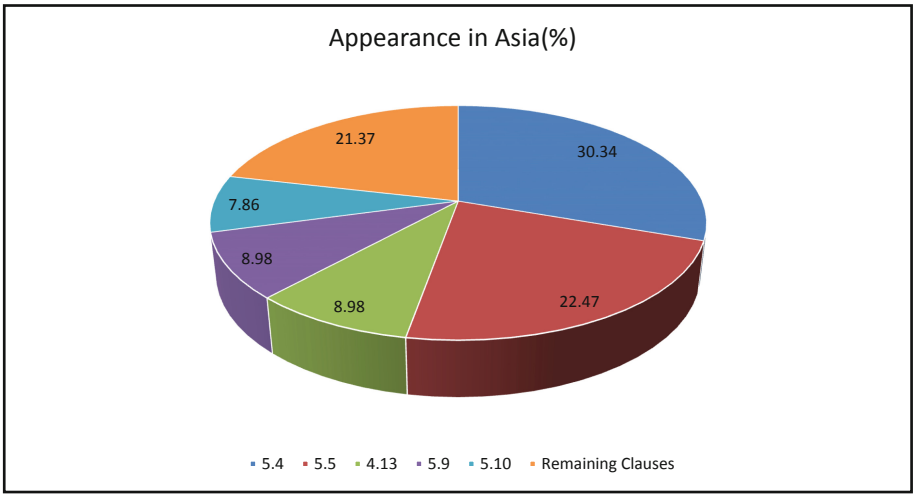

Fig. 12. Appearance in Asia (%)

In the region of Asia, most of the non-conformities were cited on the following clauses:

1. 5.4 (Test and calibration methods)
2. 5.5 (Equipment)
3. 4.13 (Control of records)
4. 5.9 (Assuring the quality of test and calibration results) and
5. 5.10 (Reporting the results)

The trends of Asia are characteristic of:

- Strong weakness in Technical issues mainly clauses 5.4 (Test and calibration methods) and 5.5 (Equipment) that constitute more than 50% of the non-conformities.
- Clause 4.13 (Control of records) is also high (3rd) a little less than 10%.

- Asian testing laboratories tend to underestimate the value of a well prepared test report and many times they don't take under consideration the test report requirements of the individual testing standards. Relative clause 5.10 (Reporting the results).

The overall trends among all different regions can be summarized as follows:

- Test and calibration methods and Equipment are remaining the main sources of findings.
- Internal Auditing can be considered a significant problem in the American region.
- Traceability remains a significant problem in the Europe, Middle East and Africa regions.
- Asian region is weak in Control of Records and Testing Reports.

4 Opportunities for Improvement

Usually, at the end of each accreditation (or surveillance, or re-accreditation) assessment, during the closing meeting, the Accreditation Body's Lead Assessor will present the findings and summarize whether the Laboratory's operation is in conformance or not to Standard and Management System requirements. If not fully in conformance, the Assessor will work with the management of the laboratory in order to develop a time line of corrective actions. Satisfactory proof of acceptable corrective actions should be then submitted by the laboratory to Accreditation Body. When the submitted corrective actions are implemented and accepted by the Assessor, then the laboratory can be accredited, or retain its accreditation in the case that it has been already accredited.

In addition to accreditation assessment, most accreditation standards/criteria, including ISO/IEC 17025 require from the laboratory to perform internal audits on a regular basis. Continual improvement is basic element of most management system standards so the continuing effectiveness of the laboratory's management system is a key issue.

Based on the corrective actions submitted by the assessed laboratories, in response to identified non-compliances, described in details in our present analysis, a series of opportunities for improvement have been identified and implemented. We are summarizing the main opportunities for improvement below:

1. Laboratories are advised to carefully implement the nationally/internationally recognized test methods.
2. In case, any test method is developed by the laboratory, it needs to be validated. Laboratories should modify standard methods or develop their own method, only if it is a requirement. In that case appropriate validation records must be prepared and provided
3. Laboratories need to ensure that they employ competent personnel, capable to perform measurement uncertainty understanding and being in position to explain the theory and mechanisms behind it. It is advised to train those personnel in specialized courses explaining the details of the uncertainty of measurement.

4. Testing and other related data needs to be checked and transferred carefully. The laboratory should be careful with securing control of data.
5. With regard to equipment, it is suggested that laboratory keeps the equipment inventory with all the relevant information such as calibration certificates, maintenance records and manuals in place where it can be easily accessible.
6. Maintenance should be performed in time frames described in a preventive maintenance schedule, and appropriate records should be available to trace any past problems and actions.
7. The laboratories can keep an automated system in their Laboratory Information Management Software (LIMS) reminding them on the upcoming calibration schedules well in advance to avoid the unnecessary delays.
8. The laboratories need to keep the unbroken chain of tracing the measurements to relevant primary standards of measurement standards. This is usually possible by calibrating their measuring devices at ISO/IEC 17025 accredited calibration laboratories. Attention should be paid that the calibrated instruments are covered by the scope of accreditation of the ISO/IEC 17025 accredited calibration laboratories.
9. When using reference standards, the laboratory need to keep a schedule for the calibration of reference standards and a maintenance plan for the same.
10. When using certified reference materials, laboratory staff needs to know the key parameters and the effective use of the reference materials.
11. Laboratories need to lay out a plan for internal audits and management reviews to do it periodically (recommended annually) and maintain effective documentation.
12. Please note that, while performing fixes to the findings noted during the internal/external audits, the laboratory needs to perform root cause analysis and come up with an effective action to fix it from recurring. There is distinction between correction and corrective action. The Standard is asking for corrective actions and not corrections.
13. With regard to purchasing, it is suggested to perform periodic review of the approved vendors/suppliers of critical consumables on a routine basis. Records of this evaluation/review are expected to be available.
14. With regard to assuring quality of test results, laboratories need to identify possible participation in proficiency testing, inter-lab comparison besides performing replication of tests. Other assuring quality of test results can be acceptable such as replication tests, repeatability tests, comparison of test results performed by different technicians etc.
15. A plan/schedule with regards to assuring quality of test results, as described in the point above, is expected. The plan can be from one to four years (a full accreditation cycle). It is expected that all tests under the scope of accreditation ac covered under this plan.
16. Laboratories need to pay attention to the reporting requirements of the ISO/IEC 17025 standard and appropriate technical standards using which the tests are performed. It is important to note that in addition to ISO/IEC 17025 many testing standards are also requiring specific information to be included in the test report.
17. It is recommended to perform document review and maintain proper control of documents.

18. Training is an essential element of the laboratory success. It is suggested to the labs to invest in training their personnel to Standard elements, in depth, choosing reputable training sources.
19. When the laboratory is a part of bigger organization, there should be clear demarcation between the divisions and firewalls in place.
20. Please note that ISO 9001 is not equivalent standard to ISO/IEC 17025. ISO 9001 fulfills some of the management requirements of the ISO/IEC 17025 standard, which leaves the technical requirements to be addressed in order to complete the accreditation to ISO 17025. ISO 9001 does NOT address any of the technical requirements of a Laboratory's management system.
21. Laboratories have to be careful to NOT use ISO 9001 certification logo on the test reports they are issuing. This is a requirement of the standard ISO/IEC 17021-1 [8], clause 8.3.2, that clearly states that "a certification body (means the ISO 9001 registry) shall not permit its marks (means ISO 9001 logo) to be applied to laboratory test, calibration or inspection reports or certificates".

5 Conclusions

Through a careful reading of the performed analysis it is evident that the majority of the identified non-conformities are related to the following ISO/IEC 17025 requirements:

- Equipment calibration and maintenance
- Estimation of measurement uncertainty
- Test methods
- Measurement traceability
- Internal audits
- Lack of root cause analysis in coming up with corrective actions
- Management review
- Lack of addressing key requirements and topics during Management Review
- Lack of commitment of top management (i.e. not participating in management reviews)
- No clear demarcation between the divisions, when part of a bigger organization
- Uncertainty of Measurement not calculated
- Laboratory key personnel not in position to explain Uncertainty of Measurement mechanics
- Lack of a plan for assuring the quality of test results
- No evidence of assuring the quality of all test results
- No evidence of intermediate controls
- Monitoring and Updating employees on new testing methodologies
- Evaluating employee competencies on periodic basis
- Lack of efforts by the laboratory to take part in proficiency testing, inter-lab comparisons
- Test reports/calibration certificates partially meeting the reporting requirements

Laboratories need to pay attention to implement effectively the corrective actions (with non-conformities) besides the policies and procedures in place, to avoid systemic failures that can result in an ineffective management system leading to drastic performances. Random failures can be controlled to only certain extent.

All systemic failures need to be controlled in an efficient way. That can be accomplished with total commitment of management (from top to bottom, including all the employees) by adhering to perform to meet the policies, procedures and requirements of the Standard and the Laboratory's Management System. Some opportunities for improvement are also suggested at the end this paper and the laboratory can work on creative processes to make sure they have an effective management system in place.

Finally, in order to facilitate the reader, at the Annex at end of this paper a table is included, presenting the corresponding clauses of 2005 and 2017 versions of the standard ISO/IEC 17025.

Appendix

See Appendix Table 1.

Table 1. Relating the clauses of ISO/IEC 17025:2005 to ISO/IEC 17025:2017

Clause version 2005	Title	Clause version 2017	Title
4.3	Document control	8.3	Control of management systems documentation (Option A)
4.6	Purchasing services and supplies	6.6	Externally provided products and services
4.13	Control of records	8.4	Control of records (Option A)
4.14	Internal audits	8.8	Internal audits (Option A)
5.2	Personnel	6.2	Personnel
5.4	Test and calibration methods	7.2	Selection, verification and validation of methods
5.5	Equipment	6.4	Equipment
5.6	Measurement traceability	6.5	Measurement traceability
5.9	Assuring the quality of test and calibration results	7.7	Ensuring the validity of results
5.10	Reporting the results	7.8	Reporting the results
4.1	Organization	5.0	Structural requirements
4.2	Management System	8.2	Management System documentation (Option A)
4.4	Review of requests, tenders and contracts	7.1	Review of requests, tenders and contracts

(*continued*)

Table 1. (*continued*)

Clause version 2005	Title	Clause version 2017	Title
4.5	Subcontracting of tests and calibrations	6.6	Externally provided products and services
4.7	Service to the customer	8.6	Improvement (Option A)
4.8	Complaints	7.9	Complaints
4.9	Control of non-conforming testing and/or calibration work	7.10	Nonconforming work
4.10	Improvement	8.6	Improvement (Option A)
4.11	Corrective action	8.7	Corrective actions (Option A)
4.12	Preventive action	–	–
4.15	Management review	8.9	Management review (Option A)
5.1	Personnel	6.2	Personnel
5.3	Accommodation and environmental conditions	6.3	Facility and environmental conditions
5.7	Sampling	7.3	Sampling
5.8	Handling of test and calibration items	7.4	Handling of test and calibration items

References

1. The new ISO/IEC 17025:2017, Dr. George Anastasopoulos, CAL LAB the International Journal of Metrology, pp. 30–35, July 2017
2. ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, ISO (2005)
3. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, ISO (2017)
4. ISO/IEC 17025 moves to final stage of revision, Sandrine Tranchard, September 2017. ISO site: https://bit.ly/2ACimjY
5. Facts and Figures, Table: Total Number of Accredited Conformity Assessment Bodies (CABs) (2017). ILAC site: https://bit.ly/2ANHdBt
6. ILAC MRA and Signatories (2019). ILAC site: https://ibit.ly/2ACjcx8
7. IAS Accreditation Criteria for Testing Laboratories AC89, September 2018. www.iasonline.org/wp-content/uploads/2018/10/89-Sep-2018.pdf
8. ISO/IEC 17021-1: Conformity assessment—Requirements for bodies providing audit and certification of management systems. ISO (2015)