ANALYSIS OF NONCOFRMITIES OF TESTING AND CALIBRATION LABORATORIES, HIGHLIGHTED IN ASSESSMENTS FOR RECOGNITION BY NETWORK METROLOGICAL RS.

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Abstract: This paper presents the analysis of nonconformities found in evaluations of calibration and testing candidates for approval by the RS Metrics Network. With this research it was possible to identify the requirements in ISO/IEC 17025 have a higher number of nonconformities in the evaluations of RS Metrics Network.

Key-words: Nonconformities, ISO/IEC 17025, Conformity Assessment.

1. INTRODUCTION

The measurements are present, directly or indirectly, in practically all decision making processes. The scope of metrology is very large, involving industry, trade, health, security, defense and the environment, to name just a few areas. It is estimated that about 4-6% of national PIB in industrialized countries are dedicated measurement procedures [1]. All these measurements, directly or indirectly, help the requirements of standards or regulations.

Provide a reliable measurement is an important issue for all organizations that depend on these measurements to make decisions. In order to provide reliable measurements, the calibration and testing laboratories use different mechanisms one of them is the conformity assessment. A form of conformity assessment is that the accreditation is the recognition of technical competence to carry out an activity. To demonstrate the technical competence of calibration and testing laboratories can follow normative standards, specifically the standard ISO/IEC 17025 [2].

This situation makes that more and more laboratories, to search the recognition of their technical competence through accreditation by the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), accreditation by the National Agency for Sanitary Surveillance (ANVISA) or recognition of the Network Metrology of RS, to name a few organizations that perform this type of activity. Both cases use the requirements of ISO/IEC 17025 for recognition of the competence of laboratories.

The ISO/IEC 17025 establishes guidelines for laboratories to deploy their systems of quality management in the focus of technical competence and reliability of the results of testing and calibration. Already, the Good Laboratory Practice dealing with the quality system on the organization and the conditions under which laboratory studies and field are planned, performed, monitored, recorded, reported and archived. Principles are designed for general studies concerning the safe use of products related to human health, plants, animals and the environment [5].

The Rede Metrológica RS (RMRS) is an association of-technical-scientific, non-profit, and serves as an articulator in the provision of metrology and quality. Actually, the RMRS has 326 associated laboratories, however only 176 are recognized. To be recognized the laboratory submits periodic evaluations based on the requirements of ISO/IEC 17025. These evaluations are annual and in the first year is assessed the full scope of the laboratory and in the three years following occur periodic evaluations which are rated 1/3 of the scope of the lab each year. Closing the cycle, the laboratory is the initial assessment again. If the laboratory requests increase in scope it will be evaluated for inclusion in the year [4].

As can be seen in Figures 1 and 2, the RMRS has, by the year 2010, 306 laboratories and 171 associated laboratories recognized. INMETRO has 548 laboratories belonging to the Brazilian Network of Calibration - RBC [6]. In addition, 422 testing laboratories belonging to the Brazilian Network of Testing Laboratories - RBLE [7].

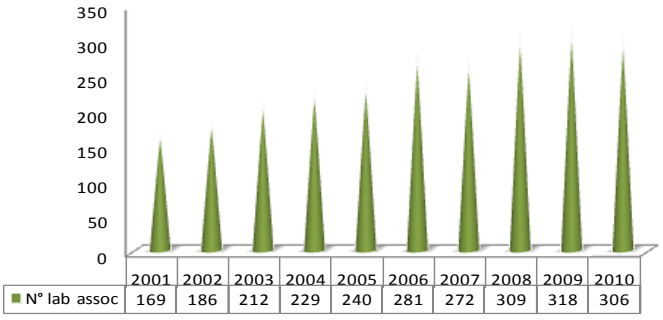

Figure 1. Number of laboratories associated with the RMRS

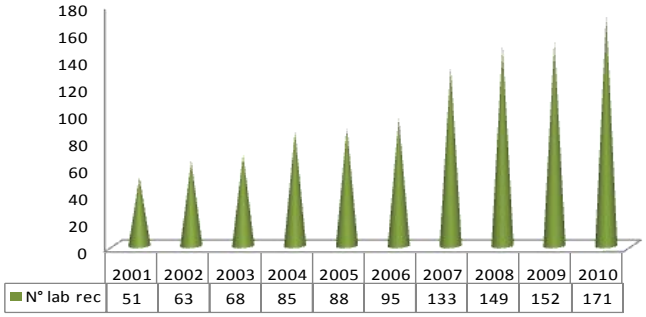

Figure 2. Number of laboratories recognized by RMRS

This article aims to analyze the behavior of nonconformities detected by the evaluators of the RMRS when assessing the calibration and testing of the years 2008 and 2009.

2. ABNT NBR ISO/IEC 17025

Normalization is a concrete fact of organizational life. For questions compulsory (government regulations) or voluntary organizations are faced with the need to conform to the requirements of certain standards.

This issue is important when it comes to testing and calibration laboratories. This type of organization usually needs to have their expertise acknowledged. This takes place through third party assessments based on the requirements of ISO/IEC 17025.

ISO/IEC 17025:2005 establishes general requirements for operation of a qualified laboratory based requirements management (Director) and technical requirements relating to its scope of action [3]. The requirements are divided in: Management (4 - Requirements direction - see Table 1) and Technicians (5 - technical requirements - see Table 2) these requirements are divided into sub-items.

Table 1. Management requirements with sub-items

4	Management Requirements
4.1	Organization
4.2	Management system
4.3	Document Control
4.3.1	General
4.3.2	Document approval and issuance
4.3.3	Document changes
4.4	Review of requests, tenders and contracts
4.5	Subcontracting of tests and calibrations
4.6	Purchasing services and supplies
4.7	Service to the customer
4.8	Complaints
4.9	Control of nonconforming testing and/or calibration work
4.10	Improvement
4.11	Corrective action
4.11.1	General
4.11.2	Cause analysis
4.11.3	Selection and implementation of corrective actions
4.11.4	Monitoring of corrective actions
4.11.5	Additional audits
4.12	Preventive action
4.13	Control of records
4.13.1	General
4.13.2	Technical records
4.14	Internal audits
4.15	Management reviews

Table 2. Technical requirements with subitens

5	Technical requirements
5.1	General
5.2	Personnel
5.3	Accommodation and environmental conditions
5.4	Test and calibration methods and method validation
5.4.1	General
5.4.2	Selection of methods
5.4.3	Laboratory-developed methods
5.4.4	Non-standard methods
5.4.5	Validation of methods
5.4.6	Estimation of uncertainty measurement
5.4.7	Control of data
5.5	Equipment
5.6	measurement traceability
5.6.1	General
5.6.2	Specific requirements
5.6.3	Reference standards and reference materials
5.7	Sampling
5.8	Handling of tests and calibration items
5.9	Assuring the quality of test and calibration results
5.10	Reporting the results
5.10.1	General
5.10.2	Test reports and calibration certificates
5.10.3	Test reports
5.10.4	Calibration certificates
5.10.5	Opinions and interpretations
5.10.6	Testing and calibration results obtained from subcontractors
5.10.7	Electronic transmission of results
5.10.8	Format of reports and certificates
5.10.9	Amendments to test reports and calibration certificates

Similar surveys have been identified to this, where nonconformities were concentrated (in descending order) requirements in 4.6, 4.10, 4.11, 4.12, 4.13, 4.14 and 5.2. These data are from 2002 and are referred to other laboratories in the American Association for Laboratory Accreditation - A2LA [8].

The same body cited above (A2LA) showed this same survey in 2008 where noncompliance were concentrated (in descending order) the requirements: 5.4, 5.5, 4.6, 4.14 and 4.13. Know the statistics for the nonconformities in the evaluation of laboratories that helps to be aware of the deficiencies that may occur during an evaluation, and from this knowledge to prepare themselves adequately for future evaluations [9].

3. METHODOLOGY

For this research data were collected regarding the evaluations of laboratories conducted in 2008 and 2009. These evaluations were conducted by evaluators who are qualified to RMRS.

To perform the data analysis groups were structured by area of laboratory calibration and test item as well as ISO/IEC 17025. The count of nonconformities in each group allowed us to verify which areas of laboratories and what requirements of a higher incidence of nonconformities. From this count were constructed bar charts to visualize data and then proceed to examine the meaning of the numbers obtained.

4. RESULTS

Calibration laboratories were divided into 12 areas, namely: acoustic, dimensional, electricity, force, torque and hardness, mass, optical, pressure, flow and level, temperature and humidity, time and frequency, viscosity, volume. We analyzed data from assessments for 2008 and 2009, 143 calibration laboratories. Since the areas of pressure, flow and level, dimensional and temperature and humidity are the ones with the highest percentage of calibration laboratories evaluated.

Nonconformities relating to the requirements of direction (Session 4 of ISO/IEC 17025:2005) of the evaluations of 2008 and 2009 totaled 99. Items that had the highest percentages of nonconformities were 4.13.2.1 (Technical Records), 4.13.1.1 (General) and 4.1 (Organization). Figure 3 presents the requirements of the direction which together totaled 30.3% of nonconformities.

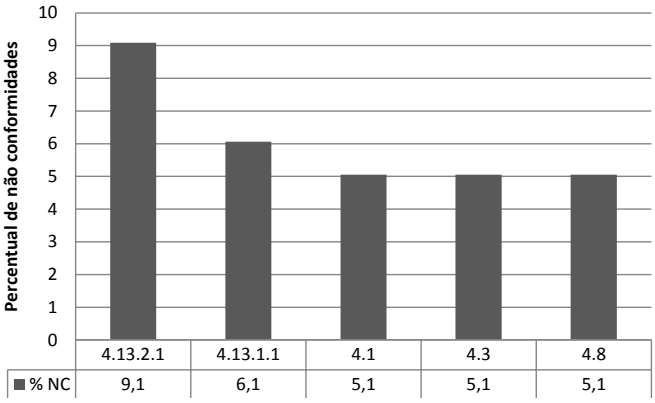

Figure 3. Percentage of nonconformities in the direction of the requirement for calibration laboratories

Nonconformities relating to technical requirements (Section 5 of ISO/IEC 17025:2005) totaled 177, with areas dimensional temperature and humidity and pressure, flow and level responsible for the greatest percentage of nonconformities. Items that had the highest percentages of nonconformities were 5.4.2 (selection of methods), 5.4.6 (estimation of measurement uncertainty) and 5.10 (presentation of results). Figure 4 presents the technical requirements, which together totaled 61.0% of nonconformities.

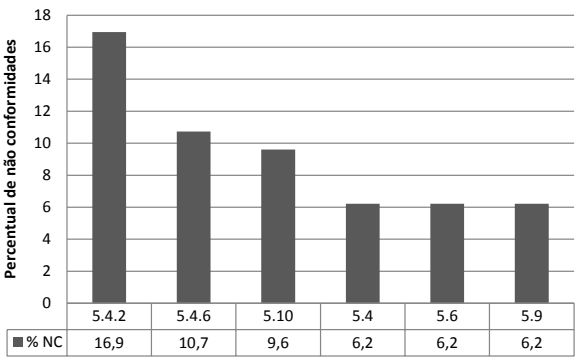

Figure 4. Percentage of nonconformities in the technical requirement for calibration laboratories

If we consider both technical and managerial requirements, nonconformities (the top three) for the calibration laboratories are distributed as follows: 5.4.2 (selection of methods), 5.4.6 (estimation of measurement uncertainty) and 5.10 (presentation results), and as shown in Figure 5.

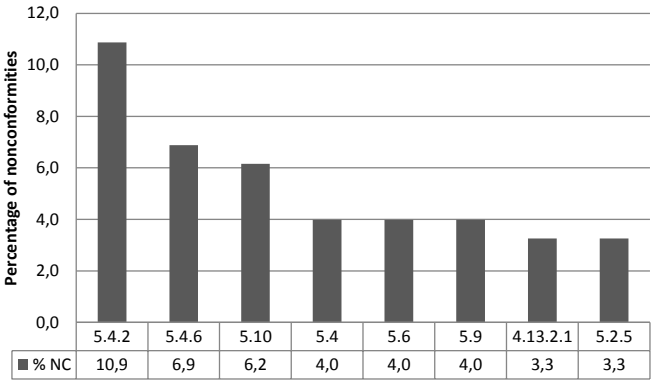

Figure 5. Percentage of nonconformities requirement for managerial and technical laboratories in the calibration

The testing laboratories were divided into five areas, namely: chemical testing and physical-chemical, microbiological testing, biological and toxicological tests, mechanical tests and biochemical assays.

We analyzed data from assessments for 2008 and 2009, 93 testing laboratories. Since the areas of chemical testing and physical-chemical and microbiological contaminants are those with the highest percentage of laboratory trials.

Nonconformities relating to the management requirements (Section 4 of ISO/IEC 17025:2005) of the evaluations of 2008 and 2009 totaled 190. Items that had the highest percentages of nonconformities were 4.13.2 (records technicians), 4.13 (control of records) and 4.2 (system management). Figure 6 presents the requirements of the direction, which together totaled 45.3% of nonconformities.

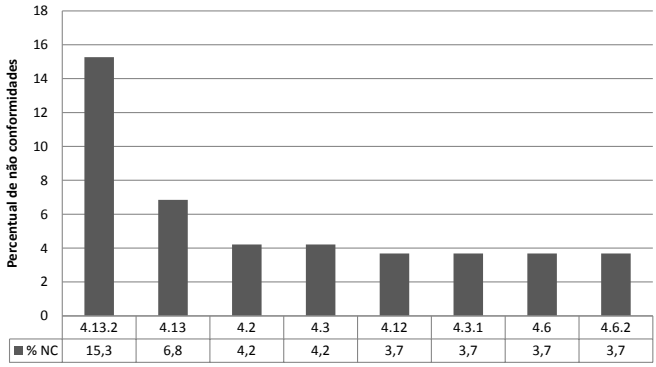

Figure 6. Percentage of nonconformities in the direction of the requirement for testing laboratories

Nonconformities relating to technical requirements totaled 332, with the areas of chemical testing and physical-chemical and microbiological responsible for the greatest percentage of nonconformities. Items that had the highest percentages of nonconformities were 5.6 (measurement

traceability), 5.4.1 (method of testing and calibration and validation of methods - General) and 5.9 (quality assurance of results of testing and calibration). Figure 7 presents the technical requirements, which together totaled 48.5% of nonconformities.

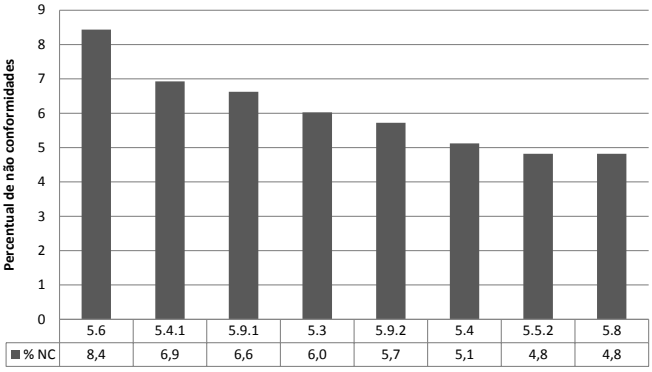

Figure 7. Percentage of nonconformities in the technical requirement for testing laboratories

If we consider both technical and managerial requirements, nonconformities (the top three) for the test facilities are distributed as follows: 4.13.2 (technical records), 5.6 (measurement traceability) and 5.4.1 (method of testing and calibration and validation of methods - General) as shown in Figure 8.

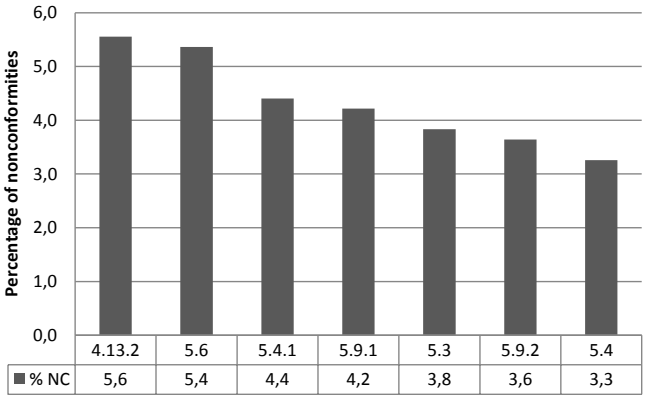

Figure 8. Percentage of nonconformities by the requisite technical and managerial testing laboratories

If we consider all nonconformities both laboratory testing and calibration, the three requirements with the highest percentage of nonconformities are: 5.4.2 (selection of methods), 5.6 (measurement traceability) and 5.10 (display results) as shown in Figure 9.

Another way to present the data and considering only the macro requirements without sorting by sub-items can be seen in Figure 10. In this situation, the requirements with the highest percentage of nonconformities are: 5.4 (methods of testing and calibration and validation methods), 5.5 (equipment) and 4.13 (control of records). The requirements presented in Figure 10 represent 81.2% of all nonconformities identified in the assessments of calibration and testing laboratories relating to both technical and managerial requirements.

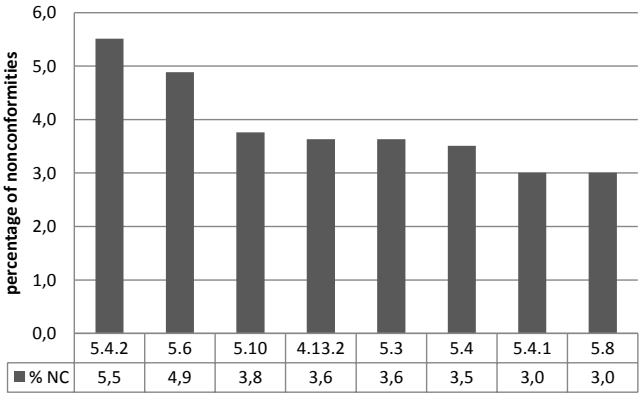

Figure 9. Percentage of nonconformities in the requirement for calibration and testing laboratories

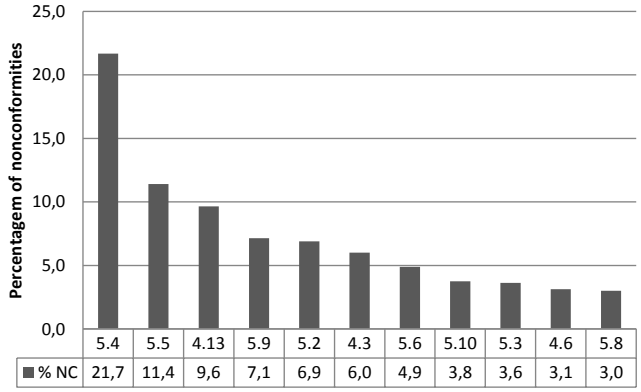

Figure 10. Percentage of nonconformities requirement for calibration laboratories in the macro test

4. DISCUSSION OF RESULTS

From the results obtained in the research and can make inferences about the behavior of nonconformities in the assessment of calibration and testing laboratories.

In the case of calibration laboratories the requirement that management had a higher percentage of nonconformities was 4.13.2.1 (technical records) and the technical requirement that had the highest percentage was 5.4.2 (selection of methods). Considering managerial and technical requirements, the highest percentage of nonconformities is the requirement for 5.4.2.

For testing laboratories the behavior is similar in requirements management as the responsible for the largest percentage of nonconformities was a requirement 4.13.2 (technical records). Already, in relation to the technical requirements, one that had the highest percentage was the requirement 5.6 (traceability of measurement). Considering managerial and technical requirements, the highest percentage of nonconformities was related to the requirement 4.13.2.

It is also possible to conclude that the management requirements for both calibration and testing laboratories the critical requirement were 4.13.2. However, technical requirements in relation to the behavior are different for calibration and testing because the requisite number of more nonconformity is different.

When considering all requirements and all nonconformities of calibration and testing laboratories the highest percentage was related to the requirement 5.4.2 (selection of methods), followed by the requirement 5.6 (traceability of measurement) and the requirement 5.10 presentation of results).

Finally, when considering the requirements without the sub-items, the responsible for the highest percentage of nonconformities was the requirement 5.4 (methods of testing and calibration and validation methods), followed by requirement 5.5 (equipment) and finally the requirement 4.13 (control records).

The discussion so far carried out is presented in summary form in Table 3.

Table 3. Summary of requirements with the highest percentage of nonconformities in the evaluations of RMRS

	Calibration Laboratories	Testing Laboratories
Requirements management (4)	4.13.2.1	4.13.2
Technical Requirements (5)	5.4.2	5.6
Management and technical	5.4.2	4.13.2
Requirement	5.4 (1º); 5.5 (2º); 4.13 (3º)	

When these results are compared with those obtained by A2LA in 2002 [8] we can see a difference between them. While nonconformities of the laboratories evaluated by A2LA were due for the most part, the requirements management (4.6, 4.10 and 4.14), the nonconformities of the laboratories evaluated by RMRS are due to the technical requirements.

Already, the results presented by A2LA, 2008 [9] there is similarity of requirements account for most of the nonconformities in this case the requirement 5.4, followed by the requirement of 5.5 and 4.6.

Comparing the results of research on assessments and evaluations of RMRS A2LA, one can conclude that in 2002, the laboratories had more difficulties A2LA (detected nonconformities) with the management requirements. In 2008 these laboratories have to have more difficulty with the technical requirements. There is not possible to make a comparison with the results of evaluations of RMRS in 2002 since these data were not surveyed. However, it is possible to make a comparison with the 2008 data which can be said that the laboratories are in the RMRS same face of maturity or development laboratories of A2LA.

It is necessary to comment on other points about the data. It is known that the evaluation of the laboratories, even being done based on the same pattern is performed by people trained and prepared to do so. For more complete is the preparation of the evaluators there is always room for subjectivity of people. However, in the case of the 2008 data of the A2LA and the data from 2008 and 2009, the RMRS there is a great similarity in the nonconformities identified with the highest percentage. This fact might suggest that the behavior is similar laboratories and assessors of the two institutions have similar forms to evaluate. To confirm this fact they must be made with other research institutions that carry out assessments of laboratories based on the requirements of ISO/IEC 17025.

5. CONCLUSION

This paper presented the results of research conducted on data from calibration and testing laboratories RMRS evaluations. With it was possible to identify the requirements of ISO/IEC 17025 are responsible for the largest percentage of nonconformities. Considering management and technical requirements the three requirements with the highest percentage of nonconformities in descending order were: 5.4 (methods of testing and calibration and validation methods), followed by requirement 5.5 (equipment) and finally the requirement 4.13 (control of records).

The paper also compared the survey data with data from a similar survey conducted in the laboratories of the A2LA in 2002 and 2008. The comparison showed that the results of nonconformities in the 2008 A2LA assessments were similar to those of nonconformities of the 2008 and 2009 RMRS assessments.

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