Legal metrological verification in health area in Brazil

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Abstract. Presents the method used by Inmetro to measure the coverage of periodic metrological verification of sphygmomanometry and clinical scales in Brazil in 2018. It was used the Metrological Verification Coverage Ratio, that represents the percentage of healthcare facilities that received the periodic metrological verification service on the total number of healthcare facilities in the country. The results reveal great opportunity for growth of the instrument verification in several sectors, helps to size of the workforce and provides strategic information for the planning and execution of mandatory metrological verification in Brazil.

1. Introduction

According to data from the Brazilian Ministry of Health, there are more than 300,000 health facilities in the country, most of which make use of various measuring instruments in their day-to-day activities.

Clinical scales and sphygmomanometers (blood pressure meters) are examples of important measuring instruments regulated by Inmetro - National Institute of Metrology, Quality and Technology, because blood pressure and body mass are fundamental information for the good medical diagnosis of a patient.

Therefore, sphygmomanometers and clinical scales are subject to legal metrological control, so that they present an adequate level of confidence in their measurements [1]. When in use, these instruments must receive a legal and annual metrological verification, performed by the 26 Public Bodies that integrate the Brazilian Network of Legal Metrology and Quality (RBMLQ). It is estimated that there are over 200,000 clinical scales and more than 500,000 sphygmomanometers in use in Brazil, in a various kind of health facilities [2, 3].

A major problem for Inmetro in the field of legal metrology was to find out how much of this great universe of measuring instruments was receiving the annual metrological verification of the RBMLQ.

In this sense, Inmetro has carried out studies in order to expand the periodic metrological verification in clinical scales and sphygmomanometers [4, 5], and to improve the quality of measurement of these instruments [6].

In one of these works, Inmetro and RBMLQ developed the MVCR - Metrological Verification Coverage Ratio, an indicator that shows the capacity of Inmetro and each RBMLQ Public Body to meet the demand for mandatory metrological verification in measuring instruments [6].

The MVCR is the ratio of the number of facilities that received RBMLQ services, like metrological verification in clinical scales, and the number of facilities subject to RBMLQ services.
The objective is present the MVCR calculation report and its results in some sectors in health area in Brazil, like hospitals, health clinics and doctors' office, among others. The paper will be presents the MVCR ranking of all 26 RBMLQ Public Bodies, in a composition of sectors in health area.

2. Legal metrological control in clinical scales and sphygmomanometers in Brazil
The consolidation of the legal framework of metrological control in health in Brazil began in the 90's with the establishment of Technical Metrology Regulations for non-automatic weighing instruments - weighing scales for adults and children, thermometers and sphygmomanometers.

Currently, health scales and sphygmomanometers are subject to the following controls specified in regulations:

a) Technical model assessment: this is the approval procedure for the prototype of the instrument, comprising systematic tests of the performance of the measurements.

b) Initial verification: this is the first verification of the instrument after it has been manufactured to confirm that it retains the metrological characteristics of the approved model in the technical assessment.

c) Periodic verification: it is the subsequent verification, carried out annually on the instruments in use to contact if it maintains the reliability of the measurements.

d) Verification after repair: is the verification performed after the instrument has been repaired.

e) Inspection: is the verification conducted on a special inspection operations or for the care of complaints or legal expertise.

Figures 1 to 6 present traditional examples of mechanical and digital scales for weighing adults and children, and mechanical and digital sphygmomanometers.
This study focuses on the scope of Periodic Verification in the universe of these instruments in use in Brazil, by calculating the index of coverage of this service.

3. Metrological Verification Coverage Ratio (MVCR)

One of the most important tools used by Inmetro to follow the metrological verification services in Brazil is the SIMCS - System for Monitoring the Coverage of RBMLQ Services, whose main result is the MVCR - Metrological Verification Coverage Ratio [6].

The MVCR shows the percentage (%) of facilities that the RBMLQ Public Bodies has the capacity to visit, within the universe of existing facilities that make use of measuring instruments regulated by Inmetro [6].

In this way, the MVCR is a percentage calculated by the ratio between the visited facilities and the total of facilities subject to visit:

\[ MVCR_{i,j} = \frac{VF}{UE} \]

where:
- \( MVCR \) is metrological verification coverage ratio;
- \( VF \) is visited facilities by RBMLQ public bodies;
- \( UE \) is universe of facilities engaged in economic activities using regulated measuring instruments;
- \( i \) is index that represents any sector on commerce, industry or service providers;
- \( j \) is index that represents any geographical areas (city, state, region or country).

The data sources of the \( VE \) and \( AE \) are, respectively, the Inmetro's Integrated Management System (SGI) and the Annual Social Information Report (RAIS) of the Brazilian Ministry of Labor and Employment (MTE).

One important SIMCS filter is the code and the description of the economic activities, that are selected by association with the use of measuring instruments regulated by INMETRO.

SIMCS is a systematized database that monitors the coverage of periodical metrological verification services in Brazil, in several geographic areas and several economic activities. It can calculate MVCR in any sector on commerce, industry and service providers, in geographical areas that can range from a municipality or state, to even a big region or the entire country.

For this paper, it was extracted information related to some kind of health facilities that make use of clinical scales and sphygmomanometers in a hole country and in each of the 26 states of Brazil.

4. Results and discussions

In this section, the Metrological Verification Coverage Ratio (MVCR) reveals the percentage of establishments visited by RBMLQ, to perform periodic metrological verification services on clinical scales and sphygmomanometers.

Table 1 presents the Coverage Ratio of periodic verification in some kind of health facilities in Brazil in 2018: hospitals, health clinics, doctors’ office, pharmacies and fitness center. It is important to note that this study does not contemplate the Municipal Health Posts, because these establishments were not included in the database used.

The results show a great potential for growth in the number of facilities visited and the consequent number of new periodic checks on clinical scales and sphygmomanometers.

Although Brazil has a robust framework of regulations for legal metrological control of clinical scales and sphygmomanometers, there is a long way to go to establish this control periodically of the instruments that are in use.
Table 1. Metrological Verification Coverage Ratio in health area - Brazil/2018.

| Economic Activity   | Nº Establishments | MVCR 2018 |
|---------------------|-------------------|-----------|
| Hospitals           | 8,868             | 7.3 %     |
| Health clinics      | 16,612            | 1.3 %     |
| Doctors’office      | 40,823            | 0.7 %     |
| Pharmacies          | 60,092            | 2.7 %     |
| Fitness center      | 15,731            | 0.7 %     |

The MVCR reveal that there is a large gap in the periodic metrological control in Brazil in all health sectors studied. It helps in directing investments to better meet such demand.

Table 2 presents the MVCR ranking of all 26 RBMLQ Bodies (plus DF – Capital of Brazil) in 2018 in a group formed by the just following medical facilities: hospitals, health clinics and doctors’ office.

Table 2. MVCR Ranking – medical scales and sphygmomanometers – Brazil/2018.

| Position | RBMLQ Body | Number of Establishments | MVCR  |
|----------|------------|--------------------------|-------|
| 1        | SE         | 518                      | 15.6 %|
| 2        | AL         | 488                      | 11.3 %|
| 3        | AM         | 482                      | 7.9 % |
| 4        | CE         | 1,496                    | 6.9 % |
| 5        | PE         | 1,686                    | 6.1 % |
| 6        | AP         | 90                       | 5.6 % |
| 7        | MS         | 956                      | 4.5 % |
| 8        | PI         | 563                      | 4.4 % |
| 9        | RN         | 740                      | 4.3 % |
| 10       | AC         | 149                      | 4.0 % |
| 11       | ES         | 1,668                    | 3.8 % |
| 12       | MA         | 703                      | 3.7 % |
| 13       | BA         | 3,236                    | 3.6 % |
| 14       | PR         | 4,728                    | 3.3 % |
|          |            | BRAZIL                  | 66,303| 2.3 % |

The average MVCR of RBMLQ in hospitals, clinics and doctor’s offices in 2018 was only 2.3 %. Even in the State of Sergipe (SE) that had the highest MVCR, with 15.6 %, there is a great possibility of expanding coverage of periodic verification in health facilities. This results denotes the need for structural and management actions throughout Brazil, such as:

a) Expand and train the number of metrological verification teams in all RBMLQ Bodies to work in the health area.

b) Establish goals for this service in the Annual Work Plan that the RBMLQ Bodies agrees and sign with Inmetro.

c) To make the owners of health establishments aware of the importance of periodic metrological verification of scales and sphygmomanometers for the correct diagnosis and medication of patients.

Knowing the MVCR is fundamental to dimension the quantitative of the labor force and of the vehicles and equipment needed to meet the real demand for periodic verification. It allows the comparison of
performance between the RBMLQ Bodies, and is also important to define strategic planning scenarios and goals.

5. Conclusion
This survey represents a very close picture of the periodic metrological verification coverage of clinical scales and sphygmomanometers use in the health facilities in Brazil.

The Metrological Verification Coverage Ratio (MVCR) is an important indicator to monitoring the legal metrology control. In 2018, the MVCR average of clinical scales and sphygmomanometers in hospitals, health clinics and doctors' office was only 2.3 %, revealing great opportunity for growth of these services.

By showing the gap between the visited facilities and the total volume of facilities subject to the visit, the MVCR becomes valuable information in the adjustment of the current capacity of the RBMLQ, so that it can meet the demand for its periodic verification services.

Some potential impacts of MVCR use in Brazil are:
- a) reveals an estimate of demand for periodic verification services at each location in the country;
- b) provides information for dimensioning the number of verification teams, vehicles and equipment;
- c) allows the comparison of performance between the RBMLQ Bodies;
- d) supports strategic planning and goals.

With a simple calculation memory, the MVCR can be replicated in any country that has basic information about the healthcare facilities and metrology services performed.

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