Assessment of the application of quality management systems requirements related to computer systems in laboratories by assessors and their application by accredited laboratories

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INTRODUCTION

Standards that orient laboratory activities needed to incorporate guidelines on the use of computerized systems in quality management systems over the years [1, 2]. However, it is not uncommon for laboratories not to fully apply these rules. In addition, the assessment of compliance with requirements related to computerized systems depends on the level of knowledge of the auditors themselves [3]. Thus, this study aims to compare the laboratories' perception of the assessors' collection of the requirements of the standards and the laboratories' execution of them, as well as to analyze the auditors' level of knowledge about computerized systems applied to QMS using an online questionnaire.

METHODOLOGY

- Data collection via Google Forms;
- Creation of different forms to collect responses from auditors and laboratories;
- Contact with participants via e-mail and social networking groups related to auditors and laboratories with implemented management systems.

RESULTS AND DISCUSSION

- There were 111 laboratories participating, located in thirteen different Brazilian states;

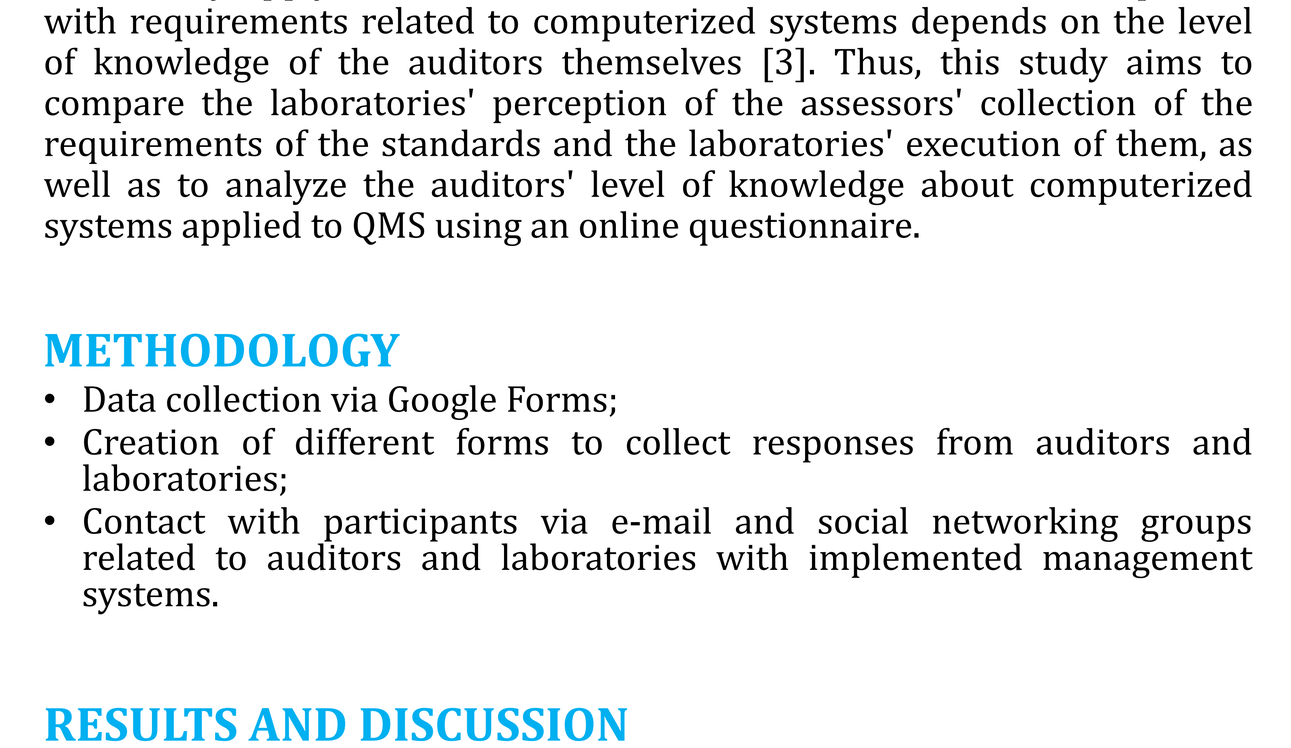

Fig. 1 – Percentages of participating laboratories and of RBLE-registered laboratories by Brazilian states

- Most of the participating institutions - 69.37% - declared to be private. In this group, only 3.90% are not accredited to ISO/IEC 17025, and 2.60% are in the process of accreditation;
- 36.94% of laboratories work with chemical tests, another group in which accreditation in ISO/IEC 17025 prevails: 87.80% are accredited in this standard;
- Regarding the total number of laboratories, 59.46% are accredited only to ISO/IEC 17025, 12.61% are also accredited to ISO 9001, 9.01% have a third accreditation (to ISO 14001), and 6.31% of the laboratories are accredited to both ISO/IEC 17025 and ISO 14001;
- The purpose of evaluating the non-conformities received by the laboratories during their last external audit was not only to identify the items related to computer systems with the highest incidence of NCs, but also to ascertain the verification rate of the auditors of each item

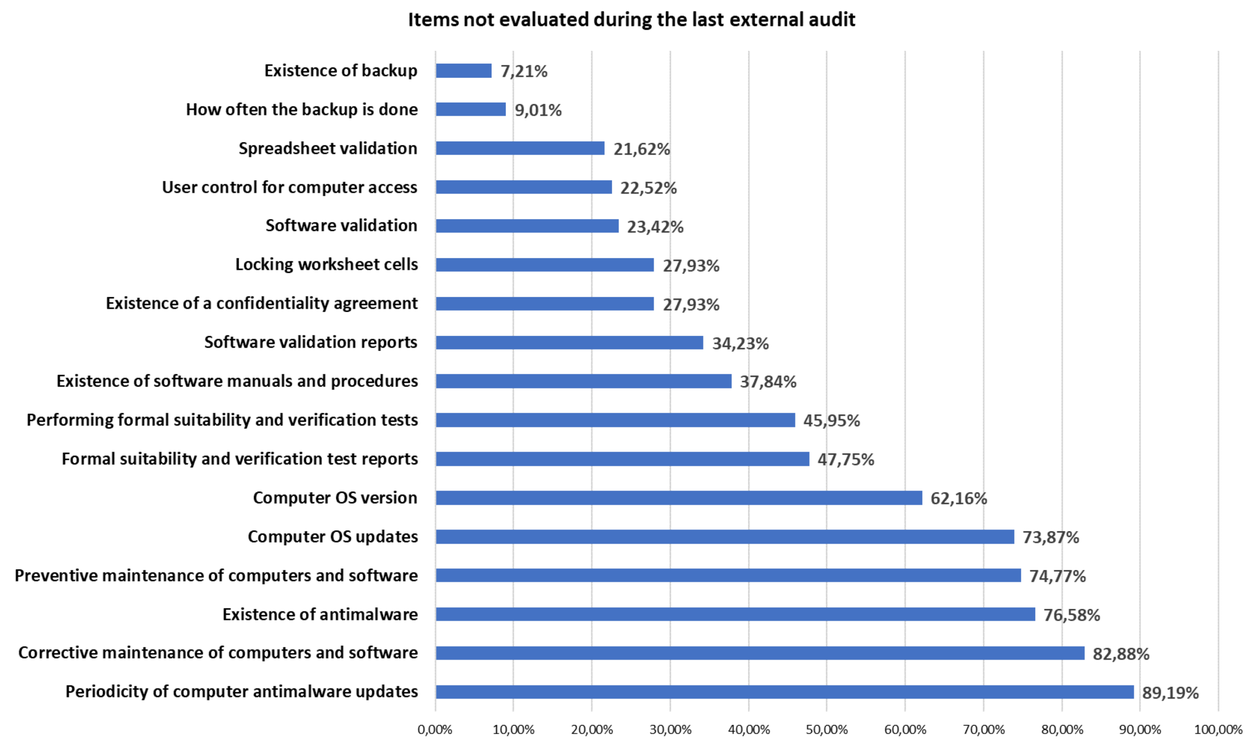

Fig. 2 – Items not evaluated in the last external audit, according to the laboratories

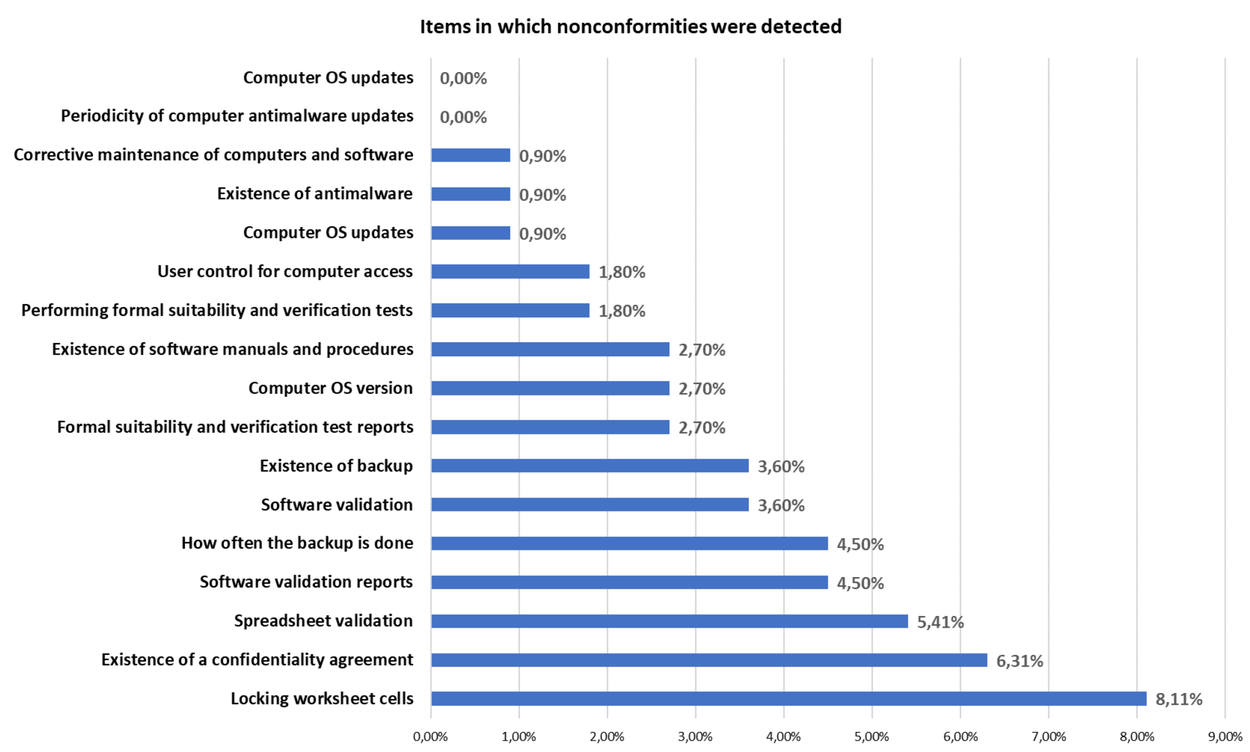

Fig. 3 – Items in which non-conformities were detected in the last external audit, according to the laboratories

CONCLUSIONS

- A high number of auditors fail to evaluate several items related to computerized systems, even when there is the possibility of data security being affected;
- With the exception of the items related to backups, even those with higher values of verification performed had responses corresponding to "the rater did not check this item" in the 20 to 25% range;
- The percentage of non-compliance detected is low - the highest of all was the blocking of cells, with 8.11%;
- Items with the highest non-compliances rtaes are simple to be corrected by the laboratories;
- The five items with the highest percentages of non-verification are also the five items with the lowest rate of detected non-conformities. However, it is still not possible to know if this is really due to their absence or the evaluators' inability to detect them, reinforcing the need to examine their knowledge.

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ACKNOWLEDGEMENTS

Grant n° 130679/2019-4