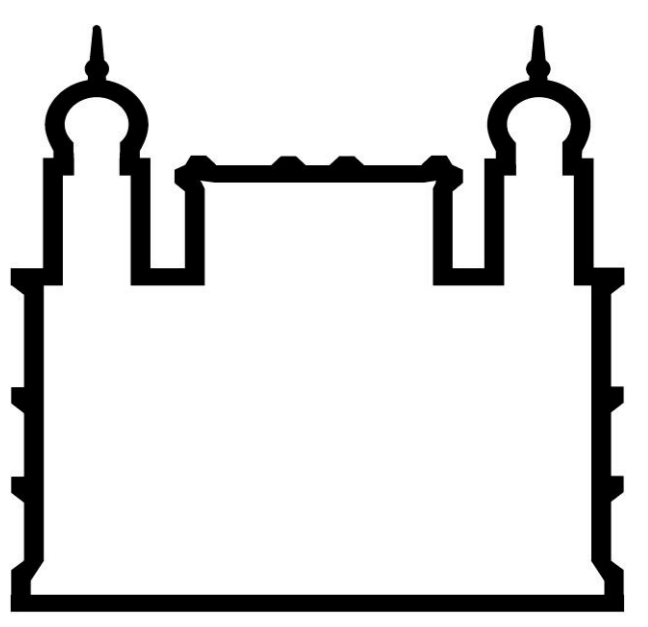




# EVALUATION OF A FUNGAL COLLECTION FROM THE HEALTH SECTOR BASED ON APPLICABLE QUALITY STANDARDS



FIOCRUZ

Tatiana Forti\*, Carlos R. S. do Nascimento, Marília Martins Nishikawa, Fernanda Peres Sabagh, Rosane Temporal, Manuela da Silva, Marise T. Wanderley Hübner

Oswaldo Cruz Foundation - FIOCRUZ, Rio de Janeiro, Brazil

\*tatiana.forti@incqs.fiocruz.br

## 1. INTRODUCTION

The difficulties found in the acquisition of biological reference material from the international market, either due to the high costs and time consuming involved or the emerging legal, technical and sanitary barriers associated, led the National Institute of Quality Control in Health / Oswaldo Cruz Foundation - INCQS/FIOCRUZ in 1983 to define as one of its strategies the establishment of the Collection of Reference Microorganisms on Health Surveillance [1].

To ensure traceability of the strains, security and reliability in the supply of biological material the implementation of specific quality standards is necessary.

## 2. OBJECTIVES

To evaluate purity, viability and authentication tests performed by the INCQS/FIOCRUZ Division of Reference Fungi, where the Fungal Collection (part of the Collection of Reference Microorganisms on Health Surveillance) is located, based on ABNT ISO / IEC 17025 [2] in order to accredit these tests by the Brazilian Accreditation Body – CGCRE/Inmetro (General Accreditation Coordination/National Institute of Metrology Standardization and Industrial Quality).

## 3. MATERIALS AND METHODS

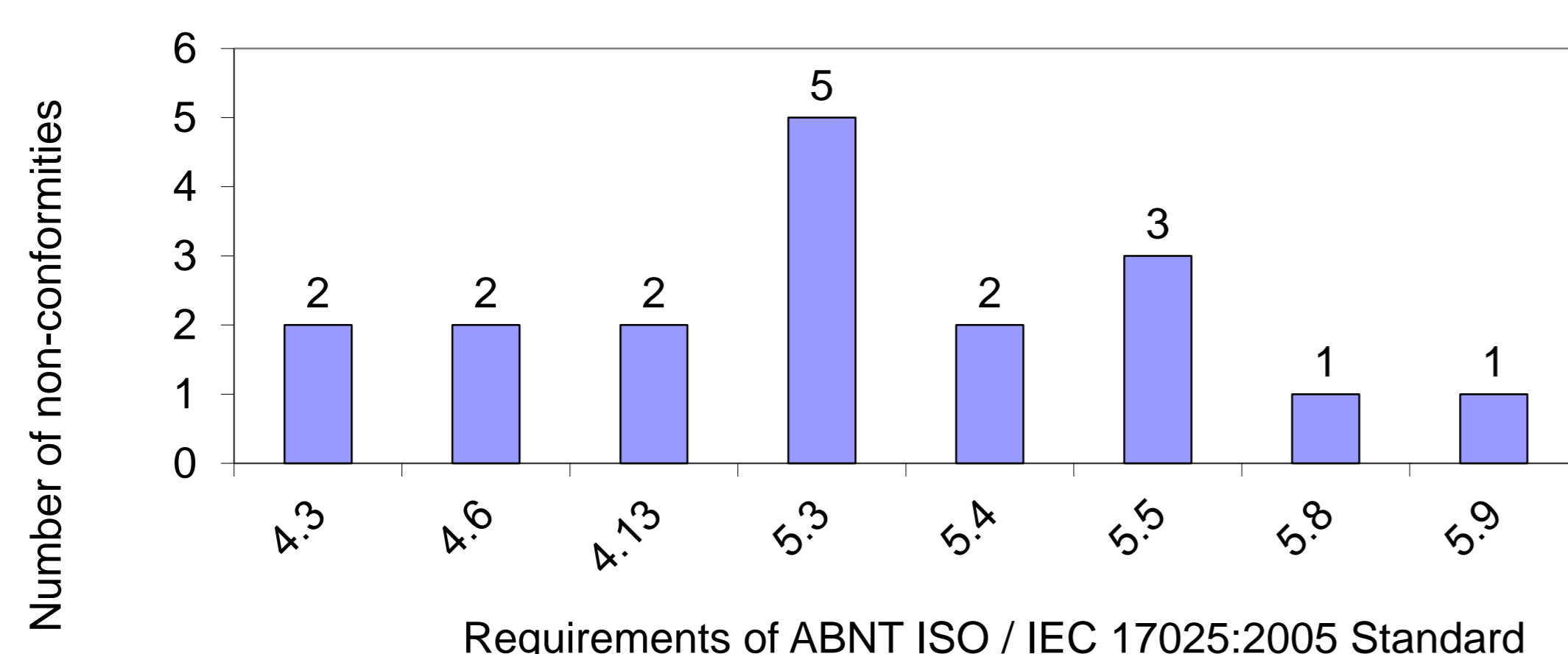
The evaluation of the purity, viability and authentication tests were conducted through a systematic internal audit which is described in the SOP 65.1120.043 [3] that is based on the ABNT ISO 19011:2002 - Guidelines for Quality and Environmental Management Systems Auditing [4].

The audit criteria were the ABNT ISO / IEC 17025:2005. The non-compliances detected were recorded in a specific form. Following the internal audit the accreditation of these tests was requested to the Brazilian Accreditation Body.

## 4. DISCUSSION OF RESULTS

4.1. Results regarding the implementation of the standard ABNT ISO / IEC 17025:2005 before the evaluation by Brazilian Accreditation Body

Through the audit, that occurred on August 2010, 18 non-conformities were identified related to the requirements of ABNT ISO / IEC 17025:2005 standard. The non-compliances are listed in the chart below (Figure 1):



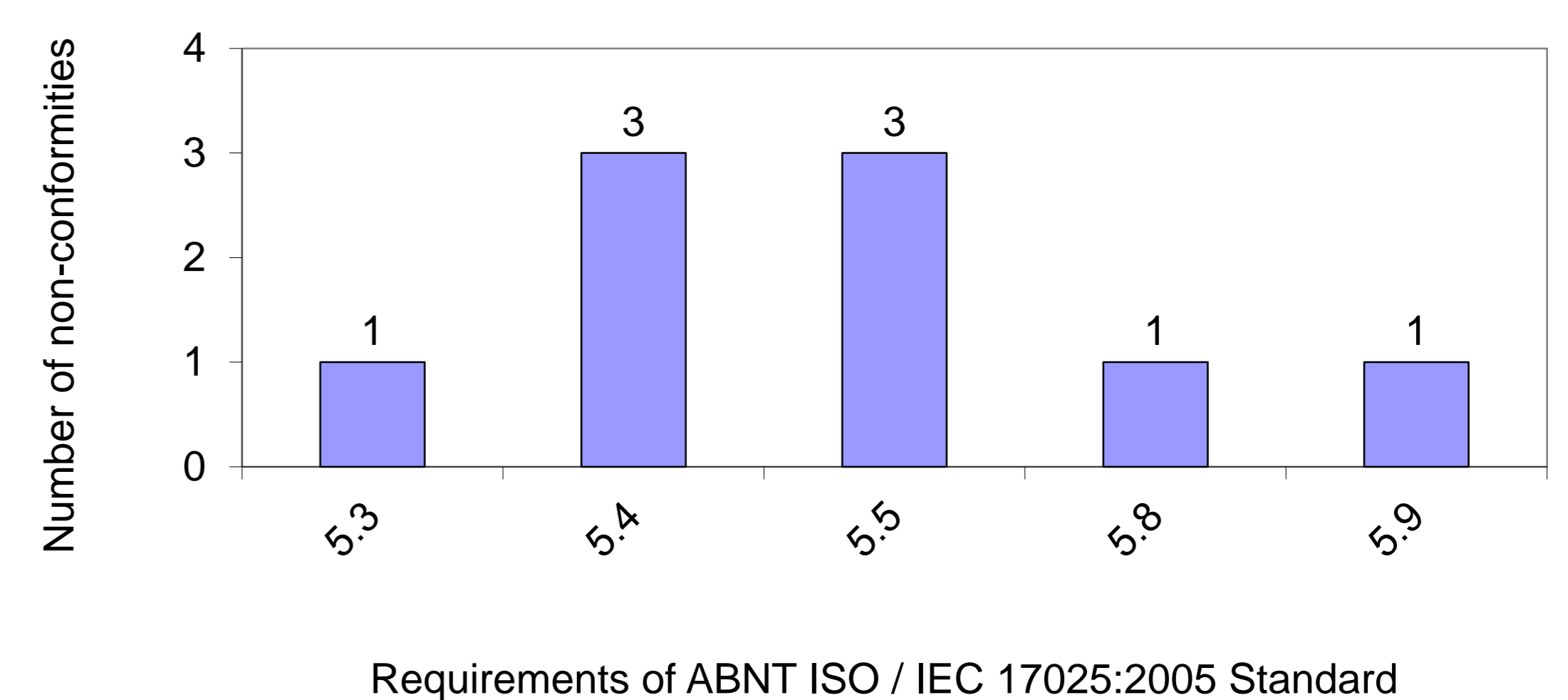
Note: 4.3-Documents Control; 4.6-Procurement of services and supplies; 4.13-Control of Records; 5.3-Accommodation and environmental conditions; 5.4-Test and calibration methods and method validation; 5.5-Equipment; 5.8-Handling of test and calibration items; 5.9-Assuring the Quality of Test and Calibration Results.

**Figure 1** - Non-conformities detected in the Fungal Collection by the internal audit and the related requirements of ISO / IEC 17025:2005 standard.

Figure 1 shows that most of the non-conformities are related to the accommodation and environmental conditions. Therefore the compliance of the corrective actions regarding these non-conformities had the involvement of the institutional top management since they concerned infrastructure.

## 4.2- Evaluation by the Brazilian Accreditation Body

After the compliance of the corrective actions, on January 2011, a request for the accreditation of the purity, viability and authentication tests was sent to the Brazilian Accreditation Body – CGCRE/Inmetro (General Accreditation Coordination/National Institute of Metrology Standardization and Industrial Quality) and the external audit was conducted on July 2011 and identified 9 non-conformities (Figure 2).



Note: 5.3-Accommodation and environmental conditions; 5.4-Test and calibration methods and method validation; 5.5-Equipment; 5.8-Handling of test and calibration items; 5.9-Assuring the Quality of Test and Calibration Results.

**Figure 2** - Non-conformities detected in the Fungal Collection detected by the external audit and the related requirements of ISO / IEC 17025:2005 standard.

There was a reduction of 50% of non-conformities from the internal (18) to the external (9) audit and the non-conformities detected during the external audit were more related to documentation (mainly small details), compared to the internal audit results, which had more non-conformities regarding infrastructure.

## 5. CONCLUSION

The result of this process demonstrated that the ISO / IEC 17025:2005 standard is implemented in the Fungal Collection/Division of Reference Fungi/INCQS/FIOCRUZ for the purity, viability and authentication tests for fungal strains. Consequently, on June 2012, the Brazilian Accreditation Body announced the publication of the accreditation scope for these tests on the Inmetro website.

In parallel CGCRE/Inmetro developed an accreditation program for Biological Resource Centres (BRCs) that resulted in the elaboration of an internal standard (NIT-DICLA-061) [5], based on OECD Best Practice Guidelines for Biological Resource Centers, ISO/IEC 17025/05 and ISO Guide 34. Fiocruz has been preparing and organizing its culture collections regarding quality and information management and it is planned to have the NIT-DICLA-061 applied to these collections, including the INCQS Fungal Collection.

## REFERENCES

- [1] Collection of Reference Microorganisms for Health Surveillance. <http://cmrvs.fiocruz.br/>
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- [5] NIT-DICLA-061: Requirements for the accreditation of testing laboratories and reference material production activities in Biological Resources Centres. Rio de Janeiro: Inmetro, 2012.