



System proposal for implementation of risk management in the context of ISO/IEC 17025

Fabiane Rodrigues da Silva¹ · Inês Hexsel Grochau^{1,2} · Hugo Marcelo Veit¹

Received: 26 February 2021 / Accepted: 30 October 2021 / Published online: 9 November 2021
© The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2021

Abstract

Many higher education institutions in the world have testing laboratories linked, or not, to their teaching and/or research programs. However, only a small proportion of these laboratories have accreditation in accordance with the ISO/IEC 17025 standard. The ISO/IEC 17025 establishes the management and technical requirements necessary for the implementation and maintenance of a quality management system (QMS) in laboratories that perform testing, calibration and/or sampling activities, being used by them to demonstrate their competence in carrying out their activities. One of the requirements of the current version of the standard is the need to carry out risk management (RM), introduced with the demand for risk-based thinking. The objective of this research was to propose a system for the implementation of RM in laboratories, through mapping, identification, classification, critical analysis, and treatment of risks. The research considered the history of actions taken, the risks verified by the laboratory team, the evaluation of their impacts and the probabilities of their occurrence, their classification and the identification of actions necessary to accept, mitigate or eliminate these risks. The system proposed was applied in a testing laboratory at a university in southern Brazil, enabling the maintenance of its accreditation.

Keywords Risk management · Testing laboratory · ISO/IEC 17025 · ISO 31000 · Higher education institutions

Introduction

Universities have always played a fundamental role in the technological context of countries, especially those in development, such as Brazil. Although they are basically teaching and research institutions focused on the qualification of human resources and the production of knowledge, universities also respond to society's demands, interacting with other institutions and companies [1]. To meet these demands, several laboratories of Higher Education Institutions (HEIs) have quality management system (QMS) implemented and accredited in accordance with the ISO/IEC 17025 standard [2]. Accreditation has a positive impact on teaching and research activities, evidenced by the increase in the reliability of results and the qualification of personnel [3]. In addition, it was observed that HEI laboratories may

be meeting demands not met by commercial laboratories [4] and that the number of accredited laboratories has a positive correlation with the country's GDP [4–6], directly influencing the socioeconomic conditions of the countries.

The ISO/IEC 17025 standard establishes the necessary requirements for the operation of a QMS in laboratories that perform testing, calibration and/or sampling activities. Their management system requirements, based on ISO 9001 [7], are complemented with specific technical requirements. Thus, for a laboratory to have ISO/IEC 17025 accreditation, it must have an established management system, be able to generate technically valid results, have been evaluated by an accrediting body and have been considered technically competent.

Likewise ISO 9001, ISO/IEC 17025 has been revised over time. The current version, launched in 2017, incorporated the risk-based thinking included in the 2015 version of ISO 9001 [8, 9], resulting in the need to carry out risk management (RM). The RM includes support strategies, methods and tools to identify and control risk at an acceptable level. Its main objective is to recognise all possible risks within a project, company or associated with a process. To be effective, it is necessary that the RM is considered as an

✉ Fabiane Rodrigues da Silva
fabianerviana@gmail.com

¹ PPGE3M, Federal University of Rio Grande Do Sul, Porto Alegre, RS, Brazil

² PPGEF, Federal University of Rio Grande Do Sul, Porto Alegre, RS, Brazil