

Keys of success of ISO 15189: 2003 implementation

Navapun Charuruks, MD*

Abstract

Central Laboratory, King Chulalongkorn Memorial Hospital (KCMH), Thai Red Cross Society, is one of the best medical laboratories in Thailand. All laboratory services performed in the Central Laboratory have been organized by Department of Laboratory Medicine, Faculty of Medicine, Chulalongkorn University since it had been established in 1971. At present, more than 2.2 million routine tests per year are performed in this laboratory. From the beginning until now, the quality control has been considered as the most important part of the service. The internal quality control (IQC) and external quality assurance scheme (EQAS) have been strictly performed to assure all of laboratory results. Anyhow, in order to step to the international level, ISO 9002: 1999, the international standard, had been implemented in 2000 and maintained until the expired date in 2003. The standard provides quality management to cover all laboratory processes from pre-analytical, analytical, and post-analytical processes. According to our experience, we found that not only the standard could be used to assure the quality system but it also could be used to support us create a new culture of continuous quality improvement. In realization of the usefulness of the standard, the new ISO 15189: 2003 edited from combination of ISO/IEC 17025 and ISO 9001: 2000 has been selected and implemented successfully on 30th April 2004. Thus the Central Laboratory, KCMH, becomes the first laboratory of Asia accredited by this standard. In order to stimulate the other laboratories to achieve ISO 15189: 2003, the knowledge of implementation should be provided to ones interested by this standard. The author wrote the 10 key steps of ISO 15189: 2003 implementing in order to share the experience and keys of our success.

Key words: ISO 15189: 2003 • implementation • key of success

*Department of Laboratory Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand