Chapter 5
An Extensible Cloud-Based Medical Instrument Calibration Mechanism

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ABSTRACT

To obtain effective data from a medical instrument, instrument calibration, an important process within the laboratory activities, is required. Many mobile medical devices are widely and routinely utilized for monitoring people's physiological data by home-care users. However, it is necessary to let these test data be as effective as laboratory reports, so physicians can recognize as well as refer to them. The chapter proposes a Medical Instrument Calibration (MIC) process to let all connected instruments share and store their current calibration information in a global MIC's Database (MICDB). The MICDB is based on the ISO 15189:2012 standard and provides cloud-based functions via Web Services. It also shares collaborated information that is provided by other medical instruments and vendors. A MIC process for calibrating the instrument is not only required for the laboratory, but it can also be adapted for mobile medical devices and home-care instruments.

INTRODUCTION

In order to obtain effective data from a medical instrument, instrument calibration, an important process within the laboratory activities, is required. Most of the calibration process can be documented by hand, even created as electronic forms, for further reference. Based on most quality management standards, the documentation is required for clinical laboratories. However, it is too cumbersome for a technician to take care of the document's lifecycle. It is time to propose a manageable information technology (IT) supported procedure to simplify the quality manager's life in the laboratory (Neumann, 2013).

A simplification of the quality management life cycle might promote laboratory productivity. It seems an advantageous part for laboratory managers and might be worth while well-establishing it. Conversely, do the laboratory reports be trusted by physicians, if we follow the present procedures of laboratory quality management? Although the

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impact factors for the laboratory reports can be numerated, none of the technicians can say very confidently that the report is one hundred percent correct for a specific medical instrument. Anyhow, the quality of the laboratory report is one of the key indexes to let physicians trust the report contents (Chien, 2012).

Some of the laboratory reports are doubted by the physicians, let alone the data that is created from the cheap mobile instruments such as blood glucose, blood pressure. Further, some engineers proposed similar intelligent visions for people to promote the home-care services by connecting many inexpensive, effective and portable medical devices as well as routinely collecting people's physiological data. Although the physiological data is collected, it seems that not all physicians treat it as official reports and even refer to it. It is so wasteful for healthcare resources; hence it is necessary for engineers to adjust some IT parts to pull the direction to the right way. Fortunately, one of the directions we can solve is to establish a global medical equipment calibration mechanism and let most medical instruments refer to the standardization data bank and calibrate themselves before we use these instruments.

BACKGROUND

To understand the importance for the research topic of our proposed mechanism, this section illustrates the following topics: ISO/IEC 15189:2012 standard, ISO-related standards, equipment calibration, and global computing.

ISO/IEC 15189:2012 Standard

As we knew, the International Organization for Standardization (ISO) is a worldwide federation of national standards organization. The ISO works closely with the International Electrotechnical Commission (IEC) on most of the electrotechnical standardizations. Because the ISO/IEC standards are trustable, most countries follow and adapt these standards as their national standards. For example, the ISO 9001 and the ISO/IEC 15189.

The ISO/IEC 15189 is an important revised international standard and mainly illustrates medical laboratories of particular requirements for quality and competence (ISO/IEC, 2012). Medical laboratory services are fundamental tasks to patient care. Healthcare enterprises engaged in the medical laboratory can utilize this standard as the basis for their routine processes. Anyhow, this standard discloses several particular requirements for clinical laboratory quality and competence, including 15 management requirements and 10 technical requirements. Table 1 illustrates the details.

Because of our research interests, our research team focuses on one of the particular and important quality processes, the medical instrument calibration and its affiliated contents. Inside the ISO/IEC 15189 standard (ISO/IEC, 2012), at least eight sections mention the related terms of the calibration that is listed in Table 2.

In summary, the expressions of the calibration-related sections of the ISO/IEC 15189:2012 standard, most of the definitions or descriptions emphasize that a clinical laboratory shall implement a feasible procedure to routinely execute appropriate instrument calibration processes and even record necessary data for preventive calibration usage. Likely, there are some ISO-related standards, which mention calibration process, and we explain them in the following sections.

ISO Related Standards

As the introduction section of the ISO/IEC 15189:2012 standard expressed, its content is based upon the ISO/IEC 17025 and the ISO 9001 standards. Therefore, these related standards are illustrated below.

First, the ISO/IEC 17025:2005 is a revised international standard and illustrates general requirements for the competence of testing and