Medical measurements are present in everyday life and are fundamental processes in the prevention, diagnosis and treatment of diseases, risk assessment and monitoring of patients. Such measurements are performed every day; moreover, as the measurement results become more important in medicine so they must be more accurate and also comparable in different locations over time. There is therefore growing interest in the role of metrological decisions and conformity assessment, notably where measurements are made to safeguard health. The role of metrology in the health sector and the impact of legal control of medical devices with a measuring function and metrological traceability is critical within the health sector.

The science of measurement, as a field of technical and scientific activity, comprises a range of activities with a key role in all sectors of society. In the health sector, due to the inherent potential risk to life it is necessary to measure quantities as accurately as possible. Although measurements that are used to arrive at a medical diagnosis are only “pieces” within the complex process of medical decision-making in general, they contribute incrementally. Therefore, the accuracy and reliability of medical measurements have direct consequences on each individual’s health. Medical decisions are often based on statistical analysis and on the conclusions of clinical studies. Medical measurements are incorporated within these studies and are correlated with other medical findings. Consequently, each medical decision may be influenced by the results of previous studies, including data from medical measurements carried out previously.

Taking into account that medical measurements are related to SI (International System of Units) units such as mass, temperature, length, etc., the same concepts used in the areas of industrial and legal metrology can more or less be directly used in the medical field to improve the metrological traceability of measuring instruments (reproducibility and repeatability conditions). Hence, quality assurance of measurements should be ensured by metrological tools (e.g. calibration, legal metrological control and reference measurement methods). Considering this analogy with other sectors of society in which legal, metrological control is required, the accuracy of measurements and the traceability chain are equally essential for the reliability of medical measurement results.

The principal phases in the life-span of a medical device include the conception and development, planning, manufacturing, packaging and labeling, advertising, sale and use. Any of these may overlap and interactions can affect the safety and performance of a medical device. Although many instruments are covered by the Medical Devices Directive, this sphere of regulation allows each Member State to consider additional measures to protect public health and its citizens. In fact, after placing them on the market and putting them into service, the National Metrology Institutes in the various countries are required to conduct periodic examination and calibration or verifications, to ensure accuracy is maintained. As a result, in Guyana monitoring is done twice yearly to address same.

The importance of accurate measurements in medical diagnosis and the prevention and treatment of diseases to optimize patient care and to efficiently manage healthcare cannot be over emphasized. As a result, the need for certification or accreditation of public and private Hospitals and testing laboratories is critical to obtaining maximum efficiency and effectiveness and credible testing results within the health sector. At present, the requirements of the metrological traceability standard are sometimes neglected. Thus, as a part of accreditation or certification activities, the measuring instruments used by these facilities must demonstrate compliance with the metrological
traceability chain by means of periodic calibration or verification, which is often verified by the certification or accreditation body during audits of their operation, through the submission of test certificates. These certificates are valid if issued by an Independent Accredited Calibration Laboratory. Training of health professionals is also essential and another fundamental pillar is the consolidation of metrological knowledge, which must be part of any organization’s strategy. The development of this culture and its consequent application to safety and the performance of instruments require long-term actions with widespread monitoring.

These aspects are important towards obtaining credible and reliable results. The manufacturer is responsible for ensuring that products conform to the applicable legal requirements, and plays an important role in producing the devices.

In order to demonstrate the impact of ensuring adequate traceability of medical equipment in public health, several studies have been conducted, mainly focusing on the accuracy of measurements and the traceability chain as an essential tool to guarantee accurate and reliable results. As a result, several countries have adopted OIML Recommendations, or have developed their own regulations. This requires implementing legal metrological control, but can also be viewed as a voluntary act, in the case of calibration.

The combined application of medical safety by measurement standards and reference standards reduces the potential health hazard to both patients and medical personnel to a minimum. Therefore, standardization should include requirements for technical service and calibration of medical devices. This article gives a brief overview of the key role of metrology and legal control in the field of medicine.

However, the principle of the metrological traceability chain is missing. This may be achieved by the implementation of a reliable measurements and monitoring system. Indeed, this new approach will cover the specific metrological requirement for those instruments that are in use. If it is demonstrated that they are operating outside their metrological limits (i.e. the maximum permissible errors) then they will be rejected. Taking into account specific national operating conditions.

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