INTERNATİONAL STANDARDS İN THE HEALTH SECTOR: İMPACT ON THE QUALİTY OF MEDİCAL AND DİAGNOSTİC DEVİCES

Antonieta del Carmen Peralta Santamaria[1]

1.Pediatrician / Master in Quality Management / Independent Consultant
revista@srs.gob.sv

Opinion Article

Received:
May 3, 2026

Accepted:
May 8, 2026

Published:
August 07, 2026

Discussion

International standards from the International Organization for Standardization (ISO) initially emerged in the industrial field with the objective of establishing standards that facilitated international trade, product quality, and interoperability between countries. Since its founding in 1947 in Geneva, Switzerland, the organization has developed thousands of standards applicable to different productive sectors (ISO, 2023a).

The incorporation of these standards into the healthcare sector began primarily in the 1990s, when hospitals, clinical laboratories, and medical device manufacturers started seeking certifications and applying quality management principles based on the ISO 9000 family of standards. Subsequently, specific standards were developed for the healthcare field, such as ISO 15189 for clinical laboratories and ISO 13485 for the medical device industry. The requirements of the latter standard are applicable to all organizations that provide medical devices, regardless of their type or size (Alvarado Cuenca, 2024).

The first countries to adopt these standards in healthcare organizations were primarily European, including the United Kingdom, Finland, Sweden, and the Netherlands, where advanced accreditation and quality control systems for clinical laboratories already existed. Subsequently, these standards expanded to other developed countries such as Japan, the United States, and Canada, and later to healthcare systems in Latin America, Asia, and Africa, contributing to the improvement of quality, patient safety, and the reliability of diagnostic results (Plebani, 2010; ISO, 2023b).

Keywords: quality, medical devices, healthcare

The implementation of international quality standards in El Salvador has experienced progressive development over recent decades, especially following the consolidation of a legal framework aimed at strengthening the national quality infrastructure. A fundamental milestone in this process was the enactment of the Law for the Creation of the Salvadoran Quality System, published in the Official Gazette in 2011, which established the institutional foundations for promoting technical standards, normalization, accreditation, and conformity assessment within the country.

The establishment of this national quality infrastructure initially responded to the need to integrate the country into international trade and ensure that Salvadoran products and services met globally recognized technical requirements. The Salvadoran Quality System (SSC in Spanish), created by the aforementioned law, is the institution responsible for guaranteeing and directing compliance with the National Quality Policy of El Salvador, in accordance with the powers and duties conferred upon it by said law (Sistema Salvadoreño para la Calidad, 2011).

The Salvadoran Quality System integrates various specialized technical bodies, including the Salvadoran Normalization Body, the Salvadoran Technical Regulation Body, the Salvadoran Accreditation Body, and the Metrology Research Center, which together enable the development and application of technical standards, conformity assessment, and the guarantee of measurement traceability.

These institutions facilitate the adoption of international standards, including ISO standards, to improve organizational efficiency, service quality, and institutional transparency.

The Salvadoran Normalization Body has obtained accreditations that allow it to certify quality management systems based on ISO 9001, and recently on ISO 37001, which strengthens confidence in certification processes and promotes the adoption of these standards in both public and private institutions within the country.

These certifications contribute to improving the efficiency of administrative processes and guaranteeing the quality of services offered to the public (Organismo Salvadoreño de Normalización, 2025).

In this context, various national organizations have begun implementing management systems based on ISO standards. The 2024 edition of the ISO Survey of Management System Standard Certifications, published by the International Organization for Standardization (ISO) and the International Accreditation Forum (IAF), shows that the Central American region, including El Salvador, is advancing toward a management culture based on quality, sustainability, and integrity (Perdomo, 2024).

The most certified ISO standards in El Salvador mainly correspond to integrated management systems related to quality (ISO 9001), environment (ISO 14001), and occupational health and safety (ISO 45001), which form the foundation of organizational management systems across multiple productive and institutional sectors.

The growing adoption of these standards reflects the trend of Salvadoran organizations to align with international standards that promote continuous improvement, transparency, sustainability, and competitiveness in a globalized economic environment.

In recent years, Salvadoran regulatory development has also driven the mandatory adoption of certain international standards related to institutional integrity and transparency. A significant example is the implementation of anti-bribery management systems based on the ISO 37001 standard, the adoption of which has been promoted by legislation regarding public procurement (Corte de Cuentas de la República, 2025).

However, there is an aspect related to ISO standard certification that still needs to be strengthened, the principle of relationship management: "Organizations must manage their relationships with interested parties, such as suppliers and partners, to optimize their performance" (ISO, 2015).

The relationship management principle established in ISO 9001 highlights the importance of organizations developing effective and mutually beneficial relationships with relevant interested parties, particularly with suppliers and strategic partners.

In the healthcare field, this principle is especially relevant for organizations that provide health services or participate in the supply chain for pharmaceuticals, medications, nutritional supplements, medical devices, and other health technologies. The application of this approach implies selecting reliable suppliers, establishing clear technical quality criteria, periodically evaluating supplier performance, and maintaining communication channels that ensure compliance with regulatory and normative requirements.

Likewise, proper relationship management facilitates traceability, quality control of acquired products, and continuous improvement of procurement and supply processes. In highly regulated sectors, such as pharmaceuticals and medical devices, close collaboration between suppliers, distributors, and healthcare organizations contributes to ensuring that products meet standards of safety, efficacy, and quality, which is essential for protecting public health and strengthening confidence in health systems and sanitary supply chains (ISO, 2015; WHO, 2020).

The quality and safety of products used in health systems depend largely on compliance with manufacturing, quality control, and risk management requirements established in international standards.

These requirements aim to ensure that products used in medical care are safe, effective, traceable, and reliable, reducing risks for patients and healthcare professionals. In this context, the standards developed by the International Organization for Standardization (ISO) play a fundamental role by establishing technical requirements for the design, manufacturing, and evaluation of medical devices and sanitary equipment (ISO, 2023b).

One of the most important standards applicable to health technology manufacturers is ISO 13485, which establishes the requirements for quality management systems in the medical device industry. This standard defines the procedures that manufacturers must follow to ensure that medical devices consistently meet regulatory and safety requirements throughout their entire life cycle, from design to distribution and post-market surveillance (ISO, 2016). ISO 13485 is complemented by ISO

14971, which provides a framework for identifying, evaluating, and controlling risks associated with medical devices, contributing to the guarantee of patient safety (ISO, 2023b).

In the case of personal protective equipment used in healthcare settings, there are specific standards that establish design, performance, and testing method requirements. For example, medical masks used in hospitals must comply with technical standards such as EN 14683, which sets requirements for bacterial filtration, fluid resistance, and breathability, as well as test methods to evaluate their performance. Additionally, the ISO 22609 standard defines a test method to evaluate the resistance of masks to penetration by synthetic blood, an important requirement for ensuring the protection of healthcare personnel against splashes of biological fluids. These standards are used in conjunction with other quality control requirements and microbiological testing during the manufacturing of these devices (WHO, 2023).

Likewise, the manufacturing of medical devices requires compliance with standards related to biocompatibility, sterilization, microbiological control, and labeling. For example, the ISO 10993 series of standards establishes methods for the biological evaluation of medical devices and their interaction with human tissues, while the ISO 11737 standard defines microbiological methods to determine the microbial load present on healthcare products before sterilization. These standards are especially relevant for devices that come into direct contact with the patient, such as probes, sensors, or diagnostic equipment (WHO, 2023).

Manufacturing requirements also apply to complex biomedical equipment used in diagnosis and treatment, such as ultrasonography machines, clinical monitors, laboratory analyzers, or non-invasive measurement devices. The manufacturing of these devices must comply with ISO-based quality management systems, as well as technical standards related to electrical safety, medical software, and clinical evaluation. These provisions seek to ensure that medical devices maintain adequate levels of precision, reliability, and safety during their clinical use (ISO, 2023b).

In the case of hospital disinfectants and cleaning products used in clinical environments, manufacturers must demonstrate through laboratory testing that their products meet microbiological efficacy and chemical safety requirements, as well as maintain quality control systems throughout their production; in synthesis, compliance with international manufacturing standards constitutes an essential element for guaranteeing the safety and quality of products used in healthcare.

The proper management of public procurement constitutes an essential element for ensuring efficiency in the provision of goods and services used within health systems; in this context, it is fundamental that those responsible for defining technical specifications, bid evaluation committees, and contract administrators possess knowledge of international quality standards, such as the norms mentioned herein.

The incorporation of these standards into procurement processes allows for the establishment of clear and verifiable technical requirements for the acquisition of medicines, medical devices, biomedical equipment, and other sanitary supplies, thereby ensuring that the purchased products meet international safety and performance criteria. In conclusion, the standards developed by the International Organization for Standardization contribute significantly to improving quality and safety within health systems.

Among the most relevant standards are ISO 15189, which establishes requirements to guarantee the reliability of diagnostic results; ISO 13485, which specifies the requirements for a quality management system applicable to organizations involved in one or more stages of a medical device's life cycle, from design and production to distribution, installation, maintenance, and final disposal (ISO, 2016); as well as ISO 14971, which provides manufacturers with a systematic framework for managing risks associated with injury to the patient, the user, or other people, as well as damage to property or the environment (ISO, 2019).

The fact that bidding companies have these standards implemented contributes to patient safety, promotes continuous improvement, and fosters confidence in the health technologies used in medical care (ISO, 2023b; WHO, 2021).

The knowledge and application of these standards by the actors involved in public procurement not only strengthen the transparency and quality of purchasing processes but also favor the rational use of resources and the efficiency of budget expenditures. Furthermore, it guarantees that the sanitary supplies and technologies used in medical care are safe and of high quality, which directly impacts the protection of public health and the improvement of healthcare service outcomes (Asamblea Legislativa de El Salvador, 2023; ISO, 2023b).

References

Alvarado Cuenca, R. I. (2024). Normas ISO en gestión sanitaria: revisión sistemática. Ciencia Latina Revista Científica Multidisciplinar, 8(4), 5035–5058. https://doi.org/10.37811/cl_rcm.v8i4.12727

Asamblea Legislativa de El Salvador. (2023). Ley de compras públicas. Diario Oficial de El Salvador.

Consejo Nacional de Calidad. (s. f.). Marco institucional. https://cnc.gob.sv/marco-institucional/

Corte de Cuentas de la República. (2025). Capacitación sobre sistema de gestión antisoborno ISO 37001. https://www.cortedecuentas.gob.sv

European Committee for Standardization. (2019). EN 14683: Medical face masks—Requirements and test methods.

International Organization for Standardization. (2015). ISO 9000:2015 quality management systems—Fundamentals and vocabulary.

International Organization for Standardization. (2016). ISO 13485: Medical devices—Quality management systems—Requirements for regulatory purposes.

International Organization for Standardization. (2019). ISO 14971: Medical devices—Application of risk management to medical devices.

International Organization for Standardization. (2023a). The ISO survey of management system standard certifications. https://www.iso.org

International Organization for Standardization. (2023b). ISO standards for medical devices and healthcare technologies. https://www.iso.org

Medtecs Business Solutions. (2022). What is EN 14683? The European standard for face masks! https://business.medtecs.com/en14683/

Organismo Salvadoreño de Normalización. (2025). Acreditación del organismo salvadoreño de normalización bajo la ISO 37001. https://www.osn.gob.sv

Perdomo, A. (2024). ISO survey 2024: Tendencias y desafíos para El Salvador y Centroamérica.

Plebani, M. (2010). The detection and prevention of errors in laboratory medicine. Annals of Clinical Biochemistry, 47(2), 101–110. https://doi.org/10.1258/acb.2009.009222

Sistema Salvadoreño para la Calidad. (2011). Ley de creación del Sistema Salvadoreño para la Calidad. Diario Oficial de El Salvador.

World Health Organization. (2020). WHO's good distribution practices for pharmaceutical products. https://www.who.int

World Health Organization. (2021). Medical device regulations and standards. https://www.who.int

World Health Organization. (2023). Technical specifications for pre-market assessment of medical masks. https://iris.who.int