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## Medical Technology Management in Hospital Certification in Mexico

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### 5.1 Introduction

Mexican health policy is promoting the quality of health services by hospital certification meeting the NMX-CC standards family, which is the Mexican equivalent of the ISO 9000 standards family. These standards can help both product- and service-oriented organizations achieve standards of quality that are recognized and respected throughout the world in developing a quality management system (QMS).

In hospital certification, one important aspect to be evaluated is the availability of technical supplies. In this sense, the incorporation of technical support services into healthcare organizations has become very important. That is why many hospitals in Mexico, both public and private, have incorporated into their organization a Biomedical Engineering Department (BED) with the purpose of integrating all engineering and management processes for assurance of the optimal use of all technological supplies in the hospital, helping in the quality of health services provided to patients.

The purpose of this study is to show how the medical technology management done by the BED at the hospitals contributes both to health services quality and as an element required for certification. In general, it describes several projects developed in different hospitals (public and private) with different health levels in Mexico City. Each of them contributed to the certification of different clinical processes.

### 5.2 ISO 9000 Certification

ISO standards are voluntary. As a nongovernmental organization, ISO has no legal authority to enforce their implementation. Some ISO standards (mainly those concerned with health, safety, or the environment) have been adopted in some countries as part of their regulatory framework, or are referred to in legislation for which it serves as the technical basis. Such adoptions are sovereign decisions by the regulatory authorities or governments of the countries concerned; ISO itself does not regulate or legislate. However, although ISO standards are voluntary, they

may become a market requirement, as has happened in the case of the ISO 9000 QMSs. By QMS we understand a management strategy that is characterized by: a focus on process management; a focus on quality, based on the participation of all members in the organization; getting profit through client satisfaction and providing benefits to all members in the organization and in the society.

For governments, international standards provide the technological and scientific bases underpinning health, safety, and environmental legislation. For consumers, conformity of products and services to international standards provides assurance about their quality, safety, and reliability. For customers, the worldwide compatibility of technology that is achieved when products and services are based on international standards brings them an increasingly wide choice of offers, and they also benefit from the effects of competition among suppliers [1]. In this sense there are some important quality management principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, and mutually beneficial supplier relationships.

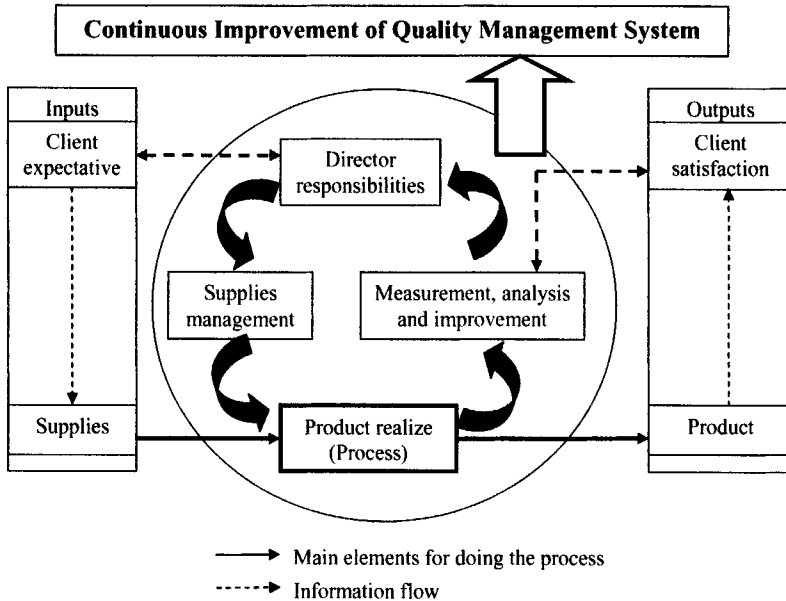
In particular, the process approach (from procedures to processes) is based on the following principles:

- identifying processes needful for the QMS;
- demonstrating the ability of processes to achieve planned results and monitor, measure, analyze, and improve them;
- developing information on characteristics and trends of processes;
- top management reviewing process performance and improving effectiveness;
- greater effectiveness when activities and resources are managed as a process;
- more customer focus;
- more cost effective;
- meeting business objectives.

### **5.3 ISO 9000 Family and its Mexican Equivalent NMX-CC**

The term ISO 9000 refers to a set of quality management standards. ISO 9000 currently includes three quality standards: ISO 9000:2000, ISO 9001:2000, and ISO 9004:2000. The ISO 9000 2000 standards apply to all kinds of organizations in all kinds of areas and present the requirements, whereas ISO 9000:2000 and ISO 9004:2000 present the guidelines. All of these are process standards (not product standards).

This approach is based on the development of a QMS that meets the new quality standard, in order to control or improve the quality of your products and services, to reduce the costs associated with poor quality, or to become more competitive, or because your customers expect you to do so, or because a governmental body has made it mandatory. You then develop a quality management system that meets the requirements specified by ISO 9001:2000.



**FIGURE 5.1.** The process-based approach for improving QMS.

In Mexico, the ISO 9000 2000 family have been translated by the “Spanish Translation Task Group,” providing the Mexican standards NMX-CC, a set of standards to assist any organization with implementing a management quality system. In this study we just use the following Mexican standards:

- NMX-CC-9000-IMNC-2000. Quality Management System. Concepts and Vocabulary [2]. This describes the fundamentals and specifies the terminology for the QMS.
- NMX-CC-9001-IMNC-2000. Quality Management System. Requirements [3]. This specifies the requirements for the QMS for any organization which needs to demonstrate its capability to provide products that comply with the legal and their clients’ requirements, in order to improve their clients’ satisfaction.

Figure 5.1 shows a process-based QMS approach using the Mexican set of standards NMX-CC. It shows the links between all parts involved with the inputs to the system and the main role the clients have in determining the input requirements.

## 5.4 Quality in Health Services: A National Policy

The National Crusade for Quality in Health Services is a government policy developed by the Health Ministry of Mexico. Its purpose is to lead to more effective medical services in all Mexican health institutions [4]. This policy proposes

elevating quality in health services and standardizing it throughout the country. To achieve this purpose, the policy has been developed through 10 statements. One of these concerns the certification of organizations and individuals. This action helps public and private institutions improve the satisfaction of both the personnel and the customers (patients). It reduces heterogeneity in the quality level among different types of health service, whether public or private, throughout the country. In addition, the population will gain an improved perception about the quality of services with veridical information, which allows people's trust in the health system to be raised. Likewise, it will look to incorporating the population in supervision of quality health services.

## **5.5 Importance of Technology Management in Hospital Certification**

Many hospitals in Mexico City have been working to comply with the requirements of the Mexican standards NMX-CC in order to become certificated. This procedure certifies each clinical service (in an individual way), which is considered as a *process* by the standard. In this sense, hospitals must develop the required documentation for all procedures related to each *process*, including clinical, technical, and administrative aspects.

With regard to technical aspects, the department generally in charge of the medical technology management at a hospital is the BED. Its main functions are medical equipment maintenance (preventive and corrective), medical equipment assessment, training, security, and risk management. However, the most important function that demands most of the technical personnel's time is medical equipment maintenance [5]. It is clear that all these activities have the objective of assuring optimal functionality of the available medical technology at the hospital. In this way, the technology management turns into a fundamental element in hospital certification, and thus all the services and procedures related to medical technology management provide by the BED must also comply with the Mexican standards family NMX-CC.

In what follows, we will describe some projects developed in different hospitals in Mexico City related to different clinical services (processes) where the BED developed several manuals about specific procedures for medical equipment management in order to contribute to the certification of these services.

### **5.5.1 Project 1: Guaranty Quality Program for a Radiology Service**

Project 1 [6] was developed in a secondary care private hospital with 125 beds. This hospital had implemented a guaranty quality program, based on the NMX-CC-9001-IMNC-2000 standard. It was developed specifically for the management of radio-diagnostic equipment. This program includes procedures concerning

physical inspection and equipment functionality according to the manufacturers' technical specifications, as well as quality control tests. Afterwards, the tests were applied according to the Mexican official norm NOM-158-SSA-1996 related to technical specifications for diagnostic medical equipment that uses X-rays. Preventive maintenance tests were developed. These included physical, mechanical, and electrical aspects for monitoring the most significant functionality parameters in the equipment, in order to assure their stability as a function of time. Quality tests were also developed. These evaluate functionality parameters with the objective to get a reference value (control value). These parameters were: focal point, exposure time, performance, field coincidence, center coincidence, fuzzy alignment, exposure rate for conventional fluoroscopy, and dose in breast tumor radiation. Both preventive maintenance and quality tests were applied to 12 items of radio-diagnostic equipment (which included X-ray, CAT, mastograph, and fluoroscopy equipment) at the hospital during three consecutive weeks. Failures were detected in some equipment, and the optimal functionality of other equipment was probed.

### ***5.5.2 Project 2: Medical Equipment Maintenance Quality Plan for a Biomedical Engineering Department***

Project 2 [7] was developed in a 125-bed private hospital that decided to implement a QMS based on the NMX-CC-9001-IMNC-2000 standard. The purpose was to assure the quality of the health services provided to their patients. The hospital developed a quality manual that provides information about the quality plans. These plans are documents that specify the facilities and activities necessary to realize the health processes in an effective way.

On the other hand, the hospital's BED has the function to maintain the medical equipment in optimal condition. That is why the objective of this study was to develop a quality plan (based on NMX-CC-9001-IMNC-2000) containing the process related to this activity, in order to support the implementation of a QMS and the certification of three specific health services at the hospital, namely pathology, clinical laboratory, and blood bank. Moreover, this quality plan also provides the necessary information to enable the technical personnel to carry out the maintenance process on the medical equipment.

First, we identified three processes related to maintenance. (1) Revision routines, which corresponds to visual and functionality inspection of hospital facilities and medical equipment done in a scheduled way. This requires diagnostic instrumentation, simulators, and noninvasive tests, such as fluids level analysis, temperature, and pressure tests. (2) Preventive maintenance, which is defined as a programmed serial inspection of functionality, security, and calibration realized in regular periods. The purpose is to avoid failures in medical equipment and enable hospital facilities to operate at optimal levels of efficiency. (3) Repair, which covers activities such as spark replacement, component adjustment, reconditioning, etc. whose purpose is to restore the normal function, performance, and security of the equipment in the least possible time. It is important to say that the

equipment maintenance could be done by technical personnel from the hospital BED or by external technical personnel, depending on the technical complexity of the equipment.

The quality plan developed in this study contains the general procedure to realize each process with a flow diagram showing the graphics of the process. Likewise, it points out the register form (service order, revision process, etc.) required in each case.

### ***5.5.3 Project 3: Procedures for the Right Use and Management of Medical Technology Utilized in Minimal Invasive Surgical Procedures***

Project 3 [8] was developed in a private hospital with 100 beds. It has a surgical area consisting of 12 surgical rooms. Five of these have endosuites, surgical suites designed to create the optimal operating environment for the surgeon, staff, and, most importantly, the patient. Today it is the most versatile room design, and serves a large number of minimally invasive procedures (endoscopy, laparoscopy, and arthroscopy) [3]. The system's functions and images are displayed on multifunction flat-panel monitors, which are also capable of showing images.

The purpose of this study was to develop a procedures manual about the use and management of the medical technology utilized in minimally invasive surgeries at the hospital, in order to provide information about the adequate management of the equipment to the technical personnel from the DIB and adequate use of this equipment for the medical personnel, as well as to contribute to the certification of the surgical process.

The procedures were generated by clinical and technical information. The methodology for obtaining and organizing these procedures is described below.

1. Identification of the types of minimally invasive surgery done in the hospital. They were classified into five medical categories: gynecology, general surgery, thoracic, orthopedics, and otorhinolaryngology.
2. Identification of the medical technology used in each surgery. Six technology sets were defined, according to the medical categories identified. In the case of orthopedics, this requires two different technology sets, i.e. one for shoulder surgery and other for knee surgery.
3. We consulted 16 technical manuals with the purpose of obtaining the technical specifications of the equipment, as well as the manufacturers' recommendations for the use and management of the equipment.
4. Fourteen technical schedules were developed with the next information: (a) description of the equipment (including alarms); (b) physical inspection procedure; (c) management of the equipment (washing, sterilization (if necessary), warehoused, and care); and (d) warnings and precautions. This information was incorporated in the procedure in order to provide the technical elements about the functionality of the equipment to the technical personnel from the BED.

5. Six generic procedures about the use and management of electronic devices and medical equipment used in each minimally invasive surgery identified were elaborated. It is important to say that biomedical engineering helps the physician in all the procedures related to the minimally invasive surgeries done at the hospital. In this sense, the procedures included in the manual will be an instrument for technical and medical personnel for learning the adequate use of the medical technology, and so the optimization of the resources and the technical capability of the hospital.

The procedures developed here are actually incorporated into the documentation of the management quality system of the hospital. This system provides the regulation for optimal functionality of all services (medical and administrative) from the hospital.

#### ***5.5.4 Project 4: Procedures for Maintenance and Risk Management for Medical Equipment at a Research Center of Infectious Diseases***

Project 4 [9] was developed at the National Health Institute in its Infectious Diseases Research Center (CIENI). The center works with the human immunodeficiency virus, *Mycobacterium tuberculosis*, influenza virus (H5N1) and the SARS corona virus. It has three laboratories designed with the necessary bio-safety standards, levels BSL2 and BSL3. The laboratory equipment has two kinds of contact with the infectious agents, namely *direct* and *indirect*. For example, pipettes have *direct* contact and CO<sub>2</sub> incubators have *indirect* contact because the virus is in Petri boxes. That is why the technology requires specific management and control.

The objective of this study was to develop preventive maintenance procedures for the laboratory equipment present in this center, involving aspects about risk management and quality control. The importance of these kinds of procedure is that activities related to the maintenance and the sanitation procedures attending bio-safety should decrease the biological risk for technical personnel. In this sense, the partial goals of this study were to provide to the technical personnel from the BED the bio-safety procedures necessary for minimizing biological risk during the execution of work:

- A complete preventive maintenance procedure for each specific piece of equipment.
- Technical and quality specifications required during the execution of the maintenance procedures and equipment calibration.
- Minimization of equipment failure, assuring continuous operation of the equipment and extending its useful time.

- Contribution to the certification process of several clinical and research laboratory processes at the center by complying with the Mexican standard MX-NMX-CC.

There were 13 pieces of equipment selected: (1) two doors sterilizer, (2) analytical digital balance, (3) extraction bench, (4) laminar flux bench, (5) centrifuge and micro-centrifuge, (6) refrigerated centrifuge and ultracentrifuge, (7) laser diffraction particle-size analyzer, (8) CO<sub>2</sub> incubator, (9) microscope, (10) pipettes, (11) digital potentiometer, (12) refrigerator, (13) ultra-freezer.

The procedures were structured as follows:

1. *Introduction.* This includes general information about the features of the different research laboratories at CIENI.
2. *General and security rules.* These provide the security procedures required for access to the center and for equipment maintenance.
3. *Procedure for preventive maintenance.* Each procedure contains the following information: maintenance periodicity, security procedures (the security equipment required for doing it), maintenance procedure (including general external cleaning, external inspection, internal cleaning, internal inspection, lubrication, spare parts replacement, calibration, revision of electrical security, and full functionality tests).
4. *Equipment, tools and spare parts.* This section provides information about the tools and spare parts necessary for carrying out preventive maintenance on the equipment, as well as consumables for the operation and calibration.
5. *Quality control.* Some actions recommended for quality control were included, such as: a daily register of parameters (temperature, pressure, humidity, etc.) in order to monitor their fluctuations; instrumentation necessary for maintenance, certificated by the Mexican Entity of Accreditation [10].
6. *Registration form.* This form includes general data about the equipment (generic name, trademark, model, serial number, inventory number, and the clinic area where it is placed), periodicity of the maintenance, the report of the functionality tests, electrical security, and calibration.

Furthermore, there three appendices were incorporated: A<sub>1</sub>. Cleaners and lubricators, A<sub>2</sub>. Disinfectors' substances, and A<sub>3</sub>. Procedures in accident cases [11].

## 5.6 Conclusion

This study had described four different projects related to medical technology management developed by BEDs in different hospitals in Mexico City. The primary objective of all these projects was to provide knowledge about the maintenance procedures and quality control tests to the technical personnel to carry out their jobs and to contribute to the certification process by the NMX standards for the clinical services at the particular hospital.



This study shows the importance of having documented procedures related to the management of medical technology in order to optimize the technical facilities available in the hospital, as well as for the certification.

In Mexico, hospital certification is a new process, and projects developed in this way will be very important in the hospital environment in order to guarantee the quality of the clinical services provide.

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