



Politics for the Integration of the Activities of Insurance Metrological to the Process of Maintenance of Biomedical Equipments

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POLÍTICA PARA LA INTEGRACIÓN DE LAS ACTIVIDADES DE SEGUROS METROLÓGICOS AL PROCESO DE MANTENIMIENTO DE EQUIPOS BIOMÉDICOS

POLÍTICA PARA A INTEGRAÇÃO DAS ATIVIDADES DE SEGUROS METROLÓGICAS AO PROCESSO DE MANUTENÇÃO DE EQUIPAMENTOS BIOMÉDICOS

Abstract— In this article, is postulated the integration of the activities for metrology and EB's maintenance (medical equipments), in order that this could be adopted for clinics and hospitals of the national territory. In a such way, which they have a theoretical support to be able to restructure the present flowcharts in his departments of clinical engineering.

For such an intention, there has effected an exhaustive technological vigilance relating to subject matter that compete with the regulation, policies and functions that apply to these activities in the country and international entities; giving evidence across a comparison between these, of the diverse discrepancies and failings that are demonstrated on having developed these activities of a way independent, since also, from the opportunities of improvement that can present the institutions of health in Colombia, on having had integrated inside his engineering departments to the above mentioned areas.

Finally, all the information gathered is brought to the Colombian context to be applicable to the national healthcare system. The politics of integration is outlined and the model proposes closely for mix the metrology and the maintenance of medical equipment, of a such way that are in limit with the laws that govern them in Colombia.

Keywords—Integration; Metrology; Maintenance; Regulation; Model.

Resumen— En este artículo se postula la integración de las actividades de metrología y mantenimiento de EBs (equipos médicos), con el fin de que estas puedan ser adoptadas para clínicas y hospitales del territorio nacional. En una forma tal, que las instituciones tengan un soporte teórico para poder reestructurar los actuales diagramas de flujo en sus departamentos de ingeniería clínica.

Con ese objetivo, se ha efectuado una exhaustiva vigilancia tecnológica relacionada con los temas que competen con la regulación, las políticas y las funciones que se aplican a estas actividades en el país y por las entidades internacionales. Este proceso ha generando evidencias a través de una comparación entre estos, de las diversas discrepancias y fallas que se demuestran al haber desarrollado estas actividades de manera independiente. Esto permitirá a su vez, oportunidades de mejora que se pueden obtener y compartir en las instituciones de salud en Colombia, al haber integrado en el interior sus departamentos de ingeniería a las áreas antes mencionadas.

Por último, toda la información recogida se lleva al contexto colombiano para ser aplicable al sistema nacional de salud. Las políticas de integración se esbozan. El modelo propone una estrecha mezcla para la metrología y el mantenimiento de equipos médicos, de manera tal que se encuentran en cumplimiento de las leyes que los rigen en Colombia.

Palabras clave— Integración; reglamento; modelo; metrología; mantenimiento.

Resumo— Este artigo discute a integração de atividades de metrologia e de manutenção de EBs (equipamento médico), para que estes possam ser adotadas para clínicas e hospitais no território nacional. De tal forma, que tenham um relatório teórico para reestruturar os atuais diagramas de fluxo em departamentos de engenharia clínica.

Com esse objetivo, se procedeu a uma exaustiva vigilância tecnologia relacionada com os tópicos relacionados com a regulamentação, as política e as funções que se aplicam a essas atividades no país e por entidades internacionais; gerando evidências através de uma comparação entre estes das várias discrepâncias e falhas que são mostradas ao ter desenvolvido essas atividades de forma independente, permitindo que a partir de oportunidades de melhoria que se podem obter nas instituições de saúde da Colômbia, para ser integrado dentro de seus departamentos de engenharia das áreas tratadas acima.

Finalmente, toda a informação recolhida é levada ao contexto colombiano para ser aplicável ao sistema nacional de saúde. As políticas de integração são descritas e o modelo propõe uma estreita mistura para a metrologia e manutenção de equipamentos médicos, para que eles estejam em conformidade com as leis que regem na Colômbia.

Palavras chave— Integração; Regulamento; Modelo; Metrologia, Manutenção.

I. INTRODUCTION

The biomedical equipments play a leading paper in the provision of services of health; being considered to be a key tool for the effective prevention, the accurate diagnosis, the effective treatment and the patients' suitable rehabilitation. Affecting directly the practice and the effective results of the modern medicine.

With base in this importance and the complexity commonly associated with the technology of medical equipments, there arises the need to do a meticulous and exhaustive follow-up for the good functioning of the same ones [1].

For such an intention in Colombia, the clinical engineering seeks protection in a conglomerate of procedure, resolutions and decrees that demand and endorse that the execution of the actions applied to the insurance of the quality and reliability of the operation of the biomedical technology, are Effected by means of such processes as the metrology and EB's maintenance.

Nevertheless, this regulation tends to be interpreted of diverse manners, generating negative consequences to the plan of management of medical devices.

Initially, propitiates to that both activities of technical service (metrology and maintenance), are developed by

independent entities; giving place to which, the one who realizes processes of maintenance it could not exercise activities of metrology because one would incur the imagination of: judge and part. Restriction that in turn, it has created a conjuncture between these two activities, and it has propitiated the gestation of diverse conflicts of interest, being of benefit to third parties and reducing the economic growth of the hospitable entities [2].

Attach to this, the quality in the service meets significantly affected, due to the fact that the processes are carried out by personnel and different times, which does not allow to execute the activities of preventive, corrective maintenance and of insurance metrological at par. Motivating to that the equipments are not treated under suitable standards and the coordination is restricted both from tasks and of processes to that the devices could turn exposed. Finally, it has stayed in evidence, of which this concerns significantly the safety of the patient as the reliability and the efficiency of the medical technology in the sector health [3].

Having in counts the presented problematics, the integration of the activities of metrology to the maintenance of biomedical equipments, it would allow the ideal fulfillment of the normative requirements and would offer a better performance of the technologies in the clinical area. Of here the need to develop policies and

specific limits, to implement a methodology that combines the characteristics of quality and integrity of the insurance metrological of these equipments; including aspects, and warning of operability, reliability, clinical use, competition of the welfare and technical personnel cost / benefit of the process of maintenance, for the suitable application of the processes relative to the safety-confiabilidad-efectividad in the use of these medical equipments.

II. METHODOLOGY

Analysis of existing national policies and legislation related to metrological verification processes to biomedical equipment

For the development of this study all relevant information to the subject which sets out the relevant rules and policies that describe and guide the activities of metrology biomedical equipment in Colombia was collected.

Importantly, in addition to the analysis of biomedical metrology regulations, it was necessary to collect and evaluate the regulations related to the maintenance of this technology.

SWOT matrix for the analysis of the National Policy and Legislation

Weaknesses: In reviewing specific legislation for metrology applied to biomedical equipment in Colombia is not evidence. Colombian law currently applies to biomedical equipment in the area of metrology, has been the result of a migration of concepts, from industrial metrology [4-6]. For this reason, the search horizon and revision of regulations on the maintenance of biomedical equipment expands, finding specific legislation for this activity. It is a general law, it is not detailed, did not specify how, who and why, that is to say how to conduct the activities, the person making them and why it should be done and its importance [7, 8].

Opportunities: Colombia Biomedical engineering is a relatively new discipline, which means that we have a picture that strengthens the discipline towards establishing best practices in relation to the maintenance and metrology applied to medical technology [9].

Threats: The Colombian law applied to maintenance and metrology for biomedical technology, directed or interpreted in an inappropriate manner, it promotes the implementation of maintenance and calibration activities without greater quality control, allowing unqualified staff the run. It has also encouraged the creation of some metrology laboratories that do not meet all the requirements and criteria necessary to ensure adequate provision of calibration, being in some cases to biomedical equipment metrology activity with low added value and profit.

Assessment of current policies and international legislation related to metrological verification processes to biomedical equipment.

Of the international consulted bibliography there is highlighted that the activity of maintenance to biomedical equipments includes the activities of calibration and check of the calibration to these; on the other hand one thinks that the above mentioned activities must be realized for personnel trained to realize this one labor. That bibliography found on calibration speaks only about tests of model validation and prototypes in the phase of manufacture [10-15].

SWOT matrix for the analysis of the International Policy and Legislation

Weaknesses: biomedical equipments do not demonstrate an international specific legislation of metrology applied, the nearest thing to this they are the recommendations of the OIML, which are focused on the model validation (premarket stage) [16]. For this reason, the horizon of the review is extended to the international legislation in the maintenance of biomedical equipments.

To comply with international law must take high costs and training of personnel performing maintenance activities, plus tools - Analyzers and malingerers - for such activity.

Opportunities: The advance of biomedical and clinical engineering in developed countries, especially the United States and the European community, have legal frameworks that allow them to establish within institutions plans and programs of biomedical equipment maintenance, mostly addressed to reduce the risks associated with the use of this technology [10, 12, 17-19]. Which allows them to realize retrospective analyses focused in the evaluation of the practice of the maintenance, there being established measures that strengthen the experiences that generate better results; equally, one seeks to modify the practices that redound to investment of time and resource extra, that in turn incur major risks. As result of the path and across the analysis of this one, the opportunity has of directional the legal frame, recommendations, quality standards, towards the optimization of resources and mitigation of the risk.

Strengths: The great strength that possesses the international legislation is based on the continuous and awkward investigation on the topic related to management of biomedical equipments. This allows a constant innovation in particular activities of maintenance, repair and check of the conditions of functioning of the medical technology [13, 17, 20-22]. In the analysis of the international legislation there is demonstrated that the regulations in the maintenance of biomedical equipments is detailed and specific, explaining all the activities, the roles and the necessary tools to realize the activities with quality and safety, in ad-

dition his syntax is sufficiently clear, which does not lend to multiple interpretations.

Comparative analysis between Colombian legislation and international legislation related to maintenance and biomedical equipment metrology

Comparison sets

To realize the joint between normative models, first it is necessary to classify the information and segment it in 4 criteria, which are:

Intentionality

The procedure, decrees, policies and standards that frame the activities of maintenance and biomedical metrology equipments they possess a definite well premeditation; this is, a clear direction towards which his goals and aims are orientated. This criterion seeks to relate the procedure and processes to the royal value to give a service of health of high quality. Seeking to define or to identify the fundamental direction that must assure the applicable legislation and with it to orientate the development of complementary criteria relative to the safety in the management of the biomedical technology.

Theoretical framework

They designate the concepts and theoretical criteria that base the procedure; with base in suppositions and / or postulates that are coherent with the practice of the norm or concept. Generally analyzed by the professional in clinical engineering and related disciplines on having developed the work of planning, management and execution of the program of maintenance to the biomedical technology; as fundamental support in the service in the institutions of health.

Flexibility and adaptability of the legislative model

There were identified procedure and decrees that allow his adjustment diverse situations and experiences of the practice in the execution of the programs of maintenance to biomedical equipments. Opening the possibility of having several interpretations of the same norm and allowing to apply them in contexts for which were not conceived. In other instances, from his conception they are written in such a way that only a way exists to exercise them. For it, this criterion tries to evaluate the particularities that possess some procedure and decrees to be adapted to practical concrete situations.

Applicability of the standard (Relevance)

It refers to those aspects that they must be analyzed with depth on having raised a practical situation: level of

structure, way of implementation and applicability in the context of maintenance to biomedical equipments.

Later one shows the comparisons between the Colombian and existing international standards shown by the criteria above.

It is necessary to highlight that the major differences in the regulations, are based on the integration of the activities of calibration and check of the calibration to the process of maintenance that in Colombia they are realized separately.

Table 1. Comparison by comparison criteria

LEGISLATIVE FRAMEWORK	COMPARISON SETS
	Intentionality
Colombian	Legislation is not raised from his original intention, for directional the specific activities of metrology to biomedical equipments, if not to the capacity and competition of the productive sector in general. [7, 8].
International	Legislation raised from his original intention, to orientating and directional the plans of maintenance, repair, check of the functioning and calibration of the biomedical technology [10, 12, 13, 15, 18].

Table 2. Frame by comparison criterial theoretical

LEGISLATIVE FRAMEWORK	COMPARISON SETS
	Theoretical Frame
Colombian	The theoretical concept that bases the Colombian legislation is that of quality in products and in the provision of services. The theoretical concept that it bases to the maintenance is of safety and prevention is supported by redundant activities.
International	The theoretical concept that bases the international legislation is that of risk and safety in the presentation of the services focused explicitly on health. Check of the functioning and calibration of the biomedical technology [10, 12, 13, 15, 18].

Table 3. Flexibility by comparison criteria

LEGISLATIVE FRAMEWORK	COMPARISON SETS
	Flexibility
Colombian	The Colombian legislation, it allows from his conception several interpretations that can give place to inconsistencies in his systematic application, in addition for not being specific and detailed there are institutions in the excess of the activities and others on the contrary omit activities.
International	The International Legislation is clear from his syntax, and to his reading there exists little probability that is interpreted of inadequate form, is specific and detailed in the procedures and activities.

Table 4. By comparison applicability criteria (relevance)

LEGISLATIVE FRAMEWORK	COMPARISON SETS
	Applicability (Relevance)
Colombian	Metrology activities applied to biomedical equipment is supported in existing legislation to the activities of biomedical equipment maintenance standards and quality assurance of goods and services but is essential to implement and strengthen the measurement practices associated with activities calibration; incorporating objective guidelines to standardize processes.
International	They are the references that regulate the practice, development and commercialization of medical equipments worldwide; recommended practices and minimal considerations to achieve the commercialization of medical equipments in the world. You often subject to review and update as part of a process of continuous improvement.

III. RESULTS

Based on the previous bibliographical study where versus place the national regulations the international ones, there is postulated the creation of the model who brings together the politics of integration of the activities of metrological insurance with EB's maintenance.

Design integration policy

The design of the policy is framed in three stages:

- **Guidelines:** At this stage of the policy's purpose, scope, objectives and definitions that will develop policy fall.
- **Roles and Responsibilities:** there are established in this stage the responsibilities and roles defined for the actors - boarders and day pupils - who intervene in the development and implementation of a politics that guarantees an integral and suitable maintenance to the biomedical equipments.
- **Implementation:** there are described the processes and activities to develop to achieve the aims and scope defined by the politics..

Guidelines

Politics for the insurance of the quality in the maintenance of the Biomedical Technology and an effective management of this technology from the purchase up to his final disposition.

Introduction

This political capture like point of item the duty to be of the maintenance of biomedical equipments and is an offer for the system of health led by the Department of the Social Protection, the territorial entities, institutions providing health services (IPS), companies health care providers (EPS) and especially for engineering and maintenance departments. With it seeks to assure and to minimize the

risks associated with the use and maintenance of biomedical technology. The implementation of this politics assures the fulfillment of the national and international standards in the maintenance of Biomedical Technology.

Purpose

The purpose of the policy is to provide guidelines and directiveses for implementing an effective program for biomedical equipments maintenance, integrating the activities of calibration and calibration check as part of the maintenance of biomedical equipments.

Scope

Biomedical technology is a key tool in the institutions providing health services and is of great importance in the effectiveness, efficiency, quality and safety in health care processes. Proper management of biomedical equipment maintenance is vital to ensure that biomedical equipment remains safe and effective for its intended use; maximized the lifespan of technology and minimizing the costs to maintain it.

This policy can be applied to all entities responsible for the management of biomedical technology, used in patient care for diagnosis, treatment, prevention and rehabilitation.

Roles and responsibilities

Manager or Director

You must ensure that inside the strategic platform there should be supported the technological, financial and human resources for the development and implementation of the program or plan of maintenance of biomedical equipments assuring the quality, efficiency and opportunity.

All employees

They must be conscious of the importance, complexity and risks of biomedical technology, and understand it as the tool with which caregivers providing the health service for the diagnosis, prevention, treatment and rehabilitation.

Committee on Risk and Quality

The risk and quality committee must realize the matrix of risk for service and of being possible for equipment, to design and implement the necessary barriers to prevent potential adverse events with the use of technology.

Committee on Technology Management

The organization must create a multidisciplinary committee which involved a representative of each of the following areas: ethics committee, medical direction, projects, financial, Biomedical Engineering / Clinic epidemiology and that the organization considers necessary for proper decision-making on evaluation, innovation, acquisition, use and management of technology; towards

meeting the existing needs of the population, that meets the conditions of the "market" positive results on human health and to support the quality and safety of patients and others interested.

Clinical Engineering Leader

Generally, the leader of Clinical Engineering is the representative chosen by the direction of the institution of health as the person in charge of the management of the maintenance of the biomedical equipment.

Provides/ Manufacturer

Manufacturers and suppliers for regulations should guarantee quality standards and safety of biomedical equipment that provide.

Implementation

To achieve and ensure the purpose of this policy is necessary to start from the evaluation and acquisition of technology.

Evaluation and Selection of Technology

The evaluation of health technologies is conceived as the integral way of investigating the technical, economic and social consequences of the employment of the technology, both in the short and long term as well as their direct and indirect effects, intended and unintended. To evaluate a technology in health provides elements that orientate the capture of strategic decisions related to the coverage of the insurance in health and the assignment of resources.

Inventory

The institution must guarantee and ensure inventory as reliable as possible biomedical technology. This is essential for the maintenance management and control technology, in the case of a call (Recall) by the INVIMA, the institution must know if it possesses this technology and in what service it is operating.

Initial tests Acceptance Inspection and Installation

The health institution shall develop and implement a protocol to ensure that all new biomedical technology that should be included inside the inventory; and in the maintenance program will perform the initial inspection testing and verification that are necessary prior to first use. These tests must be it sufficiently strict to determine that the equipment expires with the specifications of the manufacturer and operates of sure and efficient form. These tests should be documented, recorded and filed inside the team resume.

Education and Training

The health institution should have a training program, training and retraining for staff in the correct and safe use of biomedical technology before being used with patients.

Maintenance

Routine maintenance should be performed according to manufacturer protocols. Therefore, it is understood that the protocol is specific and contains measuring intervals that must be verified for each particular form or every equipment.

- Competent Personnel
- Data Information System
- Test Equipment and Tools
- Maintenance Protocols
- Physical inspection
- Electrical Safety
- Operation Inspection
- Performance Tests
- Technovigilance
- Assessment and Audits
- Policy Review

The review of this Politics will be carried out every two years or if it is the case with the emergence of new governmental regulations or certification schemes for specific health facilities; this in order to maintain the current and effective policy.

IV. DISCUSSION

In the development of this work have identified some situations around metrology activities biomedical equipment in current practice, and constitute areas of opportunity for improvement in the Colombian regulation. The Discussion appears from the following topics:

Metrology activities (calibration verification or calibration), are often carried out by personnel who have not received certified training by the manufacturer.

Measuring equipment used by laboratories to perform metrology tasks to biomedical equipment, simulators and analyzers regularly without traceability to a national or international standard reference, since there are few specific standards for biomedical equipment. In this vein, the activities currently being carried out, they correspond to verify the correct operation of technology.

Biomedical technology is very dynamic and constantly changing, so laboratories providing calibration services are not fully updated.

By ignorance of the rules of the "mandate" of "outsourcing" the metrological service, thus maintaining biomedical equipment in Colombia has increased in value is favorable.

V. CONCLUSION

With the development with political this one seeks to provide guidelines and directives for the implementation of an effective program of maintenance of biomedical equipment that integrates the activities of calibration and calibration check as part of the maintenance process, minimizing the risks associated with cycle biomedical technology management. The raised politics describes the activities and personnel involved in them, giving response to how, who and why.

The proposed policy reinforces the process and maintenance program biomedical technology, determining a trained specialist technology and technical manager, to generate sufficient safeguards that minimize the risks and maximize the aforementioned costs.

The correct address of metrological assurance activities integrated into the maintenance, as designed and implemented plans to biomedical technology in the institutions providing health services, allows:

- Lower costs associated with the maintenance of biomedical equipment.
- Increase the productivity of biomedical equipment, routing through the integrated maintenance so that the time available technology at the service of medical procedures is optimized metrological activity.
- Mitigate the risk associated with inappropriate use of biomedical technology by unqualified personnel to intervene in it.
- And deepen the scientific and technical knowledge of biomedical technology to reach a reliability centered maintenance.

The proposed policy becomes the first tool that seeks to regulate the practice of the two major activities to support biomedical equipment in Colombia, maintenance and metrology applied to biomedical equipment, making explicit not only should be, but the duty make these activities. This policy is a concrete step forward in the area of regulation of the safety of medical equipment, which seeks to enrich the practice of biomedical engineering in the country. To maintain your fitness this policy should be

periodically reviewed at least every two years, in order to adjust and update the processes and activities described.

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