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Management Model for the Application of Legal Metrological Control and Conformity Assessment in Biomedical Equipment

A.F. Ramírez Barrera [1,ψ], J.F. Martínez G. [1], E. Hidalgo Vásquez [2]

[1]*Biomedical Research Group GI2B, Medellin, Colombia*

[2]*Biomedical Metrological Lab of ITM, Medellín, Colombia*

Instituto Tecnológico Metropolitano – ITM

***Abstract*—** At present, the country faces major changes regarding regulations oriented toward technological management to be applied to biomedical equipment. In addition to those significant changes today, the National Quality System has introduced others regarding metrological control that have to be applied to some equipment in healthcare services. As such, this paper aims to present a proposal based on a management model which integrates legal metrological controls applied to biomedical equipment, along with the application of measurement processes for activities associated to conformity assessment. This model also uses a method of characterization of requirements established in different regulations aimed at ensuring equipment measurements also oriented toward conformity assessment. The most significant expected result will be the proposal of a management structure enabling engineering units of healthcare service providers to not only comply with said regulations, but also to offer high quality services based on reliability, as support for activities aimed at patient safety.

***Keywords* —** Metrological management, calibration, biomedical equipment, legal metrological control, patient safety

Modelo de gestión para la aplicación del control metrológico legal y la evaluación de la conformidad en equipos biomédicos

***Resumen* —** En la actualidad el país enfrenta grandes cambios referentes a las normas orientadas a la gestión tecnológica que se debe aplicar a los equipos biomédicos. Además de grandes cambios que hoy el Subsistema Nacional de Calidad ha presentado al control metrológico legal que se debe aplicar a algunos equipos que prestan sus servicios en el área de la salud. Dado lo anterior este trabajo pretende presentar una propuesta basada en un modelo de gestión que integra los requerimientos del control metrológico legal aplicado a los equipos biomédicos y a su vez la aplicación de procesos de medición para las actividades asociadas a la evaluación de la conformidad, utilizando como metodología un proceso de caracterización de las exigencias establecidas en las normas de Colombia asociadas al control metrológico legal y en diferentes normas para el aseguramiento de las mediciones en equipos, esto orientado a la evaluación de la conformidad, obteniendo como resultado más significativo una propuesta de

ψ Author's Mailing Address: andresramirez@itm.edu.co

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estructura de gestión que le permitirá a las unidades de ingeniería de las entidades prestadoras de servicio de salud, no solo cumplir con lo exigido en las normas actuales sino a prestar unos servicios de alta calidad basados en confiabilidad como apoyo a los actividades encaminadas a la seguridad del paciente.

Palabras clave — Gestión metrológica, calibración, equipo biomédico, control metrológico legal, seguridad del paciente.

Modelo de gestão para o aplicativo do controle metrológico legal e a avaliação da conformidade em equipamentos Biomédicos

***Resumo*—**Na atualidade o país enfrenta grandes mudanças referentes às normas orientadas à gestão tecnológica que se deve aplicar aos equipamentos biomédicos, além de grandes mudanças que hoje o subsistema nacional de qualidade a apresentado e orientado ao controle metrológico legal que se deve aplicar a alguns equipamentos que prestam seus serviços na área da saúde, dado o anterior este trabalho pretende apresentar uma proposta baseada num modelo de gestão que integra os requerimentos do controle metrológico legal aplicado às equipamentos biomédicos e a sua vez o aplicativo de processos de medida para as atividades associadas à avaliação da conformidade, utilizando como metodologia um processo de caracterização das exigências estabelecidas nas normas da Colômbia associadas ao controle metrológico legal e ao estabelecido em diferentes normas orientadas à garantia das medidas em equipamentos, isto orientado à avaliação da conformidade, obtendo como resultado mais significativo uma proposta de estrutura de gestão que lhe permitirá às unidades de engenharia das entidades prestadoras de serviço de saúde, não só cumprir com o exigido nas normas atuais senão também a emprestar uns serviços de alta qualidade baseados em fiabilidade como apoio às atividades encaminhadas à segurança do paciente.

***Palavras-chave*—**gestão metrológica, calibração, equipamento biomédico, controle metrológico legal, segurança do paciente.

I. Introduction

Healthcare service providers establish Technology Management associated to biomedical equipment as fundamental among their strategic lines in quality standards. They understand biomedical technology makes part of the vital tools for the optimal development of medical care, offering better results in the services of prevention, protection and treatment, among others. They are aware of the condition of this technology, from acquisition, through upkeep and until final write-off [1]. The technology undergoes different processes, such as measurement assurance during use, along with activities guaranteeing these measurements and their results over time [2]. These institutions undertake manufacturer recommendations and the support of traceable measures, taking as reference different regulations, not only from the biomedical equipment itself but also recommendations from the International Organization of Legal Metrology (IOLM), as well as, regulations which control or measure each one of these machines.

Given the above, the country has different legislation regulating the activities the keeper, manufacturer or supplier of medical technology must clearly take into account at the time of use or commercialization of said technology, as is the case of resolution 2003 of 2014 [3], from the Ministry for Health and Social Protection. This norm involves maintenance and calibration activities in its allocation standard. This regulatory body also issued decree 4725 of 2005 [4], defining that the responsibility of the equipment's functioning is shared between the manufacturer, or his representative in Colombia if the equipment is from abroad, and the owner or keeper during the post-sale stage. It also states that the title holder or keeper of the biomedical equipment must guarantee the capacity to offer necessary and ongoing technical support services during the machine's lifetime, along with spare parts and tools for its maintenance and calibration, allowing for its upkeep within the safety ranges initially established by the manufacturer.

Subsequently, the Ministry of Commerce, Industry and Tourism, issued Decree 1471 of 2014 [5], "by which the National Quality Subsystem is reorganized and Decree 2269 of 1993 is modified," which makes part of the Only Decree for the Regulation of the Commerce, Industry and Tourism Sectors from May 26, 2015 (Decree 1074 of 2015). Lastly, this was modified by Decree 1595 of August 5, 2015, specifically in Article 3, which modifies Chapter 7 of title 1, part 2 of the book of decree 1074 of 2015, establishing one of the guidelines aimed at the importance of measuring processes in the country and a strengthening of the National Quality Subsystem, as a requirement to improving competitiveness, as well as, the environment for productive development. Decree 1595 of 2015 [6] states that measuring instruments used to measure, weigh and count and which can affect the life,

health or physical integrity of a person are specifically required to undergo legal metrological controls. From this, we can infer that biomedical equipment should be classified under three large categories: the first category would be equipment that weighs, measures or counts, requiring legal metrological controls. The second would be equipment that does not weigh, measure or count but which has subsystems that do. Lastly, the third category would be biomedical equipment that neither weighs, measures or counts, nor has subsystems to do that. Although the last two categories are not specified within the realm of Decree 1595 of 2015, it is important for them to undergo assessments regarding conformity with manufacturer recommendations and technology standardization that will enable an assurance of reliability of its measurements or results. As such, this paper proposes a management model for the application of legal metrological controls in accordance with current regulations. It also presents a set of integral activities to support the healthcare provider in biomedical equipment conformity measurement activities.

II. Methodology

The basis for the proposed legal metrological control and evaluation management model for biomedical equipment is the current Colombian legislation [3] [4] [5] [6]. The first reason for this is to achieve clarity related to what is applicable to legal metrological control of biomedical equipment, as well as, which equipment, according to manufacturer recommendations. However, considering the requirements of any direct measurement equipment or equipment with measurement subsystems, which are critical in decision making, we also based our proposal on the NTC-ISO 10012:2003 Measurement Management System, requirements for measurement processes and equipment [7], and the Colombian Technical Guide GTC62 for Work Safety and Service Quality, Maintenance, Terminology [9]. The consideration all of these regulations is important for the integral notion of the minimum requirements biomedical equipment should meet in the measurement processes so as to provide reliability, given that these national and international regulations pose specific models for measurement assurance of instruments. These regulations are entirely applicable to biomedical equipment and contribute to conformity assessment models aimed at patient safety. This proposal also takes into account the topic of Risk Management as an activity for the identification of risk associated to biomedical equipment and based on ISO 31000 [10] and NTC 5254 [11] regulations.

The proposal poses three major processes: (1) Biomedical Technological Evaluation, (2) Legal Metrological Control stages, and (3) Technical Support for Biomedical Equipment, all of which contain, immersed within, activities with certain conditions that enable logical analysis in the measurement of biomedical equipment assurance. It is noted that some these conditions are determined by the current Colombian legislation while others by recommended norms oriented toward the assurance of measurement instruments. These processes are not mutually exclusive. On the contrary, all processes are harmonized by activities that begin from the moment of equipment acquisition to their rejection. The added value is each process' internal activities that support decision making. Decision making, then, becomes more objective based on the measurement and conformity processes of the equipment, since said decisions are supported by data obtained from measurements based on error and uncertainty results.

The entire management model contemplates measurement assurance, beginning with the acquisition of medical equipment, which constitutes one of the most complex management processes for healthcare providers, due to the fact that so many aspects must be taken into consideration in order to achieve the end result, improvement in the efficiency and quality of healthcare service provision stemming from medical assistance needs [12]. Subsequent to equipment acquisition based on assistance needs, there is an evaluation for the classification of biomedical equipment in order to determine if said equipment requires legal metrological control. In any case, it will be necessary to give technical support which will contemplate conformity assessment within its activities, determining among others, electrical safety, risk management and financial performance, to finally make objective decisions and to be able to reject equipment which does not comply with said conditions and then initiate a new acquisition process for new biomedical equipment, as the case may be. Given the above, the management model contemplates an evaluation proposal according to the measurement results, when making decisions with error and uncertainty results, as well as, a financial exercise contemplating all the variables of a management analysis that does not contradict patient safety assurance, and lastly is within a risk identification framework associated to biomedical equipment, an entire risk matrix.

III. Results

The management model for legal metrological control and conformity assessment for biomedical equipment (BE) is based according to what is stated in different notions of

management systems established by ISO, specifically what is stated in new systems changes based on processes in version NTC-ISO 9001:2015. Thus, this model begins with a process identifying the needs in the area of assistance, as well as, other relevant areas, such as, medical technology or special service suppliers. This needs identification is understood as input requirements to subsequently execute what is established in the three major processes, (1) Biomedical Technology Assessment, (2) Legal Metrological Control stages and (3) Technical Support for Biomedical Equipment, all of which have clinical activities and are not isolated among themselves. On the contrary, they maintain permanent interaction so as to achieve internal or external client satisfaction, all within the framework of of activities aimed at patient safety, as shown in Fig. 1. The proposed model begins with the Biomedical Technology Assessment, as is shown on Fig. 2, where the need for the area of assistance and if said area requires the acquisition of new biomedical equipment are at the heart of the matter. We analyze whether the machine is considered biomedical equipment which measures, weighs or counts, since, according to what is established in the 1595 of 2015 decree [6], legal metrological control must be carried out. If it is a machine which does not weigh, measure or count, we must analyze if the biomedical equipment's (BE) manufacturer recommends calibration. If calibration is recommended, the same conditions for legal metrological control must apply. However, if there is no need to purchase new biomedical equipment, upkeep activities must be applied. If said upkeep is under the category of equipment that does not measure, weigh or count, this task would fall under the process of technical support.

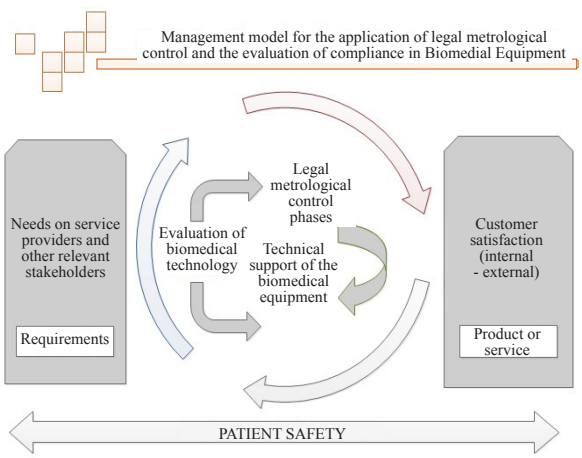

Fig. 1. Management model for the application of legal control measurement and conformity assessment of BE

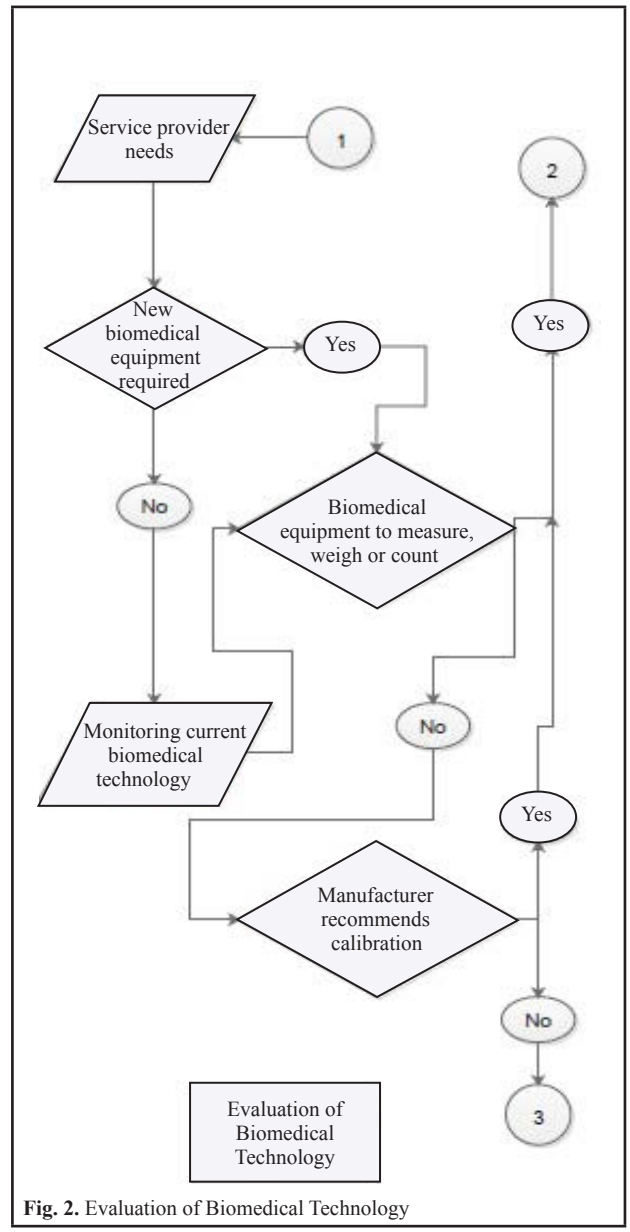

Fig. 2. Evaluation of Biomedical Technology

When biomedical equipment requires legal metrological control, we must begin with conformity assessment as is shown in Fig. 3, taking into account that this assessment is based on manufacturer recommendations and regulatory processes and are fundamental in the completion of a Metrological Assurance Plan (MAP) that will enable referencing the Metrology activity program the healthcare provider has contemplated to ensure the reliability of measurement equipment in each one of the processes, from the most critical, to equipment which only verifies working criteria, defining calibration priorities and Metrological Requirement of the Client (MRC).

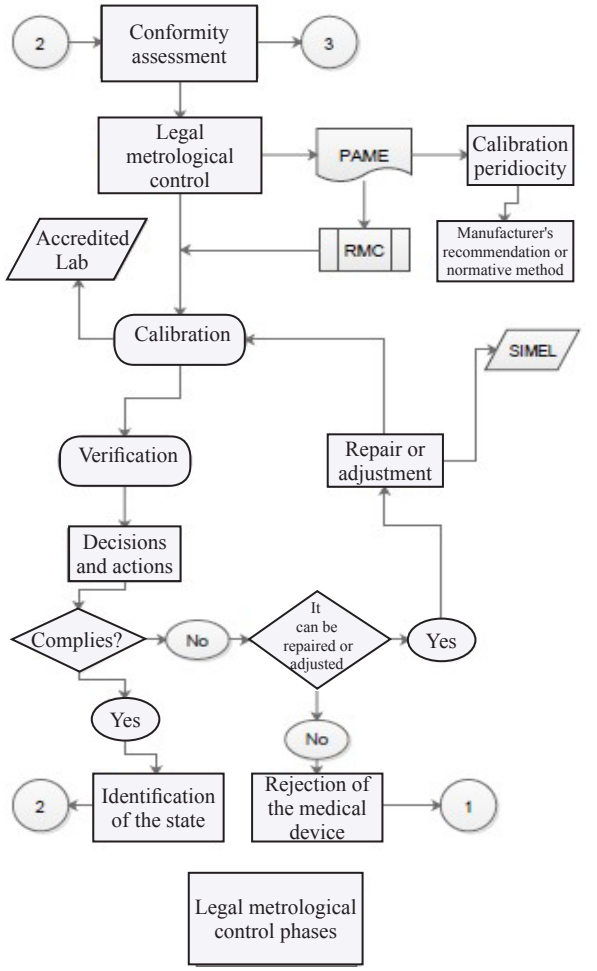

Fig. 3. Legal Metrological Control Stages

Subsequently, there is the calibration process in accredited labs and verification so as to, consecutively, take action and make decisions regarding equipment and established parameters, equipment compliment is identified and the conformity assessment process continues and, likewise, passes to the technical support process for maintenance control. However, if the equipment does not comply, an inspection must be made to define whether or not the equipment can be repaired or adjusted, so as to repair it internally, or with manufacturer or brand representatives, which must be registered in the Legal Metrological Information System (LMIS). This System integrates all the information of Legal Metrology of the actors who intervene in the country's Metrological Control, among which we have: producers, importers, sellers, repair personnel and users of measurement instruments. Likewise, the System includes Authorized Organisms for Metrological Verification (AOMV) and the administration as guarantors of the safety in transactions made by said instruments.

If the equipment complies after repairs, then calibration and verification activities follow in order to guarantee conformity. In the case the equipment still does not conform to specifications, then it must be rejected and go to the biomedical equipment evaluation process in order to assess the need for new equipment acquisition. Lastly, the management model for legal metrological control and conformity assessment of Biomedical Equipment contemplates that an integrated system of measurement assurance possesses a technical support process, as Fig. 4 shows. This cross-cutting process is applicable for both equipment requiring legal metrological control and equipment that does not require it and determines measurement activities defining Maximum Errors Permitted (MEP) recommended by manufacturers, or regulations, guaranteeing that these measurements be done with traceable patterns.

Consecutively, from determining activities related to measuring processes, it goes to adding the biomedical equipment into a preventive maintenance plan as a strategy for the strict upkeep of the technical workings of equipment. In addition, an analysis is made of the financial performance of each piece of equipment, identifying all direct and indirect costs associated to its technical conformity, along with the application of electrical safety tests and an appropriate risk management. If after this analysis, if the Biomedical Equipment does not comply, the corresponding repair or adjustment activities must follow so that the equipment will meet optimal working conditions and later be added again in the preventive maintenance process. However, if the equipment cannot be repaired, it must be rejected, be written-off and go to the process of technological evaluation of biomedical equipment in order to analyze the need for and proceed to acquire new equipment. Lastly, as Fig. 5 shows, the processes immersed in the management model contemplate an integrated system of measurement assurance in biomedical equipment that is an integral proposal of a set of activities aimed at, not only completing a series of activities that comply with existing regulation, but also activities that support the reliability of measures and data supplied for this equipment. Moreover, the stages proposed are articulated among themselves, enabling a significant contribution to technological management of healthcare providers.

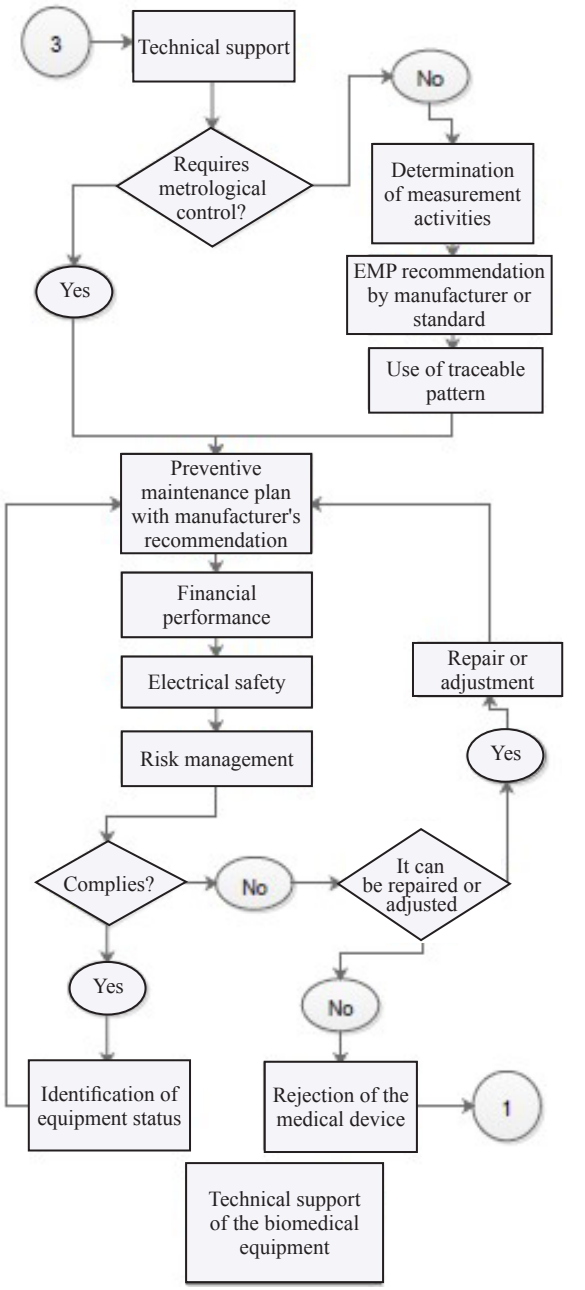

Fig. 4. Technical Support of Biomedical Equipment

IV. Discussion

Recently, Colombia has been posing different discussions related to the importance, or not, of binding activities for the calibration of medical equipment in the cases where legal metrological control is not applied, taking into account these activities are immersed in minimum quality requirements as is standardization, according to manufacturer recommendations, and the inclusion of measurement processes in the health industry with legal metrological controls in the new National Quality Subsystem. In this sense, the assurance of measurement of biomedical equipment is very important for the processes of calibration and adjustment of equipment and indirectly fundamental for the reliability of the results associated with diagnostics, so as to guarantee patient safety in healthcare providing institutions.

Taking into account Colombian legislation, specifically Decree 1595 of 2015 of the Ministry of Commerce, Industry and Tourism, Resolution 2003 of 2014 of the Ministry of Health and Social Protection and Decree 4725 of 2005 of the same Ministry, we could offer patients better quality service, given the certainty that medical equipment will be operating under quality service standards and the reliability added by the results for routine calibration and measurement processes, preventive maintenance, financial analysis electrical safety and risk management. As such, this paper presents a management model which contemplates different activities, not only in processes of measurement assurance application, but also, in complementary activities that aid in the determination of a conformity assessment of biomedical equipment, highlighting the need to promote new research based on the current legislation of Colombia in this matter. This would encourage the creation of new methodologies, experiments, tests and devices oriented toward the improvement of the provision of healthcare services.

V. Conclusion

This paper presents a focus from the existing legislation aimed at the importance of having measurement assurance in biomedical equipment and how it impacts activities aimed at the reliability of results. As such, an integral proposal is presented which will enable healthcare providers to implement strategies of assurance based on international regulations and aimed at compliment of current legislation. On the other hand, it is important to note that the proposal presented in this paper offers starting points aimed at the fact that measurement processes should not only be applied to biomedical equipment subject to legal metrological control, but also routinely on equipment that does not weigh, measure or count, since this enables decision making with objective evidence. This objective evidence consists of maximum errors permitted compared to other data obtained and based on manufacturer recommendations, as well as, recommendations from national or international assurance regulations.

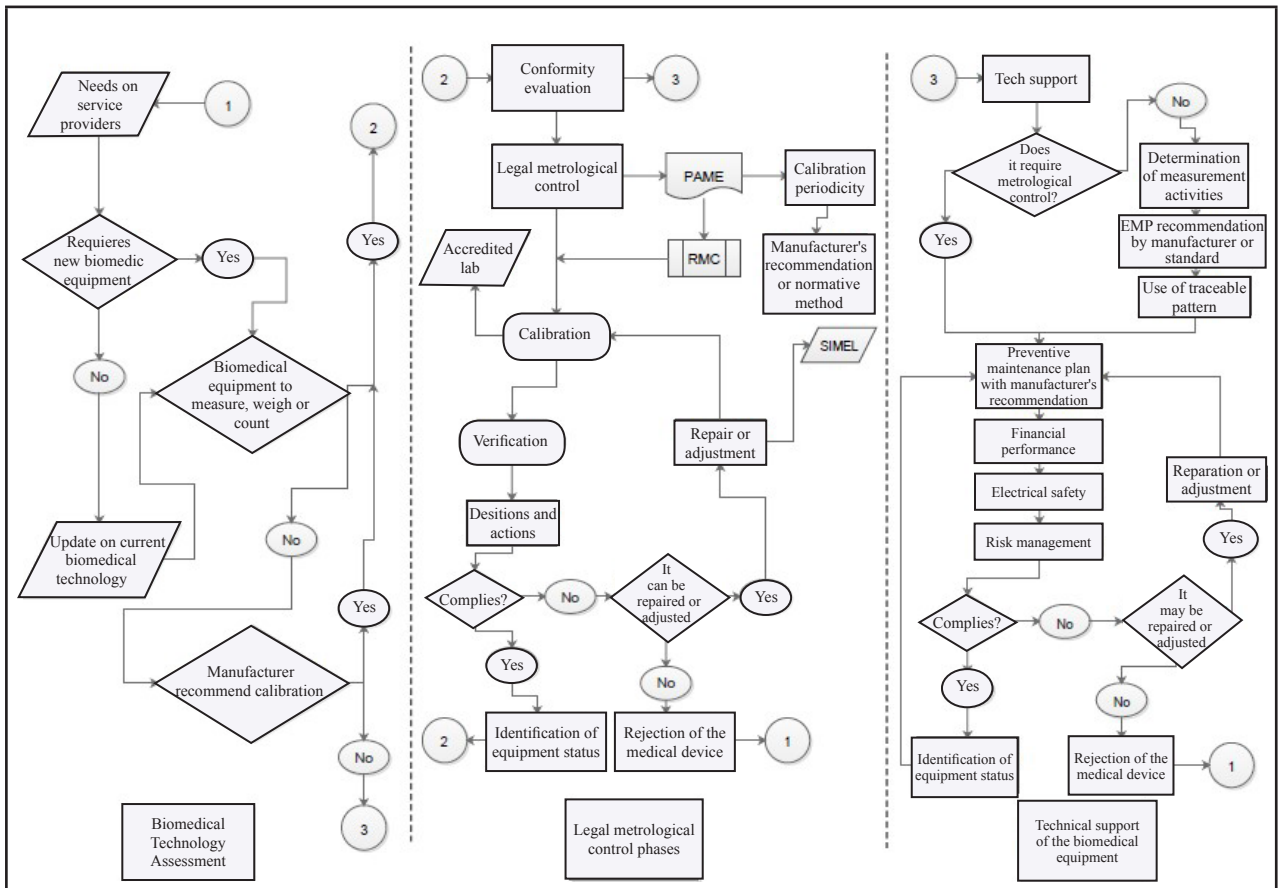

Fig. 5. Integrated measurement assurance system in biomedical equipment

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