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RCM-PMBOK HYBRID METHODOLOGY FOR MANAGING THE MAINTENANCE OF CRITICAL BIOMEDICAL EQUIPMENT IN IPS OF MEDIUM COMPLEXITY

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The research carried out resulted in the proposal to create a hybrid methodology between two topics such as RCM and PMBOK applied to the management of critical equipment maintenance in the biomedical area in health service providers (IPS) of medium complexity of the city of Cúcuta, Colombia. The hybrid methodology is based on a five-phase project structure, with overall management and tactical activities, deliverable documents for biomedical maintenance management (GMB) and more for GMB activity documentation, recommended tools and techniques for the implementation of activities, in addition to recommended guidelines and formats, where this was applied directly in four medium complexity Health Service Providers (IPS) Institutions of Cúcuta-Colombia, in which product of the professional and teaching experience of the author of this research with the design and execution of maintenance plans based on reliability for these institutions, are considered as case studies since they have the design basis of the RCM in three of them and the fourth is presented as a pilot where the hybrid model to be designed was implemented from scratch.

Keywords: Reliability-focused maintenance (RCM), PMBOK, biomedical equipment, medium complexity IPS, methodological guide

1 INTRODUCTION

Throughout human history, technological advances have marked changes in social, economic and cultural fields. The development brought by the industrial revolution is undoubtedly one of the most outstanding technological advances. Since then, having new equipment, machines and ever more complex and expensive infrastructure is not new. Organizations, social or business, public or private, for profit or not, have had to adapt or die. The implementation, maintenance and optimization of this emerging technology has played an important role in this adaptation process.

Another perspective to take into account is the budgetary conditioning imposed on health institutions by the national government in relation to the item prepared to invest in maintenance activities. It is also important to consider the aspects that most influence the loss of efficiency and reliability of hospital equipment and facilities, such aspects are: human resources, mainly represented by the low specialization and qualification of hospital maintenance technicians; spare parts, which is influenced by poor planning and standardization for their acquisition; suppliers of equipment and maintenance, since economic items are only considered for purchase and not for maintenance; and access to resources that facilitate this work. [1]

The RCM has a characteristic that the other models known today do not contemplate with the same relevance; this characteristic is the reliability of the equipment, understood as the ability to function during the service life without failure under the operating conditions for which equipment was designed. Its focus on reliability allows the RCM to analyze the consequences of potential failures, how to prevent them, how to increase availability, reduce costs and corrective repair times. In addition, since its appearance in the 60s as a maintenance model, it has been consolidated as a systematic process that allows determining what must be done for a machine, equipment or installation to fulfill the operational functions for which it was built. [2]

The RCM-PMBOK hybrid methodology consists of five main stages where they focus on the main aspects that are to achieve that the IPS present a quality service from the approach of the operation of bio-equipmentAs well as strengthening maintenance management systems from the perspective of the project structure, this methodology allows us to gather the cycle of planning-executing-measuring-acting, anticipating failures and project management. The stages consist of activities organized according to their priority of execution, all have a flow chart that directs a step by step with their respective deliverables or documentation that is achieved in each activity and can be implemented in their management system, because its main focus is to offer all the elements necessary to strengthen its health service and achieve quality in this, because biomedical equipment are the main pillars of the human resource for the provision of health service.

It also proposes a methodology for continuous improvement when the IPS have already implemented the hybrid RCM-PMBOK methodology and have been applying the recommended instruments or formats at each stage where the records are obtained, at this point the IPS must apply the methodology of continuous improvement which will

offer five stages that will cover all the actions to improve resulting from the processes where the implementation of the hybrid methodology was evaluated.

Finally, this methodological guide RCM-PMBOK fills the main gap that is exposed in terms of the maintenance of biomedical equipment, which is a step-by-step procedure based mainly on criticality and failure analysis, in conjunction with the PMBOK methodology, where it exposes all the instruments to form a maintenance management system under the main objective that is to get ahead of the failure of an equipment, because in the medical part the human life is at risk, under the operating conditions that may generate a biomedical equipment, for this reason this proposed methodology guide gathers all the gaps present in biomedical maintenance and managing to mitigate the possible corrective actions generated during the implementation of this under an intrinsic methodology of continuous improvement of the guide methodological.

1.1 Research questions

In the current era, companies have recognized that their future is conditioned by the level of competitiveness and performance. These factors are closely related to effective and efficient management of their resources. This orientation towards asset management and many other strategies, which integrate maintenance not as a compulsory evil but as a strategic opportunity, generate the need to make the greatest possible effort to manage it properly. [3]

In addition, a biomedical team can be the cause of adverse events in the patient, the operator or the environment. According to Resolution 4816 of 2008 an adverse event is an "unintended damage to the patient, operator or environment that occurs as a result of the use of a medical device" [4], that is, it includes any injury, physical or otherwise, including death. When the cause of this adverse event is a biomedical team, there are two possible sources of origin; the first and most common is the malpractice of the person when using the device; the second is the poor management of the maintenance of the devices. To detail each of the sources, it is necessary to mention their main characteristics and context.

So it is presented that a biomedical equipment can present multiple failures that cause a malfunction. Maintenance should not only repair equipment when it fails, but also prevent those failures and make them never happen. However, equipment throughout its useful life deteriorates and increases the probability of failure, which makes it necessary to diagnose its failure modes constantly. Identifying failure modes at a high level of detail requires synergy of highly trained professionals and a sufficiently practical methodology. The best fault analysis methodology includes RCM that guides reliability-focused maintenance.

There is also a lack of skills, tools and methodologies to manage human resources, schedules, costs, knowledge, risks and objectives of maintenance plans, before, during and after their design; so it is valid to raise the following questions:

As the RCM is the most recognized model worldwide for designing maintenance plans, is the normativity associated with the RCM sufficiently effective to guarantee good results in the long term?

Does hospital maintenance -as an activity- have the characteristics to be analyzed as a project? If so, are project management models such as PMBOK applicable to hospital maintenance?

Would the effectiveness of diagnosis, planning, execution, monitoring and control of hospital maintenance plans based on MCR be improved in the medium complexity IPS of Cúcuta (Colombia), if they are guided by a project management methodology that defines their stages, techniques, tools, resources and processes, from the application of the PMBOK?

What changes could be evidenced when evaluating the management of hospital maintenance in the medium complexity IPS proposed as a case study, before and after the application of the hybrid methodological guide to be designed between the PMBOK and the RCM?

Is it possible to establish a standard methodological guide for the management of RCM hospital maintenance projects for the other medium and low complexity IPS of Cúcuta (Colombia) that manage similar critical assets?

1.2 Research objetives

1.2.1 General objetive

Design a hybrid methodological guide between the RCM and the PMBOK for the maintenance management of critical biomedical equipment in medium-complexity Health Service Providers (IPS) in Cúcuta, Colombia.

1.2.2 Specific Objectives

- Diagnose the maintenance management traditionally carried out by the medium complexity Health Service Providers Institutions (IPS) of Cúcuta, Colombia.
- Study the normativity associated with the RCM, its phases and development requirements, as well as its scope.
- Analyze the principles of the PMBOK project management model, ISO standard 21500 (2012) and ISO standard 55001 (2014) to identify its applicability to maintenance as a project.

- Design a hybrid methodology between RCM and PMBOK that establishes the ideal stages, techniques, tools, resources and processes for the development of maintenance projects in critical biomedical equipment.
- Apply the methodology designed to corroborate the improvement in the processes of diagnosis, planning, execution, monitoring and control of maintenance plans in the medium complexity IPS in Cúcuta, Colombia.
- Establish the applicability of the hybrid methodological guide to the other medium and low complexity IPS, which require maintenance plans focused on the reliability of critical biomedical equipment.

2 MATERIALS AND METHODS

The aim of this research is to design a hybrid methodological guide between the RCM and the PMBOK for the Maintenance Management of critical biomedical equipment in medium-complexity Health Care Providers (IPS), understood within the context of hospital maintenance and asset management, therefore it is necessary to review the national and international context in relation to hospital maintenance management, especially of critical equipment and oriented towards their reliability.

2.1 Colombian context for hospital maintenance

In 1994, as a result of Law 100, the National Hospital Fund was dissolved and the Comprehensive Social Security System was created, which led to the organization of Health Service Providers (EPS), Health Service Providers (IPS) and State Social Enterprises; leaving it under its responsibility and autonomy to carry out maintenance management under government policy guidelines, as currently maintained. [1] [5]

On the other hand, in the regulatory context, the Ministry of Health and Social Protection (Minsalud) is the body that coordinates everything related to Public Health and the Social Security System of the Colombian population, and among its functions is to define the requirements that IPS must meet to be qualified and accredited for the provision of health service to patients. The same body classifies Health Care Providers into 4 groups: (a) Entities with a social purpose other than the provision of services; (b) Health Care Institutions (IPS); (c) independent health professionals; and (d) special patient transport services. [6]

It should be noted that this research focuses only on Health Service Providers (IPS) in Colombia, and that within the IPS group are all those facilities that provide hospital and/or outpatient services; specialized hospitals and clinics and comprehensive services; institutions providing complementary pre hospital care, diagnostic imaging centres and clinical laboratories; and new models of home care and tele-medicine [7]. The classification of IPS and its regulatory context are described below.

2.2 Classification of ips

In Colombia, according to their mode of administration and regulation, IPS are divided into two types: private and public. According to data provided by the Ministry of Health and Social Protection of Colombia through the most recent annual report on the ratio of public and private IPS to the level of care and installed capacity, on January 2, 2019 Colombia had 10,385 registered IPS, of which 4,592 (44%) are public, while 5,729 (55%) are private and 64 Mixed (1%). [8]

In addition to their mode of administration and regulation, IPS can be classified or grouped across five criteria. According to:

a) The type of administration described in Law 10 of 10 January 1990;
b) The degree of complexity of the services provided, as described in Decree 1760 of 2 August 1990;
c) The level of complexity of services, interventions and procedures, described in Resolution No. 5261 of 1994;
d) The level of complexity of the surgical groups offered, described in Resolution 5261 of 1994;
e) The type of service provided, described in Resolution 1043 of 2006 and Decree 1011 of 3 April of the same year, adjusted by Resolution 1441 of 6 May 2013.

2.3 State of the art in Hospital Maintenance Management

Research on the state of the art showed that this area is still booming for researchers in the biomedical and maintenance sector, as no predominant methodology or model was identified that could be followed by hospital institutions to ensure the long-term effective results in ensuring the quality and reliability of their most critical physical assets. However, the main ideas and research found in the main available scientific databases are presented below.

2.3.1 Global context

In Moreno's study on the optimization of the maintenance of hospital equipment in a military medical center, again exposes the common denominator in this context, the lack of importance with which hospital maintenance is assimilated, poor preventive planning and heavy reliance on maintenance after failure [9]. In the particular case, Moreno argues that a more rigorous control of all maintenance activity is required through actions and management techniques oriented towards the management of the life cycle of physical assetsRegarding the impact of hospital

maintenance, Santos analyzed the organization and management of maintenance from the point of view of risks for patients. Argues that hospital maintenance is a means of preventing biological, physical and chemical risks associated with hospital equipment [10]

Nahdatul Arm argue that the fact that hospitals operate 24/7 implies that no trial-error strategies can be applied in hospital maintenance, since a failure of an equipment or facility can cost a human life. Also the same authors try to analyze in their research on the perception of maintenance management strategy in medical centers, whether there is a correlation between the maintenance strategies implemented and end-user satisfaction with the service. [11]

From the position of Marian indicates how it was possible to implement an integrated quality risk management system based on the requirements of the ISO 9000 and ISO 31000 series, but considering expressly the provisions of public procurement legislation and compliance with internal control in public sector organisations, emphasising that their research is a doctoral thesis, which derives recommendations to increase the performance of the public procurement process by implementing an integrated quality risk management system. [12]

Sanjurjo proposes a Process Maturity Model for BizDevOps: MMBDO, based on international standards relevant to the IT sector, allowing achieving significant progress in management aspects, such as the evaluation of practices and processes involved in the area, the above doctoral thesis brings to research an effective approach to the interaction between development and operational functions under information technology (IT), which allow to establish a breakthrough in management systems, specifically on the tools that can be applied in the development of the hybrid methodology. [13]

In view of the above, it is necessary to mention from the position of Hlebni-kovs and Kovamees that argues as the management problem of the coordination of shift maintenance within a continuous flow process industry, the above contributes to the research as a way to solve the maintenance challenges associated with the service provided in the industry, allowing to apply it to the environment of the area of biomedical health and maintenance, covering efficient maintenance as management reduction in all stages associated with shift change, because service in this area should never be continuous, as long as people's health problems are always addressed [14]. Panizzi considers the development of an im-pact model in the improvement of the quality of the deployments of the software systems of its SMEs (small and medium-sized enterprises) due to the fact that the above is a contribution of a doctoral thesis that allows to guide the improvement in the quality of the integrated management systems that are handled in the IPS either manual or systematized by platform or digital documentation [15]. Likewise, Borges, Dos Santos, and Zequeira emphasize that, for the models, standards and methodologies more managed given the practicality that results to evaluate and improve the management of software projects, which reveals a process that can be adapted by the biomedical maintenance area in the IPS if they decide to carry out a development in a software to improve the use of the instruments normally used by these [16].

2.3.2 National context

As can be seen from the background research, Colombia has not been the exception in terms of research on hospital maintenance. However, few studies and investigations have as a central theme to analyze models of management of hospital maintenance.

It is clear that, in the national and international context, hospital maintenance is presented as a great challenge to cope with by hospital administrators, especially when taking into account factors of biomedical equipment such as criticality, lifetime, complexity, acquisition and maintenance costs, sophistication and high technology. Without ignoring the consequences of poor management, such as the cost of not using medical equipment.

2.4 Diagnosis of hospital maintenance management in study cases

In the development of research for the design of the PMBOK-RCM hybrid methodology for the maintenance management of critical biomedical equipment in medium complexity Health Service Providers (IPS) of Cúcuta, The following IPS of medium complexity will be taken as study cases (see Table 1 for details):

Tabla 1. IPS analizadas en el caso de estudio

IPS	Descripción Misional	Tipos de equipos biomédicos
IPS 1	It is an institution providing health services of medium complexity that contributes to the care of the North American population, through enabled services (emergency, hospitalization, imaging, transfusion service, surgery and pharmaceutical service) qualified personnel and technologies in health; ensuring the provision of humanized, timely, effective and quality care to the patient and his environment.	X-ray equipment, vital signs monitors, mechanical fan, tensiometer, analog scale, digital abalance, microscope, anaesthesia machines, phonendoscopes, centrifuges, mazzini agitators, electrobisturi, cielitic and pielitic lamps, flow meters, vacuometers, glucometers, digital thermometers, nebulizers, suction, defibrillator
IPS 2	It is an IPS of Specialized Services of High Complexity in Critical Care of Adults, Hemodynamics and Diagnostic Imaging with	Angiograph, Defibrillator, Electrocardiograph, Organ Equipment, Fonendoscope, Bayer Injector, Laryngoscope, Anaesthesia

IPS	Descripción Misional	Tipos de equipos biomédicos
	suitable human talent, supplies and advanced medical technology, providing human care, and safe to all our patients.	Machine, Pacemaker, Vital Signs Monitor, Secretion Aspirator, Sphygmomanometer, Vacuum Meter, Analog Scale, Swan Neck Lamp, Fluid Heater, Fluid Mixer, Vaporizer, Glycometer, Thermohydrometer, Ultrasound, Electric Bed, Steam Autoclave, Air Compressor, Oil Free Compressor, Hydro Washer, Incubator, Sealant, Sterrad Sterilizer.
IPS 3	It is an institution providing health services of medium complexity that contributes to the care of the North American population, through enabled services (emergency, hospitalization, imaging, transfusion service, surgery and pharmaceutical service) qualified personnel and technologies in health; ensuring the provision of humanized, timely, effective and quality care to the patient and his environment.	X-ray equipment, vital signs monitors, mechanical fan, tensiometer, analog scale, digital abalance, microscope, anaesthesia machines, phonendoscopes, centrifuges, mazzini agitators, electrobisturi, cielitic and pielitic lamps, flow meters, vacuometers, glucometers, digital thermometers, nebulizers, suction, defibrillator
IPS 4	It is an institution providing health services of medium complexity that contributes to the care of the North American population, through enabled services (emergency, hospitalization, imaging, transfusion service, surgery)	X-ray equipment, vital signs monitors, mechanical fan, tensiometer, analog scale, digital abalance, microscope, anaesthesia machines, phonendoscopes, centrifuges, mazzini agitators, electrobisturi, cielitic and pielitic lamps, flow meters, vacuometers, glucometers, digital thermometers, nebulizers, suction, defibrillator

Fuente: Own elaboration

2.5 Variables

Considering the context presented in the previous paragraphs and taking into account the questions raised in the identification of the problem, each of the variables studied in this research is defined and conceptualized, and which will serve to verify or refute the research hypotheses raised.

2.5.1 Dependent variable

The main objective of the research is to design a hybrid methodology between the RCM and the PMBOK for the maintenance management of critical biomedical equipment in medium-complexity Health Service Providers (IPS) of Cúcuta; Therefore, it is necessary to be able to measure maintenance management from the administrative and operational perspective that characterizes it.

Effectiveness of Maintenance Management: it is considered the level of performance of the different administrative and operational areas of hospital maintenance in IPS of medium complexity. This variable is measurable through a quantitative percentage scale whose range is defined between 0 and 100.

2.5.2 Independent variable

Table 2 defines each of the independent variables that were studied to determine the level of effectiveness of maintenance management in IPS of medium complexity. These variables are determined after carrying out the activities of phase 1 of the research. In addition, criteria of reliability, criticality and asset management obtained from international standards and bibliographic references were considered, which allow to raise the basic principles by which each independent variable is composed and with which the compliance with the objectives set in the maintenance management of the IPS of medium complexity is measured. The basic principles that compose and quantify each of the independent variables are described below.

Table 2. Independent variables and basic principles to be evaluated in research

Independent areas/variables	Description	Basic principles
1. Organization of the company	It measures the level of business management and its influence on the maintenance department.	1.1. Mission and vision
		1.2. Roles and responsabilities
		1.3. Authority and autonomy
		1.4. Information system
		2.1. Context of the organization

Independent areas/variables	Description	Basic principles
2. Organization of the maintenance department	It measures the level of administrative management of the maintenance department based on asset management criteria.	2.2. Support from senior management
		2.3. Policies and objectives
		2.4. Roles and responsabilities
		2.5. Authority and autonomy
		2.6. Information system
		2.7. Leadership
3. Methodology of maintenance management	It measures the level of efficiency of the maintenance department's operational tasks.	3.1. Goals and targets
		3.2. Planning policies
		3.3. Operation
		3.4. Monitoring and evaluation of performance
		3.5. Continous improvement
4. Asset reliability	It measures the level of reliability of physical assets to maintain based on RCM principles.	4.1. Risk analysis, criticality and asset ranking
		4.2. Functionalities of the assets
		4.3. Functional failures of the assets
		4.4. Modes of failure of assets
		4.5. Effects of asset failure
		4.6. Consequences of asset failure
		4.7. Fault management policies
		4.8. Scheduled tasks
5. Maintenance personnel	It measures the level of human resources management involved in the maintenance department.	5.1. Quantification of the staffing requirements
		5.2. Selection and training
		5.3. Motivation and incentives
		5.4. Skills and performance
6. Maintenance costs	It measures the level of efficiency in the management of the economic resources involved in maintenance.	6.1. Budget
		6.2. Cost records
		6.3. Cost analysis
		6.4. Control and monitoring of costs
7. Logistica	It measures the level of efficiency in the operational logistics of the maintenance department.	7.1. Administrative support
		7.2. Management support
		7.3. General support
		7.4. Outsourcing
8. Resources	Measures the level of operational management of physical resources used for maintenance.	8.1. Equipment
		8.2. tools
		8.3. Instruments
		8.4. Materials and spare parts
9. Proactive Maintenance (Preventive and Predictive)	Measures the level of effectiveness in managing proactive maintenance tasks.	9.1. Planning
		9.2. Programming and implementation
		9.3. Monitoring and evaluation
10. Maintenance in the absence of (Breakdown and corrective)	Measures the level of effectiveness in managing maintenance tasks in the absence of.	10.1. Attention to failures
		10.2. Planning
		10.3. Programming and implementation
		10.4. Monitoring and evaluation
11. Operational maintenance (routine)	Measures the level of effectiveness in the management of operational maintenance tasks.	11.1. Planning
		11.2. Programming and implementation
		11.3. Monitoring and evaluation

Fuente: Own elaboration

2.6 Instruments for measuring and analysing research

2.6.1 Initial and final diagnosis of maintenance management in the study sample

It began with the qualitative characterization of the context of hospital maintenance at the national and international level, proceeded to analyze the main needs and background through a self-diagnostic survey of the population sample, in order to determine the main areas of influence on the effectiveness of maintenance management that allow defining study variables.

It is important to highlight as a diagnostic method the effectiveness of the maintenance management of biomedical equipment in IPS of medium complexity of Cúcuta. The instruments proposed were designed under the parameters

and principles of Covenin 2500 (1993) [17], SAE JA1011 (1999) [18], ISO 55001 (2014) [19], ISO 31000 (2018) [20], ISO 14224 (2016) [21], and criteria postulated in theoretical benchmarks. The instrument was developed in an Excel spreadsheet, in which each of the independent variables categorized as evaluated areas are structured, as well as the basic principles and demerits (merits) audited in the interview/survey.

The principle of calculation of the instruments proposed above is for the Covenin regulation each of eleven areas that make up it, the regulation proposes score or value to obtain which is interpreted incrementally, each area has subareas which also have a score or attainable value, according to this the following equations 1,2, and 3 apply:

$$\%Cumpliance\ (sub\ area) = \frac{Value\ obtained\ item}{Value\ attainable\ item} * 100\% \quad (1)$$

$$\%Full\ compliance(Area) = \frac{\sum Value\ obtained\ item}{Value\ attainable\ \ sub\ area} * 100\% \quad (2)$$

$$Total\ Area = \frac{(\frac{\sum Value\ obtained\ sub\ area}{Number\ of\ sub\ areas})}{Value\ attainable\ area} * 100\% \quad (3)$$

Likewise, for the SAE JA 1011 regulation was divided into 17 areas which, like the previous norm, also has sub-areas, but this regulation is rated from two options which are oriented to the application of the requirement already a Yes or No applying the same formulations as above. Finally, in ISO 55001, the same calculation principle was applied as in Convenin 2500.

Based on the above, through the data presented in equation 4, The level of effectiveness of Egm maintenance management can be established in a percentage score that fluctuates depending on the basic principles evaluated by each independent variable, and specifically for the present study, Egm takes five possible values:

- Excellence: grades between 90-100%. It allows us to infer that maintenance management has the highest effectiveness at administrative and operational level.
- Very good: ratings between 80-89%. It can be inferred that maintenance management is very effective, but there is still a small gap to improve at the administrative and operational level.
- Good: grades between 60-79%. It suggests that maintenance management is more effective than the acceptable average, and that considerable improvements are needed at the administrative and operational levels.
- Acceptable: scores between 40-59%. It can be inferred that there is an administrative and operational maintenance organization, but the basic principles of asset management, reliability and PHVA cycle (Plan, Do, Validate, Act) are unknown.
- Poor: grades between 0-39%. It allows us to infer that there is no maintenance management at the administrative and operational level, which is below average, and that a very wide gap to improve.

In each case, the score is defined as:

$$E_{gm} = \sum_{i=1}^{n}\sum_{j=1}^{n}\sum_{z=1}^{n}\left[\left(\frac{A_i - PD_{ijz}}{A_i}\right) * 100\right] \quad (4)$$

Where: Ai represents the maximum score of each area/variable i

PDijz represents the score obtained for each area i in the diagnosis according to the sum of the merits z of each basic principle j

2.6.2 Diagnosis of compliance with the hybrid RCM-PMBOK methology

The proposed instrument meets all the requirements to be met by an IPS when applying the hybrid RCM-PMBOK methodology, is a very useful tool to achieve compliance with the methodology, therefore, the instrument in figure 28 is proposed, that qualifies compliance with the scale from 1 to 0, where 1 is full compliance from 0.9 to 0.1 is when the IPS succeeds in partially complying with the requirement but lacks some elements to obtain full compliance and 0 to 0.09 is when the IPS does not meet or have any compliance with the requirement to evaluate.

For the measurement of this instrument the following calculations are established to determine the percentage of compliance, as shown in the following equations 5.6, and 7:

$$\%Cumpliance\ (Activities) = \frac{Value\ obtaine\ \ act}{attainable\ value} * 100\% \quad (5)$$

$$\%Full\ compliance\ (STAGE) = \frac{\sum value\ obtaine\ \ act}{stage\ value\ obtained} * 100\% \quad (6)$$

$$Full\ compliance = \frac{\sum stage\ value\ obtained}{total\ achievable\ value\ methodology} * 100\% \quad (7)$$

3 RESULTS

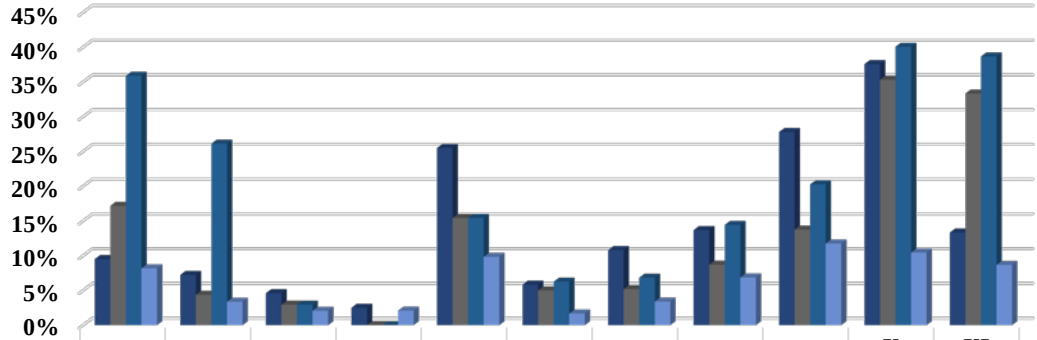
3.1 Results of the initial diagnosis of maintenance management in the study sample prior to the implementation of the Methodology

Therefore, the diagnostic instruments were applied to the IPS of medium complexity in the case of osmari studies, it is important to mention that the initial diagnosis was applied in 2019, where the following results were obtained, as seen in Figure 1.

According to Figure 1, it was possible to analyze the IPS case studies evaluated with the initial diagnostic instruments of the Covenin 2500 standards [17], SAE JA 1011 [18] and ISO 55001 [19], it can be concluded that according to the level of effectiveness of the maintenance management Egm exposed above, all the IPS are at the level of deficient where the values of the ratings are between 0% to 39%, which determines that in the IPS there is no maintenance management at administrative and operational level, which denotes a great need to strengthen and implement a maintenance management system under reliability.

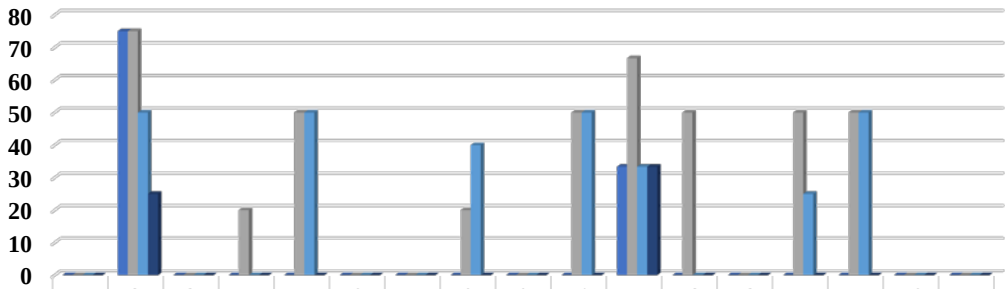
Finally, the initial diagnosis provided a real vision of how the IPS were in terms of robust maintenance management that can anticipate failures and provide excellent medical service from the biomedical equipment that make up each these. It is also clear that these IPS must apply some methodology that manages to guide and remedy all the gaps and breaches of the evaluated regulations.

COMPARATIVE INITIAL DIAGNOSIS COVENIN 2500

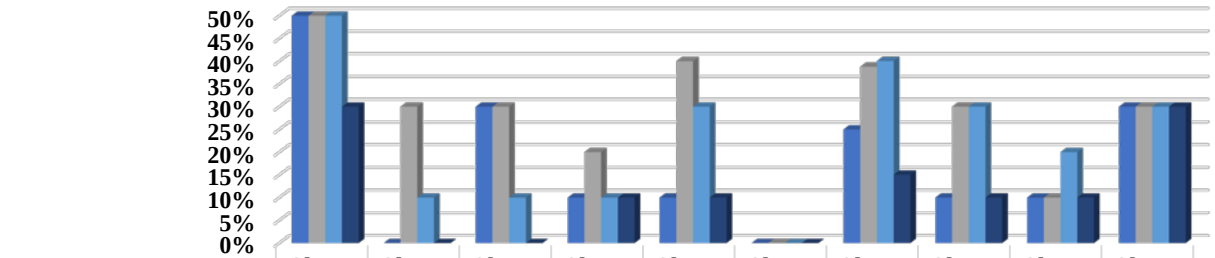


	I ORGANIZATION OF THE COMPANY	II MAINTENENCE ORGANIZATION	III MAINTENANCE PLANNING	IV ROUTINE MAINTENANCE	V SCHEDULED MAINTENANCE	VI CORRECTIVE MAINTENANCE	VII PREVENTIVE MAINTENANCE	VIII BREAKDOWN MAINTENANCE	IX MAINTENANCE PERSONNEL	X LOGISTICAL SUPPORT	XI RESOURCES
% Total obtained IPS 1	10%	7%	5%	3%	26%	6%	11%	14%	28%	38%	13%
% Total obtained IPS 2	17%	4%	3%	0%	15%	5%	5%	9%	14%	35%	33%
% Total obtained IPS 3	36%	26%	3%	0%	15%	6%	7%	14%	20%	40%	39%
% Total obtained IPS 4	8%	3%	2%	2%	10%	2%	3%	7%	12%	10%	9%

INITIAL DIAGNOSTIC COMPARISON SAE JA 1011



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
% Total obtained IPS 1	0	75	0	0	0	0	0	0	0	0	33,33	0	0	0	0	0	0
% Total obtained IPS 2	0	75	0	20	50	0	0	20	0	50	66,67	50	0	50	50	0	0
% Total obtained IPS 3	0	50	0	0	50	0	0	40	0	50	33,33	0	0	25	50	0	0
% Total obtained IPS 4	0	25	0	0	0	0	0	0	0	0	33,33	0	0	0	0	0	0



	Clause 1	Clause 2	Clause 3	Clause 4	Clause 5	Clause 6	Clause 7	Clause 8	Clause 9	Clause 10
% Total obtained IPS 1	50%	0%	30%	10%	10%	0%	25%	10%	10%	30%
% Total obtained IPS 2	50%	30%	30%	20%	40%	0%	39%	30%	10%	30%
% Total obtained IPS 3	50%	10%	10%	10%	30%	0%	40%	30%	20%	30%
% Total obtained IPS 4	30%	0%	0%	10%	10%	0%	15%	10%	10%	30%

Figure 1. Bar diagram of the comparison between the standards of the initial diagnosis results.

3.2 *Hybrid methodoly RCM-PMBOK*

The hybrid methodology RCM-PMBOK consists of five main stages where they focus on the main aspects that are to get the IPS present a quality service from the perspective of the operation of biomedical equipment and also strengthen management systems maintenance from the project structure perspective.

The hybrid methodology is shaped by the life cycle proposed in the five stages is adaptive since the project management components are defined as the stages and activities develop, given the changing and complex nature of the operational context of the biomedical assets of the IPS, Likewise, in Figure 2 gathers in a flowchart all the proposed hybrid methodology, which exposes the five stages with their respective activities, which direct the development of the methodology in a more practical way.

Figure 2 shows in detail what activities are of the RCM methodology, which are PMBOK and which are complementary to both, it is important to note that this hybrid RCM-methodologyPMBOK is adapted to the nature of medium complexity IPS in conjunction with biomedical maintenance management, in addition to the work observed in the field, consisting of five stages which are synthesized as follows:

- Organizational stage: this stage consists of seven activities where the first is a hybridization between RCM-PMBOK and the others are guided by the PMBOK methodology, this stage brings together all the main activities to start the project, each activity breaks down sectionally each step to follow, as the staff or work team to be formed to constitute the beginning of the methodology, it is important to note that this stage does not require any contract-type expert personnel or external advice from IPS to carry out this, it is recommended that the work team be composed of IPS staff because their daily experience is vital for the development of the rest of the methodology.
- Stage of planning, analysis and execution of the RCM: in this stage emphasis is placed on 9 activities which, two are oriented by PMBOK, five are instructed by the RCM and two are hybridizations between RCM-PMBOK, this stage is very relevant because this stage performs all the analysis of the RCM regarding biomedical equipment handled in an IPS, at this stage it is recommended in case of doubts about the results obtained in the application of the instruments and steps established at the stage, to consult an expert in RCM and maintenance management to validate the determined.
- Phase of identification, programming and implementation of maintenance protocols: in this phase nine activities are marked, where one activity is guided by the PMBOK and the others are directed by RCM, At this stage, the mechanisms to be implemented regarding maintenance management directed by the results determined in the RCM are established, at this stage it is recommended if you have doubts to do what was mentioned at the previous stage.
- Phase of implementation and closure of maintenance tasks: this activity consists of three activities, of which one is directed by the PMBOK and the others are instructed by the RCM, this stage already implements the established maintenance tasks and applies biomedical maintenance indicators, this stage does not need expert contract personnel or external advice from the IPS to carry out this, because the members of the work team have the ideal profile to carry out these activities.

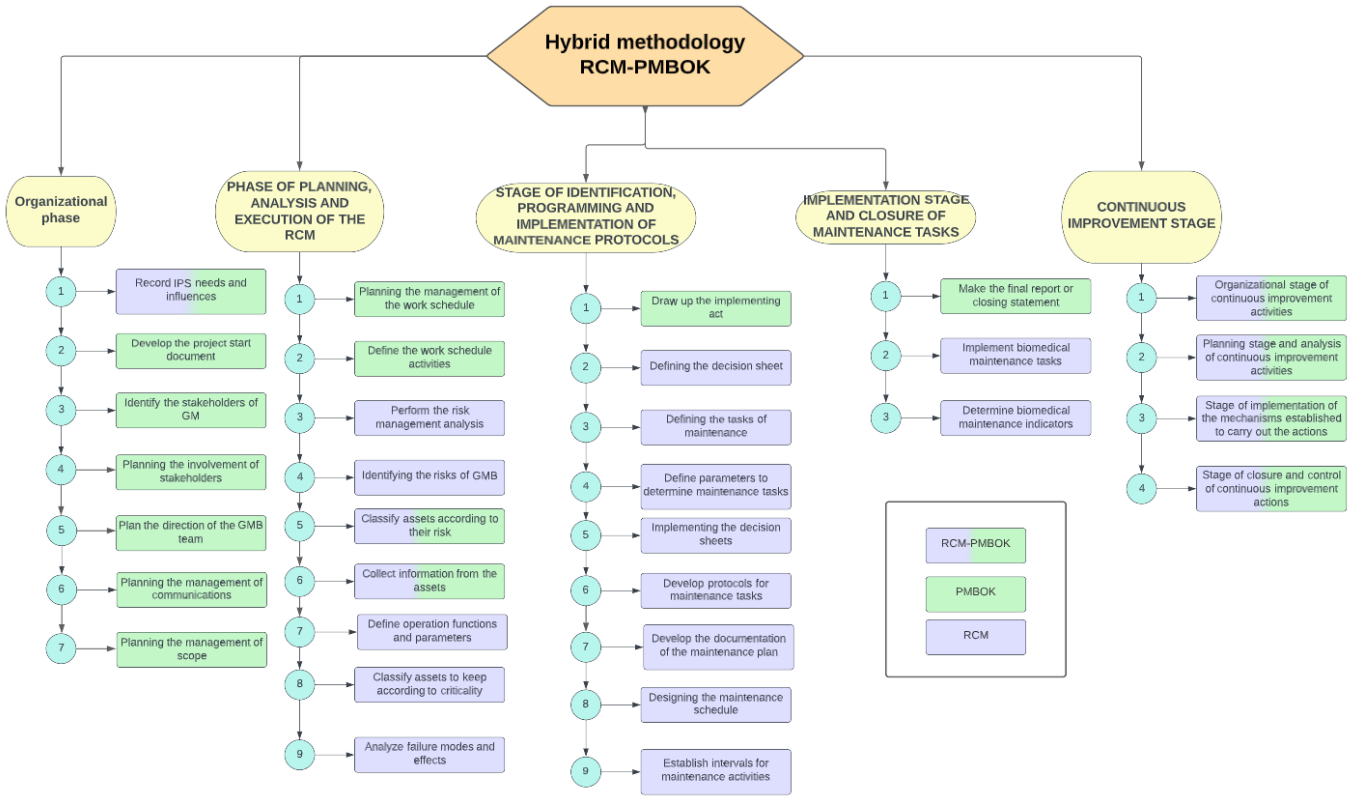


Figure 2. RCM-PMBOK Hybrid Methodology Flow Chart for Maintenance Management

- Continuous improvement stage: In the case that the IPS has already implemented the hybrid methodology for the maintenance management of critical biomedical equipment, it is recommended to apply the following methodology based on the continuous improvement of projects, which focuses on four stages guided by the PMBOK methodology, this consists of the following stages and activities that guide the IPS when the methodology is already implemented and also strengthen the established maintenance management system. The methodology for continuous process improvement is described in detail below and shown in the flow diagram in Figure 3:
    a) starting stage: this level frames the development of a starting document that can gather all the corrective actions listed from the implementation of the hybrid methodology, therefore, the persons involved should be established, equipment, objectives and scope of this project.
    b) Planning stage: a schedule of activities is made according to the list of corrective actions obtained, The Commission must establish times in which it intends to carry out the activities proposed to mitigate or eliminate the non-conformities that caused these corrective actions.
    c) Implementation and control stage: at this level, the established corrective actions should be analyzed, which is recommended to review the historical ones of the previous corrective actions and whether the actions implemented were efficient for their mitigation or elimination, for this it is suggested to follow the following activities:
        - Make requests for corrective actions by following the format proposed in the investigation
        - Carry out the analysis of the causes of these corrective actions
        - Define the plans or action plan to be followed for the implementation of activities resulting from the analysis of causes
        - Implementing the activities proposed in the action plan
        - Closing of established corrective actions

Subsequently, monitoring and control mechanisms should be applied, with the aim of achieving the validation of compliance with the deadlines established in the schedule of activities and also, evaluate the efficiency of the activities or actions carried out to close such corrective actions, for this purpose the compliance of the management indicators must be verified and its relevance in the system analyzed.

    d) The closing stage: at this stage, a closing document should be drawn up, setting out the objectives and scope achieved, the persons involved in the team, the results obtained and conclusions, and proposing the next step to be followed and lessons learned.

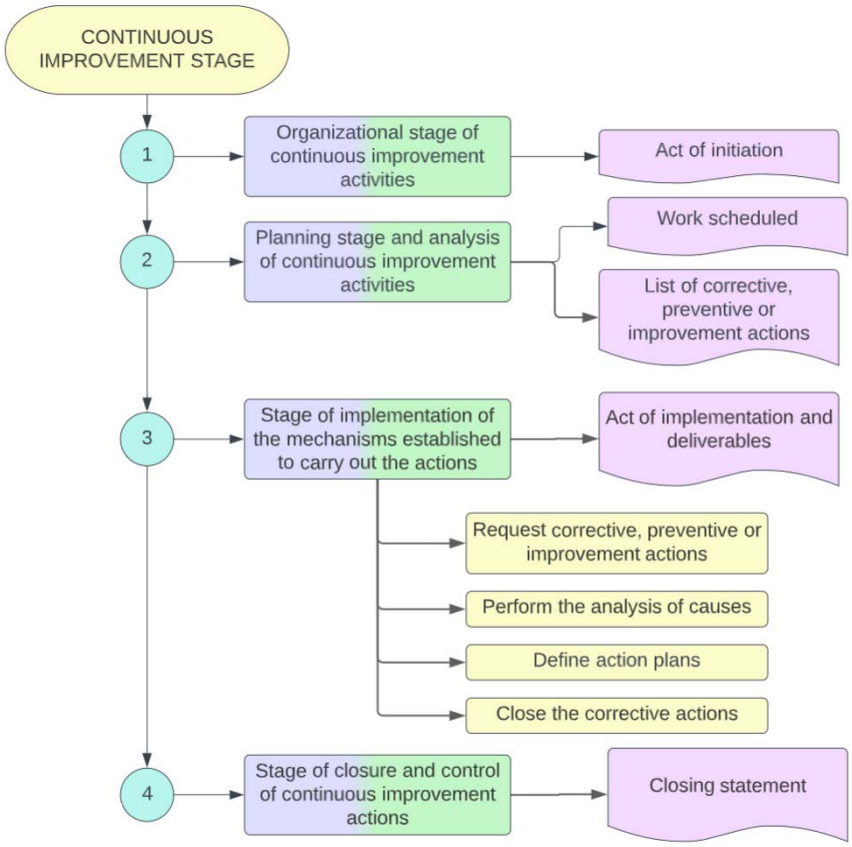


Figure 3. Flow chart of the continuous improvement methodology

3.3 Results of the diagnosis of compliance with the RCM-PMBOK hybrid methodology

The results of the diagnosis applied to the IPS study cases for compliance with the hybridization methodology RCM-PMBOK, shown in Figure 4 below, the results obtained from the application of the summary table of ratings obtained from the application of the compliance instrument for each IPS being IPS 1, IPS 2, IPS 3 and IPS 4.

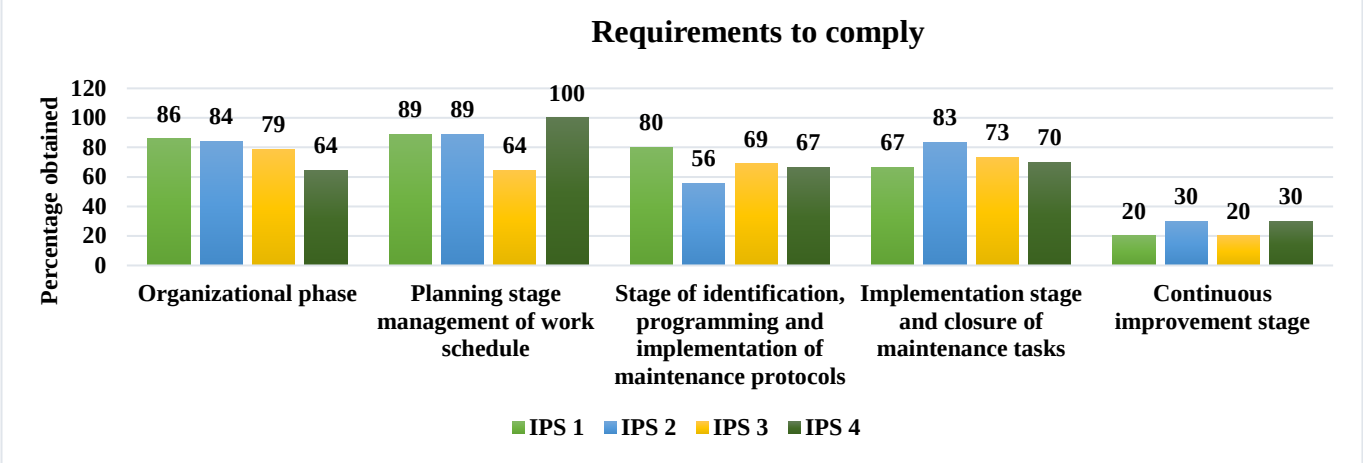


Figure 4. Bar diagram of the results of the diagnosis of compliance with the RCM-PMBOK Hybrid Methodology according to its percentage obtained per stage

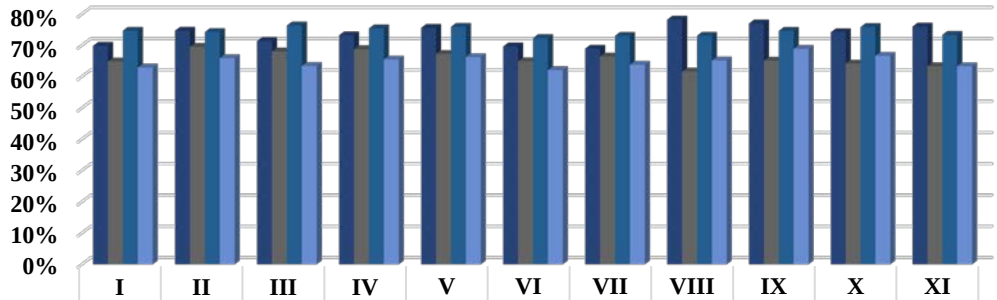
According to the figure presented above, it is possible to show the total average obtained from compliance that among the 4 IPS evaluated there is 70% of compliance to date, it is important to stress that the current state of the IPS is good when it comes to the application of the hybrid methodology because it behaves like a cyclical management system that must be kept under continuous improvement to always maintain and improve the result, this philosophy is the one that seeks the hybrid methodology to be applied in order to provide a quality service.

3.4 Results of the final diagnosis of maintenance management in the study sample prior to the implementation of the Methodology

In the final diagnosis, the instruments created under the parameters and principles of the Covenin 2500 standards [17], SAE JA 1011 [18] and ISO 55001 [19] were again applied to the four IPS case studies in October 2022, in order to observe and analyze the impact of the implementation of the hybrid RCM-PMBOK methodology in the biomedical

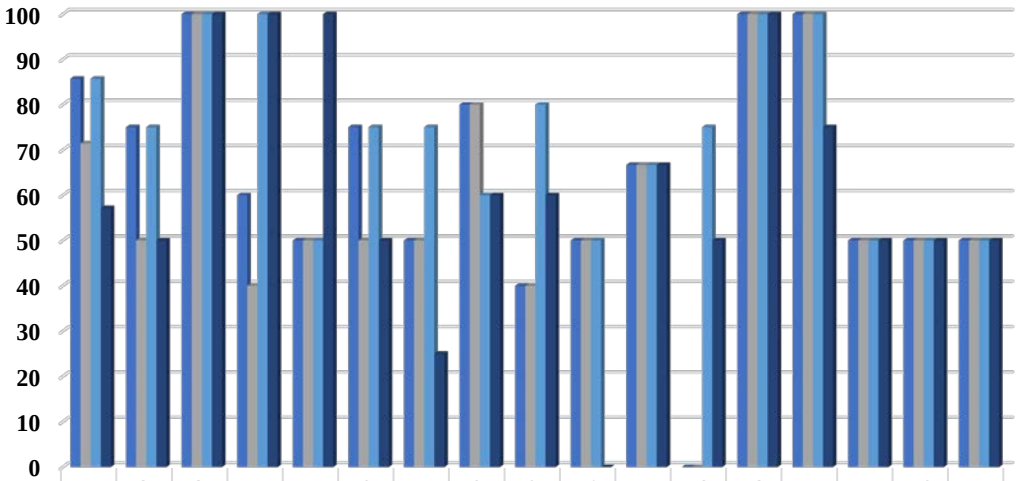
maintenance area of these IPS. Figure 5 shows the comparisons between the IPS and the regulations evaluated, with the aim of analysing them more easily in each area.

COMPARATIVE FINAL DIAGNOSIS COVENIN 2500

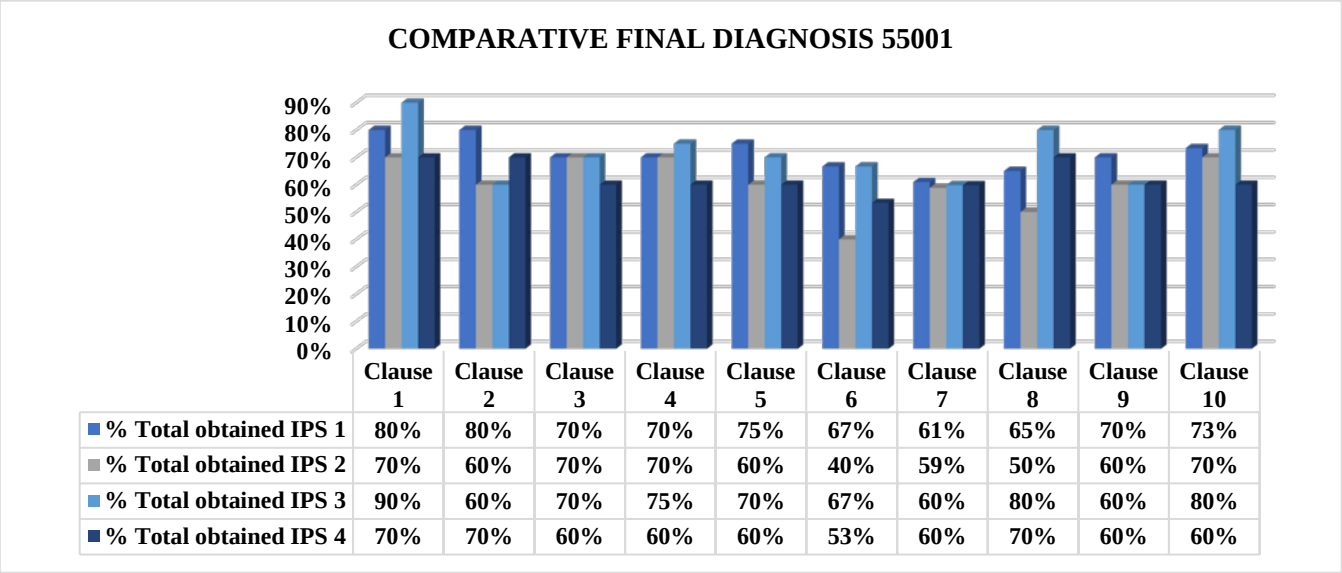


	I ORGANIZATION OF THE COMPANY	II MAINTENENCE ORGANIZATION	III MAINTENANCE PLANNING	IV ROUTINE MAINTENANCE	V SCHEDULED MAINTENANCE	VI CORRECTIVE MAINTENANCE	VII PREVENTIVE MAINTENANCE	VIII BREAKDOWN MAINTENANCE	IX MAINTENANCE PERSONNEL	X LOGISTICAL SUPPORT	XI RESOURCES
% Total obtained IPS 1	70%	75%	71%	73%	76%	70%	69%	78%	77%	74%	76%
% Total obtained IPS 2	65%	70%	68%	69%	67%	65%	66%	62%	65%	64%	63%
% Total obtained IPS 3	75%	74%	76%	75%	76%	72%	73%	73%	75%	76%	73%
% Total obtained IPS 4	63%	66%	63%	65%	66%	62%	64%	65%	69%	67%	63%

FINAL DIAGNOSTIC COMPARISON SAE JA 1011



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
% Total obtained IPS 1	86	75	100	60	50	75	50	80	40	50	67	0	100	100	50	50	50
% Total obtained IPS 2	71	50	100	40	50	50	50	80	40	50	67	0	100	100	50	50	50
% Total obtained IPS 3	86	75	100	100	50	75	75	60	80	50	67	75	100	100	50	50	50
% Total obtained IPS 4	57	50	100	100	100	50	25	60	60	0	67	50	100	75	50	50	50



	Clause 1	Clause 2	Clause 3	Clause 4	Clause 5	Clause 6	Clause 7	Clause 8	Clause 9	Clause 10
% Total obtained IPS 1	80%	80%	70%	70%	75%	67%	61%	65%	70%	73%
% Total obtained IPS 2	70%	60%	70%	70%	60%	40%	59%	50%	60%	70%
% Total obtained IPS 3	90%	60%	70%	75%	70%	67%	60%	80%	60%	80%
% Total obtained IPS 4	70%	70%	60%	60%	60%	53%	60%	70%	60%	60%

Figure 5. Bar diagram of the comparison between the standards of the initial diagnosis results

Based on the above, it was possible to analyze the IPS case studies evaluated with the initial diagnostic instruments of the Covenin 2500 standards [17], SAE JA 1011 [18] and ISO 55001 [19], it can be concluded that according to the level of effectiveness of the maintenance management Egm exposed above, all the IPS are at the level of good because ratings on average are between 60-79% where it means IPS are above the acceptable average, but it becomes necessary to strengthen the administrative and operational level in the maintenance management system under reliability, because the system is always under continuous improvement where the observations and non-conformities given from the application of the instruments are corrected, where these are covered by the continuous improvement methodology and achieve compliance with the maintenance management system under the control of the indicators that are included in the integrated management system that IPS has.

Finally, the initial diagnosis provided a real vision of how the IPS were in terms of robust maintenance management that can anticipate failures and achieve an excellent medical service from the biomedical equipment that make up each these. It is also clear that these IPS must apply some methodology that manages to guide and remedy all the gaps and breaches of the evaluated regulations.

4 CONCLUSION

Analyzing the results obtained in the initial diagnosis in the IPS case study in order to verify its real state with maintenance management, it was determined that according to the levels of effectiveness of the maintenance management are at the level of deficient it is important to emphasize that it is essential to create and implement the hybrid methodology so that it succeeds in remedying and strengthening all breaches of the regulations denoted in the initial diagnosis applied.

In line with the above, the main knowledge used in the structuring of the hybrid RCM-PMBOK methodology was presented, which consists of five stages which allow any IPS to implement it in its management system, because its main focus is to offer all the elements necessary to strengthen its health service and achieve quality in this, because biomedical equipment are the main pillars of the human resource for the provision of health service.

In order to conclude the above results, we were able to highlight the improvement that the IPS had at the time of the application of the first diagnosis compared to the final diagnosis, because it was possible to go from a deficient level to an acceptable level, it is clear that even these IPS need to strengthen their biomedical maintenance management system through the hybrid RCM-PMBOK methodology, because any management system is always in continuous improvement for this the proposed methodology is applied in continuous improvement, because it is necessary to obtain over time more records and documentation that may yield information, to be able to analyze and with this achieve decisions and improve the system, because it is always a cyclical process that will be strengthening, giving a vital contribution in the area of biomedical maintenance which does not manage any kind of methodology to remedy a maintenance management system.

The results obtained from the application of the proposed instrument for the evaluation of the hybrid methodology achieved the compliance of 70% of the requirements or activities established, this means that the IPS case studies still need to apply the methodology for at least one year to obtain results in terms of management indicators, internal audits and analysis of the applied records, to make adjustments according to what was found and to be able to achieve compliance with the methodology at least 90%, to provide a quality service ahead of the failures of the equipment in service.

Finally, it is noteworthy that the medium complexity IPS of the city of Cúcuta, at the level of integrated management systems they must be in legal operation must have implemented the regulations NTC-IS0 9001:2015 Quality

management systems [22], NTC- ISO 45001:2018 Occupational Safety and Health Management System [23] and NTC- ISO 14001 Environmental Management Systems [24], these standards encompass the main requirements that a company must meet according to its methods, personnel and equipment from the vision of safe handling. The above gives rise to explain that the IPS mostly do not have a maintenance management system integrated to their management systems, they sometimes use some formats or instruments to collect information about the maintenance of biomedical equipment, but do not have in their master system this documentation connected to a management system, this is because these IPS do not have sufficient economic resources to buy a software specialized in maintenance management or GMAO, for these reasons, they hire a biomedical engineer who will take care of this department and hand in hand with the quality management system to create and implement mechanisms to handle some maintenance management system requirements, for all of the above, it is concluded that according to the economic capacity of the IPS can implement the proposed methodology with all the exposed instruments or can buy a GMAO software that facilitates maintenance management, but it is important to mention that when implementing the methodology, the proposed instruments and documents must be integrated with the other management systems applied in the IPS in order to bring all the regulations and documents as a whole into a control and monitoring system, to assess compliance and continuous improvement.

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