Diagnosis for integration of quality and innovation management systems in a biomaterials research center

Integración de los sistemas de gestión de la calidad y la innovación en un centro de investigación en biomateriales

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***Abstract*—Quality management and innovation are priority issues in research facilities that close the cycle from research to products delivery for its social use. The objective of this work is to diagnose the conditions for the implementation of the Integrated Quality and Innovation Management System in the Biomaterials Center of the University of Havana, based on the standards: NC-ISO 9001:2015; NC-ISO 13485:2018 and NC 1307:2019. To do this, the stages to manage the change were established, and a diagnostic tool based on the integration of the mentioned standards was designed and applied. As a result, it was identified the need to strengthen the aspects related to: the strategies for achieving the vision, the management of ideas, the execution of projects by product, the transfer of results, the monitoring and measurement of the management of research, development and innovation activities and their results. In addition, the existing documents in the Center's management system must be modified in order to detail the implementation and monitoring of innovation activities. The integrated management, of the regulatory requirements for biomaterials, and the quality and innovation management, constitutes an organizational innovation that will facilitate the development of innovative products for the National Health System, contributing to the achievement of the organization's vision and the fulfillment of strategic objectives.**

***Index Terms*— biomaterials; innovation; integrated management system, quality; research facilities.**

***Resumen*— La gestión de la calidad y la innovación son temas prioritarios en las instituciones que cierran el ciclo desde la investigación hasta la entrega de productos para su uso social. El objetivo de este trabajo es diagnosticar las condiciones para la implantación de un Sistema Integrado de Gestión de Calidad e Innovación en el Centro de Biomateriales de la Universidad de La Habana, basado en las normas: NC-ISO 9001:2015; NC-ISO 13485:2018 y NC 1307:2019. Para ello, se establecieron las etapas para gestionar el cambio, se diseñó y aplicó un instrumento de diagnóstico basado en las normas objeto de integración. Como resultado, se identificó la necesidad de fortalecer los aspectos relacionados con: las estrategias para el logro de la visión, la gestión de ideas, la ejecución de los proyectos por producto, la transferencia de los resultados, el seguimiento y medición de la gestión de las actividades de investigación, desarrollo e innovación y sus resultados. Además, se deberán modificar los documentos existentes en el sistema de gestión del Centro con vistas a detallar la realización y el seguimiento a las actividades de innovación. El manejo integrado de los requisitos regulatorios de los biomateriales, de gestión de la calidad y la innovación constituye una innovación organizacional que facilitará el desarrollo de productos innovadores para el Sistema Nacional de Salud, contribuyendo al logro de la visión de la organización y al cumplimiento de sus objetivos estratégicos.**

***Palabras claves*— biomateriales, calidad, innovación, instalaciones para la investigación, sistema integrado de gestión.**

I. INTRODUCTION

THE international practice has shown that innovation is essential for the development of a country, and companies and other institutions of society need to be in constant transformation, through radical or incremental innovations, to maintain their competitiveness and achieve sustainable success. This is possible if there is a willingness to innovate, incentives to stimulate it, and an appropriate culture to drive it [1].

In Cuba, innovation processes are promoted from State policies to comply with the National Plan for Economic and Social Development (NPESD) until 2030, aligned with the Sustainable Development Goals (SDG) of the 2030 Agenda [2]. While the SDG are comprehensive in nature and innovation impacts all of them, SDG 9 “Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation” makes a direct reference to this activity.

The guidelines to change and the transformation process of Higher Education in Cuba, aligned with the NPESD, are aimed at strengthening the contributions of universities to the National Science, Technology and Innovation System. In this way, the dissemination and application of the scientific research results

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and the introduction of new management and administration methods aim at making universities an important engine of development [3] and, within them, their research centers. In this context, the improvement of the science and innovation management process is a highly relevant and topical research problem in Cuban universities, with a view to achieve superior performances [4], for which the proven quality improvement methodologies are very useful.

It is widely recognized that standards help in making research and development results easier to reach the market [5]. In addition, they provide good practice and guidance for all types of organizations trying to systematically manage innovation [6]. Specifically, management system standards are aimed at reducing risks to achieve organizational success and sustainability. Research, Development and Innovation (R&D&I) activities are also subjected to the risk management, since during the development of the project the state of the art and other factors of the context can be modified and, therefore, generate unforeseen consequences, that alter its planned execution. To manage these risks and achieve success in planned innovations, R&D&I management system standards are very useful.

Among the innovation management models internationally recognized, is the R&D&I management system [7], updated in 2014 in the UNE 166002:2014 standard [8]. The standards of the UNE 166000 series were adopted and used in several countries and served as the basis for the preparation of the European normative documents of the CEN/TS 16555 series. Based on the Spanish and European experiences, the Technical Committee ISO/TC 279 of the International Organization for Standardization (ISO) is working on the standards series ISO 56000 for innovation management [9], [10].

Until June 2021, ISO/TC 279 has published five normative documents:

- ISO 56000:2020 Innovation management. Fundamentals and vocabulary.
- ISO 56002:2019 Innovation Management. Innovation management system. Guidance.
- ISO 56003:2019 Innovation management. Tools and methods for the innovation partnership. Guidance.
- ISO/TR 56004:2019 Innovation Management Assessment. Guidance.
- ISO 56005:2020 Innovation management. Tools and methods for intellectual property management. Guidance.

Other normative documents in preparation are:

- ISO/AWI 56001 Innovation management. Innovation management system. Requirements.
- ISO/FDIS 56006 Innovation management. Tools and methods for strategic intelligence management. Guidance.
- ISO/AWI 56007 Innovation management. Tools and methods for idea management. Guidance.
- ISO/AWI 56008 Innovation management. Tools and methods for innovation operation measurements. Guidance.
- ISO/DTS 56010 Innovation management. Illustrative examples of ISO 56000.

In addition, ISO/TC 279 works on two documents to facilitate the understanding of the vocabulary that is used in the ISO 56000 family of standards and the implementation of innovation management systems (IMS) in organizations. These documents are:

- Handbook: Innovation Management. A systemic approach to deploy an innovation management system in your organization.
- ISO/TS Innovation management. Layman's Guide to Innovation.

The Handbook is intended to guide organizations starting out in these processes on how to implement an IMS based on international best practices. It follows the structure and content of the ISO 56002 standard, giving guidelines for its application. On the other hand, the Layman's Guide to Innovation will provide descriptions, explanations and examples related to the terms and definitions used in the ISO 56000 standards.

In accordance with international trends, the Cuban Technical Committee for Standardization NC/CTN 128 Innovation Management [6] has been established, and in its first works it has approved the standards:

- NC 1306:2019 R&D&I management: Terminology and definitions of R&D&I activities. (Adoption of the UNE 166000: 2006 standard) [11].
- NC 1307:2019 R&D&I management: R&D&I system requirements. (Adoption of the UNE 166002: 2014 standard) [12].
- NC 1308:2019 R&D&I Management: Monitoring and intelligence system. (Adoption of the UNE 166006: 2018 standard) [13].
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Until the approval of these standards, many Cuban organizations had used the Spanish R&D&I management system standards, in the absence of a national document. The process of analysis and identical adoption of the Spanish standards as Cuban standards responds to the interest of having a certifiable IMS standard, since the published international standard, ISO 56002, is a guidance for IMS, without the certification purpose.

Innovation management is the part of the general management system of the organization in charge of developing, implementing, carrying out, reviewing and updating the organization R&D&I policy, establishing the R&D&I objectives and the necessary processes to fulfill them, the identification of the necessary organizational structure and the planning of activities, responsibilities, practices, procedures and the human, material and financial resources required, their adequate execution, evaluation and improvement.

It is important that the innovation activities management is integrated in a coherent way with the rest of the existing systems in organizations. It is recognized that the integrated management of systems generates multiple benefits to organizations, such as: improvement in decision-making, reduction of the risk of redundancies and conflicts between activities, and greater efficiency from better use of resources to

improve the satisfaction of all the interested parties [14], [15]. In this sense, not only technological innovations are of vital importance, but also organizational innovations in processes and forms of management.

Integrated management systems arise from the implementation of two or more management standards and were originated when the organizations perceived the convenience of integrating quality management systems, ISO 9001, with environmental management standard, which saw the light for the first time in the British standard BS 7750:92 and subsequently in the European Eco-Management and Audit Scheme (EMAS), published in 1993 and put into effect in 1995. The publication of the first ISO standard for environmental management ISO 14001 in 1996 consolidated the trend towards systems integration, a process to which occupational health and safety standards (OHSAS 18001 and ISO 45001) and other standardized management systems were also incorporated. The publication by ISO in 2012 of Annex SL has contributed to facilitate the management systems integration process for both implementation and audits [16].

The integration of systems is not a spontaneous process, instead due to its complexity it must be adequately planned and managed as a profound process of change in the organization, which requires modifying the organizational culture, and the way of thinking and acting of workers and managers [17], [18]. Everyone must understand the needs and expectations of all relevant stakeholders and the necessity to respond to them in a balanced way, without affecting their satisfaction when making managerial decisions. The logic of integration starts from the assumption that the processes constitute the basis of the management system and that all its requirements are reflected in them. That is why, for the success of the integration, the barriers between the functions must be eliminated and the process approach must be incorporated as the basic structure, which enables the fulfillment of the integrated system objectives, with its multiple inputs, outputs and interrelations [16].

Although there is no simple or unambiguous relationship between innovation and quality management, the negative or positive influence that quality management has on innovation depends on the way in which quality is approached, from a control perspective or based on organizational learning. Several authors [19] - [22] have evidenced the synergies between quality and innovation and others [23], [24] have discussed the integration between ISO 9001 quality management systems and innovation management systems.

Although there has been works on the quality management of the science and innovation processes at the universities [4], [25], in the literature consulted, there are few studies that jointly analyze quality management and innovation at the universities and, specifically, in their research centers [26] - [28], neither experiences in integrated quality and innovation management systems in university research centers have been documented. On the other hand, there are no previous studies regarding the integration of the quality management system for medical devices for regulatory purposes with R&D&I management.

The Biomaterials research facility (BIOMAT) of the University of Havana has a more than 30 years of research history, development and innovation for the health sector [27], [29], [30], and has gone through several stages in its innovative path, in order to achieve safe and effective medical products. For this, BIOMAT has a certified quality management system since 1991, which has passed through the different applicable standards, up to the current NC-ISO 9001:2015 [31]. In addition, to comply with existing regulations in the medical device sector [32], the Center has implemented the NC-ISO 13485:2018 standard [33].

Despite the results achieved, with several products (Tisuacryl®, Apafill-G® and Biograft-G ®) introduced in the services of Dentistry and Maxillofacial Surgery in the country, BIOMAT needs to enhance the innovation management to achieve greater impacts of its science results. To contribute to this goal, the international and national standards referring to innovation management systems in companies and other organizations are very useful. Based on these considerations, the objective of this work is to diagnose the conditions for the implementation of the Quality and Innovation Integrated Management System (QIIMS) in the Biomaterials Center of the University of Havana, based on the standards: NC-ISO 9001:2015; NC-ISO 13485:2018 and NC 1307:2019.

In the first part, the Biomaterials Center is characterized; later the methodology for the implementation of the QIIMS is presented. Then the common requirements and the particularities of the three systems that are the object of the integration are established, from which an instrument is designed and the diagnosis is made as the basis of the action plan to be executed for the success of the integration.

II. CHARACTERIZATION OF THE BIOMATERIALS CENTER

The creation of the Biomaterials Center originates from the Department of Chemistry-Physics of the Faculty of Chemistry in 1984, when a group of researchers focused on the study of materials to be used in medicine and dentistry. With the development of this topic and initial funding granted by the State Council, the Laboratory of Synthetic Materials was created in 1990, in its initial phase as part of the Faculty of Chemistry, and later approved as a Research Unit-Development of the University of Havana by the Academy of Sciences of Cuba. In 1994 it received its current name, more appropriate to the mission of the Center and in 2005 the Ministry of Science, Technology and Environment awarded BIOMAT the category of Research Center [34].

The investigative activity ranges from the search for solutions to the theoretical problems in Biomaterial Sciences, to obtaining marketable products, through applied research and development. Biomaterials comprise any natural, synthetic or modified natural material that is in contact and interacts with a biological medium, forming a medical device that treats, augments and/or replaces any tissue or function of the body, by itself or in a set formed by various elements [32]. Research areas include: biomaterials for tissue replacement, restoration and regeneration and tissue engineering, controlled release systems for bioactive agents, materials for diagnosis,

purification and immobilization of biomolecules.

BIOMAT staff has competence in the development of biomaterials and in conducting their chemical and physical evaluation. The Center's staff has 46 employees, of which 25 are researchers, five are graduates in training and eight are technicians. Eleven researchers are PhDs in chemical, physical or technical sciences, four are working towards PhDs, five are Masters of Science, and four are in these studies. In addition, relationships have been established with clinical and hospital institutions in Havana, and other provinces of the country, which collaborate in the preclinical and clinical evaluation of the developed products.

So far, the innovation strategy at BIOMAT focuses on the realization of small productions, which have managed to satisfy the demands of the Ministry of Public Health, as the main client. However, at the current stage this strategy has faced limitations in material and financial resources to achieve the planned objectives [30].

Until 2019, the following products had been produced and marketed: Tisuacryl® (Tissue Adhesive), Apafill-G® (hydroxyapatite granules for bone filling) and Biograft-G® (dense β-tricalcium phosphate granules for bone filling). In different stages of development, but with projects halted due to lack of funding are: Multilatex® (Polystyrene latex, base for diagnostic reagents); Bonacryl® (acrylic bone cement); Obtudent-FC® (light-cured dental sealant) and Cubridem-FC® (light-cured dental sealant).

The years 2020 and 2021 have been characterized by the suspension of face-to-face activities due to COVID-19 and the prioritization of the country's resources towards medical care, action protocols for confronting the pandemic and the development of vaccines and lung ventilators to do it. This situation has slow down the research, development and manufacture of the Center's products, which are not related to the therapeutic schemes associated to COVID-19. However, based on the massive vaccination of the population, which should culminate in the third quarter of 2021, it is expected to resume activities in the country, for which BIOMAT requires new R&D&I strategies and to strengthen the management of the innovation.

Currently, the BIOMAT Management System integrates the requirements of the NC-ISO 9001:2015 standard and the elements of the Strategic Planning and Internal Control of the University of Havana. It also includes the regulatory aspects established in the field of medical equipment according to the NC-ISO 13485:2018 standard, elements of the NC-ISO 14001:2015 Environmental Management Systems and NC-ISO 45001:2018 Occupational Health and Safety Systems.

R&D&I is governed by the legislation in force in the country for the research projects development and applies the elements of the relevant standards to the design and development of products, even when these aspects are only applied to projects by products, conceptualized as technological innovation projects for the design and development of products, biomaterials and other processed materials, with a view to their production and marketing [35].

BIOMAT managers have identified the processes that influence the satisfaction of internal and external stakeholders and have determined the sequence and interaction between these processes. They are:

- Strategic processes: Strategic and Operational Management; Management of Material and Financial Resources; Management of Human Resources; Performance Evaluation and Improvement.
- Key processes: Undergraduate and Postgraduate Teaching; Research and Product Development; Transfer of Research Results.
- Support processes: Computerization; Material Assurance

Two of the key processes (Research and Product Development and Transfer of Research Results) are responsible for managing and executing R&D&I activities.

The Management Manual [32] describes the process structure, the scope of the Management System and makes reference to the System Procedures (PS) and the Standard Operating Procedures (SOP), which constitute the basic documented information for the implementation. of the processes and the performance of the control activities, based on the commitment of the Management, which is reflected in the Policy and the Objectives of the Center. In addition, the documented information includes: Technical Instructions; Product Master Files, Master Records for production activities; Product specifications (raw materials, intermediate products, final products and other inputs for production); Records; and other documents necessary to maintain and evidence the operation of the Management System.

III. METHODOLOGY FOR THE IMPLEMENTATION OF THE QIIMS

There is an extensive literature on systems integration studies conducted in different organizations. Also, specifications, guides and other normative documents have been developed to assist organizations in the process of integrating their management systems. Among these documents are the publicly available British Specification BS PAS 99:2012 and the Spanish standard UNE 66177:2005. Both documents are based on the Deming cycle PDCA (Plan, Do, Check and Act), however they have different approaches. The UNE 66177:2005 refers to the application of the PDCA cycle to the management systems integration process, while the PAS 99:2012 specification combines it with the common requirements to obtain the structural diagram of the integrated management system [16]. Both PAS 99 and UNE 66177 can be used by organizations when addressing the process of management systems integration, since two aspects must be taken into account:

- The instrument to harmonize the common and specific requirements of the standards to be integrated.
- A methodology to manage the change process.

The integration process must be approached with a defined methodology, which allows facing each stage in a planned manner and taking into account the results of the previous stages, starting from precisely knowing the initial situation and the goals you want to reach. That is why a four-stage management systems integration methodology is established:

Stage I Context analysis
- Analysis of regulations, applicable standards and the needs of the organization.
- Definition of the scope and level of integration.
- Diagnosis of the initial situation.

Stage II Planning
- Planning of the integration process: schedule, resources and people in charge.
- Definition of the necessary documentation for the integrated management of the systems.

Stage III Implementation
- Development and implementation of the system: execution of scheduled activities, monitoring and control of possible deviations.
- Training and dissemination. Activities to be carried out at different times of the project in order to publicize the integrated system and communicate the modifications that it entails in the usual work procedures.

Stage IV Maintenance and improvement
- Audit, review and improvement of the integrated system.
- Management system certification (if applicable).

In this work Stage I of this methodology is approached. In the introduction made and in the characterization of the Biomaterials Center, the first two aspects of this stage were addressed, giving way to the initial diagnosis, as the starting point of the required change process.

IV. Diagnosis for the Implementation of the QIIMS

To carry out the diagnosis, the identification of the common and specific requirements of the standards NC-ISO 9001:2015, NC-ISO 13485:2018 and NC 1307:2019 was the point of departure.

Table I reflects the standards requirements, taking as a starting point the generic standard NC-ISO 9001 and making reference to the sections numbered by one and two digits, except for the items that require greater specificity because they are more developed in some of the standards. This is the case of NC-ISO 9001 requirement 7.1.6 Knowledge of the organization, which is more widely deployed in NC 1307, including essential aspects for the management of R & D & I such as:

- 7.7 Intellectual and industrial property and knowledge management.
- 7.8 Collaboration.
- 7.9 Technological surveillance and competitive intelligence.
- 8.2 Idea management.

Although NC-ISO 9001:2015 and NC 1307:2019 standards maintain the high-level structure implemented in the ISO Directives of 2012, the NC-ISO 13485:2018 follows the structure of the previous standard NC-ISO 9001:2008 to facilitate its alignment with regulatory requirements, appropriate for quality management systems in organizations involved in one or more stages of the medical devices life cycle.

NC-ISO 13485:2018 does not have the strategic focus of the other two standards to be integrated, but is aimed at demonstrating the organization's ability to provide medical devices and related services that consistently meet customer requirements and applicable regulations. In addition, it is focused less on business performance and improvement and more on managing the risks of medical devices.

TABLE I
REQUIREMENTS OF THE STANDARDS OBJECT OF INTEGRATION

		NC-ISO 9001:2015	NC-ISO 13485:2018	NC 1307:2019
4		Context of the organization.	4	4; 7.9
	4.4	Management system and its processes	4.1	4.3
5		Leadership	5.1-5.5;	5; 7.1
6		Planning	5.4; 8.5.4	6
7		Support	6	7
	7.1	Resources	6	7.2
	7.1.6	Organization knowledge	6.2	7.7;7.8;7.9;8.2
	7.2	Competence	6.2	7.3
	7.3	Awareness	6.2	7.4
	7.4	Communication	5.5.3	7.5
	7.5	Documented information	4.2	7.6
8		Operation	7	
	8.1	Planning and operational control	7.1	8.5
	8.2	Requirements for products and services	7.2	8.5
	8.3	Design and development of products and services	7.3	8
	8.4	Control of externally supplied processes, products and services	7.4; 4.1.5	7.2
	8.5	Production and service provision	7.5	8.5
	8.6	Release of products and services	7.4.3; 8.2.6	
	8.7	Control of non-conforming outputs	8.3	
9		Performance evaluation	8	9
	9.1	Monitoring, measurement, analysis and evaluation	8.1; 8.2; 8.4	9.1; 8.6
	9.2	Internal audit	5.7	9.2
	9.3	Management review	5.6	9.3
10		Improvement	8.5	10
	10.2	Non-conformity and corrective action	8.3; 8.5.2	10
	10.3	Continuous improvement	8.5	10

With the details of each of the requirements to be considered, a checklist with 63 items was created as a tool to carry out the initial diagnosis. Based on PAS 99:2012 the requirements of the integrated management system included in the list are divided according the PDCA cycle: Plan – 29 items; Do – 23 items; Check – 7 items, and Act – 4 items.

The checklist was answered in a group activity by consensus of all the members of the Board of Directors (7) and the Scientific Council of the Biomaterials Center (5) of the Biomaterials Center, under the coordination and advice of the authors of this work. For each item on the list, three response levels were established: fully implemented, partially implemented, and not implemented, and observations illustrating how the requirements were met, were done. In this way were identifies which items are meet within the framework of the system already implemented in BIOMAT and the existing shortages, fundamentally to strengthen R&D&I

management.

The vision of the Center by 2023 is: to be leaders in Cuba in the research and development of biomaterials, achieving their introduction in social practice and the creation of exportable products with high added value, as well as in the training of specialists in the science of biomaterials [34].

The research carried out in BIOMAT is channeled through the projects approved in the National Programs of Basic Sciences and Nanotechnology and in collaborative projects with foreign institutions. The scientific results obtained gave rise to publications, as well as the accomplishment of academic and scientific degrees. However, in recent years the innovative capacity of the Center has been diminished due to the lack of its own resources, derived from the commercialization of its products or due to budget allocations for Science and Innovation. These causes, together with the deterioration of the Center's infrastructure and the lack of incentives for innovation, has led researchers to focus their efforts mainly to research and publication of their results, aspects that are fundamental in the development of their professional careers.

It should be noted that in the medical products sector, including biomaterials, there are multiple challenges to innovation derived from the regulations established to protect society from products that may create a risk to patients due to their form of action or because they are not effective for the required treatment [36]. Hence the difficulties to innovate in biomaterials and the need for large resources to close the cycle from research to the use of the products [37].

Every day new technologies are generated in the field of materials for medical use, and disruptive innovations come mainly from the field of biotechnology and nanotechnology, with the introduction of third-generation biomaterials and the tissue engineering. All this development requires infrastructure, resources and high-level scientific specialists in line with these trends. In Cuba, with an important development in biotechnology, the strengthening of alliances with this sector would result in greater contributions to science that the staff of BIOMAT is capable of making, but that does not find an adequate productive outlet at this time.

The NC 1307:2019 standard raises the need to carry out an analysis of the internal and external context, as well as the selection of R&D&I ideas to be developed in the project portfolio, considering risk factors, among other aspects. The PS 08 Design and development strategy approved in BIOMAT establishes the activities required for the design and products development, following quality management standards, including planning, review, verification, validation, transfer of design and development and changes in the products, as well as the responsibilities and authorities for these activities. However, projects by products existing have been halted due to lack of financing and new ones have not been generated to incorporate the research results into new products.

The considerations made are consistent with the results of a previous study [27] in which a survey was carried out with BIOMAT managers and workers to find out their perceptions about how the categories knowledge management (KM) and innovation management are manifested (IM), starting from their incorporation in the current practices of quality management (QM). According to the results obtained, KM activities are perceived with a higher degree of accomplishment in the Center than those related to QM and IM, with 60% - 80% of the respondents in total agreement on the following aspects:

The organization has effective training programs for new workers (KM).

Participation in knowledge networks (KM).

The search for updated and relevant information is carried out (KM).

The causes of quality system non-conformities are used as a source of knowledge (KM).

The knowledge of the people of experience in the organization is transmitted (KM).

The organization has the documented information necessary for the development of its activities (QM).

Organizational workers support innovative ideas (IM).

The managers of the organization promote the development of creativity and innovation (IM).

Although several authors [38] have found a positive relationship between QM and performance, as well as between KM and innovation, which in turn impacts the performance of organizations, in the results of the survey applied in BIOMAT, no significant relationships were found between the studied attributes of QM, KM and IM and the organizational performance evaluated by the results in new products, improved processes and customer satisfaction. The lack of resources for research and incentives at the individual level to achieve innovative results can be factors that interfere the analyzed relationships and make them not perceived by the members of the organization.

When planning the QIIMS, the organization must take into account internal and external analysis, the needs, expectations and interested parties requirements, as well as the integrated policy of the organization, and must determine the risks and opportunities that need to be addressed in order to: ensure that the QIIMS achieves its intended results; prevent or reduce unwanted effects and achieve continuous improvement. Likewise, the organization must plan actions to deal with these risks and opportunities, integrate and implement them in the system processes, as well as evaluate the effectiveness of said actions.

BIOMAT carries out comprehensive risk management, including the risks related to R&D&I [39]. However, when analyzing the risks that affect innovation, only the lack of financing for projects by products is identified, without delving into other aspects that could affect the performance of the Center in innovation processes, such as the risks related with:

loss of highly trained personnel;

technological surveillance and competitive intelligence

management of intangible assets and intellectual property;

selection of collaborators and forms of collaboration;

internal collaboration;

forms of commercial exploitation of the results.

Although the research activities are part of the current BIOMAT management system, not all of them are within the scope of certification by the NC-ISO 9001:2015 standard, so to

implement the QIIMS, the R&D&I activities that should be further developed in the integrated system, were identified. They are:

- Idea management.
- Development of projects by products.
- Protection of results.
- Transfer of results.
- Market studies.
- Monitoring and measurement of R&D&I management and its results.

Although R&D&I activities are carried out in the current management system, they must be strengthened to achieve better performance in innovation. For each element of the vision, the current strategies should be reviewed and the pertinent actions strengthened. In addition, the general documents of the System should be reviewed to further incorporate planning, monitoring and improvement of R&D&I activities. Among the documents to review are:

- Management manual.
- Policy and strategic objectives.
- PS 01 Responsibilities, authority, relationships and functions of the personnel.
- PS 02 Control of documented information.
- PS 03 Comprehensive risk management.
- PS 04 Planning and review of the Management System.
- PS 05 Identification of needs and allocation of resources.
- PS 08 Design and development strategy.
- PS 13 Internal audits.
- PS 16 Corrective Actions.

On the other hand, the person in charge of the Research and Product Development process must assess the usefulness and convenience of documenting a specific procedure for knowledge management, technological surveillance and competitive intelligence, to facilitate the strengthening and monitoring of these activities. For this, it is useful to consult the standards:

- NC 1308:2019 R&D&I Management: Monitoring and intelligence system [13].
- ISO 30401:2018 Knowledge management systems. Requirements [40].

The implementation of QIIMS in the Biomaterials Center will be an organizational innovation that will facilitate the development of innovative products for the National Health System, based on the competencies of the researchers and the use of recognized management tools. It shall contribute to the achievement of the Vision of the organization and the fulfillment of the strategic objectives planned by the Center Management.

V. CONCLUSION

The integration of management systems brings benefits to organizations, but due to its complexity, this change process must be adequately planned and carried out. As a methodology for the change, four stages are proposed in this work: context analysis; planning of the integration process; implementation; maintenance and improvement. The diagnosis made for the integration of quality and innovation management systems in the Biomaterials Center of the University of Havana, based on the standards: NC-ISO 9001:2015; NC-ISO 13485:2018 and NC 1307:2019, allowed to identify the changes needed in the existing system. To do this, a diagnostic instrument based on the integration of the mentioned standards was designed and applied. As a result, it was identified the need to strengthen the aspects related to: the strategies for achieving the vision, the management of ideas, the execution of projects by product, the transfer of results, the monitoring and measurement of the management of research, development and innovation activities and their results. In addition, the existing documents in the Center's management system must be modified in order to detail the performance and monitoring of innovation activities.

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