**INTRODUCTION**

The National Control Center for Medical Devices (CCEEM) is the Cuban regulatory authority that guarantee the safety, efficacy and effectiveness in medical devices that are introduced in the National Health System (SNS).

The regulatory activity is exercised by means of a system based in the Regulatory Program of Medical Devices. The tasks for the development of this program began in 1992, with the establishment of The Regulation for the State Evaluation and Registration of Medical Devices like guiding document.

The Regulation, revised and updated according to the national and international practice, now the Regulations for Evaluation and State Control of Medical Devices, incorporate the strategies defined in the health policy of our country and adopt a legislative dimension, in agreement with its own precepts and formulations. It also defines the concepts of state control and evaluation of the medical devices as well as the performance of quality management and surveillance. Based on its contents, this document favors regulatory technical harmonization by applying international regulations and practices to ensure the safety of the medical device for a patient, with minimal risks during the medical practice.

**RESULTS and DISCUSSION**

The regulatory activity of medical devices has evolved through different stages, where changes have occurred both nationally and internationally. In turn, it has accumulated experience on par with the technological development of medical devices, which leads to the need to update the regulation for a greater impact on the national scenario and continue the process of international harmonization.

Having a renewed Regulations for Evaluation and State Control of Medical Devices, we contribute in the evolutionary process of implementation and development of the Regulatory Program, and therefore we face the challenge of:

- Reinforcement of Regulatory Authority’s leadership by the increment of normative and legal base, going deeply into ethic and scientific-technical aspects.
- More sensitivity about the role of the regulatory culture as a determinant issue for security, efficacy, and effectiveness of the medical equipments inside the National Health System.
- Remarkable concordance with the international regulatory harmonization.
- Reinforcement of the quality and security of the equipment and devices in the National Health System.
- Act in accordance with the requirements demanded by the Cuban State to regulatory authority.

Its scope covers the life cycle of technology, processes of selection, hiring, purchase and use of medical devices. Its main objective is to establish requirements to be compliment by medical devices, according to the risk level, security, efficiency and effectiveness. This Regulation is obligatory for all natural or legal person: manufacturers, producers, suppliers, national distributors, users and importers of medical devices, as well as the institutions of the National Health System involved in activities related to assessment and state control of medical devices during its life cycle.

This regulation provides:

- A new action which generates a Sanitary Register Process
- New figures in the Cuban regulatory field of medical devices, and their obligations
- Classification and risk reclassification
- Registration of manufacturer, importer and supplier of medical devices
- A chapter dedicated to medical imaging equipment for diagnosis and therapy
- A chapter on the control of importation and other special permits
- A chapter for Vigilance and Inspection
- A chapter devoted to infractions and sanitary safety measures

**CONCLUSIONS**

The control of medical devices has become a major task for the staff at the CCEEM because of the development of the Cuban industry and following the increase in their importation, while considering the renovation and the increased use of the medical technology at health institutions. In this sense, changes were required in the evaluation and registration processes for medical devices and in the actions for their control and follow-up from the primary healthcare level to the national institutions.

Establishing the Regulatory Program for Medical Devices in Cuba and constantly improving the Regulations for the Evaluation and State Control of Medical Devices are an essential part of the development in the regulatory field, to ensure scientific novelty through the discussions in the international arena on the regulatory situation, scientific development and technological innovation.

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