Electromedical Devices Test Laboratories Accreditation

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Abstract. In the last years, the technology and equipment at hospitals have been increase in a great way as the risks of their implementation. Safety in medical equipment must be considered an important issue to protect patients and their users. For this reason, test and calibrations laboratories must verify the correct performance of this kind of devices under national and international standards. Is an essential mission for laboratories to develop their measurement activities taking into account a quality management system. In this article, we intend to transmit our experience working to achieve an accredited Test Laboratories for medical devices in National technological University.

1. Introduction
Biomedical equipment is used to diagnostic, monitoring and treatment of patients. The interaction between device – patient and sanitarian assistance is expose to many risks. One of them is produced by technology risks, which should be minimized to prevent accidents. As examples of these accidents it can be mentioned:

- Ventricle fibrillation, caused by leak currents of devices.
- Burns, caused by high frequency surgical equipment.
- An increase of corporal temperature caused by an abnormal working of incubations.
- An increase of respiratory vias pressure caused by an abnormal working of ventilators.

As recommendation, all biomedical devices should be examined before the first use and after every repair. The test in biomedical devices has to pass the application of the particular standard of the equipment. There are two kind of test realized by the laboratories:

- Routine test
- Safety test
A- Routine Test

Routine tests are very important in intensive care equipment. These tests are realized under the preventive maintenance of the equipment that includes the security and performance test. In the same way, is very useful in equipment where is necessary to improve the precision through the adjustment or calibration.

It is important to consider, in preventive maintenance, the performance test of the device. This test confirms the efficient working of the device, but is difficult to determinate the acceptance range of the analyzed parameters.

B- Safety Test

These tests are described in national and international biomedical devices standard. All the components, insulations and constructive characteristics are tested. If they don’t work correctly, this can be a reason of security risk. In Argentina, the IRAM 4220-1-1 (equivalent to IEC 60601-1-1) defines all the general security requirement in the patient environment. This standard mentions all the points to be tested or verified.

2. Description

2.1 Biomedical Equipment certification

International organizations and agencies: In different countries exists programs and vigilance systems dedicated to biomedical devices. Even though programs and vigilance systems change according to laws and regulations of every country, all of them have a unique objective, which is the contribution to guarantee the security of patients, minimizing the risks associated with medical equipment. There are agencies and institutions which work in the development of recommendations, regulations and standards for organizations related to health [1]. Some of these international organizations are:

- FDA (Food and Drug Administration)
- AAMI (Association for the Advancement of Medical Instrumentation)
- ANSI ( American National Standard Institute)
- ECRI (Emergency Care Research Institute)

Organizations and agencies in Argentina: In Argentina is extremely necessary to obey the demanded requirements establish by the Administración Nacional de Alimentos, Medicamentos y Tecnología Médica (ANMAT), if we want to certificate a biomedical device. This regulator entity contributes with the protection of human health, checking all the medical products and equipment which can affect it [2].

One of the requirements for products certification in ANMAT is the electrical security test. This test is established by the IEC 60601-1-1 Standard “General requirements of security for biomedical devices”. In addition, is necessary to obey all the particular Standards 60601-1-2 “Electromedical devices: Particular requirements for security”.

All device verifications should be done by laboratories which are authorized by ANMAT.
It is absolutely necessary for the laboratories which evaluate risk on the health field to have a program in order to warranty the quality system specified in ISO / IEC 17025 Standard. This accreditation ensures that the laboratory has the appropriate personal, approve test methods and confidentiality.
2.2 Accreditation of test and calibration laboratories
Accreditation provides the reliance in competence, technical aptitude and capacity of the entities, which participate in the evaluation and certification of products or services. The Argentine Organism of Accreditation (OAA) is an organization deprived without aims of profit, created within the frame of the National System of Norms, Quality and Certification.

2.3 Biomedical laboratories
The LEDIB (Laboratorio de Ensayos de Dispositivos Biomedicos) and the IRB (Instituto Regional de Bioingenieria) are tests laboratories which belong to the Universidad Tecnologica Nacional. They were created in 2004 in order to specialize technician in the security of biomedical devices.

Verification of biomedical equipment must be done according the requirements of security and performance of particular device-specific standards. The implementation of a great number of protection standards demands specialized laboratories which have the serious mission to protect patients and expect to be certificated organisms. For this reason, they must be accredited in order to be recognized their technical competence. To apply their technical competence, laboratories have some analyzers devices, to verify the electrical security and particular standards of each device. These are some standards which are used in laboratories.

- IRAM (Instituto Argentino de Racionalizacion de Materiales)
- ISO (International Organization for Standardization)
- IEC (International Electrotecnical Comition)

2.4 Steps for accreditation
In attention of quality and security, we realized that we have to do a suitable analyse about the performance of equipment. For this reason, we have to work under a qualified management system to ensure confidence of the technical competition through accreditation. To do that, we established some steps we should follow to reach our objectives and demonstrate our technical aptitude.

- QMS Documentation
- Standard Study
- Test and Procedures
- Uncertainty measurement
- Equipment Tracking
- Training
- Quality management system documentations (QMS): The first step is to establish a commitment by the laboratory direction in order to arrive to a satisfactory implementation of a quality system. A quality manual and procedures manual must be written. They describe the manner of working of laboratories with regards the ISO/IEC 17025.

- Standard Study: Some groups were form to study national and international normative which refer to biomedical devices. With this, we could write particular test procedures for each device.

- Test and Procedures: The test procedures are documents which describe the specific sequence of operations and methods to be applied in the laboratory with a specific finally. The procedures describe the unique manner to do every issue.

- Uncertainty measurement: The laboratories have to express the result of every measurement with the expression of uncertainty associated. The uncertainty of measure is a parameter which is associated with the result of measurement and characterizes the dispersion of the result. We can see that the uncertainty indicate how exactly is the measure. To assure the quality of results, some items were established to estimate the uncertainty of measures.

- Equipment Tracking: the calibration of devices and tracking of measures with national patterns are important requirements for the properly function of tests and calibrations laboratories. Control, calibration and maintenance of test equipment make sure correct measures. Finally, all the results must be compared with national and international patterns. The Instituto Nacional de Metrología Industrial (INTI) is the maximum reference of metrology in Argentina. This institute contains the majority of national patterns which are the source of tracking for physics magnitude associated.

- Training: Other important aspect to consider is the continuous capacitation of the personal who integrate the laboratory. The training should be organized through metrology, quality management and technical courses.

- Accreditation Form: the laboratory has to present the accreditation solictude to OAA, with the necessary documentation and establish which procedures want accredited [4].

- Auditory: OAA begins with the accreditation with a formal analyze of documents by an area coordinator. To do this evaluation, a group of specialize auditors is designed. This group is form by an evaluator coordinator and one or more technical experts according the accreditation. This group evaluates the complete documentation of the laboratory by the requirements of IRAM 301 Standard. OAA prepare a report with the items which do not fit the standard recommendation.

- Accreditation certificate: auditors give the laboratory a report with the disagreement and all the points to take into account. The laboratory has to solve all the problems mention in the report.

- Control and continuous evaluation: with all the information, the OAA decides if the accreditation is possible. The period of the accreditation is for 4 years with auditors visits.
3. Results
With the tests made to different biomedical devices we afford to applied procedures of calibration and verification of international and national standards.

| Device              | Number of test | Test type     |
|---------------------|----------------|---------------|
| Ventilator          | 120 Performance | 80 Electrical safety |
| Anaesthesia machine | 68 Performance | 39 Electrical safety |
| Parametric monitor  | 205 Performance | 150 Electrical safety |
| AF surgical machine | 55 Performance | 48 Electrical safety |
| Defibrillator       | 72 Performance | 63 Electrical safety |
| others              | 84 Performance | 52 Electrical safety |

Laboratories have Quality documents, which are actually in use. It was established agreements between test laboratories of universities in order to unify the validation and procedure tests.

4. Conclusion
We must take special care in the quality system and safety offered to patients, this means we should study the performance of the devices under a strict QMS (Quality Management System). Universities are in condition to afford this metrological achievement, with an exceptional human resource and infrastructure to reach the objectives. Work structures and plans under this system have the advantage of making work easily between laboratories and results studies. To achieve our mission, laboratories must dedicate enough time and resources; it must exist a strong decision in this direction.

5. References
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