CUBA

Regulations for the metrological control of measuring instruments in the Republic of Cuba

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Although still considered a developing economy, Cuba is recognized by many countries as being an authority in the medical domain on account of a number of factors:

- Its success with the educational program for training medical, paramedical and electro-medical service personnel;
- The progress made in creating teaching and health-care units;
- The introduction of free national medical and hospital care; and
- The existence of health indicators which are comparable to (and in some cases better than) those of developed countries.

The concept of *medical authority* includes not only the above elements, but also the assurance that both imported and domestic equipment used within the national health system operate in a safe and reliable way.

Medical equipment, many of which are in fact measuring instruments, plays an important role within the national health system since many of the parameters used as supports for clinical diagnosis are obtained as a result of measuring processes. It is not hard to imagine the negative impact of a measurement result intended to be used for a diagnosis or a therapy treatment if the instrument fails to operate correctly. Just by way of example one could mention:

- A lack of accuracy in radiotherapy equipment may lead to harmful radiation emissions or may cause negative effects on a tumor;
- A sphygmomanometer registering unequal figures of maximum and minimum blood pressure values, or showing an error that is outside the maximum permissible values established, has a negative influence on the determination of a patient's blood pressure pattern;
- If the electrical impulse for cardiac muscle stimulation is not properly quantified, an energy value lower or higher than the correct one is likely to be applied, thus paving the way for alterations in the impulse and irreversible damage being done to the patient.

In brief, the essence of safety and reliability in the use of medical equipment lies in the assurance of its correct performance and the accuracy of its measurements, aspects contained within the object of study of the metrological science and, particularly, of the activities related to metrological control.

Each country takes care of the coordinated development of these aspects depending on its own (state or non-state) metrological activity. In this regard, the Cuban government is responsible for ensuring the correct operation of the said metrological infrastructure to protect the population, but the factors that contribute to the design, development, manufacture, import, marketing and ultimate use of measuring instruments - in the present case medical instruments - are also involved.

Cuba's level of development in medical equipment production and the fact that the majority of this equipment is currently imported triggered the decision to create and develop a methodological, organizational and scientific-technical infrastructure which allows the trueness of the technical, metrological and safety-related characteristics stated by the manufacturers to be assessed.

Testing also provides information about:

- The technical level of the equipment according to modern-day technological developments;
- The behavior with regards to external influence quantities;
- The possibility to carry out metrological control of the equipment; and
- The facilities for the maintenance and repair activities, among others.

The main objective is clearly to ensure the highest possible level of product quality and to this end the OIML, with its 107 Members (among which Cuba, one of the founders) attempts to guarantee a proper credibility level concerning test results and thus facilitate international harmonization of regulations and metrological controls applied by national metrology services, promote international cooperation and contribute to the elimination of technical barriers to trade. A significant role is played therein by OIML D 19

Pattern Evaluation and Pattern Approval, adopted by Cuba and discussed in further detail later on.

Decree-Law 183 on Metrology, which came into force in Cuba as of July 2, 1998, contains two chapters directly linked to our object of study:

Chapter VI: On metrological control; and

Chapter VII: On the manufacture, repair and sale of measuring instruments.

Metrological control

Metrological control addresses measuring instruments and methods as well as the conditions under which the results are obtained, expressed and used. Measuring instruments in use or to be used in specified regulatory measurements are subject to metrological control, including:

- Standard instruments used in the verification and calibration of measuring instruments;
- Instruments used in public health;
- Commercial transactions;
- Environmental protection;
- Technical safety;
- Official registers;
- Instruments used in consumer-related activities; and
- Others of public interest.

Only those measuring instruments that have been submitted to metrological control with satisfactory results can be used.

Any measuring instrument submitted to metrological control that fails to meet the regulatory requirements will be declared unfit for use or sale until it does. If the instrument cannot be conditioned to meet the requirements of this Decree-Law, its provisions will be withdrawn or confiscated, as applicable.

The metrological control of measuring instruments is a group of activities comprising:

- Pattern approval;
- Initial and subsequent verification; and
- Supervision of use.

For the moment, pattern approval and supervision of use (metrological supervision) will be dealt with.

Pattern approval

Pattern approval is regulated in Cuba according to the provisions laid down in:

- NC OIML D 19 (1994) *Pattern Evaluation and Approval*, and
- Joint Resolution 1-95 of the Ministry of Economics and Planning and the Ministry of Foreign Trade on *Procedure for Measuring Instrument Pattern Evaluation and Approval*, published in the Official Gazette of the Republic of Cuba, June 28, 1995.

The Normative Document NC OIML D 19 is a general document that contains:

- Introduction;
- Definitions;
- Instruments submitted for pattern approval;
- Procedures for pattern approval;
- Pattern evaluation plan and examination; and
- Pattern approval decision.

The procedure for measuring instrument pattern evaluation and approval is laid down in a separate document with a view to the nationwide implementation of NC OIML D 19, and it contains:

- Evaluation and approval bodies;
- Responsibilities for pattern approval;
- Procedure for pattern approval and evaluation;
- Annex 1: Content of the pattern approval certificate; and
- Annex 2: List of measuring instruments submitted for pattern approval.

In the case of medical science, the list given in Annex 2 includes measuring instruments the legal nature of which refers to measuring the characteristics of human beings and animals, therapy uses, instruments used in chemical, biological and biochemical analyses, identification of biological and chemical substances and species, and definition of contents, concentrations, etc.

This document is mandatory for all state and private entities operating in the country in the development, production, importation, marketing and use of measuring instruments comprised within their scope.

Likewise, it is mandatory for state and private investment entities that import into the country any measuring instruments covered by this procedure. The procedure establishes that:

- Assessment bodies and testing laboratories must meet the requirements laid down in NC ISO 9002 on "Quality management and assurance" and NC ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories".
- The assessment bodies are the laboratories located in entities that belong to the system of the National Bureau of Standards, namely the National Metrology Research Institute and the Territorial Metrology Centers. Other laboratories outside the system of the

National Bureau of Standards may be used provided they meet the above-mentioned requirements.

- The pattern approval body is the National Bureau of Standards, which has put the National Metrology Research Institute in charge of approving, registering and issuing the certificates.
- The approval body can accept pattern approvals issued by any other country(ies) as long as there are bilateral or regional agreements signed to this end. It can also accept pattern approvals emanating from other competent bodies, after a case-by-case discussion with the applicant.
- Measuring instruments imported before both NC OIML D 19 (1994) and the *Procedure for Measuring Instrument Pattern Evaluation and Approval* came into effect, and put into use in places of strategic economic importance or where a very stringent safety level is required, must remain under the metrological control of the National Bureau of Standards, and their importation is prohibited until they are evaluated and approved.

So far the OIML Technical Committee for Medical Instruments (TC 18), together with other TCs, have issued twelve International Recommendations which are very useful for the evaluation of various types of medical measuring instruments, among which electrocardiographs, electroencephalographs, sphygmomanometers, audiometry equipment, dosimeters, ergometers and clinical thermometers.

Metrological supervision

State inspectors carry out metrological supervision on:

- Production, testing, calibration and verification of measuring instruments;
- Proper use and application of measuring instruments;
- Maintenance, reparation or modification of measuring instruments;
- Production, control and sale of prepacked and prepackaged products; and
- Importation of measuring instruments and prepacked and prepackaged products.

Manufacture, repair and sale of measuring instruments

Decree-Law 183 on Metrology establishes, among others, the following provisions:

- Any measuring instrument importer shall provide, as applicable and together with the final user and other relevant parties, the necessary means for the assembling, use, maintenance and repair of the instruments.

It also points out that:

- Any manufacturer, importer, renter, trader or user of measuring instruments of a new pattern shall ensure that they are included in the block diagram of the corresponding hierarchy. Otherwise, they are responsible for guaranteeing their traceability through the National Metrology Research Institute or the Territorial Metrology Centers.

It is important to underline the fact that Chapter X of this Decree-Law includes the means available for dealing with offences.

Decree-Law 271 of the Executive Committee of the Council of Ministers on "Contravention of regulations established on Metrology, January 10, 2001", will come into force in the country ninety days after its publication in the Official Gazette of the Republic of Cuba.

Any offences concerning the above regulations will lead to administrative sanctions being taken, in addition to any civil, legal or other liabilities which may arise.

In the event that any of the above offences are imputable to a physical person, he/she will be partially or totally, temporarily or definitively banned from carrying out the specific activity he/she had been authorized to carry out, as applicable. The incumbent will be personally liable in accordance with the relevant contravention.

Finally, as additional information on the level of performance of Cuban metrological control activity regarding pattern evaluation with a view to approval, it can be stated that the Testing Laboratory of the National Metrology Institute ranks among the entities that have offered this service by assessing various types of medical measuring instruments, such as:

- Line of electrocardiographs;
- System for cardiac rhythm recording and processing;
- Baby scales;
- Dosimeter readers;
- Blood pressure monitor; and
- Bone density measurer. ■