LEGAL METROLOGY INFRASTRUCTURES

Creation of a subsystem for the execution of tests on measuring instruments in the Republic of Cuba

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1 Summary

The importation, production or use of measuring instruments which do not guarantee measurement reliability because they either fail to fulfill the relevant technical and/or metrological requirements or operate in an unsatisfactory manner under environmental conditions, led to the need for an in-depth, objective study of the situation that existed some years ago in Cuba and for efforts to find a solution to achieve a progressive decrease in the negative economic, social and technical consequences that resulted from such a situation.

The conception and gradual realization of the subsystem presented in this paper to help solve these problems have made it possible to implement one essential element to control the production and importation of measuring instruments, and thus positively influence the Cuban economy.

This is a modest example of the implementation of such an important aspect of metrological control, as a part of legal metrology, in a developing country.

2 Introduction and background

Metrology includes measurement theory, units of measurement and their physical realization, the characteristics of measuring instruments, measuring procedures and methods, and the people and organizations involved in implementing measurements [1]. Legal metrology, as a part of applied metrology, deals with the technical obligations and legal requirements necessary to ensure the appropriate guarantees in terms of the safety and precision of measurements in fields such as technical safety, public health, national and international trade and product control [2], among others.

The subsystem presented is a part of the metrological control established in Cuba concerning the development, design, production, importation, marketing and subsequent use of measuring instruments [3]. It summarizes several years of work by the group of specialists who created and put it into practice.

3 Brief summary of the status of measuring equipment in the national context of the past decade

From 1981 to 1988 Cuba invested around 30 million pesos annually in measuring instruments and test equipment - a considerable sum which nevertheless proved insufficient, since the demand was almost twice the quantity of instruments imported. By way of example, retail trade alone needed 85 000 weighing instruments.

Industrial investment projects also had a bearing on the situation, since they included instruments for which sometimes no brand or pattern could be chosen and which had unknown technical and metrological characteristics. This situation tended to worsen because of the continued acquisition of defective measuring instruments; national production of measuring instruments was only just beginning, was still restricted in variety and quantity, and suffered from a high rejection rate. There was no testing of measuring instruments, due to the lack of local information and expertise to create and develop this activity. To sum up, the situation concerning measuring instruments was as follows:

- substantial importation with little attention paid to metrological issues;
- national production based on poor scientific and technical bases and high percentage of unfitness for use; and
- lack of an infrastructure to carry out tests.

As a result, some aspects were generally not taken into account during these actions, namely:

- quality;
- adequacy for the expected use;
- behavior under influence quantities;
- the system used to express the units of measurement; and
- conditions for any repair work and nationwide metrological control.

Because of this, the following events developed:

- importation and production of measuring instruments which failed to meet the requirements;
- misuse of supplies and services made available by exporting enterprises;
- problems in submitting claims based on existing information since the proper scientific-technical character was often lacking;
- difficulties in verifying, calibrating and repairing the instruments; and
- deviations from their planned use.

All of the above led to serious economic problems brought about by potential losses, sometimes real and irreversible, due to the use of instruments which did not guarantee the satisfactory development of a productive process, product or service quality control, or the right execution of a testing or measuring method, along with the resulting impact on production, services and research.

4 Testing and development

Efforts then focussed on executing tests to ascertain whether given instruments could be used for specific purposes under specific conditions, with the following aims:

- ascertain the truthfulness of the technical and metrological characteristics claimed by the manufacturers in order to achieve the required uniformity and accuracy of measurements;
- rationalize the available measuring instruments;
- help guarantee the metrological control of the instruments; and
- ensure the necessary technical level and quality of the instruments manufactured in the country.

To this end, the following development elements were taken into consideration (as described in 4.1 to 4.4):

- methodological-organizational basis;
- technical-material basis;
- normative basis; and
- human potential basis.

4.1 Methodological-organizational basis

As a developing country with no system to carry out state testing of measuring instruments, no well-equipped facilities and no skilled staff (but with a large number of measuring and testing instruments and a large normative and legal basis) Cuba had to approach the problem as a whole, albeit gradually and objectively, considering its real possibilities.

The first priority was to implement those elements that would immediately allow this activity to be started: procedures for the prior-to-purchase analysis and the metrological evaluation of measuring instruments were devised, as well as provisions for state testing of instruments and medical equipment pattern approval. These procedures were gradually implemented as the appropriate conditions materialized.

In the beginning, no attention was paid to legal concerns, hence any improvement of these activities was mainly dependent upon the level of awareness that could be reached with manufacturers and importers alike, through the understanding of the need to carry out the said tests.

As progress was made, the procedures had to be revised more than once to fit them to existing conditions. In the early 1980's prior-to-purchase analyses and metrological evaluations of measuring instruments were started so as to decide whether or not they met the requirements for use and whether or not they could be verified in the country (taking account of the information given in documentation or the results obtained from partial checks made on the instruments).

At national level, after consolidating the concept of "total quality" (amongst others) in the mid 1980's [4, 5], worldwide actions enlarged to embrace effective quality management and assurance in enterprises and other entities, with a view to reaching higher quality levels. International organizations began to draw up a number of documents aimed at assuring quality as one of the major aspects of optimal performance for any activity.

ISO issued a series of standards on *Quality management and quality assurance* [6] and, together with the IEC, the *General requirements for the competence of calibration and testing laboratories* [7]. The OIML issued a series of International Documents on the execution of metrological controls, among which (and of special interest to INIMET) OIML D 19 *Pattern evaluation and pattern approval* [8].

At the same time in Cuba, a reorganization was taking place in which national production had to increase to reduce imports and make potential exports possible. Thus the term *quality* became a must in the face of fierce competition, therefore fostering understanding on the part of national manufacturers about

the role of testing as a contribution to improving product quality.

As an OIML and ISO Member State, Cuba could not be left on the sidelines of such new work, so the early 1990's witnessed the beginning of actions to adopt the above-mentioned international documents.

The adoption of OIML D 19 provides a vantage point to develop work in the field of testing, since:

- it allows for harmonization between countries regarding terms, definitions and organizational issues;
- its general provisions can easily be adjusted to each country's characteristics; and
- it is very flexible by providing varied ways to include testing in the stages of equipment development, production and use.

To introduce OIML D 19 in Cuba several topics were developed, including the *Procedure for the evaluation and pattern approval of measuring instruments* [9], the models for the pattern evaluation report with the corresponding annexes, and the *Procedure for the organization and content of the test program*. The former is of paramount importance within the subsystem created since it facilitates foreign interaction with modest (yet modern) terms and provides a stronger scientific rationale, which permits:

- a definition of which types of instruments are to be submitted for mandatory pattern approval;
- a distinction between the *evaluation body* and the *approval body*, creating the methodological-organizational basis for their respective operation; and
- the emphasis to be put on the need to assure the competence of the testing laboratory, taking into account these international guidelines.

All this called for substantial changes in the subsystem and provided the opportunity to move up to a higher development stage from the conceptual and documentary viewpoint, so that work not only focussed on supervising the fulfillment of the necessary requirements in order to obtain reliable results (as had been the case until then) but also on a commitment to actually demonstrating it.

The starting point was proving INIMET's technical capability, for which the existing *Quality System* was redesigned and the *Quality and Procedures Manuals* were developed.

The following specific steps were taken:

- improvement of the work organization;
- specialization of testing;
- preparation of specifications to develop non-repetitive testing;
- elaboration of instructions for quality control of laboratory activity; and
- definition of boundaries to interact with the fundamental interfaces.

Details of this work were published in the OIML Bulletin [10].

Finally, in December 1997, after the fulfillment of the existing requirements for laboratory competence had been verified, the National Bureau of Standards granted INIMET the status of "Accredited".

4.2 Technical-material basis

In the mid 1980's the necessary material conditions were progressively created to carry out tests involving measurements of various physical quantities. The acquisition of a climatic chamber later in the decade made it possible to start testing influence quantities, particularly humidity and temperature tests.

The acquisition of specific measuring instruments to test medical equipment and the construction by laboratory specialists of the necessary devices allowed INIMET to expand the nomenclature of both the tests and the types of equipment to be tested. Also considered were tests to verify the fulfillment of electrical safety requirements, including immunity trials for low frequency disturbances, through which the first and simpler steps were made in the field of electromagnetic compatibility. Within this framework, a reference material was made as well, the "Striped pattern", to verify the resolution of densitometers, equipment produced in Cuba or imported for use in bio- and pharma-sample analytical laboratories.

All this allowed INIMET to increase its capabilities concerning the information obtained about the general behavior of the equipment tested.

The purpose and scope of the laboratory accreditation supports testing work in the following fields:

- parametric tests (length, angle, mass, hardness, kinematics, temperature, ambient humidity, electricity and radio);
- electrical safety;
- electromagnetic compatibility; and
- climatic tests.

The service covers testing of measuring instruments, controlling equipment and medical devices.

Instrument types evaluated so far include:

- weighing instruments;
- multimeters, ammeters, watt-meters;
- temperature and humidity meters and various kinds of thermometers;
- measuring tapes, vernier calipers, micrometers;
- electrocardiographs;

- electroencephalographs; and
- systems for diagnostic techniques.

Hundreds of the above tests have been made in more than 400 evaluations, covering instruments manufactured nationally or imported from around 20 countries in Latin America, Europe and Asia.

4.3 Normative basis

Due to the strengthening of INIMET's links with international organizations, the main normative basis used nowadays is that of the OIML, ISO and the IEC, without neglecting that of developed countries in the case of specific tests and equipment.

As a rule and when applicable, INIMET has used national documents related to measuring methods and instruments, testing, verification, classification and technical requirements, as well as the elaboration of internal measuring procedures.

4.4 Human potential basis

The main labor source of the testing laboratories has been INIMET's verification and calibration facilities, both for the laboratory staff itself and for the supporting personnel who occasionally participate in this activity. This has made it possible for the staff to achieve a significant improvement in the sphere of measurements by using standard measuring instruments and systems of the various physical quantities.

It has been customary for staff to attend postgraduate courses offered by INIMET or by other centers on complementary subjects of a general nature, or on subjects needed by the experts with a view to their integrated qualification.

The experienced laboratory staff is responsible for the qualification of newcomers in order to ensure their ability to carry out the testing work. The evidence of this result and its introduction is given by the creation of the subsystem itself, by its implementation and also by its use in industry and elsewhere.

The subsystem is extended to the Territorial Metrology Centers (TMC) which conform to the system of the National Bureau of Standards (ONN) of the Republic of Cuba, with the relevant modifications according to the characteristics and possibilities of those centers and what they produce in their territories.

5 Conclusions

In concluding, it can be stated that the subsystem has allowed INIMET to:

- help to guarantee measurement reliability in various activities of public interest such as health and trade, among others;
- contribute to increased product quality and the saving of many kinds of resources by obtaining production supported by scientific-technical bases;
- contribute to the enhancement of product reliability by providing technical support to goods-related contracts or claims both in Cuba and abroad;
- eliminate technical barriers to trade between countries;
- interact with other international systems and activities such as the *OIML Certificate System for Measuring Instruments* and the actions for mutual recognition of test results, pattern approvals and measuring instrument verifications;
- make a modest contribution to the development of metrology in Cuba and in the region, since INIMET ranks high among the countries with a certain level of expertise in the field; and
- play a major role in the international context from an updated position over the same concepts, despite any limitations inherent to a developing country.

The introduction and achievement of this result is just the starting point for continued interaction within the field. Some difficulties still exist which should soon be overcome, and INIMET is faced with important tasks to be undertaken so as to increase its generalization and improvement. ■

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