Technical Infrastructure for Quality[1]

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It is clear that products (and services) have to be of good quality for safety, health, consumer and environment protection, and global competitiveness. Towards this end, we have to have an infrastructure of different components that are not only individually effective but also operating in coordination with each other. Here are the major components of this infrastructure.

STANDARDS (documentary)

Documentary standard connotes a level of quality, or an accepted or approved characteristics against which others are judged. If a part of the standard for ball pen is the capacity to write a minimum of so many kilometres, then a specific ball pen at hand can be compared to the standard and see whether it meets the standard.

The descriptive term "documentary" is used to distinguish its meaning from that of a **physical standard** (e.g., a standard kilogram).

Standards are **not limited to product** or materials but exist for processes, procedures, policies, etc. Thus we have "Good Manufacturing Practices" as a standard for manufacturers, or Quality Management System for a school for example. As an specific example, we have the ISO 17025 "General Requirements for the Competence of Testing and Calibration Laboratories", which is an international standard.

By purpose or range of applications we have **factory standards, industry standards, national, regional or international standards.**

While compliance to specific standards is usually required by regulatory bodies, role of standards is not always as a yardstick for compliance. On the **other side** of it, standards help manufacturers source raw materials (e.g. screws for automobiles) from different sources without matching or fitting problems (a nut not fitting a screw). It enables a food processor maintain food safety by following HACCP or ISO 2200 for example. The processor need not study and develop its own basic policies or monitoring system for food safety. That is, once done and published, it is free for anyone to adopt.

The biggest **international standards formulating body** is the International Standards Organization (**ISO**). Other international bodies are the Electro Technical Commission (**IEC**) which came earlier that than ISO and the International Telecommunications Union (**ITU**) (their names describe their fields of work). **Codex Alimentarius** on food standards is still another international body.

In the Philippines we have the Bureau of Product Standards (**BPS**) under the Department of Trade and Industry. From international point of view, BPS, which is a member of ISO, is our **national standards body**. BPS formulates standards for industrial products while the Bureau of Agricultural and Fisheries Product Standards **BAFPS** of the Department of Agriculture

[1] Also in the PhilMSTQ website

develops standards relevant to its name. **Regulatory agencies** have the tendency to develop standards appropriate to their needs.

Ideally, standards are voluntary and it is up to regulatory bodies, or buyers to require compliance to certain standards. For example, we may have standard specifications for Class A, B, and C of plywood. These are voluntary standards. The constructor or an owner may require that Class A be used for the ceiling of a house (in other words the user or a **regulatory body** makes compliance to specific standard **mandatory**).

There is also an standard for standards developing bodies. This standard touches on appropriate representation in the technical committees, review and approval process, etc.

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- ISO/IEC Directives, Part 2: Rules for the structure and drafting of International Standards

METROLOGY

In all aspects of life we make use of measurements, e.g., when we go to the market we talk of kilograms of rice or meat, in petrol stations we fill our cars with several litres of gasoline, in the hospital so many millilitres of medicine is introduced in the IV line, speed of a typhoon is expressed in so many kilometres per hour, food is processed at certain degrees Celsius.

In Metrology, the science of physical measurements, theoretical and practical knowledge and skills are applied to different fields to see to it that measurements are of adequate accuracy required of the job on hand.

Reliable measurements can be assured only if **major components** are in order:

> **Definition** of the quantity being measured (measurand), e.g. when we talk of highest building in the world, do we measure from sea level or from local ground level; do we include the structure at the very top supporting an antenna?
>
> **Units of measurements**, e.g., metre which is agreed to be the length of path travelled by light during a time interval of specific fraction of a second. (part of international units of measurements or SI).
>
> **Metrological controls** (pattern or type approval, verification, calibration) on measuring instruments to see to it that measurements done in one location or country is equivalent with that done elsewhere (i.e. the results are traceable to the internationally agreed upon standards).
>
> **Measurements methods** and consideration of environmental conditions are based on sound concepts and are applied properly.

Laboratory measurements **comparison programs** (wherein a sample or “artifact” is circulated among many laboratories to be measured by each participating laboratory) in turn are a measure of the over-all performance of a laboratory.

In as much as metrology cuts across most of the fields of endeavours of man, it is of major importance in safety, health, fair trade, consumer protection, and environment protection. E.g., was the strength of reinforcing bars used in that building accurately determined?, is that cavan of rice really 50 kilograms?

As one browse through the other pillars, he realizes metrology is closely linked with standards (S, in MSTQ) e.g., used in defining the units of measurements, and on the application of metrological controls; with testing (T) with respect to calibration or verification of measuring equipment of testing laboratories; with accreditation or certification (Q, quality assurance) e.g., the calibration laboratory itself are accredited with respect to its technical competence.

Structure

Internationally and nationally, metrological infrastructure is pyramidal or hierarchical (by accuracy level) in nature. At the apex of the pyramid is the definition of units of measurements and their physical realizations as agreed upon by the members of BIPM (International Bureau of Weights and Measures), next lower to this is the national physical standards (established and maintained by what is commonly called as a national metrology institute or NMI), next comes the reference, secondary, and working standards of the NMI, and at the base are the measuring equipment or devices coming from the customers of the NMI.

Structure wise, the national pyramid has the NMI at the top, followed by third-party (commercial) calibration laboratories, in-house calibration laboratories of manufacturers or equivalent, and at the base are the production units using the direct measuring equipment.

In the Philippines, we have the **National Metrology Laboratory** of ITDI, DOST (Industrial Technology Development Institute, Department of Science and Technology) as the NMI (other entities maintain other standards -- time of the day is maintained by PAGASA, DOST, and ionising radiation by PNRI, DOST and BHDT, DOH). Next comes the DOST calibration laboratories and accredited commercial calibration laboratories as third-party calibration laboratories, then at the base are the in-house calibration laboratories of the industry, and the production and quality units that do the product measurements.

The National Metrology Laboratory (NML), ITDI is a full member of the Asia Pacific Metrology Program (APMP – organization of NMI's in the region), and the Asia Pacific Legal Metrology Forum (APLMF), and an Associate Member of General Conference on Weights and Measures (CGPM – delegates of the Metre Convention).

NML has laboratories in the following fields: mass, force, pressure, volume, flow, viscosity, moisture, length, temperature, humidity, photometry, electricity, and frequency. These laboratories have been participating in laboratory comparisons organized by APMP and APLAC. NML-ITDI is signatory to the Mutual Recognition Agreement under the BIPM and has the goal of being a recognized NMI by its peers. Towards this end, NML first applied for, and gained accreditation (ISO 17025) from the accreditation body of Germany (DAKKS, formerly DKD) for the fields of mass, temperature, and pressure.

There are also public and private calibration laboratories offering calibration services at middle accuracy levels.

Legal Metrology

Legal metrology pertains to those applications affecting health, safety, fair trade, consumer protection, environment protection, and others of legal importance. In the Philippines, traceability for measurements in this area is done through the same infrastructure and laboratories as that for scientific and industrial applications. Enforcement on the other hand is based on specific laws and through different agencies of the government, e.g., weighing scales at the market place by the local government units, petroleum-dispensing tanks by the Department of Energy.

The recent National Metrology Act, R.A. 9236 is an encompassing law that covers all measurements in the controlled areas of application (legal metrology above) – all fields, and all accuracy levels. The law mandates the use of SI units, metrological controls, and registration of entities using or trading measuring equipment intended for the controlled areas of application. A National Metrology Board consisting of Ex-officio members from the government and private associations is created by the Act.

Proficiency Testing

The calibration laboratories can monitor their performance through inter-laboratory comparison programs, which may serve a proficiency testing. Local laboratories are able to participate in APLAC-run comparisons through PAO. In addition, NML runs a local comparison programs in which accredited and non-accredited laboratories can participate. Programs covered different fields, e.g., mass, pressure, temperature, electricity, and length.

TESTING

What normally comes to one's mind when testing is mentioned is that kind of testing required for acceptance of goods or for getting a product certification. **Acceptance testing** is already at the end of the complicated way to have quality and safe product. The product either complies or not to the buyer's (or regulatory body's) requirement. Such testing is not the most important. Sad to say -- almost nothing more can be done if the product fails the tests.

There are more important tests.

At the very start in conceptualising a product, testing helps greatly in checking **soundness of concept**. Testing allows a guess or gut feel to have a "scientific basis" in saying that such product is possible, there is a potential for the product, or how far yet is the product from production or commercialisation.

Once a product is prepared for the **production line** or is on the production line, a batch of tests is performed, the number and type dependent on the product itself. The tests could check the **safety** aspect (e.g., mechanical or on toxicity), **quality** (e.g. reliability, ease of use), or **efficiency** of production or of the product itself (fuel consumption in the manufacture of the product or energy efficiency of the product e.g. refrigerator)

Part of **quality assurance** is the internalisation of importance quality in the minds of the production people, (in the old days, quality control group monitors independently output of the production unit). However to help production people monitor their own performance, series of **tests are performed at different stages of production**, including the tests of incoming raw ingredients or parts.

Needless to say, testing is done by testing laboratories, **in-house or by third party** outside laboratories. There are laboratories doing chemical analysis, material strength testing, electrical testing, biological testing, etc. The tests could be at different accuracy levels e.g. proximate analysis, rapid or field-testing, high accuracy, or trace analysis, or primary methods to establish traceability. A testing laboratory has to be competent on the service it is offering, but assessment of this competence brings us to another component of MSTQ – **Quality** assessment or accreditation.

ACCREDITATION AND CERTIFICATION

While it is important that products and raw materials are tested for safety and quality, it is equally important that we are assured that the test results are reliable, meaning that the **testing laboratory is technically competent** to perform such test. In the past, an entity needing a certain test may base its selection of a testing laboratory through visits and second-party assessment. This practice is an expensive one since an entity may need the services of a number of laboratories. On the other side, a laboratory is assessed by a number of entities needing its services, this is a duplication of assessment work as well as time wastage for the testing laboratories due to multiple visits.

The solution to the problem is the use of a **third-party** accreditation system. Third party means that the entity doing the assessment is a neutral one, totally independent of the laboratory or its client. It has nothing to gain in approving or disapproving accreditation applied for and therefore can do its job objectively. Once a laboratory is accredited for a certain scope of tests, potential users of its services need not re-assess the laboratory, meaning there is only one assessment for the given scope however many are the clients of the laboratory.

In the country, we have the **Philippine Accreditation Office** (PAO) of the Department of Trade and Industry. At present PAO has system for accreditation of calibration laboratories, and laboratories for chemical, mechanical, electrical, microbiological testing. These are assessed with respect to their compliance to ISO 17025 (Minimum Requirements for Technical Competence of Testing and Calibration Laboratories). Due to health issues, PAO prepared a system for accreditation of clinical laboratories, as well as the training of PAO staff and external pool of assessors.

PAO also accredits Product Certifying bodies; and Certifying Bodies, which in turn assess entities on their compliance to ISO standards on Quality Management System, Environment Management System, on Food Safety.

PAO is a member of Asia-Pacific Laboratory Accreditation Conference (**APLAC**) and the International Laboratory Accreditation Conference (**ILAC**) and has been accredited by these international organizations for its accreditation system for testing and calibration laboratories. PAO is also a member of the International Accreditation Forum (**IAF**), which recognized PAO for its system of accreditation for Quality Management System Certifying Bodies as well as Environmental Management System.

As of May 2012, PAO has accredited a total of **185 testing and calibration laboratories**, and **12 Certifying Bodies** (includes multiple entries for Quality Management Systems, environmental Management Systems, Criteria and Methods for Hazard Analysis Critical control Point Accreditation, and Food Safety Management Systems).

PAO is signatory to Mutual Recognition Agreement **(MRA)** for the scope of work where PAO is accredited by ILAC and IAF. Under the MRA, accreditation by PAO is recognized by other countries signatories to MRA. Similarly, PAO recognizes accreditation done by other MRA co-signees.

REGULATORY BODIES

Above structures alone is not enough to ensure quality of products and services since the offer of services of the implementing bodies are voluntary.

There are a number of government entities whose mandate is to regulate products and services to ensure quality. Examples are: Food and Drug Administration, DOH, Environmental Management Bureau of DENR, Bureau of Fisheries and Aquatic Resources, DA, and Local Government Units. A number acts also as Certifying Body for their area of coverage, aside from enforcement of regulations.

RELATIONSHIP AMONG MSTQ COMPONENTS

For the pursuit of quality and safety, we advantageously apply MSTQ i.e., metrology (the science of physical measurements), standards, testing, and quality recognition (accreditation and certification); in most cases, combination thereof.

While most visible for being the prescribed characteristics of raw materials and products, as well as their processing e.g., good manufacturing practices, (documentary) **standards** can be seen also as cutting across the other MSTQ components.

Appropriate standards for management system and technical operations, are prescribed for **metrology,** calibration, and **testin**g laboratories, as well as for **accreditation** and **certification** bodies. Compliance to standards ensures consistent technical competence of these entities.

For a given standard for a product, testing has to be done to check that this standard is met. Results of testing in turn are used by a product certifying body in its assessment before issuing a product quality certificate.

Manufacturing, processing, and testing entities have to maintain their equipment and measuring instruments for these to give consistently reliable results. Part of the maintenance is the calibration (metrology) of the mentioned items so that measurements done are accurate and traceable to international standards.

The Regulatory Bodies issue requirements especially those pertaining to MSTQ, and tap the MSTQ structure in their development of regulations as well as enforcement.

We can therefore say that MSTQ components are **closely knit** and the weakness or strength of one directly affects the effectiveness of the others.