

INTEGRATION OF METROLOGICAL APPROACHES INTO FOOD AND NUTRITIONAL MEASUREMENT SYSTEM

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Abstract: Society, as a client and as an end-user, looks at quality assurance (QA) in terms of net economic benefits gained by solving real-life problems that contribute to national development. As a *measurable parameter*, economic benefit is a reliable indicator of sustained attention and public support for QA. In the world of food as a trading commodity, we are moving towards a global but borderless-trade situation. Food safety being a prime concern under this scenario, reliable food and nutritional (F&N) measurements take centre stage in decision-making. A measurement process characterized by metrological concepts enhances the reliability of analytical results and ensures sustainability to the QA process. These steps infuse *authority* to the F&N analytical results, and to the ensuing public health decisions from well-designed projects. Integration of metrological concepts into the F&N measurement system strengthens the very base of nutrition education for young professionals (scientific and technical), improves institutional measurement infrastructure, and contributes to the much-needed *capacity development* in F&N areas. The World Bank and several other United Nations Agencies are now embarking on human capacity building as a critical focal point in the context of national development. Simply put, QA promotes economic benefits. This is the challenge to be met in practice in the field.

Keywords: metrology in biology, physiological and metabolic parameters, food and nutritional metrology, harmonization of chemical measurements, nutrition education, and analytical quality assurance.

1. BACKGROUND

Metrology has guided us in our understanding the science of measurements in numerous ways: high purity reference standards, validated methods, calibration approaches, natural matrix reference materials (RMs), high quality certified RMs (CRM) to facilitate one aspect of traceability, assessment of measurement uncertainty and proficiency testing approaches. Metrological progress in physics and chemistry speaks for itself.

Before we deal with the complexity of metrology in biology which includes food, nutrition, physiological and metabolic measurements among several others, it is useful to focus briefly on: (i) status of metrology in physics and chemistry, (ii) awareness of metrological concepts in biology, and (iii) the need for strengthening metrology

knowledge (capacity development) in researchers and professional staff in the life sciences. Enhancing metrological skills include the ability to assess *uncertainty* (a metrological measure reflecting the reliability level) surrounding an analytical measurement, and to establish traceability (a metrological process sourcing the roots for enhancing the credibility of analytical results).

(i): The clarity with which metrology is affiliated with physics and to a significant extent with chemistry, is well-documented [1]. Metrology in physics is well advanced, and for all practical purposes, *two* components namely, the *measure* (i.e. the unit of measurement) and the *measurand* (i.e. the entity measured) fully account for the clarity and the process of a measurement. In simple words, in the case of measuring the length of a room (the measurand), the SI unit (the measure) metre provides a direct answer sustained by metrological concepts. Metrology in chemistry, as observed through physical chemistry (measures used to express molar relationships, volume, pressure, temperature, surface tension, among others) follows the same principles of metrology as in physics. The same basis percolates to classical analytical chemistry (gravimetry for preparing high purity standards, related definitive analytical techniques, among others). However, certain transition takes place in extending the metrological principles to chemical measurements in complex chemical matrices (e.g. foods and other biological samples), as it adds a *third* component namely, *indirect measurements* (e.g. AAS determination of Zn in foods). This is a practice frequently used in field assays, and calls for additional steps to account for traceability of such chemical measurements for safeguarding reliability concerns.

(ii) Metrology in biology as a whole represents a very complex situation, and the answer demands consideration of "*total quality*" in biological terms and involves *more than three* components visualized under metrology in physics and chemistry. Let us consider the example of a physiological measurement of the type in-vivo bone density measurement in human subjects by the commonly used dual-energy X-ray absorption method (based on simple physics parameters density, volume and weight). In practice, it involves consideration of *multiple* components in effectively carrying out the measurement. The complexity increases even further when metabolic measurements such as the bioavailability of nutrients are to be carried out in human subjects. Besides the need for *inter-disciplinary expertise* for both examples cited, sampling metrology also becomes an issue in dealing with

metrology in biology (i.e. food, nutritional, physiological and metabolic measurements).

(iii) Food and nutritional metrology is an emerging discipline that is essential for projecting the reliability of analytical data. Capacity development for empowering food and nutrition students to generate sound analytical results by introducing them to metrological concepts is a long-term scientific and technical investment as a part of the human capital development. Under this background, let us consider the emerging scenario of the need for reliable food and nutritional (F&N) measurements as the key for success in a world of borderless-trade. In this context, a reasonable approach for enhancing the reliability demands integration of metrological concepts into the measurement process. This step is necessary also to ensure sustainability to the analytical quality assurance process and to infuse *authority* to the F&N results. In addition, integration of metrology into F&N measurements strengthens the very base of nutrition education for young professionals (scientific and technical) and improves institutional measurement infrastructure. Thus, it contributes to the much-needed *capacity development* in several areas of F&N. Collectively, these inputs generate concrete economic benefits from well-designed public health projects and help to meet client needs. These 3 issues are examined briefly in the following sections.

2. THE METROLOGICAL ROAD MAP AND METROLOGY IN PRACTICE

Metrology is the backbone of numerous applications as illustrated in figure 1 and several institutions have supporting links to different aspects of metrology. For example, the International Standards Organization (ISO) sets “normative” standards, while the International Bureau of Weights and Measures (BIPM), creates, maintains and disseminates physical and chemical standards that are linked to the SI units. It may be mentioned here that the issue of measurement uncertainty of chemical analytical results is still evolving. It is only now, that the current revision of the International Vocabulary of Basic and General Terms in Metrology (VIM) accounts also for chemical measurements.

Figure 1 conceptually illustrates a combination of issues. While the normative process and dissemination of physical and chemical standards among other functions, are dealt with by a set of recognized institutions such as the National Institute of Standards and Technology (NIST) and the Institute of Reference Materials and Measurements (IRMM), the different applications (e.g. F&N metrology, legal metrology, etc.) shown are indicative of specific measurement attributes of a given type of application. The fields such as the F&N metrology and partly the environmental metrology, highlight the fact that chemical metrology is still evolving. The arrows (figure 1) in and out of the road map from various groups of applications indicate two perceptions: (i) the reliance of these groups of measurements on basic concepts of metrology based on

existing metrological fundamentals, and (ii) in the case of F & N measurements, a provision to provide feed back derived from practical experience unique to these kinds of applications. In effect, this reflects the present situation in our understanding the evolving concepts in chemical (and biological) metrology.

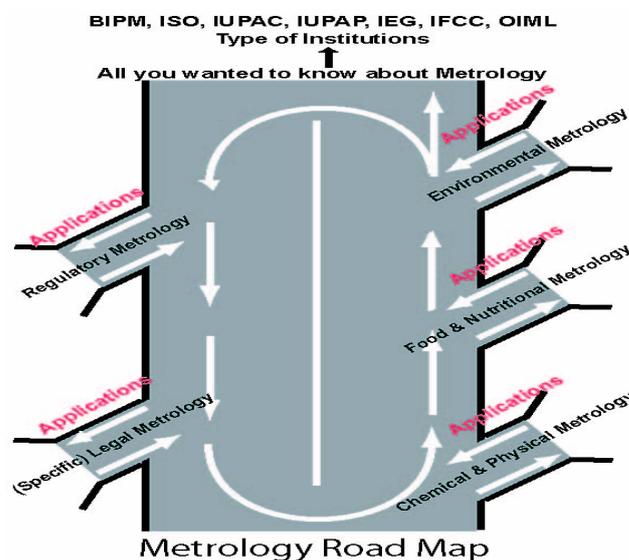


Figure 1. Examples of metrology applications in various fields

The document on Metrology in Chemistry and Biology [2] has attempted to extend the concept of traceability practiced in physical and chemical metrology to the measurements undertaken for different biological parameters. While acknowledging the complexity in defining chemical measurements in biological systems as complex, this document identifies traceability as the heart of the matter in a measurement process providing a basis for reliable measurements, which are comparable. Then, taking a functional point of view, the report focuses on *comparability* to be considered as the primary requirement and concludes that traceability is a tool to help achieve comparability. Comparability is broadly understood here as internationally recognized procedures for food measurement offering some degree of flexibility to address the SI issue because of practical reality. Applying these concepts under field conditions, the International Atomic Energy Agency (IAEA) has consistently contributed in a practical way to strengthen the analytical competence in the areas of nutrition and environment, particularly in developing countries imparting *measurable improvements* in the quality of results [3].

When decisions are made based on analytical results, it is important to be assured of the analytical quality of the results. In this context, the multidisciplinary team (e.g. analytical chemists, life sciences researchers, food science investigators, among others) is required to recognize the *shared responsibility* faced by them as a team, and diligently document the integrity of their analytical findings. This is accomplished by providing for *traceability* by benchmarking the measurement process to a common reference point (referred to as *stated reference*) such as a certified reference material (CRM) by reputable institutions (e.g. NIST,

IRMM), a reference method or an SI unit. Further it is expected that the analyst evaluate all possible sources of errors during the sampling and measurement process for a meaningful prediction of the uncertainty of the measurement. However, this situation is in a state of flux in the life sciences areas and is in need of awareness building by imparting metrological concepts.

3. PHYSIOLOGICAL AND METABOLIC MEASUREMENT SYSTEMS

Broader application of metrological principles in biology (i.e. metabolic, physiologic, clinical, food, nutritional and toxicological measurements, among others) is still in its infancy. The silver lining is that many of these measurement processes are amenable for harmonization and facilitate *comparability* (a vital requirement when results from different laboratories are evaluated). For example, metrological concepts are being successfully integrated into food safety (i.e. food labeling) measurements by internationally accredited laboratories. A second example is that of certification of natural matrix biological reference materials (RM). Further, certain clinical assays are merely physical measures (e.g. particle size determination as in cell volumes, and bone mineral density) or chemical measurements (e.g. analysis of body fluids for vitamins, minerals and trace elements) of a biological matrix. Further, cholesterol and glucose particularly make good examples since CRMs exist and *traceability* is feasible. Similar argument can be made for fat, protein, vitamin and other dietary trace element measurements in a food matrix.

Hence establishing a metrological base for biological measurements implies that betterment of the *total quality* should be aimed as envisioned by: (i) consolidation of the biologic basis for the selection of specimens, (ii) development of strategies to define the “viability” status of the specimen (and long-term stability, if required) for facilitating later data interpretation, (iii) establishment of approaches for harmonization of analytical measurements, and (iv) recognition of the need for multi-disciplinary expertise at the planning stage of an investigation.

3.1 The “bio” dimension of the measurement problem

Physiological and metabolic specificities exert unique demands on how analytical measurements are carried out in biological systems. Comments by Kimmel et al [4] that “the young animal is not a small adult” appropriately reflects the issue involved in projecting the models for assessing developmental toxicity. What it implies is that simple scaling down proportions based on body weights is not acceptable. This characterization applies to many situations in dealing with biological systems.

In order to strengthen the physiological and metabolic measurement system, it is essential to understand the impact of the overall “bio”dimension involved with biological specimens and the resultant sources of errors

needing their careful evaluation: these include both *conceptual errors* arising from our limited understanding of the numerous biological characteristics termed as *presampling factors* such as biological variations, post-mortem changes, short- and long-term variations reflecting influence of food intake, and certain intrinsic factors [5, 6], and *analytical errors* stemming from sampling, sample preparation, matrix effects, among others [7]. The main problem is that variations arising from biological factors and pathological shifts are identifiable but are not always quantifiable. Yet, their influence on the reliability of the analytical results must be understood to facilitate a meaningful interpretation of the data derived [8]. The sampling part of the metrology reflects its own problems: *valid sampling* through sample quality, quantity, validity and stability. Components of *uncertainty* arise from incomplete definition of the sample characteristics, sampling conditions and the subsequent measurement phase [9]. Evaluation of sampling constants (minimizing the errors due to sampling) is one approach.

The following recent measurement efforts are good examples of contributions to the food and nutritional metrology: Bone density measurements on a population basis showing < 5% combined uncertainty [10], body composition (fat mass, total body water and fat-free muscle mass) at measurement accuracies close to 3% or less [11], and minimizing uncertainties in the measurements of organic acids in total diets (12) and inorganic nutrients in foods such as infant formula (13) and total diet (14).

3.2 Nutrient bioavailability determinations

Bioavailability refers to how much of a given substance is in a form that can be readily used by the body. In nutrition, it is not only important to have enough of a particular nutrient present in the food, but it must also be “available” to be used by the body. Stable isotope techniques and radioisotopic methods are reliable tools available to determine the absorption, retention or utilization of nutrient by human body. From the perspective of measurement accuracy mass spectrometric tools are exceptionally reliable, and this is the strength of stable isotopic applications in human nutrition. However, the underlying physiological conditions of the subjects can significantly interfere in the actual assessment of the absorption process. For example, serum ferritin levels influence iron absorption, extending up to 100% differences [15]. Although selected sources of bias in human experiments involving stable isotope techniques have been identified [3], it is not uncommon to find huge differences in the absorption of several nutrients even among subjects examined and found to be of normal health. Even if these differences in absorption are of biological origin, the extent of their influence need to be systematically evaluated to enable assigning a realistic *uncertainty* value to the bioavailability results from metabolic studies.

Several other physiological measurements are carried out under complex conditions and are frequently assessed by indirect means. These include measurements for body

composition, dietary energy intake and energy expenditure among others, by traditional methods that lack evidence of a proven traceability link. These deficiencies are amenable for metrological improvements using stable isotope techniques based on single or double-labeled water and utilizing mass spectrometry for ratio measurements. However, systematic studies designed to examine the metrological aspects to estimate uncertainties are lacking. With increased attention being focused on obesity and associated chronic disorders, there is a need to strengthen the validity of these types of measurements.

4. CLINICAL, FOOD AND NUTRITIONAL MEASUREMENT SYSTEMS

4.1 Clinical measurements

A review of the progress with cholesterol measurements in human serum reveals that reliability of cholesterol measurements has narrowed from over $\pm 24\%$ to 1% (Table 1). The improvements accomplished in this part of the clinical metrology are the result of sustained efforts by the NIST over 40 years [16]. Three major mechanisms played a role: (i) development of a series of standard reference materials (SRM) for cholesterol used by instrument companies to validate their equipment; (ii) development of high accuracy reference measurement methods replicated by researchers who need to validate their new measurement technology on a wide range of blood samples; and (iii) NIST's close collaboration with the College of American Pathologists (CAP), the premier clinical measurement testing and quality assurance organization in the USA. The CAP provides an array of proficiency samples to over 18,000 U.S. clinical laboratories and uses them for testing of measurement accuracy. Strict attention to quality assurance by analyzing reference materials is part of the exercise. The CAP has established a reference laboratory at NIST and actively collaborates with NIST. This kind of effort is needed to bring about sustainable metrological improvements.

Table 1. History of NIST certified standards for cholesterol in human serum
Uncertainty vs improvement with time

Cholesterol measurement status (routine specimens)		NIST Cholesterol Standards introduced	
Year	% Uncertainty	Year	SRM
1949	± 23.7	1967	SRM 911 (pure chol.)
1969	± 18.5	1980	Def method for chol
1980	± 11.1	1981	SRM-909, H. serum
1986	± 6.4	1988	SRMs 1951 and 1952
1990-1994	± 5.5 to 7.2	1994	Further meth. dev.
2000 onwards	$\pm 1\%$ or less	2003	SRM 1951a

Impact
Significant reduction of false negatives and false positives (diagnosis); savings from not needed treatment costs

Similar examples are available for glucose [17] standards (addressing laboratory assay needs to monitor over 16 million diabetes patients in the USA costing billions of US dollars per year). By introducing a series of standards covering a range of blood glucose levels and

facilitating stricter method validation, the number of false positives and negatives could be minimized (Table 2).

Table 2. NIST Glucose in Frozen Human Serum Standard SRM 965a

Concentration levels ^a	mg/dL
Level - 1	34.56 ± 0.36
Level - 2	78.5 ± 0.86
Level - 3	122.1 ± 1.3
Level - 4	292.6 ± 3.5

^a Concentrations apply to serum thawed to room temperature

4.2 Food and nutritional measurements Even routine chemical measurements are expected to reasonably conform to basic metrological requirements (i.e. use of validated method and assessment of the analytical uncertainty of the measurement under practical conditions) so that the results generated are interpreted with a measure of confidence. Therefore, initiating steps for harmonization of chemical measurements is a basic requirement. In this context, it may also be mentioned that with respect to many measurements connected with foods, there are different procedures followed to ensure QA/QC. For example, in some regions there is emphasis on Association of the Official Analytical Chemists methods, while other regions of the world accept any method validated by appropriate CRMs to safeguard traceability, practical under field conditions.

The need for frequent movement of food as a commodity between countries highlights the concerns between QA and health safety. The food importers are held responsible for the commodity when it exceeds regulatory limits for toxic substances, while food processors are the key in preventing such foods from reaching the public distribution network. Although these are routine chemical measurements, the economic and legal implications involved here exert a strong pressure on the need for generating reliable results that can stand legal or other challenges, if any. In other words, the measurement system should link itself to a traceable metrological domain, in this case for example use of an appropriate CRM from a reputable institution. For example, in the United States regulatory directives such as the infant formula act of 1981, the nutrition labelling and education act of 1990, the dietary supplement health and education act of 1994, and the food quality protection act of 1996 among others, have ushered in a new era in many areas of food chemistry. Further, the need for harmonization in generating analytical data calls for mandatory laboratory accreditation, proficiency testing and collaborative efforts between laboratories belonging to government, academia and industry. The task of translating regulatory act into practice keeping in focus the industry's technical capabilities and providing realistic metrological link is pivotal and can be accomplished by the use of a CRM.

5. IAEA IN SUPPORT OF FOOD AND NUTRITIONAL METROLOGY

For more than 3 decades the IAEA has supported projects using nuclear and isotopic techniques in several areas such as food, nutrition and environment with the objective of strengthening analytical capabilities in the IAEA Member States. Over time such efforts have led to the development of proper study designs, harmonization of sampling protocols, adequate contamination control and evaluation of the suitability of competing analytical techniques for specific analyte determinations. These in turn have contributed to the emergence of coherent and practical analytical approaches resulting in measurable improvements in the quality of analytical data generated by the IAEA Member States. These positive impacts are demonstrated by (i) the development of many natural matrix RMs, (ii) enhancement of the capacity of participants for upgrading the existing RMs for establishing reference values for project specific analytes, and (iii) improvement in biomonitoring techniques in the areas of occupational exposure to heavy elements and sampling of airborne particulate matter. Over time these efforts were also extended to improve measurement processes in the human physiology area resulting in further progress. These include: (i) development of the characteristics of a Reference Asian Man to strengthen radiological safety approaches in the Asian region; (ii) establishment of reference values for human milk and dietary intake of minor and trace elements, and (iii) use of isotopic techniques to strengthen the FAO/WHO/UNU global recommendations on human energy intake and expenditure [18]. Collectively, these consistent IAEA initiatives nurtured over a period of several years have promoted harmonization of chemical measurements to a significant degree, thus infusing a measure of metrological awareness at the level of field projects (figure 2). This has been possible since over the years, the IAEA has gone through a process of continuous refinement, modelled on accumulating practical experience [3].

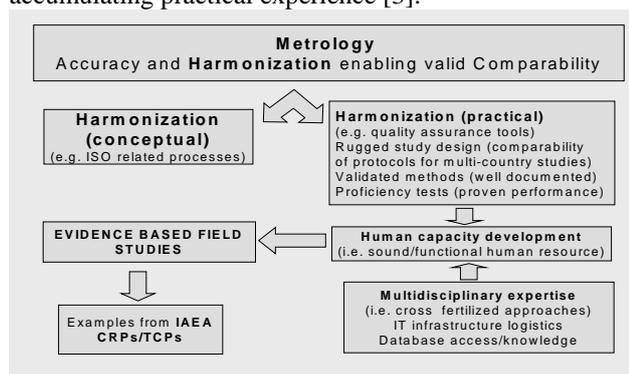


Figure 2. Multidisciplinary input for human capacity development in F&N

6. INTEGRATION OF METROLOGY AND CAPACITY DEVELOPMENT ISSUES

Enhancing human skills to address global nutritional challenges is a daunting task. Currently, several United Nations (UN) agencies, bilateral organizations, non-governmental members, national institutions and international societies are supporting this effort by

unequivocally recognizing leadership and capacity building as corner stones of national development endeavours [19]. IAEA [3] experience is shown as an example in Figure 3.

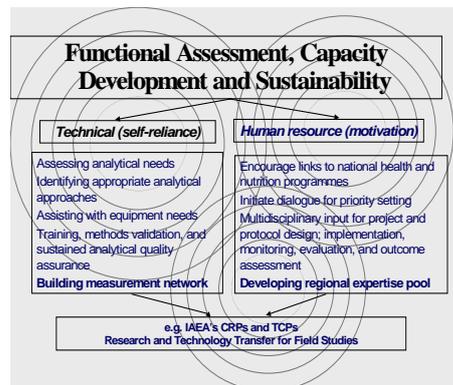


Figure 3. Development of technical Expertise to sustain capacity building

An important goal of leadership and capacity development (LCD) in F&N is to increase and strengthen national and regional professional base for providing solutions as part of national development. The LCD efforts encompass both institutions and individuals and call for skillfully designed approaches for developing sustainable initiatives. The expressions *sustainability* and *sustainable development* are used frequently in this context, and they mainly signal long-term concerns and the need for integration of measures to safeguard issues ranging from environment, public health and other topics surrounding development in general. The Brundtland commission in 1987 defined it as “development that meets the needs of the present without compromising the ability of future generations to meet their own needs” [20].

Several international institutions are striving to strengthen LCD in F&N in different global regions. A part of the *accomplishment* is seen in empowering the regions (i.e. policy makers, project implementers and the project beneficiaries in some cases) with self-sustained problem solving expertise on alleviating malnutrition and creating awareness to the economic benefits of investing in nutrition. Thus, once a problem is identified for scrutiny, the required LCD initiative can be envisioned under (i) management (ii) communication, (iii) scientific, and (iv) technical needs.

The *management* component addresses issues surrounding project needs, resource mobilization and utilization for successful implementation of a given initiative. Considerable experience in this area is now available at national levels in several countries in a given region, but not in all countries in some regions. The *communication* segment provides the crucial link needed to interface management with science and technology. Specifically, it's pivotal role in linking policy makers, project implementers and the beneficiaries of the project helps lay the groundwork for the much-needed sustainability. Thus, the communication web extends all the way from formulation of project effectively, sustainability of contacts during the resource mobilization phase, project implementation, skilful data interpretation and dissemination

of results to reach the anticipated outcome. Developing any appropriate *scientific competence* is a daunting task and the recipients in a given country should possess adequate basic training and ability and opportunity to attain higher standards of knowledge. The *technical* part focuses on methodological issues (e.g. analytical quality assurance) within the context of F&N laboratories.

The 4 compartments (management, communication, scientific and technical competence) are inter-related and cannot be strictly separated in practice while dealing with LCD initiatives. However, scientific and technical requirements are quite specific, and therefore, a certain degree of harmonization is feasible between these two segments. Hence it is possible to share solutions for methodological problems, using international communication network to draw on global technical expertise, and preparation of peer reviewed scientific communications, that are contributing to strengthen the scientific or technical skills. This process of harmonization between the scientific and technical segments is helpful for integrating the metrological concepts to F&N measurements for strengthening nutrition education.

7. CONCLUDING REMARKS

In conclusion, measurement efforts dealing with biological systems need a systematic evaluation of how to incorporate the benefits of metrological concepts that have elevated the excellence of measurements carried out in the areas of physics and chemistry. The beginning that has already been made in the areas of food safety (e.g. food labeling), development of well characterized natural matrix RMs, refinements in cholesterol and glucose measurements, among others should be extended to other types of measurements. Integration of metrology into life sciences measurements strengthens the very base of education for young professionals and improves institutional measurement infrastructure and contributes to the much-needed *capacity development* in several areas of life sciences. A statement made by de Bievre [21] appropriately reflects the situation: "Unfortunately, in many parts of the world, teaching such basics of the process called *measurement* is almost absent in the educational system".

Food safety is a global issue and the efforts aimed at strengthening LCD in F&N should keep this in focus. Importantly, in some parts of the world the movement of foods has assumed the status of borderless-trade. Robust metrological infrastructure and recognition of the need for analytical capacity by the trading partners have played a key role here. The Latin America-USA-Canada trading hub (known as NAFTA) is a good example. The mutual recognition agreement is made possible between groups of countries in this region, based on the strong measurement leadership by national metrological institutions. To quote Quinn [22] "The globalization of trade has brought pressing new requirements for worldwide collaboration to assist in the provision of accurate and reliable measurement results

in areas such as health care, safety and, in respect of safe and wholesome food is a challenge".

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