

Review Article

Overlapping ISO/IEC 17025:2017 into Big Data: A Review and Perspectives

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Abstract: The greatest common standard for the expertise of testing and calibration laboratories has recently been brought up to date, considering the newest improvements in laboratory environment and work practices. ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*, is the international reference for laboratories implementing calibration and testing actions through the globe. This article gives a short review on ISO/IEC 17025:2017 and its related data which are increasingly produced every day in the laboratory and suggests Big Data as a fundamental tool of treating such data. ISO/IEC 17025:2017 is gaining a huge part in laboratory legal status and activities; in its side, Big Data is reaching high level of mastery and expansion. On the other hand, there is a huge amount of data around and inside laboratory everyday activities. Besides the experimental and analytical results, there are findings from its financial management. Therefore, Big Data through its enormous capabilities of managing details would imbricate ISO/IEC 17025:2017. The near future would provide more details of how will be the final figure of this intersection.

Keywords: ISO/IEC 17025:2017, Measurement Uncertainty (MU), Proficiency Testing (PT), Reference Materials (RMs), Big Data

1. Introduction

The greatest common standard for the expertise of testing and calibration laboratories has recently been brought up to date, considering the newest improvements in laboratory environment and work practices. ISO/IEC 17025:2017 [1], *General requirements for the competence of testing and calibration laboratories*, is the international reference for laboratories implementing calibration and testing actions through the globe [2].

Generating well-founded findings that are largely relied on constitutes the most important reason of laboratory actions. ISO/IEC 17025:2017 [1] lets laboratories to apply a

high-quality procedure and prove that they are strictly expert and capable to generate correct and authoritative findings [2, 3]. ISO/IEC 17025 as well lets simplify collaboration among laboratories and different associations upon producing larger approbation of findings among nations. Experiment reports and certificates can be regarded as true from one nation to another without the requirement for additional experimenting, which successively enhances international trade [2, 4].

So as to reveal the up-to-the-minute modifications in market environment and engineering, the fresh version of the

standard encloses the actions and novel manners of performing of laboratories this present day. It includes technological improvements, language and enhancements in information technology (IT) methods and considers the newest publication of ISO 9001 on quality management [5].

Laboratories previously accredited to ISO/IEC 17025:2005 [6] will require switching their procedures to the

fresh edition during a three-year phase from the publication date of the novel standard (i.e., before the end of 2020) [5].

ISO/IEC 17025:2017 [1] was modernized cooperatively by ISO and the International Electrotechnical Commission (IEC) under the responsibility of the ISO Committee on conformity assessment (CASCO) [5, 7, 8]. Table 1 summarizes the principal modifications in the 2017 edition [1].

Table 1. Main modifications in the newest edition [5].

Change	Description
Change #1	The scope has been reassessed to comprise testing, calibration and sampling linked to subsequent calibration and testing.
Change #2	The process approach now coordinates with more recent standards like ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies).
Change #3	The standard possesses now a stronger focus on ITs and includes the usage of computer systems, electronic records and the generation of electronic findings and reports.
Change #4	A novel chapter presents the idea of risk-based thinking [9].

On the other hand, measurement uncertainty (MU) is a crucial side of the measurement finding which is largely employed while evaluating the conformity to regulatory and/or specification prerequisites [10]. Laboratories are asked to assess the MU taking into account all related parameters [11]. Fundamental prerequisites are established in the standards mentioning their specialization [12], which frequently requires to be proved through their accreditation (Figure 1) [13]. For this purpose, over and above parameters linked to their proper functioning, they require to take into account MU features concerning the functions given by their external suppliers whose expertise may as well be established by their accreditation following applicable standards [14]. Prerequisites founded in ISO/IEC 17025 [1] and ISO 15189 [15] employed for the accreditation of laboratories are examined depending on prerequisites for calibration [16] services, reference material producers (RMPs) and proficiency testing (PT) schemes founded in ISO/IEC 17025 [1], ISO 17034 [17] and ISO/IEC 17043 [18], respectively [10].

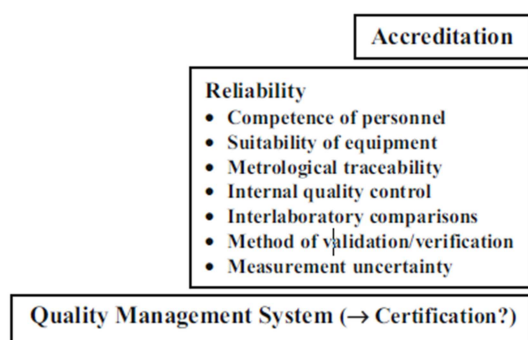


Figure 1. Required stages in the direction of assuring accuracy of the laboratory activity [12].

This paper presents a brief review on ISO/IEC 17025:2017 [1] and its related data which is generated every day in the laboratory. Moreover, focus is accorded to Big Data, as a fundamental tool of treating data; employing Big Data at the laboratory level, may be a promising solution in order to deal with ISO/IEC 17025:2017 [1] norms and challenges.

2. Standards and Additional Documents

The standards founding the prerequisites for the expertise of laboratories and additional conformity assessment bodies (CABs) are the ones employed by accreditation bodies in the assessment of CABs for their accreditation [10]. For this purpose, while mentioning these standards across this paper, the words “accreditation standards” are employed [19]. In a general manner, these standards are usable, and they do not need particular requirements in every domain [20]. Therefore, some more particular standards have been founded to treat the requirements of specified domains and features [20]. At the same time, additional documents give advice and helpful clarifications to both laboratories and accreditation bodies (Figure 2). These are mainly publications presented by the International Laboratory Accreditation Cooperation (ILAC) [21] and regional accreditation organizations, like the European cooperation for Accreditation (EA) [22]. Moreover, additional institutions such as the Bureau International des Poids et Mesures (BIPM) [23], the International Organization of Legal Metrology (OIML) [24, 25], and the Joint Committee for Guides in Metrology (JCGM) [26] present highly helpful publications inside their field, i.e., on terminology, metrological traceability and MU. These documents include a crucial fraction of the foundation for a coordinated manner for the peer evaluation in the framework of both the Multilateral Agreement (MLA) with EA (and similarly with other regional accreditation organizations) and the Mutual Recognition Arrangement (MRA) with ILAC. For this purpose, they are very significant for national accreditation bodies (NAB). Simultaneously, they are very helpful for laboratories and other CABs both the accredited ones and those which are being prepared to be accredited [27]. Additional crucial publications are the guides provided by Eurachem [28], some of them cooperatively produced with the Co-Operation on International Traceability in Analytical Chemistry (CITAC) [29] as well as others suggested by Eurolab [30]. Laboratories have to mention such publications in the arrangement of their daily function and also in instruction, particularly of freshly hired staff [10]. Figure 3 shows the series of different sources of facts.

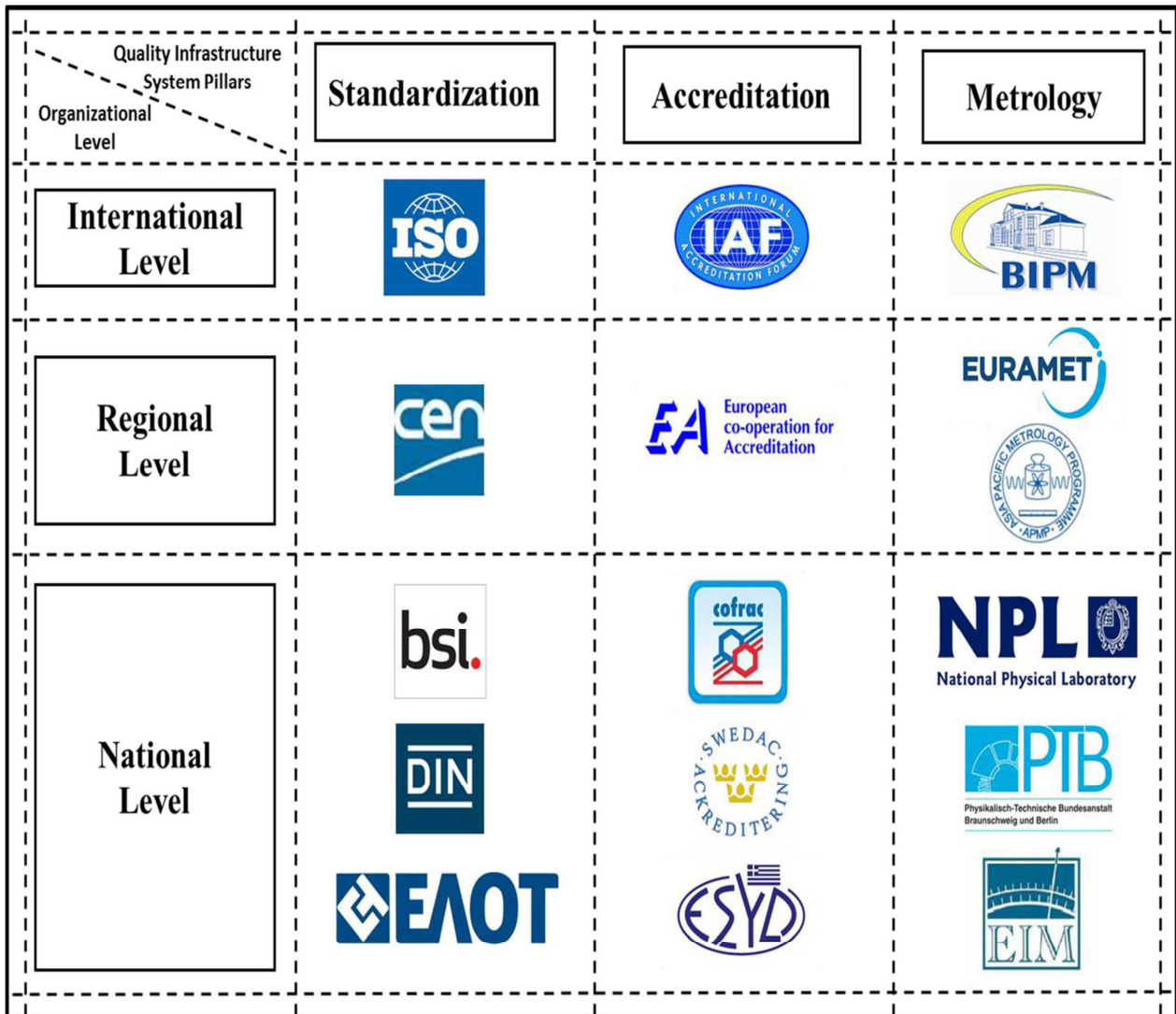


Figure 2. Presentation of different levels of organization of standardization, accreditation, and metrology [20].

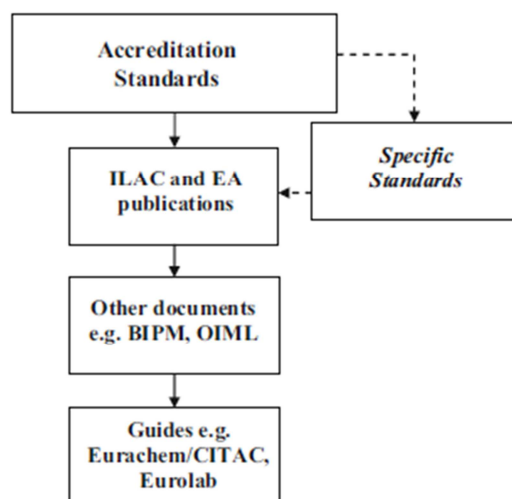


Figure 3. Arranging of publications to be adopted by a laboratory. Dashed-line arrows illustrate that not all domains require particular standards [10].

The pyramidal quality infrastructure system is graphically presented in Figure 4 [20].

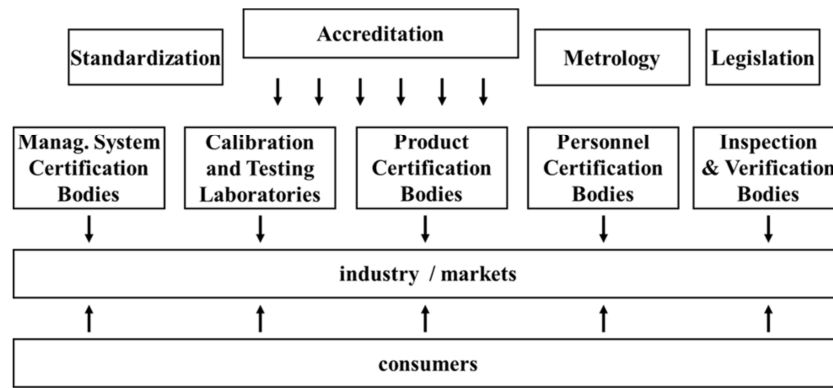


Figure 4. Quality infrastructure system [20].

3. Laboratory's Required Standards

Following the novel standard ISO/IEC 17025:2017 [1], “laboratory is a body that performs testing, calibration or sampling, associated with subsequent testing or calibration” [10]. Concerning their accreditation, laboratories, mainly concentrating on ISO/IEC 17025, frequently undervalue the necessity to be conscious and mention additional accreditation standards as suitable [31]. Accreditation standards include the complete collection of conformity assessment activities which, following the pertinent definition given in the new standard ISO/IEC 17011 [32], comprise, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of PT, production of reference materials (RMs), validation and verification [33].

The fundamental accreditation standard for testing and calibration laboratories is ISO/IEC 17025 [1]; in the case of medical laboratories, ISO 15189 [15] is the most suitable. Laboratories are supported by some suppliers who, in case they are implied in conformity assessment activities, are accreditable against specific standards [1, 17, 18]. Laboratories implicated in R&D and non-routine analysis may require considering the pertinent Eurachem/CITAC Guide [34], which is also under revision [10].

4. Particular Publications for MU

The accreditation standards suggest some prerequisites for all features of the procedure of the specific conformity assessment to which they mention. One of them is the MU [35]; the standards state the necessity for its estimation and how it is communicated [10].

A set of publications mention MU [36, 37]. Some of them are particular standards treating in more detail this issue or applicable in some fields [38-40]. JCGM 100 sets of publications consist of guides on the expression of uncertainty. Among them, ISO/IEC Guide 98-4 [41] concerns the contribution of MU in conformity assessment. EA and ILAC publications, i.e. EA-4/02 M [42], EA-4/16 G [43], ILAC P10:01 [44], ILAC-P 14 [45] and ILAC G 17 [46] concern MU and traceability. For this purpose, they are important not only to NABs but to laboratories as well in view to be conveniently arranged for their assessment by the NAB. It is foreseeable that

many of these publications will be shortly revised in view to better support the new standard ISO/IEC 17025 [1]. Some of numerous publications from professional networks, reference is made to the pertinent documents of Eurachem/CITAC [47-49] and Eurolab [50]. Further to these, the NABs prepare additional documents, both informative of their policy and guidance to the laboratories in the country [10].

5. Laboratory's Reviewed Activities

Laboratories, both testing and calibration, have to evidently comprehend and deal with the prerequisites of the implementable standard, i.e. ISO/IEC 17025 [1] or ISO 15189 [15]. Both standards mention that laboratories have to estimate the MU of their findings; moreover, ISO/IEC 17025 [1] supports the communicating of the findings [10].

Concerning calibration, laboratories have to implement a method to evaluate the uncertainty of measurement for all calibrations they perform [51, 52]. This is needed in testing also; if this is not easy, laboratories have at least to try to define all the constituents and perform an acceptable evaluation. In both situations, all uncertainty constituents of significance have to be considered [10].

While communicating, a declaration of the evaluated uncertainty has to be comprised where required for the explication of findings. This is needed in the situation of (1) testing laboratories, while attached to the authenticity or implementation of test findings, while imposed by the customer or while it influences conformity to a statement restriction; (2) calibration laboratories, while an assertion on conformity with an established metrological statement is performed [10].

Concerning MU, principal modifications performed in the novel ISO/IEC 17025 [1] mention the following: (1) allusion to the contributions from sampling; this is attributed to the implication of sampling as a task of a laboratory in the definition of the standard. A Eurachem/Eurolab/CITAC/Nordtest/AMC guide [53] is extremely useful for laboratories implied in sampling, (2) the “decision rule” that defines how MU is interpreted while mentioning compliance with a particular prerequisite is given [10].

The decision rule is of great significance in situations where the statement or the pertinent standard does not mention it.

The fresh standard [1] describes that in these situations the decision rule has to be announced to, and in agreement with, the customer. The matter in question is treated minutely in ISO/IEC Guide 98-4 [41]; this guide describes how restrictions, acceptance and rejection zones are defined. A Eurachem/CITAC guide [49] is also extremely useful for laboratories [10].

In terms of communicating results, ISO/IEC 17025 [1] enumerates frequent prerequisites for all kinds of laboratory tasks; while mentioning a laboratory implicated in sampling (linked with following testing or calibration), it shows that, where needed, important information about sampling has to be considered in the estimation of MU [10].

In the case of medical laboratories, ISO 15189 [15] states that medical laboratories have to: (1) define MU for each measurement method, (2) determine the efficiency features for each situation, (3) periodically revise evaluations of MU, (4) take into account MU when explaining measured quantity estimates. If demanded, the laboratory must render its evaluations of MU accessible to laboratory users [10].

6. Relationships Between the Laboratory and Its Providers

The laboratory is assisted by three kinds of CABs, that is to say calibration laboratories, RMPs and PT suppliers [54]. Their externally supplied services are extremely vital as they influence laboratory tasks and the global uncertainty budget [55]. Following ISO/IEC 17025 [1], the laboratory has to make certain that exclusively appropriate externally supplied products and services are employed. For this purpose, suitable methods have to be applied concerning criteria, records and transmission of prerequisites. In similar fashion, ISO 15189 [15] supports authenticated methods for the choice norms and acceptance following the laboratory's prerequisites [10].

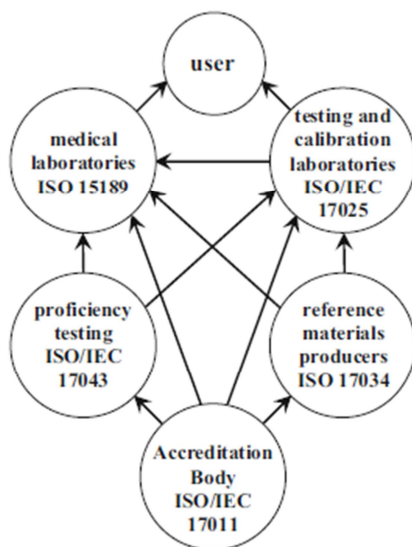


Figure 5. Reciprocal influence among a laboratory and other bodies, and the effect of the pertinent accreditation standards [10].

Figure 5 shows the relationships of the laboratory with its providers and the NAB; accreditation standards implementing in each situation may be employed as the choice norms.

These mutual relations corroborate that it is not sufficient for a laboratory to take into account at most the prerequisites mentioning its proper tasks. This may be crucial to the user also. Are all users of the MU sufficiently aware of how to employ this information? [10].

7. External Providers' Requirements

Moreover than the global prerequisites precisely fixed by ISO/IEC 17025 [1] or ISO 15189 [15], the laboratory has to define minutely with the MU prerequisites fixed in the standards mentioning the expertise of external providers (the pertinent accreditation standards) and to what should be proved by them [10]. Except that while laboratories are conscious and suitably prepared on the prerequisites linked to their providers will they are capable, not only to examine them, but also affirm their convenient registration. Professional expertise of the aforementioned providers is the principal choice norm.

7.1. Calibration Services

Every testing or calibration laboratory is asked to prove and preserve metrological traceability of its measurement findings [56, 57]. For a long period, it was not evident which must be the prerequisites to be satisfied virtually by the calibration services provider [10].

If the calibration laboratory is accredited, two additional interrogations require a positive reply: (1) is the specific characteristic comprised in the accreditation field? (2) Is the calibration and measurement capabilities (CMC) announced suitable for purpose? [10].

If this is not the situation, how does the calibration laboratory establish its metrological traceability? The laboratory to be served is asked to register that it has to estimate the case itself and suitably report it [10].

In any situation, it is foreseeable that NABs possess obvious policy to assist the aforementioned activity of the laboratory and the evaluation of the laboratory; this is needed in the framework of the estimation of the NAB by EA [10].

The preceding problems are treated in ILAC P10:2013 [44], a policy document established to assist the ILAC MRA. It obviously shows the necessity for the calibration laboratory to be accredited; but, it is accepted that this is not the single manner; consequently, additional fashions are defined therein [10].

The fresh ISO/IEC 17025 [1] adheres to the identical series and defines the case in an instructive Annex [10].

7.2. RMs

RMs are employed in all steps of the measurement procedure, comprising method validation, in-house calibration and quality control as well as in inter-laboratory comparisons.

(Note: The term “method” is employed in line with the ISO/IEC 17025 [1] whereas in VIM3 [58] the term “procedure” is employed instead. In ISO 15189 [15] the term “examination” is employed). ISO 17034 [17] mentions that the RMP has to treat, among others, the following: (1) determining uncertainty budgets and evaluating uncertainties of certified value (s), (2) describing acceptance norms for measurand levels and their uncertainties [10].

Moreover, the RMP has to: (1) give proof of the metrological traceability of the certified value to a mentioned reference, (2) recognize the uncertainty roles to be comprised in the specified uncertainty, (3) record the parameters influencing the uncertainty of the certified value [10].

Until lately, laboratory accreditation standards did not give much assistance. ISO 15189 [15] (and, identically the preceding version of ISO/IEC 17025 [6]) does not make any reference to ISO Guide 34 [59] which was employed as the foundation for the expertise of RMP, lately substituted by ISO 17034 [17]. Nevertheless, the novel ISO/IEC 17025 [1] advocates the usage of RMs [60] from producers who satisfy ISO 17034 [17] prerequisites. If the producer is accredited, expertise is recorded. If the producer is not accredited, the laboratory has to seek additional methods to prove the needed expertise [10].

7.3. PT Plans

Following ISO/IEC 17043 [18], the PT schemes supplier has to register and give details for a set of questions, comprising the origin, metrological traceability and MU of assigned values, considering all parameters comprising issues in homogeneity and stability [10, 61].

One of the objectives of interlaboratory comparisons is the validation of uncertainty chains [62-64]. In calibration, PT schemes must have assigned values with metrological traceability [65], comprising MU; in testing, metrological traceability and linked MU have to be established considering particular prerequisites [10, 66].

The laboratory accreditation standards give assistance on this problem. The novel ISO/IEC 17025 [1] mentions that PT suppliers, satisfying the prerequisites of the ISO/IEC 17043 [18], are viewed as expert. This could not be true with the former version of the standard [6] because the ISO/IEC 17043 [18] was released subsequently. Moreover, the ISO 15189 [15] affirms that the (medical) laboratory must play a role in schemes that greatly satisfy the prerequisites of the ISO/IEC 17043 [18]. In every situation, the specific scheme must also be indicated [67]. If the supplier/scheme is accredited, expertise is registered. If this is not the situation, the laboratory must research different methods to affirm the needed expertise [10].

7.4. Manner by Which Details Are Employed at the Laboratory

A laboratory employs details given by RMP and PT schemes considering it while planning its uncertainty budget [10, 68]. Their technological expertise needed is the principal

choice norm [69]. For this target, a fundamental interrogation is if they are accredited and, if this is true, if the specific task becomes their accreditation extent [70, 71]. Nevertheless, it is not every time practical to locate accredited providers in each domain, especially RMP; the accreditation standard of the ISO 17034 [17] has been documented lately, therefore not many RMP are accredited following it as yet. Even before this, not many RMPs had been accredited according to ISO Guide 34 [59].

In situation of no accreditation status, the laboratory must take another action of evaluating the expertise of the provider. In spite of how the provider proves expertise, the laboratory must be capable to conveniently announce and profit from the information the provider gives [10].

8. Overlapping ISO/IEC 17025:2017 into Big Data

As seen above, ISO/IEC 17025:2017 [1] is gaining a huge part in laboratory legal status and activities; in its side, Big Data is reaching high level of mastery and expansion [72].

On the other hand, there is a huge amount of data around and inside laboratory everyday activities. Besides the experimental and analytical results, there are findings from its financial management.

Big Data through its enormous capabilities of managing details would imbricate ISO/IEC 17025:2017 [1] (Figure 6). The near future would provide more details of how will be the final figure of this intersection.

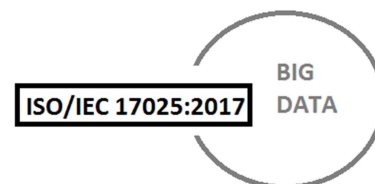


Figure 6. Overlapping ISO/IEC 17025:2017 into Big Data.

With a view to attain more accurate disease prevention, diagnosis, and treatment, clinical and genetic data need extensive and systematically associated study. As one way to achieve precision medicine, a laboratory information management system (LIMS) can effectively associate clinical data in a macrocosmic aspect and genomic data in a microcosmic aspect. Chen et al. [73] summarized the application of the LIMS in a clinical data management and implementation mode. It also discusses the principles of a LIMS in clinical data management, as well as the opportunities and challenges in the context of medical informatics. Chen et al. [73] concluded: “*Although there are many limitations and obstacles in the way of the clinical LIMS application, we firmly believe that a LIMS can facilitate the “seamless connectivity” between clinical data and genetic data, realize the system researches of disease, improve early disease prevention, also facilitate decision-making, improve quality and productivity of disease care services, promote the development of 4P medicine (predictive medicine, preventive*

medicine, personalized medicine, and participatory medicine), and, lastly, achieve precision medicine.”

At our best knowledge, Chen et al. [73] appear to be the sole researchers who mentioned Big Data and ISO/IEC 17025:2017 [1, 74-76]. This is an optimistic sign for a fruitful

combination between Big Data [77] and ISO/IEC 17025:2017 [1] (Figure 6).

Figure 7 shows some standards of quality management system where the data processing is required [74].

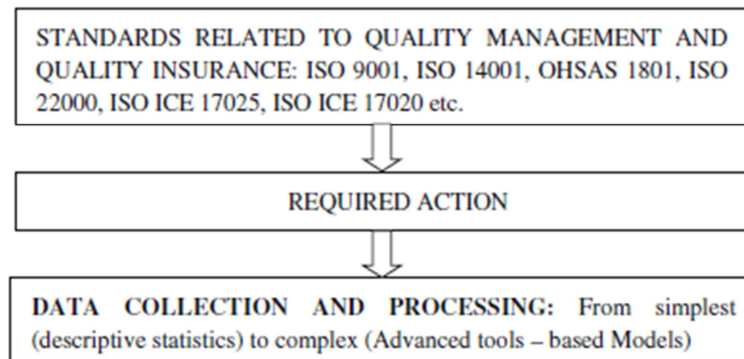


Figure 7. Principle of data—based quality management [74].

9. Forming ISO Engineers and Managers Specialists

Nowadays, it is unacceptable that after ending school, engineers and different much taught persons have no understanding of norms and standardization [75]. In matter of academic requirements, it is crucial that the suitable persons acquire understanding needed for their particular professional job (such as developers, designers, production control engineers and/or production management engineers, process analysts, inspectors, etc.). Executives must as well possess a global understanding on norms, particularly in the fields of business strategy, regulations, social responsibility and sustainable development. It is as well vital to increase consciousness on standardization as long as to obtain familiarity on the manner by which norms may be employed as an administration instrument. This specifically has relevance to the impacts of the initiation and application of norms in all types of institutions (manufacturing companies, service companies, Research and Development centers, regulators, etc.), as long as promoting products in the global market [75].

Because norms possess a crucial effect on practically all domains of existence and work, studying norms and standardization is a traditional training in industrialized nations [12]. Universities provide various programs/courses including the issues in the domain of standardization, which are convenient for several professional orientations. Even less industrialized nations are focusing more on this domain as standardization is comprised in formal academic courses. As an example, in some of these nations, like China and South Korea, particular organizations for the formation of students at various grades and in changing domains of standardization have been formed. Moreover, the discussion between academic organizations and national standardization bodies is fundamental as long as the dynamic implication of academic organizations in the procedure of acceptance of norms. The causes are multiple, and the advantages are mutual [75].

In 2016, before the arrival of ISO/IEC 17025:2017 [1], Saeed [76] asked this fundamental question: “Can single-operator laboratories comply with all of the requirements of ISO/IEC 17025:2005 [6]?”. Saeed [76] argued that ISO/IEC 17025:2005 [6] affirms that its prerequisites are “applicable to all laboratories regardless of the number of personnel” and would consequently comprise single-operator laboratories. Nevertheless, there are doubts as to if these laboratories can satisfy all of the prerequisites without threatening freedom of recognition and impartiality. In like manner, there are some prerequisites of ISO/IEC 17025:2005 [6] comprising staff supervision, internal communication processes and appointment of deputies that are supposed improbable to implement to a single-operator laboratory. Until now, the ISO/IEC 17025:2005 [6] remains largely employed as the international standard of quality assurance by which accreditation bodies evaluate the expertise of testing and calibration laboratories. A conflict, nevertheless, among accreditation specialists seems to occur when evaluating single-operator laboratories. Several accreditation bodies accredit single-operator laboratories, at the same time others need supplementary human resources before allowing accreditation [76].

Authors are unable to state about if such discrepancies remain in ISO/IEC 17025:2017 [1] since it is just published.

10. Conclusions

The main important points drawn from this review may be listed as:

ISO/IEC 17025:2017 is gaining a huge part in laboratory legal status and activities; in its side, Big Data is reaching high level of mastery and expansion. On the other hand, there is a huge amount of data around and inside laboratory everyday activities. Besides the experimental and analytical results, there are findings from its financial management. Therefore, Big Data through its enormous capabilities of managing details would imbricate ISO/IEC 17025:2017. The near future

would provide more details of how will be the final figure of this intersection.

In the following years, ISO management specialists should be formed and recruited besides engineers in every laboratory to help them in managing the laboratory's accreditation activities.

ISO 17025:2017 should have a clear limit and solid separation between its wise recommendations and well-established bureaucratic procedures. ISO 17025:2017's risk-based thinking should not neglect bureaucratic procedures viruses' infection in its own "do this" and "do not do that" instructions.

Acknowledgements

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Abbreviations

BIPM	Bureau International des Poids et Mesures
CAB	Conformity assessment body
CASCO	ISO Committee on Conformity Assessment
CITAC	Co-Operation on International Traceability in Analytical Chemistry
CMC	Calibration and Measurement Capability
EA	European cooperation for Accreditation
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	Information technology
JCGM	Joint Committee for Guides in Metrology
MLA	Multilateral Agreement
MRA	Mutual Recognition Arrangement
MU	Measurement uncertainty
NAB	National Accreditation Body
OIML	International Organization of Legal Metrology
PT	Proficiency testing
RM	Reference material
RMP	Reference material producer

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