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Implementing essential requirements of the ISO 17043:2023 for a proficiency testing provider as a step towards accreditation achievement

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ABSTRACT

Successful participation in Proficiency Testing/Interlaboratory Comparison (PT/ILC) schemes is a method to ensure validity of results for any laboratory. It is also a component of a complex of means for demonstrating technical competence of a laboratory as an organization. The new accreditation standard ISO 17043 for PT providers together with the newly updated ILAC Policy of PT participation introduce a different perspective on the activity of PT provider in regard to quality assurance.

Technical and management requirements from the ISO 17043:2023 that are essential for a competent activity of PT/provider are identified with a rationale for their increased importance. This importance is related both to the practical impact on the PT/ILC providers' customers (laboratories) activity and laboratory benefits of participation in PT/ILS schemes besides the traditional qualitative and quantitative interpretation of their participation.

Identified requirements are accompanied by a practical and explained potential implementation strategy which is aligned with the ILAC Policy on PT/ILC participation.

Successful implementation of the essential requirements of the ISO 17043:2023 is a necessary step for any PT/ILC provider that seeks credibility on the proficiency testing market. Such implementation may also be an important step towards full implementation of the ISO 17043:2023 and achieving accreditation thus benefiting from full confidence in the activities of the provider.

Keywords: accreditation, interlaboratory comparisons, ISO 17043, medical laboratory, proficiency testing

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Quality assurance plays an important role in any field of activity. Quality assurance has multiple valences ranging from consumers' protection, commerce fairness to technical competence. Of particular importance is the application of quality assurance in the healthcare field as the activities involved have a direct implication on the patients' well-being and safety. There are several tools that may be used to evaluate the quality of a service. An interesting example that demonstrates the wide range of quality assurance tools, i.e. a cross-sectional descriptive study, was used in anesthesiology and focused on patients' safety culture implemented as a survey with answering options on an ordinal scale of answers [1]. In case of medical laboratories, quality assurance is a combination of several components: traceability, control of records, internal quality assurance and proficiency testing participation. All these elements contribute to ensuring confidence in the quality of results, without giving prevalence of one component over the other, nor compensating one with another. Reference intervals and medical decision limit are important concepts for a medical laboratory activity and they are also integral part of the technical competence demonstration via accreditation as prescribed in the ISO 15189:2022 [2]. Reference intervals definitions are to be explored by each laboratory in order to ensure correct results.

Successful participation in proficiency testing/ interlaboratory comparison (PT/ILC) schemes is one of the

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key components of the quality assurance mechanisms for laboratories. Medical laboratories make no exception to this. It is important to reiterate that, while contributing to demonstration of technical competence, successful participation in PT/ILC schemes is not by itself a guarantee for technical competence of a laboratory but an option to ensure validity of results [3]. Given the importance of this activity, a medical laboratory must make an informed decision regarding the selection of a PT/ILC provider. The ILAC P-9 Policy [3] provides a list of criteria the CABs may be used when making the selection. Accreditation bodies have their own criteria that must be followed by accredited laboratories. These criteria are documented in specific Accreditation Bodies' (AB) Policies, some being more prescriptive, some leaving more room for decision for the laboratory [4]. Just like in case of any Conformity Assessment Body (CAB), technical competence can be achieved in several ways. Accreditation is one of the methods to demonstrate technical competence. Therefore, selecting a PT/ILC provider that is accredited against the dedicated accreditation standard ISO 17043 [5] by an AB signatory of the ILAC-MRA accord is always an enough proof of technical competence [6]. However, technical competence can also be achieved without accreditation. For example, Finland's AB acknowledges PT/ILC schemes organized by highly respected professional societies as technically competent [7]. Ultimately, the laboratory is responsible for confirming the technical competence of the PT/ILC provider by any of the available means: ISO 17043-accreditation, reputation of the organizer or even an individual assessment carried by the laboratory of the PT/ILC provider against essential requirements of the ISO 17043.

From the perspective of a PT/ILC provider, the ILAC P-9 Policy [3] is also applicable. As a general rule, in order to be considered adequate, the provider must fulfill at least the following two criteria: i) its services be offered in national language or in a language that the CAB has professional competency; ii) participation results must be available in a timely manner as formalized by the CAB's participation plan. The technical competency of the PT/ILC provider has a multiplication factor because based on the issued reports, there might be a direct impact on its customers: accreditation status in case of accredited laboratories, access to funding (e.g. insurance companies). Also, based on the participation reports, the laboratory might make decisions of keeping or replacing an equipment judging it fit/unfit for the intended technical activity. In several cases where the CAB uses PT/ILC to evaluate its staff, the impact of the PT/ILC provider extends to the CAB employees too. The ISO 17043-accreditation criteria, being part of a respected professional organization are not mutually exclusive criteria for establishment as technically competent on the proficiency testing market. A PT/ILC schemes organized in an accredited framework by a respected professional organization greatly increases the credibility of the provider on the market. Meeting those two criteria also boosts trust in the impartiality of such a PT/ILC organizer. Achieving ISO 17043 accreditation can be a challenge for many PT/ILC providers given the volume of resources needed (incl. logistics) but also human expertise for each marketed scheme and applied statistics. Without implying there is a hierarchy in the importance of each accreditation requirement, several of them are essential for a minimalistic run of PT/ILC schemes in a credible fashion.

ISO 17043 [5] is the accreditation standard for PT/ILC providers. The document has an important section of Terms Definitions. These definitions are of importance since the implementations of the requirements must reflect the intended purpose of terms used. The essential terms are: interlaboratory comparison, outlier, proficiency testing item, proficiency testing provider and standard deviation for proficiency assessment. The standard has four broad sets of requirements grouped in five separate sections: General, Structural, Technical (Resource and Process) and Management System. The standard also includes two informative Annexes that explain various types of PT schemes and a summary (from the ISO 13528 [8]) of the most widely used statistical methods in PT/ILC activities.

Any activity in an accredited framework assumes a high level of impartiality and a certain degree of confidentiality. ISO 17043 introduces a set of impartiality requirements and a set of confidentiality requirements including details of special cases when confidentiality can be breached. While rather abstract in formulation, these two sets of requirements are key to establishing a high level of credibility of the PT/ILC provider since technical competence might not always be synonymous to credibility.

The Structural set of requirements outline the basic criteria that have to be met by the PT/ILC provider as an organization. At this stage, roles and limits of authority and responsibility have to be defined. Communication principles and references to integrity of the management system are identified.

The Technical requirements are grouped as Resource and Process requirements. A competent PT/ILC provider must have access to personnel, facilities, equipment, systems and support services necessary for its activities. Proficiency testing items in the medical field must be assessed for homogeneity and stability according to the ISO 15189 [2]. An important part of the PT/ILC provider is the individual technical competence and limits

of authority and responsibility of the personnel. These detailed requirements are defined in Chapter 6.2 of the ISO 17043. Access to facilities is essential for reliable activities of a PT/ILC provider and ISO 17043 provides requirements especially for facilities and environment conditions. It is important to mention that "facilities" do not refer only to constructed areas but also to equipment. Most PT/ILC providers use external products and services (e.g. the computing platform, the computerized information systems). However, not all the activities of a PT/ILC provider can be outsourced. The non-outsourceable activities are individualized and it can be inferred that they are at the core of any PT/ILC providers. As with any outsourced activity, there must be a strict control of records, including acceptance criteria for the products and services acquired. Setting up a PT/ILC provider is not enough to provide a high-quality service. The provider must define at least the objectives of the offered schemes and acceptance criteria for interested participating laboratories. The ISO 17043 [5] outlines detailed requirements for communication with participants. Planning and design requirements are detailed in the accreditation standard with focus on meeting customer requirements. There are also requirements for the statistical design which, besides being sound from the mathematical point of view, has to meet the declared objectives of the PT/ILC scheme. Special cases (e.g. small number of participants) are highlighted by special requirements. Determination of the assigned value is another critical aspect when designing and running a PT/ILC scheme. Documented procedure for establishing the assigned value, including the measurement uncertainty (especially in the case where the assigned value is determined as consensus values). Homogeneity and stability tests of the proficiency test items is especially important when the PT/ILC is preparing and packing the items in-house rather than just distribution of purchased items. Proficiency test items storage, handling, packaging, labelling, and transportation are regulated in dedicated requirements since these can influence the outcome of the participation results. Given the variability of PT/ILC schemes, instructions for participants play an important role and ISO 17043 [5] defines very detailed requirements a PT/ILC provider must fulfill in order to minimize the chance errors due to suboptimal communication. Evaluation of participation requirements are linked to both data analysis requirements and statistical design all contributing to effective evaluation of performance of the participants. The level of detail for requirements of the PT/ILC participation report mirrors the one from the participation instructions thus minimizing the risk of misunderstandings in the report on the participant side or legitimate 3rd party recipient of the report. Any qualitative activity must have a feedback loop including complaints and appeals to the decision. ISO 17043 [5] details the set of requirements for dealing with handling complaints and appeals to the reports published.

The last set of requirements of the standard deals with the management system. These requirements are aligned with the ones specified in the ISO 9001 [9] and comprise the following: control of records, risk based-approach in the implementation, corrective action, internal audits and management reviews.

Careful analysis of the new ISO 17043 [5] must take into account the fact that this version offers a higher flexibility for the PT/ILC provider. That means the quality manual, the designated quality manager and technical manager are no longer required. From the quality management system documentation, the document control procedure, and master document list are also no longer required. In terms of procedural contents, the planning does no longer require name and the address of the PT/ILC provider, nor the name of coordinator. It is important to highlight that reducing the documentation volume does not make them obsolete or irrelevant. However, this is important to be taken into consideration especially by the PT/ILC providers that focus only on the essential requirements of the ISO 17043 as a preliminary step towards full implementation seeking accreditation. This reduction in requirements aligns the ISO 17043 [5] with ISO 15189 [2] and ISO 17025 [10].

In terms of definitions, the new ISO 17043 [5] is also applicable to ILC providers not only to PT providers as seen as entities that organize PT schemes but they do not participate themselves. An important definition is the one for outliers. In this scope, it is further explained such that action signals are not necessarily triggered by outlier values. The clarification is important since there is a wide reductionist approach according to which only outliers can trigger signal actions. This observation is of major importance when developing the statistical methods to be used.

Thorough implementation of the Impartiality requirements ensures an increased trust in the services provided by the PT/ILC provider. One of the best ways to implement these requirements is to first collect the statements of conflict of interest from each member of the organization that might trigger a conflict of interest. The ISO standards do not provide a final definition for conflict of interest, therefore the safest way for the implementation is the use of the one defined by local legislation where the PT/ILC operates. In the widest acceptance legal doctrine terminology, conflict of interest is defined as a situation where a person exercising a decision role in the PT/ILC provider's activity has a personal

interest of patrimonial nature which could influence the objective fulfillment of assigned duties. As noticed, this definition involves a certain level of uncertainty, therefore a possible approach for the implementation of the Impartiality requirement is the use of a risk analysis for each decision-maker person of the PT/ILC provider.

The first section of the web-portal (public interface) should list all the documents required by the ISO 17043 [5]: quality policy, confidentiality statements, impartiality statements, complaints procedure, available schemes (including objectives), sample participation contract, applicable fees, minimum participation criteria for interested participants etc. At this stage, potential participants should have an option to electronically provide objective evidence that they meet the general participation criteria set by the PT/ILC provider. If successful, a personalized client-account is automatically generated together with the participation contract. In order to further increase confidentiality, the system should require the customer to update the login credentials yearly.

The second section of the web-portal (client area) should allow the customers to select their desired PT/ILC schemes and add them to a shopping-cart with an e-payment option included. Effective implementation of the communication requirements is via a message center in the client area. Once the participation in a specific scheme is registered, relevant information should become available (e.g. instructions, timelines, etc.). The message center should also allow bidirectional message exchanges with the PT/ILC provider for optimal communication. The client area should allow the participant to input their results and submit via the web-portal. Especially in the case of the medical laboratories where there several types of measurement units, in order to minimize risk of misreporting, the customer should be allowed to select their routine measurement units and the system should automatically convert to S.I. units and perform the further computations in S.I. units. Participation reports should be delivered as attachments to the messages delivered to the message center and simultaneously the appeal form should become available for the time-window defined by the PT/ILC and specified in the publicly available documents. As a rule of thumb, five business days should be enough for a participant to evaluate the obtained results report and make an informed decision on whether to appeal or not.

The third section of the web-portal (administration area) should allow the PT/ILC provider to perform all the activities except the proficiency testing item preparation and packaging namely: documentation update, interaction with participants via the message center, validation and verification of the automatically statistical engine generated participation reports, final authorization of reports, etc. Clearly, the administration area sections should have feature restricted access for PT/ ILC provider personnel based on their role and authorizations in the organization. Traceability should be readily available for each activity for both customers and PT/ILC provider's staff by means of an audit trail (automatic logs) containing at least the computer IP address, username and time-date stamp from where the activity occurred. Also, the web portal should allow the feature of sending automatic instant messages to the contact number of each participant for each milestone of the interaction with the customer: proficiency testing item dispatch, reminder to submit the results when deadline approaches and reports available.

While the three sections are relatively common for every web portal that translates to a paperless business, the statistical engine is the major feature of a PT/ILC provider web portal. The ISO 17043 [5] specifies the PT/ILC provider is responsible for design and adequate statistical methods. This means that the provider is free to define their own statistical methods on the assumption these methods can be mathematically proven as sound. ISO 13528 [8] is a standard that specifically describes statistical methods for PT/ILC providers. All mathematical models are detailed and sample datasets are available. This is a useful feature since these datasets can be used for validation of the statistical methods used by the PT/ILC provider. The presented methods, if implemented adequately, are considered fit for most common PT/ILC schemes, including the ones in the medical laboratories field. It is true that the PT/ILC provider may decide to implement personalized statistical models, but in this case, these must be individually proven as mathematically adequate. It is important that the statistical engine is implemented in such a way that the potential outliers are automatically identified yet leaving the statistical expert and field expert of the PT/ILC provider to decide if those values are indeed outliers to be treated as such or not.

It is true that the new version of ISO 17043 [5] no longer requires a statistically random selection of PT items for homogeneity assessment nor a homogeneity assessment prior to PT items shipping, yet such a procedure is useful, especially in the case where the PT/ILC provider is preparing the PT items not just dispatching purchased items which are accompanied by a quality certificate. A simple yet effective way to validate homogeneity and stability is to run an inferential study on the classical pattern of inferential statistics: H0 (null hypothesis) there is no statistically significant difference between the measured samples and if such a difference is observed, it is due to sampling/measurement errors; H1 (alternative

hypothesis) there is statistically significant difference between the measured samples and such a difference is observed, it is not due to sampling/measurement errors. Decision of accepting the alternative hypothesis or failing to reject the null hypothesis is made by comparing the calculated F-value with the Distribution Table of the F-values at the confidence level of 95%. Starting with 10 test items on the first run is a large enough sample with an option of decreasing the number on the subsequent runs in case of success and assuming the preparation condition and source has not changed. An interesting option to further ensure PT items remains viable during transportation is to add an irreversible temperature-sensitive strip so that the participation would know if the sample was in a correct temperature range at all times during transportation.

Running PT/ILC schemes is first and foremost a great responsibility activity given the various impacts on the activity of the laboratories. Performing the activities in a quality environment provides confidence for the participating laboratories. Given the diversity of challenges for the provider (technical experts, statistics experts, resources to generate reliable PT items that genuinely mimic the routine samples analyzed in the laboratory, etc.) it is always best to couple the formal implementation of the ISO 17043 [5] demonstrated by an accreditation certificate with the reputation of the PT/ILC provider on the market. Ensuring commutability, even though not expressly required by the accreditation standard, brings added benefit to the participating laboratories by ensuring they meet the mandatory participation criteria in terms of technical requirements (e.g. no restriction on the testing method). Obviously, it is difficult to create a hierarchy based on the importance of the requirements yet the ones provided with the implementation details should allow at least a minimalistic functionality in terms of credibility for a PT/ILC providers.

The essential requirements of the ISO 17043 [5] are best implemented using a unitary approach via a web-based portal. This approach offers several advantages: i) full traceability of activities, ii) rigorous control of records, iii) efficient use of resources and sustainability by using as many e-records as possible, iv) ease of customizing further implementation at the revision of the accreditation referential. The entire web portal should have a webshop architecture with several modules: client area, administration area, and statistical processing engine.

Practical details of implementing the essential requirements to demonstrate technical competence of a PT/ILC provider were introduced. This implementation may be viewed as a first step towards full implementation and accreditation. An ISO 9001 [9] certified implementation greatly supports full implementation of the ISO 17043 [5] since the management system requirements are essentially the same.

AUTHORS' CONTRIBUTION

Dan Adrian Luțescu, Ruxandra Ionela Sfeatcu, Laura Iosif, Andreea Wagner, and Ana Maria Cristina Țâncu declare equal contribution with the first author.

All authors have read and agreed to the published version of the manuscript.

CONFLICT OF INTEREST

None to declare.

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