sciendo Revista Română de Medicină de Laborator 2024;32(2):123-134 REVIEW
DOI:10.2478/rrlm-2024-0014

A comprehensive review of Proficiency Testing / Interlaboratory Comparisons Policies of the EA-MLA signatories applicable to medical laboratories

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ABSTRACT

Introduction: Proficiency Testing/Interlaboratory Comparisons play an important role that is widely accepted in demonstrating the validity of results of any laboratory and inspection body. To ensure a coherent approach in the field within an economy, accreditation bodies develop specific policies for laboratories and inspection bodies' participation in proficiency testing/interlaboratory comparisons.

Methods: 39 Proficiency Testing/Interlaboratory Comparisons policies of accreditation bodies were reviewed for key requirements: initial accreditation, participations of accreditation per accreditation cycle and acceptance criteria of PT/ILC providers.

Results: Within the analyzed policies a wide range of approaches was identified especially for the number of participations and acceptance criteria set by different bodies

Conclusions: Even though the analyzed policies belong to accreditation bodies which are signatories of the same regional agreement, there is no harmonized approach with respect to Proficiency Testing/Interlaboratory Comparisons usage in the accreditation process

Keywords: accreditation, interlaboratory comparisons, medical laboratory, proficiency testing, quality assurance

Received: 16 March 2024; Accepted: 25 March 2024; Published: 2 April 2024

INTRODUCTION

Quality assurance plays an important role in the medical field. Kazamer et al. [1,2] describe a questionnaire-based method applied to physicians which can be used at the clinical level in order to better understand the challenges related to patient safety in the hospital Intensive Care Units.

There are several methods by which laboratories (medical, testing, calibration) and/or inspection bodies demonstrate the validity of their results. In the accreditation terminology, laboratories and inspection bodies are referred to as Conformity Assessment Bodies (CAB). It is worthwhile mentioning that there is no hierarchy of importance for these methods (internal control, audits, external quality assurance) nor a precedence of one over the other. A novel strategy for developing quality assurance for hematology is based on two models namely Medical Decision Level and the mean value of each QC level is described [3]. Each method provides its input for the management analysis to continuously improve CAB's quality management system (QMS). External Quality Assurance (EQA) provides valuable input and helps identify possible systematic errors in routine activity because the CABs results are compared to other CAB results or the reference value. There are two main ways of implementing an EQA program (proficiency testing and interlaboratory comparisons). The main difference is that proficiency testing is organized and run by a non-participant 3rd party, while interlaboratory comparisons are organized and run without third-party involvement. The workflow is essentially the same in both strategies (design, planning, sample preparation, sample shipment, data collection, statistical processing, and results dissemination). For proficiency testing organizers, there are supplementary requirements (i.e., management requirements)

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should accreditation be envisaged as a matter of proving technical competence. The whole set of requirements is detailed in the ISO 17043 standard updated in 2023. The wide range of tests carried out in laboratories (both testing and medical) or types of calibrations performed (in the case of in calibration laboratories) makes it sometimes problematic to identify a suitable proficiency testing organizer. Besides the issue of identification of a potential PT-provider, there are other equally important challenges that need to be overcome. For example, the potential PT-provider, might be geographically distant or the round of interest is run at a time that is not useful for the CAB, i.e. in the distant future. There are also cases where the proficiency testing market is very limited in terms of the numbers of providers operating on the global market [4], which also narrows the realistic options of a CAB for securing an adequate EQA program. In these cases, interlaboratory comparisons are a viable option for an EQA program.

The aim of facilitating trade by promotion of acceptance of accredited tests and calibration results was achieved by setting up the International Laboratory Accreditation Cooperation - Mutual Recognition Arrangement (ILAC – MRA). This international accord consists of 114 signatory accreditation bodies worldwide with 100.000 laboratories, 14.400 inspection bodies, 680 proficiency testing providers and 290 reference materials producers that benefit from results mutual recognition via accreditation on applicable standards (ISO 17025, ISO 15189, ISO 17043, ISO 17034) [4]. Membership of the accreditation bodies seeking the status of the ILAC – MRA signatory is mainly subject to successful peer review against the requirement of ISO 17011 standard by an assessment team appointed by at least one recognized regional (usually geographical) cooperation. These are: Inter American Accreditation Cooperation (IAAC), European co-operation for Accreditation (EA), Asia Pacific Accreditation Cooperation Incorporated (APAC), Arab Accreditation Cooperation (ARAC), African Accreditation Cooperation (AFRAC), Southern African Development Community Cooperation in Accreditation (SADCA). The Structure of the organizations is pyramidal as detailed in a previous work [5]. The ILAC – MRA Document Portfolio consists, besides the Scope and Obligation of signatories, of several packages of high-level documents the most relevant being the Policies (P-Series), Rules (R-Series), and Guidance (G-Series). While these documents are not directly applicable to CABs but to accreditation bodies (AB), they contain important information and references for CABs which help develop their own documentation because these are the highest-level documents possible. The rationale for this is that each AB has to develop its own policies and regulations which are to be in accordance with the corresponding ILAC documents. For a medical laboratory, the most relevant documents are: ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing [6], ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results [7], ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration [8], ILAC R7:05/2015 Rules for the Use of the ILAC MRA Mark [9], ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing [10], ILAC G24:2022 Guidelines for the determination of recalibration intervals of measuring equipment [11].

In the framework of this review, starting from the ILAC P9:01/2024 Policy [6], the corresponding ILAC-recognized European regional cooperation document and the corresponding national policies with respect to the use of proficiency testing activities in the accreditation process were analyzed. Since the focus of the review is on medical laboratories, only the policies of the accreditation bodies that are signatories of the EA-MLA for medical laboratories ISO 15189[14] were included.

European Cooperation for Accreditation is a Dutch-registered non-profit association appointed by the European Commission by Regulation EC 765/2008 to develop and maintain a multilateral agreement of mutual recognition, based on a harmonized accreditation infrastructure [12]. Just like in the case of ILAC-MRA, the purpose of the agreement is to facilitate fair trade and reduce technical barriers to trade [13]. The corresponding ILAC-MRA agreement is the EA – MLA (EA Multilateral Agreement). However, unlike in the case of ILAC-MRA, membership to EA-MLA is further limited to accreditation bodies that among others: i) have been appointed by the Government as the single national accreditation body, ii) operate accreditation as public authority activity generally limit their activities within national borders with clear limited exceptions as outlined in EC 765/2008. It is important to highlight that EA-MLA signatories are not only accreditation bodies from the European Union Member States but also other countries. In fact, while the EU comprises 27 Member States, the EA-MLA has 49 accreditation bodies signatories [13]. There is no specific requirement regarding the entity type of the accreditation body, therefore there is a breadth of organizational types: Government agencies, departments within a specific ministry (usually Minister of Economy) or non-governmental entities which have specifically been delegated to perform accreditation functions on behalf of the Government.

METHODS AND RESULTS

The main aim of the review is to gather knowledge about practices at the European Level in the field of policies

of using PT/ILC in the CABs activity. Some accreditation bodies have specific requirements for medical laboratories which might be useful for the labs operating in a different economy and still find these requirements useful for developing an adequate PT program and a sound justification for the level of participation and frequency of participation. The review is based on the policies published and freely available online on the web pages of ABs, ILAC and EA.

Updated in 2024, the ILAC P-09 Policy [6] sets forth the ILAC policy regarding the use of proficiency testing and/or Interlaboratory comparisons other than Proficiency Testing in demonstrating technical competency by accredited CABs. While the main purpose is to set the requirements regarding the use of proficiency testing and/or Interlaboratory comparisons for AB seeking ILAC membership, this Policy also provides useful information for CABs for an informed and consistent approach with respect to EQA program participation. The updated ILAC P-09 [6] document is mainly motivated by the recent updates of the accreditation standard of medical laboratories (ISO 15189) in November 2022 [14] and proficiency testing providers (ISO 17043) in May 2023[15]. The document clarifies it is applicable to all types of testing laboratories, medical laboratories as well as calibration laboratories. The document clearly defines a *proficiency testing* and the *interlaboratory comparisons.* The Policy clarifies the role of EQA participation as "*an integral part of monitoring the validity of results*". From the operational point of view, the CAB often has to decide between selecting an EQA offered by a PT provider or an ILC. That is especially the case when the tests performed by the CAB are not very common, therefore there is limited availability on the EQA market. The Policy recommends the prevalence of the PT provider selection over the ILC. It is worthwhile mentioning that, although in an informative section of the Policy, practical criteria for *availability* are defined: i) offered in the national language or a language understood by the CAB; ii) participation results available in a timely manner, with respect to the requirements of the CAB and *appropriateness* of a PT – scope is similar to the current practice of the CAB. The Policy requires accreditation bodies that are ILAC-MRA signatories to define their own Policy with respect to CABs' EQA program. It is important to mention that the ILAC P9 [06] does not stipulate the volume and frequency of an EQA participation of a CAB. It is the CAB that has to define its participation program and this program should be developed by a customized risk assessment for each CAB. Therefore, it is the CAB's plan that generates the volume and frequency of participation and the assessment towards accreditation has this participation plan as a starting point. The accreditation body must assess that the participation plan is *satisfactory* for the entire accreditation scope before granting an accreditation. Accreditation bodies must ensure that the CAB implements prompt and corrective actions in case of unsatisfactory participation results. Since there is no prescriptive requirement of always selecting a proficiency testing provider and the CAB has the choice of selecting an alternative approach, i.e. laboratory intercomparisons, the accreditation body must assess the rationale for this decision of the CAB. Also, according to ILAC P9, the accreditation body has to document in its own Policy how it deals with cases when a CAB uses PT and or PT/ILC other than PT and in cases when a CAB has demonstrated poor performance. The accreditation body must define the measures to be taken when CAB's participation plan is deemed unsuitable with respect to accreditation scope. Since the CAB can choose an ILC program, the accreditation body must ensure that the CAB has obtained evidence of the technical competence of that ILC provider. Even though at the informative level, the ILAC P9 exemplifies, without establishing a hierarchy, types of evidence that may be taken into account when selecting a provider: i) ISO 17043-accredited provider by an ILAC-MRA signatory for PT, ii) ISO 17043-accredited provider by a non-ILAC-MRA signatory, iii) ILC organized according to the relevant requirements of the ISO 17043. ILAC P9 specifies that only i) is considered formal recognition of technical competence. For the rest, it is the CAB that has to demonstrate the technical competence of the selected provider.

At the European regional cooperation level, the EA – MLA documents, do not have a mandatory policy for PT/ILC participation for the signatory accreditation bodies. The Document EA – 4/18: 2021 [16] is a Guidance document which contains a set of recommendations for accreditation bodies when assessing the volume(level) and frequency of participation of a CAB under assessment. The Guide [16] lists a set of 12 items for the level risk assessment. These items span from metrology to personnel structure and frequency of tests. The document also clarifies that ILC may be an appropriate option. For the level of participation, it is acknowledged that participation for every measurement process and every characteristic is an ideal case while in practice, the CAB must document its subset of participation with appropriate technical justification [16]. The milestones for a sound justification are: i) technical competence, ii) measurement process and iii) characteristics/products. With respect to the lifecycle of a participation plan, [16] recommends developing it for at least 1 accreditation cycle with the option of an annual update after the annual management review. The Guide [16] also has six practical examples for different types of laboratories. There are two cases for medical laboratories. In both ex-

amples, the first step is to identify all the measurement processes and all the characteristics from within its activity scope. As a second step, technical competence is defined either based on sample type or the impact of the measurement result. The level of participation can either be prescriptive by national legislation or can be identified by the CAB based on the risk assessment. In both cases, it is shown that each laboratory technique and each device should be individualized in the participation program.

In Belgium, the National Accreditation Body (BELAC) documented the use of PT/ILC in the BELAC 2-106 Rev 2-2022 document [17]. This document identifies the BELAC requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories. The document is not prescriptive with respect to the frequency of participation of each CAB, the assessment being focused on the individual participation plan of each CAB and the rationale defining the frequency. For the level of participation, the key document is the CAB's own risk analysis based on the 12 items exemplified in the EA – 4/18:2021 document, again without any specific prescriptive requirements. BELAC acknowledges the usefulness of ILC, especially in the cases where it is difficult to identify an appropriate provider, having in mind the concept that the PT provider is considered a service supplier. It also acknowledged that the adequacy of a provider may also take into account the "*price/efficiency ratio*" as stated in section 4.2.1 of the Document. Specific criteria for selecting the provider, the suitability of the risk assessment used when determining the level and frequency of participation, how the CAB established the competence of the provider and all the derived aspects are a matter of onsite assessment.

In Bosnia and Herzegovina, the National Accreditation Body (BATA) documented the use of PT/ILC in the OD 07 – 04 document [18]. This document identifies the BATA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories. BATA requires laboratories to have at least one successful participation for each major technical area prior to accreditation granting/extension. The document is not too prescriptive with respect to the frequency of participation of each CAB, yet at least one successful participation must be achieved for each subdiscipline during an accreditation cycle (4 years). The final frequency of participation is to be determined by the CAB based on a risk analysis taking into account items exemplified in the EA – 4/18:2021[16]. With respect to selection criteria for PT providers, BATA recommends, with priority, providers accredited according to ISO 17043. However, BATA acknowledges there are cases when suitability and accessibility reasons determine the CAB not to use an ISO 17043-accredited PT provider. Criteria for accessibility are: operated in the official languages of Bosnia and Herzegovina or English. Criteria for suitability are: similarity to daily CAB routine and economic aspects. The document strengthens that economic aspects should not prevail over the accreditation criterion and from the economic point of view, suitable means:" no *significant impact on the overall cost of the test service*" as stated in the 5.4 requirement. The CAB may use ILC and this is accepted by BATA if a proper justification is provided for selecting an ILC over an accredited PT provider. Both the participation plan derived from the risk analysis and the justified selection of the PT/ILC are evaluated during the assessment. The document also has provisions for the case when a CAB has a repeated unsatisfactory performance in proficiency testing.

In Bulgaria, the National Accreditation Body (BAS) documented the use of PT/ILC in the QR- 18 document [19]. This document identifies the BAS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories. BAS requires laboratories to have at least one successful participation prior to accreditation granting. The document is not too prescriptive with respect to the frequency of participation of each CAB, yet at least one successful participation must be achieved for each "*subfield*" during an accreditation cycle (4 years). The definition of the subfield is the responsibility of the CAB taking into account the examples and definitions in the EA – 4/18:2021. The level and frequency of participation have to be documented and evaluated during the assessment and justified by means of a risk assessment. BAS recommends the use of 17043-accredited PT providers either by BAS or EA, APLAC, ILAC, EURAMET, BIPM, European Commission or other organizations entitled to organize PT rounds. This list is detailed in section 3.2.2 in the document, without establishing a hierarchical structure for the selection. In case the CAB is not able to find a suitable PT provider, the CAB must apply for formal confirmation by the Technical Committees of BAS that indeed in that particular case, there is an impossibility to find a PT provider. Also, the CAB should detail the unsuccessful research done in order to identify a suitable PT provider.

In Croatia, the National Accreditation Body (HAA) documented the use of PT/ILC in the HAA-PR-2/6 document [20]. The document identifies the HAA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories except for the frequency of participation which must be at least the minimal legal

requirement. Prior to accreditation granting, the CAB must successfully participate in the PT round for at least one subdiscipline while for the rest, in case of no participation, other ways of ensuring the validity of results. The level and frequency of participation must be documented in the participation plan for the entire accreditation cycle (5 years). Determination of the level and frequency of participation is established by means of a risk assessment. The document clarifies that HAA accepts as proof of technical competence schemes organized according to ISO 17043. HAA recommends, without specifying a hierarchical structure, the use of schemes accredited to ISO 17043 and schemes organized by qualification-proven entities. The document specifies it is the responsibility of the CAB to identify the adequate PT schemes which also must be "*economically justified*" as detailed in 5.2.2.

In Cyprus, the National Accreditation Body (CYS-CYSAB) documented the use of PT/ILC in the Procedure 8 document [21]. The document identifies the CYS-CYSAB requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency participation. For Clinical Laboratories, the CAB must participate with all parameters. Also, all the matrices must be included in the participation plan. There is no need for participation for computational parameters as long as the results for parameters involved in the computation fall within ±2 range of Z score. For Molecular Testing Laboratories, the CAB must ensure all the subdisciplines and matrices have to be covered but not all the parameters. A prerequisite for granting accreditation is successful participation for each subdiscipline in the accreditation scope. Identification of the "*subdiscipline*" and the "*parameters*" is detailed in Annex 2. The CAB is responsible for documentation of the participation with details for level and frequency. These have to be established based on a risk assessment which is exemplified in the Annexes of the Procedure. Yet, for Clinical Laboratories a volume of 10 participations/year is suggested. Regarding the choice of the PT-provider, the Procedure offers a hierarchical criteria list of providers – art. 4.1 and art. 4.2: ISO 17043-accredited providers that document compliance to ISO 17043 and only in case of non-availability ILC can be considered. Should the CAB choose a provider that is not accredited to ISO 17043, it is the CAB's responsibility to establish compliance with ISO 17043 requirements.

In Czechia, the National Accreditation Body (CAI) documented the use of PT/ILC in the MPA 30-03-23 document [22]. The document identifies the CAI requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency participation. A prerequisite for granting accreditation is successful participation in proficiency testing. The CAB is responsible for documentation of the participation plan with details for level and frequency for at least 1 accreditation cycle. These have to be established based on a risk assessment with exemplification from EA – 4/18:2021. CAI preferentially accepts participation in ISO 17043-accredited programs by EA/MRA as described in 6.6 for selection criteria. Only in cases such providers are not available, other programs are acceptable if they are "*open and transparent*", yet, the responsibility for evaluation of such a program falls to the CAB.

In Denmark, the National Accreditation Body (DANAK) documented the use of PT/ILC in the AB-3 document [23]. The document identifies the DANAK requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency participation. Annex 2 clarifies that the CAB is responsible for subclassifying the scope of accreditation and thereafter deciding the volume of participation. PT participation must be documented in a plan that enables the evaluation of the whole accreditation scope. It is acknowledged that one subarea ensures representativity for the whole scope. Regarding the frequency of participation, DANAK exemplifies a method based on the metrological traceability to S.I. units and CRM. Furthermore, is clarified that CAB is free to identify other criteria for the level and frequency of participation. ILC must be used when PT-providers are not available with establishing a set of criteria for PT-providers as stated in 3.2.

In Estonia, the National Accreditation Body (EAK) documented the use of PT/ILC in the EAK J5 – 2016 document [24]. The document identifies the EAK requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in one PT/ILC round for each parameter within the accreditation scope. The CAB is responsible for documentation of the participation plan with details for level and frequency for at least 1 accreditation cycle (5 years). The level and frequency of participation defined and documented in the participation plan must be developed based on the guidelines of the EA – 4/18:2021. Regarding the choice of the PT-provider, there is no hierarchical criteria list but participation in schemes organized according to ISO 17043 is recommended as specified in 2.1. It is also recommended to use the EPTIS [25] database for selection of providers.

In Finland, the National Accreditation Body (FINAS) documented the use of PT/ILC in the A2 document [26].

The document identifies the FINAS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. The CAB must develop a 4-year participation plan (1 accreditation cycle) documenting the level and frequency of participation based on a risk assessment analysis. Prior to accreditation granting, the CAB must demonstrate correctness and comparability of results by means of reference measurements or another way, e.g. PT/ILC. Regarding the choice of the PT-provider, there is no hierarchical criteria list, yet the organizer must meet the ISO 17043 criteria or be a well-known organization in the field as stated in 1 – General Principles. The participation plan must take into consideration also other requirements, if any, of public authorities, professional organizations, etc.

In France, the National Accreditation Body (COFRAC) documented the use of PT/ILC in the SH REF-02 document [27]. The document identifies the COFRAC requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. Prior to granting accreditation, the CAB must participate with satisfactory results in PT rounds if available in a timely manner. Medical laboratories must participate at least yearly or even quarterly in PT rounds. The level and frequency of participation must be documented in a participation plan developed, based on a risk analysis. The items taken into account in the risk analysis can be CAB-defined (e.g. level of matrix commutability) or EA – 4/18:2021- defined. Also, the plan must consider mandatory legally required participations and the plan must encompass all the examinations within the scope of accreditation.

In Germany, the National Accreditation Body (DAkkS) documented the use of PT/ILC in the 71 SD 0 010 document [28]. The document identifies the DAkkS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. However, the CAB must participate at least once per accreditation cycle for each subdiscipline in the accreditation scope. Prior to accreditation granting, the CAB must successfully participate in each technical area from the accreditation scope. The level of and frequency of participation must be documented in a participation plan developed based on a risk analysis. The plan must be developed for 3-5 years ahead. It must take into account specific legal requirements in the field of CAB activity regarding PT participation.

In Hungary, the National Accreditation Body (NAH) documented the use of PT/ILC in the NAR-03 document [29]. The document identifies the NAH requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. The Medical laboratory must participate at least 4 times/year in proficiency testing as specified by the Dec. 60/2003 of the Ministry of Health. The level and frequency of participation must be documented in the participation plan which is to be developed based on a risk analysis. The minimum level (for all CABs) of participation is once for each technical area per accreditation cycle (5 years). For medical laboratories, the preferred choice of the provider is an ISO 17043--accredited one as defined in 4.7.

In The Republic of Ireland, the National Accreditation Body (INAB) documented the use of PT/ILC in the PS 1 document [30]. The document identifies the INAB requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. CABs must participate in EQA schemes for immunohistochemical and special histochemical stains. For manual special histochemical stains, EQA participation is required for each stain on the accreditation scope. Prior to accreditation granting, a CAB must successfully participate in PT/ILC if schemes are available and relevant to the accreditation scope. Moreover, participation in formal EQA is required for all immunohistochemical stains with potential therapeutic implications as specified in Appendix I. Histopathologists signing accredited reports must participate in EQA schemes. Each CAB must participate with at least 2 histopathologists. The level and frequency of participation must be documented in the 1 accreditation cycle (5 years) participation plan which is to be developed based on a risk analysis. The plan must meet the specific requirements of the other regulatory bodies or professional body requirements. The Policy recommends the use of ISO 17043-accredited providers whenever possible as stated in 3.2. EPTIS database is suggested as an option for suitable PT-providers since it is endorsed by the EA and Eurachem.

In Israel, the National Accreditation Body (ISRAC) documented the use of PT/ILC in the 1-681001 document [31]. The document identifies the ISRAC requirements concerning the participation of laboratories in proficiency testing. The Policy sets the equivalence between the PT and ILC as stated in 5.1. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC if schemes are available. The level and frequency of participation must be documented in the 1 accredi-

tation cycle participation plan which is to be developed based on a risk analysis having in mind this activity must be integrated into CAB's overall quality assurance strategy and the area the CAB operates. The Policy establishes a hierarchal list for selecting a PT-provider, the top being an ISO-17043-accreditation recommendation and reputability of the provider the last being intralaboratory comparisons as described in 7.3.2.

In Italy, the National Accreditation Body (Accredia) documented the use of PT/ILC in the RT-24 document [32]. The document identifies the Accredia requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC with at least one analyte for each discipline. The level and frequency of participation must be documented in the participation plan which is to be developed based on a risk analysis. During an accreditation cycle, the minimum level of participation is at least one analyte related to each subdiscipline in the accreditation scope. The Policy states it is the responsibility of the CAB to define and justify the selection of the disciplines and subdisciplines. An example, taking into account the material/matrix/product/measurand/property of such definition is stated in 7. The CAB is responsible for ensuring the technical competence of the PT-provider which can be demonstrated either by ISO 17043-accreditation or by an individual assessment done by the CAB ensuring ISO 17043-compliance.

In Latvia, the National Accreditation Body (LATAK) documented the use of PT/ILC in the D.007-10 document [33]. The document identifies the LATAK requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in EQA programs, for every field in the accreditation scope. During an accreditation cycle, the minimum level of participation is at least one field from the accreditation scope. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on a risk analysis. Yet, the Policy clarifies that in special fields, (including healthcare) a higher level of participation might be required. Also, regulating bodies or professional bodies can require a higher frequency of participation. The Document clarifies that even though CABs should participate in PT/ILC schemes with all the properties this is always viable logistically and economically as stated in 3.4. CABs can select the appropriate provider, yet recommend ISO 17043-accredited programs.

In Lithuania, the National Accreditation Body (LA) documented the use of PT/ILC in the V-11 document [34]. The document identifies the LA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC at least once for each technical area in the accreditation scope. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on a risk analysis, yet the minimum level of participation is at least once every five years or a frequency established by a regulatory body. The Policy defines a hierarchical criteria list for selecting a PT/ILC program, the choice of preference being an ISO-17043 accredited provider and in the absence of such a provider, ILCs meeting the requirements of ISO-17043 can be used.

In Luxembourg, the National Accreditation Body (OLAS) documented the use of PT/ILC in the A-015 document [35]. The document identifies the OLAS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC at least once for at least one main technical area in the accreditation scope. The level and frequency of participation must be documented by the CAB. OLAS has several criteria for selecting an adequate PT-provider and recommends cooperation with the CAB when selecting one. The list of criteria is not a hierarchal one as specified in 6. For medical laboratories, PT/ILC schemes organized by public authorities are automatically considered adequate.

In Montenegro, the National Accreditation Body (ATCG) documented the use of PT/ILC in the PA.04-1 document [36]. The document identifies the ATCG requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC at least once. The minimum participation level is once for every major subdiscipline per accreditation cycle (4 years) or any other minimum level specified by legislation. The 4-year participation plan must define the level and frequency of participation and the CAB is responsible for determining the subdisciplines it participates in PT/ILC. If a CAB does not select a specific subdiscipline, a rationale is required based on availability, appropriateness, and organizational and economic reasons as described in 4.2.1. The Document specifies that the CAB is

recommended to choose an ISO 17043-accredited provider or select from the EPTIS database or others from regional and international arrangements without specifying a hierarchy for the decision.

In Norway, the National Accreditation Body (NA) documented the use of PT/ILC in the D00534 document [37]. The document identifies the NA requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ILC at least once. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on a risk analysis, and the CAB must participate for each parameter during the accreditation cycle without specifying a minimum level.

In Poland, the National Accreditation Body (PCA) documented the use of PT/ILC in the DA-05 document [38]. The document identifies the PCA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once. During the accreditation cycle, the CAB is responsible for identifying the level of participation, according to its own strategy. This has to be documented at the level and frequency of participation based on a risk analysis. The main criterion for selecting a PT-provider is technical competence. ISO 17043 accreditation is considered sufficient proof of competence. If a laboratory selects a non-accredited PT-provider when one is available and appropriate, a sound justification must be provided. In such a case, the CAB must provide evidence of the technical competence of the PT-provider and self-declaration of competence of the PT-provider is not considered sufficient. A list of items which ensure technical competence of a non-accredited PT-provider is detailed. If that option is not available/appropriate, the CAB can use ILCs which meet the requirements of ISO 17043.

In Portugal, the National Accreditation Body (IPAC) documented the use of PT/ILC in the DRC-005 document [39]. The document identifies the IPAC requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once for a representative scheme. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on a risk analysis. The Document specifies the acceptability criteria: ISO 17043 accreditation by IPAC or other bodies signatories of the EA or ILAC-MRA agreements, national metrology institutes or EPTIS-registered suppliers. It is clarified that simple EPTIS- registration is not synonymous with recognition of competence and impartiality.

In The Republic of Moldova, the National Accreditation Body (MOLDAC) documented the use of PT/ILC in the P-02 document [40]. The document identifies the MOLDAC requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. The Document lists criteria for selecting a PT-provider without establishing a hierarchy for selection. Prior to accreditation granting, a CAB must successfully participate in PT/ILC scheme at least once for each subdiscipline in the accreditation scope. The minimum participation level after granting accreditation is once every two years for each subdiscipline in the accreditation scope. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on a risk analysis.

In The Republic of North Macedonia, the National Accreditation Body (IARNM) documented the use of PT/ILC in the P-06 document [41]. The document identifies the IARNM requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once for each subdiscipline in the accreditation scope. The level and frequency of participation must be documented for one accreditation cycle and this is to be developed based on its own quality assurance strategy and modifications in the laboratory structure, yet a recommendation for minimum of one participation for each subdiscipline is recommended for the one accreditation cycle (4 years).

In Romania, the National Accreditation Body (RENAR) documented the use of PT/ILC in the P-04 document [42]. The document identifies the RENAR requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once. The level and frequency of participation must be documented for one accreditation cycle (4 years) in a participation plan. For medical laboratories, the minimum participation level is two successful participations per year for each subdiscipline in the accreditation scope. Besides, the medical laboratory must also participate at least once per accreditation cycle in a

scheme where a reference value is used as an assigned value. The Document provides a list of types of PT/ILC providers that are recognized without specifying a hierarchy for selection.

In Serbia, the National Accreditation Body (ATS) documented the use of PT/ILC in the ATS-PA-02 document [43]. The document identifies the ATS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once. The Policy recommends the selection of ISO 17043-accredited providers which is considered sufficient proof of technical competence, yet the laboratories can use other PT-providers but have to ensure these latter schemes are organized according to ISO 17043 as described in 3. The level and frequency of participation must be documented for one accreditation cycle (4 years) in a participation plan, yet a minimum of 1 successful participation for each major subdiscipline is required. Article #3 in the Policy defines a set of criteria for CAB to determine the level and frequency of participation.

In Slovakia, the National Accreditation Body (SNAS) documented the use of PT/ILC in the PL-23 document [44]. The document identifies the SNAS requirements concerning the participation of laboratories in proficiency testing. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once for each sub-area of the accreditation scope. The level and frequency of participation must be documented for one accreditation cycle in a participation plan for each sub-area of activity in the accreditation scope. The definition of the sub-area is the responsibility of the CAB and guiding instructions are available. ILCs can be used when no suitable PT-providers are available.

In Slovenia, the National Accreditation Body (SA) documented the use of PT/ILC in the 0A-05 document [45]. The document identifies the SA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once. The CAB must select with priority an ISO 17043-accredited PT/ILC provider. If such an option is not available, then ILCs can be used. The level and frequency of participation must be documented in a participation plan. The Policy details in 4.1 a strategy to determine the participation level taking into account the measurement process, characteristics and types of test items to be measured.

In Spain, the National Accreditation Body (ENAC) documented the use of PT/ILC in the NT-03 document [46]. The document identifies the ENAC requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme. The level and frequency of participation must be documented in a participation plan and a guiding document for this is available [G-ENAC-14]. The Policy defines in Art. #8 a hierarchal structure for selecting adequate PT/ILC providers.

In Sweden, the National Accreditation Body (SWEDAC) documented the use of PT/ILC in the Doc 06:9 document [47]. The document identifies the SWEDAC requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme. The level and frequency of participation must be documented in a participation plan based on risk assessment. The plan is recommended to cover at least 4 years. Also, requirements from regulators or other stakeholders must be taken into account when defining the level and frequency of participation. The Policy urges CABs to primarily select ISO 17043-accredited PT/ILC providers.

In Switzerland, the National Accreditation Body (SAS) documented the use of PT/ILC in the DO 330.ew document [48]. The document identifies the SAS requirements concerning the participation of laboratories in proficiency testing. The document does have special provisions for medical laboratories with respect to frequency and level of participation. The level and frequency of participation must be documented in a participation plan based both on risk assessment and other strategies (regular use of CRMs, comparisons of analysis by independent techniques, etc) and should encompass at least one accreditation cycle. The Policy clarifies that if there is unlikely feasibility, (logistically and economically) a CAB can participate in all the accredited methods; therefore, a participation subgroup can be defined as stated in 4. ISO 17043-accredited by ILAC members PT providers are considered competent yet the CAB is encouraged to use the EPTIS database for an adequate PT program. Medical laboratories are legally required to participate in PT schemes (SR 832.10 article 58, SR 832.102 article 77). For all the subdisciplines that are not covered by the mandatory PT-program, it is the responsibility of the laboratory to participate in a scheme or alternative method.

In The Kingdom of Netherlands, the National Accreditation Body (RVA) documented the use of PT/ILC in the

RVA-T0-NL document [49]. The document identifies the RVA requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Art. #4 clarifies 6 types of PT participation. It is clarified that is the responsibility of the CAB to establish the competence of the provider. An ISO 17043-accreditation is sufficient proof of technical competence, yet the laboratory may select and demonstrate the technical competence of another supplier that functions according to the ISO 17043 standard. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once per competency area. During an accreditation cycle, the CAB must successfully participate in PT/ILC schemes at least once. Yet, if there are legal requirements for a higher level of participation, these are prevailing. The definition of competency areas is detailed in the Appendices of the Policy.

In Tunisia, the National Accreditation Body (TUNAC) documented the use of PT/ILC in the DO.L.09 document [50]. The document identifies the TUNAC requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ILC scheme at least once per main technical area as defined in cooperation with TUNAC. The level and frequency of participation must be documented in a participation plan. The minimum level of participation is at least once per main technical area during an accreditation cycle (5 years). The Policy establishes a criteria list for selecting an adequate PT-provider without a hierarchical structure. Yet the selection is recommended to be done in cooperation with TUNAC as detailed in Art. #6.

In The Republic of Turkiye, the National Accreditation Body (TURKAK) documented the use of PT/ILC in the P704 document [51]. The document identifies the TURKAK requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. The level and frequency of participation must be documented in a participation plan. The minimum level of participation is at least once every 48 months for each technical competence area. Technical competence areas are defined by the laboratory such that all methods within the accreditation scope are represented. The Policy establishes a criteria list for selecting an adequate PT-provider with a hierarchical order.

In The United Kingdom, the National Accreditation Body (UKAS) documented the use of PT/ILC in the TPS-47 document [52]. The document identifies the UKAS requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in PT/ ILC schemes. The level and frequency of participation must be documented in a participation plan developed on a risk analysis, level of other quality assurance activities and historic performance in PT/ ILC. The Policy recommends the use of ISO 17043-accredited PT providers while the EPTIS database may be a useful place to select providers from. Art. #4.2 clarifies that the CAB is ultimately responsible for deciding on the appropriateness of a PT/ILC scheme.

In Ukraine, the National Accreditation Body (NAAU) documented the use of PT/ILC in the ZD-08.00.29 document [53]. The document identifies the NAAU requirements concerning the participation of laboratories in proficiency testing. The document does not have special provisions for medical laboratories with respect to frequency and level of participation. Prior to accreditation granting, a CAB must successfully participate in the PT/ ILC scheme for each main technical area of the accreditation scope. The minimum level of participation is at least once every accreditation cycle for each technical competence area main technical area of the accreditation scope. The level and frequency of participation must be documented in a participation plan developed according to EA – 4/18: 2021[16].

DISCUSSION

There is a breadth of approaches for the implementation of [6]. This is probably due to at least the following reasons: i) unlike in the case of ILAC P6 which is transposed into an EA-MLA mandatory document EA M5, there is no mandatory policy for the use of PT/ILC but only two guiding documents; ii) the variability in the medical legislation among EA-MLA signatories is so large that it is difficult to develop a harmonized policy at the entire EA-MLA level; iii) each Policy document should reflect the realities within the particular economy; iv) the Policy should applicable to all types of laboratories and inspection bodies that use PT/ILC which essentially means the entire economical spectrum while the variability in the EA-MLA signatories' economies is very high. Despite that, there are several common denominators of all the policies: i) CABs are required to develop a technically justified participation plan and actively use PT/ILC results in order to assess the validity of results in their reports; ii) the preference of using an ISO 17043-accredited PT provider when appropriate and available; iii) ILC should be used as a de-

fault option when no PT providers are available in terms of appropriateness. Also, it is worthwhile mentioning a limitation of this review, that is, it only takes into account the Policy document of itself. The implementation of the Policy is also a matter of legal interpretation and possible 2nd tier documents that are specific to each legal system of each country. Yet, the purpose of this review is not to contrast policies with the potential purpose of shaping an ideal policy. It is the competence of the peer review assessment teams to assess the compliance of a national policy with [6] and the ABs as an association to decide if a harmonized policy is appropriate in order to ease commerce and remove trade barriers.

CONCLUSIONS

The variability within the PT/ILC policies can be noticed at the following levels: i) with respect to medical laboratories, some ABs have special requirements while others do not distinguish from testing/calibration laboratories; ii) some ABs are more prescriptive regarding the minimum level and frequency participation by establishing thresholds, while several ABs leave this matter at the discretion of the CABs or bind it to their national sectorial legal requirement; iii) some ABs provide a hierarchical list of criteria when selecting a PT/ILC provider while some ABs provide a non-hierarchized list.

AUTHORS' CONTRIBUTION

Dan Adrian Luțescu, Ruxandra Ionela Sfeatcu, Iulian Gherlan, Rucsandra-Elena Dănciulescu-Miulescu, and Ana Maria Cristina Țâncu declare equal contribution with the first author.

CONFLICT OF INTEREST

None to declare.

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