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A new terminology for the approaches to the quantification of the measurement uncertainty

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Abstract A new terminology for the approaches to the quantification of the measurement uncertainty is presented, with a view to a better understanding of the available methodologies for the estimation of the measurement quality and differences among them. The knowledge of the merits, disadvantages and differences in the estimation process, of the available approaches, is essential for the production of metrologically correct and fit-to-purpose uncertainty estimations. The presented terminology is based on the level of the analytical information used to estimate the measurement uncertainty (e.g., supralaboratory or intralaboratory information), instead of the direction of information flow ("bottom-up" or "top-down") towards the level of information where the test is performed, avoiding the use of the same designation for significantly different approaches. The proposed terminology is applied to the approaches considered on 19 examples of the quantification of the measurement uncertainty presented at the Eurachem/CITAC CG4 Guide, Eurolab Technical Report 1/2002 and Nordtest Technical Report 537. Additionally, differences of magnitude in the measurement uncertainty estimated by various approaches are discussed.

Keywords Uncertainty · Terminology · Metrology · Quality

Introduction

Since the publication of the ISO/IEC 17025 Standard [1] the Analytical Community of Accredited Laboratories has been deeply involved in the estimation of the produced results uncertainty. For most chemical laboratories, this task has been extremely cumbersome, since it must be coordinated with the laboratory daily work and involves a large investment of time in understanding the principles of the estimation of results quality. Many times after a large expenditure of time and financial resources in consultancy and training, the produced model for the estimation of results quality is not approved by the Accreditation Body Auditors. Most times these divergences are due solely to differences in the interpretation of the "sate-of-the-art" at the estimation of the measurement uncertainty, rather than to lack of solutions to overcome the natural difficulties in the presentation of results with an objective measure of their quality. One of the possible reasons for those divergences is the misinterpretation of the particularities and differences of the available alternatives for the quantification of the measurement uncertainty.

In the last decade, several approaches have been developed for the estimation of the measurement uncertainty, based on different sources of information (e.g., inter- or intralaboratory data of different kinds). To produce reliable uncertainty estimations, understanding the principles involved in the chosen pathway to estimate the measurement uncertainty is essential. Laboratories often mix the different methodologies for the estimation of the measurement uncertainty producing unbalanced uncertainty models that either do not include or double count relevant sources of uncertainty, which could be easily or correctly estimated by using the available data.

The structure of the most popular general guides for the quantification of the measurement uncertainty [2–4] does not always help the analyst in understanding the differences of the available approaches for the estimation of results quality. In these guides, the presentation of the general

principles of this subject is followed by their application in different assays without discussing the fact that different approaches are used in the various examples. Another reason for the difficulties in the interpretation of the differences between the approaches is the terminology used to designate those approaches. Often, different approaches are presented under the same designation, thus promoting misunderstanding.

In this work, a new terminology is proposed to designate the approaches developed for the quantification of the measurement uncertainty, aiming at helping the analytical community in discussing the differences and merits of the number of paths that can be followed in order to produce objective analytical information.

The proposed terminology for the approaches for the quantification of the measurement uncertainty is applied to the methodologies exemplified in three popular general guides for the quantification of the measurement uncertainty. The 19 studied tests represent examples of various analytical fields. The use of examples from well-known guides for the quantification of the measurement uncertainty, two of which are easily downloaded from their website for free, allow the illustration of the application of the proposed terminology to various cases.

The commonly used terminology

The ISO guide for the expression of uncertainty in measurements (GUM) [5] presents an approach for the estimation of the measurement results quality based on the quantification and combination of all the individual sources of uncertainty, associated with the random and systematic errors that can be responsible for the measurement error (i.e., the difference between the measurement result and the "true" value [6]). Since the application of this methodology to most chemical measurements is extremely difficult, and even impossible considering the production of objective measurement uncertainty values (i.e., without Type B [5] estimation of relevant sources of uncertainty), the "Analytical Methods Committee" (AMC) of the "Royal Society of Chemistry" proposed an approach [7] to estimate the uncertainty associated with results produced in the laboratory (i.e., in intralaboratory environment) using available interlaboratory data. These data can be extracted from collaborative assays, proficiency tests or from the interlaboratory certification of reference materials. More recently, ISO published a Technical Specification [8] to guide laboratories in using data from a collaborative study to estimate their measurements uncertainty.

Interlaboratory data are extremely useful to estimate the measurement uncertainty, since they reflect the variation of the analytical method (or methods) performance with extremely important factors, some of which can hardly be estimated within a laboratory. However, the interlaboratory information is expensive and often is not available, nor it includes information about all the analytical steps affecting the measurement uncertainty (e.g., processing of solid samples). Since this information is considered to be of a higher level, in relation to the information generated to characterise a sample (usually results concerning each sample are obtained within one laboratory), the approach for the quantification of the measurement uncertainty based on interlaboratory data is designated as "top-down" approach [7]. This designation reflects the flow of information from a higher level to estimate the quality of measurements generated at a lower level (i.e., within a laboratory, usually in repeatability conditions).

Considering that the information about the performance of single analytical steps or the one about the impact of individual factors (e.g., effect of acid concentration in analyte recovery) in the measurement quality is considered to be positioned at a lower level of information in relation to the level where measurements are performed, the approach proposed at the GUM [5] is designated as "bottom-up". In this case, the information flows from a level characterised by information which is specific to each of the analytical steps or factors that contribute to the measurement uncertainty, up to an information level characterised by the adequate combination (i.e., considering the uncertainty combination law) of information of the previous information level, producing the measurement combined uncertainty.

Since both the "bottom-up" and the "top-down" approaches have some severe disadvantages that make them virtually impossible to apply in important analytical fields (e.g., where the analytical methods involve complex analytical steps, or where interlaboratory information is not available), approaches were developed which can lead to the estimation of the measurement uncertainty from the performance of the analytical method estimated in intralaboratory environment in the framework of the in-house method validation and/or routine analysis quality control. Since the method performance usually varies from day-to-day, because of operator, equipment, and other experimental and environmental uncontrolled conditions, the intralaboratory information used to estimate the results quality includes data collected in a broader frame (i.e., several days, different operators or equipments, etc.) than the one managed in a single test. Since the intralaboratory information used to estimate the measurement uncertainty is positioned at a level higher than the one managed within one test and therefore the information flows from a higher to a lower level, this approach is also currently designated as "top-down". In order to distinguish between the two "top-down" approaches (i.e., the one based on interlaboratory data, and the one based on intralaboratory data) they can be named, one as "top-down approach based on interlaboratory data" (the original one) and the other one as "top-down approach based on intralaboratory data". Distinguishing these two approaches is most useful since they represent different philosophies in estimating the measurement uncertainty.

The "Reconciliation Approach" [9, 10], developed by Ellison and Barwick, presented at the Eurachem Guide [2], is one of the most popular "top-down approaches based on intralaboratory data" since it is extremely easy to apply. Maroto et al. [11] and Jülicher et al. [12] also proposed "top-down" approaches based on intralaboratory data which use,

respectively, Analysis of Variance and Factorial Analysis with a view to extracting more information related to the measurement performance.

Although the approaches for the quantification of the measurement uncertainty are defined considering the direction of the flow of information, it is not always possible, or advisable, to strictly follow this definition in the development of the model used to estimate a measurement uncertainty; i.e., many times it is not possible to develop uncertainty models completely "pure" in terms of the information flow, e.g.

1. When interlaboratory data are used to estimate the uncertainty associated with the analysis of solid samples and the interlaboratory test does not involve the analytical steps prior to the analytical portion (e.g., samples processing), it is necessary to combine the interlaboratory data with data, generated within the laboratory about the performance of the first operations of the measurement;
2. When the in-house validation of the analytical method involves the estimation of the method accuracy from the analysis of Certified Reference Materials, interlaboratory data are also used for the uncertainty budget.

When the measurement uncertainty is estimated considering sources of information from different levels, the estimation approach is designated considering the major direction of the information flow. This procedure is only possible when there is a direction of information flow responsible for a major fraction of the measurement uncertainty.

More recently, a new approach was developed, for the quantification of the measurement uncertainty, which involves important flows of information in both directions, and therefore cannot be designated as "bottom-up" or "top-down". This approach, designated as "Differential Approach" [13, 14], is based on the comparison of the global method performance parameters estimated in intralaboratory environmental, with the performance of the analytical steps which can be estimated from well-known models (e.g., gravimetric, volumetric and instrumental quantification steps), in order to estimate the other analytical steps performance by difference, considering the uncertainty propagation law. Subsequently, the estimated sources of uncertainty combined with the sources of uncertainty maintained constant within the experimental assays, lead to the estimation of the global method performance parameters, producing a detailed model of the method performance independently from its complexity. Since the information flows abundantly up and down towards the information level where the test is performed, it can be classified as a "Transversal Approach."

Considering the relevance of knowing the merits, disadvantages and differences in the estimation process, of the approaches developed for the quantification of the measurement uncertainty, for the production of metrologically sound and fit-to-purpose measurement uncertainties, as well as the weaknesses of the currently used terminology to distinguish the available approaches, a new terminology is proposed.

The new proposed terminology

Figure 1 presents a schematic representation of the levels of analytical information that can be used to estimate the measurement results uncertainty. The estimation of the measurement uncertainty can be based on results either from

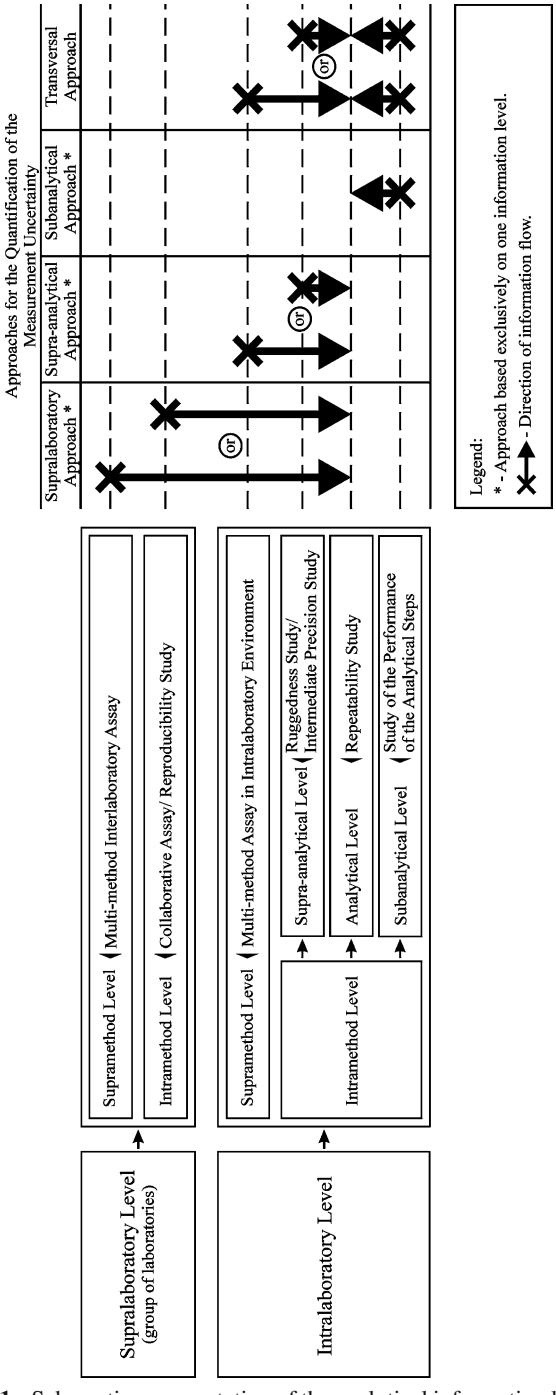

Fig. 1 Schematic representation of the analytical information levels which can be used to estimate the measurement uncertainty, and presentation of four approaches using data from those information levels to estimate measurements quality. The various approaches are presented using a scheme that represents the information flow towards the level where the analytical result is obtained (Analytical Level)

the in-house method validation or routine analysis quality control generated at the Intralaboratory Level of analytical information, or based on results collected by several laboratories when characterising equivalent or shared items consisting of information at the Supralaboratory Level. The approach for the quantification of the measurement uncertainty based on Interlaboratory data is named "Supralaboratorial Approach." This designation should be used even when the Supralaboratory information has to be combined with data from other levels of information every time the interlaboratory data are used to quantify most of the measurement sources of uncertainty. Considering that the Supralaboratory approach is based on interlaboratory data, this approach can also be designated as Interlaboratory approach, using a widespread term.

This approach is currently designated as "top-down," or, in a more descriptive way, "top-down approach based on interlaboratory data."

The Supralaboratory information level can be divided into two levels:

1. The Supramethod Level, and
2. The Intramethod Level (Fig. 1).

When the laboratories participating in the interlaboratory assay use different analytical methods (rational methods [15]) to study the same measurand, the interlaboratory data reflect the performance characteristics of several analytical methodologies. In this case, the Supralaboratory information is positioned at the Supramethod Level. When the Supralaboratory information includes data generated by several analytical methods based on various physical and chemical principles, in some cases it can be assumed that the variability of the results from the various laboratories and methods count for the uncertainty associated with the methods bias [7].

When all laboratories participating in the interlaboratory assay use the same analytical method, the generated information is positioned at the Intramethod level. When the used or studied analytical method is a rational one, the Supralaboratory Intramethod information can only reveal the method bias if the analysed items have a known value. When the used method is an empirical one [15] there is no method bias to be considered [7].

Similar to the Supralaboratory Level, the Intralaboratory information level can also be divided into two levels:

1. Supramethod Level, and
2. Intramethod Level (Fig. 1).

The Supramethod Level, from intralaboratory information, includes results from the analysis of reference or unknown items by two analytical methods implemented in the same laboratory, one of which usually being the reference one. When developing a new method of analysis, it can be useful to compare the performance of the new method with the reference one in order to find out if the new methodology is equally accurate and precise.

The Intramethod Level, from intralaboratory information, is divided into three levels according to the different approaches for the quantification of the measurement uncertainty which use data about the performance of a single method collected in a single laboratory: (i) Analytical Level, (ii) Supra-Analytical Level and (iii) Sub-Analytical Level (Fig. 1).

The Analytical Level is the one at which, usually, the tests are performed. Normally, the analytical result that characterises the analysed item, is estimated by an operator using the equipment strictly necessary for the analysis and in a short period of time considering the time scale associated with the test. The repeatability studies are also performed at the Analytical Level. When the result from the analysed item is the average of results obtained by different operators or in different days, the test is performed at a higher level than the Analytical Level.

The highest level of the Intralaboratory–Intramethod Level is the Supra-analytical level. This level includes results from several tests performed using, alternatively or randomly, the different resources (e.g., operators and equipment) available at the laboratory to perform the test, and obtained in a sufficiently large time scale to include results affected by the usual variation of uncontrolled environmental and instrumental factors that affect the measurement quality. Intermediate precision studies [16] and ruggedness tests [17] are examples of studies that can produce information pertaining to Supra-analytical level.

The approach for the quantification of the measurement uncertainty based on Supra-analytical information is designated as Supra-Analytical Approach (Fig. 1). The "Reconciliation Approach" [9, 10] is an example of a Supra-analytical approach. Considering that there are no relevant differences between the methodologies for the quantification of the measurement uncertainty based on Supra-analytical or Intralaboratory Supramethod information, the approach based on Intralaboratory Supramethod information is also designated as Supra-analytical (Fig. 1). This approach is currently designated as "top-down approach based on intralaboratory data."

The lowest level of laboratory information that can be used to estimate the measurement uncertainty is designated as Subanalytical Level. This level includes data about the performance of single analytical steps or about the relevance of environmental or instrumental parameters to the performance of the analytical step. The uncertainty associated with the mass of the analytical portion, or the impact of temperature in the recovery of the analyte in a mass transfer step are examples of sub-analytical information. The approach for the quantification of the measurement uncertainty, which bases calculations in sub-analytical information is designated as Sub-Analytical Approach (Fig. 1). This approach is currently designated as "bottom-up" approach.

The approaches for the quantification of the measurement uncertainty that involve the combination of equally relevant supra-analytical and subanalytical information can be designated as Intralaboratory Transversal Approaches (Fig. 1). The Differential Approach [13, 14] is an example of such an approach.

Examples of application of the proposed terminology

Table 1 presents the application of the proposed terminology to the examples of the quantification of the measurement uncertainty presented at the Eurachem/CITAC CG4 Guide [2], Eurolab Technical Report 1/2002 [3] and Nordtest Technical Report 537 [4].

Since the Eurolab [3] and Nordtest [4] technical reports present the application of various approaches for the quantification of the uncertainty associated with the results from the same test, in the same example in the Guide, it is necessary to distinguish the various approaches by their order of presentation. The notation used, in this section and in Table 1, for the studied approach for the quantification of the measurement uncertainty is the following: "example number" ("approach order"). Accordingly, the second approach for the quantification of the measurement uncertainty presented as the third example of the Guide has the notation "#3(2)".

The examples from the different guides are discussed separately:

1. Eurachem/CITAC CG4 Guide [2]:
   a. Examples/Approaches A1, A2, A3, A5 and A7 illustrate the application of the sub-analytical approach to a fraction (A1 and A2, Table 1, for involved operations) or to a complete analytical method (A3, A5 and A7, Table 1, for involved tests). Example A5 for the determination of cadmium release from ceramic ware, illustrates how difficult the application of the sub-analytical approach to a complex analytical method can be. Many times the routine laboratory has not available or cannot afford gathering all the information needed for the application of the sub-analytical approach to complex analytical methods.
   b. Example A4, for the determination of pesticide residues in bread, illustrates the combination of supra-analytical information with sub-analytical information regarding the sub-sampling uncertainty, with a view to estimate the measurement uncertainty. In this case, the objective of the test is to estimate the mean content of pesticide residues in bread and, therefore, it is necessary to estimate how the heterogeneity of pesticide residues in bread and the sub-sampling strategy can affect the quality of the estimated sample result. Given that, in the presented example, the largest fraction of the measurement uncertainty drives from global method performance parameters (analytical method precision and accuracy) estimated in intralaboratory environment, at least in different days, this approach is named Supra-analytical. In this case, the magnitude of the uncertainty attributed to sub-sampling (referred to in the guide as "inhomogeneity of analyte in bread") is equivalent to the one associated with the measurement precision (referred to in the guide as "repeatability"). However, there is no doubt that the followed philosophy for the quantification of the measurement uncertainty is based on gathering global method performance information estimated within

Table 1 Application of the proposed terminology to examples of the quantification of the measurement uncertainty from the literature

	Examples of the Quantification of Measurements Uncertainty								
	Eurachem/ CITAC CG4 [2]			**Eurolab TR 1/02** [3]			**NordTest TR 537** [4]		
	A1, A2, A3, A5 and A7	A4	A6	#1(1)	#1(2)	#1(3)	#1(1); #2(1); #2(2); #3(1); #3(2) and #4(1)	#1(2) and #2(3)	**REF** [14]
Uncertainty estimation approach									
Supralaboratorial			✓	✓		✓		✓	
Supra-analytical		✓			✓		✓		
Sub-analytical	✓								
Transversal (Differential)									✓
Information flow diagram									
Information level									
Supralaboratory – Supramethod									
Supralaboratory – Intramethod									
Intralaboratory – Supramethod									
Intralaboratory – Supra-analytical (Intramethod)									
Intralaboratory – Analytical (Intramethod)									
Intralaboratory – Subanalytical (Intramethod)									

Test/ Operation: Eurachem/CITAC GC4: A1 – Preparation of a calibration standard; A2 – Standardising a NaOH solution; A3 – Acid/base titration; A4 – Determination of pesticides residues in bread; A5 – Determination of Cd release from ceramic ware; A6 – Determination of crude fibre in animal feeding stuffs; A7 – Determination of lead in water; **Eurolab TR 1/2002:** #1 – Determination of sulphate in waste water; **NordTest TR 537:** #1 – Determination of ammonium in water; #2 – Determination of biological oxygen demand in waste water; #3 – Determination of PCBs (polychlorinated biphenyls) in sediments; #4 – Determination of Pb in water; **Reference [14]**: Determination of pesticide residues in apples.

Legend: #*i*(*ii*) – "test number *i*"("approach order *ii*") (example: "#2(1)" – first approach from the second test); (➔) – Major information flow;

(⇢) – Additional information flow.

the laboratory and combining it with the information necessary to produce measurement uncertainties in full agreement with the studied measurand.

c. Example A6 for the determination of crude fibre in animal feeding stuffs, represents the estimation of the measurement uncertainty from Supralaboratory–Intramethod information. Since the analytical method is an empirical [15] one and therefore the measurement result is traced to the method there is no method bias to be considered.

2. Eurolab Technical Report 1/2002 [3]:
This technical report illustrates the quantification of the measurement uncertainty for four tests presented in four examples. The forth example leans on "Example A1" from the Eurachem/CITAC CG4 Guide [2] which was already discussed. The second and third examples are not discussed in this work since they are, respectively, examples of the quantification of the uncertainty associated with results from a mechanical test (Example #2) and represent the estimation of the measurement uncertainty based on the information collected in a survey from "well experienced experts" in the studied analytical field, not necessarily supported on objective analytical data (Example #3). Therefore, only the first example of the guide is discussed in this section. This example includes the description of three approaches for the quantification of the uncertainty associated with results from the determination of sulphate in waste water by ion chromatography.

   a. The first approach from Example #1 (Align 1a from the report [3], identified in Table 1 as "#1(1)") is an example of the Supra-laboratory approach based on results from participants in a proficiency test. Since the analytical method is a rational one [15], and the uncertainty associated with the method bias is not considered, the used data belong to the Supralaboratory–Supramethod level.
   b. The second approach from Example #1 (Align 1b from the guide [3], identified in Table 1 as "#1(2)") is an example of an Supra-analytical approach. In this case, the uncertainty associated with the method precision should be combined with the uncertainty associated with the method accuracy referred to as the "Note" from this example.
   c. The third approach from Example #1 (Align 1c from the guide [3], identified in Table 1 as "#1(3)") is another example of a Supralaboratory approach. However, in this case it is used Supralaboratory-intramethod information collected from a collaborative trial conducted for the interlaboratory validation of the analytical method. Since the analytical method is a rational one and there is no allowance for the method bias, the measurements presented with the estimated uncertainty are traceable to the analytical method and, therefore, not directly comparable with results produced by another analytical method for the determination of sulphate in waste water (for instance, a gravimetric method).

3. Nordtest Technical Report 537 [4]:
This report presents three different ways of estimating the measurement uncertainty.

   a. The approaches #1(2) and #2(3) from the report are examples of Supralaboratory approaches based on Supralaboratory–Supramethod information collected from proficiency tests. In these cases, since the studied analytical method is a rational one, the participants in the proficiency test use various analytical methods and the dispersion of the results from the proficiency test also reflects the methods bias variability.
   b. The approaches #2(1) and #3(1) are examples of the supra-analytical approach where the uncertainty associated with the method and laboratory bias is estimated from results of the analysis of Certified Reference Materials.
   c. The approaches #1(1), #2(2) and #3(2) are examples of the supra-analytical approach where the uncertainty associated with the method and laboratory bias is estimated from the bias estimated from various results of the participation of the laboratory in proficiency tests. In these examples, the information from the method and laboratory bias cannot be considered from the Supralaboratory information level, since it is not derived from the dispersion of results from the various laboratories participating in the proficiency test. This approach involves the treatment of the results from the analysis of the proficiency test reference samples, as considered when analysing Certified Reference Materials, where the reference content is the one claimed by the proficiency test promoter.
   d. The example #4 describes the application of a supra-analytical approach to estimate the uncertainty associated with results produced by an analytical method applicable to a broad concentration range where the measurement uncertainty varies over the concentration range. This example consists in the study of the trend of the method performance, estimated within the laboratory, throughout the concentration range in order to produce a model of the measurement uncertainty for the method scope.
   e. The Nordtest report [4] proposes the combination of the observed method and laboratory bias with all the other sources of uncertainty as proposed by IUPAC [15], in order to avoid the need for the evaluation of the relevance of the magnitude of the method and laboratory bias and, when necessary, their correction in the final result. This approach is not entirely in agreement with the GUM [5] that states that the sources of uncertainty should be combined as standard uncertainties.

Table 1 also presents one example of the application of the Differential Approach for the quantification of the uncertainty associated with the results of the determination of pesticide residues in apples [14]. This example illustrates the individual estimation of the uncertainty associated with various analytical steps, namely, the samples processing

and the combination of the mass transfer steps (combination of the extraction, filtration, evaporations and cleanup).

Comparison of estimated uncertainties

Some laboratories might expect that the measurement uncertainties estimated for the same measurement result, following different approaches, should be statistically equivalent at a high confidence level. However, it is possible to have two technically correct uncertainty estimations of the same measurement, with a difference of one order of magnitude. Frequently, the uncertainties estimated by the Supralaboratory approach are significantly higher than the ones estimated by the Supra-analytical or Sub-analytical approaches. This occurrence is due to the fact that despite the laboratory and analytical method being the same, the perception of the test performance is different depending on the chosen pathway to estimate the measurement uncertainty. Since the interlaboratory information is often affected by uncontrolled systematic errors from regular laboratories it gives a pessimistic image of the performance of a high quality laboratory. In those cases, it is not surprising if a high-quality laboratory can build an in-house method validation scheme capable of supporting much smaller measurement uncertainties than the ones estimated from interlaboratory data.

Considering a high-quality laboratory, although its analytical work is always conducted with the same care and using high-quality chemical references, its knowledge of the quality of the analytical results is more "uncertain" (i.e., involves the production of results with higher uncertainties) if the laboratory uses Supralaboratory data to estimate the measurement uncertainty. On the other hand, when the laboratory makes an effort to gather information specifically related to a result produced in the laboratory, its perception of the measurement quality is nearer the "reality," and therefore associated with a lower uncertainty.

The Eurolab and Nordtest guides [3, 4] for the quantification of the measurement uncertainty, present examples of the comparison of uncertainty values estimated from Supralaboratory and Supra-analytical approaches that illustrate the fact that, most of times, the interlaboratory data lead to the estimation of higher uncertainties than the information collected within a laboratory.

When two technically correct approaches for the quantification of the measurement uncertainty produce statistically different measurement uncertainties, it is possible to estimate, by difference, a fraction of the magnitude of the uncertainty that is introduced by the pathway producing the higher uncertainty. This uncertainty, which is specifically allocated to a pair of measurement uncertainties estimated for the same measurement from different approaches, can be designated as Specific Approach Uncertainty. Often, it is not possible to estimate the whole portion of an estimated measurement uncertainty owing to the weaknesses of the chosen approach to estimate the measurement uncertainty, because of the fact that most times it is not possible to gather detailed information about the magnitude of all sources of uncertainty needed to produce the necessary highest quality result uncertainty.

Conclusion

The authors believe that, once the differences between the available approaches for the quantification of the measurement uncertainty are perceived by the laboratory community, most mistakes that are hampering the widespread production of metrological sound chemical measurements can be avoided. Additionally, the analytical community should be aware that different sources of information can produce statistically different measurement uncertainty estimations, in order to avoid unfruitful discussions between laboratories when comparing different estimated measurement uncertainties. The above presented terminology for the approaches to the quantification of the measurement uncertainty, intends to be a contribution to the required harmonisation at international level.

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