Human being as a part of measuring system influencing measurement results

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Abstract:	The role of human being as a part of a measuring system in a chemical analytical laboratory is discussed. It is argued that a measuring system in chemical analysis includes not only measuring instruments and other devices, reagents and supplies, but also a sampling inspector and/or analyst performing a number of important operations. Without this human contribution a measurement cannot be carried out. Human errors, therefore, influence the measurement result, i.e. the measurand estimate and the associated uncertainty. Consequently, chemical analytical and metrological communities should devote more attention to the topic of human errors, in particular at the design and development of a chemical analytical/test method and measurement procedure. Also mapping human errors ought to be included in the program of validation of the measurement procedure (method). Teaching specialists in analytical chemistry and students how to reduce human errors in a chemical analytical laboratory and how to take into account the error residual risk, is important. Human errors and their metrological implications are suggested for consideration in future editions of the relevant documents, such as the International Vocabulary of Metrology (VIM) and the Guide to the expression of Uncertainty in Measurement (GUM).
Response to Reviewers:	Attached

Human being as a part of measuring system influencing measurement results

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****** The author is Convener of the Joint Committee for Guides in Metrology (JCGM) Working Group 1 (Guide to the expression of uncertainty in measurement - GUM). The opinion expressed in this paper does not necessarily represent the view of this Working Group.

Abstract

The role of human being as a part of a measuring system in a chemical analytical laboratory is discussed. It is argued that a measuring system in chemical analysis includes not only measuring instruments and other devices, reagents and supplies, but also a sampling inspector and/or analyst performing a number of important operations. Without this human contribution a measurement cannot be carried out. Human errors, therefore, influence the measurement result, i.e. the measurand estimate and the associated uncertainty. Consequently, chemical analytical and metrological communities should devote more attention to the topic of human errors, in particular at the design and development of a chemical analytical/test method and measurement procedure. Also mapping human errors ought to be included in the program of validation of the measurement procedure (method). Teaching specialists in analytical chemistry and students how to reduce human errors in a chemical analytical laboratory and how to take into account the error residual risk, is important. Human errors and their metrological implications are suggested for

consideration in future editions of the relevant documents, such as the International Vocabulary of Metrology (VIM) and the Guide to the expression of Uncertainty in Measurement (GUM).

Keywords: human error, measuring system, measurement uncertainty, method validation, chemical analysis

Introduction

The International Union of Pure and Applied Chemistry (IUPAC) and the Cooperation on International Traceability in Analytical Chemistry (CITAC) have published recently the joint IUPAC/CITAC Guide: Classification, modeling and quantification of human errors in a chemical analytical laboratory (IUPAC Technical Report) [1]. The classification includes commission errors (mistakes and violations) and omission errors (lapses and slips) under different scenarios at different steps of the chemical analysis. A 'Swiss cheese' model is used for characterizing the interaction of such errors with a laboratory quality system including different components, whose weak points are represented by holes in slices of the Swiss cheese. Quantification of human errors in chemical analysis, based on expert judgments, i.e. on the expert's knowledge and experience, is applied. Scores related to the error quantification are defined. They concern the likelihood and severity of the human errors, and the effectiveness of a laboratory quality system against these errors. Monte Carlo simulation is used to propagate variability of the expert judgments, represented by appropriate probability mass functions. The residual risk of human errors, remaining after the error reduction by the laboratory quality system, and consequences of this risk for the quality of the laboratory measurement results are discussed in this Guide. It is shown also that the measurement uncertainty budget is not complete without taking into account such residual risk of human errors [1, 2].

For a few fully automated systems, such as a spacecraft robotic laboratory [3, 4] which samples and analyses without human participation, only latent human errors (in development and construction of the system) are possible [5]. In general, they can be revealed and eliminated during the system validation for the intended use. There is a rise of autonomous robots having an ability to perform different steps of testing, such as sample preparation in analytical laboratories serving uranium industry [6, 7], or some kinds of blood and urine analysis in clinical laboratories [8]. Nevertheless, using these robots by the laboratory staff may also provoke a number of scenarios

of human errors. Moreover, in routine laboratories having lower level of automation, human errors may happen quite easily and should be taken into proper account.

Therefore, the role of human being in chemical analysis, still essential in most measurement methods and procedures, is discussed in the present article. It is suggested to include human being in the updated definition of measuring system in the International Vocabulary of Metrology (VIM) [9]. Such update would probably impact also on other metrological definitions, as well as on the measurement uncertainty evaluation in the Guide to the expression of Uncertainty in Measurement (GUM) [10].

Measurement method, procedure and measuring system

According to the VIM, *measurement method* [9--2.5] is a "generic description of a logical organization of operations used in a measurement", while *measurement procedure* [9--2.6] is a "detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result". However, this distinction is not universally recognized, since the term 'method' is often used as including 'procedure' [11], especially in chemical analytical practice [12].

The main steps of a measurement procedure in chemical analysis include sampling, sample preparation, analysis of a test portion, and calculation of test results and reporting. Sampling means taking at a particular time a sample/portion (sampling target) of material, which the sample is intended to represent. When the composition of a batch is tested, the sampling target should have the analyte concentration close as possible to the mean concentration value in the whole batch. When the spatial or temporal variation of the material composition is under study, separate sampling targets are necessary for obtaining information about analyte concentrations in each specific location or time. Any sampling target is analyzed according to the analytical/measurement procedure to obtain the measurement results of the analyte concentrations, i.e. measurand estimates and associated uncertainty [13]. Sampling needs not necessarily be included in a measurement. In such case it would not contribute to uncertainty. Whether or not sampling is included in the measurement is reflected in the definition of the measurand. For example, measuring 'the mass concentration of chromium VI in the material delivered to the laboratory' does not involve sampling, whereas 'the mean mass concentration of chromium VI in Sydney Harbor' does.

Sample preparation includes selection of the test portion, drying (or freezing, e.g. grapes), sieving, milling, splitting, homogenization, decomposition (e.g., geological samples), etc.

Analysis of a test portion may start from an analyte extraction from a test portion and separation of the analyte from other components of the extract. After that, a qualitative analysis is possible, including identification and confirmation of the analyte. Then, a quantitative part of the analysis consists of calibration of a measuring system and measurement of the analyte property – usually concentration or mass fraction.

The measurement procedure documents human participation at each step of the analysis/testing. Detailed examples of human error scenarios at such steps, from sampling to reporting results, are provided in the Guide [1] for pH measurement of groundwater, multi-residue pesticide analysis of fruits and vegetables, and ICP-MS analysis of geological samples.

In the VIM *measuring system* [9--3.2] is a "set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds". Human beings are not included in this definition. However, no system of this kind can provide alone the necessary information unless it is a part of a fully robotic laboratory. In a routine chemical analytical laboratory, a measuring system without a sampling inspector and/or an analyst is not complete. Furthermore, in the case of qualitative testing (e.g. organoleptic testing), a measuring system for nominal and ordinal property values [14-16] may consist of just an analyst (expert), for example an expert for testing color of freshwater cultured pearls [17].

Validation of measuring instrument vs method validation

According to VIM *validation* is "verification, where the specified requirements are adequate for an intended use" [9--2.45], whereas *verification* is "provision of objective evidence that a given item fulfils specified requirements" [9--2.44]. When a purchased measuring instrument has been installed in a laboratory, an experiment should be designed to obtain objective evidence (experimental data) that the instrument performance meets the manufacturer specification [12]. For example, the experiment design for verification of a high-performance liquid chromatograph (HPLC) intended for analysis of pesticide residues in drinking water, includes qualification of 1) pump gradient and precision, flow rate and on-line vacuum degasser; 2) ultraviolet/visible (UV/Vis) diode-array detector with holmium oxide filter for automated wavelength calibration,

detector baseline noise and wavelength accuracy; 3) auto sampler with necessary number of samples, variable volume of test portions without hardware change, needle flush and wash to minimize sample carryover; 4) chromatographic column compartment and its temperature precision; 5) instrument ability to detect leaks in each module and to switch the pump off in the case when a leak is detected; 6) computer and software, etc. [18].

If the data confirm that the instrument performance is satisfactory, it may be used in a specific procedure according to the appropriate analytical/measurement method. Note, a measuring instrument performance (ability) is provided by its manufacturer and does not depend on sampling inspector and/or analyst/operator in the analytical laboratory that purchased the instrument.

The performance characteristics for the method validation and their limits (criteria) are set by the laboratory upon agreement with the customer as fit for the intended use [19]. Commonly evaluated characteristics are: selectivity; limit of detection (LOD) and limit of quantification (LOQ); working range; analytical sensitivity; trueness (bias and recovery); precision (repeatability, intermediate precision and reproducibility); ruggedness (robustness); and measurement uncertainty [19-21]. Their choice is a balance between costs, risks and technical possibilities [11]. Then evaluation of these characteristics is performed using measurement results obtained by a specified experiment design.

When a method prescribes human participation, it is necessary to consider possible human errors during design and development of the method, since further measurement/analytical results may be influenced by these errors. Therefore, mapping possible human errors at different steps of analysis/testing should be required also as one of the validation characteristics of the method [1].

Thus, in general a method validation is validation of the measurement procedure for operating a measuring system including not only instrument(s), devices and reagents, but human being(s) as well.

Measuring system and measurement uncertainty

The measurement result obtained with a measuring system "…is generally expressed as a single measured quantity value and a measurement uncertainty" [9--2.9]. Identifying uncertainty sources is vital for correct evaluation of the uncertainty associated with the measurand estimate. It may be useful to consider discrete operations of the measuring system at different steps of the analysis and

to assess each operation separately to evaluate the associated uncertainty. Then, the uncertainty contributions of the operations are suitably summarized in the combined uncertainty [22].

When human beings are involved in some of the operations, a risk of human error remains after the error reduction by the laboratory quality system. This residual risk is also a source of a contribution to the measurement uncertainty. As such, it should be included in the uncertainty budget and taken into account in the appropriate way [1, 2].

At the same time, for the sake of justice, one should note that the most successful way of solving problems arising in an analysis is human as well [23]. Therefore, it is important that specialists in analytical chemistry and students would be educated and trained on how to reduce human errors in a laboratory and how to take into account the residual risk of human error.

The reference document in the field of measurement uncertainty, the GUM gives little attention to human errors. According to it, "Blunders in recording or analyzing data can introduce a significant unknown error in the result of a measurement. Large blunders can usually be identified by a proper review of the data; small ones could be masked by, or even appear as, random variations. Measures of uncertainty are not intended to account for such mistakes" [10--3.4.7]. Thus, in the GUM, only some among the possible human errors are recognized, and anyway they are not included as a source of uncertainty.

We think that a reliable evaluation of uncertainty should in principle account for human errors. To this purpose, the scope of the GUM should be broadened to include uncertainties caused by human errors when appropriate, for example, in the field of analytical chemistry. Suitable tools are now available that can probably be adapted to and incorporated in the procedures described in the GUM or in its Supplements 1 and 2 [24, 25].

Conclusion

Recognizing the role of human being as a part of measuring system in a routine chemical analytical laboratory requires:

1) definition of human errors and their metrological consequences in future VIM and GUM editions;
2) considering possible human errors during design and development of a method;
3) mapping possible human errors as a task during validation of a measurement procedure;

4) teaching specialists in analytical chemistry and students how human errors can be reduced in a laboratory and how to take into account the residual risk of human error.

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REVIEWER COMMENTS AND RESPONSES OF THE AUTHORS - ACQA-D-16-00078

Reviewer #1:
The message of the short paper is that human errors should be considered when uncertainty of measurement is being calculated, and that the operator of a measurement system should be regarded as a part of it. Two of the authors (Kuselman and Pennecchi) have recently published an IUPAC technical report with guidance for how to estimate the impact of human errors on measurement uncertainty.

The paper is well written and brings important topics for discussion. The reader interested in how to calculate the impact of human errors are referred to the IUPAC technical report. Some examples of human error scenarios are given. Somewhat surprisingly none of two of the probably most frequent "human errors" are exemplified; mixing of samples and data transfer errors. It could have been of interest for the reader if and how these types of errors can be expressed as measurement uncertainty, if not eliminated.

- Scenarios of human errors in sampling (including a sample identification/mixing) and in calculation and reporting (data transfer) are described in the IUPAC/CITAC Guide (IUPAC technical report) [1]. As other human errors in this report, they are quantified using expert judgments on the error likelihood and severity by a special scale. How such expert judgments can be transformed into the measurement uncertainty component is also shown in the IUPAC/CITAC Guide [1].

In the present paper the statement is discussed that a man involved in the measurement process is a part of the measurement system. It is proposed to take this into account in further issues of VIM [9] and GUM [10].

Reviewer #2:
General Comments:
- During an analysis you may expect human errors/mistakes (under which I would understand calculation errors, wrong manipulations, using wrong units,…) but also normal variability due to different operators (as included in the method validation according to ISO 5725 standards: operator-different intermediate precision). The authors should clarify in the paper the difference between these two and explain better if this paper deals with both or only with "human errors".

- The “normal variability due to different operators” in ISO 5725 reflects native variations of the operator actions in the tolerances required by the analytical method under validation. This variability is not related to human error, defined in the IUPAC/CITAC Guide [1] as “any action or lack thereof that leads to exceeding the tolerances of the conditions required for the normative work of the chemical analytical (measuring/testing) system with which the human interacts”.

Analysis of kinds of human errors, their scenarios at different steps of chemical analytical/measurement procedure – classification, modelling and quantification of human errors – are described in the IUPAC/CITAC Guide [1]. It is impossible to repeat that in the present paper.

- What about outlier detection (Grubbs tests - Cochran test). Can these tests not be used as a tool to deal with human error as these tests will remove outlying data caused by human error from datasets? Please comment.

- The statistical tests (Grubbs, Cochran and others) allow finding an outlier, but are not helpful in understanding the outlier root cause: is it a human error or an instrument malfunction, or inhomogeneity of the analyzed sample, or anything else. Outlier detection and investigation are the task of the laboratory quality system. In general, outliers caused by 'gross' human errors are removed from dataset and treated further with CAPAs (correction and preventive actions). However, it is not the subject of the present paper.

- I miss in this paper some proposal(s) how to handle human error.

- 'How to handle human errors' is formulated in the IUPAC/CITAC Guide [1], free available at the websites of the PAC journal and CITAC (open access).

Specific Comments:
P3 L52: The authors should review their statement "In such case it would not contribute to (the measurement) uncertainty". In case the laboratory has not participated in sampling and it measures the test item as delivered to the laboratory the measurement uncertainty contribution due to sampling cannot be evaluated by the laboratory. This does not necessarily mean that the uncertainty contribution due to sampling is negligible when compared with other sources of (measurement) uncertainty which can be evaluated by the laboratory. Authors are invited to consider revising their statement.

- It is written in the next lines 53-56: "Whether or not sampling is included in the measurement is reflected in the definition of the measurand". When sampling is not included in the measurement, it cannot contribute to the measurement uncertainty. This part of the paper is corresponding to VIM [9] and GUM [10]. There is no a reason to change it.

P5 L33: The experimental design selected and used for method validation should cover (whenever possible) all conceivable sources of uncertainty during their normal (future) routine conditions of application. Hence, it is normal practice for a competent laboratory to include different (well trained) operators/analysts to carry out the measurements intended for the validation of any new measurement procedure introduced in the laboratory. The effect "analyst/operator" is so taken on board (see nested designs in ISO 5725-3) and evaluated in the experimental design followed for the evaluation of the intermediate precision. Only in case (as with other sources of uncertainty) it is found as negligible when compared with other sources of variability that can be excluded from the uncertainty evaluation. The "human factor" is not necessarily ignored! Please comment.

- After the method validation, during its use, any experienced analyst remains a human being with all consequences described in the IUPAC/CITAC Guide [1]. Results of investigation of out-of-specification test results in the pharmaceutical industry, for example, show that about 70-80% of them are caused by human errors. The same is in the results of investigations of incidents and accidents in the aircraft industry (where operators are also trained and experienced) and others: a man is a man in any field of his/her activity. Therefore, human errors during the post-validation method use are inevitable. Our purpose is to minimize their likelihood (frequency) and severity and evaluate the residual risk.

P6 L52: I agree with the authors for point 2 and 3. In my opinion point 4 should read "teaching specialists in AC and students how the uncertainty associated with the human factor contribution can be evaluated and, eventually, how human errors can be reduced …

- The authors would like to thank the reviewer for the valuable discussion and his wish to help, in particular to formulate the conclusion point 4, but prefer to keep the current version of this point.

EDITORIAL REQUESTS
((referencing to the PDF version of the manuscript with page-no./line-no.))

1/40 isn't it the "human" (being) rather than his/her "role", as a "role" may be ascribed and predefined,
- the "measuring system" is made up from devices [VIM], isn't the reliable or faulty action of a human part of the "measurement procedure"?

- Corrected

3/22,24 please make it "[9--2.5]" etc. (there are hints this may be acceptable to the typesetters, so far we had to use a more explicit notation); similar 4/24, 4/45, 5/53, 6/30

- Made

3/35 "main steps are" does not fit well with "for example", suggest to use "include" (without "for example")

- Corrected

3/37 "test" is getting popular, however it is not a VIM concept; according to ISO usage it includes judgement of a measurement result with respect to norms, standards, regulations (e.g. compliance): suggest "sample portion", "the measurement results" analogically 4/4, 4/8

- "Test portion" is defined in the IUPAC Gold Book as "the amount or volume of the test sample taken for analysis, usually of known weight or volume", http://goldbook.iupac.org/T06284.html. According to ISO usage "test" does not necessarily include conformity assessment. For example, ISO 17025 General requirements for the competence of testing and calibration laboratories – "specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling". The same is in the ASTM test methods, in the pharmaceutical industry, etc. Therefore, please allow us to keep the use of "test portion" as is.

3/41 I would think that the target of sampling is to obtain material that is representative of the whole system/material with respect to the measurand, the quantity intended to be measured. In so far "sampling target may be an analyte concentration" is quite shorthand (isn't this the target of the analysis or the measurement, to which sampling contributes?).

- Corrected.

3/43-44 shouldn't (for a given analyte) "composition of the whole

batch" be equal to "mean concentration in the whole batch" and hence the sampling target should be to select samples so that *their* "mean analyte concentration" represents the composition of the whole batch?

- Corrected.

3/48 how can a target "generate"? - presumably "sampling leads to ..."
Isn't it the measurand which defines a target such as "concentration of a certain component in a system"?

- Corrected.

4/12 "confirmation" ?

- Yes, see for example, our paper: I. Kuselman, P. Goldshlag, F. Pennecchi. *Accred. Qual. Assur.* **19**, 361 (2014). Confirmation is the required step of qualitative analysis, e.g. pesticide residues in food, when after an identification of the analyte (a pesticide forbidden for use), its confirmation is necessary by an orthogonal/ independent analytical method to increase reliability of the finding. The reason is the significant economic and/or public health consequences of this finding.

4/44 please consider "VIM defines validation" or "According to VIM" or else

- Accepted.