



Finntesting-yhdistys
Kevätseminaari 21.5.2026

Eurachemin validointiopas (2025)
“The Fitness for Purpose of Analytical methods”

Anna-Liisa Pikkarainen

Sisältö

- Eurachem-organisaatio, menetelmävalidointiryhmä
- Validointiopas “The Fitness for Purpose of Analytical methods”
- Lisätietoa

Eurachem General Assembly

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Executive Committee Members
Liaison Organisation Representatives

Eurachem Executive Committee

Chair
Vice-Chair, Past-Chair
Secretary
Treasurer
6 Ordinary Members
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Eurachem Working Groups

Experts nominated by Eurachem Members and Liaisons

Ref. <https://www.eurachem.org>

Eurachem – organisaatio & ohjeistukset

- **Tavoite: Eurachem** edistää analyttisten mittausten parhaita käytäntöjä <https://www.eurachem.org/>
- **Kokoukset** – Executive Committee, General Assembly, työryhmät
- **Asiantuntijatyöryhmät** eri aihepiireistä: menetelmävalidointi, koulutus, mittausepävarmuus ja jäljitettävyys, pätevyyskokeet, vertailuaineet, näytteenoton epävarmuus, kvalitatiivinen analyysi, analyttiset laitteet ja systeemin kvalifiointi, <https://www.eurachem.org/index.php/euwgs>
- **Ohjeistukset**- asiantuntijatyöryhmät valmistelevat <https://www.eurachem.org/index.php/publications>
 - julkaistaan Eurachemin verkkosivuilla <http://www.eurachem.org/>
 - ajantasaisuus ylläpidetään tarkastelemalla sisältöjä säännöllisesti ja päivittämällä dokumentit tarpeen mukaan.

Eurachemin menetelmävalidointiryhmä

Edistää parhaita käytäntöjä menetelmävalidoinnissa

- Laatii, täydentää ja päivittää validointiohjeistuksia ja esitelehtisiä
 - <https://www.eurachem.org/index.php/publications/guides/mv>
 - <https://www.eurachem.org/index.php/publications/leaflets>
- Osallistuu yhteistyöhön ja yhteistyöryhmiin
 - Mm. Eurachemissa: kvalitatiivinen analyysi, mittauspävarmuus (ml. näytteenotto), esitteiden valmistelu, non-targeted methods (validointi).
 - Ylläpitää “Reading List”:n julkaisujen menetelmävalidointiosiota yhteistyössä Eurachemin koulutustyöryhmän kanssa.
- Jakaa informaatiota esim.
 - Osallistumalla workshopien suunnitteluun ja järjestämiseen
 - Pitämällä esityksiä tilaisuuksissa (webinaarit, workshopit)
 - Valmistelee parhaillaan Podcast’ia menetelmän validoinnista ja verifioinnista

Eurachemin validointiopas ja täydennysosat

“The Fitness for Purpose of Analytical Methods”

Validointiopas:

- 1. painos 1998
- 2. painos 2014
- 3. painos 2025 (77 s.)

Linkki verkkosivuille:

<http://www.eurachem.org/>

- Publications
 - Eurachem Guides

Opasta täydentävät:

- Planning and Reporting Method Validation Studies
 - 1. painos 2019
 - 2. painos 2025 (26 s.)
- Blanks in Method Validation
 - 1. painos 2019
 - 2. painos 2025 (8 s.)

Menetelmävalidointi

Lyhyt informatiivinen esite “Leaflet” (2025)

Esite ”The importance of method validation” on päivitetty ja nimetty uudelleen v. 2025:

“The importance of being fit for purpose”

Johdanto validoinnin yleiseen prosessiin ja tutkittaviin keskeisiin suorituskykyominaisuuksiin.

Viitteet yksityiskohtaisempiin ohjeisiin.

Ref.

https://www.eurachem.org/images/stories/leaflets/mv/mvintro_2nd_ed/Eurachem_MV_leaflet_EN_2nd_edn_2025.pdf

Validointiopas “The Fitness for Purpose of Analytical Methods” (2025)

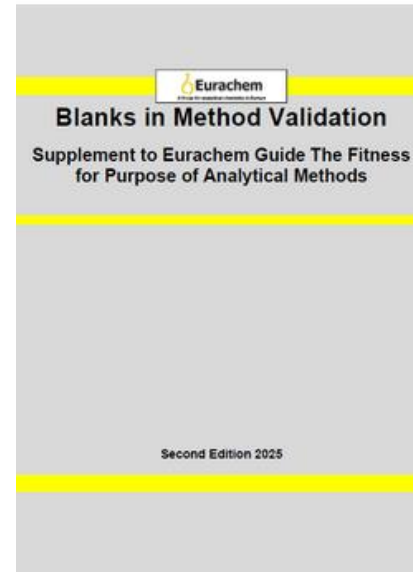
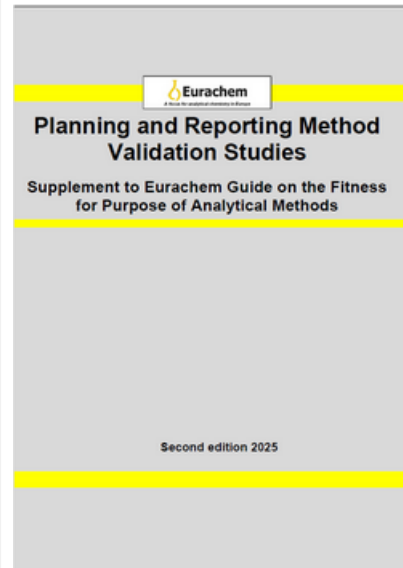
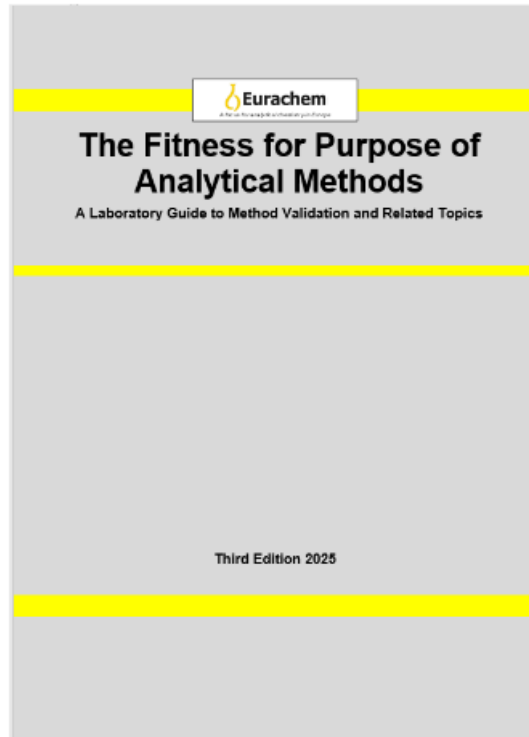
Oppaan kolmannessa painoksessa mm.:

- Tarkoitukseen soveltuvuuden tärkeys
- Menetelmän validoinnin ja verifioinnin käsitteet
- Menetelmän validointi- tai verifiointitutkimus – suorittaminen ja laajuus
- Näytteenotto ja näytteen käsittely menetelmävalidoinnin yhteydessä
- Validointiparametrit (suorituskyky)
- Validointitutkimuksen seuranta (raportointi, suorituskykytietojen käyttö sisäisessä laadunvalvonnassa)
- Analyyttisten menetelmien dokumentointi

Validointiopas “The Fitness for Purpose of Analytical Methods” (2025)

- Uusi osio (4.7) näytteenotosta ja näytteen käsittelystä menetelmävalidoinnin yhteydessä (standardissa ISO/IEC 17025:2017 näytteenotto mukana)
- Kalibrointifunktioon (osio 5.2) liittyvää tietoa lisätty
 - Keskittyminen kvantitatiivisten menetelmien validointiin
 - Kvalitatiivisen analyysiin liittyvää tietoa on Eurachem/CITAC –oppaassa “Assessment of performance and uncertainty in qualitative chemical analysis” (2021)
- Oppaaseen täydennysosat: lisäohjeet menetelmien validointiin liittyvistä aiheista (lisäosia käytetään yhdessä validointioppaan kanssa):
 - Validointitutkimusten suunnittelu ja raportointi (suorituskyky, mallipohjan muoto)
 - Nollanäytteet (“Blank”) menetelmävalidoinnissa

Eurachemin menetelmävalidointidokumentit (2025)



Reading List for Analytical Scientists

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Introduction and scope	2
Introduction to metrology and terminology	3
Traceability of measurement results	5
Uncertainty of measurement	7
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Ref. <https://www.eurachem.org>

Eurachem in menetelmävalidointiesite (2025) Leaflet: The importance of being fit for purpose

https://www.eurachem.org/images/stories/leaflets/mv/mvintro_2nd_ed/Eurachem_MV_leaflet_EN_2nd_edn_2025.pdf

The importance of being fit for purpose

Introduction

Millions of tests, measurements and examinations are made every day in thousands of laboratories around the world. There are innumerable reasons underpinning them, for example: as a way of valuing goods for trade purposes; supporting healthcare and construction; checking the quality and safety of food and feed; and in forensic analysis and environmental monitoring. Virtually every aspect of society is supported in some way by analytical work.

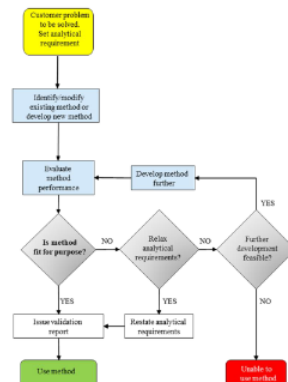
The cost of carrying out these measurements is high and additional costs may arise from decisions made on the basis of the results. For example, tests showing food to be unfit for consumption may result in compensation claims. In addition, tests confirming the presence of banned drugs could result in fines or imprisonment. Clearly it is important to make a correct measurement and be able to show that the result is correct.

The validation/verification process

Most analysts know that method validation/verification is important, but exactly why, how and when it should be done is not always clear.

Method validation/verification is the process whereby the laboratory demonstrates whether or not a method is 'fit for purpose' (Fig. 1). This means that the tests carried out should be appropriate with respect to uncertainty, cost, time etc. The final report should present analytical data in such a way that the customer can, readily, interpret it and draw appropriate conclusions.

Fig. 1. The method validation/verification process. The laboratory 'translates' the customer's problem into an analytical requirement, i.e. the method performance required to solve the problem. Method validation/verification includes a stage where various performance characteristics are evaluated and then compared with analytical requirements.



The Eurachem Guide

A Guide from Eurachem (Fig. 2) gives practical advice on how method validation/verification can be accomplished. The Guide and its supplements [1-4]:

- Introduce the basic concepts related to method validation and method verification;
- Indicate how to plan, record and report validation and verification studies to best support the statement of 'fitness for purpose';
- Provide key definitions and the rationale behind the experiments for assessing the various performance characteristics and related topics (Fig. 3);
- Include quick reference tables that suggest experiments together with the necessary statistical calculations for evaluation and reporting each performance characteristic;
- Provide support to the analyst on how to make the best use of method validation data for setting up an internal quality control plan.



Fig. 2. The Eurachem Guide is available free of charge at www.eurachem.org.

How should methods be validated/verified?

Precision
• Repeatability
• Intermediate precision
Trueness
Selectivity
Working range
Analytical sensitivity
Limit of detection
Limit of quantification
Ruggedness

The guide focuses on a single-laboratory approach to method validation/verification and gives guidance on planning, carrying out and reporting method validation and verification studies.

Any method validation or verification study will require the laboratory to investigate several performance characteristics (Fig. 3). Exactly which characteristics are studied will depend on the analytical application. Verification of the performance of a standard method requires substantially less work than validation of a method developed in-house. Legislative/sectoral requirements must also be considered.

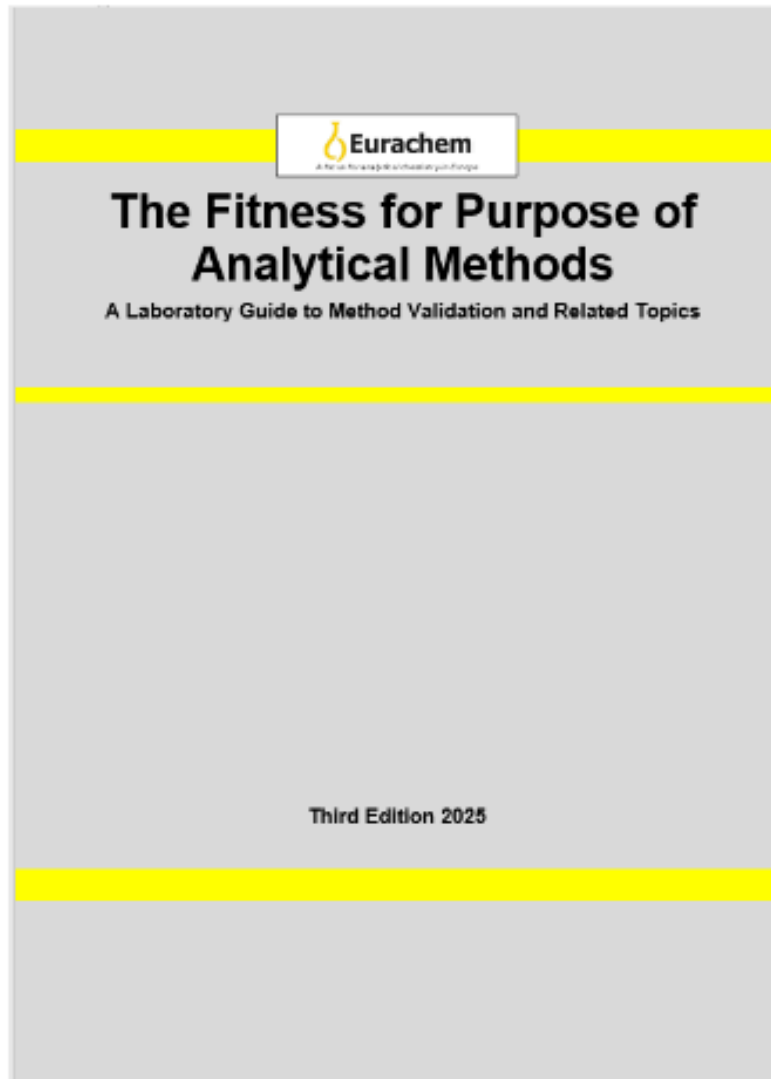
Sampling and subsampling can be part of the measurement or testing procedure and must, in those cases, be validated.

Fig. 3. The most common performance characteristics studied during in-house method validation.

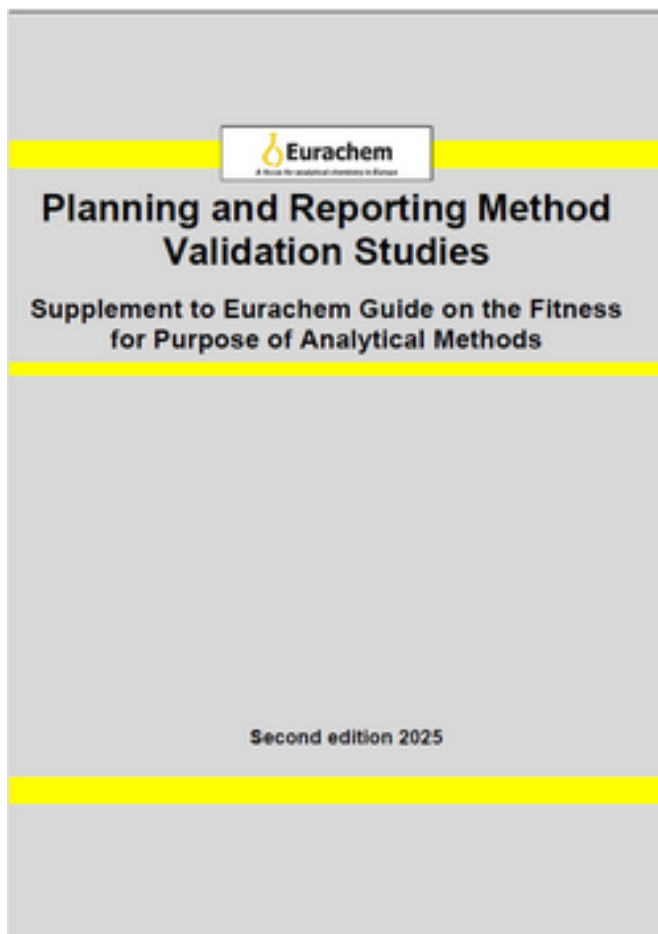
More information / further reading

1. H. Carroll (ed.) Eurachem Guide: The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics, (3rd ed. 2023). Available from www.eurachem.org.
2. V. Barwick (ed.), Planning and Reporting Method Validation Studies – Supplement to Eurachem Guide on the Fitness for Purpose of Analytical Methods (2nd ed. 2023). Available from www.eurachem.org.
3. H. Carroll (ed.) Statistics in Method Validation – Supplement to Eurachem Guide on the Fitness for Purpose of Analytical Methods, (2nd ed. 2023). Available from www.eurachem.org.
4. M. H. Ramsey, P. D. Roalson, P. C. Raposo (eds.) Eurachem/EUROLAB/CITAC/Verdetec/ANIC Guide: Validation of Measurement Procedures that Include Sampling, Eurachem (2nd ed. 2024). Available from www.eurachem.org.

Produced by the Eurachem Method Validation Working Group
Second English edition, 2025
www.eurachem.org



- Foreword to the third edition
- Foreword to the second edition
- Foreword to the first edition
- Abbreviations and symbols
- 1. Introduction
- 2. The importance of fitness for purpose
- 3. Method validation and method verification
- 4. How should methods be validated?
- 5. Method performance characteristics
- 6. Using validated methods
- 7. Using validation data to design quality control
- 8. Documentation of validated methods
- 9. Implications of validation data for routine use of analytical methods and reporting results
- Annex A – Method documentation protocol
- Annex B – Statistical basis of limit of detection calculations
- Annex C – Analysis of variance (ANOVA)
- Annex D – How to select and assure validity of a test kit
- Bibliography



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Foreword

1 Abbreviations and symbols

2 Introduction

3 Points to consider when planning a validation study

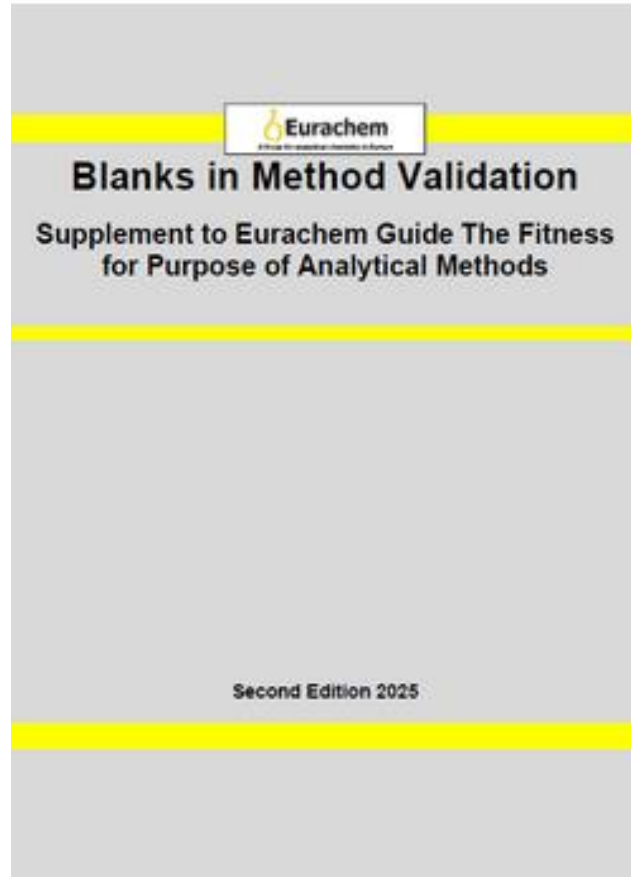
4 Notes on completing the validation plan for each performance characteristic

5 Example planning and reporting document

Appendix 1: Checklist for a validation study

Appendix 2: Experimental plan – example of a nested experimental design

Bibliography



Contents

Foreword to the Second Edition

1 Introduction and scope

2 Types and uses of blanks in method validation

2.1 Blanks associated with sampling.

2.2 Calibration blank

2.3 Procedural blank

2.4 Reagent blank

2.5 Solvent blank

2.6 Sample blank

2.7 Approaches to dealing with situations where no suitable sample blank is available

3 Bibliography

“Eurachem reading list”

- <https://www.eurachem.org/index.php/publications/mnu-rdlst>
- Lista päivitetään aihepiireittäin vuosittain
- Analyysimenetelmien validointi - viitetiedot:
 - Standardit
 - Oppaat
 - Kirjat
 - Esitteet
 - Artikkelit ja raportit

1. Introduction to metrology and terminology

2. Traceability of measurement results

3. Uncertainty of measurement

4. Qualitative analysis

5. Sampling

6. Statistics

7. Validation of analytical methods

8. Reference materials

9. Proficiency testing

10. Internal quality control

11. Quality assurance and accreditation

12. Equipment qualification

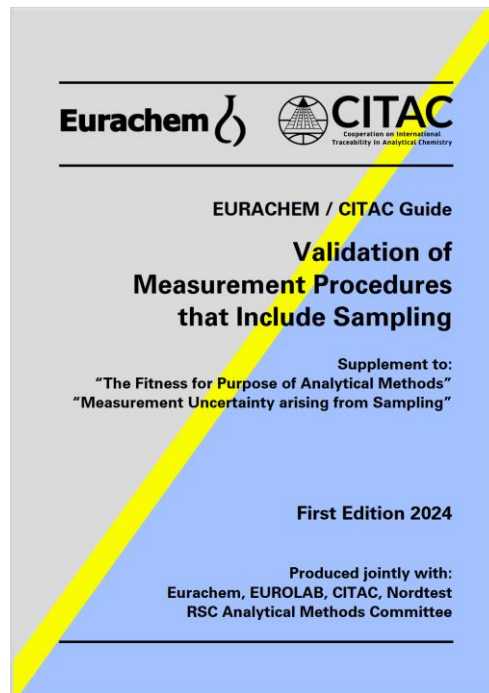
Menetelmävalidointityöryhmä - yhteistyössä

Eurachemin työryhmien kanssa:

- Kvalitatiivinen analyysi – kvalitatiivisten menetelmien validointi;
- Näytteenoton epävarmuus – näytteenoton sisältävien menetelmien validointi
- Koulutus – esitteet, “reading list”

Eurachem/CITAC Guide: VaMPIS - Validation of Measurement Procedures that Include Sampling (2024)

- <https://www.eurachem.org/index.php/publications/guides/vampis>
- <https://www.eurachem.org/index.php/publications/leaflets/mnu-il-vampis>



VaMPIS - Validation of Measurement Procedures that Include Sampling

1. Introduction

Validation of analytical methods (i.e. procedures) usually excludes the primary sampling, but this is now widely recognised as the first step in the measurement procedure [1] (Fig. 1). **Validation of the whole measurement procedure therefore requires consideration of a performance characteristic that reflects the quality of all of the steps (including sampling and physical sample preparation).** The uncertainty of the final measurement value is that key characteristic that unifies this whole measurement procedure and enables its validation, particularly when supported by performance characteristics that have an established role in the validation of an analytical procedure as a standalone activity [2]. This leaflet summarises the new Eurachem/CITAC guidance on the Validation of Measurement Procedures that Include Sampling (VaMPIS) [3]. It can be applied to the whole measurement process either **simultaneously**, where the sampling and analytical procedures are validated as a unified measurement procedure, or **sequentially** when the analytical procedure has previously been validated in isolation.

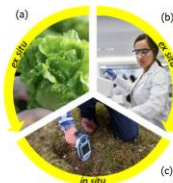


Figure 1. Representation of the whole measurement process that requires validation. In the *ex situ* mode this includes the two steps of (a) primary sampling (in this case of a bay of lettuce heads) followed by (b) chemical analysis. In *in situ* mode this usually requires just one step (c) both sampling and analysis within the same measurement process (in this case in situ pXRF on an area of soil).

2. In situ and ex situ measurement

There are now many *in situ* measurement techniques (e.g. portable XRF in Fig. 1c), where the measurement is taken directly from the sampling target, without the need to extract a physical sample. This **new mode of measurement** highlights the need for an integrated approach to the definition of the measurement process so that it includes sampling. This approach is also equally applicable to the traditional mode of *ex situ* measurement (Fig. 1b) of a physical sample extracted from a sampling target (Fig. 1a). Both modes require the primary sampling to be included within the measurement procedure, its validation, and in the estimation of measurement uncertainty.

3. How to apply VaMPIS

The only parameter of a measurement procedure that can effectively integrate the effects on data quality from all of the steps in the procedure (including sampling) is the **measurement uncertainty**. This uncertainty is stated within the final measurement result. It allows the user of that result to assess the effects of both random and systematic effects arising at every stage of the measurement procedure on decisions that are to be made using that result (e.g. compliance of a batch of material with a regulatory threshold). The VaMPIS approach therefore uses the uncertainty of the measurement value to judge the **fitness for purpose** (and hence validity) of the whole measurement procedure by comparing it with a 'target' uncertainty. It is **essential that the target uncertainty should also include the contribution from sampling**, and it can either be set by an external body (e.g. a regulator)

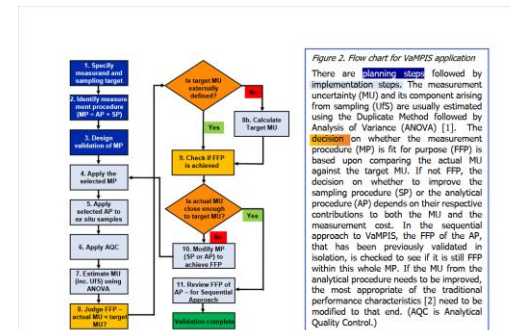


Figure 2. Flow chart for VaMPIS application

There are **planning steps** followed by **implementation steps**. The measurement uncertainty (MU) and its component arising from sampling (SP) are usually estimated using the Duplicate Method followed by Analysis of Variance (ANOVA) [1]. The **decision** on whether the measurement procedure (MP) is fit for purpose (FFP) is based upon comparing the actual MU against the target MU. If not FFP, the decision on whether to improve the sampling procedure (SP) or the analytical procedure (AP) depends on their respective contributions to both the MU and the measurement cost. In the sequential approach to VaMPIS, the FFP of the AP, that has been previously validated in isolation, is checked to see if it is still FFP within this whole MP. If the MU from the analytical procedure needs to be improved, the most appropriate of the traditional performance characteristics [2] need to be modified to that end. (AQC is Analytical Quality Control.)

or, if that is not available, by the user, using a technique such as the **Optimum Uncertainty method** ([3] Appendix B). **Worked examples** of validation are given where the whole measurement procedure is applied, either *ex situ* (Appendix A1: Nitrate in extracted composite samples of lettuce, Fig. 1a) or *in situ* (A2: Pb in soil by pXRF without removal of physical samples, Fig. 1c). There are eleven broad steps for the application of VaMPIS (Fig. 2). Measurement uncertainty is generally estimated using the **Duplicate Method** in which duplicate primary samples are taken from at least eight sampling targets by an independent reinterpretation of the sampling procedure. Both duplicate samples are then analysed in duplicate. The measurement uncertainty, and its main components from sampling and analysis (as repeatability), are estimated by applying ANOVA to the resultant measurement values, and also including analytical bias and sampling bias where possible [1]. The **fitness for purpose of the procedure** is judged by comparing the estimated measurement uncertainty against a value of target uncertainty set for that particular purpose [3].

The VaMPIS guide [3] also includes a discussion of the role of ongoing quality control of the whole measurement procedure (integrated measurement quality control, IMQC) to ensure ongoing quality compliance after the initial validation. One major challenge for implementation that is also discussed, is to ensure effective communication and cooperation between the laboratory staff and the off-different organisation that takes the samples.

More information / further reading

- [1] Ramsey M. H., Ellison S. L. R. and Rostrom P. (eds.) Eurachem/EUROLAB/CITAC/Nordtest/AMC Guide: *Measurement Uncertainty Arising from Sampling: a Guide to Methods and Approaches*. Eurachem (2nd ed. 2019)
- [2] Cirtwell H. (ed.) Eurachem Guide: *The Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics*. Eurachem (2nd ed. 2022).
- [3] Ramsey M.H., Rostrom P.D., and Raposo F.C. (eds.) Eurachem/EUROLAB/CITAC/Nordtest/AMC Guide: *Validation of Measurement Procedures that Include Sampling*. Eurachem (2024).

All available from <http://www.eurachem.org>.

Produced by the Joint Technical Group on VaMPIS with representatives from the Eurachem and AMC Sampling Uncertainty and Eurachem Method Validation Working Groups, as well as from CITAC & Nordtest. First English edition, [April 2025]. www.eurachem.org

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Eurachemin tilaisuuksista tietoa

Eurachemin verkkosivuilla

Linkit aikaisempien workshopien (2012, 2016, 2019) aineistoihin:

- Validation of targeted and non-targeted methods of analysis (2019)
 - <https://www.eurachem.org/index.php/events/completed/257-wks-ntrg2019>
- Method Validation - Current Practices and Future Challenges (2016)
 - <https://www.eurachem.org/index.php/events/completed/193-wks-mv2016-cmp>
- Validation, Traceability and Measurement Uncertainty (2012)
 - <https://www.eurachem.org/index.php/events/completed/71-evmumv2012>



Kiitos