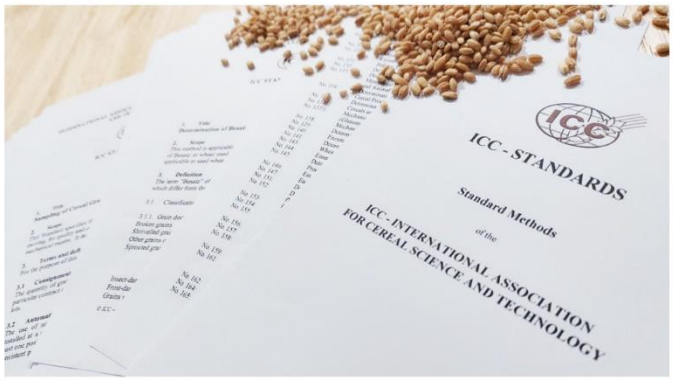
Standard Operation Procedure (SOP) for

ICC STANDARD METHOD VALIDATION



Summary: This document describes the requirements and procedure for the ICC Standard Methods Validation

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1. Introduction

For nearly 70 years ICC has been validating and publishing analytical standard methods applied in safety and quality assessment of cereals and crops, cereal based products, foods and feed. Reliable analytical methods are required for compliance with national and international regulations in all areas of analysis. ICC Standard Methods help to harmonize the specifications of cereal based raw materials and products and break down barriers to international trade. Validation of methods is a very important instrument for quality assurance required by authorities within the scope of accreditations and approval procedures. Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice and involves the establishment of the performance characteristics and limitations of a method and the identification of influences which may change those characteristics.

ICC's primary objective is the development of internationally approved and accepted standard testing procedures for cereals, pseudo-cereals, cereal products and flours as well as related raw materials and derived products that serves international trade, national and international legislation, industry standards such as ISO and CEN, and as guidelines for food manufacturers, control and research laboratories. The testing methods, that can be qualitative and/or quantitative, may include but are not limited to screening analysis, confirmatory analysis, and limit tests. Methods may be validated for one or more measures and, one or more matrices, and one or more instruments or platforms. Validated methods are published in the ICC Standards Collection and can be purchased via ICC Services. Some of the ICC Standard Methods are part of the Codex Standard 234-1999/2023 "Recommended Methods of Analysis and Sampling".

Who may apply?

Eligible Method Proposers		
Organisations	**Associations & Companies** (Public and Private Sector)	**Individuals**

Those companies, institutions and individuals may apply who:

- have a new and innovative original method.
- would like to expand the scope of an existing method to include an additional measurand.
- would like to expand the scope of an existing method to include additional matrices.
- have changes in the intended use of an existing method.
- have modifications to a method that may alter its performance specifications (e.g., changes to the fundamental science of an existing method, significant changes to reagents, apparatus, instrumental parameters, sample preparation and/or extraction, or modification of a method's range beyond validated levels).

ICC is also the right partner for you if you have identified methodological gaps in your field or industry, or if you notice that the methods currently available on the market do not cover your requirements. In principle, already established methods of analysis with approved standards from other standard developer organisations (SDOs) can be considered for validation at ICC. The ICC requirements for a collaborative study should be met. The requirements of the usual procedure should be followed, although certain procedural steps may be recognized or implemented in an abbreviated manner upon presentation of existing documents. ICC will not accept a method from another standards organisation unless approval to co-publish is discussed and can be provided.

2. ICC Standard Method Validation

ICC Standard Method Definition

An ICC Standard Method is a document that sets out specific requirements for the determination (chemical and/or physical quantification) of a specific measurand and/or property in appropriate matrices. In detail, this document describes a particular method or analytical procedure employed for a specific test. The primary use of ICC test methods is to determine the specified biological, chemical and physical properties of cereals and cereal derived products and by-products.

Objectives

The main purpose of validating a method of analysis is to ensure that the method is suitable for its intended purpose (fit for use).

The protocol or method of analysis is a set of permanent instructions for the conduct of the method of analysis. Method validation is a distinctive phase in method development/ optimization and should be performed subsequently to (or "in line with") method development. The method developer validates a method by conducting trials to determine the specific performance characteristics to define and quantify method performance.

The method of analysis that is finally approved should be exactly the same as the one that was used and revised during the collaborative study.

Scope and Purpose

The ICC methods include those that have proven practical and scientific value to food technology in general and cereal science in particular. ICC methods development provides an international platform for scientists and researchers to validate testing methods. ICC requirements for validation are detailed in this standard operating procedure, which clearly specifies the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. It is necessary to point out that not all validation requests are successfully completed due to several reasons, e.g. inappropriate method, unsuitable collaborative test, etc. Method developers do not have any legal entitlement to a successful validation if, in the view of the ICC experts, the prerequisites are not met.

ICC Standard Methods have been developed through a process that is open to participation by representatives of all interested members that have recognized the need for internationally accepted standards to help rationalize the international trading process.

Content and Output of an ICC Standard Method

ICC aims to support the global cereal sector, with innovation being one of its main tools. An ICC Standard Method must be innovative which can be reflected in various ways:

- Innovative techniques (principle and equipment) for addressing a proven testing need.
- Improved accuracy and/or reliability.
- Quicker response time.

For more information on the output and content of an ICC Standard Method, a detailed description is provided in the instruction "Formatting Guidelines for ICC Standard Methods".

3. Abbreviations

AOAC	Association of Official Analytical Chemists
CEN	European Committee for Standardization, Comité Européen de Normalisation
EC	Executive Committee
FAO	Food and Agriculture Organisation
GA	General Assembly
ICC	International Association for Cereal Science and Technology
ISO	International Standard Organisation
IUPAC	International Union of Pure and Applied Chemistry
TC	Technical Committee
TD	Technical Director
MD	Method Developer
MP	Method Provider
SDO	Standards Development Organisation
SOP	Standard Operation Procedure
WG	Working Group

4. Definitions

ANOVA	Analysis of variance (ANOVA) is used to examine the variance of the mean values of several different samples with each other. The dependent variable is measured at different levels of one or more factor variables. Total variance is partitioned into factor-related components and measurement error with the goal of quantifying the factor effects.
Chemical Quantification	The accurate determination of the absolute or relative abundance of one, several or all particular substances of a sample.
F-Test	The F test is a statistical test that is used in hypothesis testing to check whether the variances of two normally-distributed populations or two samples are equal or show significant differences in the variances.
Food Matrix	The nutrient and non-nutrient components of samples (e.g. primary products, foods) and their molecular relationships, i.e. chemical bonds, to each other.

ICC Committees	ICC Technical Committee (TC), ICC Executive Committee (EC) and ICC General Assembly (GA) are representative bodies of ICC according to its statutes and by laws.
ICC Standard Method	An ICC Standard Method is a document that sets out specific requirements for the determination (chemical and/or physical quantification) of a specific measurement and/or property in food related matrices. In detail this document describes a particular method or analytical procedure employed for a specific test.
Limit of Detection (LOD)	LOD is the lowest signal, or the lowest corresponding quantity to be reliable detected from the signal, that can be observed, with the chosen method, with a sufficient degree of confidence or statistical significance.
Limit of Quantitation (LOQ)	The LOQ is the lowest concentration or content of the analyte in a test sample which can be quantitatively determined with an acceptable level of precision and accuracy.
Method Developer (MD)	Synonym: Standard Developer Person / Organisation / company who applies for the validation of its method at ICC and goes through the validation process together with ICC. Method Developer can act as well as Method Proposer
Method Proposer (MP)	Person / organisation / company proposing the validation of a new method
Physical Quantification	The process of determining a physical property of a material or a system that can be expressed as a numerical value and a unit of measurement.
Proprietary method of analysis	A proprietary method of analysis is defined as a method that is developed by an "entity" to which the patent belongs and ICC shall acknowledge the fact that it is the protected intellectual property of the owner until expiry (depending on country of origin and/or Member States rules).
Reference Standard Method	A reference method is a method by which the performance of an alternative or new method (potential standard method) may be measured or evaluated for a specific measurand.
Collaborative test	A collaborative test (sometimes called ring trial or "Round Robin") is a method of external quality assurance for measurement procedures and measurement and testing laboratories. Basically, identical samples are tested with identical procedures in different environments. The comparison of the results allows statements to be made about the measurement accuracy in general or about the measurement quality of the participating institutes. In **collaborative tests** a single, carefully described, procedure is used by all participant laboratories. In that respect they differ from **proficiency tests** where participants are nearly always free to use a method or procedure of choice.
SI units	The International System of Units

TD Board	Board of ICC Technical Directors: ICC Technical Director and Technical Co-Directors
Validation	The process used to confirm that the integrity, accuracy and quality of an analytical procedure employed for a specific test is suitable for its intended use.
Working Group	After approval of the application, ICC forms a working group to work on the method. The working group consists of members of ICC TC, other experts may be called in by the working group leader as needed. The lead of the working group is decided by the TD-Board.
Working Group – Leader	Person who organizes the processing of the submitted standard for validation and leads the working group.

5. Terms and Conditions

governing ICC Standard Method ownership, validity and expiry

Ownership

ICC Standard Methods are owned by ICC and thus are protected by ICC copyright. ICC Standard Methods are sold by ICC Services GmbH and authorized distributors contracted by ICC. Any submission of ICC Standards to CEN, ISO, and Codex Alimentarius by any national / regional government or other institution needs to be approved by ICC and the authorship of ICC needs to be referred to in the publication / submission form.

ICC is the sole copyright holder for its scientific publications including draft standard methods and approved ICC Standard Methods. For the period of copyright, the copyright owner has the following exclusive rights, as specified in the Berne convention and the World Intellectual Property Organisation (WIPO).

None of the actions below can be carried out without permission:

- The right to authorize translations of the work.
- The exclusive right to reproduce the work, though some provisions are made under national laws which typically allow limited private and educational use without infringement.
- The right to authorize public performance or broadcast, and the communication of broadcasts and public performances.
- The right to authorize arrangements or other types of adaptation to the work.
- Recitation of the work (or of a translation of the work).
- The exclusive right to adapt or alter the work.

ICC has the following moral rights:

- to claim authorship
- to object to any treatment of the work which would be 'prejudicial to his honor or reputation'
- to prevent full disclosure of information about the method and/or restricting or limiting the use
- to distribute the method or materials for its performance without express permission or licensing

For ICC purposes, a proprietary method of analysis is defined as a method that is developed by an "entity" to which the patent belongs and ICC shall acknowledge the fact that it is the protected intellectual property of the owner until expiry (depending on country of origin and/or Member States rules).
However, once the "proprietary" method is validated as an ICC standard method, the association holds solely all copyrights.
The owner of the "Proprietary method" shall be held responsible for updating the testing procedure when deemed necessary. For this purpose, he/she will approach the method developer at regular intervals with a questionnaire on changes. In addition, method developers and users of these methods are encouraged to report comments and changes to the ICC at any time.

Validity and Expiry

ICC will check its ICC Standard Methods regularly if a revalidation is necessary. Reasons for a revalidation could be for example:

- Expansion of the scope of an existing method to include additional measure method(s).
- Expansion of the scope of an existing method to include additional matrices.
- Changes in the intended use of an existing method.
- Modifications to a method that may alter its performance specifications (e.g., changes to the fundamental science of an existing method, significant changes to reagents, apparatus, instrumental parameters, sample preparation and/or extraction, or modification of a method's range beyond validated levels.)
- Justified complaints by users of the ICC Standard.

ICC reserves the right to request method revisions in certain intervals, if the advancements and method developments in a certain field of analysis demand a more rapid turnover.
ICC reserves the right to ask for revision or a withdrawal of an ICC Standard Method in case of doubt.
The method provider is obliged to inform ICC, if changes or additions have been made to a published method. When changes have been made to an existing ICC Standard, ICC reserves the right to request a new collaborative test for the modified / improved method for continued use and circulation as ICC Standard. Failure to provide updating information for a modified method / appliance will result in the withdrawal of the method as ICC Standard and informing its users and collaborating SDOs about the withdrawal.

When an ICC Standard Method is changed by international committees, such as ISO, CEN, Codex Alimentarius, ICC requests to be informed about the proposed changes by the submitting agency and/or the Method Provider.

6. Procedural Guidance for Method Validation

Documentation of Validated Methods

The documentation of validated methods refers to the required method format, precision and performance data.

In principle ICC validation studies / collaborative tests follow the requirements of the IUPAC / AOAC / ISO international harmonized protocol for collaborative trials (W. Horwitz, Pure and Applied Chemistry, 67 (1995): 331-343). However, the ICC protocol also accounts for several issues that have been discussed at Codex Alimentarius level more recently (e.g. recovery, recovery correction, measurement uncertainty, etc.). The ISO Guide 35:2017 and ISO/DIS 33405 gives statistical principles to assist in the understanding and development of valid methods to assign values to properties of a reference material, including the evaluation of their associated uncertainty, and establish their metrological traceability.

Existing Protocols, Standards, and Guides

A number of protocols and guidelines on method validation and uncertainty have been prepared through international harmonization projects and can be used as reference in the process of method validation. This SOP brings together the essential scientific principles of the documents below to provide information acknowledged internationally and, more importantly, to point the way forward for best practice in method validation.

- Harmonized guidelines for single laboratory validation of methods of analysis – IUPAC Technical Report. Pure & Appl. Chem., Vol. 74, No. 5, pp. 835–855, 2002
- IUPAC - Protocol for the design, conduct and interpretation of method-performance studies – Technical Report, Pure &Appl. Chem., Vol. 67, No. 2, pp. 331-343, 1995.
- ISO 5725-1:2023. Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions (and Corrigendum 1:1998).
- ISO 5725-2:2019. Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method (and Technical Corrigendum 1:2002).
- ISO 5725-3:2023. Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate measures of the precision of a standard measurement method (and Corrigendum 1:2001).
- ISO 5725-4:2020. Accuracy (trueness and precision) of measurement methods and results – Part 4: Basic methods for the determination of the trueness of a standard measurement method.
- ISO 5725-5:1998. Accuracy (trueness and precision) of measurement methods and results – Part 5: Alternative methods for the determination of the precision of a standard measurement method (and Corrigendum 1: 2005).
- ISO 5725-6:1994. Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values (and Corrigendum 1: 2001).
- EURACHEM 2nd edition-2014 The Fitness for Purpose of Analytical Methods-A Laboratory Guide to Method Validation and Related Topics.
- AOAC official methods of analysis (2023), Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis. Official Methods of Analysis of AOAC International. 22 nd. Edition, Ed. G. W. Latimer.
- AOAC Official Methods of Analysis (2016), Appendix F: Guidelines for standard Method Performance Requirements.
- FAO Food and Nutrition. A Report of a Joint FAO/IAEA Expert Consultation 2-4 December 1997, Vienna, Austria, Validation of Analytical Methods for Food Control, Paper 68: 1997.

Requirements of the Validation Study

The requirements for the collaborative test of any ICC validation study are given below and may serve as guidelines for organizers and evaluators of collaborative tests within the ICC standardization program. It is recommended to discuss the performance of the validation study with the TD board before starting the process. Already available data e.g. from an in-house validation may be used for the validation process after the quality of the data has been checked by the TD board.

Collaborative test

- The collaborative test is an integral part of the method validation. Therefore, the accurate planning and execution of the collaborative test as well as the statistical evaluation of the results is of utmost importance. An insufficiently performed collaborative test leads to the fact that the method cannot be validated successfully. The study plan of the collaborative trial, including templates for reports and procedure for statistical analysis, must be submitted to approved by the TD board, before undertaking the study. If a study was not planned with the TD board it can be submitted to ICC Headquarters for approval / acceptance, but ICC reserves the right to turn down the certification as ICC Standard Method. For this purpose, all results of the collaborative test must be submitted to the ICC as required below.
- The submitting organisation / institution or individual and the coordinating institution / laboratory must be an ICC Member.
- A minimum of eight useful data sets from eight different laboratories are required; ICC recommends including at least 12 laboratories (after elimination of outliers and non-compliant laboratories).
- To be counted as an international collaborative test, a minimum of three countries needs to be involved. Regionally used methods may have their justified place in the ICC Standards Collection, however, collaborative tests not meeting the international scope need to highlight this limitation in the scope.
- Participating laboratories must be approved by ICC and must be competent and reputed structures of international or national standing, e.g. laboratories accredited ISO/IEC 17025 or substantially equivalent. A 50% of participating laboratories from ICC member organisations and institutions is encouraged.
- Trial participants from non-member countries may be invited upon the request of the organiser but require approval by ICC.
- No more than a maximum of 30% of the participating laboratories may show an organisational relationship (e.g. laboratories in various locations, but belonging to the same company or distribution network). However, laboratories from the same institution must be independent from each other using their own instruments and personnel.
- It is strongly recommended that participating laboratories have experiences with basic techniques of the method under validation to ensure reliable and traceable results.
- If specific instruments or equipment are needed for the performance of the method, it is necessary that the participating laboratories have this at their disposal or are provided with it.
- A detailed description of the collaborative test setup and a full report including a copy of all original data and statistical calculations must be provided to ICC for review by the ICC Technical Director and Co-Directors and final discussion and approval by the ICC Technical Committee.
- The collaborative tests will be conducted in an anonymous manner towards the participating laboratories and the ICC Technical Committee. Besides the study director, who is responsible for the performance of the validation process for the method provider, only the Technical Director and Co-Directors will have full information about the applicant. This is to ensure pure objectivity. The Technical Director and Co-Directors shall be informed about the results directly from the participating laboratories. After a method has been validated and published as a standard method, the submitting organisation may be disclosed.

- Joint validation and/or joint submission/publication of Standards in collaboration with related SDOs (Standards Development Organisations) are recommended. However, they must be disclosed to the ICC.
- If a method / appliance /test kit or reference material is jointly validated with other SDOs a mutual recognition / equivalence needs to be stated in the published methods, respectively.

The method will describe the range of values of the measurand for which it is applicable. The collaborative study must test the full range of variation of the measurand in the relevant matrixes, as indicated in the method's scope.

Statistical evaluation

- The MP must have an experienced statistician to accompany the validation process - it is recommended to hire an external statistician for this purpose.
- The expertise of a statistician must already be taken into account when planning the collaborative tests.
- For final analysis of the results the statistical methods used must be clearly described by the method provider. Details of who performed the statistical calculations should be given and ICC has to check the expertise by the TD board if necessary. Statistical evaluation of the method must include the following parameters:
    - Description of the method / appliance /test kit / reference material used.
    - Description of the "measurand".
    - Description of the "sample" / reference material.
    - Homogeneity test (e.g for spiked or incurred material) results of the sample material (if necessary) (usually performed by the organizing laboratory and / or confirmed by 1-2 additional laboratories, e.g. F-test, ANOVA on 10 replicate samples tested taken from the same lot).
    - Detailed report including all used instruments, chemicals, environmental conditions (like room temperature) etc.
    - Details of participating laboratories including name of operator, operator's function. Copy of original results / data including lot number, serial number, etc.
    - Repeatability.
    - Reproducibility.
    - Recovery, where applicable.
    - Limit of Detection (LOD) and Limit of Quantitation (LOQ,), where applicable. Parameters can be calculated from the results of the collaborative test if appropriate samples were included or the method provider provides appropriate data reviewed for suitability by TD board
    - Measurement uncertainty.
    - Traceability to SI units, where applicable.

The ICC reserves the right to call in an external statistical expert under the cost coverage of the Method Developer.

Samples

- Any material used as a sample needs to be well described (origin, ingredients, concentration, matrix, etc.).
- Homogeneity and stability (e.g for spiked or incurred material) need to be tested, documented and monitored throughout the collaborative test.
- In agreement with the TD board it will be decided that at least a part of these samples should be produced and tested for homogeneity and stability by an independent institution other than the method provider/developer/applicant. The decision depends on the needed sample material and will be done by on case to case basis.

- According to the IUPAC / AOAC / ISO international harmonized protocol for collaborative trials, at least five different samples or two different matrix samples at four different concentration levels (including a zero / blank sample) shall be used.
- The samples must be representative for the range of variation of the measurand in the specified matrices. The samples shall be selected to cover the relevant range of application of the method with concentrations distributed across the whole application range.
- It is recommended to carry out a "small" collaborative test with few participating laboratories before starting the regular collaborative test to check if everything works well. If the small collaborative test was successful, the results can also be included into the regular collaborative test.
- Depending on the sample material and the method to be validated it is recommended that the samples for the collaborative test should be at least from three different regions/countries and the sample preparation steps e.g. milling have to be included in the protocol. Agreement with the TD board is necessary.

ICC's method format takes into account the requirement of:

- ISO 78-2:1999 Chemistry - Layouts for standards - Part 2: Methods of chemical analysis.
- ISO 78-3:1983 Chemistry - Layouts for standards - Part 3: Standard for molecular absorption spectrometry.
- EURACHEM 2nd edition-2014 The Fitness for Purpose of Analytical Methods-A Laboratory Guide to Method Validation and Related Topics.

Any relevant instrumentation and software should be the same or comparable in each laboratory. Other instruments may vary (e.g. model of centrifuge, provided that it is capable to reach the prescribed acceleration). Whilst it is desirable that all methods should have the same document format, it should also be recognized that not all methods warrant the same degree of detail and frequently it will be appropriate to omit some of the recommended sections from the documentation.
The format specified in the "Formatting Guidelines for ICC Standard Methods" is for reference as a suitable layout. It is for guidance only and could be adapted to suit any special requirements.

Approval of Standard Methods from a Different Organisation

Generally established methods of analysis currently recognized as a standard method from a different standards organisation can be considered for adoption as an ICC approved method. In this case already existing documents (in particular collaborative tests and their statistical evaluations) including a confirmation for the approval to co-publish the method as ICC standard must be submitted to the TC for review.

7. The Validation Process

Figure 7.1 describes the steps and defines the deadlines to be able to estimate the duration of the validation process:

Terms:
AQ: Application Questionnaire **MD**: Method Developer and/or Method Proposer **TD**: ICC Technical Director **TC**: ICC Technical Committee **WG**: Working Group

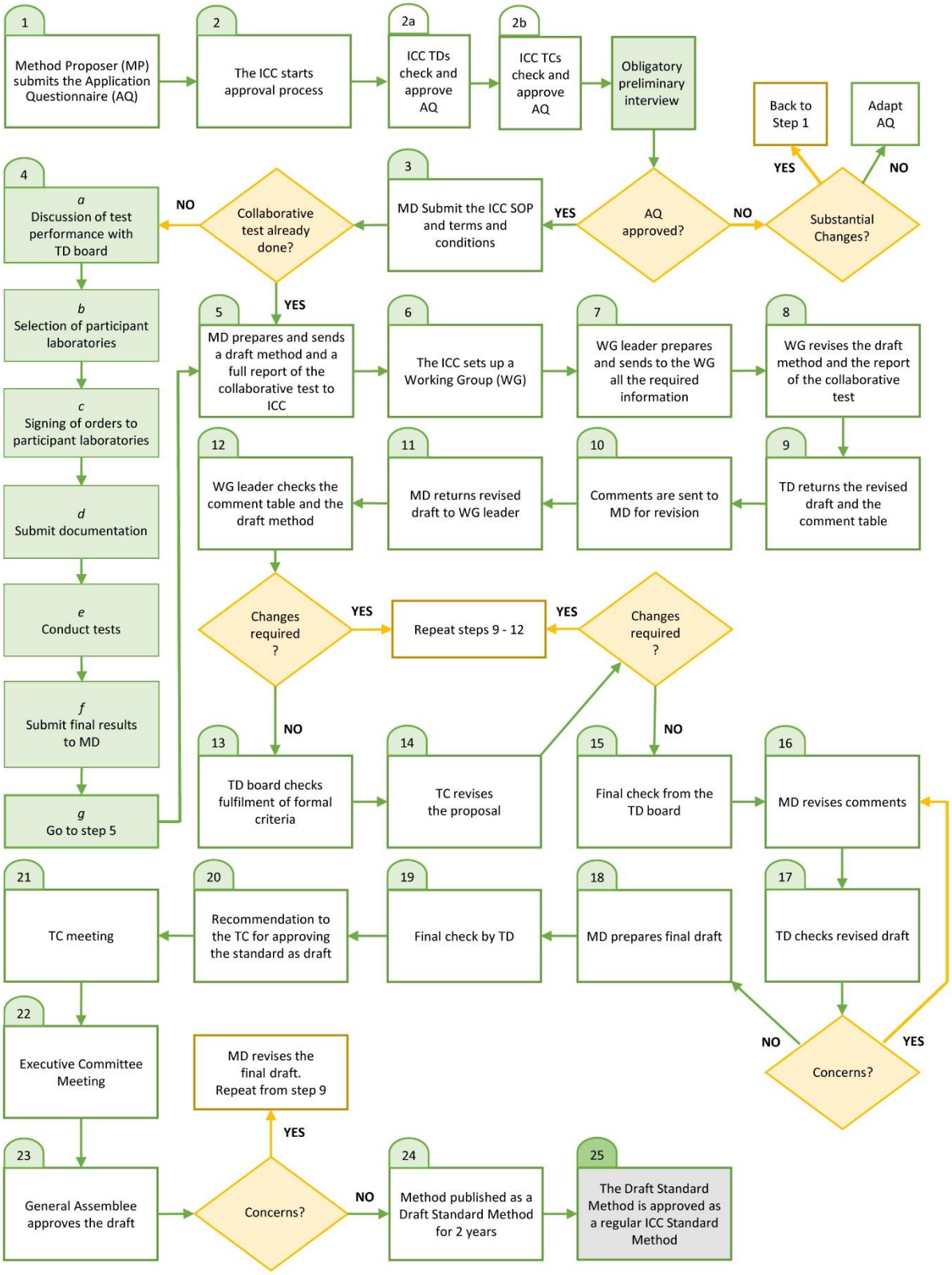

Fig. 7.1: Flow diagramFlowdiagramm of the Validation process

Step 1:	Method Proposer (MP, can be as well the Method Developer, MD) submits the _ICC Application Questionnaire draft to ICC Headquarters.
Step 2:	ICC starts the approval process: An ICC standard validation request has to be approved by the TC.
2a	check of the approval by the TDs
2b	check of the approval by the TC
2c	response to MP
	○ No concerns: Starting with Step 3 ○ Asking MP for changes: if this is necessary Step 2a and/or 2b has to be repeated after revision of the draft as often as necessary. *(In case of a new validation at this stage a meeting between MP and TD is strongly recommended.)*
Step 3:	Signing of a standard validation agreement between MD and ICC.
Step 4:	Collaborative Test
4a	Discussion of collaborative test performance with TD board
4b	Selection of participant laboratories
4c	Signing of orders to participant laboratories
4d	Submit documentation
4e	Conduct tests
4f	Submit final results to MD
4g	Go to step 5
Step 5	MD prepares and sends a draft method and a full report of the collaborative test to ICC.
Step 6:	After submission of the method proposal by MD and approval by TDs, ICC set up a working group (WG) for the concrete standard validation process:
Step 7:	Working Group leader prepares all requested information for the group.
Step 8:	Working Group members give advice at the proposal and send comments to the ICC HQ, ICC HQ summarizes remarks from the working group members and provides information to the Working Group chair for approval.
Step 9:	After approval of the comments received from the WG members by the WG chair the ICC HQ send them to the TD for checking, whether all formal comment-requirements are fulfilled. Feedback slope to WG if necessary.
Step 10	Then it will be forwarded to the MD for revising the standard.
Step 11:	MD then returns a new draft carefully revised according to the suggestions of the WG to ICC HQ and/or the WG leader. All suggestions, remarks and corrections have to be taken

	into consideration by the MD. Additionally, to the new draft MD sends a table in which the answers of the MD are compared with the suggestions, remarks and corrections of the WG.
Step 12:	The Technical Director Board checks whether the comments from WG are integrated, gives feedback if necessary to the MD, **2 weeks, if no feedback to MD necessary**
Step 13:	TD checks fulfilment of formal criteria.
Step 14:	TC members give advice to the proposal.
Step 15:	The following is a new re-check from TDs.
Step 16:	MD revises the comments from TC and TD and then returns a new draft to the TD.
Step 17:	The TD checks the new draft whether the comments from TC are integrated and gives feedback to the MD if necessary. If there are relevant concerns step 16 has to be repeated as often as necessary.
Step 18:	The MD prepares a final draft.
Step 19:	Final check from the TD.
Step 20:	Recommendation to the TC for approving the Standard as Draft.
Step 21:	ICC Technical Committee Meeting.
Step 22	ICC Executive Committee Meeting: if there are relevant concerns, steps 9-21 have to be repeated as often as necessary.
Step 23:	ICC General Assembly approves by vote: if there are relevant concerns, steps 9-22 have to be repeated as often as necessary.
Step 24:	Method published as a Draft Standard Method.
Step 25:	The Draft Standard Method is approved as a regular ICC Standard Method.

8. Cost for Proprietary Methods

The costs for ICC Standard Method Validation are set in the “Application Form ICC Method Validation”. The costs for validation studies can vary depending on each case. For more details contact: office@icc.or.at

9. Publication

After approval of the standard by the working group of experts from the Technical Committee of the ICC, the method is given into the Executive Committee for acceptance before the General Assembly makes the final approval.

After final approval of an analytical method by the General Assembly, it is published as ICC Draft Standard Method, until a second review after two years of first issue. ICC Draft Standards may become regular ICC Standard Methods by approval after trial period of two years as Draft Standard. If experts from the Technical Committee or Executive Committee have raised serious concerns about the method or parts of the method, the method provider is obliged to address these concerns within the two-year period. Otherwise, ICC has the right to withdraw from the method.

ICC Standard Methods can be purchased either as single method standard or as part of the ICC Standard Method Collection. The method provider and organiser of the collaborative test shall receive one free copy of the ICC Standard. ICC requires the publication of the obtained results of the validation study in a peer-reviewed journal. The report shall be written and submitted for publication by the organiser of the collaborative test or the method provider. Publication in the official ICC Journal is recommended.

10. Liability

ICC is only liable for the content and the performance data at the time of evaluation and publication. ICC is not responsible for deviations of performance quality due to manufacturing or non-compliant method application. Any changes and/or additions to ICC validated methods need to be communicated to the ICC Headquarters as early as possible.

11. Application for Standardisation

Applications to have a method validated/standardised according to ICC requirements must be submitted to the ICC Headquarters, by filling the “Application Questionnaire” form (PO/ICC/01).

The application must include a short description of the principle of the method, its application, its current significance and potential future use. The ownership of the method must be clearly stated (generic or proprietary). Contact details of the method provider and the organiser of the collaborative test must be provided to ICC Headquarters.

Once the submitted method is considered for ICC standardisation, the payment for handling and publication must be received prior to validation/standardisation and is non-refundable irrespective of the results of the validation study.

Standard validations that cannot be finally approved by the ICC for reasons of content will nevertheless be invoiced at a second rate according to time and effort.