MICROVAL®

MicroVal Rules

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This is version 9.4 of the MicroVal Rules and Certification Scheme. This document may be subject to changes.

Changes shall be approved by the MicroVal General Committee. The latest version of this document can always be obtained from the MicroVal secretariat or at www.microval.org

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MicroVal Rules - Version 9.4, December 2024

Foreword

This is version 9.4 of the MicroVal Rules, the certification scheme of MicroVal. The MicroVal rules were drafted by the MicroVal secretariat and the MicroVal General Committee. The MicroVal rules are approved by the MicroVal General committee. NEN is the scheme owner.

When compared to the previous version 9.3, the following changes have been made

- Validation against EN-ISO 16140-7 has been added throughout the document
- The establishment of working groups under the MVTC has been added in clause 5.2.8
- Emergency validation protocol has been added in clause 9.11 and Annex C

Experts from the following organizations were involved in drafting the MicroVal Rules:

- 3M Food Safety
- ADRIA Développement
- Anses
- bioMérieux
- Bio-Rad
- Campden BRI
- Cargill
- Eurofins
- FVST
- Hygiena
- LRQA
- Merck KGaA
- MXNS
- Neogen
- Nestle
- NEN
- NVWA
- Post Holdings
- R-Biopharm AG
- Thermo Fisher Scientific

Introduction

MicroVal operates as an international certification scheme for the validation and approval of alternative methods for the microbiological analysis of food and beverages. MicroVal facilitates validation and certification against ISO 16140-2:2016, ISO 16140-6:2019, ISO 16140-7:2024 and other validation standards.

A MicroVal Certificate shows that a proprietary method performs equally well as an (internationally standardised) reference method.

MicroVal validates and certifies alternative methods to demonstrate that such proprietary methods perform equally well as the (internationally standardized) reference methods. MicroVal certification of alternative methods can support their acceptance by governmental inspection laboratories and laboratories in the food trade, thus facilitating international trade.

Alternative Methods

MicroVal is a third party certification scheme. The scheme is based on EN ISO 16140-2 ‘Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method’. The scope generally covered is foods, animal feeding stuffs, beverages (excluding water analysis) and food environmental samples, although test methods outside of this can be considered on a case by case basis.

Confirmation Methods

MicroVal also allows validation and certification of confirmation methods in accordance with ISO 16140-6 Microbiology of the food chain — Method validation — Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures.

The MicroVal organization is governed by the MicroVal General Committee and includes the MicroVal Secretariat, the MicroVal Technical Committee and the MicroVal Certification Body.

This document covers all facets of MicroVal including the organization of the MicroVal bodies, the MicroVal expert labs, the requirements for certification and the rules for the issue, renewal and modification of certificates.

Legislation

MicroVal validates and certifies alternative methods to meet the European requirements in Commission Regulation (EC) No 2073/2005, Article 5: Specific Rules for Testing and Sampling.

The US Food and Drug Administration (FDA), Centre for Food Safety and Applied Nutrition (CFSAN) has recognized MicroVal Certification as a validation organization of alternative test methods.

1 Scope

This certification scheme gives guidelines for the validation of alternative methods for microbiological analysis of foods, animal feeding stuffs, beverages and food environmental samples.

NOTE 1 Microbiological analysis includes the micro-organism, its components and/or proprietary methods.

NOTE 2 Food environmental samples include process water, air sampling, surface samples, swabs and residues etc. taken from the food handling or production areas in order to monitor the hygiene of the handling environment.

MicroVal certification is based on the following standards:

- EN-ISO 16140-2, *Microbiology of food and animal feeding stuffs - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method;*
- EN-ISO 16140-6, *Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures;*
- EN-ISO 16140-7, *Microbiology of the food chain - Method validation - Part 7: Protocol for the validation of identification methods of microorganisms.*

The MicroVal Technical Committee will review requests where EN-ISO 16140-2, EN-ISO 16140-6 or EN-ISO 16140-7 cannot be applied in full during the validation of the alternative test methods. An appropriate validation protocol based on the nature of the proposed method and technical consensus on the best reference methodology will then be recommended. More information can be found in Clause 7.5.

2 Normative References

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the references document (including any amendments) applies.

EN-ISO 16140-1:2016, *Microbiology of the food chain – Method validation – Part 1: Vocabulary*

EN-ISO 16140-2:2016, *Microbiology of food and animal feed – Method validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

EN-ISO 16140-6:2019, *Microbiology of the food chain – Method validation – Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures*

EN-ISO 16140-7:2024, *Microbiology of the food chain – Method validation – Part 7: Protocol for the validation of identification methods of microorganisms*EN-ISO 9001:2015*, Quality management systems – Requirements*

EN-ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

EN-ISO/IEC 17021-1:2015, *Conformity assessment - Requirements for bodies providing audit and certification of management systems*

EN-ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

EN-ISO/IEC 17065:2012, *Conformity assessment - Requirements for bodies certifying products, processes and services*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document the terms and definitions given in EN-ISO 16140-1:2016 and EN-ISO 17065:2012 and the following apply.

3.1.1 proprietary method

method with a trademark/brand name, which is owned and generally marketed by a commercial company

EXAMPLE: Commercially available enzyme-linked immunosorbent assay (ELISA) or polymerase chain reaction (PCR) methods.

NOTE 1 to entry: Generally, some of the components of the method are undisclosed.

[SOURCE: EN-ISO 16140-1]

3.1.2 method developer

company or organization producing, supplying or marketing one or more proprietary methods

3.2 Abbreviated terms

- MGC - MicroVal General Committee
- MVTC - MicroVal Technical Committee
- MCB - MicroVal Certification Body
- MCS - Method Comparison Study
- ILS - Interlaboratory study

4 General provisions

4.1 Ownership arrangement

NEN, the royal Netherlands standardization institute is the owner of this scheme. NEN complies with the requirements as specified in NTA 8813. The MicroVal General Committee is responsible for supervising the functioning of the certification scheme and for adjusting the certification scheme, if necessary.

4.2 NEN Scheme management guide

In addition to the MicroVal rules the certification system is supported by the NEN Scheme management manual, which has been developed to secure the whole primary process of developing and implementing the certification system. The NEN Scheme management manual is administered by NEN and is provided to all parties concerned, like members of the Committee of Experts and certification bodies that have entered into an agreement with NEN.

4.3 Changes in the MicroVal rules

The MGC supervises and approves all changes to the certification scheme.

Changes in the MicroVal Rules will be effective at least 30 days after publication by the scheme owner. The scheme owner ensures that all parties involved will be informed of the changes and the day of their commencement.

4.4 Confidentiality

All persons involved in MicroVal shall sign a MicroVal non-disclosure agreement. The non-disclosure agreement is provided by the MicroVal Secretariat. The signed non-disclosure agreements are kept by the MicroVal Secretariat.

5 Organization of the MicroVal bodies

5.1 MicroVal General Committee (MGC)

5.1.1 Responsibilities

The MGC is responsible for controlling the validation programme that consists of the validity of the validation processes within the predefined field of expertise, its applicability in relation to current regulations and the continuity of new validation assignments. The tasks of the MGC include:

- checking if all reference documents (e.g. MicroVal Rules) and all forms (e.g. application forms) are up-to-date, relevant and compliant; and approving modifications and/or revisions when they occur;
- determining and guarding the organization structure of MicroVal and supervising the compositional balance, responsibilities and activities of the MicroVal bodies;
- exploring new business opportunities for MicroVal;
- proposing and participating in promotion activities to increase the brand awareness of MicroVal and its services.

5.1.2 MGC Membership

5.1.2.1 Composition

The MGC consists of voluntary members with a relevant background in food safety, regulatory affairs and standardization, method validation and certification.

The MGC consists of the chair, the MicroVal secretariat, the chair of the MVTC and members who are professionally related to the following stakeholder categories:

- public authorities;
- method developers;
- end users of methods;
- certification bodies;
- other validation bodies: AOAC INTERNATIONAL and NordVal International.

The MGC shall not consist of more than 20 people and strives to have a balanced representation of the different stakeholder categories. Admission of new members to the MGC will be judged as needed, on a case by case basis.

5.1.2.2 Duration of the members' term of office

The members of the MGC and the chair are appointed for a period of four years. The chair is elected by the MGC members and is an active member of the MGC.

The members' term of office is renewable by tacit agreement. Member participation may automatically renew upon agreement of the individual participant. The chair's term of office is renewable after approval of the MGC.

The MGC members shall assess the application of new members. The appointment of new members is based on peer review. Members sign a confidentiality agreement.

If a MGC member changes employer or company, the continuation of their membership shall be decided upon on a case by case basis. The membership cannot be passed on to a colleague within the company. New members shall always go through the application procedure as described in clause 5.1.3.

In exceptional circumstances the MGC can decide to vote a MGC member out.

5.1.2.3 MCG member profile

MGC members

- have a general knowledge on certification;
- have a general knowledge on the principles of validation studies;
- have a general knowledge on the role and importance of alternative methods versus reference methods in Europe, the US and other relevant regions.
- read, speak and write English

In addition, specific knowledge might be added on areas of specific interest to MicroVal, e.g. marketing.

All committee members specifically commit themselves to:

- regular participation in meetings (face to face or by web conferencing);
- confidentiality for which they will sign the confidentiality agreement;
- the promotion of MicroVal Certification.

In addition committee members shall:

- make inputs and decisions in the best interest of MicroVal (not based on individual interests);
- put forward any specific knowledge they have on subjects discussed/ to be decided on in the MGC;
- ensure that they are able to fill the position and have relevant support for this from their company.

Through the sharing of their knowledge and expertise, each committee member contributes to the functioning and credibility of MicroVal Certification.

The chair represents the MGC for all actions in which members wish to engage.

5.1.3 MGC application procedure

The MGC application procedure consist of the following steps:

- The candidate member submits a resume and a rationale for becoming an MGC member to the secretariat.
- The secretariat informs the candidate about the procedure and the expected timelines.
- The MGC evaluates the application.
- When MGC members have questions regarding the application, these will anonymized and sent to the candidate member for clarification.

- The MGC decides on the membership of the candidate.
- The secretariat informs the candidate member about the decision of the MGC within a week after the meeting.

5.1.4 Meetings

MGC meetings are convened by the MicroVal secretariat once or twice a year. If considered necessary, additional meetings can be convened on the instruction of the chair or at the request of at least two members.

The MGC chair leads the MGC meetings. In case the MCG chair cannot be present at a meeting, the MicroVal secretariat will ask and appoint a replacing chair for that meeting.

During meetings, all decisions and voting shall be conducted in accordance with clause 5.5.

5.2 MicroVal Technical Committee (MVTC)

5.2.1 Responsibilities

The MVTC is responsible for the governance of the validation process towards certification and conducting the validation studies. The tasks of the MVTC include:

- reviewing, commenting, discussing, evaluating and approving validation studies at predetermined stages within the validation process. This also applies to modifications that may require an additional validation study;
- after a validation study has been completed, deciding whether a method can move forward to certification and informing the MCB of this decision;
- reviewing, commenting, discussing, evaluating and approving certificate renewal requests;
- evaluating and responding to all technical questions that may have an impact on the validation study (e.g. matrix extensions, inclusion of pre-existing data, the required minimum of naturally contaminated samples, etc);
- establishing, evaluating and, if necessary, revising the technical interpretations document that provides the additional clarification for the conduct of validation studies in accordance with a validation standard such as EN-ISO 16140-2, EN-ISO 16140-6 and EN-ISO 16140-7. However, in no case the requirements specified by the MVTC shall be less restrictive than the validation standard.

5.2.2 Composition

The MVTC consists of voluntary members with a relevant background in microbiological food safety, laboratory research, and methods and method validation and certification.

The MVTC consists of the chair, the MicroVal secretariat and members who are professionally related to the following stakeholder categories:

- Public authorities;
- Method developers;
- End users of validated microbiological methods;
- MicroVal expert laboratories;
- Certification bodies.

The MVTC shall strive to have a balanced representation of the different stakeholders in such a way that no single interest predominates. Admission for new members to the MVTC will be judged on a case by case basis.

5.2.3 Duration of the members' term of office

The members of the MVTC and the chair are appointed for a period of four years. The chair is elected by the MVTC members and is an active member of the committee.

The members' term of office is renewable by tacit agreement. Member participation may automatically renew upon agreement of the individual participant. The chair's term of office is renewable after approval of the MGC.

If a MVTC member changes employer or company, the continuation of their membership shall be decided upon on a case by case basis. The membership cannot be passed on to a colleague within the company. New members must have certain skills and shall always go through the application procedure, described in clause 5.2.5.

In exceptional circumstances the MGC can decide to vote a MVTC member out. This may for instance be the case if someone ceases to play an active supporting role in the MVTC. The MVTC chair and/or the secretariat will make a recommendation the MGC.

5.2.4 MVTC member profile

MVTC members:

- Have general scientific training in microbiology;
- Have a minimum of five years of recent experience in an organization involved in food microbiology, including working within an ISO 17025 quality management system;
- Have working knowledge of the ISO 16140-2, -6 and other parts, including method comparison studies, interlaboratory studies statistical analysis;
- Have experience with microbiological reference and alternative methods;
- Are fluent in English.

All MVTC members specifically commit themselves to:

- Being present at MVTC meetings either in person or through web call;
- Taking part in the review of the MicroVal validation studies;
- Confidentiality, for which they will sign the confidentially agreement;
- Support the objectives of MicroVal.

5.2.5 Application procedure

The MVTC application procedure consist of the following steps:

1. The candidate member submits a completed application file to the secretariat. This file includes a nondisclosure agreement.
2. The secretariat informs the candidate about the procedure and the expected timelines.
3. The MVTC evaluates the application and express its position in terms of a recommendation for approval or disapproval to the MGC.
4. When MVTC or MGC members have questions regarding the application, these will anonymized and sent to the candidate member for clarification.
5. The MGC formally decides about the MVTC membership of the candidate member.
6. The secretariat informs the candidate member about the decision of the MGC within a week after the meeting.

5.2.6 Meetings

MVTC meetings are convened by the MicroVal secretariat four times a year. If considered necessary, additional meetings can be convened on the instruction of the chair or at the request of at least two members.

The MVTC chair leads the MVTC meetings. In case the MVTC chair cannot be present at a meeting, the MicroVal secretariat will ask and appoint a replacing chair for that meeting. During the meetings, the validation studies shall be discussed according to the validation procedure set out in Annex A.

Votes shall be conducted and recommendations shall be made in accordance with the voting procedure as described in 5.6.

5.2.7 Technical expert group

All technical questions brought forward to MicroVal can be forwarded to a technical expert group consisting of the chair and one representative from each of the subgroups in the MVTC: labs, users and manufacturers. The technical expert group can either answer the question or prepare a proposal for discussion in the full MVTC.

5.2.8 Working groups

Working groups can be established under the MVTC after the approval of the MGC. The aim of these groups is to review methods with a specific scope. Working groups can be established when the review requires specific knowledge. The following applies for working groups:

- Members of working groups are appointed by the MGC following the MVTC application procedure
- Working groups have their own meetings
- Working groups have a convenor and are supported by the MicroVal Secretariat
- The working group reviews methods, and recommends to the MVTC if a method can move forward to the next stage or to certification. These recommendations are discussed in the MVTC. The MVTC decides is whether a method can move forward to certification and informs the MCB of this decision.

5.3 MicroVal Secretariat

5.3.1 Responsibilities

The MicroVal secretariat performs a general function within the MicroVal organization and is staffed by NEN.

The MicroVal secretariat handles all information regarding MicroVal validation studies with confidentiality.

The MicroVal secretariat is mandated by the MGC to:

- support the activities of the MGC, MVTC and MCB;
- administer the application, validation, certification and renewal process;
- inform the MicroVal Certification Bodies and method developers on any changes in the certification process;
- register suppliers, update the database and maintain the MicroVal website;
- promote and represent MicroVal;
- establish the fee structure of MicroVal.

5.4 MicroVal Certification Bodies (MCB)

5.4.1 Responsibilities

The MCB is responsible for:

- drafting and signing, and owning the validation contract with the method developer;

NOTE A method developer also signs a contract with a MicroVal expert lab.

- charging the study related MicroVal fees;

NOTE The MicroVal expert laboratory will also charge fees to the method developer.

- checking whether the production site has a quality systems management certification (ISO 9001 or ISO 13485) and if it has been issued by a certification body that is accredited by a member of the international accreditation forum;
- acting upon the recommendations of the production site auditors under the MicroVal rules and certification scheme;
- acting upon the recommendations of the MVTC;
- taking certification decisions;
- granting the MicroVal certificates.

The MCB shall apply the rules as defined in this document as well as in EN-ISO 16140-2 , EN-ISO 16140-6 and EN-ISO 16140-7 and its interpretations as agreed by the MVTC.

The MCB has a signed licence agreement with the scheme owner, NEN.

5.4.2 Requirements

The MCB shall be EN ISO/IEC 17065 accredited by an IAF/MLA member. The MCB shall be ISO 17021-1:2021:2015 accredited. The scope of this accreditation shall cover ISO 13485 and ISO 9001.

5.4.3 MCB harmonisation

MicroVal can have more than one MCB. When more than one MCB is active, MCB's shall harmonize the way they operate where possible. MCB's shall meet at least once a year in a meeting where they discuss and align their way of working.

5.5 MicroVal liaison organizations

5.5.1 Liaison organizations

MicroVal liaison organizations are independent organizations that, through their recognized expertise, can provide relevant input to the work of MicroVal and vice versa. In case of mutual interest an organization can be appointed as Microval Liaison organization by the MGC. The MGC can decide to end the liaison status at any given moment. Every five years the MGC will assess whether the liaison is still valuable for both parties, and based on that assessment decide to renew or end the liaison.

Currently there are two MicroVal liaison organizations:

- NordVal international
- AOAC INTERNATIONAL

5.5.2 Liaison members

Each MicroVal liaison organization can appoint one liaison member to the MGC. Liaison members do not go through the regular MGC assessment process for new members. Liaison members sign a confidentiality agreement. Liaison members are invited to and can actively take part in MGC meetings, however they do not have voting rights. In exceptional circumstances the MGC can decide to vote a Liaison member out.

5.6 Decisions

5.6.1 Consensus

When decisions have to be made, MicroVal always tries to reach consensus. When consensus cannot be reached, voting is used to reach a decision.

5.6.2 Voting procedure

In all cases where a vote is required, every effort shall be made to reach unanimity.

A voting decision may be reached either by a show of hands at the meeting or outside a meeting by correspondence. When a decision is taken by vote, only members may vote and only one vote per member may be cast. Organizations can have more than one member in the MVTC or MGC. In this case there is only one vote per organization.

The following conditions apply to the voting procedure:

- The voting possibilities are:
  - 'Yes' or 'Agree';
  - 'Yes' or 'Agree' with comments;
  - 'No' or 'Disagree' with reasons for disagreement;
  - 'Abstention' with reasons for abstention.
- An abstention shall not be counted as a vote. When a vote is conducted by correspondence, votes not cast (no replies) are considered as abstentions.
- Votes from all members are counted, and the proposal shall be adopted if:
  - a simple majority of the votes cast (abstentions not counted) is in favour;
  - at least two thirds of the members have cast their vote.
- If a vote is conducted by correspondence, a predetermined deadline shall be communicated as part of the vote. In case of a lack of responses, the opportunity can be provided to extend the deadline with one additional week. This shall be communicated through a reminder of the vote.
- If, as a result of a vote by correspondence, an approval is not achieved, the voting document shall be scheduled for discussion at the next meeting.

6 MicroVal Expert laboratories

6.1 Responsibilities

An independent MicroVal expert laboratory executes the validation study. It is chosen by the method developer from the database of laboratories established by the MGC.

The independent MicroVal expert laboratory is in charge of the co-ordination and the supervision of the three phases of the validation procedure:

1. Development of the validation protocol;
2. A method comparison study of the alternative method against the reference method;
3. An interlaboratory study of both methods.

Each step is evaluated by the experts of the MicroVal Technical Committee

6.2 Requirements for MicroVal expert laboratories

6.2.1 Accreditation

The MicroVal expert laboratory shall be EN-ISO 17025 accredited in the field of the expertise claimed. The accreditation shall be granted by an organization that is a full member of ILAC (International Laboratory Accreditation Cooperation). The field of expertise is described as the types of micro-organisms to be tested as well as the techniques used within the validation of the proposed alternative method.

At their first application, and after the four-year renewal of the EN-ISO 17025 certificate, the MicroVal expert laboratory shall send a copy of the EN 17025 certificate to the MicroVal secretariat.

In every study protocol, the MicroVal Expert laboratory shall demonstrate that it will be fully trained in the use of the alternative method to be validated, and that their staff is considered technically competent to operate the alternative method, before validation work begins.

In every study protocol, the MicroVal expert laboratory shall demonstrate that they have the reference method in their scope of accreditation. The MVTC checks this

6.2.2 Other requirements

The Microval expert lab and the method developer they performing studies for shall not have a financial or business relationship with each other, except as customers. Exceptions on this can be made on a case-by-case basis by the MVTC.

The Microval expert lab and the method developer they performing studies for shall not have regulatory relationship with each other. Exceptions on this can be made on a case-by-case basis by the MVTC.

For all MicroVal expert laboratories an initial application fee and annual membership fees apply. More information on MicroVal fees can be found in clause 13.

An MicroVal expert laboratory that is running MicroVal studies shall take part in the MVTC meetings and the MicroVal study review process. An exception to be rule can be made on the condition that

- The MGC agrees.
- The expert laboratory pays an additional fee.

6.3 Requirements for collaborative laboratories

In order to be able to conduct the inter laboratory study the expert laboratory will make use of collaborative laboratories. These collaborating laboratories are selected by the expert laboratory in cooperation with the method developer.

The collaborative laboratories must be representative of the users of the method. The collaborative laboratories do not have to be EN-ISO 17025 accredited. The expert laboratory must check whether the laboratory has an adequate quality system in place, not necessarily based on EN-ISO 17025, in order to be able to participate in the validation study.

6.4 Application procedure

To become a MicroVal expert laboratory, an application file must be completed. This file includes proof of experience on performing validation studies within the context of MicroVal, relevant EN-ISO 17025 accreditation, and the signing of a confidentiality agreement.

The MVTC will evaluate the application to give a recommendation for approval or disapproval to the MGC. The MGC decides on the suitability of the method developer to become an expert laboratory in the area of expertise claimed.

Laboratories that have not performed a MicroVal validation yet have to ensure that technical support is available during the study. The technical support must be specified and agreed upon by the MVTC.

The MicroVal secretariat will add the expert laboratory to the list of MicroVal expert laboratories on the website, indicating their area of expertise.

6.5 Selection of an expert laboratory for a validation study

The method developer selects a laboratory from the list of MicroVal expert laboratories when applying for MicroVal certification of a method. The list published on the MicroVal website.

If an expert laboratory has not performed a MicroVal validation before, the method developer should take into account the fact that the validation study might take more time. This is due to the limited expertise as well as additional costs for the technical support that the expert laboratory has to guarantee during the execution of the study.

6.6 Logo

MicroVal expert laboratories can use the MicroVal logo on their website and other communication. Details of the logo can be found in annex B.

7 Certification requirements

7.1 Requirements for proprietary methods

Requirements for proprietary methods are given in in EN-ISO 16140-2:2016, EN-ISO 16140-6:2019, EN-ISO 16140-7:2024 and the reference method or methods the method developers choses to have their methods tested against.

7.2 Validation study

The requirements and procedure for validation study is given in EN-ISO 16140-2:2016, EN-ISO 16140-6:2019, EN-ISO 16140-7:2024 and/or the reference method or methods the method developers choses to test their methods against.

7.3 Proprietary method batches used in the validation process

MicroVal only validates proprietary methods that are market ready. Design and development of the methods is not covered by the MicroVal certificate. The validation study shall be performed on the actual commercialized proprietary method. Exceptions to this rule can be made on a case by case basis to be agreed by the MVTC and MCB.

7.4 Requirements to be met by the method developer

7.4.1 General

In order to enable the certification process of the proprietary method, the method developer shall:

- sign a certification agreement with the MCB;
- sign an agreement with the MicroVal expert laboratory for the execution of the study.
- agree with the arrangements for the selection and sampling processes, testing, assessments and auditing;
- meet the arrangements for the selection and sampling processes, testing, assessments and auditing;
- fulfil the payments of necessary fees;
- provide the requested proprietary method information;
- provide the requested information to demonstrate conformity.

MicroVal validation and certification is only possible on methods that are market-ready.

The study fees are charged before the start of the study. If the fees are not paid in time, the MicroVal secretariat will put the validation study on hold. The study will not be discussed at MVTC meetings, and no certificate can be issued.

7.4.2 Application for certification

The method developer sends an application form to the MicroVal secretariat and/or MCB containing the information needed to start the validation process. Application forms are available on the MicroVal website. In addition, if the facility has EN-ISO 13485 and/or ISO 9001 certification, those certificates shall be submitted at the time of application. The detailed application process is described in Annex A.

7.4.3 Requirements for the production facility

The requirements for an audit of the production facility shall be met before granting the certificate and upon renewal of the certificate.

The basis for the quality system of the production facility is ISO 9001:2015 and/or EN-ISO13485:2016. The scope of the ISO 9001:2015 and/or EN-ISO13485:2016 certificate of the production facility shall cover the production of the candidate method.

If the facility is certified against ISO 9001:2015 and/or EN-ISO13485:2016 the certificate(s) shall be provided with the MicroVal application form or upon request.

In addition to the QMS certificate (ISO 9001:2015 and/or EN-ISO13485:2016) the following is requested from the applicant:

- The certificate(s) shall be:
  - issued by a certification body, accredited by an accreditation body which is a member of the International Accreditation Forum (IAF);
  - valid (not suspended or withdrawn).
- In addition to the certificate(s) the following information shall be provided:
  - initial certification or most recent recertification audit reports, and the latest surveillance report including the status of all outstanding nonconformities;
  - information on overdue audits;
  - information on any engagement with regulatory bodies;
  - information on any other concern which may cause the threat of suspension or withdrawal of the certification.

Based on a review of the above information, the MCB may request additional clarification to ensure the organizations' continuing ability to consistently provide proprietary methods and services that meet customer and applicable statutory and regulatory requirements.

If the facility is not certified against ISO 9001:2015 or EN-ISO 13485:2016, a full scope audit must be conducted.

The time needed for the audit depends on the applicable Mandatory Documents issued by the International Accreditation Forum, which can be found on their website.

In the event an audit is required, the MCB will select an auditor that complies with the requirements of EN-ISO/IEC 17021-1. The auditor shall be qualified as Lead Auditor for ISO 9001 and/or EN-ISO13485 in accordance with the EN-ISO/IEC 17021-series.

Upon the expiry of the ISO 9001:2015 and/or EN-ISO13485:2016 certificate the applicant shall send the renewed certificate to the MCB.

7.5 Validation of test methods outside the scope of EN-ISO 16140

MicroVal can also provide a service for the validation of test methods outside the scope of EN-ISO 16140-2, EN-ISO 16140-6 and EN-ISO 16140-7 , for instances methods for the analysis for dairy. For these types of methods the following procedure and requirements apply.

1. Upon receiving a request from a method developer the secretariat collects the following information to get a first indication of the feasibility and the possible acceptance of the proposal:
    - availability of a reference method against which the alternative method can be compared;
    - availability of experts and expertise in the MVTC regarding the analyte(s) for which the method will be evaluated;
    - business case potential (number of potential method developers that may require such an alternative method validated);
    - availability of a proper validation protocol (or the opportunity to develop this);
    - consent of the management of the respective Certification Body;
    - availability of an expert laboratory that can operate the agreed reference method.

2. An application is prepared by the method developer with help from the secretariat for discussion and approval by MVTC;
3. The MVTC prepares a proposal for the management of the respective Certification Body and MGC;
4. The Certification Body management decides if they can certify on the proposed scope and conditions;
5. The decision of the Certification Body is sent to the MGC for either final approval or discussion.

7.6 Joined studies

Methods can be validated at MicroVal and AOAC INTERNATIONAL and/or Nordval International in parallel. All three organizations have their own certificate and process, however part of the data generated can be reused.

7.7 Excluding MicroVal method developers members from review

Candidate methods are reviewed by all MVTC members. This means that members from competing method developers review each other's methods. All members have signed and NDA.

On request MicroVal offers method developers the possibility to do a MicroVal validation study in which the MVTC members representing method developers do not take part in the review. In this case the

candidate is discussed outside the regular MVTC meetings and the online review system is not used. The MVTC and MGC chair and secretariat have to approve this request. An additional extra fee applies.

8 The MicroVal certificate

The certification document(s) shall identify/include the following:

a) name of the alternative method
b) the name and geographical location of the certified client (production site & distribution/supplier site);
c) reference method;
d) the scope of certification, without being misleading or ambiguous;
e) the effective date of granting, expanding or reducing the scope of certification, or renewing certification which shall not be before the date of the relevant certification decision;
f) the expiry date consistent with the recertification cycle;
g) the name, address and mark of the certification body and the MicroVal-logo from NEN;
h) a unique identification code;
i) the signature or other defined authorization of the person(s) of the certification body assigned such responsibility;
j) the version number and date of the instruction for use (IFU);

NOTE: IFU versions will be added to the certificate at the first issue or renewal after publication of the MicroVal rules version 9.3

k) an overview of modifications.

NOTE Modifications will only be stated after the publication of the MicroVal rules version 9.3.

NOTE The date of the relevant certification decision is usually the date on which the MVTC recommended certification or renewal.

The certification documents shall state that:

a) the alternative method has been validated and revealed to be at least equivalent to the reference method as demonstrated by the validation study report. The summary of the validation report is available on the MicroVal website: www.microval.org;
b) the validation and certification has been performed in accordance with EN ISO 16140-2:2016, EN ISO 16140-6:2019, ISO 16140-7:2024 and/or other MicroVal approved validation standards;
c) the validation and certification has been performed in accordance with the MicroVal Rules and the Certification Scheme, also stating the version number of the rules at the date of issue or renewal.

8.1 MicroVal certificate template

The MCB issues a draft certificate template to MGC. The MCB shall only issue certificates with this content and design after approval of the content and design from the MGC.

Changes in design or content are always submitted to MGC for approval.

9 Validation and certification procedure

9.1 General

The MVTC and the MCB assess information provided by the method developer to determine the extent to which the method developer demonstrates its fulfilment of certification requirements. Annex A gives a detailed overview of the MicroVal validation procedure. The main steps in the process are:

1. Evaluation of the proprietary method
    a. The MicroVal expert laboratory compares the candidate method to the reference method to which the method developer claims equivalence. The laboratory writes their conclusions in a study report in accordance with clause 7.2
    b. The MVTC reviews the study report and conclusions and advices the MCB on whether the method meets the requirements for certification in accordance with clause 7.
2. Evaluation of the production location quality management system (QMS)
    a. The MCB assesses if the production location meets the demands for the quality management system in accordance with chapter 7.4.

9.2 Nonconformities quality management system

If the certification body does not have sufficient evidence that the production location has demonstrated that certification requirements have been fulfilled, it informs the method developer of those aspects which do not comply with applicable requirements as nonconformities.

If the method developer undertakes corrective actions, these have to be completed within a specified time limit set by the certification body. The certification body may repeat the necessary parts of the on site evaluation, assessment and audit to verify whether the nonconformity has been adequately addressed.

NOTE This clause only applies when the MCB has done a quality audit.

9.3 Certification decision

When the outcome of the review is positive, a decision is made by the MCB to grant certification.

The certification decision is granted based upon:

- a positive recommendation of the MVTC on the final validation report based on the Method Comparison Study (MCS) and Inter Laboratory Study (ILS) results;
- the existence of the required ISO management systems certificate(s), or the positive result of the audit of the production facility.

The MCB takes the certification decision and sends the MicroVal Certificate to the method developer , either digital or in hard copy. The MCB sends an electronic copy of the MicroVal Certificate to the MicroVal secretariat for inclusion on the MicroVal website.

When the outcome of the review is negative, a decision is made not to grant certification. The method developer is informed with the reasons for the negative decision.

The MicroVal expert laboratory prepares a summary report on the MCS and ILS for publication on the MicroVal website.

Details and optional explanations and performance ranges of the proprietary methods may be listed in an annex of the certificate.

A certificate can contain more than one method. Decisions on this are made on a case by case basis by the MCB and MVTC.

After the certificate has been issued, an annual fee applies. More information on the MicroVal fees can be found in clause 13.

9.4 Publication of the certificate

The certificate, the summary report and optional additional information are published on the MicroVal website.

All information not presented in the certificate, the summary report or the optional additional information on the website is confidential and can only be made available outside MicroVal after the agreement of the method developer.

9.5 Validity of the certification

The certification is valid for four years, provided the criteria of the MicroVal Rules and Certification Scheme are met. The certification will expire in accordance with 9.8, Suspending a certificate; 9.9, Withdrawing a certificate and/or 9.10 Misuse of the logo.

In exceptional cases it can be necessary to temporarily prolong the validity of the certification. This can happen for instance when a renewal study cannot be completed in time due to unforeseen circumstances. In such a case the MVTC, MicroVal secretariat and MCB can agree to temporarily prolong the validity of the certification. This is only possible when all parties involved agree that it is likely that the issue can be resolved and that the study can be successfully completed. Decisions on this are made on a case by case basis.

9.6 MicroVal logo

As long as the certificate is valid, the method developer may use the MicroVal logo. The logo will be supplied to the method developer by the MCB, upon request. Details on the use and design of the logo can be found in clauses 12.2 Use of the logo, 9.10 Misuse of the logo, and annex B.

9.7 Transfer of certificates from other organizations

MicroVal does not take over certificates from other organizations.

It is possible to validate and certify a test kit based on data generated in a validation study done for another certification body under the following conditions:

1. the validation study has been performed by a MicroVal expert lab; this lab or another MicroVal expert lab shall present the data to the MVTC
2. an assessment of the data and the method of data generation shall be performed in order to evaluate whether the data fullfill the MicroVal rules and MicroVal technical interpretations of ISO 16140-2, -6 and -7. In order to be accepted the data must fit the requirements of these rules and interpretations;
3. a gap analysis shall be conducted in order to decide whether additional data are required for evaluating the results of the validation study and to ensure that the data available fit the requirements of the MicroVal rules and interpreations.

In case the data available do not fit the requirements of the MicroVal rules and technical interpretations, additional data may have to be generated by the MicroVal expert lab and/or method developer. A decision on this is taken by the MVTC on a case by case basis

A transfer fee applies.

Certifying a test kit based on data generated in a validation study done for another certification body will not be accepted when the sole aim of the procedure is to avoid the MicroVal study fee.

Studies can be performed in parallel with AOAC INTERNATIONAL or Nordval International, more information is available upon request at the MicroVal secretariat.

9.8 Suspending a certificate

The applicability of the license to a specific method may be suspended for a limited period (a maximum of 6 months), for example in the following cases:

- if a case of improper use of the certificate or the mark (e.g. misleading publications or advertisement) is not solved by suitable retractions and appropriate corrective actions by the licensee;
- if there has been any other contravention of the proprietary method certification scheme or the procedures of the certification body;
- modifications of validated methods and/or production processes are not reported to the MicroVal Secretariat;
- The quality management system certificate is suspended;
- Clients are not able to fulfil their obligations under the contract.

The method developer is prohibited from identifying as certified any proprietary method that has been manufactured under a suspension of the license as applicable to that proprietary method.

A license may also be suspended after mutual agreement between the certification body and the licensee for a limited period of non-production or for other reasons.

An official suspension of a license is confirmed by the certification body in a registered letter to the licensee (or by equivalent means).

The method developer may give notice of appeal, and the MCB, when considering the appeal, may or may not (depending on the nature of the case) decide to proceed with its decision to suspend the certificate.

The MCB indicates under which conditions the suspension would be removed.

The certificate remains suspended until:

- the suspension can be lifted and the approval is reinstated;
- the expiry date of the certificate, if it falls within the suspension period. After the expiry date the certificate is no longer valid.

At the end of the suspension period, the certification body investigates whether the indicated conditions for re-instituting the license have been fulfilled.

On fulfilment of these conditions, the suspension is removed by notifying the method developer.

When a major modification has not been reported to MicroVal and requires a full validation study, the certificate will be withdrawn. This is decided on a case by case basis by the MCB after recommendation of the MVTC.

9.9 Withdrawing a certificate

Apart from the suspension of a license, a license is withdrawn in the following cases:

- if the licensee fails to comply with the due settlement of the financial obligations;
- if there is any other contravention of the licensing agreement;
- if inadequate measures are taken by the licensee in the case of suspension.
- at any action of the method developer that may damage the reputation of MicroVal

In the above cases, the certification body has the right to withdraw the certificate by informing the licensee in writing.

The method developer may give notice of appeal, and the certification body when considering the appeal may or may not (depending on the nature of the case) decide to proceed with its decision to withdraw the certificate.

Prior to withdrawal of a certificate, the certification body decides upon the consequences in relation to proprietary methods certified under the license, whether the logo needs to be removed from all proprietary methods in stock, and perhaps even, if practicable, from proprietary methods already sold, or whether a clearance of the stock of marked proprietary methods is permissible within a short period of time. The certification body decides if other actions are required.

Furthermore, the certificate may be withdrawn in the following cases:

- if the method developer does not wish to maintain the license;
- if the reference method, validation standard or rules are changed and the licensee either will not or cannot ensure conformity with the new requirements;
- if the proprietary method is no longer made or the licensee goes out of business;
- on the grounds of other provisions specified in the licensing agreement.

9.10 Misuse of the logo

The MCB takes action when unauthorized, incorrect, or misleading use of the certificates or MicroVal logo is found. Incorrect references to the certification scheme or misleading use of certificates or the logo found in advertisements, catalogues, etc., are dealt with by suitable actions, which could include legal or corrective action or publication of the transgression. In cases of misuse of certificates or the logo by method developers, corrective action is taken in accordance with ISO Guide 27. Withdrawal of a license due to misuse of the certification mark, may be published by the certification body.

9.11 Emergency validation protocol

At times there may be an urgent public health need for rapid deployment of new analytical methods for an emerging threat. Method developers and method users familiar to third-party method validation may find the normal method validation time too long for immediate method use. Annex C gives an emergency method certification protocol that accelerates the time to certification. This protocol is not appropriate as a substitute for the normal process of method certification.

10 Renewals

10.1 General

MicroVal certificates are valid for four years. For renewal, the method developer shall present a complete and up to date documentation of the alternative method to the MCB, no later than 6 months before the certificate expires. This shall include a statement on whether changes have occurred in:

- the validation standard
- the reference method
- the types tested
- the proprietary method

The MVTC studies the information provided by the method developer . Based on this MVTC can advise to:

- renew the certification with respect to changes in the method and/or validation requirements;
- repeat (a part of) the validation study.

The MCB decides on renewal of the certification based on the advice of the MVTC and the results of the renewal audit of the production location as described in clause 9.

After renewal, the certificate is valid for an additional four years.

For all renewals a renewal fee applies. More information on the MicroVal fees can be found in clause 13

10.1.1 Changes to the validation standard

If any changes have occurred to EN-ISO 16140-2:2016 EN-ISO 16140-6:2019 and/or EN-ISO 16140-7:2024, the MVTC shall decide on a case by case basis if a new validation study has to be done. This can either be a full or partial study.

10.1.2 Changes to the reference method

If any changes have occurred to the reference method as stated on the certificate of the method, the MVTC shall decide on a case by case basis if a new validation study has to be done. This can either be a full or partial study.

If the reference method has been updated but no further validation is deemed necessary by the MVTC a refence to this will be added on the certificate.

10.1.3 Changes to the (food) types claimed under the scope

If any changes have occurred to the (food) types claimed under the scope of the validation study, the MVTC shall decide on a case by case basis if a new validation study has to be done and the extent of the study.

10.1.4 Changes to the proprietary method

If any changes have occurred to the method, the MVTC shall decide on a case by case basis if a new validation study has to be done. This can either be a full or partial study.

NOTE If changes are made to the proprietary method at any moment during the validity of the certificate the method developer shall immediately inform the MicroVal secretariat.

10.1.5 Assessment of the production process and audit of the internal quality control system

The MCB assess the quality management system of the production process..

10.2 Non-renewal

In case of non-renewal of the certification for a method, the certificate and summary report are removed from the website of MicroVal by the Secretariat, a note on the withdrawal is placed on the MicroVal website by the Secretariat and the method developer is informed formally in writing of the removal by the Secretariat.

11 Modifications

11.1 General

It is the responsibility of the method developer to immediately inform the MicroVal secretariat and MCB of any change in the proprietary method, prior to implementation.

It is the responsibility of the method developer to immediately inform the MicroVal secretariat and MCB of any change in the certification status of the production facility, prior to implementation.

For all modifications a modification fee applies. More information on the MicroVal fees can be found in clause 13.

11.2 Changes by the method developer

If there are any changes in the proprietary method, proprietary method design, materials, method developers, production methods and/or production locations, the MicroVal secretariat and MCB shall be informed prior to the implementation of these changes. These changes include new software versions.

Modifications may require a minor or major review, depending on the change to the existing method, the production thereof or the kit insert. The method developer must submit a copy of the revision(s), and other appropriate data.

An exact determination of the level of the modification can only be made after a written explanation and supporting data are received and reviewed by the MVTC. The MVTC and MCB hereupon decide if a modification is a major review or should be handled as new method.

The MVTC and MCB study all the modifications. They can decide:

- to maintain the current certification;
- to accept the change as a minor change, or;
- that the change is a major change.

The MVTC and MCB decide if and which tests and/or inspections and/or assessments will be carried out on the modified proprietary methods or situation in order to maintain certification.

A modification fee applies. For minor modifications a fee is set. For major modifications a fee will be calculated on a case by case basis, based on the amount of work.

11.3 Minor modification

Minor modifications do not alter the performance of the validated test method. The method developer/supplier shall submit a written explanation of the change(s) including a statement that the modification does not alter the performance of the validated test method. It is always up to the MVTC and MCB to define if a modification is minor or major.

Examples are:

- labelling changes;
- deletion of validated claims or procedures;
- restatements of existing validated claims;
- add or strengthen an instruction that is intended to enhance the safe use or efficacy of a proprietary method;
- additional precaution/warnings or labelling changes that strengthen a warning or precaution and/or;
- changes to manufacturing process, or;
- quality Assurance/Quality Control.

11.4 Major modification

Major modifications are changes that could influence the performance of the validated test method. They require appropriate data to be submitted by the method developer, with or without assistance of a MicroVal expert lab. This submission is reviewed by the MVTC. In some cases the MVTC can advise that additional testing by a MicroVal expert laboratory is necessary. It is always up to the MVTC to define if a modification is indeed major or should better be handled as a new method.

Examples of major reviews are:

- entirely new procedure;
- removal of a precaution statement or warning, depending on the importance of the existing precaution;
- modification to reagents such as changes in formulation, concentration, phase (solid or liquid) or format;
- modification to, and/or changing of detection or measuring equipment/instrumentation and/or;
- addition or deletion of regents and/or measuring instrumentation
- Matrix or scope extensions.

11.5 Changes to the validation standard

The scheme owner shall inform the MCB when EN-ISO 16140-2, EN-ISO 16140-6 or EN-ISO 16140-7 is updated. The MGC shall assess if and which changes have to be made to the scheme and determine the transition period of implementation.

12 Publicity and Promotion

12.1 General requirements

The method developer can demonstrate certification of its proprietary method by:

- Using the MicroVal logo on the proprietary method, packaging or kit insert;

- Including a copy of the entire certificate in the packaging,
- Using the logo in advertising provided the scope of certification and the reference method are declared close to the logo.

In all cases the certificate number shall be declared close to the logo.

The method developer has the right to publish the fact that:

- an identified proprietary method has been certified;
- the method developer has been authorized to:
    - use a valid certificate of conformity, and
    - apply a logo for proprietary methods to which the license applies. In every case, the method developer takes sufficient care of its publications and advertising so that no confusion arises between certified and non-certified proprietary methods.

The method developer does not specify any function or make any claim or the like in user information that could lead purchasers to believe that performance of the proprietary method or its use is covered by the certification when in fact it is not. A method developer does not publicly claim any status by having entered the process of becoming certified.

12.2 Use of the logo

The MicroVal logo is a mark owned by NEN, intended for proprietary methods that have been certified according to the requirements of this certification scheme. Certificate holders are not obliged to use the logo. In cases of MicroVal logo expressions, the following conditions apply:

- use of the MicroVal logo is only allowed after approval by the certification body in writing. Approval is granted to the certificate holder, who is responsible for the correct use of the MicroVal logo;
- it is allowed to use MicroVal logo logo on invoices and writing paper, on packages or proprietary methods related to communication, and on promotional material like websites, brochures and catalogues provided that a clear relationship exists with the certified proprietary method(s);

EXAMPLE 1 Allowed is: 'Company X has the MicroVal certificate for proprietary method Y'.

EXAMPLE 2 Not allowed is: MicroVal certified'.

- the use of the MicroVal logo is only allowed in own communication related to own proprietary methods that belong to the scope of the MicroVal certificate;
- the MicroVal logo shall not exceed the size and prominence of the proprietary method name, brand name and or trade name. Only communication and presentation as a label is allowed. Suggesting that MicroVal would be a trademark is not allowed to other parties than the scheme owner and certification bodies after approval in writing.

The (visual) presentation of the MicroVal logo shall be in accordance with the requirements as presented in Annex B.

12.3 Register

The MicroVal secretariat presents an overview of all MicroVal certified methods on the MicroVal website.

12.4 Website

The website of MicroVal is MicroVal.org. The website is managed by the MicroVal secretariat.

13 MicroVal fee structure

The following MicroVal fees apply:

- **Study fee**
  This fee covers the costs of the certification procedure. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged before the study is started. Not paying the fee in time will result in the review being put on hold.
- **Additional Study fee – method developers excluded**
  In case method developers members are excluded from the MVTC review process during a validation study, in accordance with 7.7, an additional fee applies. This fee covers the additional work done by the MicroVal secretariat. The fee is charged to the method developer by the MCB.
- **Quality management system audit fee**
  This covers the cost of the audit of the factory, including travel costs, should an audit be required. This fee is charged to the method developer by the MCB.
- **Expert Laboratory study fee**
  This fee covers the cost of the validation, renewal, modification and/or transfer studies performed by the Expert Laboratory. This fee is charged to the method developer by the MicroVal Expert Lab.
- **Annual fee (annual renewal fee)**
  For every issued certificate an annual fee applies. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB.
- **Renewal fees – no changes**
  This fixed fee applies to the four year renewal in accordance with clause 10. It applies when no changes have occurred in accordance with clause 10.1. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged after the renewal is completed.
- **Renewal fees – additional study**
  This fee is applied to the four year renewal in accordance with clause 10.1. It applies when additional study is necessary because changes have occurred in for instance the method, or the reference method. The fee is dependent on the amount of work and calculated on a case by case basis. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged after the renewal is completed.
- **Minor modification fee**
  This is a fixed fee for minor modifications, in accordance with clause 11.3. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged after the modification is completed.
- **Major modification fee**
  This fee applies to major modifications in accordance with clause 11.4. It is dependent on the amount of work and calculated on a case by case basis. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged after the modification is completed.
- **Transfer fee**
  This fee covers the costs of the validation of a validation and certification of a test kit based on data generated in a validation study done for another certification body in accordance with clause 9.7. The fee covers the work of the MicroVal secretariat and the MCB. The fee is charged to the method developer by the MCB. The fee is charged before the study is started. Not paying the fee in time will result in the review being put on hold.
- **MicroVal Expert Laboratory application fee.**

Upon initial application to become a MicroVal expert laboratory an initial application fee applies. The fee is charged to the MicroVal Expert by MicroVal secretariat.

- **MicroVal Expert Laboratory annual fee - basic**
  Every MicroVal expert laboratory pays an annual membership fee. The fee is charged to the MicroVal Expert by MicroVal secretariat.
- **MicroVal Expert Laboratory annual fee - active**
  Every MicroVal expert laboratory that is running MicroVal validation studies pays an additional fee. The fee is charged to the MicroVal Expert by MicroVal secretariat.
- **MicroVal Expert Laboratory annual fee – non reviewing**
  In exceptional cases a MicroVal expert laboratory can run validation studies, but not take part in the MVTC review process, in accordance with clause 7.7. In this case an additional fee applies. The fee is charged to the MicroVal Expert by MicroVal secretariat.

- **Other fees**
  For specific cases additional fees may apply.

Each calendar year, the MicroVal secretariat determines the MicroVal fees. Fees will be provided to interested parties upon request.

14 Product liability

In this scheme, all questions related to product liability are dealt with on the basis of the relevant legal system(s).

15 Complaints, appeals and technical questions

15.1 Complaints and appeals

Any complaint regarding the MicroVal certification process or the conduct of the validation studies and/or audit process can be raised in writing to the MicroVal secretariat. The MicroVal secretariat registers and confirms receiving the complaint to the complainant and brings it forward to the MGC as the responsible party. The MGC will investigate as required and respond to the complainant via the MicroVal secretariat. Depending on the outcome of the review of the complaint the MGC can propose corrective actions and in the worst case withdrawal of the MicroVal acceptance of the party involved.

The method developer has a right to complain to the certification body about aspects of the service provided. The method developer may also appeal to the certification body against its decisions on issuing, maintaining, extending, suspending and withdrawing certification. In all of these cases, the certification body’s complaints and appeals process will apply, as described in ISO/IEC 17065:2012, 7.13.

15.2 Technical questions

Any technical question regarding the MicroVal validated methods, certification process or the conduct of the validation and/or studies audit process can be raised in writing to the MicroVal secretariat. The secretariat will register the question and consult with the chair of the MVTC and/or MGC on how to provide an answer.

Questions are treated confidentially and can be anonymized on request.

The question can be discussed in the MVTC and/or MGC. The expert laboratory and/or method developer can be asked to join the discussion. MicroVal will respond to the question trough the secretariat.

Annex A
Detailed validation and certification procedure

A.1 Stage 1 – application and contracts

1. **method developer** submits an application form to MicroVal by email at microval@nen.nl.
2. The **MicroVal certification Body** signs a contract with the **method developer.**
3. **The method developer** choses a MicroVal **Expert Lab.** An overview of all MicroVal expert labs can be found on MicroVal.org. The method developer and the expert lab sign a contract. MicroVal takes no part in this contract.
4. **The secretariat** appoints two or more **selected reviewers** to the study.

NOTE 1 A method developer always signs two contracts for a MicroVal study: with MicroVal and with the MicroVal expert lab.

NOTE 2 If no contract has been signed between the method developer and MicroVal, the study will not be discussed at MVTC meetings. This means the study is put on hold. (Add: All risk is for the method developer)

A.2 Stage 2: Study

- A MicroVal study consist of 3 stages: Protocol, Method Comparison study (MCS) and Inter Laboratory Study (ILS). For some methods no ILS is needed, this is to be decided by the MVTC.
- The steps taken during the protocol, MCS and ILS stage are very similar.
- Based on the protocols and reports submitted by the expert lab, the MVTC decides whether a study can start or proceed to a next stage. These decisions are made during MVTC meetings.
- The MVTC meets four times a year with regular intervals. Meetings are planned a year ahead.
- In case of special circumstances additional MTVC meeting may be organized.
- method developers who are not an MVTC member do not have to be present at MVTC meetings. However they can attend the discussion of their method, on their own request or on request of the MVTC.
- Selected reviewers may also be contacted when issues arise that do not need to be discussed by the full MVTC.

A.2.1 Stage 2.1: Protocol

3 weeks before MVTC meeting

1. **The Expert Lab** drafts a protocol and submits it to the secretariat.
2. **The secretariat** publishes the draft protocol online for MVTC review.
3. Review
    a. **The selected reviewers** *must* review the protocol
    b. The **other MVTC members** *can* review the protocol

1 week before MVTC meeting

4. **The Expert lab** responds to the online comments and prepares a presentation for the MVTC meeting. The presentation includes the comments and replies.

At the MVTC meeting

5. **The expert lab** gives the presentation on the protocol.
6. The **MVTC members** discusses the protocol and decides whether it can move forward to the MCS stage.

7. **The secretariat** notes the decision in the study progress sheet. Often small changes to the protocol will need to be made. These cover issues that are not big enough to halt the study. These changes are noted on the study progress sheet.

After the MVTC meeting

8. **The secretariat** sends the study progress sheet to all MVTC members.
9. **The secretariat** sends presentations given by the expert labs to all MVTC members.

2 weeks after the meeting

10. **The expert lab** updates the protocol to meet the agreed changes in the study progress sheet and submits it to **the secretariat**.
11. **The secretariat** publishes the draft protocol online and notifies the selected reviewers.
12. **The selected reviewers** check if agreed changes have been made and confirm this to **the** secretariat and the expert lab by email.

A.2.2 Stage 2.1: Method Comparison Study (MCS)

3 weeks before MVTC meeting

1. **The Expert Lab** drafts an MCS report and submits it to the secretariat.
2. **The secretariat** publishes the draft MCS report online for MVTC review.
3. Review
    a. **The selected reviewers** *must* review the draft MCS report.
    b. The **other MVTC members** *can* review the draft MCS report.

1 week before MVTC meeting

4. **The Expert lab** responds to the online comments and prepares a presentation on the study and the draft MCS report for the MVTC meeting. The presentation includes the comments and replies.

At the MVTC meeting

5. **The expert lab** gives the presentation on study the draft MCS report.
6. The **MVTC members** discusses the draft MCS report and decides whether it can move forward to the interlaboratory study (ILS) stage.
7. **The secretariat** notes the decision in the study progress sheet. Often small changes to the draft MCS report will need to be made. These cover issues that are not big enough to halt the study. These changes are noted on the study progress sheet.

After the MVTC meeting

8. **The secretariat** sends the study progress sheet to all MVTC members.
9. **The secretariat** sends presentations given by the expert labs to all MVTC members.

2 weeks after the meeting

10. **The expert lab** updates the draft MCS report to meet the agreed changes in the study progress sheet and submits it to **the secretariat**.
11. **The secretariat** publishes the draft MCS report online and notifies the selected reviewers
12. **The selected reviewers** check if agreed changes have been made and confirm this to **the** secretariat and the expert lab by email.

A.2.3 Stage 2.3: Interlaboratory study (ILS)

NOTE Not all studies have an ILS stage.

3 weeks before MVTC meeting.

1. **The Expert Lab** adds the ILS data and conclusions to the final MCS report. This results in a draft MCS-ILS report. The Expert lab submits the report to the secretariat.
2. **The secretariat** publishes the draft MCS-ILS report online for MVTC review.
3. Review
    a. **The selected reviewers** *must* review the draft MCS report.
    b. The **other MVTC members** *can* review the draft MCS report.

1 week before MVTC meeting

4. **The Expert lab** responds to the online comments and prepares a presentation on the study and the draft MCS-ILS report for the MVTC meeting. The presentation includes the comments and replies.

At the MVTC meeting

5. **The expert lab** gives the presentation on study the draft MCS report.
6. The **MVTC members** discuss the draft MCS-ILS report and decides whether it can move forward to certification.

NOTE The final decision on certification is taken by the MCB.

7. **The secretariat** notes the decision in the study progress sheet. Often small changes to the draft MCS-ILS report will need to be made. These cover issues that are not big enough to halt the study. These changes are noted on the study progress sheet.

After the MVTC meeting

8. **The secretariat** sends the study progress sheet to all MVTC members.
9. **The secretariat** sends presentations given by the expert labs to all MVTC members.

2 weeks after the meeting

10. **The expert lab** updates the draft MCS report to meet the agreed changes in the study progress sheet and submits it to **the secretariat**.
11. **The secretariat** publishes the draft MCS-ILS report online and notifies the selected reviewers.
12. **The selected reviewers** check if agreed changes have been made and confirm this to **the** secretariat and the expert lab by email.

A.3 Stage 3: certification

The MCB decides if a certificate van be issued based on

- The assessment of the quality management system of the production facility.
- The MVTC assessment of the method.

1. **The MCB** issues the certificate and send a digital copy to the secretariat
2. **The expert lab** provides a summary report that does not include sensitive data
3. **The secretariat** publishes both the certificate and the summary report on the MicroVal website

A.4 Stage 4: Renewal

Every method is reviewed every four years.

1. **The MCB** contacts the method developer.
2. **The method developer** provides a statement in writing on changes in the method, the reference method or any other subject that may influence the validity of the certificate. If nothing has changed, the method developer states that.

MicroVal shall always be notified immediately of changes that could influence the validity of the certificate.

3 weeks before the MVTC meeting

3. **The secretariat** posts the information provided by the method developer online/sends an email to the selected reviewers and the lab that did the original study.
4. **The selected reviewers and expert lab that ran the original study** assess the information provided and complete the renewal form provided by the secretariat

At the MVTC meeting

5. **The selected reviewers** report their assessment of the method and the documents provided.
6. **The MVTC members** decide if the method can be put forward for renewal, and if additional study is necessary.
7. **The secretariat** notes the MVTC advice in the study progress sheet.

After the MVTC meeting

8. Based on the information provided by the MVTC, the assessment of the quality management system at the production facility and all other contractual agreements, **the MCB** decides whether or not to renew the certificate for another four years.
9. **The MCB** sends a digital copy of the certificate to the method developer and the secretariat.
10. **The secretariat** publishes the new version of the certificate on the website.

Annex B
Guideline for the visual presentation of the MicroVal logo

B.1 Shape and structure

Figure B.1 — MicroVal logo

B.2 Positioning

The logo shall be positioned upright with the long side horizontally.

B.3 Using the logo

The logo may only be used in the version prescribed and provided by MicroVal. The following stipulations apply:

— **Diapositive:** Use the logo in color, unless this is impossible. Using black on a light background or white on a dark background is permitted if using color is not possible.

— **Dimensions:** If necessary, the logo may be enlarged or reduced in size, provided that the original proportions are maintained.

— **Margins:** The file formats supplied by MicroVal contain the correct margins (white space) around the logo. These may not be cut off and must always be retained.

— **Registered logo:** The MicroVal and NEN logos are registered logos and may never be used by third parties without permission.

Annex C
Emergency response protocol

C.1 Introduction

At times there may be an urgent public health need for rapid deployment of new analytical methods for an emerging threat. Method developers and method users accustomed to third-party method accreditation may find the normal method accreditation time too long for immediate method use. Therefore, MicroVal recognizes the importance of rapid response and offers an emergency method certification protocol that accelerates the time to certification. This protocol is not appropriate as a substitute for the normal process of method certification. The MVTC chair, MGC chair and Technical expert group will review applications for emergency certification on a case-by-case basis. In case the application falls within the scope of an existing MicroVal Emergency Response Commitee, this commitee will take part in the review. This annex indicates where the emergency response protocol is different form the regular validation process.

C.2 Responsibilities of the Method Developer

- Consult the regular method certification process in this document and on https://microval.org/en/certification-procedure/how-do-i-become-microval-certified/.
- Contact the MicroVal Secretariat to discuss consideration of pursuing an emergency response method validation application.
- Submit an application form with a notation that it will be considered for emergency response.

C.3 MicroVal Emergency Response Committee (MERC)

The MicroVal Secretariat, MicroVal Technical Committee Chair and MicroVal General Committee Chair and members of the MicroVal Technical expert group will define the scope of work of the MicroVal emergency response committee (MERC) select and appoint MERC members who are method experts and available to rapidly review an emergency response application. To help speed the review process, the method developer shall provide a list of non-affiliated experts qualified to review the application. The number of MERC members appointed shall be based on expertise and availability to quickly perform an application review. To bring the required valuable scientific and technical insights around the addressed topic, relevant stakeholders who are recognized in the field, but not involved in MicroVal can be invited to the MERC. They will sign the MicroVal NDA. The MicroVal Certifcation body will take part in the MERC as an observer.

C.4 Application review

The MERC shall determine whether an application is suitable for emergency response consideration, is better as a submission to the regular method certification process, or is outside the MicroVal scope. The application submitted to review by the MERC will include available inclusivity & exclusivity data, including for instance, *in silico* analysis done by the method developer. Submission of validation results, compiled inclusivity and exclusivity data, and kit manufacturing quality management information will assist application review.

C.5 Expert Laboratory

After receiving a MERC recommendation for emergency review, the MicroVal Secretariat and MERC will review the expert laboratory recommendation from the method developer. In exceptional circumstances , for instance if none of the MicroVal expert laboratories has the required background/expertise and biological resources to run the study, the study can be run by a laboratory that is not a MicroVal Expert Laboratory. A decision on this will be made on case-by-case basis by the MCG chair, MVTC Chair and technical expert group. This lab will sign the MicroVal NDA.

C.6 Emergency Validation process

A validation study protocol will be reviewed by the MERC taking into account the context of the emergency response regarding the study feasibility in a short timeframe and the available resources. The MERC will recommend protocol edits as needed. Once the protocol is approved by the MERC, the laboratory will perform a method comparison study of the reference method (if available) and the alternative method. An inter-laboratory study may or may not be expected by the MERC.

C.7 Production facility

Clause 7.4.3 (Requirements for the production facility) applies for emergency validations. If an audit of the method developer production location is required, this will be performed by the MicroVal Certification Body.

C.8 Certification decision

Results of the study will be presented to the MERC. The MERC can decide to involve the MicroVal Technical Committee in the assessment. When the results are satisfactory, the MERC will recommend certification approval to the MicroVal Certification Body.

The MERC will recommend the duration of the validity of an Emergency Response Certificate. The MERC recommendation will be communicated to the MicroVal Secretariat and the MicroVal Certification Body.

The MicroVal Certification Body takes the final certification decision. The certificate will be issued for a defined period.

C.9 After the issue of the certificate

The MERC will inform the full MVTC of the process and results at the first regular MVTC meeting or at an ad hoc meeting

Method developers with a certificate resulting from an emergency validation are recommended to submit their method for a regular validation as soon as possible after the ergency valaidation

C.10 Fees

The study fee, annual fee and expert Laboratory fee (clause 13) apply to emergency validations. In case a quality management system audit has to be performed, the quality management system audit fee applies. In case the method developer decides to submit the method to a regular validation after the emergency validation, the Major modification fee applies.

C.11 Certificate lay out

The lay out of a certificate issued following the emergency response validation shall differ from the regular certificates so that it is easy to distinguish between the two.

Bibliography

NTA 8813: 2017, *Requirements for development and management of conformity assessment schemes by independent scheme owners*