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Certification rules for the mark

Validation of alternative analysis methods

Application to the food industry

The reference base for this application of the NF VALIDATION mark consists of the general rules of the NF VALIDATION mark, the present certification rules, and the additional requirements and standards that are referenced therein.

These are the certification rules as specified in the French Consumer Code.

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The present certification rules were approved by AFNOR Certification's legal representative on 04/09/2024.

They cancel and replace all previous versions.

AFNOR Certification undertakes with the representatives of the manufacturers, users and technical experts to ensure the relevance of these certification rules in terms of the certification and definition of requirements process relating to market developments.

The certification rules can be revised, in whole or in part, by AFNOR Certification and in all cases following consultation with the Validation Commission. Each revised version is then approved by AFNOR Certification's legal representative.

CHANGE HISTORY

Part changed	Version No.	Date of approval	Changes made
NF102 standard and all applicable technical standards	12	04/09/2024	Version updates for all documents Modification of the technical reference document entitled "Requirements for studies (preliminary and interlaboratory) carried out by an Expert Laboratory / Protocol for the validation of methods for the detection and quantification of veterinary drug residues in agri-food products": following the repeal of European decision CE/2002/657 and the transition to regulation CE/2021/808 : - Replacement of decision 2002/657 by regulation CE/2021/808 in the document - Replacement of the CRL 2010 guide by the LRUE 2023 guide in the document - Page 7: replacement of "Authorised limit: Maximum Residue Limit (MRL) (e.g. in Europe, Regulation No 470/2009EC (2009) or other maximum tolerance applicable to substances and established in the reference legislation, such as the Minimum Required Performance Limit (MRPL) (e.g. in Europe, Decision 2002/657/EC (2009)), by "Permitted limit: Maximum Residue Limit (MRL) (e.g. in Europe, Regulation No 470/2009/EC (2009) or other maximum tolerance applicable to substances and established in the reference legislation, such as the Reference Value (RV; reference point for action (RPA)) (EU Regulation 2019/1871)." - Page 7-8: delete the definition: "Minimum Required Performance Limit (MRPL): minimum analyte content in a sample which must at least be detected and confirmed. Minimum Required Performance Limits (MRPL) are applicable to analytical methods to be used for substances for which no authorised limit has been defined and, in particular, for substances whose use is not authorised or is specifically prohibited in the European Community. The LMPR is an analytical performance parameter, i.e. any screening method dedicated to the detection of this prohibited antibiotic must be systematically capable of detecting the analyte at this level and above" and replace it with the following: "Reference value (RV; reference point for action (RPA)) : Reference values are established under Regulation (EU) 2019/1871 and take into account both

			analytical considerations and the toxic potential of these substances. Food of animal origin containing residues of a pharmacologically active substance at or above the reference value shall be considered to be non-compliant with Union legislation." - Page 27: replacement of the table "Minimum accuracy of quantitative methods". - Update of document references Addition of paragraphs concerning confidentiality and the use of AFNOR Certification COFRAC accreditation. Updates to the conditions for membership of the Technical Board and the Validation Commission: removal of the requirement for manufacturers to be members of SYDIALE and of the "Public Authorities" category for members of the Validation Commission (now included in the "Technical Organisations" college). Update of documents and addition of information contained in reports from the 2024 working groups : "Pathogen confirmation and detection enumeration", "Free DNA reagents and dilutions" and " Non-accredited expert laboratories ".
NF 102 (entire document)	11	14/12/2022	Incorporation of addenda 1,2 and 3 and other changes : - Update of the COFRAC logo on cover page of NF102 certification rules. - Composition of the Technical Boards: update of the number of representatives from the "Technical Organisations" colleges (§ 2.3.3) - Withdrawal of part 0 - Update of obligations concerning the quality system (§ 3.3.4)
Addendum No. 02 NF102	10	05/03/2020	Update in answer to requirements of NF EN ISO/IEC 17065 standard, by adding the following: - Types of non – conformities (§ 4.4.1)

Addendum No. 01 NF102 (entire document)	10	21/05/2015	Replacement of « AFNOR Certification's legal representative » by «AFNOR Certification's legal representative » Update in answer to requirements of NF EN ISO/IEC 17065 standard, by adding the following: - Impartiality agreement of the members of the Validation Commission and Technical Boards (§ 2.2.1 and § 2.3.1) - Possible attendance of an observer during audit (§ 4.4.1 and § 5.2.1) - Details related to the list of certified products and systems (§ 4.5) Clarification on controls and tests on principal and associated raw materials (§ 3.3.5.5) Update of the dedicated website's address (§ 3.4.1.5 and 3.4.2.2) Details on responsibilities incumbent upon the applicant before submitting a certification request (§ 4.2.3) Information on annual fee invoicing (§ 6.4.1 and § 6.4.2)
NF 102 (entire document)	10	15/06/2012	Total reworking of the NF102 reference based on the NF reference model Update of references to AFNOR Certification Update of references to the mark (change of name and logo) and definition of applicable transition times (§ 3.4.2) Update of the methods for renewing the mandate of the President of the Validation Commission (§ 2.2.3) Review of the number of seats allocated to the members of SYDIALE in the "Methods manufacturers" college of the Technical Boards (§ 2.3.3) Update of the normative references applicable for the quality requirements (§ 3.3.3) Modification of the mandatory information to be inserted in the technical notices (§ 3.4.1.2) Clarification of the conditions for recognition of the quality certificates of production sites and update of the standards taken as reference (§ 4.4 and § 5.1) Description of the management of the changes to technical notices (§ 5.3.1.5) Creation of a tariff sheet updated annually (§ 6.1)

Part 1 OVERVIEW AND SCOPE

The present certification rules are taken in application of the general rules for the NF VALIDATION mark.

The present certification rules have been put in place by AFNOR Certification to certify the alternative analysis methods in the food domain.

1.1 Definitions

An **alternative analysis method**, referred to in these certification rules as an "alternative method", is a commercial alternative method which can be used, for a given category of products, to analyse or estimate the same aspect as the one measured by a reference method, but which also meets one or more of the following criteria:

- speed of analysis and/or response,
- ease of use and/or automation,
- analytical characteristics (limit of detection, specificity, etc.)

The term "alternative method" refers to the product, equipment and test procedure. It includes all the ingredients, material or otherwise, which are required to implement the alternative method.

Important note: For the NF VALIDATION mark, the test procedure of the alternative methods for detecting pathogenic micro-organisms (*Listeria* spp., *Listeria monocytogenes*, *Salmonella*, *E. coli* STEC, *Vibrio*, *Cronobacter*, *Campylobacter*) must include a stage for the confirmation of positive results.

A **reference method** is a standardised method when one exists, or an official method, or if necessary a widely known and used method, taken as reference.

1.2 Scope

The NF VALIDATION mark applied to the food industry is intended to certify that the results of tests obtained by application of specific "alternative methods" are comparable in terms of the objectives of the analysis, with those which could have been obtained by the application of reference methods.

These methods concern measurements of physical properties, the doses and chemical, biochemical, biological and microbiological detection in the food domain (including the food production environment).

The comparison is made by application of the references defined in § 3.2 of the present document.

The **certification of an alternative method** relates simultaneously to the test procedure recommended by the manufacturer, the test products and equipment required for implementation of the method, and to a specified scope.

The certification includes tests on the alternative method and inspections on its manufacturing site.

The tests are carried out during the **validation study**. This includes a **preliminary study** and an **inter-laboratory study**, the conditions for completion of which are defined in the references of § 3.2.

Inspections are carried out on the manufacturing site in order to check the quality assurance system of the manufacturer, in accordance with the methods determined in § 4.4 and § 5.2 and based on the audit reference defined in § 3.3.

The certification of an alternative method leads to the issuing by AFNOR Certification of a **certificate** of the right to use the NF VALIDATION mark (see § 3.4.1).

A method which has been granted the right to use the NF VALIDATION mark is a certified method, also known as a "validated method" in the terms of the present certification rules.

Part 2 GENERAL CERTIFICATION ORGANISATION

This section contains a description of the participants in the management and the functioning of the NF VALIDATION mark covered by these certification rules.

2.1 The certification body: AFNOR Certification

AFNOR has granted AFNOR Certification, SAS a French simplified joint stock company, a licence to use the NF VALIDATION mark. It is a European collective certification mark, use of which is authorised according to the conditions that are stipulated by its general rules and by these certification rules.

AFNOR Certification is responsible for implementing the NF VALIDATION mark. All decisions are announced by AFNOR Certification. The decisions are binding from the date on which they are announced.

As such, AFNOR Certification takes responsibility for the application of these certification rules and for all of the decisions taken within the context of these rules.

AFNOR Certification carries out all administrative management of the NF VALIDATION mark, in particular:

- Establishing the certification rules defining the procedures for evaluation and inspection of conformance with the standards and any additional specifications by staff, as well as the requirements relating to the management by staff of the quality of their services,
- Management of the Validation Commission and its Technical Boards, if applicable,
- Processing of applications for the right to use the NF VALIDATION mark,
- Organisation of the inspections specified by the certification rules and monitoring of the conformance of the analysis methods,
- Relationships with applicants, holders and third Parts, in particular for the purposes of checking that the NF VALIDATION mark is being used correctly,
- Decisions, sanctions and their follow-up,
- Sector-based promotion and the development of the application concerned by the NF VALIDATION mark.

AFNOR Certification also undertakes not to communicate, even partially, to any other person, information of which it becomes aware during the performance of the contract, without the prior written consent of the applicant/holder. If, legally, information must be disclosed to third parties, the applicant/holder is advised of the information provided by AFNOR Certification within the limits prescribed by law. However, AFNOR Certification is authorized to communicate:

- COFRAC staff and any person authorized by COFRAC, also bound by a professional confidentiality agreement, all the information it has on the applicant/holder to manage the certification and prove General rules NF mark (Common to all NF certifications) compliance with the accreditation rules, therefore that the certification concerned is in the process of being accredited by COFRAC or is issued under accreditation. This information relates in particular to the audit report, property of AFNOR Certification. When, for this purpose, AFNOR Certification has to communicate documents belonging to the applicant/holder to COFRAC or its representatives, AFNOR Certification informs the applicant/holder beforehand.
- to members of the AFNOR* Group all the information it has on the applicant/holder, with the exception of purely technical information from audit reports. This information is in particular that relating to the identification of the applicant/holder, to the standard(s) concerned and to the scheduled expiry dates.

AFNOR Certification and the other members of the AFNOR Group may cite the applicant/holder in their commercial documentation. The provisions of this article will remain in force at the end of this contract for a period of five (5) years.

* The AFNOR Group designates the whole composed of the AFNOR association and the companies, associations and groups in which AFNOR has, directly or indirectly, a stake or in which AFNOR exercises a dominant influence or appoints the administrative or management.

2.2 Validation Commission

A consulting body, called the "Validation Commission", has been created at AFNOR Certification, specific to the food application.

2.2.1 Remit of the Validation Commission

The Validation Commission is responsible for giving opinions on:

- the general policy for the operation, development, promotion and quality of the NF VALIDATION mark,
- draft certification rules and revisions to the approved certification rules,
- decisions to be taken in accordance with the certification rules,
- the creation of Technical Sector Boards when required,
- appeals presented by applicants or holders of the NF VALIDATION mark, concerning the opinions issued by the Technical Boards,
- projects for advertising and promotion actions linked to its activities,
- the choice of control and audit bodies,
- body authorisation projects,
- the review and implementation of recognition agreements.

It may be consulted on any other issue relating to the application concerned.

The members shall act impartially when exercising their functions and maintain confidentiality of the information disclosed, in particular personal information.

2.2.2 Operation of the Validation Commission

The Validation Commission issues guidelines; these are adopted by simple majority, with the President having the deciding vote if there is a parity of votes. Any experts called upon to assist the Validation Commission do not take part in the votes.

Deliberations are only valid if at least half the voting members are present or represented, and if all the colleges are represented.

Members of the Validation Commission may not receive any compensation for the duties assigned to them.

The Validation Commission establishes the frequency and the dates of its meetings. It meets when convened, approximately once a year.

2.2.3 Composition of the Validation Commission

The standard composition of the Validation Commission, members of which are spread across various colleges, is established so as to respect a balanced representation of the different Parts concerned, without a single interest dominating.

One AFNOR Certification representative and one AFNOR representative designated by its Director General are ex officio members of each Validation Commission.

The members of the Validation Commission are appointed by AFNOR Certification’s legal representative. Their mandate is for three years, and can be renewed.

The President of the Validation Commission is also appointed by AFNOR Certification's legal representative under the same conditions. Previously, a call for candidates is made within the various colleges of the Validation Commission.

Only the named member may carry out the functions of a member of the Validation Commission. However, each holder member may designate a single deputy, specified by name, designated under the same conditions.

The representatives of the "Manufacturers" college must be holders of the NF VALIDATION mark or undertake to apply for it within a period of one year starting from their nomination (except in the event that there is no competent Technical Board in the domain).

The standard composition of the Validation Commission is specified below:

One president (chosen from the members of the Validation Commission)
One or two secretary(ies) – AFNOR Certification
One representative for AFNOR Standardisation

"MANUFACTURERS" COLLEGE **5 to 7 representatives**

Manufacturer/distributor representatives.

"USERS" COLLEGE **4 to 6 representatives**

Representatives of industrial laboratories, representatives of public laboratories and private laboratories

"TECHNICAL ORGANISATIONS" COLLEGE **5 to 8 representatives**

Representatives of bodies concerned by the activity, including for example (on condition of voluntary candidature): the ACTIA (French association of technical centres for the food industry), the ANSES (French health and safety agency), the COFRAC (French Committee for Accreditation), etc.

This college includes the **authorities**, with representatives of the ministries concerned.

2.3 Technical Boards of the Validation Commission

The Validation Commission proposes the creation of Technical Sector Boards. It may be consulted on their theoretical composition, based on their competence.

2.3.1 Remit of the Technical Boards

The Technical Boards are responsible for **issuing opinions** on:

- the production, within their scope, of the requirements relating to the studies (preliminary and inter-laboratory) carried out by an expert laboratory (see § 3.2),
- the technical examination of the certification and extension applications (see section 4 and section 5),
- the technical examination of renewals.

The members shall act impartially when exercising their functions and maintain confidentiality of the information disclosed, in particular personal information.

2.3.2 Operation of the Technical Boards

The Technical Boards issue guidelines to AFNOR Certification on the decisions to be taken in application of these certification rules, in particular the follow-up required to applications for the validation of alternative methods.

These are adopted by simple majority, with the President having the deciding vote if the votes are level. Any experts called upon to assist the Boards do not take part in the votes. A systematic vote is held after the presentations of the results.

Deliberations are only valid if at least half the voting members are present or represented, and if all the colleges are represented.

Members of the Technical Boards may not receive any compensation for the duties assigned to them.

The Technical Boards establish the frequency and the dates of their meetings so that the processing of the applications and the inspection of any control reports take place within a time period coherent with the time required for the laboratory tests. They meet when convened.

The applicant may ensure that alternative method manufacturers that form part of the Technical Boards can not take part in the examination of their application, for reasons of competition. In this case, the deliberations are valid if, without counting the manufacturers college, at least half of the members are present or represented, and if all the other colleges are represented.

2.3.3 Composition of the Technical Boards

The standard composition of the Technical Boards is established so as to respect a balanced representation of the different Parts concerned, without a single interest dominating.

The members of the Technical Boards are appointed by AFNOR Certification's legal representative. Their mandate is for three years, and can be renewed.

The President of the Technical Board is also appointed by AFNOR Certification's legal representative under the same conditions.

The functions of a member of the Technical Board are strictly for personal use. However, each holder member may designate a single deputy, specified by name, designated under the same conditions.

The representatives of the "Manufacturers" college must be holders of the NF VALIDATION mark or undertake to apply for it within a period of one year starting from their nomination

The standard composition of the Technical Boards is specified below:

One President (chosen from amongst the members of the Technical Board)
One or two secretary(ies) – AFNOR Certification

"MANUFACTURERS" COLLEGE **5 to 8 representatives**

Manufacturer/distributor representatives.

"USERS" COLLEGE **5 to 8 representatives**

Representatives of industrial laboratories, representatives of public laboratories and private laboratories

"TECHNICAL ORGANISATIONS" COLLEGE **4 to 6 representatives**

This college includes the **authorities**, with representatives of the ministries concerned.

2.4 Expert laboratories and auditors

2.4.1 Expert laboratories (role and methods of approval)

2.4.1.1 Role

The studies into the alternative methods are carried out and/or supervised by an expert laboratory approved by AFNOR Certification after an opinion from the Technical Board concerned.

For each application, an expert laboratory is chosen by the manufacturer from the list of approved laboratories. The list of laboratories already approved by AFNOR Certification is available from AFNOR Certification.

2.4.1.1 Modalities of approving

The methods of approving the expert laboratories are defined below:

The expert laboratories must be **accredited** by the COFRAC (or by a foreign accreditation body recognised by the COFRAC), for the **parameter** concerned and **the reference method** in accordance with which the alternative method to be validated is assessed (see note at the bottom of this paragraph).

The expert laboratory must address to AFNOR Certification, with a view to its **approval**, a document including at least the following elements:

1 - Name of the laboratory, address, telephone, fax, e-mail, name of the manager.

2 - General area of expertise, workforce per area of expertise, number of analyses per year.

3 - Accreditation(s): enter the accreditation program(s), provide certificates of accreditation and its technical appendix (this appendix must mention the reference method for the analysis corresponding to the approved domain) (see 4).

4 - Approved domain requested: a reference method corresponds to a domain.

5 - Elements allowing the Technical Board to judge whether the laboratory is suitable for implementing the validation protocol applicable as described in § 3.2 of the certification rules.

By way of example, the laboratory should present the following elements (non-exhaustive list): experience in the organisation of inter-laboratory studies, access to a culture collection consisting of the main species and serotypes to be tested during studies, capacity to stress the bacteria in accordance with the methods required, statistical skills, etc.

This document is presented, during a session of the Technical Board, by the representative of the candidate laboratory. The Technical Board gives its opinion on the approval of the candidate laboratory.

If this opinion is positive, the expert laboratory is invited by AFNOR Certification to attend a following session of the Technical Board, as an observer, in order to immerse themselves in the problems raised during meetings and the methods of presenting applications implemented within the Technical Board.

Following this observation session, approval is given by AFNOR Certification's Director General.

An approved expert laboratory does not have to present a new application for each specific study, unless this study is not within the approved domain initially requested.

If the laboratory loses the accreditation issued by the COFRAC (or by a foreign accreditation body recognised by the COFRAC), it will automatically lose its approval for the NF VALIDATION mark.

Note: in the situation where an expert laboratory qualified by AFNOR Certification is not accredited for a reference method (derived from an internal method) - category combination, a derogation may be granted following a formal request made to AFNOR Certification on condition that :

- The expert laboratory submits a draft study to the Technical Board to demonstrate its competence in implementing the reference method for the category concerned. This draft study must be the subject of a document drawn up by the expert laboratory, which will be put out to consultation before being accepted by AFNOR Certification. The expert laboratory's contract will then be reviewed.
- That no other expert laboratory is accredited for this reference method-category pairing.
- That the expert laboratory is already accredited for the reference method (in-house) in FLEX 3.
- The expert laboratory is accredited for another reference method for the category of interest.
- The expert laboratory has been audited by AFNOR Certification.

It should be noted that if an expert laboratory extends its scope of accreditation for the reference method and the category concerned, this note does not apply.

2.4.2 **Auditors**

The auditors responsible for the audits are approved and appointed by AFNOR Certification.
The manufacturer is entitled once to reject the auditor appointed by AFNOR Certification.
The list of auditors already qualified by AFNOR Certification is available from AFNOR Certification.

Part 3 REFERENCE BASE

The reference base for this application of the NF VALIDATION mark consists of the general rules of the NF VALIDATION mark, the present certification rules, and the additional requirements and standards that are referenced therein.

These are the certification rules as specified in the French Consumer Code.

3.1 The general rules of the NF VALIDATION mark

The NF VALIDATON mark is a registered European collective certification mark with general rules which establish the overall organisational structure and the conditions for using the mark.

These certification rules, which have been incorporated within the context of the certification of products and services other than foodstuffs provided in Articles R-115-1 to R 115-3 and L 115-27 to L 115-32 of the French Consumer Code, stipulate the conditions for application of the general rules of the NF VALIDATION mark to the products stipulated in § 1.1.

The right to use the NF VALIDATION mark is granted on the basis of conformance with a standard or standards and, in general, with all the rules stipulated in this section, for a product from one applicant and one or more specific production/distribution sites.

3.2 Applicable technical references

The references used in the context of the NF VALIDATION mark applied to the **food** industry are as follows:

3.2.1 For the general case of microbiological food analysis

- **Standard EN ISO 16140** – Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods

- **Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory**: this is a document produced by the microbiology Technical Board, which applies in addition to the standard EN ISO 16140. It constitutes a guide to the application of this standard and contains specific provisions applicable to the NF VALIDATION mark. It is updated on each modification made by the corresponding Technical Board and/or by AFNOR Certification.

  It is the subject of controlled distribution on each update, to the approved expert laboratories, to the corresponding Technical Board and to holders with validated methods.

3.2.2 For alternative methods of detection of residue of antibiotics and other molecules with similar effect

The standard EN ISO 16140 does not apply.

The applicable protocol is the one described in the document produced by the Technical Board with the reference "**Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory / application to the methods of detection of residue of antibiotics and other molecules with similar effect**".

3.2.3 For any other cases

If an alternative method does not fall within the scope of specific documents applicable to the NF VALIDATION mark, the Technical Board will decide on a case-by-case basis the experimental conditions relating to the application of the standards.

3.3 Quality requirements of the manufacturer

3.3.1 Purpose

This section defines the **obligations** concerning the quality system and the process for the production of alternative methods that the manufacturer (applicant or holder of the NF VALIDATION mark) undertakes to adopt and to implement in the context of these certification rules.

These obligations constitute the reference which will serve as a base for the audits defined in § 4.4 and § 5.2.

"Manufacturer of alternative methods" is understood to mean the company responsible for shaping and checking the functional characteristics of the alternative methods.

"Product" is understood in the sense of standard ISO 9001 to be an alternative method, namely the product, equipment and test procedure. It includes all the ingredients, material or otherwise, which are required to implement the alternative method.

3.3.2 Scope

The quality system of the manufacturer must meet the requirements of the standard **ISO 13485** (with the restrictions mentioned in the table of § 3.3.4), to which are added the requirements specific to the NF VALIDATION mark (described in § 3.3.5).

In the paragraphs taken from the standard ISO 13485, the expression "medical device" is to be replaced by "**alternative method**" in the sense of the definition of these certification rules.

If the manufacturer calls sub-contractors for the shaping and/or checking of the functional characteristics of the alternative methods, these sub-contractors must meet the requirements specified in this chapter.

3.3.3 Normative references

ISO 9001 Quality management systems - Requirements

ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes

3.3.4 Obligations concerning the quality system

The following chapters of the ISO 13485 standard are applicable (only the titles of the chapters are indicated; for the content, see the standard).

Chapter	Title of the chapter of the ISO 13485 standard
4	**Quality management system**
4.1	**General requirements**
4.2	**Documentation requirements**
4.2.1	General
4.2.2	Quality manual
4.2.4	Control of documents
4.2.5	Control of records
5	**Management responsibility**
5.1	**Management commitment**
5.2	**Customer focus**
5.3	**Quality policy**
5.4	**Planning**
5.4.1	Quality objectives
5.4.2	Quality management system planning
5.5	**Responsibility, authority and communication**
5.5.1	Responsibility and authority
5.5.2	Management representative
5.5.3	Internal communication
5.6	**Management review**
5.6.1	General
5.6.2	Review input
5.6.3	Review output
6	**Resource management**
6.1	**Provision of resources**
6.2	**Human resources**
6.3	**Infrastructure**
6.4	**Work environment**
6.4.1	Work environment
6.4.2	Contamination control

Chapter	Title of the chapter of the ISO 13485 standard
7	**Product realization**
7.1	Planning of product realization
7.2.1	Determination of requirements related to product
7.2.2	Review of requirements related to product
7.2.3	Communication
7.3	**Design and development**
7.3.1	General
7.3.2	Design and development planning
7.3.3	Design and development inputs
7.3.4	Design and development outputs
7.3.5	Design and development review
7.3.6	Design and development verification
7.3.7	Design and development validation
7.3.8	Design and development transfer
7.3.9	Control of design and development changes
7.3.10	Design and development files
7.4	**Purchasing**
7.4.1	Purchasing process
7.4.2	Purchasing information
7.4.3	Verification of purchased product
7.5	**Production and services provision**
7.5.1	Control of production and service provision
7.5.6	Validation of processes for production and service provision
7.5.8	Identification
7.5.9	Traceability
7.5.9.1	General
7.5.11	Preservation of product

Chapter	Title of the chapter of the ISO 13485 standard
7.6	**Control of monitoring and measuring devices**
8	**Measurement, analysis and improvement**
8.1	**General**
8.2	**Monitoring and measurement**
8.2.1	Feedback
8.2.2	Complaint handling
8.2.4	Internal audit
8.2.5	Monitoring and measurement of processes
8.2.6	Monitoring and measurement of product
8.3	**Control of nonconforming product**
8.4	**Analysis of data**
8.5	**Improvement**
8.5.1	General
8.5.2	Corrective action
8.5.3	Preventive action

3.3.5 Additional specific requirements applicable

The provisions defined below must be applied in addition to those defined in § 3.3.4.

3.3.5.1 Definitions

- "Principal raw material" refers to a specific material with a direct effect on the suitability of the method. (Examples: antibodies for an immunological method, major ingredients for a medium, etc.)
- "Associated raw material" refers to a material with an indirect effect on the suitability of the method. (Examples: wash buffer, supports for the methods in solid phase, etc.)

3.3.5.2 Product life span

The method for determining the life span of each type of product must be documented.

3.3.5.3 Product identification and traceability

A) Identification

The identification of the finished product is **contractually required**, in accordance with the methods defined in the "Conditions of use for the NF VALIDATION mark" chapter (§ 3.4.2) of these certification rules.

B) Traceability

The manufacturer must provide a definition for the concept of batches for principal raw materials and for products, and ensure the traceability of the principal raw materials and the finished products.

3.3.5.4 Control of processes

A) Manufacturing sub-contracting relation

When a manufacturer sub-contracts all or part of the manufacturing, either due to unforeseen circumstances (for example volume of work, need for additional technical knowledge, or temporary inability to work), or on an ongoing basis (for example under the terms of permanent contracts for sub-contracting relations), the activities must be granted to a competent sub-contractor. A sub-contractor is considered competent if they comply with these requirements for the activities in question.

B) Special methods

The manufacturer must ensure that the records relating to the quality of special products identify:

a) The work instructions used
b) The date on which this special method was used
c) The identity of the user of this special method

3.3.5.5 Inspections and tests

The manufacturer must:

- define the principal raw materials and the associated raw materials. As for the product risk analysis, the manufacturer must, notably, evaluate the interaction between the matter or the material and the analysis in order to demonstrate the lack of direct impact on the performance of the method when this matter or material is changed.

- justify the relevance of inspection plans implemented, i.e. to check that the sampling and inspection methods are regularly examined whilst taking into account reports relating to nonconforming units, quality audit reports and feedback to confirm their relevance.

A) Methods concerning the principal raw materials

a) The manufacturer must define, for each principal raw material, a specification.

b) The manufacturer must produce a reference system allowing them to specify the level of performance of each principal raw material using reproducibility tests.

The internal checks are carried out with the following frequency:

- at least one check per batch received,
- in the event of storage, at least one check per batch or per aliquot of batches after storage and before manufacture.

The principal raw materials can be identified by codes so as to preserve the anonymity of the raw materials used with regard to the auditor.

Exceptions:

- if the principal raw material comes from a supplier, the manufacturer must guarantee from this supplier,
- if a technical impossibility is proven, the reproducibility tests will be carried out on the product.

B) Methods concerning the associated raw materials

The manufacturer must define, for each associated raw material, a specification and the methods for checking these specifications.

C) Methods concerning any detection of the signal (methods integrating a physical measurement)

The three essential phases in the detection are:

- the physical principle of detection,
- the processing of the signal,
- the processing of the information.

The manufacturer must, for each of these phases:

- document their level of performance,
- define the inspections.

D) Methods concerning the products

The manufacturer must produce a reference system for the internal inspection of the suitability of each product and justify its relevance.

This reference system will integrate as a minimum:

- the limit of detection,
- the specificity,
- the detection threshold of the signal, if necessary.

One internal inspection per batch is preferable.

3.3.5.6 Delivery

The manufacturer must require each authorised representative to keep updated records of the distribution of alternative methods, and these records must be available for any inspection.

3.3.5.7 Quality records

The manufacturer must retain quality records for a period equivalent to the life span of the alternative method they have defined. This duration must not be less than one certification cycle for the NF VALIDATION mark (starting from the date on which the NF VALIDATION mark was issued).

The manufacturer must produce and keep updated a record relating to each batch of alternative methods which provides traceability under the terms required by § 3.3.5.3 and which identifies the quantity manufactured and the quantity issued for the distribution.
The record of the batch must be checked and authorised.

N.B.: A batch may only consist of a single alternative method.

3.3.5.8 Statistical techniques

The manufacturer must produce and update procedures aiming to ensure that the sampling methods are regularly inspected, taking into account reports relating to nonconforming units, quality audit reports, feedback (see § 3.3.5.10) and any other relevant consideration.

3.3.5.9 Modifications

The quality system must integrate management of the modifications to:

- the principal raw materials,
- the processes,
- the products.

Any modification (whether in terms of protocol or equipment) which may have an effect on the suitability of the method must be declared to AFNOR Certification. The processing methods are defined in § 5.4.

3.3.5.10 Customer complaints

Any feedback, including complaint reports from customers and returned products, must be the subject of documents, investigations and interpretations, the collection and distribution of information in accordance with the procedures defined by a designated person.

The manufacturer must update the records of all investigations relating to complaints. If the investigation observes that activities a long way upstream have influenced the subject of the complaint, a copy of the report must be sent to those people involved with those activities.

3.4 Marking conditions for the NF VALIDATION mark

3.4.1 Documents relating to the certification

3.4.1.1 Validation certification

For each method validated, AFNOR Certification allocates to the applicant a certificate of the NF VALIDATION mark which attests that the alternative method is certified. It includes administrative information and a technical section relating to the performances of the alternative method. Validation certificate templates can be produced by the Technical Board concerned.
The holder must make free copies of the NF VALIDATION certificate available to users.

3.4.1.2 Technical notice of the validated method

The technical notice must indicate as a minimum the following characteristics:

1) number of the certificate issued by AFNOR Certification,
2) the end of validity date for the certificate, or a text prompting the reader to consult the end of validity date on the validation certificate available on the website dedicated to the NF VALIDATION mark and/or on request to the holder,
3) scope for the NF VALIDATION mark.

These three elements appear on the first page of the certificate provided by AFNOR Certification.

The technical notice must be identified by the holder in such a way that the revision versions are indicated. The identified reference will be reported by AFNOR Certification on the validation certificate.

3.4.1.3 Validation studies summary report

AFNOR Certification and/or the holder may send, to the users who so wish, additional information to that contained in the NF VALIDATION certificate, in particular via the validation studies summary report, written by the expert laboratory, and if applicable based on the template produced by the Technical Board concerned.

3.4.1.4 List of validated methods

AFNOR Certification produces and distributes, without control and periodically after each Technical Board meeting, the list of validated methods. This list includes, for each method, the contact details of the holder (and distributor/production site, if applicable), the commercial reference of the method, the objective of the test (detection/count and analyte required), the initial date of validation and any renewal and/or extension dates, and the end of validity date.

3.4.1.5 Website

AFNOR Certification makes available to the public a website dedicated to the NF VALIDATION mark, at the following address: http://nf-validation.afnor.org/ (French version) or http://nf-validation.afnor.org/en (English version).

General information and the information available concerning the validated methods (list of methods, certificates, summary reports) may be downloaded on this site.

3.4.1.6 Reproduction of documents and reference to accreditation

Reproduction and affixing of the COFRAC logo and reference to AFNOR Certification accreditation by the applicant / holder (and its clients) are prohibited by AFNOR Certification.

AFNOR Certification only authorises full reproduction of the reports and certificates it has issued.

3.4.2 Conditions for use of the NF VALIDATION mark

This paragraph explains how reproducing the NF VALIDATION logotype, how making reference to the NF VALIDATION mark, and presents the marking of the certified methods and the information given to the purchaser of validated products on the certified characteristics.

Without prejudice to the sanctions set out in article 14 of the general rules of the NF VALIDATION mark, any erroneous announcements expose the holder to the possibility of legal action for fraud and/or misleading advertising.

3.4.2.1 Logotype

The logotype is as follows:

In the context of the alternative analysis methods validated in accordance with the protocol of the standard EN ISO 16140, the following logotype, referring to this protocol, may be used:

The NF VALIDATION logotype must be placed by the manufacturer on the technical notice of the products and may be placed directly on the products and/or their packaging, in respect of the **graphics charter for use** defined by AFNOR Certification. Other supports referring to the validated products - such as documentation, advertising (…) - may also refer to the NF VALIDATION mark in the same conditions.

3.4.2.2 Compulsory marking associated with the logo

Communication on the information regarding certification of products and services is set by regulations. The goal of these regulations is to make the meaning of the labels, certification marks, etc. transparent for consumers and users.

Thus, Article R 115-2 of the Consumer Code stipulates that:

"Whenever reference is made to the certification in advertising, labelling or presentation of any product or service as well as on commercial documents of any kind pertaining thereto, the consumer's or user's attention shall be drawn to the following information:

- the name or corporate name of the certification body or the collective certification mark,
- the denomination of the reference base serving as a basis for certification,
- the terms under which the certification reference base may be consulted or obtained. "

In application of this article, **the manufacturer must indicate on the technical notice of the certified products** – and if they so wish, on the products and/or their packaging or on any documentation referring to the NF VALIDATION mark – **at least the following elements, alongside the logotype:**

XXX aa/bb – cc/dd*

ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS

http://nf-validation.afnor.org/en

** This is the reference of the NF VALIDATION certificate assigned, by AFNOR Certification, to each validated method.*

The application of these new marking methods is **immediate** for all methods certified after **the 1st January 2011**.

For the methods already certified on this date, the holders have a **transition period of three years starting from the 1st January 2011** to update the NF VALIDATION marking on the technical notices and, if applicable, on the associated communication supports. The marking obligation is **deferred**, in all cases, until no later than the **next renewal** of the certification.

Manufacturers who wish to do so can update their documents before this time.

Meanwhile, marking including the old logo continues to co-exist alongside marking with the new logo.

Part 4 OBTAINING CERTIFICATION: acceptance arrangements

4.1 Conditions of use for the NF VALIDATION mark

4.1.1 Granting of the right to use the NF VALIDATION mark

Any company marketing alternative methods on an ongoing basis, the performances of which are equivalent to those of the reference method and which meet the requirements set out in § 3.3, may request the right to use the NF VALIDATION mark. Such a request is hereafter referred to as the "application", while the company which makes it is known as the "applicant".

The granting of these usage rights is declared by AFNOR Certification's legal representative in view of the results of the examination of the application and the commitments made by the applicant on this occasion.

If this right is granted, its beneficiary is named the "holder".

For each validated method, AFNOR Certification allocates to the applicant an NF VALIDATION certificate. This certificate is valid for four years and can be renewed under the conditions defined in § 5.3 and § 7.3.

4.1.2 Limits for the right to use the NF VALIDATION mark

The right to use the NF VALIDATION mark is strictly limited to the "alternative methods" for which it has been granted, in other words duly defined alternative methods, from duly defined factories and manufactured under the conditions specified by these certification rules and in particular in § 3.3.

As a consequence, in particular:

- **any modification** that the holder wishes to make to a validated alternative method, including a change in the trade name, a change of sub-contractor, a change of installation, etc. must be the subject of an extension or modification application (see methods defined in § 5.4).
- the holder must only **refer to the NF VALIDATION mark**, in particular where its commercial documents (confirmations of orders, invoices, delivery slips, advertising brochures, catalogues, etc.) are concerned, in order to distinguish validated "alternative methods", without there being any risk of confusion with those which are not validated.

4.2 Application for validation of an alternative method (1st application)

4.2.1 Definition of the applicant

The applicant is identified as the legal entity requesting the right to use the NF VALIDATION mark for one or more of their alternative methods and for one or more determined production sites and undertaking the quality management thereof.

Any company, manufacturer and/or distributor of alternative methods in the European Economic Area (EEA) that meets the conditions set out in § 4.1.1 may request this procedure.

If the applicant is based in a country which is not a member of the EEA, the validation application must be made jointly with the legal representative of the applicant in the EEA.

If the applicant markets the alternative method and is not the manufacturer of said alternative method (as defined in § 3.3.1), the validation request is made jointly with the manufacturer (see appendix 1), who undertakes to respect these certification rules, in particular with regard to the quality assurance provisions, in order to ensure consistent quality of the validated alternative method.

4.2.2 Applicant commitments

The applicant must **accept all the conditions** which appear in these certification rules for the NF VALIDATION mark and its appendices, in particular:

- carry out the checks for which they are responsible, in accordance with § 3.3,
- facilitate the work which the checking officers are required to carry out, based on these certification rules and in accordance with § 4.4 and § 5.2.

They must undertake to comply with these same conditions throughout the period that the NF VALIDATION mark is used.

4.2.3 Filing a validation application

The application must be produced in accordance with the instructions of appendix 1 of these certification rules.

Before submitting a request, the applicant must ensure that all the requirements regarding the product and related sites provided in these certification rules, notably part 3, are met at the time of application. The applicant shall make sure that the regulations applicable to the product are respected (e.g.: CE marking). The applicant shall agree to comply with these conditions throughout the license period granted for the NF VALIDATION mark use.

If the applicant does not comply with these rules, the file examination may be stopped or suspended. In particular, it is not possible to refer to the NF VALIDATION mark before obtaining the right of use, or to submit counterfeit products to certification.

The applicant must associate its application with an **independent expert laboratory**. This laboratory must be qualified by AFNOR Certification for the domain concerned (see qualification procedure in § 2.4.1). The list of qualified expert laboratories is available from AFNOR Certification.

This laboratory is responsible for carrying out and/or supervising the tests on the alternative method proposed for validation.

In the event that part of the tests is sub-contracted, the expert laboratory must indicate in its draft study the extent of the sub-contracting relation and the name of the sub-contractor.

4.3 Administrative and technical examination of the application

Any validation application is registered by AFNOR Certification, and an acknowledgement of receipt will be provided. AFNOR Certification checks that the administrative elements making up the certification application are complete. The technical examination of the application may only be carried out if the application is complete.

The technical aspects of the validation applications are examined by the Technical Board concerned.

Each application is examined without anonymity. The members of the Technical Board are bound by professional secrecy.

The applicant may ensure that alternative method manufacturers that form part of the Technical Boards can not take part in the examination of their application, for reasons of competition, no matter what the stage of the presentation of the results of the study.

The technical examination of the application by the Technical Board takes place in three stages and in accordance with the validation protocols in force (see § 3.2):

1st stage Presentation of the draft preliminary study

2nd stage Presentation of the results of the preliminary study and a draft inter-laboratory study

3rd stage Presentation of the results of the inter-laboratory study to the Technical Board (and the audit report if required by AFNOR Certification)

A **maximum delay of one year is permitted between each stage** of the technical examination of the application.

The aim of the preliminary study is to evaluate the alternative method proposed for the validation with regard to the reference method, following the technical protocol described in § 3.2. This study leads to the drafting, by the expert laboratory, of an evaluation report for the alternative method, presented to the experts of the Technical Board.

The aim of the inter-laboratory study is to determine the variability of the results obtained in different laboratories using identical samples, and to compare these results with those obtained during the preliminary study, following the technical protocol described in § 3.2.

The expert laboratory is responsible for managing the inter-laboratory study. It is also responsible for collecting, implementing the results obtained and writing a report, presented to the experts of the Technical Board.

Before each of the presentations to the Technical Board, the expert laboratory must send AFNOR Certification the draft studies and study reports at the set date (approximately 1 month before the meeting), so that AFNOR Certification can distribute them to the members of the Technical Board.

The draft studies and study reports are presented to the Technical Board by the representative of the expert laboratory, who may be accompanied by the representative of the manufacturer.

The Technical Board studies and evaluates the content of the study reports (drafts and results).

For each study, reviewers are appointed during the 1st stage by the Technical Board. These reviewers, chosen from the Technical Board (all colleges), will more closely study the applications for which they are responsible. They will have the possibility of contacting the expert laboratory before the meetings, in order to obtain additional information and if necessary to allow the expert laboratory to provide the response before the Technical Board meeting. During the meeting, the reviewers will give a brief spoken report on the studies presented by the expert laboratory.

The detailed modes for examination of the validation studies are defined in the document entitled "Requirements regarding the studies carried out by an expert laboratory" (see § 3.2).

4.4 Manufacturer audit

4.4.1 General modalities

In parallel to the completion of the inter-laboratory study, AFNOR Certification has an audit carried out on the manufacturer so as to ensure that they have a quality assurance system which complies with the requirements of § 3.3. These audits are carried out under the responsibility of AFNOR Certification.

If the manufacturing of the alternative method is the result of the assembly of principal raw materials, some of which are produced outside the site, the auditor will pay close attention to the control modalities of the supplier(s).

If the subcontractor(s) have certification in accordance with the ISO 9001 or ISO 13485 standards for the production of the aforementioned principal raw materials, a copy of the certificate shall be provided to AFNOR Certification. Otherwise, AFNOR Certification determines the opportunity to carry out audits on the sub-contractor's premises (nature, duration and frequency to be defined during the examination of the application, based on a risk analysis).

This audit is carried out in accordance with the general principles of the ISO/IEC 19011 standard for the performance of a quality audit. The audit plan priorly sent to the company describes the scopes and arrangements for the audit.

The audit may be performed in the presence of an observer who shall respect confidentiality. This observer may be compelled to AFNOR Certification by standards or signed agreements. The observer's presence is systematically notified in prior by AFNOR Certification to the applicant.

AFNOR Certification can also suggest the participation of any other observer to the applicant.

The auditor shall have access to all means (premises, facilities and equipment) necessary for the performance of the audit; qualified personnel may be requested to participate if needed.

The auditor may take copies of any documents considered necessary with prior consent of the applicant.

AFNOR Certification analyses the relevance of the manufacturer's response to the deviations which may be issued following the audit. AFNOR Certification may request that an additional full or partial audit be carried out.

There are two types of non-conformities:

- **Major non-conformity:** Non-satisfaction of a requirement of the scheme (certified characteristic or organization, monitoring or steering arrangement) that involves a proven risk (that is to say based on objective elements) of non-compliance, recurrent, or unique in case of very important risk, with a requirement relating to the concerned product.

- **Minor non-conformity:** Failure to meet a requirement of the scheme (certified characteristic or organizational, monitoring or control provision) that does not involve a significant risk of non-compliance with a concerned product requirement.

Certification can not be issued or maintained if a major non-conformity remains unsolved.
A set of minor non-conformity that have not been lifted from the current audit can also lead to an unfavorable decision. Certification may be issued or maintained if there are minor non-conformities for which the analyses and treatment actions have been deemed satisfactory, insofar as the remaining differential constitutes a tolerance to the certification scheme.

The relevance of the response is analysed and an additional assessment can be requested to verify the implementation of corrective actions (documentary assessments and/or full or partial audits/inspections and/or tests).

Information on the results of the audit may be provided by AFNOR Certification to the Technical Board during the 3rd stage (see § 4.3).

AFNOR Certification may call upon two reviewers in the event of any difficulty in judgement for the audit report. In this case, these reviewers receive the audit report and present their opinions to the Technical Board, at the same time as their opinion on the results of the inter-laboratory study.
The audits are carried out in French or in English. If the documents are in another language, AFNOR Certification and/or the auditor may request a translation.

4.4.2 Audit modalities

If applicable, the companies must provide AFNOR Certification with the copy of the valid quality assurance certificate. This must clearly specify that the scope of the certification includes the manufacturing of the validated method, and must include the limit of validity of the certification.

1st scenario:

The company is <u>neither certified</u> ISO 13485 nor ISO 9001
Or the company is certified with regard to one of these models, but not for the production unit relating to the method validated (or being validated).

☛ A two-day audit is carried out on the site for the admission. This audit may be reduced to one day if the main stages of the manufacturing are sub-contracted to another site which is already certified.

The audit reference system is the one described in § 3.3.

The auditors who carry out the audits are approved by AFNOR Certification

If a company wishes, a local auditor (or the same auditor as the auditor of the quality assurance certifying body) may be appointed by AFNOR Certification for the audits of this company. However, in this case, the company is responsible for the cost of the qualification of this auditor.

2nd scenario:

The company is certified ISO 9001* for the production unit relating to the method validated (or being validated).

The corresponding certificate must be issued by AFNOR Certification or any other certifying body accredited by an Accreditation Body which is a member of the EA (European co-operation for Accreditation) or the IAF (International Accreditation Forum).

☛ A one-day audit is carried out on the manufacturing site.

The audit reference system will include the chapters of § 3.3, in addition to the standard ISO 9001 (requirements specific to the standard ISO 13485 and requirements specific to the NF VALIDATION mark).

3rd scenario:

The company is certified ISO 13485*, for the production unit relating to the method validated (or being validated).

The corresponding certificate must be issued by AFNOR Certification or any other certifying body accredited by an Accreditation Body which is a member of the EA (European co-operation for Accreditation) or the IAF (International Accreditation Forum).

☛ There is no audit on the manufacturing site **on admission**.

The requirements described in § 3.3.5 of these certification rules (additional specific requirements to the NF VALIDATION mark) will not be checked **on admission**.

* Only the quality assurance certificates produced in accordance with the standards in force are taken into account for a streamlining of the audits.

4.5 Decision

The Technical Board gives its opinion to AFNOR Certification on the follow-up to be taken for the application which has been examined, after each stage.

After the 3rd stage (presentation of the results of the inter-laboratory study and evaluation of the audit report), if the opinion of the Technical Board is favourable, it determines if necessary the validation limits and the specifications to be made to the technical notice (protocol of use) for the method proposed by the manufacturer.

Any specifications are attached to the validation certificate of the alternative method. This validation certificate is written by AFNOR Certification based on the template defined if necessary by the Technical Board and sent to the manufacturer, after the opinion of the Technical Board concerned.

The Certification decision is taken by AFNOR Certification's legal representative**.**

At the proposal of the Technical Boards, AFNOR Certification may take the following decisions:

- grant the right to use the NF VALIDATION mark for four years,
- grant the right to use the NF VALIDATION mark for a determined period, on expiry of which a validation confirmation must take place based on the specific procedures proposed by the Technical Board,
- refuse the right to use the NF VALIDATION mark.

The holder may appeal against the refusal by submitting an application in accordance with Article 11 of the general rules of the NF VALIDATION mark.

When the right of use of the NF VALIDATION mark is granted, the responsibility of AFNOR Certification cannot in any way substitute the holder's legal responsibility.

Communication terms governing the NF VALIDATION certification are defined in part 3.4 of these certification rules.

Information on certified products is available on the website http://nf-validation.afnor.org/en. It notably consists in:

- the product identification;
- these certification rules;
- the holder's identification;
- the certified characteristics.

AFNOR Certification shall provide information, upon request, about the validity of a given certification.

If the license holder provides copies of the certification documents to others, the documents shall be reproduced in their entirety.

Part 5 MAINTAINING CERTIFICATION: Follow-up arrangements

5.1 Purpose

The holder is required to regularly monitor the validated methods, in order to permanently ensure the performances of the validated alternative method, in accordance with the requirements established in § 3.3 of these certification rules.

Monitoring of the conformance of the alternative methods with the requirements of these certification rules is carried out by AFNOR Certification upon granting of the right to use the NF VALIDATION mark.

Normal monitoring involves:

- periodic audits, carried out in accordance with the requirements of § 3.3, and the frequency and duration of which are defined in § 5.2,
- every four years, a renewal study, the modalities for the examination of which are defined in § 5.3.

In parallel, **any modification** that the holder wishes to make to a validated alternative method or to the organisation of their production must be declared without delay to AFNOR Certification. The modification must be the subject of an extension or modification application in accordance with the instructions of appendix 1 of these certification rules. The processing modalities for the modifications are described in § 5.4.

AFNOR Certification, after the opinion of the Technical Board if applicable, can undertake or delegate the completion of any audit and/or additional studies aiming to ensure that the performances of the validated method are maintained following disputes, complaints, opposition, etc. of which they are aware and which relate to the use of the NF VALIDATION mark.

5.2 Manufacturer monitoring audits

5.2.1 General modalities

The monitoring audits are carried out under the responsibility of AFNOR Certification.

If the manufacturing of the analysis method is the result of the assembly of principal raw materials, some of which are produced outside the site, the auditor will pay close attention to the control modalities of the supplier(s).

If the subcontractor(s) have certification in accordance with the ISO 9001 or ISO 13485 standards for the production of the aforementioned principal raw materials, a copy of the certificate shall be provided to AFNOR Certification. Otherwise, AFNOR Certification determines the opportunity to carry out audits on the sub-contractor's premises (nature, duration and frequency to be defined during the examination of the application, based on a risk analysis).

This audit is carried out in accordance with the general principles of the ISO/IEC 19011 standard for the performance of a quality audit. The audit plan priorly sent to the company describes the scopes and arrangements for the audit.

The audit may be performed in the presence of an observer who shall respect confidentiality. This observer may be compelled to AFNOR Certification by standards or signed agreements. The observer’s presence is systematically notified in prior by AFNOR Certification to the applicant.

AFNOR Certification can also suggest the participation of any other observer to the applicant.

The auditor shall have access to all means (premises, facilities and equipment) necessary for the performance of the audit; qualified personnel may be requested to participate if needed.

The auditor may take copies of any documents considered necessary with prior consent of the applicant.

AFNOR Certification analyses the relevance of the manufacturer's response to the deviations which may be issued following the audit. AFNOR Certification may request that an additional full or partial audit be carried out.

The audits are carried out in French or in English. If the documents are in another language, AFNOR Certification and/or the auditor may request a translation.

5.2.2 Audit modalities

If applicable, the companies must provide AFNOR Certification with the copy of the valid quality assurance certificate for the production site. This must clearly specify that the scope of the certification includes the manufacturing of the validated method, and must include the limit of validity of the certification.

If applicable, the companies must also provide the copy of the quality assurance certificate for the sub-contractor sites which manufacture the principal raw materials.

1st scenario:

The company is neither certified ISO 13485 nor ISO 9001, or the company is certified with regard to one of these models, but not for the production unit relating to the validated method

☛ A one-day audit is carried out on the manufacturing site every two years for monitoring.

The audit reference system is the one described in § 3.3.

2nd scenario:

The company is certified ISO 9001* for the production unit relating to the validated method.

The corresponding certificate must be issued by AFNOR Certification or any other certifying body accredited by an Accreditation Body which is a member of the EA (European co-operation for Accreditation) or the IAF (International Accreditation Forum).

☛ A one-day audit is carried out on the manufacturing site every four years for monitoring.

The audit reference system will include the chapters of § 3.3, in addition to the standard ISO 9001 (requirements specific to the standard ISO 13485 and additional requirements specific to the NF VALIDATION mark).

3rd scenario:

The company is certified ISO 13485* for the production unit relating to the validated method.

The corresponding certificate must be issued by AFNOR Certification or any other certifying body accredited by an Accreditation Body which is a member of the EA (European co-operation for Accreditation) or the IAF (International Accreditation Forum).

☛ A one-day audit is carried out on the manufacturing site every four years for monitoring.

* Only the quality assurance certificates produced in accordance with the standards in force are taken into account for a streamlining of the audits.

5.3 Renewal study

5.3.1 Preliminary phase

The **holder** of the "alternative method" chooses an **expert laboratory** (from the list of laboratories approved by AFNOR Certification) which will be responsible for this renewal study.

The expert laboratory presents to the members of the Technical Board, in a meeting, a renewal application concerning the alternative method, the content of which is explained below in § 5.3.2.

Two reviewers are appointed from among the members of the Technical Board, if possible before the presentation by the expert laboratory. Ideally, this appointment is made during the previous session.

5.3.2 Content of the renewal application

The list of **six elements making up the renewal application** presented by the expert laboratory during an initial meeting is indicated below. :

1) <u>A reminder of the alternative method, including the following headings</u>

- Date that the NF VALIDATION mark was first awarded and previous extension and renewal date(s)
- Principle of the method
- Protocol for use in the form of a diagram
- Reference method(s) to which the alternative method has been compared
- Updated technical notice (protocol) and all previous technical notices which have been in force since the previous validation or renewal, indicating the modifications

  Note: The applicant must provide the expert laboratory with these versions of technical notices.
- Specific characteristics (scope of the validation, any restrictions on using the method, etc.)
- Summary of the results obtained during the initial validation and any renewals and extensions
- Report of the modifications which have been made to the alternative method, which may or may not have led to extension of the validation

  Note: The applicant must provide the expert laboratory with a detailed report of all the modifications which have been made since the last validation or renewal or extension.

2) <u>A bibliographical study including, if applicable:</u>

- A list of the publications since the last validation or renewal of the method

  Note: The information elements come both from the applicant and as a result of the bibliographical research carried out by the expert laboratory. They are, if necessary, completed by the information from the rapporteurs.
- A summary produced by the expert laboratory based on these publications, including elements of information on the performances of the method
- A report of the external validations carried out by bodies other than AFNOR Certification (date, body, nature of the validation protocol, indication of the reference method)

  Note: The applicant must provide the reports concerning these validations to the expert laboratory, which makes them available to the Technical Board during the presentation.

3) <u>A report of the user complaints concerning the method</u>

If applicable, the applicant must provide the expert laboratory with the elements used to bring to the attention of the Technical Board any anomalies detected and which have led to modifications to the protocol, or exclusions of matrices for example.

Furthermore, audits are regularly carried out on the production site of the method, on behalf of AFNOR Certification, during the validation application and during monitoring (see § 3.3).

A chapter covering complaints appears in the audit reference system. The information concerning complaints registered since the last validation or renewal (type, importance, processing) may be sent to the Technical Board in the form of a report, on the opinion of AFNOR Certification and the auditor, if it proves that they are sufficient to call into question the performances of the method.

Complaints gathered by AFNOR Certification will also be passed to the expert laboratory to be included in the dossier.

4) A presentation of the modifications which have occurred since the previous validation

- In the **technical reference guide** of the NF VALIDATION mark (document describing the protocol for completing the preliminary and inter-laboratory studies carried out by the expert laboratory).
- In the **reference method** to which the alternative method has been compared with a view to its validation

5) A presentation of any modifications envisaged in the alternative method itself

The expert laboratory establishes a diagnosis and gives its opinion on whether or not it is necessary to carry out an additional study.

The new draft technical notice (supplied by the holder) should feature in the dossier.

If the holder envisages an extension to the validation of the method (major modifications made to the method or to the protocol for use, or modification of the scope of the validation), the procedure relating to the extension methods is applied simultaneously (§ 5.4.1).

6) A draft additional validation study

If applicable (see below), the additional studies to be carried out will be proposed, respecting the requirements of the validation reference system.

5.3.3 Examination of the renewal application

The Technical Board examines all six of the parameters presented in the renewal application and issues one of the following verdicts:

- **IF NO MODIFICATION HAS BEEN MADE TO THE TECHNICAL REFERENCE GUIDE OF THE NF VALIDATION MARK OR IN THE REFERENCE METHOD**

  AND IF ANY MODIFICATIONS TO THE ALTERNATIVE METHOD DO NOT JEOPARDISE THE PERFORMANCES OF THE METHOD

  AND IF THE ANALYSIS OF THE COMPLAINTS AND THE BIBLIOGRAPHICAL EXTRACTS DOES NOT JEOPARDISE THE PERFORMANCES OF THE METHOD:

  ☛ The Technical Board gives its positive agreement to renew the validation for four years, without any additional testing (so long as the application presented is complete)

- **IF THERE HAS BEEN A MODIFICATION TO THE TECHNICAL REFERENCE GUIDE OF THE NF VALIDATION MARK:**

  ☛ The Technical Board requests that a full or partial study be carried out*, based on the diagnosis established by the expert laboratory.

  ** The evaluation of the importance of the modifications and the definition of the additional studies to be carried out is the responsibility of the Technical Board.*

➢ **IF THERE HAS BEEN A MODIFICATION TO THE REFERENCE METHOD:**

☛ The Technical Board requests that a full or partial study be carried out*, based on the diagnosis established by the expert laboratory.

** The evaluation of the importance of the modifications and the definition of the additional studies to be carried out is the responsibility of the Technical Board.*

➢ **IF MODIFICATIONS TO THE ALTERNATIVE METHOD ARE PRESENTED:**

a) In the event of (a) major modification(s) affecting the method:

- modification of a main material (= specific material with a direct effect on the suitability of the method - e.g.: antibodies for an immunological method, major ingredients for a medium, etc.), or
- major modification of the protocol (including introduction of an automatic control system with an effect on the protocol).

☛ The Technical Board requests that an additional study be carried out, based on the diagnosis established by the expert laboratory.

b) In the event of (a) minor modification(s):

- modification of an associated raw material (= material with an indirect effect on the suitability of the method - e.g.: wash buffer, supports for the methods in solid phase, etc.), or
- minor modification of the protocol (including introduction of an automatic control system reproducing in full the validated protocol).

☛ After studying the documentation during a session, the Technical Board can give its positive agreement to renew the validation without any further study.

If the Technical Board considers the modification to affect a principal raw material (and not an associated material) or that the modification is liable to have an effect on the suitability of the method, the processing will be carried out in accordance with case a).

If they consider it useful, the Technical Board may request additional information which will be studied during a subsequent session.

c) If the method includes results software, and this has been updated:

☛ The expert laboratory must check whether or not the results obtained during the initial validation or renewal are modified by the more recent use of the software. If the results are modified, the Technical Board requests that an additional study be carried out, based on the diagnosis established by the expert laboratory.

➢ **IF COMPLAINTS OR BIBLIOGRAPHICAL EXTRACTS ARE LIABLE TO BRING INTO QUESTION THE PERFORMANCES OF THE METHOD:**

☛ The Technical Board requests the completion of additional validation studies, or the provision of additional documents, with the aim of proving that these performances remain satisfactory with regard to the NF VALIDATION mark.

If several of the aforementioned scenarios occur simultaneously, the Technical Board proposes additional preliminary and/or inter-laboratory studies, taking into account all the parameters.

The Technical Board examines the renewal application. After each stage (draft study and results if applicable), it issues a verdict to AFNOR Certification on the follow-up required for the renewal application. The decision-making modalities are presented in § 4.5.

In the event of renewal, the NF VALIDATION certificate of the alternative method is updated by AFNOR Certification and sent to the manufacturer, after the agreement of the Technical Board concerned. A summary report is written by the expert laboratory. It includes a summary of the different headings presented, as well as the summary of the additional studies carried out if applicable.

In the event of a refusal, the holder may appeal against the decision by submitting an application in accordance with Article 11 of the general rules of the NF VALIDATION mark.

5.4 Extension, modification of the validated methods

Any modification that the holder wishes to make to a validated alternative method or to the organisation of its production must be declared immediately to AFNOR Certification (see appendix 1).

Modifications relating to the protocols, reagents, components, technical notices, etc. of the alternative method, or to its manufacture (suppliers of raw materials, manufacturing methods, place of manufacture, etc.) are liable to lead to a variation in the performances of the alternative method. Their processing modalities are defined below.

5.4.1 Modification relating to the alternative method

5.4.1.1 Modification of one of the principal raw materials

The modification must be studied by an expert laboratory which establishes a diagnosis and sends the application to AFNOR Certification. The draft additional study is presented by the expert laboratory to the Technical Board.

The holder designates an expert laboratory which must be qualified by AFNOR Certification for the domain concerned (see qualification procedure in § 2.4.1). The list of expert laboratories is available on request from AFNOR Certification.

5.4.1.2 Modification of one of the associated raw materials

The modification must be documented by the holder and sent directly to AFNOR Certification, which sends the application to the members of the Technical Board for their opinion. A presentation is made by the manufacturer to the Technical Board if they request it.

5.4.1.3 Other modifications concerning the validated method

Any other modification made to the validated method (in the protocol, the scope, etc.) must first be declared to AFNOR Certification.

The modification application is submitted to the Technical Board, which decides on the possibility:

- either of proceeding with the examination of an extension study if the modification is a major one.

  In this case, the extension study must be carried out by an expert laboratory chosen by the holder and qualified by AFNOR Certification for the domain concerned (list of expert laboratories available on request from AFNOR Certification).
- or accept the modification without an additional study, for minor modifications.

5.4.1.4 Specific case of the use of an automatic control system

The following specifications apply:

- If the use of an automatic control system is not a compulsory element of the method, the automatic control system cannot be validated. The approval of the automatic control system is the responsibility of the user: it is a metrology issue.
- If the automatic control system reproduces a validated protocol in full, it is not necessary to extend the usage right.
- If the automatic control system requires a modification to the protocol, the extension applies to this modification of the protocol.

5.4.1.5 Decision

The Technical Board examines the modification applications. After each stage (draft study and results if applicable), it issues a verdict to AFNOR Certification on the follow-up required for the modification application. It decides on the possibility of maintaining the rights to use the NF VALIDATION mark, with or without an additional study. The decision-making methods are presented in § 4.5.

5.4.1.6 Modification of the technical notice

Any revision of the technical notice by the holder must be the subject of a written declaration to AFNOR Certification. The holder must explain the purpose of the modifications, even minor ones, and support the declaration of the new technical notice. AFNOR Certification may request the opinion of the Technical Board based on the modifications made.

Pending the agreement of AFNOR Certification on the revised version of the technical notice, this version may not be distributed by the holder for use under the NF VALIDATION mark.

5.4.2 Transfers of production activities

The holder must inform AFNOR Certification immediately and in writing of any decision involving a total or partial transfer of the production of the products and equipment required for the implementation of the alternative method to another manufacturing location, or a change of supplier.

It is up to AFNOR Certification to examine, after consultation with the Technical Board if required, the methods for maintaining the right to use the NF VALIDATION mark for the validated method.

It is up to AFNOR Certification to judge the need to carry out an additional audit (total or partial) of the sites concerned and if necessary to carry out an additional study, with the corresponding costs being at the holder's expense.

5.5 Transfer of company

The holder must inform AFNOR Certification immediately and in writing of a decision leading to a legal modification to their company, whether that be a change of company name, a merger, a liquidation or an absorption of the holder.

In the event of the holder's merger, liquidation or absorption, any NF VALIDATION mark usage rights that the holder may have cease automatically.

A new application may be filed for each of the methods concerned, the examination of which may be streamlined depending on the changes made.

5.6 Temporary or permanent production shutdown

If the holder definitively stops manufacturing, marketing or performing checks on any validated "alternative method", under the conditions of the present certification rules, they must immediately inform AFNOR Certification and supply an evaluation of the remaining stock of this method, estimating the time that it will take for this to run out.

On the basis of this information, it may be decided to withdraw the right to use the NF VALIDATION mark for the "alternative method", under the decreed conditions, after the opinion of the Technical Board.

The holder must also keep AFNOR Certification informed of any temporary production or marketing shutdown for a validated "alternative method".

Any temporary production or marketing shutdown for a validated "alternative method" may justify, after analysis by AFNOR Certification, a suspension or withdrawal of the right to use the NF VALIDATION mark for the method (see article 10 of the general rules of the NF VALIDATION mark).

The decision to suspend or withdraw the right to use the NF VALIDATION mark is declared by AFNOR Certification.

5.7 Conditions for removing the mark

Any suspension or withdrawal of the right to use the NF VALIDATION mark leads to a prohibition on using the NF VALIDATION mark and making reference to it. Likewise, products which are accidentally nonconforming must have their mark removed.

Consequently, in these cases, the NF VALIDATION mark must no longer be present on the products, their packaging, documentation, advertising or any other manufacturer supports.

Each holder must put into place a procedure for removing marking from the products.

The holder is required to inform user customers, in real time, of any decisions to withdraw, suspend, modify or extend the validation declared by AFNOR Certification for its method.

Part 6 FINANCIAL SYSTEM: TARIFFS

6.1 Purpose

This section defines the methods of payment and the detail of the costs relating to the promotion of the NF VALIDATION mark and the management by AFNOR Certification of the certification procedure, namely the validation, renewal, monitoring and annual fees.

These costs include:

- a registration fee - charged for each company - and the examination of the applications for which the payment is made in one instalment by the applicant at the moment the application is filed (this payment remains due, even in the event that the right to use the NF VALIDATION mark is not granted or the applications are abandoned during the examination),
- the audits and any samples and tests, carried out in the context of the checks defined in § 4.4 and § 5.2,
- an annual tariff-based usage right allocated to the promotion, legal protection and development of the NF VALIDATION mark,
- the annual management corresponding to the general operation of the NF VALIDATION mark

The detail and the modalities of collection of the sums corresponding to these costs are presented below.

The amounts corresponding to these various costs are reviewed annually based on the rate of inflation as a minimum. **They are published at the start of each year in the form of a tariff sheet, available on request from AFNOR Certification.** The amounts are shown **excluding taxes, in euros**.

6.2 Payment for costs

The management costs are invoiced by AFNOR Certification during the 1st semester of the current year, for methods already validated.

For any new validation request, the acceptance costs are invoiced after the application is filed. The annual costs defined in § 6.4.1 and § 6.4.2 are calculated in proportion to time, starting from the date the method is validated.

The costs relating to the tests carried out by the expert laboratory (preliminary and inter-laboratory study) are the responsibility of the applicant. The tariffs applied are those in force in the laboratories concerned. Testing costs are invoiced directly by the laboratory.

Payment deadline: The total tax inclusive amount shown on the invoice must be paid within the period indicated by the "deadline", that is **no later than 30 days** after the invoicing date.

The applicant or the licence holder must pay the due amounts within the prescribed conditions: any failure on their part is effectively a hindrance to AFNOR Certification undertaking their inspection and intervention responsibilities and obligations with respect to these certification rules.

In the event that a first official notice sent by registered mail with acknowledgement of receipt does not bring about payment within one month of all sums owed, AFNOR Certification:

- will impose sanctions against the holder as provided for in chapter 10 of the general rules of the NF VALIDATION mark for all certified products,
- will send the invoices that have not paid by the applicant/licence holder to the legal department.

6.3 Application costs

6.3.1 Validation application

The validation application fees include:

- **Registration of the company**: This fee is charged only for the 1st application by the Company for the right to use the NF VALIDATION mark.
- **Examination of the validation application** (by method proposed).

These amounts remain due to AFNOR Certification, even if the method is not validated.

6.3.2 Admission audit

The audit costs on the manufacturing site include:

- **Costs of the site visit**:
  - 1 day on site + ½ day preparation/report
  - Additional expenses if audit outside European Union: + 1 day
- **Travel/accommodation expenses**.

Audit cancellation:

Any cancellation of an audit whose date was fixed, as agreed upon between AFNOR Certification and the audited company, shall be invoiced on the following basis:

- cancellation between 15 and 8 days before the scheduled date: 50% of the cost of the audit,
- cancellation between 7 and 3 days before the scheduled date: 75% of the cost of the audit,
- cancellation 2 days or less before the scheduled date: 100% of the cost of the audit.

This financial penalty shall be applied in accordance with the reason for cancellation and proof provided.

6.4 Costs after validation

6.4.1 Annual fees

The annual fees consist of the right to use the NF VALIDATION mark and the annual general administrative fees.

6.4.1.1 Annual right to use the NF VALIDATION mark

An annual fee, called **usage right**, allows AFNOR Certification to protect and support the validation activity (defence of the interests of manufacturers and distributors of validated alternative methods, information to users), and to develop and promote the NF VALIDATION mark.

The annual usage right is established for each validated method, as follows:

- **1st validated method**: Full rate.
- **2nd validated method**: 1st decreasing rate.
- **From the 3rd validated method** onwards: 2nd decreasing rate.

The extensions for a validated method are not counted as additional methods.

When the NF VALIDATION mark is granted in the course of the year, the fees for the right of use and annual management fees shall be prorated based on the number of months following the certification decision. These fees shall be forfeited even in case of withdrawal or suspension during the year.

6.4.1.2 Annual management fee

This cost allows AFNOR Certification to ensure the general operation of the activity. It is counted **by validated method.**

When the NF VALIDATION mark is granted in the course of the year, the fees for the right of use and annual management fees shall be prorated based on the number of months following the certification decision. These fees shall be forfeited even in case of withdrawal or suspension during the year.

6.4.2 Monitoring audit

The audit costs on the manufacturing site include:

- **Costs of the site visit**:
  - 1 day on site + ½ day preparation/report
  - Additional expenses if audit outside European Union: + 1 day
- **Travel/accommodation expenses** (Real auditor expenses)
- **Audit administrative management service** (by manufacturing site)

The frequency of the monitoring audits is given in § 5.2.

6.4.3 Examination of the renewal study

The renewal fees are counted by validated method, as follows:

- **1st scenario**: presentation of the project leading to the renewal without additional tests
- **2nd scenario**: preliminary study to be repeated (in part or in full)
- **3rd scenario**: preliminary study and inter-laboratory study to be repeated (in part or in full)

The frequency of the renewal study is given in § 5.3.

6.4.4 Extension and modification applications of the validation

These fees are counted by validated method, as follows:

- **Extension**: with additional study or audit (see below)
- **Modification**: without additional study or audit, leading to the re-edition of the certificate of the validated method

If an additional audit is necessary on the manufacturing site, the costs include:

- **Costs of the site visit**:
  - 1 day on site + ½ day preparation/report
  - Additional expenses if audit outside European Union: + 1 day
- **Travel/accommodation expenses** (real auditor expenses)
- **Audit administrative management cost** (by manufacturing site)

Part 7 CERTIFICATION FILES

7.1 Initial application

The application for the right to use the NF VALIDATION mark must be sent, by post, to AFNOR Certification's legal representative, via the certification application available in appendix 1.

The examination of the application is carried out in accordance with the procedure defined in section 4 of these certification rules.

7.2 Extension or modification application

The application for an extension to the right to use the NF VALIDATION mark or modification declaration must be sent, by post, to AFNOR Certification's legal representative, via the extension application available in appendix 1.

The processing modalities are described in § 5.4 of these certification rules.

The extension applications may only relate to alternative methods already validated, and which have usage rights for the NF VALIDATION mark.

7.3 Renewal application

The usage right for the NF VALIDATION mark is awarded for four years. If they so wish, the holder may request renewal of the certification for the validated alternative method concerned. In this case, they must notify AFNOR Certification in writing with sufficient time to allow validation of the renewal application before the expiry date for the certification.

The renewal modalities are described in § 5.3 of these certification.

APPENDIX: Applications for validation, extension or modification