

Identification No.: **NF148**
Version No.: **10**
Date of approval: **15/06/2012**
Edition date: **29/10/2012**

Certification rules for the mark



Validation of alternative analysis methods

Application to the food industry

APPENDIX Validation, extension or modification applications

Certification Body:
AFNOR Certification
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93571 La Plaine Saint Denis Cedex - France
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<http://www.afnor-validation.com>
<http://www.afnor.org>
certification@afnor.org



This appendix specifies the content of the **certification/extension application** to be presented to AFNOR Certification by the applicant/holder. The application must be drafted in **French** or in **English** and sent to the following address:

AFNOR Certification

11 rue Francis de Pressensé – 93571 La Plaine Saint Denis Cedex – France

It includes the following documents:

- 1 - **General information** about the applicant and the expert laboratory chosen by the applicant/holder of the certification (see standard document A),
- 2 - **Certification application letter** signed by the applicant, accompanied by a joint commitment letter signed by both the applicant and his mandatory if the applicant is outside European Economic Area (EEA) or Switzerland (see standard document B).
- 3 - **Description of the alternative method** which is the subject of the application and the reference method (see standard document D), with detailed identification of the origin and the nature of all of the chemicals and materials which may be needed to implement this alternative method and those which are not supplied by the manufacturer,
- 4 - ⁽¹⁾ **Comparative study draft** drawn up by an Expert Laboratory, according to the applicable validation protocol and its related specific requirements if existing.

Only documents 4 is presented to the Technical Board.

⁽¹⁾ The delivery of the comparative study draft may be postponed. However, this document must be sent to AFNOR Certification within the specified time, generally no later than one month before the presentation date.

In the case of a **modification or extension application**, this must be notified by the holder to AFNOR Certification using the model of extension application letter (standard document C), accompanied by a joint commitment letter signed by both the applicant and his mandatory if the applicant is outside European Economic Area (EEA) or Switzerland. If applicable, documents 1 and/or 4 must be filled in or modified.

The certification/extension applications are examined in accordance with sections 4 and 5 of the applicable certification rules.

STANDARD DOCUMENT A

GENERAL INFORMATION ABOUT THE APPLICANT

1 NAME OF THE ALTERNATIVE METHOD CONCERNED

.....
.....

2 APPLICANT'S CORPORATE NAME (Company responsible for putting the alternative method to be certified on the market)

- Corporate name:
- Address:

- Legal representative's name and occupation ⁽¹⁾:
- Telephone:
- E-mail:
- SIRET no. (French business registration number) ⁽²⁾:
- Intracommunity VAT number ⁽³⁾:

3 MANUFACTURING SITE (to be completed if different from applicant designated above)

- Corporate name:
- Address:

- Legal representative's name and occupation ⁽¹⁾:
- Telephone:
- E-mail:
- SIRET no. (French business registration number) ⁽²⁾:
- Intracommunity VAT number ⁽³⁾:

4 CORPORATE NAME OF THE REPRESENTATIVE COMPANY IN EUROPE (to be completed if the applicant is outside EEA or Switzerland)

- Corporate name:
- Address:

- Legal representative's name and occupation ⁽¹⁾:
- Telephone:
- E-mail:
- SIRET no. (French business registration number) ⁽²⁾:
- Intracommunity VAT number ⁽³⁾:

⁽¹⁾ The legal representative is the individual legally responsible for the company

⁽²⁾ To be entered for French companies

⁽³⁾ Essential for countries in the European Economic Area (EEA)

5 PRINCIPAL RAW MATERIAL(S) AND SUPPLIER(S)

List here all the **principal raw material(s)** as defined in chapter 3.3.5.1 of the certification rules. All **suppliers** of these principal raw material(s) shall also be declared.

Note: This information will remain strictly confidential to AFNOR Certification.

Principal raw material (critical product):	Supplier no. 1 Name: Name of official: Certification ⁽⁴⁾ :	Address: Telephone: E-mail:
Principal raw material (critical product):	Supplier no. 2 Name: Name of official: Certification ⁽⁴⁾ :	Address: Telephone: E-mail:
...

⁽⁴⁾ Specify whether the supplier is ISO 9001 and/or ISO 13485 certified, and attach the corresponding certificates.

6 EXPERT LABORATORY CHOSEN

- Name and address of the Expert laboratory:

- Contact:

- Telephone:

- E-mail:

Note: The list of Expert laboratories approved for carrying out the validation studies for the domain concerned is available on request from AFNOR Certification.

STANDARD DOCUMENT B

Certification application letter to be drafted on applicant's headed letter paper

AFNOR Certification
The legal representative
11 rue Francis de Pressensé
F-93571 La Plaine Saint Denis Cedex
France

SUBJECT: APPLICATION FOR THE RIGHT TO USE THE NF VALIDATION MARK

Dear Sir or Madam,

I am pleased to request for the right of use of the NF VALIDATION mark for the following alternative method:

- Full trade name: _____

- Requested scope (target, products): _____

- In relation to the following reference method(s) ⁽¹⁾: _____

⁽¹⁾ NF/EN/ISO standard(s).

I hereby declare that I know and approve the general rules of the NF VALIDATION mark, the certification rules of the NF VALIDATION mark (NF148 - Application to food industry) and related appendices.

This letter formalizes the contractual relationship (governed by French law and subject to the French courts in case of dispute) and I undertake to:

- complying wholly and unreservedly with the requirements of the said documents, throughout the duration of the right to use the NF VALIDATION mark, as well as the decisions taken or to be taken in application of the requirements by AFNOR Certification when instructed by the Technical Board,
- facilitating the tasks to be undertaken by the auditors mandated by AFNOR Certification in light of the certification rules and its appendices,
- drafting in either English or French all of the documents concerning the products in question and the organisation of their quality assurance, as well as providing an interpreting service during the audits carried out by the auditors mandated by AFNOR Certification (if a language other than French or English were to be used),
- settling the amounts established in the financial framework of the certification rules for the NF VALIDATION mark and making any subsequent payments demanded of me in compliance with these certification rules,
- not using the NF VALIDATION mark before obtaining the right of use.

I certify that the product concerned by this request comply with the regulatory requirements and I undertake not to submit counterfeit products for certification.

I also commit myself to respecting the deadlines decided by AFNOR Certification concerning the organisation of Technical Board meetings, in particular to related documentation before the deadline decided by AFNOR Certification (study draft(s), study results report(s), draft technical notice(s) and any other necessary document).

Furthermore, I take notice that AFNOR Certification will only put on the next meeting agenda the validation files (draft study or study report) for which the complete documents are published before the deadline.

Consequently only completed studies – the results of which are known when drafting the meeting agenda – shall be part of the next meeting agenda. Any study not completed when drafting the agenda will not be presented at the next meeting. Its presentation shall be delayed to another meeting. This procedure aims to guarantee the best organisation for Technical Board meetings.

Yours faithfully,

Date, name and signature of the legal representative of the applicant

If applicable ⁽²⁾

Date, name and signature of the legal representative of the company manufacturing the product

⁽²⁾ If the applicant markets the product and does not manufacture the said product, the certification application is made jointly with the company manufacturing the product (see § 4.2.1 of the certification rules).

**(1) Joint commitment letter to be added if the applicant is outside EEA or Switzerland
(On the applicant's headed letter paper)**

AFNOR Certification
The legal representative
11 rue Francis de Pressensé
F-93571 La Plaine Saint Denis Cedex
France

**SUBJECT: APPLICATION FOR THE RIGHT TO USE THE NF VALIDATION MARK
JOINT COMMITMENT LETTER**

Dear Madam, Sir,

I authorize the following company <*company's full name and address*> represented by <*name of the Legal representative*> acting as <*occupation*> to be my mandatory in the European Economic Area (EEA) or in Switzerland for any question related to the NF VALIDATION mark (NF148), in accordance with the mandate enclosed with this request and for the following alternative method which is the subject of the attached usage rights application: <*name of the alternative method*>.

I undertake to immediately inform AFNOR Certification if changes occur in the aforementioned mandatory.

I thereby commit myself, jointly and severally with the aforementioned company, to complying with the general rules of the NF VALIDATION mark, the certification rules of the NF VALIDATION mark (NF148) and its appendices for the domain concerned, as defined in the attached usage rights application.

Yours faithfully,

***Date, name and signature of the legal representative
of the applicant***

To be preceded by the handwritten text
"Valid for proxy"

***Date, name and signature of the aforementioned
representative in EEA or Switzerland***

To be preceded by the handwritten text
"Valid for acceptance of proxy"

(1) The company asking for the certification must appoint a Company to representing him in Europe or Switzerland and a physical person (see § 4.2.1 of the certification rules).

STANDARD DOCUMENT C

Extension application letter to be drafted on applicant's headed letter paper

AFNOR Certification
The Legal representative
11 rue Francis de Pressensé
93571 La Plaine Saint Denis Cedex
France

SUBJECT: APPLICATION FOR THE EXTENSION OF THE RIGHT TO USE THE NF VALIDATION MARK FOR AN ALTERNATIVE METHOD

Dear Sir or Madam,

As holder of the NF validation mark for the alternative method identified under the following references:

- Full trade name:
- Certificate no.:
- Certified scope (target, products):
- Reference method(s) ⁽¹⁾:
- Manufacturing site (name, address):

⁽¹⁾ NF/EN/ISO standard(s).

I would like to request for an extension of the right to use the NF VALIDATION mark for the following reason(s) (choose among proposal(s) here after and explain change(s)):

Modification of the ALTERNATIVE METHOD:

.....
.....
.....

Extension of the SCOPE of this alternative method for the following area(s):

.....
.....
.....

Modification of the ALTERNATIVE METHOD and extension of the SCOPE:

.....
.....
.....

This modified alternative method replaces the initially certified alternative method:

No Yes

Full trade name of the modified alternative method (if different from the previous one):

.....

I hereby declare that the other characteristics of the alternative method concerned by this request comply with the product already certified NF VALIDATION and manufactured in the same conditions.

This letter formalizes the contractual relationship (governed by French law and subject to the French courts in case of dispute) and I undertake to:

- complying wholly and unreservedly with the requirements of the said documents, throughout the duration of the right to use the NF VALIDATION mark, as well as the decisions taken or to be taken in application of the requirements by AFNOR Certification when instructed by the Technical Board,
- facilitating the tasks to be undertaken by the auditors mandated by AFNOR Certification in light of the certification rules and its appendices,
- drafting in either English or French all of the documents concerning the products in question and the organisation of their quality assurance, as well as providing an interpreting service during the audits carried out by the auditors mandated by AFNOR Certification (if a language other than French or English were to be used),
- settling the amounts established in the financial framework of the certification rules for the NF VALIDATION mark and making any subsequent payments demanded of me in compliance with these certification rules,
- not using the NF VALIDATION mark before obtaining the right of use.

I certify that the product concerned by this request comply with the regulatory requirements and I undertake not to submit counterfeit products for certification.

I also commit myself to respecting the deadlines decided by AFNOR Certification concerning the organisation of Technical Board meetings, in particular to related documentation before the deadline decided by AFNOR Certification (study draft(s), study results report(s), draft technical notice(s) and any other necessary document).

Furthermore, I take notice that AFNOR Certification will only put on the next meeting agenda the validation files (draft study or study report) for which the complete documents are published before the deadline.

Yours Faithfully,

Date, name and signature of the legal representative of the applicant

If applicable ⁽²⁾

Date, name and signature of the legal representative of the company manufacturing the product

⁽²⁾ If the applicant markets the product and does not manufacture the said product, the certification application is made jointly with the company manufacturing the product (see § 4.2.1 of the certification rules).

**(1) Joint commitment letter to be added if the applicant is outside EEA or Switzerland
(On the applicant's headed letter paper)**

AFNOR Certification
The legal representative
11 rue Francis de Pressensé
F-93571 La Plaine

**SUBJECT: APPLICATION TO EXTEND THE RIGHT TO USE THE NF VALIDATION MARK
JOINT COMMITMENT LETTER**

Dear Madam, Sir,

I authorize the following company <*company's full name and address*> represented by <*name of the Legal representative*> acting as <*occupation*> to be my mandatory in the European Economic Area (EEA) or in Switzerland for any question related to the NF VALIDATION mark (NF148), in accordance with the mandate enclosed with this request, for the following alternative method which is the subject of the attached usage rights extension application: <*name of the alternative method*> with certificate reference no. <*reference of the NF VALIDATION certificate*>.

I undertake to immediately inform AFNOR Certification if changes occur in the aforementioned mandatory.

I thereby commit myself, jointly and severally with the aforementioned company, to complying with the general rules of the NF VALIDATION mark, the certification rules of the NF VALIDATION mark and its appendices for the domain concerned, as defined in the attached application for extension of the usage rights.

Yours faithfully,

***Date, name and signature of the legal representative
of the applicant***

To be preceded by the handwritten text
"Valid for proxy"

***Date, name and signature of the aforementioned
representative in EEA or Switzerland***

To be preceded by the handwritten text
"Valid for acceptance of proxy"

(1) The company asking for the certification must appoint a Company to representing him in Europe or Switzerland and a physical person (see § 4.2.1 of the certification rules).

STANDARD DOCUMENT D

This document must include:

1. A descriptive section which must present:
 - the principle behind the alternative method, a diagram or a photo of the method, in-depth instructions of use for the method (operating manual, technical notice, etc.), any restrictions on the use of the method and the method's history (first manufacturing and first sale dates).
 - the scope requested for validation,
 - the reference method's description or number, if a standard is concerned,
 - items indicating the originality and interest of the alternative method (e.g. a list of users) and approximate costs.
2. A bibliographical section which must include (if applicable)
 - a list of publications,
 - a summary of these publications which could contribute to the comparative study as outlined in the applicable validation protocol and its related specific requirements.
3. In the case of the alternative method is validated by AOAC, the following minimum requirements are needed:
 - the AOAC validation reference, specifying the programme followed (AOAC Official methods, AOAC Performance Tested Methods, etc.)
 - an AOAC certificate stating that the validation is still valid and has not been annulled, expired or modified since the validation date,
 - a description of the reference method used for the AOAC validation.
 - the list of products tested for the AOAC validation.