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Certification rules for the mark

Validation of analysis methods

Application to water analysis

APPENDIX Validation, extension or modification applications

Certification Body:
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cofrac
CERTIFICATION DE PRODUITS INDUSTRIELS
ACCRÉDITATION N° 5-0030 PORTÉE DISPONIBLE SUR WWW.COFRAC.FR

This appendix specifies the content of the **certification application** to be presented to AFNOR Certification by the applicant. 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 chapters:

1 - **general information** about the applicant and the expert laboratory chosen by the applicant (please see standard document A),

2 - a **letter of commitment** from the applicant which is also signed by his **legal representative in the European Economic Area (EEA)**, if the applicant is outside of the EEA (please see standard document B),

3 - detailed identification of the origin and the nature of all of the chemicals and materials which may be needed to implement this method and which are not supplied by the manufacturer,

4 - * a **description of the method** which is the subject of the application and the reference method (please see standard document D),

5 - ** a **preliminary draft study** drawn up according to the guidelines in the document "Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory".

Only documents 3, 4 and 5 are presented to the Technical Board.

* The items in standard document D can also be included in the preliminary draft study specified in point 5.

** The delivery of the preliminary draft study may be postponed. However, this document must be sent to AFNOR Certification at least one month before the presentation date.

In the case of a **modification or extension application**, this must be drafted by the holder according to the model letter in standard document C, accompanied by a commitment by his legal representative in the European Economic Area (EEA) if the holder is from outside the EEA. The application must be drafted in **French** or in **English** and sent to the address mentioned above. If applicable, documents 1, 3, 4 and/or 5 must be filled in or modified.

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

STANDARD DOCUMENT A

GENERAL INFORMATION ABOUT THE APPLICANT

1 NAME OF THE COMMERCIAL ANALYSIS METHOD CONCERNED

……

……

2 APPLICANT'S CORPORATE NAME *(Company responsible for putting the product to be validated on the market)*

- Corporate name:
- Address:

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

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

- Corporate name:
- Address:

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

4 CORPORATE NAME OF THE REPRESENTATIVE IN EUROPE *(to be completed if the applicant is based outside of the EEA)*

- Corporate name:
- Address:

- Legal representative's name and capacity [(1)]:
- Telephone: - Fax:
- 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 SUPPLIER(S)

All of the **suppliers** must be listed, as must **the products that they produce**. The principal raw materials are specified in § 3.3.5.1 of the certification rules.

NB: This information will remain strictly confidential at AFNOR Certification.

Supplier no. 1 Name: Name of official: Certification [(4)]:	Address: Telephone: Fax: E-mail:	**Product manufactured:**
Supplier no. 2 Name: Name of official: Certification [(4)]:	Address: Telephone: Fax: E-mail:	**Product manufactured:**
...	...	...

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

6 NAME OF THE EXPERT LABORATORY CHOSEN BY THE APPLICANT

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

- Name and address of the expert laboratory:

- Contact:
- Telephone:
- Fax:
- E-mail:

STANDARD DOCUMENT B

Validation application to be drafted on applicant's <u>headed letter paper</u>
(Include the letter on page 6/10 if the applicant is outside of the EEA)

The Managing Director
AFNOR Certification
11 rue Francis de Pressensé
93571 La Plaine Saint Denis Cedex
France

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

INCLUDED: Technical dossier

Dear Madam,

May I please ask you to process this validation application dossier for the analysis method hereafter known as:

Name of the analysis method: .....

Area of application requested (Scope): .....……..

[If applicable, in relation to the following reference method: .....]

I hereby declare that I am familiar with the general rules of the NF VALIDATION mark, the certification rules of the NF VALIDATION mark (application to water anaysis) and its appendices.

I commit myself to:

- complying 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,

- informing AFNOR Certification of any significant change to the organisation of manufacturing and monitoring processes and, in general, the quality management of the validated method,

- 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 management 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),

- complying wholly and unreservedly with the decisions taken in accordance with the general rules of the NF VALIDATION mark, the certification rules of the NF VALIDATION mark and its appendices,

- 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.

I also commit myself to respecting the deadlines decided by AFNOR Certification (ACE) concerning the organisation of Technical Board meetings as follows:

1. The expert laboratory shall send the draft preliminary study document to ACE, **before the deadline decided by ACE** (in general 3 to 4 weeks before the meeting date)

2. The expert laboratory shall send the preliminary study report or the inter-laboratory study report (and any additions) or any other necessary document (such as draft technical notices, etc.) to ACE, **before the deadline decided by ACE** (in general 3 to 4 weeks before the meeting date)

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,

	(If applicable [1]:)
On (date)….in (place)…	On (date)….in (place)…
Company's stamp (if existing) Name and signature of the legal representative of the applicant	Company's stamp (if existing) Name and signature of the legal representative of the manufacturer

[1] If the applicant markets the product and is not the manufacturer of said product, the certification application is made jointly with the manufacturer (see § 4.2.1 of the certification rules).

Letter to be included if the applicant is outside of the EEA
(on the applicant's headed letter paper)

The Managing Director
AFNOR Certification
11 rue Francis de Pressensé
93571 La Plaine Saint Denis Cedex
France

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

INCLUDED: Technical dossier

Dear Madam,

The analysis method…….which is the subject of the attached application for usage rights dated…….. will be sold in the European Economic Area (EEA) through [(1)]:

Company's full name and address:

……..

……..

……..

I authorise Mr or Mrs …….. (named in person) to act on my behalf when in contact with AFNOR Certification for all issues regarding the validated methods which are sold throughout the EEA.

I agree to immediately report any change of the aforementioned representative to AFNOR Certification.

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 usage rights application.

Yours faithfully,

On (date) … in (place) …

Company's stamp (if existing)
Name and signature of the legal representative of the applicant

To be preceded by the handwritten text
"Fit for Representation"

On (date) … in (place) …

Company's stamp (if existing)
Name and signature of the aforementioned representative

To be preceded by the handwritten text
"*Fit for acceptance of the representation*"

[(1)] The manufacturer must appoint a physical person who represents him in the EEA (see § 4.2.1 of the certification rules).

STANDARD DOCUMENT C

Extension application to be drafted on applicant's <u>headed letter paper</u>
(Include the letter on page 9/10 if the applicant is outside of the EEA)

The Managing Director
AFNOR Certification
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 A VALIDATED ANALYSIS METHOD

INCLUDED: Technical dossier

Dear Madam,

On the ……. (validation date), the right to use the NF VALIDATION mark was granted for the following method:

- Full trade name:……..
- Certificate no.:……
- Scope:……..
- [If applicable, reference method:……]
- Manufactured in the plant .....……, located at .....…… (plant's complete address), which is under my authority.

Choose one of the following options (1), (2) or (3):

(1) I would like to apply for an extension to the right to use the NF VALIDATION mark for the following reason:

<u>Modification of the validated analysis method</u>

- Listing of the modifications made to the validated method:

  . .....

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

  .....
- Manufactured in the plant .....……, located at .....……(plant's complete address), which is under my authority.

I hereby declare that no other modification has been made to this alternative method.

This new method replaces ❒
does not replace ❒
the initially validated method.

(2) I would like to apply for an extension to the right to use the NF VALIDATION mark for the following reason:

<u>Extension of the scope of this validated analysis method for the following area(s):</u>

. .....

. .....

. .....

I hereby declare that no other modification has been made to this alternative method.

(3) I would like to apply for an extension to the right to use the NF VALIDATION mark for the following reason:

<u>Modification of the validated analysis method AND extension of the scope:</u>

- Listing of the modifications made to the validated method:

  . .....

  . .....

  The scope is extended to:

  . .....

  . .....

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

  .....

- Manufactured in the plant .....……, located at .....……(plant's complete address), which is under my authority.

I hereby declare that no other modification has been made to this alternative method.

This new method replaces ❒

does not replace ❒

the initially validated method.

Yours faithfully,

	(If applicable [1]:)
On (date)….in (place)…	On (date)….in (place)…
Company's stamp (if existing) Name and signature of the legal representative of the applicant	Company's stamp (if existing) Name and signature of the legal representative of the manufacturer

[1] If the applicant markets the product and is not the manufacturer of said product, the certification application is made jointly with the manufacturer (see § 4.2.1 of the certification rules).

Letter to be included if the applicant is outside of the EEA
(On the applicant's headed letter paper)

The Managing Director
AFNOR Certification
11 rue Francis de Pressensé
93571 La Plaine Saint Denis Cedex
France

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

INCLUDED: Technical dossier

Dear Madam,

The analysis method …….with certificate reference no. ……..... subject of the attached application to extend the usage rights dated …….. will be sold in the European Economic Area (EEA) through [(1)]:

Company's full name and address:

……..

……..

……..

I authorise Mr or Mrs …….. (named in person) to act on my behalf when in contact with AFNOR Certification for all issues regarding the validated methods which are sold throughout the EEA.

I agree to immediately report any change of the aforementioned representative to AFNOR Certification.

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,

On (date) … in (place) …

Company's stamp (if existing)
Name and signature of the legal representative of the applicant

To be preceded by the handwritten text
"Fit for Representation"

On (date) … in (place) …

Company's stamp (if existing)
Name and signature of the aforementioned representative in the EEA.

To be preceded by the handwritten text
"*Fit for acceptance of the representation*"

[(1)] The manufacturer must appoint a physical person who represents him in the EEA (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 commercial analysis 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,

   - [If applicable, the reference method's description or number, if a standard is concerned,]

   - items indicating the originality and interest of the commercial analysis 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 preliminary study as outlined in the corresponding validation protocol (see § 3.2).

3. In the case of a validation granted by another body (for example: AOAC, etc.), the following minimum requirements are needed:

   - the AOAC validation reference, specifying the programme followed if applicable (example for AOAC: Official methods, AOAC Performance Tested Methods, etc.),

   - a certificate form this body 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 validation (if applicable),

   - the list of products tested during the validation study.