LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

Organisme certificateur mandaté par
AFNOR Certification

CERTIFICATION RULES

NF MARK-MICROBIOLOGICAL SAFETY STATIONS

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Author ref. AC/EG - LNE

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Approved by AFNOR Certification:
December 26th 2023

First applied: July 1983

Reference document:
GENERAL RULES OF THE NF MARK
Approved by the President of AFNOR on 23 April 2012

National Metrology and Testing Laboratory • Public Industrial and Commercial Institution
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Founded in 1938, the NF mark is a collective certification mark to certify the compliance of products with the national, European and international standards documents that relate to them, and which may be supplemented by additional specifications, in conditions defined by the certification reference standards. It is granted by AFNOR Certification and its network of partner bodies, making up the NF network.

The NF mark is a voluntary product certification mark; it satisfies the requirements of the Code de la Consommation, notably by associating the interested parties with the validation of the certification reference standards, by defining marking rules for certified products and by clear and transparent communication on the main characteristics certified.

The right to use the NF mark is granted on the basis of compliance with one (or more) standard(s) and more generally to the whole certification reference standard*,* for a product coming from an applicant and a designated design and/or manufacturing and/or marketing process. Attribution of the right to use cannot in any circumstances substitute LNE's responsibility for that which is legally incumbent upon the company holding the right to use the NF mark.

The NF mark checks the characteristics covering the safety of persons and goods, the suitability for use and the durability of products, as well as any additional characteristics enabling products to be distinguished in the market.

In accordance with the General Rules of the NF mark, AFNOR Certification entrusts the management of mark NF095 to LNE, the mandated certifying body.

LNE is responsible to AFNOR Certification for operations which are entrusted to it and are covered by a contract with AFNOR Certification.

Reminder:
It is specified that all products or services must satisfy the regulations, independently of any certification application, concerning for example forgery, compliance and safety requirements, etc.

CERTIFICATION RULES

Who should you contact?
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The documents applicable in this certification are:

- the general rules of the NF mark laying down the general organisation and conditions of use of the mark,
- these certification rules which define, in part 2, the technical characteristics to be respected.

These certification rules were submitted for the approval of AFNOR Certification for acceptance in the NF certification system. They have been approved by the Legal Representative of AFNOR Certification.

They cancel and replace all previous versions.

Hence the certification rules can be revised, in part or in whole, by LNE after consultation with the interested parties.

UPDATING

Certification rules	Reason for update	Revision	Date
Part 1: **Scope of Standard**	- Addition of the definitions of “model” and “model family”	Rev. 6	December 2023
Part 2: **Quality requirements to be observed by the manufacturer**	- Updating of the regulatory texts	Rev. 6	December 2023
Part 3: **Obtaining certification**	/	Rev. 6	December 2023
Part 4: **Surveillance process of certified products – Modifications and developments**	- Clarifications regarding the follow-up tests	Rev. 6	December 2023
Part 5: **Participating organisations**	- Clarifications regarding the participating organisations	Rev. 6	December 2023
Part 6: **Applicable fees – Invoicing terms**	/	Rev. 6	December 2023

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CERTIFICATION RULES

NF MARK - SAFETY ITEMS
SAFETY STATIONS

PART 1

SCOPE – NF MARKING

CONTENTS

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1.1. SCOPE

The products concerned by the NF certification rules are as follow:

Type II microbiological safety items

The essential certified properties within the framework of the NF mark-Microbiological Safety Items are as follows:

- Safety requirements
- Flow velocities (down-flowing air and incoming air)
- Sound level
- Staff protection
- Protection against cross-contamination
- Alarms
- Filter integrity
- Product protection

It is the responsibility of the applicant/holder to ensure that the regulations applicable to its product are adhered to (e.g. CE marking)

The applicant/holder is solely responsible for the compliance of its products; LNE inspections cannot replace the responsibilities of the applicant/holder.

1.2. DEFINITIONS

Applicant/holder:
Artificial Person who manages and/or is responsible for compliance with all of the requirements defined in these certification rules of the NF mark.
These requirements cover at least the following stages: design, manufacture, assembly, quality control, marking, packaging and putting on the market, and specify the critical points at each stage.
If the applicant/holder is not established in the European Community they should appoint an authorised agent.

Agent:
Artificial or Natural Person established in the European Economic Area (E.E.A.) who acts as representative of the applicant/holder outside the E.E.A. and has a written mandate from the latter meaning that he can act in its name in the NF mark certification process according to the provisions of the certification rules.

The authorised agent may also be the distributor, or the importer of the certified products, in which case their different functions are clearly identified.

Distributor:
Artificial Person distributing the applicant's/holder's or its authorised agent's products who does not act upon the product or its packaging. If the distributor puts NF products on the market independently of the authorised agent, it takes responsibility for verifying conformity with the NF certification rules and the applicable standards.

The types of distributor may be as follows:

- distributors who distribute the product under the trademark of the holder. In this case, no action is to be taken with regard to the NF Mark.

- distributors who distribute the product with a change in trademark. The applicant/holder and the distributor must formulate a maintenance application to maintain the right to use.

If the distributor does not want to make an explicit reference to the manufacturing site, a certification application must be made by the distributor. In this case, the production plant is not mentioned on the certificate. Depending on the operations performed by the applicant/holder or distributor, the audited sites and the audit period within the framework of the initial certification or surveillance are defined case by case.

Model:
A type II MSC model is defined (excluding any option) by:
- its dimensions
- its HEPA filters
- one or several fans
- its control system
- its alarms

Models family:
Several models with the same specified characteristics except the dimensions define a models family.

Batch:
A batch is a quantity of products with identical characteristics, i.e. that meet the requirements for a single product definition dossier, of uniform components, that are quality inspected by the manufacturer via its own quality system.

1.3. NF MARKING

The NF mark is represented by the NF logo, which is shown below:

The standards for marking the products, packaging and technical and commercial documents are defined in section 2.
The graphics charter for the NF mark are available on request from LNE.

The purpose of the marking rules is to guide the holder in how to meet the regulations and the requirements of the NF certification. The general rules of the NF mark specify the conditions of use, of validity and the penalties in the event of abusive use of the NF mark.

Without prejudice of the sanctions laid down in the General Rules of the NF mark, any incorrect announcement of the certified features and any fraudulent use of the NF logo expose the holder to lawsuits for fraud and/or misleading advertising.

1.4. CERTIFIED PRODUCTS

The list of certified products is available using the certificate search engine on the www.lne.fr website, under the section entitled "Certification", "Certificates issued by LNE", "Certificate search engine".

Upon request, LNE can provide information regarding the validity of a given certificate.

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CERTIFICATION RULES

NF MARK - SAFETY ITEMS
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PART 2

REQUIREMENTS TO BE MET BY THE APPLICANT/HOLDER

CONTENTS

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2.1 PRODUCT REQUIREMENTS

2.1.1 REFERENCE STANDARDS

- **NF EN 61010-1/A1** (February 2019): “Applicable safety rules for electrical measuring, regulation and laboratory equipment-Part 1: General requirements”.

- **NF EN 12469** ” (July 2000): “Biotechnology- Performance criteria for microbiological safety control stations

- **NF EN 61326-1** (May 2013): “Electrical measuring, control and laboratory equipment: Requirements relating to EMC”.

2.1.2 ADDITIONAL STANDARDS

- **NF ISO 3966** (August 2021): "Measurement of the flow of fluids in closed pipes - Exploration method for the speed field for regular leaks using double Pitot tubes".

- **NF EN ISO 14644-1** (February 2016): “Clean rooms and associated controlled environments. Part 1: Classification of the air particle cleanliness test”

- **NF EN 1822-1** (April 2019): “Very high efficiency air filters and very low penetration air filters (HEPA and ULPA) – Part 1: Classification, performance tests and marking.”

2.1.3 REGULATORY TEXTS

- Order no. 94-352 dated 4 May 1994 on the protection of workers against risks resulting from exposure to biological agents and amending the labour code (OJ dated 6 May 1994, p.6620-6623).

- Order dated 18 July 1994 determining the list of pathogenic biological agents (OJ dated 30 July 1994, p. 11078-11081), as amended by the order dated 17 April 1997 (OJ dated 26 April 1997, p.6361-6362) and the order dated 30 June 1998 (OJ dated 22 July 1998, p.11207-11208).

- The Order dated 16 July 2007 establishing the technical prevention - and in particular containment - measures to be implemented in laboratories used for research, teaching, analysis, pathological anatomy and cytology, autopsy rooms and industrial and agricultural establishments where workers are likely to be exposed to pathogenic biological agents.

2.1.4 OTHER REFERENCE TEXTS

Manual of the High Committee on Biotechnologies for the contained use of GMOs (version dated 30 November 2014)

2.1.5 ADDITIONAL SPECIFICATIONS

The conditions that follow supplement or specify in more detail the properties and specifications covered by the reference standards. The contents of the informative appendices to standards apply as specifications.

They apply to type II microbiological safety control stations, to a basic model excluding forbidden options with certification or continued certification (see below). We again refer you to the paragraphs corresponding to the standard as regards the specifications.

The permitted options that have certification or for which certification is continued are as follows:
- taps and fittings (gas, vacuum)
- electrical sockets
- gas supply points
- smartports

The forbidden options with certification or continued certification are as follows:
- the armrests covering the entire width of the PSM
- additional or supplementary UV banisters without secure connection
- active coal
- scales

2.1.5.1 Classification of microbiological safety control stations in accordance with the specified conditions for use

A type II microbiological safety control station is intended for the handling of dangerous or potentially dangerous biological agents (risk classes are defined in the order dated 18 July 1994), as well as of any preparations likely to contain them, except for corrosive, toxic, radioactive, carcinogenic, mutagenic and toxic to reproduction substances (CMRs). Their presence is made compulsory from containment level 2 by:

- the order dated 16 July 2007,
- the Biotechnologies High Commission (HCB) manual for the contained use of Genetically Modified Organisms (GMO) of November 2014.

2.1.5.2 Properties

2.1.5.2.1 Usable dimensions for safe operations under PSM

With a view to avoiding the same work being done by 2 different people on a single PSM, a user warning is posted on all devices along with illustrated instructions for the user of the device (see part 2 § 2.3. of the certification rules).
The dimensions provider are those for the volume of work (usable dimensions for safe operations under PSM) and are indicated on the front of the PSM.

2.1.5.2.2 Recommendations for materials – design and production (see informative Appendix A of the NF EN 12469 standard)

Materials, general information:

A microbiological safety control station is made up of a chamber for which the air duct cannot be detached from the control station, the aim of which is to preserve the station's integrity, whatever the intervention.

The microbiological safety control station materials likely to be in contact with micro-organisms are uniformly resistant to corrosion, non-flammable, non-adsorbent and UV resistant.

The external casing is made of a non-porous and leachable material and does not give off toxic vapours in case of fire (see NF X 70-100 de 2006 parts 1 and 2).

The control construction materials that are also required for proper functioning cannot be damaged by any decontamination system.

The materials and products used to produce the seals must be able to provide resistance over time to cleaning and disinfecting products (including UV) and under normal usage conditions for the microbiological safety control station.

Tipping stability
(see § 7.4 of standard NF EN 61010-1.)

Height of openings, window panels, screen:
The opening height of the window above the work surface must be fixed and not adjustable under normal operating conditions:

- A specific alarm system must be activated upon detection of any movement (raising or lowering of the window panel compared to the fixed height defined for the reference forming the object of the application for certification.
- The alarm must trigger immediately and as described in part 2.1.5.2.6 of these rules, and must not be affected by a disconnection (see § 7.2 of the NF EN 12469 :2000 standard).

In addition, the window height range must be between 160 and 250 mm.

If the station has a guillotine screen, it must be built in such a way that it avoids the risk of falling and putting the operator in danger in the event of a suspension system failure. In all cases, the screen must be able to be manoeuvred in complete safety to allow the installation of the equipment required for handling before work is started.

Lighting:
The lighting source must be isolated from the volume of work and must be installed outdoors.

<u>Lighting value specification:</u>

Measurements are performed at 7 cm above the work surface in accordance with the mapping of air flow velocities (see mapped diagram below) to ensure that lighting is higher than or equal to the threshold value of 750 lux at each of the measurement points.
A check is carried out to ensure that the values found are not affected by the presence of ambient lighting to an extent greater than 10%.
Lighting is measured using a light meter that complies with standard NF C 42-710 (class C).

Sound level:

When the microbiological safety control station is in use, the weighted sound pressure level must be lower than or equal to 64 dB(A).

This level is measured under the conditions specified by standard NF EN ISO 11202 (December 2010), in nominal operating conditions at the centre of the PSM width, at 0.30 m from the front and at a height of 0.38 m above the work surface.

Temperature:

After 4 hours of continuous operation, the station interior temperature - measured using the volume of work - must not be more than 8°C above the ambient temperature in the laboratory.

Leak tightness:

The PSM envelope, in which the contaminated air is subjected to positive pressure and can escape directly to the outside, must undergo a leak tightness test at a pressure of 500 Pa.

2.1.5.2.3 Filters (see §7.5 of standard NF EN 12469 :2000)

The replacement of any filter elements must take place without specialist tools and without access being in any way restricted for qualified persons.
The filters must meet the requirements of standard NF EN13091 and class H14 or higher of NF EN 1822-1 of April 2019.

2.1.5.2.4 Ventilators

The(s) ventilator(s) provide a continuous automatically regulated blow and extraction air flow, depending on the degree of clogging of the filters. It is not permitted to use a clock or bearing system for this purpose. They are the subject of a technical file which is part of the manufacturer's file.

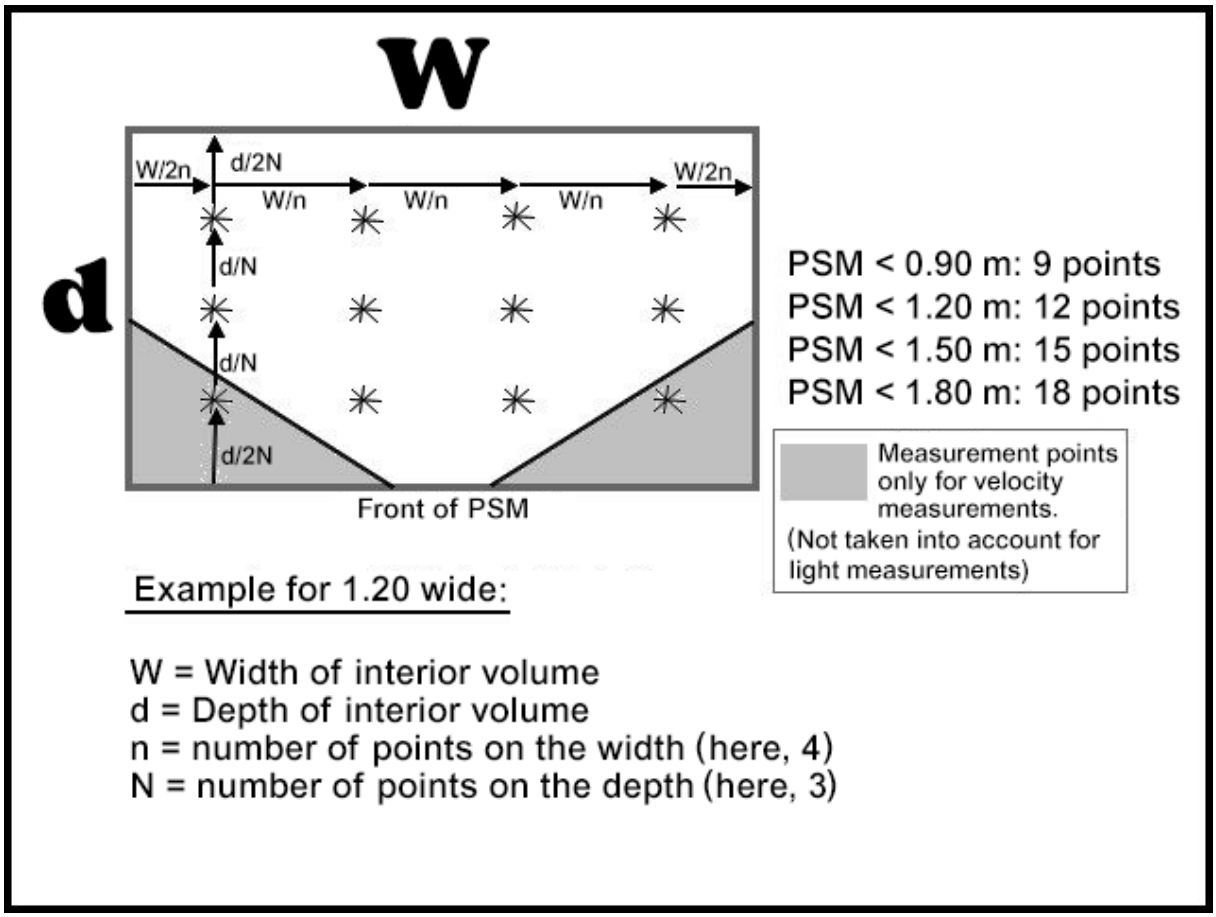
2.1.5.2.5 Air flow speeds (Appendix H of standard NF EN 12469 :2000)

Incoming air:
The air flow speed for incoming air must be above or equal to 0.4 m/s. It can be ascertained using the method described §2.1.6.

Down-flowing air:
The nominal average down-flowing air speed is set by the manufacturer with a tolerance of ± 10%. The individual velocity values are measured according to the mapping (see diagram 1 below), at 100 mm above the bottom of the protective window pane; they must not be further than 20% from the average value.

DIAGRAM 1

ASCERTAINING OF THE POSITION AND NUMBER OF MEASUREMENT POINTS FOR AIR FLOW SPEED MEASUREMENTS



2.1.5.2.6 Alarms

Alarms must trigger:
- where the protective screen is wrongly positioned (immediate response)
- where there is disruption to the incoming air flow beyond the limits allowing the PSM to perform its protective functions (response time below 15 seconds)
- in case of disruption to the down-flowing air flow beyond the limits allowing the PSM to perform its protective functions (response time below 60 seconds).

Under no circumstances must the operator be able to deactivate the alarms during operation and if the system breaks down.

2.1.5.2.7 Cleaning capacity (see § 6.3 of standard NF EN 12469 :2000)

The PSM volume of work is the interior volume limited by the work surface and the side walls up to a height that allows avoidance of accidental contamination of the return filter during the test. Checking of cleaning capacity also covers the retention zone below the work surface.
Any areas that cannot be cleaned in full (perforations, reinforcements, guillotine window guides etc.) must be accessible (if possible, use round-head screws).
The ability to clean other zones is checked using the following method:

Test protocol:

a) Pollution simulation:
Reference liquid: arginine suspension in water at 500 mg/l

The contents of a 50ml beaker of the reference liquid are sprayed onto the work surface and the adjacent vertical surfaces, with the container held approximately 3 to 5 cm from the surfaces to be contaminated.

b) Cleaning:
Immediately after the previous operation, cleaning of the contaminated parts is started in accordance with the manufacturer's instructions.

c) Visual inspection:
A visual inspection is carried out with the naked eye of the zones cleaned and exposed to white natural or artificial light.
A check will have been carried out prior to the pollution simulation to check the initial cleanliness of the work zone.

d) Search for residual pollutants using the ninhydrin method in accordance with standard NF EN 12296(1998):
The surfaces subjected to testing are swab sampled using a moistened cotton swab. A search for amino acids is then carried out directly on the cotton swab, by placing a few drops of ninhydrin reagent and subjecting it to a temperature of 110°C for 30 minutes. The presence of residual amino acids is revealed by the formation of a dark violet colouring on the surface of the cotton swab.

Reagent preparation: via addition of 0.3 g of ninhydrin at 100 ml of n-butanol and 3 ml of ice cold acetic acid.
The limit value for the arginine method is around 1 mg/m^2
The control method must not demonstrate any residual pollution.

2.1.5.2.8 Sterilisation capacity (see § 5.3 and 6.4 of standard NF EN 12469 :2000)

Taking into account the performance class specified by standard NF EN 12469 for type II PSMs, only the disinfection capacity is required.

It is checked based on a case-by-case inspection of the disinfecting method via fumigation (with formaldehyde or another disinfectant applied by fumigation), or another approved method, described by the manufacturer, and of the equipment implemented to apply it.

This examination in particular includes a check of the process aptitude for risk-free implementation for the operator and to allow the contacting and effective retention of the disinfectant during the stipulated process. In accordance with § 7.1 of standard NFEN 12469 :2000, the option of air-and leak- tight sealing of all PSM openings is in particular a point checked on site using a detection device adapted to the product used to check the absence of leaks (for example, using a formaldehyde detection tube (of Draeger type) during fumigation).

NB: checks do not include the quantification of biological activity. Indeed, a PSM's capacity for disinfection using formaldehyde or another substance with comparable disinfectant effect is proven if the disinfectant remains inside the station.

2.1.5.2.9 Position of the limit of the protective barrier

The limit of the protective barrier for the work surface is determined according to the method described in **§ 2.1.6**.

It must be inside the station between the zone of the work surface usable for secure operations under PSM and the protective window pane. The position of this limit is checked 1 cm above the work surface, on the left, on the right and in the centre.

In addition, the device marking in accordance with §8 of standard NF EN 12469 : 2000 includes an indication of the work zone usable for secure operations under PSM indicated on the front of the PSM.

2.1.6 TEST METHODS

2.1.6.1 Incoming air flow measurement (see standard NF X 10-112)

The new air flow introduced into type II PSMs corresponds to the extracted air flow. This makes it possible to calculate the incoming air flow velocity based on the dimensions of the device opening zone.

Extracted air flow measurement must be carried out in accordance with standard NF X 10-112.

Extracted air at a type II PSM outlet is most frequently evacuated into the open air via a high efficiency filter to protect the environment.

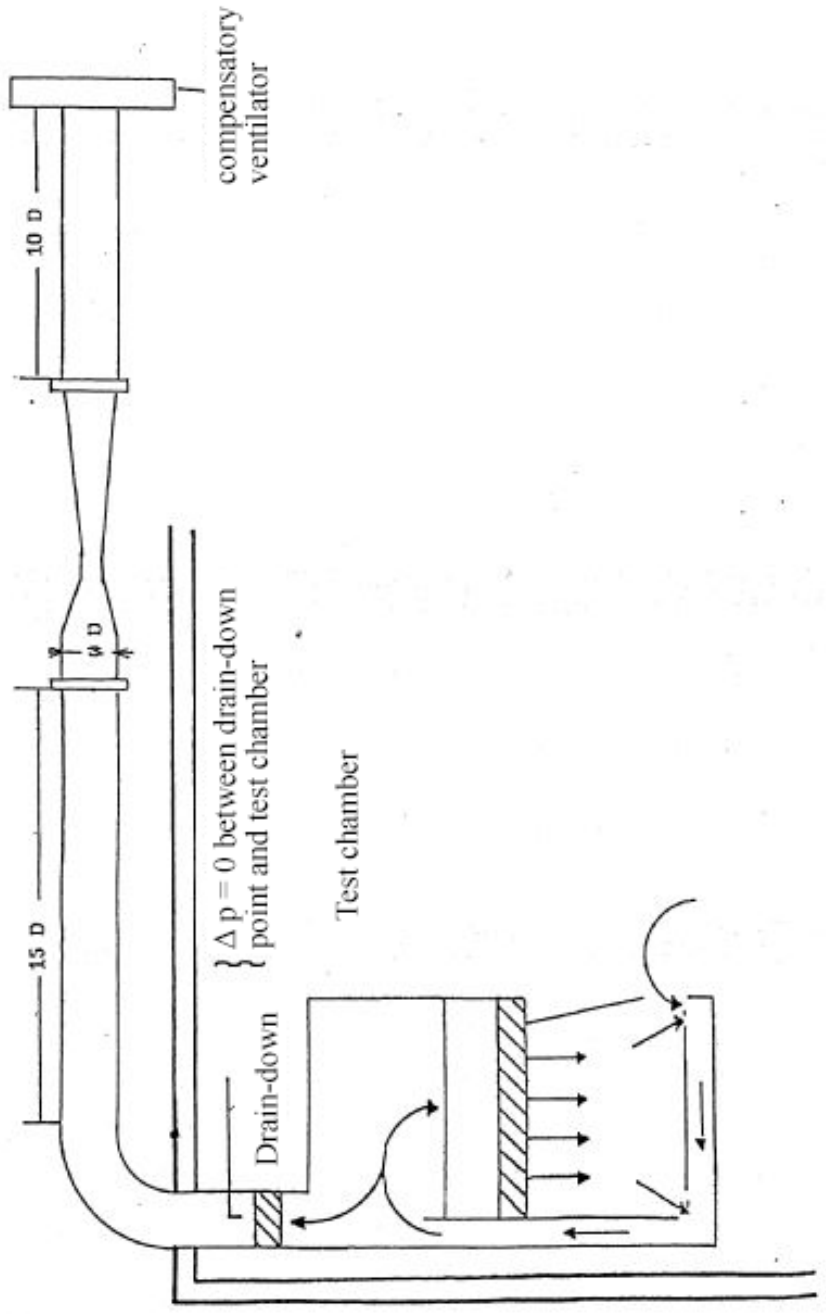
The method recommended in the standard means the filter outlet section must be connected to a ventilation duct.

The ventilation duct and adaptation parts (convergent - divergent) generate an additional loss of load which the PSM extraction motor is more or less able to compensate. This loss of load will be compensated using a compensation ventilator placed downstream of a circuit including a tee connection from the PSM to a piping circuit of sufficient length to perform the flow measurement at regular flow (see diagram 2 below).

The measurement of air flow extracted from the PSM is carried out for zero differential pressure loss between the test chamber and a point (see diagram 2) located as close as possible to the PSM outlet filter, by equipping the compensation motor with flow regulation and a standardised flow measurement system.

DIAGRAM 2

MEASUREMENT OF THE EXTRACTION FLOW OF PSMS



2.1.6.2 Measurement of the position of the limit of the protective barrier

In type II PSMs, the protective barrier is linked to the inherent design of the station and to flow distribution.
Tests carried out in the laboratory under specific conditions have shown that the position of this protective barrier could be defined in relation to the protective work surface (as the position of the limit of the protective barrier can be moved when the flow ratio is changed). These measurements are carried out in a laboratory in an experiment chamber with dust control.

2.1.6.2.1 Operating procedure

The PSM is activated 30 minutes before the test in a non-air conditioned room in order to achieve ambient particle pollution.

a) Probe carrier positions (3 positions)
The horizontal arm supporting the sampling probe will be located 1 cm above the work surface, in the following 3 positions: on the vertical plane in the centre and in those positions located 10 cm from the station side walls.

b) Position of the sampling probe
For each probe carrier position, the sampling probe will be positioned 20 cm inside the chamber and will be brought forward cm by cm until it reaches a position up to 5 cm from the front window on the outside of the PSM.

c) Performing the tests
Activate the microbiological safety control station 30 minutes before the tests and once air flow stabilisation has been achieved, place the sampling probe in position as defined above.

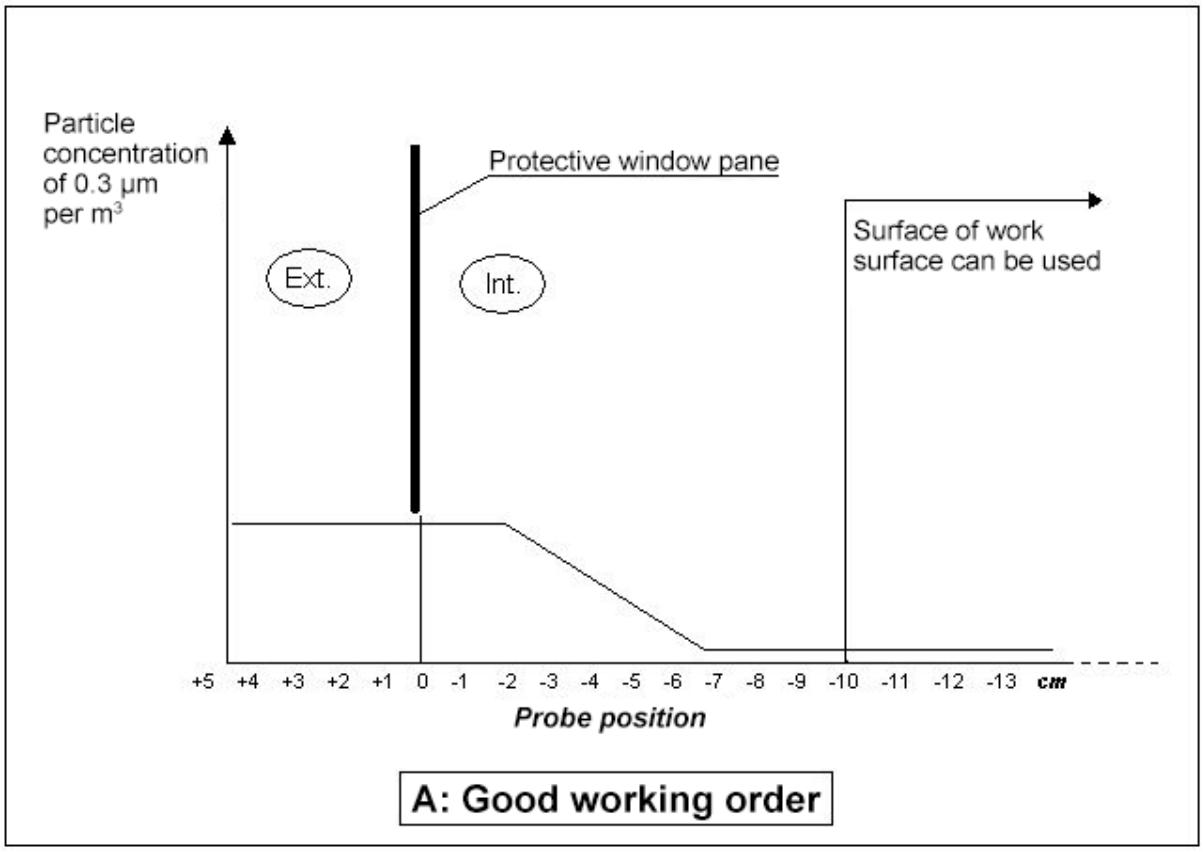
Start up the optical particle counter and perform a blank test in the room to determine ambient dust. Once this test is complete, the sampling probe will be moved from the “clean” zone (inside the PSM) to the “dirty” zone (outside the PSM) for every cm on a horizontal axis. Note the concentration of particles of diameter 0.3 µm.
Double testing per position.

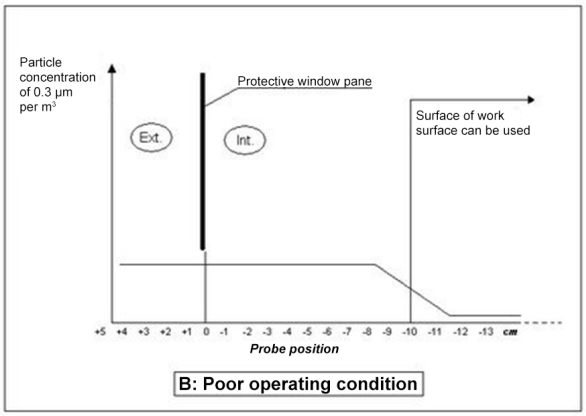
2.1.6.2.2 Reporting of results:

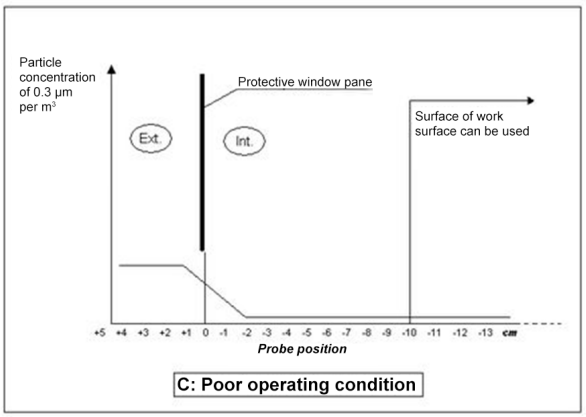
The position of the protective barrier is defined as the sampling probe position for which the particle concentration becomes equal to 0 (see diagram 3).

DIAGRAM 3

DETERMINATION OF THE POSITION OF THE LIMIT OF THE PROTECTIVE BARRIER







Each of the protective barrier limits must be located inside the PSM in accordance with § 2.1.4.2.9.

The position of the protective barrier retained is that of the measurement point giving the highest value. This position must be consistent with the position indicated by the manufacturer.

2.1.6.3 Test method – determination of the efficiency of staff protection (see Appendix C of standard NF EN 12469 :2000)

Ascertaining of the efficiency of staff protection must be carried out in accordance with paragraph C.4 of Appendix C of standard EN 12469 : 2000.

2.2 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

The current chapter lists the minimal quality management system requirements which the applicant/holder must meet in order to use the NF mark. This assures that products which use the NF mark are manufactured in accordance with the current certification rules.
An efficient quality management system is required manage the certified products and to test the raw materials to be used in the finished product before, during and after manufacture.

2.2.1 LEADERSHIP

2.2.1.1 Quality policy

The applicant/holder's management much establish a quality policy, its objectives and reach. They must be up-to-date. They must also be communicated, understood and used within the company.

2.2.1.2 Roles, responsibilities and authority within the company.

2.2.1.2.1 Responsibilities and authority

The management must ensure that people's responsibilities and authority are communicated to every person involved:
- in the production stages with a direct impact on the quality of the product
- in inspections and tests
- in the release of the compliant product
- in the assessment and processing of non-compliant product material

The management must ensure that the responsibilities and authority are defined in such a way as to assure that the requirements of the certification standard are implemented permanently.

2.2.1.2.2 Testing means and staff

The applicant/holder must:
- Identify and implement measures to monitor the quality of the finished product, during the appropriate stages (upon receipt, during manufacture and on the finished product.)
- Foresee the necessary tests
- Appoint competent individuals to verify that the product meets the specified requirements.

2.2.2 PERFORMANCE EVALUATION

2.2.2.1 Management Review

At planned intervals, management should review the established quality management system in order to:
- comply with the requirements of these certification rules,
- ensure that it always remains appropriate and effective.

Documented information from these reviews shall be kept and made available (see 2.2.3).

The monitoring of objectives related to the quality of the products and the efficacy of the actions implemented must be a part of each management review.

2.2.2.2 Internal audit

Internal quality audits must be carried out at planned intervals in order to establish whether the quality management system meets the requirements placed by the applicant/holder as well as those listed in the certification rules.
The applicant/holder must keep the results of these internal audits, and carry out any appropriate corrective action(s).

2.2.3 DOCUMENT MANAGEMENT

Quality management system documentation must be read, evaluated and approved before being disseminated by authorised persons. Quality management system documentation must be managed in such a way as to assure that only valid documents are available.

The holder/applicant must manage the documented information. To do this, they must carry out the following actions, when applicable:

a) Approve documentation, with regards to their adequacy, before dissemination.
b) Review and update documents if necessary.
c) Ensure that any modifications, and the validity period of the documents are identified.
d) Ensure the availability of the documents wherever they are required.
e) Ensure that the documents are legible and easily identifiable.
f) Ensure that external documents are identified, and that their dissemination is managed.
g) Prevent any unintentional use of expired documents and identify them appropriately if they are kept for any reason whatsoever.

2.2.4 PURCHASES

2.2.4.1 Purchase specifications

The holder/applicant must ensure that the purchased product conforms to the purchase specifications.

To do this, they must identify the requirements that they will place on the supplier, the checks to be carried out on supplied products, as well as any other steps necessary to ensure that the purchased products satisfy the purchase specifications. The importance of a purchased product on the conformance of a final product will determine the number and scope of any requirements placed on suppliers and purchased products.

Purchase documents must describe the purchased product and provide a reference. If this is not possible, they must state the applicable version of the purchase specifications.

2.2.4.2 Subcontracting of NF manufacturing

Subcontracting operations are governed by the following principles:

- The holder who has requested the subcontracted job, is responsible for the conformance of the NF certified products, in accordance with the certification rules. In the case of non-

conformance, the necessary checks must be carried out either at the manufacturer's site, or at that of the subcontractor, in keeping with the quality duties adopted for the subcontracted work.

- The subcontracted duties must be agreed to in advance by LNE, and they must be clearly recorded, both by the subcontracted manufacturer and by the subcontractor (in particular, the manufacturer's lot and identification numbers and any testing carried out must be recorded.
- Orders must state clearly which product is being ordered (reference, technical specifications, quantity, time periods etc.) They must make reference to the specifications made in the design brief, if this is not possible, they must indicate the Certificate of Analysis.

If all or part of product manufacturing is subcontracted, the manufacturer must:

- assess and select subcontractors on the basis of their ability to satisfy sub-order requirements, including quality system requirements and all specific quality assurance requirements;
- define how and to what extent the manufacturer will manage the subcontractors' activities. This shall depend on the type of product ordered from the subcontractor, the impact this product has on the quality of the end product and, where applicable, the subcontractor's previous quality audit reports and/or performance levels and capability records;
- draw up, keep up to date and maintain quality records on acceptable subcontractors.

2.2.5 IDENTIFICATION AND TRACEABILITY

The applicant/holder must provide instructions on product identification by marking products in accordance with the requirements of § 2.3 below.

The NF mark requires traceability. Unique product identification must be managed at every stage of the manufacturing process, by defining the rules to follow and the appropriate means to carry this out.
Identification must allow product and its history to be traced. It should be possible to trace the lots of the raw materials used and the tests carried out upon their receipt, during the manufacturing process and on the final product.

The applicant/holder must also determine the state of the products and compare them to the monitoring and measurement requirements, throughout the entire production process (from the time of receipt, as far as the final product). They must keep any documentation required for traceability.

2.2.6 PRODUCTION MANAGEMENT

Production must be managed at every stage of the process.
This is the case from the start of manufacturing, until the final product is packaged.

To do this, the applicant/holder should:

- define the production methods associated with the types/product ranges,
- define the manufacturing parameters for each type/product range at each stage of production,

- arrange access to manufacturing instructions, product properties, inspection plans and associated monitoring equipment during production activities,

The manufacturing equipment must be kept in good condition.

The applicant/holder must arrange for checks and periodic maintenance tasks to be carried out on manufacturing equipment. The applicant/holder must keep the relevant records of this.

2.2.7 TESTING

Responsibilities and authority within a company must be given to people who carry out testing and those release conforming products.

2.2.7.1 Tests to carry out upon receipt

The applicant/holder must ensure that product purchased are used only after they have been shown to conform to the purchase specifications.

For example, using defined and regular testing upon receipt, Certificates of Conformity for technical specifications given by the suppliers, or design briefs.

Tests carried out must be recorded, along with acceptance criteria, and any decisions taken in the case of non-conformance.

2.2.7.2 Tests carried out on products which are being manufactured and those which are finished.

The applicant/holder must implement the planned actions, at the appropriate time points, in order to check that the specified requirements are being satisfied.

They must assure themselves that every required test has been carried out at the specified frequencies. This applies during receipt of the product (see § 2.2.7.1), manufacture and on the finished product (see table below). The results must show that the product conforms with the specified requirements.

The testing plan must ensure that products which have passed conform to the requirements listed in § 2.1. As a minimum, it must include the following checks on properties (see Table1).

The results of these tests must be recorded, along with the acceptance criteria and any decisions taken in the case of non-conformance.

The client must not be given the products before all planned tests have been carried out satisfactorily.

Certain tests may be subcontracted, as long as this does not affect the manufacturing process (for example due to the turnaround time.)

The subcontracting terms and conditions must be formalised and recorded (e.g. how “subcontractor” is defined, the frequency in which the tests will be carried out, the turn-around times required, the written communication of results, the procedure to follow in case of non-compliance).

In order to verify that the subcontracting laboratory conforms with the required regulations, LNE reserves the right to audit it.

Table1: Summary of the tests to be performed and the related requirements

Test type	Technical specifications	Inspections carried out by the manufacturer
A - Down-flowing air flow speed	The velocity measurements are made 10cm above the lower edge of the protective window in accordance with § G.3.2.1. of the informative Appendix to standard NF EN 12469 and in accordance with § 2.1.5.2.5. The individual speeds must be between + or - 20% of the average, which must not be over 10% of the value defined by the manufacturer.	yes
B - Incoming air flow velocity	The incoming air flow velocity into the PSM must be above or equal to 0.4 m/s. These measurements are done in accordance with standard NF X 10-112.	yes
C - Sound level	The weighted sound pressure level of the PSM while operational must be ≤ than 64 dB	yes (according to 1 sampling plan)
D - Employee protection	Each test at the operator's position must not exceed 10 UFC. Each non-disrupted test must not exceed 5 UFC, in accordance with Appendix C of EN 12469.	yes (in accordance with § C.4 of standard EN 12469
E - Product Protection	The product's protection is assessed by analysing the contamination level of culture dishes distributed over the work surface using a bacterial aerosol created by a canister placed outside the PSM in accordance with Appendix E of EN 12469. Threshold limit: 5 UFC.	-
F – Cross-contamination	Protection against cross-contamination is assessed by analysing the contamination of the Petri dish by an aerosol of spores sprayed from the other side of the volume of work in accordance with Appendix F of EN 12469. Threshold limit: 2 UFC.	-
G – Alarm checks	Alarms must trigger in accordance with § 2.1.5.2.6 of the certification rules for mark NF PSM	Yes
H – Temperature check	After nearly 4 hours of continuous operation, the station"s interior temperature, measured in the centre of the work volume, must not rise by more then 8°C compared to the ambient air temperature in the laboratory, (part 2 - §2.1.5.2.2 of the certification rules)	yes according to a frequency set by the manufacturer
I – Lighting check	The measurements are performed 7cm above the work surface in accordance with the mapping of air flow velocity values (see mapped diagram part 2 - § 2.1.5.2.2.) to ensure that lighting is higher than or equal to the threshold value of 750 lux at each of the measurement points	Inspection based on certificates on receipt
J - Cleaning capacity	The test is carried out via a coloured reaction which demonstrates possible pollution (part 2 - § 2.1.5.2.7 of the certification rules)	-
K - Sterilisation capacity	Taking into account the performance class specified by standard EN 12469 for type II PSMs, only disinfection capacity is required (part 2 - § 2.1.5.2.8 of the certification rules)	-
L - Stability	No tilting under test conditions, in accordance with § 7.4 of standard NF EN 61010-1	Inspection on design
M - Aerosol test method to detect leaks from the high efficiency filter system (HEPA) installed.	The integrity of the high efficiency filter system (HEPA) installed on the PSM is assessed by subjecting the station to an aerosol sprayed upstream and by measuring the flow of the aerosol downstream, in accordance with Appendix D of standard NF EN 12469.	Yes
N - Measurement of the position of the limit of the protective barrier	The position of the protective barrier is defined as the sampling probe position for which the particle concentration becomes equal to 0 from the protective window (part 2 - § 2.1.5.2.9 of the certification rules)	-
O - Integrity for leakage	The PSM housing, in which the contaminated air is subjected to positive pressure and can escape directly to the exterior, must undergo an integrity test for leaks at a pressure of 500 Pa and a pressure of 250 Pa on each station, in accordance with a sampling plan in all other cases.	Yes
P - Electrical safety	Inspections are performed in accordance with standard NF EN 61010-1	Yes

<u>Leak integrity of the external housing</u>

This check is carried out as follows:

- on each station, for models where under normal operation the housing is overpressure compared to the ambient atmosphere. The test pressure is 500 Pa.
- in accordance with a sampling plan defined by the manufacturer in all other cases, with a test pressure of 250 Pa.

Filters and filter housing
The filter supplier must send a certificate of conformity.
Every filter must be identified (batch no.) and accompanied by the inspection file drawn up by the supplier.
An inspection is performed by the PSM manufacturer on each station (hot or cold generation according to the methodology – see Appendix D of standard NF EN 12469).

Air velocities:
An inspection on each station of the velocities and their dispersions, specified for incoming air and down-flowing air.

Noise
Inspection to be performed by the manufacturer (per station or based on a sampling plan).

Lighting
Definition of the specifications of lamp properties in the supplier specifications.
Inspection based on supplier certificates on receipt.

Electrical safety
Inspection to be performed by the manufacturer in accordance with standard NF EN 61010-1 or equivalent on each station:
- breakdown test,
- ground continuity,
- leakage current.

If during construction there is an interruption in ground continuity (removable work surface), an additional inspection should be performed.

Stability
Check to be carried out during design.

Temperature
To be checked at a frequency set by the manufacturer.

Ventilators
Definition of the specifications of ventilator properties in the supplier specifications.
Inspection based on supplier certificates on receipt.

Automatic ventilator regulation system
A method to inspect automatic regulation and the triggering of associated alarms will be defined by the manufacturer.
An inspection should be performed on each station.

Staff protection
Check using the KI Discus method, via counting the presence of an operation simulator or using another method correlated to the reference method. To be performed on each station

The other tests may be considered as benchmark tests and may therefore possibly be outsourced.

Frequencies must be defined by the manufacturers.

The results of these tests must be recorded, along with the acceptance criteria and any decisions taken in the case of non-conformance.

2.2.7.3 Recording of inspections and tests

Documents relating to testing must be drawn up and kept, in order to prove that the products conform to the requirements of this certification. They must be legible, easy to identify and accessible.

The applicant/holder must ensure that the documents relating to testing carried are identifiable, properly stored, protected and accessible. They must also ensure the amount of time that they will be kept for, and their subsequent elimination.

2.2.7.4 Subcontracted testing:

Certain tests may be subcontracted, as long as this does not affect the manufacturing process (for example due to the turnaround time.)

The subcontracting terms and conditions must be formalised and recorded (e.g. how "subcontractor" is defined, the frequency in which the tests will be carried out, the turn-around times required, the written communication of results, the procedure to follow in case of non-compliance).

In order to verify that the subcontracting laboratory conforms with the required regulations, LNE reserves the right to audit it.

2.2.8 MANAGEMENT OF INSPECTION, MEASUREMENT AND TEST EQUIPMENT

Principles of calibration:

Calibration involves the comparison of the values given by a piece of measurement equipment or system, to known values given by a standard.

The standard's value must be traceable to the value given by a national standard, using un uninterrupted calibration chain, described by documents (traceability).

Calibration methods of measurement equipment or system:

There are two possibilities:

- The holder's laboratory has its own standards, which are compared to national standards at defined intervals. The holder calibrates their equipment themselves.
- The holder's laboratory sends their equipment off to be calibrated by a service provider, which is accredited by COFRAC, or its equivalent, according to the applicant/holder's country of origin. If the service provider is not COFRAC accredited or equivalent, depending on the country of origin of the applicant/holder, it must in all cases have established standards that are regularly integrated with the national standards for the standardisations concerned.

The applicant/holder must have equipment to ensure that the results are valid.

Management of measurement equipment:

Measurement equipment must be:

- Calibrated against standards linked to national or international standards (if these standards do not exist, the calibration reference used must be registered). They must be re-calibrated or checked at specified intervals or before their first use
- Identifiable, in order to allow the validity of the calibration to be checked.

The standard's uncertainty must be sufficiently small with regards to the uncertainty expected from the measuring equipment or system to be calibrated.

When a piece of equipment is found to be non-conforming, the applicant/holder must check the validity of previous results obtained. They must take appropriate action on the equipment and on any affected products. This information must be recorded. The records of the calibration and verification results must be kept.

These requirements apply to every laboratory, regardless of whether they carry out all, or a part of the internal measurement checks.

2.2.9 MANAGEMENT OF NON-COMPLIANT PRODUCTS

The applicant/holder must ensure that each product which does not conform to the specified requirements is identified and managed so that it does not get used or delivered unintentionally.

The applicant/holder must treat a non-conforming product marked with the NF mark in the following ways:

- By carrying out actions which eliminate the non-conformity.
- By allowing its use, release or acceptation by derogation- in this case, the previous agreement must be obtained from the client and from LNE.
- By carrying out actions which prevent it from being used (e.g. scrapping of the product).

Responsibilities and authority must be given to people who carry out testing and those who take actions in order to remedy the product.

The applicant/holder must keep documentation which describes non-conformities along with their remedy.

2.2.10 CORRECTIVE ACTIONS:

The holder/applicant will define the requirement and will keep proof of actions carried out in order to:

a) Review non-conformities (including client complaints).
b) Determine the cause(s) of non-conformities.
c) Evaluate the need to undertake actions so that non-conformities are not repeated.
d) Determine which actions are necessary, and put them into place.
e) Evaluate the effectiveness of the actions taken.
f) Record the results of the actions put in place.

Records of any complaints made regarding certified products, and their remedy must be made and kept.

2.2.11 PRODUCT PRESERVATION

2.2.11.1 Storage

The applicant/holder must provide areas or premises for the storage of stockin order to avoid causing damage or deterioration to the product before it is used or delivered.

The condition of the stock must be assessed at defined and appropriate time intervals, in order to detect any deterioration.

2.2.11.2 Packaging

The holder/applicant must manage the wrapping, packing and marking of products as needed, in order to ensure that they conform to the specified requirements.

2.3 EXMARKING REQUIREMENTS

Marking makes up an integral part of the certification of a product.

As well as allowing for identification and traceability of a product, marking a product with the NF logo ensures that users will receive better protection: it also protects holders from abusive use of the product and from counterfeit goods.

Without prejudice of the sanctions laid down in the General Rules of the NF mark, any incorrect announcement of the certified features and any fraudulent use of the NF logo expose the holder to lawsuits for fraud and/or misleading advertising.

It is strictly forbidden to use or affix the AFNOR logo, or AFNOR/LNE certification without prior agreement from those institutions.

The holder undertakes to respect the NF mark's graphic charter.

NF certified products have a different designation and identification to non-NF certified products. The holder must only use the NF logo to identify NF certified products. They may only do this if there is no risk of confusion with other products, especially those which are not NF certified.

The holder is advised to submit all documentation making reference to the NF mark to the LNE before use.

REMINDER:
Article R 433-2 of the Consumer Code states that:
"When reference is made to certification in advertising, labelling or in the presentation of any product or service or in associated documents of any nature, the following information must always be brought to the consumer's or user's attention:

- *The name or corporate name of the certifying body or the warranty mark,*
- *The denomination of the certificate reference standard used.*
- *Methods to consult or obtain the certification reference standard."*

2.3.1 Marking on an NF certified product

Each PSM must permanently and visibly display the NF logo in line with the requirements of the graphic charter as outlined in the template below and in accordance with the specific standards and regulations in force.

SAFETY STATIONS
SAFETY STATIONS
www.lne.fr

PSMs must be marked in a permanent and legible fashion indicating the following information:
- coding to guarantee product traceability (e.g. batch number/serial number),
- trade name (brand and commercial reference) of the model stated on the certificate,
- type of microbiological safety station (marking on the front),
- name and address of the manufacturer,
- number and date of the European standard reference: EN 12469:2000,
- voltage, frequency and electrical consumption,
- useful dimensions of the work surface,
- year of manufacture,
- “biological risk” safety warning signal,
- “one user only” marking (marking on the front),

The English version "certified by LNE" is available from LNE.

Failing that, copy this information onto the packaging or the document accompanying the product.

2.3.2 Documents accompanying the microbiological safety station

Each PSM is accompanied by documents provided by the manufacturer in French.

These documents are as follows:
- a technical file specifying the main properties of the PSM and its components,
- a file regarding the illustrated instructions, guidelines and advice
  . for start-up and installation, including the prior system checks that have to be performed.
  . for the qualification of the required staff,
  . for use,
  . for maintenance and the inspections that have to be carried out,
  . for electrical safety risks (non-flameproof equipment)

- a file containing:
  - the PSM user manual in French with information on decontamination and sterilisation
  - the device's internal inspection report
  - the commercial documentation for the model subjected to periodic testing
  - 1 photo of the PSM, front and side
  - 1 PSM ventilation diagram
  - 1 work surface diagram etc.
  - the following specific equipment for tests:
    - 1 extraction duct for flow measurement
    - 1 power cord fitted with a 220V station in accordance with French standards
    - 1 electrical by-pass to allow measurement of the ventilator power voltage

- the PSM containment class in accordance with the procedures defined by standard EN 12469 :2000.

The instructions for use accompanying the delivery of products must permanently, visibly and continually display the NF logo in accordance with the requirements of the graphic charter and according to the template below (the English version "certified by LNE" is available from LNE) and in accordance with the specific standards and regulations in force.

SAFETY STATIONS
SAFETY STATIONS
www.lne.fr

The NF logo must be accompanied by the following information:
- coding to guarantee product traceability (e.g. batch number/serial number),
- trade name (brand and commercial reference) of the model stated on the certificate,
- the essential certified properties, as defined in § 1.1.

2.3.3 Markings on documentation (technical and commercial documents, posters, advertisements, internet sites, etc.)

References to the NF standard in the documentation (order confirmations, invoices, delivery notes, advertiser pamphlets, catalogues etc.) must be made in such a way as to make it impossible to confuse certified products with non-certified products.

Reproduction of the NF mark on documentation and advertising must be carried out in accordance with the requirements of the NF mark graphic charter according to the template below.

It is recommended that the holder submit to LNE beforehand all commercial documents where the mark is mentioned, including during modification of these documents.

The holder must communicate, at the request of LNE, any document in which reference is made, directly or indirectly, to the NF mark.

2.4 Applicant's/Holder's commitments

The applicant/holder commits in general to giving LNE the means to carry out the operations necessary for the correct progress of the assessment and follow-up of their file and in particular to:

- comply at all times with the requirements defined by these certification rules, and to implement the necessary changes within the deadlines prescribed by LNE in the event of changes in the certification rules,
- communicate the information and working documents necessary for a proper evaluation procedure to representatives authorised by LNE;
- only communicate information that the applicant/holder knows is fair and sincere;

- appoint a responsible individual as an LNE interlocutor;
- designate recipients within the company who will receive LNE test and audit reports and inform LNE of changes to be made in case of a change of recipient within the company or e-mail address;
- introduce the staff assigned to the various tasks to the authorised LNE representatives;
- instruct staff to work with authorised LNE representatives, and to agree to participate in any interviews;
- provide authorised LNE representatives with a way to access and move around the sites and work areas, including the subcontractors' sites, as the case may be;
- inform the authorised LNE representatives about the safety and hygiene provisions and instructions applicable to the sites and work areas and the staff there, and make any equipment necessary available to them for this purpose;
- pay LNE the sums due for the evaluation, in accordance with the financial conditions defined and accepted by the applicant/holder
- Authorise the presence of an observer who is required to respect confidentiality. This observer can be imposed on LNE by the standards or agreements of which they are a signatory. Information regarding the presence of this observer is always communicated to the applicant/holder by LNE prior to the audit.
- take the necessary measures in the event of non-compliance, within the deadlines specified by LNE,
- return the duly completed non-compliance sheets to the lead auditor within 3 weeks of the last day of the audit,
- implement the necessary actions to enable the certificate to be issued within a maximum of 11 months after the initial audit. After this period, a new initial audit will have to take place before certification,
- send the samples taken under the conditions defined in Parts 3 and 4 to the standard's laboratory.

It is also the responsibility of the certificate holder to:

- display the NF mark only on the products covered by the certificates issued by LNE and in accordance with the applicable requirements;
- reserve the product's commercial name only for the products covered by the certificates issued by LNE and in accordance with the applicable requirements;
- communicate to LNE beforehand any modification of the product or any information likely to affect conformity with the requirements of the present rules, the methods of evaluation being defined in part 4,
- make available to LNE any data or information necessary to establish and maintain the certificate;

- keep a record of all claims of which the holder is aware of the conformity of the product(s) with the certification requirements and make these records available to LNE upon request, and
    - take any appropriate action with respect to these claims and imperfections in the products that affect their compliance with the requirements of the certification,
    - document the actions taken.

- in the event of suspension, reduction, withdrawal or refusal of renewal of the certificate, stop using any references to the certification of the products concerned and stop using all the means of communication that make reference to this,

- authorise follow-up evaluations during the period of validity of the certificate, on the basis of the frequency specified in Part 4 and any duly justified additional assessment.

- make statements about certification consistent with the content of the certificate,

- not use the certification issued by LNE in a manner that could damage LNE, nor make a declaration regarding the certification of its products that LNE may consider misleading or unauthorised;

- reproduce the certificates in their entirety, including the appendices in case of supply to a third party.

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

Organisme certificateur mandaté par
AFNOR Certification

CERTIFICATION RULES

NF MARK-MICROBIOLOGICAL SAFETY STATIONS

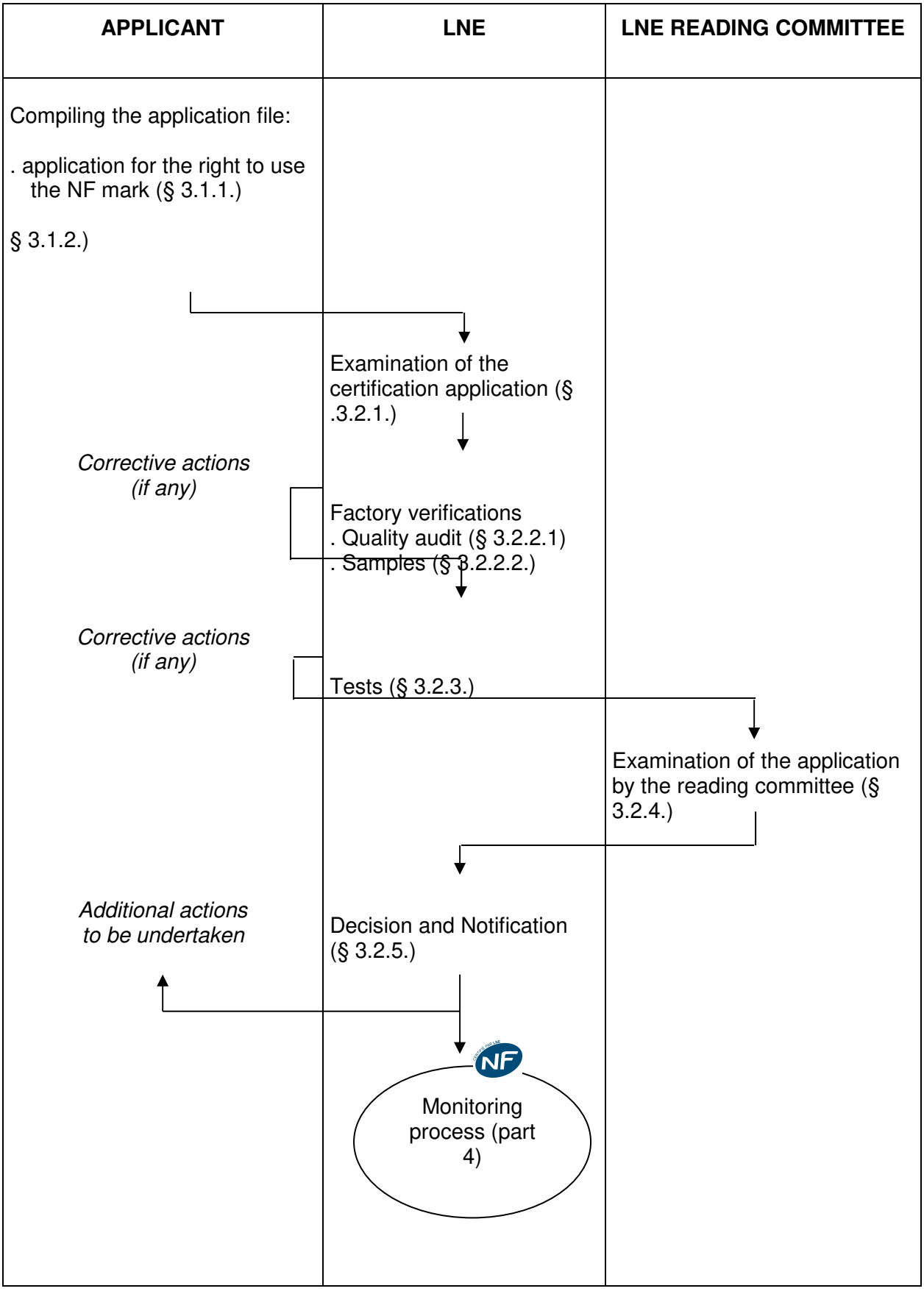
PART 3

OBTAINING CERTIFICATION

CONTENTS

Rev. 6 – December 2023

PROCESS FOR OBTAINING CERTIFICATION



Before making an application, the applicant must ensure that (at the time of the application) they fulfil all the requirements stated in these certification rules, especially Part 2, which concern their products and sites.

They must undertake to comply with said conditions throughout the period of using the NF mark.

If they fail to respect these rules, the applicant/holder exposes himself to the interruption or suspension of the processing of his file. Notably, it is not possible in any circumstances to make reference to the NF mark before obtaining the right to use the NF mark, or to present forged products for certification.

3.1. COMPILING THE APPLICATION FILE

Any company manufacturing one or more products covered by this application of the NF mark can request the right to use the mark. A request of this kind is known in this document as an "application" and the person formulating it as the "applicant".

3.1.1. APPLICATION FOR THE RIGHT TO USE THE NF MARK

Any manufacturer wishing to obtain the right to use the NF mark on a product it manufactures must first read carefully the certification rules for the Mark and declare that it accepts them.

The application is drawn up on the manufacturer's letterhead paper as shown in the template (Form no. 1a) and must be sent to LNE.

It specifies the models to be presented as part of the certification application.

Definitions:

A type II PSM model (excluding all options), is characterised by the following:

- its external and internal dimensions,
- very high efficiency filters,
- one or more ventilation systems,
- control devices.
- effective alarms

For every factory that will produce the products for which certification is requested, the applicant must provide a file containing the documents or information listed in § 3.1.2. (below).

The request will only be accepted if the checks set out in Part 2 of these rules have been carried out regularly for the products in question for at least three months.

All the documents must be written in French or English.

The application must be accompanied by the applicable fees for reviewing the application and the initial audit.

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When the applicant is from a country outside the European Economic Area, they must submit their application jointly with a representative who is established in the European Economic Area. The representative shall be duly accredited and responsible for producing the goods for which NF certification is requested and which are to be sold in France.

He is known as the "authorised agent".

Before using the NF mark, LNE must be informed about all modifications made to the range submitted for certification purposes. LNE will decide if extra testing needs to be carried out on those products.

3.1.2. DOCUMENTS TO BE SUPPLIED

- A certification application template letter (Form 1a), written on the manufacturer's headed paper, as per the attached template (with the Appendix and associated mandate co-signed (as per Form 1d) if the application is made from outside the European Economic Area),
- General information form (form 1b).
- List of models for which the NF mark is requested (form no. 1c).
- Description of quality management measures in place:
    - Quality manual and/or plan(s) (if these documents may not be taken off-site, they must be given to the auditors during the audit).
    - Description of the manufacturing process and associated inspection plan (detailing the measures and tests conducted as well as their frequency).
    - Description of the different processes with definition of inputs, outputs, activities taken into account in each process (with reference to ISO 9001: 2015),
    - Certificate of conformance of the quality management system (where appropriate).
    - A copy of the CE mark certificates, in the applicant's/holder's name and currently valid; these certifications must cover the product references which are the subject of the application (where applicable).

- Technical file:
    - the full PSM user manual in French with information on decontamination and sterilisation
    - the full and final internal audit report drafted for the device
    - the test reports concerning electrical safety and electromagnetic compatibility design vis-à-vis the standards defined in § 2.1.1
    - the commercial documentation for the model
    - 1 photo of the PSM, front and side
    - the proposed product marking
    - 1 PSM ventilation diagram
    - 1 work surface diagram etc.
    - the following specific equipment for tests:
        - 1 extraction duct for flow measurement
        - 1 power cord fitted with a 220V station in accordance with French standards

All the documents must be written in French or English.

FORM No. 1a
CERTIFICATION APPLICATION
(To be written on the manufacturer's headed notepaper)

For the attention of the General Manager of
LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
Division Certification Plurisectorielle
1, rue Gaston Boissier
75724 PARIS Cedex 15 - France

PURPOSE: Application for the right to use the NF-095 mark

Dear Sir,

I the undersigned (name and position) .....
representing the company (identification of the company - head office).....
request that LNE carry out the verifications necessary for the right to use the NF mark on the products listed in the attached table, in accordance with the specifications defined in part 2 of the rules for the NF 095 mark.

These products are manufactured in the factory belonging to (company identification and full address of factory)

Option in case of modification of a certified product:

The products manufactured by us, differ from the NF certified products due to the following modifications: (describe the modifications carried out).

This product replaces the certified product: .....

This new product manufactured by us is identified by the following reference numbers: .....

I hereby declare that the other features of the products concerned by this application are in strict conformity to the product that is already NF certified and manufactured in the same conditions.

Option in case of maintenance application:

This application also relates to products sold by ..... under the references (see attached maintenance application).

I declare that I am familiar with the reference standards, the general rules of the NF mark and the NF095 certification rules (in particular paragraph 2.4 concerning my commitments) and in general I undertake to comply with them throughout the period of use of the NF mark.

I attest that these products satisfy the regulatory requirements applicable to them and I undertake not to present forged products for certification.

Date
Stamp and signature
of the applicant

APPENDIX TO THE APPLICATION FOR CERTIFICATION (1)

Furthermore, I authorise the company (2)..... .....
represented by Mr./Ms. (name and position). .....

who accepts the terms of the attached mandate, to act on my behalf in France for all matters relating to the use of the NF mark.

I undertake to notify LNE immediately if I appoint a new authorised agent to replace the authorised agent named above.

Yours faithfully,

Date

Stamp and signature
of the authorised agent's representative (3)

Stamp and signature
of the applicant's representative (3)

(1) This appendix is only to be completed by applicants located outside the European Economic Area. It must be accompanied by a co-signed mandate (see sample Form 1d)

(2) The designation of the representing company must include: company name, legal form, head-office and Companies Register number.

(3) The signatures of the applicant and his/her agent must be preceded respectively by the hand-written words "Proxy agreed" and "Acceptance of proxy agreed".

FORM No. 1b

GENERAL INFORMATION SHEET

Applicant's corporate name:

Address of the applicant
Contact:
Telephone:
Website of the company or site(s) mentioned in the application E-mail:

ISO 9001 certified site: Yes ☐ No ☐

Contact information of the correspondent(s) for receiving the test and audit reports from LNE via email:

Name of the contact	Job-position	E-mail	Audit report	Test report

Billing address (if different from the address mentioned for the corporate name of the applicant), with undertaking if different from the applicant

_____

_____

Location of the various steps of manufacturing

	Address and contacts of the site responsible for each stage*	Size of the site mentioned in the certification	Area of the site
Design			
Manufacturing (1)			
Assembly			
Final check			
Marking			
Packaging			
Storage			

Any aspect not covered by the applicant is subject to a contract defining the respective responsibilities with its provider
(1) Details (if necessary) of the manufacturing stages or of outsourced manufacturing.

Trademark :

* Owner of the trademark:

List of distributors, people responsible for the market launch, whose name appears on the package*:

Issued at

on

Signature

*** Indicate the company name, address, contact person, phone number and e-mail address if different from the applicant.**

FORM 1c

REFERENCE OF THE PRODUCTS COVERED BY THE CERTIFICATION APPLICATION

TRADEMARK	TRADEMARK OF THE MODEL(S)	CODING OF THE BATCHES (1)

Applicant's name

Date

Stamp and signature

(1) In reference to the definitions of part 1, § 1.2

FORM No. 1d
EXAMPLE OF A MANDATE
(to be drawn up on the applicant/authorised agent's letterhead paper)

List of information to be supplied:

- Corporate name: _____
- Address: _____
- Country: _____
- Telephone:_____ Fax: _____
- SIRET No.:_____ NAF code: _____
- Name and profession of the legal representative:_____
- Name and profession of the correspondent (if different): _____
- VAT ID number: _____
- Email address of contact person: _____
- Email address of the Company:_____
- Website:_____

Identification of the roles of the authorised agent to be included in the mandate between applicant/holder and authorised agent

Applicant/Holder: .....

Authorised agent:.....

Minimum requirements which must be shown in the mandate:

- assignments and associated responsibilities
- financial aspects (invoicing relating to the NF mark)
- complaints
- certifying body contact

Mandate:

The mandate should be mentioned in the applicant/holder's quality system.

A copy of the mandate in French or English should be attached to the co-signed admission application.

Compliance with the mandate arrangements is checked during audits.

Date of the initial mandate

Co-signature of the representative of the authorised agent and the applicant

3.2. INITIAL ASSESSMENT PROCESS

3.2.1. EXAMINATION OF THE CERTIFICATION APPLICATION

The application and enclosed file sent to LNE are examined before factory verifications and tests are carried out.

Upon receiving the application, LNE checks that:
- all the requested documents are enclosed in the application file according to § 3.1.2.,
- the elements in the file comply with the requirements of the certification rules.
- fees are paid.

Test reports in French and/or English drawn up by a notified/accredited laboratory less than 2 years old are subject to an assessment by LNE to check that all the applicable points of the certification rules have been verified and are compliant.
NB: when the reports are not provided or are considered “inadmissible”, the tests are carried out at the mark's laboratory.

LNE checks that it has all the means for responding to the application and may request additional information required for the admissibility of the file when this is incomplete.

Once the application is admissible, LNE organises the inspections and informs the applicant about the organisation methods (auditor, duration of the audit, audited sites, laboratories, sampled products etc.) and, if applicable, the due date for the additional items.

The checks carried out in connection with the NF mark are as follows:
- Audits, which aim to cover all those involved in design, manufacturing, assembly, quality control, marking and packaging of products (see § 3.2.2).
- Product testing (see § 3.2.3)

Test samples are taken during the initial audit and sent by the applicant to the designated laboratory.

3.2.2. AUDIT

The examination of the application involves an initial audit of the factory where the products presented in the application file are manufactured. It also includes, if applicable, an audit of the various sites participating and described in the certification application, on the basis of the same standard.
It is carried out by auditors, qualified at LNE, who are bound to confidentiality.

3.2.2.1. Quality audit

This audit is conducted according to the general principles defined in standard ISO 19011 for conducting a quality audit. In particular, the scope of the audit and details of the procedure are specified in an audit plan sent to the company before the audit

The initial audit is carried out by a qualified auditor and a technical expert (where applicable).

The auditor(s):

- Carry out a quality audit aimed at checking whether there is a quality management system, as well as its implementation. It will also check the system's adherence to section 2 of these rules.

- Check(s) that the inspections required in Part 2 have been carried out regularly on the model(s) forming the object of the certification applicationto verify the application of the planned frequencies, operating procedures and criteria defined by NF certification rules and ensure that compliance testing on the models forming the object of the application is conducted in their presence. The tests are preferably carried out on the type of sample taken for the standard's laboratory tests.

NOTE: test results obtained during the audit do not prejudge results obtained by the mark laboratory.

- Takes the samples required for initial testing

- If appropriate, examine the scope of the contract with the agent and/or with the different sites involved and described in the application for certification.

The on-site audit lasts 2 auditor days.

The duration of the audit can be adapted to the sites to be audited (with prior consent of the applicant).

With the company's agreement, the auditors can take a copy of any document they consider necessary.

Case of companies with a certified quality management system

If the compliance of the quality management system is the subject of a valid certification whose scope and field includes the sites and activities concerned by the NF standard, and issued by a body accredited in accordance with ISO/CEI 17021, the length of the audit period is adjusted (reduction by 1 day).

The audit reports drawn up by the quality management system certifying body must be sent to the auditor or consulted on site.

The chief auditor prepares an audit report which he/she gives to the applicant at the end of the final meeting, drawing special attention to the effectiveness of the quality system set up, the strong points, the points to be improved upon and a report of non-conformities with comments. It also includes the report of tests carried out during the audit and the sampling sheet.

A non-conformity is classified as major when, on the basis of objective proof:

- there is a significant risk to the conformity of the product in relation to the specified requirements (these requirements are set out by the reference document, the company or its clients), or
- there is a significant risk in terms of the management system's ability to control product conformity for a specified requirement, or
- there is systematic or repeated non-compliance with a given requirement.

In all other cases, the non-conformity is classified as minor.

The applicant must respond to any notified non-conformity with a causal analysis, corrections and corrective actions. An action plan to address major or minor non-conformities is sent within three weeks following the end of the audit to the Audit Leader for assessment.

In the case of a major non-conformity:

- Tangible proof guaranteeing the implementation of the correction to eliminate this non-conformity must be sent with the action plan.
- LNE must receive tangible proof guaranteeing the implementation of the corrective action associated with this non-conformity within the timeframes it has specified.

In the case of minor non-compliance, LNE must receive tangible proof that guarantees that the correction to eliminate this non-conformity is implemented along with the associated corrective action. Failing that, it will be checked at the latest during the next on-site audit, unless specified otherwise by LNE.
The complete report is sent by LNE by email to the correspondent(s) designated by the applicant, with a copy (where applicable) to the authorised agent.

3.2.2.2. Samples

The manufacturer must make available all product model(s) submitted for certification to the lead auditor for sampling purposes.

The auditors will take the samples necessary, which have been validated as per the manufacturer's quality control system, for testing.

Sampling is defined during the examination of the application.

The samples taken are marked by the auditors with a distinctive sign used to authenticate them later, and must be accompanied by information allowing the samples taken to be identified.

The manufacturer then sends the samples within 15 days by/and under its responsibility to the mark laboratory (see Part 5 of these rules). The laboratory is responsible for carrying out the tests, together with the sample sheet, unless the auditors decide to carry them out themselves.

3.2.3. TESTS

The inspections and tests specified are carried out on the samples taken during the audit or sent by the manufacturer and are carried out in accordance with the standardised methods and the specifications of the standards (see table below).

Test type	Technical specifications	Certification tests
A - Down-flowing air flow speed	The velocity measurements are made 10cm above the lower edge of the protective window in accordance with § 3.2.1. of standard NF EN 12469 and G.3.2.1. of the informative appendix to standard NF EN 12469 and in accordance with § 2.1.5.2.5. The individual speeds must be between + or - 20% of the average, which must not be over 10% of the value defined by the manufacturer. The average air flow velocity of down-flowing air must be between 0.25 m/s and 0.50 m/s in accordance with appendix H of standard NF EN 12469.	yes
B - Incoming air flow velocity	The incoming air flow velocity into the PSM must be above or equal to 0.4 m/s. These measurements are done in accordance with standard NF X 10-112.	yes
C - Sound level	The weighted sound pressure level of the PSM while operational must be ≤ than 64 dB	yes
D - Employee protection	Each test at the operator's position must not exceed 10 UFC. Each non-disrupted test must not exceed 5 UFC, in accordance with Appendix C of EN 12469.	yes (5 Tests)
E - Product Protection	The product's protection is assessed by analysing the contamination level of culture dishes distributed over the work surface using a bacterial aerosol created by a canister placed outside the PSM in accordance with Appendix E of EN 12469. Threshold limit: 5 UFC.	yes
F – Cross-contamination	Protection against cross-contamination is assessed by analysing the contamination of the Petri dish by an aerosol of spores sprayed from the other side of the volume of work in accordance with Appendix F of EN 12469. Threshold limit: 2 UFC.	yes
G – Alarm checks	Alarms must trigger (part 2 § 2.1.5.2.6. of the certification rules)	yes
H – Temperature check	After nearly 4 hours of continuous operation, the station interior temperature, measured in the centre of the work volume must not rise above 8°C compared to the laboratory ambient air temperature., (part 2 - § 2.1.5.2.2. of the certification rules)	yes
I – Lighting check	The measurements are performed 7cm above the work surface in accordance with the mapping of air flow velocity values (see mapped diagram part 2 - § 2.1.5.2.2..) to ensure that lighting is higher than or equal to the threshold value of 750 lux at each of the measurement points	yes
J - Cleaning capacity	The test is carried out based on a coloured reaction which demonstrates potential pollution (part 2 - § 2.1.5.2.7. of the certification rules)	yes
K - Sterilisation capacity	Taking into account the performance class specified by standard EN 12469 for type II PSMs, only disinfection capacity is required (part 2 - § 2.1.5.2.8. of the certification rules)	yes
L - Stability	No tilting under test conditions, in accordance with § 7.4 of standard NF EN 61010-1	yes
M - Aerosol test method to detect leaks from the high efficiency filter system (HEPA) installed.	The integrity of the high efficiency filter system (HEPA) installed on the PSM is assessed by subjecting the station to an aerosol sprayed upstream and by measuring the flow of the aerosol downstream, in accordance with Appendix D of standard NF EN 12469.	yes
N - Measurement of the position of the limit of the protective barrier	The position of the protective barrier is defined as the sampling probe position for which the particle concentration becomes equal to 0 from the protective window (part 2 - § 2.1.5.2. of the certification rules)	yes
O - Integrity for leakage	The PSM envelope, in which the contaminated air is subject to positive pressure and can escape directly to the outside, must undergo a leak tightness test at a pressure of 500 Pa.	yes
P - Electrical safety	Inspections are performed in accordance with standard NF EN 61010-1	yes

The tests are the subject of a test report that is sent by LNE by email to the correspondent(s) designated by the applicant; a copy is sent to the authorised agent where applicable.

IMPORTANT NOTE:

If non-compliant results are detected by LNE, the sample is sent back to the manufacturer.

The manufacturer must then do the following:

- identify the extent of the non-compliance, and whether it applies to other products (identification of products potentially concerned by the non-compliance).

- analyse the causes of the non-compliance

- adopt and implement the corrections to allow the non-compliance to be eliminated for the product(s) concerned.

- apply the measures specified in part 2 § 2.2.2. (Control of non-compliant product) to inform its customers, recall products and remove the non-compliance.

- send the corrected sample (or another defined by LNE) to the laboratory to carry out the relevant tests.

and notify LNE of this.

The manufacturer also informs LNE of any corrective actions adopted following the detection of noncompliance, specifying the associated period.

3.2.5. DECISION AND NOTIFICATION

On the basis of the results obtained during examination of the application and the LNE reading committee recommendations, LNE notifies the applicant of one of the following decisions:

a) Certification accepted
This decision may be accompanied by suspensive conditions which define the conditions to be met by the applicant before the certificate is awarded.

b) Certification refused

The certification decision must be made no later than one year after the initial audit.

In virtue of the certification decision notified by LNE, AFNOR Certification grants the right to use the NF mark.

Once the right to use the NF standard has been given, its beneficiary will be known as the “holder”. Maintaining this right is subject to the results of the verifications defined in Part 4.

The exercise of the right to use the NF Mark is strictly limited to the products for which it was awarded, in other words the duly defined products from the duly defined factories, and manufactured under the conditions set out in these Rules.

After approval of the right to use the NF mark, the first manufacturing batch for each approved model must be inspected by LNE before being marketed, with marketing only being possible after compliant results have been obtained and with LNE’s written approval.

3.2.6. APPEAL AGAINST A DECISION

The applicant may appeal against any decision taken. The procedure is set out in Article 11 of the General Rules of the NF Mark. The appeal is filed by registered letter with acknowledgement of receipt within 15 working days.

LNE will initially re-examine the file in light of the facts giving rise to the appeal. It notifies confirmation of the decision or the new decision to the applicant within 30 working days.

Should the applicant wish to maintain its challenge, an appeal may be made by the applicant or certification beneficiary against the decision of LNE.

Explanations for this appeal, which does not have a suspensive effect, must be given. It is lodged by sending a registered letter with acknowledgement of receipt within 15 working days. It is reviewed by LNE upon receipt.

The appeal is presented to the LNE Certification and Impartiality Preservation Committee, which proposes its conclusions after examination.

This last appeal is subject to a lump-sum payment by the applicant.

The company will be informed of the final decision by LNE.

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

Organisme certificateur mandaté par
AFNOR Certification

CERTIFICATION RULES

NF MARK-MICROBIOLOGICAL SAFETY STATIONS

PART 4

CERTIFIED PRODUCT SURVEILLANCE PROCESS {MODIFICATIONS AND CHANGES

CONTENTS

Rev. 6 – December 2023

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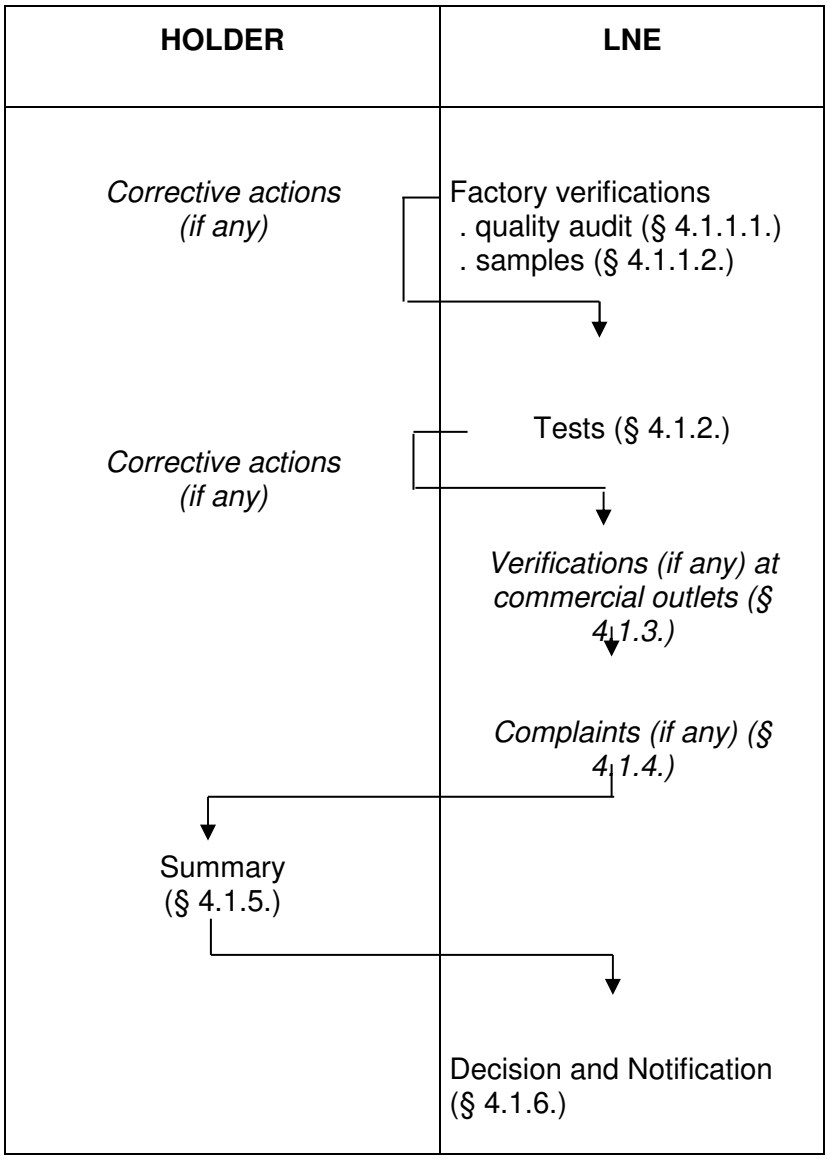
SURVEILLANCE PROCESS



Throughout the duration of the certification, the holder must:

- Comply with the regulations and marking methods described in part 2.
- Systematically inform LNE of any changes to the characteristics of the certified products and/or of the company's structure which may affect certification:
  - modifications concerning the holder (§ 4.2.1.)
  - transfer of the production site (§ 4.2.2.)
  - Change to the certified product, new products (§ 4.2.3.)
  - temporary stoppage of production (§ 4.2.4.)
  - definitive stoppage of production or surrendering the right of use (§ 4.2.5.)

In addition, LNE reserves the right to carry out any checks it deems necessary following:

- a modification concerning the certified product or the quality organisation of the various intervening sites and described in the original certification application file.
- complaints, challenges, disputes of which it has been informed and relating to the use of the NF Mark.

4.1 CERTIFIED PRODUCT SURVEILLANCE PROCESS

LNE arranges monitoring of certified products.
The first follow-up audit occurs no later than six months after the certification decision.

The purpose of this surveillance is to monitor compliance by the manufacturer with the requirements of these certification rules.

The surveillance methods depend on the decisions made as a result of previous inspections.

4.1.1 AUDIT

At least one audit is carried out per year at the main manufacturing site and at the site responsible for the final checks on the certified products.

LNE defines, on a case-by-case basis, which sites are to be audited in addition and the associated frequency among different intervening sites and described in the original certification application.

The duration of the audit can be adapted:

- depending on the sites to be audited in accordance with the requirements of § 3.2.2.1 (with prior consent of the holder)
- if a holder has several authorised agents,
- if several holders use the same subcontractor.

The examinations carried out concern primarily any modifications made since the previous audit that affect manufacturing, inspection methods or organisation of the quality management system.

This quality audit is conducted according to the general principles defined in standard ISO 19011 for conducting a quality audit. In particular, the scope of the audit and details of the procedure are specified in an audit plan sent to the company before the audit.

A sample of products can be taken where necessary during the audit for mark laboratory tests.

During the audit, the auditor will ask for conformity checks to be carried out on the certified products in his or her presence. This is to check the conditions under which the manufacturer carries out inspections. It is preferable to carry out these tests on the type sampled for tests in the mark laboratory.

NOTE: test results obtained during the audit do not prejudge results obtained by the mark laboratory.

With the manufacturer's agreement, the auditor can take a copy of any document he/she considers necessary.

4.1.1.1 Quality audit

The quality management system checks involve verifications during the audit to ensure compliance with the requirements, which are specific to the NF mark (see § 2.2., Part 2).

The on-site audit lasts 1.5 days (including the audit and on-site report writing).

The audit leader prepares an audit report which they give to the holder at the end of the closing meeting, detailing in particular the effectiveness of the quality system set up, the strong points, the points to be improved and a commented report of non-compliance. It also includes the report on tests carried out during the audit and the sampling sheet, if applicable.

A non-conformity is classified as major when, on the basis of objective proof:

- there is a significant risk to the conformity of the product in relation to the specified requirements (these requirements are set out by the reference document, the company or its clients), or
- there is a significant risk in terms of the management system’s ability to control product conformity for a specified requirement, or
- there is systematic or repeated non-compliance with a given requirement.

In all other cases, the non-conformity is classified as minor.

The holder must respond to any notified non-conformity with a causal analysis, corrections and corrective actions. An action plan to address major or minor non-conformities is sent within three weeks following the end of the audit to the Audit Leader for assessment.

In the case of a major non-conformity:

- Tangible proof guaranteeing the implementation of the correction to eliminate this non-conformity must be sent with the action plan.
- LNE must receive tangible proof guaranteeing the implementation of the corrective action associated with this non-conformity within the timeframes it has specified.

In the case of minor non-compliance, LNE must receive tangible proof that guarantees that the correction to eliminate this non-conformity is implemented along with the associated corrective action. Failing that, it will be checked at the latest during the next on-site audit, unless specified otherwise by LNE.

The completed report is sent by e-mail, by LNE to the contact person or people designated by the holder. If applicable, a copy shall be sent to the agent.

Case of companies with a certified quality management system

If the conformity of the quality management system is the subject of a valid certification (whose scope and field includes the sites and activities concerned by the NF standard), and issued by a body accredited in accordance with ISO/CEI 17021, the verification of the quality management provisions is easier.

The audit reports drawn up by the quality management system certifying body must be sent to the auditor or consulted on site.

The duration of the on-site audit is 1 day (including on-site report writing).

4.1.2 SAMPLES

Samples for follow-up tests are either taken by the auditor during the follow-up audit or by the holder at the test laboratory.

LNE notifies the holders of products that are subject to sampling (during the audit or addressed by the holder). The following sampling rules are applied:

Each model is annually tested. For models families, a model of each family is annually tested by alternating the tested models. For example in the case of a models family having two models:

- N+1 tests: model 1
- N+2 tests: model 2
- N+3 tests: model 1
- N+1 tests (next cycle) : model 2
-

If needed the sampling can be adapted by the LNE.

4.1.2.1 Sampling carried out during the follow-up audit

The auditors take the samples required for the compliance tests under the specifications defined in part 2 and which have been validated in accordance with the manufacturer's inspection.

The products are sampled after an inspection of the finished product carried out by the manufacturer. In the event that products are not in stock, the auditor shall indicate to the manufacturer's representative the procedures according to which the equipment to be tested must be sent to the laboratory.

They will be marked by the auditor with a distinctive sign so that they can be authenticated later and sent by and under the responsibility of the manufacturer to the mark laboratory responsible for running the tests, accompanied by the sampling sheet, unless the auditor decides to take responsibility for them.

4.1.2.2 Sample addressed to the laboratory by the holder

At LNE's request, the holder sends the information regarding the requested products straight to the laboratory.

4.1.3 TESTS

Follow-up tests, carried out after the NF mark certification tests are defined vis-à-vis the referenced year of certification *n*.

Tests vary depending on the year of reference, as specified below.

Follow-up tests n+1: A, B, G, C, D, E and N in accordance with the table below
Follow-up tests n+2: A, B, G, C, D and F in accordance with the table below

Follow-up tests n+3 (A, B, G, C, D and M)
The year that follows follow-up tests n+3, the test cycle resumes at follow-up tests n+1.

The tests run by the mark's laboratory on the samples taken during the follow-up audits, and performed in accordance with the standardised methods and specifications of the standards (see part 2) are defined in the table below.

Test type	Technical specifications	Periodic Tests
A - Down-flowing air flow speed	The velocity measurements are made 10cm above the lower edge of the protective window in accordance with § G.3.2.1. of the informative appendix to standard NF EN 12469 and in accordance with § 2.1.5.2.5. The individual speeds must be between + or - 20% of the average, which must not be over 10% of the value defined by the manufacturer. The average air flow velocity of down-flowing air must be between 0.25 m/s and 0.50 m/s in accordance with appendix H of standard NF EN 12469.	yes
B - Incoming air flow velocity	The incoming air flow velocity into the PSM must be above or equal to 0.4 m/s. These measurements are done in accordance with standard NF X 10-112.	yes
C - Sound level	The weighted sound pressure level of the PSM while operational must be ≤ than 64 dB	yes
D - Employee protection	Each test at the operator's position must not exceed 10 UFC. Each non-disrupted test must not exceed 5 UFC, in accordance with § 5.4 (table 4) of standard NF EN 12469	yes (3 Tests)
E - Product Protection	The product's protection is assessed by establishing the contamination of culture dishes distributed over the work surface using a bacterial aerosol created by a canister placed outside the PSM in accordance with § 5.4 (table 4) of standard NF EN 12469. Threshold limit: 5 UFC.	Yes (n+1)
F – Cross-contamination	Protection against cross-contamination is assessed by establishing the contamination of the Petri dish by an aerosol of spores sprayed from the other side of the volume of work in accordance with § 5.4 (table 4) of standard NF EN 12469. Threshold limit: 2 UFC.	Yes (n+2)
G – Alarm checks	Alarms must trigger (part 2 § 2.1.5.2.6. of the certification rules)	yes
H – Temperature check	After nearly 4 hours of continuous operation, the station"s interior temperature, measured in the centre of the work volume, must not rise by more then 8°C compared to the ambient air temperature in the laboratory, (part 2 § 2.1.5 2.1. of the certification rules)	-
I – Lighting check	The measurements are performed 7cm above the work surface in accordance with the mapping of air flow velocity values (see mapped diagram part 2 - § 2.1.5.2.2.) to ensure that lighting is higher than or equal to the threshold value of 750 lux at each of the measurement points	-
J - Cleaning capacity	The test is carried out based on a coloured reaction which demonstrates potential pollution (part 2 - § 2.1.5.2.7. of the certification rules)	-
K - Sterilisation capacity	Taking into account the performance class specified by standard EN 12469 for type II PSMs, only disinfection capacity is required (part 2 - § 2.1.5.2.8. of the certification rules)	-
L - Stability	No tilting under test conditions, in accordance with § 7.4 of standard NF EN 61010-1	-
M - Aerosol test method to detect leaks from the high efficiency filter	The integrity of the high efficiency filter system (HEPA) installed on the PSM is assessed by subjecting the station to an aerosol sprayed upstream and by measuring the flow of the aerosol downstream, in accordance with Appendix D of standard NF EN 12469.	Yes (n+3)

system (HEPA) installed.		
N - Measurement of the position of the limit of the protective barrier	The position of the protective barrier is defined as the sampling probe position for which the particle concentration becomes equal to 0 from the protective window (part 2 - § 2.1.5.2. of the certification rules)	Yes (n+1)
O - Integrity for leakage	The PSM envelope, in which the contaminated air is subject to positive pressure and can escape directly to the outside, must undergo a leak tightness test at a pressure of 500 Pa.	-
P - Electrical safety	Inspections are performed in accordance with standard NF EN 61010-1	-

A report on the tests carried out on the samples evaluated is sent by email, by LNE to the contact person or people designated by the applicant. If applicable, a copy shall be sent to the agent.

IMPORTANT NOTE:

If non-compliant results are detected by LNE, the sample is sent back to the manufacturer.

The manufacturer must then do the following:

- identify the extent of the non-compliance, and whether it applies to other products (identification of products potentially concerned by the non-compliance).
- analyse the causes of the non-compliance
- adopt and implement the corrections to allow the non-compliance to be eliminated for the product(s) concerned by the non-compliance.
- apply the measures specified in part 2 § 2.2.2. (Control of non-compliant product) to inform its customers, recall products and remove the non-compliance.
- send the corrected sample (or another defined by LNE) to the laboratory to carry out relevant tests within a period of three months following the observation of non-compliance results.
- and notify LNE of this.

The holder also informs LNE of any corrective actions adopted following the detection of noncompliance, specifying the associated period.

4.1.4 VERIFICATIONS AT COMMERCIAL OUTLETS

In addition to the previous measures, LNE may request verifications to be carried out in the distribution circuit. The results are sent to the holder concerned.

4.1.5 COMPLAINTS

If there are user complaints, the inspections may include sampling or tests at the places where accepted products are marketed or used (in this case the holder is invited to arrange for representation during the sampling and tests).

4.1.6 SUMMARY TO HOLDERS

A summary of all the inspections carried out is presented by LNE to holders at an agreed frequency.

The documents examined during each session, or sent to holders, must be presented anonymously.

4.1.7 DECISION AND NOTIFICATION

Based on the results of the inspections carried out or any recommendations made by the LNE reading committee, LNE will notify the holder of their decision, which will be one of the following:

a) Renewal of the certificate, possibly with a request to carry out corrective actions.
b) Renewal of the certificate with formal notification to cease the infractions identified within a given time period. This may or may not be accompanied by an increase in the number of checks, tests and audits carried out (which may be unannounced).

c) Suspension of the certification (suspension has a maximum duration of 6 months and is renewable once only. After this, withdrawal of the certification is pronounced.)

d) Withdrawal of certification.

For sanctions b), c) and d), the fees for additional verifications are charged to the holder, regardless of their results. The decisions are enforceable as from the date of notification.

If there is a serious breach of the Certification Rules, LNE may, as a precautionary measure and after confirmation of the breach, take any of the decisions listed above. The decisions thus taken shall be reported to the holders.

Certificates are renewed by periods of 3 years.

4.1.8 APPEAL AGAINST A DECISION

The holder may appeal any decision made under Article 11 of the NF Mark's General Rules. The appeal is filed by registered letter with acknowledgement of receipt within 15 working days.

LNE will initially re-examine the file in light of the facts giving rise to the appeal. It notifies confirmation of the decision or the new decision to the applicant within 30 working days.

Should the applicant wish to maintain its challenge, an appeal may be made by the applicant or certification beneficiary against the decision of LNE.

Explanations for this appeal, which does not have a suspensive effect, must be given. It is lodged by sending a registered letter with acknowledgement of receipt within 15 working days. It is reviewed by LNE upon receipt.

The appeal is presented to the LNE Certification and Impartiality Preservation Committee, which proposes its conclusions after examination.

This last appeal is subject to a lump-sum payment by the applicant.

The company will be informed of the final decision by LNE.

4.2 MODIFICATIONS AND DEVELOPMENTS CONCERNING THE COMPANY STRUCTURE OR THE CERTIFIED PRODUCT

4.2.1 MODIFICATION CONCERNING THE HOLDER

In the case of a merger, liquidation or acquisition of the holder's company, any right to use the Mark that it might exercise shall cease automatically. The holder must inform LNE without delay of any decision likely to result at a later stage either in a modification of the company's legal status or a change in the company name.

Non-compliance with this obligation observed by LNE can lead to suspension or withdrawal of the right to use the NF mark.

The LNE maintains the right to examine, in consultation with the LNE reading committee if appropriate, the terms and conditions for renewed certification, if requested.

In case of merger or consolidation involving only a change of company name, without modification of the product, manufacturing process, material and human resources, quality organisation and methods of control, the NF certificate may be updated upon receipt of written notification of the new company name on the company's letterhead paper.

4.2.2 MODIFICATION CONCERNING SITES COVERED BY THE CERTIFICATION

Before total or partial transfer of an activity described in the application file, the holder shall inform LNE in writing of any new arrangements envisaged. As of the date of transfer, no mention of the mark should be made until receipt of LNE's decision.

The LNE’s decision will be made after it has audited the new site and, if applicable, made a presentation to the LNE reading committee (renewal of the certification or review of a new application with full or partial testing).

4.2.3 CHANGE TO THE CERTIFIED PRODUCT – NEW PRODUCTS

NF certified products shall conform to the technical file that was submitted with the application for acceptance, and shall take into account any observations made when the certification was granted.

Accordingly, any change (including changes to the production and inspection means and the quality management system put in place that may have a decisive influence on production compliance) that the holder wishes to make to the certified products must be reported in writing to LNE.

The request for a new type and/or model will be the subject of an extension request for the right to use the NF mark.

The modification will be examined as shown in the table below. It cannot be carried out until LNE has agreed. LNE must inform the holder of the method of investigation (acceptance, prior testing or referral to the LNE Reading Committee) within 15 days.

The samples necessary to carry out testing will be sent by/under the responsibility of the applicant to the mark laboratory tasked with carrying out the tests. They must be marked so that they can be identified at a later time and they must be accompanied by instructions to identify the lot numbers of the materials used in their manufacture.

Type of change	Application to be sent to LNE	Examination of the application	Change notification conditions
Change in authorised agent	Request as per Form 1a-b-c, Part 3	Complete procedure. The procedure can be simplified in view of the conclusions of the last audit or the last test results if the product covered by the application is identical to the previous certified model.	Upon consultation with the LNE reading committee
Designation of an additional authorised agent	Request as per Form 1a-b-c, Part 3	Complete procedure. The procedure can be simplified in view of the conclusions of the last audit or the last test results if the production and inspection conditions are unchanged with respect to the previously accepted model.	Upon consultation with the LNE reading committee
Application for extension (1) for a new product	Request as per form 1a – b –c part 3 with technical file	On the basis of the file, with tests and audit if necessary.	On the basis of the test results and the audit where applicable (without consulting the LNE reading committee if no particular problems are found)
Modification of the accepted product	Application in accordance with form 1a part 3, description of product changes and test plan	On the basis of the file, with tests if necessary	On the basis test results where applicable (without consulting the LNE reading committee if no particular problems are found)
New commercial reference for a model which has already received the NF standard	Request for continuance (2) as per Appendix 1 and 2 of the current section	On the basis of the file	Without consulting the LNE reading committee
Other cases	Report modifications	On a case-by-case basis	On a case-by-case basis

If the product involved in the request for change has received approval to maintain the right to use the NF mark, the application shall include a new maintenance application, jointly signed by the holder and distributor.

After notification of the change, the first batch (new product or modification to a product) must be inspected by LNE before being marketed, with marketing only possible after obtaining compliant results and with LNE's written approval.

(1) Extension of approval

NF certified products shall conform to the technical file that was submitted with the certification application, and shall take into account any observations made when the right to use the mark was granted.

Any change, even minor (including changes to the means of production and control and the quality assurance system put in place that may have a decisive influence on production compliance) that the holder wishes to make to the certified products must be reported in writing to LNE. This product can only be marketed after receiving written approval from LNE.

Requests for a new model and/or range require a request for an extension to the right to use the NF mark (Forms 1a – 1c described in Part 3 and update of the technical file).

The checks to be made may call for the Mark Committee to be consulted. (A general rule will then be able to be introduced into the certification Rules).

In the case of devices belonging to a single product range, i.e. that call for the same design and the same component architecture and essentially only differ in terms of their dimensions, after a first device has been approved, other devices from the same range may be inspected without it being necessary to perform all the tests described in the rules; in such cases, tests may be limited to checking purposes only:,

- air flow velocities
- efficiency of staff protection according to the microbiological method described in Appendix C of standard EN 12469, and by reducing the number of repeated tests from 5 to 3,
- protection against cross-contamination,
- the protective barrier limit position,
- the sound pressure level
- alarm checks

Test type	Technical specifications	Extension tests (*)
A - Down-flowing air flow speed	The velocity measurements are made 10cm above the lower edge of the protective window in accordance with § 3.2.1. of standard NF EN 12469 and G.3.2.1. of the informative appendix to standard NF EN 12469 and in accordance with § 2.1.5.2.5. The individual speeds must be between + or - 20% of the average, which must not be over 10% of the value defined by the manufacturer. The average air flow velocity of down-flowing air must be between 0.25 m/s and 0.50 m/s in accordance with appendix H of standard NF EN 12469.	yes
B - Incoming air flow velocity	The incoming air flow velocity into the PSM must be above or equal to 0.4 m/s. These measurements are done in accordance with standard NF X 10-112.	yes
C - Sound level	The weighted sound pressure level of the PSM while operational must be ≤ than 64 dB	yes
D - Employee protection	Each test at the operator's position must not exceed 10 UFC. Each non-disrupted test must not exceed 5 UFC, in accordance with § 5.4 (table 4) of standard NF EN 12469	yes (3 Tests)
E - Product Protection	The product's protection is assessed by establishing the contamination of culture dishes distributed over the work surface using a bacterial aerosol created by a canister placed outside the PSM in accordance with § 5.4 (table 4) of standard NF EN 12469. Threshold limit: 5 UFC.	-
F – Cross-contamination	Protection against cross-contamination is assessed by establishing the contamination of the Petri dish by an aerosol of spores sprayed from the other side of the volume of work in accordance with § 5.4 (table 4) of standard NF EN 12469. Threshold limit: 2 UFC.	yes
G – Alarm checks	Alarms must trigger (part 2 § 2.1.5.2.6. of the certification rules)	yes
H – Temperature check	After nearly 4 hours of continuous operation, the station"s interior temperature, measured in the centre of the work volume, must not rise by more then 8°C compared to the ambient air temperature in the laboratory, (part 2 § 2.1.5 2.1. of the certification rules)	-
I – Lighting check	The measurements are performed 7cm above the work surface in accordance with the mapping of air flow velocity values (see mapped diagram part 2 - § 2.1.5.2.2.) to ensure that lighting is higher than or equal to the threshold value of 750 lux at each of the measurement points	-
J - Cleaning capacity	The test is carried out based on a coloured reaction which demonstrates potential pollution (part 2 - § 2.1.5.2.7. of the certification rules)	-
K - Sterilisation capacity	Taking into account the performance class specified by standard EN 12469 for type II PSMs, only disinfection capacity is required (part 2 - § 2.1.5.2.8. of the certification rules)	-
L - Stability	No tilting under test conditions, in accordance with § 7.4 of standard NF EN 61010-1	-
M - Aerosol test method to detect leaks from the installed high efficiency filter system (HEPA).	The integrity of the high efficiency filter system (HEPA) installed on the PSM is assessed by subjecting the station to an aerosol sprayed upstream and by measuring the flow of the aerosol downstream, in accordance with Appendix D of standard NF EN 12469.	-
N - Measurement of the position of the limit of the protective barrier	The position of the protective barrier is defined as the sampling probe position for which the particle concentration becomes equal to 0 from the protective window (part 2 - § 2.1.5.2. of the certification rules)	yes
O - Integrity for leakage	The PSM envelope, in which the contaminated air is subject to positive pressure and can escape directly to the outside, must undergo a leak tightness test at a pressure of 500 Pa.	-
P - Electrical safety	Inspections are performed in accordance with standard NF EN 61010-1	-

(*) in the case of devices belonging to the same range

(2) Application to retain rights

If a manufacturer wishes to change the commercial reference of an approved product, with all technical properties remaining unchanged, it must submit an application to retain the right of use in accordance with Appendix 1 and 2 of this part.

Retention of the right of use is granted without any need for new tests.

NB: any changes to the PSM - even minor - shall be considered as an extension of approval.

4.2.4 TEMPORARY CESSATION OF PRODUCTION

The holder must keep LNE informed of any temporary stoppage of the production of a certified product if the stoppage lasts at least six months.

The holder must request a provisional suspension to the right of use of the mark (maximum length: **1** year) provided they no longer have any products bearing the NF mark in stock. After this time, the right of use will be removed.

Before expiry of the suspension, if production is restarted, the holder must notify LNE which will carry out an audit before the products are marketed under the NF mark.

4.2.5 DEFINITIVE STOPPAGE OF PRODUCTION OR SURRENDER OF THE RIGHT OF USE

If the holder ceases production of an accepted product definitively or if it surrenders the right to use the mark, it must inform LNE, indicating the time it considers necessary for depletion of the remaining stock of products bearing the mark. LNE lays down the conditions under which this stock can be depleted, after seeking the LNE reading committee's opinion if necessary.

The certificate issued by LNE remains valid as long as it remains with the holder of NF-marked product stock, as surveillance checks on certified products are maintained.

APPENDIX 1 of part 4

FORM
MAINTENANCE APPLICATION FOR THE RIGHT TO USE

(to be prepared on the requesting manufacturer's letterhead paper or to be completed with the company stamp and signature of the company's legal representative).

For the attention of the General Manager of
LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
Pôle Certification Plurisectorielle
1, rue Gaston Boissier
75724 PARIS Cedex 15 - France

Purpose: Application to retain the right to use the NF mark NF Mark-Microbiological safety stations

Dear Sir,

In my capacity as..... (1), representing the company .....(2), I kindly request to maintain the right of use of the NF mark for the products listed below, in accordance with the certification rules for NF 095

which differ from the products admitted to the NF mark only by the brand and the commercial reference.

This application pertains to products sold through means of (3):

Reference of the NF certified basic model	Corresponding certificate	New mark(s)
Trademark and commercial reference already approved	Certificate no.	and/or requested trade reference(s)

The commitment from the above-mentioned distributor is attached to this application (see Appendix 2), along with the following documents:
- Certificate of national or international registration for the mark(s) or commercial reference(s) forming the object of the application,
- Proposed product marking
- Instructions and commercial documentation

Stamp and signature of Holder
or of authorised agent (*):

Date

---

(1) Position
(2) Identification of the company (head office)
(3) Distributor's name and address
(*) Concerns a manufacturer outside the European economic area

APPENDIX 2 of part 4

DOCUMENT ENCLOSED WITH THE MAINTENANCE APPLICATION FOR THE USE OF THE NF MARK - MICROBIOLOGICAL SAFETY STATIONS

(Distributor's undertaking to be written on the distributor's letterhead paper)

I the undersigned,_____

acting as_____

of the company: _____

recognise that by placing my trademark: _____, to replace /be added to that of the above-mentioned models, I am committed to the associated liabilities.

In particular, I declare that I hold an exclusive right to use these trademarks and references, having registered them in compliance with industrial property legislation in force,

and I agree to market the abovementioned model(s) for which this application is made without making any change of any type whatsoever.

Issued at on

Signature

Distributor's stamp:

Stamp and signature of Holder
or authorised agent:

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

Organisme certificateur mandaté par
AFNOR Certification

CERTIFICATION RULES

NF MARK-MICROBIOLOGICAL SAFETY STATIONS

PART 5

PARTICIPATING ORGANISATIONS

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Rev. 6 – December 2023

National Metrology and Testing Laboratory • Public Industrial and Commercial Institution
Head Office: 1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tel. : 01 40 43 37 00 - Fax : 01 40 43 37 37
info@lne.fr • lne.fr • RCS Paris 313 320 244 - NAF : 7120B - TVA : FR 92 313 320 244

5.1. AFNOR CERTIFICATION

AFNOR is the owner of the NF mark and has granted an exclusive operating licence to AFNOR CERTIFICATION. AFNOR Certification manages and oversees the NF certification system, which defines the rules of governance and the modalities of operation of the NF mark.

5.2. MANDATED BODY

AFNOR Certification entrusts management of the Mark application to LNE.

LNE is thus accountable to AFNOR Certification's for all management operations entrusted, in accordance with Article 3 of the NF mark's general rules.

All persons involved in the NF mark process are bound to professional secrecy under Article 8 of the General Rules of the NF mark. If necessary, on request from manufacturers, an agreement can be signed between LNE and the manufacturer.

5.3. AUDIT BODY

LNE entrusts audits to the following organisations:

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (LNE)
1, rue Gaston Boissier
75724 PARIS Cedex 15 - France
Tel. 01 40 43 37 00

However, it may call upon the expertise of duly qualified external auditors according to LNE's procedures. This outsourcing of audits is formalised in the form of contracts (due to independence and confidentiality requirements).

The holder or applicant must facilitate the operations that officers in charge of audits and inspections must perform as part of their assigned duties.

LNE must be informed of any challenge concerning the members of an audit team within 10 days from when the audit team receives the notification in order for it to be taken into account.

5.4. TEST BODIES

The LNE entrusts tests to the mark laboratories named below:

LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS
.
Direction de la Métrologie Scientifique et Industrielle (Directorate of Scientific and Industrial Metrology - DMSI)
1, rue Gaston Boissier
75724 PARIS Cedex 15 - France
Tel. 01.40.43.37.00

5.5. GUIDANCE COMMITTEE

5.5.1. COMMITTEE COMPOSITION

It is made up of a guidance committee. All holders, experts and, where applicable, various interested parties are invited to participate in the guidance committee.

The guidance committee remit is to:
- provide an opinion on the certification rules and changes to the process.
- give an opinion on projects for communication or promotional activities relating to the mark. A special budget must be validated by the committee and earmarked for promotional activities,
- give an opinion on the summary of all inspections conducted. The guidance committee must give these opinions in compliance with principles of impartiality.

The Guidance Committee recommendations are adopted unanimously, unless otherwise indicated in the report.

LNE calls the members of the committee together or informs them in writing at least once a year to present a summary of all the checks performed.

All committee members undertake to:
- contribute their expertise to the operation of the NF mark,
- maintain confidentiality on all information of an individual nature that is provided, and until this publication by AFNOR Certification or LNE,
- attend meetings regularly, and if necessary, regularly inform their deputy, and to communicate all relevant documents,
- contribute to the development of the NF mark that is to say, promote products or services certified under the mark.

The members have a mandate that is renewable by tacit agreement.

In order to preserve the credibility and effectiveness of the Committee's work, LNE reserves the right to terminate a member's mandate in the following cases:
- non-compliance with the confidentiality agreement,
- repeated unjustified absences from meetings,
- failure, in general, to comply with the above commitments.

LNE coordinates the committee and aims for consensus in its opinions.

Members of the Guidance Committee exercise their functions on a strictly individual basis. However, if a member is absent, a proxy is appointed by LNE.

LNE draws up the minutes of the committee meeting with the comments and proposals put forward, as well as any views opposing the opinion delivered by the committee. These minutes are sent to all members of the Guidance Committee.

If necessary, LNE invites AFNOR Certification to take part in committee meetings.

As part of the revision of the certification rules, LNE organises the consultation and the validation of the certification reference documentation (notably with consultation with AFNOR Certification as a stakeholder).

5.5.2. GUIDANCE COMMITTEE COMPOSITION

The guidance committee is composed of NF PSM mark stakeholder representatives. The list of committee members detailed below is indicative, non-exhaustive and can be modified as necessary. LNE updates the complete list of committee members.

Certifying body
The representative(s) of the mandated body: LNE – Pôle Certification

Manufacturers, Distributors
All NF mark holders

Users and prescribers
Representatives from:
- ASPEC (Association for the Prevention and Studying of Contamination)
- IRM
- Hospital Sector
- CNRS
- Institut Pasteur INSERM

Bodies, laboratories and experts
The representative(s) of the test laboratories
The AFNOR Certification representative

Government
Representatives from:
Ministry of Labour

5.6. LNE READING COMMITTEE

The reading committee is responsible for handing down an opinion on the certification decision and is composed of at least:
- one management representative (who can act as certification project manager having not participated in the audit),
- a certification project head independent of the file presented (who has not participated in the audit and is not in charge of the file),
- a certification project head in charge of presenting the file.

The committee is chaired by the LNE management representative.

The reading committee is responsible for:
- reviewing the audit and test reports and formulating an opinion and a recommendation on the decisions to be taken,
- where appropriate, considering in the first instance appeals against decisions of LNE and formulating an opinion on the follow-up,
- evaluating the quality of reports.

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

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PART 6

APPLICABLE FEES – TERMS OF PAYMENT

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The pricing schedule for the current year is available free of charge on LNE's website (www.lne.fr) or on request from LNE.

6.1. APPLICABLE FEES

Fees for the services involved in obtaining certification and surveillance of certified products are indicated in a list of charges which may be revised annually. The list of charges for the current year is sent to all holders of the mark.

A special budget is decided upon in consultation with the holders and earmarked for promotional activities.

The fees are given in Euros, excluding tax. With regard to test fees, samples must be delivered to the mark laboratory carriage-free and customs-cleared if necessary.

6.1.1. LIVING AND TRAVELLING EXPENSES

Living and travelling costs are payable by the applicant or holder.

Living and travelling expenses are invoiced as follows:

Travel in mainland France

- travel expenses
Meal-related and accommodation expenses incurred by LNE (except those directly paid by the manufacturer) are subject to an all-in charge per night spent at the location.

- travel expenses
travel expenses incurred by LNE (except those directly paid by the manufacturer) are subject to an invoice based on their actual cost.

Travel abroad

Food and accommodation expenses incurred by LNE (except those directly paid by the manufacturer) are subject to an all-in charge according to the scale applicable to the country concerned.

Travelling expenses incurred by LNE (except those directly paid by the manufacturer) are subject to an invoice based on their actual cost.

6.1.2. CANCELLATION OF AN AUDIT

Cancellation of an audit whose date has been fixed by agreement between LNE and the audited company is invoiced as follows:

- cancellation 15 days to 8 days before the scheduled date: 50% of the audit fee
- cancellation 7 to 3 days before the scheduled date: 75% of the audit fee
- cancellation 2 days before the scheduled date: 100% of the audit fee.

Travelling expenses can be invoiced up to 100% if they are not reimbursable or subject to retention/penalties.

6.2. TERMS OF PAYMENT

6.2.1. COLLECTING PAYMENT

The LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (NATIONAL LABORATORY OF METROLOGY AND TESTING), the mandated body, is authorised to collect all payments due.

Invoices issued by LNE must be paid within 45 days.

The applicant or holder must settle these invoices under the terms set out: any failure on the part of the holder will prevent LNE from exercising the inspection and operating responsibilities incumbent on it by virtue of these regulations.

If the first enforcement order, sent by registered letter with acknowledgement of receipt, does not result in payment of the total amount due within one month, LNE will be entitled to take precautionary measures regarding the certifications issued under the NF mark, for all the holder's accepted products.

6.2.2. OBTAINING CERTIFICATION

The services correspond to examination of the files, the audits and tests, for each application.

The fees relating to the evaluation of the application are paid once, at the time the application is submitted, and they are for: the evaluation of the application, the presentation of the case to the standard committee and the general functioning of the standard.

No fees relating to examination of the application can be refunded, regardless of the result of the examination.

6.2.3. CERTIFIED PRODUCT SURVEILLANCE

Sums charged correspond to NF mark usage rights paid to **AFNOR Certification**, file monitoring, audits and tests.

In the event of approval during the year, billed amounts correspond to the services provided; file monitoring (technical investigation of the file) is billed *pro rata*.

Following product certification, the holder is billed **by the LNE** for an annual right to use the NF mark, paid to **AFNOR Certification**.

This licence fee is intended to cover:

- general operation of the NF mark (monitoring of bodies in the NF network, management of the NF mark committee)
- defence of the NF mark: filing and protection of the mark, legal advice, processing of abuses of the NF mark, court fees,
- contribution to the general promotion of the NF mark.

The charge for file monitoring (technical investigation of the file) is non-refundable even if the certification is withdrawn or suspended following a decision by LNE or at the request of the holder.

As long as the holder holds stock of NF-marked products, inspections are maintained as well as the billing of related costs, as file monitoring (technical investigation of the case) is billed *pro rata*.

6.2.4. ADDITIONAL VERIFICATIONS

Costs resulting from additional verifications resulting from a decision by LNE are payable by the applicant/holder, regardless of the results.