SPECIFIC RULES FOR THE CERTIFICATION OF SENSOR SYSTEMS FOR AIR QUALITY MONITORING

ENVIRONMENTAL INSTRUMENTATION CERTIFICATION

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1. SCOPE OF APPLICATION

This document provides the specific rules for the certification of sensor systems (also referred to as "products" in this document) for air quality monitoring.

This voluntary certification is intended for manufacturers and distributors of sensor systems wishing to certify the performance of products which have been placed on the market.

This certification does not replace the technical conformity assessment carried out by the Central Laboratory for Air Quality Monitoring (LCSQA) on equipment intended for regulatory measurement in accordance with Directive 2008/50/EC on "Ambient Air Quality and Clean Air for Europe".

Under no circumstances does the certification according to these rules alone entitle the holder to claim, unless explicitly stated on the certificate:

- Compliance with regulatory constraints relating to the products concerned,
- Compliance with regulatory constraints relating to the manufacture of products.

2. REFERENCE DOCUMENTS

– ISO Standard 17065 (June 2018) "Conformity assessment - Requirements for bodies certifying products, processes and services".

3. DEFINITIONS

See below several definitions which are useful for understanding this document:

Certificate:

A dated statement issued by a third party, relating to products, processes and systems in accordance with a certification reference system.

Certification scheme:

Technical document(s) defining the characteristics that a product must have and the procedures for checking compliance with these characteristics, as well as the certification communication procedures. The reference frame must define as a minimum:

☞The beneficiaries of the certification;

☞The prerequisites for certification, where applicable;

☞The specifics of the use of the certification reference scheme in certain geographical areas, if use may differ depending on the area;

☞The specific assessment procedures or applicable standards.

Certification Body:

The certification body is responsible for applying the certification scheme. It makes the decisions after assessments have been carried out. It issues certificates and monitors certified products. It deals with appeals, redress and complaints.

Assessment body:

The assessment body is named by the certification body. It determines the scope of the assessment service. It directs the different stages of the assessment, either for an initial application or monitoring:

- Assessment of admissibility
- Test management
- Performance of audits
- Analysis of the results of the different phases of the assessment to advise the certification body.

Applicant:

Legal entity representing a company which manufactures or supplies the product and which is applying for the certification. The applicant assumes control over and responsibility for compliance with all the requirements defined in the specific certification rules. The applicant is the holder of the certification.

Representative:

Where the applicant/holder is not based in the European Community, he/she must appoint a representative.

A legal or natural entity based in the European Economic Area (E.E.A.) which has a representative function for the applicant/holder outside the E.E.A. and has a written mandate from the applicant/holder stating that they can act on their behalf in the certification process in accordance with the provisions of the applicable certification rules. The representative may also be a distributor or importer of the certified products, in which case its different roles are clearly identified.

A manufacturer may file applications for several representatives. Each application is considered separately, in which case, the product model must be different for each representative.

Distributor: Legal entity distributing the products of the applicant/holder or their representative and not involved in the manufacture of the product or its packaging. When the distributor places the certified products on the market independently of the agent, they confirm that compliance with the provisions of the applicable certification rules has been confirmed.

The kinds of distributors permitted are as follows:

- Distributors who distribute the product under the holder's trademark and model name. In this case, it is not required to take any steps regarding the certification.
- Distributors who distribute the product changing the trademark and model name. The applicant/holder and the distributor must apply for ongoing certification.

If it is the distributor's wish not to make any explicit reference to the manufacturing site, a request for certification must be made by the distributor. In this case, the manufacturing site will not be mentioned on the certificate.

Depending on the operations carried out by the applicant/holder or the distributor (e.g. reconditioning by the distributor), the provisions applicable to each party in the context of initial certification or monitoring are defined on a case-by-case basis.

Sensor system:

Hardware which integrates at least one sensor (or a sensitive element) and software to detect a quantity and/or measure a concentration of compounds (gas, aerosol) in a predefined time step.

Note 1: A sensor system should have the following basic components (or functions), which should be adapted to fit the usage:

- the collection system;
- the supply system;
- data processing;
- data storage ;
- transmission and/or visualisation or restitution of data;
- the box.

Note 2: The measuring information may relate to the sensor system, to the sensors which are part of it or to the sensitive elements separately.

Note 3: The following terms are also used to refer to a sensor system: "single/multi-sensor system(s), mini station, pod, sensor node".

4. ASSESSMENT BODIES

4.1. GENERAL PROVISIONS

The bodies in charge of assessment as designated by the "Environmental Instrumentation Certification" (CIE) association, to carry out the assessment operations described in this reference certification scheme, are the founding members.

- INERIS - French National Institute for Industrial Environment and Risks - Parc technologique Alata • BP 2 • F-60550 Verneuil-en-Halatte

- LNE – French National Laboratory of Metrology and Essays - 1 rue Gaston Boissier 75724 Paris Cedex 15

Each body which is responsible for the assessment ensures or has ensured the application of the sensor system assessment protocol with the reference MO-1347, and applies the requirements described in this document.

4.2. USE OF THE TRADEMARK

As part of the activity pursuant to the certification scheme, the association "Environmental Instrumentation Certification" (CIE) holds the certification brand and the associated logo below, confirming compliance with the provisions of the certification scheme. The Air Quality Sensor certification trademark is an integral part of product certification.

Image 1: Air Quality Sensor certification mark logo

In addition to the identification of a certified product and ensuring traceability, brand product labelling ensures better protection for users and enables holders to stop misuse and counterfeiting.

The certification holder undertakes to comply with the logo's terms and conditions of use. These conditions will be communicated to them together with the product's certificate of conformity.
The certified product is designated and identified separately from non-certified products. The holder may only use the trademark to designate certified products without there being any risk of confusion with other product, in particular with products which are not certified under the "Air Quality Sensor" certification.

Both the certificate reference and the product performance rating for the parameter that has been assessed (cf. § 6.1) are displayed underneath the trademark logo.

5. COMMITMENTS OF THE APPLICANT/HOLDER

In general terms the applicant/holder undertakes to provide the assessment body with the means to carry out the operations necessary to correctly assess their dossier and in particular to:

- meet at all times the requierments set in the certification rules and, in the event of changes to these certification rules, implement all changes needed within the time limits set by the CIE association;
- send the information and working documents required for the smooth performance of the assessment to the representatives authorised by the assessment body;
- only transfer information which the applicant/holder has ensured is honest and truthful;
- appoint a representative as the main contact person for the assessment body;
- where appropriate, designate persons within the company to be the recipients of the test and assessment reports issued by the assessment body, and, in the event of a change of recipient within the company or of a change of e-mail address, to inform the assessment body of any changes that need to be taken into account;
- where appropriate, to introduce the staff to the authorised representatives of the assessment body who have been assigned to the various tasks;
- where appropriate, give instructions to its staff to work with the authorised representatives of the assessment body, and agree to take part in any interviews;
- where appropriate, provide the authorised representatives of the assessment body with means of access and transport within the sites and places of work, including to subcontractors' sites;
- where appropriate, inform the authorised representatives of the assessment body about the safety and health provisions and instructions which are applicable to the sites and places of work and to its staff, and to make available to them any equipment which may be necessary to comply with said health and safety provisions;
- pay the sums due to the body in charge of the assessment body, in accordance with the financial terms and conditions as defined and duly accepted by the applicant/holder;
- take the necessary measures in the event of non-compliance, within the time limits specified by the assessment body;

- if appropriate, return the duly completed non-conformity sheets to the audit manager within 3 weeks of the final day of the audit;

- if appropriate, implement the required actions in order to enable the certificate to be issued within a maximum of 11 months after the initial assessment. After this period, a new initial assessment will have to take place before certification can be granted;

The certification holder is also responsible for carrying out the following tasks:

- affixing the "Air Quality Sensor" label only to products which are covered by the certificates issued by the certification body and which comply with the requirements that apply;

- using the business name of the product only for those products that are covered by the certificates issued by the certification body and which comply requirements that apply;

- as soon as available, sending to the assessment bodies any product modifications or information likely to affect conformity with the requirements of the certification rules that apply;

- making available any data or information required by the assessment bodies to issue and preserve the certificate;

- keeping a record of all complaints of which, the holder has become aware regarding the product's (s') conformity with the certification requirements and make these records available to the assessment bodies upon request, and
    - taking all appropriate action in relation to these claims and to any imperfections found in the products that may affect their compliance with the certification requirements.
    - keeping records of the actions taken,

- in the event of the suspension, withdrawal or refusal for the certification to be renewed, to cease all references to the certification of the products concerned and to cease using all communication media which refer to it;

- authorising follow-up assessments to be carried out in the course of the certificate's three-year validity period, as well as any properly justified additional assessments;

- making statements regarding certification which are consistent with the certificate's scope;

- not to use the certification issued by the certification body in a way that may be detrimental to it, nor to make any statement concerning the certification of its products which the certification body may consider to be misleading or unauthorised;

- reproduction of certificates in their entirety, including the annexes should they need to be transferred to a third party.

6. OPERATION

6.1. INITIAL AWARDING OF THE CERTIFICATION

The certification of a product mainly involves analysing the request against the certification scheme. A product is certified when the outcome of the product assessment makes it possible to ascertain that the product has met the requirements of the reference scheme.

Depending on the complexity of the product, the certification offer is issued once the application has been made or after a preliminary assessment of the application and whether it is admissible have been carried out.

The following steps are required for the initial awarding of the certificate for a sensor system and for measuring specific pollutants:

1. Application for certification submitted to the certification body,
2. Designation of an assessment body by the certification body,
3. Study of the admissibility of the applicant's file,
4. Assessment of the product to be certified according to the protocol for the assessment of sensor systems for air quality monitoring, (MO-1347)
5. Assessment of the design and manufacture of the product and of the applicant's quality system during an audit, depending on the audit reference frame (PR-1086),
6. Awarding of the certificate of compliance with the standard and a performance rating valid for a period of three years,
7. Specification of the annual monitoring arrangements during the period in which the certificate is valid.

There are three performance divisions depending on the outcome of the tests performed on the products and the observations made in the course of the audit. The ratings are A, B and C.

The measurement criteria for identifying the metrological performance rating for a given system and pollutant are set out in the protocol for the assessment of sensor systems for air quality monitoring (MO-1347). The metrological performance division is coupled with the audit observations to define a rating for the overall performance of the sensor system and per pollutant. These performance ratings are associated with the intended use of a sensor system as described below:

Division A: category of data quality objectives defined in the evaluation protocol MO-1347 and compliant with the data quality objectives (uncertainty, data capture) for Indicative Measurement as described in the Directive 2008/50/EC.

Division B: category of data quality objectives defined in the evaluation protocol MO-1347 and compliant with the data quality objectives (uncertainty, data capture) for Objective Estimation as described in the Directive 2008/50/EC.

Division C: category of data quality objectives defined in the evaluation protocol MO-1347 but that are out of the scope of the Directive 2008/50/EC. For this division, the level of requirements in terms of uncertainty is only sufficient for citizen science studies, educational action, etc.. defined as Awarness Studies

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6.2. CONSTITUTION OF THE CERTIFICATION APPLICATION FILE

When the applicant is not from a country within the European Economic Area, they must submit their application jointly with a representative established within the territory of the European Economic Area, that has been duly appointed and responsible for all production likely to be covered by the "Air Quality Sensor" trademark and marketed on French territory. They are designated as the "Representative".

The following documents (written in French or English) must be sent to the certification body.

- Standard letter requesting certification copied onto the manufacturer's letterhead;
- General information sheet and the list of products for which the Air Quality Sensor certification is requested;
- Specific technical file: refer to the assessment protocol for sensor systems for air quality monitoring (MO-1347)

The certification body designates an assessment body and forwards the dossier to it. The assessment body acknowledges receipt of the application and indicates whether additional information may be required.

The application is then examined by the assessment body based on the certification reference scheme.

6.3. REVIEW OF THE APPLICATION FOR CERTIFICATION

- Assessment of the sensor systems - metrological tests in the laboratory and on site

Tests are carried out on sensor systems for which an application for certification has been made in accordance with the MO-1347 protocol for the assessment of sensor systems for air quality monitoring.

These tests determine the metrological performance rating of the sensor systems according to the methods and criteria described in the protocol for assessing sensor systems for air quality monitoring.

The laboratory and on-site tests are carried out on at least three strictly identical models of candidate sensor systems. Test results cannot be accepted for certification if fewer than three devices are tested according to the MO-1347 operating procedure. At the end of the tests, the devices are returned to the applicant.

The tests carried out in the laboratory by the applicant can be used by the assessment body if:

- the organisation which has carried out the tests can demonstrate that it meets the quality management and general testing requirements of this certification scheme through its valid accreditation according to ISO/IEC 17025 for the test and calibration methods which relate to these tests

or

- the organisation which carried out the tests has received a successful assessment from the metrological verification body by an audit. This audit is carried out on based on the ISO/CEI 17025 standard in its most recent version and the assessment of sensor systems MO-1347 protocol. The audit includes in particular the identification of the means upstream of the tests. The audit is carried out at the applicant's expense.

The organisation shall provide a validation file of the identification of the atmospheres generated in the enclosure at any point in the enclosure. At least 5 points must be identified, as described in the MO-1347 evaluation protocol.

The expert responsible for the assessment will decide on the qualification of the structure in charge of the tests.

- ## Audit of the applicant's quality, design, manufacture and release of the product system

The initial certification audit performed at the applicant's expense, is carried out in accordance with the general principles defined by the ISO 19011[1] standard for performing a high-quality audit; the scope of the audit and the details of how it is to be undertaken are specified in an audit plan sent to the applicant beforehand.
The audit is performed by an audit team which should include a qualified technical expert in metrology accepted by the assessment body in the field of air quality, and an auditor accepted by

[1] NF EN ISO 19011 (July 2018) "Guidelines for auditing management systems"

the assessment body to carry out audits in accordance with the ISO 9001 standard in its current version. These two roles can be performed by the same person.

The way in which the audit is organised is defined by each assessment body.

These include:

- The admissibility of the certification request
- Audit planning
- Submission of the audit report
- Any exchanges between the applicant and the assessment body after the audit: response to cases of non-conformity, possible disputes and any other exchanges.

The audit is carried out in accordance with the "Quality audit of sensor system manufacturers and distributors" PR-1086, which defines the scope of the audit.

The length of the audit is calculated by the assessment body on the basis of criteria as defined in the PR-1086 audit reference scheme .

When any cases of non-compliance are identified, the applicant shall complete the various sections of the non-compliance sheets and send them within the agreed time limit to the lead auditor for assessment.

The person responsible for the audit draws up an audit report which they give to the applicant, specifying particularly the effectiveness of the quality system put in place, the strong points, the areas for improvement and an explicit statement identifying non-conformities if they exist.

- Decision and notification

On the basis of the findings:

- in the assessment reports established in accordance with the MO-1347 protocol,
- in the audit report,

the assessment body sends its appraisal of the product's compliance to the CIE association. If the opinion is favourable, the CIE association issues a certificate of compliance for a given use, in a specified technical configuration which determines the performance division attributed to the parameter assessed.

This dated certificate is valid for three years and is identified by a certification number linked to the manufacturer determined by the CIE association.

The tables of the parameters of metrological performance for field and laboratory tests for each pollutant assessed are appended as annexes to the certificate and must be sent as attachments to the certificate.

The certificate is issued at the applicant's request, and all completed and active certificates are posted on the LNE and Ineris websites. At the applicant's request, it is possible for a certificate not to be issued, in which case an assessment report will be given to the applicant.

A decision may be postponed in order to examine the application more thoroughly.

The right to use the "Air Quality Sensor" trademark is granted in accordance with the certification decision issued by the CIE association, and is strictly limited to the duly defined products.

In the event of a refusal to grant, the applicant is informed of the results of the assessment as described in §7.3.

7. CONDITIONS FOR RETAINING, EXTENDING, REDUCING OR REFUSING CERTIFICATION

7.1. SURVEILLANCE

During the validity of the certificate, monitoring operations are carried out at regular intervals. The monitoring operations are adapted according to the system performance division and the observations made during the audit and during the metrological assessments. These monitoring operations are commercially-provided services.

- Monitoring of sensor systems of division A and B

Follow-up audits are carried out annually in accordance with the procedures described in paragraph 6.3.2 above and the PR-1086 audit framework.

The first monitoring audit is carried out within a maximum period of twelve months after the certification decision and the awarding of the performance rating are made. The second surveillance audit takes place within 8 to 12 months after the first monitoring audit.

Holders certified in accordance with ISO 9001 by a certification body accredited in accordance with ISO 17021 are audited once in the certification cycle within 16 to 18 months after the certification decision has been taken.

Monitoring via partial tests: Partial tests are carried out at each monitoring audit on the basis of sampling. Partial testing includes the assessment of the following performance characteristics: accuracy, linearity, definition of the detection limit and repeatability. The partial tests are to be carried out as described in sections 4.3.1 and 4.3.2 of the MO-1347 protocol for the assessment of sensor systems for air quality monitoring. To achieve this the holder must ensure that all certified product models are made available to the auditor. The auditor takes the samples that are required for the tests and that have been validated in accordance with the manufacturer's test plan.

Model sampling consists of taking three units of the same batch, along with the instructions for use, in order for them to be checked. The samples taken are marked by the auditor with a distinctive sign, enabling them to be authenticated at a later date.

Depending on the results obtained during the assessment carried out during the initial application or when applying for renewal of the certificate according to the assessment of sensor systems for air quality monitoring MO-1347 protocol, additional partial tests may be requested to check certain metrological parameters. This request is proposed by the body in charge of verification in its advice provided to the certification body during the decision-making and notification phase, as described in paragraph 6.3.3 of this document.

The laboratory tests carried out by the applicant can be used by the assessment body as described in paragraph 6.3.1 of this document.

- Monitoring of sensor systems of division C

Each year, the holder shall send the assessment body the number of sensor systems covered by the certificate it has sold. Partial tests shall be carried out by the assessment body pro-ratad to the number sold. Partial testing includes the assessment of the following performance characteristics: accuracy, linearity, definition of the detection limit and repeatability. The partial tests are to be carried out as described in sections 4.3.1 and 4.3.2 of the MO-1347 protocol for the assessment of sensor systems for air quality monitoring. The first partial test shall be carried out within a maximum of 12 months after the certification decision and the awarding of the performance rating. The second partial test takes place within 8 to 12 months after the first partial test.

The number of tests is determined as follows:

Number sold	Number of partial tests
0 to 1000 products	1
1000 to 10,000 products	2
Over 10,000 products	3

The laboratory tests carried out by the applicant can be used by the assessment body as described in paragraph 6.3.1 of this document.

7.2. RETAINING THE CERTIFICATION

It is the responsibility of the holder to inform the body which has performed the assessment of the product concerned of any modifications made to the product, whether this modification is made to the hardware elements of the sensor system (hardware, change of design, materials, suppliers, trade name, etc.) or the data processing software (software and firmware integrated into the product or data processing outsourced to the Cloud). The holder must precisely describe the modification made to the sensor system and its impact on the results of the measurements it takes.

After reading the declaration, the assessment body may request a complete technical file which will be analysed. This analysis is available as a business service.

Depending on the level of modification, different additional assessments may be recommended in order to retain the certificate. If the assessment results are positive, a letter or a report (for an audit or additional tests) is given to the applicant to justify the certificate being retained. If the assessment results are unfavorable, the holder is informed of this by letter, as described in paragraph 7.3 of this document.

- Minor modification

These are modifications that do not affect the results of the measurements. This type of modification does not require an additional assessment for the certificate to be retained. The technical file submitted to the assessment body must be able to substantiate that this modification does not impact the results of the metrological performance of the system. The assessment body shall confirm whether the modification is of a minor nature or not.

- Moderate modification

This is a modification that has a limited impact and does not change the fundamental principles of the system's operation. The assessment body shall determine the impact of this modification by using the most relevant of the following means to judge the impact of the modification:

- Assessment of the tests performed by the manufacturer guaranteeing that there is no impact on the metrological performance of the product. This method can only be used if the holder's methods of internal testing have been audited, and the conclusions of the audit have been judged as satisfactory by the assessment body.
- Performance of validation tests recommended by the organisation in charge of the assessment. These tests may be carried out:
    - Externally by one of the assessment bodies
    - Externally by a laboratory accredited in accordance with ISO 17025 and whose recommended tests fall within the scope of accreditation,
    - Internally if the holder's testing facilities have been audited as is described in paragraph 6.3.1, and the conclusions of the audit have been judged as satisfactory by the assessment body.
- Design audit. This audit will be carried out based on the design requirements in accordance with audit reference PR-1086.

- Major modification

This is a modification that affects the basic principles of the system operation and may alter the measurement results. The performance rating attributed to the system may be challenged. This type of modification requires a new metrological assessment of sensor systems for air quality monitoring (MO-1347), to be carried out in the laboratory and on site.

The laboratory tests carried out by the applicant can be used by the assessment body as described in paragraph 6.3.1 of this document.

If it is required by the extent of the modifications, the certificate is then updated, for example: a change in the commercial name of the product, the serial number on which the modification was based.

- Monitoring the versioning of the sensor system

The applicant shall inform the assessment body of its versioning system, with the version of the sensor systems being indicated on the certificate; this is to be clearly identified and defined. If the certificate holder changes the version number, the certificate holder must inform the assessment body of this change, specifying the modifications that led to the change of version. If minor changes result in a change of version, the certificate may be updated to cover a range of versions.

7.3. REFUSAL OF CERTIFICATION

Certification may be refused if:

- One of the requirements described in the reference document and its associated procedures is not met,
- One of the potential issues of non-compliance, as identified during the initial audit, has not been remedied.

The reason for refusal will be explained to the applicant by the assessment body.

8. WITHDRAWAL / SUSPENSION OF CERTIFICATE

The certificate may be suspended/withdrawn if:

- The monitoring as described in chapter 7.1 is not carried out,
- any non-conformity found during the initial audit or monitoring audits have not been dealt with,
- manufacturing of non-compliant products,
- failure to comply with the brand's charter of use,
- wrongful use of the certificate.

When a certification is suspended, during the suspension period the applicant may not make any declarations which may mislead another party as to the status of their certification. They shall cease to use the certification label on products manufactured after the date on which the suspension notification is issued.

During this suspension period, no products identified by the "Air Quality Sensor" label shall be placed on the market, and products which may no longer meet the requirements for certification shall be subject to corrective action, including a product recall if necessary.

If a recall is necessary, the holder must stop displaying its certification and take all measures to remove the display of its certification from its commercial and technical documents, advertising inserts and signs, as well as from all documentation of any kind.

Products that have been supplied to a user before the certificate is withdrawn are not affected.

9. RENEWAL OF THE CERTIFICATE

No less than six months before the certificate expires (validity lasts three years), the holder applies to the assessment body for renewal.

The renewal of the certificate is dependent on:

- the performance of metrological assessments as described in paragraph 6.3.1 of this document.
- the performance of an audit in accordance with the methods described in paragraph 6.3.2 of this document.

10. APPEALS, CLAIMS AND DISPUTES

The applicant/holder may contest any decision taken concerning him on the basis of supporting evidence by contacting the assessment body.

Appeals, complaints and disputes are to be forwarded to the Chairman of the Board of Directors of the "Environmental Instrumentation Certification" (CIE) association for examination by the said Board.