



Rules for Conformity Assessment of Non-Automatic Weighing Instruments in accordance with Directive 2014/31/UE (NAWI)

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Technical Rules

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CHAPTER 1. GENERAL

1.1

These Rules describe the procedures applied by RINA Services S.p.A. (hereinafter referred to as "RINA") for Conformity Assessment of Non-Automatic Weighing Instruments (NAWI) in accordance with the provisions of D. Law no. 83/2016 and any subsequent amendments (hereinafter referred to as D.L. 83/16) based on European Directive 2014/31/UE (hereinafter referred to as 'NAWI Directive' or 'Directive'), and the modalities that Organisations must observe to request, obtain and maintain this certification.

1.2

All Organisations can apply for certification irrespective of whether they belong to any Association/Group or not. For the certification activity RINA will apply its tariffs in force, ensuring fairness and uniformity of application.

1.3

The certificate relevant to non-automatic weighing instruments is issued by RINA to the applicant Organisation, where the term Organisation refers to a public or private company, enterprise, firm, body or association, either legally recognized or not, acting with its own functions and administration or a natural person. In the presence of Organisations with several operational units, a single operational unit can be defined as Organisation.

1.4

Any information acquired during the certification activity is considered and treated as confidential.

1.5

These Rules use the terms found in the NAWI Directive.

1.6

RINA's identification number to be applied on the plates of non-automatic weighing instruments covered by RINA certification is **0474**.

This number must be affixed in accordance with the NAWI Directive.

CHAPTER 2. REFERENCE LAWS

2.1

The following laws apply to Conformity Assessment of Non-Automatic Weighing Instruments:

- D. Law 29/12/1992 no. 517 published on G.U (Italian State Gazette) 306 of 31/12/1992 – Implementation of Directive 90/384/CEE on the harmonization of the laws of the Member States relating to non-automatic weighing instruments and subsequent amendments;
- D. Law 19/05/2016 no. 83 published on G.U. 121 of 25/05/2016 – Implementation of Directive 2014/31/UE concerning harmonization of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

Any provisions of the reference laws that are not mentioned in these Rules are deemed to be applicable.

For homogeneous application and interpretation of the NAWI Directive, RINA uses the Guidelines issued by the Working Group on Measuring Instruments (Wgmi) of the European Commission, the last published version of the Blue Guide and the WELMEC guides applicable to these instruments.

CHAPTER 3. ISSUE OF CERTIFICATES

3.1

The Organisations that wish to obtain the above certification for non-automatic weighing instruments to be placed on the market must send a specific request, by fax, mail or e-mail, filling in the NAWI-QI document with all information, in compliance with the applicable requirements set forth in the Directive, required to prepare the service proposal, such as:

- a. name and address of the applicant Organisation;
- b. all relevant information on the category of the instruments concerned;
- c. selection of the conformity assessment module (Modules D, D1, F, F1);
- d. any acquired certificates (for the assessment in accordance with Modules D and D1 it is necessary to specify the presence of a Quality Management System, hereinafter referred to as QMS, certified in compliance with the ISO 9001 standard, whereas for Modules D and F it is necessary to attach any complete EU-type examination certificate(s), and in particular for Module D, each relevant technical documentation;
- e. any company or independent contractors to whom the Organisation has assigned the consultancy activity (e.g., design or drawing-up of technical or other documents) or the design, manufacturing, inspection activities;
- f. the number of workers (employees, collaborators, subcontractors) only for modules D and D1;
- g. any standards used for the design, manufacture and control of non-automatic weighing instruments.

RINA performs a preliminary check to verify whether the supplied information is sufficient to prepare a service proposal and may ask for further details, if necessary, also with reference to the requirements of the annexes to this document. According to this information RINA prepares a service proposal which will be sent together with these Rules and form "NAWI-DOM-CERT: Application for NAWI Conformity Assessment".

3.2

Whenever the Organisation intends to accept the service proposal, it must send the NAWI-DOM-CERT form duly filled in and provided with all annexes specified in the same form and foreseen by the NAWI Directive.

Upon reception of the NAWI-DOM-CERT form, duly filled in, for acceptance of the issued service proposal, RINA will have 5 working days to enter comments to these proposals or reject them; if no action is carried out within this term, the request will be considered automatically accepted, therefore any RINA interventions which are carried out in accordance with these Rules will be deemed to be contractually formalized.

The NAWI-DOM-CERT form duly filled in by the Organisation, and the relevant acceptance by RINA contractually formalize RINA's interventions carried out in accordance with these Rules.

The contract stipulated between RINA and the Organization includes:

- the initial audit consisting of two stages and, upon successful completion, the issue of the certificate;
- subsequent surveillance and recertification audits.

RINA requests the documents specified in the annexes to these Rules, applicable according to the selected module, for examination purposes.

RINA will inform the Organisation of the file manager's name and then the file manager will provide the name(s) of the technician(s) who will carry out the audits to the works; the Organisation can object the appointment of these auditors by justifying the reasons for the objections.

To ascertain that the methods of evaluation adopted by RINA comply with the reference standards, the Body in charge of the certifications issued (Accreditation Body) may request the participation of its observers in the audits carried out by RINA.

Participation in the audits of personnel of the Accreditation Body as observers is previously agreed between RINA and the Organization.

If the organization does not grant its approval, the evaluation process is suspended until approval is given for verification and for a maximum period of 3 months.

3.3

Assessment procedures based on quality assurance in accordance with Modules D and D1:

RINA will carry out an audit to the Organisation after communicating the names of the audit team members who must decide whether the quality system adopted by the Organisation satisfies the provisions of the NAWI Directive applicable to the non-automatic weighing instruments mentioned in the application.

The Organisation can object the appointment of these auditors by justifying the reasons for the objections.

It is necessary that the Organisation has its own QMS certified in accordance with ISO 9001 by an Accredited Body; different cases will be evaluated case by case.

The initial audit consists of two stages:

Stage 1 audit, which can be performed:

- partially in the office and partially at the Organization's site

or

- completely at the Organization's site

Stage 2 audit - on site.

During the initial audit, the Organization must demonstrate that the Management System is fully operational and actually apply the System itself.

Stage 1

The purpose of the stage 1 audit is to:

- examine the technical documentation and documentation relating to the quality system relevant for NAWI purposes;
- evaluate the location and particular conditions of the customer's site and undertake an exchange of information with the customer's staff in order to establish the degree of preparation for the stage 2 audit;
- review the status and understanding of the customer regarding the requirements of the NAWI Directive, with special reference to the identification of key performance or significant aspects, processes, objectives and functioning of the Management System;
- collect the necessary information regarding the scope of application of the Management System to the NAWI Directive, the processes and the customer's location (s), including the related legal and regulated aspects and compliance with them;
- review the allocation of resources for the stage 2 audit and agree with the client the details of the stage 2 audit;
- focus on the planning of the stage 2 audit, acquiring sufficient knowledge of the Management System and the activities of the customer's site, with reference to the possible significant aspects relating to the NAWI Directive;
- assess whether the internal audits and management review have been planned and performed and that the level of implementation of the Management System provides evidence that the customer is ready for the stage 2 audit.

Stage 2

The stage 2 audit must be carried out within a maximum period of 6 months from the conclusion of the stage 1 audit, after which the stage 1 audit must be repeated.

In particular cases, RINA may consider extending this limit to 12 months.

The stage 2 audit at the Organization is carried out to verify the correct and effective implementation of the Management System.

Before carrying out the stage 2 audit at the site / s, RINA sends the organization an audit plan which contains, in detail, the description of the activities and provisions for conducting the audit.

If the activities to be verified are carried out on several operating sites, the audit is carried out according to criteria previously established and communicated by RINA to the Organization.

The stage 2 audit is carried out by qualified RINA technicians on the basis of the stage 1 audit report and the documented information prepared by the Organization for the correct and effective implementation of the Management System, in the updated review.

Essentially, the stage 2 audit consists of:

- an initial meeting with the management of the client Organization and, where appropriate, with those who are responsible for the functions or processes to be audited to explain the purposes and methods of carrying out the audit, confirming the provisions of the audit plan;
- a verification of the implementation of effective adaptation actions relating to the findings that emerged during the stage 1 audit;
- a visit to the offices, the manufacturing, inspection, test and storage site (s), as well as the laboratory (s) to verify the compliance of the factory production control system with the applicable reference standards;
- a final meeting to illustrate the conclusions of the audit.

At the end of the stage 2 visit, an Inspection Report is delivered to the Organization, on which any non-conformities and recommendations found are reported.

The Organization may note any reservations or observations, regarding the findings made by RINA technicians, in a specific space in the audit report.

The content of this report is subsequently confirmed by RINA by means of a written communication.

In the absence of written communication from RINA, the report is considered confirmed three working days after its delivery to the Organization.

The Organization, after analyzing the causes of any non-conformities reported in the above report, must propose to RINA, by the date indicated on the report itself, the necessary corrective actions and the time limits for their implementation.

The acceptance of these proposals and the expected time for implementation is communicated in writing by RINA to the Organization.

In the presence of type A findings (see next paragraph) the certification process is suspended; in the case of other findings, the number of which, in the opinion of the evaluation team, is such as to jeopardize the correct functioning of the system, the certification process is likewise suspended.

In such cases, within three months, RINA may carry out an additional check aimed at ascertaining the correct application of the proposed corrective actions; upon successful completion of this verification, the certification process resumes. The additional audit can be carried out on the site or on a documentary basis based on the type of corrective actions to be verified in the opinion of the audit team.

If the aforementioned term is exceeded, the QMS adopted by the Organization is subjected to a complete review within a period of six months from the date of the survey.

Once the aforementioned six-month period has elapsed without a positive conclusion of the assessment, RINA can consider the certification procedure closed, charging the time and expenses incurred up to

that moment. In such cases, the Organization wishing to continue with RINA certification must submit a new request and repeat the certification process.

The aforementioned time limits may in particular cases be changed upon a reasoned request from the Organization, in the opinion of RINA.

All expenses related to any additional audits resulting from deficiencies in the Management System are to be considered borne by the Organization.

RINA's audit team verifies that the Organisation's QMS is adequate so that the manufactured instruments comply with the reference Modules B and meet all applicable essential requirements set forth in annex I to the NAWI Directive; in the presence of any deficiencies or discrepancies with respect to the information present on the system documents, the audit team can raise one or more non-conformities.

During the audit the Organisation must demonstrate, not only that it has all the applicable reference standards but also that the system is fully operating and it effectively implements this system and the relevant documented procedures.

To this aim, also during periodic surveillance audits (specified below at p. 3.8), RINA technicians must freely access the production sites, the personnel and the documentation and must have the necessary assistance by the personnel in charge of the audit.

The organization must guarantee to RINA access to the documentation of the approved and applied quality system (points 2.4.2 and 3.6.2 of Annex II of Directive 2014/31 / EU) and keep available at its premises a copy of the documentation transmitted at the time of the certification request and the one that has been submitted for approval also following subsequent changes to the system.

The documentation to be made available is indicated in points 2.3 and 3.2 of Annex II for the respective modules D and D1 of Directive 2014/31 / EU.

If the Organisation MQS is already certified by RINA and if it covers the design, manufacturing and installation of non-automatic weighing instruments, the conformity assessment procedures in accordance with Modules D and D1 of Directive 2014/31/UE and the audit will be limited to conformity assessment of the designed and/or installed products with the essential requirements of Annex I to Directive 2014/31/UE.

Assessment procedures based on quality assurance in accordance with Modules F and F1:

RINA will carry out an audit to the Organisation after communicating the names of the audit team members who must check conformity of the instruments listed in the application with the provisions of the NAWI Directive.

The Organisation can object the appointment of these auditors by justifying the reasons for the objections.

The assessment visit will consist of:

- an initial meeting with the Organisation to agree upon the auditing modalities;
- examination of the technical documents (only for Module F1) (as an alternative, this examination can be preliminarily carried out);
- a visit at the manufacturing or installation site to perform examinations and tests aiming to verify conformity of the instruments with the approved type described in the EU-type examination certificate (for Module F), or with the applicable provisions of the NAWI Directive (for Module F1).

The examination is carried out for each instrument that is subject to suitable tests, described by harmonized standard EN 45501:2015 and subsequent amendments, and/or to equivalent tests foreseen by other applicable technical specifications provided by the manufacturer;

- a final meeting to explain the outcome of the audit.

3.4

In the audit report relevant to Modules D and D1:

Findings can be subdivided into the following types:

A- *A-type findings (major non-conformities):*

- when one or more of the essential requirements of the directive or the requirements of the reference standards are totally disregarded;
- a situation that may cause the delivery of a product that is not compliant with the regulations applicable in the Member State where the product will be placed on the market;
- the non-observance of one or more requirements of these Rules;
- a situation that can cause a serious deficiency in the QMS or reduce its capacity to ensure control of the product to be marked.

B- *B-type findings (secondary deficiencies or minor non-conformities):*

- a condition that, in RINA auditing team's opinion, based on their experience, cannot cause a serious deficiency of the QMS and does not reduce its capacity to ensure product control.

C- *C-type findings (recommendations, observations):*

- suggestions to improve the system, which are not directly related to the provisions of the reference standards applicable to the product.

The possible presence of findings during surveillance visits or unannounced visits is managed by RINA as follows:

In the presence of major non-conformities or other findings, whose number in the opinion of the evaluation group is such as to prejudice the manufacturing process, the Organization is subjected to an additional verification within the time established by RINA, in relation to the type of non-conformities themselves and, in any case, no later than three months from the end of the surveillance visit aimed at verifying the effectiveness of the corrections and corrective actions proposed.

If the non-conformities are not resolved within the established times or if the non-conformities detected are such as not to ensure the compliance of the product supplied with the applicable standards, RINA may suspend the certification until the non-conformities have been corrected.

If the subsequent audit also had a negative outcome, RINA will proceed with the revocation of the Certificate of conformity.

In the audit report relevant to Modules F and F1:

The results of the tests and checks carried out on the instruments to be certified are divided into the following types:

S – Satisfactory

N – Not Satisfactory

NA – Not Applicable

3.5

The inspection activities foreseen for non-automatic weighing instruments are carried out in the presence of RINA inspectors, according to the requirements of the applicable assessment procedures (modules) described in the annexes to these Rules.

Test equipment is usually made available by applicant Organisations.

This equipment must be suitable to carry out the expected tests and, in particular, mass samples, if not primary as stated in the next paragraph, can be calibrated by applicant Organisations provided they have adequate mass comparators and procedures.

If calibration is performed within the Organisation (for modules D/D1), the reference samples used must be, as an alternative:

-
- property samples metrologically tested by LAT centers or by a Body that is a signatory of mutual recognition agreement EA or ILAC;
 - samples also supplied by third parties that are metrologically tested by LAT centers or by a Body that is a signatory of mutual recognition agreement EA or ILAC and that the Organisation has agreed upon appropriate transfer procedures with third parties;

and that have been entered into a planned control system and, in any case, comply with the maximum values permitted for the instrument under examination.

The applicant Organization must provide evidence of the characteristics and methods of calibration; the following will be assessed: the suitability of the calibration procedures, the suitability of the reference / comparator tools, the competence of the operators, etc.

RINA inspectors check the identification of the instruments and the relevant calibration certificates with metrological traceability.

If the instruments required for test execution are not made available or if the adequacy and calibration of these instruments is not ensured, these tests won't be deemed to be valid for certification purposes.

For those instruments for which the use of ballast is possible, as set forth in the EN 45501:2015 standard and subsequent revisions, the ballast must be made available by applicant Organisations.

In addition, for the F / F1 modules, the applicant Organization must provide evidence that it is aligned with the contents of OIML R 111-1 as regards:

- relationship between the classes of the assets to be used and the classes of instruments that must be subjected to evaluation;
- methods and timing of calibration;
- methods for assessing the suitability of the masses used (e.g., number of times they have been used after calibration, storage methods, methods and timing relating to the controls in operation between two calibrations, etc.)

3.6

If all examinations and tests set out in the annexes to these Rules, applicable according to the selected module, and specified in the service proposal sent to the Organisation and accepted by it are successfully carried out, RINA will issue the certificate/authorization/approval foreseen by the selected assessment module.

In case of negative result of the checks (e.g., when the essential requirements and related standards are not complied with), RINA will inform the Organisation about this result, which prevents the conformity certificate from being issued, by explaining the reasons in detail and will agree upon any re-assessment with the Organisation.

3.7

If the assessment procedure is carried out in accordance with Modules D and D1, after the first assessment audit is successfully completed, RINA will perform periodical checks aimed at verifying that the Organisation maintains and applies the assessed quality system and undertakes to provide the Organisation itself with a report on the checks carried out.

RINA also reserves the right to conduct unannounced visits at the Organisation's premises, as prescribed by the NAWI Directive (Modules D and D1).

CHAPTER 4. CERTIFICATION VALIDITY

4.1

The validity of the certificate/authorization/approval issued by RINA follows the Directive or, if not envisaged by the Directive itself, equal to 3 years for the authorizations or approvals relating to Modules D and D1.

In the presence of certificates or authorizations relating to Modules F and F1, issued for single non-automatic weighing instruments, the certificate validity is unlimited.

CHAPTER 5. VALIDITY EXTENSION

5.1

The validity of an authorization or approval relating to Modules D and D1 can be further extended by three-year periods provided that the procedure laid down in these Rules is repeated.

CHAPTER 6. MODIFICATION OF CERTIFICATION AND COMMUNICATION OF CHANGES

6.1

The Organization which holds the certification may request a modification or extension of the same by submitting a new certification request, accompanied by the documentation referred to in point 3.1, duly updated.

RINA reserves the right to examine the requests on a case-by-case basis and to decide the evaluation procedures for the issue of a new certification, in compliance with the "GENERAL CONDITIONS OF CONTRACT FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS, PERSONNEL AND INSPECTION" and to the Standard or reference normative document for the Management System.

6.2

The Organization must promptly notify RINA of any changes that have taken place on aspects that may affect the ability of the management system to continue to meet the requirements of the standard used for certification.

These provisions concern, for example, variations to:

- the legal, commercial, organizational or property status;
- organization and management (e.g., key managers or technical personnel decision-making process, change in number of employees, etc.);
- contact addresses and sites;
- the scope of activities covered by the certified management system;
- significant changes to the management system and processes.

In the above cases it is therefore necessary that the Organization transmit to RINA a specific prior request attaching the relevant documentation, to allow the Notified Body to carry out the evaluation of the proposed modifications and decide if the modified system continues to comply with the requirements set out in Annex II of Directive 2014/31 / EU or if a new verification is necessary.

RINA informs the manufacturer of the decision, specifying the reasons and attaching the conclusions of the evaluation.

RINA reserves the right to carry out additional audits, or other appropriate actions, at the Organization if the communicated changes are deemed particularly significant for maintaining the compliance of the Management System with the requirements of the reference standard and with this regulation or revising the economic conditions for possible modification of the contract.

6.3

RINA promptly informs the organization of any changes in the reference standards or RINA certification regulations.

6.4

RINA reserves the right to conduct audits with short notice or without notice, at the Organization, to investigate complaints or in response to changes or as a consequent action against customers whose certification has been suspended.

CHAPTER 7. SUSPENSION, REINSTATEMENT AND REVOCATION OF CERTIFICATES (MODULES D, D1)

7.1

The validity of the Certificate in conformity with Modules D and D1 can be suspended in accordance with the provisions of the GENERAL TERMS AND CONDITIONS FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS, PERSONNEL AND INSPECTION" and in the specific cases listed here below:

- if, during the conformity monitoring activity following the issue of the certificate, RINA finds out that any non-automatic weighing instruments are no longer compliant with the requirements of the Directive and of the other reference standards;
- if the Organisation has made considerable changes to the certified instruments without informing RINA or if these changes prevent the instrument to comply with the requirements of the Directive or of the other reference standards;
- if the Organisation does not allow the planned audits to be carried out according to the required schedule;
- if, within the QMS, any non-conformities are found that are not solved within the times established by RINA;
- if the Organisation did not comply with the terms established for the communication of the corrective actions, as a result of non-conformities/observations written in the audit report;
- if the Organisation has made any significant changes to its QMS that have not been accepted by RINA;
- in case of rejection of or obstacle to the participation in the audits of any observers of an Accreditation Body;
- in the presence of evidence that the QMS does not ensure compliance with the laws and regulations currently in force and applicable to the activities and/or the site(s);
- in the presence of any justified and serious complaints received by RINA.

Furthermore, the Organisation can ask RINA, by justifying the reasons, for suspension of its certification for a period of time that is generally not greater than six months and, in any case, not exceeding the expiry date of the certificate.

Suspension is notified in writing, specifying the certificate reinstatement conditions and the term within which the required actions must be taken.

RINA informs the Ministry of Economic Development of any approval, rejection, limitation, suspension or withdrawal of a certificate/authorization.

7.2

A certificate can be reinstated only following verification that the deficiencies which caused said suspension have been removed by an audit to the product and the Organisation aimed at ensuring that the product and the Organisation comply with all the requirements of the reference standard.

This reinstatement is notified in writing to the Organisation and the Ministry of the Economic Development.

7.3

Non-compliance of the conditions specified under point 6.2 above within the specified term causes the Conformity Certificate to be revoked.

The decision on Conformity Certificate revocation can be taken in accordance with the "GENERAL TERMS AND CONDITIONS FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS, PERSONNEL AND INSPECTION" and in the following specific cases:

- in the presence of any conditions, like those mentioned under point 6.1 for suspension, that are judged to be particularly serious;

- if the Organisation suspends its activities or services which are the object of the certified QMS and/or the conformity assessment of non-automatic weighing instruments for a period of time greater than six months;
- if the Organisation does not accept the new economic conditions established by RINA for any contract amendment;
- for any other serious reason, according to RINA's judgement, like for example, but not limited to, the proven inability of the system to pursue its own objectives relating to the compliance with legal or contractual restrictions or to product safety.

If the Conformity Certificate is revoked, RINA will:

- a. send a written notice to the Organisation providing it with detailed reasons for the decision of this revocation and informing it of the possibility to appeal against this decision;
- b. if the appeal is not successful, directly inform the Ministry of Economic Development, providing details of revoked certificates;
- c. inform the Technical Secretariat of the group of European Notified Bodies for non-automatic weighing instruments of the data relating to the revoked certificate.

An Organisation which, after revocation, intends to be certified again, must submit a new application following the entire procedure set out in these Rules.

In case of suspension or revocation of its certificates, the Organisation cannot market the products relating to said certificates that are stored in the warehouse or being delivered.

CHAPTER 8. LIST OF ISSUED CERTIFICATES

8.1

RINA makes available the list of issued, revoked, suspended or rejected certificates to the Ministry of the Economic Development.

This list can be published by RINA on its web site.

This list contains:

- the Organisation's name and address;
- the number of Certificate / authorization / approvals;
- the description of the certified non-automatic weighing instrument(s);
- the issue date of the Certificate/authorization/approval;
- the expiry date of the Certificate/authorization/approval;

The above information can also be provided by RINA to:

- the national Accreditation Body,
- any associations of Certification Bodies to which RINA belongs,
- any other Notified Bodies.

CHAPTER 9. CERTIFICATE TRANSFER (MODULES D AND D1)

9.1

If the company's name changes, the Organisation must inform RINA of the changes made, by sending the following documents:

- a copy of the new Chamber of Commerce registration certificate or an equivalent document,
- a copy of the notarial act certifying this change.

After performing all necessary checks, RINA will issue a new conformity certificate and make the previous one not valid.

CHAPTER 10. APPEALS AND COMPLAINTS

The Organization must refer to RINA "General Terms and Conditions for the certification of Systems, Products, Personnel and Inspection", in the edition in force that can be found at the www.rina.org website.

CHAPTER 11. RENUNCIATION OF CERTIFICATES (MODULES D, D1)

The certified Organisation can send a formal renunciation notice to RINA, before the certificate expires, including when the Organisation itself does not intend to or cannot meet the new requirements set out by RINA.

Upon reception of the above notice, RINA starts a procedure to make the certificate status not valid.

As a general rule, within one month from the date of the notice, RINA will update the certificate status.

CHAPTER 12. COMMUNICATIONS AND ADVERTISING BY ORGANISATIONS, USE OF THE TRADEMARK

The Organization must refer to RINA "General Terms and Conditions for the certification of Systems, Products, Personnel and Inspection", in the edition in force that can be found at the www.rina.org website.

CHAPTER 13. CONTRACTUAL CONDITIONS

With regard to contractual conditions, the provisions of the following RINA document apply: "General Terms and Conditions for the certification of Systems, Products, Personnel and Inspection", in the edition in force that can be found at the www.rina.org website.

ANNEX 1 – CONFORMITY ASSESSMENT PROCEDURES (Annex II to NAWI Directive)

Chapter 2 - MODULE D: Conformity to type based on quality assurance of the production process

2.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2 and 2.5 and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2.2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3 and shall be subject to surveillance as specified in point 2.4.

2.3. Quality system

2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- b) a written declaration that the same application has not been lodged with any other notified body;
- c) all relevant information for the instrument category envisaged;
- d) the documentation concerning the quality system; and
- e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

2.3.2. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

2.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2.3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

2.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

2.3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

2.4. Surveillance under the responsibility of the notified body

2.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

2.4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

a) the quality system documentation;

b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

2.4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

2.4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

2.5. Conformity marking and EU declaration of conformity

2.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

2.6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

- a) the documentation referred to in point 2.3.1;
- b) the information relating to the change referred to in point 2.3.5, as approved;
- c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

2.7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

2.8. Authorised representative

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Chapter 3 - MODULE D1: Quality assurance of the production process

3.1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of this Directive that apply to them.

3.2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

- a) a general description of the instrument;
- b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc;
- c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
- d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- e) results of design calculations made, examinations carried out, etc.
- f) test reports.

3.3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3.4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5 and shall be subject to surveillance as specified in point 3.6.

3.5. Quality system

3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

- b) a written declaration that the same application has not been lodged with any other notified body;
- c) all relevant information for the instrument category envisaged;
- d) the documentation concerning the quality system;
- e) the technical documentation referred to in point 3.2.

3.5.2. The quality system shall ensure compliance of the instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Surveillance under the responsibility of the notified body

3.6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- a) the quality system documentation;
- b) the technical documentation referred to in point 3.2;
- c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

3.6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

3.6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

3.7. Conformity marking and EU declaration of conformity

3.7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

3.7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

3.8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

- a) the documentation referred to in point 3.5.1;
- b) the information relating to the change referred to in point 3.5.5, as approved;

c) the decisions and reports of the notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

3.9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

3.10. *Authorised representative*

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Chapter 4 - MODULE F: Conformity to type based on product verification

4.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.5 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

4.3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

4.4. Verification of conformity by examination and testing of every instrument

4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

4.5. Conformity marking and EU declaration of conformity

4.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 4.3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities, for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

4.6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

4.7. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 4.2.

Chapter 5 - MODULE F1: Conformity based on product verification

5.1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3 and 5.6 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of this Directive that apply to them.

5.2. Technical documentation

5.2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

- a) a general description of the instrument;
- b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
- d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- e) results of design calculations made, examinations carried out, etc.;
- f) test reports.

5.2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

5.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the applicable requirements of this Directive.

5.4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of this Directive.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

5.5. Verification of conformity by examination and testing of every instrument

5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

5.5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5.6. Conformity marking and EU declaration of conformity

5.6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

5.7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

5.8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2.1 and 5.3.

CHAPTER 7- COMMON PROVISIONS

7.1. The conformity assessment according to Module D, DI, F, FI or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.

7.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression «at the place of use of the instrument» may be read as «in the gravity zone of use of the instrument».

7.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

7.2.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

7.2.3. A manufacturer who has opted for Module D or DI in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or FI as appropriate.

7.2.4. The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

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