APPROVED
EXECUTIVE DIRECTOR
PhD eng. Poenaru Maria-Magdalena
15.12.2021

GENERAL REQUIREMENTS FOR CERTIFICATION WITHIN DIRECTIVES 2014/32/EU – MEASURING INSTRUMENTS (annex II, sections 6, 7, 8, 9, 13, 14) AND 2014/31/EU - NON - AUTOMATIC WEIGHING INSTRUMENTS (annex II, sections 2, 3) Code I.MRC.OCS.8.1

Prepared by
Certification Director
Eng. Poenaru Liana

Checklist of edition/revision

No.	Subject of change	Amendment sheet	Date	Prepared
1/ 0	Initial elaboration		12.05.2010	E. Nica
1/1	Alignment to the requirements of EN ISO/IEC 17021:2011	FM no. 188	10.01.2012	E. Nica
1/2	Correlation with EN ISO/IEC 17065:2013	FM no. 225	15.01.2014	A. Padeanu
1/3	Correlation of responsibilities with the organizational structure in force from 01.09.2014 and correction of terminology used according to EN ISO/IEC 17065:2013	FM no. 236	15.10.2014	A. Padeanu
1/4	Completions on certification withdrawal and cancellation	FM no. 247	05.06.2015	A.Padeanu
1/5	Correlation with new requirements for accreditation and certification of systems and products	FM no. 254	15.11.2015	E. Nica
2/0	Completions on certification withdrawal and cancellation	FM no. 286	30.08.2017	E. Nica
2/1	Revision of the process related to scope extension application	FM nr, 328	11.07.2019	L. Poenaru
2/2	Change of visual identity elements of MRC (logo, mark)	FM nr. 357	15.12.2021	A. Anghel

1. PURPOSE and SCOPE

1.0 The instruction describes the general requirements to be met by an organisation requesting MRC to assess the conformity of products under Directives 2014/32/EU - MEASUREMENT EQUIPMENT and 2014/31/EU - NON-AUTOMATICALLY OPERATED WEIGHING EQUIPMENT.
The procedure shall be applied by MRC for the assessment and certification of conformity of products in accordance with the requirements of SR EN ISO 17065:2013 and the conformity assessment modules provided by:

- DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to making available on the market of non-automatic weighing instruments (recast)
- DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to making available on the market of measuring instruments (recast)

These rules apply to certification, recertification, maintenance, extension, restriction, suspension, and withdrawal activities and are an integral part of the certification contract concluded with MRC.
1.1 The Certificate of Conformity issued by MRC for the following products according to DIRECTIVE 2014/32/EU:

- water meters - Annex III (MI-001);
- gas meters and volume conversion devices - Annex IV (MI-002);
- active electrical energy meters - Annex V (MI-003);
- thermal energy meters - Annex VI (MI-004);
- measuring systems for the continuous and dynamic measurement of quantities of liquids other than water - Annex VII (MI-005);
- automatic weighing instruments - Annex VIII (MI-006);
- taximeters - Annex IX (MI-007);
- material measures - Annex X (MI-008);
- exhaust gas analysers - Annex XII (MI-010).
- Non-automatic weighing devices (according to DIRECTIVE 2014/31/EU).

The Certificate of Conformity is the document which attests that the quality system approved by MRC ensures conformity of the product with the type described in the EU Type Examination Certificate and with the applicable requirements of the Directive (Government Decision - GD) for modules D, D1, E, E1 and the quality system approved by MRC ensures conformity of the product with the relevant (essential general and specific) requirements of the Directive (GD) for modules H and H1. In addition, for H1, an EU Product Design Examination Certificate is granted, which attests that the design meets the requirements of the Directive (GD).

2. REFERENCE DOCUMENTS

2.1. Government Decision No. 710/2015 on establishing the conditions for making non-automatic weighing instruments available on the market;

2.2. Government Decision No. 711/2015 on laying down the conditions for making measuring instruments available on the market

2.3. DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to making available on the market of non-automatic weighing instruments (recast);

2.4. DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to making available on the market of measuring instruments (recast).

2.5. SR EN ISO 19011:2011: Guidance on auditing quality and/or environmental management systems.

2.6. EN ISO/IEC 17021:2011 - Conformity assessment. Requirements for bodies providing audit and certification of management systems.

2.7. SR EN ISO/IEC 17065:2013 - Conformity assessment. Requirements for bodies certifying products, processes and services.

3. DEFINITIONS and ABBREVIATIONS

3.1 Definitions

The definitions in ISO 9000:2015 - Quality management systems. Fundamentals and vocabulary. In addition, the following definitions apply:

3.1.1. Non-conformity - absence or lack of capability to implement or maintain one or more of the requirements of the directive applicable to the design, production, final factory inspection control system.

3.1.2. Observation - deviation from the requirements, which does not constitute a risk to the effective operation of the design, production, final inspection control system in the factory, but which by repetition could lead to non-conformity.

3.1.3. Observer = person who accompanies the audit team but does not audit

3.1.4. Guide = person appointed by the client to assist the audit team

3.2 Abbreviations

MS = Management System
AT = Audit Team.
S = Quality System
ATL= Audit Team Leader
CPEA = College of Professional Ethics and Appeals

4. RESPONSIBILITIES

The responsibilities are shown in the process flow chart in Annex 2.

5. GENERAL CONDITIONS

5.1. MRC - CONFORMITY ASSESSMENT BODY is organised in accordance with the requirements of EN ISO/IEC 17065:2013 and operates in the European area.

5.2. The general requirements contain besides general information also specific requirements of MRC for informing applicants about:

- obtaining certification;
- maintaining certification during surveillance;
- renewal, extension or withdrawal of certification.

The conformity assessment modules based on a quality system implemented by the manufacturer are described in Annex II, section 6, section 7, section 8, section 9, section 13, section 14 of Directive 2014/32/EU and Annex II, section 2 and section 3 of Directive 2014/31/EU.

Module D

QS covers production, product final inspection and testing of the measuring instrument and is subject to surveillance;

QS ensures conformity of the product with the type described in the EU type examination certificate and with the applicable requirements of the Directive.

Module D1

QS covers production, final product inspection and testing of the measuring instrument and is subject to surveillance;

QS ensures conformity of the product with the applicable requirements of the Directive.

Module E

QS covers the final inspection of the product and testing of the measuring instrument and is subject to surveillance;

QS ensures conformity of the product with the type described in the EU type examination certificate and with the applicable requirements of the Directive.

Module E1

QS covers the final inspection of the product and testing of the measuring instrument and is subject to surveillance;

QS ensures the conformity of the product with the applicable requirements of the Directive.

Module H

QS covers the design, production, final product inspection and testing of the measuring instrument;

QS ensures the conformity of the product with the applicable requirements of the Directive.

Module H1

QS covers design, production, final product inspection and testing of the measuring instrument concerned.

QS ensures the conformity of the product with the applicable requirements of the Directive.

In addition to Module H, it also involves examination of the adequacy of the technical design of the measuring instrument.

5.3. Attestation of conformity systems provide for the division of tasks between the manufacturer and MRC

5.3.1. In order to obtain and maintain certification, the organisation shall:

- comply with the requirements of the reference standard and applicable legislation;
- comply with the requirements of these general rules;
- comply with the requirements for the use of the certificate of conformity issued by MRC and the CE conformity marking;
- issue a declaration of conformity, based on the certificate of conformity issued by MRC;
- make all necessary arrangements for the conduct of the assessment, including arrangements for the review of documents and records and access to all areas by persons designated by MRC who carry out assessment, surveillance, unannounced audits or resolve complaints;
- to regularly pay invoices issued by MRC according to the signed certification contract.

5.3.2. During audit activities, MRC auditors should consider as contact persons only those who are listed in the organisation's organisation chart. If the organisation wishes other persons to participate in the audit (e.g. consultants), it is obliged to ensure that their role is that of observer.

5.3.3. On the other hand MRC audit team may include observers (e.g. accreditation body assessors, monitors) and/or trainee auditors.

The general outline of the certification stages is presented in Annex 2.

5.3.4. Access to MRC certification services is free and non-discriminatory. It is not conditioned by the size of the organisation or its membership in an association or group.

5.3.5. MRC certification services do not include any form of consultancy for the applicant for certification.

5.3.6. MRC belongs to the Romanian Movement for Quality which is a legally constituted entity with legal liability.

5.3.7. The principles that provide guidelines for decision-making are the following:

- impartiality: decisions are made on the basis of objective evidence of compliance (or non-compliance) and are not influenced by other interests or other parties;
- competence: the demonstrated ability of MRC staff to apply knowledge and skills at all levels.
- accountability: MRC has the responsibility to evaluate sufficient objective evidence on which the certification decision is based.
- transparency: MRC provides appropriate access to, or dissemination of, non-confidential information related to the audit and certification processes, as well as that related to the status of certification (i.e., granting, extending, maintaining, renewing, suspending, restricting or withdrawing certification) to provide confidence in the integrity and credibility of certification.
- Confidentiality: MRC keeps confidential any information that constitutes client property, ensuring an appropriate balance between the principles of transparency and confidentiality.
- response to complaints: stakeholder complaints are always investigated and processed in an appropriate manner.

5.4. Requirements of the Directives related to QS

All 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. This quality system documentation shall permit a uniform interpretation of quality programmes, plans, manuals and records.

In particular, the QS documentation must contain an adequate description of:

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

In addition, for modules *H and H1* only, the documentation shall also contain:

- specifications of the technical design, including standards, that will be applied and, where the relevant documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Decision that are relevant to the measuring instruments will be met;
- the systematic design control and design verification techniques, processes and actions that will be used during the design of measuring instruments of the category concerned.

Quality system refers to the type of measuring instrument as described in the manufacturer's technical documentation.

Presumption of conformity of the manufacturer's quality system

In its conformity assessment activities, MRC takes into account quality system approvals granted by itself or by another notified body, as well as certificates issued by an accredited certification body, in so far as MRC is able to guarantee that these approvals or certifications (for the same product or a product of the same category) cover the applicable provisions of the Directive.

As part of the process of ensuring that the requirements of the relevant Directive are met, the notified body assesses all documents on which the quality system approval is based, including audit reports, management reviews and control plans.

Based on this assessment, MRC determines whether the scope of assessment can be reduced or not. MRC has procedures detailing how it takes into account the quality system approval granted by other notified bodies or certificates issued by accredited certification bodies. Certification according to ISO 9001 in itself does not imply that the requirements of the directive are met but is merely a presumption of conformity.

5.5. STAGES OF CERTIFICATION

5.5.1. General aspects

The manufacturer completes, directly or through an authorised representative, all applicable fields of the certification/ recertification application and submits it to MRC together with the QS documentation.

After receiving the certification application and the QS documentation, MRC performs its analysis and determines the duration of the audit based on the information provided by the organisation, and taking into account:

- the complexity of the conformity assessment modules based on a quality system implemented by the manufacturer, as described in Annexes E, E1, D, D1, H, H1 of Directive 2014/31/EU and Directive 2014/32/EU;
- the complexity of the product technology;
- the number of production sites at which the product is manufactured, without accepting sampling;
- number of products with the same technology from a product family;
- the activities are carried out in a QMS certified according to ISO 9001 requirements.

Afterwards, MRC sends the certification contract to the organisation, based on the approved tariffs.

By returning a signed copy of the certification contract, the organisation undertakes to comply with the specifications and general conditions of the contract, as well as these general rules for certification and use of the notified body identification number.

To start the certification, the organisation shall submit to MRC the quality system documents, which must cover the production, the in-flow controls and the final inspection of the product in the factory, according to the provisions of the directives and harmonised standards specific to each product applied for certification, as follows (in all cases, the submission of the documents specified below is mandatory):

- Quality manual and laboratory test manual;
- Quality system procedures, including manufacturing and inspection procedures;
- test procedures;
- EU-type examination certificate (for modules D, E, H);
- initial verification reports for each product for which certification is requested;
- organisation chart;
- List of QMS documents;
- List of QMS records;
- Maintenance schedule for production equipment;
- List of Measuring and Monitoring Equipment;
- Inspection/testing plan for raw materials/component materials;
- Inspection plan for production process;
- Inspection/testing plan for products during production;
- Final product inspection/testing plan.

Depending on the specifics of the product technology, all or some of the inspections/tests may need to be performed.
The established contractual conditions remain valid if the organisation starts the certification within 6 months from the date of the contract. If this period is exceeded, the organisation is obliged to update the certification/ recertification application, considering any changes that have occurred. In this situation, MRC has the right to modify the terms of the contract.
If a product is produced in multiple locations, a complete audit of the design, production, final inspection control system of the product shall be carried out for each production location.

5.5.2. Eligibility criteria for the applicant

The design, production, final factory inspection control system for a product/product family must be structured, implemented, and maintained in accordance with the specific requirements of the harmonised directives/standards for measuring instruments and NAWI (Non-automatic weighing instruments) and must be subject to regular internal audits at all locations/working facilities as well as a management review at central level.
The organisation must be able to demonstrate that by implementing and maintaining design control, production, final factory inspection, it keeps under control the performance of the product established by type testing.
The organisation shall appoint a quality system representative (design control, production, final factory inspection) with overall responsibility for maintaining the quality system in the factory.
If not all of the working facilities of an organisation subject to certification are ready to be certified at the same time, the organisation must inform MRC which working facilities it wants to include in the certification at a later date.
The audit periods and the names of the appointed auditors will be communicated to the organisation, which must give its agreement.
The organisation has the right to recuse the audit team or a member of the audit team, in writing and giving reasons, within 5 days from the date of notification.
Audits must be carried out during the period in which the organisation operates all production lines, all products for which it has applied for certification and the organisation is responsible for ensuring this.

5.5.2. General framework for conducting the audit

The certification (quality system approval) audit is carried out in two steps:
- Initial inspection, which can take place at MRC premises or at the production site - Stage 1 Audit - P6;
- Certification audit (design control, production, final product inspection at the factory) - Stage 2 Audit -P8.

Classification of findings

Deviations found during the certification audit concerning non-compliance with certain requirements are considered as non-conformities.
The non-conformity affects the functioning and/or effectiveness of the design, production, final factory inspection control system so that the product placed on the market cannot satisfy the relevant requirements.
Examples:
- lack of formal designation of specific production control responsibilities;
- lack of records of a batch of products at various stages of manufacture or following tests carried out;
- failure to comply with the pre-established test plan etc.

5.5.3. Stage I - Initial inspection (P6)

At least 5 days prior to the start of the Stage 1 Audit, the lead auditor submits the Audit Plan to the organisation.
The Stage 1 Audit Plan is the planning and documentation file for the objective of the Stage 1 Audit consisting of:
- analysis of the quality system documentation and clarification of some aspects resulting from the evaluation of the submitted documentation;
- analysis of the state of understanding and implementation of the requirements for placing on the market of measuring instruments / automatic weighing instruments, EC type examination, approvals held etc;
- assessment of the customer's site and site-specific conditions to determine the organisation's readiness for the certification audit;
- assessment of production/laboratory premises and technological facilities, applied technology, machinery and production equipment, availability and suitability of measuring and monitoring devices used;
- identification of significant aspects, processes, objectives, performance and operations of the management system;
- assessment of management review and internal audits; assessment of the level of implementation of the quality system to determine whether the client is ready for the certification audit (stage 2 of the audit);
- analysis of resource allocation and detailing, for stage 2 of the certification audit;
- correct definition of the types of products required to be certified according to directives/harmonised standards;
- pre-established inspection/test plan for the product (characteristics checked, frequency and test methods, acceptance criteria, responsibilities).

5.5.4 Stage II-Certification Audit

The planning of the Stage 2 Audit is sent to the client at least 5 days before the audit start date (if the Audit Plan has not been distributed to the client at the end of Stage 1).

During the certification audit the audit team checks at each production site the implementation of all requirements laid down in the technical specifications and applicable documentation.

Sampling of production sites is not accepted, so all sites where the product is manufactured will be audited.

The certification audit (Stage 2) has the following objectives:

a) verification of the resolution of non-conformities found during the Stage 1 Audit

b) operational control of the manufacturing process, measurement, reporting, objectives and targets proposed

c) quality plan, with reference to:

- the production processes;
- the controls, checks and tests carried out, before, during and after manufacture and assembly of the product;
- the surveillance measures;
- frequency of execution of the controls, checks and tests;
- records, including declarations of conformity;

d) assessment of process performance regarding compliance with legislation

e) any other information that helps to assess the conformity of the product with the requirements of Directive 2014/31/EU, Directive 2014/32/EU, harmonised standards and WELMEC guidelines relating to MID and NAWI respectively;

f) assessment of consistency between regulatory requirements, objectives, targets and policies related to responsibilities, competencies, personnel, procedures, performance;

g) product evaluation (product verification):

- verify whether the system ensures that harmonised standards are implemented in production;
- other examinations or tests required by the harmonised standards;
- conformity to type (EC type-examination certificate);
- preparation of test reports;
- declarations of conformity in compliance with the guidelines - Welmec recommendations;

h) evaluation of inspection staff:

- qualification/certification/authorisation (name, surname, registration, training/re-authorisation programme)
- assessment of means of verification:
  - equipment and control P/I for Measuring and Monitoring Equipment;
  - standards (e.g. standard weights), names, codes, series;
  - calibration certificates etc.;

i) analysis of the fulfilment (implementation) of training programmes, internal audits, analysis carried out by management with application to compliance with the requirements of Directive 2014/32/EU-MID, respectively Directive 2014/31/EU – NAWI;
j) analysis of management's responsibility for compliance with the requirements of Directive 2014/32/EU-MID and Directive 2014/31/EU - NAWI respectively
The auditor shall complete in the Audit Questionnaire conclusive evidence of the functioning of the design, production, final product inspection control system for all specific aspects.
Emphasis is placed on gathering evidence on:
- compliance with the pre-established inspection/test plan and evaluation of the results of these tests against the defined acceptance criteria;
- verification of the adequacy of the frequency of inspections/tests;
- verification of product performance against the established type test values;
- treatment of non-conformities found; repetition of tests after resolution of non-conformities.
The stage 2 audit is completed by:
- establishing the audit conclusions/findings, documenting them in the Stage 2 Audit Report and communicating them to the client;
- determination and documentation by the client in the Audit Report of the causes of the non-conformities/observations, corrections and corrective actions to eliminate the non-conformities/observations found during the audit;
- analysis, until acceptance by the audit team, of the corrections/corrective actions proposed by the client;
- finalisation of the drafting and submission of audit documents to the client and MRC.

5.5.5 NON-CONFORMITY MANAGEMENT

The certification (approval) of a manufacturer's quality system is granted only if no non-conformities are detected during the audit or after their resolution.
Non-conformities found are documented in the Non-conformity Report form which is part of the Stage 2 Audit Report.
A Report shall be completed for each non-conformity per product or product family, which shall be related to the affected clause of the referenced standard.
The maximum time limit for the implementation of corrections/corrective actions shall not exceed 2 months from the date of completion of the audit.
Verification of the resolution of a non-conformity may require a follow-up audit of part or all of the design, production, final product inspection control system.
If the non-conformities relate to system documentation and/or procedures already implemented, verification can be done by document analysis only, without the need for an on-site visit.
If the follow-up audit cannot be carried out within the 2 months' time limit or the organisation has not implemented the appropriate corrective actions, then a full second stage audit will be carried out again.

5.5.6 GRANTING CERTIFICATION – P10

After completion of the second stage of the quality system certification audit and acceptance of the corrections/corrective actions and/or verification of the implementation of these corrections/corrective actions for the non-conformities found, as well as after technical analysis of the certification file (P9), the Certification Committee takes the certification decision and the organisation is issued with the certificate of conformity with a unique registration number.

A. Issuance of certificates of conformity

The numbering of the certificate of conformity is as follows:

RO-2275-YZ00X, where: RO = Romania
2275 = identification number of the notified body
YZ = last two digits of the year of issue of the certificate
00X = serial number of the certificate

In case the space reserved in the certificate is insufficient, it will be continued in an annex.
At recertification (when there is continuity of the certification process), the same serial number of the certificate is kept; otherwise, it is considered a new certification and a new serial number is allocated, which is part of the number of the certificate of conformity.

B. Issuance of the EU Declaration of Conformity by the organisation.

During the validity period of the certificate of conformity for modules D, D1, E, E1, H, H1 the organisation is obliged to complete the Declaration of Conformity and affix the CE conformity marking.
The declaration of conformity is issued under the sole responsibility of the manufacturer, is identified by a unique number and refers to at least:

- the model of the instrument/ the instrument (product number, type, batch or serial number);
- name and address of the manufacturer and, where appropriate, of its authorised representative;
- subject of the declaration (identification of the instrument allowing traceability; if necessary for the instrument identification, a picture may be added):
- the relevant harmonised standards used or references to other technical specifications in relation to which conformity is declared;
- the notified body which carried out the assessment and issued the certificate;
- the number of the certificate issued by MRC;
- additional information;
- relevant harmonisation legislation.

C. Application of the CE conformity marking

➢ The CE marking is subject to the general principles laid down in Article 30 of Regulation (EC) No 765/2008.

- The supplementary metrology marking shall consist of the capital letter 'M' followed by the last two digits of the year in which it was affixed within a rectangle. The height of the rectangle shall be equal to the height of the CE marking.
- The CE marking and the supplementary metrology marking shall be affixed visibly and legibly to the measuring instrument or its data plate. Where this is not possible or justified on grounds relating to the nature of the measuring instrument, the markings shall be affixed to the accompanying documents and, where appropriate, to the packaging. On removal, the CE marking and the supplementary metrology marking shall self-destruct.
- If a measuring instrument consists of a set of devices, not sub-assemblies, operating together, the CE marking and supplementary metrology marking shall be affixed to the main device of the measuring instrument.
- The CE marking and supplementary metrology marking shall be affixed before the measuring instrument is placed on the market.
- The CE marking and supplementary metrology marking may be affixed to the measuring instrument during the manufacturing process if justified.
- The supplementary metrology marking shall be located immediately after the CE marking.
- The CE marking and supplementary metrology marking shall be followed by the identification number of MRC as notified body (2275). The number 2275 shall be affixed by MRC or, as instructed by MRC, by the manufacturer or his authorised representative, shall be indelible and shall not be removed without destruction.
- The CE marking, the supplementary metrology marking and, where appropriate, the identification number of MRC, may be followed by any other marking indicating a special risk or use.

The correct issuance of EU declarations of conformity and the correct application of CE conformity markings are verified by the designated market surveillance bodies and are also subject, among others, to surveillance audits scheduled by MRC.

The affixing on a measuring instrument of markings which are likely to deceive third parties as to the meaning and/or form of the CE marking and supplementary metrology marking shall be prohibited. Any other marking may be affixed to the measuring instrument provided that it does not reduce the visibility and legibility of the CE marking and supplementary metrology marking.

5.5.4. MAINTAINING THE CERTIFICATION

The certificate of conformity is valid for 3 years from the date of issue, provided that the annual surveillance audit is carried out and the manufacturer's quality system continues to be implemented and effective.

Before the validity of the certificate expires, a recertification audit is performed and a new certification cycle starts.

5.5.8. SURVEILLANCE AUDIT

The surveillance audit of the quality system is carried out according to the same rules as the certification audit.

Two surveillance audits are carried out during the validity of the certificate: the first at 12 months after the end of the certification audit and the second at 24 months after the end of the certification audit.

Periodic surveillance ensures that the quality system remains compliant with the certification requirements.

The audit team verifies:

- at each production site, maintaining conformity of all elements of the quality system (design control, production, final inspection with technical specifications and applicable documentation);
- if there are changes to the quality system that may affect product performance (changes in technology, replacement of raw materials etc.). If the organisation has not declared these changes, the quality system certification is suspended.

The manufacturer must keep and make available, at the request of MRC, records of non-conformities and complaints relating to the certified product.

5.5.9. Unannounced audit

The unannounced audit is conducted:

- for the assessment of the changes communicated by the organisation, during which MRC will decide whether the modified quality system still meets the requirements laid down in the applicable technical specifications;
- in case of complaints or at the request of the competent designating authority.

The unannounced audits are notified in advance to the certified organisations 24 hours before they are carried out.

Management of non-conformities

If non-conformities are found during the surveillance/unannounced audit, the deadline for resolution is also 2 months. If the 2 months' period is exceeded until resolution, certification will be suspended.

In this situation, MRC notifies the competent authority and the client within 24 hours about the suspension of the certificate. From that moment, the organisation is no longer entitled to use the certificate and CE conformity marking in relations with third parties for the product concerned.

If it is found that non-conformities have not been resolved within 3 months, the certification is withdrawn.

5.6. RECERTIFICATION

The recertification process must be initiated by the organisation at least 3 months before the expiry of the certificate.

The organisation must submit a firm certification/ recertification application to MRC for the conclusion of the recertification contract.
The purpose of the recertification audit is to confirm continued compliance with all quality system requirements in relation to the directives and other referential.
The recertification audit covers all the requirements of the referential, includes the analysis of the quality system documents as well as the analysis of the previous surveillance audit reports.
Recertification audits must include an on-site audit and are carried out in accordance with stage II of the certification audit. The recertification audit may have a stage I only in situations where significant changes to the manufacturer's quality system have occurred.
The decision to re-certify is made in the same way as the certification decision, based on the evidence established by the recertification audit.
When non-conformities are identified during the recertification audit, MRC together with the organisation must define the period of time in which the organisation must implement the corrections and corrective actions so that their verification (on-site or documentary follow-up audit) is carried out before the expiry of the certificate.
The issuance of a new certificate is done after the certification decision has been taken by the Certification Committee.

5.7. EXTENSION

The extension of the quality system is requested by the client by submitting an application which is analysed by MRC and an Addendum to the existing Certification Contract is concluded.
The extension audit is carried out in the same way as the quality system certification audit and can be carried out at the same time as the surveillance audit for products already certified.
In case a manufacturer applies for extension of certification and if the analysis of the technical documentation referring to the extension shows that the product continues to meet the requirements of the applicable directive (no additional tests to those carried out at the initial certification or at the previous extension are required), the lead auditor completes the report on the analysis of the documentation for the certification of conformity and recommends on it the extension or not of the certification. The decision to extend certification is taken by the Certification Committee.
The scope extension application is accepted at the time of the certification audit, as mentioned in the audit report; the extension request refers only to the same product group(s) for which the applicant is certified.

5.8. RESTRICTION

Restriction takes place at the request of the client, e.g. due to a reduction in the range of products manufactured or the relocation of a production site.
The customer's application is considered by MRC and an Addendum to the existing Certification Contract is concluded.

5.9. SUSPENSION

The situations leading to suspension of certification are:

- at the scheduled surveillance audit, the lead auditor has found non-conformities and the product no longer meets the requirements of the reference standard;
- the certified organisation does not allow surveillance audits to be carried out at the required frequency or within the planned/agreed timeframe;
- breach of the certification contract (including missed payments);
- incorrect use of the certificate and CE conformity marking;
- failure to inform MRC of significant changes made that may affect the effective operation of the approved quality system;
- the certified client voluntarily requests suspension.

During the period of suspension, the right to use the certificate of conformity and the CE conformity marking is prohibited.

In case of suspension, MRC shall send an official notification to the organisation specifying the reasons for the decision, as well as the deadline for the revocation of the suspension and the measures to be taken by the certificate holder which may be as appropriate:

- withdrawal of certified products, possibly non-compliant, from users, the retail market or distribution sites and their return to the place of manufacture or other acceptable place for corrective action;
- removal of the CE conformity marking from withdrawn products, reprocessing or replacement of withdrawn products.

MRC shall notify the competent authority of the suspension of the certificate within 24 hours.

5.10 WITHDRAWAL AND CANCELLATION OF THE CERTIFICATE

Situations resulting in withdrawal and cancellation of the certificate

- the organisation does not pay the fees for carrying out activities prior to certification or for carrying out surveillance activities;
- the organisation does not apply the requirements resulting from the modification of MRC certification documents, which have been brought to their attention;
- the organisation fraudulently applies the notified body number (e.g. on products not subject to certification; on products that have undergone changes compared to the certified product);
- the organisation violates contractual requirements;
- the organisation is dissolved or goes bankrupt.

5.11. NOTIFICATION OF CHANGES

5.11.1. Changes to the certification scheme

In case of important changes to the certification rules (including fees) and/or the reference standard MRC will:

- notify the organisations concerned;
- take into account any comments from stakeholders on the changes;

- specify the date from which the changes take effect, allowing a reasonable period of time for the organisation to comply.

The organisation (already certified or in process) is entitled to withdraw certification if it considers that it cannot comply with the new requirements. Such a decision must be notified in writing and forwarded to MRC at least 30 days before the final compliance date.

5.11.2. Changes made by the organisation

The organisation must inform MRC without delay of any changes in its legal status, such as: change of registered office, name, address, object of activity of the organisation for review by MRC in order to update contractual data.

If the representatives of the organisation decide to transfer, assign, merge, absorb the company to another legal or natural person, they are obliged to inform MRC 10 days before the start of this procedure, in order to be able to decide on the conditions under which this contract takes effect.

The organization must also notify MRC at least 30 days in advance of changes it intends to make to the quality system that may affect the capability of the quality system, such as:

- changes in technology;
- changes in technological equipment;
- changes in raw material/resources etc.

The organisation must not supply certified products as a result of the announced changes without a written agreement from MRC.

MRC will analyse the nature of each change made by the organisation and if it may influence the already certified quality system, will schedule a new audit.

6. CONFIDENTIALITY

MRC guarantees the confidentiality of information obtained during certification activities, unless otherwise required by law.

MRC staff and collaborators (auditors/ contracted experts) sign and undertake not to disclose information collected during the audit process to a third party without written authorisation from the organisation.

7. MANAGEMENT OF COMPLAINTS AND APPEALS

The organisation has the right to make written complaints or appeals with full identification of contact details.

The appeal is the organisation's refusal to accept the decisions taken by MRC regarding assessment and certification activities. Disputes arise from the organisation's refusal to accept MRC's decision in the case of an appeal.

The appeal shall be made in writing and submitted to MRC no later than 30 days from the date the notification of the decision was received.

An acknowledgement of receipt of the appeal is sent to the appellant.

MRC reviews all documented sources on the subject.

After obtaining all necessary information, MRC communicates the decision to the appellant.
If the appeal is justified, MRC orders the necessary corrections/corrective/preventive actions and ensures that they have been implemented.
The period for resolving the appeal is 30 days from receipt of the appeal by MRC, unless there are objective reasons that require an extension.
If the client is dissatisfied with the response received, they may appeal MRC's decision. In this case, the Executive Director of MRC is obliged to bring the appeal to the attention of the CPEA.
The Commission will make an independent investigation and analysis and its decision will be final.
The costs associated with the investigation will be borne by the appellant if the CPEA finds the appeal to be unfounded and decides in favour of MRC, and if the CPEA decides that the appeal is meritorious and rules in favour of the appellant, all costs associated with conducting the investigation will be borne by MRC. Necessary expenses of the investigation means all expenses incurred for the purpose of disposing of the appeal (e.g. costs of the CPEA, payment of witnesses, expert opinions etc.).
If, following the resolution given by the CPEA, the appellant considers himself wronged, he may apply to the competent courts, triggering a dispute which will be settled according to the provisions of the Romanian legislation in force.
The complaint concerns the organisation's dissatisfaction with the administrative or technical performance of MRC or with the management system of a client of MRC.
Complaints are registered by MRC, which:

- acknowledges the receipt of the complaint to the complainant;
- informs the complainant client about the receipt of the complaint.

MRC reviews the complaint and all related data.
If the complaint is founded, MRC determines the necessary action and informs the complainant accordingly.
Certification by MRC does not include certification of facilities. MRC does not assume any responsibility for the occurrence of damage or accidents in the faulty or negligent operation of processes and facilities within the organisations nor for defective products.
As a result, complaints in these categories do not fall within the competence of MRC as a certification body.
The decision on the resolution of the complaint is determined/approved by persons not previously involved in the subject of the complaint.
The complaint resolution period is 30 days from receipt by MRC, unless there are objective reasons that require an extension.

OTHER INFORMATION

MRC publishes the following general rules on its website www.mrco.ro:
- detailed description of the certification activity, the initial one and the process of certification itself, maintenance, restriction, extension, suspension, withdrawal and recertification;
- regulatory requirements relating to certification;

- certification requirements for potential clients.

MRC informs clients, through the contract, of the fees for certification and for maintaining certification.

At the request of any interested party, MRC makes public information about the client and its certified products and also undertakes to confirm in writing, by fax or e-mail, or by telephone on request, the validity of a certification granted.

In exceptional cases, access to certain information may be limited at the request of the customer.

MRC may make information concerning the client available to a third party only with the client's prior consent, except in cases expressly provided for by law.

The procedure becomes effective upon approval by the Executive Director of MRC from the date of obtaining accreditation.

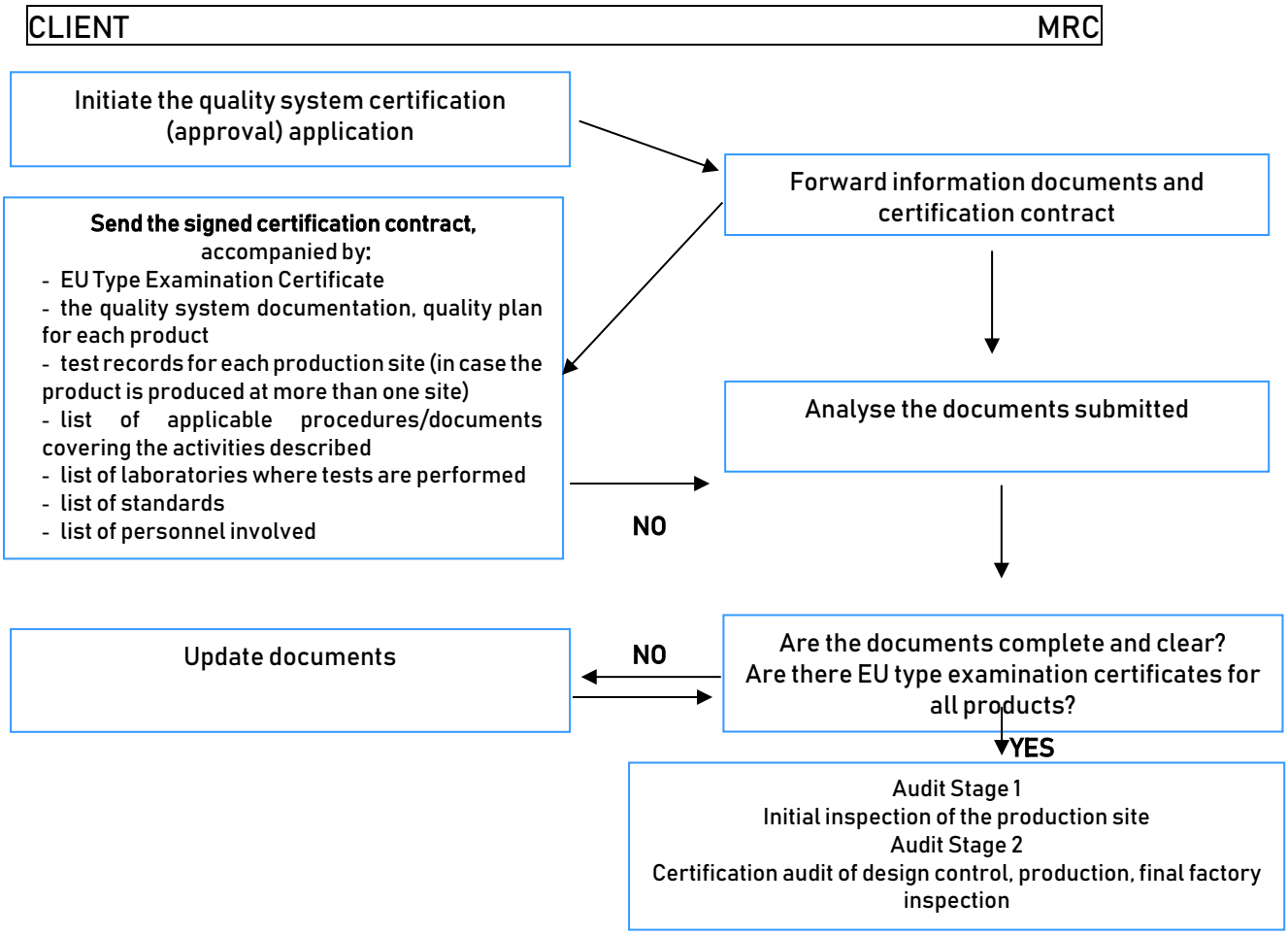
8. ANNEXES

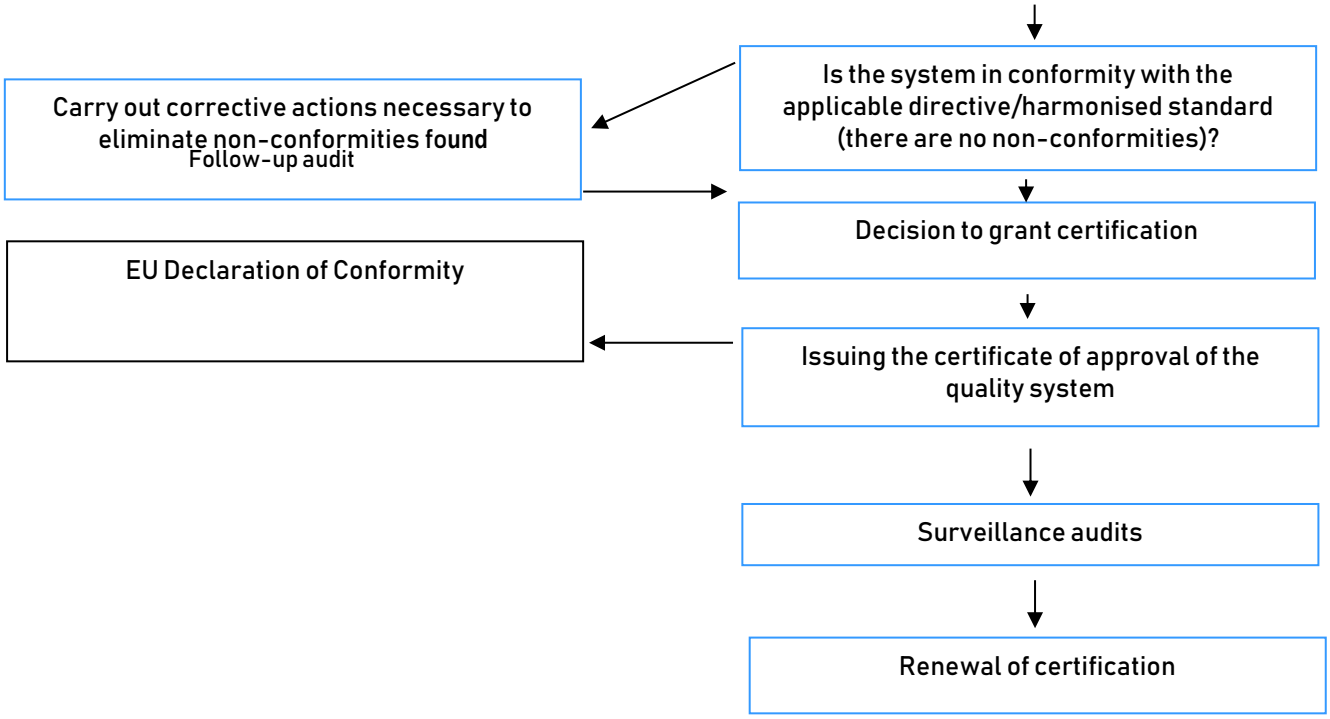
Annex 1 - Stages of the product conformity assessment process under Directives 2014/31/EU and 2014/32/EU

Annex 2 - Certification process

Annex 1

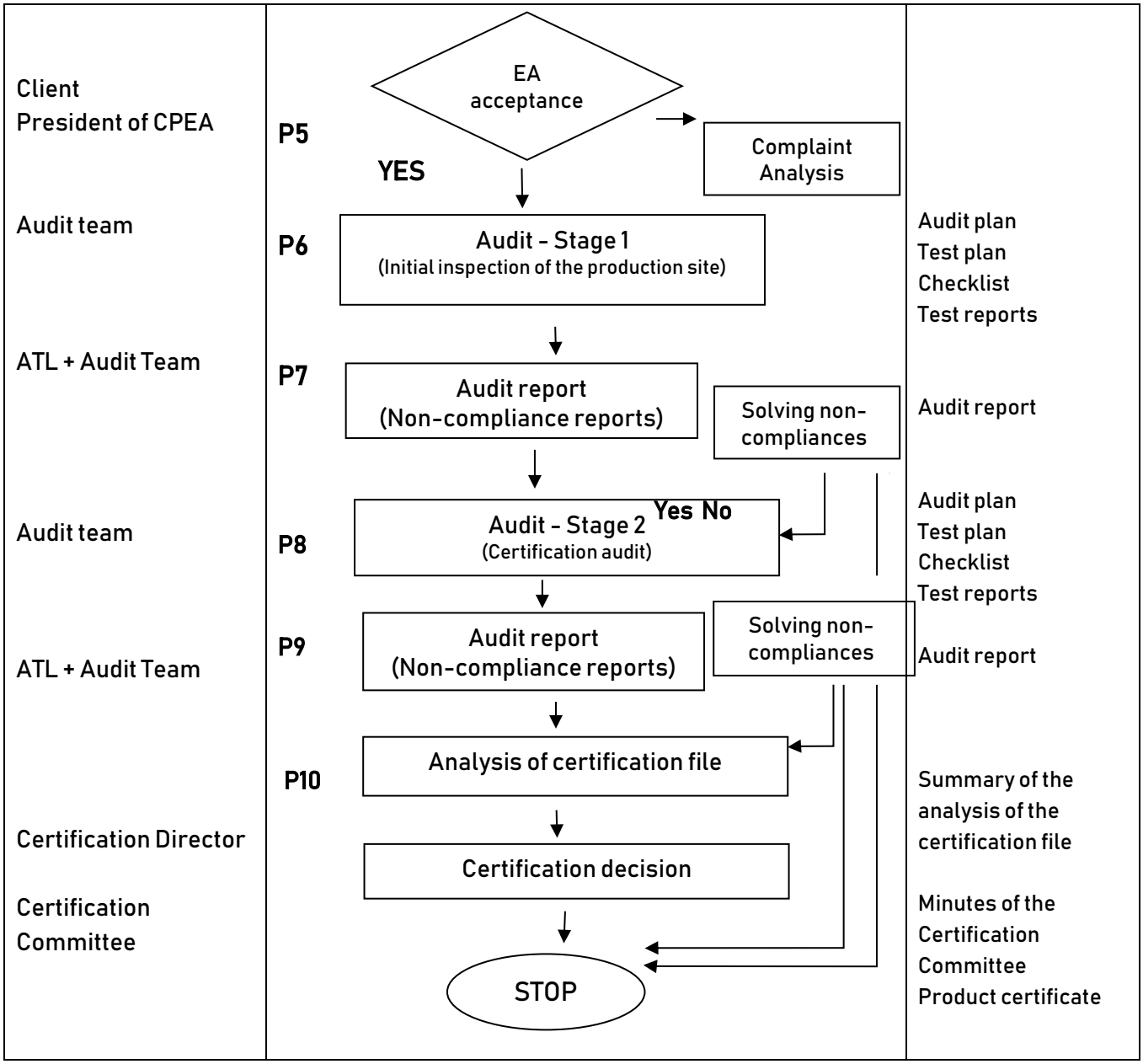
STAGES OF THE CONFORMITY ASSESSMENT PROCESS





Annex 2

Responsible	Process flow chart	Documents and Records
Certification Director Executive Director	START P1 Analysis of certification application	Certification order Certification contract and client documents
File manager	P2 Analysis of certification application	Certification file
Certification Director	P3 Analysis of certification application	EA appointment order
Certification Director	P4 Analysis of certification application	Client communication


Client
President of CPEA
Audit team
ATL + Audit Team
Audit team
ATL + Audit Team
Certification Director
Certification Committee
P5
P6
P7
P8
P9
P10
EA acceptance
YES
Complaint Analysis
Audit - Stage 1
(Initial inspection of the production site)
Audit report
(Non-compliance reports)
Solving non-compliances
Yes No
Audit - Stage 2
(Certification audit)
Audit report
(Non-compliance reports)
Solving non-compliances
Analysis of certification file
Certification decision
STOP
Audit plan
Test plan
Checklist
Test reports
Audit report
Audit plan
Test plan
Checklist
Test reports
Audit report
Summary of the analysis of the certification file
Minutes of the Certification Committee
Product certificate