Assessment of measuring instruments in accordance with directive 2014/32/EU (MID)
Foreword

A manufacturer can apply the CE-mark on Measuring Instruments after performing necessary activities as described in Directive 2014/32/EU.


Evaluation and testing are based on harmonised standards/normative documents and when these are lacking, the essential requirements in annex I of the Directive accompanied by the instrument specific requirements.

The rules can be revised as necessary to suit new and revised harmonised standards/normative documents. Revision may also be necessary if the Directive changes or as a consequence of experience gained from the application of the system, within the framework of the Directive.

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1 Scope

These rules cover procedures in accordance with the following for assessment of measuring instruments in accordance with Directive 2014/32 EU (MID) with the aim of issuing documents for CE marking. The services which RISE can offer are specified in the table below.

Table 1 RISE services within MID

<table>
<thead>
<tr>
<th>Products</th>
<th>B</th>
<th>D</th>
<th>F</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI-001 Water meters</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI-003 Active electrical energy meters</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI-004 Heat meters</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI-005 Measuring instruments for liquids</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>MI-006 Automatic weighing instruments</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>MI-007 Taxi meters</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI-008 Material measures</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

The procedures are based completely on what stated in the Directive. The Directive includes the following confirmation modules where a notified body is involved: (modules in italics cannot currently be offered by RISE)

Module B  EU-type examination
Module D  Conformity to type based on quality assurance of the production process
Module D1 Quality assurance of the production process (based on technical documentation)
Module E  Conformity to type based on product quality assurance
Module E1 Quality assurance of final product inspection and testing
Module F  Conformity to type based on product verification
Module F1 Conformity based on product verification
Module G  Conformity based on unit verification
Module H  Conformity based on full quality assurance
Module H1 Conformity based on full quality assurance plus design examination

The following confirmation modules can be used for the respective products: (next page)
Table 2 applicable confirmation modules (for the products included in RISE services)

<table>
<thead>
<tr>
<th>Products</th>
<th>Possible confirmation modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI-001 Water meters</td>
<td>B+D or B+F or H1</td>
</tr>
<tr>
<td>MI-003 Active electrical energy meters</td>
<td>B+D or B+F or H1</td>
</tr>
<tr>
<td>MI-004 Heat meters</td>
<td>B+D or B+F or H1</td>
</tr>
<tr>
<td>MI-005 Measuring instruments for liquids</td>
<td>B+D or B+F or G or H1</td>
</tr>
<tr>
<td>MI-006 Automatic weighing instruments</td>
<td>B+D or B+E or B+F or D1 or F1 or G or H1</td>
</tr>
<tr>
<td>mechanical systems</td>
<td>B+D or B+E or B+F or G or H1</td>
</tr>
<tr>
<td>electromechanical weighing instruments</td>
<td>B+D or B+E or B+F or G or H1</td>
</tr>
<tr>
<td>electromechanical weighing instruments or weighing instruments which contain software</td>
<td>B+D or B+F or G or H1</td>
</tr>
<tr>
<td>MI-007 Taxi meters</td>
<td>B+D or B+F or H1</td>
</tr>
<tr>
<td>MI-008 Material measures</td>
<td>B+D or D1 or F1 or G or H.</td>
</tr>
</tbody>
</table>

The prerequisites for the respective modules are described in the following document in sections 2-6. Within certain frameworks the manufacturer chooses which modules he wants to use, and in the same manner the manufacturer chooses which notified body/bodies shall perform which task.
2   EU-type examination (Module B)

2.1   General
This section describes the EU-type examination (certification) of measuring instruments, which is based on Directive 2014/32/EU, annex II, module B, and involves examining that the product meets the applicable requirements of the Directive. EU-type examination can be performed in one the following ways:
- Examination of a sample which is representative of the production
- Assessment of the technical design by means of review of the technical documentation as well as examination (testing) of one or several critical parts of a sample. The sample shall be representative of the production
- Assessment of the technical design through review of the technical documentation. (No testing takes place in this case).

RISE decides which manner is appropriate for the current product using Welmec guide 8.3. See also below evaluation section 2.3.3. Other conditions are listed in section 7.

2.2   Required characteristics

2.2.1 Measuring instruments which conform to harmonised standards
Measuring instruments manufactured according to harmonised standards/normative documents are presumed to satisfy the relevant requirements in the Directive.

2.2.2 Other measuring instruments
An evaluation programme is prepared for the instrument in question. The programme should, as far as possible, be based on the relevant parts of harmonised standards or normative documents. The evaluation of the parts that do not conform to the standard is to be based on official guidelines from Welmec or a documented method (with method a procedure or way of evaluation is meant and it could be documented as a SP-method/RISE-method) from application in previous similar cases. The requirements of the programme should be at the same level as that of the standard, and ensure that all essential requirements of the Directive are fulfilled.

Feedback is sought from the manufacturer before the evaluation begins. Feedback can also be obtained from Welmec, especially following major deviations.

The established programme, in terms of general principles for the type case, is documented as a procedure/SP-method that is then used to supplement the standard when applied to similar cases.

2.3   Assessment

2.3.1 Application
Applications for EU-type examinations (certification) shall be in writing and shall be accompanied by:
- The manufacturer’s name and address and, if the application is submitted by an authorised representative, his/her name and address as well.
- A written declaration that the application has not been submitted to another notified body.
- Technical data (see below).
- When applicable, the measuring instrument which is representative of the type shall be placed at RISE disposal for review.
• Documents which illustrate that the technical design is appropriate. The document should cover or refer to all the documents which have been used, particularly in cases where harmonised standards/normative documents are not complied with. If necessary, the documentation should also comprise of reports from testing and risk analysis which the manufacturer has conducted or allowed another party to conduct. (see also below 2.3.1.1).

An application form is available on RISE website, www.ri.se.

2.3.1.1 Technical data
Technical data shall describe, among other things, the design, manufacture and operation method of the instrument. This means that it in relevant parts shall contain:

• a general description of the instrument
• design and manufacturing drawings and circuit diagram, layout and bill of components, sub-assemblies, circuits, etc.
• Manufacturing procedures which ensure a consistent production quality
• If appropriate, a description of electronic devices including drawings, diagrams, flow charts as well as information which explains properties and functions
• descriptions and explanations necessary for understanding the above
• a list of the harmonised standards applied, in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive’s annex 1 and instrument specific requirements when the harmonised standard or normative document has not been applied
• results of design calculations and examinations
• testing reports, particularly to show that the measuring instruments; conform to the requirements of this directive during nominal operating conditions and during specified disturbances in the environment; sustainability specifications for gas, water and heat energy meters and for fluids other than water
• EU-type examination certificate or EU design examination certificates of measuring instruments containing parts identical to those in the design
• Specifications of where seals and markings have been placed
• Conditions for compatibility with interfaces and sub-assemblies if appropriate

All documents including drawings, product descriptions, assembly instructions, user manuals etc. shall be given a name or number and date as well as date of last revision.

2.3.2 Review of application
When reviewing the application, RISE checks that the application is complete and that the application can be handled within RISE notification. The review may mean that RISE cannot accept the assignment, which is then communicated to the manufacturer with an explanation.

If the application is accepted, the manufacturer is notified by means of a confirmation. An evaluation plan is prepared if this does not already exist. When a harmonised standard/normative document is followed, this largely represents the evaluation plan. If a subcontractor has to be engaged, this is communicated to the manufacturer. The manufacturer is entitled to object to the selected subcontractor.

If this is not done together with the application, the manufacturer is encouraged to send test samples to the extent that the evaluation plan requires this.

2.3.3 Evaluation
During the evaluation process, depending on the method which is chosen (see 2.1) it is either checked that:
• The product has been manufactured in accordance with the technical data, and that it meets the requirements that the standard or specification requires. The evaluation process includes tests and examinations that are carried out to the extent that the requirements specification and/or evaluation plan specifies. In some cases, previous test results can be used for the evaluation. The requirements for these tests include that they shall have been carried out by an accredited independent testing laboratory. The evaluation also includes a review of marking and information to the user etc.

or

• That the technical documentation can show that the design fulfils the requirements.

In cases where the product and/or documentation shows deficiencies, i.e. does not meet the requirements, the evaluation may be cancelled. The manufacturer will be informed, and will get the possibility to add supplementary data and documentation. If the product itself shows deficiencies, the manufacturer will be able to modify the product. If a complete retest is necessary depends on the type of modification and will be judged from case to case.

Results of the evaluation are summarised in an evaluation report which is presented to the manufacturer. The report is confidential and may not, in full or part, be disseminated without the manufacturer’s consent.

If the results of the evaluation show that the product and documentation meet the requirements of the specification, the process proceeds to review and then decision.

2.3.4 Review and decision
The evaluation work is reviewed, and following successful results, the process proceeds to the decision phase. When a decision on certification has been taken, an EU-type examination certificate is issued to the manufacturer. This certificate can be used by the manufacturer as a part of the documentation required to issue a declaration of conformity and to CE mark the product.

2.4 EU-type examination certificate

2.4.1 Validity
EU-type examination certificates for measuring instruments are normally issued with a validity period of ten years from the date of issue. The validity period may then be extended for a maximum of ten years at a time. In the event of revision of a certificate, the original validity period is retained.

2.4.2 Extension of validity period for the certificate issued.
Applications for extension shall be made in writing, at least 6 months before the end of the validity period. For the application, an assessment is made of the measures required for the extension. If no changes are made to the regulations, specifications, etc., the certificate can be extended without any further action, provided, of course, that the product is unchanged relative to the original certification or the latest revision. The applicant shall certify that no changes have been made. A current set of the technical documentation shall be attached (see 2.3.1.1).

If changes are planned for the product, the application shall be supplemented with details about this. This may result in that additional assessments and/or tests need to be performed.

In this case, the manufacturer shall be informed thereof and may then also be given a price quotation for this.
2.5 Changes to certified products
Note that no changes may be made to the certified product, without this being assessed and approved by RISE. The manufacturer shall therefore notify RISE of any planned changes to the certified product. Along with this notification, a description of the changes along with the addition of the technical data are to be attached. RISE will then assess if the changes can be included in the current certificate or if the certificate needs to be revised. If current certificate can include the changes the manufacturer is notified.

If the changes cannot be included a judgement regarding which supplementary examinations/testings that has to be carried out. In this case, the manufacturer shall be notified thereof and may then also be given a price quotation for this. If the result fulfils the requirements the certificate is revised with the new information.

2.6 Placing on the market and CE marking
In order to place a measuring instrument on the market the manufacturer shall, in a supplement to a valid EU-type examination certificate, also engage a notified body to perform any of the confirmity procedures stated in point 1.3, table 2 above. The manufacturer chooses the applicable confirmity procedure to be used and which notified body will carry out the task.
The CE marking shall be supplemented with the metrology marking and the identification number of the notified body which performs this task. See more on this in section 7. See section 3 and onwards for the different procedures.
3 Conformity to type based on quality assurance of the production process (Module D)

3.1 General
Directive 2014/32/EU states a number of options which manufacturers can choose from proving conformity of type-approved/certified measuring instruments with the aim of approving them for the market. One option is the quality assurance of production, that the manufacturer is responsible for, and which is followed up through surveillance, which RISE is responsible for. This is based on Directive 2014/32/EU, annex II, module D. Other conditions are listed in section 7.

For module D it is necessary that the manufacturer has one or several applicable EU-type examination certificates for the measuring instruments which will be covered.

3.2 Application
The application for assessment (certification) of the quality system shall be in writing and be accompanied by:

- the manufacturer’s name and address, and if the application is lodged by an authorised representative, his/her name and address as well.
- a written declaration that the application has not been submitted to another notified body.
- all information of significance for the concerned category of measuring instruments
- quality manual or equivalent documentation for the quality system
- the technical documentation for the type/types and a copy of the EU-type examination certificate/certificates.

* By manufacturer the company placing the product on the market under its name is meant.

An application form is available on RISE website, [www.ri.se](http://www.ri.se).

The application shall also state if the quality system covers all or parts of the company, or all or parts of the production. In addition it shall be stated if manufacturing takes place at any other company.

3.3 Quality system requirements
The requirements of the quality system are specified in annex II, module D of the Directive. The quality system shall ensure that the measuring instruments comply with the type-approved and satisfy the applicable requirements of the Directive. The system shall be documented in accordance with point 3.4 below.

The manufacturer shall undertake to:

- maintain the approved quality system to ensure its continuing suitability and effectiveness.
- inform RISE about all changes which are planned in the quality system.

3.4 Documentation requirements
The documentation shall describe:

- quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality
- manufacturing processes, methods and techniques for quality control and quality assurance as well as the systematic actions that will be taken
- the examinations and tests that will be carried out before, during and after manufacture, including frequency
- quality documents, for example, audit reports, test results, calibration results, documentation of the qualifications of staff, etc.
- the methods of monitoring that the set quality objectives are achieved and that the quality system works effectively

All relevant information such as quality documents and design documents shall be kept available for RISE.

3.5 Review and assessment of the quality system

3.5.1 General
During the assessment (audit), auditors and technical experts who are employed or contracted by RISE are used. At least one of the members in the audit team has experience of the product area. Auditors or technical experts may not participate in an audit if impartiality can be questioned. Companies undergoing an audit can veto an auditor without needing to state the reason why. The assessment (audit) shall be carried out where the manufacturing and/or final inspection takes place. Agreements on dates and times for assessments are normally made between the lead auditor in question and the manufacturer. The requested documentation shall be sent to the auditor in question.

3.5.2 Initial audit stage 1
The initial audit stage 1 is carried out in order to plan the initial audit stage 2 and to ensure that the quality system is auditable. Review of documentation and examination of product certificates, type approvals and similar which are covered by the quality system are also conducted. The final scope of the stage 2 audit is determined after audit stage 1, as well as a plan for the coming three years. The audit team is also settled. In some cases audit stage 1 has to be performed on site, otherwise the audit can be performed as a remote audit.

3.5.3 Initial audit stage 2
Initial audit stage 2 is conducted to assess the conformity of the quality system with all requirement elements in the directive. All departments, units, functions or similar that are covered by the audit shall be reviewed.

3.5.4 Report
An audit report containing the results, recommendation on approval and the scope of the audit is compiled for the audit. The result contains information on any deviations against requirements which emerged during the audit. Deviations are classified as major deviations, minor deviations or notes. Major deviations are serious and mean that corrective actions shall be performed immediately, and shall be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified. A note is an observation which may be useful to consider, but there is no requirement for any measure.
The company shall report corrective measures for deviations (major and minor) within the period stipulated in the report. The auditor checks and approves the corrective actions and sends a statement of acceptance to the manufacturer.

3.5.5 Post audit
In the event of major deviations from the requirements set out in the directive, a complementary post audit is required. This can be performed as a document review or audit on site at the company and is charged in accordance with the applicable price list.

3.5.6 Re-audit
If initial audit Stage 2 results in a large number of major deviations, an entirely new audit (stage 2) may be required.

3.6 Certificate
When corrective actions of all non-conformities, if any, are finished, reported and accepted, RISE can take a decision on approval of the quality system. As a receipt, an Assessment Decision (certificate) will be issued. The certificate allows the manufacturer to use RISE identification number, see section 7. The validity period of this certificate is 5 years, provided that all conditions are fulfilled.

3.7 Marking
See section 7.

3.8 Surveillance of quality system
RISE will conduct audits at regular intervals, normally once a year, and submit audit reports as described under 3.5.3 above. RISE may visit the manufacturer without notice and/or conduct/allow the conduct of testing. RISE reports results in the audit report and/or testing report.
If major deviations are found, corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified, but the manufacturer will have 6-8 weeks respite to report this.
A note is an observation which may be useful to consider,

3.9 Renewal of certificate
The certificate can be renewed every fifth year. One of the conditions for renewal is that surveillance audits has been performed as scheduled and with approved result.
4 Conformity to type based on product verification (Module F)

4.1 General
The procedure entails that the manufacturer takes all necessary measures for ensuring that manufactured instruments conform to the requirements and that RISE establishes that manufactured instruments conform to that which is stated in EU-type examination certificate. For module F it is necessary that the manufacturer has one or several applicable EU-type examination certificates for the measuring instruments which will be covered.

4.2 Application
The manufacturer applies for assessment of its measuring instruments. A list of the products which are covered by the assessment the quantity involved and, when applicable, the EU-type examination certificates which exists, alternatively the technical documentation, shall also be attached to the application.

4.3 Evaluation
RISE conducts/allows the conduct of examinations/testing in order to check conformity with type in accordance with the description in EU-type examination certificates and technical documentation. Testing is conducted of each instrument or of a number of products which have been selected in accordance with a statistical selection procedure. The examination can be conducted at the manufacturer or at another site. The results of the evaluation are summarised in an internal evaluation report.

4.4 Review, decision and Certificate of Conformity
The evaluation work is reviewed, and following successful results, the process proceeds to the decision phase. When a decision on certification has been taken, a Certificate of Conformity for the actual weighing instrument(s) or combination is issued. The certificate shall contain an identification, e.g. serial numbers, of the products which have been approved.

4.5 Marking
See section 7.

4.6 Failed products
For failed lots, RISE shall take appropriate measures to prevent placing on the market. In principle this means that the products shall be destroyed or reworked. A renewed examination/test shall be conducted following any rework.
5 Conformity based on unit verification (Module G)

5.1 General
This section describes the unit verification of a single measuring instrument, which is based on Directive 2014/32/EU, annex II, module G, and involves examining that the product meets the applicable requirements of the Directive.

5.2 Required characteristics

5.2.1 Measuring instruments which conform to harmonised standards
A measuring instrument manufactured according to harmonised standards/normative documents is presumed to satisfy the relevant requirements in the Directive.

5.2.2 Other measuring instruments
An evaluation programme is prepared for the instrument in question. The programme should, as far as possible, be based on the relevant parts of harmonised standards or normative documents. The evaluation of the parts that do not conform to the standard is to be based on official guidelines from Welmec or a documented method (with method a procedure or way of evaluation is meant and it could be documented as a SP-method/RISE-method) from application in previous similar cases. The requirements of the programme should be at the same level as that of the standard, and ensure that all essential requirements of the Directive are fulfilled.

Feedback is sought from the manufacturer before the evaluation begins. Feedback can also be obtained from Welmec, especially following major deviations.

The established programme, in terms of general principles for the type case, is documented as a procedure/SP-method that is then used to supplement the standard when applied to similar cases.

5.3 Assessment

5.3.1 Application
Applications for unit verification shall be in writing and shall be accompanied by:
- The manufacturer’s name and address and, if the application is submitted by an authorised representative, his/her name and address as well.
- A written declaration that the application has not been submitted to another notified body.
- Technical data (see below).
- Documents which illustrate that the technical design is appropriate. The document should cover or refer to all the documents which have been used, particularly in cases where harmonised standards/normative documents are not complied with. If necessary, the documentation should also comprise of reports from testing and risk analysis which the manufacturer has conducted or allowed another party to conduct. (see also below 2.3.1.1).
- Information about where the examination of the instrument can be performed, i.e. where the instrument shall be located.

An application form is available on RISE website, www.ri.se.
5.3.1.1 Technical data
Technical data shall describe, among other things, the design, manufacture and operation method of the instrument. This means that it in relevant parts shall contain:

- a general description of the instrument
- design and manufacturing drawings and circuit diagram, layout and bill of components, sub-assemblies, circuits, etc.
- If appropriate, a description of electronic devices including drawings, diagrams, flow charts as well as information which explains properties and functions
- descriptions and explanations necessary for understanding the above
- a list of the harmonised standards applied, in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive’s annex 1 and instrument specific requirements when the harmonised standard or normative document has not been applied
- results of design calculations and examinations
- testing reports, particularly to show that the measuring instruments; conform to the requirements of this directive during nominal operating conditions and during specified disturbances in the environment; sustainability specifications for gas, water and heat energy meters and for fluids other than water
- Specifications of where seals and markings shall be placed
- Conditions for compatibility with interfaces and sub-assemblies if appropriate

All documents including drawings, product descriptions, assembly instructions, user manuals etc. shall be given a name or number and date as well as date of last revision.

5.3.2 Review of application
When reviewing the application, RISE checks that the application is complete and that the application can be handled within RISE notification. The review may mean that RISE cannot accept the assignment, which is then communicated to the manufacturer with an explanation.

If the application is accepted, the manufacturer is notified by means of a confirmation.

5.3.3 Evaluation
During the evaluation process, it is checked that the instrument has been manufactured in accordance with the technical data, and that it meets the requirements that the standard or specification requires. The evaluation process includes tests and examinations that are carried out to the extent that the requirements specification and/or evaluation plan specifies. In some cases, previous test results can be used for the evaluation. The requirements for these tests include that they shall have been carried out by an accredited independent testing laboratory. The evaluation also includes a review of marking and information to the user etc.

In cases where the instrument and/or documentation shows deficiencies, i.e. does not meet the requirements, the evaluation may be cancelled. The manufacturer will be informed, and will get the possibility to add supplementary data and documentation. If the product itself shows deficiencies, the manufacturer will be able to modify the product. If a complete retest is necessary depends on the type of modification and will be judged from case to case. If the results of the evaluation show that the product and documentation meet the requirements of the specification, the process proceeds to review and then decision.
5.3.4 Review and decision
The evaluation work is reviewed, and following successful results, the process proceeds to the decision phase. When a decision on certification has been taken, a Certificate of Conformity is issued to the manufacturer. This certificate can be used by the manufacturer as a part of the documentation required to issue a declaration of conformity and to CE mark the product.

5.5 Marking
See section 7.
6 Conformity based on full quality assurance (module H)

6.1 General
The assessment consists of an initial inspection, in accordance with section 6.3, which is an evaluation of the implementation, application and efficiency of the quality system. If the quality system can be deemed to fulfil the set requirements, RISE issues a module H certificate. RISE will also issue an assessment report. (The assessment report is not official). Other conditions are listed in section 7.

6.2 Application
The manufacturer applies for assessment of its quality system.

The requirements on the quality system are stated in MID Annex H 3.2. The manufacturer attaches documentation of the quality system to the application. A list of the products which are covered by the quality system which will be reviewed, and when applicable, the EU-type certificates which exist, shall also be attached to the application.

The application for assessment (certification) of the quality system shall be in writing and be accompanied by:
- the manufacturer’s name and address, and if the application is lodged by an authorised representative, his/her name and address as well. In addition it shall be stated if manufacturing takes place at any other company.
- The technical documentation (in accordance with the description in article 18 of the Directive) for a model of each category of products which are planned to be manufactured. The documentation shall enable assessment of whether the instrument fulfils applicable requirements in the Directive and shall also contain a satisfactory analysis and assessment of risks. The documentation shall also contain a description of the design, manufacturing process and mode of operation.
- A written declaration that the application has not been submitted to another notified body.

*By manufacturer the company placing the product on the market under its name is meant.

An application form is available on RISE website, www.ri.se.

Furthermore, a quality manual or equivalent documentation of the quality system, which in particular shall contain:
- Quality objectives, organisational structure
- A description of the responsibilities and powers of the management with regard to product quality
- Methods, processes and systematic procedures which are used to verify the design work for the concerned instruments
- Methods, processes and systematic procedures which are used for the manufacturing process in order to safeguard the product’s characteristics
- Which tests, inspections and process controls are used in the manufacturing process, including frequency
- Control of the quality documentation, such as audit and test reports, calibration results, competence and qualifications of the staff
- Methods to monitor that the design and product quality are attained and that the quality system functions efficiently
• design work for the concerned instruments

The manufacturer shall undertake to:
• Maintain the approved quality system to ensure its continuing suitability and effectiveness.
• Inform RISE about all changes which are planned in the quality system.

6.3 Review and assessment of the quality system

6.3.1 General
During the assessment (audit), auditors who are employed or contracted by RISE or who are approved by RISE Certification as subcon-tractors are used. At least one of the auditors have experience of the product area. An audit team is formed when the same person does not have both competencies. Auditors or technical experts may not participate in an audit if impartiality can be questioned. Companies undergoing an audit can veto an auditor without needing to state the reason why. The assessment (audit) shall be carried out where the manufacturing and/or final inspection takes place. Agreements on dates and times for assessments are normally made between the lead auditor in question and the manufacturer. The requested documentation shall be sent to the auditor in question.

6.3.2 Initial audit stage 1
The initial audit stage 1 is carried out in order to plan the initial audit stage 2 and to ensure that the quality system is auditable. Review of documentation and examination of product certificates, type approvals and similar which are covered by the quality system are also conducted. Following the initial audit stage 1, the total scope of the initial audit is determined. If it differs from what was stated in the original tender, a new tender is submitted. In some cases audit stage 1 has to be performed at the manufacturer premises.

6.3.3 Initial audit stage 2, - audit
Initial audit stage 2 is conducted to assess the conformity of the quality system with all requirement elements in the directive. All departments, units, functions or similar that are covered by the audit shall be reviewed.

6.3.4 Report
An audit report containing the results, recommendation on approval and the scope of the audit is compiled for the audit. The result contains information on any deviations against requirements which emerged during the audit. Deviations are classified as major deviations, minor deviations or notes. Major deviations are serious and mean that corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified. A note is an observation which may be useful to consider, but there is no requirement for any measure.

The company should report corrective measures for deviations (major and minor) within the period stipulated in the report. The auditor checks and approves the corrective measures and sends an acceptance of measures statement to the manufacturer.

6.3.5 Post audit
In the event of major deviations from the requirements set out in the directive, a complementary post audit is required. This can be performed as a document review or audit on site at the company and is charged in accordance with the applicable price list.
6.3.6 Re-audit
If initial audit Stage 2 results in a large number of major deviations, an entirely new audit (stage 2) may be required.

6.4 Certificate
When corrective measures of all non-conformities, if any, are finished, reported and accepted, RISE can take a decision on approval of the quality system. As a receipt, an assessment decision (certificate) will be issued. The certificate allows the manufacturer to use RISE identification number, see section 7. The validity period of this certificate is 3 years, provided that all conditions are fulfilled.

6.5 Marking
See section 7.

6.6 Surveillance of quality system
RISE will conduct audits at regular intervals, normally once a year, and submit audit reports as described under 6.3.3 above. RISE may visit the manufacturer without notice and/or conduct/allow the conduct of testing. RISE reports results in the audit report and/or testing report.
If major deviations are found, corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified, but the manufacturer will have 6-8 weeks respite to report this.
A note is an observation which may be useful to consider,

6.7 Renewal of certificate
The certificate can be renewed every third year. One of the conditions for renewal is that surveillance audits has been performed as scheduled and with approved result.
7 General conditions

7.1 Marking
CE-marking of measuring instruments takes place on the manufacturer’s responsibility, and shall also contain meteorology marking. In those cases where RISE has carried out the assessment procedures according to modules D-H, RISE ID number as notified body (0402) shall be placed adjoining the CE mark. Only products that comply with the requirements in the Directive may be marked. Misuse of RISE ID number can lead to legal action.

7.2 Certificate
The validity of the certificate is based on continuous compliance with the conditions. Certificates are not transferable. Copies of certificates and associated documents may only be reproduced in their entirety, unless otherwise agreed with RISE.

7.3 Responsibility
The certificate holder is responsible for:
- fulfilling all requirements connected to the certification including notified changes in certification rules or conditions,
- not providing any misleading information about the extent or conditions of the certification which can harm the confidence for the certification or RISE
- ensuring that CE-marked products comply with the applicable requirements in one or more directives, with corresponding national provisions and the requirements specified in the certificate

RISE is responsible for:
- ensuring that all processing is carried out with the necessary care and in accordance with the procedures of RISE quality system.
- the certification rules
- to inform about changes in the certification rules and conditions.

RISE has no responsibility for certified products.

7.4 Withdrawal of certificate
RISE, either definitely or permanently, can withdraw a certificate if:
- the product no longer meets the set requirements
- the assessed quality system do not fulfil the defined requirements any longer.
- errors in the certificate come to light
- demands for continual examination are not met
- the internal examination shows serious shortcomings
- shortcomings in the internal examination are not remedied in the time prescribed
- there are failed results in examination testing in the regulatory examination
- the product is not suitable for its purpose or can cause injury or problems
- changes are made to legislation, regulations or similar
- the competent authorities or coordinating body for a notified body recommends RISE to do so
- the holder has used the certificate in connection with products that do not meet the requirements or are not covered by the certificate
- fees are not paid within the prescribed deadline, the certificate holder is subject to bankruptcy, has gone into liquidation or has transferred operations
- breach of the conditions for the certificate.
If a certificate is withdrawn, the holder shall cancel all reference to the certificate and RISE name and id.no. 0402 in his EU Declaration of Conformity and marking. The holder may neither refer to the certificate or RISE in advertisements or other publications for the product in question.

7.5 Changes to products, quality systems, organisation
Changes to certified products, see 2.4
In terms of quality systems in accordance with modules D and H, changes to the quality system shall be notified to RISE. Even major organisational changes or other factors which may impact the certificate shall be notified.

7.6 Information obligation, confidentiality and access
As a notified body, RISE is in some cases obliged to reveal information on certificates to other notified bodies and competent authorities. RISE informs Swedac about issued certificates as well as refusals, restrictions, suspensions and withdrawals of certificates.

RISE keeps a register of certificate holders, certificates, certified products and certified quality systems, manufacturing sites, validity period for certificates etc. This information may be published, for example, on RISE websites. RISE may provide copies of or publish the certificates. RISE is also entitled to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is classified.

The manufacturer, or its representative, shall ensure that RISE, the control body that RISE has approved, or observers (e.g. from the accreditation body) have access to premises and documents that are needed to perform the duties described in the sections 2-6.

7.7 Revised rules
RISE reserves the right to modify these rules in order to harmonise them with standards, changes to the Directive or rules for Notified Bodies, or as a result of experience of application of the system.

7.8 Fees
Fees are set according to agreement and shall be paid by the certificate holder. Costs for work resulting from deviations in the continuous examination shall be paid by the certificate holder. The fees for another examination shall only be paid by the certificate holder if the examination results show that the requirements of the certification regulations are not fulfilled.

Application and registration fees are normally not reimbursed when an assignment is cancelled or a certificate cannot be issued. In the case of assignments that are not estimated to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.

7.9 Appeals
Appeals against RISE decisions shall be made in writing. Decisions on measures necessary as a result of appeals are taken by the RISE Certification Board.