Assessment of non-automatic weighing instruments in accordance with directive 2014/31/EU (NAWI)
Foreword

A manufacturer can apply the CE-mark on Non-Automatic Weighing Instruments after performing necessary activities as described in Directive 2014/31/EU.

This document contains RISE rules for assessment of Non-Automatic Weighing Instruments which are covered by Directive 2014/31/EU. The document presents the procedures for conformity assessment applied by RISE, acting as a notified body.


Evaluation and testing is based on the requirements in EN 45501:2015 and relevant WELMEC guides, or when EN 45501:2015 is not applicable, on the essential requirements in annex I of the Directive.

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.

This version of the rules replaces the previous version dated 2021-12-21

Borås, August 2023

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Contents

FOREWORD................................................................................................................................. 2
CONTENTS..................................................................................................................................... 3
1 SCOPE ........................................................................................................................................ 4
2 EU-TYPE EXAMINATION (MODULE B) .................................................................................. 5
  2.1 General.................................................................................................................................. 5
  2.2 Required characteristics......................................................................................................... 5
  2.2.1 Weighing instruments that comply with EN 45501:2015 ................................................. 5
  2.2.2 Other weighing instruments............................................................................................... 5
  2.3 Assessment............................................................................................................................. 6
  2.3.1 Application......................................................................................................................... 6
  2.3.2 Review of application........................................................................................................ 6
  2.3.3 Evaluation........................................................................................................................ 7
  2.3.4 Review and decision .......................................................................................................... 7
  2.4 EU-type examination certificate............................................................................................ 7
  2.4.1 Validity .............................................................................................................................. 7
  2.4.2 Extension of validity period for the certificate issued....................................................... 8
  2.5 Changes to certified products................................................................................................ 8
  2.6 Placing on the market and CE marking ................................................................................. 8
3 CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D)................................................. 9
  3.1 General.................................................................................................................................. 9
  3.2 Application............................................................................................................................. 9
  3.3 Quality system requirements.................................................................................................. 9
  3.4 Documentation requirements................................................................................................ 9
  3.5 Review and assessment of the quality system....................................................................... 10
  3.5.1 General............................................................................................................................ 10
  3.5.2 Initial audit stage 1.......................................................................................................... 10
  3.5.3 Initial audit stage 2.......................................................................................................... 10
  3.5.4 Report............................................................................................................................... 10
  3.5.5 Post audit........................................................................................................................ 10
  3.5.6 Re-audit........................................................................................................................... 11
  3.6 Certificate............................................................................................................................ 11
  3.7 Marking................................................................................................................................ 11
  3.8 Surveillance of quality system.............................................................................................. 11
  3.9 Renewal of certificate........................................................................................................... 11
4 CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION (MODULE F)........................................................................................................... 12
  4.1 General.................................................................................................................................. 12
  4.2 Application/Order................................................................................................................ 12
  4.2.1 Application....................................................................................................................... 12
  4.2.2 Orders ............................................................................................................................. 12
  4.3 Evaluation............................................................................................................................. 12
  4.4 Review, decision and Certificate of Conformity ................................................................. 13
  4.5 Marking................................................................................................................................ 13
  4.6 Failed products.................................................................................................................... 13
5 GENERAL CONDITIONS......................................................................................................... 14
  5.1 Marking................................................................................................................................. 14
  5.2 Certificate............................................................................................................................ 14
  5.3 Responsibility....................................................................................................................... 14
  5.4 Withdrawal of certificate..................................................................................................... 14
  5.5 Changes to products, quality systems, organisation ............................................................ 15
  5.6 Information obligation, confidentiality and access .............................................................. 15
  5.7 Revised rules....................................................................................................................... 15
  5.8 Fees.................................................................................................................................... 15
  5.9 Appeals................................................................................................................................ 15
1 Scope

The procedures in this document are based completely on what is stated in Directive 2014/31/EU annex II.

The figure below shows the different methods in diagram form for CE marking of a non-automatic weighing instrument. RISE services includes assessment according to modules B, D and F (grey shaded fields) See explanations below.

Module B: EU-type examination of specimens of products, in accordance with section 2 of this document (annex II, section 1 of the Directive), fulfils the technical requirements (however, does not apply to weighing instruments which do not use electronics and do not have spring-based load cells)

Module D: Conformity to type based on quality assurance of the production in accordance with section 3 of this document (annex II, section 2 of the Directive)

Module F: Conformity to type based on product verification in accordance with section 4 of this document (annex II, section 4 of the Directive)

Module G: Conformity based on unit verification (annex II, section 6 of the Directive. Not offered by RISE)

As a basis for the CE marking, B+D or B+F or only G is required, based on the manufacturer’s choice. (For weighing instruments which do not use electronics and do not have a spring-based load cell, it is not necessary to apply module B. Here modules D1 or F1 are applied. These services are not offered by RISE)
2 EU-type examination (Module B)

2.1 General
This section describes the EU-type examination (certification) of non-automatic weighing instruments, which is based on Directive 2014/31/EU, annex II, section 1.2, and involves examining that the product meets the applicable requirements of the Directive.
EU-type examination can be performed in one the following ways:
• Inspection (testing) 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 inspection (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 section 2.3.3 below. Other conditions are listed in section 5.

2.2 Required characteristics

2.2.1 Weighing instruments that comply with EN 45501:2015
Type examination is performed according to EN 45501:2015, annex A. For electronic weighing instruments type examination is also including SS-EN 45501:2015 annexes B and C.

Metrological requirements are specified in Chapter 3 of the standard. Chapter 4 specifies technical requirements, and requirements for electronic weighing instruments are specified in Chapter 5.

Weighing instruments manufactured according to harmonised standards are presumed to satisfy the relevant requirements in the Directive.

During testing and evaluation, the RISE method 2031 is used, which is based on the standard and contains requirements for documentation, checklists, etc.

2.2.2 Other weighing instruments
An evaluation plan is prepared for the weighing instruments in question. The plan shall, as far as possible, be based on the relevant parts of SS-EN 45501:2015. The evaluation of the parts that do not conform to the standard is to be based on the standard, RISE method 2031, official guidelines from Welmec or a documented method from application in previous similar cases. The requirements of the programme shall be at the same level as the standard.

Feedback is sought from the manufacturer before the evaluation begins. Feedback can also be obtained from Welmec WG2, especially following major deviations.

The parts that deviate from SS-EN 45501:2015 shall be stated during the evaluation and notified to the manufacturer, unless the deviation is not pre-announced to RISE by the manufacturer.

The established programme, in terms of general principles for the type case, is documented as a 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. If the applicant differs from the manufacturer, a power of attorney from the manufacturer is required.
- A written declaration that the application has not been submitted to another notified body.
- Technical data (see below).
- When applicable, the weighing instrument/instruments which is/are representative shall be placed at RISE disposal for review.
- Documents which illustrate that the technical design is appropriate. The document shall cover or refer to all the documents which have been used, particularly in cases where harmonised standards are not complied with. If necessary, the documentation shall also comprise of reports from testing which the manufacturer has conducted or allowed another party to conduct. (see also below 2.2.3).

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

2.3.1.1 **Technical data**

Technical data shall describe, among other things, the design, manufacture and working method of the weighing instrument. This means that the appropriate sections shall contain:

- a general description of the weighing instrument
- design and manufacturing drawings and charts of components, sub-assemblies, circuits, etc.
- 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 when the harmonised standard has not been applied
- results of calculations and inspections
- test reports
- risk analysis

A detailed list of the necessary documentation is attached to the application form.

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 it does not already exist. When a harmonised standard 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 examination 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.

The 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. The 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 non-automatic weighing 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. Shorter validity periods may be applied, for example, if a for the area new technology has been applied. The certificate may then be issued with a validity period of two years. This also applies if the manufacturer wants to change a certified product and then apply one for the area new technology. That a shorter validity period will be applied is notified to the manufacturer before the certification process starts or when the certificate is revised. Certificates issued with a validity period of two years in accordance with the above, may be extended by three years at a time. In the event of revision of a certificate, the original validity period is retained, except in cases described in 2.5, when the validity period may be shortened. The validity time of the certificate can be shortened if it, during the validity of the the certificate shall be evident that the requirements of the weighing instrument is no longer fulfilled, caused by the technical development. The holder of the certificate will then be informed and have the possibility the update the measuring instrument.
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 2.2.1.1).
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. If you also introduce a new technology for the area, the validity period may be shortened (see also 2.3 and 2.5 Changes to certified products).

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 is attached. RISE will then assess what measures need to be made in order for the certificate to remain in force after such changes have been made. The assessment may result in that additional tests need to be performed. In this case, the manufacturer shall be notified thereof and may then also be given a price quotation for this. The changes may also impact the validity period of the certificate, for example, if new technology is applied, see below 2.3. If the result of the change means that the certificate is still valid, the certificate is revised with the new data.

2.6 Placing on the market and CE marking
In order to place a product to the market, the manufacturer in addition to the EU-type examination shall engage a notified body to perform one of the conformity procedures Module D or F presented in the scope above. The manufacturer chooses the applicable conformity procedure to be used and which notified body which will carry out the task. The CE marking shall be supplemented with the identification number of the notified body which performs this task. See sections 3 and 4 for the different options RISE offers.
3 Conformity to type based on quality assurance of the production process (Module D)

3.1 General
According to Directive 2014/31/EU, applicants are given two options to choose from for proving conformity of type-approved/certified non-automatic weighing instruments with the aim of approving them for placing on 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. Other conditions are listed in section 5.

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 planned category of weighing instruments
- a quality manual or equivalent documentation for the quality system
- the technical documentation for the approved type/types and a copy of the EU-type examination certificate or certificates

An application form is available on RISE website, 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, section 2.3 of the Directive. The quality system shall ensure that the weighing instruments comply with the type-approved one 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 power 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 the 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 actions for deviations (major and minor) within the period stipulated in the report. The auditor checks and approves the corrective actions and sends an acceptance statement 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 several 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 5.1. The validity period of this certificate is 3 years, provided that all conditions are fulfilled.

3.7 **Marking**
See section 5.1.

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 third 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
According to Directive 2014/31/EU, manufacturers are given two options to choose from for proving conformity of type-approved/certified non-automatic weighing instruments with the aim of approving them for placing on the market. One of these options is product verification. This procedure means that the manufacturer takes all the necessary measures to ensure that manufactured weighing instruments or combination of weighing instruments and peripheral equipment comply with the requirements and that RISE determines that manufactured type-approved weighing instruments/combinations are consistent with what is stated in the certificate (EU-type examination certificate/test certificate).

4.2 Application/Order

4.2.1 Application
The application shall be submitted on the designated form, which can be obtained from RISE, and shall contain:

- The name and address of the applicant
- Make of weighing instruments, model designation
- Copy of EU-type examination certificate. Note that the certificate shall be valid at the time of the verification.
- Test certificates for any peripheral equipment and software if applicable. (*)
- Declaration of Conformity for weighing instruments and the combination in applicable cases. (*)
- A “Compatibility of modules” calculation/Welme 2 point 10/ if there is a statement in the cited certificate which states as in Welme 2.4 A.5 (which begins: “Any load cells may be used for the instruments...”) in this case a test certificate is needed for all constituent modules
- If necessary, a power of attorney from the representative or owner of the EU-type examination certificate (*)

(*) This applies for the verification of combinations of weighing instruments and peripheral equipment.
The application may cover verification of several objects if the documentation is the same.

4.2.2 Orders
When RISE has received an application and approved it an order form is sent to the applicant. The order form includes, among other things, links to the project numbers. The order is then used as call off for the verifications.

4.3 Evaluation
RISE examines each weighing instrument/combination to be certified (CE-marked). The examination includes review of the conformity between the accompanying documents to the certificate (EU-type examination certificate) and weighing instrument/peripheral equipment, and testing in accordance with section 2, to the required extent.
The examination is normally conducted at the manufacturer or at another site. For the examination to be carried out at another site than the site where the weighing instrument is to be used, transfer of the weighing instrument to this site shall not assume that interventions need be made to the weighing instrument that might affect its
properties. Other reservations for examination at another site are stated in annex 2, section 5 of the Directive. 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 or combination is issued.

4.5 Marking
See section 5.1.

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 General conditions

5.1 Marking
CE marking of non-automatic weighing instruments takes place on the manufacturer’s responsibility, and shall also contain supplementary metrology marking. In those cases where RISE has carried out the assessment procedures according to modules D and F 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.

5.2 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.

5.3 Responsibility
The certificate holder is responsible:
- to fulfil all requirements connected to the certification including notified changes in certification rules or conditions,
- to not provide any misleading information about the extent or conditions of the certification which can harm the confidence for the certification or RISE
- 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.

5.4 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 fulfill 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 or 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.

5.5 **Changes to products, quality systems, organisation**

Changes to certified products, see 2.4.

In terms of quality systems in accordance with module D, 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.

5.6 **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 2-4.

5.7 **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.

5.8 **Fees**

Fees are set according to agreement and shall be paid by the applicant of certificate or 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.

5.9 **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.