

0 Introduction

These general rules apply to RISE product certification as well as the services RISE carries out as a Notified Body, read more under "RISE services as a Notified Body". RISE general conditions apply in addition to these rules.

Certification is carried out in line with product-specific rules or specifications, referred to below as certification rules. These specify standards, test methods, criteria, contents and scope of continuing controls, certification marks etc. The contents of individual product-specific certification rules may contain deviations from these general rules.

The certification rules may be revised in the future, for example to comply with European or international standards.

0.1 Application

Application for certification shall be in writing.

0.2 Marking

A certificate holder has the right to mark the products that are covered by the certificate with the applicable certification mark and to use the mark in connection with publications and advertising for the products. Confusion between marked and unmarked products must be prevented.

Misuse of a certification mark or certificate can result in legal proceedings.

0.3 Certificates

A certificate can be issued when assessment verifies that the product, the manufacturing process and internal factory production control (FPC) or other procedures meet relevant requirements. The validity of the certificate is based on continuous fulfilment of the conditions. Certificates are not transferable. The validity period of a certificate is normally five years, or as specified in the relevant certification rules. Copies of certificates and appertaining documents may only be presented in its entirety, except with the prior written approval by RISE.

0.4 Responsibility

The certificate holder is responsible:

- for ensuring that certified products, marked with the certification mark, complies with the requirements specified in the certificate,
- to fulfil all other 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

RISE is responsible for the certification rules, and that the certification is executed with proper competence. RISE is also responsible to inform about changes in the certification rules and conditions. RISE has no responsibility for certified products.

0.5 Withdrawal of certificates

RISE can, on temporary or permanent basis, revoke a certificate if:

- the product no longer meets the specified requirements
- errors in the certificate are discovered
- requirements for continuous control are not met
- FPC shows major nonconformities
- corrective action to rectify nonconformities has not been taken in due time
- results of FPC do not meet the requirements
- products are not suited to their intended use or can cause injury or problems
- changes are made to legislation, directives or similar

- the authorities, or a coordinating body for Notified Bodies, recommends RISE to do so
- the holder has used the certificate for, or in connection with, products that do not meet the requirements or are not covered by the certificate
- fees are not paid as due, the holder is subject to bankruptcy, has gone into liquidation or has transferred operations
- the holder has not adhered to the conditions of certification.

If a certificate is revoked and if RISE demands it, the holder is obliged to cancel all reference to the certificate in advertisements or other publications for the product in question and shall remove the certification mark from all stocked items.

When a certificate is revoked due to incorrect marking of products, i.e. products that fail to meet the certification requirements, RISE can demand that the holder of the certificate pays all costs associated with replacing the substandard products with ones that meet the terms of the certificate.

0.6 Changes to products

Before making changes in design, material or manufacture, the certificate holder is obliged to inform RISE, which will then assess whether the changes are such that new tests and a new assessment are required. This also applies to a quality system if the certificate refers to such a system.

0.7 Confidentiality

RISE maintains a register of certificate holders, certificates, associated documentation, certified products, manufacturing locations, certification validity periods and the use of manufacturing controls. This information may be publicised on RISE website, for example. RISE can provide copies of or publicise certificates and associated documentation. RISE also has the right to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is kept confidential.

As a notified body, RISE is in some cases obliged to reveal information about certificates to other notified bodies and applicable authorities.

0.8 Fees

Fees are set by agreement and shall be paid by the certificate holder. Costs for work resulting from deviations found during regular inspection shall be paid by the certificate holder. Fees for other, essential, inspections shall only be paid by the certificate holder if the results show that the certification rules have not been 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 expected to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.

0.9 Appeal

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.

General certification rules for certification of products CR000

Certification

This is a general description of the most significant aspects of the certification process. The degree to which they apply depends on product-specific rules.

1 Application

Application for certification shall be in writing and be accompanied by:

- technical documentation (test reports, product descriptions, drawings, assembly instructions etc.)
- description of the factory production control (FPC) system proposals for marking
- whatever is prescribed in the certification rules or directives

Application for extension of validity period shall be accompanied by:

- report from the latest audit inspection
- previously issued certificates
- documentation specifying any requested changes (if any) in the certificate or any associated documents.

2 Initial assessment

Initial assessment entails a review of the technical aspects. This can result in a need for further tests or assessments. The initial assessment may also cover the company's internal FPC documentation as well as inspection of the manufacturing site, how FPC procedures are implemented and their compliance with submitted description etc.

Continuous assessment shall consist of the internal FPC and surveillance audits, and be stipulated in the agreement between the certificate holder and RISE¹.

3 Technical requirements

Technical requirements and test methods are covered by the relevant certification rules. The bodies performing tests and inspections shall be approved by RISE and normally accredited for the actual task.

4 The manufacturer's production control

Internal factory production control (FPC) shall ensure that products marked with the certification mark fulfil the requirements of the current certification rules.

4.1 The certificate holder shall normally have:

- an organisation that is responsible for the FPC
- an organisation that carries out the FPC
- personnel that are familiar with the work and are sufficiently trained

4.2 The management shall conduct documented reviews of the FPC process at set intervals, in the form of internal audits, or equivalent, in order to assess the process and take measures to ensure its effectiveness.

4.3 The FPC shall be documented in a quality manual or equivalent. The production process and the way it is controlled shall be adequately described. Documents must be controlled and traceable. Results from the FPC shall be documented in a journal which shall be available to the inspection body, and shall be retained for at least five years or as long as the rules in question require.

4.4 Testing and inspection shall be carried out as specified by the relevant certification rule, on:

- incoming raw materials, parts etc.,
- manufacturing process
- final inspection of the finished product.

4.5 Appropriate equipment for manufacturing and for testing shall be available. The equipment shall be maintained and calibrated to a necessary extent.

4.6 Products that do not meet the specified requirements shall be clearly separated until a decision about action is taken.

4.7 Nonconformities identified during the production and control processes or audit inspection shall be investigated and corrective actions shall be taken to avoid reoccurrence.

4.8 Damage and deterioration must be prevented during handling, storage and delivery.

4.9 It must be possible to trace delivered products back to manufacturing as specified in the current certification rules.

4.10 Complaints concerning certified products, marking, marketing etc. from, for example customers, as well as the measures taken, shall be retained and remain available for the inspection body.

5 Surveillance audit

Continuous surveillance audits shall verify that the FPC is operating as desired. During visits RISE or the inspection body approved by RISE shall check stock, manufacturing, journals, test equipment etc. as well as, if necessary, select or purchase test samples for further testing.

The holder of the certificate shall give RISE, the inspection body approved by RISE or an observer (e.g. from the accreditation body) access to facilities and document in order to verify the factory production control.

If control tests and/or examination of the manufacturer's FPC result in non-approval, the causes shall be investigated. The investigation may result in a further control visit, retesting or non-approval of the FPC

6 RISE services as a Notified Body

RISE role as a Notified Body includes both conformity assessment and assessment and auditing of quality systems. Certificates can have different designations depending on the relevant directive, and which items are included. The certificate holder can use the certificate as a basis for CE marking.

Where RISE services include examination of finished products and/or quality system, RISE identification number as Notified Body (0402) should normally be applied together with the CE mark.

Examination of manufactured products and/or quality systems or the like is carried out by RISE through visits to the manufacturer or its representative.

Where the RISE certification as a Notified Body concerns quality systems, this will be governed by the same general rules as for products.

¹ For type approval in line with PBL, the manufacturer shall select the inspection body. This also applies to certification according to some EU Directives.