Assessment of equipment and protective systems intended for use in potentially explosive atmospheres in accordance with directive 2014/34/EU (ATEX)
Foreword

A manufacturer can apply the CE-mark on equipment and protective systems intended for use in potentially explosive atmospheres, after performing necessary activities as described in Directive 2014/34/EU.

This document contains RISE rules for assessment of equipment and protective systems intended for use in potentially explosive atmospheres, which are covered by Directive 2014/34/EU. The document presents the procedures for conformity assessment applied by RISE, when acting as a notified body. In this document ‘directive’ refers to Directive 2014/34/EU (ATEX).

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

Borås, May 2023

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1 Scope

These rules cover procedures for assessment of equipment intended for use related to potentially explosive atmospheres in accordance with Directive 2014/34 EU (ATEX) with the aim of issuing documents for CE marking. The rules cover equipment, protective systems, components, safety- and regulation equipment and combinations of these intended for use in potentially explosive atmospheres. For components the same requirements on assessment applies, but components shall not be CE-marked and the EU-declaration of conformity is replaced by a written declaration of conformity which shall accompany the components.

Figure 1 below shows the different methods for assessment that are applicable, and is fully based on the procedures described in the directive.

Method a)
- Equipment group I & II
- Equipment category M1* och 1*, and protective systems

Method b)
- Equipment group I & II
- Equipment category M2* och 2*

Method c)
- Equipment group II
- Equipment category 3*

Method d)

Within the framework the manufacturer chooses which modules he wants to use, and in the same manner the manufacturer chooses which notified body/bodies should perform which task.

Shadowed figures requires the involving of a notified body
* also components and equipments if they are assessed separately
** Combustion engines are not within RISE notification
(Source: Directive 2014/34/EU)
2 EU-type examination (Module B)

2.1 General
This section describes the EU-type examination (certification) of equipment and protective systems intended for use in potentially explosive atmospheres, which is based on Directive 2014/34/EU, annex III, module B, and involves examining that the product meets the applicable requirements of the Directive. Other conditions are listed in section 8.

2.2 Assessment

2.2.1 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 documentation (see below).
- Test specimens representative of the production envisaged.

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

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

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

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. They shall contain complete and correct information of significance to the product's explosion protection, and correspond to the controlled test items.

2.2.2 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. This confirmation is the start of the certification agreement between the parties.
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 is to be contracted, it will be 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.

2.2.3 Evaluation
During the evaluation process it is checked that the product has been manufactured in accordance with the technical documentation, 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 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.

2.2.4 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.

2.3 EU-type examination certificate

2.3.1 Validity
EU-type examination certificates for equipment and protective systems intended for use in potentially explosive atmospheres are normally issued without any specified validity time.

2.4 Changes to certified products
Note that no changes, of significance to the explosion protection, may be made to the certified product, without 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 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 supplemented. If current certificate can include the changes the manufacturer is notified.

If the changes cannot be included, a decision regarding which supplementary examinations/testings that has to be carried out is to be made by RISE. 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, a revised certificate is issued.
2.5 Placing on the market and CE marking
In order to place a product on the market the manufacturer shall, in addition to a valid EU-type examination certificate, also allow a notified body to perform any of the conformity procedures presented in figure 1. The manufacturer chooses the applicable conformity procedures to be used and which notified body shall carry out each task.
The CE-marking is to be supplemented with the the identification number of the notified body responsible for modules C1-G. See more on this in section 8. See section 3 and onwards for the different procedures.
3 Conformity to type based on internal production control plus supervised product testing (Module C1)

3.1 General
This section is based on Directive 2014/34/EU, annex VI, module C1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EU-type examination certificate and with the requirements of the Directive that apply to them.

3.2 Application
The manufacturer applies for assessment. The application shall be in writing and be accompanied by:
- Quality plan and other relevant documentation
- The technical documentation for the type/types and a copy of the EU-type examination certificate or certificates.

The quality plan documentation shall include a description of the enterprise and organisation, marketing material, test and inspection instructions.

3.3 Evaluation
RISE assesses the quality plan, instructions and test equipment during an initial visit at the manufacturer's premises. RISE decides which tests shall be supervised. During production the manufacturer perform the tests and inspections on each manufactured item, according to quality plan. The manufacturer addresses RISE, who will visit the manufacturer and supervise those tests earlier decided. The results of the evaluation are summarised in an internal evaluation report.

3.4 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 Conformity to Type Notification is issued. The notification shall contain an identification, e.g. serial numbers, of the products which have been approved.

3.5 Marking
See section 8.
4 Conformity to type based on quality assurance of the production process (Module D) and Conformity to type based on product quality assurance (Module E)

4.1 General
This is based on Directive 2014/34/EU, annex IV, module D and annex VII module E. The manufacturer sets up a quality management system for the production or final inspection of equipment, systems or components. Other conditions are listed in section 8.

4.2 Application
The application for assessment of the quality management 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 to the product category envisaged.
- quality manual or equivalent documentation of the quality management system
- the technical documentation for the type/types and in terms of module D, a copy of the EU-type examination certificate or certificates.

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

The application shall also state if the quality management 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.

4.3 Quality management system requirements
The requirements of the quality management system are specified in annex IV, module D and annex VII module E of the Directive, respectively.

The quality management system shall ensure that the equipment comply with the type-approved and satisfy the applicable requirements of the Directive. The requirements are defined in EN ISO/IEC 80079-34 and correspond to the requirements furnished in EN ISO 9001 (with the exception of certain requirements which, for example, relate to design and development) and supplemented with special requirements for manufacturing, among other activities, of products according to the ATEX directive.

The system shall be documented in accordance with point 4.4 below.

The manufacturer shall undertake to:
- maintain the approved quality management system to ensure its continuing suitability and effectiveness.
- inform RISE about all changes which are planned in the quality management system.

4.4 Documentation requirements
The documentation shall describe:
- quality objectives and the organisational structure, responsibilities and authorities of the management with regard to product quality.
• quality documents, for example, audit reports, test results, calibration results, documentation of the qualifications of staff, etc.
• the methods of monitoring that the set of quality objectives are achieved and that the quality management system works effectively.

and,

for module D:
• 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.

for module E:
• the examinations and tests that will be carried out after manufacture.

Documentation should also fulfil applicable requirements according to the above-mentioned EN ISO/IEC 80079-34.

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

4.5  Review and assessment of the quality management system

4.5.1  General
Assessment (audit) are to be performed by, auditors and technical experts, who are employed or contracted by RISE. 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 could 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.

4.5.2  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 management system is auditable. Review of documentation and examination of product certificates, type approvals and similar, which are covered by the quality management 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 remotely.

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

4.5.4  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 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 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 a statement of acceptance of the measures to the manufacturer.

4.5.5 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.

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

4.6 Certificate
When corrective actions of all non-conformities, if any, are finished, reported and accepted, RISE can take a decision of approval of the quality management system. As an evidence, a certificate (Production Quality Assurance Notification or Product Quality Assurance Notification) will be issued. The certificate allows the manufacturer to use RISE identification number, see section 8. The validity period of this certificate is 3 years, provided that all conditions are fulfilled.

4.7 Marking
See section 8.

4.8 Surveillance of quality management system
RISE will conduct audits at regular intervals, normally once a year, and submit audit reports as described under 4.5.4 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 the manufacturer has a quality management system certified according to EN ISO 9001 by an accredited body that can demonstrate compliance with EN ISO/IEC 17021, surveillance assessments take place within 18 months (in addition to re-assessment before the expiration date if a renewed certificate is desired).

If major deviations are found, corrective actions 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.

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

5.1 General
This is based on Directive 2014/34/EU, annex V, module F. The procedure entails that the manufacturer takes all necessary measures for ensuring that manufactured products conform to the requirements and that RISE establishes that manufactured instruments conform to that which is stated in EU-type examination certificates.

5.2 Application
The manufacturer applies for assessment of its products. A list of the products which are covered by the assessment, the quantity involved and, the EU-type examination certificates which exists, shall also be attached to the application.

5.3 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 product. The examination can be conducted at the manufacturer or at another site. The results of the evaluation are summarised in an internal evaluation report.

5.4 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 product or products is issued. The certificate shall contain an identification, e.g. serial numbers, of the products which have been approved.

5.5 Marking
See section 8.

5.6 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.
6 Conformity based on unit verification (Module G)

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

6.2 Assessment

6.2.1 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).
- Information about where the examination of the equipment can be performed, i.e. where the equipment shall be located.

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

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

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.

6.2.2 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.

6.2.3 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.

6.2.4 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 Unit Verification 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.

6.3 Marking
See section 8.
7 Retention of technical documentation

7.1 General
The ATEX Directive 2014/34/EU (Directive), Article 13, paragraph 1, point (b) (ii), requires in some cases that manufacturers technical documentation shall be communicated to a notified body for retention.

This requirement is valid for category 2 equipment (2G and 2D) and category M2 equipment – equipment other than electrical equipment and combustion engines. This documentation must comply with the requirements according to the Directive’s Appendix VIII, point 2.

7.2 Procedure and ordering
RISE offers this service and for more information about this a specific information sheet, including an order form, is available on RISE website.
8 General conditions

8.1 Marking
CE-marking of equipment intended to be used in potentially explosive atmospheres takes place on the manufacturer’s responsibility. In those cases where RISE has carried out the assessment procedures according to modules C1-G, RISE ID number as notified body (0402) shall be placed adjoining the CE mark. Only the products that comply with the requirements in the Directive may be marked. Misuse of RISE ID number can lead to legal action.

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

8.3 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 or undermine 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 management system.
- the certification rules
- to inform about changes in the certification rules and conditions.

RISE has no responsibility for certified products.

8.4 Withdrawal of certificate
RISE can, either definitely or temporarily, withdraw a certificate if:
- the product no longer meets the applicable set of requirements.
- the quality management system / quality plan 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 the related legislation, regulations, or similar, and the new requirements are not met.
- 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.

8.5 Changes to products, quality management system, organisation
Changes to certified products, see 2.4
In terms of quality plans and quality management system, in accordance with modules C1, D and E, changes shall be notified to RISE. Even major organisational changes or other factors of significance to the certificate shall be notified.

8.6 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 and the relevant authorities and stakeholders 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 management systems, manufacturing sites, validity period for certificates etc. This information may be published, for example, on RISE website. RISE may provide copies of or publish the certificates. RISE is also entitled to publicize decisions on the withdrawal of certificates and the misuse of certificates or marking for relevant authorities and stakeholders, i.e. Swedish Electrical Safety Authority (Elsäkerhetsverket) and the Work Environment Agency (Arbetsmiljöverket). Other information is classified.

The manufacturer, or its representative, shall ensure that RISE, the inspection 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 2-7.

8.7 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.

8.8 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.

8.9 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.