Aspects Regarding the Certification of Electrical Equipment Used in Potentially Explosive Environments in Accordance with EU Directive 2014/34

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Abstract. EU Directive 2014/34 establishes the standards for the certification of electrical equipment used in potentially explosive atmosphere. The EU has established standards for the certification of electrical equipment used in potentially explosive atmosphere. EU Directive 2014/34 sets out the requirements for certification and compliance. The directive applies to all electrical equipment to be used in potentially explosive atmosphere. The directive applies to manufacturers of electrical equipment and their authorized representatives. The directive sets out the safety requirements that electrical equipment must meet before it can be certified for use in potentially explosive atmosphere. The directive classifies potentially explosive atmosphere into three categories: Zone 0, Zone 1 and Zone 2. The directive also sets out requirements for marking electrical equipment that has been certified for use in potentially explosive atmosphere.

Certification of electrical equipment involves testing the equipment to ensure that it meets safety requirements. Testing is performed by certified testing laboratories. Testing laboratories are accredited by the relevant national accreditation bodies. The testing laboratories follow the procedures laid down in the directive for testing electrical equipment. Testing includes testing the equipment for electrical safety, mechanical safety and thermal safety. The testing also includes testing the equipment for its ability to prevent ignition of potentially explosive atmospheres.

1. Introduction
The provisions of Directive 2014/34/EU, as implemented into Romanian legislation in HG 245/2016, apply to equipment and protective systems manufactured in Romania or imported for use in potentially explosive atmospheres. This decision covers safety devices, control devices, and regulating devices that are designed for use outside of potentially explosive atmospheres but are required or contribute to the safe operation of protective equipment and systems in terms of explosion hazards. Equipment is defined as machinery, apparatus, fixed or mobile devices, control components and instrumentation, and detection or prevention systems that, individually or collectively, are intended for the generation, transfer, storage, measurement, control, and transformation of energy and/or processing materials and have the potential to cause an explosion through their own potential sources of ignition.

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Protective systems are devices, other than the equipment components defined above, that are placed on the market separately for use as stand-alone systems and are intended to quickly stop incipient explosions and/or limit the effective range of an explosion. Components are any necessary portion for the proper operation of protective equipment and systems that does not perform an autonomous function.

Groups and types of technical equipment exist:

- a) Group I equipment - equipment intended for use in deep mines and elements of surface mine facilities that may be exposed to soot and/or flammable dust;
- b) Group II equipment - equipment designed for use in other locations where explosive atmospheres may exist.

The following factors must be considered when considering the compliance of equipment:

A. Groups I and II of equipment. M1 and 1 are the two categories.
   To obtain the CE marking, the manufacturer or his authorised agent must follow the EC type examination procedure outlined in Annex No. 3, as well as:
   a) the process outlined in Annex No. 4 for assuring product quality; or
   b) the product verification procedure outlined in Annex No. 5.

B. Groups I and II of equipment. M2 and 2 are the two classifications.
   a) In order to use the CE mark on internal combustion engines and electrical equipment from these groups and categories, the manufacturer or his authorised representative must follow the EC type examination procedure in Annex No. 3, as well as the type conformity procedure in Annex No. 6, or the product quality assurance procedure in Annex No. 7.
   b) In order to use the CE mark on other equipment from these groups and categories, the manufacturer or his authorised representative must follow the procedure for internal production control outlined in Annex No. 8, and submit the technical documentation to the notified body, which must confirm receipt and retain it as soon as possible.

C. Equipment from Group II. 3rd category
   In order to use the CE mark, the producer or his authorised agent must follow the internal production control process outlined in Annex No. 8.

D. Groups I and II of equipment
   In addition to the methods outlined in letters A, B, and C, the manufacturer or his authorised agent may follow the procedure outlined in Annex No. 9 for EC verification of the product unit in order to apply the CE mark.

The terms of para. (1) lit. A or D is used to evaluate the compliance of autonomous protective systems.

Except for the application of the CE marking, the procedures must be followed for the components covered by this decision. The manufacturer or his authorised representative must issue a written certificate of conformity declaring the conformity of the components with the provisions of this decision that refer to them and stating their characteristics and how they must be incorporated into equipment or protective systems to help comply with the essential health and safety requirements applicable to complete protective equipment or systems.

Furthermore, in order to use the CE mark, the manufacturer or his authorised agent can follow the procedure for internal production control outlined in Annex No. 8, with reference to the security concerns outlined in Annex No. 2.

(As an exception, the Ministry of Labour, Social Solidarity, and Family may, on a justified request, authorise the introduction to the market and/or operation on Romanian territory of the equipment, protective systems, and individual devices specified in art. 1 paragraph (2), in relation to which the procedures specified in the preceding paragraphs were not followed and whose use is in the interest of protection.)
Documents and communication relating to the proceedings must be written in Romanian or one of the official languages of the European Union member states in which the procedures are applied, or in a language acceptable by the notified authority.

2. Module: ec type examination, Appendix No. 3

This module covers the procedure used by a notified entity to determine and certify that a representative specimen of the production in issue complies with the relevant applicable requirements of HG 245/2016.

The manufacturer or his authorised representative must submit the application for EC type examination to a recognised authority of his choice.[1]

The name and address of the manufacturer (and the name and address of his authorised representative, if the request is submitted by the latter); a written statement stating that the same application has not been submitted to any other notified body; and the technical documentation must be included in the request. [1]

The applicant must furnish the notified authority with a representative sample of the production in question, referred to as the "type" below. If additional copies are required for the test programme, the notified body may request them. Product conformance must be assessed using the technical documentation. The notified body must examine the technical documentation and determine whether the type was manufactured in accordance with the technical documentation; carry out or have carried out the necessary examinations and tests to determine whether the solutions adopted by the manufacturer comply with the essential requirements of the standards used to manufacture the product; and agree with the applicant on the location where the necessary examinations and tests will be carried out.[1]

If the type conforms with the provisions of this decision, the notified body must issue an EC type examination certificate to the applicant, which will include the name and headquarters of the manufacturer, the examination conclusions, and the data required to identify the approved type. A list of the significant elements of the technical documentation must be attached to the certificate, and the notified body must keep a copy.[1]

If a type certification is refused to the maker or his agent, the notified authority must disclose comprehensive reasons for the refusal.

A provision for an appeal mechanism should be drafted.

All changes made to the approved equipment or protective system that must receive subsequent approval must be reported to the notified body that holds the technical documentation relating to the EC type-examination certificate, where such changes may affect compliance with the essential requirements or prescribed conditions for using the product. This additional approval is provided as an addendum to the initial EC-type examination certificate. [3]

3. Appendix 4: Production Quality Assurance Module

This module describes the procedure by which the manufacturer fulfilling his or her obligations ensures and declares that the respective products are in conformity with the type, as described in the EC type examination certificate, and that they meet the requirements of the applicable technical regulation. The CE marking must be applied to each piece of equipment by the manufacturer or his authorised representative, together with a written certification of conformity. The CE marking must be accompanied by the notified body's identification number, which is responsible for EC supervision. [1]

The manufacturer must use an approved quality system for production, final inspection, and testing of equipment, as specified in point 3, and must be monitored. [1]

The quality management system
The manufacturer shall submit an application for the evaluation of the quality system for the equipment in question to a registered organisation of his choice.[1] The quality system must verify that the equipment conforms to the type as indicated in the EC type examination certificate as well as the requirements of the applicable technical regulation. All aspects, requirements, and provisions adopted by the manufacturer must be recorded in the form of written plans, methods, and instructions in a systematic and orderly manner. The documentation for the quality system must allow for substantial interpretation of quality programmes, plans, manuals, and records. [1]

The notified body must assess the quality system to see if it meets the standards. Compliance with these requirements is expected for quality systems that apply the applicable harmonised standard. At least one member of the audit team must have prior experience analysing the technology of the equipment under examination. An inspection visit to the manufacturer's facility must be part of the evaluation method. The manufacturer must be informed of the decision. The examination conclusions and the reasoned evaluation choice must be included in the communication. [1]

The manufacturer agrees to meet the duties arising from the approved quality system and to keep it at an adequate and efficient level.

Any intention to change the quality system must be communicated to the notified authority that approved the quality system by the manufacturer or his authorised representative. The notified body must review the proposed changes and determine whether the amended quality system still meets the standards or if a reassessment is necessary. He plans to notify the manufacturer of his decision. The examination conclusions and the reasoned evaluation choice must be included in the communication. [1]

The notified body is responsible for supervision. The goal of supervision is to guarantee that the manufacturer is meeting its commitments under the authorised quality system. The manufacturer must allow the notified body access to the production, inspection, testing, and storage premises for the purpose of the inspection and must make all necessary information available to it, including: quality system documentation, quality records, such as: reports inspection and test results, calibration results, reports on the qualification level of the personnel involved, and so on. Furthermore, the notified authority may conduct unannounced inspections of the manufacturer's premises. During these visits, the notified authority may conduct or request that tests be conducted to ensure that the quality system is operating properly. The notified body shall provide the manufacturer with a visit report as well as a test report if a test was performed.[1]

4. 5th appendix: module: product verification

This module describes the procedure for verifying and certifying that the equipment subject to the provisions of point 3 conforms to the type described in the EC type examination certificate and complies with the relevant requirements of this decision by a manufacturer or his authorised representative. [1]

The manufacturer must take all necessary steps to ensure that the manufacturing process ensures that the equipment conforms to the type stated in the EC type examination certificate as well as the requirements of this decision that pertain to them. The manufacturer or his authorised representative must attach the CE marking to each piece of equipment and create a conformity declaration. [1]

By examining and testing each product as indicated in point 4, the notified body must carry out the examinations and tests required to verify the conformity of the equipment, protective system, or device with the applicable requirements of this decision. After the
declaration of conformity, the manufacturer or his authorised representative must preserve a copy for at least 10 years after the final piece of equipment was manufactured. [1]

Examination and testing of each piece of equipment for verification

All equipment must be examined individually, and appropriate tests must be performed in accordance with the provisions of the relevant standard(s) or equivalent tests must be performed to ensure conformity with the type described in the EC-type examination certificate and the relevant requirements of this decision. The notified body must apply or have its identification number applied to each piece of approved equipment and provide a certificate of conformity based on the results of the testing. [1]

The manufacturer or his authorised agent must ensure that he can deliver the notified body's certifications of conformity upon request. [3]

5. Appendix 6: module: type conformance

This module describes the procedure by which the manufacturer or his authorised representative ensures and declares that the equipment in question is of the type described in the EC type-examination certificate and complies with the requirements of this decision that must be applied to it. The manufacturer or his authorised representative must attach the CE marking to each piece of equipment and create a conformity declaration. [1]

The manufacturer must take all necessary steps to guarantee that the manufacturing process ensures that the manufactured equipment conforms to the type stated in the EC type examination certificate as well as the applicable requirements of this decision. [1]

A copy of the declaration of conformity must be kept by the manufacturer or his authorised representative for at least 10 years from the date of manufacturing of the last piece of equipment. If neither the manufacturer nor his authorised representative is domiciled or headquarterled in Romania or a European Union member state, the obligation to keep technical documentation available must fall on the person who places the equipment or protective system on the market. [1]

Tests linked to the explosion protection characteristics of the product must be performed by or on behalf of the manufacturer for each piece of equipment manufactured. The tests must be conducted under the supervision of a notified authority specified by the manufacturer. [1]

During the production process, the manufacturer must use the notified body's identification number, which is under the control of this body. [2]

6. Appendix No. 7: Product Quality Assurance Module

This module outlines the mechanism by which the manufacturer, in accordance with point 2, ensures and declares that the equipment is of the type stated in the EC type examination certificate. The CE label must be applied to each product by the producer or his authorised representative, together with a declaration of conformity. The CE marking must be accompanied by the identification number of the appropriate notified authority. [1]

For the inspection and final testing of equipment, the manufacturer must use an approved quality system and submit it to surveillance. [1]

The quality management system

The manufacturer must apply to a registered organisation of his choice for an examination of the quality system for equipment.

Each piece of equipment must be reviewed as part of the quality system, and suitable tests must be performed in accordance with the provisions of the applicable standard(s) or similar tests to guarantee compliance with the relevant requirements of this decision. All aspects, requirements, and provisions adopted by the manufacturer must be recorded in the
form of written plans, methods, and instructions in a systematic and orderly manner. This documentation for the quality system must allow for a substantial interpretation of quality programmes, plans, manuals, and records. [1] The quality system must be evaluated by the notified body to see whether it meets the standards. Compliance with these requirements is expected for quality systems that apply the applicable harmonised standard. At least one member of the audit team must have prior experience analysing the technology of the product under review. The assessment approach must involve a visit to the manufacturer's facility. The manufacturer must be informed of the decision. The communication must include the examination's findings as well as a rationale for the assessment decision. [3] The manufacturer must meet his duties under the authorised quality system and keep it running at an adequate and effective level. Any intention to change the quality system must be communicated to the notified authority that approved the quality system by the manufacturer or his authorised representative. The notified entity must review the proposed changes and determine whether the amended quality system still meets the standards or if it needs to be reassessed. The manufacturer is advised of the notified body's decision. The examination conclusions and the reasoned evaluation choice must be included in the communication. [1] The notified body is in charge of supervision. The goal of supervision is to verify that the manufacturer meets its commitments under the authorised quality system. The manufacturer must allow the notified body access to the inspection, testing, and storage premises for inspection purposes and must provide it with all necessary information, including: quality system documentation; technical documentation; quality records such as inspection reports and test results, calibration results, reports on the qualification level of the personnel involved, and so on. The notified authority must conduct frequent audits to ensure that the manufacturer maintains and applies the quality system, and an audit report must be sent to the manufacturer. Furthermore, the notified authority may conduct unannounced inspections of the manufacturer's premises. [1] During these visits, the notified body may do or ask tests to be performed in order to verify the proper operation of the quality system, if judged appropriate; he must give the manufacturer with a visit report and, if a test was performed, a test report. [3] 7. Module: internal production control (Appendix No. 8). The module defines the technique by which the maker or his authorised representative guarantees and declares that the equipment meets the requirements of the decision that must be applied to them in order to meet the obligations. The CE label must be applied to each piece of equipment by the manufacturer or his authorised representative, along with a declaration of conformity. The maker shall prepare the technical documentation indicated in point 3 and retain it, or his authorised representative, at the control body's disposal for at least 10 years from the date of manufacture of the last piece of equipment. If neither the manufacturer nor his authorised agent is domiciled or based in Romania or a member state of the European Union, the person who introduces the equipment to the market is obligated to retain the existing documentation. [1] The technical documentation must allow for an assessment of the equipment's compliance with the relevant requirements of this decision. It must pertain to the product's design, manufacture, and functioning to the extent required for this evaluation. After the declaration of conformity, the manufacturer or his authorised agent must preserve a copy alongside the technical documentation. [3]
The manufacturer must take all necessary steps to ensure that the manufacturing process ensures that the manufactured equipment is in accordance with the technical documentation specified in point 2 as well as the requirements of this decision that must apply to this equipment. [4]

8. Module: ec verification of the product unit (Appendix No. 9).

This module outlines the procedure by which the manufacturer assures and declares that the protective equipment or system accompanied by the certificate specified in point 2 complies with the current ruling's applicable standards. The CE label must be applied to the protective equipment or system by the manufacturer or his authorised representative, together with a declaration of conformity. [1]

To guarantee compliance with the relevant requirements of this decision, the notified body must examine the equipment and the protective system individually and perform the necessary tests as specified in the relevant standard(s), or similar tests. The notified body must apply or have its identification number attached to approved equipment or protective systems and produce a certificate of conformity for the tests performed. [1]

The technical documentation's objective is to allow assessment of conformity with this decision's requirements as well as understanding of the design, construction, and operation of the protective equipment or system. [3]

9. Conclusion

In practise, if explosion-protected equipment manufacturers want to manufacture multiple copies of the same type of equipment in categories M1, 1, M2, and 2, it is recommended that their certification be carried out in accordance with Annex 3 (EC type examination) in conjunction with the quality system notification in accordance with Annex 4 (production quality assurance) or Annex 7 (product quality assurance), depending on the equipment category.

In this method, certification costs are decreased by lowering the number of tests performed by the notified body, requiring only one copy, or a reduced number of copies (as the case may be) of that type of equipment to be verified by the testing station.
References

2. SR EN 60079-0:2007, Electrical apparatus for explosive gas atmospheres. Part 0: General requirements