ORGALIME

Guidance Paper

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Validity of EU Type-Examination Certificates and EU Declarations of Conformity under the ATEX Directive (currently: 94/9/EC)

1. INTRODUCTION

The alignment of the Directive on equipment and protective systems for potentially explosive atmosphere (ATEX 94/9/EC) with the New Legislative Framework (Regulation 765/2008) calls for the update of guidelines on the measures manufacturers should take in case a new edition of a harmonised standard relevant to their products is published. These are not legally binding guidelines, but intend to facilitate the adaptation of manufacturers to the principles of the New Legislative Framework.

2. BACKGROUND INFORMATION

Manufacturers intending to place a product on the Community market, should fulfil the requirements of the relevant European directives and confirm this fact in a legally binding European Union Declaration of Conformity (DoC).

For equipment for use in potentially explosive atmospheres the ATEX Directive 94/9/EC specifies various conformity assessment procedures, which depend on the equipment category and act as a basis for issuing the DoC.

The manufacturer of a product (or the person who is responsible for placing a product on the market) has to take into account the current state of the art (technological knowledge available at the time of the placing on the market) when affixing the CE marking and issuing the DoC. This applies to equipment of all categories, regardless of whether or not a notified body was involved in the conformity assessment procedure.

3. CHANGES IN HARMONISED STANDARDS PROVIDING PERSUMPTION OF CONFORMITY

The relevant standards applied are cited in the DoC. If a harmonised standard is applied, the reference of which has been published in the Official Journal of the EU (OJEU), compliance with the pertaining essential health and safety requirements (EHSRs) of the Directive is presumed. After the publication of a new or revised harmonised standard the superseded standard ceases to grant presumption of conformity. The date of cessation is given in the OJEU. This raises the question whether the manufacturer can use an existing EU type-examination certificate and the DoC based on a superseded standard to continue to place his products on the market.

The ATEX Guidelines for the application of the Directive 94/9/EC state that an EU type-examination certificate does not necessarily become invalid when the standard is modified[1]. The decisive factor is whether or not there have been substantial changes in the new edition of the

[1] Chapter 10.3 ATEX Guidelines for the application of the Directive 94/9/EC

Orgalime, the European Engineering Industries Association, speaks for 37 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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standard which create a further development of the state of the art, such that the specifications originally applied no longer ensure that the type examined complies with the EHSRs. The decision of whether the modified standard contains such substantial changes is made by "the technical community of the stakeholders" as they are represented in the Technical Committee of the responsible European Standardisation Organisation (ESO). The result of this evaluation is indicated in the Annex ZY of the respective standard.

In Annex ZY the ESO will specify the modifications including a statement for each change, whether it is considered as:

a. a minor and editorial change, or;
b. an extension without increasing the requirements for products complying with the previous edition of the standard, or;
c. a major technical change, which increases the requirements significantly.

After the reference to a new edition of a European standard is published in the OJ and the superseded standard loses its presumption of conformity, there are different scenarios for the manufacturer to state compliance of his product with the EHSRs of the Directive (Note: The following scenarios 1, 2, 3 do not constitute a one-to-one reference to the classifications a, b, c given above.) The manufacturer should perform a risk assessment of his product in relation to the changes in the standard indicated in Annex ZY. The result of the risk assessment is the assignment to one of the following scenarios:

4. PRODUCTS UNAFFECTED BY THE STANDARD MODIFICATION

In this case the product either is not in the scope of the changes listed in the Annex ZY of the new edition of the standard or the changes include cases and extensions where the new requirements are not relevant for the conformity assessment of the product (as described in case b above).

Examples

- A substantial change of the state of the art affects luminaires, but the product concerned is a sensor.
- The reference pressure for flame proof enclosures "Ex d" has to be determined at the minimum ambient temperature, if used below -20 °C, but the product is specified for ambient temperatures above -20 °C.
- The minimum clearance and creepage distances have been increased for voltages above 500 V, but the product does only operate with a maximum voltage of 230 V
- The minimum clearance and creepage distances for intrinsically safe circuits are reduced, but the product was designed in conformity with the larger (safer) distances of the former edition of the standard

Consequences

- The product design remains unchanged.
- The manufacturer declares that his product is not in the scope of the changes listed in Annex ZY and hence also conforms to the new edition of the standard. The manufacturer includes this declaration in the DoC and in his technical documentation.
- The manufacturer updates the DoC, referring to the new edition of the standard.
- The manufacturer continues to use the existing EU type-examination certificate[2], which remains valid.

5. PRODUCTS AFFECTED BY "MINOR OR EDITORIAL CHANGES"

In this case the products are affected only by „minor or editorial changes" by the standard modification (case a)

Examples

- The marking on the name plate changes from "EEx" to "Ex".

[2] Provided that an EU Type-Examination Certificate was issued, e.g. for electrical apparatus in the categories 1 or 2

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- The threads for cable glands in Ex d enclosures shall be marked.
- Intrinsic safety: changes in the table of 'Temperature classification of tracks on PCB's' to allow correlation with IPC-2152

Consequences[3]

- The product design can remain unchanged.
- The manufacturer declares that his product is only affected by minor or formal changes listed in Annex ZY of the new edition to the standard. These changes are not relevant for compliance with the EHSRs and consequently the product still complies with the ATEX Directive 94/9/EC. The manufacturer adds this declaration to the DoC and to his technical documentation.
- The manufacturer updates the DoC, referring to the new edition of the standard.
- The manufacturer continues to use the existing EU Type-Examination Certificate[4], which remains valid.

6. PRODUCTS AFFECTED BY TECHNICAL CHANGES

As described in case c above, the modification of the standard can result in technical changes that affect the product. Then, the manufacturer performs a risk assessment and up-dates his Declaration of Conformity according to the following alternatives:

The manufacturer applies the new edition of a standard partially[5]

- Based on his risk assessment the manufacturer identifies the relevant technical changes of a relevant harmonised standard, which affect his product.
- The manufacturer undertakes measures (e.g. safety instructions) to reduce the risk of potential ignition sources, related to the relevant major technical changes of the relevant harmonised standard[6].
- The manufacturer documents the relevant technical changes of the relevant harmonised standard and the undertaken measures for risk reduction in his technical documentation and in the instruction manual (as far as relevant for the user) of the product.
- The manufacturer refers to the existing EU type-examination certificate[7] and up-dates the EC-Declaration of Conformity.
- He confirms that the product partly complies with the new edition of the standard, and indicates the clauses of the standard which are not fulfilled but for which alternative measures were introduced.
- The manufacturer may refer in his Declaration of Conformity to additional documents or technical specifications he applied to fulfil the Directive although he is deviating from the standard.
- The manufacturer involves the notified body to get a confirmation about the up-date he has performed, or

The manufacturer applies the new edition of a standard entirely

- Additional tests or a modification of the product are required
- If an EU type-examination certificate[8] was issued the manufacturer submits an application to a notified body to perform the necessary assessment and to revise the existing EU type- examination certificate.
- The manufacturer updates the DoC with the new edition of the standard and (if relevant) refers to the revised EU Type-Examination Certificate1.

[3] It is recommended, that the manufacturer informs the Notified Body about the actions he has undertaken
[4] Provided that an EU Type-Examination Certificate was issued, e.g. for electrical apparatus in the categories 1 or 2
[5] ref. Blue Guide, Art. 1.2 and Art. 4.3
[6] Either the product is x-marked or the marking contains a reference to the instructions
[7] Provided that an EU Type-Examination Certificate was issued, e.g. for electrical apparatus in the categories 1 or 2
[8] Provided that an EU Type-Examination Certificate was issued, e.g. for electrical apparatus in the categories 1 or 2

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7. CONCLUSION

The scenarios and procedures described above assure that the state of the art is properly respected when standards are changed. On the other hand an unnecessary re-certification is avoided in the event of changes or extensions of standards, which are not significant with regard to the fulfilment of the EHSRs. In all cases the manufacturer has to document the considerations and actions taken and demonstrate this by updating the DoC and his technical documentation. This is in line with article 10.3 of the Guideline, which re-affirms that the overall responsibility for compliance of the product rests with the manufacturer.

Irrespective of this, it is common practice that for *new* products, *new* EU Type-Examination Certificates *including all amendments* of the latest editions of the standards are applied.

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