ORGALIME

Position Paper

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ATEX Guide 3rd edition June 2009, Art. 10.3
Validity of EC Type-Examination Certificates/ EC Declarations of Conformity under the ATEX Directive 94/9/EC

Introduction

If a manufacturer intends to place a product on the Community market, he has to fulfil the requirements of the relevant European directives and confirm this fact in a legally binding EC-Declaration of Conformity (EC-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 EC-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 EC-DoC. This applies to equipment of all categories, regardless of whether or not a notified body was involved in the conformity assessment procedure.

The relevant standards applied are cited in the EC-DoC. If a harmonized standard is applied, the reference of which has been published in the Official Journal of the EU (OJEU), compliance with the relevant Essential Health and Safety Requirements (EHSRs) of the Directive is presumed. After the publication of a new or revised harmonized standard the superseded standard ceases to grant presumption of conformity.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the question whether the manufacturer can use an existing EC Type-Examination Certificate and the EC-DoC based on a superseded standard to continue to place his products on the market.

The issue

Chapter 10.3 of the ATEX Guidelines, 3rd edition of June 2009, for the application of the Directive 94/9/EC states that an EC Type-Examination Certificate does not necessarily become invalid when the standard is modified. The decisive factor is whether or not there have been substantial changes to the generally acknowledged state of the art, such that the specifications originally applied no longer ensure the type examined complies with the EHSRs. The decision of whether the modified standard contains such substantial changes is not left to discretionary interpretation by the notified bodies, but it shall be made by “the technical community of the stakeholders”. As the publication of a revised harmonised standard is one way to recognise a development in the state of the art, the responsible European Standardisation Organisation (ESO), e.g. CLC TC31 and CEN TC 305, shall determine whether the state of the art concerning the EHSRs has changed substantially and if so, in what respects. The ESO

www.orgalime.org

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

shall indicate this in the foreword[1] of each standard. The manufacturer can refer to the foreword to check whether or not the state of the art has changed substantially with respect to the EHSRs and whether or not his product is affected by the changes of the standard. In this foreword the ESO will specify the modifications including a statement for each change, whether it is considered as:

a) a minor or editorial change, which does not affect the EHSRs, or
b) an extension of the state of the art, which does not affect the conformity of products, complying with the previous edition of the standard, or
c) a substantial change of the state of the art concerning the EHSRs.

After a new edition of a European standard is published in the OJEU and the date of withdrawal (DOW) of the former edition has passed, there are different scenarios for the manufacturer to state further compliance of his product with the Essential Health and Safety Requirements (EHSRs) of the Directive:

1. i) The product is not affected by the changes listed in the annex of the new edition of the standard. This includes cases where the changed requirements are not relevant for the conformity evaluation of the product or are "extensions" according to clause b)

Examples:

- A substantial change of the state of the art affects luminaries, 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 contain 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

ii) The product is affected by only "minor" or "editorial changes" according to clause a) which are not considered as substantial changes regarding the EHSRs.

Examples:

- The marking on the name plate changes from "EEx" to "Ex".
- 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
- introduction of tests to measure the maximum pressure in sealed battery containers

<u>Orgalime therefore believes that the following should apply:</u>

- The EC Type-Examination Certificate[2] remains valid and the product design can remain unchanged
- In case 1i) the manufacturer declares that his product is not in the scope of the changes listed in the annex of the new edition of the standard and hence consequently conforms to the new edition. The EC-DoC is up-dated and refers to the new edition of the standard.
- In case 1ii) the manufacturer declares that his product is only affected by minor or editorial changes, listed in the annex of the new edition of the standard. These changes do not affect the EHSRs and consequently the product still complies with the relevant requirements of the ATEX Directive 94/9/EC.The EC-DoC referring to the former edition of the standard remains unchanged.
- The manufacturer adds this declaration to the EC-DoC or to his internal technical documentation and may send it to the certifying body for information.

[1] The ESO has decided to include this information in an Annex of the standard

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2. The product is affected by "a substantial change of the state of the art regarding the EHSRs" according to clause c)

Orgalime therefore believes that the following should apply:

- Additional tests or modifications of the product are required to ensure compliance with the new edition of the standard.
- The manufacturer submits an application to a notified body to perform the necessary tests and to revise the existing EC Type- Examination Certificate or to provide a statement about the compliance of the product.
- The manufacturer updates the EC-DoC with the new edition of the standard and refers to the revised EC Type-Examination Certificate

Conclusion

The scenarios and procedures described above reflect the Ex Notified Bodies clarification sheet No. ExNB/09/347/CS and 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 EC-DoC and/or 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 who, where required, must ensure that a valid certificate is in his possession, as well as that all relevant conformity documents correspond to the current state of the art.

Today, according to the current list of harmonized standards, a number of standards can already no longer be applied to demonstrate conformity with the requirements of the Directive. Nevertheless, the manufacturer can check whether the state of the art has changed substantially with regard to his product by comparing the standards listed in his EC-DoC with the standards currently referenced in the list of the OJEU.

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