

Title Short:

Updates of conformity assessment certificates for product variations

Fiche Nr:

20

Subject: Manufacturers request the possibility to get updates of already issued conformity assessment certificates corresponding to product variations, including if these variations occur after the repeal date of recast Directives.

Last Update:
10/09/2014

Category: Obligations of manufacturers

Legislative references:

- Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive. (article 17 Directive 2014/34/EU).
- Member States shall not impede the making available on the market or the putting into service of products covered by Directive 94/9/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016 (article 41.1 Directive 2014/34/EU).
- Certificates issued under Directive 94/9/EC shall be valid under this Directive (article 41.2 Directive 2014/34/EU).

Guidance references

- Notified bodies are designated to assess conformity with the essential requirements, and to ensure consistent technical application of these requirements according to the relevant procedures in the applicable Union harmonisation legislation. (Blue Guide, section 5.2.3)
- At the end of the transitional period, all lists of notified bodies for the old legislation will be removed from the 'current' to the 'expired/withdrawn' list on the NANDO web site. Only those notified bodies which are then notified under the aligned legislation will be authorised to operate. ("CERTIF 2013-11-REV1 – Time frames for notification of NBs following the entry into force of the Alignment Package")

REQUEST

Orgalime requests the Commission to ensure that manufacturers will still be able to receive updates of existing conformity assessment certificates on product variations, even after the repeal of revised-aligned Directives, under which the original certificates were issued. This should apply to all aligned Directives that require the participation of a notified body for the conformity assessment procedure. We use the example of updates of certificates issued under Directive ATEX 94/9 on this interpretative fiche to illustrate the issue.

DESCRIPTION OF THE ISSUE

It is common practice for manufacturers to request notified bodies to update existing certificates of conformity whenever they make a small change or "variation" to the design of the product, without substantially modifying it.

In this case, the notified body assesses the variation detailed in the engineering drawings, confirms that the product still meets the standard listed in the certificate and indicates the variation.

As a result, the cost and time to get an update of a certificate of conformity is significantly lower than that to obtain a new certificate of conformity for the whole product including the variation. In the latter case, the production of a new certificate (which will have a new numbering) will oblige the manufacturer to update labels, literature and the Declaration of Conformity of the product, which will delay the introduction of the variation into production, which in turn could lead to loss of sales or delay improved profitability.

In the framework of the alignment of Directives with Decision 768/2008 the Commission's guidance¹ specifies that all "*at the end of the transitional period, all lists of notified bodies for the old legislation will be removed from the 'current' to the 'expired/withdrawn' list on the NANDO web site. Only those notified bodies which are then notified under the aligned legislation will be authorised to operate*".

This is of concern to manufacturers of products covered by these Directives, because notified bodies may refuse to provide updates of existing certificates for product variations according to the Directives to be repealed, as they will no longer be notified under them.

This would significantly impede the making available of products already placed on the market before the Directive is repealed because it would become too burdensome to certify small changes to them.

PROPOSED SOLUTION

Therefore, we suggest that the updates of certificates initially issued under the "old" legislation, such as ATEX Directive 94/9/EC, should also refer to the "new" recast-aligned legislation, such as Directive ATEX 2014/34, after 20 April 2016 in so far as the notified body which issued the certificate under the old directive remains a notified body under the new directive.

This solution would be possible because the certificates refer to product conformity with the applicable Directive's essential requirements, which have remained unchanged during the alignment process.

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¹ [CERTIF 2013-11-REV1](#) – "Time frames for notification of NBs following the entry into force of the Alignment Package"