



30 July 2020

Subject: Revision of standards and validity of certificates

For the safety assessment of products to the Essential Requirements of a Regulation typically product standards are being used. These standards do not only reflect Essential Requirements but may also include additional requirements covering performance or classification of products.

Standards get updated on a regular basis to include additional products or other technical solutions, to align them with other standards or to add clarifications. Sometimes new requirements are introduced. Technical knowledge is being considered to further improve products.

Standards which are found to have shortcomings addressing Essential Requirements of the applicable Regulations are to be subjected to a safeguard clause to have them withdrawn.

Unless the Essential Requirements have changed in between one edition of a standard and the next, the assessment which has already been made using a standard for the product does stay valid. This does also apply if referenced dated standards get updated in between. If noncritical improvement potential is identified in a standard, the standard will be amended accordingly.

Products certified to the previous version of the standard can still be placed on the market unless a safeguard clause is issued and demands a different procedure.

Shortcomings identified in standards and affecting safety will lead to a safeguard clause.

In any way, if a manufacturer's assessment finds that the product needs to be modified for future placing on the market, **only then it must be re-certified.**

Source:

Excerpt from the "Blue Guide" (2016/C 272/01) on the implementation of EU product rules, Chapter 4.1.2.6.Revision of harmonized standards (emphasis added)

Unless decided otherwise on the basis of a proposal by the Commission, the removal of the reference of a harmonized standard from the Official Journal after its revision does not automatically invalidate existing certificates issued by notified bodies; it only concerns the conformity that is conferred onto new conformity assessments that follow the new harmonized standard.

Products produced according to the old certificate may still benefit from the continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies.

However, manufacturers must assess the extent of the changes to the superseded version of the standard. The kind of action to be taken by the manufacturer depends on the nature of the changes in the harmonized standards, in particular whether these changes are material with regard to the coverage of the essential requirements and whether they concern the product in question.

In addition, the notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.