Technical Guidance Note TGN 28 on Products modified during tests to obtain conformity.

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1. Introduction

This TGN covers products modified during testing to obtain conformity.

One of the roles of a Notified Body is to verify that the products, in the state where they are presented by the applicant, satisfy the tests applied.

The conclusion can thus be only "not compliant results" if the product did not satisfy the tests.

However, the Notified Body usually perform the investigation and the advice in order to help the manufacturer when the product does not satisfy the tests. These practices go sometimes until the modification of the product and the execution of measurements showing that the product satisfied the test after modification by the manufacturer or a test laboratory.

Question: Can a report of test indicate "compliant results" whereas the product was modified during the tests?

2. Guidelines:

YES
It is thus appropriate:

To issue a test report explaining clearly that the product satisfied the tests applied with the described modifications. This report must be precise to distinguish the tests carried out with the modifications and those without the modifications.

This report precise :

- the type of the modifications made to the product. However these modifications must be presented as carried out AFTER the test (presented in appendix of the report, for example).
- The results of corresponding measurements must be given to show the credibility of the modification.

Comments :

It has to be considered that the "entity in charge of putting on the market" is fully responsible for the conformity to the essential requirements of his product, whether it is singled manufactured or in series.

The modifications can be made by the laboratory only with one aim: to show the manufacturer that his product can satisfy the tests.

Indeed, the modification by the manufacturer for his mass production, has other constraints not controlled by the laboratory : constraints of provisioning of the components, costs and optimisations of implementation in series, easier establishment, electrical safety, etc.

There can also be products already manufactured without the modification and it is not sure that the modification will be applied to the mass production.

If the modification is applied, it is not sure that the results will be equivalent.

Note: This TGN is based on TECHNICAL DECISION n° 12E : Edition 1 – 03/12/08 of the Working Group of French Notified Bodies for EMD Directive 2004/108/EC.