GNB-CPD position paper

The consequences for NBs of corrigenda, amendments and revisions to harmonized European standards

General scope, limitations and aim of this guidance for notified bodies

This position paper contains guidance for Notified Bodies (NBs) involved in certifying the attestation of conformity of products or their FPC to harmonized standards subject to corrigendum, amendment or revision. The purpose is to help NBs work equivalently and come to common judgments. This guidance contains informative material (which NBs should or may follow) and/or normative guidance (which NBs shall follow or at least work equivalently to as circumstances demand).

This guidance is thought necessary to provide clarity and completeness for NBs so that they can work equivalently. It supplements and makes practical for NBs the relevant harmonized technical specifications, and Standing Committee guidance in the form of GPs, which also apply - unless otherwise explicitly stated in this guidance. This position paper should not contradict nor extend the scope of the work and role of a NB, nor impose additional burdens on the manufacturer, beyond those laid down in the CPD and the relevant technical specifications.

This guidance should be considered valid until guidance from the Commission or SCC has changed on relevant matters. Whereupon, the paper should be considered for withdrawal/revision and be replaced by new guidance as necessary.

This position paper was considered approved in its original form by Advisory Group (AG) on 7 October 2008, and in its revised form on 12 February 2011.

This position paper was revised to reflect changes to the Commission’s practice and advice regarding co-existence periods for harmonized standards, and to add a footnote proposing that, as a service to its client, a NB might suggest that the manufacturer requests a revised certificate if he considers he needs one to refer to an amendment or corrigendum to a standard.

1 Introduction

Section 2 of this GNB-CPD horizontal position paper gives guidance for NBs working as test laboratories, or issuing FPC certificates under AoC system 2.

Section 3 gives guidance for NBs certifying products or processes with surveillance (AoC systems 1+, 1 and 2+).
2  **Guidance for NBs working as test laboratories**

Notified bodies (NBs) are expected always to be aware of changes to specifications against which they are notified. Such changes may require modified test procedures. Test reports should state the precise version of the technical specification against which the product was tested. However, it is not the test laboratory’s responsibility to inform manufacturers or certification bodies if test reports it has issued in the past are no longer valid because of changes to the specification.

Similarly, a NB that has issued FPC certificates under AoC system 2, which does not require continuing surveillance, has no responsibility to inform manufacturers if certificates it has issued in the past are no longer valid because of changes to the specification.

**NOTE**  Currently, EN 459-1 is the only standard at AoC system 2.

3  **Guidance for NBs certifying products or processes with surveillance (AoC systems 1+, 1 and 2+)**

3.1  **General guidance**

NBs are expected always to be aware of changes to specifications against which they are notified, as should manufacturers be aware of changes to specifications. It is the responsibility of the manufacturer to decide whether he needs to make any changes to his product or process to ensure compliance with the changed standard, and to bring these to the attention of the NB. Notwithstanding the above, the NB shall not certificate a product as being compliant with a superseded standard (taking into account any co-existence period) for the purpose of CE marking. Therefore, the NB shall ensure that any procedures or products that it certifies for manufacturers, and its own procedures for undertaking this, remain valid following changes to a specification, ie:

- the NB must ensure that its own procedures conform with a currently cited version of the standard, and;
- the NB must satisfy itself that the manufacturer’s procedures or products that it certifies conform with a currently cited version of the standard.

Responsibility for ITT will depend on the AoC system.

If changes to a specification are likely to have a significant impact on the requirements for CE marking, there will normally be a co-existence period for the two versions. NBs should ensure that procedures are changed, and any documents issued to the manufacturer that require revision are revised, during this co-existence period\(^1\).

3.2  **Guidance on introduction of a corrigendum or amendment**

If a corrigendum or an amendment to a harmonized standard is issued, the NB shall assess whether the changes to the standard affect the validity of any of its current certificates issued against that standard.

\(^1\) *By implementing its changes at the beginning of the co-existence period, a NB will give its clients a better service.*
If the NB considers, in coordination with the Sector Group, that any changes to ITT for which it has responsibilities as a product certification body, or to its own surveillance procedures, are required, it shall implement these. Similarly, if the NB considers that any changes to the product or process are needed to ensure compliance with the corrected or amended standard, it is advisable to inform the manufacturer of these issues as soon as possible. The NB shall then ensure that any relevant documents issued to the manufacturer comply with the corrected or amended standard, and refer to the appropriate version of the standard.

Any changes that the manufacturer and the NB are required to make should be made within the co-existence period if there is one. (If there is no co-existence period, changes should be made in a timely manner.) However, if the co-existence period has expired, the NB shall use the next surveillance visit to check that the product or process complies with the corrected or amended standard. If it is not satisfied that the manufacturer’s product or process complies with the corrected or amended version of the standard, the NB shall suspend or withdraw its certificate.

When the NB first issues a certificate, that certificate shall include a full reference to the version of the standard it is issued against, including the most recent of any amendments and corrigenda. However, the certificate becomes the property of the manufacturer. Hence, if the manufacturer begins working to a subsequent corrected or amended version of the standard, it is the manufacturer’s responsibility to decide whether he needs a revised certificate that refers to the latest amendment or corrigendum, and to request a revised certificate from the NB if he requires it2.

3.3 Guidance on revision or replacement of a standard

If a standard is revised or replaced, the NB shall treat the updated standard as a new standard. It shall assess the implications of the changed standard on each product or process that it has certified3. The NB shall satisfy itself that the manufacturer’s product or process complies with the updated standard, by the end of the co-existence period with the preceding standard at the latest. Similarly, if the NB considers that any changes to ITT that it is responsible for, or to its own surveillance procedures, are required, it shall implement these before the end of the co-existence period. If the NB is to continue to certify the product or FPC, a revised certificate with appropriate references shall be issued. Any certificates the NB had issued against the superseded version of the standard would cease to be valid at the end of the co-existence period. (All certificates should have a dated reference to the standard, which will identify whether they were issued against a current or superseded version of the standard.)

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2 As a useful service to its client, a NB should consider informing the manufacturer that a new version of the standard is available and suggesting to him that it may be advisable to request an update of the certificate specifying the new version of the standard. However the final decision in this regard belongs solely to the manufacturer.

3 Such an assessment may require more than a standard surveillance visit and include some form of inspection of factory and FPC.
Annex A  Background information - CEN and Commission Services
treatment of corrigenda, amendments and revisions

A.1  Background to citing of hENs and changes to hENs in the OJEU and on NANDO

The principle underlying the procedures adopted by the Commission for citing harmonized
standards (hENs) and any changes to hENs in the Official Journal of the European Union (OJEU)
for the purpose of CE marking, is that each change introduced by CEN (whether corrigendum or
amendment) is cited with its own DApp (date of applicability) and DECP (date of the end of the co-
existence period), in addition to the original hEN having its own DApp and DECP. These dates are
published in the OJEU and are listed on the NANDO database

CE marking is therefore to the original hEN and all appropriate corrigenda and amendments; they
may be applied following their DApps, and they become compulsory after their DECPs. It is not
possible to CE mark to an individual corrigendum and/or amending text alone (even though they
have their own DApp and DECP cited in the OJEU); the original hEN is required as well.

- In the case of an amendment, CE marking after the DECP must be to the version of the
  standard incorporating the amendment, and any previous amendments for which the DECP
  has passed.
- In the case of a standard superseded by revision or a replacement standard with a different
  number, CE marking after the DECP must be to the revised or replacement standard.

A.2  Corrigenda to standards

Corrigenda are issued by CEN to correct errors or ambiguities inadvertently introduced in the text,
and should not change technically what was intended when drafting the uncorrected version of the
standard.

CONSTRUCT 09/872, tabled by the Commission at the 70th meeting of the Standing Committee on
Construction (26 and 27 January 2010), states “For Corrigenda, no coexistence period is foreseen.
Date of citation equals Date of Applicability.”

- Ideally, standards would not require correcting, or the need for corrections would be identified
  and corrigenda issued and cited before CE marking was possible. However, in practice and
  for a variety of reasons, corrigenda are not usually published until CE marking has
  commenced.

A.3  Amendments to standards

Amendments are issued by CEN to alter or add to existing standards. CONSTRUCT 09/872 states
“With regards to Amendments or Revisions of hENs, in principle, no coexistence is foreseen unless
CEN request it on the grounds of sound technical arguments for a coexistence period (e.g. new
testing methods that requires more time, capacity of notified bodies, product adaptation, etc.)”
A.4 Revisions of standards

Revisions are treated as superseding standards. They have the same standard number as the superseded standard, but a different year, and normally retain broadly the same scope.

Before the DApp of the revised version of a standard, CE marking may only be applied in conformity with the outgoing version of that standard. According to CONSTRUCT 09/872 (see A.3 above) there will usually be no co-existence period for revisions, but if one is granted, either version may be used during this period. After the DECP, CE marking may only be applied in conformity with the revised version of the standard.