GNB-CPR **GNB-AG**	**Co-ordination of the Group of Notified Bodies for the Construction Products Regulation, (EU) No. 305/2011**	**NB-CPR/14/594r5** Issued 24 February 2022 **Approved Guidance**

REVISED POSITION PAPER:

Use of facilities outside the testing laboratory of the notified body

1 FOREWORD

Article 46 of CPR allows under certain conditions notified bodies to carry out tests using testing facilities outside the testing laboratory of the notified body.

CPR Article 46 states:

1. *On request of the manufacturer and where justified by technical, economic or logistic reasons, notified bodies may decide to carry out the tests referred to in Annex V, for the systems of assessment and verification of constancy of performance 1+, 1 and 3 or have such tests carried out under their supervision, either in the manufacturing plants using the test equipments of the internal laboratory of the manufacturer or, with the prior consent of the manufacturer, in an external laboratory, using the test equipments of that laboratory.*

   Notified bodies carrying out such tests shall be specifically designated as competent to work away from their own accredited test facilities.

2. *Before carrying out those tests, the notified body shall verify whether the requirements of the test method are satisfied and shall evaluate whether:*

   (a) test equipment has an appropriate calibration system and the traceability of the measurements is guaranteed;

   (b) the quality of the test results is ensured.

One of the conditions is that the notified body shall be specifically designated as competent to work away from their own accredited test facilities. Therefore, this guidance is only relevant for notified bodies designated as competent by their Member States.

CPR does not define any criteria for the assessment of such competence and does not require compliance with any specific accreditation standard. Therefore, the bodies designated under CPR article 46 are not limited to accredited testing laboratories but may also comprise notified certification bodies.

It has been noticed that in some cases, notified bodies have been designated under CPR Article 46 in connection with harmonised standards to which AVCP System 2+ apply. In this regard it is recalled that CPR Article 46 only concerns AVCP systems 1+, 1, and 3.

This position paper defines that notified bodies shall adhere to the accreditation standard for testing laboratories, EN ISO/IEC 17025 when conducting testing away from their own premises. This version of the position paper has been updated to EN ISO/IEC 17025:2017.

For notified testing laboratories accredited to EN ISO/IEC17025, compliance with that standard is assumed to be ensured by their management system and practices. Therefore, the guidance to follow EN ISO/IEC17025 is particularly important for non-accredited notified bodies and notified bodies accredited to other standards than EN ISO/IEC 17025.

However, all notified bodies should be aware that regarding independency, CPR has more strict requirements than EN ISO/IEC17025.

CPR article 45 defines requirements for notified bodies subcontracting (part) of their tasks. Practical experience has shown a need for guidance on the distinction between subcontracting according to CPR article 45 and the use of facilities outside the testing laboratory of the notified body according to article CPR 46.

It has been reported that some manufacturers and notified bodies have considered CPR Article 46 as allowing for arrangements where manufacturers carry testing on behalf of notified bodies. This position paper should make it clear that notified bodies shall not enter into such arrangements.

This paper aims at providing guidance to notified bodies which have been designated as competent according to article 46(1).

The designation of notified bodies according to CPR article 46 is the responsibility of the notifying authorities of the member states. This paper is not intended to provide guidance to notifying authorities on the designation of bodies as competent according to article 46

2 BASIC CONSIDERATIONS

1) CPR Article 46 introduces certain limits regarding the notified bodies' possibilities for using testing facilities. Other provisions for tests carried out by notified bodies, notably EN ISO/IEC 17025, do not limit the testing to any particular locations and do not define any criteria for using other facilities than those of the notified body itself. Hence, CPR Article 46 does not define any particular rights, neither for notified bodies nor for manufacturers, which they would not have without CPR Article 46.

2) CPR Article 46 defines *use of facilities outside the testing laboratory of the notified body* as an option for the notified body; it does not define any circumstances in which notified bodies would be required to *use of facilities outside the testing laboratory of the notified body.*

3) Certain conditions can be derived from CPR Article 46(1), which all shall be fulfilled, for the *use of facilities outside the testing laboratory of the notified body*:

    - A request has been made by the manufacturer;

    - the use of facilities outside the testing laboratory of the notified body is justified by technical, economic, or logistic reasons,

- The testing shall be carried out either for the purpose of assessment of performance in AVCP systems 1+, 1, or 3, or for the purpose of audit testing in AVCP system 1+.

4) Though CPR Article 46 allows, in certain conditions, notified bodies to carry out or have carried out testing in the manufacturing plant, CPR Article 46 does not in any way change the division of responsibilities, which are defined by the systems of AVCP. In systems 1+, 1, and 3, the notified body remains solely responsible for the assessment of performance, including the testing forming basis for it.

5) Notified bodies are required, before carrying out any testing outside its own facilities, to evaluate if *the quality of the test results is ensured.* That would by nature be an ex-ante evaluation, which would have to be confirmed ex post, i.e. after the testing has been carried out. Ensuring the *quality of the test result* would then need be interpreted broadly in the sense that the reliability of the results shall not be adversely affected.

6) It is recognised that testing outside the facilities of the notified body may present certain challenges to the independency and integrity of the testing:

   - The necessary controlling of physical access to the test equipment, specimens and or the testing activities, may be difficult to exercise.
   - Personnel of the manufacturer may be present and maybe even assist during the testing.
   - The test equipment may not be under the permanent control of the notified body

   Therefore, as part of ensuring the quality of the test results notified bodies should only carry out testing outside their own laboratory when they have satisfied themselves that no such circumstances will have adverse effects regarding the independence and integrity.

3 REFERENCE STANDARD

The harmonised accreditation standard for testing laboratories, EN ISO/IEC17025, is applicable as well to testing conducted at the permanent facilities of the laboratory as to testing conducted at sites away from the permanent facilities[1].

The use of facilities outside the testing laboratory of the NB shall not in any way compromise the NB's compliance with EN ISO/IEC 17025[2].

Clauses of which the notified body should be particularly aware when using facilities outside the testing laboratory of the notified body are:

6.2. Personnel;

6.3 Facilities and environmental conditions;

6.4 Equipment, and;

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[1] See EN ISO/IEC 17025 clause 5.4.

[2] Some national accreditation bodies may consider that EN ISO/IEC17025 would not cover testing outside the laboratory of the accredited laboratory and may not grant accreditation for such testing. Irrespective of that, the principles of EN ISO/IEC 17025 shall always apply to testing under CPR Article 46.

6.5 Metrological traceability.

6.6 Externally provided products and services

1 REQUEST AND JUSTIFICATION

CPR article 46(1) allows for the use of facilities outside the testing laboratory of the NB only on request of the manufacturer.

Therefore, the notified body shall keep records of the manufacturer's request.

CPR article 46(1) mentions possible justifications for conducting tests outside the testing laboratory of the NB:

Technical reasons

or

Economic reasons

or

Logistic reasons

The notified body shall keep records of the reasons justifying the use of facilities outside the testing laboratory of the NB.

2 INDEPENDENCY AND IMPARTIALITY

The requirements of CPR regarding independency (art. 43(3)) and impartiality (art. 43(5)) do always apply to notified bodies - also when operating away from their own premises.

When subcontracting specific tasks, the notified body is responsible for ensuring that the subcontractor meets the same requirements.

Conformity with EN ISO/IEC17025 allows for a presumption of conformity with the requirements on impartiality in article 43(5) which states:

> *A notified body and its personnel shall carry out the third party tasks in the process of assessment and verification of constancy of performance with the highest degree of professional integrity and requisite technical competence in the specific field and* ***must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their assessment and/or verification activities, especially from persons or groups of persons with an interest in the results of those activities****.*

When operating away from their own premises, the notified bodies shall have its own procedures and practices in place to ensure that independency and impartiality is maintained.

The notified bodies shall ensure that working at external facilities and possibly assisted by personnel not belonging to their own organisation will not compromise the impartiality.

Hence, the notified body shall take the measures necessary to effectively ensure that any representative of the manufacturer and any member of the staff of the manufacturer assisting the notified body or conducting testing activities under the supervision of the notified body will not have any possibility of influencing the assessments and test results.

Such measures shall include:

- Ensuring that results are not affected by unauthorised access to the locations where testing is conducted, and where equipment and test samples are stored,

- Monitoring of all activities with a potential to influence the results,

- Measurement results read and recorded only by personnel of the notified body.

Notified bodies shall not enter into any arrangement where the manufacturer carries out testing, fully or partially, for the purpose of reporting by the notified body.

3 DISTINCTION BETWEEN SUBCONTRACTING AND USE OF FACILITIES OUTSIDE THE TESTING LABORATORY OF THE NOTIFIED BODY

It is emphasised that a clear distinction shall be kept between *subcontracting* (according to CPR article 45) and the *use of facilities outside the testing laboratory of the notified body* (according to CPR article 46).

Notified bodies may subcontract specific tasks in accordance with CPR article 45. Article 45(1) requires the notified body to ensure that the subcontractor meets the requirements of article 43.

When assessing the compliance of subcontractors with article 43, notified bodies shall be particularly aware of the independency requirements in article 43(3) as these requirements go beyond the requirements of EN ISO/IEC17025. Therefore, an accreditation to EN ISO/IEC17025 does not allow for a presumption of conformity with CPR article 43(3).

The below cases (non-exhaustive list) are considered subcontracting and thereby requiring a subcontracting agreement in accordance with CPR article 45:

- Testing carried out without personnel of the notified body present at all times to manage and/or supervise the testing activities.

- Reporting done by personnel that are not part of the organisation of the notified body and with whom the notified body has no contract.

NOTE: A notified body cannot subcontract any tasks to the manufacturer, as the manufacturer would not meet the requirements on independency in CPR article 43(3), and as it would be contrary to the division of tasks defined by the systems of AVCP.