

<p>GNB-CPR</p> <p>GNB-AG</p>	<p>Co-ordination of the Group of Notified Bodies for the Construction Products Regulation (EU) No. 305/2011</p>	<p>NB-CPR 23/938r2 Issued: 19 February 2024</p> <p>APPROVED GUIDANCE</p>
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Position Paper:

Maintaining CPR certificates in extraordinary situations

1 Foreword

Extraordinary situations such as natural disasters, war, upheaval, health crises etc. may affect the operations of manufacturers as well as notified bodies.

The outbreak of the COVID-19 pandemic in March 2020 required the Group of Notified Bodies to urgently consider and provide guidance to notified bodies on how to maintain already issued certificates.

In March 2020, in cooperation with the Commission Services and the GNB President TechSec issued an informative document regarding possibilities for maintaining certificates if either the operations of the manufacturers or their own operations were affected by the COVID 19.

In the autumn of 2020, that informative document was further developed to the position paper NB-CPR 20/852 to be applied as general guidance by all notified bodies.

In May 2023, the World Health Organization, WHO, declared that the COVID-19 would no longer meet the definition *Public Health Emergency of International Concern (PHEIC)*.

Unfortunately, the end of the COVID-19 pandemic will not mean that personnel of notified bodies can travel freely and safely everywhere. At the time of drawing up this position paper, some countries and regions are in war or under rebellion. In these countries and regions notified body personnel may be facing safety issues if visiting manufacturing plants. In those countries and regions, the operations of manufacturers may also be affected,

Hence, it may still be relevant to provide guidance to notified bodies regarding on how to maintain already issued certificates if either the operations of the manufacturers or their own operations are affected by *extraordinary circumstances*. Such guidance should benefit from the experience gained during the COVID-19, notably the experience gained using remote auditing techniques and other additional AVCP activities.

2 Basic considerations

- 1) Extraordinary situations such as natural disasters, war, upheaval, health crises etc. may affect the operations of manufacturers as well as notified bodies. Such situations may be considered as "force majeure", they are unforeseeable and not the fault of any of the two parties. Situations that were known at the time of the certification agreement may not be considered as force majeure; neither may situations specifically related to either of the parties.

- 2) Notified bodies are involved in the assessment and verification of constancy of performance for the purpose of protecting public interests. By maintaining a certificate, the notified certification body assumes responsibility for its assessment that the manufacturer has ensured the constancy of performance.
- 3) Certificates are issued only when the notified certification body has found that the manufacturers have ensured the constancy of performance (see CPR Art. 52(3))
- 4) As basis for the issuance of certificates, notified certification bodies shall carry out the assessments and verification described by CPR Annex V for the relevant system of AVCP.
- 5) Once a certificate is issued, it remains valid until restricted, suspended or withdrawn by the notified certification body.
- 6) As basis for the maintenance of certificates, notified certification bodies shall carry out continuing surveillance, assessment, and evaluation of factory production control. In AVCP system 1+, the notified certification body shall also carry out audit testing.
- 7) Periodic surveillance inspections shall be carried out as on-site audits at the locations where significant manufacturing processes physically take place (see NB-CPR 17/722, section 11).
- 8) The continuing surveillance will primarily have the form of such periodic surveillance inspections, which in stable conditions are carried out at a prescribed frequency. However, continuing surveillance may also comprise other elements.
- 9) If an extraordinary situation would prevent the notified body from conducting the periodic surveillance and/or audit testing, if the manufacturer wishes to maintain the certificate, in line with the principle of proportionality the notified body should consider other means of verifying the constancy of performance. Such other means measures should be decided on the basis of an adequate risk assessment and may include additional activities beyond the activities defined for the applicable system of AVCP.

3 Definitions

Extraordinary situation

Acts, events or circumstances beyond the control of the parties, affecting the operations of the manufacturer and/or the notified body; for example, natural disasters, health crisis/pandemic, or the outbreak of hostilities.

NOTE: The above definition of an extraordinary situation shall apply only to situations officially recognised by Member States, e.g. an officially declared health crisis, official travel restrictions, declaration of martial law. Notified bodies cannot themselves decide whether or not a given situation would qualify as an “extraordinary situation”.

4 General scenarios

The notified certification bodies may be faced with the following situations (non-exhaustive listing):

- 1) The manufacturing and/or FPC processes have been modified, e.g. due to personnel shortage / changes (including changes to outsourced processes);
- 2) Raw and incoming materials have changed due to supply problems;

- 3) Visits to the manufacturing plant are impossible or unsafe for the assessment personnel of the notified body;
- 4) The notified certification body is unable to provide (usual) services, e.g. caused by personnel shortage or insufficient IT-infrastructure.

The above and other situations may occur in a variety of forms and combinations.

NOTE: For the assessment of the safety of assessment personnel in relation to a visit to a manufacturing plant, Member States publish travel recommendations, typically on the websites of the foreign ministries. It is generally assumed that notified bodies have to follow the recommendations of their Member States. In the Monitoring Report M/05 , available on CIRCABC, is found a list of websites with Member States' travel recommendations.

5 IAF Guidance

The International Accreditation Forum, IAF, has issued an informative document on the management of extraordinary events, IAF ID 3:2011. For several reasons that document seems not directly applicable:

- 1) it aims primarily at voluntary certifications;
- 2) it does not take into account the particular role of a notified body;
- 3) it primarily concerns cases where a single organisation is affected by extraordinary circumstances;
- 4) it does not take into account the rules for notification and the responsibilities of the notifying authorities.

It is emphasised that IAF guidance cannot prevail over the CPR and current GNB guidance. Hence, even where general IAF documents may seem to permit audits/inspections to be carried out remotely, the specific GNB guidance requiring audits/inspections to be carried out on-site would take precedence.

Nonetheless, the document IAF ID 3:2011 provides a line of thoughts which may be useful for notified certification bodies, and which also served as part of the background for this document.

6 Risk assessment

Notified certification bodies shall carry out an assessment of the risks presented by the extraordinary situation regarding:

- 1) Effects on the manufacturers' operations
- 2) Effects on the notified certification body's own operations
- 3) Experience with the manufacturer
- 4) Actual surveillance phase

The risk assessment should focus particularly on the effectiveness of the *verification of constancy of performance* carried out by the manufacturer, i.e. the risk of construction products being placed on the market without having the declared performance.

Moreover, the risk assessment shall take into Account the size of the manufacturer's organisation, the sector in which the manufacturer operates, their structure, the degree of complexity of the product technology in

question and the mass or serial nature of the production process, and the part played by the product for the fulfilment of all basic requirements for construction works.

In principle, the assessments should be made individually for each manufacturer. However, as many of the elements may be common for a number of manufacturers, notified certification bodies may choose to group the manufacturers and carry out the risk assessments groupwise.

If many manufacturers are affected, it may not be possible for notified certification bodies to immediately carry out risk assessments for all affected manufacturers. In that case notified certification bodies should plan their work in order to have risk assessments carried out for all affected manufacturers within a reasonable time. Priority may be given to risk assessments related to manufacturers for whom it is considered likely to find a high risk. As manufacturers for whom audit/inspection is due need to be informed about how the notified certification body will proceed, the risk assessment related to those manufacturers may also be prioritised.

Moreover, it should be recognised that the extraordinary situation may change, both regarding effects on the manufacturers' operations and on those of the notified certification body. If the basis for a risk analysis changes, that risk analysis may need to be updated accordingly.

At a later stage, other circumstances may present other risks to take into consideration, e.g. when manufacturers will restart the manufacturing (see section 8), or if the notified certification bodies experiences "bottlenecks" when catching up on postponed activities.

On the basis of the risk assessment, notified certification bodies may decide how to proceed for the individual manufacturers.

6.1 Effects on manufacturers' operations

As basis for the risk assessment, notified certification bodies shall obtain information about how the manufacturer has been affected by the extraordinary situation with regard to:

- 1) Volume of production, if any, and type thereof;
- 2) availability of key personnel;
- 3) supply of raw materials;
- 4) availability of supporting services, e.g. testing and calibration;
- 5) changes to the normal procedures to mitigate effects of the extraordinary situation.

6.2 Effects on the notified body's operations

Also, as part of the risk assessment, notified certification bodies shall consider their own ability to provide a sufficient basis for their decisions either to maintain or to restrict, suspend or withdraw certificates.

The below should be considered:

- 1) Restrictions to the free movement of persons preventing auditors from visiting the manufacturing plants and/or conducting sampling for audit testing
- 2) Company policies with the same effect as above.
- 3) Availability of assessment personnel
- 4) Laboratories may have interrupted or limited their activities (Only relevant in system 1+)

6.3 Experience with the manufacturer

When assessing the risk, the experience gained from the cooperation with the manufacturer should be taken into account.

- 1) History of assessments, including cases of non-compliances, if any
- 2) Experience of the products, their essential characteristics, and the performances declared.
- 3) Stability of the FPC,

NOTE: A long lasting cooperation would not itself reduce the risk but would provide a good basis for the risk assessment.

6.4 Actual surveillance phase

The notified certification body should also take into consideration the actual phase of the surveillance

- 1) Surveillance audit/inspection not due
- 2) Surveillance audit/inspection due
- 3) Audit testing (including sampling) due (only system 1+)

7 Possible measures

Below is listed a number of possible measures which notified certification bodies may decide upon on the basis of the risk assessment. The below list of possible measures is not considered exhaustive.

- 1) Business as usual
- 2) Postponing audits
- 3) Additional AVCP activities
- 4) Extraordinary audits
- 5) Restriction, suspension or withdrawal of certificates

When deciding on measures, the principle of proportionality shall apply. Hence, notified certification bodies shall choose the least onerous measures consistent with the risks identified.

For instance, certificates should not be restricted, suspended, or withdrawn only because the notified certification bodies for the time being is prevented from visiting the manufacturing plant.

The notified certification body should document their decisions and the basis upon which they were taken.

As notified bodies are required to operate with transparency as regards the manufacturer, the notified certification body shall inform the manufacturer about which measures is intends to apply.

7.1 Business as usual

If it is found that the extraordinary situation has no significant impact on the stability and effectiveness of the manufacturer's operations, the assessment personnel of the NB is available, and, if surveillance audit/inspection is due, visits to the manufacturing plant would be possible, there would be no reason to take any particular action.

7.2 Postponing audits/inspections

When the operations of the manufacturer are considered not seriously affected by the extraordinary situation, but the NB would not have the possibility to visit the manufacturing plant, postponing the audit/inspection might be the most reasonable and least onerous measure. In this regard, sampling for audit testing is considered part of the audit/inspection.

Postponing audits/inspections may be combined with one or more of the following "additional AVCP activities".

Postponement of audits/inspections should not result in general lowering of the frequency of visits. Hence, the programme/schedule of subsequent audits/inspections should be maintained.

Planned postponements should not exceed 6 months.

However, for some products/standards/sectors with a high frequency of audits/inspections and/or audit testing, depending on the duration of the restrictions, it may not be possible or reasonable to maintain the programme/schedule without modifications.

7.3 Additional AVCP activities

Depending on the circumstances, notified certification bodies may decide on the below measures, which should neither substitute nor replace on-site audits/inspections, but may form (part of) the basis for a decision to maintain the certificate while postponing on-site audits/inspections. However, the below measures will only be possible if the manufacturer has the necessary personnel available.

The decision whether or not to carry out additional AVCP activities would very much depend on the risk assessment.

Notwithstanding that current GNB guidance requires continuing surveillance to be carried out as on-site audits, it is assumed that assessments and verifications, which the notified certification body considers adequately carried out by the below additional AVCP activities, would not need to be repeated at the subsequent on-site audit/inspection.

A notified certification body with the capability of conducting remote auditing to IAF MD 4 may apply remote auditing techniques as (part of) the additional AVCP activities. However, physical on-site audit/inspection shall be carried out when it becomes possible.

7.3.1 Submission of information and evidence

Notified certification bodies may request manufacturers to submit information and/or evidence relevant to the assessment of the stability and effectiveness of the FPC.

Such information and evidence may comprise, but would not be limited to, results of test and inspections, calibration results, and/or changes to procedures or organisation.

However, requesting the manufacturer to submit information and/or evidence would only be relevant if the notified certification body's assessment personnel is available.

7.3.2 Telephone interviews

As relevant, notified certification bodies may arrange telephone interviews with selected (key) persons of the manufacturer.

This will of course only be relevant if the assessment personnel of the notified certification body remains available.

7.3.3 Video conferences

Video conferences may serve the same purpose as telephone interviews and may allow an auditor to view selected people and processes without going to the manufacturing plant.

As for telephone interviews, video conferences will only be relevant if the assessment personnel of the notified certification body remain available.

7.3.4 Remote sampling for audit testing

For products in AVCP system 1+, guidance on the sampling for audit testing is found in the document NB-CPR 15/639. If it is found that audit testing should not be postponed, in some cases it may be possible, as an exceptional measure, to let the manufacturer carry out the taking of sampling under instructions from the notified certification body and under video monitoring. Measures should be taken to avoid “engineered samples”, e.g. by requesting the manufacturer to submit a list of serial or batch numbers from which the notified certification body can choose the sample to be taken.

As for the other additional AVCP activities, “remote sampling” would prerequisite the availability of assessment personnel of the notified certification body. Remote sampling would only be meaningful if the laboratory is ready to receive and test the samples taken.

If it is found impossible to have the samples tested at the (subcontracted) laboratory of the notified certification body, it may be considered – as an exceptional ‘emergency solution’ - to request the manufacturer to carry out testing of the samples taken, under remote monitoring by the notified certification body, provided that the manufacturer has previously demonstrated the capability of conducting tests correctly. In such cases, a “counter sample” should be taken for the purpose of later testing by the laboratory of the notified certification body. When assessing the two sets of test results, it should be taken into account that some properties of some products may change over time. Hence, a direct comparison may not be possible.

Such testing by the manufacturer would *not* fall under the *use of facilities outside the testing laboratory of the notified body* as provided for by CPR Article 46. Guidance on the use of facilities outside the testing laboratory of the notified body is found in the approved position paper NB-CPR 14/594.

7.3.5 Testing samples taken from the marketplace

None of the systems of AVCP defined by CPR Annex V include the testing of samples taken at the marketplace. Nonetheless, such testing may strengthen the basis for the notified body’s assessment as to whether or not the manufacturer has ensured the constancy of performance.

It is emphasised that testing of samples taken at the marketplace can only be done with the expressed agreement of the manufacturer.

7.4 Extraordinary inspection

If the operations of the manufacturer are considered seriously affected, it may be relevant for the notified certification body to carry out an extraordinary inspection. Guidance on extraordinary audits is found in NB-CPR 17/722 section 13.

However, extraordinary inspection would only be possible if the manufacturer has the necessary personnel available, if it is possible to visit the manufacturing plant, and if the notified certification body’s assessment personnel is available.

7.5 Restriction, suspension or withdrawal of certificates

If it is found that the stability and/or the effectiveness of the operations of the manufacturer is so much affected that the NB concludes that the manufacturer has not ensured the constancy of performance, it may be relevant to restrict, suspend, or withdraw the certificate.

It should be clear that these are the ultimate and most burdensome steps a notified certification body can take. Therefore, these measures should only be applied as a very last resort and taking into account the viewpoints of the manufacturer.

If the manufacturer finds or acknowledges that for the time being, he will not be able to ensure the constancy of performance, the notified certification body may inform him of the possibility to request a voluntary suspension.

Guidance on the restriction, suspension or withdrawal of certificates is found in NB-CPR 17/722 section 14.

8 Periodic review

At regular intervals not exceeding 6 months, risk assessments (see section 5) and planned actions (see section 6) should be reviewed and revised as necessary.

If the extraordinary situation continues over long time so that it continues to be impossible or unsafe to visit the manufacturing plant, the periodic review may conclude that it would be necessary to further postpone physical visits.

It needs however to be recognised, that repeated postponements of physical visits may significantly reduce the certainty of the notified body's verification of constancy of performance. Therefore, notified certification bodies shall normally not maintain a certificate for more than 2 years after the last physical visit at the manufacturing plant.

9 Returning to the normal situation

At a point in time, after the extraordinary situation, both manufacturers and notified bodies will go back to the normal situation as before the outbreak.

Notified certification bodies should consider potential risks in connection with the "going back to normal" and consider if there would be a need for it to carry out (additional) AVCP activities.

It should be considered that for some products and manufacturing processes, the restarting phase may be sensitive in terms of constancy of performance. Some harmonised technical specifications may have particular provisions regarding restarting the production after it has been idle for a period of time.

If a surveillance audit/inspection has been postponed during the outbreak it may be relevant to carry out that audit/inspection in connection with the manufacturer's restart of the production.

Notified bodies should also consider that catching up on postponed surveillance audits/inspections may cause an extra workload. Therefore, notified certification bodies should make a plan to ensure that delays are minimised and that the work is prioritised according to risks identified.

10 Information to the notifying authority

In order to satisfy themselves that they meet the expectations of their Member States, notified certification bodies may inform their notifying authorities about their processes under the extraordinary conditions. Notifying authorities may also require their notified certification bodies to provide such information. Where the monitoring of notified bodies is carried out by the national accreditation body, information may be provided to and/or required by the national accreditation body.

Should a notified certification body find that effects of the actual extraordinary conditions has made it unable to meet the requirements of CPR Article 43, or has made it unable to meet its obligations, that notified certification body would be required to inform the notifying authority, which will then have to decide if the notification can be maintained (see CPR Article 53(1)b).

11 SUPERSEDED GUIDANCE

This position paper supersedes the previously issued position paper NB-CPR 20/852.