

<b>GNB- CPR</b>	<b>Co-ordination of the Group of Notified Bodies for the Construction Products Regulation 305/2011/EU</b>	<b>NB-CPR/ALL/20/172</b> Issued: 27 March 2020 <b>INFORMATION</b>
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# **INFORMATION: Maintaining CPR certificates under the COVID-19 outbreak**

## **1 Foreword**

The outbreak of COVID-19 outbreak affects us all. Unfortunately, the construction products industry and the notified bodies are not exempt from the effects of COVID-19.

Manufacturers may experience different kinds of problems, e.g. unavailability of personnel, delayed incoming materials, supporting services not being supplied.

Notified certification bodies may also face a variety of challenges like absent personnel and restrictions to the free movement of persons. However, even with the personnel available and no official restrictions to the free movement, legitimate company policies, either on the side of the manufacturer or the notified body, may prevent the notified certification body from physically visiting the manufacturing plant.

Notified certification bodies should also consider the risk that the practice of visiting many clients could contribute to the spread of the corona virus and bring at risk the health of the auditors/inspectors as well as the representatives of the manufacturers.

This informative document is intended to provide informative guidance to notified certification bodies regarding how to maintain certificates if either the operations of the manufacturers or their own operations are affected by the COVID-19 outbreak.

The document does only consider maintenance of already issued certificates; issuance of new certificates is not considered

Due to the extraordinary circumstances, this document has not gone through the normal approval procedure of the GNB Advisory Group. Hence the document will not have the status of approved guidance.

However, for the purpose of establishing a high degree of consensus, members of the GNB Advisory Group are being consulted and offered the possibility to provide comments.

At the time of issuance of this document (27 March 2020), it's impossible to estimate the duration of the epidemic and the restrictions introduced for its mitigation. However, it seems likely that the partial shutdown of most of Europe may last for months. As the general picture may change rapidly, the guidance and information in this document may be changed accordingly.

## **2 Basic conditions**

Legally, the basic conditions for the work of notified certification bodies have not changed.

- 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))

- 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.
- Once a certificate is issued, it remains valid until restricted, suspended or withdrawn by the notified body.
- 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.
- 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).
- 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.
- By issuing and maintaining a certificate, the notified certification body assumes responsibility for its assessment that the manufacturer has ensured the constancy of performance.

### **3 General scenarios**

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

- The production is limited or has ceased;
- The manufacturing and/or FPC processes have been modified, e.g. due to personnel shortage / changes (including that of subcontractors);
- Raw and incoming materials have changed due to supply problems;
- Visits to the manufacturing plant are impossible, e.g. due to travel restrictions or company policies;
- 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.

### **4 IAF Guidance**

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

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

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 inspiration for this document.

## **5 Risk assessment**

Notified certification bodies should carry out an assessment of the risks presented by the COVID-19 outbreak regarding

- Effects on manufacturers' operations
- Effects on the notified body's operations
- Experience with the manufacturer
- Actual surveillance phase

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.

It must be recognised that the risk assessments will draw on the resources of the notified certification bodies and that not all risk assessments can be made immediately. Priority may be given to risk assessments related to manufacturers for whom it is considered likely to find a high risk and to manufacturers for whom audit/inspection is due.

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

### **5.1 Effects on manufacturers' operations**

As basis for the risk assessment, notified certification bodies should obtain information about how the manufacturer has been affected by the COVID-19 outbreak with regard to:

- Volume of production, if any, and type thereof
- Key personnel, e.g. quality manager
- Supply of raw materials
- Availability of supporting services, e.g. testing and calibration
- Changes to the normal procedures to mitigate effects of COVID-19.

### **5.2 Effects on the notified body's operations**

Also, as part of the risk assessment, notified certification bodies should 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:

- Restrictions to the free movement of persons preventing auditors from visiting the manufacturing plants
- Company policies with the same effect as above.
- Availability of assessment personnel

### **5.3 Experience with the manufacturer**

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

- History of assessments, including cases of non-compliances, if any
- Experience of the products, their essential characteristics, and the performances declared.
- 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.

## **5.4 Actual surveillance phase**

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

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

## **6 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.

- Business as usual
- Postponing audits
- Additional AVCP activities
- Extraordinary audits
- Restriction, suspension or withdrawal of certificates

When deciding on measures, the principle of proportionality shall apply. Hence, notified certification bodies should 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 these were taken.

### **6.1 Business as usual**

If it is found that COVID-19 outbreak has no significant impact on the stability and effectiveness of the manufacturers 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.

### **6.2 Postponing audits/inspections**

When the operations of the manufacturer are considered not seriously affected by COVID-19, 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.

## **6.3 Additional AVCP activities**

Depending on the circumstances, notified certification bodies may decide on the below measures, which should not replace audits/inspections, but may form (part of) the basis for a decision to maintain the certificate while postponing 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 or 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.

### **6.3.1 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.

### **6.3.2 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.

### **6.3.3 Video conferences**

Video conferences may serve the same purpose as telephone interview 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 remains available.

### **6.3.4 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.

## **6.4 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.

## **6.5 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.

## **7 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 COVID-19 outbreak. Notifying authorities may also require their notified certification bodies to provide such information.

If a notified certification body finds that effects of COVID-19 outbreak has made it unable to meet the requirements of CPR Article 43, or has made it unable to meet its obligations, the notified certification body may inform the notifying authority, which will then have to decide if the notification can be maintained.