POSITION PAPER: Frequencies for the surveillance, assessment and evaluation of factory production control

1 FOREWORD

Some harmonised specifications indicate frequencies for the audits (inspections, visits) conducted by notified certification bodies as part of their surveillance of the factory production control. Other harmonised specifications have no such frequencies specified. However, in rare cases the frequencies indicated by harmonised specifications may give rise to concern amongst notified bodies.

This paper aims at giving guidance to notified bodies on 2 situations:

- 1) The harmonised specification does not contain any indications regarding audit frequencies, and
- 2) The audit frequency indicated by a harmonised specification appears not to be suitable.

2 GENERAL CONSIDERATIONS

In general, notified bodies are supposed to apply the audit frequencies indicated by the relevant harmonised specification.

In case the harmonised specification does not indicate any audit frequency the notified bodies will need to decide on an appropriate frequency. To facilitate a harmonised approach sector groups may develop guidance related to harmonised specifications which do not indicate any audit frequencies.

In some cases, a sector group may consider that the audit frequency indicated by a harmonised specification gives rise to concern; either because of a high frequency that may place too much burden on the manufacturer or because of a low frequency that would not ensure an appropriate level of protection.

Article 52(2) states:

Assessments and verifications of constancy of performance shall be carried out with transparency as regards the manufacturer, and in a proportionate manner, avoiding an unnecessary burden for economic operators. The notified bodies shall perform their activities taking due account of the size of the undertaking, the sector in which the undertaking operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing, the notified bodies shall nevertheless respect the degree of rigour required for the product by this Regulation and the part played by the product for the fulfilment of all basic requirements for construction works. When developing guidance on audit frequencies sector

groups shall ensure that a reasonable balance is kept between the burdens on the manufacturers and the protection level required. Generally, Notified bodies are not supposed to deviate from the audit frequencies indicated by harmonised specifications or GNB guidance. To adapt their activities to the actual circumstances as required by CPR Article 52(2), Notified bodies should adapt the duration of audits rather than the audit frequencies. Extraordinary audits (e.g. in case of non-conformities) are not considered as deviating from the frequency specified.

3 CASES WHERE THE HARMONISED SPECIFICATION DOES NOT INDICATE ANY SURVEILLANCE FREQUENCIES

If a harmonised specification does not specify any audit frequencies, the relevant Sector Group may develop guidance on the matter (subject to approval by GNB-AG).

When developing guidance on audit frequencies, sector groups should consider "once per year" the preferred frequency of unless particular circumstances related to the products and the sector to which the harmonised specification applies would require a higher frequency. Frequencies indicated by other harmonised specification for similar products should be taken into account by the sector group.

Generally, sector group guidance should not indicate audit frequencies lower than once per year.

Audit frequencies indicated by approved GNB-CPR Guidance should be considered similarly to those indicated by harmonised specifications.

In the absence of GNB-CPR Guidance, notified bodies shall apply a frequency of once per year.

4 CASES WHERE AN INDICATED FREQUENCY GIVES RISE TO CONCERNS

Notified bodies should bring up the matter in the relevant Sector Group if they consider that the frequency indicated by a harmonised specification gives rise to concern, either because it generally places unjustified burdens on the manufacturers or because it will not allow the notified bodies to act with the degree of rigour generally required for the products concerned.

The above may for instance be the case if a harmonised specification indicates surveillance frequencies significantly higher or lower than what is indicated by other comparable harmonised specifications or if the audit frequency indicated is lower than once per year.

In such cases, the relevant sector group may develop guidance¹ to notified bodies allowing for general deviations from the frequencies indicated by the harmonised specification.-<u>The sector</u> group shall ensure that the Technical Committee responsible for the harmonised specification is informed accordingly.

It is emphasised that individual notified bodies shall not deviate from the frequencies indicated by the harmonised specification unless allowed for by approved GNB guidance.

¹ Guidance developed by the sector group will be subject to the approval process according to the internal rules of GNB-CPR.