



CO-ORDINATION OF NOTIFIED BODIES

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RECOMMENDATION FOR USE

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☐ Vertical Group

n/a

☒ Horizontal Committee

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☐ EU PPE Expert Group

Question related to

☒ PPE Regulation ☐ PPE Guidelines☐ EN/prEN:☐ Other:

Article:

Annex: VIII

Clause:

Module D

Key words:

Re-assessment of approved quality systems

Question:

Shall approved quality systems be re-assessed?

Solution:

Yes, at a maximum frequency of every fifth year, with surveillance audits being carried out once per 12 month period following issue of approval.

Each surveillance audit shall review any significant changes that have taken place, or are planned to take place, to determine if a reassessment is required before the due date.

NOTE: The principles of ISO 17021-1 must be considered, and deviation from them reasoned. In addition, the PPE Regulation has a maximum validity for module B certificates of 5 years and the same approach is considered acceptable and reasonable for module D approvals.