

CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425

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RECOMMENDATION FOR USE

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Origin: NB 2849			X	Vertical Group Horizontal Committee EU PPE Expert Group	22/11/2023 26/05/2024
Question related to		☐ EN/p	rEN:		U Other:
Article:	Annex: V: 6.1, 6.2(i), 7.5, 7.6	Clause:			
Key words:					
Renewal date, renewal, review, simplified review					
Question: How may a Notified Body represent issue and renewal dates, following review, to ensure compliance with Annex					

Solution:

To avoid punishing manufacturers who are early in application for renewal, and achieve early renewal, notified bodies may permit the continued use of the originating certificate where no change has occurred, for the remaining validity period.

V 6.1 and 6.2(i), where the renewal process has complied with Annex V 7.5 and 7.6?

Where a change has occurred, the notified body must consider if the originating certificate may retain validity, or must be suspended, reduced or withdrawn.

A post-dated type-examination certificate may be issued following positive renewal, inclusive of a new period of validity of up to 5 years.

The post-dated issued renewal type-examination certification should contain the following information:

- the date of first issue,
- the date of expiration of the previous period of validity, starting the new period of validity,
- the date on which the period of validity of renewal expires.

Additionally, there could be an explanation of the type of renewal, for example:

- "Reissued following simplified review procedure."
- "Reissued following review procedure, inclusive of Amendments considering Change in the State of the Art."
- "Reissued following review procedure, inclusive of Amendments to technical documentation."
- "Reissued following review procedure, inclusive of Amendments to product."

Note 1: While ISO 17065:2012, Cl 7.7.1 does require that the date certification is granted does not precede the date on which the decision is completed, it does not exclude specifying an effective granting date which succeeds the date on which the decision was completed.

Note 2: ISO 17020:2012 does not exclude specifying an effective granting date which succeeds the date on which the decision was completed.