	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.080 Version: 2 Language: E

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Question related to ☐ PPE Regulation ☐ EN/prEN: ☒ Other:

Module D Clause

Key words:
Module D, audit duration, EA documents, IAF MD5

Questions:
Document EA 2/17:2020 specifies that notified bodies "should" take into account the **relevant IAF MD** documents while assessing quality management system-based modules, how should IAF MD 5 be taken into account for Module D?

Answers:
IAF MD 5 (at time of publication Issue 4, Version 3) presents management system auditing guidance and a framework for assigning audit time to activities for primarily the first audit cycle of 3 years. For individualized and subsequent cycles, it recommends a now withdrawn (not available publicly) IAF MD3 document titled "Advanced Surveillance and Recertification Procedures".

(EU) 2016/425 Module D does not require an audit cycle of 3 years, and instead requires annual audits, in the pattern of an Initial audit followed by annual Surveillance audits. ISO 17021-1 encourages a 3 year cycle, and may be applied by Notified Bodies. See RfU 00.016.

Notified Bodies should consider and apply the IAF MD 5 general guidance on:

a. 'Audit activities' which contribute to Audit time;
b. 'Audit day' as being equivalent to 8 hours;
c. Effective number of personnel (for example, top management, those involved in manufacturing, and QC oversight of the Module D product, and those handling customer complaints/product concerns; considering shift patterns);
d. 'Risk Category' should not be considered "Low", as failure of the PPE due to poor quality control could put life at risk, or cause injury or illness;
e. Audit time proportioning between on-site (minimum, production) and off-site;
f. Factors for Adjusting audit time.

Notified bodies should review the specifics of each Module D application, against that guidance, i.e. 'Application Review' as per ISO 17021-1, and record this information.

Notified bodies should not apply the "Table QMS 1 – Quality Management Systems, relationship between Effective Number of Personnel and Audit Time (Initial Audit only)" in any audits, as IAF MD 5 Table QMS 1 is based on Systems which have broader components and procedures than (EU) 2016/425 Module D. See RfUs 00.017 and 00.018.

Instead, for a first cycle comprising Initial / surveillance / reassessment audits, the notified body should apply as a base:

Effective number of personnel		Audit time / hours (days)		
Min	Max	Initial	Surveillance	Reassessment
1	50	12 (1.5)	8 (1.0)	12 (1.5)
51	250	16 (2.0)	12 (1.5)	16 (2.0)
251	500	20 (2.5)	16 (2.0)	20 (2.5)
501	1000	24 (3.0)	16 (2.0)	24 (3.0)
1001	2000	28 (3.5)	20 (2.5)	28 (3.5)

As Module D audits are highly individualized, the Factors for Adjustments of Audit Time should be applied to modify the above base values, and records retained. In doing so, care should be taken such that:

1) No combination of decreasing Factors reduces Initial audit time below 8hrs (1day);
2) No combination of decreasing Factors reduces audit time below 4hrs (0.5days) for any site where production occurs;
3) No combination of decreasing Factors reduces Reassessment audit time below equivalent Surveillance audit time;
4) Increasing factors are reasoned and justified.

Where there are multiple sites involved in the manufacturer's Quality Control System, the notified body should differentiate between 'production sites' and 'non-production sites' (Sales, Warehousing, Customer services etc.). One or more production sites of a set of multiple sites should be audited annually. Similarly, final product inspection / control should be considered. Records should be retained with differentiation of sites, and justification of visit patterns.

Sites not under the direct control of the manufacturer, i.e. subcontracted or outsourced companies involved in production or otherwise in the quality control system, should be considered for auditing following a risk analysis.

Where considering non-production sites, the application of IAF MD 01 rules is possible, with the following conditions:

- The sampling methodology may only be applied after the completion of one full certification cycle.
- All sites must be audited at least once during each subsequent certification cycle.