Clin Chem Lab Med 2017; 55, Special Suppl, pp S1 – S1121, June 2017 • Copyright © by Walter de Gruyter • Berlin • Boston

EFLM Symposium Wednesday 14 June - PERFORMANCE SPECIFICATIONS IN LABORATORY MEDICINE

DEFINING PERFORMANCE SPECIFICATIONS IN LABORATORY TESTING

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Measurements in clinical laboratories produce results needed in the diagnosis and monitoring of patients. These results are always characterized by some uncertainty. What quality is needed and what measurement errors can be tolerated without jeopardising patient safety should therefore be defined and specified for each analyte having clinical use. When these specifications are defined, the total examination process will "fit for purpose" and the laboratory professionals should then set up rules to control the measuring systems to ensure they perform within specifications. The laboratory community has used different models to set performance specifications. Recently, it was felt that there is a need to revisit different models to try to simplify them and, at the same time, to emphasize the presuppositions for using the different models. To this aim, in 2014 the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) organized a Strategic Conference in Milan. It was felt that there was a need for more detailed discussions on, for instance, performance specifications for EQAS, which measurands should use which models to set performance specifications and how to set performance specifications for the extra-analytical phases. There was also a need for more quality data on biological variation and further discussing the use of total error concept. Consequently, EFLM established five Task Finish Groups (TFGs) to address each of these topics. The TFGs are finishing their activity on June 2017 and the program of this symposium includes deliverables from these groups.