

THE FITNESS FOR PURPOSE OF ANALYTICAL METHODS: A LABORATORY GUIDE TO METHOD VALIDATION AND RELATED TOPICS

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Method validation is an important requirement in the practice of analytical sciences. Most analytical chemists are aware of its importance, but why it should be done and when, and exactly what needs to be done, is not always clear. The purpose of the Eurachem Guide [1] is to discuss the issues related to method validation and increase readers' understanding of what is involved and why it is important, also giving practical guidance on how it can be accomplished. The aim of method validation is to demonstrate that the test results are fit for their intended use. From this, it follows that a clear statement of the analytical requirements underpinning the fitness for purpose of the test results represents the first step of the validation. Translating the customer's stated or implied needs into analytical requirements is part of the job of the analyst. For example, if the customer's request is to determine the cadmium content in chocolate to state compliance to existing legal limits, it is the analyst's duty to assess the maximum allowable measurement uncertainty and other related analytical requirements. The extent of validation required may vary, however, in general, it is necessary to test several characteristics of a test method. Limit of quantification, precision and trueness will almost always be among the parameters assessed. The Guide provides the reader with the rationale behind the determination of the various parameters and quick reference tables to help put this knowledge to work. A wealth of information is produced during a validation study. The Guide indicates how to record and report it in the best way, to support the statement of "fitness for purpose". In addition, the validation study is the best source of information on which to base the on-going monitoring of the method performance in routine use. The Guide provides support to analysts on how to make the best use of these data for setting up an Internal Quality Control plan. Last, but not least, several reference documents are mentioned in the bibliography. The Method Validation Working Group also provides input to the Eurachem "Reading list", a bibliography of documents related to several aspects of the quality of tests and measurements, updated yearly.

[1] B. Magnusson and U. Örnemark (eds.) Eurachem Guide: The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics, (2nd ed. 2014). ISBN 978-91-87461-59-0. Available from <http://www.eurachem.org>