



Application of ISO/IEC 17025 Technical Requirements in Industrial Laboratories

M.L. Jane Weitzel, Wesley M. Johnson

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The book introduces the new concepts of target measurement uncertainty and decision rules and explains how to use them to demonstrate a method is fit-for-purpose. As well, they can be used to set the acceptance criteria for a method validation clearly and quantitatively. Examples are given that illustrate the concepts so that the reader can easily apply decision rules and target measurement uncertainty to their methods. The book covers all aspects of method validation from stating the purpose of the method using a Decision Rule, calculating the target measurement uncertainty, deciding the required parameters that need to be included in the method validation, estimating the measurement uncertainty, and setting the acceptance criteria. With this approach the reader will fully understand the method, what its critical control points are and what to control and monitor during routine use. This approach fits in well with the lifecycle approach to analytical methods. The book covers the basics and advanced aspects of method validation so that it is useful for people new to method validation and those with experience. The book is applicable for laboratories in many industries, from mining to pharmaceutical manufacturing to food analysis.

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