Measurement Verification in the Clinical Laboratory

Verifying the acceptable performance of new analytical instruments or methods is critical to the provision of an acceptable clinical service. The process needs to be well defined, objective and appropriately documented if it is to meet the exacting scrutiny of post-procurement disagreements or clinical liability claims.

Method and instrument validation is part of the laboratory landscape that is 'good laboratory practice' and yet during the turmoil of introducing a new instrument into a busy and often under-resourced laboratory, GLP itself can be severely tested. This 'Verification Guide', compiled by a group of expert clinical laboratory analysts, provides the tools to help make instrument and method validation as painless as possible whilst maximising the information it derives.

For a new instrument, verification serves a variety of purposes, it allows confirmation that *your* procurement specifications have been meet and that *your* instrument is performing to the specification claims made by the manufacturer. You need to determine current performance so that deterioration can be objectively demonstrated but you also need to know how it compares with older or established instruments; unexpected and unsolicited step changes in clinical results can carry significant clinical implications.

Important spin-offs of the verification procedure include, consolidation of training, confirmation that data handling is working effectively, assessment of the internal quality control processes and ranges pertinent to your instrument and finally, assessment of the training requirements and likely consumable supply arrangements. A well planned verification exercise prior to the introduction a new instrument or method will prove valuable to all lab staff, the clinician and the patient.

This guide helps unravel the evolving language of analytical measurement; measurands, traceability, intermediate precision, trueness, commutability etc. It makes simple recommendations for the assessment of imprecision and bias, provides a series of Excel spreadsheets for their calculations and gives worked examples to help you understand the statistics. The role of manufactures in providing specifications that have been determined using appropriate ISO, CEN, IFCC, or CSLI recommendations is important to the validation process and the involvement of two leading diagnostic companies in the development of this guide is promising.

Stephen P. Halloran
Director: Guildford Medical devices Evaluation Centre
Member: MHRA Committee on the Safety of Devices