Method validation

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Measurement methods are newly developed and evaluated for different purposes. The aim may be to create a new or alternative research tool for studying a particular scientific problem. Sometimes I even get the impression that the main goal is just to publish the resulting new method in a prestigious journal. Alternatively, data for decisions in areas such as healthcare, industrial production, trade or regulatory compliance may be needed which cannot be obtained by existing approaches and new methods may be required. In all cases, we need confidence that the measurement method can provide results of adequate quality for the specific purpose. Therefore, the method, actually the complete measurement procedure, has to undergo a performance characterization process before it is applied. This is commonly called method validation.

There are various definitions for the process ‘(method) validation’. For instance, the Eurachem Guide ‘Terminology in Analytical Measurement—Introduction to VIM-3’ (2011) describes it as ‘a set of experiments to establish that the performance of the measurement procedure meets the customer’s requirements’. Such requirements differ, and consequently, a uniform validation protocol cannot exist. However, it is now expected to report performance characteristics as listed in ISO/IEC 17025. These include (in current terminology) the measuring interval, linearity, selectivity, trueness, precision (repeatability, reproducibility), robustness against external influences and cross-sensitivity against interference from the matrix. The achieved method characteristics should be carefully documented within the laboratory. However, the reporting of this to clients will differ depending upon the client’s

request. Several of these method parameters may be communicated to provide information on the performance of the method, typically via the associated quality control data obtained in conjunction with the commissioned measurements on the customer’s sample. Alternatively, an achievable measurement uncertainty is reported, which encapsulates these performance data.

As many measurement methods are intended to be used by different laboratories, a so-called ‘full method validation’ often makes use of an interlaboratory study (also described as collaborative study or ring trial) for estimating the influence of human factors and other varying laboratory settings. Unfortunately, there are still measurement communities which focus such studies on the characterization of the achievable method precision and do not consider the trueness of the results. It is recognized that it can be very challenging to assess the latter when adequate certified reference materials (CRM) are lacking. However, such challenges also create opportunities. One of them is to publish in *Accreditation and Quality Assurance* (ACQUAL) novel approaches for evaluating trueness without having a CRM available.

A frequently observed shortcoming in reports on validation studies submitted for publication is the missing link to the customer requirements, i.e. to the intended use of the method. One has to clearly list these requirements in order to be able to compare the achieved method performance with them. Moreover, there are still statements made which often generalize the applicability of a new measurement method despite only limited studies on the type of sample, ranges of potential interferences, etc., having been performed.

Validated methods are a prerequisite for reliable measurement results. However, their known performance characteristics have to be confirmed before applying the method in another laboratory (which did not participate in

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the method validation) or in case of significant modifications in the original laboratory. Such method verification is more and more accepted as a quality management requirement, but not always properly executed. When publishing measurement results, one would ideally expect a brief reference to, and potentially also some underpinning data from, the method verification. However, ACQUAL would usually not consider this process as a main topic for a manuscript.

Besides new approaches to method validation, the readership of ACQUAL may appreciate receiving information about available explanatory or guidance documents for method validation tailored to the needs of specific

application sectors of measurements in chemistry and biology. Moreover, expanding the validation concepts to methods addressing other properties than quantities, such as molecular structures or classifications of biological species (i.e. covering ‘qualitative analysis’), could deliver valuable insights and advance quality assurance of such endeavors. I am inviting potential authors to challenge the ACQUAL Editors and reviewers with their ideas and corresponding manuscripts!

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