Fundamentals of Quality Assurance in the Analytical Laboratory

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According to the ISO definition, quality assurance involves "all the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality." In plain English, quality assurance is what the analysts do to make sure that the answers they produce are correct. No analytical measurement is perfectly accurate, and it is the role of the analyst to minimize the uncertainty. Before performing any measurements, the objectives and the specifications should be defined. Quality assurance itself begins with proper sampling. Sample chain of custody should be properly documented. Any method used for the analysis should be properly validated by determining a number of characteristics including specificity, linearity, accuracy, precision, range, limits of detection/quantitation, as well as reporting limits. Robustness of the method should also be evaluated. Once a validated method has been implemented, its performance should be monitored continuously. Analysis of blanks makes it possible to account for interferences by other species and for traces of the analyte that may be present in the reagents used for sampling, sample preparation and analysis. Various types of blanks should be analyzed, including reagent blanks, method blanks, trip blanks, field blanks, etc. Potential matrix effects should be evaluated by analyzing matrix spikes. During the final determination step, stability of the instrument calibration should be closely monitored by including calibration checks at regular intervals. The correctness of the calibration itself is monitored by periodically analyzing performance test samples. All steps involved in quality assurance should be described in detail in standard operating procedures that all personnel involved in the analysis must adhere to. The above concepts will be described in detail and illustrated with selected real life examples.