What every operator should know about laboratory quality assurance and control

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Knowledge	Principle	A practical consideration
Quality assurance/quality control (QA/QC)	Quality assurance is the process of setting forth standards to ensure a level of quality. Quality control is the measuring of products/procedures to guide production to the level of quality expected.	While the terms quality assurance and quality control often are used interchangeably, they really are two parts of a whole. Quality assurance is the planning and evaluation of work, including method selection, standard-operating-procedure writing, and auditing. Quality control consists of the actions taken to ensure quality during production, such as analyzing control samples, keeping careful documentation, and performing instrument maintenance and calibration.
Standard operating procedure (SOP)	A standard operating procedure provides step-by-step instructions on how to perform a particular test. It includes such things as sample requirements, apparatuses, reagents, interferences, and QA/QC practices.	SOPs should be user-friendly and accurately reflect the way in which tests are performed. When writing SOPs, use everyday language. Keep in mind that their main goal is to be a reference tool for how to perform a task.
Precision	The ability of a measurement to be reproduced consistently is precision. Also called repeatability, it is the degree to which repeated measurements under similar conditions yield the same result.	Precision is assessed through the analysis of duplicate samples and the calculated relative percent difference (RPD). An RPD no greater than 5% is good for most analysis. $$RPD = \frac{A - B}{[(A + B)/2]} \times 100$$ where A = sample B = duplicate sample
Accuracy	Accuracy refers to how close a measurement is to the actual value. Calculating accuracy requires a standard reference material with a known value.	Accuracy is commonly expressed as percent recovery. When running a batch of analyses, include a standard and perform the following calculation: $$\text{Percent recovery} = (OV \div KV) \times 100$$ where OV = observed value KV = known value A percent recovery of ±10% of the known value indicates good accuracy.

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Control samples	A control sample is a substance that is analyzed along with test samples to evaluate the validity and accuracy of the analyst and the analytical method for that batch. Positive controls, such as standard reference materials and known positives, show that methods work and are performed correctly. Negative controls, such as blanks and false positives, show that the analysis itself doesn't interfere with data outcome.	For each lot of media received or made in a laboratory, a series of analytical checks should be made. For example, lauryl tryptose broth should be tested to make sure it grows only total coliforms at 35.5°C. This test requires two samples to be inoculated and incubated. The first is a positive control with *Escherichia coli*; the results should be positive (show growth). The second test is a negative control with *Pseudomonas sp.*; the results should be negative (no growth). These tests show not only that the medium can grow the target analyte, but also that it retains its selective growth properties.
Traceability	Traceability refers to being able to verify the location, amount, and use of supplies or samples along every step of the process chain.	To create traceability requires documenting all laboratory activity – providing written information about the analysis, supporting preparations, and supplies. When a mistake is made on a laboratory document, draw a single line though the writing, and date and initial the strikethrough. Never use correction fluid or correction tape.
Data review	Data review refers to checking laboratory data for data qualifiers, invalidated corrections, and/or missed calculations.	Review of data is an essential part of any QA/QC program. Having a second set of eyes look over worksheets, crunch the numbers, and scrutinize the precision and accuracy of measurements provides that necessary check to discriminate between acceptable and nonacceptable data. It provides clients with assurance that the results reported are accurate.
Audit	An audit is an unbiased review of laboratory documents, personnel, and procedures. An audit can be performed by internal quality assurance personnel or external state regulators.	Simply put, an audit is a systematic review of laboratory documents to ensure that standard operating produces and quality assurance and control measures are being followed. An audit also can be used to evaluate your choice of analytical method; what changes or updates has the health department instilled? Are your choices still economical and valid? With advancing Technologies, the choices for method application are ever-improving.

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