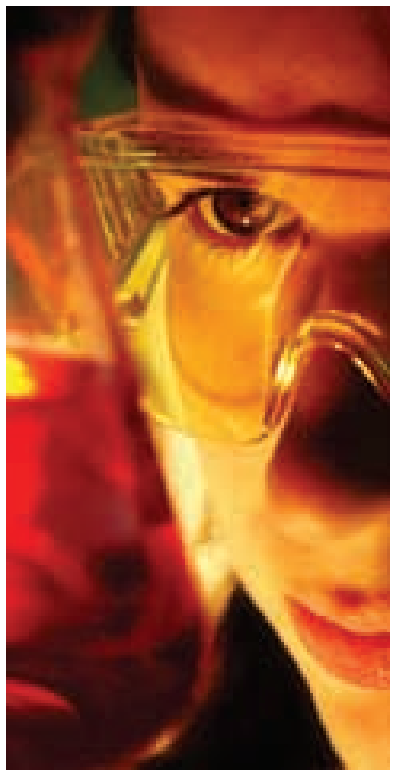

Ensuring Quality

By Sarah Zrout

The value of International Standard ISO/IEC 17025

The primary goal of any laboratory is to generate technically valid results. Many factors come into the equation in order to successfully do this, but there is no better way than to follow the requirements contained in the International Standard ISO/IEC 17025—general requirements for the competence of testing and calibration laboratories.

This standard encompasses all of the requirements that testing labs have to meet if they wish to demonstrate that they operate a management system, are technically competent and are able to generate technically valid results. Additionally, if testing labs comply with the requirements of this standard, they will operate a quality management system for their testing and calibration activities that also meet the principles of ISO 9001 (quality management systems), which is more widely referenced and well known within the industry.

The International Standard

ISO/IEC 17025 is applicable for all organizations performing tests and calibrations. These include first-, second- and third-party labs, as well as labs where testing and calibration forms part of the inspection and product certification. When a lab does not undertake one or more of the activities covered in this standard, the requirements of those clauses do not apply. Although the standard is written for both testing and calibration labs, it is easily understood which clauses apply to which type of lab and what sections may not be applicable to one type or the other.

The standard is broken into two main sections: management requirements and technical requirements.

Management System

Management requirements revolve around the management system of a lab. This means the lab must have a management system appropriate to the scope of activities, including documenting all of its policies, systems, programs, procedures and instructions in order to assure the quality of test results. The system needs to be communicated to, understood by, available to and implemented by all appropriate employees. The most comprehensive way this can be accomplished is by having a well-maintained quality manual available to all involved parties.

There are several clauses with instruction on how the lab should maintain an acceptable management system. The most important clauses are: document control; review of requests; tenders and contracts; control of nonconforming testing; corrective actions; and internal audits.

Document control encompasses all procedures, software, standards, methods, instructions and any other item that can be considered part of the management system of the lab. All documents must be reviewed, approved and maintained to ensure that only the most recent and applicable documents are being utilized, and this can be accomplished by keeping a master list of all documents. All changes to documents also must be recorded and kept for the life of the document.

Review of requests gives guidance to contracts between the customer and the lab. The contracts must be acceptable to both parties and can be written or oral. Most importantly, the lab must only accept contracts that the lab is capable of and fully understands the testing requirements. The appropriate method must be used and any deviations must be recorded and communicated to the customer. If any aspect of the results do not conform to the contract, work may be halted, the significance of the nonconformity must be reviewed and the work may be recalled.

Other important functions of the management system involve internal auditing to make sure employees have received adequate training. Internal audits may lead to corrective actions, which only further improve the quality of tests performed.

Technical Requirements

The technical requirements cover the technical competency of the staff, the validity and appropriateness of the methods, traceability of measurements and calibrations to national standards, appropriate application of measurement uncertainty, suitability, calibration and maintenance of test equipment, the testing environment, sampling, handling and transportation of test items, and quality assurance of test, inspection or calibration data.

Test methods are the core of any lab administering correct testing. Instruction must exist on the use of all equipment, the handling and preparation of items for testing, as well as the actual test procedure itself. They must be accurate, current and available for involved personnel. Once a lab has created all methods of which they are capable, the next step is to correctly select the method to be used. The customer must be notified and it must be clearly identified in the results.

All equipment used during testing shall be capable of achieving the required accuracy and comply with all specifications required. The equipment should have records, be identified uniquely and be safeguarded from adjustments. Likewise, all items to be tested must also be uniquely identified and protected during testing and storage.

After testing is complete, the data must be validated and presented to the customer in an accurate, clear and objective way. All calculations and data transfers must be checked and validated before the report is given and all data must be protected from editing. Deviations or any other noncompliance that occurred during testing must also be included. The customer should be made aware of the entire testing process.

It can take years for a testing lab to operate in accordance with ISO/IEC 17025, but the effort made and dedication to the standard helps ensure the work being produced is accurate. It is the first and most important step in gaining customers' trust and business. *wqp*

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Sarah Zrout, CWS-VI, is quality manager for the Water Quality Association. Zrout can be reached at 630.929.2541 or by e-mail at szrout@wqa.org.

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