About Us…

Quest Technologies, a 3M company, is a design, manufacturing and marketing company with distribution in over 50 countries worldwide. Quest has built a strong reputation for rugged and reliable instrumentation and software systems that monitor and evaluate occupational and environmental health & safety hazards including noise, vibration, heat stress, indoor air quality and toxic/combustible gases. Quest monitoring instruments serve a variety of occupations and industries with clients in mining, research, enforcement, military, education, insurance and manufacturing business sectors.

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About The Author

Sheila Goodson, Director of Quality

Sheila Goodson is Director of Quality at Quest Technologies, a 3M company, in Oconomowoc, WI. She is a senior member of ASQ and an ASQ Certified Manager of Quality & Organizational Excellence with more than 20 years experience in quality management and laboratory accreditation. She is a member of the American Association for Laboratory Accreditation's (A2LA) Measurement Advisory Committee, U.S. TAG to ISO TC176 for Quality Management and Quality Assurance and ASC ZI Subcommittee on Quality Management.

3M
Occupational Health & Environmental Safety Division
Quest Technologies, now part of 3M
ISO 9001 Registered Company
ISO 17025 Accredited Calibration Lab
1060 Corporate Center Drive
Oconomowoc, WI 53066
Customer Service: 262 567 9157
Toll Free: 800 245 0779

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ALL CALIBRATIONS ARE NOT CREATED EQUAL:

Exploring The Value Of Accredited Calibration Laboratories

By: Sheila Goodson, Director of Quality

Most people would probably agree that regular maintenance and calibration of equipment and instrumentation is the best way to ensure the accuracy of the device and further the value of the original investment. ISO 9001 and similar standards also require the calibration of devices that affect quality and/or the quality of inspection and test results. But, how do you know that the calibration laboratory you use is providing you with accurate results? And, by what criteria do you determine whether you are using a reliable and credible laboratory? This article will explain why the only way to be sure of the accuracy of the calibration results and the technical credibility of the laboratory is to use an ISO/IEC 17025 accredited laboratory as your calibration source.

Understanding Key Terminology

The terms "accreditation", "registration" and "certification" are **not** synonymous in the laboratory world.

"Accreditation" is the evaluation of a laboratory to ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories. The evaluation is conducted by a third-party organization that performs a technical assessment of the lab and its personnel in order to determine technical competence. Additionally, the lab's quality management system is evaluated for compliance to the standard.

To achieve accreditation, the lab must be found to be competent and compliant with the standard as well as any additional requirements that are imposed by the third-party organization.

In order for the accreditation to be considered valid, this organization must be a recognized accrediting body, that is, a body that has been evaluated nationally or internationally and invited to sign a mutual recognition arrangement (MRA) as a

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recognition of its technical proficiency. ILAC, APLAC and EA are examples of associations who recognize accrediting bodies. Reference the following websites for additional information: www.ilac.org, www.aplac.org, www.european-accreditation.org.

"Registration" applies to an independent third-party evaluation of the company's quality management system to ISO 9001 or other similar standards. A registration assessment is not an evaluation of technical competency. A laboratory may be registered to ISO 9001, however that does not mean that they are compliant with ISO 17025.

"Certification" applies to product that has been tested and found to meet design, safety or regulatory requirements, e.g., UL certified product. Certification may also apply to individuals who have successfully completed an evaluation of their technical knowledge by an independent recognized body, e.g., an ASQ Certified Quality Engineer. The terms "registration" and "certification" are sometimes used interchangeably regarding approval to ISO 9001 and other similar standards.

What It Means To Be "Accredited"

ISO 17025 shares many of the same quality management system (QMS) requirements as ISO 9001 and similar standards; but with a greater technical focus. Like ISO 9001, the ISO 17025 standard includes requirements for document control, contract review, internal audits, documentation of customer complaints, management review, etc.; however the standard adds another set of technical requirements. The lab must not only show evidence of compliance with the standard, but also demonstrate an acceptable level of proficiency.

Depending upon the accrediting body and the additional policies and requirements placed upon them by the associations that provide their recognition, there are likely to be additional requirements that the lab must adhere to in order to achieve accreditation. Requirements above and beyond ISO 17025 for measurement traceability, proficiency testing, calibration programs and others are not uncommon.

The accreditation assessment to ISO 17025 is an assessment of the technical operations of the laboratory. Assessors are assigned by the accrediting body based upon their technical expertise in the type of calibrations being performed by the laboratory and their experience in the respective industry. Listed are critical areas of importance that are assessed in detail:

- Laboratory personnel are required to understand how to operate the equipment they use and how it affects the calibration results. Additionally, they must show that they can competently perform calibrations and evaluate the results. To be authorized to perform accredited calibrations, they need to understand the measurements they are taking, why they are taking them and evaluate the results to determine the correct operation of the instrument. Supervision, internal audits and external audits verify through interview and observation that laboratory personnel are competent in these areas.
- The laboratory's environment must be monitored to ensure that conditions do not invalidate the results of the calibrations or adversely affect the required quality of any measurement. Conditions that may be monitored include temperature, humidity, barometric pressure, sound and vibration levels, etc. Records show evidence that the monitoring activity occurred as well as any actions that were taken if acceptable conditions were exceeded.

- All equipment used to calibrate items must be traceable through an unbroken chain of calibrations or comparisons to relevant national standards, e.g., NIST. According to the ISO 17025 standard, a calibration certificate provided by an accredited laboratory is sufficient evidence of traceability.
  - Oftentimes companies rely upon the National Institute of Standards and Technology (NIST) traceable number on the calibration certificate as evidence of traceability. According to a position statement by NCSL (National Conference of Standards Laboratories) on May 7, 1996:

    "Test report numbers issued by the NIST of the United States Department of Commerce are intended to be used solely for administrative purposes. Although they are often used to uniquely identify documents which bear evidence of traceability, test report numbers should not be used nor required as proof of the adequacy or traceability of a test or measurement."

- In order to assure the quality of calibration results, laboratories are required to participate in proficiency testing and/or interlaboratory comparison programs where they exist. These programs verify the laboratory's actual performance and the results are an indication of the lab's competence.
- Periodic internal checks of primary and reference standards are conducted to verify that the standards are working correctly and providing accurate results. Primary and reference standards are the devices used to take measurements and perform calibrations.

- All measurements have some degree of error. That amount of error is the measurement uncertainty. Accredited laboratories are required to calculate measurement uncertainty for each calibration parameter. The measurement uncertainty is listed on the laboratory's scope of accreditation. The scope identifies the types of calibrations the lab is accredited to perform along with the measurement uncertainty. The accrediting body analyzes the claimed measurement uncertainty for completeness and accuracy.

So, Why Aren't All Calibrations Created Equal…

All calibrations are not created equal because all laboratories are not created equal. The process to achieve laboratory accreditation is rigorous and should not be taken lightly. Maintenance becomes a way of life; an unquestioned operational approach that sets the accredited lab apart from its "unaccredited" competitors.