

White paper

Accurate measurements matter, and the role of quality laboratory accreditation

Metrology plays a significant role in our everyday lives, whether we are aware of it or not. Without accurate measurements at the laboratory level, much of the technology that gives our lives order would devolve into chaos.

ISO/IEC 17025—the World Standard

To maintain continuity and trusted testing methods, the International Organization for Standardization (ISO) has established standards and general requirements for the competence of testing and calibration laboratories. Applicable to all laboratories performing tests and/or calibrations, the ISO/IEC 17025 is rapidly becoming the standard, both domestically and abroad, for which most labs must hold accreditation. It enables laboratories to demonstrate that they follow strict guidelines which promotes confidence in the validity of testing results and, ensures the lab is technically competent. Suppliers and regulatory authorities will not accept test or calibration results from a lab that does not carry the 17025 seal.

Accreditation

To be accredited, a laboratory must undergo a rigorous and in-depth on-site assessment of its competency in testing or calibration. Some things that are verified by an independent assessor include:

- Training for personnel involved in the lab's work
- The lab's environmental controls and history
- Documented, validated procedures
- Uncertainty analyzed for each parameter on the lab's scope of accreditation
- Equipment traceability
- Calibrations witnessed
- Calibration reports

A matter of life or death

For medical devices, ISO/IEC 17025 compliance matters a great deal to the device manufacturers, the hospitals and the patients. For manufacturers metrology involves:

- Research and development—validation of design concept, validation testing
- New product introduction—setting product specifications
- Operations—calibration and verification during the manufacturing process
- Quality—supporting lean manufacturing, final inspection, and conformance
- Service—calibration and verification
- Sales and marketing—making/delivering claims to specifications

At the hospital level, where the use of the devices is critical to patient care, metrology involves:

- Meeting strict regulatory requirements for patient safety
- Choosing adequate medical instrumentation
- Verification and adjustment of medical devices
- Service and repair

If these processes are not handled in-house at the hospital, then choosing capable and competent vendors to support and maintain deployed instrumentation is crucial. For patients, even though they may not be aware, metrology and a trusted laboratory partner really matter when instruments could save a life.

A partner you can trust

Adhere to a higher standard, one you should expect from any laboratory. We maintain laboratory accreditation through the National Voluntary Laboratory Accreditation Program (NVLAP) administered by NIST, in areas of DC/LF, Time and Frequency, Mechanical, Thermodynamics, and Ionizing Radiation. Traceability is the foundation of a metrology system and that any break in the traceability chain means subsequent measurements are not valid. We are rigorous in our testing and use sound practices that enable measurements and trusted results.

Fluke Biomedical

28775 Aurora Road
Cleveland, OH 44139 U.S.A.

For more information, contact us at:

(800) 850-4608 or Fax (440) 349-2307
Email: sales@flukebiomedical.com
Web access: www.flukebiomedical.com

©2019 Fluke Biomedical. Specifications subject to change without notice. Printed in U.S.A.
7/2019 6012572a-en

Modification of this document is not permitted without written permission from Fluke Corporation.