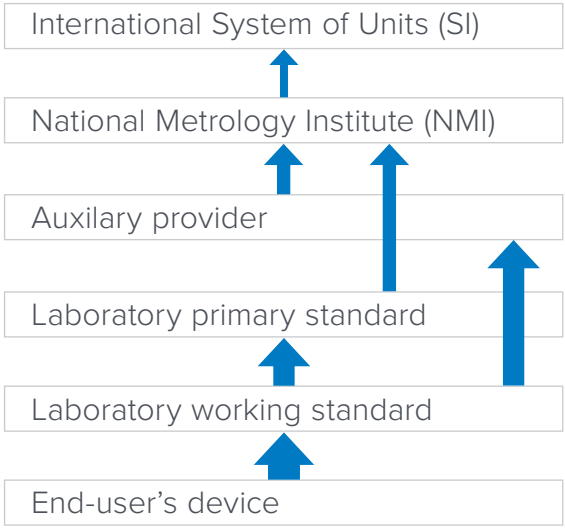
White paper

Traceability and instrument calibration—why it matters

With highly specialized medical instruments, it is imperative that rigorous and verifiable calibration be documented. The international vocabulary of metrology defines traceability as the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

What makes traceability so important is that it requires an established calibration hierarchy; a step-by-step transfer process. Each step in the process builds a chain that clearly shows how each link in the chain relies on the links above it for traceability—all the way back to the SI (International System of Units). If any link in the chain breaks, traceability is lost in subsequent transfers.

Using the illustration below to explain the process, let's start at the bottom with the end user's device. This device is first calibrated against the laboratory's working standards. These working standards are, in turn, calibrated against the lab's primary standards.



It is important to note here that most laboratories keep their primary standards isolated from end user instruments.

1. It prevents the possibility of a defective end user's device from damaging expensive primary standards.
2. The more the primary standard is handled or measured, the higher the risk that the primary standard could be compromised.
   a. For example, Fluke's primary laboratory 1-ohm resistance standards units have been characterized over several decades and have a predictable drift on the order of under 1 part in 10 million.
   b. It takes careful and lengthy time to study the behavior of these instruments – if a standard is damaged, you've not only lost the device but also potentially years' worth of historical observational data.

Following the lab's primary working standards, the device may be sent to a third-party/auxiliary vendor for additional calibration (rather than in-house calibration) Finally, the standards are calibrated at a national metrology institute or NMI. International organizations provide support for national institutions to insure global standards for calibration and measurement are met.

Measurement standards

The BIPM, (International Bureau of Weights and Measures), maintains the SI which is the foundation of our worldwide measurement system. In addition, each country has its own national metrology institute or NMI. This is important because an instrument can be traceable through a different country's NMI. For example, if you have a new instrument purchased from a manufacturer in Germany, or you send a device back for calibration to the OEM in Germany, it very likely has its traceability path through Germany's NMI. Similarly, if you've acquired an instrument from a vendor in China, it is most-likely traceable through NIM, China's NMI. It is important to note that traceability is through any given NMI to the SI—not to the NMI itself. The NMI is a link in the

traceability chain. The BIPM maintains the Key Comparison Database which is accessible on the BIPM website—bipm.org. The database lists the calibration and measurement capabilities of each NMI. Fluke Biomedical and RaySafe participate all the way to the SI.

Measurement uncertainty

While all steps are taken to ensure accuracy, there are some measurement uncertainties. The chart illustrates the traceability chain with respect to measurement uncertainty. The best possible representation of a given quantity value is the SI representation. Remember, the SI is **the** measurement reference.

The NMI realizes this quantity and calibrates your provider's standard, or possibly your own laboratory's primary standard. At this point, the inherent uncertainty in the NMI's reference is transferred to your standard as well as a small amount of uncertainty from several sources: noise or variation in the measurement data, temperature, pressure, bias in the measurement system, etc. This laboratory's primary standard is then used to calibrate the lab's working standards which, in turn, are used to calibrate the end users' devices.

The chart shows a general traceability process. There could be more or fewer steps for any given instrument. The uncertainty components can be present at every transfer or link in the chain, thus increasing the quantity's stated uncertainty at every transfer.

Today, there are increasing regulatory guidelines, higher quality standards and, rapid technological growth that pressure medical professionals to work faster and more efficiently. The rigorous measurement and traceability standards put in place by the international organizations and, adherence to the SI, provide the accuracy and reliability needed to ensure patient safety.

Fluke Biomedical and RaySafe are leading medical device manufacturers of biomedical test tools and automated performance testing and documentation systems. We provide a diverse range of software and medical equipment test tools that help reduce maintenance downtime while improving quality assurance; assess new technologies to ensure the best quality, reliability and accuracy from medical devices and, provide risk management analysis and systems to healthcare teams, administrators and patients.

NIST – USA

NPL – UK

NRC – Canada

NIM – China

PTB – Germany

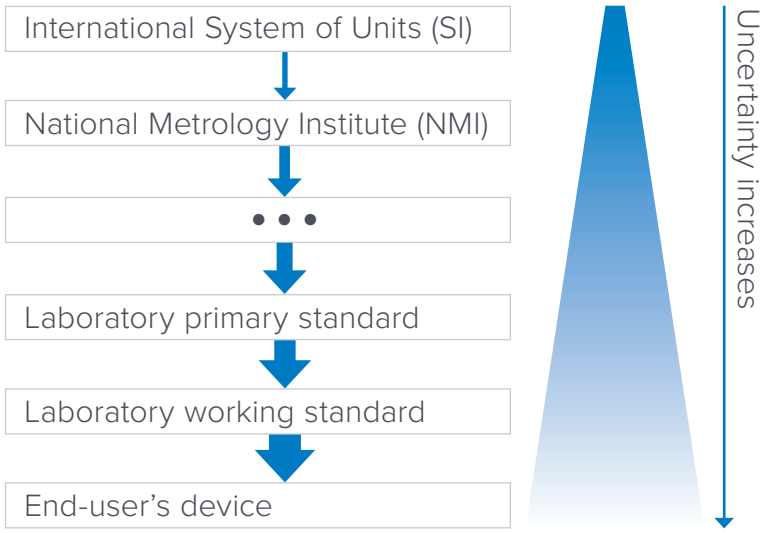
NMIJ – Japan

LNE – France

CENAM – Mexico

BIPM Key Comparison Database accessible at bipm.org

This is not a complete list as each country has its own national metrology institute —each with varying capability.



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