

# Policy on Traceability

- Traceability of sensor products through the manufacturing process
- Traceability of Calibrations to NIST

## **Traceability of sensor products through the manufacturing process**

FUTEK maintains full traceability of each sensor throughout the manufacturing process including original raw materials used, production operations and operators, and calibrations performed. This traceability also extends to outside vendors providing full traceability to outside processes such as anodizing, heat treating, welding and grinding. Traceability documentation is maintained as controlled quality records in Oracle as a permanent record.

Traceability identification is achieved by engraving a unique serial number on every sensor produced by FUTEK. The serial number is laser engraved on the sensor at the beginning of the manufacturing process, just after machining, so that every step in the production process for that sensor is recorded. The serial number is also linked directly to the calibration certificate for that sensor. Customers are able to access the full calibration data and history using the serial number through the FUTEK website, [www.futek.com](http://www.futek.com).

As an ISO 9001:2000 certified laboratory, we are required to maintain a unique identification number of each end product. We go well beyond this minimum specification requirement and keep complete traceability records through production back to the raw materials.

## **Traceability of Calibrations to NIST**

FUTEK performs an individual calibration of every sensor delivered to the customer. Both our standard commercial calibrations and those accredited calibrations performed to ISO 17025:2005 are fully traceable to NIST. FUTEK occasionally receives a request to provide NIST Test Report Numbers associated with the standards used to calibrate sensors in our calibration laboratory. We have endeavored to acquire these from the next tier down outside calibration laboratories, but find they are not available to us. In general, independent calibration laboratories are reluctant to share their certificates because of competitive and/or confidentiality concerns. While it may be possible for the independent agency to approach these laboratories and find out whom they used for the calibration of each of the reference standards they use, it could be a very long trail back to NIST.

In fact, both NIST and A2LA discourage the use of NIST Report Numbers to establish traceability since the report number itself is no guarantee that the discipline has been followed through the entire chain-of-calibrations. While NIST states that traceability is established through "an unbroken chain of comparisons, all having stated uncertainties." They go on to say Test Report Numbers issued by NIST are used solely for administrative purposes. Although they often uniquely identify documents that bear evidence of traceability, test report numbers themselves do not address the requirement for an unbroken chain of comparisons and should not be considered as the sole evidence of traceability.

Both A2LA and the National Conference of Standards Laboratories International (NCSLI) state that test report numbers issued by NIST are intended to be used solely for administrative purposes and shall not be used nor required as proof of the adequacy or traceability of a test or measurement.

It should also be noted that nationally and internationally recognized standards dealing with test and measurement quality requirements such as ANSI/NCCL Z540-1, ISO 10012, ISO/IEC 17025 and the ISO9000 series do not require the use or reporting of NIST test report numbers to establish traceability.

So, how does an accredited laboratory establish traceability to NIST? This is the purpose of the primary multi-lateral recognition agreements established amongst accrediting bodies: APLAC (Pacific), EA (European), ILAC (international) and IAAC (American). As signatories to these multi-lateral agreements, each organization is committed to promoting the recognition and acceptance of accreditations granted by its fellow signatories. Accredited test and calibration results, reported by laboratories that are accredited by the accreditation bodies recognized by any of these multi-lateral agreements, and reported in a test or calibration report endorsed by the accrediting body's logo, or which otherwise makes reference to accredited status are recognized by each member as satisfying the requirements pertaining to measurement traceability to NIST.

As a practical implementation of this process, traceability is established by using accredited calibration laboratories who are signatories to the multi-lateral recognition agreements (MLAs) through the accrediting bodies mentioned above. That is, the responsibility of the accredited laboratory (FUTEK in this case) for establishing the full chain-of-calibration traceability to NIST is satisfied by establishing that they have used a fully accredited laboratory. The responsibility for establishing traceability through those laboratories back to the source was responsibility of the accrediting body for each of those laboratories (NVLAP, A2LA, ISA, ACLASS, etc.). Since these accrediting bodies are signatories to the MLA as an accreditation organization through IAAC, the accreditation traceability of the individual independent laboratories to NIST has been established through their accreditation.

See [http://ts.nist.gov/Traceability/supplmatls/suppl\\_matls\\_for\\_nist\\_policy\\_rev.cfm#FAQ\\_Generall](http://ts.nist.gov/Traceability/supplmatls/suppl_matls_for_nist_policy_rev.cfm#FAQ_Generall)

See <http://www.dosimetryresources.com/PDF/A2LA%20Traceability%20Policy.pdf>