Frequently Asked Questions Regarding Calibration Standards Compliance

Does ESSCO have to comply with X standard?

Frequently our quality manager is asked whether we calibrate to and / or comply with standards other than ISO 9001:2008, ANSI/NCSL Z540-1-1994, ISO/IEC 17025:2005, ISO 10012:2003, ISO 13485, and TS 16949. And, when required contractually, 10CFR21 and 10CFR50 APP. B.

Some of the standards requested are:

AMS 2750D
AS9100
QS 9000
CISPR 16-1-1
21 CFR Part 211
21 CFR Part 83
ULDAP
FAR 145

The short answer is no. Calibration laboratories and traceable calibration processes comply with three specific standards, i.e. ISO 9001 (for any business type), ISO/IEC 17025 (specific to calibration and testing laboratories) and ANSI/NCSL Z540 (specific to calibration laboratories). Other standards that calibration laboratories are asked to comply with, and even document on the certificate of calibration, are actually only relevant to specific manufacturing or testing processes of the customer, not the calibration process of the calibration laboratory. In many cases, manufacturing standards will reference the use of calibrated instrumentation from a *certified or accredited calibration source.* This means the calibration source complies with calibration standards such as ISO/IEC 17025, not manufacturing standards. As a manufacturer, it is your quality program that must comply with the specific standards imposed upon your processes. Other than the portion requiring calibration, manufacturing standards do not trickle down to the calibration laboratory. Essco may contractually comply with 10CFR21 and 10CFR50 App. B. etc.
Note: when a calibration laboratory is accredited to ISO/IEC 17025, it is also compliant to ISO 9001 without additional auditing, per *ILAC, International Laboratory Accreditation Coopeeration.*

Is the use of an accredited laboratory sufficient to satisfy the need for accredited calibrations?

No. You must request accredited calibrations and the measurement capability must be within the scope of accreditation for that calibration laboratory.

As an FDA regulated business, do I need to audit my calibration supplier?

Yes. The *FDA, The Food and Drug Administration* now requires you to perform actual site audits of all your calibration suppliers.

Do I need documented uncertainties with every accredited calibration?

Yes. *ILAC, International Laboratory Accreditation Council,* now requires that uncertainties must be included on the data sheet for each measurement taken.

Why do calibration suppliers have so many complex and confusing "levels" of service?

It's marketing. Many manufacturers see calibration as a necessary evil, so they shop for price rather than quality and service. To satisfy this misguided thinking, calibration suppliers cut corners to reduce prices and attract uneducated consumers. All calibrations should be performed in accordance with the instrument manufacturer's guidance. *NAVLAP, The National Voluntary Laboratory Accreditation Program* and *A2LA, The American Association for Laboratory Accreditation* even adds additional requirements to accredited laboratories calibration procedures. You do get what you pay for, even from calibration suppliers, so you assume a degree of unnecessary risk. *See "How to choose a calibration supplier" on this site.*