Too Many Quality Standards, Too Little Quality – Is it Too Late to Change our Direction?

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Abstract

This paper presents a strategy that embraces the international reliance on ISO/IEC 17025 [1] as a competence standard for calibration and testing laboratories, while utilizing ISO 10012 [2] as a conformance standard to evaluate calibration programs. This reliance would lead to the elimination of all other metrology oriented quality standards in the United States.

The author provides objective evidence of several areas in which the existing ANSI/NCSL Z540-1-1994 [3] standard is lacking and in which its existence actually serves to deprecate the quality of work performed. Also addressed is the commitment level required from the both the manufacturing and metrology communities, and the objectives, which will have to be achieved in order to make this evolution a reality. The failure to embrace the concept of streamlined quality standards in this community will serve as yet another nail in the coffin of our nation's industrial base.

1 Introduction

Americans pride themselves in being innovators, as well as being unique from the remainder of the world. While this has served our nation well throughout our history, there are occasions when being different for the sake of being different can be wrong. It is the author's perspective that the desire to continue to propagate ANSI/NCSL Z540 as a quality management standard in the field of metrology is one such example where we are completely wrong.

While preparing for the ASQ Certified Calibration Technician (CCT) examination last year, I was reminded of why I left the commercial calibration field, after a career of many years in that industry sector. As the Quality Manager of an accredited laboratory, it was my responsibility to interface with a customer base whose purchases orders reflected the desire for their calibration vendor to adhere to various quality standards including ISO 17025, ANSI/NCSL Z540, ISO 10012, QS9000, ISO/TS 16949, and AS9100, as well as FDA/GMP criteria, Nuclear regulations, and a plethora of other assorted quality documents.

The references provided by ASQ to study for the CCT examination emphasize many of these varying standards, and highlight the need of American Industry to be unique, with the examination itself occasionally serving as a treasure hunt to identify differences between ISO 17025 and ANSI/NCSL Z540. In a similar fashion, those calibration laboratories that provide services to other organizations spend so much time differentiating between levels of service and pounding square pegs into round holes that their quality departments are taxed to the breaking point.

The net result is that numerous critical elements including proficiency testing, intermediate checks of calibration standards, internal system audits, the development of valid uncertainty budgets, and the refinement of calibration procedures do not receive the attention they deserve. This has a direct impact on product quality and customer service.

2 How We Arrived at this Destination

While the history of the quality measurement systems for metrology is a review for many, it is still important to revisit because it influences our current dynamics. It is interesting to note that while ANSI/NSCL Z540 was created in good faith as a simplification effort, its existence has not achieved its primary goal.

This goal was expressed in 1995 by a Quality Assurance Engineer for Westinghouse named James Lloyd who penned an article that painted an exciting view for metrology professionals. He wrote that "*A single national standard for calibration laboratories and equipment is becoming a reality. The standard has been published, federal agencies and industry are specifying work based on it, and accreditation is available for calibration laboratories. The new standard is expected to reduce the number of compliance documents, decrease redundant audits, and ensure compliance with international standards*." [4] He goes on to state that this document was developed, "*In response to the confusion and inconsistency of quality standards in the United States for calibration requirements*."

Eleven years later, this goal of simplification has not been achieved. Sadly, many dedicated professionals have invested thousands of hours into the effort and things seem almost as confused and inconsistent as they were in 1995.

It is ironic that the United States is so stratified in this arena because we were actually among the first to develop substantial quality programs that related to metrology. In 1962, the U. S. Department of Defense (DOD) made a significant impact on the evolution of all future standards by using MIL-STD 45662 [5) to place requirements on their DOD laboratories, contractors, and subcontractors. The standard included the original concept of Test Accuracy Ratio which was developed by Jerry Hayes of the US Navy.

Another critical characteristic of MIL-STD 45662 was that all measuring and test equipment had to be calibrated utilizing reference standards whose calibration were certified as traceable to the National Bureau of Standards, had been derived from acceptable values of fundamental constants, or had been derived by the ratio type of self-

calibration techniques. Reference standards used in the calibration of DOD equipment and systems had to be supported by certificates, reports, or data sheets attesting to the date, accuracy, and conditions under which the results were obtained.

Although other U. S. government agencies established similar requirements, the requirements of MIL-STD-45662 were the most significant, since the DOD was one of the largest purchasers of goods and services in the world.

By the late 1960's, George Nelson, the President of ASTM helped established the ASTM E36 committee for laboratory accreditation. The E36 committee developed ASTM E548 – Requirements for Laboratory Accreditation, which served as the root document for ISO/IEC Guide 25 – General Requirements for the Competence of Laboratories. In 1982, ISO Guide 25 became the basis for laboratory accreditation throughout the world.

During the 1970's, the US laboratory community lobbied the Department of Commerce to initiate a program of laboratory accreditation that would be administered by NBS (now NIST), in which individual laboratories would be accessed.

This program came to fruition by 1976 in the form of the National Voluntary Laboratory Accreditation Program (NVLAP). The original program was extremely narrow in scope and only addressed specific tests. It would not be until 1995 that NVLAP would provide an accreditation program for calibration laboratories.

In the interim, privatized organizations also began to be organized in order to perform accreditation assessments. A2LA was chartered in 1978 and was subsequently followed by several other accrediting bodies.

All the efforts to develop quality programs were not of course limited to the United States. The Europeans had no faith in the claims of calibration laboratories that they met the requirements of MIL-STD 45662 because these requirements were so haphazardly enforced. The U S military had sold MIL-STD 45662 as an international NATO Standard (AQAP 6), but the Europeans elected to not use this document.

By 1971, the United Kingdom had released BS 9000, which was developed for the electronics industry in response to the many problems that were occurring in that fledgling industry. Many other industries quickly followed suit, then in 1979 all of these discrete quality standards were rolled into BS 5750. In 1987, BS 5750 served as the primary basis for ISO 9000.

This marked the end of a period of committee work organized by the International Organization for Standardization and reflected a decision to promulgate the Standard throughout the international business community. For those not familiar with it, the International Organization for Standardization (ISO), based in Geneva, is a world-wide federation of national standards bodies whose role is to promote the development of standardization and related activities to facilitate the international exchange of goods and services.

While ISO 9000 was adopted to facilitate world trade, it actually took a significant level of coercion (even in the United Kingdom) before this goal was achieved. With worldwide acceptance for ISO 9000, it was inevitable that other ISO documents would also begin to play a pivotal role in the metrology community.

In the United States, the role of ISO/IEC Guide 25 [6] was already emerging. The NBS Office of Weights & Measures had started certifying laboratories against the criteria in Handbook 143, Program Handbook. The 1985 criteria were based on ISO Guide 25 (1982), General Requirements for the Competence of Calibration and Testing Laboratories.

After ISO Guide 25 was updated in 1990, the Office of Weights and Measures began the process of updating their Program Handbook in 1991. At approximately the same time, the National Conference of Standards Laboratories (NCSL), Total Quality Management (TQM) Committee initiated work on the development and adoption of a single U.S. national standard for calibration laboratories.

This NCSL TQM Committee included representatives from NIST, Department of Defense, Department of Energy, Nuclear Regulatory Commission, Federal Aviation Administration, and numerous industries. This committee became an official ANSI standards writing body (Committee Z 540) and published the new U.S. standard as Z540-1-1994 (July 1994). ANSI/NCSL Z540-1-1994 incorporated ISO Guide 25 and many elements of MIL-STD 45662A into the new standard.

At the time that this document was completed, its stated objectives included the desire that it be used for the purpose of laboratory accreditation in order to facilitate the following objectives:

- Reduce the number of redundant laboratory audits;
- Improve measurement compatibility and acceptance of measurement results between laboratories in the United States and internationally
- Comply with the ISO-series standards for quality.

The key to widespread acceptance of the new Z540 document was section 2 which added the quality assurance elements for a supplier's calibration system that were a critical part of MIL-STD 45662A. Within a year of release, the Department of Defense rescinded MIL-STD 45662A in favor of the Z540-1-1994 standard.

NVLAP began performing accreditations for calibration labs in 1995, with A2LA continuing to expand their market share as well. Still, laboratory accreditation was gaining momentum much slower than in Europe and other locations.

For many in the metrology industry, laboratory accreditation seemed to be an abstract concept that only top tier labs needed to be concerned with until the automotive industry released the 3rd edition of QS-9000 in 1998. Section 4.11.2.b.1 of this document contained a statement that required commercial and independent laboratories to be

accredited to ISO Guide 25 or the equivalent. A deadline of January 1, 2001 was given in order to adhere to this provision.

This proved to be a watershed moment for calibration providers, especially those delivering 3rd party service. The race was literally on to see which organizations would gain accreditation first and capitalize best on the automotive industries calibration requirements.

Along with several of my peers, I encouraged my employer to seek accreditation in order for us to not only retain our existing market share, but to expand on it. In retrospect, we were so naïve about measurement uncertainty, proficiency testing, and many other elements of ISO Guide 25 that it seems ridiculous. With a great deal of hard work we learned what we had to learn and became a multi-site accredited organization. That initial accreditation encompassed both ISO Guide 25 as well as the Z540 standard.

Then in late 1999, the divergent paths began taking over again. ISO Guide 25 evolved into ISO 17025:1999 [7] and the differences between it and Z540 became significant. Anyone who was accredited at the time can testify to the long hours that were required to develop a quality program to cover the entire gap analysis that our accrediting bodies were reviewing. A new release of Z540 proved to be difficult to develop; consequently ANSI/NCSL Z540-1-1994 was reaffirmed without change in 2001.

Several more years passed and a revised ISO 17025 was released in 2005. While a new Z540 looms on the horizon, it seems unlikely that it will do anything to relieve the confusion our industry is going through.

3 Industry meets the Multi-headed Metrology Standard Monster

For demonstration purposes, we will examine what happens when a fictional business attempts to have its metrology requirements fulfilled. While many of these examples are based on my personal experience, the examples have been modified in order to avoid negative comments towards any individual or groups organizations.

3.1 Background

Company Profile - Zeus Manufacturing

- A multi-location firm that builds Dilithium crystal based fusion reactors.
- Products are sold both commercially and for military applications.
- Products are also sold both domestically and internationally.
- Several manufacturing locations are registered to ISO 9000:2000.
- Company was seeking the best solution for their calibration needs.

Leonardo Kelvin, the Quality Manager for Zeus Manufacturing was tasked with finding this calibration solution. Before embarking on this quest, he did his best to educate himself about metrology and the related quality management standards. During this

process, he discovered that the metrology community within the United States is truly suffering from an identity crisis.

He has found firms providing calibration service that claim adherence to ISO 17025, ISO 10012, ANSI-NCSL-Z540-1-1994, MIL-STD 45662A, and ANSI/ASQC M1-1996, as well as the relevant sections of AS 9100, QS9000, ISO/TS 16949, NASA NPD 8730.1B, FDA/GMP criteria, and Nuclear regulations.

Leonardo correctly determined that he should typically be using calibration providers that are compliant with ISO 17025 for his ISO 9000 locations. He noted that many of his military contracts invoke a requirement to use calibration vendors that are compliant to ISO 17025 or ANSI/NCSL Z540, so he felt it was incumbent to also evaluate providers who claimed compliancy with only Z540. He also felt it was logical to consider the Original Equipment Manufacturer (OEM) for some calibrations. Consequently, he created several broad categories for the organizations he evaluated as is reflected in Table 1.

Table 1 -Leonardo's Taxonomy of Calibration Providers

Category	Lab Type
A	Labs that have been accredited to ISO 17025
B	Labs that state compliance with ISO 17025 (may also state compliance to ANSI/NCSL Z540)
C	Labs that state compliance with ANSI/NCSL Z540
D	Original Equipment Manufacturers

Excluding labs that are only compliant to Z540 from ISO work is typically appropriate because Z540 alone does not meet the requirements of ISO 9000:2000. This could be overcome by including the appropriate elements in their quality system, but it seems unlikely that a firm would elect to do this, but not make the effort to be compliant with ISO 17025.

Zeus Manufacturing is committed to excellence, so Leonardo was afforded the opportunity to perform on-site evaluations of a number of vendors. His findings reflect an industry that is full of inconsistencies and which demonstrates the confusion that we have worked so hard to avoid. A few of the most critical areas of concern are discussed below:

3.2 Traceability

To his chagrin, Leonardo found that his potential providers of calibration services could not even agree on this most fundamental of metrology principles. His internal lab owns 2 banks of DC Zener Reference Standards, each of which consists of 4 separate Zener cells. As a trial, he sent one cell to a laboratory representing each of his metrology categories. His purchase order, requested measurement uncertainty as part of the calibration and stated that traceability IAW the international definition must be maintained.

While each organization met the requirement to provide measurement uncertainty, the level of compliance with the traceability request varied as is reflected in Table 2.

Table 2

Lab Category	Traceability Compliance
A – ISO 17025 accredited	Full compliance per the international definition; as an added bonus only accredited laboratories were included in the traceability chain.
B - ISO 17025 compliant	Full compliance per the international definition; although one non-accredited laboratory was in the traceability chain, it too was fully compliant with the international definition.
C – Z540 compliant	Failed to meet the international definition for traceability. The calibration certificate for the vendor's Zener reference that they use when performing calibrations did not reflect the measurement uncertainty associated with the calibration. Their vendor's certificate did state "calibrated per manufacturer's specification", but this would not have had any value unless the vendor was privy to prior calibration data (specification is based on drift, not a nominal value).
D - OEM	Full compliance per the international definition; the OEM is accredited and this measurement falls within their scope.

In this scenario the Zener reference standard's 10 V DC output has an annual drift specification of ± 1.2 ppm, but no specification relative to the nominal 10 V value. A calibration certificate stating calibrated per manufacturer's specification would fall far short of meeting the international definition for traceability.

This is probably the area where Z540 most significantly deprecates the quality of calibration. The Z540 definition for traceability (3.26) is stated as follows: "*traceability: The property of a result of a measurement where by it can be related to the appropriate standards, generally national or international standards, through an unbroken chain of comparisons*."

This statement has been paraphrased from the VIM, with several key words omitted. The VIM definition actually reads: "*Traceability - property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties*."

The key phrase is, "all having stated uncertainties"! If for no other reason the Z540 document is significantly devalued by this omission.

It should be noted however, that for many instruments it might not be inappropriate to state calibrated per manufacturer's specifications. While a case can be made that if a calibration certificate states, "calibrated per manufacturer's specifications" and there is nothing that reflects a deviation from a 4:1 TUR, then the devices specifications will

typically serve as the uncertainty contributor when applied at the next tier of uncertainty calculations.

3.3 Personnel

With his background in quality, Leonardo assumed that he would find the individuals performing calibrations to be highly qualified and holding some type of personal certification. He knew that Zeus Manufacturing would have never hired him if weren't an ASQ Certified Quality Manager. In addition, all of the quality technicians that work in his department are ASQ Certified Quality Technicians, and he has mandated that all of the firm's internal calibration technicians achieve ASQ Certified Calibration Technician status.

During his assessments, Leonardo found the metrology community to be well qualified, but almost totally lacking in independent certification. His findings are discussed in Table 3.

Table 3

Lab Category	Personnel Training
A – ISO 17025 accredited	Many personnel were formally trained by the military, substantial evidence of On-the-Job-Training, significant evidence of a tiered internal training program with lower levels requiring varying levels of supervision, and an evolving commitment to personnel certification.
B - ISO 17025 compliant	Many personnel were formally trained by the military, substantial evidence of On-the-Job-Training, significant evidence of a tiered internal training program with lower levels requiring varying levels of supervision, little commitment to personnel certification.
C – Z540 compliant	Many personnel were formally trained by the military, substantial evidence of On-the-Job-Training, little evidence of a tiered internal training program with no objective evidence that lower levels require supervision, little commitment to personnel certification.
D - OEM	A few personnel were formally trained by the military, substantial evidence of On-the-Job-Training in including factory certifications, little evidence of a tiered internal training program with no objective evidence that lower levels require supervision, no commitment to personnel certification for calibration. In this scenario the OEM is a leading producer of high voltage equipment with no commitment to achieving any type of international certification.

These findings are a direct by-product of the Quality Management Systems that are governing them. Those programs developed around ISO 17025 tended to have a much

higher commitment to training of personnel. While Z540 is very general and vague in comparison to ISO 17025, there are two key areas in which Z540 is particularly lacking.

- Section 5.2.1 of the ISO 17025 in part states that, "*When using staff undergoing training, appropriate supervision shall be provided*".
- Of even greater consequence is Note 1 of Section 5.2.1 which states, "*In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification*." This clause was a significant impetus for the establishment of ASQ's Certified Calibration Technician (CCT) program. Now that the CCT program is reaching a mature state, it is reasonable to assume that this clause can now be more properly evaluated within the metrology community.

3.4 Calibration Procedures, Conformance with Specifications, & Tolerance Declarations

Because of their close relationship to one another, Leonardo chose to evaluate these elements in unison. As he did so, he found that there is much more to this topic than meets the eye. He submitted a standard oil bath resistor to each of the 4 categories of laboratories. Table 4 reflects his findings in this area.

Table 4

Lab Category	Conformance
A – ISO 17025 accredited	Provided a measured value at a specific temperature with stated uncertainty. No tolerance declaration was made nor was an attempt made to state specifications criteria.
B - ISO 17025 compliant	Provided a measured value at a specific temperature with stated uncertainty. An in tolerance declaration was made based on the unit not exceeding the customer provided specifications that allowed drift of ± 5 ppm/year.
C – Z540 compliant	Provided a measured value at a stated uncertainty. A specification of ± 10 ppm was assigned based on the military procedure that was being used. The resistor was declared to be out of tolerance because it was 25 ppm higher than its nominal value at the time of manufacture.
D - OEM	While the OEM is no longer in business, another firm has purchased their product lines and provides OEM level service. A specification of ± 30 ppm is established based on the original documentation for the resistor dated 1967. The resistor was declared to be in tolerance because it was 28 ppm lower than nominal value at the time of manufacture.

One of the primary differences between Z540 and ISO Guide 25 was the additional clauses regarding calibration procedures that were added to section 10.2 of Z540. While these guidelines do an exemplary job of detailing how a calibration procedure should be

formatted and what the contents need to be, the standard fails to adequately define the level of testing required and what a recommended method for defining it is.

The example shown above is based on events that actually occurred and which probably reoccur quite frequently. While ISO 17025 mandates that that a customer must be notified of and approve test methods, Z540 allows the laboratory performing the work to make this determination.

Consequently many laboratories end up using calibration procedures that are not appropriate for the task at hand. While military procedures are well designed and have significant merit, they are designed for the military. Other organizations are allowed to use these procedures through either the GIDEP or DOD-MIDAS programs and they often neglect to evaluate them for their needs. A branch of the military may completely excise a number of tests from a manufacturer's recommended procedure because they are not relevant to the military application. Use of these procedures by non-military organizations is widespread and typically done without review.

3.5 Measurement Uncertainty

Like many who are introduced to it for the first time, Leonardo was somewhat intimidated by the subject of measurement uncertainty. With assistance from a quality manager counterpart at an accredited laboratory, he was able to overcome this level of intimidation. What he was unable to overcome was the confusion that results when a laboratory claims compliance to both ISO 17025 and Z540. A 6 inch digital caliper with both resolution and accuracy of 0.0001 inch was sent to several laboratories for calibration His findings are summarized in Table 5.

Table 5

Lab Category	Measurement Uncertainty
A – ISO 17025 accredited	The laboratory stated that the device was calibrated per agreed upon procedures and provided the measurement uncertainty for each measurement, but made no claims regarding Test Uncertainty Ratios or conformance with specifications.
B - ISO 17025 compliant	Stated that the device was calibrated per agreed upon procedures and provided the measurement uncertainty for each measurement. The device was stated to meet specifications and that the Test Uncertainty Ratio is 0.87:1.
C – Z540 compliant	Stated that the device was calibrated per manufacturer's specifications and that a 4:1 TAR was maintained.
D - OEM	Discovered 2 distinct categories – OEMs that are accredited and exceedingly compliant in regards to this topic and organizations that are clueless in regards to measurement uncertainty and who still live a MIL-STD existence.

ANSI/ NCSL Z540 requires laboratories to ensure that calibration uncertainties are "sufficiently small" so as not to affect the adequacy of a measurement. Documented and defined uncertainty analyses may be used in verifying the measurement process, but when not used, Z540 states that the collective uncertainty of the measurement standards should not exceed 25% of the acceptable tolerance for each characteristic—i.e. the 4:1 test accuracy ratio (TAR).

ISO 17025 differs by requiring a comprehensive uncertainty analysis for all calibrations. This is predicated by the belief that traceability of a measurement cannot be established without knowing the expanded uncertainty. A 4:1 TUR (or TAR) may be stated on the calibration report; however, it must be in addition to the quantified uncertainty of the measurement.

The above example reflects the diversity that can be experienced when out-sourcing the simplest of devices. While working for both accredited laboratories and for a non-accredited laboratory that claimed compliance to ISO 17025, I saw this frustration every day. Because a manufacturer makes an unrealistic claim regarding accuracy relative to resolution, calibration providers are left with a quandary.

If a legitimate uncertainty budget is developed for this caliper, the stated uncertainties are atrocious. At the same time, there is a very good chance that the calibration provider down the street who claims compliance to Z540 and wouldn't know uncertainty if a truckload of budgets fell on him is stating that his TUR (or TAR) is better than 4:1.

3.6 Quality Audits

Having spent much of his career performing audits, this was perhaps the easiest element for Leonardo to evaluate. Keeping in mind that many of his facilities are ISO 9000 registered, he chose to evaluate his prospective suppliers on that basis. A summary of this evaluation is presented in Table 6.

Table 6

Lab Category	Quality Audits
A – ISO 17025 accredited	Fully compliant with all of the audit requirements of ISO 9000.
B - ISO 17025 compliant	Fully compliant with all of the audit requirements of ISO 9000.
C – Z540 compliant	Compliant with many aspects of the ISO 9000 audit requirements, but fails to mandate follow ups and to evaluate their effectiveness.
D - OEM	A self proclaimed ISO 9000 manufacturer of a niche type of test equipment was evaluated. Their audit program failed to conform to almost all ISO 9000 audit requirements.

The results are as expected this criteria. Procedures for internal audits and review are part of the quality manual requirements of Z540. Z540 also requires findings and corrective

actions resulting from audits to be documented and that the individual responsible for quality should ensure that corrective actions are completed on time. Since follow-up activities were not mandated when ISO Guide 25 was written, they also fail to appear in the Z540 requirements.

ISO 17025 is much more stringent about requiring internal audits to cover all the elements of the quality system and that they are planned under the quality manager according to a predetermined schedule. ISO 17025 also requires documentation of follow-up activities including corrective actions and demands that their effectiveness be evaluated.

3.7 Calibration Intervals & Due Dates

As he had come to expect, this area of Leonardo's evaluation was also full of surprises. His previous experience with calibration had led him to believe that a calibration sticker with a due date on it was one of the most important aspects of calibration. When he learned that ISO 17025 compliant laboratories do not normally provide calibration due dates, he was amazed. To learn the remainder of his surprising findings, refer to Table 7.

Table 7

Lab Category	Calibration Intervals & Due Dates
A – ISO 17025 accredited	Calibrated the device and returned it with all the appropriate documentation including a calibration sticker that had been completed except for the due date.
B - ISO 17025 compliant	Calibrated the device, contacted Leonardo for the proscribed calibration interval (18 months) and due date (End of month), and returned it with the appropriate documentation and calibration interval.
C – Z540 compliant	Calibrated the device, assigned a 36 month calibration interval based on the existing Air Force interval for the same instrument and completed all paperwork and stickers accordingly.
D - OEM	Calibrated the device, assigned a 12 month calibration interval based on their internal policy for this same instrument and completed all paperwork and stickers accordingly.

This is clearly compelling evidence that mandating that calibration labs place due dates on equipment can be a poor practice. Calibration intervals are assigned on a basis that frequently lacks metrological merit.

ISO 17025 is clearly more stringent than Z540 about not placing calibration due dates on calibration certificates and calibration labels unless directed to do so by the client, or when it is legally required. If this occurs, then the calibration interval should be stated in the contract or purchase order or otherwise agreed to with the client before it is indicated

on the calibration report or label. While this may initially be perceived as a weakness, it is actually one of the real strengths of the ISO 17025 standard.

The goal of calibration interval analysis is to reduce out-of-tolerance conditions to an acceptable level based on the quality requirements of the organization. No one is in a better position to do this than the owner of the equipment because he is the only one familiar with its handling, usage, and history.

While manufacturers may designate time periods over which products should perform without degradation, it can not be certain that this will apply in every situation because of all the unknown factors.

In a similar manner, it is typically not appropriate for a calibration provider to base a calibration interval on their unique experiences or on the cycles prescribed by the military. All of these circumstances are unique and may not be relevant in this specific case.

3.8 Client & Customer Service Requests

Leonardo once again chose to evaluate his prospective suppliers based on ISO 9000 criteria. The results of this evaluation are presented in Table 8.

Table 8

Lab Category	Client & Customer Service Requests
A – ISO 17025 accredited	Fully compliant with all of the contract review requirements of ISO 9000.
B - ISO 17025 compliant	Fully compliant with all of the contract review requirements of ISO 9000.
C – Z540 compliant	Provided objective evidence of some contract review requirements, demonstrating no evidence that calibration methods had been agreed upon and lacking documentation for some of the review details.
D - OEM	Provided objective evidence of some contract review requirements, demonstrating no evidence that calibration methods had been agreed upon and lacking documentation for some of the review details.

While ISO 17025 proscribes a procedure for the review and retention of all records pertaining to requests, tenders, or contracts, Z540 does not make such demands. ISO 17025 goes on to require that the laboratory shall ensure that the client's requirements are well defined, documented and understood by all participants that the laboratory's capabilities and resources shall meet the customer's requirements, that the client and the laboratory must agree upon the appropriate method of calibration, and detailed records must be maintained through the entire process.

3.9 Proficiency Testing

Leonardo found that the level of proficiency testing is roughly equivalent to the level of arm twisting an organization experiences. His findings are presented in Table 9.

Table 9

Lab Category	Proficiency Testing
A – ISO 17025 accredited	Fully committed and very involved in fee based proficiency testing.
B - ISO 17025 compliant	Committed to inter-laboratory comparisons, but not active in the fee based proficiency testing programs.
C – Z540 compliant	Active in inter-laboratory comparisons when time permits.
D - OEM	Little to no commitment to proficiency testing.

While it is not always the case, this area is comparable to going to the dentist; few people go of their own free will. Proficiency tests are identified by Section 5.9 of ISO 17025 as one of the primary means by which the quality of calibration results can be assured. This is required in order to detect trends and examine data. As a result those labs that self proclaim ISO 17025 compliance are often fairly active in inter-laboratory comparisons, while accredited laboratories must meet strict and demanding criteria for proficiency testing participation.

Conversely, section 4.2.j of Z540 is much less directive when it states, "The laboratory, where appropriate shall participate in inter-laboratory comparisons and proficiency testing programs." As a result, most Z540 compliant organizations see inter-laboratory comparisons as a non-mandatory requirement and treat it accordingly.

Unless an OEM happens to claim ISO 17025 or Z540 compliance, they have little to no incentive to participate in either proficiency tests or inter-laboratory comparisons.

For those not familiar with the two concepts, most proficiency tests are currently administered by an objective 3rd party that is in many cases accredited to administer proficiency tests. They are typically for fee and are utilized primarily by accredited laboratories.

Inter-laboratory comparisons follow the same concepts, but are less formal with one of the participants frequently administering the process. They are consequently less recognized internationally and may provide the appearance of being less than objective.

3.10 Laboratories scope of calibrations and verifications

Leonardo found that while proficiency testing activity tends to peak with accredited laboratories, the opposite is true for the accuracy claims made in scopes of calibration. Leonardo also learned that while a laboratory may be accredited, it is never accredited for all types of measurements. The proper questions need to be asked to ensure that an

accredited laboratory is capable of providing accredited service for a specific discipline. These results are summarized in Table 10.

Table 10

Lab Category	Scope of Calibration
A – ISO 17025 accredited	Provided a tightly controlled scope of accreditation for accredited calibrations and documented all other capabilities using NCSLI RP-9 - *Calibration Laboratory Capabilities Documentation Guidelines* in conjunction with the GUM for measurement uncertainty
B - ISO 17025 compliant	Documented all capabilities using NCSLI RP-9 - *Calibration Laboratory Capabilities Documentation Guidelines* with some attempts to use the GUM for measurement uncertainty
C – Z540 compliant	Documented all capabilities using NCSLI RP-9 - *Calibration Laboratory Capabilities Documentation Guidelines*
D - OEM	Unable to provide a scope of their calibration capability (typical, unless the OEM is claiming compliance to Z540 or ISO 17025).

While accrediting bodies closely scrutinize anything that appears in an accredited laboratory Scope of Accreditation, all other claimed capabilities are excluded from this review. The Scope of Accreditation capabilities are the result of very detailed uncertainty budgets that typically produce a larger uncertainty value than is originally anticipated. As a rule of thumb, these laboratories follow the same procedures for developing their capability scopes in non-accredited disciplines.

When an organization self proclaims their compliance, no external organization is evaluating their capability claims. The ISO 17025 self proclaimers tend to perform more comprehensive uncertainty analysis, hence their budgets often present larger quantities than the Z540 laboratories.

Clause 5.2.h of ANSI/NCSL Z540 states that, “The quality manual and related documentation shall also contain the laboratory’s scope of calibrations and/or verifications.” This leaves the subject wide open to interpretation with some incredibly ambitious claims made by those organizations unfamiliar with calculating measurement uncertainty.

4 Other problems with competing standards

While ANSI/NCSL Z540 has its flaws, an even larger problem is the effect that the competing standards have on one another and how they impact industry within the United States. As has been previously mentioned, the multiplicity of calibration standards serves to deprecate them all.

4.1 International Relations

- Perception can be everything and in this case we are looked at as the country who doesn't wish to play by the rules, so we take our ball and start our own game.
- In this era of a global economy, why would we want to erect artificial trade barriers that only hurt our manufacturers? Every manufacturer is just one business deal away from being a global trading partner. Making the transition from Z540 to ISO 17025 can be both costly and time consuming, both issues that could be deal breakers.
- Evidence of this transformation is evident even at this gathering. In the last few years NCSL has become NCSLI because of expanded ties to the international community.

4.2 3rd Party Calibration Providers

- More than anyone, 3rd party calibration providers are the firms that are left to deal with the fallout of the competing metrology standards.
- This can result in major conformance issues – standards are unique enough that they at times oppose one another
- It can make it very difficult to write comprehensive quality documentation
  - A typical quality manual tact is to write the documentation in a format very similar to the standard. With multiple standards this can't be done. Efforts to combine the elements of both standards can make the documentation very unpalatable for some auditors.
  - There are even widely known cases in which organizations developed sets of quality manuals and brought out the one that best fits a customer's needs during audits.

4.3 Large Multi-discipline Manufacturers

- At the heart of the U S economy are many firms whose breadth of products range from military weapons to commercial avionics. These firms are aligned into divisions based on the scope of product, but they share calibration as a common ground with multiple internal calibration labs existing.
- Unfortunately, since some of these divisions base their quality programs around Z540 and some around ISO 17025, they are frequently unable to share resources. Their traceability requirements vary, their calibration procedures do not satisfy one another, and they basically exist as separate business entities.

4.4 General

- Within the quality and purchasing departments of the U S, Z540 and ISO 17025 are treated as strict equivalents, even though this is far from the truth.
  - Air Force T.O. 00-20-14, Section 4.5.1.1 states, "*When authorized to contract any part of the calibration, this work shall be placed with a laboratory complying with the requirements of ISO Std 17025 or ANSI/NCSL Z540-1-1994*."
  - Army Regulation 750-43, Section 6.7.b states, "*All contracts with a commercial laboratory for calibration services will specify that the commercial laboratory*

adhere to International Organization for Standardization (ISO)/IEC 17025:1999 or American National Standards Institute (ANSI)/NCSL Z540–1–1994 for all measurement parameters required for the calibration(s).”

- NASA Policy NPB 8730.1B, Section 1.c states, “*It is NASA policy to accomplish the following: Require that suppliers of calibration laboratory services be accredited to ANSI/ISO/IEC 17025:2000, where it is appropriate and beneficial to NASA to require independent accreditation, and be compliant with the calibration laboratory competency requirements identified in ANSI/NCSL Z540.1-1994 (R2002)”.*
- Similar requirements can be seen in the purchasing and quality documents of hundreds if not thousands of companies across the country.

- The more quality standards there are, the more likelihood there is of self declared claims of compliance. Although it is really a complete side issue, the issue of compliance is very germane to the topic and should at least be addressed. It has been stated that **compliant** is the most overused word in American industry. Compliant by whose measure?
  - Accreditation completely proves system compliance issues.
  - Some 2nd party compliance programs exist within the automotive and aerospace industries, but these programs are not accepted outside of their specific industry.

5 Objections of the ANSI/NCSL Z540 Advocates

5.1 ISO 17025 is effectively a trade barrier put in place by the European Community

- While it is obvious that ISO 17025 is an international standard, it is certainly not something that has been shoved down our throats. In fact, its origins are very American, as was previously discussed (the roots of ISO Guide 25 were based on ASTM E548).
- American representation has always been significant within the work groups that develop the metrology based standards. For example, of the 27 members of Working Group 10 who developed what became ISO 17025 in December of 1999, 4 were Americans. No other country had a larger representation

5.2 Z540 can easily be updated so it is once again parallel with ISO 17025

- The facts speak for themselves regarding this topic.
- ISO Guide 25 was internationally released in 1982 and updated in 1990. The U S committee to write Z540 was formed in 1991 and completed Z540 in 1994.
- By 1999 Guide 25 had been updated to ISO 17025 and another U S committee was formed to update Z540. A consensus could not be arrived at to update Z540, so it had to be reaffirmed without change in 2001.
- ISO 17025 was subsequently updated and released again in 2005. Z540 is now 2 generations removed from the document it initially mirrored. Why should anyone believe that it is a good idea to continue this mirroring process?

5.3 Most industries don't actually require ISO 17025

- Once again the facts speak for themselves.
- Any organization that is ISO 9000 registered or which makes claims about being ISO 9000 compliant should obviously be using ISO 10012 and ultimately ISO 17025 to evaluate calibration providers (See section 7.6).
- The same holds for the chief automotive industry standard, ISO TS 16949 2002 (See Section 7.6)
- Section 7.6 of AS9100B also invokes ISO 10012, which in turn invokes ISO 17025

5.4 Too many existing contracts invoke ANSI/NCSL Z540 as a requirement to change now

- Unless we plan to keep this revision of Z540 in existence forever, this doesn't really matter. Just as contracts had to be revamped when MIL-STD 45662A was rescinded in 1995, the same will be true of any replacement for the existing Z540.

5.5 ISO 17025 is too encumbering

- A colleague who works for NASA has heard this mentioned by long time employees on many occasions. Does anyone else find irony in the fact that NASA finds an aspect of quality to be too encumbering?
- Measurement uncertainty is frequently cited as the most encumbering of all the aspects of ISO 17025. Obviously they aren't familiar with Z540 because the same basic requirements exist with it as well. The Z540 standard specifically states, "…the collective uncertainty of the measurement standards will not exceed 25% of the acceptable tolerance".
- This seems to make it clear that the measurement uncertainty must be known for each measurement performed, although some claim that only processes have uncertainty associated with them, so this must actually be accuracy.

6 A Prospective Solution

Is it too late to change things? No, of course it is never completely too late to modify the path one is on, but there is no time like the present. An effective action plan might consist of the following elements:

6.1 All concerned stakeholders

- Utilize ISO 17025 as a competence standard for calibration and testing laboratories,
- Utilize ISO 10012 as a conformance standard to evaluate calibration programs.
- Focus our collective efforts on updating and improving these documents, not creating our own standards.
- Report perceived deficiencies and issues directly to the clearing house that is established to provide updates to future releases of ISO 17025 and ISO 10012American representatives in on the International writing committees.

- Collectively hold OEMs to a much higher level of compliance than we are currently doing.
- Avoid buying a sticker just because it represents the best economic solution. Our field is one of integrity and there is not room for this option.

6.2 NCSLI

- Serve as a clearing house for deficiencies in ISO 17025 and ISO 10012. At the present time there is not a place where the normal stakeholder can turn for interpretation, guidance, and most importantly for input. Serve in this capacity and keep the masses informed of what is going on.
- Continue to support the metrology community by developing Recommended Practices that amplify on these standards.
- Instead of working a parallel metrology standard, work to infiltrate the auditing industry – those people who still cite 45662A, look for NIST #'s, list Guide 25, Handbook 52, etc. in their audits.

6.3 OEM Metrology Laboratories & their Parent organizations

- No one really has more to gain than the test equipment manufacturer that embraces ISO 17025 and goes as far as to seek accreditation. This opens markets internationally that are probably closed at the present.

6.4 Internal Metrology Laboratories & their Parent organizations

- Continue to seek self improvement by becoming compliant to ISO 17025.

6.5 3rd Party Metrology Laboratories

- Motivate yourselves to truly become ISO 17025 compliant, and if at all possible to become accredited.
- Invest in your personnel and in your industry. Stop being a leech and seek instead to be a leader in the field.

6.6 The Radical Plan

- Develop and embrace a plan I like to refer to as Accreditation-Lite. Involve the Aerospace, Automotive, Medical, Nuclear industries as well as general manufacturing concerns and independent calibration laboratories. Develop a 2nd party evaluation team that will evaluate all of the entities that currently make self declarations of their compliance to ISO 17025.
- Created an open registry that can be viewed and utilized by all interested stakeholders.
- This type of program could motivate even the internal metrology laboratories that only provide service to a parent organization that there is value in embracing not only

ISO 17025, but accreditation itself. If this doesn't occur, then this huge gap will continue to exist.

7 Conclusion

Change does not come easily, but if we are willing to make the collective effort, we will be richly rewarded. Much like it makes sense for physical measurement standards (etalons) to be standardized, the same should be true of paper administrative standards.

As Charles Ehrlich and Stanley Rasberry wrote in their landmark paper, Metrological Timelines in Traceability, "*Worldwide commerce requires a coherent measurement system within which the consistency of measurements is easily maintained and demonstrated. Buyers and sellers needed such a system in order to evolve from barter to patterns of trade which use specifications to describe such things as size or performance*." [8]

While their focus was on the traceability aspect of the measurement process, one can also conclude the same philosophy applies to all elements of the quality process.

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