Meeting ISO 17025 Requirements for Complex Electronic Test Equipment

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Hardly anything seems to be as confusing as interpreting ISO/IEC 17025 compliance for complex electronic test equipment (M&TE). The difficulty of the measurement uncertainty analysis for modern M&TE adds an additional impediment to the task of comparing the manufacturer's specifications to evaluation of available calibration services. Calculating measurement uncertainties for a single parameter such as DC voltage is relatively straight forward, but to do so for a complex microwave spectrum analyzer that relies on digital signal processing is another matter. This paper will explore the ways in which one equipment manufacturer, Agilent Technologies, is approaching in pragmatic and cost effective ways the balance between a metrologically correct ISO 17025 calibration and the needs of the equipment end user.

What To Look For In A Calibration

Metrologists are known for their attention to detail, aversion to risk, and concern with the scientific and mathematical underpinnings of their work. Unfortunately, the vast majority of calibration services for electronic test equipment bought today are purchased using two criteria: price and furn-around time. Frequently selection of calibration services is made by an economic buyer, and not the technical end user. Quality is sometimes very low on the criteria list in this process. The technical buyer can specify a documentary standard and this may assure some degree of technical integrity for the calibration. As far as the purchasing agent is concerned, however, compliance is a digital function: either the supplier is compliant or they are not.

Documentary standards can provide the technical assurance that a calibration was done correctly. How does a buyer assure that the supplier complies with every requirement of the standard? In the past this was accomplished by second party audits. Accreditation has evolved to introduce a third party into the picture: the accrediting agency.

In 1989, Gary Davidson, then with TRW in southern California, began an exchange of letters with Dave Mednick of the U.S. Army who was responsible for MIL-STD-45662A. This initial exchange was the beginning of much work, resulting in ANSI / NCSLZ-540-I-1994 based upon ISO Guide 25. The writing committee developed a vision statement that included among other things:

- o Techniques to improve measurement (quality) processes without increasing costs.
- . Coupling calibration to product in a more effective way.
- . Accommodation of new measurement technologies.
- Reduction of audit redundancy. [1]

The reduction of the number of audits through the process of accreditation has been partially achieved in the thirteen years intervening since the ANSI / NCSLI writing group started its work. The mark has been missed for complex electronic test equipment (M&TE) because the concepts applied by the accrediting systems are drawn primarily from the standards laboratory environment not processes used for test equipment management.

Calibration laboratory accreditation is effective for parameter specific, standards laboratory level measurements. However, a complex spectrum analyzer or microwave source uses many parameters. Some of these find a tortured traceability path to International System (SI) units. It is difficult for a calibration laboratory to have the complete range of parameters necessary to cover all of the manufacturing specifications of these instruments.

Some accreditors allow calibration laboratories to display the accreditation logo on a certificate that shows mixed results: those covered by the laboratory's scope of accreditation, and those outside of the scope. Accreditors require the identification of those measurements that are covered by the scope. However, it is not uncommon for a calibration laboratory to display the logo on a report that has no results covered by their scope. Some accreditors are beginning to tighten up on this requirement. A2LA instituted a policy April 30, 2002:

The " A2LA Accredited" Iogo shall not be used on certificates and reports if none of the results presented are from tests or calibrations included on the A2LA Scope(s) of Accreditation.^[2]

Labs that currently put their logo on certificates that have no parameters included in their scope may not intend to deceive a customer. Some calibration customers want to send work to an accredited lab, but don't want to

pay the extra expense associated with the specific technical requirements of the accreditation. The buyer's logic is this: "if a lab is accredited in some areas, their overall quality system must be pretty good even if it is not directly applied to the parameters in question." This does not reflect the intention of accrediting systems as the A2LA advertising policy also points out:

It is the ethical responsibility of nccredited and applicant laboratories to describe their accredited status in a manner that does not imply accreditation in areas that are outside their nctual scope of accreditation or for other testingl calibration facilities not covered under A2LA accreditation. [3]

For accredited calibration services to be effective, the buyer must understand the associated limitations and cost. Philip Stein points out some critical things to consider:

- 1. Is the laboratory for which you want to buy calibration services accredited to ISO/IEC 17025?
- 2. Is the body that accredited this laboratory a signatory to one of the laboratory accreditation agreements?
- 3. Are the measurement parameters you wish to have calibrated listed on the laboratory's scope of accreditation? Are the ranges of the parameters you have chosen within the scope?
- 4. Have vou specified accredited service on your purchase order to the laboratory?
- 5. Do all the certificates you received from the laboratory have a logo from the accreditation body, and are no exceptions taken for specific results? [4]

The accrediting laboratory should have all of the necessary parameters used by the instrument to the degree of uncertainty that matches the instrument specifications in order to fully calibrate a piece of M&TE. Figure 1 shows that to check a complex instrument against the manufacturer's specifications, the accredited laboratory should have all of the necessary parameters to sufficient measurement uncertainty within their scope of accreditation.

A number of standards have evolved over time to provide a level of assurance for the customer of calibration services. Older standards such as MIL-STD-45662A relied upon 4:1 Test Accuracy Ratios to assure levels of producer and consumer risk. ISO Guide 25 evolved into ISO 17025 that requires full ISO Guide to the Expression of Uncertainty in Measurement (GUM) uncertainties $[5]$.

This level of uncertainty analysis is more appropriate to a standards laboratory measurement rather than shop floor M&TE. Two other standards exist that can be useful for M&TE and are referenced by ISO 9000:2000. They are:

- ISO 10012-1 Quality Assurance Requirements for Measurement Equipment - Part 1: Metrological confirmation system for measuring equipment.
- . ISO 10012-2 Quality Assurance for Measuring Equipment - Part 2: Guidelines for control of measuring processes.

Neither of these, however, have found as wide an acceptance in the metrology community as ISO 17025. Today there are at least three sets of standards in use for M&TE, but the predominant one internationally is ISO 17025 (Figure 2).

The Missing Link

Retirements, downsizing of the defense aerospace industries, and the curtailing of metrology training by the military has resulted in the lack of new metrology experts being developed. It is increasingly important that non-technical purchasing agents be able to purchase calibration service without having to understand the subtleties of the relation between parameter and laboratory scope that is required by 17025 accreditation of M&TE.

What is missing is a practical standard for M&TE half way between the rigor of the parameter specific methods of ISO 17025 and the broad strokes of quality system registration outlined in ISO 9000. It is important to clarify differences between

Figure 1. Matching accreditation and manufacturer's specifications.

Scope -vs- Equipment Specifications

Figure 2. Evolution of calibration standards.

accreditation, registration and certification. As defined by the NCSL International Position on Laboratory Accreditation, Registration, and Certification and Appropriate Use of the NCSL International Logo and Name, these terms are:

• Accreditation: procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

• Registration: procedure by which indicates body relevant a characteristics of a product, process or service, or particulars of a body or person, in an appropriate, publicly available list.

· Certification: procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements [6].

The International Laboratory Accreditation Cooperation has similar definitions in its document ILAC 12:1994 - Testing, Quality Assurance, Certification and Accreditation that points out differences in the uses of the terms between Europe, the U.S. and Canada [7]. In common with all definitions is the requirement for accreditation procedures to apply the concept of competency. This the means that applicant organization must demonstrate the technical proficiency to carry out the work for which it seeks accreditation. calibration For laboratory accreditation to ISO 17025, this is accomplished by tracing an electrical parameter to a fundamental SI unit.

Accreditation works well for simple parameters readily traceable to international standards. An example of this is length when measuring gage blocks. The method breaks down for complex instruments such as microwave sources, spectrum and network analyzers that were designed ten to twenty years ago. These instruments were developed at the time with good engineering practices but before the Guide to the Expression of Uncertainty in Measurement (GUM) became a more common practice. Reverse engineering the equipment specifications to achieve a true ISO 17025 and GUM based calibration is an expensive proposition.

For these older instruments, there are several ways to achieve 17025 compliance. The first is to fully rework the calibration procedures for the instruments, recalculating the measurement uncertainties, and adding guard banding to account for the uncertainties. This meets the requirements of ISO 17025 Section $5.4.6.3$

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis [8].

For more complex instruments, the procedures are usually embedded in software. This means rewriting software in a potentially obsolete language.

Then there is the question of uncertainties. Ten to twenty years ago, adequacy of calibration standards usually assured by using a comparison of specifications through the use of Test Accuracy Ratios. This method is an acceptable technique for both MIL-STD-45662A and for ANSI/NCSL Z-540-1. Some of the original laboratory notebook documentation behind the design of the instrument may no longer be available, since just the TARs were recorded. Resurrecting these measurement equations can be done, but sometimes at great cost. If a calibration procedure has been found adequate for use for twenty years, why should it be redesigned for the purposes of documentation?

This investment can be viewed through a risk/reward curve, modeled on H. James Harrington's resultant versus controllable poor quality costs [9]. The resultant costs are those caused by inadequate calibration yielding poor measurements or bad product. As more investment is made in the calibration procedure, such as recalculating the measurement uncertainties and substituting newer, more accurate standards, it is possible to drive the cost of resultant failures down, but at the expense of controllable investment.

Figure 3. Optimal calibration procedure investment.

Setting up elaborate type-A experiments further raises the investment costs. As Figure 3 suggests, there is an optimal point at which the "maximum benefit-lowest risk" is met for the minimum investment. Unfortunately, the word "cost" does not appear anywhere in the ISO 17025 standard, an important consideration when balancing customer needs, perceived value, and price of services.

The most thorough way to accomplish compliance to ISO 17025 for M&TE is through formal accreditation. Generally this service is more expensive than a simple automated instrument calibration. For most M&TE users, the objective of a calibration is to assure that the instrument is performing to the manufacturer's specifications. To accomplish this, a calibration laboratory must compare the published specifications against their scope of accreditation. In the case of measurements that are correlated, such as resolution bandwidth, this will provide traceability to two or more accredited parameters such as power level and frequency. For further details on this example, refer to "Accreditation for Complex Electronic Instruments" presented at the May 2001 Simposio de Metrología. [10]

Most users of M&TE expect that the calibration laboratory will verify the performance of the unit against the manufacturer's specifications using appropriately traceable standards and adequate measurement uncertainty. Some accreditors take a strict standards lab level approach to calibration and do not allow a statement of conformance to manufacturer's specifications. In those cases, the customer receives a calibration report of results with associated measurement uncertainties. By studying the report, the user can determine if the device meets manufacturer's specifications. The use of accreditation for stating compliance to specifications is covered by ILAC-G8:1996 Guidelines on Assessment and Reporting of Compliance with Specifications. [11].

On the opposite end of the spectrum, quality system registration such as ISO 9000:2000 has little to say about the specific competency of a calibration laboratory. Part II of ANSI/NCSL Z540-1-1994 Calibration Laboratories and Measuring and Test Equipment - General Requirements does address "Quality Assurance Requirements for Measuring and Test Equipment (M&TE)," but these requirements were not adopted in ISO 17025.

ISO 10012-1 and 10012-2 are a mid level solution to provide a standard for M&TE, but my company has not seen a wide adoption of this standard by our customers. The general purchasing requirements we see are either for ISO 17025 "compliance" or ISO 9000 registration. It doesn't matter that there is so such thing as a third party recognition of ISO 17025 compliance, that is what customers want. ISO 17025 accreditation generally is more than an MT&E user requires. The dashed line boxes in the Figure 4 demonstrate the missing link in calibration standards.

With no widely accepted third party process to address MT&E, the result is the application of ISO 17025 and GUM to complex test equipment. Although there is no technical reason this cannot be done, the result is very expensive both for the consumer and producer with strict adherence to the technical components of ISO 17025.

The unavoidable conclusion regarding this gap is that there is currently no appropriate third party evaluation system that provides a practical, cost effective solution for complex MT&E. ISO 17025 applied at the laboratory level is too rigorous given the cost/benefit ratio, and ISO 9000:2000 is too broad a standard to bring technical substance to bear.

Philip Stein sums up this issue well:

... there are many applications where accuracy and traceability of dimensional measurements are crucial, both for the immediate customer and to support a more global interchangeability. What's happened here, though, is that blind application of the rule has resulted in unnecessary costs and trouble-and I believe that a large majority of calibrations done in the United States today fall into this overkill category. [12]

The missing link: Third party accreditation of M&TE

Figure 4. Third party assessment of M&TE calibration.

Enough History - On To Solutions!

My arguments to this point have been about what in the test equipment business is known as "Iegacy" procedures. That is, these are the legacy, the procedures we have inherited through the years that were developed prior to the implementation of new methods or standards. In this case specifically the implementation of ISO 17025 accreditation and the widespread use of the GUM. NCSLI's keynote speaker last year, Byron Anderson of Agilent Technologies, only half jokingly referred to a "grandfather" clause to set aside these older procedures and products. [13]

Looking at products being developed today, it becomes an easier problem. An instrument currently being designed can have good documentation recorded of measurement equations and resulting uncertainties as the product moves through the development cycle. This is the best time to record these equations, when the product is being designed. When the product is put into production, additional statistical information about the manufacturing process is collected that helps the designing engineers understand more clearly how to characterize and calibrate the complex instrument.

Software Architecture Approach

The calibration procedure for complex M&TE is generally done in software with an automated calibration system. For some instruments with memory resident calibration factors, it's not possible to manually calibrate the instrument. The use of software enables architectural leverage that isn't possible in a traditional manual analysis.

Software developers consider a number of things when designing a calibration procedure:

- . Measurement is based on a well-defined algorithm. Experience with developing other pieces of code is used to leverage a documented measurement methodology.
- . M&TE must use standard functionality so that specifications are available. In other words ... no tricks.
- Take settling and averaging into account.
- o Consider external influences such as house time bases.
- o Appropriate use of instrument calibration cycle (i.e. 90 day versus 1 year specs). [14]

This approach represents a traditional method of precalculating the uncertainty for a given algorithm and set of MT&E used as standards. The MT&E is chosen for sufficient accuracy to support the calibration of the unit under test (UUT). An error equation is then constructed for that specific configuration including components such as connector mismatch error, type-A uncertainties derived by experiment, and other components contributed by the uncertainty of the test equipment used. This approach has

the advantage of easily documented measurement uncertainties, but lacks flexibility. Some automated calibration systems have been in place for many years and the M&TE they rely on for traceability and uncertainty budgets has become obsolete. Substituting new equipment sometimes necessitates completely reconstructing the error equations to accommodate the new instrument's characteristics. A pre-calculated uncertainty method does not allow for easy equipment substitution as newer standards become available.

Increasing use of Digital Signal Processing (DSP) within the instrument being tested adds another layer of complexity to evaluating calibration software. Traditional functions such as filtering are more frequently done in the digital domain with DSP rather than in the analog domain with crystals or RLC circuits. The contributor for error of the DSP computation is quantization noise caused by the limitations of the number of bits of sampling in the A/D converters. Other factors such as the nonlinearity in the ADC's can introduce errors [15]. A challenging task for accreditation is to explain the black box of the DSP equations to an assessor trying to understand the relationship between power level and frequency in a resolution bandwidth measurement that is done through a DSP computation.

One way of developing measurement uncertainties for complex error equations with many correlations is by use of the Monte Carlo method [16]. The error equation is developed including the components of the set up that affect the overall result of the measurement. The individual distributions of the contributing factors are determined. Then a computer using a random number generator runs the error equation multiple times using the distributions of the contributing factors to simulate the overall reaction of the complex interaction. This generates a new mean and distribution for the measurement that is used to estimate overall uncertainty of parameters for very complex microwave equipment.

Further experimentation with the actual hardware configurations is used to validate the simulation. Some instrument manufacturers use typical specifications for parameters that are characteristic of the instruments function, but not warranted. For these typical specifications, the results of production runs are used to build confidence in the number, but Monte Carlo and GUM methods are usually not used for these typical specifications.

The trend in M&TE requirements for more complex measurements with greater accuracy means that development cycles for equipment are getting much shorter. In the past, it was not uncommon to expect M&TE to have a useable life of twenty or more years. Today's newer equipment may have a much shorter lifespan due to changing application requirements. This puts an even larger strain on creating reusable software components.

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specific stimulus or test. In this example, the stimulus delivered by module A is measured by the output power module B and the combined result of the test is summarized in module C.

The complexity of these tests can be shown by expanding one of these measurements, the maximum output power. The following measurement algorithm is developed based upon using a power meter and power sensor.

From the top level of Figure 6, the "Measure Power Algorithm":

$$
u(P) = P^* \sqrt{\frac{\Gamma_{src} \Gamma_{rcv} }{ \left|1-\Gamma_{src} \Gamma_{RCv} \right|^2} + \frac{u^2 (P_{RCv})}{P_{RCv}^2} }
$$

where:

$$
\frac{\Gamma_{SRC}\Gamma_{RCV}}{\left|1-\Gamma_{SRC}\Gamma_{RCV}\right|^{2}}
$$

is the error due to mismatch between source and receiver, and

$$
\frac{u^2(P_{RCV})}{P_{RCV}}
$$

is the error due to the inaccuracies of the receiver's measured power.

Then for the actual power meter and sensor the math becomes much more involved, with the measurement equation defined as:

$$
P_{gZ_0} = \frac{P}{IKLm}
$$

where:

 $P = measured power$

- $m =$ gain term set so that the power meter displays the calibrator power with the power sensor connected to the calibrator. This gain term is determined during the power meter calibration.
- $I =$ instrumentation gain term that represents the change in m after calibration,
- $K = correction factors$
- $L =$ correction factor as a factor of power (linearity)

Figure 5: Measurement uncertainty decomposition within measurement modules.

There are many engineering hours spent on the complexity of creating traceable measurements and that investment must be leveraged across succeeding models. Customers are demanding more flexibility, such as custom calibrations, where they define the range of parameters to be tested for an instrument that focus on their application. Custom calibration requires an extremely flexible test executive that can dynamically calculate the measurement uncertainties for the variable test points chosen by the customer.

One such example is the calibration of the Agilent E84xx family of performance signal generators that requires sixteen tests that must be run to validate the various guaranteed parameters. These are listed in Appendix A. Taking a quick look at only one of those parameters, maximum output power, will give the reader a sense of the complexity associated with analyzing the performance of the entire instrument.

Figure 5 demonstrates how measurement decomposition and encapsulation within a software

framework provides a mechanism for achieving some of this reusability of code [17]. At the lowest level of the architecture are "drivers" and "assets." The driver is unique to the M&TE that is being controlled by the test executive. It contains the programming codes necessary to send to the instrument through whatever interface is used: GP-IB IEEE-488, serial, FireWire IEEE 1394 - and includes the information necessary to parse the results sent back. The asset module provides a software interface to the information about the specific instrument or sensor in use, sometimes even down to the level of the serial number. This information can include items such as calibration factors for power sensors, reference cal factors for meters, and other data necessary to calculate the measurement uncertainty for the particular test module.

The next level in the diagram shows the measurement modules that combine the driver information and asset information to calculate the measurement uncertainty for that

Figure 6. Modular software architecture for 'measure power' algorithm.

Then using GUM methodology and a long series of calculations, the overall uncertainty can be determined as follows:

$$
u(P_{g_{\sigma_0}})=P_{g_{\sigma_0}}\sqrt{\frac{\Gamma_{PS}}{2}+\frac{V_{g_{\sigma n}}}{\sqrt{2}}}+\frac{u^2(P_m)+u^2(P_n)+u^2(P_d)}{\left(P_m-P_d-P_z-P_n \right)^2}+\frac{u^2(I)}{I^2}+\frac{u^2(K)}{K^2}+\frac{u^2(L)}{L^2}+\frac{\Gamma_{cal}*\Gamma_{PS}}{|\mathbf{l}-\Gamma_{cal}*\Gamma_{PS}|^2}+\frac{u^2(P_m)+u^2(P_m)}{|\mathbf{l}-\Gamma_{cal}*\Gamma_{PS}|^2}+\frac{u^2(P_m)}{|\mathbf{l}-\Gamma_{em}-\mathbf{P}_z|^2}+\frac{u^2(R_{e_{\sigma_0}})}{R_{e_{\sigma_0}}^2}+\frac{u^2(R_{e_{\sigma_0}})}{R_{e_{\sigma_0}}^2}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-P_{me}-P_z}-\frac{1}{P_m-P_d-P_z-P_n}\sqrt{\frac{u^2(P_z)}{2}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-P_{me}-P_z}}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2(P_{e_{\sigma_0}})}{R_{me}-R_{me}-P_z}+\frac{u^2
$$

These terms are all defined now with respect to any power sensor and meter. They are used to determine the design requirements for these software components when measurement uncertainty is to be calculated dynamically. These terms apply no matter what meter or sensor combination is used.

Taking steps to decompose this measurement within software architecture provides abstraction at various levels and hence provides a level of software re-use. If for some reason, the power sensor needs to be replaced with another, or a different power meter is required, only the lower level terms need to be modified. A new driver or asset module substitution will allow the exchange of the hardware more easily than in the past when the entire uncertainty equation had to be readdressed The information required to calculate measurement uncertainty is essentially integrated into the software code.

Clearly, this example would be worth an entire paper's discussion but it is presented here to give the reader a better understanding about the complexity of applying ISO 17025 to complex M&TE.

Summary

Caveat Emptor Development of standards, such as the evolution from MIL-STD-45662A to ANSI/NCSL Z-540-1 to ISO 17025 represents a normal evolution in customer expectations and alignment with technological progress. Properly applied, ISO 17025 will result in greater assurance that the calibration service that is purchased meets the challenging needs of the user. As we've attempted to show, the buyer of these calibration services must look beyond the appearances of simple compliance, the logo on the certificate, to the technical depth and underpinnings behind the supplier's statements. Calibration of a simple gage block is much different than that of the microwave source we looked at in this paper. Caveat Emptor - you get what you pay for, so look at the detail. The evolution of 17025 has put greater demands on suppliers of test equipment, and this paper briefly touched upon some of the methods that are being used to rise to this challenge.

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APPENDIX A

Agilent E84xx microwave source Sixteen tests to validate Manufacturer's Specifications

* Typical (typ): performance is not warranted. It applies at 25°C. 80% of all products meet typical performance 2002 NCSL International Workshop and Symposium

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