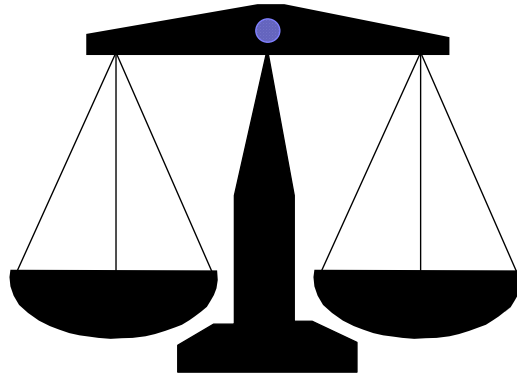




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Selecting & Working With Third Party Calibration Labs

Paper Author & Presenter

Charles J. Ellis

Email: cellis@proficiency.org

www.proficiency.org



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ABSTRACT

Due to the increased workload, emphasis on accuracy, and additional quality requirements in calibrating test equipment, many companies need to seek out and utilize the services provided by an external calibration laboratory for more of their internal calibrations. How do you know which calibration lab is right for you? Finding the right lab to fit your needs can be cumbersome at best. This paper will address the many concerns the manufacturing industry in choosing and dealing with outsourcing calibration services. It will also assist anyone in overcoming some of the apprehension currently associated with selecting & using an outside calibration source.

INTRODUCTION

With the increased requirements of getting your test equipment calibrated, the question is how to get test equipment calibrated? In many cases, it is too costly to do all calibrations in-house, either due to lack of staff or lack of technical capabilities to perform the required calibrations. Additionally, establishing an in-house calibration service represents a significant investment in facilities, equipment, and trained personnel. It becomes necessary to ask yourself, *do I need to support the test equipment internally, or can I find a third party calibration provider to do the calibrations for my company?*

Many thoughts go into the process of how one would justify whether or not the item in question should be supported internally or if it is more appropriate to send the item to a calibration provider. The answer can either be a simple one, or it could warrant a cost justification analysis prior to deciding whether to support the item internally or externally. Each organization has different requirements, so the selection on whether to calibrate each piece of test instrument in-house or to send the unit to a calibration provider is an independent decision. This paper does not address how to perform a cost analysis to determine if you should perform the calibrations in-house or if you need to find an outside provider, it is assumed at this point that the decision has been made to find a calibration provider to assist with calibration requirements. The goal of this paper is to educate individuals in the manufacturing community on some the finer points of successfully selecting and working with a calibration provider.

One of the main goals in selecting an outside calibration provider should be to improve the quality and degree of calibration services you receive from the vendor. Work to eliminate unnecessary costs, improve the quality of calibration, and establish a user-friendly atmosphere for working with the calibration provider.

Once the calibration providers that you know are not going to provide you with a quality calibration have been separated out from those identified as having a sound foundation, it is time to begin establishing a working relationship with the calibration providers left on your list.



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IDENTIFY YOUR REQUIREMENTS

Making sure that measuring instruments are properly calibrated is critical to quality manufacturing operations. An instrument that does not read accurately and is not repeatable can compromise the integrity of quality control, quality assurance documentation, and destroy confidence in measurement results. What are your requirements? The requester needs to identify these parameters before approaching a calibration provider. Before you send an item out for calibration, you should know what type of calibration you want performed. It is also important to note if there are any special circumstances associated with the items being subcontracted. If you do not know what you want done to the instrument, how can you be sure that the calibration provider is indeed providing you with a calibration that will meet your quality requirements? The organization requesting calibration services should have a control program in place that defines how their instruments are going to be calibrated. A well-designed program defines the categories of test equipment, the personnel responsible for maintaining records, and the operation of the program. This procedure should establish guidelines for handling calibration needs. It should also define responsibilities for all calibration providers.

I have witnessed manufacturing companies that have implemented supplier evaluation plans that control and monitor calibration providers. Some of these plans are very simple in nature, while others are somewhat complex and cumbersome to manage. The control documentation associated with selecting and using calibration providers can be either a complicated matter or a simple process. Each organization should implement its own supplier evaluation plan appropriate to meet its quality requirements.¹

The first thing to do is compile a list of all items that you will be subcontracting. Once you have assembled the list, put them in a table format and assign associated tolerances with each piece of test equipment. Now you know what items need to be subcontracted, to what level of accuracy, and are able to begin your search for calibration providers.

FINDING A CALIBRATION PROVIDER

How do you know a lab is right for you? You need to be assured that all of your quality concerns are addressed and that there is a minimum risk to your organization. In the past, any vendor who claimed they could do calibrations was enlisted to do the job. It was simply assumed that vendors were qualified, excepting special circumstances, calibration or otherwise.

The first question is that of where to start. You may want to start with the calibration providers in your local area. Find out if your local vendors can handle your workload. If not, you would naturally need to expand your search. The National Conference of Standards Laboratory's (NCSL) Directory of Standards Laboratory is an excellent source. You may even want to try the yellow pages, the internet, or even simply asking an associate whom they use for their calibration services.

¹ Appendix A of this paper is an example of an evaluation procedure that a manufacturing company has implemented into its quality program to ensure that all of its objectives, required by their quality program when subcontracting calibrations, are adhered to. This is only an example of how to control and manage calibration providers. You may wish to use this example as a template when implementing your calibration provider program.



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It is very important that you not merely look for an outside calibration source, but find a calibration provider that fits into your program and will support your needs. It is recommended that companies try to limit the number of calibration labs that they contract with. This allows for closer working relationships with the calibration providers and better overall service. It takes time to develop a comfortable working relationship with a calibration provider. What you are really doing is creating a partnership with your calibration providers.

INITIAL QUALIFICATIONS

Put together a checklist for evaluating calibration providers before leaving your office. By having a list ahead of time, you will avoid a lot of problems and save time when evaluating vendors. Review your quality manual to determine what is required of your vendors. If these requirements are not stated in the quality manual, augment your quality manual to include subcontract requirements for calibration providers. Who are your calibration providers now? Are they doing what is expected when compared to your requirements?

- ✓ Get a listing of their capabilities and what standards they use. A laboratory should be able to provide you with a specification data sheet that would show disciplines, ranges per each discipline, and the uncertainty associated with that range for each parameter that they are able to calibrate.
- ✓ Review a copy of their quality manual. Do they have a manual that addresses all quality requirements to a calibration quality standard? At this stage of qualification, you are not trying to review their quality manual for completeness. However, before going further with any organization, make sure they have the basic foundation that you are looking for.
- ✓ Get copies of their Certificates. Are they complete? Do they report all the parameters that you will need to satisfy your requirements?
- ✓ Identify if the lab is capable of providing you with a calibration that will meet all your requirements.

It is not my suggestion that you become an expert in every discipline that you need to subcontract, but you do need to be educated enough where you are comfortable when talking to your calibration provider about your requirements. It should be a relationship of trust. That will assure you receive the kind of calibrations you request and require. This is in part why you want to establish relationships with only a couple of calibration providers. You do not have the time to build strong relationships with twenty different calibration providers.

COMPARING PRICE vs. SERVICE

How do calibration providers compare when providing services? There is very little difference in most calibration providers. Differences may include customer service issues, personality issues, or ability to calibrate a certain discipline. Whatever it is, it is important to feel comfortable and assured that you are receiving a proper calibration on your test equipment.



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Part of being a metrologist is being dedicated to providing a quality calibration. This is why I state that calibration providers generally do not intentionally perform bad calibrations. If such does occur, it is often due to the lack of a sufficient quality system in place. You can help them improve their systems by providing your requirements to them upfront and demanding a proper calibration be done on your test equipment. When an organization has shortcomings in its QA system, it is our responsibility to identify these to the vendor to assist them in making better measurements. If they are not willing to improve their measurement process, as a community we should evaluate if we really want to be doing business with them.

It is good business to want to get the best possible calibration meeting our quality requirements, at a reasonable cost. The cost for calibration services between calibration providers is a large factor that needs to be considered. During your selection process, make sure you are getting what you are paying for, and that the costs associated with the calibration is reasonable for the services provided. Remember that paying the most does not prove that you are getting the best calibration for your money. The same holds true on the other end of the spectrum. Sometimes paying the least does not mean you are going to get the worst calibration available.

A number of questions to ask when figuring out if you are getting a fair price are:

- ✓ Does this price include a certificate of calibration?
- ✓ Does this price include adjustments to the unit (if necessary)?
- ✓ Does this price include data taken during the calibration?
- ✓ Does this price include charges for shipping and handling?
- ✓ Does this price include a documented calibration procedure used to calibrate the unit?
- ✓ Is it a manufacturers calibration procedure, a military procedure, or a procedure developed in-house?

It is a “buyer- beware” market. Unfortunately, in any business there are always going to be unscrupulous characters. Many times there are different prices for different types of calibration on the same instrument. Know what type of procedure is being done on your equipment. Know exactly what you are paying for; be sure that you are comparing apples to apples.



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ACCREDITED vs. NON-ACCREDITED vs. ISO 9000

When the military standard (MIL-STD 45662A) was the quality standard of choice for calibration services, most calibration providers claimed compliance with the standard. In fact, many did not. In most cases, this was not intentional. Much of it could be contributed simply to a lack of knowledge concerning how to implement the standard. Since new quality standards have come into play, ISO Guide 25 *GENERAL REQUIREMENTS FOR THE COMPETENCE OF CALIBRATION AND TESTING LABORATORIES*, ANSI/NCSL Z540-1-1994 *GENERAL REQUIREMENTS FOR CALIBRATION LABORATORIES AND MEASURING AND TEST EQUIPMENT*, etc., many laboratories would rather simply state that they comply with these standards and not become accredited to one of these quality standards. Many of these same labs feel that not becoming accredited to a national standard will not effect their place in the market. Many of the smaller labs feel that these new quality standards are being forced on them and see no benefit from complying with them. So, until you the consumer require that all calibration services provided to you be by an accredited laboratory (to a national standard), there will always be calibration providers that do not feel the need to go through the added time and expense of becoming accredited to a particular quality standard.

I am not stating whether or not a laboratory should be accredited. There are plenty of folks who are more qualified to speak on that subject. I mean only to point out that until the calibration market demands that calibration laboratories become accredited, there will always be the argument as to whether or not they should become accredited.

Working with an accredited laboratory basically means that they have proven to an independent organization that they are competent to perform the calibrations listed under their scope of services. This is not the end in if you are able to work with a calibration provider. There are details manufacturers must take care of to allow trust that all expectations of the calibration provider's services are being met.

While many advertisements for laboratories boast that they are ISO 9000 certified, what does this really mean in terms of providing a proper calibration to your specifications? While ISO certification does a lot in the way of documenting competency, it should be taken with a grain of salt when deciding if lab is qualified to perform calibrations to your requirements. It should not be taken for granted that if a company is ISO 9000 registered, it means they are able to perform calibrations to your expectations. The only exception to this would be additional accreditation under the ISO Guide 25 or similar quality standard.

In interviewing for this paper, many companies, large and small, shared the following:

About 70% of ISO 9000 registered calibration providers that they audited for subcontracting through were not capable of calibrations listed in their scope of services (if the company in question had one).

Many claim they meet certain requirements even if they do not. Most audit teams spend a small amount of time when looking at the calibration area of a company. One interviewee stated, "all that was being done was a white wash on the calibration department." One company interviewed found that of the 200 vendors they were using, only 30 were capable of what they claimed. If you are going to accept ISO registration as deciding criteria, be sure that the quality standard used to audit against was ISO Guide 25 or ISO 10012 as a minimum.



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Simply because a calibration provider has been accredited by an outside agency does not tell you whether or not you will be able to establish a relationship with them that is mutually beneficial. Many times, an onsite evaluation will have to be undertaken in order to satisfy your requirements.

ORIGINAL EQUIPMENT MANUFACTURE vs. THIRD PARTY LABORATORIES

Who should perform your calibrations, OEM or Third Party Calibration Providers?

The calibration provider industry is one that many manufacturers accept with some hesitation and uncertainty. Many manufacturers would like to be able to handle the calibration requirements as a service. Today, most manufacturers of test equipment do not have enough space or service capability to perform calibration on all the instruments they have sold. Therefore, contract calibration is seen by many suppliers as something of a necessity. The cost to have an instrument calibrated by the OEM is usually higher than the third party calibration laboratory. With cost considerations always playing a factor in operating budgets, an organization must consider all the alternatives when selecting a calibration provider.

The original equipment manufacturer is still a large source for providing calibrations. Some of the equipment manufacturers have welcomed the opportunity to continuously service their equipment, while other OEM's have expressed that they don't want to provide after market calibrations to their instruments due to stringent quality requirements placed on them.

There seems to be a trend where the original equipment manufacturer does not require the same in depth investigation/evaluation that is required of a third party calibration provider. The question is, why not? Shouldn't the same investigation for providing calibrations be enforced for any calibration provider?

Many independent calibration services are available, and more are popping up everyday. Choosing the right one depends upon your particular calibration needs. Rather than send all of your test equipment out to one calibration house, you may need to find many specialized calibration providers to perform only certain aspects of your calibration requirements. Try to reduce the number of vendors you subcontract to, thus a number of redundant activities will be eliminated. Also, do a complete investigation of any laboratory you intend to subcontract to in order to determine their competency.

DOES THE CALIBRATION PROVIDER MEET YOUR NEEDS.

Some companies do very little when evaluating calibration providers, while other companies will go to extreme measures when working with calibration provider labs. Do whatever is necessary to insure that your quality requirements are adhered to and your test equipment returned to you meeting the specifications required by your company standards.



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Preliminary Questions

Because there is no shortage of laboratories and contractors ready and willing to perform your calibrations, be ready to ask the potential provider a lot of questions. Listed below are some questions that will assist in revealing just how good of a calibration provider/partner they will be. Feel free to use this as a starting point or template when building your checklist to evaluate the calibration provider's performance.

Calibration Requirements

- What type of calibration do you need?
- Certificate of Conformance, Label only, As-found data, All data, what do you need?
- An uncertainty statement, Uncertainty statements on the paperwork, what does it mean?
- How many disciplines can they calibrate?
- On-site calibrations: What type of problems might arise from bringing in a calibration provider? Does the provider charge extra for onsite service?
- Can the company help project your annual calibration costs, i.e. doing it yourself as opposed to their program?
- Will better measurements result in greater profits or are you attempting to satisfy a quality requirement?
- What amount of downtime can you handle? Will it make a difference when deciding what calibration provider to use?
- How do you want data coming back to you from the calibration provider? Is the organization capable of providing electronic transmission? What types of data storage transfer options are available? Do you require a hard copy?

Company Information

- How long have they been in business?
- Are they an established company or "one person shop"?
- Get references from other companies and check them out.
- What is their knowledge of your regulatory requirements or standards?
- Do they understand your quality requirements?
- Are they in compliance with these standards?
- Will the work be done by them or do they subcontract some of their workload out?
- Has the lab achieved accreditation or are they pursuing it?
- Many times organizations say they are pursuing accreditation, but after several years are they still pursuing it? Do not accept any answer as gospel, monitor the organization to insure that progress is being made on their commitment to you to become accredited.



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Quality System

- Will the calibration provider meet the requirements of your quality manual?
- Does the vendor meet requirements as a calibration provider?
- Does the service have a quality program in place?
- What is the quality standard they adhere too?
- Is the service accredited or just compliant?
- Were their report audit results satisfactory?
- Is an internal audit of their quality systems part of their overall quality system?

Personnel

- Does the employee have a thorough understanding the calibration process at the vendor?
- What training have their employees received? Is it documented?
- What is their employee turnover ratio?
- Is there a well-documented training program in-place?
- Does it cover both technical and clerical personnel?
- Are there training records for each staff member?
- Does the calibration provider have enough technical staff to service your calibration needs?
- Is the technical staff periodically evaluated for current capability in their areas of expertise?
- Is a high degree of professionalism displayed at all times?
- Are records available for inspection? Ask to see records.

Accommodation & Environment

- Is the lab clean and organized enough to promote reliable calibrations?
- Is there a system in the lab to control and monitor environmental requirements?
- Are their calibration standards evaluated to assure adequacy of measurements?
- Is the calibration workload organized and tightly controlled?

Equipment & Reference Materials

- Are their standards adequate?
- Is there traceability to reference standards (national, intrinsic, consensus)?
- Can they provide proof of traceability for all standards in use?
- Do the personnel exhibit a thorough understanding of traceability?
- Are calibration standards on a strict comprehensive program of re-calibration?
- Are all standards currently in a state of proper calibration?
- Are the standards evaluated for compliance to customer accuracy requirements?
- Do the standards meet or exceed the required accuracy principal?
- Are measurement uncertainty issues addressed?
- Are documented laboratory operation procedures in place and adhered to?



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Calibration Records

- Require that the calibration report states tolerances, resolutions, accuracy of the measurement results, and indicates the specifications for industry standards used to perform the calibration
- Uncertainty statements on paperwork – how does the laboratory address uncertainty statements in the laboratory and how is the uncertainty of the calibration to you?²
- Are the reports given to you understandable?
- Do they have adequate data storage?
- What are their backup systems, so that your records won't go down with their mainframes
- What reports can they generate for you?
- How do you want your data coming back to you from the calibration provider? i.e. via hard copy, electronic transmission, data storage transfer, etc.

Calibration Procedures

- Are validated calibration procedures implemented and are they readily available?
- Are they familiar with manufacturer calibration work recommendations?
- If the organization is using a calibration procedure that was developed internally, ask if their procedure meets or exceeds the manufacturer specifications; does it meet with your specifications?³
- What are the calibration procedures that are being used by the calibration provider?⁴
- Are operations evaluated overall to assure compliance to measurement requirements?

Calibration Certificates

- Do they supply a certificate of traceable calibration (states the instrument is to be returned within current manufacturer specifications & test equipment used) that is traceable to appropriate standards?
- Are customers automatically notified in advance of items coming due for calibration
- Are data management systems in place to store and protect calibrated data?
- Does the content of calibration certifications and reports conform to quality standards required?
- Is the reverse traceability capability available regarding out-of-spec lab standards?
- How are specific errors in calibration data dealt with? Ask for a true example.
- What type of database do they use? Can you benefit from it?

² Although this is a relatively new requirement being placed on calibration providers, until it is something that is demanded by the customer, not all calibration providers are rushing to provide proper uncertainty analysis and understandable uncertainty statements to their customers.

³ Too many times calibration procedures are internally developed to meet the certain criteria of test equipment and should not be used as an all encompassing procedure.

⁴ A procedure can be an approved procedure under any system, but not carry any technical weight. Be aware of what type of procedure the company is using and if the calibration provider has a procedure from a outside source you still need to check the procedure for technical competency.



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Handling of Calibration Items

- How are you going to get the item to the provider, shipping, pickup by the provider, drop off and pickup of the item, etc.?
- What are the costs related with each one of these options? Did these play a part in your cost analysis? What effect does this have on the test equipment?
- What effects will transportation have on the unit? Can you afford to lose the item or have the item damaged in shipping?

Customer Service

- What type of customer service department do they have, are people employed in the customer service role?
- Get references from other organizations that have worked with this calibration provider.
- Can they help with cost control?
- How quickly can they respond to an emergency?
- Are calibration management services available?
 - a) What are the additional charges for the services?
- Does the calibration provider notify you of repair costs prior to the repair being done?
- Does the calibration provider offer free pickup in delivery of equipment?
- How fast is the turnaround? Is it what is claimed? Ask to see examples of when an item was received and then when it was sent back to the owner.
- What are the turnaround times for the lab? What is customary? What are they currently running? Is there an extra charge to be provided a faster turnaround time?
- Can the lab handle software upgrades or hardware upgrades on your test instruments, should it be necessary?
- Do they charge extra for onsite calibration
- Are they familiar with the most up-to-date versions of quality standards? How have they changed since the last version was released?



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PERFORMING THE AUDIT

It is important to perform regular audits of your calibration providers. How do you perform an audit and are you looking for the right details during the audit? There have been many books and papers written on auditing. If you wish to become an expert on auditing, further advice on auditing is available from one of those sources. In the short term, the basics on this touchy subject will be covered. Learn to perform audits to a quality standard that will meet or exceed your own quality requirements. What type of audit depends on the quality requirement of your organization. Any company you subcontract to must meet your quality requirements. Reputable organizations welcome these visits from customers because it gives them the opportunity to monitor their operations and correct any discrepancies that exist, while giving them the chance to build a working relationship with the client.

- ✓ Which auditing checklist is right for you? If you are going to have them comply with a particular quality standard then I would suggest you use the checklist associated with that quality standard. For example, ANSI/NCSL Z540-1-1994 has its own checklist, both NVLAP (National Voluntary Laboratory Accreditation Program) and A2LA (American Association for Laboratory Accreditation) have checklists that comply with the ISO Guide 25 requirements.⁵
- 🕒 During the audit, it is important to stay on track. When a company tries to steer you away from the audit, be careful. The time that you are able to spend on site with a vendor is usually limited; use that time wisely. Some calibration providers know and use this to their advantage. The more time they can keep you from reviewing their records, the less likely you are to find a deficiency in their calibration program. Follow a format/plan developed prior to the audit.
- 📄 Review the quality manual they have in place. Is it used in a daily manner or is it just something that was written to impress an auditor? The quality manual should be well structured to where it is a living breathing document.
- 🔗 Ask to review specific gauge calibration procedures. Make sure they are proper for your instruments based upon your requirements for accuracy and for meeting your quality specifications.
- 👉 Besides doing a quality system audit, your evaluation should include a technical assessment of their personnel. There are certain areas that you need to consider; what is the employee turnover, what is the education of the staff, what are the requirements by the organization for hire? What type of ongoing training is used at the organization? Do they have enough staff to support their workload?
- 📁 During an audit, ask for a specific demonstration of a calibration capability the organization has. This demonstration should be relevant to something you would be subcontracting to them. Have them explain to you where the calibration procedure is found, how the employee knows this is a current & correct procedure for the calibration they are about to perform, are they using it during the calibration, and what type of training they have on that equipment.

⁵ If you do not have access to any of the named checklists, or if any of the above checklists do not meet your particular requirements, please see Appendix C. This appendix is an example of a quality audit form that could be used as a template.



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WORKING WITH YOUR SELECTED CALIBRATION PROVIDERS

When subcontracting, the calibration must be performed to your specifications. For example, if you want the calibration optimized, at what percentage of tolerance would you want your unit adjusted? In cases where no direction is given to the calibration provider, if the unit is within the tolerance specified by the procedure they are using, no adjustment will be performed to the unit under test. If an adjustment is to be made for whatever reason, an additional request usually must accompany the purchase order.

Top Ten List – Items that Need Attention

1. Communication – Stay informed on what is happening with your equipment while it is at the provider's facility. Ask to be informed immediately of any repairs, cost increases, or variations from the original work order. This information is not always communicated to you by the provider. Insist on better customer service.
2. Turnaround Time – This is a major issue for most manufacturers. Some are willing to pay a premium for less turnaround time. The provider should stipulate a standard turnaround time for various types of equipment and guaranty its practice. Ask for the prices of expediting service on your equipment before you tell them you want expedite service. These costs can be staggering, plus you still have the original cost of the calibration. This problem is not limited to just local calibration labs, manufacturers want a reasonable turnaround time from the OEM, which is often even worse than the local vendors.
3. Calibration Provider Qualifications – Are they qualified to your company requirements?
4. Training/Turnaround of Staff – Conduct as in depth of a check of training records as is possible, or references from other companies. Make your best effort to verify training of their personnel and their qualifications to perform calibration services
5. Information on Certificates of Calibration – Make sure the provider meets your quality requirements and that you can understand the data you receive from them.⁶
6. Wrong Tolerances During Calibrations – This usually comes from using a procedure that does not meet the needs of the company. Verify that the provider is using the correct tolerances for the equipment being tested, and the equipment being used to calibrate with. A proofing of the procedure or equipment called out on the specification sheet can be used to verify these requirements.
7. Price - Verify all costs for items such as found data, as left data, and any other service that you receive.
8. Measurement Uncertainty – Why is value reported by the provider better than what NIST reports? Why is there no standard way to report it? Ask the provider what they use, compare it to NIST, and compare it to your quality requirements.
9. Wrong Documentation – The certificate of calibration needs to be sent with the unit back to the requester, in many cases the unit can not be put back into service without reviewing the certificate of calibration.
10. Misrepresented Quotes – Many calibration providers give one quote but bill charges not on the original quote. Whether or not justified is not the point, regardless of what happened the customer was not kept informed.

⁶ Requested information is many times not on certificates of calibration and the information is presented in an unorganized fashion. In some instances it can be proper or necessary to include on a PO exactly what you require from the calibration provider. In Appendix C is an example of calibration requirements that are sent with test equipment to the calibration lab. These requirements are then made part of the purchase order that the calibration provider must adhere to. This type of instruction should be included in the purchase order when requesting calibration services. Some companies have even sent a copy of this calibration requirement with every item sent to the calibration provider.



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IMPROVE UPON

Their needs to be a single point of contact at your organization and at the calibration provider you are sending items to. Too many times there are several individuals within an organization that contract out calibration services. This can lead to confusion for both parties. To avoid this, it is recommended that there be a single contact person for each organization.

Most companies only give feedback when unhappy, you need to give positive feedback to calibration providers as well as negative feedback.

When an item is repaired, in many cases what was actually repaired on the unit is not listed on any paperwork sent back with the unit. The owners of the equipment would like to know exactly what has happened to their test equipment.

The equipment should be cleaned prior to calibrating the unit. Some companies are asking how a dirty piece of test equipment can be calibrated. Sometimes the test equipment is in worse condition when it is sent back to the customer.

FOLLOW UP

Once a calibration provider has been put on approved status, this does not mean the end to the review process. Constantly strive to improve relationships with your calibration providers. By doing this you can reduce the time and effort put into the calibration administration maintenance costs, and improve the support mechanisms within your organization.

CHANGING YOUR CALIBRATION PROVIDER

A majority of manufacturers would like to have a local calibration source that is competent and qualified to perform most of their calibrations. As you consolidate your calibrations, you may want to find a source that can service more of your requirements, or work with your current calibration provider to upgrade their current scope of services to facilitate the continued handling of your calibration requirements.

Different companies have many different reasons & methods for changing calibration providers. While some companies will stop doing business with a lab after the first mistake is made, others will wait until the 3rd mistake. Evaluate the situation and made a decision based on your history with the organization. For example, if you have worked with a calibration provider for ten years and a pressure gage comes back with no uncertainty statement, you are probably more likely to ask if it was an honest mistake, what they did to correct it, and if the problem was resolved in an efficient manner. As long as these issues are handled by the calibration provider in accordance with your expectations, you may not even consider changing calibration providers. If a calibration provider came into your facility and destroyed a piece of test equipment, and was not willing to step up and take ownership of the problem, serious thought has to be given to their commitment to the relationship and whether or not you want to do business with them. Many times it simply comes down to if you have had a good working relationship with a provider in the past. Depending upon your working relationship history, chances are whatever conclusions you draw will be based upon your satisfaction level. One of the most important aspects to address is the ability to have a comfortable working relationship with the calibration providers you choose.



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Appendix A

Example of Internal Procedure for Selecting Third Party Calibration Source

PURPOSE

The contents of this instruction describe the calibration supplier selection and auditing process, the requirements suppliers must meet when supplying calibration certificates, and the process for sending equipment to the supplier.

This instruction should be used for any combination of the following conditions:

- Workload** – Manpower is insufficient to calibrate in-house
- Turn-around Time** – 2 weeks is acceptable as long as the down time is scheduled
- Capability** – the ability to repair or calibrate is not available in-house or is not cost-effective (pay-back period of greater than 3 years).

APPLICABLE DOCUMENTS

MIL-STD 45662A

ISO Guide 25

General Requirements For The Competence Of Calibration And Testing Laboratories

ANSI/NCSL Z540-1-1994

General Requirements For Calibration Laboratories And Measuring And Test Equipment

ISO 9000

ISO 10012

RESPONSIBILITY

It is the responsibility of the Calibration Manager and Calibration Personnel to perform this work instruction and maintain quality records. It is the responsibility of a Metrologist, Senior Metrologist, or Calibration Manager to approve & sign all supplier audits.

DEFINITIONS

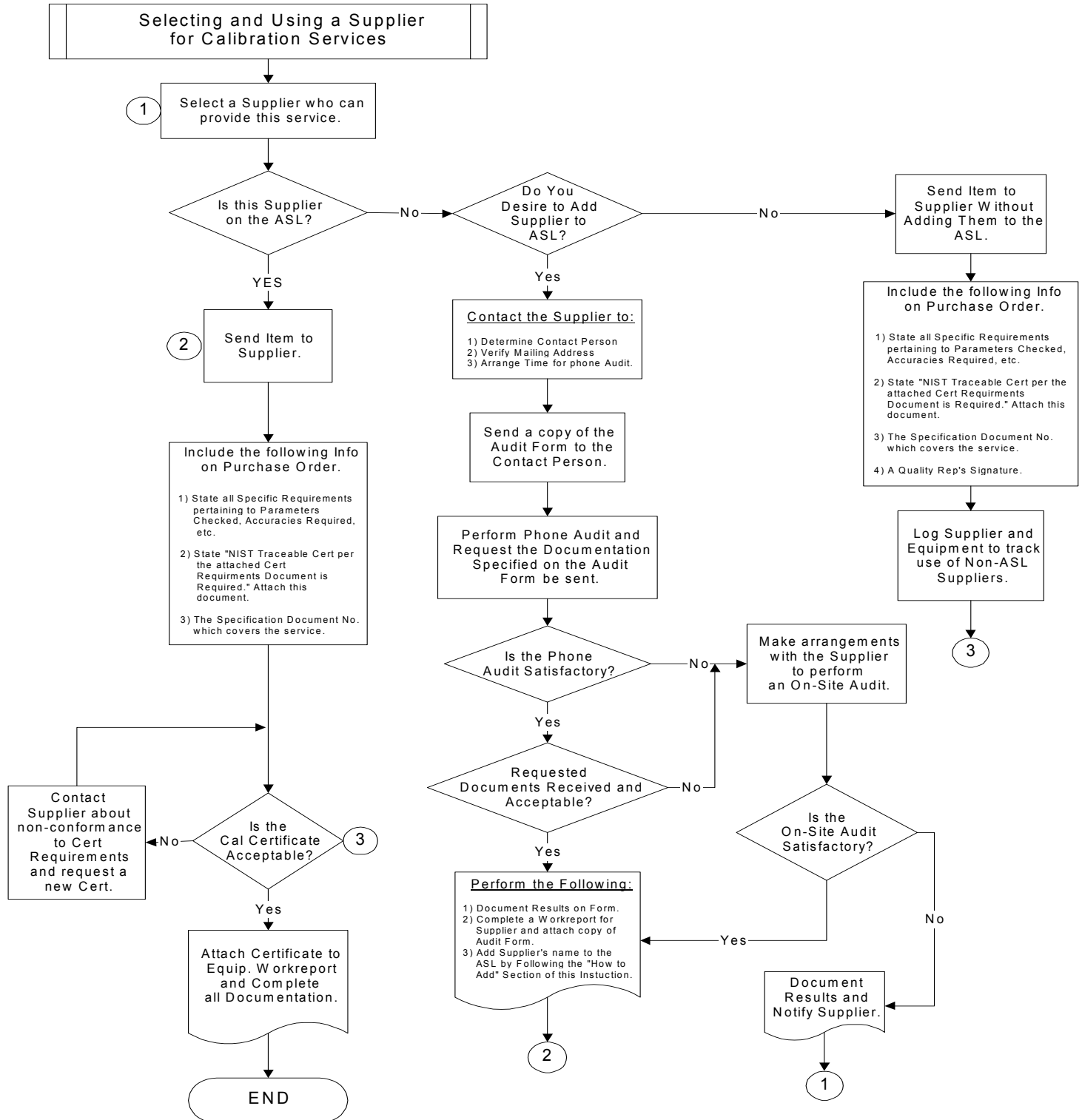
ASL - Approved Supplier List



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FLOWCHART





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PROCEDURE

Calibration Supplier Selection Process

Search the Approved Supplier List (ASL) for a Supplier who can provide the desired service.⁷ If no appropriate Supplier is listed, search for an alternative source.

- If this Supplier will be used on a periodic basis and you desire to add them to the ASL, perform the *How to Add a Supplier to the ASL* section.
- If you do not desire to add the Supplier to the ASL, skip to the *Using a Supplier not on the ASL* sub-section of the *Sending Equipment Out* section.
- If an appropriate Supplier is listed, determine if their audit is current as recorded in the calibration database.
- If no current audit exists for the chosen supplier, perform the *How to Add a Supplier to the ASL* section.
- If a current approved audit exists for the chosen supplier, perform the *Using a Supplier on the ASL* sub-section of the *Sending Equipment Out* section.

Sending Equipment Out

Using a Supplier on the ASL:

- +Contact the user, if necessary, to schedule device for outside service.
- +Contact the Supplier for price, lead time and return authorization number.
- +Initiate the purchase requisition or use blanket Purchase Order, if available.
- +Purchase Requisition must include the following information:⁸

Device Description

- a) Model Number
- b) Serial Number
- c) Specify the type of service to be performed and all specific requirements pertaining to parameters checked, accuracies required, etc.
- d) State "NIST Traceable Cert per the attached Cert Requirements Document is required."
- e) Attach a copy of the Cert Requirements Document to the Purchase Requisition.
- f) Any pertinent details concerning handling and how the device must be shipped (ie: Overnight, Hand-carried, Courier).
- e) Request for Shipping Authorization.

⁷ Reference the past history of the equipment to determine the Supplier who last performed this service. Other information such as test points and Standard Measurement Uncertainty can also be found in the equipment history.

⁸ Place a copy of the specific calibration requirements and Certificate of Calibration Requirements in an envelope and attach to the equipment. Give completed Purchase Requisition to the Purchasing Department. Give the equipment to the Shipping Department as deemed appropriate by them. Complete the Work report, change the status code to E (External), enter the information into the database, and print a new Work report. Place the new Work report into the SENT OUT bin.



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Using a Supplier not on the ASL⁹

- Contact the equipment's owner, if necessary, to schedule device for outside service.
- Contact the Supplier for price, lead time and return authorization number.
- Initiate the purchase requisition.
- Purchase Requisition must include the following information:^{10 11}
 - +Device Description
 - +Model Number
 - +Serial Number (if none, use the Calibration Number)
 - +Specify the type of service to be performed and all specific requirements pertaining to parameters checked, accuracies required, etc.
 - +State "NIST Traceable Cert per the attached Cert Requirements Document is required."
 - +Any pertinent details concerning handling and how the device must be shipped (ie: Overnight, Hand-carried, Courier).
 - +Request for Shipping Authorization.
 - +The Specification document number which covers this service.
 - +Obtain a Quality Representative's signature.

When Equipment Returns from a Supplier:

- Check for proper operation and damage
- Compare the new calibration data to the past data.
- Examine the Certificate of Calibration for compliance with the Cert Requirements document.
- If the Certificate is unacceptable, contact the Supplier about the non-conformance to our Certificate Requirements and request that a corrected Certificate be sent immediately.
- If the Supplier is unable to comply with the Certificate of Calibration Requirements, repeat the Calibration Supplier Selection Process until a new Supplier is found.

If the Certificate of Calibration is found to be acceptable:

- Complete and update the Work Report
- Attach the Calibration Certificate to the Work Report
- Attach the Calibration Label and appropriate Void Seals to the Instrument

⁹ If this Supplier is used on a periodic basis, give serious consideration to adding them to the ASL.

¹⁰ Reference the proper Specification document for any additional requirements needed for a particular piece of equipment.

¹¹ Place a copy of the specific calibration requirements and Certificate of Calibration Requirements in an envelope and attach to the equipment. The Calibration Supervisor or designee will log the Supplier used along with the equipment sent out for tracking purposes. Give completed Purchase Requisition to the Purchasing Department. Give the equipment to the Shipping Department as deemed appropriate by them. Complete the Workreport, change the status code to E (External), enter the information into the database, and print a new Workreport. Place the new Workreport into the SENT OUT bin.



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How to Add a Supplier to the ASL

- 1) Contact the supplier to determine a contact person, and verify their mailing address and arrange a time with the contact person to perform the Phone Audit.
- 2) Complete the Supplier Information and Specification Sections of the Audit Form.
- 3) Send a copy of the Audit Form and the Certificate of Calibration Requirements to contact person.¹²
- 4) Determine where the supplier can be added to the ASL by referencing the Supplier Master List in the back of the Calibration Supplier book (section 30).
- 5) Determine if the Supplier already has a calibration number by searching the database (not all suppliers with calibration numbers are on the ASL).
- 6) If the supplier does not already have a calibration number, assign one to them using the following information:

MFGR: (supplier name)
Model: CALIBRATION SERVICES
Serial #: SPEC # (applicable SPEC # or "NOT AUDITED" if not to be added to the ASL)
Description: SUPPLIER (try to be consistent with the rest of the company & SOPs)
Location: CALIBRATION LAB
Cost Center:
Procedure #:
Data Req: Y (If they will be on ASL & need to be audited)
 N (If they will not be on ASL)
Status: N (if they aren't yet audited but will be on the ASL)
 C (if they will not be on ASL)
Cal Inter: 36 (if they will be on ASL)
 (if they will not be on ASL)

Let the Calibration Lab ASL Coordinator know the following:

- *If you have added a new supplier to the database. Give the Dept. ASL Coordinator the calibration # and name.
- *If you want the supplier to be added to the ASL, the ASL Coordinator will need the SPEC number and name the supplier goes under, whether you plan on performing the audit yourself, and their address and phone number.
- *If you are performing the audit yourself, write an SEP (Supplier Evaluation Plan) and obtain signatures from Materials and Quality before the audit is performed. Include the following information on the SEP:
 - The Supplier's name along with the name of the parent company if applicable.
 - The Specification document number, to which the Supplier will be added, goes in the Part Number(s) box.

¹² Send the Audit Form early so that they have sufficient time to review it before the Audit is performed.



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-In the Evaluation Requirements box Check the following:

Pre-Survey Questionnaire	No
Quality Systems Survey/Audit	Yes
Technical Review	Yes
(write "Part of Audit" next to this category)	
First Article Inspection	N/A
Product Qualification	N/A
Analogous Review	N/A
Other	Yes or No

Write *Non-Disclosure Agreement* and/or *Non-Deviation Agreement* on the line provided¹³

Phone Audit:

Perform the Phone Audit and request that proof of compliance and examples of their documentation system, for the indicated items on the Audit Form, be sent. Give the supplier a reasonable, but definite, time to comply.

Have the completed Audit Form and Proof of Compliance Documents reviewed by a Metrologist, Senior Metrologist, or Calibration Manager to determine if the supplier audit is acceptable.

- If the Phone Audit is not satisfactory, proceed to the On-Site Audit section.
- If the Phone Audit is satisfactory but the requested documentation has either not been received or is unacceptable, proceed to the On-Site Audit section.
- If the Phone Audit is satisfactory and the requested documents have been received and found to be acceptable, proceed to the Approved Audit section.

On-Site Audit:

Make arrangements with the Supplier to perform an On-Site Facilities Audit.

Perform the On-Site Audit.

Have the completed Audit Form and Proof of Compliance Documents reviewed by a Metrologist, Senior Metrologist, or Calibration Manager to determine if the supplier audit is acceptable.

- If the On-Site Facilities Audit is acceptable, proceed to the Approved Audit section.
- If the On-Site Facilities Audit is not acceptable, repeat the Calibration Supplier Selection Process section.

Approved Audit

¹³ If the Supplier handles sensitive/confidential materials or will be coming on-site they will need a Non-Disclosure Agreement. If the supplier produces reference materials or deals with custom items or setpoints they will need to sign a Non-Deviation Agreement.



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Perform the following if there is an approved Audit on a new Supplier:

-Submit the Supplier to Documentation to be added to the ASL. Include the following on documentation.

Product Line Affected: All

Facilities Affected:

Part/Doc Number: The SPEC number under which the supplier will be added

Doc Type: ASL

From Rev, To Rev: Ask Documentation for these.

Part/Doc Title: ASL, and the title of the SPEC.

Interchange: N/A

Inventory Dispositions: All 6s except for N.O. and W.I.P. which are 1s

Reason for Change: "Quality System requires approved suppliers for each calibration service which is provided by an outside source."

Description of change: "Add" (Supplier name) "to the ASL for" (title of SPEC) "using the attached audit."

Fill out a VALIDATION/VERIFICATION APPROVALS form and include the following information:

Description of Change: Quality System requires approved suppliers for each calibration service which is provided by an outside source.

Originator: (Your Name)

Project/Product: Add (Supplier's Name) to the ASL

Document Number: ##### (The Specification # for the Supplier)

Activity: (Select Other)

Comments: See the attached Audit for (Supplier Name(s)).

Include in the Package submitted to QA:

- The original and the signed documents
- A completed Validation/Verification form.
- Copies of the Non-Deviation and Non-Disclosure Agreements (if applicable)
- The original completed Audit form. (Documentation does not want the Proof of compliance documents)

Place in the Calibration Lab supplier file:

- A copy of the signed document
- Copies of the Non-Deviation and Non-Disclosure Agreements
- A copy of the audit form
- Copies of all proof of compliance documents

Give to the Manufacturing Purchasing Department:



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- A copy of the documents
- Copy of the audit form
- Copies of the Non-Disclosure and Non-Deviation Agreements
- The original Proof of Compliance documents.

-Send all original Non-Disclosure and Non-Deviation Agreements to the Legal Department.

-Fill out a Workreport (Calibration Number should have already been assigned) for the Supplier after it has been submitted. Include the following information:

Traceability: (Left Blank)

Comments: Audit Performed by (Auditors Name) and found to be acceptable. Added to the ASL. Seethe. Supplier File in the Calibration Lab for Documentation.

Date Completed: (Date in which Audit was performed)

Status: A

Type: I

Update (Y/N): Y

Date Next Cal: (36 months from when Audit was performed)

Procedure, Revision Date: When the Supplier to the ASL has been signed off, obtain a copy for the Calibration Lab records located in the Supplier Audit File cabinet.



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Appendix B

Quality Assurance Program Calibration Services Supplier Evaluation¹⁴

Company: _____ Date: _____
Address: _____
Supplier Representative(s) / Title: _____
Telephone Number: () _____ Fax Number: () _____
Company Evaluator's: _____
Service Supplied: _____

1 Description of Organization

- 1.1 Services offered: _____
1.2 When founded: _____
1.3 Public/Private ownership: _____
1.4 Organizational Structure (Quality Function): _____
1.5 Certifications/ Recognition's: _____

2 Quality Assurance Plan Calibration System Requirement

- 2.1 Quality policy documented: Yes No Define: _____
2.2 Is quality assurance and calibration system documented: Yes No Define: _____
2.3 Are written procedures available followed for each system element: Yes No
Define: _____
2.4 Are deviations from standards documented? Yes No
Define: _____

3 Measurement Standards

- 3.1 Is the collective uncertainty of the measurement standards below 25 percent of the acceptable tolerance(4:1 accuracy ratio) for each characteristic being tested: Yes No
Define: _____
3.2 Is an accepted method used to determine collective uncertainty? Yes No
Describe method: _____
3.3 How are deviations from the required accuracy ratio handled? Define: _____

¹⁴ If any of the following questions can be answered by us reviewing your systems manual, please enclose a copy of that manual and refer those answers to the paragraph(s) mentioned in your manual. It is our intention to qualify you for providing services by the answers you are able to provide. We do not wish to be provided with any information you feel is private or confidential. After reviewing this survey we will make the decision if an onsite audit is necessary to use your company for calibration services.



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4 Facilities

- 4.1 Are facilities appropriate for calibration operations? Yes No Define: _____
- 4.2 Are suitable environmental conditions maintained in the calibration lab; does this condition meet the need of the discipline in which the item is being calibrated? Yes No
Define: _____

5 Intervals of Calibration

- 5.1 Are calibration intervals established for measurement standards: Yes No
Define: _____
- 5.2 What is the basis for determining the calibration interval for measurement standards?
Define: _____
- 5.3 What action is taken if measurement standards exceed the established calibration interval?
Define: _____
- 5.4 How are calibration intervals established for instrumentation calibrated at this facility?
Define: _____

6 Calibration Procedures

- 6.1 Are current, controlled, and written procedures available for use when defining the calibration of measurement in test equipment: Yes No
Define: _____
- 6.2 Do calibration procedures include adequate information on range, accuracy, and tolerances?
State example: _____
- 6.3 How are calibration procedures kept current? _____
- 6.4 Is a document control system used to make current procedure revisions? Yes No
Define example: _____

7 Personnel

- 7.1 Are personnel adequately qualified to perform the calibrations they are assigned?
Yes No Define: _____
- 7.2 Is the continuing qualification of personnel involved in the calibration process periodically verified and documented? Yes No Define: _____

8 Out of Tolerance Conditions

- 8.1 Are out of tolerance conditions defined & documented: Yes No
Define: _____
- 8.2 What is the procedure for action taken in out of tolerance conditions; are corrective actions documented? Yes No Define: _____
- 8.3 Describe how the customer is notified concerning out of tolerance conditions which may effect the calibration of their measurement and test equipment: _____



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9 Adequacy of the Calibration System

9.1 Are periodic internal audits performed on the calibration system? Yes No

Define: _____

9.2 When problems & deficiencies are uncovered in audits or during normal operations, are they documented and resolved? Yes No Define: _____

10 Calibration Sources

10.1 Is NIST (or equivalent) traceability current and fully documented? Yes No

Define: _____

10.2 Are certificates or reports of calibration available?¹⁵ Yes No

Define: _____

10.3 Have outside calibration sources, other than NIST, evaluated for capability and compliance to a quality standard; how and what quality standard: Yes No

Define: _____

10.4 Is a calibration history maintained for all measurement standards? Yes No

Define: _____

11 Reports Records

11.1 Do Reports Include:

11.1.A. Title (i.e. calibration certificate): Yes No

11.1.B. Name & address of lab and location of calibration (if different): Yes No

11.1.C. Unique identification of the report & each of total number of pages: Yes No

11.1.D. Name & address of client and date report issued: Yes No

11.1.E. Description and unambiguous identification of the item calibrated: Yes No

11.1.F. Characterization & condition of the item calibrated: Yes No

11.1.G. Date of receipt of items & date of performance of calibration: Yes No

11.1.H. Measurements & results w/condition before & after (if applicable): Yes No

11.1.I. Estimated uncertainty of calibration & how uncertainty derived: Yes No

11.1.J. Signature & title/identification of responsible party for report content: Yes No

11.1.K. Identification of any calibration performed by subcontractors¹⁶: Yes No

11.2 Are records maintained of all test items, measurement standards, and equipment used for the calibration? How long are these records maintained: Time kept: _____

If no, define: _____

¹⁵ Reports should include, at a minimum, identification of the instrument, identification of the calibration source and report #, date of the calibration, calibration assigned value with a statement of uncertainties, relevant conditions which must be applied, and a traceability statement if the calibration laboratory is other than NIST

¹⁶ We require that no subcontractors be used without prior notification and permission.



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12 Calibration Status

12.1 Are measurement standards & items' calibrated labels (when feasible) documented with date calibrated, date calibration due, and any limitations? Yes No

Define: _____

12.2 Are measurement standards & test equipment sealed to prevent tampering; is corrective action properly initiated in the instance of confirmed or suspected tampering? Yes No

Define: _____

13 Subcontractor Calibration

13.1 What methods do you employ to ensure quality standards are enforced by any subcontractor of calibration services to your organization? This organization must be notified before using any subcontractor for calibration support: Would you agreed to these terms? Yes No

If no, why: _____

14 Storage & Handling

14.1 Are measurement standards properly stored when not in use? Yes No

Define: _____

14.2 When it is necessary to ship measurement standards or measurement and test equipment, are proper packaging and handling techniques used to prevent adverse effects on these items during the shipment process? Yes No Define methods: _____

15 Additional Comments: _____



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Appendix C

Certificate Of Calibration Requirements

All Vendors must document the following information on any Certificate of Calibration.

Items which must be included for the Certificate of Calibration to be accepted by the Calibration Lab are as follows:

1) Device Under Test Information:

- a) Identification of the device under test (i.e. manufacturer name, model number, serial number, description, calibration number, etc.)
- b) Date Completed
- c) Range of Device (i.e. 100 lb.ft; Torque Wrench; Range=20 to 100 lb.ft) included in data if necessary
- d) Accuracy Specification of the Device - Requirement may be specified on purchase requisition, such as calibrate to manufacturer specifications, calibrate to Class 1, calibrate to 2-1-2, etc.

2) Procedure:

Document the measurement method used. This could be a procedure number or description of the process.

3) Results:

- Record the data obtained from the calibration. Include all calibration data test points specified on purchase requisition or addendum and the deviation from nominal found at each point
- Record the initial data and final data if the device is out of tolerance and requires adjustment
- Record the Temperature and Humidity (or any other relevant environmental factors) conditions at the time of calibration and include these values on the Certificate of Calibration

4) Equipment Used:

Identify the equipment used to perform the calibration along with the Calibration Number or ID Number that establishes traceability to N.I.S.T. When traceability to international, national or intrinsic standards of measurement is not available, traceability requirements may be satisfied by:

- a) participation in a suitable program of interlaboratory comparisons or proficiency testing.
- b) internationally accepted standards in the field concerned
- c) suitable reference materials
- d) ratio or reciprocity-type measurements
- e) mutual consent standards (clearly specified & agreed on by all parties concerned¹⁷)

5) Signature:

Include the legible signature, and printed name, of the person performing the calibration.

¹⁷ State either the measurement uncertainty and coverage factor of each Standard used, or the collective measurement uncertainty of the measurement process for each parameter tested.