Accreditation Experiences of an American Company

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Abstract

The Fluke Primary Standards Laboratory was accredited by NVLAP in June of 1995 and by the German accrediting body, DKD, in January of 1998. This paper describes the benefits we hoped to achieve, the process itself, and finally the benefits actually achieved. The differences in the US and European accreditation experience, the findings during the internal and external audits, and the costs incurred during the various phases of accreditation will be shared.

Introduction

The Fluke Primary Standards Laboratory gained certification by The National Voluntary Laboratory Accreditation Program (NVLAP) in June 1995 after a 13-month period of preparation and examination. We entered this accreditation process hoping to satisfy perceived needs by customers, reduce customer on-site audits of our lab, and most importantly, to eventually eliminate the need for recalibration of our calibration products in Europe. Unfortunately, after two years of experience, none of these expectations have been met. Many of our domestic customers withdrew from their earlier accreditation plans, customer auditors seem ignorant of the value of NVLAP accreditation, and the schedule for recognition of NVLAP by the European Corporation for Accreditation of Laboratories (EAL) was extended indefinitely.

Nevertheless, in May of 1996, we chose to expand the scope of accreditation to include calibrations produced on the factory floor for several of our calibration products. The need for accreditation by USA customers seemed to finally be increasing. We initiated joint accreditation by NVLAP and the Deutscher Kalibrierdienst (DKD). We felt accreditation by the DKD would give our calibrations recognition in Europe; thereby, eliminating the costly recalibrations required there.

Efforts for accreditation of the Primary Standards Laboratory and its Factory Annex by both NVLAP and the DKD were concluded after 15 months of work by all involved. Both accrediting agencies conducted their audits in a friendly and professional manner. Their reviews were penetrating, thorough and helpful. We feel our lab was improved by their comments and suggestions. We also value the relationships that this process has established between our laboratory personnel and the Metrologists at NIST and the PTB.

Reasons for accreditation

Fluke's Primary Standards Laboratory is a modestly sized facility with a staff of 11 engineers and technicians. In addition to our traditional task of establishing and maintaining reference standards for the Fluke Corporation, we provide calibration services to corporate entities, especially to manufacturing, and to out-of-house (outside) customers. Provided calibration services include high-end dcV and acV, dcI, acI and resistance.

Several forces combined to drive us toward accreditation. The needs of our outside customers were the initial drive. Some of them planned accreditation for themselves and notified us that they, in turn, will be requiring accredited calibration services from their suppliers. If we weren't accredited, we would loose their business. We also assumed that accreditation would reduce or eliminate time-consuming audits by our users. Furthermore, we believed that when our accrediting agency received world –wide recognition, especially in Europe, costly recalibration of our products sold internationally would be eliminated. We naively believed that mutual recognition between NVLAP and EAL would be accomplished in a year or two. This belief was shared by NVLAP leaders.

Accreditation by NVLAP

Preparations for accreditation by NVLAP began in May 1994. At that time, the Primary Standards Laboratory had already gained certification as a ISO 9001 facility. This meant that all processes were identified and documented, personnel were properly trained, procedures were in place for all calibrations and the required organization and management was in place and documented

Nevertheless, when the existing quality manual was checked against ANSI/NCSL Z540-1 (which closely resembles ISO Guide 25), 69 gaps were identified. This was very surprising to us since the Lab is a good facility with a record of providing reliable, high quality calibrations.

Our gap analysis showed deficiencies in the following areas:

- policies and procedures: Several were missing or were poorly documented.
- uncertainty analysis and documentation: Much of our uncertainty analysis did not conform with EAL-R2, "The Expression of the Uncertainty of Measurement in Calibration". Moreover, we did not have a systematic system for naming and filing the analyses.

- control charting of standards: Control charting was practiced informally by key lab members. Little documentation for the preparation and review of control charts existed, however.
- system documentation and verification: Many of the calibrations performed in our Lab were automated or semiautomated by dedicated, custom designed systems. These systems worked well according to informal evaluation by Lab personnel. Unfortunately, many did not include proper documentation. Descriptions of associated software and its verification were often missing or insufficient. Uncertainty analyses embedded in the software were sometimes not well documented.

Identification of gaps and their partial resolution (those requiring completion before processing the accreditation application) required about 5 calendar months by our four-man technical staff, Accreditation related tasks were added to our normal workload. Needless to say, workdays were often expanded to include long evenings and some weekends. Our application for accreditation was submitted to NVLAP in October, 1994.

The NVLAP application package included the following documents:
- quality manual based on NIST Handbook 150 (a super set of Z540-1)
- list of major equipment used in the Lab
- description of the Lab and its staff
- description of operations
- a detailed list of the scope of accreditation
- stage 1 fee of $1,500 (now $500)

Several weeks after our application, NVLAP began their pre stage 2 interactions with us. They reviewed our Quality Manual and identified a number of deficiencies; none required delaying the accreditation process. Most of the rework involved including items unique to NIST Handbook 150 such as guidance for the use of NVLAP certificates and logo. Additionally, they requested that we submit a sample calibration procedure, a sample calibration certificate, documentation of uncertainty analysis and a list of measurement standards for each measurand submitted in our scope of accreditation. Shortly after we submitted this material, NVLAP scheduled our on-site audit (April 18-21, 1995) and billed us $11,400 for the stage 2 fee and expenses.

The NVLAP audit team consisted of two members, Mr. Doug Faison and Mr. Norm Belecki. At that time, Mr. Faison was Senior Program Manager within the NVLAP organization. Mr. Belecki was the head of the Electricity Division at NIST, Gaithersburg, Maryland. We felt both of these men were well qualified for the audit.

Our audit began on Monday morning promptly at 8:30 AM. Mr. Faison focused on the quality system as documented in our quality manual. He spent four days comparing our manual against the requirements of NIST Handbook 150. He searched for evidence that we actually practiced our documented policies and procedures. Mr. Belecki conducted the technical review. Much of his time was spent talking to (interviewing) lab personnel including members of technical staff and our metrology technicians. He watched our

technician perform calibration procedures and asked many penetrating questions. He also reviewed several uncertainty analyses and probed their authors for possible additional unmentioned sources of uncertainties.

On Friday morning, nearly five days after the on-site audit began, our NVLAP auditors called an audit review meeting and presented their findings. Most of the staff was tired and a bit nervous. Mr. Faison quickly jumped to the bottom line. They recommended accreditation for our lab to the NVLAP review committee, provided seven deficiencies were corrected. He also required us to successfully pass a calibration proficiency test consisting of the measurement of a SR104 standard resistor.

During our final review discussions, we were surprised to learn that the NVLAP accreditation was system specific. That is, we are authorized to issue accredited calibration certificates only for those systems and procedures that were included in the scope of application and that were reviewed by the NVLAP audit team. Since our scope included only high-end calibrations, we were not authorized to perform accredited calibrations on low-end equipment unless we used the same procedures and standards as for the high-end equipment. For example, we could calibrate 5720A Multifunction Calibrators with the J Array System for dc Volts and with the 792A AC/DC Transfer System for ac Voltage. However, we could issue accredited calibrations for dc Volts and ac Volts on a small hand held DMM only if we calibrated them on the same systems. Needless to say, we were surprised and disappointed.

The Fluke Primary Standards Laboratory received its NVLAP certification on June 30, 1995, approximately 14 months after initiating application preparations. NVLAP charged approximately $13,000 for their accrediting service.

Actual Benefits of Accreditation

As mentioned earlier, we had anticipated a demand for accredited calibrations by our customers. Actually, we experienced only an occasional request for this service. Customers who had earlier expressed this need apparently delayed their accreditation plans due to difficulties justifying them financially. We have experienced a growing demand in recent months, however.

Customer audits initially were unchanged by our accreditation status. Most auditors were not familiar with NVLAP or any other accrediting agency. They were not dissuaded by our documents and explanations. In recent times, however, we have experienced few customer audits. Apparently the word has finally gotten out.

Our largest disappointment was the lack of acceptance of NVLAP accreditation by the EAL and other international accreditation agencies. We had hoped to eliminate the expensive recalibration of our high-end calibration products, especially in Europe. Every year, we were told that a mutual recognition agreement (MRA) would happen shortly. The MRA date is still uncertain three years after our initial accreditation.

Expanded Accreditation

By the summer of 1996, it was apparent that EAL recognition of NVLAP was not likely to happen in the near future. Therefore, it was in our interest to be certified by some EAL accrediting agency. Furthermore, it was important that the calibration performed in the factory be accredited, not just the Standards Laboratory. The scope of accreditation would also have to be expanded to include measurands now available in our new products including capacitance, temperature, phase and frequency. We felt that it would be desirable to be accredited by both NVLAP and the EAL.

Having decided to ask for accreditation by some EAL member, the question became, which member? Although any member of the EAL is capable and sufficient, we quickly reduced the field to the three we were most familiar with including NPL/UKAS (England), NMi/NKO (Netherlands) and PTB/DKD (Germany). Of these, representatives of the Nmi and PTB visited our laboratory and discussed accreditation, in general, and the challenge of how to accredit the test systems on the factory floor, in particular. After much consideration and debate, we chose the PTB/DKD because we felt that they were well recognized internationally, including areas outside of Europe that are important to our business.

Actually, we decided to attempt a joint accreditation with the DKD and NVLAP. This would give us acceptance across a wide area of the world. It also would provide an easy transition if and when a MRA is finally approved between the two entities.

DKD Application Documents

The procedure and documents required for the DKD accreditation application are well described in their documents DKD-1 through DKD-6. The required material is structured so that a thorough evaluation can be made of the lab and its documentation prior to scheduling an on-site audit. The application package includes the following material:

- A filled out DKD application form as provided in DKD-2, “Accreditation of Calibration Laboratories – Criteria and Procedures”
- An annex for each measurand in the claim
  Each annex includes the measurand, brief description of the calibration method, standards to be used, and a listing of instruments to be calibrated
- Calibration certificates of the reference standards for all measurands and ranges
- Proof of education and training of the head and the deputy head of the laboratory
- Quality Manual per DKD-6 or with a mapping to DKD-6
- Application fee of 2500 DM (approximately $1,500)

This material is similar to the NVLAP application package. It differs primarily in the structure and content of the quality manual and in the requirement for submitting calibration certificates for all relevant reference standards.

Preparations for Expanded Accreditation

Considerable work had to be completed before making applications for expanded accreditation. It can be
grouped into two categories- (1) organizing and documenting the Factory Annex, and (2) updating the quality manual for the expanded capability and for compatibility with the DKD requirements.

Factory Annex:

Prior to selecting our EAL accrediting agency, Dr. Klonz of the PTB, visited our facility and discussed some of our accreditation challenges. Particular attention was paid to how our test consoles in the remote factory (located about three miles from the Standards Lab) could be accredited. Dr. Klonz recommended making them an annex to the Standards Laboratory. The Factory Annex would operate under the management and quality system of the Standards Laboratory even though the automated consoles would be operated by manufacturing technicians. This form of organization was adopted after much discussion between manufacturing, quality assurance and Standard Lab management. It was not easy for manufacturing to allow a new entity into their production stream. Nevertheless, it was necessary in order to insure independence for the calibration and reporting processes.

Another challenge for the remote Factory Annex was to establish and maintain the traceability of the factory test console through the Standards Laboratory. This was accomplished using the method of Process Metrology as discussed in a previous publication [(1)].

Of course, the organization for the Factory Annex, and its operations had to be integrated into the Primary Standard's Laboratory's Quality Manual. This involved writing local area documents (MET's) on Process Metrology, test system documentation, and a description of responsibilities and interactions between factory and standards lab personnel.

Quality Manual Expansion

As mentioned earlier, we planned to expand the scope of our previous NVLAP accreditation to include the capability for calibrating recently developed multifunction calibrators. New measurands include capacitance, temperature, frequency and phase. This required adding new material for the claims, supporting standards, uncertainty analyses, and calibration method descriptions in the related section of the Quality Manual (QM).

Additional work was required to make the revised Lab quality manual compatible with the DKD requirements as described in DKD-6. It describes a well-designed, highly structured quality manual that meets the requirements of EN45001 (very similar to ISO Guide 25). It includes coupling between sections that helps establish links between

claims, standards and procedures. DKD-6 is an excellent document that I recommend highly as a model for laboratories preparing their quality manual.

In comparison, our existing quality manual was initially designed to satisfy ISO-9001. It was modified to satisfy ANSI/NCSL Z540-1 and NIST Handbook 150 by patching and adding. It is complete and satisfies NVLAP requirements, but it is not pretty. The DKD allows quality manuals with structures different than that of DKD-6, but requires paragraph by paragraph mapping. We chose to add the unique requirements of DKD-6 into our existing manual and prepare the required mapping.

One rather significant difference between the NVLAP and DKD applications was the required completeness of the DKD documentation, especially the QM. It requires that the QM include claims, uncertainty analyses, descriptions of the calibration methods, standards required for each claimed measurand and corresponding calibration procedures. All of this material is part of the Lab QM and must be included in the accreditation application. In comparison, NVLAP eventually required most of this material, but not with the application. Therefore, it was possible to process the initial application with NVLAP, get into their process queue and then complete documentation on sections such as procedures and methods during the NVLAP phase 1 review. The DKD methodology allows a thorough review prior to scheduling the on-side audit; however, it requires more initial preparation time. NVLAP's on-site review takes more time since they must review documents not previously submitted.

Our preparations for the DKD and NVLAP joint accreditation application began in October, 1996. It was completed in March, 1997 after spending approximately 12 man-months on the required work tasks. Our applications along with 2500 DM and $1,500 were sent to DKD and NVLAP respectively.

Interactions Prior To On-Site Audit

DKD

DKD responded, in April 1997, approximately one month after we sent them our application. They submitted a 15-clause DKD Contract and Arbitration Contract for our review and approval. They also appointed our auditors, subject to our approval, to be Dr. Hans Bachmair and Dr. Manfred Klonz. Mrs. Dipl.-Ing. Just was made responsible for reviewing our quality manual. We promptly approved the contracts and the suggested auditors.

A few months later, I was informed of several deficiencies in our quality manual. The most pressing problem involved control of the document by the DKD. Our QM consisted of a group of 30 separate local area documents and standard operating procedures (SOP) contained in a pair of large 3-ring binders. Each document was controlled by a revision date and an approval page signed by the author and the Metrology Manager. The DKD requested that we prepare a "kernel" document that included material of first order interest to them such as claims, listing of reference and working standards, and procedure

lists. This document also include lists of uncertainty analyses, MET's and SOP's that they deem of special significance. The kernel document is patterned according to DKD-6 with approval initials on the footer of every page. Any change to this document must be submitted to the DKD along with relevant supporting documents.

Our DKD manual reviewer also complained of the lack of links between claims, standards and procedures as modeled in DKD-6. DKD auditors asked that this linking be provided in the kernel document. We complied.

Additionally, some of the documents required by DKD-6 were missing including some system documentation and a few uncertainty analyses. These had not yet completed when the application was submitted. We had hoped to get our application into the queue and to submit the missing documents when they became available. We were thankful that this approach was accepted.

After about 9 man-months of effort, the deficiencies described above were satisfied. DKD gave their approval by scheduling our on-site audit for December 8-10, 1997. We requested that, if possible, this audit be coordinated jointly with NVLAP so as to minimize the total time and expense required. Both DKD and NVLAP auditors agreed. We were thankful for their willingness to work together.

NVLAP

Doug Faison, of NVLAP, officially acknowledged our application in July 1997. The suggested auditors, subject to our approval, were Doug Faison and Norm Belecki, as in our first NVLAP accreditation. We were happy with this selection and agreed quickly

Our documentation, as submitted, was acceptable to NVLAP except for a few missing pieces. However, we provided them with the same modifications requested by the DKD. Both agencies were eventually given identical documentation packages.

On-Site Audit

Our four auditors arrived early on Monday morning, December 8, 1998. They announced that they were working together as a team. Dr. Klonz and Dr. Bachmair, from the PTB would focus on the technical aspects of the laboratory. Mr. Faison and Mr. Belecki, from NVLAP, would make the quality aspects their focus. Practically, however, all four men shared in much of the ensuing review.

We learned that some of the technical review had already occurred at NIST in Gaithersburg. All four auditors reviewed certificates issued by NIST on our Laboratory's reference standards for the claimed measurands. Only a few recently initiated reports were missing.

The technical audit began with the claims and linked standards and procedures presented in the recently completed core document (MET 12). Each family of claims were carefully compared with the associated uncertainty analysis. The author or lab manager was often

asked to justify their assumptions, or whether or not other potential contributions to uncertainty were considered. Heavy emphasis was placed on the practicality of the claims by the PTB representatives. The best claims often were determined by limitations of anticipated test instruments rather than on the capability of the test standards. This resulted in doubling the claimed uncertainty of our Josephson Array System, for example.

Most, if not all, of the competency evaluation of key laboratory personnel apparently took place during the technical review described above. Laboratory technicians were not questioned. This was a marked change from our initial NVLAP accreditation audit during which each technician was observed and questioned by the technical auditor.

Mr. Faison, of NVLAP, sometimes participated in technical discussions, but spent most of his time comparing our Quality Manual with the requirements of NIST Handbook 150. All deficiencies that he had identified in our 1996 accreditation were checked for proper fixes. He again looked for clues that showed whether or not we actually practiced the processes described in the Quality Manual. He discovered that occasionally we did not. These items were documented later as deficiencies in NVLAP's final report.

In some areas, the technical review was particularly stringent. For example, Dr. Klonz recently calibrated a 792A Fluke transfer standard at the PTB. This standard was purchased from Fluke by a large laboratory in South America, used for a year, and then sent to the PTB for recalibration. Dr. Klonz compared the original calibration data, provided to the customer by Fluke's factory, with data he collected at the PTB. Differences were compared with the present claims for our Laboratory.

We were given another proficiency test. Dr. Klonz brought along a 1000 Volt TVC he had characterized at the PTB. While enroute, at NIST, he had it measured for ac/dc difference. We were asked to also measure its ac/dc difference. Fortunately, our measurements agreed well with those made by NIST. Unfortunately, NIST and PTB disagreed significantly at some frequencies above 1 kHz. This is a problem presently being addressed by several national standards laboratories [2,3,4,5].

All of our calibration systems associated with our accreditation claims were reviewed carefully for calibration methods, software verification and control, and its related uncertainty budget. This review resulted in some improvements in our systems and the elimination of a few faults.

We had anticipated much probing of Process Metrology, our method for linking the traceability chain between our Standards Laboratory and the remote factory test consoles. There, indeed, was some discussion and penetrating questions from both PTB and NVLAP auditors. It was apparent, however, that they had done their homework by reading and absorbing the related material provided in our Quality Manual. The team did visit our Factory Annex located approximately three miles from the Standards Laboratory. The Factory Annex area is set apart in the factory by wide blue tape around

its perimeter. Equipment storage cabinets and test consoles are also placed so as to limit access to the area.

Considerable attention was paid to how the environment of the Factory Annex is controlled and monitored. We have several temperature sensors and a few humidity sensors distributed about the area. All are controlled by a facility computer. NVLAP was less than satisfied, however, by how long it might take to observe an out of tolerance condition. This resulted in another documented deficiency in their audit report.

The on-site audit, which began Monday morning, ended three days later on Thursday morning. Dr. Bachmair summarized his findings in a hand written report and accompanying narrative. Similarly, Mr. Faison also issued a hand written report of his findings. Both groups of auditors were satisfied with our Laboratory, its documentation and its key personnel. Both stated they would recommend accreditation for our Lab and its Factory Annex provided that we resolve certain deficiencies identified in their reports. NVLAP listed 4 deficiencies in our quality system. PTB identified 4 documents of claims and 8 quality manual deficiencies that required correction. No technical deficiencies were found. We felt their review was tough but fair. We were satisfied.

Comparison of NVLAP and DKD Accreditation Audit

These two agencies are similar in many ways. Both are professional and thorough. Both also are tough but fair. Both displayed cordial, friendly, helpful attitudes throughout the process. In many ways their audit was invigorating, motivating and helpful rather than a stressful, fearful event. There are some differences, of course. Lets examine several distinct categories for comparison as follows:

Scope of accreditation:

This is perhaps that greatest difference between the two agencies. NVLAP's accreditation is system specific. That is, only the systems specified and audited during the accreditation process can deliver accredited calibrations. For example, we are accredited to calibrate high end equipment for ac and dc Volts with a J Array System and precision 792A ac/dc transfer system respectively. We are not allowed, however, to issue an accredited calibration certificate on a low-end DMM, for example, unless it is calibrated with the J Array and 792A systems rather than a less powerful multifunction calibrator.

DKD, on the other hand, accredits for best claims the laboratory is capable of. In this case, the J Array and 792A systems are our best systems for dcV and acV respectively. We are authorized, however, to issue accredited certificates on lower accuracy calibrations, using whatever standards are appropriate, provided the procedure, equipment and standards used are in accordance with the Lab's Quality Manual. Future audits could check to verify that this freedom is not abused.

Quality manual review

Both agencies conducted a thorough review of our quality system against their quality standards. The DKD review was very structured with careful attention paid to the linking between claims, standards and procedures.

Technical review

Both agencies performed a thorough, tough but fair technical review. NVLAP seemed more spontaneous (less structured) with a focus on people, including metrology technicians. Proficiency testing played a minor role. The DKD review was very structured and included comparisons of actual calibration results with those made by other laboratories, including the PTB. Only the laboratory's technical staff, not its metrology technicians, were evaluated.

Certificate of Calibration

NVLAP had no specific form for its certificates other than what is required in NIST Handbook 150. This document includes a list of the required content. It also places certain restrictions on the use of the NVLAP name and LOGO.

DKD has similar requirements and restrictions. However, they offer little flexibility in the form of their reports. Their recommended report template must be used. I understand that this inflexibility is driven, in part, by the desire to keep all accredited reports issued by EAL members nearly identical.

Attitude

Members of both agencies maintained a friendly, cooperative attitude.

Maintenance

NVLAP requires annual renewals and bi-annual on-site audits. Any changes in the Lab quality manual that significantly affects performance must be reported when it occurs. The DKD conducts annual on-site audits. All changes on the DKD controlled portion of the quality manual must be submitted to the DKD when it occurs.

Concluding Remarks

NVLAP and the PTB issued us accreditation certificates approximately 15 months after we began preparing for them. We now are including DKD calibration certificates with many of our new calibration products including the popular 5700A, 5720A, and 5500A. Many of our international customers, especially those in Europe, are now experiencing significant savings since the recalibration of this equipment by a EAL accredited laboratory is not longer necessary.

Presently, we are experiencing a growing demand for accredited calibrations. Our dual accreditation with NVLAP and the DKD should satisfy a high percentage of this demand.

Another valuable benefit of this certification is the relationships that it helped establish between staff members of the Fluke Primary Standard Laboratory and Metrologists at

NIST and the PTB. Easy access to that expertise is helping us to design, document and provide high quality, reliable calibration services.

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