NIST GCR 98-740

PB99-175606

A Selective Review of Testing Laboratory Accreditation Movements in the United States

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January 1998

U.S. DEPARTMENT OF COMMERCE
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TECHNOLOGY ADMINISTRATION
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ABSTRACT

In conjunction with a cooperative effort by the Laboratory Accreditation Working Group (LAWG), consisting of public and private sector entities that call for laboratories to be accredited, the affected laboratories, and accreditation bodies, the author has conducted a selective review of a number of previous attempts to systematize laboratory accreditation activities in the United States. In conclusion, a number of recommendations are made for the developing National Cooperation on Laboratory Accreditation (NACLA), the proposed formal structure to succeed the planning organization, LAWG.

A SELECTIVE REVIEW OF TESTING LABORATORY ACCREDITATION MOVEMENTS IN THE UNITED STATES

While there is a long history of efforts to establish and coordinate laboratory accreditation activities in the United States, perhaps 1960 is the best starting point for a review. In its Bulletin No. 245, the American Society for Testing and Materials (ASTM), in May 1960, published a report by A. T. McPherson, at that time an Associate Director of the National Bureau of Standards (now the National Institute of Standards and Technology (NIST). In his report, entitled Plan for the Self-Qualification of Laboratories.[1] McPherson wrote *"The demand for some objective method for the qualification of laboratories comes from a variety of sources. In the first place, hundreds of new standards laboratories are being established in connection with missile and special weapons programs. Some of these laboratories are operated by Federal agencies, others by contractors, and still others by independent commercial organizations. All of these laboratories, however, feel at one time or another the need of some continuing means of independently checking the accuracy of their work."*

"Another group of laboratories are those engaged in testing products for qualification or acceptance by the government or other large buyers. Here, some form of qualification is needed in the interest of both those who must contract for services on the basis of competitive business and those who are seeking business. Still another group is made up of laboratories of large industrial organizations which are concerned with procurement of raw materials and the control of quality of the finished product. The management of such laboratories needs some means of evaluating their performance in order that their services may be adequate but no more elaborate or expensive then necessary. All of these needs can be met by a standard, centrally administered, self-qualification plan in such area in which there is need to ascertain the degree or state of competence of a laboratory."

Although McPherson wrote this article in 1960, it appears that his descriptions of interested parties, requiring or needing laboratory accreditation, are still valid.

Let us now examine what McPherson saw as "criteria for the evaluation of laboratories." He discussed *"three major criteria determined the suitability of a laboratory for either product, testing, or calibration: 1) the qualifications of both the supervisor and the operating staff, 2) the facilities and equipment, and 3) the accuracy of the calibrations or tests performed as demonstrated by tests of reference samples. These criteria are not general, but must be related to specific calibrations or tests, and will change from time-to-time as the staff, the facilities, and performance change. Hence, any evaluation of a laboratory must be a continuing process."*

We should carefully emphasize that in 1960 McPherson stated a problem that is all too obvious today - just under four decades later. He stated, *"the magnitude of the task of evaluation, coupled with the absence of any agency - public or private - is now constituted or authorized to undertake the rating process, makes it highly desirable to set up a general standard against which individual laboratories can measure their own qualifications for undertaking specific*

calibrations or tests. Thus, the laboratories themselves, and not some independent agency, would, in effect, do the rating. The value of this plan would depend on the degree of objectivity with which the rating could be made."

Having stated the needs and motivations and then the magnitude of the task, McPherson summarized his plan as follows:

> *"A plan is presented whereby objective standards can be established to enable a calibration or testing laboratory to rate itself with regard to: 1) the qualifications of its staff, 2) the adequacy of its facilities and equipment for the work undertaken, and 3) his performance in the periodic measurement or testing of 'unknown' reference samples. Under the plan, standards would be set up in the specific fields in which the interest would be sufficient to warrant the expense of a reference-sample program. The standards would be established by or one or more central, non-governmental agencies in which the laboratories, the customers, and independent scientific experts would be equally represented. The laboratories participating in the plan would be authorized to report or publish the qualifications on a standard form."*

It is obvious that McPherson understood the need for an independent authority or agency to review whatever criteria might be developed for the accreditation of testing laboratories, but he determined that the time was not right for this to be initiated through government involvement. McPherson therefore left it to the laboratories themselves to perform their own self-qualification activity. As a result of McPherson's suggestions, an organization was developed shortly thereafter. That organization was, and still is, the National Conference of Standards Laboratories.[2] (As an aside, it is interesting to note that the National Conference of Standards Laboratories has over the years withstood pressures for the independent accreditation of laboratories. Furthermore, it was not until the 1990's that NCSL produced the standard, ANSI/NCSL Z540-1-1994 entitled, "Calibration Laboratories and Measuring and Test Equipment-General Requirements." That standard was developed in support of other organizational activities in the realm of accrediting calibration laboratories, not the least of which is the National Institute of Standards and Technology.)

As McPherson's suggestions may be used to consider self-qualification of testing laboratories in general, NBS/NIST itself has a history of involvement in a long-standing program which satisfies many of the criteria employed in or recommended for laboratory accreditation through peer review. As described in the paper "Construction Materials Reference Laboratories at NIST"[3] by NIST's James H. Pielert, *"In the early part of this century, a number of organizations, including ASTM, NIST, and the Portland Cement Association collaborated in activities to improve and standardize specifications and test methods for portland cement. This led to the formation of the Cement Reference Lab. as a Research Associate Program at NIST in 1929, sponsored by ASTM Committee C-1 on Cement. ASTM Committee C-9 on Concrete and Concrete Aggregates became a cosponsor in 1960, and the name was changed to the Cement*

and Concrete Reference Lab. Committees C-1 and C-9 formed a Joint Subcommittee on the CCRL to provide guidance in its operation. CCRL operates under a Memorandum of Agreement between ASTM and NIST." As another program of the NIST Construction Materials Reference Laboratories (CMRL), there is the AASHTO Materials Reference Lab. (AMRL), where AASHTO is the American Association of State Highway and Transportation Officials. Pielert tells us that "AMRL was established as a Research Associate Program at NIST in 1965, under the sponsorship of AASHTO. AMRL operates under a Memorandum of Agreement between AASHTO and NIST. AMRL's primary responsibility is to provide services that promote the uniformity of testing in construction materials testing laboratories and assist the transportation industry in obtaining reliable measurements of highway material properties. The four major functions of CCRL and AMRL are:

- *Inspection of testing laboratories,*
- *Distribution of proficiency test samples,*
- *Participation in the work of technical committees, and*
- *Studies of issues related to the testing of construction materials."*

As is evident from these events, McPherson's recommendations and the work of the CMRL at NIST, the practical technical ingredients needed to develop a laboratory accreditation system that would ensure the competence of the accredited labs were fairly well established and agreed upon at NIST in the early 1960's. More importantly, in a key segment of the economy, product and materials construction, with its high degree of standardized test methodologies, there was understanding (if not agreement) on key elements of testing laboratory accreditation among Federal, State and local government and private industry. The belief that much of the needed criteria for valid testing laboratory accreditation was already in place in the 1960's can be justified by the AASHTO Accreditation Program.[4] Established in 1988, *"The objective of AAP is to provide a mechanism for formally recognizing the competency of testing laboratories to perform specific tests on asphalt cements, cutback asphalt, emulsified asphalt, soils, aggregates, bituminous concrete, and portland cement concrete. AASHTO also recognizes a laboratory's compliance to the requirements of ASTM Practices C1077, C1222, D3666, D3740 and E329. AASHTO accreditation is available to all laboratories including independent laboratories, manufacturers' in-house laboratories, university laboratories and governmental laboratories. The AAP utilizes laboratory inspection and proficiency sample services provided by the AASHTO Materials Reference Laboratory (AMRL) and the Cement and Concrete Reference Laboratory (CCRL)."*

The citing of McPherson's recommendations and the CMRL should not suggest that the current technical and administrative criteria for testing laboratory accreditation procedures were developed only at NIST or only by NIST. Nor should it be construed that only in-house programs at NIST influenced its judgments. For the historical study of testing laboratory accreditation, we must review the work of NIST's Theodore R. Young, one of the principal procedural developers of the NIST National Voluntary Laboratory Accreditation Program (NVLAP). In his paper "History of Laboratory Accreditation,"[5] given at the 1981 Workshop on the future directions of laboratory accreditation (from which more will be cited later), the Abstract reads as follows:

"The chronological order of establishment of seventy laboratory accreditation programs is presented, including their motivation and scope of testing interest. Characteristics and historical trends of these accreditation programs are discussed with particular attention given to programs designed to serve large and/or general needs for laboratory evaluation and accreditation."

Young, who also prepared the "Summary of Workshop Proceedings" and "Summary of Post Workshop Comments,"[6] provides the following opening two paragraphs in his "INTRODUCTION:"

"A comprehensive history of testing laboratory accreditation in the U.S. would be a formidable task. One would need a reference library of the background and establishment of not only all existing accreditation programs but also those programs that may have been active in the past and that may have now passed from the scene. It is questionable that such a compendium of historical data would be of interest to many, or that it would assist the purposes of this workshop, except as a source for analysis of a characteristics and historical trends regarding laboratory accreditation in the U.S.

Mr. Charles W. Hyer, of the Marley Organization, undertook the identification and description of U.S. laboratory accreditation programs in 1978. His report, 'Principle Aspects of U.S. Laboratory Accreditation Programs,' was published by the Department of Commerce in January 1979. The information contained in that report was validated by authorities for the various accreditation programs described and has since been expanded and updated to July 1980 by Commerce's Office of Product Standards Policy, assisted by Mr. Hyer. This updated report, published by the National Technical Information Service (NTIS PB80-199086, July 1980), serves as the primary reference source for this paper. Although the report is liberal and informal regarding selection of programs termed laboratory accreditation activity and although the report is admittedly incomplete as to identification of all programs that may exist, the report provides a good basis for detecting characteristics and historical trends of laboratory accreditation in the U.S."

We are also indebted to Young's paper for its expressing, and then classifying, the "motivations" for testing laboratory accreditation. On this Young writes:

"To paraphrase an old adage, behind every successful accreditation program there is a good motivation. A good motivation inspires testing laboratories to seek accreditation and encourages laboratory users to utilize such laboratories. Motivations for accreditation programs appear to be of two basic kinds which, I suggest, lead to two types of accreditation having characteristic differences.

One kind of motivation derives from product verification needs. I have labeled accreditation programs resulting from this kind of motivation 'Type I,' and have so referenced such programs in the appendix listing. The principal parties served by such

an accreditation program are the motivation of the program and those who must have their products verified, namely the laboratory users. The viewpoints, opinions and needs of the laboratory community may be secondary to those of the principal parties in the establishment of these programs. Laboratories generally involved only to the extent that they are needed and seek accreditation by demonstrating their capability to meet the specific requirements for testing established by the program.

The other kind of motivation develops from a need to verify testing services for use by general classes of laboratory clients or by laboratory users having varied needs for testing. Accreditation programs resulting from this kind of motivation are labeled, 'Type II.' In these testing service verification programs, the testing laboratory constituency generally have a prominent or equal voice in establishing the scope, content, standards and procedures for accreditation."

Armed with a classification system which, while rudimentary, is valid and which must be understood in order to appreciate the practicality of developing a system of coordinated testing laboratory accreditation programs today, Young offered a great deal of fundamental analysis. Discussing each classification or type, he wrote:

"Fifty-four of the seventy programs listed are classified as Type I, or product verification programs. Their rate of growth since the thirty's is illustrated by the number of new programs established in each of the following decades.

Decade	*New Programs*
1931-40	*1*
1941-50	*3*
1951-60	*1*
1961-70	*20*
1971-80	*29*

Eight programs established in the sixty's are alike. They are state and local government mandatory programs for electrical product manufacturers and suppliers. It is suggested that these programs have a common source: namely, regulations referencing the National Electrical Code, section 906 which recommends use of 'nationally recognized' testing laboratories. In the absence of a national authority for recognition of testing laboratories it is likely that these programs were established to fill the void and are essentially one program operated by several states. Excluding this anomaly one may conclude that there has been an exponential growth of Type I programs in recent decades.

Typically, the laboratory user constituency of Type I programs are product manufacturers, but there may be others in the production-marketing chain, such as growers, domestic shippers, exporters and importers, packing houses, building contractors or officials. Such laboratory users are motivated to use accredited laboratories (their own or others) by federal, state, or local product regulations, by

product certification programs and procurement protocols, by international trade arrangements and by trade association product quality programs. Typically, the motivation requires or encourages the laboratory user (such as a manufacturer) to supply particular products to a defined specification, compliance to be determined by an accredited laboratory using referenced test methods. The accrediting authority for the laboratories is usually an organizational part of the entity that promulgated the motivation.

Several characteristics of these Type I accreditation programs demonstrate that the thrust of the progress is directed toward manufacturers and other product suppliers that are the laboratory users. For instance, the laboratory user constituencies of many of these programs must comply with government or private sector mandates to use accredited laboratories, however, essentially all of the Type I accreditation programs established between 1931-1980 depend upon the voluntary participation of testing laboratories."

After additional detailed analysis of the classification Type I programs, Mr. Young concluded with:

"In summary, Type I accreditation programs, whose usual objective is to assure that accredited laboratories exist to serve product assurance requirements imposed upon laboratory users, generally rely upon the voluntary participation of testing laboratories. Participation is frequently limited to commercial laboratories or other laboratories independent in relationship to the laboratory user. Other limitations, related to restricting accredited laboratories to those needed to serve the programs' objectives are sometimes imposed. Costs of accreditation services are usually borne by the accrediting authorities for government programs and by the participating laboratories in private sector programs."

Young next provided an analysis of the balance of the 70 programs reviewed with the following on Type II Programs:

"Fourteen of the seventy accreditation programs listed in the appendix are classified as Type II, or testing service verification, programs. The growth of new programs in the decades since the thirty's is shown in the following table and is note to be approximately linear since 1960.

Decade	*New Programs*
1931-40	*1*
1941-50	*1*
1951-60	*2*
1961-70	*5*
1971-80	*5*

Motivations behind this type of program are directed toward the laboratories rather than the laboratory users as in Type I programs. Typically, the laboratory constituency of these programs is public health laboratories, environmental laboratories, clinical laboratories and product testing laboratories that provide testing services directly to the public or to the government. Such laboratories are motivated to obtain approval by licensing or certification regulation, by government protocols for procurement of testing services and by peer group qualification programs. The motivation usually requires or encourages the laboratory to provide for defined disciplines, facilities, personnel, and equipment having particular qualifications; however, sometimes certain product testing competencies are specified. Similar to Type I programs, the accrediting authorities for Type II programs are usually an organizational part of the entities that provide the motivation.

Eight of the fourteen programs listed as Type II are mandatory in nature. Five mandatory programs, established in 1932, 1950, 1960, 1977, and 1978 derive from state requirements for licensing of laboratories that provide testing services for public health and for environmental, water, food, and concrete analysis. Two programs established in 1966 and 1969 serve federal licensing and certification requirements for clinical testing supporting Medicare and involving interstate commerce. One 1973 program of mandatory nature was established by the National Electrical Testing group association. Of the seven government mandatory programs for testing laboratories, only one imposes fees upon the laboratories for their accreditation (licensing): the Massachusetts program for concrete testing laboratories, initiated in 1978.

The remaining six Type II accreditation programs are voluntary in nature. Five of these programs are motivated by peer group associations or by federal procurements of testing laboratory services. The other program, started in 1951, derives from a federal-state activity to promote the quality of milk and milk products in interstate commerce. Of the six voluntary Type II programs, four impose fees upon the laboratories for their accreditations. The two voluntary programs that do not charge fees are both federal government programs.

Of the fourteen Type II programs listed, only two programs restrict accreditation to independent laboratories. Both programs accredit laboratories that seek to provide product testing services to the federal government in support of procurement activities. These two programs are also the only Type II programs that limit accreditation to laboratories on the basis of need for laboratory services.

To summarize, the Type II accreditation programs, whose usual objective is to assure that adequate testing services exist to serve the public or the government, frequently mandate the participation of testing laboratories subject to their authority. Participation of testing laboratories in mandatory and voluntary forms of Type II programs is usually open to all interested testing laboratories, regardless of their organizational structure or the public need for their services. As with Type I programs, costs of Type II accreditation

programs are usually borne by the accrediting authority in government programs and by participating laboratories in private sector programs."

By reviewing Young's analysis by years of both Type I and Type II programs, it becomes evident that NIST first had experience of its own in what was necessary for evaluating the competence of testing laboratories, especially of the Type I variety of laboratory, by the end of the 1961-170 decade. Furthermore, representing the basic measurement authority in the United States, NIST personnel were certainly to some degree aware of other programs, such as those analyzed by Ted Young. This prior knowledge and experience on the part of NIST are essential to the understanding of the development of procedures for NIST's National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP and the private sector accreditation program it spawned, the American Association for Laboratory Accreditation (A2LA) became the dominant testing laboratory accreditation programs for general needs. (For the record, A2LA is now the preferred acronym or initialization of the association as it affords a preferred pronunciation to that of the obsolete AALA.) Again, Young's paper, concluding under the caption "Accreditation Programs For The General Need--AALA and NVLAP," provides us with a specific history – to 1981 – without which an understanding of where we are with testing laboratory accreditation in the United States today is virtually impossible.

"In its planning state the National Voluntary Laboratory Accreditation Program (NVLAP), established in 1976, evolved from a government-private effort to accredit laboratories for classes of technology to a government program that accredits laboratories on a product-by-product basis or an associated service basis where the product or the service is defined by standards and test methods. In its present form NVLAP could have difficulty in establishing the kinds of Type II accreditation programs where the technical discipline to be served is not defined regarding the standards and test methods to be employed. The American Association for Laboratory Accreditation (AALA), established in 1978, retains the original intent of NVLAP to accredit laboratories on the basis of broad technical competencies. With this policy AALA could have trouble in establishing the kinds of Type I programs that are concerned with specific products, specifications, and test methods. As will be shown in another paper the problems of accommodating interest in specialized accreditation and interest in more generalized accreditation are not unique to the testing laboratory field. It appears that users of accredited institutions favor specialized accreditation program. Institutions subject to accreditation prefer accreditation in broader areas. As NVLAP's original plan was similar to that of AALA's and was then revised, a brief history of NVLAP's establishment should be reviewed.

Around a decade ago, various interests saw the need for a nationally based program to serve the general need for evaluation of laboratories. A conference of some 150 representatives from approximately sixty federal, state and private organizations and agencies met at the National Bureau of Standards, NBS, in September 1970 to consider the need and viability of a national program for evaluation and accreditation of laboratories.

An ad hoc committee, established by the conference and consisting of leaders in the standards, laboratory, product certification and procurement communities, completed in December 1970 a 'Concept of a National System for Laboratory Evaluation and Accreditation.' The concept visualized a private or quasi-public national board of accreditation composed of affected interests, the board to be assisted by technical and advisory committees from standards, laboratory and user communities. Government support in the form of technical, legal and financial assistance would be required. The system would provide inspection-evaluation of technical competencies for fees to all laboratories upon their request, and on the basis of he results of such evaluations would provide accreditations to those laboratories that serve a general clientele or the government. At its last meeting in March 1971 the committee declined to identify a lead organization for establishing the system; the committee recommended that NBS focus interest in the system and its development.

The 'Concept' document serves as a focus of discussion by many interests in the period 1971-1973. Many of these government and private interests met together at NBS in February 1973 and recommended the following:

> *the system should be quasi-public;*
> *the system should have no regulatory power;*
> *no federal legislation should be enacted or encouraged;*
> *the system should serve primarily the needs of laboratories that serve the public or the government;*
> *the system should offer more than an assessment of technical capability, namely an assessment of ability to determine product conformance to recognized standards; and*
> *criteria for judging performance of a laboratory should be established by existing standards-making bodies.*

The group, in response to ASTM and NBS proposals, concluded that ASTM should accelerate development of laboratory evaluation criteria and that NBS, with approval and support of the Commerce Department, should look into various alternative ways of establishing the system; incorporation by an independent private body; a federal charter for a quasi-public entity, government establishment under a formal administrative rule.

Promulgation in September 1973 of controversial OSHA regulations for laboratory accreditation and Congressional letters in early 1974 endorsing and proposing legislation for a national system of laboratory accreditation stimulated greater interest of the private sector and federal agencies, particularly the Department of Commerce. With concurrence of the Office of Management and Budget, the Secretary of Commerce responded to Congressional inquiries in April 1974, announcing that the Department was considering the establishment of a pilot program capable of being extended on the basis of experience and need. Proposed procedures for a National Voluntary Laboratory Accreditation Program were published in the Federal Register in May of 1975. The proposed procedures provided for the establishment of laboratory accreditation

programs for classes of technology on the basis of need, significant user constituency and identifiable product standards and testing functions. For each laboratory accreditation program, a board of accreditation composed of federal employees aided by an advisory committee of private individuals, would identify standards, and evaluation criteria and examine qualifications and recommend accreditation actions for evaluated laboratories. Thereafter, the proposed procedures were revised in two major aspects in response to extensive public comment:

> *–laboratory accreditation programs for classes of technology were deleted in favor of programs for specific product and associated service areas. Many public comments stressed the importance of establishing laboratory accreditation programs only for well defined needs. The public comments illustrated that needs varied for different products within a class of technology, thus making a justification of need unlikely across an entire class of technology; and,*
> *–boards of accreditation of federal personnel aided by advisory committees of private individuals were deleted in favor of a single advisory committee for each laboratory accreditation program. The advisory committee would be composed of government and private individuals and would function to develop and recommend criteria for the accreditation of laboratories. Considerable public criticism concerned the lack of private individuals on the proposed board of accreditation. As some of the proposed functions of the boards of accreditation were operational rather than advisory or consultative in nature, the appointment of private individuals to the boards was not legally possible without enabling legislation.*

Procedures for NVLAP were published in the Federal Register in February 1976 and NVLAP became an item in the federal budget in the following fiscal year. In recent years, formal actions have been taken to harmonize criteria for programs established under NVLAP and to allow for participation of all interested parties in the development of accreditation criteria. Optional procedures have also been promulgated for federal agencies seeking to establish NVLAP accreditation programs under their existing authority and for the private community which may wish to establish programs under NVLAP, having first justified the need in accordance with appropriate due process procedures."

Some amplification of the information provided in Young's paper may be helpful. The September 1970, conference at NIST to consider the idea of a national laboratory accreditation program was also covered in "Section III –Testing Laboratory Accreditation" of the "Report on Voluntary Standards and Testing Laboratory Accreditation," submitted to the Office of Management and Budget on July 8, 1977.[7] Here we have an augmentation, three years earlier, that may help to emphasize the degree of interest aroused by the concept.

> *" In 1969, the American Society for Testing and Materials requested that NBS participate with ASTM and other interests in establishing a Testing Agency Inspection Service that*

would provide testing laboratory examination services over a broad range of product areas wherever the need developed. In the same year the National Conference of States on Building Codes and Standards asked NBS to develop evaluation criteria and examination methodology for determining the capability of agencies that test and certify mobile homes, then being produced at the rate of several hundred thousand per year. In response to the States' request, drafts of criteria and methodology were prepared and submitted to development into consensus standards. The ASTM proposal for a Technical Inspection Service led to an NBS study. This supported the ASTM proposal but suggested that the developing needs of domestic and international commerce and the public health and safety would be benefited by a means that would also provide a public recognition of testing laboratories found qualified on the basis of such inspections."

From this point on, this report and Young's later detailing, are essentially duplicated. However, as the "Report on Voluntary Standards and Laboratory Accreditation" was at the time in the form of recommendations to OMB, it is worth examining what that report referred to as a resultant:

"Need: The Department of Commerce has no authority to require anyone, including government agencies needing such services to use the NVLAP. This limitation, in some cases, extends to a veto power for government agencies. This is expressly recognized in section 7.4(d) of the NVLAP procedures wherein the Secretary will not consider a request for a finding of need to establish an accreditation program which would affect an existing or developing testing laboratory examination or accreditation program of a Federal regulatory agency if that agency object thereto.

We believe that all agencies needing laboratory accreditation services should be required, where feasible to use NVLAP. Further, the Secretary should be given responsibility, under NVLAP, to coordinate all laboratory accreditation programs conducted by the Federal Government. One Federal agency, serving to implement and/or coordinate the accreditation of testing laboratories would promote the efficient utilization of Federal resources. Such a requirement would promote uniformity of criteria and examination procedures used to inspect and evaluate laboratories. NVLAP would provide a focus for review of government effectiveness in assuring adequate laboratory performance of requirements of government standards and regulations. As a focus, NVLAP would provide a central information link of substantiated data regarding laboratory facilities, competencies and capabilities, thus reducing the spread of duplicative laboratory examination and accreditation programs. It would also avoid the problem of a Federal agency specifying one or two testing laboratories that now have good reputations but whose dominant positions raise serious equity questions."

Returning to Ted Young's report on the meeting of February 1973 at NBS, which resulted from the focus of the 1970 "Concept of a National System for Laboratory Evaluation and Accreditation," two recommendations were specifically endorsed and are repeated here for emphasis. The first reads: *"the system should serve primarily the needs of laboratories that serve the public or the government,"* and the second *"the system should offer more than an assessment of technical capability, namely an assessment of ability to determine product*

conformance to recognized standards." These statements reflect the position of member laboratories and supporters of the American Council of Independent Testing Laboratories (ACIL), now known by its acronym ACIL. Its members, some of which also sponsored, operated and/or verified product certification programs, were early-on proponents of a National System for Laboratory Evaluation and Accreditation.

ASTM's encouragement for NIST to develop a "Testing Agency Accreditation Service," as mentioned in the Ellert/Eicher Report to OMB noted above, is attributable to the influence of ACIL members who sought a means, based on the Federal Government's credibility, of providing evidence of independent organizational status and technical equivalency with the two standards-writing organizations/certification agencies that dominated the product safety testing and certification field, the Underwriters Laboratories and Factory Mutual Research Corp. Their dominance was based on reputation earned through testing and product certification related to the National Fire Protection Association's National Electrical Code (NEC), the code most commonly adopted by State and local authorities having jurisdiction for code enforcement. In the absence of coordination among State or local government code authorities to provide a national means of establishing equivalency to UL and FM, independent potential competitors hoped that NIST could accommodate them. The idea of a Testing Agency Accreditation Service, or NVLAP, that would not only attest to a testing organization's technical competency, but would also "recognize its ability to determine product conformance," was part of the ACIL labs' quest. They also sought help from the newly established Occupational Safety and Health Administration (OSHA) of the Department of Labor, which developed and in 1973 proposed an accreditation system that, following OSHA acceptance, would provide a list with wording such as "including – but not limited to – UL and FM." Both NVLAP and OSHA were besieged on a number of fronts. First, some laboratories could demonstrate testing competency, but did not qualify as equals to UL and FM as "independents." Then there were the manufacturers who saw in such a national system of accreditation the development of mandatory requirements for third party product certification from a proliferation of government accredited resources. Many variations on these themes surfaced, and conferences and meetings and actions of various types by Federal, State and local government, as well as the private sector, were activated. NIST ultimately moved to the Type I motivated accreditation described by Ted Young.

The ACIL, with financial support from ASTM, organized A2LA as an alternative to NVLAP. Initially intended to accomplish more than evidence of technical competency, A2LA soon adopted an accepted limitation to a Type II technical competence, which is now the hallmark of both A2LA and NVLAP.

It was another decade before the proposed accreditation program at OSHA was reinvented, established, and implemented as its current Nationally Recognized Testing Laboratory (NRTL) program. The NRTL program, which limits recognition to third party testing laboratory organizations (such as but not limited to UL, FM) that also operate safety product certification programs using OSHA adopted standards, is an example of how difficult and controversial laboratory accreditation can become when more than assurance of technical competence is contemplated. The NRTL program, as well as similar others, could serve to reduce the number of different laboratory accreditation programs in the area of product safety. This could be

accomplished if OSHA were to employ NVLAP as its accreditor for testing competence and assessing the laboratories that meet the appropriate prerequisites. Since OSHA's NRTL program has long labored under budgetary restraints, this mechanism would permit OSHA to conserve its resources. Many laboratories that are now unable to apply for NRTL could become accredited under a NVLAP electrical safety program. The cost of accreditation would then be borne by those seeking accreditation, rather than by the government.

The decade commencing in the early 1970's saw many efforts that intertwined the focus on accreditation of testing laboratories with other, clearly separate, elements of conformity assessment. This period also saw the introduction of considerations of international trade and U.S. competitiveness, which is now a major motivation for harmonization of standards and regulatory conformity assessment activities. We should at least mention some of the many activities that encompassed laboratory accreditation following the establishment of NVLAP.

In the international voluntary standards arena, U.S. private sector interests were for some time concerned in various ways with conformity assessment matters, including testing laboratory accreditation. However, although most other national participants were quasi-governmental or government participants, the U.S. Government was not a recognized participant. In 1977, the first International Laboratory Accreditation Conference (ILAC) was held in Copenhagen. The U.S. Government became an important participant when the Department of Commerce's Office of Product Standards Policy hosted the 1978 Conference. These first two ILAC conferences dealt with exchanges of information on national systems of accreditation of testing laboratories. ILAC has since then developed into the key international standards body that addresses the subject of testing laboratory accreditation. The U.S. delegations have been headed by Department of Commerce (more recently NIST) officials, but have included a number and variety of interested private sector delegates.

It may be noted that an early ILAC "Task Force A" circulated an international "Questionnaire" calling for the "Analysis of Legal Problems Raised by The Recognition of Laboratory Accreditation Systems." Howard I. Forman, Deputy Assistant Secretary of Commerce for Product Standards, provided the U.S. response, dated April 27,1979.[8] The compilation for this document was supervised by Dr. Forman, a noted U.S. attorney, and its contents, as stated in the Foreword *"represents an initial comprehensive attempt to furnish a useful description and analysis of the laws and regulations pertaining to existing laboratory accreditation programs in the United States."* With the permission of its author, Mr. Albert N. Sheldon, Deputy Attorney General, California Department of Justice, Forman included the paper "Tort Liability of Independent Testing Agencies," which continues today as an important reference on the subject.

Most of ILAC's standardization development actions have become internationally accepted documents, such as ISO/IEC Guides promulgated through the International Organization for Standardization's (ISO's) Council Committee on Conformity Assessment (CASCO). Most CASCO Guides are endorsed by the International Electrotechnical Commission (IEC). Therefore, ISO/IEC Guides concerning aspects of testing laboratory accreditation formulated in ILAC and promulgated by ISO have become internationally accepted criteria for testing laboratories. It should be noted that in the United States, the voluntary standards development

focus for laboratory accreditation was established in ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies in 1973. This committee, ILAC, and CASCO (the latter two on the international level) have developed criteria standards for testing laboratory accreditation which have been essentially universally accepted. While other conformity assessment criteria remain at times controversial, standardization of the process for accrediting testing laboratories is no longer an issue. There is still a need for U.S. focus on other voluntary standards related to conformity assessment activities, notably product certification, and this has led to a wider current scope for the ASTM Committee, which has changed it title to ASTM E-36 on Conformity Assessment.

The great interest in testing laboratory accreditation generated about the time that NVLAP began its operations may be exemplified by a few specific studies and reports.

A National Conference on Testing Laboratory Performance: Evaluation and Accreditation was held at NBS on September 25-26, 1979.[9] One of the principal papers given at this Conference was titled "Laboratory Accreditation -- State-of-the-Art in 1979," by John W. Locke, then of the Department of Commerce's Office of Product Standards Policy. His paper's summary is worth noting:

> *"Laboratory accreditation systems which formally determine and recognize that a laboratory has the capability to carry out specific tests or types of tests are increasing in number and in number of laboratories examined and accredited. The need for such systems can be traced to the growing need for laboratory testing in general. These systems are being developed normally to facilitate both national and international trade. Fifty-six laboratory accreditation systems were recently examined in a Department of Commerce study. Only 2 of the systems existed in 1947. By 1970 the number had grown to 33, and by 1978 the number was 56 with a significant portion of this increase occurring in 1977 and 1978. Over 5,500 laboratories are formally recognized by these systems and, since many of the systems are new, this number should increase substantially in the 80's. There is also a growing interest in the international recognition of national accreditation systems. Public and private sector coordination to promote acceptance of accreditation criteria and consolidation of accreditation systems is a growing need."*

In addition to its prophetical contents, this summary is notable from two points of view. First, the proceedings in which the Locke paper is contained concluded with a "Proposed U.S. Position Paper For The Third International Conference on Recognition of National Programs For Accrediting Testing Laboratories (ILAC) for Sydney, Australia, October 22-26, 1979." Secondly, Locke introduces the concept that "Public and private sector coordination" may be seen "to promote acceptance of accreditation criteria and consolidation of accreditation systems" as "a growing need."

The Department of Commerce Office of Product Standards Policy (OPSP), later transferred to NBS, contracted for several reports, two of which indicate the sensitivity which that office was

showing toward the international trade challenges for industry and the role of testing laboratory accreditation.

The first was a report by Roger J. Amorosi, entitled "Assistance to U.S. Exporters by Increased Foreign Acceptance of U.S. Test Results and Certifications."[10] It identified 18 U.S. industries (different products, materials or services) which had export problems related to foreign acceptance of U.S. test results or U.S. certifications, or where U.S. test methods differed from those in a foreign country. These non-tariff barrier export problems were explained and categorized. The sources of information included contacts with trade associations, individual companies, and government agencies. Unfortunately, the report, which was presented as a series of survey questions and answers, failed to differentiate between product certification problems and test result acceptances for the most part. The survey's key question: *"Please recommend steps if taken by the U.S. Government that would be helpful"* elicited many traditional industry attitudes on government "assistance." However, some responses, typified by the following, indicated the growing recognition of a need for government involvement:

> *"Establish reciprocity of test data for certified products. Set up government inspection system to accredit certification data."*
> *"Assistance is needed in a mutual reciprocal acceptance of the various national pressure vessel codes."*
> *"Negotiate reciprocal agreements with the countries for acceptance of tests and certifications. This might require a central approval system for test data and certifications with the U.S."*
> *"Reciprocal agreement to accept test data."*

The Amorosi report was followed shortly thereafter by Ted Young's "A Comparative Survey of U.S. and Foreign Criteria for Accrediting Testing Laboratories."[11] The report "Purpose" was given as *"This study reports on a survey of criteria documents used by 24 federal government, foreign, and private association laboratory accreditation systems which accredit laboratories that test products or provide services (such as clinical analysis). The purpose of this study is to illustrate the nature of such criteria, the degree of standardization achieved, and to search for additional directions or opportunities that would further the standardization of laboratory accreditation criteria."*

In May of 1981, in a letter to Dr. Forman, Roger J. Amorosi, then President of ACIL, suggested that the NVLAP program be phased out in favor of NIST accrediting private sector testing laboratory accreditation programs, such as A2LA. In July of the same year, Louis R. Rossi, Chairman of A2LA, made a similar request to Dr. Stanley I. Warshaw, Director, Office of Engineering Standards at NIST, under whose direction NVLAP operated. The basis for these requests was that the private sector, with its general approach to accreditation (i.e, class of test, rather than NVLAP's standard-by-standard assessment criteria) would be more expedient for users and less costly for the accredited laboratories. With NIST oversight, the same degree of assurance as that offered by the NVLAP program would result. It became commonly referred to as the "accrediting the accreditors" approach. The aforementioned NBS Special Publication 632 reports the proceeding of the Public Workshop held on November 16-17, 1981, to discuss

"Laboratory Accreditation: Future Directions in the United States." Its purpose, as stated in the Federal Register Notice announcing the meeting, was *"to provide a public forum for the expression of views upon which recommendations could be developed to bring about a desirable and effective distribution of responsibilities between the government and private sectors in the area of laboratory accreditation."* As Part I of SP 632, Summary of Workshop Proceedings, indicates *"The workshop was organized according to the program description...with five sessions interspersed with discussion sessions. In each session, oral presentations or summaries of formal invited papers...were presented to generate questions and discussions from attendees. The questions and discussion periods were taped and transcribed. Opportunity was also provided for attendees to present formal written statements."* The formal statements were analyzed by Ted Young as a "Part 2 Summary of Post Workshop Comments." Never before -- and not since this in 1981 -- has the subject of NIST involvement in laboratory accreditation been so thoroughly and publicly discussed. Sixty-two percent of the responses to the question *"Whether the DOC should abandon its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector laboratories"* supported the continuation of the NVLAP program. A number of excellent suggestions were provided to the question of what *"additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements."* Among the other suggested approaches to international laboratory accreditation were:

> *"•The private sector should seek involvement in international laboratory accreditation when it is economically attractive or of interest to the voluntary standards system. Government involvement should be limited to intergovernmental actions.*
> *• The American National Standards Institute and DOC should collaborate to promote mutual acceptance of the various mandatory and voluntary approaches of participating countries.*
> *•DOC should retain an international involvement regarding laboratory accreditation while seeking a mechanism for mutual approval of test*
> *•Reciprocal agreements should be arranged with foreign countries providing for acceptance of test results rendered by NVLAP accredited laboratories.*
> *•NVLAP should be publicized as an NBS program, to better enhance NVLAP's worldwide acceptance."*

On the question of action that might be taken by the private sector and/or the Government to reduce the proliferation of accreditation activities in the United States, among the responses were:

> *"•NVLAP should seek reciprocity with credible existing programs.*
> *•NVLAP should accept responsibility for recognizing credible existing programs on request.*
> *•NVLAP should encourage Federal, State and local interests to utilize NVLAP*
> *•NVLAP accreditation of a test method under one accreditation program should be recognized under other NVLAP programs.*
> *•NVLAP should reduce the amount of paperwork required.*

•National building code groups and organizations listing laboratories should be urged to utilize NVLAP."

From the close of the NBS Workshop on Laboratory Accreditation in November 1981 until the passage of P.L. 104-113, The National Technology Transfer and Advancement Act (NTTAA) of 1995, and more specifically the NIST Plan for Implementation called for by P.L. 104-113, the subject of the direction of testing laboratory accreditation in the United States has rarely been considered separately from other conformity assessment issues. That is to say, testing laboratory accreditation as it affects or is affected by product certification and quality system management has dominated considerations, public and private, governmental and non-governmental. Private sector testing laboratory accreditation/designation programs have proliferated,[12] as have those of government agencies at all levels.

The NIST Office of Standards Services periodically publishes standards-related documents with basic information. One series commenced with a primer on U.S. standards activities[13] in 1987, provided a primer on Certification Activities[14] in 1988, and got around to Laboratory Accreditation with NIST SP 808 Directory of Federal Programs[15] and a primer on Laboratory Accreditation in 1991.[16] It remained for the study report of the National Research Council of the National Academies of Sciences and Engineering, prompted by a Congressional P.L. 102-245 mandate, to set in motion another approach to testing laboratory accreditation. This was accomplished by the study's report[17] "Standards, Conformity Assessment and Trade Into the 21st Century." More specifically, the recommendations in the Report "to Address Future Challenges and Opportunities" led directly to Congressional action in the National Technology Transfer and Advancement Act. The first two are key recommendations:

" 1. Congress should provide the National Institute of Standards and Technology (NIST) with a statutory mandate to implement a government-wide policy of phasing out federally operated conformity assessment activities.
NIST should develop and implement a National Conformity Assessment System Recognition (NCASR) program. This program should recognize accreditors of (a) testing laboratories, (b) product certifiers, and (c) quality system registrars. By the year 2000, the government should rely on private sector conformity assessment services recognized as competent by NIST.

2. NIST should develop, within one year, a ten-year strategic plan to eliminate duplication in state and local criteria for accrediting testing laboratories and product certifiers. NIST should lead efforts to build a network of mutual recognition agreements among federal, state and local authorities."

From these two recommendations one can see that the NTTAA passed by Congress was designed to set in motion the development of what may be termed a U.S. system of conformity assessment, with emphasis on private sector-involvement, based loosely on the NRC Report. The Report and its recommendations will undoubtedly significantly affect U.S. conformity assessment for years to come. However, for specific consideration of testing laboratory accreditation, the Report's extensive bibliography does not list NBS Special Publication 632, and

the absence of its history could condemn any plan to repeating and re learning the hard lessons it teaches.

P.L. 104-113 was signed by the President on March 7, 1996. The Act directs NIST, among other things, *"to coordinate Federal, State and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures."* It further directed NIST to *"within 90 days after the date of enactment of this Act, transmit to the Congress a plan for implementing the amendments made by this section."*

The NIST "Plan for Implementation" was duly completed. Under Laboratory Accreditation - Specific Activities, NIST collaborated with ANSI and ACIL to establish a Laboratory Accreditation Working Group (LAWG) to evaluate the current situation in laboratory accreditation in the United States. This LAWG group sponsored a Forum[18] on October 13,1995, to hear reports from various sectors and to arrive at some consensus on the need to improve the current situation and infrastructure for laboratory accreditation in the United States.

At that Forum, this paper was conceived to become a review of the history of testing laboratory accreditation in the United States, and from the study of that history offer a few generic suggestions that might help the community to avoid repeating endless argumentation and continued inefficiency.

Here are a few suggestions for the developing National Cooperation on Laboratory Accreditation (NACLA):

Stop using the expression ONE-STOP anything; the task is too complicated to be aided by slogans.

NIST should aggressively pursue obtaining OMB support for its Conformity Assessment Activities in order to properly coordinate Federal agency consolidation of testing laboratory accreditation.

All interests should reflect on statements made over the years and face up to the practical need to join the words COORDINATION WITH CONSOLIDATION.

Commercial testing laboratories and manufacturer/supplier interests must be satisfied with testing laboratory accreditation as establishing a laboratory's technical competence, period. It is the attempt to introduce a link between the quality of test data and the acceptance of the product tested that has set back coordination/consolidation.

Laboratory accreditation potentially represents job security and commercial income for many individuals and companies, therefore both the government and private sector authorities should be mindful of time and cost resources.

To sum up, consider all interests in testing laboratory accreditation as players in a game entitled to equal consideration, but responsible individually to play by all of the rules. Exceptions based on economic clout - or lack thereof - must not be considered, and trading off interests for the bigger picture won't work in the long run.

[1] A. T. McPherson, Plan for The Self-Qualification of Laboratories, ASTM Bulletin, **245** (May 1960).
[2] National Conference of Standards Laboratories (NCSL) is located at 1800-30th Street, Suite 305B, Boulder, CO 80301.
[3] ASTM Standardization News (December 1989).
[4] AASHTO Material Reference Laboratory, NIST, Bldg. 226, Room A365, Gaithersburg, MD 20899.
[5] J. W. Locke, ed., Laboratory Accreditation: Future Directions in the United States, Proc. of Workshop, November 16-17, 1981, Natl. Bur. Stand. (U.S.) Spec. Publ. 632 (1982).
[6] T. R. Young, Natl. Bur. Stand. (U.S.) Spec. Publ. 632.
[7] R. B. Ellert, Assistant General Counsel for Science and Technology, Department of Commerce, and L. D. Eicher, Manager, Standards Information and Analysis Section, National Bureau of Standards.
[8] H. I. Forman, U.S. Department of Commerce, U.S. Reply to Questionnaire of Task Force A, Analysis of Legal Problems Raised by The Recognition of Laboratory Accreditation Systems, to International Conference on Recognition of National Programs for Accreditation of Testing Laboratories (ILAC) (April 27, 1979).
[9] G. A. Berman, ed., Testing Laboratory Performance: Evaluation and Accreditation, Proc. of Natl. Conf., Natl. Bur. Stand. (U.S.) Spec. Publ. 591 (April 1980).
[10] R. J. Amorosi, Assistance to U.S. Exporters by Increased Foreign Acceptance of U.S. Test Results and Certification, Roger J. Amorosi Associates, Inc., National Technical Information Service PB 80-210156 (July 9, 1980).
[11] T. R. Young, A Comparative Survey of U.S. and Foreign Criteria for Accrediting Testing Laboratories, Natl. Bur. Stand. (U.S.) Grant 79NAAB5388 (January 1981).
[12] C. W. Hyer, ed., Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs, Natl. Inst. Stand. Technol. (U.S.) Spec. Publ. 831 (March 1992).
[13] M. A. Breitenberg, The ABC's of Standards-Related Activities in the United States, Natl. Bur. Stand. (U.S.) IR 87-3576 (May 1987).
[14] M. A. Breitenberg, The ABC's of Certification Activities in the United States, Natl. Bur. Stand. (U.S.) IR 88-3821 (July 1998).
[15] M. A. Breitenberg, Directory of Federal Government Laboratory Accreditation/Designation Programs, Natl. Inst. Stand. Technol. (U.S.) Spec. Publ. 808 (February 1991) .
[16] M. A. Breitenberg, Laboratory Accreditation in the United States, Natl. Inst. Stand. Technol. (U.S.) IR 4576 (May 1991).
[17] Standards, Conformity Assessment and Trade into the 21st Century, National Academy of Sciences, 2101 Constitution Ave., NW, Washington, DC 20055 (1995).
[18] W. Leight and L. Galowin, eds., Proceedings of the Open Forum on Laboratory Accreditation at the National Institute of Standards and Technology, October 13, 1995, Natl. Inst. Stand. Technol. (U.S.) Spec. Publ. 902 (June 1996).