EVALUATION AND ACCREDITATION OF INSPECTION AND TEST ACTIVITIES

Harvey Schock, *editor*

ASTM STP 814

EVALUATION AND ACCREDITATION OF INSPECTION AND TEST ACTIVITIES

A symposium
sponsored by ASTM
Committee E-36 on
Criteria for the Evaluation
of Testing and Inspection
Agencies
Washington, D.C., 28–29 April 1981

ASTM SPECIAL TECHNICAL PUBLICATION 814
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Product Assurances Consultant

ASTM Publication Code Number (PCN)
04-814000-32

1916 Race Street, Philadelphia, Pa. 19103

Library of Congress Catalog Card Number: 82-74447

ISBN 0-8031-0253-4

NOTE

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Printed in Baltimore, Md. (b)
August 1983

Second Printing, Baltimore, Md.
May 1985

Foreword

The symposium on Evaluation and Accreditation of Inspection and Test Activities was presented in Washington, D.C., 28–29 April 1981. The symposium was sponsored by ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. Harvey Schock, Product Assurances Consultant, presided as symposium chairman and editor of this publication.

Related ASTM Publications

Directory of Testing Laboratories, 6th edition, STP 333E (1982), 04-333050-32

The ILAC Directory (International Directory of Testing Arrangements and Testing Laboratory Accreditation Systems), 1982, 13-117082-32

Computer Automation of Materials Testing, STP 710 (1980), 04-710000-32

Computerized Laboratory Systems, STP 578 (1974), 04-578000-34

A Note of Appreciation to Reviewers

The quality of the papers that appear in this publication reflects not only the obvious efforts of the authors but also the unheralded, though essential, work of the reviewers. On behalf of ASTM we acknowledge with appreciation their dedication to high professional standards and their sacrifice of time and effort.

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Introduction

Growing complexities in testing and inspection have resulted in the need for a clear base to communicate information and criteria on actual capabilities and performance of testing and inspection agencies. Facts are required for business transactions and in capability reviews of outside party skills especially for new technologies. These facts are also useful as part of formal contracts and international understandings and treaties.

Proper use of evaluation and possibly resulting accreditation facts and practices should permit benefits without permitting systems to grow beyond commensurate value to concerned parties and the public. Obviously such systems should not impose any unnecessary restraints or release proprietary information.

To better understand these opportunities, an international Symposium was held in Washington on 28–29 April 1981, providing a forum for the exchange of experiences on benefits and problems encountered with evaluation and accreditation in the United States and in several other countries.

This publication provides papers presented at the Symposium arranged according to:

1—Evaluation and Accreditation Concepts.
2—Laboratory Applications and Computer Systems.
3—Evaluation and Accreditation in Government.
4—International Evaluation and Accreditation.

The development and use of evaluation and accreditation are growing rapidly in the United States and on a bilateral and multinational base internationally. This Special Technical Publication provides background to encourage participation in the further development of necessary standards and practices. Interested parties are cordially invited to participate in the generic work of ASTM Technical Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies and in the specific work of many other committees working on the development of national and international standards and their application to products and methods.

The assistance of the authors, reviewers, and ASTM staff in the presentation of this material has been appreciated. Your interest and successful ap-

plication of this information is ample reward to all of those involved in this effort.

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Evaluation and Accreditation Concepts

D. M. Dymond[1]

Some Viewpoints on Evaluation/Accreditation Systems

REFERENCE: Dymond, D. M., **"Some Viewpoints on Evaluation/Accreditation Systems,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 5–10.

ABSTRACT: This paper describes the early development of ASTM Standard E 548, Recommended Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies. It describes some of the essential concepts developed by Committee E-36 and its task forces and shows how these concepts relate to the work of other ASTM committees and to national and international accreditation programs. He defines the goals of a successful accreditation system as (1) credibility and (2) acceptance. He hopes that ASTM through its Committee E-36, working with the other ASTM committees and outside organizations, can provide national and international leadership in the development of accreditation systems.

KEY WORDS: laboratory accreditation, systems evaluation, laboratory evaluation

The purpose of this paper is to provide information concerning some of the essential concepts developed by Committee E-36 and its task forces and to show how these concepts relate to the work of other ASTM committees and to national and international accreditation programs. The overall objectives and outline of the work program of ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies are described in the paper by G. A. Berman beginning on page 11.

The Resources Task Group that originally structured ASTM Recommended Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies (E 548) was formed in 1973 and consisted of representatives from a number of organizations including testing laboratories, inspection agencies, associations, governments, and public interest groups. The representatives of testing laboratories included those from industry and from independent laboratories.

Documents issued by the American Council of Independent Laboratories, the National Bureau of Standards, the College of American Pathologists,

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and the Occupational Safety and Health Administration were used as reference materials by the original Resources Task Force.

During the discussions that lead to the formulation of ASTM method E-548–76, it was recognized by the Resources Task Force that a comprehensive approach to standardization in the evaluation of testing and inspection agencies should be undertaken by ASTM. The Appendix to the first edition of E-548 issued in 1976 reflected those concerns. The Resources Task Force was disbanded in 1976 when the first edition of E 548 was published.

The following statements were included in the Apendix to E 548–76:

> These basic criteria should be supplemented by more specific criteria and requirements for each particular class of testing and inspection agencies. Since this document is only a part of an ultimate system of judgement, it cannot be used in isolation. For specific services or applications the document (E548–76) must be supplemented by additional criteria.

This theme was taken a step further in 1978 when a new task force was appointed by Committee E-36 to review and report on future plans, programs, priorities, and resources. This new Task Force recommended a "framework" for an effective system for accrediting testing or inspection agencies. The framework developed by the Task Force took the form of a *triangle* consisting of four levels.

The apex of the triangle was an "overall systems document," which stated the scope and purpose of an accreditation system, and specified documentation, follow-up, and requirements for appeals and redress. The second level of the triangle would hold two documents: E-548 covering "accreditees" and a new generic standard for "accreditors." The third level of the triangle would include documents by discipline, field, or product and would provide specific guidance in the application of an accreditation system. The fourth level, or base of the triangle, would include the detailed methods of test, inspection, and evaluation of those materials, products, and processes covered under the accreditation system. This framework is outlined in Fig. 1.

When the Task Force was preparing its recommendations, a detailed study was made of accreditation systems, not only in North America but also in Australia, New Zealand, and other countries. By 1978, a number of public and private accreditation systems either were operating or were under development in several countries, including the United States. Within ASTM several technical committees also had activities underway related to the objectives of E-36.

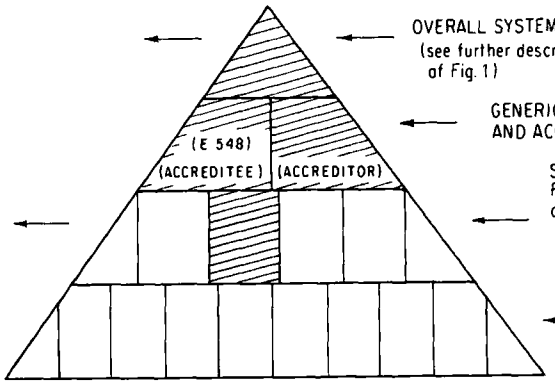
In 1980, another task force was established by Committee E-36 to develop the criteria for a model accreditation systems document (that is, the apex of the triangle) and the generic criteria for assessors. Work on these two docu-

NOTE 1: OVERALL SYSTEM DOCUMENT COVERS:

- Scope of system
- Purpose of system
- Criteria for accreditor
- Criteria for follow-up
- Procedures for appeals and redress

NOTE 2: SPECIFIC GUIDELINES DEVELOPED:

- Either through E 36, providing coordination and assistance to committees of ASTM (and other organizations) via guide details on organization, material resources, human resources, quality systems, and procedures and results
- Or through E 36, preparing guidelines in discipline or field or product category, upon request, provided the description of the discipline/field/product is acceptable to E 36 and fits into the overall E 36/ASTM organizational objectives. These guidelines would provide a meaningful response to a demonstrated need if suitable expertise can be obtained to assist in the preparation of the requested guidelines



OVERALL SYSTEM DOCUMENT (NEW)
(see further description at other side of Fig. 1)

GENERIC CRITERIA FOR ACCREDITOR (NEW) AND ACCREDITEE (E 548)

SPECIFIC GUIDELINES DISCIPLINE/ FIELD/PRODUCT(S) (For further description, see Notes 1 and 2)

DETAILED METHODS OF TEST/INSPECTION/ EVALUATION OF MATERIAL/PRODUCT/ PROCESS (including procedures relative to their application in the overall accreditation system if not included in the specific guidelines referenced above)

FIG. 1—*The accreditation of testing or inspection agencies or both: a recommended framework for an evaluation system. An Accreditation System is viewed as being composed of a series of documents serving various levels of need, starting with an overall system statement (represented by the apex of the triangle) and ending with detailed testing/inspection/evaluation methods (represented by the base of the triangle). It is considered that Committee E-36 should develop the outline of an overall system document (such as NVLAP) and the two basic or generic accreditation standards (E 548 for those being accredited; and a new standard for those doing the accrediting). Committee E-36 also might be involved in the preparation of guidelines by disciplines/field/products or alternatively would provide assistance and coordination (via direct consultation with the technical committees of ASTM and other concerned organizations) who are prepared to develop such guidelines as appropriate. The detailed standards or test methods used in the testing/inspection/evaluating procedure are provided by the appropriate technical committee of ASTM or other concerned organizations. The shaded areas pertain to E-36 generated documents; the unshaded areas refer to document generated by other committees.*

ments is proceeding at this time, and it is likely that suitable ASTM standards will be available by 1982.

It is proposed that the ASTM model "systems" document be patterned after the conditions for entry into the draft of the Directory of Laboratory Accreditation Systems being prepared by the International Laboratory Accreditation Conference (ILAC). This ILAC activity is being related to the work of the International Organization for Standardization (ISO) Guide 25 to ensure harmony between ILAC and ISO activities. It is considered desirable that the future work of ASTM Committee E-36 also be related to ILAC/ISO activities. By relating the ASTM model systems document to international activities in the field of laboratory accreditation, those establishing accreditation schemes based on the ASTM model should be able to achieve recognition in the international arena.

The conditions specified in the draft ILAC directory include criteria that are basic to the operational accreditation systems covered in the directory. The current draft of the directory lists accreditation systems in operation in eleven countries, including a number of North American systems. It is of interest to note that the United States is represented by 13 federal government systems, 8 state systems, and 12 professional and trade association systems.

The conditions for entry in the draft ILAC directory, although comprehensive, do not cover some criteria considered desirable to ensure credibility and broad acceptance. For example, it is proposed that the ASTM model systems document include adequate appeal procedures in the event of disagreements during the process of accreditation. Consideration also is being given to criteria for fully documented procedures, for an interpretation service, for discipline, for withdrawing accreditation, for follow-up evaluations, and for independent audit.

The generic criteria documentation being developed for "evaluators" or "assessors" poses a unique challenge to ASTM. There is, as yet, no international documentation containing criteria for assessors. Some national activity is underway in Canada to develop documentation to assess "technical auditors."

The development of generic criteria for assessors is complicated by the need to include criteria not only for individuals and organizations who carry out assessments, but also for teams of assessors who may represent different groups or organizations. Some national accreditation schemes already involve such team assessments (for example, the U.S. nuclear industry).

The short-term interpersonal relationships that are important to the success of a team assessment must be considered when criteria for assessors are prepared; particularly important are those cases where the team members come from different organizations and indeed from different backgrounds. Further complications are introduced in attempting to quantify criteria related to the personal traits and other attributes of individual assessors and teams of assessors. Yet the credibility of an accreditation scheme and ulti-

mately the acceptance of such a scheme can hinge upon the personal traits and other characteristics of individual evaluators.

One further area that the current Task Force is addressing is the relationship between testing laboratories and inspection agencies. The original Resources Task Group that prepared ASTM Standard E 548 considered that it was important to address both testing laboratories and inspection agencies. Testing laboratories and inspection agencies may or may not be interrelated in a particular accreditation scheme. Some may, in fact, rely on one or the other scheme, not both, thereby creating a duality of purpose. The title of the current edition of E-548 reflects this duality of purpose.

Because of recent international developments that relate to ILAC, coupled with the objectives of accreditation schemes being developed nationally by the American Association for Laboratory Accreditation (AALA) and the National Voluntary Laboratory Accreditation Program (NVLAP), it is likely that this duality of purpose will have to be reviewed once again. There are a number of successful accreditation schemes in existence that operate without the direct support of testing laboratories. The existence of these schemes poses a problem in terms of developing a dual-purpose model accreditation system. It may be that further documentation will have to be developed by Committee E-36 to overcome this duality of purpose or that the scope of Committee E-36 will have to be modified.

In some sectors of industry, inspection-based accreditation systems are the norm. A number of multinational agencies operate such systems on a worldwide basis in transportation, energy, and other sectors. The use of testing laboratories often is peripheral or incidential to such systems, with the main emphasis placed upon the inspection or audit activities of individuals or teams of assessors. For such systems it is essential that comprehensive documentation be developed that relates to the performance of individual assessors and teams of assessors. A comprehensive technical audit may be compared to a financial audit. Some of the performance criteria applied to standards for financial auditors may be useful in developing criteria for individuals operating in an inspection-based accreditation system. In such systems, criteria that relate to individual judgment, to independence and uniformity in application of judgments, to knowledge of auditing techniques and principles, and to other factors such as evaluating documentation and reporting systems are of considerable importance.

Conclusion

In developing accreditation systems for testing and inspection agencies, a number of important issues have to be considered and resolved. Many of these issues have been addressed by ASTM Committee E-36 and its task forces.

An ongoing task for Committee E-36 is relating to the work of other

ASTM technical committees concerned with accreditation or evaluation. Liaison also is maintained with a member of organizations external to ASTM with the view toward providing a coordinated national approach to the basic concepts involved in an accreditation system. The generic criteria documentation produced by Committee E-36—the first two levels in Fig. 1—should facilitate the establishment of accreditation systems by other committees and organizations.

Organizations operating accreditation systems then can put their expertise to work in developing or identifying suitable documentation for the third and fourth levels of the systems triangle in Fig. 1. Such an approach ensures that the collective resources, experiences, and expertise available to the different committees and organizations involved in the development of documentation for accreditation systems are put to the best use.

The most important goals of a successful accreditation system are credibility and acceptance. The contents of the model documents being developed by Committee E-36 are designed to reflect concern for credibility and acceptance, and ultimately for the success of accreditation schemes patterned after the ASTM model. The authors hope that ASTM, through its Committee E-36 working with other ASTM committees and with outside organizations, can provide national and international leadership in the development of accreditation systems.

Gerald A. Berman[1]

ASTM Committee E-36 Activities in Standards Development for Laboratory Evaluation and Accreditation

REFERENCE: Berman, G. A., "**ASTM Committee E-36 Activities in Standards Development for Laboratory Evaluation and Accreditation,**" *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 11–17.

ABSTRACT: Accreditation is a formal determination and recognition that a laboratory has the capability to carry out specific activities. It is conferred by an accreditor following an assessment of a laboratory against applicable criteria. Since its formation in 1973, ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies has been actively working to develop consensus criteria that could be used by others to evaluate and accredit laboratories. This paper highlights the activities, accomplishments, and future plans of Committee E-36 in the development of standards for laboratory evaluation and accreditation.

KEY WORDS: ASTM Committee E-36, laboratory accreditation, laboratory evaluation, accreditation criteria, evaluation criteria

Accreditation is a means frequently used to identify competent testing laboratories. It implies that a laboratory has been evaluated by a recognized authority and found capable of conducting specific activities. In the early 1940s there were only two or three formal accreditation systems in the United States operated by recognized authorities. That number has grown steadily over the years and now includes about 70 formal systems. These are identified and described in a report prepared in 1980 by the Department of Commerce.[2]

Of the 70 systems examined in the report, 26 are sponsored or operated by the federal government, 20 by state and local governments, and 24 by professional and trade associations. While not identifying each specifically, the re-

[1] National Bureau of Standards, Washington, D.C. 20234

[2] U.S. Department of Commerce, "Principal Aspects of U.S. Laboratory Accreditation Systems," NTIS Acquisition No. PB80-199-86, National Technical Information Service, Springfield, Va., July 1980.

port also indicated that literally hundreds of formal and informal private accreditation systems exist that serve principally to fulfill contractual requirements between producers and users of goods and services. It is estimated that these private systems, along with the 70 identified formal systems, evaluate and accredit some 60 000 laboratories in this country, ranging from one-person test stations to complete multidisciplinary commercial testing organizations.

Little reciprocity seems to exist between these accreditation systems. It is apparent therefore that in order to do business some laboratories must undergo evaluation by several different accreditors. This duplicative effort is costly in terms of time and money. While it may be argued that the lack of reciprocity between systems exists for "political" reasons, that is, the unwillingness of accreditors to give up "turf," the fact is that the evaluation criteria and procedures used in the various systems differ. Some systems use criteria and related assessment procedures that are very demanding. Others are less rigorous and thorough. This naturally leads to differences in the meaning and significance of accreditation and provides technical grounds for the autonomous operation of accreditation systems with little interrecognition of accredited laboratories.

It became apparent that some of the burden on laboratories, particularly the necessity for duplicative evaluation caused by nonreciprocal systems, could be reduced if standards for laboratory evaluation existed. For this reason, in 1973 ASTM established Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. Since its formation the committee has been actively working to develop consensus criteria that could be used by others to accredit laboratories. It must be emphasized at this point that neither the committee nor ASTM accredits or intends to accredit laboratories.

To date, the major achievement of Committee E-36 has been the preparation of E 548, the ASTM Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies. This standard provides guidelines for information disclosure in the categories of laboratory organization, human and physical resources, operational procedure, and quality assurance practices. However, it does not define a complete evaluation system or provide generic requirements that should be met by laboratories seeking accreditation. The responsibility for establishing requirements for accreditation in each category has been viewed as the province of accreditors based on the individual system needs and intended rigor and thoroughness.

Although quite different in detail, the requirements of many existing accreditation systems show a number of generic similarities. For example, all systems generically require laboratories to have competent staffs, a qualified technical director, and appropriately maintained and calibrated equipment. The benchmarks that define the level of adequacy of each are the specific details that distinguish accreditation systems. In the area of health care, the benchmark of adequacy for the director of a laboratory is frequently a licensed M.D. In some physical construction materials testing areas, the

benchmark is a professional engineer, and in yet other areas the benchmark is simply demonstrated competence without the need for licenses or degrees.

While ASTM E 548 has been widely referenced in many accreditation systems, Committee E-36 clearly recognizes the need for further work in establishing a basis for standardization in accreditation. To this end the committee has embarked on the development of additional documents. Accreditation can be viewed in terms of components that include an accrediting authority, accreditation criteria, and an evaluation and monitoring process. The committee has structured these components into a model consisting of a framework of documents arranged in hierarchical order. This model is shown by the triangle in Fig. 1. At the top of the triangle are generic guidelines for a laboratory accreditation system. An accreditation system can be thought of as an ordered arrangement of rules, procedures, and management that governs the function of an accrediting authority. The system guideline identifies the attributes that should be present in any accreditation system.

Every accreditation system involves an evaluation process. Guidelines for system managers are viewed as the second level from the top in the triangular model. These guidelines describe the necessary characteristics of the evaluation process and include elements of proficiency testing, on-site review, quality assurance audit, calibration practice, and assessor selection and qualifications.

In the model (Fig. 1), generic criteria for use in the accreditation of laboratories are shown on the same level as guidelines for the evaluation process. The current ASTM standard E 548 is viewed as part of this document in that it provides guidelines for the information that should be sought from laboratories being evaluated. It is anticipated that this document will also contain generic requirements that a laboratory should meet in order to be accredited. In context of the discussion presented earlier, these criteria would be a compilation of the generically similar requirements found in the many accreditation systems that currently exist. Combining common requirements into a single document will provide a basis for standardization of criteria and the possible harmonization of language among current and future accreditation systems. Examples of generic criteria that could be included in such a document are:

Personnel

Be staffed by individuals having the necessary education, training, technical knowledge, and experience for their assigned functions.

Facilities and Equipment

Have available all items of equipment and facilities for the correct performance of the tests and measurements for which recognition is granted. Hold out of service any item of equipment which is defective or out of calibration or gives suspect results until it has been repaired or recalibrated.

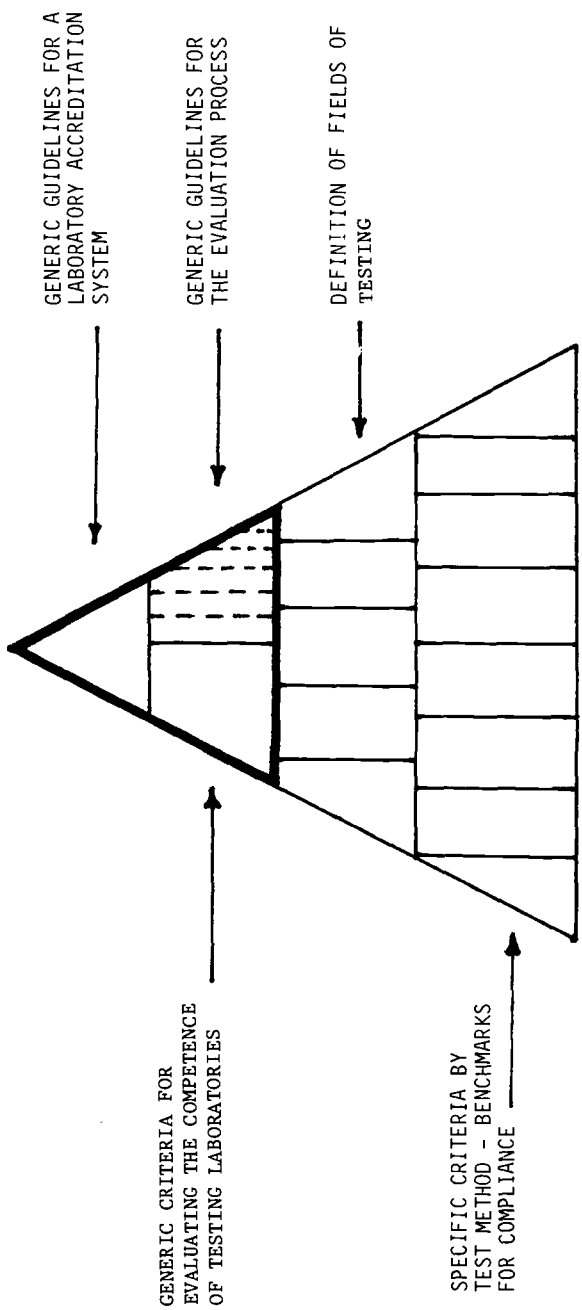


FIG. 1—*Laboratory accreditation model.*

Calibration

New testing equipment must be calibrated before being put into service. In-service testing equipment must be recalibrated at regular intervals specified or approved by the accrediting authority.

Establishment of requirements that are specific to a particular field of testing, or the benchmarks as earlier characterized, would still be the province of an accreditor based on particular systems needs or intended rigor and thoroughness. Alternatively, benchmarks or other specific requirements could be established by technical groups or committees having jurisdiction for particular test methods. Within ASTM, for example, the technical committee having responsibility for a given test method may wish to add a laboratory evaluation appendix to the standard. This would enhance the possibility for the uniform evaluation of a laboratory conducting the test regardless of the accrediting body, with the added potential for reciprocity among accreditors.

The concepts outlined above are captured by the documents composing the third and fourth levels of the accreditation model shown in Fig. 1. The third level represents the definitions of fields of testing categorized in terms of test methods or procedures. The fourth level represents specific requirements for particular test methods. These are the benchmarks for compliance with the generic criteria and guidelines that form the upper levels of the accreditation model. For example, where the generic criteria require a laboratory to calibrate in-service equipment, the benchmark for a particular test method may specify the equipment subject to calibration and the frequency of calibration.

It is anticipated that when a need exists, these specific requirements or benchmarks will be prepared by technically qualified individuals working in the context of standards-writing bodies, criteria committees, advisory committees, or peer assessors engaged by an accrediting authority. Committee E-36 would be available to provide coordination, as required, to ensure uniformity and compatibility with the generic criteria and guidelines of the accreditation model.

An example of the application of the documents composing the accreditation model is shown in Fig. 2. This example traces only selected elements in each document as they apply to a specific test method. The test method is the ASTM Test for Steady-State Thermal Transmission Properties by Means of the Guarded Hot Plate (C 177). Technical materials relative to C 177 were developed by the author as an example and should not be ascribed to ASTM Committee C-16 on Thermal Insulation, which has responsibility for the standard. The example shows the type of benchmarks that could be provided by a technical committee.

A number of specific criteria documents currently exist as ASTM standards. Examples include Criteria for Evaluation of Agencies Involved in Testing, Quality Assurance, and Evaluating Building Components in Accord-

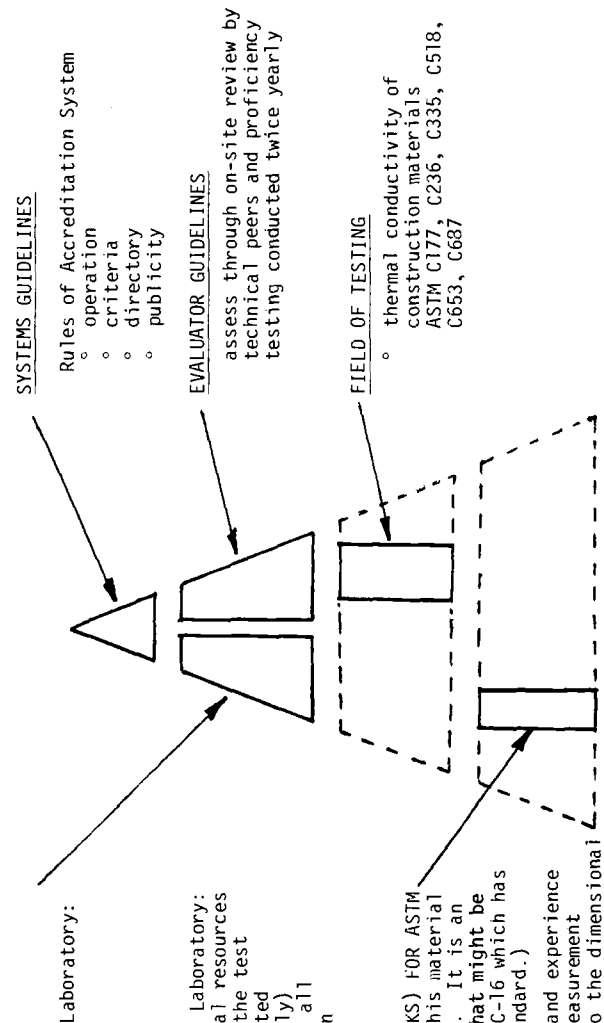


FIG. 2—*Example of application of laboratory accreditation model to a specific thermal transmission properties test method.*

ance with Test Methods Promulgated by ASTM Committee E-6 (E 699), the Practice for Inspection and Testing Agencies for Concrete, Steel, and Bituminous Materials As Used in Construction (E 329), Criteria for Agencies Engaged in System Analysis and Compliance Assurance for Manufactured Building (E 541), the Practice for Evaluating Laboratories Engaged in Sampling and Analysis of Water and Wastewater (D 3856), and Evaluating Laboratories Engaged in Sampling and Analysis of Atmosphere and Emissions (D 3614). These have been independently developed by ASTM technical committees over the past several years without strong coordination from Committee E-36. As a result the language in the standards is inconsistent and sometimes redundant with E 548. It is hoped that with development of the documents composing the accreditation model, future specific criteria will be presented in a uniform format so as to initiate establishing a basis for standardization in accreditation activities.

Finally, an issue of particular concern to Committee E-36 is the laboratory accreditation activities occurring on the international scene. The sixth meeting of the International Laboratory Accreditation Conference (ILAC) was held in Tokyo, Japan, in October 1982. One of the purposes of ILAC is to explore means of lowering barriers to trade by mutual recognition of product testing among trading nations through reciprocity of accreditation systems. ILAC Task Groups are developing an accreditation model and related documents based on this ASTM E-36 model. Work with regard to accreditation is also progressing in the International Organization for Standardization (ISO). That body in response to a request from ILAC has revised ISO Guide 25, "General Requirements for the Technical Competence of Testing Laboratories." This document sets forth the general requirements with which a testing laboratory must comply if it is to be recognized as technically competent.

Committee E-36 intends to monitor and interact when appropriate with these organizations in the hope of developing standards that provide a basis for uniformity in testing laboratory evaluation and accreditation, both nationally and internationally.

John W. Locke[1]

Toward Adoption of a Universal Laboratory Accreditation Criteria

REFERENCE: Locke, J. W., **"Toward Adoption of a Universal Laboratory Accreditation Criteria,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 18–23.

ABSTRACT: This paper presents a comparison of five laboratory accreditation criteria in six basic categories: organization, human resources, material resources, operating procedures, record keeping, and other. A brief analysis of each set of criteria points out their strengths and weaknesses. The intent of the paper is not to present a proposed set of universal criteria but rather to present comparisons of the elements of the criteria in order to assist standards development organizations to expedite the evolution of such a universal set of criteria.

Laboratory accreditation criteria for measuring the competence of testing laboratories significantly affects the acceptance of test data produced by laboratories in different accreditation systems. In determining whether one system will accept test data produced by laboratories accredited by another system, a detailed comparison of criteria used by each system must be made. Differences must be resolved, either by accepting the fact that one or more criteria are absent in one system as compared to another or else by causing the criteria in one or both systems to change so that the criteria in both systems are in harmony with each other.

KEY WORDS: laboratory accreditation criteria, criteria comparisons

There are those who claim that the differences in criteria between accreditation systems are unimportant. To play down these differences, claims sometimes are made that the criteria are "based on the International Organization for Standardization (ISO) Guide 25" or "just like ASTM E548 (Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies)." However, when you are operating a laboratory accreditation system that requires visits to the laboratories to specifically determine compliance with the accreditation criteria, "being based on" or "just like" isn't good enough. The assessors of the laboratories cannot apply what amount to vague generalities as the criteria by which they must evaluate laboratories.

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Criteria vary markedly from one laboratory accreditation system to another. Mr. T. R. Young prepared a report in January 1981 entitled "A Comparative Survey of U.S. and Foreign Criteria for Accrediting Testing Laboratories" that graphically illustrates the point and has led me to the conclusion stated in the first paragraph above. Young states:

> Differences must be resolved, either by accepting the fact that one or more criteria are lacking in one system as compared to another or else by causing the criteria in one or both systems to change so that the criteria in both systems are in harmony with each other.

When criteria change to be more alike we have a tendency toward achievement of universal criteria.

My review of the criteria for a variety of systems leads me to believe that the criteria are different, not by design, but because different groups of people, at different points in time, and with different backgrounds, came together to develop them. I have high hopes that the experience gained to date in developing and applying criteria can be brought together through ASTM, ISO, or some other internationally recognized organization so that differences in criteria, many of which are not critical, can be eliminated.

Before going any further, let me say that there will be very legitimate reasons for some differences in criteria among various technical disciplines and possibly among various countries. These should be kept to an absolute minimum and each deviation from the universal should be explained fully.

Basis for Analysis

To fully compare several prominent criteria, I categorized them and printed them side by side. Detailed comparisons brought three questions to mind:

1. Are there substantive differences?
2. If I were organizing an accreditation system, what kind of procedures would I have to use to assure that my accredited laboratories meet these criteria?
3. Would there be substantive differences between the procedures and the criteria?

The goal in establishing universal criteria should be to eliminate trivial differences in language and to treat the substantive differences as exceptions.

The basic elements of my categorization scheme are fundamental to all accreditation system criteria, where *accreditation criteria* are defined as a set of requirements that a testing laboratory must meet to achieve recognition by

an accreditation body. The basic categories of criteria for the evaluation of a testing laboratory are:

- Organization.
- Human resources.
- Material resources.
- Operating procedures.
- Record keeping.
- Other.

When comparing criteria, one of the most difficult issues to resolve is the tremendous difference in the way different systems treat the same accreditation element. In some instances, key personnel (management) are treated under "organization." Elements affecting personnel evaluations appear in a variety of other categories as, for example, under "procedures," or under the quality assurance systems, which I have placed in the category "other." Of course, there is the usual problem of distinguishing between quality control and quality assurance as applied to laboratory operations.

Existing Criteria

A comparison of laboratory accreditation criteria from five different sources was made in preparation for this paper. The documents studied were these:

1. ASTM E 548.
2. National Voluntary Laboratory Accreditation Program (NVLAP) General and Specific Criteria for Accrediting Testing Laboratories, published in the *Federal Register,* January 23, 1980.
3. ISO Guide 25-1978(E), Guidelines for Assessing the Technical Competence of Testing Laboratories.
4. ISO/CERTICO ad hoc group Guide 25/2, Proposal for a Further Development of ISO Guide 25, dated February, 1981.
5. Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice for Testing Chemicals, presented at the International Laboratory Accreditation Conference (ILAC) 80, dated 21 October 1980.

I'd like to make a few comments on what I believe are the strengths and weaknesses of each criteria document.

ASTM E 548

These criteria get off to a good start—organizational requirements are clear. The human resources section is weak, since there do not appear to be

any measurables. There is no requirement that equipment appropriate to the test methods be available. The term *quality system* causes confusion. Information about procedural systems affecting calibration programs does not really result in a requirement. A quality assurance system is suggested, separate from quality control. Any relationship between that quality assurance system and the accreditation procedures is unstated. (In a sense, the accreditation provides elements of a quality assurance system at the laboratory.)

NVLAP

Criteria are separated into general criteria dealing with the laboratory as an entity and specific criteria dealing with the competence of the laboratory in performing a test. This is the only criteria document in the group that attempts to deal with professional and ethical practices. A quality control system is required but not clearly defined. The significance of a laboratory director or approved signatory for accredited laboratory test reports is not recognized. The criteria do require that employees be explicitly found capable of performing specific tests, an important element not found in the other criteria.

ISO Guide 25

Requirements relevant to the laboratory organizations are practically nonexistent. There is no reference to training or personnel record keeping requirements. Requirements for facilities and equipment are relatively complete. The requirements for documented test procedures or a test plan are missing, although some elements of such a plan are present. Requirements for record keeping are relatively complete.

Proposed Guide 25

This is the only criteria document that recognizes the distinction between providing information to the laboratory accreditor to identify characteristics of the laboratory and criteria that the testing laboratory must comply with in order to be accredited. Requirements for internal quality assurance programs, internal audit procedures, and involvement in proficiency testing are weak and unclear. There is a melding of records and test report requirements, which should be separated and clarified.

OECD Good Laboratory Practices (GLP)

The format used for the GLP is considerably different from the others. There are few requirements relevant to the organization of the laboratory. Emphasis is placed on the responsibilities of management (which other criteria seem to presume is the laboratory). There is considerable repetition in these criteria, which start out with the responsibilities of the personnel, much

of which is then repeated under other headings. In addition, there are a number of criteria dealing with animals and other living systems that are not contained in the other four criteria documents and must clearly be added to a universal set of criteria for these types of tests. In this criteria document there is also a very heavy emphasis on the complete control, performance, and documentation of a single study. Such emphasis on a single study is probably not warranted in other types of laboratory accreditation.

The Link Between Criteria and Test Methods

Criteria in and of themselves do not provide all that is needed to evaluate a laboratory. Accreditation relates to the competence of a laboratory to perform tests properly, thereby obtaining correct answers. Some laboratory accreditation systems stress frequent and periodic proficiency tests and close monitoring of results obtained by the laboratory. In effect, this is an end item check (end item as far as the laboratory is concerned) of results based upon high frequency sampling. In this case, exact compliance with test methods is not critical.

But in most systems such end item check testing is not possible, either because of the nature of the product or because of the complexity and expense of performing the check testing. In these cases it becomes much more important, when determining the competence of a laboratory, that the laboratory perform the tests as specified. The laboratory accreditation criteria then must not only set out requirements expected of the laboratory but must assure that the test methods are being performed properly. This often leads to confusion—just how much detail needs to be in the criteria? Resolution of this question also affects the fundamental nature of the criteria.

The ASTM E 548 criteria document, at one extreme, provides practically no detail with respect to the performance of tests according to the test methods. Unfortunately, it does not stress the need for the laboratory to follow the test methods. The NVLAP criteria are much more explicit with respect to this need. The GLP, on the other hand, provides much more detail in its criteria, relying less on the specifics of the test methods. To a certain extent, the characteristics of these criteria are affected by the degree of specificity in the test methods. When the test methods are detailed and clear, specificity in the criteria is not required. When the test methods are general and details are absent, then detail may need to be provided in the criteria.

Although I have limited my observations to laboratory accreditation criteria, believing that much can be done to clarify and unify language, I must point out that the procedures used in assessing the laboratory will have some impact on the nature of the criteria. The Australian National Association of Testing Authorities (NATA) system uses assessors who are expert in the test methods for which a laboratory is to be accredited. They are expected to know the specific requirements of the test methods and make their judge-

ment on laboratory performance accordingly. The NVLAP system uses expert assessors also, but goes one step farther by providing supplemental information to the criteria that describes how the criteria will be interpreted for each specific test method in the program. The OECD is presently evolving their implementation procedures. The ISO Guide 25 and ASTM E 548 do not relate to implementation procedures.

Concluding Remarks

It has not been the intent of this paper to recommend specific universal criteria. Rather, I have tried to put down certain observations that should be considered by those groups that are developing criteria. These observations are based on a side-by-side comparison of the five accreditation criteria documents. It is my hope that this small service will expedite the evolution of universal criteria or, if not, at least that the different criteria will include as many identical statements as possible. I will be glad to provide a copy of the side-by-side comparison of the documents upon request.

Laboratory Applications and Computerized Systems

Ronald D. Graham[1]

Quality Assurance in a Coal Analysis System

REFERENCE: Graham, R. D., **"Quality Assurance in a Coal Analysis System,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 27–38.

ABSTRACT: The rebirth of coal as a fuel and feedstock has increased the concern about and the need for accurate and precise analytical results. As environmental policies and regulation become more stringent and as worldwide energy costs continue to rise, the economic incentives associated with compliance testing increase. This presentation explains how one coal producer is attempting to meet this need for timely, cost-effective analytical results and how this relates to accreditation activities.

KEY WORDS: quality assurance, coal analysis, certification, round robin testing

The goal of every analytical laboratory and of every analyst is to produce precise and accurate analyses in a timely and cost-effective manner. The rebirth of coal as an energy source and as a feedstock for other technologies has evaluated the need for increased quality certification of coal shipments. This is partly due to continually rising worldwide energy costs and the economic incentives associated with compliance testing. Stricter environmental regulations make it essential that required analyses are not only precise and accurate but also rapid. Adding to the difficulty in obtaining accurate analyses are the demands made by an ever-increasingly more technologically oriented society. Because of great strides and achievements made by technology in other areas, consumers and regulating agencies insist that coal and coal-related analyses always be done more quickly and more accurately at lower and lower concentrations.

At present there is no certifying or accrediting body specifically for laboratories engaged in coal and coal-related activities. Therefore, each independent producer must be certified or accredited in whatever manner is acceptable for their own peculiar situations. This accreditation is formed by the various forces impinging upon the group: by the state and federal regulations under which the group operates, by the contracts formed by the producer and its customers, by economic concerns, and by acceptable good laboratory practices.

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AMAX Coal Company, a division of AMAX, Inc., operates ten mines in Illinois, Indiana, and Wyoming. In 1981 AMAX Coal Company produced and shipped 40.5 million tons of coal under contract, primarily to electric utilities throughout the United States. This makes AMAX Coal Company the nation's third largest producer of coal.

This work will endeavor to show how AMAX Coal Company is attempting to meet the challenge of the need for fast, accurate, and precise analyses and to show how this relates to accreditation activity on the national and international levels.

The Initial Step: Exploration Drilling

Whenever a coal shipment leaves any one of the mines, the analysis of the sample representing that shipment marks neither the beginning nor the end of the certification process. It is merely one in a series of events that establish the values of the characteristic properties of the coal.

The first step in the process of guaranteeing the analysis of the shipped product could actually begin years before the first shipment of coal leaves for market. This initial process begins with exploration drilling and coring. Core hole locations are selected based upon the geology and the topography of the area and the need to supplement information available from other sources. These other sources could be the Bureau of Mines, the Geological Survey, past and present neighboring operations, prior drilling data if available, and publications from other sources.

All cored exploration samples are subjected to a basic analytical scheme. The proximate analysis, sulfur, and Btu values so determined allow for a general characterization of the coal resources in an area. Washability data are generated, from which washability curves (such as Fig. 1) can be produced. Based upon these curves and assumptions about the type of preparation facility proposed, its expected operating efficiency, and the expected out-of-seam dilution, projections about the marketability of the coal can be made.

Additionally, at least one fifth of all cored exploration samples are designated special analysis samples and as such are analyzed for a complete suite of routine analyses for which the central laboratory, the Midwest Area Laboratory, is equipped and staffed. This provides better quality information for marketing purposes. Based upon the results of the analysis of the exploration cores, additional developmental drilling may or may not proceed. In some exploration projects only three to six core samples may be taken. It would not be unusual to perform the complete suite of routine analyses upon all cored samples from such a project.

Developmental Drilling

Developmental drilling occurs whenever decisions have been made to develop or expand a mine, whenever additional information is needed to pro-

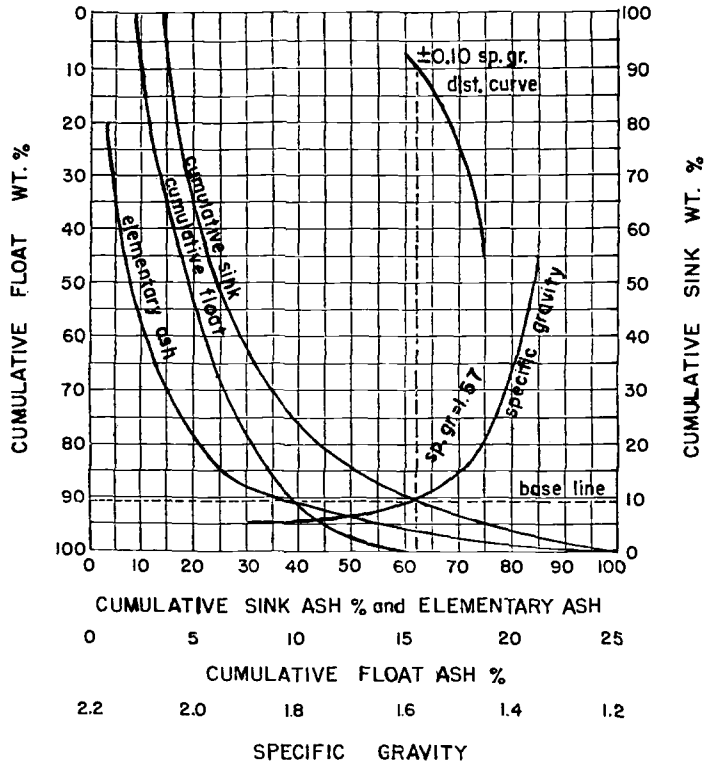

FIG. 1—*Typical washability curve taken from Ref* 2.

ject mining plans, or whenever more information is needed to inventory the quality of reserves. Development drilling occurs on a tighter pattern than does exploration drilling; that is, if exploration cores are taken, say, one per square mile, developmenta drilling will core a substantially higher number.

Developmental core samples are subjected to the same basic analytical scheme as exploration core samples and at least one fifth of all cored developmental samples are also designated as special analysis samples. Thus developmental core samples supplement and define to a much higher accuracy the data developed during the exploration phase of the project. Developmental core drilling and analysis are ongoing processes during the life of an active mining operation. Core samples are taken yearly and tend to be concentrated in the areas that make up the proposed mining plan for the next few years.

Based upon core hole data, isopleths can be made. Isopleths are lines connecting points on a map that have equal or corresponding values with regard to a particular parameter. These isopleths can be based upon the *in-situ* quality of the coal or they can be projections of anticipated produced quality (see Fig. 2). These isopleths are plotted and drawn while making use of core hole coordinates supplied by geology, core sample analysis provided by the laboratory, and computer programs developed to suit the requirements of fore-

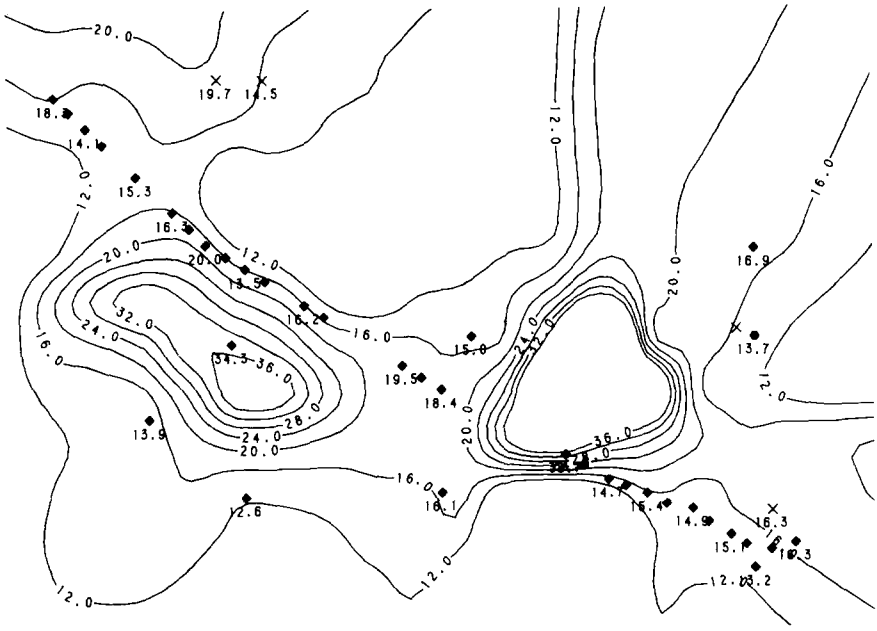

FIG. 2—*Typical isopleth showing ash distribution.*

casting coal quality. Thus a means of predicting mined coal quality by staff personnel is feasible. Based upon new core hole data supplemented by in-pit channel samples and revised mining plans, these projections are updated on a yearly basis. These forecasts are the best available estimates of what the mined coal quality will be.

The Mining Process

During the mining process, the produced or washed coal is continuously sampled by using mechanical sampling systems. Depending upon operational circumstances at the particular mine, the samples are collected either by the shift, the day, or the shipment. The sampling system can be located between the preparation facility and the washed coal storage silo or it can be located between the washed coal storage silo and the load-out area (see Fig. 3).

There are advantages to having the sampling system located between the preparation facility and the washed coal storage silo. The greatest advantage is that a quick analysis of the sampler product will immediately tell how the preparation facility is performing. Adjustments can be made to the pit operations or to the preparation facility to assure that acceptable quality is maintained on a more or less continuous basis. This could not be done as readily if the sample were taken on the other side of the washed coal storage silo. This is due to the two- to three-day delay that sometimes occurs between the time the coal is produced and the time it is shipped.

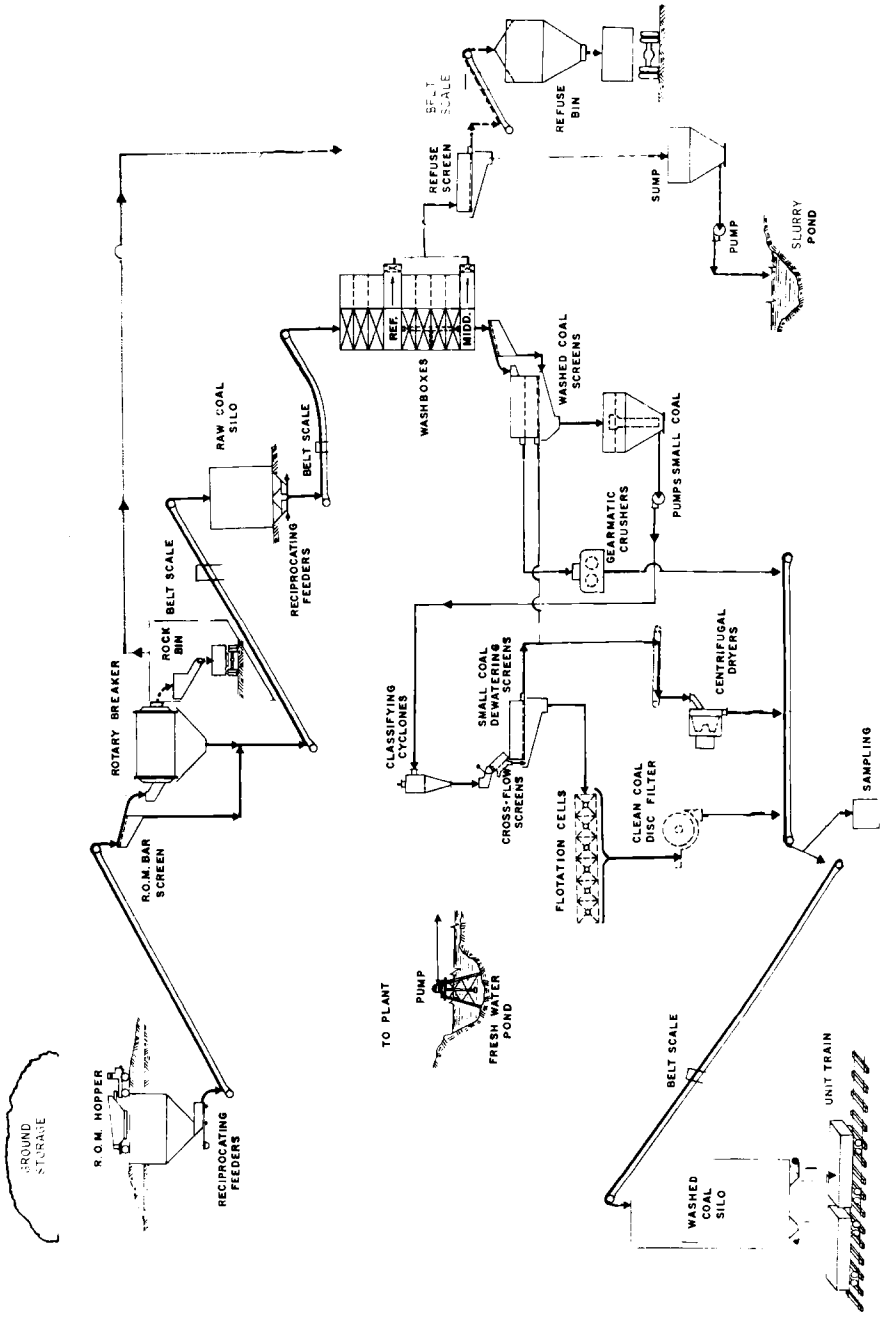

FIG. 3—*Typical preparation facility.*

There is also a distinct advantage to having the sampler located at the load-out. This sampler position will yield a sampler product that is representative of the unit train being shipped rather than one representative of the coal produced during that day. If the mine is a captive mine, that is, if it has but one customer, the discrepancies of shipping coal based upon produced samples rather than shipped samples will be negligible over the course of the contract. By providing daily analysis of the produced coal, it allows each preparation facility to more accurately modify operating parameters and thus assure a more constant uniform compliance product than could be expected if adjustments were made based upon analyses of shipped samples.

Contracts

Many contracts under which producers operate do not necessarily reflect the best interests of the buyer or the seller whenever they are strictly interpreted. Flexibility is always built into such a contractual relationship by reason of the individuals who administer enforcement of the contract. Each side must consider the intent of the contract and make adjustments in the enforcement provisions to make allowances for operational problems incurred by the other, problems incurred by a third party (e.g., a carrier), and acts of God that may prevent the carrying out of the provisions of the contract. At times the buyer or seller may find themselves in situations where because of improper advisement certain provisions of the contract cannot be fulfilled. This is because it is not always possible for legal and marketing personnel to completely understand operational nuances, which may prevent absolute compliance with certain contract provisions. Therefore, it is always best to have someone who represents the operations group participate in contract approval.

One typical provision of many contracts requires that sampling and analysis be representative of a particular day's shipment. There has been much discussion as to whether this is possible, depending upon the location of the sampling station. This is an important consideration as variances in sampling and sample preparation will introduce greater variability in analytical differences between buyer and seller than will the analysis itself. Other possible sources of concern include:

1. The number of reserve samples prepared and the length of time they are retained. (Coal samples deteriorate with time, especially if not adequately protected from contact with the atmosphere.)
2. The manner in which disputes are settled whenever discrepancies exist between the analysis of the seller's sample and the analysis of the buyer's sample. The two parties usually negotiate a mutually agreeable settlement.
3. The time frame in which copies of analyses are mailed, the protest period allowed after receipt of the analyses, and the time given for retention

of the reserve samples often allow for disposal of the reserve sample before the end of the protest period in which the buyer may request that the sample be sent to an independent commercial laboratory for analysis.

Some tests are so empirical in nature that without exact duplication of equipment, operating conditions, and measurement technique there could be no agreement between even the most conscientious individuals (for example, volatile matter or moisture analysis of low rank coals). Thus while objectivity may require that in compliance testing the participatory factions obtain their respective analyses independently, common sense will require that their initial action be agreement upon common or standard procedures by which each shall independently procure, prepare, and analyze the material in question.

Sample Exchange Programs

The laboratory should engage in more than one proficiency testing program, especially in those sponsored by federal agencies such as the U.S. Environmental Protection Agency, the National Institute for Occupational Safety and Health, and the Department of Commerce. These provide an economic source of high-quality standards and under some circumstances, participating can be paramount to certification.

A special type of proficiency sample is that from a program set up for interlaboratory comparison. These split sample or round robin samples can be done routinely to monitor or to assess results produced by different laboratories or it can be done whenever two or more laboratories produce disparate results.

Whenever undertaken for the latter reason, the exchange should be preceded by a visit to each laboratory by members of the other's staff. This audit or assessment is done as an attempt to eliminate any obviously nonstandard practices or to select potential sources of error that will be monitored by the exchange. Whether the bias is caused by something within the laboratory or whether the bias has been introduced in the sampling or preparation steps of reduction and division could be determined by such a visit. This could be less expensive than conducting a sample exchange that may otherwise not locate the source of the disparity.

If the source of the bias is not located by the exchange visits, then the length of the sample exchange, the type of sample exchanged, and the analyses determined will depend upon the nature of the suspected problem. Representatives of AMAX Coal Company's customers routinely visit the laboratories of our system to evaluate their operation. These visits are often in conjunction with sample exchanges.

The sample exchange program must be well planned in order to guarantee that once the exchange is complete, meaningful results will be obtained that

will either locate and identify the source of the bias or will give direction as to what to do next.

As already stated, improper sampling or sample preparation has a far greater potential of introducing bias into the analytical results than does the analysis itself. Considering the technique necessary to properly take a representative sample from ten thousand tons of a material as heterogeneous as coal, dividing and reducing this representative sample into 50 to 100 g of laboratory sample suggests the validity of this statement.

Reproducible methods of receiving, logging, and storing samples must be included as a part of the protocol. These should allow for tracing the history and custody of the sample for later reference (chain of custody). The method of logging and storing samples as they are received can also be applicable to logging and storing reserve splits and analytical samples after analysis.

Special consideration should always be given to instrument calibration and standardization. Accurate chemical analyses cannot be based solely upon the response of a device, be it an instrument, human eye, or black box. One needs to consider the change of the response of the test instrument to the characteristic properties of the sought-for component as it changes with concentration, time, temperature, humidity, and other environmental factors. The effect of other properties of the component being sought and the properties of other components within the matrix of the sample being tested must also be considered.

If the exchange is a periodic interlaboratory comparison mutually agreed upon in advance by the parties, it is important to establish what methods will be used by each participant. Different methods can yield slightly different results. A slightly positive or slightly negative bias by one method as compared to another is not to be unexpected. The report form should contain space to state which method is used or how the method used varies from the standard procedure.

Some round robin programs are available commercially and are especially useful to laboratories that have inadequate time or expertise to formulate their own program or to those who want an independent third-party basis for their quality control program.

Presently, AMAX Coal Company is engaged in numerous round robin programs. Several of these are initiated by our central laboratory. In one such program approximately 25 of the utilities that purchase coal from AMAX Coal Company participate twice a year in a round robin exchange. This exchange involves analysis of a −60 mesh sample for residual moisture, ash, sulfur, and Btu.

Another of our exchange programs involves the sending of −60 mesh samples to approximately 25 commercial and other coal producers' laboratories throughout the United States. This is done twice a year. In this exchange not only the basic analysis of residual moisture, ash, sulfur, and Btu are de-

termined; additionally, participating laboratories determine ultimate analysis, mineral analysis of coal ash, forms of sulfur, and ash fusion temperatures.

On a weekly basis AMAX Coal Company participates in an internal round robin program with our seven mine laboratories in the Midwest and our Western Division and Midwest Area Laboratories. Residual moisture, ash, sulfur, and Btu are determined in this exchange.

Our system also participates in several round robin programs originated through other organizations. These exchanges and other analytical exchange programs such as participating in the work of ASTM Committee D-5 on Coal and Coke is another link in our "accreditation" process. These occur on a continual basis under normal working conditions and will, therefore, be of more value than a single proficiency sample done one or two times a year.

Other Analytical Determinations

Briefly, other processes which affect the overall characterization and validity of the analytical results produced by the system will be described.

1. Two times per year, each over a two-month period, composites of daily production samples are taken from each mine. Additionally, the under 1.65 specific gravity material recovered from monthly washability tests of channel samples from each active mine is composited over the respective six-month period. All of these samples are subjected to the full suite of routine analyses for which the Midwest Area Laboratory is equipped. Trace elemental analysis is also performed upon each composite. All these tests help to further characterize the coal being produced from each mine.
2. A schedule of monthly in-plant sampling is carried out. Various points are sampled several times per week and are then immediately analyzed or are composited and analyzed on a monthly basis. These tests provide insight into both the physical nature of the run-of-mine coal and the condition of circuits within the preparation facility.
3. All daily production samples are performed in duplicate. If the two duplicate analyses do not agree within acceptable limits of repeatability, the sample is analyzed a third time. A reserve split is analyzed if no agreement can be attained by reanalysis of the same sample. At the Midwest Area Laboratory, two −8 mesh splits are prepared for each daily production sample and separately analyzed. At the mine laboratories, the −60 mesh sample is analyzed in duplicate, and only if agreement cannot be attained from duplicate analysis of the same −60 mesh sample is a second −8 mesh reserve sample analyzed.
4. Correlation between dry ash results and dry Btu results have been established. These ash-Btu correlations, as well as ranges derived from the past few months' analysis trends and repeatability limits established for each test, are the basis for our recheck criteria of daily mine production analyses. The

ash-Btu correlation is both a simplification and an extension of work previously done by various individuals and groups. Essentially the correlation is based upon the premise that the calorific value of the pure coal substance, or the dry, mineral matter–free coal substance, from a given location and coal seam is typically quite constant. The calorific value of a coal shipment can then be calculated provided that the moisture, ash, and in some cases, the sulfur values are known. For a more complete description of this process refer to the *Chemistry of Coal Utilization* [*1*].

AMAX Coal Company has independently determined these ash-Btu correlations from both core sample data and daily production samples. Table 1 gives the values of the multiple linear regression coefficients and constant term determined for various coal seams at various locations in the West and Midwest. Figure 4 gives typical ash-Btu correlation curves established for some seams at some locations.

Accreditation

Up to this point, this paper has noted the various links in AMAX Coal Company's "certification" scheme. Several references will now be cited that either have or will possibly have an impact upon the accreditation efforts of sundry groups, possibly including AMAX Coal Company at some time in the future:

1. The National Voluntary Laboratory Accreditation Program (NVLAP) procedures as published in the *Federal Register* on 23 Jan. 1980 (45 FR 5572–5600) and the proposed ammendments thereto as published in the *Federal Register* on 27 Jan. 1981 (46 FR 8910–8919).
2. The Office of Management and Budget Circular No. A-119 issued 17 January 1980.
3. The Final Procedures under Part 19 of the Code of Federal Regulations, Federal Interaction with Voluntary Standards Bodies, as published in the *Federal Register* on 6 Jan. 1981, (46 FR 1574–1587).
4. H.R. 2313, the Federal Trade Commission Improvements Act of 1980, Public Law 96-252.

These regulations affect or will affect standardization and accreditation processes throughout the United States.

National accreditation is a double-edged sword. On the one side, accreditation will help to improve quality or at least will project an image of improved quality. Most independent coal-testing laboratories do a good job of producing high-quality results, but accreditation will encourage more emphasis on quality assurance. National accreditation will lead to the belief that as long as a laboratory is accredited the quality of its results are assured. This will

TABLE 1—*Typical ash-Btu correlations.*[a]

Mine Location and Type	Multiple Linear Regression			
	Constant Term		Regression Coefficient	
	Daily Production Data	Core Data	Daily Production Data	Core Data
Indiana, surface	14 358	14 285	149	149
Indiana, surface	14 600	14 595	161.5	158.4
Illinois, surface	14 764	14 672	161	159.5
Indiana, surface	14 325	14 420	136	147
Indiana, surface	14 411	14 420	143	147
Indiana, surface	14 543	14 420	150	147
Illinois, surface	14 289	14 185	146	143
Illinois, surface	14 410	14 491	122	156.3
Illinois, surface	14 537	14 491	145	156.3
Illinois, underground	14 559	14 386	155	150.5
Indiana, surface	14 409	14 467	154	163.3

[a] Formula used to calculate dry Btu from the dry ash value: [constant term—(dry ash) (regression coefficient)]=(calculated dry Btu).

improve the consumer's confidence in the accredited laboratory and it may even improve quality as well.

On the other side, the need for national accreditation implies that the independent laboratory is presently not producing results of adequate quality. Are there really laboratories doing unacceptable work, or do we simply have a public relations problem? Certain unscrupulous businessmen will take ad-

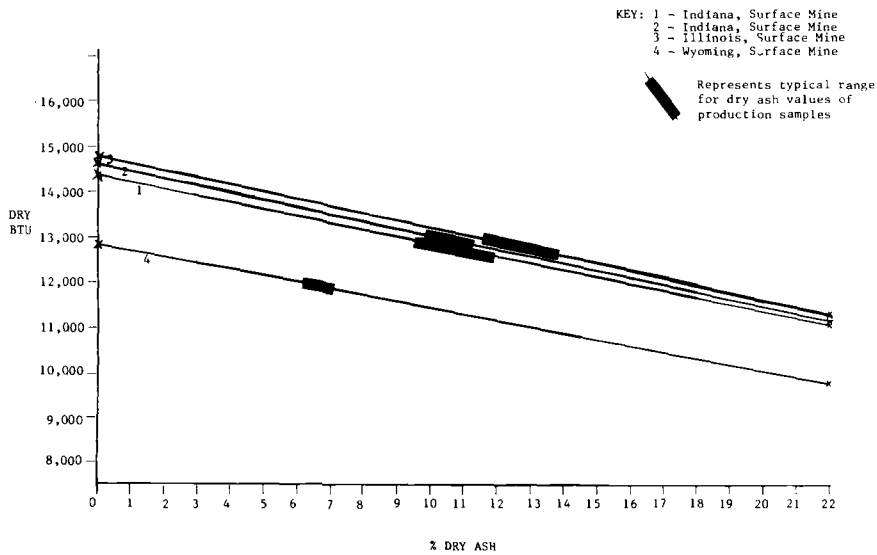

FIG. 4—*Typical ash-Btu correlation curves.*

vantage of the public and the system whether accreditation is part of that system or not. But it is difficult to believe that in today's highly competitive market, laboratories that produce inaccurate, imprecise analyses could survive. But this may only be naivete.

Conclusion

In the area of coal testing there is no accrediting authority. This author believes that a national accrediting body would be valuable for this area of testing. However, it is felt that such a body is not the only alternative to greater acceptance. Furthermore, such national accreditation without changes in other areas would not be worthwhile.

Education in the why's and how-to's of quality assurance, sampling theory, and information handling would be a great boon to coal testing laboratories.

More commitment to development of effective standards is essential. For years the western coal fields were largely ignored as a source of fuel. The standards that were written and work extremely well for Eastern and Midwestern coals are not quite adequate for some Western subbituminous coals. Standards that will find applicability and acceptance for coal conversion techniques must be developed.

Most importantly, upper management must make a commitment to achieve the goals of a national accreditation program. This could be accomplished either through a federal program or through actions generated within the coal testing community. The latter option has the greater appeal to this author. The coal testing laboratories of the United States *are* performing adequately and such an accreditation program should prove this. Let's hope that politics and regional differences do not interfere with the accomplishment of these goals.

References

[*1*] Lowry, H. H., *Chemistry of Coal Utilization,* Wiley, New York, 1945, pp. 138–143.
[*2*] Decker, H. W., *Coal Preparation,* Pennsylvania State University, University Park, Pa., 1973, p. 148.

W. Robert Woodall, Jr.[1]

A Public Utility's Approach to Evaluating Laboratory Test Activities

REFERENCE: Woodall, W. R., "**A Public Utility's Approach to Evaluating Laboratory Test Activities,**" *Evaluation and Accreditation of Inspection and Testing Activities. ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 39–45.

ABSTRACT: The purpose of this paper is to discuss a public utility's approach to obtaining satisfactory and reliable evaluation, verification, and accreditation of its laboratory testing. These activities include fuel testing, chemical testing, identification and analysis of biological samples, testing of electrical equipment, and the like. An essential need is to demonstrate credible results and test procedures that will be accepted by regulatory agencies, fuel vendors, and the courts if necessary.

This paper will present the pros and cons of several evaluation techniques. These include a company-wide quality assurance program, sample verification by expert consultants and third party laboratories, split sample analyses with vendor laboratories and sister utilities, and sample splits with government laboratories.

The licensing or certification of individuals, laboratories, and equipment is important in the context of this discussion. Although individuals and equipment can be tested and certified, it is difficult to certify technique in the daily laboratory routine. This paper will also review the concept of a national standardized accreditation program versus accreditation by professional societies and organizations closely allied to certain disciplines.

KEY WORDS: accreditation, evaluation, quality control, quality assurance

In my position at Georgia Power Company, I am responsible for the centralized testing of fuel, water, and environmental parameters.

This includes analysis of coal and oil for heating value, sulfur, ash, and moisture; fuel oil stability; engine and turbine oils for metals analysis; mineral, microbiological, and other standard analyses of water for environmental permits; calibration of oil receiving meters; amount and composition of boiler tube deposits; analysis and collection of meteorological data; collection of radiochemistry samples in the environs of nuclear power stations; collection, identification, and interpretation of terrestrial and aquatic biological data; and any other function that can be addressed by chemists, meteorologists, biologists, or engineers with specialities related to those disciplines.

Other laboratories in the company test electrical equipment and soils. At

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the power plants, laboratories perform chemical analyses and (at nuclear plants) radiological analyses essential to the daily operation of the facility. Although these latter three categories are not a functional part of our central laboratory group, this paper attempts to express the collective opinions of all laboratory management within Georgia Power Company. Personnel from our service company, Southern Company Services, have also contributed to this paper, especially in the area of fuel analysis.

The basic premise upon which this paper is based is that laboratory evaluation is something that must be handled on a case-by-case basis to the mutual satisfaction of the parties involved. Let us begin by defining the terms *accredit* and *evaluate.*

Accredit—To put into a reputable category; to give official authorization to or approval of; to provide with credentials; to vouch for as in conformity with a standard [*1*].

Evaluate—To examine or judge.

Quality assurance and quality control are both integral parts of a laboratory evaluation program. For the purpose of this particular industry application, these terms are defined as follows:

Quality control (QC)—Inspection, surveillance, and review activities performed for the purpose of process control or product acceptance, or to verify that an activity conforms to specified requirements. Those things done before or during any operation so that the finished product is within specifications. (The preceding definition appears in the American Nuclear Society/American National Standards Institute [ANSI] standard, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants [ANSI N18.7].) Quality control is considered to be a line function.

Quality assurance (QA)—All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. It applies to all activities associated with doing a job correctly as well as verifying and documenting the satisfactory completion of the work. (Definition from ANSI N18.7.) In other words, checks to determine if quality control is effective. Quality assurance is considered to be a staff function.

Our quality control efforts exist at the first line level in the laboratory. These consist of cross-checks in the laboratory, reruns of suspect samples, internal sample splits, round robin analyses, etc.

Quality assurance begins with verification and documentation within a particular laboratory section. This is followed by periodic inspection by the company QA organization or by the service company QA organization. Another level of QA comes from regulatory agency audits or visits from representatives of vendor laboratories with whom we split samples.

T. E. Byerley, our manager of environmental affairs, says, "First, we must determine if we are doing the right job. Then we must determine if we are doing the job right." Finally, we must determine if the job was done right. Regulatory agencies, upper management, or contracts tell us what the right job is. Then, it is up to line and middle management to determine that the job is done right, by developing and enforcing proper procedures.

I shall first discuss methods by which we satisfy ourselves that our scientists, engineers, and technicians are performing credible work, then discuss the means by which we decide that our vendors are performing credible work, and finally describe how we have demonstrated to regulatory agencies or courts that our work is credible. The final discussion will examine the problems associated with a national accreditation program and will suggest some alternatives that we believe are quite effective.

Evaluation of Our Staff and Facilities

Every laboratory operation has a different approach that is tailored to management philosophy, regulatory requirements, and company needs. In our environmental laboratory all the scientific personnel hold at least a bachelor's degree in the discipline in which they work. About half hold master's degrees. Others have advanced training in addition to their degree. The academic training is varied among biology, entomology, zoology, mechanical engineering, environmental health, ecology, wildlife, botany, meteorology, and other fields. In the chemistry laboratory, all analysts have degrees in chemistry or laboratory technology. The fuel laboratory is staffed by non-degreed personnel and chemistry and physics graduates with special expertise in coal. Clerical personnel are selected for their ability to deal with technical and scientific material. Supervisory personnel have advanced degrees or extensive experience in the public utility laboratory. We feel this mix provides a good array of education and experience to address our needs.

Our first consideration is that our own laboratory work and that of vendor laboratories meets the approval of the supervisor and company management. Having passed this test, the work is generally acceptable to regulatory agencies.

Mutually agreed upon procedures are used. In the case of a regulatory requirement, we may follow or modify an Environmental Protection Agency (EPA) guide, a Nuclear Regulatory Commission Regulatory Guide, American Public Health Association *Standard Methods,* or an ASTM procedure.

The methodology is generally agreed upon through discussions between both parties at the technical level, whether we are dealing with a vendor or a regulatory agency. In the case of coal analysis, some vendors have their own laboratories and participate in cross-checks with our company. In most types of environmental sampling, work is done in-house, and third parties or consultants are seldom used for routine analysis, although they are used for

verification. (Our state regulatory agencies prefer this approach.) A substantial proportion of our radiological work is performed by contract laboratories.

In our laboratories, instrument calibration is performed and recorded routinely according to the manufacturers' specifications and instructions. Where applicable, standards are used. For example, National Bureau of Standards calibrated thermometers are used to calibrate thermographs, benzoic acid is used to standardize calorimeters, and gold wire is used as a standard in ash fusion tests.

In the environmental laboratory, each program is audited annually by a scientist in the laboratory who is familiar with that program but is not working directly with it. In the laboratory, approximately 10% of the biological samples are cross-checked at random by peer inspection. Routinely, individual organisms are sent to accepted outside experts, usually at a respected academic institution, who verify the correctness of sample identification. In the case of nuclear power plant sampling, once each year the company quality assurance representative inspects the laboratory programs. The company inspection is followed by an audit from the U.S. Nuclear Regulatory Commission. In the case of studies performed for the State of Georgia, the state scientists have visited our laboratory and observed work in progress. Occasionally, samples are split with a state laboratory.

In the fuel laboratory, quality control is handled by duplicates, retests on suspect results, comparison with past and current results, and sample splits with other labs. There are many comparisons with fuel vendor and commercial laboratories on routine analysis, and comparisons among different methods of analysis.

In the chemistry laboratory, we follow the EPA recommendation of running duplicate tests on 10% of samples and running QC standards for each parameter once per quarter. A QC supervisor for each month is appointed from within the laboratory.

In our physical testing facilities, the ASTM standards are used extensively and incorporated into our procedures manual. (One court case that involved a challenge to our results concerned a procedure that had been slightly modified to meet our needs. The judge ruled in favor of our company because our procedures more closely followed ASTM than those of the plaintiff.)

Evaluation of Vendor or Consultant Laboratories

Informal opinions of colleagues from other utilities have strong influence on the acceptability of a consultant laboratory. Another important aspect in the selection of a vendor laboratory is its willingness to provide service. Such service includes providing prompt analyses when requested, processing reruns, answering inquiries responsibly, and the ability to promptly determine the status of a sample that is being processed.

Our laboratories cross-check and split samples with vendors and contrac-

tors and thereby we satisfy ourselves that their work is acceptable. Before a vendor laboratory is selected, we satisfy ourselves that credible work will be produced. The staff and facility are inspected or at least the staff is interviewed by our technical people. In some instances, third parties are brought in to perform independent analyses. In other cases, samples are split with a state regulatory agency.

The Accreditation Question

Laboratories seeking national accreditation run the risk of falling into the same trap that snares academic institutions. A facility may have all the ingredients for being accredited, save one. In the case of a university, it may be too few books in the library, or one too few PhDs on the faculty. I can envision a laboratory that cannot be accredited because one of its staff may not have the proper academic degree, even though he or she may have 20 or 30 years of experience and be the best chemist in the state. With respect to grandfather clauses, we face the problem of the employee with longevity who may be the worst chemist in the state.

Both academic training and certification are important. A dean's list student may be clumsy or sloppy in laboratory work. However, the academic credentials can indicate something about the candidate's ability to think scientifically. In some laboratory applications this is more important than in others.

A number of our laboratory personnel have become certified in their discipline by peers in professional societies. This is encouraged by management, but not required. If the certification process functions properly, it is an adjunct to the employee's credentials. If not handled properly and conscientiously, it becomes a farce.

If the conditions of a contract can be satisfied to the agreement of the customer, client, vendor, regulatory agency, or other parties involved, then no additional accreditation is necessary. This could be accomplished by following ASTM procedures, an EPA manual, or a mutually acceptable procedure from the literature.

Evaluation of a laboratory must be handled on a case-by-case basis. Outside inspectors and auditors can only inspect a procedures manual or interview employees. They are seldom capable of assessing the quality of techniques used, the credibility of the individual technicians, or the calibration and reliability of all equipment. These items must be handled by the frequent attention of an employee in that laboratory who is intimately familiar with its operation. Employees should know that management expects quality work and stands behind them.

National programs are too inflexible and too susceptible to bureaucracy. National accreditation of personnel will most likely be done through: (1) testing, (2) a requirement of experience, and (3) the possible added require-

ment of a recommendation of one or more persons who are already accredited. Let us look at these individually.

Many persons are not adept at taking written examinations: an excellent laboratory technician might fair poorly on a written exam. By the same token, an individual with extremely poor laboratory techniques might perform very well on a written test.

Second is the requirement of experience. The saying that "experience is the best teacher" is often, although not always, true. This area also includes grandfather clauses, which were discussed earlier.

Recommendations by peers offer little uniformity. We only ask persons to serve as references whom we expect to give us a good recommendation. This aspect of certification or accreditation has the "fraternity" approach.

Standards for evaluating laboratories are good and necessary, but should be applied by the individual laboratory using the accepted literature in its field. A laboratory's reputation spreads quickly. Most potential clients will check with other customers before selecting a laboratory and then invoke the criteria of cross-testing split samples, previously mentioned, before making a final decision. A laboratory that produces poor work will not survive in today's business and regulatory climate.

Standards that include experience, education, techniques, procedures, evaluations, audits, etc., are fine, but the willingness and ability of a laboratory to implement those qualities and to expedite work are much more important. Standards should be invoked voluntarily in the form of individual laboratory goals, guidelines, and accepted manuals.

Certification by professional societies may be the best type of certification. A national association that attempts to certify all types of laboratories is impractical. It will be by nature inflexible and prone to bureaucratic bog-down.

Next is the possibility of federal management of the accrediting body. Before long, standards become regulations, or at the least, regulatory guidance which if not followed could result in a laboratory's data not being accepted or a revocation of laboratory certification. Then there is the possibility that an accrediting agency would not agree with a regulatory agency and the corporate laboratory would be caught in the middle.

Another negative aspect of a federally controlled standards organization is that it would be supported with tax dollars, so everyone pays for the service whether they use it or not. Independent evaluation as discussed in this paper, rather than blanket accreditation, places the expense on the user, who because it is his money and not everybody's money, will be more conscientious about the costs of evaluation.

Bureaucratic systems generate paperwork. There is already enough of this. Time, money, and resources would be wasted filling out the forms, check lists, and audit reports that would result from a nationwide program. A program this general would not be specific enough to many clients and the independent evaluations would continue.

General Conclusions

Laboratory evaluation can be accomplished most effectively by the companies that are involved. It is the responsibility of laboratory management to evaluate company and vendor laboratories using voluntary standards, such as those developed by ASTM, and to assure upper management that these laboratories are in conformance with these standards.

Acknowledgments

I wish to thank the following individuals for contributing to the development of this manuscript: James H. Boykin, T. E. Byerley, C. B. Boatright, H. R. Reese, W. H. Ollinger, B. L. Maulsby, F. D. Scott, and J. B. Sills of Georgia Power Company, and G. A. Linton and W. N. Thurman of Southern Company Services.

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Robert Harris[1] *and G. Tom Castino*[1]

Laboratory Accreditation: More Than Rules

REFERENCE: Harris, R. and Castino, G. T., **"Laboratory Accreditation: More Than Rules,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 46–53.

ABSTRACT: Effective accreditation of third-party laboratories offering product evaluation and follow-up inspection services requires a prescription of laboratory performance and measures to assure compliance with the prescription. While documenting the established criteria can be considered the major hurdle for effective laboratory accreditation, the most difficult step may well be assuring that the accredited laboratories meet and maintain desired levels of performance. An effective accreditation program is more than rules: it is evaluation, audit, and follow-up.

This paper reviews key elements of laboratory accreditation programs that must be considered to achieve the targets that the rules have established. Consideration is also given to the critical elements required by agencies implementing laboratory accreditation programs.

An analysis of hypothetical programs that lack these critical elements is presented with the purpose of demonstrating that accreditation programs lacking one or more of the critical elements are ineffective and allow laboratory performance to be lowered to a marginally acceptable level.

KEY WORDS: accreditation, laboratories, accrediting agencies, critical elements, follow-up, audit, standards, performance, evaluation

The stated goal of most laboratory accreditation programs is to verify that a laboratory providing specific testing services is technically competent. This goal may be achieved only when testing laboratories seek the accreditation and are found, by valid evaluation procedures, to meet the qualification criterion established. It should be emphasized that completing an application form, which provides a written response as a means to show compliance with the rules, should not by itself be relied upon to determine that testing laboratories meet the established qualification criterion. Laboratory accreditation is more than rules!

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Establishing the Standard of Performance

A laboratory accreditation program must strive to establish an overall standard of performance, with sufficient detail and procedural guidance aimed at producing a suitable level of performance, if it is to become the criterion adopted by the industry and regulatory community. The standard of performance chosen, while meeting the objective of the accreditation program, can also influence such factors related to the testing operation as demand for and cost of the service, competitive incentives, and management complexities. Furthermore, this influence may not always be beneficial. An accreditation program does not, by its nature, provide assurance that the overall effort will be for the good of all. Developing an accreditation program that will achieve the stated goal while remaining essentially free of special interest influence is not an easy task.

A laboratory accreditation program must consider more than written rules to be effective. In addition to establishing the criterion to which a laboratory's testing program is evaluated, and providing a means whereby each organization can be examined against the rules, additional factors must be considered. For example, the information provided in the written application from the laboratories should be determined to be accurate. This may only be accomplished by including in the evaluation process an inspection of the laboratory facilities. It is during the inspection of a facility that an opportunity is provided to spot-check the documentation provided by the laboratory and confirm that the written responses agree with the laboratory's performance ability. It would also be reasonable for an accreditation program to consider conducting future unannounced inspections as a means of ensuring that the competency is maintained.

A laboratory accreditation program should include a procedure to handle the violations noted where procedural documentation has been required. The ability to efficiently resolve an appeal by a laboratory disputing the violation should be considered. The procedure must be established without bias and with the purpose of evaluating disputes against the original objective of the accreditation program, considering current information.

Additionally, the accreditation program should, where documentation is required, insist that the written descriptions correlate with the current and accepted practice. Where alternative practices are considered and accepted, and documented procedures are required, these too should be formalized by the accredited laboratory.

When variations of the documented practices are discovered by inspections of a laboratory facility, that laboratory should make a formal response to the accreditation agency for review, detailing the action proposed by the laboratory.

Critical Elements of Laboratory Accreditation Programs

What are the critical elements that must be considered in establishing an effective laboratory accreditation program?

The general criteria should determine the capability of a laboratory to perform the testing program to be accredited, objectively and competently, without conflict of interest. To accomplish this, the accrediting process must measure, to a reasonable and generally accepted degree, levels of engineering and technical proficiency, testing accuracy, and ethical practices. The procedures should also determine that the services provided by the organization are without prejudice due to such matters as affiliations with other agencies or organizations.

An accreditation program must insist that the information provided contain the detail necessary to disclose limitations or deficiencies of the laboratories being considered for accreditation. A program effective in this endeavor obtains an important measure of credibility.

To maintain long-range effectiveness, an accreditation program must require accredited laboratories to report in writing fundamental changes that occur after the original application was submitted and accepted. In this regard, fundamental changes are such things as changes in the laboratory's ownership, affiliations, facilities, key personnel, major test equipment, basic testing procedures, and business interest.

Review of Information

Following the development of an effective application form and the methodology to acquire the basic information needed by the accrediting authority, the next important aspect of the program to be considered is the process used for evaluating the submitted information.

The evaluation of the information provided in the application form and the basis for judging a laboratory's conformance to the applicable test program criteria will necessitate the development of a norm or standard to assess the effectiveness of the accreditation program. This norm or standard should be developed in advance of implementing the laboratory accreditation program and should adopt the generally accepted guidelines for good laboratory practices. Establishing the criteria used to judge applicants in advance will reduce subjective judgements and the need to revise the criteria each time a new situation is encountered.

The information should be confirmed by an on-site inspection that will also countercheck conformance to the specific criteria applicable to the test program for which the laboratory seeks accreditation. The inspector conducting the audit of the laboratory must be capable of making independent and unbiased judgements based on valid written and uniform criteria. To support the inspector in this effort and to speed the audit process, the appli-

cation form information should be assigned priorities indicating relative importance.

The desire to audit the data provided by applicants may suggest to some an indictment that, in general, laboratories will provide only favorable information or bias their responses in the accreditation process. However, a closer look at the audit function will show that this is not the case. The audit process serves many purposes.

The audit process will help maintain and enhance the desired level of competence by providing a means to confirm that the intended meaning of the questions in the application form was properly interpreted. It also allows for verification that the criteria level established is reasonable. The facility inspection audit can provide an accreditation agency, through their inspector, with feedback on the impact of any rule with regard to time or cost for the laboratory operation, which in turn could be helpful in judging requests for revisions. Again, the accreditation effort must be more than regulations.

Requiring a Quality Assurance Program

Currently, laboratory accreditation programs sponsored by federal, state, and local regulators place a major emphasis on the written documentation of conformance to established criteria, stressing testing, calibration, and maintenance programs as primary basis for judging compliance with accreditation rules. However, limited attention is given to the quality assurance programs within the laboratory being accredited. The quality assurance programs provide the control that maintains the overall accuracy and uniformity of the test results for that laboratory. Perhaps, then, laboratory accreditation programs should permit a determination that a quality assurance program is suitable and in operation and that the program maintains the desired control of the laboratory operations.

Laboratory quality assurance programs should be based on generally accepted guidelines for the quality control of the laboratory's method of operation. The guidelines should:

1. Be documented and include specific information and procedures for conducting each individual test program being accredited.
2. Respond to the detail required by the accreditation program criterion to the extent that applicable requirements of the specific criteria are described.

Where then must accreditation programs go beyond these rules?

The Facility Audit

Accreditation programs that require the laboratories to provide, in writing, laboratory quality control practices have, as a result, established rules

that define the objectives for the entire program. To be more than rules, the accreditation program must conduct an on-site audit of the quality control practices. This audit should include determining that the information provided in the application is in effect and is adequate to guide a testing technician in conducting the tests accredited under the program.

Few currently active accreditation programs provide for meaningful audit of the laboratory facilities and operation. Accreditation programs that do require a laboratory facility audit generally place little or no emphasis on countercheck procedures or other methods to verify the details of the descriptive procedures submitted. Too frequently, the inspection is only a cursory examination that provides little more than an opportunity for the examiner to visit the laboratory and make general facility observations. An accreditation program must direct more attention to the actual evaluation of personnel capabilities and the accuracy of test equipment required to perform the tasks for which the laboratory is being accredited. Detailed specific criteria must be provided that will require a decision by the accreditors. Additionally, the site inspections must be more than a one-time effort of limited scope and must include follow-up confirmation in the future. Here is where accreditation programs must go beyond the rules!

Reference Testing

The follow-up inspection of a laboratory's facilities and quality control procedures on some periodic and unannounced basis will reasonably assure that the desired criteria of the accreditation program are satisfied. However, it may not assure that the test and evaluation service covered by the accreditation program meets the intended level of quality. Therefore, reference testing should be another critical element. An accreditation program that includes reference testing in the accreditation process further enhances the program's achievement of the stated goal. Further, the reference testing policy must be mindful that an initial evaluation that shows that a laboratory is capable of performing the testing program provides no assurance that the laboratory will continue to do so in the future. A laboratory's capability is affected when personnel change or are transferred or promoted and the new personnel are not adequately trained to fully understand the accredited testing programs. Also, the desire to reduce costs can produce an unintended reduction in quality. Therefore, the critical element should be a policy of periodic reference testing by an independent facility. This random countercheck test function may also serve as the basis to measure the effectiveness of the accreditation program.

Without All Critical Elements

Consider for the moment an accredited laboratory operation where all critical elements of an effective accreditation program are not included.

First, consider the accreditation program that does not have an on-site inspection requirement to determine that the criteria established by the rules are in fact being met. It has already been acknowledged that accreditation programs of this type would allow the applying laboratories to have the opportunity to present information in the application without the need to be able to support that information.

It is also recognized that this approach reduces the opportunity for the accrediting agency to validate the feedback it receives on the program. The ability to change a criterion that is ineffective, inappropriate, or just expensive to implement, when considering the little perceived benefit obtained by the criterion, is hampered. In these situations, laboratories participating in the accreditation program who choose not to, or for various reasons cannot fully satisfy the accreditation agency's requirements may have an effect of lowering the performance level to which other laboratories accredited under the program must compete. Consider then, the effect this would have on other accredited laboratories if the accreditation program has, in effect, tended to equalize competition for the testing program accredited. Would it, for example, have the effect of forcing all laboratories to a level of performance equivalent to the lowest level of performance? If so, this would be contrary to the basic objective desired by the laboratory accreditation effort.

Second, consider an accreditation program that has on-site inspection but does not require future follow-up to assure that a laboratory continues to provide a technically competent testing service. Recognizing that accreditation programs tend to neutralize any difference in the performance of competing laboratories, some laboratories may, in order to be more competitive, desire to reduce the costs of their service. Without the threat of future inspections to confirm that the level of technical competence is being maintained, it is conceivable that these laboratories may find that reducing the quality control on the service performed provides the easiest way to reduce cost. While the intent may not be to reduce the quality of the testing services, wouldn't one expect that such measures as reducing the testing technicians training program, abbreviating the quality assurance program, or curtailing other laboratory practices would result in a reduction of overall testing quality? Usually, any change in testing ability tends to be a gradual process that may only be detected by a continuous unannounced audit of a laboratory's operation. Here then is another reason for accreditation programs going beyond the simple implementation of rules. There must be future unannounced inspections by examiners qualified to evaluate the established criteria.

Finally, consider the laboratory that has tried to meet all of the criteria required of an accredited laboratory, at least on paper. Reference testing conducted under the supervision of the accreditation agency may find that the product testing being conducted by the laboratory does not satisfy the applicable testing requirements. Impossible? Not really. Testing personnel, while technically competent, may not be fully informed on the accredited testing

methods. The allowance for subjective decisions by the quality assurance program in effect within a laboratory may allow the actual results to diverge from the intended results. All of us, on occasion, have found great difficulty in explaining how a mistake that should not by all standards have occurred was discovered through countercheck procedures.

When a program designed to verify a laboratory's technical competence fails, who is to blame? Is it the manufacturer, who produced a product that is only marginally able to meet the specified testing criteria? Is it the laboratory that failed to conduct the level of evaluation necessary to disclose a marginal design? Maybe it is the laboratory accreditation program that does not go beyond the rules to assure compliance with the stated goal.

There is no one right answer and no single blame. The real point to be made is that compliance with an adopted testing program is the responsibility of all concerned. Again, the laboratory accreditation program must go beyond the rules.

Summary

Based on the considerations that have been discussed herein, and the experience that has been gained to date with laboratory accreditation programs, a recommendation can be made that these programs include:

1. The maintenance of performance records.
2. Feedback mechanisms for program improvements.
3. Procedures in case of noncompliance or errors.
4. Unannounced audits of the laboratory facilities at random intervals.
5. A quality assurance program.
6. Evaluation of personnel proficiencies.
7. Independent countercheck reference testing.

These critical elements establish the points where laboratory accreditation goes beyond the written rules.

Laboratory accreditation programs encompassing the key ingredients of the recipe discussed in this paper can meet their established objectives. These guidelines will also permit laboratories accredited under the program to be able to function objectively and competently.

This paper has stressed the methods by which laboratory accreditation programs can achieve their stated goal. It must also be emphasized that laboratory accreditation is only the process whereby a determination is made that a laboratory is capable of performing a testing program properly. There is nothing in the accreditation process that states or guarantees that a laboratory will perform the test method properly. Also, there is no implied or established standard or range of values to evaluate the quality of testing that a laboratory performs. It is important, therefore, that an accreditation pro-

gram recognize the program's limitations and not try to promote or allow accredited laboratories to advertise their accreditation on products tested by the laboratory. An advertisement hangtag or label on a product announcing that the laboratory is accredited tends to assure the end user that the product meets a standard. This is not the objective or intent of laboratory accreditation programs.

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Quality Assurance at the Ford Motor Company Central Laboratory: A Dynamic Approach to Laboratory Quality

REFERENCE: Gaft, S. and Richards, F. D., **"Quality Assurance at the Ford Motor Company Central Laboratory: A Dynamic Approach to Laboratory Quality,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 54–61.

ABSTRACT: Quality assurance can be realized by integrating the concepts of quality of data, certified calibration of equipment, and approved methodology. At the Ford Motor Company Central Laboratory, this is accomplished by enlisting employee commitments to quality into a program that measures the laboratory output (reports) for equipment calibration and standards, test methods and sampling, overall report quality, and record retention. This paper describes a quality assurance program developed and implemented at Central Laboratory in 1978. The program has been readily accepted by laboratory management and engineers and has yielded an impressive reduction in significant discrepancies in laboratory reports since its inception.

KEY WORDS: accreditation, quality assurance, quality control, laboratory audit, evaluation, detection, feedback, assessment

Testing laboratories have a responsibility to ensure the information they provide is free of bias and truly describes the conditions their tests claim. At Ford Motor Co. Central Laboratory Services, a program to assure that laboratory data met these requirements was implemented in 1978. The program, called "The Quality Audit," consists of assigning one individual the responsibility to sample reports completed during the previous month and conduct a detailed evaluation of all data reported. Special emphasis is placed on equipment calibration and standards, test methods and sampling, test outcomes, report quality, and record retention. The audit is conducted in a con-

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fidential, nonthreatening manner between the "auditor" and laboratory personnel. The findings, expressed in generalities rather than specifics, are reviewed and agreed upon by supervisors and selected laboratory engineers before being forwarded to laboratory management. This paper describes that program: how it is organized, the dynamics and mechanism of its operation, and its results. It is being presented as our contribution to the present dialog on laboratory quality and accreditation with the hope that other laboratories might repeat, and possibly confirm, our success.

Audit Procedure

To appreciate the details of our audit program, it is necessary to describe the function and organizational structure of the laboratory. Central Laboratory is Ford Motor Company's largest nonresearch materials testing laboratory. It consists of a technical staff in excess of 100 people and over $4 million worth of equipment with approximately 4000 m^2 (45 000 ft^2) of test area. The primary function of the laboratory is to support engineering, manufacturing, and purchasing decisions on material/component usage in company products and manufacturing operations. Materials tested include metals, plastics, elastomers, paints, fuels, lubricants, textiles, adhesives, sealers, deadeners, wastewater, and ceramics. The laboratory performs work for all divisions of the company and charges fees to the requesting activity only for the work requested.

The laboratory is divided into three organizational groups reporting to a Services Manager: Metallurgy Department, Chemistry Department, and an Administrative/Development Group. All testing is concentrated within the two operating departments while the Development Group acts in a staff or supportive role. The quality program centers the auditing responsibility in the support arm. It audits the tests performed in the operating departments using a single auditor.

In addition to this formal organizational structure, there is also an informal structure. It is composed of supervisors of all departments who are members of a long-standing committee that discusses laboratory-wide problems and recommends corrective actions or procedures. Problems relative to billing and operating procedures and administrative issues are routinely channelled to this committee. Quite naturally, this committee plays a key role in the quality audit program. The initial guidelines were accepted by it and any changes in the audit procedure must have its approval. This is a crucial point of the audit and contributes to its acceptance by the supervisors since they are involved in the procedure formally by reason of their operational role and informally by reason of their association through the supervisors'

committee. The three principal steps of the Central Laboratory quality audit are:

- Evaluation and detection
  Test engineer(s)
  Supervisor(s)
  —Standards
  —Specifications
  —Calibration
  —Methodology
    Procedures
    Sampling
    Testing/retesting
    Computations
  —Report
  —Record retention
- Assessment
  Supervisors
  —Discrepancies
    Minor
    Significant
  —Categories
    Equipment calibration and standards
    Test methods and sampling
    Test outcomes
    Report quality
    Record retention
- Feedback
  Quality audit report
  —Section review
  —Supervisory review
  —Management report

Evaluation and Detection

The initial step in the quality audit includes evaluation and detection. First, the auditor selects ten reports randomly from the approximately 700 reports completed in the preceding month. Second, each report is evaluated by the auditor to determine if the customer's request has been met by comparing the final report with the initial request. Then, all of the standards, specifications, and test methods used or noted in the report are studied. Next, the auditor conducts in-depth interviews with the engineers and super-

visors responsible for the ten reports selected. The meetings are confidential, and none of the details of the evaluation are revealed to others by the auditor. During this phase, a review is made of the calibration and standardization of all equipment, solutions, and test fluids used to develop the test data. Additionally, laboratory engineers' notebooks and other retained records of the section are used to reconstruct all of the tests performed. Special attention is given to sampling, testing and retesting, all computations, and record retention. Section records are reviewed to ensure the most current specifications, standards, and procedures were used. Printouts from computerized equipment and data from recording devices such as *x-y* plotters are reviewed. Sometimes it is necessary to run some tests over to confirm the original data. Reruns are requested only when the test data indicate a possible error or misinterpretation. Also, during this phase of the audit all potential discrepancies are identified.

Assessment

The second step in the quality audit is the assessment phase. During this phase, all questionable results or practices are reviewed privately between the auditor and the section supervisor responsible and any discrepancies are classified as minor or significant discrepancies. A significant discrepancy is one which effects the conclusion of a report. All other discrepancies are considered minor. The audit program requires that the section supervisor assign and rank the discrepancy; that is, even though the auditor may detect a questionable result or practice, it does not become one unless it is verified by the section supervisor. At first appearance, one might expect that this practice would risk bias. On balance, it is the opinion of the authors that the section supervisors have been quite realistic and straightforward in accepting discrepancies during the assessment phase.

Feedback—The Quality Audit Report

A quality audit report is written by the auditor. It includes statistical data regarding the discrepancy rate on the current audit and how it relates to previous audits. All discrepancies are reported in very general terms so that anonymity is preserved. The focus is on identifying the discrepancy rather than the individual, section, or department where it occurred. This point is crucial to the audit procedure. A great deal of caution is taken to ensure that the actual discrepancy cannot be traced to the individual involved. It is necessary, however, to provide enough information to alert the entire laboratory as to the kind of discrepancy that has occurred. The report also contains a section for remarks, which provides a means of communicating recommendations and alerts of conditions that are uncovered during the audit to all levels of the laboratory. The review has proven to be a powerful tool to highlight areas of

difficulty as they are encountered. Since the report is addressed to management, high-level visibility is easily and rapidly obtained. Management support for the audit program is evidenced not only by its original insistence that it be instituted but also by its quick response to the items detailed in this section.

Another important feature within the feedback process is the review of the auditor's report with a small group (15 to 20) of test engineers. A rotating schedule provides that each test engineer will be invited to participate in this review at least once every four months. This practice encourages greater participation and more support on the part of laboratory engineers. The report requires the concurrence of the people attending the meeting before it can move to the next level of acceptance. Every effort is made to reach a consensus before the report is forwarded to The Supervisors Committee for its review and approval.

Usually, only minor changes or recommendations are made before the "final report" is sent to the department managers and the laboratory services manager. The report provides management with a quantifiable measure of quality in the laboratory and a tool to implement corrective actions on quality issues. The report is reviewed at the management staff meeting and with the supervisors at department meetings. Each step of this entire process of feedback concentrates on the reinforcement of the concepts of quality. The amount of time spent at meetings dealing with quality is minimal compared to the overall benefit.

Results and Benefits

The Quality Audit Program at Central Laboratory has been very successful in improving laboratory quality. Figure 1 shows the reduction in discrepancies from August 1978 through November 1980. The numbers along the horizontal axis represent the numbers of months and the vertical axis represent the discrepancy rate per audited sample. All discrepancy categories used to evaluate quality, except for minor discrepancies in report quality, have shown impressive reduction since the introduction of the audit system. To improve in this area, a formal procedure for report writing has been prepared and is currently being reviewed by the laboratory supervisors.

In general, the laboratory audit program has been an extremely useful tool to identify problems and assure that corrective actions are taken. One such example was the lack of adequate equipment certification and calibration. It has been decided by the supervisors committee (as a result of the quality audit) that certification must be accomplished on no less than an annual basis. Certification is the responsibility of the section supervisor who determines how often equipment is to be certified if less than annually. In the course of the audit, the certification documents are reviewed, as are the values obtained during the course of the analyses. Calibration and repair records are maintained for each instrument and piece of equipment.

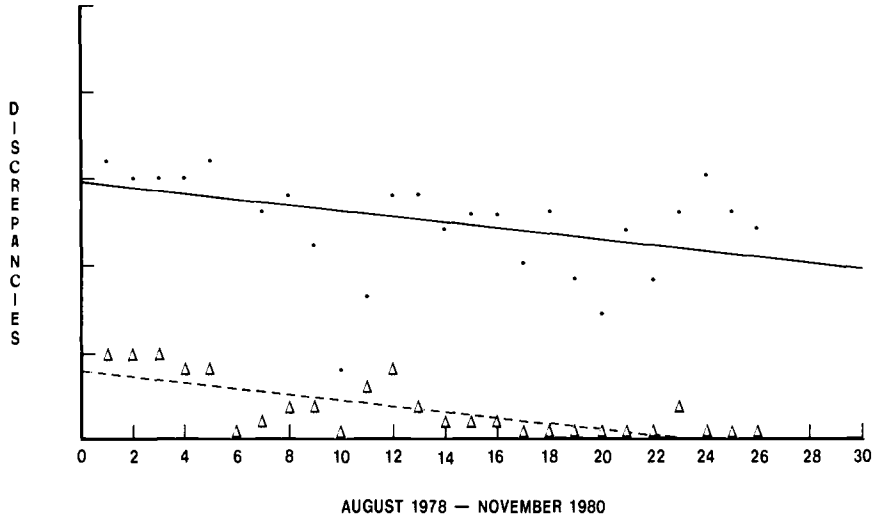

FIG. 1—*Central Laboratory quality audit report.*

Another example deals with test methods. ASTM standards and practices are used extensively in the testing conducted at Central Laboratory. In those cases where ASTM does not provide suitable standards, Ford laboratory test methods are used. For tests where there are no published methods, either industry or corporate local methods are developed in the laboratory. The audit has identified these local methods as a potential risk.

Quality has become a visible consideration in the laboratory during the 2½ years that Central Laboratory has used this quality assurance program. Issues are now discussed regularly between personnel in the auditing group and in the operating departments. Items identified as discrepancies are reviewed with affected sections after the audit report to insure that recommended changes have been made. Current discussions are underway in the laboratory at this time on new test methods, calibration of new equipment, and programs on repeatability and statistical analysis of results. The quality program has made "quality" a high priority item throughout the laboratory by addressing quality issues to the supervisors and test engineers and laboratory management. The program involves everyone in the laboratory, especially the people who really have the greatest impact on quality—the laboratory engineers.

Auditor Qualifications

The qualifications of the auditor must be carefully considered when a quality program is being initiated. The original auditor's background con-

sisted of experience in manufacturing, laboratory testing, and engineering (approximately ten years in each area). This background was instrumental, if not necessary, in the formulation and implementation of the quality audit program but was found not to be a requirement for its continuation. The auditor should have a technical background, be analytical and inquisitive, and be willing to do the necessary detail work of reading through the sometimes lengthy test procedures and specifications. This observation has been supported by our experience of employing three different auditors with varying backgrounds. These auditors were selected by asking for volunteers from among the operating department supervisors and the Development Group. The first "trainee" was a computer programmer who had three years of previous testing laboratory experience. He observed one audit and then successfully conducted the second audit with a minimum of support from the regular auditor. The second volunteer was from one of the operating departments. To maintain separation between the auditing activity and the "operating" departments, the volunteer was transferred on special assignment to the Development Group. Here again, the volunteer observed an audit and the next month conducted the audit alone. This procedure was repeated a third time using an administrative supervisor who had ten years of previous laboratory testing experience. The results of the audit conducted by the substitutes were well within the discrepancy rate we were experiencing during the period. Additionally, we find merit in the idea of training others to perform the audit both from the standpoint of cross-training and from the positive effect the experience has on the trainees' attitude about laboratory quality and, specifically, the quality within the individual's section.

Costs

The direct cost for the Central Laboratory Quality Audit is 130 hours per month or slightly less than two hours per month for each person working in the laboratory in a testing or report-writing capacity (see Table 1). These costs represent less than 1% of all time charged.

TABLE 1—*Hours per audit.*

Phase	Auditor	Supervisor	Test Engineer
Evaluation and detection	30	20	20
Assessment	10	10	...
Feedback	12	...	32[a]
Total	52	30	52

[a]A group activity includes a maximum of four hours of supervisors' time.

Conclusion

The movement towards laboratory accreditation is a positive step in establishing higher levels of quality and professionalism within the laboratory community. The criteria established in the ASTM Practice for Generic Criteria for use in the Evaluation of Testing and Inspection Agencies (E 548) are a significant contribution towards accreditation; however, a major weakness in these criteria is the absence of performance criteria. As published, the criteria are static, in that they provide a framework that can be constructed in any time frame and then stored on a shelf. Under the current system, an accredited laboratory would not necessarily produce quality results. From our experience at Central Laboratory, we believe that to improve laboratory quality, a dynamic quality program is necessary. Similarly, if accreditation is to be meaningful, the accreditation procedure must be a dynamic one.

A second concern is cost. The present annual costs associated with accreditation under the National Voluntary Laboratory Accreditation Program cannot be justified from the perspective of cost versus benefit for any laboratory that cannot tack on the accreditation costs to the cost of doing business. Under the federal accreditation program, it would cost $3370 to evaluate nine simple, seven intermediate, and two complex test methods for accreditation. (See Example 5, *Federal Register,* Vol. 45, 16, 23 Jan. 1980, p. 5600.)

If accreditation is to become a true instrument of quality and professionalism, the costs to be a fully accredited laboratory would be so enormous a burden that the accreditation movement would become a limited procedure to qualify suppliers of federally mandated materials. It would take a full-time evaluator at least one year to accredit all the tests performed at Central Laboratory, and the effect on quality would be minimal at best, without an ongoing detection, evaluation, and feedback system. The need for less costly ways of achieving accreditation is apparent. One of the ways might be to provide laboratory-wide accreditation rather than accreditation by specific test. On-site inspection should be retained, but more emphasis is needed to ensure that the laboratory have an active and dynamic quality control program.

Acknowledgments

The authors wish to thank Dr. H. B. Aaron, former Services Manager, Central Laboratory for his support during the initial phase of this program; W. A. Goering, Central Laboratory Services Manager, for his critical review of the manuscript and continued support of the quality program; and the department managers, section supervisors, and laboratory engineers, for without their cooperation and support this program would not have been successful.

George W. Barton, Jr.[1]

Quality Assurance Requirements for Automated Water Quality Laboratories

REFERENCE: Barton, G. W., Jr., "**Quality Assurance Requirements for Automated Water Quality Laboratories**," *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 62–73.

ABSTRACT: In the course of assisting the U.S. Environmental Protection Agency and the U.S. Geological Survey in automating their water quality surveillance laboratories, quality assurance requirements for this function have been investigated in detail. It was found that while computerization of instruments and functions can be of great assistance in operations, scientific insight must, in the end, be the final judge of quality. These laboratories engage in several kinds of activities that differ in important details. One of them had the primary mission of analytical methods development and validation. Another was an analytical facility for sewage treatment process development. The others engaged in three different activities, special surveys to establish baseline water standards, routine surveillance to detect variations from baseline, and special studies to collect the data for action against polluters. The similarities and differences of requirements in these various situations will be discussed.

KEY WORDS: automation, water quality, quality assurance, computers

The design and implementation of a computerized automation system that will produce quality work is not a simple task. A systematic approach, as advocated in the standards developed by ASTM Committee E-31 on Computerized Systems (see Table 1), is imperative. If one goes into an automation project without it, it is almost impossible to produce a quality system without many iterations, costly delays, and intolerable frustration. The members of E-31 have learned this the hard way.

In 1972 the National Environmental Research Center of the U.S. Environmental Protection Agency (EPA) in Cincinnati commissioned a study by a University of Cincinnati team to determine if automation of the EPA laboratories was a valuable and economically feasible thing to do. The study concluded that it was, but the EPA staff did not have the in-house expertise to do it by themselves. They searched in the private sector and concluded that appropriate help was not available at that time from commercial firms. In 1973

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TABLE 1—*Standards developed by ASTM Committee E-31.*

Designation	Title
E 622	Generic Guidelines for Computerized Laboratory Systems
E 623	Guidelines for Developing Functional Requirements for Computerized Laboratory Systems
E 624	Guidelines for Implementing Computerized Laboratory Systems
E 625	Guidelines for Training Users of Computerized Laboratory Systems
E 626	Guidelines for Evaluating Computerized Systems
E 627	Guidelines for Documenting Computerized Laboratory Systems
E 730	Guide for Developing Functional Designs for Computerized Systems
E 731	Guide for Procurement of Commercially Available Computerized Systems

an interagency agreement was entered into between the EPA and the then-Atomic Energy Commission (AEC) for the services of scientists and engineers from the Lawrence Livermore National Laboratory (LLNL). The first laboratory was to be the Environmental Monitoring and Support Laboratory (EMSL—then the Methods Development and Quality Assurance Laboratory) in Cincinnati.

We agreed that this job should be done in an orderly fashion, in stages from functional requirements all the way through to final documentation. It is no accident that the Standard Guides for computer automation, produced by ASTM Committee E-31, so closely resemble the procedure used here. Jack Frazer, and then I, directed the EPA project, and Jack, and then I, chaired E-31. It was not all one way, though. The experience in our project was combined with the experience of others in the forum provided by E-31 to produce the current standards.

Procedure

As we produced the first of the functional requirements we established many things. This laboratory is a methods development laboratory. The automation system must be flexible and able to accommodate many variations of a proposed procedure. Accuracy and precision of the results must be established over a wide range of conditions by using the best available statistical techniques. In order to do this, many standards, blanks, and samples must be run, with multiple repeats and spiked samples included.

We chose to implement the system using time-shared BASIC. After our experiences with writing a time-sharing operating system for a PDP-7, we certainly did not want to do that again. To be sure, operating systems that would support time-sharing in other languages than BASIC were available, but we wanted one that would require minimum modification. That way, the supplier would be in charge of finding and fixing most bugs (errors), not us. Now, only eight years later, all major computer manufacturers supply oper-

ating systems that make it easy to time-share a mix of BASIC, FORTRAN, PL/1, etc., but this was not true in 1974.

The advantages of BASIC in the development laboratory are many. The chemist has great flexibility to make changes in the operation, data collection, and data reduction. Sophisticated statistical calculations were programmed and made available, including Shewhart and Cusum real-time calculations and periodic charts. Calls to the instrumental functions were inserted into the BASIC interpreter, which returned data and flags directly to the BASIC program. Program branches were taken according to the status of the flags.

The configuration of the system installed is shown in Fig. 1. Actually, not all of these instruments are installed on any of the six systems now operational, and some others are included in some locations, but they all can be installed, according to the needs of the particular laboratory.

The next laboratory automated was the Municipal Environmental Research Laboratory (then the Advanced Waste Treatment Laboratory), also in Cincinnati. We again followed a systematic procedure, revised and improved as we and E-31 learned more. This laboratory differs from EMSL in that it is an analytical laboratory in support of research into improvements in sewage treatment plants. Analytical procedures are well worked out. They just have to cope with a high sample rate and wide concentration ranges. The quality assurance protocol is enforced by the computer program, and exceptions are reported to the operator as soon as a duplicate or spiked sample gives a result outside the established limits.

I will illustrate the principles by referring to the procedure for the Technicon AutoAnalyzer [*1*][2] (Fig. 2). This instrument is a continuous flow colorimeter used for analysis for many anions, as well as other species. Samples are placed in the circular tray at the right of the picture and aspirated into a continuous stream of reagents. A coiled tube provides time for the colorimetric reaction to take place, and finally the sample passes into a photometer. The output of the photometer is an almost linear function of the concentration of the sample.

The computer program prompts the operator for the sequence of samples required by the quality assurance protocol (Fig. 3). The three synchronization standards are used to indicate the start of the run to the data acquisition routines. They are also used to refine the nominal sample rate entered by the operator. This rate continues to be refined throughout the run by measurements on those sample peaks whose signal exceeds a set threshold. Two blanks follow, to establish the baseline of the measurement, in turn followed by up to ten calibration standards. Two more blanks follow, to determine if there is a drift in the baseline. A small drift is corrected for, and a calibration

[2] The italic numbers in brackets refer to the list of references appended to this paper.

FIG. 1—*Configuration of a typical automated water quality laboratory system. Components include (counterclockwise from the upper right) atomic absorption spectrophotometer, AutoAnalyzer, electronic balance, total organic carbon analyzer, ultraviolet and visible spectrophotometer, and the computer.*

curve is established. If the drift is too great, the run is aborted and the operator notified. The calibration curve need not be linear, as the program will fit to linear, quadratic, or cubic polynomials, as directed by the operator. A coefficient of determination is calculated and printed, and if the calibration samples deviate too much from the fitted curve, the run is again aborted.

The instrument has now been calibrated, and the samples are run. This typical sample wheel pattern cycles through the pattern indicated on the right of Fig. 3 until all the samples have been completed. If the known check standard differs from the calibration by a little, the operator receives a message. If it differs too much, the run is aborted. The five unknowns are then

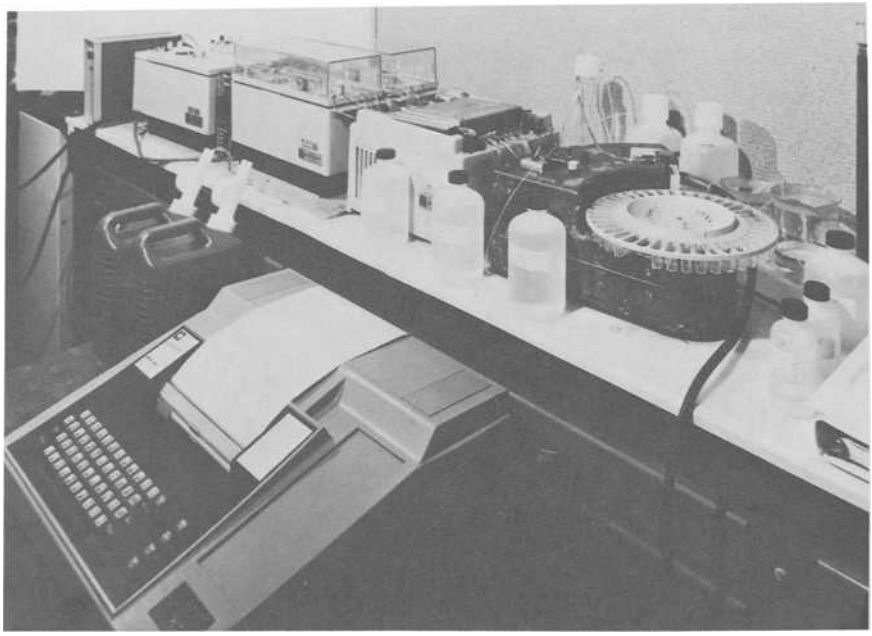

FIG. 2—*Technicon AutoAnalyzer.*

measured, followed by a spiked sample. This is a previously run sample, spiked by a known amount of the analyte of interest. A percent recovery is calculated and printed, and if this differs too much from 100 percent, a message is printed indicating that there are other species in the sample that are interfering with this measurement. A duplicate of a previous sample is measured and then two blanks for the baseline. If the instrument is misbehaving, the operator is notified or the run aborted, as appropriate.

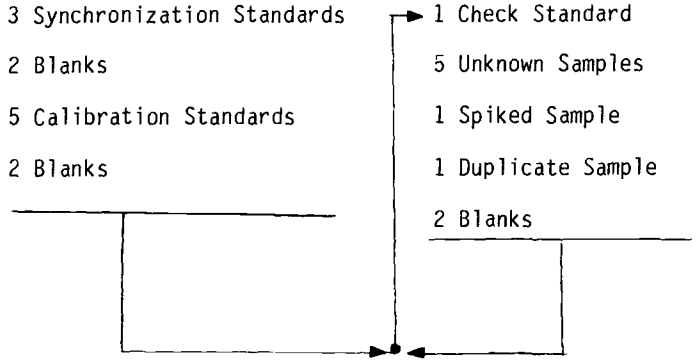

FIG. 3—*Typical quality assurance pattern.*

Four more laboratories have been automated, EPA Region V in Chicago [2], Region III in Annapolis [3], and the U.S. Geological Survey (USGS) National Water Quality Laboratories in Denver and Atlanta [4]. These are four of the routine working surveillance and analysis laboratories for maintenance of the nation's water quality. They have three major responsibilities:

(1) They conduct regional surveys to establish the baseline conditions for water composition.

(2) They conduct routine surveillance analyses to detect anomalous conditions.

(3) Finally, if they find a condition requiring action, they must measure samples to establish the factual basis for a legal action against a polluter.

As we established the functional requirements for these laboratories, an additional important requirement appeared, data management [5]. These laboratories have a large volume of data, which needs to be examined in many ways. Measurements of different analytes in the same sample need to be brought together. Measurements of the same analyte in different samples need to be displayed. Time histories of sampling stations need to be examined. Outliers must be detected. Consolidated reports must be prepared. These things were being done by hand, but transcription errors are always a problem with hand-prepared tables. Computerized handling of data greatly simplifies the preparation of these tables and greatly simplifies the selection and manipulation of these numbers. Furthermore, once a datum is entered correctly into a good data management system, it stays correct through all these manipulations.

To emphasize this problem, let us examine Fig. 4. Based on reports from previous studies, the field engineers, in cooperation with the analytical laboratory management, plan the study. They choose locations for sampling, times of sampling, shipping arrangements, and analyses to be made in the field and the laboratory. As the samples and field data are collected, they are entered into the sample log. From the sample log, a laboratory work plan is developed, so that all the analyses needed can be completed in the alloted time, and before the samples deteriorates. Quality control is assured, and the field data are combined with the laboratory data in the data log.

Other quality control tests are made on the data log, and local reports are produced. In one of the systems implemented in EPA, the data are entered as shown into a national database through ILDMS (standing for Interim Laboratory Data Management System, a prototype for systems now being implemented) and additional quality control checks, some of which are redundant, are made. Finally, when the manager of this study is satisfied that the values are as correct as they can be, the data are sent to STORET (for storage and retrieval), the statutory national water quality data base.

Finally, STORET reports are produced. These, together with local reports, are used by environmental scientists for scientific studies, by lawyers

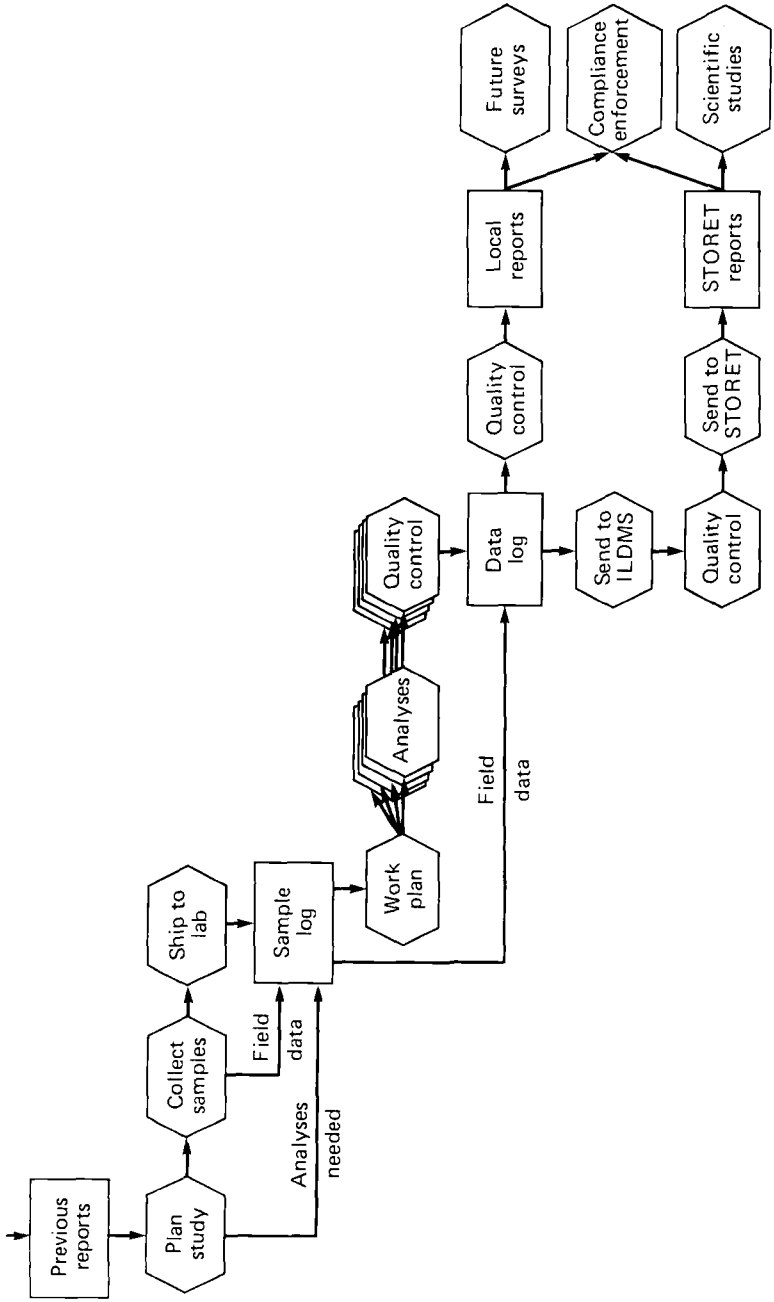

FIG. 4—*Data flow in a water quality laboratory.*

for enforcement of laws, rules, and regulations, and finally to plan future surveys, thus closing the loop. This system just described is being maintained and enhanced by EPA-Cincinnati with a nationwide network of PDP-11s. A similar system, which was delivered by us to USGS to run on Data General ECLIPSE C-330s, is being maintained and enhanced by USGS.

We found that BASIC still had advantages in the routine laboratory, but some disadvantages appeared. Bugs in programs were still easily fixed. It continued to be simple to install new programs in these geographically separate locations. But, under the pressure of the sample load, some operators have made changes in the programs that simplified their operations, but bypassed some of the on-line quality assurance checks. The data management system in Fig. 4 has several quality control checks in it. This redundancy detected the problem, and the missing program steps were restored.

It is difficult to balance the requirements for flexibility and ease of maintenance with those for quality assurance. If we introduce a powerful system manager at the national level, and give him absolute control over program changes, his staff has to be traveling much of the time to fix bugs and introduce changes. If we have local system managers at each laboratory, they have to have a level of skills and integrity that cannot easily be found at the salary levels prescribed for such functions. The ordinary computer system manager has to understand programming, accounting, and auditing. The people we need have to understand chemistry and statistics as well.

Conclusion

What about the future? Figure 5 shows the timesharing configuration that was still the most cost-effective as late as 1977, when we produced the feasibility study for the USGS [*4*]. The rapid drop in microcomputer prices and improvement in their hardware and software capabilities had changed that by the time the system was installed in 1979. Instead of automating an existing atomic absorption spectrophotometer in the timesharing mode as we did in 1977, it had become more cost-effective to replace it with one of the many new "smart" instruments. With other instruments, if a smart version is not yet available, it is more cost-effective to automate it by giving it a dedicated microcomputer.

Some things have not changed. Programming costs are still high, but if the manufacturer of a smart instrument can spread the cost over many instruments, the incremental cost to each instrument is small. Even if an instrument is automated as a one-time project, the elimination of interactions between instruments makes programming much easier. The cost of mass storage on magnetic disks has come down, but nowhere near as dramatically as the cost of microcomputers.

Smart instruments are still not smart enough. They do not or cannot pro-

PRESENT TIMESHARING USES A SINGLE CPU

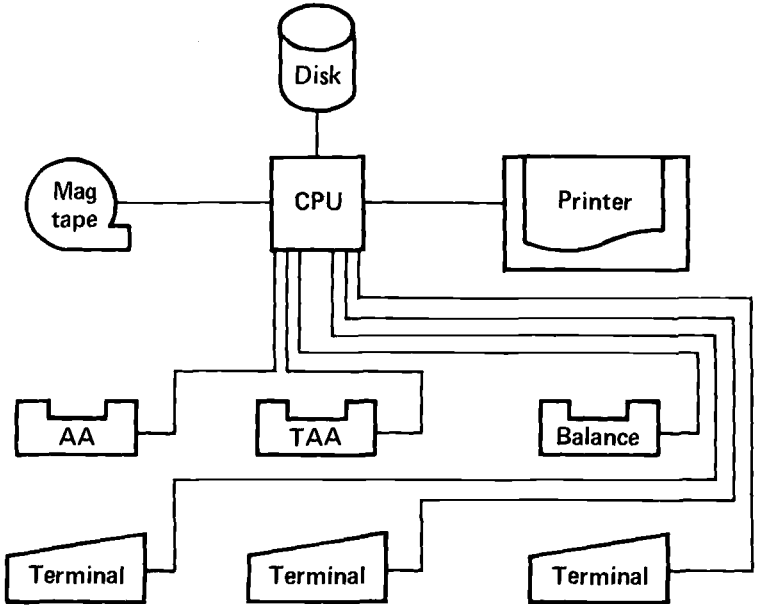

FIG. 5—*Time-sharing computer controlling several instruments.*

vide many of the features described earlier and in the feasibility studies. They do not now provide the elaborate quality assurance needed, and may never provide a flexible capability tailored to the needs of each laboratory. They cannot produce consolidated reports of the results from many different instruments, or archival storage of all this data in machine readable form. They cannot produce retrospective reports summarizing what is in the data archives. For these, we will continue to require a central processing unit somewhere in the network to perform data management and archival storage and retrieval.

Figure 6 shows an abbreviated network of the kind we see for the foreseeable future. In this system all the real-time instrumental functions are carried out by microcomputers dedicated to their respective instruments. There are also two special functions shown on this figure. The computer at the top is in charge of consolidating all the data, producing reports, storing data permanently, and recalling it on command. The graphics terminal on the lower right has a TV-like picture tube that allows the user to examine many possible displays of the information before outputting it to a high-quality graphics device ready for the camera.

The Lawrence Livermore National Laboratory has now withdrawn from this consulting business. We still establish functional requirements for our

FUTURE AUTOMATION WILL INCLUDE MANY CPUs

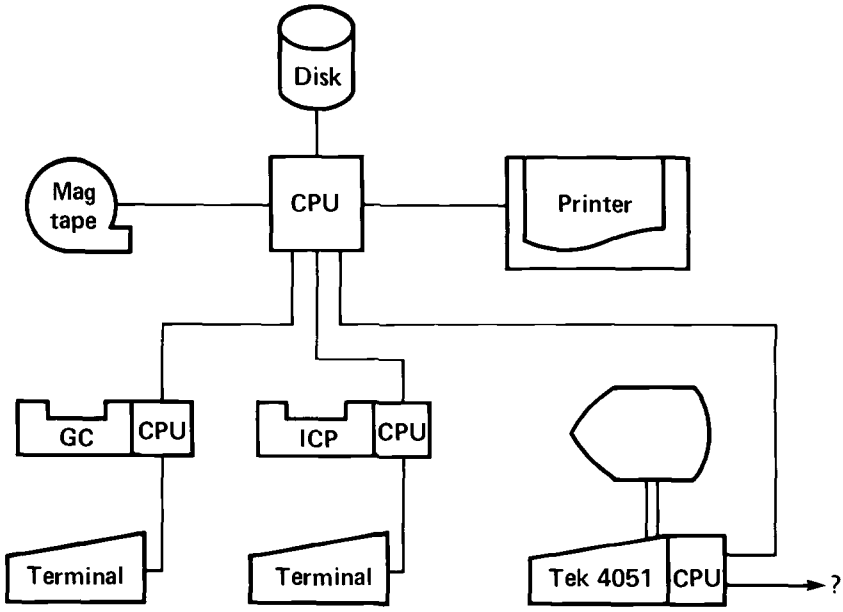

FIG. 6—*Resource sharing using many computers.*

own instruments, and implement systems if they cannot be procured from the private sector. Several things contributed to our decision. Smart instruments are readily available. Competent consulting has become available from private firms. This kind of work is not in the basic charter for the U.S. Department of Energy, but belongs properly in the private sector. Finally, when we received inquiries from firms like U.S. Steel or Celanese, there was no way we in government could help them, so it is better that we, too, work with private firms to give them the experience they need to do a first-rate job.

Acknowledgments

I do not want to give the impression that I did all this myself. Among the many scientists and engineers who had a major impact on this work were: **LLNL chemists**—W. Boyle, R. Bystroff, R. Crawford, J. Frazer, W. Morris, E. Peck, L. Rigdon, and F. Stephens. **LLNL engineers**—H. Ames, J. Elliott, J. Fisher, R. Gertz, V. Hendricks, A. Kray, M. Maples, and L. Taber. **EPA**—B. Almich, D. Ballinger, W. Budde, M. Carter, B. Fairless, L. Lobring, J. Logsdon, T. Martin, and J. Teuschler.

The work described in this paper was performed under the auspices of the U.S. Department of Energy by the Lawrence Livermore National Laboratory under Contract W-7405-ENG-48.

APPENDIX

Automating water quality laboratories seems like a strange area for a nuclear weapons research and development laboratory to be in, so I will explain some background.

The Lawrence Livermore National Laboratory started in 1952 as the Livermore branch of the University of California Radiation Laboratory, 40 miles away. Its specific mission was to be a second laboratory to work on nuclear weapons for the Atomic Energy Commission in parallel with the Los Alamos Scientific Laboratory. Over the years it has grown and changed names several times to become what it is now, a National Laboratory reporting to the Department of Energy (DOE). As the range of responsibility of the former AEC has changed to that of DOE, so has the laboratory.

I joined the Chemistry Group in 1952 and Jack Frazer joined in 1953. My field at that time was isotope ratio mass spectrometry and Jack's was vacuum fusion for trace impurities in metals. We consulted on each other's problems, and came to realize that there was a real need for automation in both our areas. Before 1960, I was routinely using ion counting and accumulation [6] in a digital multichannel analyzer connected to a mass spectrometer. In the early 1960s the affordable minicomputer became available. We realized that it was a powerful extension to the capability of the multichannel analyzer because it could control experiments and perform calculations as well as just collect data. Minicomputers were then still quite expensive, and could not be justified for a single instrument. For a production operation, with a number of instruments, they could barely be justified (hence, the founding of the Control Data Company), but we were in a research laboratory.

Jack managed to justify a Digital Equipment Company PDP-7 on the basis that it would be used in a timesharing mode for the automation of many instruments; indeed, at the peak of its use it operated eight instruments, two of which required dedication of the computer. At that time, higher level languages were not available, so all work had to be done in assembly language. Even worse, a time-shared operating system for the computer had to be written from scratch. But it was the first time-shared laboratory automation computer system.

Things improved after that. Digital brought out the PDP-8 at a price that could be justified for single instruments. High-level languages such as FORTRAN and BASIC were made available. Operating systems were developed by the manufacturers and were delivered with the computers. Other manufacturers entered the business, and prices fell and fell.

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Harland E. Fargo[1]

An Industry Approach to Laboratory Quality Assurance and Accreditation Programs

REFERENCE: Fargo, H. E., "**An Industry Approach to Laboratory Quality Assurance and Accreditation Programs**," *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 74–82.

ABSTRACT: A computerized approach to the massive record-keeping involved in a modern laboratory quality assurance program is described, with the Technical Center of Owens-Corning Fiberglas Corporation being used as an example.

KEY WORDS: information retrieval, computerized systems, quality assurance

According to Webster, a laboratory is a place for experimental study in a science or for testing and analysis of a product. Laboratory quality assurance is the auditing of the factors contributing to a quality laboratory. Quality control is concerned with "are we doing things right?"—quality assurance is concerned with "are we doing the right things?" This is the reason that a laboratory quality assurance program provides an audit of the factors that make a quality laboratory, such as the organization, the competence of the human resources, the adequacy of the physical resources, and the quality control system.

Corporate laboratories have always concentrated on these four factors by nature of their business. Historically, the customer required some assurance that the product purchased met the standard that had been selected, and in many instances, also listed requirements for a quality laboratory. Today, with the current product liability situation, the manufacturer in effect becomes the only one who can certify a product. The manufacturer is required to declare in writing that the product has certain performance values and meets certain standards. This puts even more emphasis on the need for effective laboratory quality assurance programs.

The ASTM Practice for Generic Criteria for Use in the Evaluation of Test-

[1] R&D Services, Technical Center, Owens-Corning Fiberglas Corporation, Granville, Ohio 43023.

ing and Inspection Agencies (E 548) requires that a laboratory shall establish a quality assurance system and accompany that system with a written manual. Similar requirements exist in most of the various laboratory accreditation programs around the world.

Developing a quality assurance manual using E 548 as a guide is relatively easy for a corporate laboratory, by assembling existing documents. It already has its organization established and a variety of documents such as the Annual Report and Technical Center Brochure to satisfy the needs of Section 4 in E 548, "Organization of the Agency." Conformance to Section 5, "Human Resources of the Agency," is not difficult because each laboratory usually has an organizational chart. Every position has a written description including education, training or experience required, and other qualifications. Every employee has a personnel file that maintains records of the employee's qualifications, experience, achievements, training, and an annual performance appraisal. The requirements of Section 6, "Material Resources of the Agency," can be met with a documentation of the test equipment, storage and sample conditioning facilities, calibration standards and equip-

TABLE 1—*Elements of a corporate quality assurance manual.*

Section 4. Organization of the Agency
1. Annual report
a. Legal name and address
b. Name of principal officers
c. List of internal organizations
2. Technical center brochures
a. Laboratories covered
b. Listing of services
c. Organizational structure
Section 5. Human Resources of Agency
1. Organizational charts by laboratory
2. Position descriptions
3. Personnel record system
a. Employee qualifications
b. Employee work experience
c. Employee work achievements
d. Employee training
e. Employee annual performance appraisal
Section 6. Materials Resources
1. Test equipment
2. Storage facilities
3. Sample conditioning facilities
4. Calibration standards
5. Library of standards and procedures
6. List of test methods
7. Data processing equipment
Section 7. Quality Systems of the Agency
1. Laboratory operation manual
2. Equipment maintenance and calibration procedures
3. Audits of test results and round robin results
4. Test report records

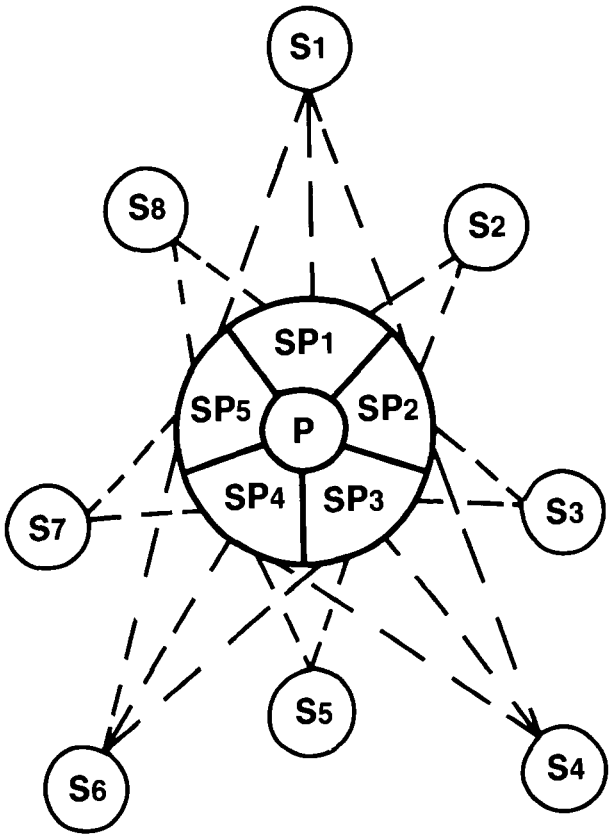


FIG. 1—*Owens-Corning Fiberglas laboratory system.*

ment, library of standards and procedures, data processing equipment, etc. Section 7, "Quality Systems of the Agency," is covered by a description of the quality control program describing the laboratory method of operation, equipment maintenance and calibration programs, system of auditing test results and detecting errors, and basic rationale of quality assurance (see Table 1).

Therefore, generating a quality assurance program and manual is not difficult for a corporate laboratory. The major problem of the quality assurance program in a large, high-activity laboratory is finding a means of bringing under control the flood of information and records generated. The purpose of this paper is to outline an approach used by Owens-Corning Fiberglas Corporation in its laboratories. This system utilizes a computer but can be applicable to smaller laboratories since even the smaller home computers are capable of handling the needs.

The Owens-Corning Fiberglas (OCF) primary laboratory is located at the

Corporate Technical Center in Granville, Ohio. Other laboratories within the corporation are satellites of this laboratory and by corporate directive use the same test methods, equipment, calibration standards, and quality assurance procedures. A sketch of this system is shown on Fig. 1.

Notice the primary laboratory P is composed of several specialized laboratories, SP-1, SP-2, etc., which include laboratories that study and test in the fields of thermal, sound, fire, chemical, electrical, physical, metallurgical, rheological, and air handling testing, etc. Under this system the satellite laboratories, S1, S2, etc., receive their quality assurance assistance and audits from several qualified sources.

With a laboratory complex such as this, a key issue is the execution of the equipment maintenance and calibration system traceable to accepted metrology standards. A computer system was established to identify and log every piece of equipment used in the laboratory covered by a quality assurance manual. An example of the print-out of this is shown on Fig. 2. Each piece of equipment is given a number that identifies the laboratory location, the department within the location, and the type of test for which it is used (physical, chemical, thermal, etc.). The information specified in E 548, such as description, range, accuracy, frequency of calibration, calibration procedure, calibration standard, and date of last calibration, is also included in the system. The calibration can be done either by OCF personnel or an outside contractor who can provide traceable standards.

Every month or on demand, the computer will itemize by laboratory, in a form shown on Fig. 3, the list of equipment that requires traceable calibration. Notice the double asterisk for attracting special attention to past due equipment inspections. When the scheduled equipment calibration has been completed, the record of calibration data is put in the equipment file, and the computer is notified of the new calibration date. Each laboratory manager is responsible for ensuring that calibration is maintained on a current basis.

Other issues in a laboratory quality assurance program that can be managed by the computer are tracking the work request (Fig. 4), recording and retrieving test records, and personnel records (Fig. 5). In this manner, the records for the equipment, the people who run the equipment, and the procedures used to produce test results can be maintained in the computer in a form to ensure laboratory quality control without being an administrative nightmare.

The conclusion to be drawn from this system is that laboratory accreditation does not become burdensome for laboratories involved in a broad spectrum of testing and several accreditation programs. This approach provides a method for the laboratory to satisfy the requirements of a product-based National Voluntary Laboratory Accreditation System (NVLAP) accreditation system or the discipline-based accreditation system, favored by the American Association for Laboratory Accreditation, Australia's National

OWENS-CORNING FIBERGLAS — PAGE 2

DATE: 02-06-91 — LABORATORY EQUIPMENT CALIBRATION STANDARDS — PTG20

LAB NO	DESCRIPTION	SERIAL	COF	RANGE	ACCURACY	FR	PROCEDE	STANDARD	DATE	LOC
50089P5011	SCOTT TESTER JZ VERT	84105	11645	100 LB	0.2 LB	12	BENZ	BENZ	1179	30
50089P5012	SCOTT TESTER IP4	84E709	62536	50 LB	0.5 LB	12	BENZ	BENZ	1179	30
50089P5013	INSTRON TM	15E	62724	200 LB	0.1%	12	ZABEL	ZABEL	1179	30
50089P5014	INSTRON TTC	1083		10000 LB	0.1%	12	ZABEL	ZABEL	1179	30
50089P5015	BALDWIN TEST MACHINE	37025	10598	60000 LB	0.1%	12	ZABEL	ZABEL	1179	30
50089P5016	DEFLECTOMETER INSTRON PDIM	1049	69573	1 IN	0.001 IN	12	CC0501	50089S8CC05	1179	30
50089P5017	DEFLECTOMETER INSTRON PDIM	278		1 IN	0.001 IN	12	CC0501	50089S8009	1179	30
50089P5018	COMPRESSOMETER DCTM	1010		0.2-1 IN	0.001 IN	12	CCC5C1	50C89S8009	1179	30
50089P5021	EXTENSOMETER PS6M	1078		0.2 2 IN	0.001 IN	12	CC0501	50089S8009	1179	30
50089P5025	INSTRON	3365	C6349	20,000 LB	0.1%	12	ZABEL	ZABEL	1179	30
50089P8003	INSTRON WEIGHTS			5-25 LB	0.01%	12	SKIDMORE	SKIDMORE	0880	30
50089P8004	SECURITY STOPWATCH			0-60 SEC 0-30 MIN	1/5 SEC	12	CT08C3	50089S8004	0280	30
50089P8026	BALANCE WEIGHTS			100-1000 GM	0.001%	12	SKIDMORE	SKIDMORE	0380	30
50089P8027	BLUE M OVEN		B6051	400 F	2F	12	CT0402	50089S3C02	0480	30
50089P8028	AMINCO OVEN 4-3562	13562-6	69545	525F	5 DEGREES	12	CT0402	50089S3002	0480	30
50089P8029	LABLINE OVEN 3702	251		250C	1C	12	CT0402	50089S3C02	0480	30
50089P8030	BLUE M OVEN 13361	7673	A5197	400F	2F	12	CT04C2	50089S3C02	048C	3C
50089P8031	BLUE M OVEN 256F-1	P14-1510	F3857	650F	5F	12	CT04C2	5CC89S3002	0480	30
50089P8032	BLUE M HUMIDITY CABINET SC7702A3188		A6070	220 DEGREES F	2 DEGREES F	12	CP0EC5	50089S3002	058C	3C
50089P8033	BLUE M COLD BOX TC40-100	T3-300		-40F	1F	12	CT0402	50089S3002	0480	30
50089P8034	BLUE M OVEN SM604GX	E34801	F5328	400F	1 DEGREE F	12	CT04C2	5CC89S3C02	0480	30
50089P8035	JADE HUMIDITY CABINET		A5241	350 DEGREES F	2 DEGREES F	12	CP08C5	50089S3002	018C	30
50089P8036	BLUE M HUMIDITY CABINET 7652CX33330		A5199	200 DEGREES F	2 DEGREES F	12	CP08C5	50089S3002	0180	30
50089P8037	DYNATROL MUFFLE FURNACE P212HC5376-1		C7456	2500 DEGREES F	50 DEGREES F	12	CT04C2	50089S3002	0480	3C
50089P8038	DYNATROL MUFFLE FURNACE P212 11C62			2000 DEGREES F	50 DEGREES F	12	CT04C2	50089S3002	0480	30
50089P8039	DYNATROL MUFFLE FURNACE P21c 42269		A1848	2000 DEGREES F	50 DEGREES F	12	CT04C2	5CC89S3002	0480	30
50089P8040	DYNATROL FURNACE P212 10260		66679	2500 DEGREES F	50 DEGREES F	12	CT04C2	50089S3002	0480	3C
50089P8041	BLUE M HUMIDITY CAB FR441FX	A4413	A5117	0-200 F	1 F	12	CP08C5	CAL THERM	018C	30
50089P8042	WEIGHTS CHAUS			1-1000 GM	0.1 %	12	SKIDMORE	SKIDMORE	C380	3C
50089P8043	CHAUS WEIGHTS			1/32 OZ - 2 LB	0.1 %	12	SKIDMORE	SKIDMORE	C18C	3C
50089P8045	CALIBRATED SPRING			0-140 LB		24	INSTRCN	INSTRCN	0479	30
50089P8046	CALIBRATED SPRING			0-1000 LB		24	INSTRCN	INSTRUN	C479	3C
50089P8047	CALIBRATION WEIGHTS			10-100 GM WEIGHTS	0.01 GMS	12	SKIDMORE	SKIDMORE	0380	30
50C89P8043	DYNATROL FURNACE F212H J29763		C9781	2500 DEGREES F	50 DEGREES F	12	CT04C2	5CC89S3002	0480	30
50089P8049	FISCHER DIG. STOP WATCH 14-648D8C2			60 MIN.	0.1 SEC	12	CT0803	50089S8C04	C68C	30
50089P8050	ELECTRONIC STOPWATCH RATIONWID			99 MIN.	0.01 SEC.	12	CT0803	50089S8004	0580	76
50089P8052	FISHER OVEN 176			320 DEGREES C	1 DEGREE C	12	CT04C2	50089S3C02	C58C	76
50089P8053	BLUE M OVEN SW-177A	S3 3625		40 - 200 DEGREES C	1 DEGREE C	12	CT04C2	50089S3C02	058C	76
50089P8054	BLUE M HUM. CABINET SC7602M21K2-2715		A5198	- TO 200 DEGREES F	2 DEGREES F	12	CPCEC5	5CC89S3002	0178	72
50089P8055	SUB ZERO HUMIDITY CAB HU27HX15757323			0-150 DEGREES F	+/- 1 DEGREEC3		CPCEC5	CAL THERM.	088C	72
50089P8056	SUB ZERO HUMIDITY CAB HU27HX15757324			0-150 DEGREES F	+/- 1 DEGREEC5		CP0805	CAL THERM.	0880	72
50089P8057	CHAUS GRAM WEIGHTS			10 GM - 1000 GM	+/- 2%	12	SKIDMORE	SKIDMORE	0780	71
50089P8058	CHAUS GRAM WEIGHTS			1 GM - 500 GM	+/- 2%	12	SKIDMORE	SKIDMORE	C18C	71
50089S2001	GAGE MRS CALIB WEBBER	31077.10		0.1-4.0	.6310(-6)	5C	WEBER	NBS216242	0577	30
50089S2002	36 IN ST-EL FLEX STARRETT	607R		36 IN	0.01 IN	60	STARRETT	GGG-R-791F	0377	30
50089S2004	MICROMETERS STARRETT			0-4 IN	0.0005 IN	60	CC0205	50089S2001	0677	30
50089S2005	SLIDE CALIPER STARRETT	424		0-3.5 IN	1/32 IN	6C	CD02C5	5CC89S2001	0677	30
50089S2006	PI TAPE 47498			2-12"	0.003"	60	NBS	NBS	C2P0	30
50089S3002	LEN K3 POTENTIOMETER	1521570		0-1.6110 VOLT	0.C1%	12	CTD302	50089S3003	0680	30
50089S3004	EPPLEY STND CELL	857725		1.01925	0.005?	48	EPPLEY	NBS214671	C277	3C
50089S3005	CURRENT SHUNT 490	01509		1-10 AMP	0.1 %	12	FLUKE	FLUKE	0980	30
50089S3006	DIGITAL VOLTMETER 8800A	56989	C3632	SEE SPECS	SEE SPECS	12	FLUKE	FLUKE	C58C	3C
50089S3007	FLUKE DIGITAL VOLTMETER 8502A	2086050		MULT RANG & FUNCTION	REFER TO MFG24		FLUKE	FLUKE	0179	
50089S3008	LEN POTENTIOMETER 8686-3	1812756		0-10	0.C2%	12	CTC3C2	5CC89S3001	0680	76
50089S4001	THERMOMETER			1-201 C	0.2 C	40	KESSLER	NBS	1277	3C

FIG. 2—*Sample laboratory equipment log.*

DATE: 02-06-31 PLANT PROCESS--QUALITY CONTROL MANAGE---WAXAHACHIE PLANT PAGE 6

EQUIPMENT REQUIRING CALIBRATION DURING 02-81 PTC21

LABNO	DESCRIPTION	DATE CALIBRATED	DATE DUE	PAST DUE	COMPLETION DATE
10442C2001	DIAL GAGE AMES 13	01-80	01-81	**	
10442D8001	DIE CUTTER FAMCO	01-80	01-81	**	
10442D8002	DIE CUTTER DOUGHNUT	01-80	01-81	**	
10442D8003	TEMPLATE	01-80	01-81	**	
10442D8004	TEMPLATE	01-80	01-81	**	
10442D8005	TEMPLATE	01-80	01-81	**	
10442D8006	TEMPLATE	01-80	01-81	**	
10442D8007	TEMPLATE	01-80	01-81	**	
10442D8008	TEMPLATE	01-80	01-81	**	
10442D8009	TEMPLATE	01-80	01-81	**	
10442D8010	TEMPLATE	01-80	01-81	**	
10442D8011	DIE CUTTER	01-80	01-81	**	
10442D8012	DIE CUTTER	01-80	01-81	**	
10442D8013	K BOX GAGE PINS	01-80	01-81	**	
10442P1001	METTLER BALANCE K5	08-80	02-81		
10442P1002	TOLEDO SCALE 3710	08-80	02-81		
10442P1003	TOLEDO SCALE 3710	08-80	02-81		
10442P1004	TOLEDO SCALE 2071	08-80	02-81		
10442P1005	TOLEDO SCALE 2071	08-80	02-81		
10442P1006	TOLEDO SCALE 2181	08-80	02-81		
10442P1007	TOLEDO SCALE 2181	08-80	02-81		
10442P1008	TOLEDO SCALE 2581	08-80	02-81		
10442P1009	TOLEDO SCALE 2352	08-80	02-81		
10442P1010	TOLEDO SCALE 2352	08-80	02-81		
10442P1011	TOLEDO SCALE 2361	08-80	02-81		
10442P1012	TOLEDO SCALE 4020	08-80	02-81		
10442P1013	TOLEDO SCALE 711-2151	08-80	02-81		
10442P1014	METTLER P121C	08-80	02-81		
10442P1015	GRAM-ATIC BALANCE	08-80	02-81		
10442P5001	FLUTE SPAN TEST MACHINE	01-80	01-81	**	
10442P5002	TENSIL TEST MASHINE	01-80	01-81	**	
10442P5003	SCOTT TESTER J	01-80	01-81	**	
10442P5004	COMPRESSION TEST MACHINE	01-80	01-81	**	
10442P5005	BAG TEST MACHINE	01-80	01-81	**	
10442P5006	DETROIT TEST MACHINE TT-1	01-80	01-81	**	
10442P8001	MUFFLE FURNACE	01-80	01-81	**	
10442P8002	MUFFLE FURNACE THERMOLYNE	01-80	01-81	**	
10442S8001	WEIGHTS	01-80	01-81	**	
10442T3001	HEATED TUB L & N	01-80	01-81	**	
10442TR001	K BOX	01-80	01-81	**	

*** NOTE
PLEASE FILL IN COMPLETION DATE AND RETURN TO A. E. BAZLEN -- GRANVILLE TECH CENTER

FIG. 3—*Sample equipment calibration schedule.*

Association of Testing Authorities, or the Testing Laboratory Registration Council of New Zealand. The computer can cross-compile test methods, equipment, calibration, people, and other elements common to different programs. Each added program may require only one or two items added to those already in existence. As an example, NVLAP test 01/F02 of the insulation laboratory accreditation program (LAP) and NVLAP test 03/F01 of the Carpet LAP are identical—the ASTM Test for Surface Burning Characteristics of Building Materials (E 84). This eases the burden of multiple programs for both the administrator and the laboratory.

A more general conclusion to be drawn from laboratory quality assurance and accreditation is that both are good business for several reasons (see Table 2). The quality level is improved in all laboratories. The independent commercial laboratory is given a means to provide an attestation of its competence and proficiency. Manufacturers may have their own laboratories accredited for the same reasons. Code and regulatory authorities can request data generated from accredited laboratories and avoid the expense of establishing individual programs for their needs. Laboratory accreditation is receiving international attention via the International Laboratory Accredita-

R & D SERVICES, GRANVILLE, OHIO D.C. RICHARDS, DIRECTOR

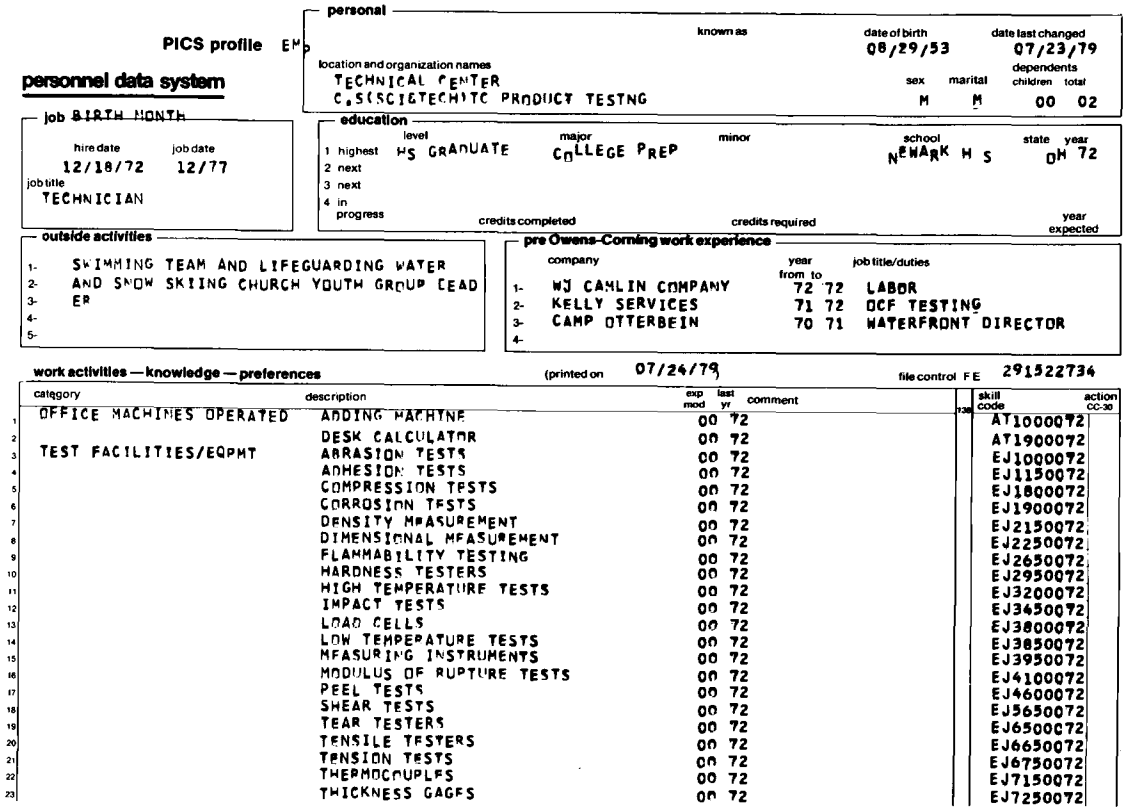
TEST REQUESTS ASSIGNED TO HEF DATE OF THIS REPORT 02-06-81

PLEASE UPDATE STATUS, REVISE ESTIMATED COMPLETION DATES WHERE NECESSARY, AND MAKE ANY OTHER CHANGES REQUIRED.
RETURN TO BRENDA THOMPSON BY FRIDAY PM.

TR NO	PROG RPT	CHG NO	TITLE	REQUESTOR	MKT DIV	TO	DATE RECD	EST COMP DATE	WK IN PROG	MANHOURS EST	ACT	DEV	STATUS	FLR DATE	DIR CHG
22844-	00	63AAB	MPI - LL APPROVAL	LC	96	HEF	01-29-81	06-01-81	1	12	2	10	IN PROG		0
22842-	00	65RAD	FIBERGLAS LOCK SHINGLES/DENVER	PORTFOLIO	96	HEF	01-27-81	06-01-81	1	12	2	10	IN PROG		0
22679-	00	81BAA	PERMA PLY NO 28	RICHARDS	96	HEF	01-15-81	04-15-81	3	5	2	3	IN PROG		0
22635-	00	61M8Y	HIGH LOI OMEGA	CORBIN		HEF	01-09-81	05-15-81	3	12	2	10	IN PROG		0
22624-	00	61M9Y	SOFTEX CEILING PANEL	CORBIN	96	HEF	01-06-81	06-01-81	4	12	2	10	IN PROG		C
22441-	00	63BAB	F/G PIPE EVA ADHESIVE QUALIFICATION	COLE	96	HEF	12-02-80	03-01-81	5	10	4	6	IN PROG		C
22341-	00	81BAA	UL REVISIONS GENERAL	YATES	96	HEF	01-13-81	03-01-81	3	5	2	3	IN PROG		0
22339-	00	81BAA	UNDERWRITERS LAB PROCEDURES	YATES	96	HEF	12-05-80	03-01-81	8	5	2	3	IN PROG		C
22235-	00	63BAB	F/G PIPE LL-723 QUALIFICATION	COLE	96	HEF	11-24-80	03-15-81	10	12	2	10	IN PROG		0
22217-	00	81BAA	FLEX DUCT CORE ADHESIVE QUALIFICATION	YATES	96	HEF	11-20-80	03-01-81	11	8	2	6	IN PROG		0
22207-	00	65RAB	EXPLORATORY WIND RESISTANCE - DENVER	PORTFOLIO	96	HEF	11-20-80	02-15-81	11	10	4	6	IN PROG		0
22054-	00	81BAA	UL AND NEW YORK BOARD OF APPEALS	FARR	96	HEF	10-28-80	12-30-80	14	8	10	-2	IN PROG		0
22047-	00	81AAF	UL APPROVAL - VALUFLEX FLEXIBLE DUCT	SMITH	K63	HEF	01-23-81	06-01-81	1	20	32	-12	IN PROG		C
22045-	00	81AAE	UL REPORT ON VALUFLEX FLEXIBLE DUCT	SMITH	K64	HEF	01-07-81	07-01-81	4	5	2	3	IN PROG		0
22042-	00	81AAF	UL APPROVAL OF FORTIFIBER PYROCURE	SMITH	K64	HEF	10-31-80	02-15-81	13	12	2	10	IN PROG		0
22040-	00	81AAE	APPR OF APAC TAPE AS CLOSURE FOR DUCT	SMITH	K64	HEF	10-29-80	01-30-81	14	5	2	3	IN PROG		C
21946-	00	81BAA	OPTIONAL G-5 12,000 GALLON UGST	YATES	96	HEF	10-20-80	12-20-80	15	5	6	-1	IN PROG		0
21763-	00	63MAD	U.L. APPROVED SAMPLES - XA-127 ADHESIV	GLEASON	96	HEF	10-06-80	02-28-81	17	12	11	1	IN PROG		C
21762-	00	63AAB	ROYAL MARK 713218/UL	WILLIAMS	96	HEF	10-06-80	01-30-81	17	12	8	4	IN PROG		C
21507-	00	65RAB	WIND RESIST TEST OF GLASS CUMBERLAND	PORTFOLIO	96	HEF	09-25-80	01-30-81	19	12	12	0	IN PROG		0
21427-	00	81BAA	UL LISTING PERMA FLASH	RICHARDS	96	HEF	09-12-80	12-30-80	20	6	6	0	IN PROG		0
21314-	00	81BAA	D-2A 2M UGST	WEAVER	96	HEF	08-26-80	06-30-81	23	5	4	1	T DELAY		0
21274-	00	81BAA	MODEL G-6 FOR BAKERSFIELD & CONROE	WEAVER	96	HEF	08-26-80	12-31-80	23	5	4	1	IN PROG		0
21253-	00	81BAA	UL LISTINGS	RICHARDS	96	HEF	08-15-80	07-01-81	24	12	8	4	REV ECD		0
21233-	00	65RAD	UL QUAL - CHAPARRAL SHINGLE	TURNER	96	HEF	08-14-80	06-01-81	25	12	16	-4	REV ECD		0
21135-	00	81BAA	90# ROOFING - COMPTON	MILLER	96	HEF	08-13-80	12-15-80	25	5	6	-1	IN PROG		0
21058-	00	63AAN	ALTERNATE FRK DUCT ECORE FACINGS	SWANSON	K64	HEF	07-28-80	04-15-81	27	12	11	1	REV ECD		C
21043-	00	81BAA	D-5 2000 GALLON UGST	WEAVER	96	HEF	07-28-80	10-15-80	27	5	4	1	IN PROG		0
20786-	00	81BAA	E 737 POLYESTER RESIN	WEAVER	96	HEF	07-08-80	12-30-81	30	12	4	8	T DELAY		C
20763-	00	61M9U	ETL REVIEW OF SOUND DIVIDER ECD SYSTEM	OBERG	95	HEF	06-30-80	12-30-81	31	20	4	16	REV SCC		0
20715-	00	81BAA	UL EXTENSION ACHILLES VINYL FACING	WILLIAMS	96	HEF	06-26-80	03-01-81	32	5	8	-3	REV ECD		C
20696-	00	65RAC	UL - SEALANT DIMENSION CHANGES	TURNER	96	HEF	06-24-80	03-01-81	32	5	4	1	T DELAY		0
20695-	00	65RAC	CLASS A COVENTRY & CRESTWOOD - UL	TURNER	96	HEF	06-24-80	03-01-81	32	20	4	16	T DELAY		0
20634-	00	81BAA	22" INTERNAL LAYUP FLANGED MANWAY	WEAVER	96	HEF	06-17-80	12-30-80	33	5	6	-1	T DELAY		0
20632-	00	63AAL	UL QUAL OF ALPHA 4315 LW FOR INL-25	GARDNER	K64	HEF	06-20-80	03-30-81	32	12	5	7	T DELAY		C
20344-	00	81BBM	ELIM OF SURFACE MAT & USE OF CAL. CAR	WEAVER	96	HEF	05-28-80	12-30-81	36	12	10	2	REV ECD		0
20193-	00	65RAZ	F.M. APPROVAL TESTING-FLRT SANDWICH	JOHNSON	96	HEF	05-09-80	12-30-80	38	16	27	-11	T DELAY		C
20152-	00	61AAA	UL SURFACE BURNING FOR CEILING BOARDS	ERNIE	96	HEF	05-07-80	03-01-81	39	24	37	-13	REV ECD		C
19990-	00	63BAL	UL QUAL. OF FERRO JACKET FOR INL-25	GARDNER	K64	HEF	04-16-80	03-30-81	42	16	8	10	T DELAY		C
19732-	00	81AAF	UL APPROVAL INL-25 FLEX DUCT	SMITH	K64	HEF	06-08-80	06-01-81	34	5	36	-31	REV ECD		C
19224-	00	81BAA	HOURLY RATED ASSY-FIBERGLAS ROOF INSUL	RICHARDS	96	HEF	02-26-80	12-30-80	45	16	68	-52	T DELAY		0
17591-	00	63BAL	DUCT WRAP/ES-25 UL ADHESIVE/FACING QUL	COLE	K64	HEF	09-24-79	12-30-80	71	12	20	-8	NO SAMPL		C
16645-	00	61AAG	UL FIRE RESISTANCE RATINGS	ERNIE	96	HEF	07-03-79	12-30-82	83	100	26	74	T DELAY		C

TOTAL NUMBER OF TEST REQUESTS 43

FIG. 4—*Sample test request log.*



PICS profile EMP

personnel data system

personal

known as

location and organization names
TECHNICAL CENTER
C.S(SCI&TECH)TC PRODUCT TESTNG

date of birth 08/29/53
date last changed 07/23/79
sex M
marital M
dependents children 00 total 02

job BIRTH MONTH

hire date 12/18/72
job date 12/77
job title
TECHNICIAN

education

	level	major	minor	school	state	year
1 highest	HS GRADUATE	COLLEGE PREP		NEWARK H S	OH	72
2 next						
3 next						
4 in progress						

credits completed
credits required
year expected

outside activities

1- SWIMMING TEAM AND LIFEGUARDING WATER
2- AND SNOW SKIING CHURCH YOUTH GROUP CEAD
3- ER
4-
5-

pre Owens-Corning work experience

	company	year from	year to	job title/duties
1-	WJ CAMLIN COMPANY	72	72	LABOR
2-	KELLY SERVICES	71	72	OCF TESTING
3-	CAMP OTTERBEIN	70	71	WATERFRONT DIRECTOR
4-				

work activities — knowledge — preferences

(printed on 07/24/79

file control FE 291522734

	category	description	exp mod	last yr	comment	skill code	action CC-30
1	OFFICE MACHINES OPERATED	ADDING MACHINE	00	72		AT1000072	
2		DESK CALCULATOR	00	72		AT1900072	
3	TEST FACILITIES/EQPMT	ABRASION TESTS	00	72		EJ1000072	
4		ADHESION TESTS	00	72		EJ1150072	
5		COMPRESSION TESTS	00	72		EJ1800072	
6		CORROSION TESTS	00	72		EJ1900072	
7		DENSITY MEASUREMENT	00	72		EJ2150072	
8		DIMENSIONAL MEASUREMENT	00	72		EJ2250072	
9		FLAMMABILITY TESTING	00	72		EJ2650072	
10		HARDNESS TESTERS	00	72		EJ2950072	
11		HIGH TEMPERATURE TESTS	00	72		EJ3200072	
12		IMPACT TESTS	00	72		EJ3450072	
13		LOAD CELLS	00	72		EJ3800072	
14		LOW TEMPERATURE TESTS	00	72		EJ3850072	
15		MEASURING INSTRUMENTS	00	72		EJ3950072	
16		MODULUS OF RUPTURE TESTS	00	72		EJ4100072	
17		PEEL TESTS	00	72		EJ4600072	
18		SHEAR TESTS	00	72		EJ5650072	
19		TEAR TESTERS	00	72		EJ6500072	
20		TENSILE TESTERS	00	72		EJ6650072	
21		TENSION TESTS	00	72		EJ6750072	
22		THERMOCOUPLES	00	72		EJ7150072	
23		THICKNESS GAGES	00	72		EJ7250072	

FIG. 5—*Sample personnel profile.*

TABLE 2—*Laboratory quality assurance and accreditation is good business.*

1. Accreditation improves the quality of all laboratories.
2. The commercial laboratory is given a means to provide an attestation of its competence and proficiency.
3. Manufacturers may have their own laboratories accredited.
4. Code and regulatory authorities may request data generated from accredited laboratories.
5. International attention is growing through ILAC and GATT.

tion Conference (ILAC) and the Section 5.2 on Standards of the General Agreement on Tariffs and Trade (GATT).

The laboratory quality assurance and accreditation programs at Owens-Corning Fiberglas have been developed to be compatible with all systems. Since we have laboratory responsibility in other countries, international systems are included in our program.

Evaluation and Accreditation in Government

Peter S. Unger[1]

Evolution of the National Voluntary Laboratory Accreditation Program Procedures

REFERENCE: Unger, P. S., **"Evolution of the National Voluntary Laboratory Accreditation Program Procedures,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 85–95.

ABSTRACT: The Department of Commerce published its original procedures for the operation of the National Voluntary Laboratory Accreditation Program (NVLAP) on 25 Feb. 1976. Three revisions have been made since then and another is currently under consideration. This paper briefly reviews the development of the NVLAP procedures since they were proposed in May 1975.

KEY WORDS: laboratory accreditation, NVLAP procedures

Last February 25 marked the fifth anniversary since the Department of Commerce published its procedures for the National Voluntary Laboratory Accreditation Program (NVLAP). Since then, three laboratory accreditation programs have been established, for test methods of thermal insulation, concrete, and carpet, and 95 laboratories have been accredited. Four other programs are under development. Although two sets of optional procedures and one amendment have been adopted in the last two years, the department is considering further revisions to streamline the procedures.

The purpose of this paper is not to evaluate or propose revisions to these procedures; rather, it is to recount the revisions that have been made and are being considered from the time the procedures were developed to the present. A chronological list of publications documenting these revisions is set out in Table 1.

Origins of the NVLAP Concept

The development of NVLAP stems from the fact that the department, through its technical agency the National Bureau of Standards (NBS), had

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TABLE 1—Federal Register *publications relative to the NVLAP procedures.*

Publication Date	Short Title
8 May 1975	Proposed NVLAP Procedures (40 FR 20092-20095)
25 Feb. 1976	Original NVLAP Procedures (Part 7) (41 FR 8163-8168)
25 Oct. 1978	Proposed Optional NVLAP Procedures (Part 7b) (43 FR 49812-49818)
26 Oct. 1978	Proposed Optional NVLAP Procedures (Part 7c) (43 FR 49994-50000)
9 March 1979	Optional Procedures for Federal Agencies (Part 7b) (44 FR 12982-12990)
25 April 1979	Optional Procedures for Private Sector Organizations (Part 7c) (44 FR 24274-24282)
23 Jan. 1980	Criteria and Fees for NVLAP Accreditation (45 FR 5572-5600)
21 April 1980	Amendment for Adding Test Methods (45 FR 26993-26994)
27 Jan. 1981	Proposed Amendment to Incorporate Criteria Into the Procedures, Establish a NVLAP Advisory Committee, and Eliminate Need for Separate Criteria Committees (46 FR 8910-8919)

for many years assisted industry and government in the evaluation of testing laboratories. Since 1929, NBS has participated with federal and state agencies and private interests in developing criteria for evaluating testing laboratories and in providing on-site examinations, proficiency test samples, and calibration standards.

In 1969, ASTM requested that NBS participate with ASTM and other interests in establishing a "testing agency inspection service" over a broad range of product areas wherever needs developed. In the same year the National Conference of States on Building Codes and Standards asked NBS to develop evaluation criteria and examination methods for determining the capability of agencies that test and certify mobile homes. In response to these requests, drafts of criteria and methods for examination were prepared.

The ASTM suggestion of a need for a testing agency inspection service involving NBS led to an NBS study. The study supported the ASTM proposal but suggested that the developing needs of domestic and international commerce and of public health and safety would benefit from a program that would also provide a public recognition (accreditation) of testing laboratories found qualified. NBS sponsored a Conference on Laboratory Evaluation and Accreditation in September 1970 to discuss the concept of a national laboratory accreditation system. An ad hoc committee was formed at the conference to pursue the concept. Active participants included ASTM, the American National Standards Institute, Underwriters' Laboratories, and the American Council of Independent Laboratories. During the period 1972 to 1974 this concept received a broad informal review. Because of evident interest in a national program for laboratory accreditation, such as that indicated by members of the U.S. Congress and the National Business Council for Consumer Affairs, the department decided to initiate NVLAP.

Proposed Procedures

The department published its proposed NVLAP procedures on 8 May 1975. The proposal specified that NVLAP would be composed of several lab-

oratory accreditation programs, one for each class of technology where a need is established and where a significant user constituency is represented. Each program established under NVLAP would consist of an identifiable set of product standards and test methods. A National Laboratory Accreditation Board made up of federal employees and a National Laboratory Accreditation Advisory Committee made up of private sector interests would be established for each program. Each board would identify, on the basis of requests, the product standards to be served and would identify or develop needed criteria, examination methods, and examiner qualifications required for the identified test methods. Each board would also recommend accreditation action. Each advisory committee would provide advice to its respective board.

Comments on Proposed Procedures

In response to the request for comments on the proposed procedures, the department received 153 written statements and 26 oral statements at two public hearings held during the 60-day public comment period. Four of the principal issues raised by the comments were:

1. Need for the program.
2. Structuring of NVLAP on a class of technology versus a product basis.
3. Participation of the private sector in the development of accreditation criteria.
4. Need to coordinate with existing or developing laboratory accreditation systems within the private and public sectors.

The department's position on each issue was recorded in a summary and analysis report dated 3 Dec. 1975. Each position as drawn from that report is paraphrased in the next four sections of this paper.

Need for the Program

A categorization of respondents according to their technological areas of interest and their opinions for or against the need for the program, is given in Table 2. The polarization of opinion suggests that it may be inadvisable to require the initiation of programs on the basis of classes of technology. For example, concrete, steel, aluminum, bituminous materials, and wood products are all generally considered construction materials. If the department were to consider proposing a program for construction materials as a class of technology, it would, on the basis of the categorization of needs in Table 2, find different needs for the products involved. However, according to the categorization, initiation of programs on a product by product basis or on the basis of similar or related products does seem feasible. Needs for accreditation programs with scope limited to particular products could be evaluated with greater specificity and existing programs serving such needs could be more readily identified. Such revision of the proposed procedures would be

TABLE 2—*Public input on the need for NVLAP programs.*

Technology	Number of Respondents Indicating	
	Need	No Need
Aerospace	3	...
Appliances, gas, electrical	3	...
Analytical; chemical, biological	14	...
Concrete, cement, aggregates	28	4
Electric, electronic	...	3
General testing	23	5
Mechanical; vehicles, tools	...	3
Metals; steel, aluminum	...	5
Petroleum; oil, gas	...	12
Safety of products	3	2
Textiles	2	...
Utilities; gas, electricity, nuclear	2	1
Wood products	5	...

responsive to those that commented concerning the broad potential scope inherent to programs developed on a class of technology basis and the possibility that implementation on such basis could result in duplication and undue overlap with effective existing programs.

Class of Technology Versus Product

The proposed procedures provided for the department's establishment of a National Laboratory Accreditation Board for each class of technology for which the department determines there is need for accredited testing laboratories. This presumed the existence of general and concurrent needs within various classes of technology for the accreditation of laboratories to test all or most of the various products within each class. The comments indicated that this assumption may not have been valid. For instance, steel and concrete are both construction materials. Comments indicated needs in the concrete area but no need for accredited laboratories in the steel area. Given this situation, the department could have been limited in establishing an accreditation program to serve concrete testing needs because a determination of need for a construction materials class of technology including steel might not be justified. Therefore, a suggested revision of the proposed procedures allowed the initiation of accreditation services on a product by product basis.

Participation of the Private Sector

The proposed procedures provided for the establishment of a National Laboratory Accreditation Advisory Committee for each board and required the board to consult with the advisory committee when developing accreditation criteria. The functions of the advisory committee (composed in part

with a chairman and members other than federal employees) are essentially limited to a consultative relationship with the board. The board, consisting of federal employees, however, was to recommend to the department the accreditation criteria to be promulgated and to make other recommendations of an operational nature in assisting the department to administer and manage the programs.

Many comments contended that the private sector should have more direct and equal involvement with the federal sector in recommending actions to the department and that recommendations for accreditation criteria should, in particular, have private sector participation. Some comments suggested that the private sector should also have a role in administering and managing the operational activities of a voluntary accreditation program, although it was recognized that this would probably require additional legislative authority.

In response to these comments, a suggested revision to the proposed procedures was to abandon the concept of separate boards and advisory committees in favor of the establishment of National Laboratory Accreditation Criteria Committees. Composed of public and private sector members, these committees would recommend to the department the accreditation criteria to be promulgated by the program. The department would consider these recommendations in promulgating criteria.

Coordination with Other Laboratory Accreditation Systems

Except for Section 15 of the proposed procedures, which provided for support of coordination efforts, the proposed procedures lacked any general or specific provisions regarding the promotion or arrangement of coordination with other systems that may exist or be in development. Many comments pointed to this deficiency. These comments indicated that a major benefit to be derived from a national institutional mechanism for laboratory accreditation would be its service as a focus for coordination of laboratory examination and accreditation systems that now exist or may develop in the public and private sectors. Such coordination would work to minimize the duplication of laboratory examination efforts, reduce confusion regarding the criteria used, and promote reciprocal recognition of adequate laboratory assessment systems, domestically and internationally.

Therefore, a suggested revision of the proposed procedures was to include a statement concerning coordination in the goal of the program and to provide for, as appropriate, the establishment of federal agency coordinating activities to advise the department on federal agency utilization of accreditation services provided under the procedures. In particular, a section was recommended for the revised procedures that would have required the department to solicit the views and participation of federal agencies affected by a program established under these procedures. In addition, this revision of the procedures allowed a federal regulatory agency to halt the establishment of a program when it would, as indicated by the agency's written objection,

adversely affect an existing or developing accreditation program of that agency.

Procedures as Adopted

Original Procedures

The department incorporated these suggested revisions and published the original NVLAP procedures on 25 Feb. 1976. As stated in the original procedures, the goal of NVLAP is to provide, in cooperation with the private sector, a national voluntary system to examine upon request the professional and technical competence of private and public testing laboratories that serve regulatory and nonregulatory product certification needs.

Anyone may request a program under the NVLAP system. Such a request is required before a program will be started. The requestor of the program must identify the product, the relevant standards, and the applicable test methods to be included in the proposed program (the term *product* is defined broadly by the procedures to include manufactured goods, constructions, installations, materials, or associated services). In addition, the number of laboratories likely to request accreditation and the number of users who will seek accredited laboratories must be estimated. The requestor must also indicate the basic need for the program in terms of its potential public benefit, the lack of existing alternative systems, the existence of standards and test methods of importance to commerce or consumer well-being, and its feasibility and practicality of administration.

The department determines the priority of the request in relation to other requests that may be pending. If resources are available, it then publishes for public review a preliminary finding of need for the program. If the public registers evidence of significant support, the department will announce a final finding of need for the program and announce the establishment of a National Laboratory Accreditation Criteria Committee to develop and recommend criteria for accrediting laboratories under the program (the committee is composed of equal numbers of public and private sector representatives).

Taking into account the recommendations of the committee, the department then publishes for public comment proposed accreditation criteria and estimates of fees that it intends to charge for the program. If the public generally supports the proposal, the establishment of the program is formally announced and applications for accreditation from laboratories are accepted. All accreditation decisions are published in the *Federal Register,* as are other major program announcements. Appeal procedures are set out should a laboratory disagree with the department's accreditation decision.

Three revisions have been made since the original procedures were published. Two sets of optional procedures were adopted in 1979 and an amendment was added in 1980. Title 15, Parts 7a, 7b, and 7c of the *Code of Federal Regulations* includes all three sets of procedures.

Optional Procedures (Part 7b)

On 9 March 1979, the department published optional procedures for use by federal agencies (these optional procedures were designated Part 7b and the original procedures were redesignated Part 7a), which differ from the original procedures in two ways. First, they eliminate the requirement for the department to make a finding of need. The federal agency involved determines whether a need exists to accredit laboratories that serve a product of interest to that agency. This is appropriate, and in the case of certain regulatory programs, necessary, when the statutory responsibility of the agency is involved. Second, they eliminate the requirement that the department establish a criteria committee to recommend criteria for accrediting testing laboratories. The requesting federal agency may elect to submit recommended criteria directly to the department for consideration, or may choose to request that the department establish a National Laboratory Accreditation Criteria Committee (NLACC) to recommend such criteria.

Two federal agencies—the Department of Housing and Urban Development (HUD) and the Nuclear Regulatory Commission (NRC)—have used the Part 7b procedures. HUD has made two requests, for a program covering the testing of carpets (which is operational) and for one on solid fuel room heaters (which is under development). NRC has requested a program (which is also under development) to accredit processors (laboratories) of radiation dosimeters used by employees of NRC licensees.

Optional Procedures (Part 7c)

On 25 April 1979, the department published optional procedures for use by qualified private sector organizations that are similar to the optional procedures for federal agencies. These optional procedures (designated Part 7c) allow any private sector organization to request a program without having the department formally determine a finding of need, as long as the requesting organization demonstrates that it arrived at the decision to make the request through open proceedings based on a consensus of all interested parties. The primary purpose of this option was to simplify the use of NVLAP by the private sector. No requestors have used this option as yet.

Amendment to Allow the Addition of Test Methods to Existing Programs

On 21 April 1980, an amendment was published to allow the department to include additional standards and test methods to an existing program when in the department's judgment the standards and test methods are:

1. Directly relevant to the product for which the program was established.
2. Found to be technically suitable.
3. Such that an evaluation of a laboratory is feasible using already established criteria.
4. Likely to be those for which laboratories will seek accreditation.

The original procedures were not clear on how one could add standards and test methods to existing programs without following the lengthy "finding of need" process.

Proposed Amendment

On 27 Jan. 1981, the department published a proposal to amend the NVLAP procedures in three ways. First, it would add to the procedures some general and specific criteria (published on 23 Jan. 1980) for accrediting all types of testing laboratories. Second, it would eliminate the need to establish separate National Laboratory Accreditation Criteria Committees to develop and recommend criteria for each program. Third, it would provide for the establishment of a National Laboratory Accreditation Advisory Committee that would advise the department on the NVLAP accreditation process, on amendments to the criteria, and on accreditation at the national and international levels. A total of 14 written comments on the proposed amendment were submitted by the March 30 deadline for public comment. These comments are currently being analyzed.

Purpose of Proposed Amendment

This section explains the basis and purpose of the proposed amendment, which is paraphrased from the text of the 27 January *Federal Register* notice.

The department believes that the criteria should be identical or as consistent as possible among various product or service areas for which accreditation is granted. It is generally understood that there are certain fundamental elements relative to the facilities, equipment, personnel, and quality control practices that all laboratories should possess. The established criteria reflect the basis of those fundamental elements as they apply to the programs for thermal insulation, concrete, and carpet. The consistent criteria for these three programs are expected to be applicable to future programs in other product or service areas.

The use of consistent criteria will tend to assure that NVLAP-accredited laboratories have been uniformly assessed regardless of the product or service area. Similarly, laboratories seeking accreditation under more than one program will be less likely to be faced with different and possibly conflicting criteria. From an operational point of view, consistent evaluation criteria, regardless of the number of programs or test methods for which a laboratory may seek accreditation, are desirable in order to minimize accreditation costs to the laboratories and the likelihood of confusion in administering the program.

The department has concluded, through the actual implementation of the criteria in assessing the approximately 100 laboratories that have requested

accreditation in the three programs, that the present criteria are appropriate to these programs and practical to the operations of NVLAP.

Since the department anticipates that the criteria will continue to be similar from one product to the next, the agency believes there is no longer a need to develop new criteria for each requested program. Using a single set of criteria would mean that a laboratory would not have to supply similar data in different formats when seeking accreditation in more than one program. The laboratory would be required to supply only additional data as needed to evaluate new test methods being added to its list of accredited methods. The testing laboratory would be supplied with supplemental information that adapts the criteria to the particular characteristics of each test method for which it has applied for accreditation.

The department realizes that changes in the universal language of the criteria may be necessary in the future, but believes these changes are likely to be few in number. Sound analysis and persuasive logic will be needed to justify proposing a change in the present criteria.

The department believes that since these criteria can be used in all future programs with only occasional changes, there is no longer any need to establish a separate criteria committee for each new product or service area. However, to continue to receive the benefit of the knowledge, experience, and expertise of individuals involved in accreditation or the operation of testing laboratories, the Department believes that a single National Laboratory Accreditation Advisory Committee should be established and maintained. This advisory committee would be composed of qualified individuals from federal, state, and local governments, testing laboratories, users of testing laboratories, academia, consultants, and consumers. The committee would meet at the request of the department and would function solely in an advisory capacity.

In the past, the criteria committees also served as an informal source of information on precision and accuracy expectations for test methods, on proficiency testing approaches, on materials and protocols for assessing a laboratory's performance, and on the generation of supplemental information to adapt the criteria to the test methods within each program. To continue to receive this valuable information on technical matters, the department plans to hold workshops for each newly proposed program as appropriate. These workshops will be open to anyone from the public and private sectors interested in the specific program, and could include people from laboratories, manufacturers, research organizations, standards writing bodies, and federal, state, and local agencies whose regulations affect the product or service area under consideration. The department believes that the combination of workshops for each newly proposed program plus a single advisory committee, approximately one-third of which will be composed of government representatives, assures greater private sector input for NVLAP.

The department believes that this amendment is necessary at this time in

order to expedite establishment of future programs and to ensure that laboratories wishing to apply for accreditation in more than one program will not be required to submit similar information in different formats. The department plans to undertake a further rulemaking proceeding to consolidate the procedures, once the advisory committee has been formed. At that time, every effort will be made to present the procedures in a fashion that will make the procedures easier to read and reference. (This completes the material that was drawn from the 27 January *Federal Register* notice to amend the procedures.)

Amendment's Effect on Part 7a Procedures

If this amendment is adopted, the major steps involved in establishing a program under Part 7a procedures would be:

1. A formal request to establish a program for a particular product or service area that meets the requirements of the NVLAP procedures is submitted.
2. The department contacts other parties, especially federal agencies and trade associations, that may have an interest or may be affected by the proposed program.
3. The department decides on the priority of the request.
4. The department publishes in the *Federal Register* for public comment a preliminary finding of need for the proposed program.
5. If there is substantial public support for establishing the program, the department publishes a final finding of need (if not, a withdrawal of the preliminary finding is published).
6. If appropriate, workshops are arranged to receive expert advice on the supplemental information and other technical details needed to implement the program.
7. Once the technical details are developed, the department announces in the *Federal Register* the establishment of the program, inviting interested laboratories to apply for accreditation. Also, a separate notice setting forth the schedule of fees for the program is published.

Amendment's Effect on Parts 7b and 7c Procedures

Similarly, for Part 7b and 7c procedures, the major steps would be:

1. A federal agency (Part 7b) or "qualified" private sector organization (Part 7c) requests a program for a particular product or service area and cites the basis for which it determined the need.
2. The department contacts other parties that may have an interest or may be affected by the proposed program.
3. The department decides on the priority of the request.

4. The department publishes in the *Federal Register* the request for the program, asking that any comments regarding the need for the program be directed to the requestor with a copy forwarded to the department.

5. If after a 60-day period both the department and the requestor agree to proceed, workshops may be arranged to receive expert advice on the supplemental information and other technical details to implement the program.

6. Once the technical details are developed, the department announces in the *Federal Register* the establishment of the program, inviting interested laboratories to apply for accreditation. Also, a separate notice setting forth the schedule of fees for the program is published.

Margaret V. Federline[1]

The Laboratory Evaluation Process of the National Voluntary Laboratory Accreditation Program

REFERENCE: Federline, M. V., **"The Laboratory Evaluation Process of the National Voluntary Laboratory Accreditation Program,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 96–104.

ABSTRACT: At least 70 laboratory accreditation systems exist in the United States today, and many of them are directed at a single discipline or narrow spectrum of products. The increase in the number of these systems in response to a growing need for laboratory testing services indicates the viability of the laboratory accreditation concept. The National Voluntary Laboratory Accreditation Program (NVLAP) was established by the Department of Commerce to provide a national, multidisciplinary laboratory evaluation scheme.

NVLAP evaluation is based upon compliance with criteria that reflect the latest technology in laboratory operation and management. These criteria are sufficiently flexible to accommodate such diverse testing areas as thermal insulation, carpet, and concrete. The evaluation of laboratories, conducted by the National Bureau of Standards, utilizes a peer review. It combines elements of questionnaire, laboratory on-site survey, and testing of proficiency samples in a comprehensive examination to determine a laboratory's capability to perform specific tests. NVLAP, an interactive system between laboratory and accreditor, provides a mechanism for overall laboratory improvement.

KEY WORDS: accreditation criteria, checklist, laboratory accreditation, laboratory assessment, laboratory evaluation, peer review, quality assurance, test methods, training

Laboratory accreditation is becoming widely accepted as a means for recognizing the capability of a laboratory to properly perform specific test procedures. Accreditation may be voluntarily requested by a laboratory or may be mandated through regulation from accrediting bodies such as the federal, state, or local governments, trade associations, manufacturers, and numerous private entities. The need for such accreditation systems arises from the demand for reliable, accurate, and authentic test results by the users of laboratory services.

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Seventy systems that formally recognize over 6800 laboratories are identified in *Principal Aspects of U.S. Laboratory Accreditation Systems* [*1*]. This represents an increase in the number of accreditation systems from two in 1947 to 70 in 1980, with a significant portion of this increase occurring between 1977 and 1980 (Fig. 1). Each system seeks to establish authenticity and creditability of test results rendered by a laboratory. Many systems, however, such as the Program for the Evaluation of Milk Laboratories (Food and Drug Administration, Bureau of Foods) and the Massachusetts Program for Licensing of Concrete Testing Laboratories (Massachusetts State Building Code Commission), address a single testing discipline or narrow spectrum of products. With the increasing number of accreditation systems, many of which address narrow fields of testing, the possibility that a laboratory will require accreditation by more than one system to conduct business is enhanced. This duplication creates an economic and manpower burden for multidiscipline laboratories, which are subject to a variety of audits from narrowly focused accreditors.

In 1976, the Department of Commerce established the National Voluntary Laboratory Accreditation Program (NVLAP) to provide a national, multidisciplinary laboratory evaluation system. This system is designed to accredit in any testing area where a need is determined. Programs established by NVLAP must be requested by an individual, a group, or a government body. NVLAP is administered by the Office of Product Standards of the De-

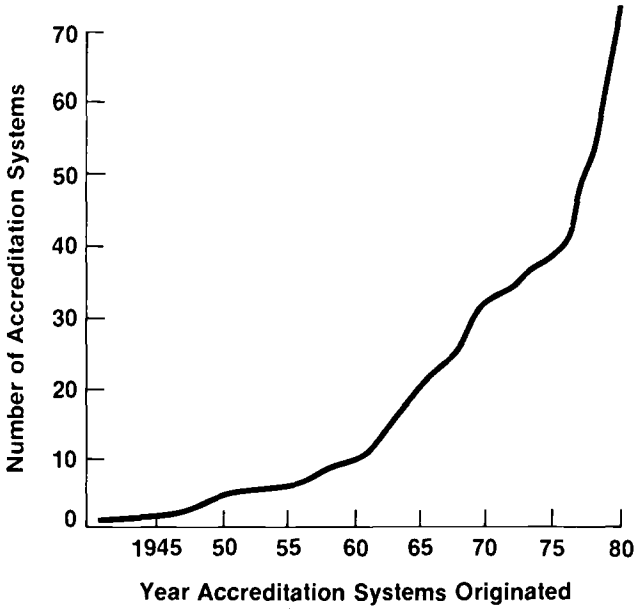

FIG. 1—*Number of U.S. laboratory accreditation systems.*

partment of Commerce, with technical evaluation of laboratories performed by the National Bureau of Standards.

In evaluating the capabilities of a laboratory under such a national system, it is necessary to define common fundamental elements expected of reputable testing laboratories. The Department of Commerce established two advisory committees, with membership representing industry, federal and state governments, academia, and the testing community to recommend criteria on which the laboratory evaluations are based. The committees were aided in the preparation of these recommendations by the NVLAP technical staff at the National Bureau of Standards, who conducted in-depth reviews of other national and international laboratory accreditation systems. The recommendations of these committees were formalized for public comment in proposed criteria of September 28, 1979. Final criteria based on guidance from these committees and public comment became effective on March 7, 1980.

The Department of Commerce has identified in these final criteria for accreditation essential elements of laboratory management and operation to assure the quality of results from specific test methods. These criteria address the operation of the laboratory by focusing on the organizational structure, technical management, professional and ethical business practices, and the system for assuring the quality and consistency of test results. The criteria also generically indicate those fundamental elements necessary for the successful performance of a test method, which include staff competence and training, laboratory facilities and equipment, test plans, equipment calibration procedures, laboratory records, data handling procedures, and quality control checks and audits. Prior to evaluation, each applicant laboratory is supplied with supplemental information that details how the criteria are to be integrated and implemented for each test method. The criteria and supplemental information establish a framework for a laboratory operations model that provides a basis for the uniform evaluation of laboratories regardless of product testing area.

Evaluation for accreditation of approximately 100 testing laboratories during 1980 in the three current laboratory accreditation programs (LAPs)—carpet, concrete, and thermal Insulation Materials—has shown these criteria to be generally applicable among the diverse testing areas. These versatile and comprehensively broad criteria enhance the prospect for a consistent quality assurance program within each laboratory and reduce the economic and manpower burdens incurred in preparing for accreditation in more than one testing area.

In the NVLAP evaluation process, the concept of peer review is key in achieving insight and depth in the technical analysis of laboratory operating procedures. Recognition of the professional and technical competence of the NVLAP peer assessors by the applicant laboratory aids in establishing a rapport that is vital in a thorough evaluation of the laboratory. Acknowl-

edgment as a peer or authority by the scientific testing community most frequently emanates from recognition of a combination of the following qualifications:

- Advanced degree in a field of science or engineering.
- Knowledge and experience of product standards and test methods in the technical field.
- Experience as a lecturer or author of technical material.
- Recent firsthand experience with laboratory management and operation.
- Contribution to consensus standards organizations.
- Understanding of laboratory practices for assuring the quality of test results in the technical field.

Peers are selected to serve as assessors by the NVLAP technical staff at the National Bureau of Standards. Nominations are sought from academia and professional and technical societies. Final selection and assignment of these peers to serve as assessors during laboratory on-site surveys or as members of the evaluation panel who review all information submitted by and about a laboratory applying for accreditation is based upon the following:

- Education, experience, and qualifications related to a specific LAP.
- Interpersonal communication skills.
- Ability to summarize observations in writing.
- Absence of all grounds for conflict of interest in the assessment or evaluation of applicant laboratories.
- Peer availability during scheduled laboratory visits and evaluations.
- Geographic proximity of peer to applicant laboratories.

The evaluation of a laboratory for NVLAP accreditation is based on three broad inputs (Fig. 2):

- Written information supplied by the laboratory in response to questions included in the application form or LAP specific questionnaires.
- Results of proficiency testing.
- On-site survey of the laboratory by a NVLAP assessor.

A laboratory initiates the accreditation process (Fig. 3) by requesting an application form from NVLAP. Following review and acceptance of the completed application, NBS notifies the laboratory of evaluation and fee requirements. Upon payment of fees, the laboratory is enrolled in required proficiency testing programs, is scheduled for an on-site laboratory survey, and is notified of additional written information that must be supplied for the evaluation. The NVLAP assessor reviews proficiency testing results and the laboratory's written information prior to the laboratory visit to become

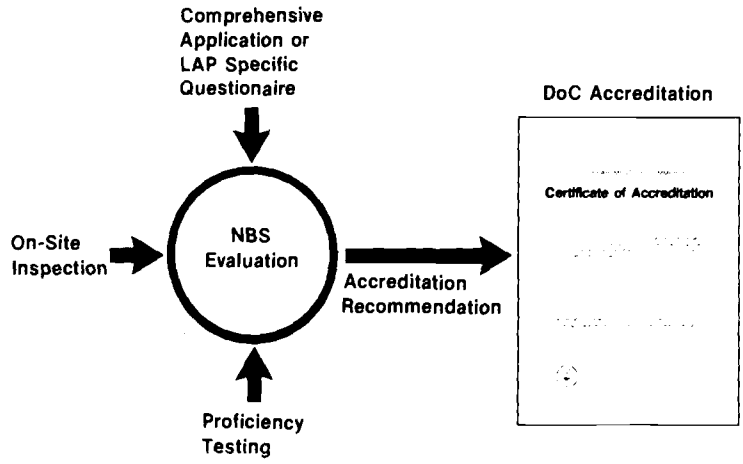

FIG. 2—*Major components of the evaluation process.*

familiar with the laboratory's operation and to identify potential trouble spots.

Since the on-site survey is a major component of the evaluation process, individuals selected to serve as NVLAP assessors undergo intensive training in NVLAP evaluation techniques. The training program is designed to thoroughly familiarize assessors with the history and operation of NVLAP so that they are comfortable with the evaluation process. Joint training sessions are held at NBS for assessors in all laboratory accreditation programs to discuss such topics as national and international implications of laboratory accreditation, the roles of DOC and NBS in the evaluation process, legal issues for the NVLAP assessor, and general practices for the audit of quality control systems in the laboratory. Individual sessions follow for assessors of each laboratory accreditation program during which NVLAP criteria, supplemental information detailing the requirements for each LAP, and the laboratory assessment form are reviewed and discussed in detail for each relevant test method. Audiovisual presentations and actual demonstration of test methods afford hands-on experience in using the assessment form. Assessors view the actual conduct of a test method while completing the NVLAP assessment form simulating on-site survey conditions. A discussion led by an NVLAP project leader follows this activity to review the assessors' responses on the forms, to pursue a uniform approach to the audit of the test method, and to exchange observational techniques among assessors. This interactive training activity is intended to convey to each assessor a uniform understanding of the NVLAP evaluation process and the effective implementation for each LAP. All training sessions are recorded and transcribed so that each assessor may refer to the information at any time during the evaluation proc-

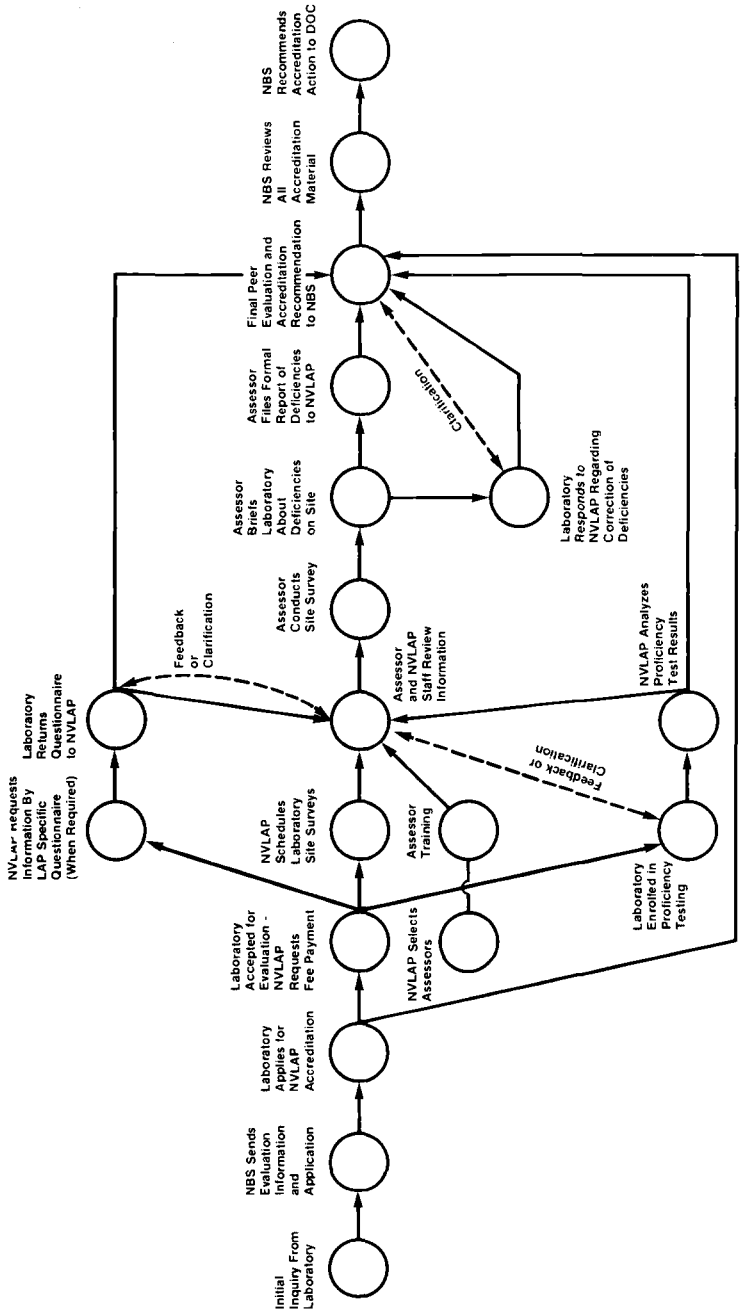

FIG. 3—*NVLAP evaluation process.*

ess. Assessors may be invited to NBS for additional training whenever required. Members of the NVLAP technical staff occasionally accompany assessors during laboratory surveys to provide feedback for future individual and general training needs and to assure uniformity of inspection among laboratories.

An important goal of the on-site survey is to achieve uniformity and objectivity in checking conformance with the criteria during normal daily operation of the applicant laboratory. During the evolution of the survey process, members of the NVLAP technical staff reviewed other major laboratory evaluation systems, visited laboratories, and talked in depth with laboratory assessors. This research led to the implementation of a quality assurance audit and a critical element audit for NVLAP laboratories. An assessment form was developed as an instrument to guide the assessor in confirming information supplied by the laboratory and determining compliance with criteria while providing a means for consistent interview techniques. Component parts of the form are (1) general operation checklist, (2) quality assurance checklist, and (3) critical element checklist.

In conducting an audit of quality assurance in each laboratory, the assessor is obliged to examine in detail all facets of laboratory operation that may affect the performance of the test method(s) for which the laboratory seeks accreditation. The number of test methods examined in detail is determined by the assessor with guidance from the NVLAP staff and is representative of all technical areas for which the laboratory seeks accreditation. The quality assurance checklist is organized so that the assessor may examine competency, training, and calibration/verification records for a selected test method to provide background for a laboratory walk-through. Following this in-depth examination of records, a representative sample is selected from the laboratory's recording system. This sample is used as a guide for the assessor to follow the laboratory's normal conduct of the test method. The assessor examines records and equipment and interviews staff members in the normal flow of operation to the final test report. If possible a demonstration of critical portions of the test method is observed.

Supervisors and technical staff members are interviewed regarding quality control practices. Staff members' notebooks, calibration/verification records, equipment maintenance logs, and other records are examined when necessary to verify discussions with staff members and observations of their performance in testing the representative sample. In the case of inconsistencies among records, observations, and responses, deficiencies are noted and another randomly selected sample is traced. Thus, the assessor in following the suggested order of the audit verifies written and actual laboratory practices in the natural progression of a test sample from receipt to test report. Specific deficiencies are noted in writing.

Once the assessor has conducted a detailed quality assurance audit for selected test methods, he or she reviews the remaining test methods for which

accreditation is sought according to a predetermined set of critical element categories (Fig. 4). Elements including environmental or sample conditioning equipment and facilities, test equipment, and procedural function are investigated to determine if they meet the requirements of each test method. Based on overall observations and interviews, assessors are asked to respond to a general laboratory operation checklist regarding factors common to the general operation of the laboratory.

The assessor must identify specific deficiencies in compliance with NVLAP criteria to laboratory management during an exit briefing and in writing to

United States Department of Commerce

National Voluntary Laboratory Accreditation Program
(NVLAP)

CRITICAL ELEMENT CHECKLIST

Name of the Laboratory_____

Assessor_____ NVLAP Lab Code #_____

Survey Date_____ LAP_____

INSTRUCTIONS FOR THE ASSESSOR:

Review the laboratory's facilities, equipment, and procedures as identified in the critical elements for each test method for which the labortory is seeking accreditation. Respond to each of the categories for each test method as appropriate: NOT APPLICABLE (N/A); MEETS NVLAP CRITERIA (Y): DOES NOT MEET NVLAP CRITERIA (N); COMMENTS WITH NUMERICAL REFERENCE (C_n).

Critical Element Categories	NVLAP Test Method Code							
Environmental or sample conditioning equipment and facilities meet requirements as specified								
Test equipment and apparatus meets requirements as specified								
Procedural functions for test methods are performed as specified								
Laboratory records show that no degradation of performance has resulted from the use of equipment, facilities, or procedures which do not strictly conform to prescribed test methods.								

FIG. 4—*Critical element checklist.*

the National Bureau of Standards. The laboratory is required to respond within 30 days regarding the correction of these deficiencies noted during the on-site survey. Upon receipt of the laboratory's response, a team of assessors are assembled at NBS to review written information submitted by the laboratory in the application form and questionnaire when required, proficiency testing results, the report of the on-site laboratory survey, and the laboratory's response regarding correction of deficiencies noted during the laboratory visit. Based on this review, the National Bureau of Standards prepares a recommendation for the deputy assistant secretary for product standards policy, who grants accreditation on behalf of the secretary of commerce. If accreditation is denied the laboratory may appeal through formal administrative procedures established by law.

The immediate reward for a laboratory's participation in NVLAP is the recognition of professional competence in testing, a valuable asset in today's competitive market of commercial testing. Through the evolution of laboratory evaluation technology, models for laboratory operation and performance are emerging. A mechanism exists in the evaluation process for self-improvement by identifying weaknesses in organization, performance, or quality assurance and providing guidance towards improvement. In this sense, laboratory evaluation technology may serve not only to assure uniformity of laboratory competence but also to promote standards of excellence.

Reference

[1] U.S. Department of Commerce, Office of Product Standards Policy, and Hyer, C. W., "Principal Aspects of U.S. Laboratory Accreditation Systems," NTIS PB80-199086, National Technical Information Service, Springfield, Va., 1980, pp. 2-6.

William R. Rutherford[1]

Inspections, Tests, and Accreditation Activities Associated with Qualification of Safety-Related Equipment for Nuclear Generating Stations

REFERENCE: Rutherford, W. R., **"Inspections, Tests, and Accreditation Activities Associated with Qualification of Safety-Related Equipment for Nuclear Generating Stations,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 105–110.

ABSTRACT: In recent years, the Nuclear Regulatory Commission (NRC) has uncovered a generic problem of gross inadequacies in safety-related equipment environmental qualifications conducted by the nuclear industry. This paper describes the NRC's response to the problem through the development of an accreditation system for laboratories conducting such environmental qualifications.

KEY WORDS: laboratory accreditation, Nuclear Regulatory Commission, nuclear power plants, safety-related equipment, environmental qualifications

Much of the equipment used to monitor and control a nuclear power plant is highly standardized and, in many cases, the reliability of the equipment has been established through many years of operation in fossil-fueled generating stations. A significant difference between the application of the equipment in a nuclear plant and a conventional generating station is the environment in which the equipment might be called on to perform safety-related functions.

Under normal operation in the nuclear plant, some of the equipment is subjected to radiation and, in the event of a loss-of-coolant accident, some of the equipment may be subjected to a combined harsh environment—such as radiation, chemical spray, and high temperatures and pressures. Because of the potential for radioactive release under accident conditions, the consequences of equipment failure in the nuclear plant are significantly more im-

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portant than in the conventional plant. For these reasons, the U.S. Nuclear Regulatory Commission (NRC) requires that all safety-related equipment that could be subjected to a harsh environment and that must continue to be operable be prototype tested in that simulated environment prior to installation in the nuclear plant.

In 1977 the Sandia Laboratories were performing method tests for the NRC. During one of the tests designed to study synergistic effect, several types of electrical connector assemblies failed to function throughout the test. Following the investigation of the connector failures several NRC *Bulletins* were issued that uncovered the generic problem of gross inadequacies in safety-related equipment environmental qualifications conducted by the nuclear industry. Over the past few years, NRC has been actively engaged in verifying the adequacy of the environmental qualification of safety-related equipment used in nuclear power plants. Our effort has resulted in the development of new criteria, intensified reviews, in-depth inspections, and the initiation of new program activities designed to improve standards and provide greater consistency, uniformity, and control of safety-related nuclear equipment qualification programs.

Study of Alternatives

On 13 April 1978, the commission directed the staff to provide the commission with an analysis of alternatives for conducting independent verification testing of environmentally qualified equipment that is required to operate in safety systems.

The NRC staff developed a plan that consisted of an analysis of the following three alternatives, each representing a course of action that provided greater NRC involvement in equipment environmental qualifications than previously existed:

1. NRC environmental test facility.
2. NRC contract environmental testing to existing Department of Energy or independent laboratories.
3. NRC review and witnessing of vendor tests conducted to meet NRC requirements.

Combinations of these alternatives were also considered in search of the optimum method of monitoring and controlling the adequacy of equipment qualifications. Under NRC's guidance, Sandia Laboratories performed the study of the alternatives in accordance with the plan developed by the staff.

Sandia completed the study and recommended the following:

1. A dedicated autonomous NRC staff, at least at a branch level, be established immediately to be responsible for reviewing, witnessing, evaluating, and approving all safety-related equipment qualification programs.
2. Within six to twelve months after its inception, the dedicated staff

should be supplemented with sufficient additional staffing to continue this study and to define and implement the longer-range activities.

3. Strong consideration should be given to the "optimal" alternative, that is, a combination of Alternatives 1 and 3.

New Program

Following the Sandia study the NRC established a dedicated branch that has overall responsibility for coordinating equipment qualification programs. NRC continued the study and proposed a program designed for short-range and long-range results.

The short-range program will monitor and control equipment qualifications through the following activities:

1. Performing in-depth inspection and witnessing of selected equipment qualifications.
2. Performing selected independent verification testing.

During implementation of the above program activities, the following long-range program activities will be developed and implemented to assure the quality and efficiency of equipment qualifications:

1. Standardization of qualification criteria.
2. Accreditation of testing laboratories.
3. Improvement of test standards, specifications, procedures, and acceptance standards.
4. Consider the addition of other equipment requiring qualification by test into this program.

On 16 Sept. 1980 the commission formally authorized the staff to develop and implement the program for conducting independent verification testing and inspection of environmentally qualified equipment and approved the initiation of the laboratory accreditation program.

The scope of the program includes all environmentally sensitive safety-related equipment located in areas potentially exposed to a harsh environment and required to function during or following an accident for safe plant shutdown, or required to mitigate the consequences or an accident. Specifically, the program covers safety-significant electrical, instrumentation, and control equipment intended for installation in plants under construction and replacement or requalified equipment for plants in operation.

As part of our overall equipment qualification program, NRC will inspect and review in depth the industry test programs of selected critical components. This will include an NRC review of equipment specifications, test plans, test procedures, and acceptance standards before the industry's qualification tests are performed. NRC will also witness the assembly and prepa-

ration of specimens, review the test set-up, and witness the actual qualification tests. This review and inspection of the ongoing qualification tests will afford NRC the opportunity to ensure that necessary changes or adjustments are made before the work is completed.

In addition to its audit of industry test programs, NRC will conduct independent qualification tests of important equipment to verify the industry results. To the extent practicable, NRC tests will be conducted on equipment that has been in use in a nuclear power facility. When this is not practical, specimens will be obtained from stock designated for a nuclear power facility, artificially aged and then tested.

One important longer range activity of our new program includes the initiation of a testing laboratory accreditation system. To implement this feature, a new regulation is being prepared that will require qualification of certain safety-related equipment by laboratories that have received a certificate of accreditation through a third party accreditation program.

Need for a Laboratory Accreditation System

Requiring that equipment be qualified in laboratories accredited for that specific purpose will help assure that all testing is conducted in a uniform, consistent, and controlled manner and that the test results are reliable.

Several types of organizations are currently involved in the equipment qualification testing business. In varying degrees of interest and involvement, these organizations include equipment manufacturers, independent testing laboratories, utilities, universities, and independent research and development institutes. The expertise and skills of these organizations vary significantly. Past reviews of laboratory reports, direct observations of laboratory activities, and discussions with laboratory clients have led to a clear conclusion that improvements in the credentials of the testing laboratories must be made in order to assure the adequacy of equipment qualifications.

We believe that the laboratory accreditation system will provide an effective and efficient method of assuring that all laboratories performing qualification testing services satisfy an acceptable performance level. At present, the nuclear utilities are responsible for assuring the adequacy of test facilities they use. This approach results in nonuniform reviews of the laboratories by many different utilities and their agents. The proposed accreditation system, conducted by a nonpartisan organization, will produce a standard and uniform review process that can be expected to produce consistent and reliable results. The system can be used by all licensees and their agents in lieu of their individual efforts.

Accreditation System

The accrediting organization will require a dedicated technical staff to aid in the development of the accreditation system and to administer the program.

The major functions of the accrediting organization will include development of accreditation policy, operating procedures, and appropriate standards, periodic survey of laboratories, review of survey reports, and issuance of certificates of accreditation.

Under the proposed system, each testing laboratory would be accredited for the scope of work for which the laboratory applies and for adequate demonstration of acceptable performance to the survey team.

The policy on accreditation can be initially based on a mandatory requirement; that is, the forthcoming regulation requiring that environmental qualification testing be performed in a laboratory accredited by an accreditation program endorsed by NRC. The regulation will identify equipment manufacturers, utilities, independent research and development institutes, universities, and independent testing laboratories as organizations that may apply for accreditation. Additional services requiring accreditation will be considered under the new regulation. These services will be discussed with the accrediting organization as the base accreditation system is developed.

NRC will assist the accrediting organization in the development of the accreditation system, operating procedures, and standards. Our joint participation will assure the development of a program that will best serve the health and safety of the public.

Our concept of the program manpower, relative to development and operation, is that it will require a permanent technical and administrative staff in addition to various volunteer subcommittees. For example, the quality assurance and technical standards can be developed by dedicated volunteer subcommittees. Participation in the subcommittees must be diverse. However, the laboratory surveys must be performed by permanent staff or consultants specifically trained for that purpose.

NRC is currently working with the Institute of Electrical and Electronics Engineers (IEEE) to initiate the laboratory accreditation system.

Schedule

NRC's program commitment requires having an acceptable laboratory accreditation system functioning by late 1982. [At the time this paper went to press, Commission action was still pending.]

In our judgment, the following are some of the actions and commitments that the lead organization should initiate to assure a successful program. These are offered as guidance to assist IEEE in its decision to assume the lead role.

1. A steering committee should be initiated to develop the appropriate criteria, procedures, and standards no later than the first quarter of 1981.
2. A staff organizational structure with suitable delegated authority should be established to manage the development and implementation of the laboratory accreditation system by the second quarter of 1981.

3. A written agreement between NRC and IEEE should be reached to document the objectives, commitments, duties, and responsibilities to be honored by the two organizations in the development and implementation of the proposed program.
4. The accreditation system should be implemented by December 1982.
5. Both NRC and IEEE should agree to implement and support the accreditation system for a period of no less than five years.

Why IEEE

At present, IEEE has taken the lead in the development of industry standards related to environmental qualification of safety-related equipment used in nuclear plants and currently has the expertise in environmental qualification.

Much of the equipment used to monitor and control a nuclear plant includes electrical, instrumentation, and control types of equipment. Many of the materials used in this type of equipment are sensitive to the harsh environments that can exist in a nuclear plant. Since IEEE develops the technical standards for the equipment of primary concern, it is logical that it is best suited, technically, to control an accreditation program addressing the testing of that equipment.

The success of the accreditation program requires the support of a technically sound organization familiar with the problems and current knowledge associated with equipment qualification. IEEE is well suited for this challenge.

Status

IEEE has established an ad hoc committee to define the laboratory accreditation system and study the legal and financial aspects associated with implementation of the system.

In June 1981, the system and the study results will be presented to IEEE's Executive Committee and Board of Directors for a final decision relative to IEEE accepting the lead in developing and implementing the laboratory accreditation system.

Genevieve E. Schwager[1]

Reliable Laboratory Data: A Look at a Successful Certification Program

REFERENCE: Schwager, G. E., "**Reliable Laboratory Data: A Look at a Successful Certification Program**," *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 111–115.

ABSTRACT: A laboratory accreditation program administered by the Illinois Environmental Protection Agency (IEPA) is described. The evolution of the program, proposed changes in the rules, procedures for certification, and cooperation between IEPA and the Illinois Department of Public Health in laboratory accreditation are covered.

KEY WORDS: accreditation, environmental control, waste water analysis, potable water analysis, land pollution, quality assurance

The following presentation describes the environmental laboratory certification program in the State of Illinois. The program is administered jointly by the Illinois Department of Public Health and the Illinois Environmental Protection Agency.

Rules for Certification and Operation of Environmental Laboratories was adopted August 1979. This document specifically applies to analyses for contaminants in potable water as specified in the Safe Drinking Water Act. The certification program and amended rules are now being expanded to include waste water and land pollution parameters of interest.

As the number of environmental programs grew in the United States during the 1970s, more and more analytical laboratory data were generated. Many new laboratories were formed. Those already in existence went into expansion programs. The regulations of pollution sources by state and federal agencies called for an enormous amount of analyses of many types of environmental samples. In Illinois, this situation drew attention to the need for some type of program to establish a common language among the various laboratories and the environmental engineers and specialists who were using the data for decision making. Data from one laboratory had to be equivalent and usable with that of another laboratory. Methods of analyses

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had to be standardized and data had to be generated under a good quality assurance program.

The passage of the Safe Drinking Water Act (SDWA) made it necessary for Illinois to establish a certification program for the chemical parameters included in this act. Since the Illinois Environmental Protection Agency (IEPA) has the public water supplies under its jurisdiction, statutory authority was sought from the General Assembly to establish a certification program. This legislation was passed in July 1977. Those responsible for the passage of this legislation showed good foresight, and the law granted the IEPA authority for certification of laboratories performing analysis for any type of environmental sample.

This law provides us with a means of implementing a comprehensive certification program for the state.

The Illinois Department of Public Health (IDPH) already had a certification program in place for bacteriological analyses, and that department also had the radiological health program for the state; therefore a memorandum of agreement (MOA) was signed by IEPA and IDPH, whereby the new chemical certification and the existing bacteriological certification were combined. The bacteriological program remained under the IDPH. A new radiochemistry certification program became the responsibility of IDPH. IDPH has also retained the milk laboratory certification program.

This memorandum created an immediate need for IEPA to establish a chemical environmental laboratory certification program. The fact that Illinois also petitioned for primary enforcement of the SDWA hastened the implementation of the program.

During the summer of 1977, when the statutory authority for certification was granted the IEPA, an interest survey letter was sent by the Division of Laboratories to members of the regulated community. Letters were sent to municipalities, county health departments, industries, utilities, statewide trade associations, and professional societies involved in environmental work. The response was largely affirmative for the proposed program. Most respondents seemed to think that such regulation was long overdue. The costs of laboratory analysis were rising rapidly, and the users were concerned about the quality of the work they were buying. Most laboratories were anxious to be certified to establish the credibility of their work.

Armed with the legislation and the favorable response of the survey, the IEPA Division of Laboratories established a certification office in the early months of 1978. Its first job was to certify laboratories for chemical analysis of public water supplies. IDPH continued the bacteriological certification under the new MOA.

Several chemists and laboratory managers from IEPA attended the short course at the U.S. Environmental Protection Agency (USEPA) training center in Cincinnati for certification officers in the state programs. We also became

acutely aware of what certification was all about when our own four state laboratories were audited for certification by Region V of the USEPA.

Procedures following the scheme set up by USEPA were drafted. Because some of our state regulations for public water supplies were more stringent than those of the SDWA, we had to make mandatory many of the rules that were guidelines or optional in the federal program.

The program is voluntary in that anyone can operate a laboratory and analyze environmental samples, whether certified or not. But if the reports are to be acceptable to the IEPA, they must be from a certified laboratory.

It was also decided early on that we would certify the laboratory and not the analysts. Our premise is that the director of the laboratory is responsible for the analysis reported from the laboratory. Certain requirements are stated in the rules for the personnel of a laboratory, but an individual analyst does not receive certification that he or she carries from one place of employment to another. It was felt by the steering committee that a person might be well qualified and competent in a given laboratory, but could be totally ineffective in another situation with differing equipment, methods, and workload. So the program was drawn up with emphasis on the laboratory output as a whole.

The certification of an environmental laboratory in Illinois is based upon filing of administrative questionnaires, performance evaluation sample analysis, and on-site visits to the petitioning laboratories by a survey officer. The survey of the laboratory includes physical facilities, personnel, instrumentation, analytical methods, and a comprehensive quality assurance program. Rules specifying acceptable conditions were promulgated in August 1979.

Since the 1979 rules were concerned primarily with the laboratories performing analysis of potable waters and their sources in order to meet the requirements of the USEPA, it has now become necessary to revise those rules and expand them to include waste water and land pollution analysis. These rules are now in proposed form and are out for public comment. It is expected that they will become final in approximately 90 days. They must wind their way through the reqiurements for rule making under the Illinois Administrative Procedures Act of 1977. This includes their registration and publication by the secretary of state, an additional 60-day hearing period, and passage through a Joint Committee of the Legislature on Rules.

The rules define certain terms used. They set down requirements concerning the use of a certificate of approval. A mechanism is included for revocation of a certificate for cause. There is also a mechanism for appeal of a laboratory that has been denied certification. The certificate is valid for two years unless either voluntarily surrendered or for some reason revoked by either IDPH or IEPA.

The certification process is not unduly complicated. One application for request for certification can initiate the process for any or all parameters in-

volved in environmental laboratory work. Applicable administrative questionnaires are sent to the requesting laboratory for the areas of analysis of its interest. Following the examination of the answers on the questionnaires by the laboratory evaluator to ascertain that the basic requirements of the rules are met, a set of performance evaluation samples are provided. These samples are to be analyzed and results reported to IDPH or IEPA within 30 days. The results are evaluated using statistical programs that have been established. If a problem with results is found, the laboratory is informed and, if desired, help is given to ascertain the cause of the poor results. When the laboratory feels that its problems have been corrected, another set of samples is sent for a new analysis. The last phase in the certification process, and perhaps the most important, is the on-site audit made by an evaluator from either IDPH or IEPA.

It is our observation that the personal communications we have with the laboratories, either by phone or in person, are the catalyst that has made the program work. We have learned much about the operations of many types of laboratories throughout the state. No two organizations are alike. Some have common problems, but these problems take on different faces.

The outstanding deficiency in most laboratories has been in the area of quality assurance. Few laboratories have a written, viable program. The analysts in some cases were doing something about quality assurance, if nothing more than noticing when "the results don't look right." Sampling techniques, preservation of samples, holding time from sampling to analysis, quality of reagent water, instrument calibrations, close adherence to standard methods, and analysis of "knowns" or of blind standards were not being done. A great deal of folklore exists in some laboratories. Methods evolve but not always by survival of the fittest.

When the rules say a laboratory must have a written quality assurance program, the laboratory director has to think seriously about what his or her laboratory is doing in these matters. When the director has to start a program, hopefully the analysts become involved. We fully realize that all results do not magically become right results because of a written document, but we do know that they are probably a great deal better than without one.

Both agencies provide assistance by persons with particular expertise in the various areas of analysis. We draw from the staffs of our own laboratories people who are particularly qualified in organic chemistry, metals analysis, microbiology, and radiochemistry. These persons assist the laboratory evaluators, who are themselves experienced in the work of the environmental laboratory and are professionals. This service to the laboratories throughout the state has been rewarding. It is done solely for the purpose of upgrading the analytical work available to the people of the state.

While the program is basically for those laboratories within Illinois, we have a reciprocity mechanism available for out-of-state laboratories to conduct analysis that are destined for use within the state. This certification may

be accomplished in one of two ways: either the state in which the laboratory is already certified has certification requirements comparable to those in Illinois, or the laboratory may go through the process as in-state laboratories do. In the latter case, the laboratory will be charged for the actual costs involved in the process. There is no certification fee for in-state laboratories at the present time.

We believe that this certification of environmental laboratories in Illinois will furnish a common language of analytical results for the use of the agencies in their many regulatory, emergency, and monitoring decisions. The environmental engineer, specialist, or attorney will not have to probe the significance of each laboratory report received. He or she will be able to interpret results in a language that will be common to all the laboratories. This could save the state agencies many dollars. Many times knowing that a pollutant does not exist is as important as knowing that one does. There is no point in going after a problem with a bulldozer if a teaspoon will alleviate it. Precision and accuracy statements of analytical results are also important for the data user.

These limits are invaluable in evaluating the data.

In summary, at the present time we have 75 laboratories certified under the potable water program, and 25 laboratories ready for legal certification for waste water or land pollution analysis when the amended rules become final. One hundred eighty-one laboratories within the state have expressed interest in becoming certified.

Out-of-state laboratories will become eligible for certification when the new rules become final. Approximately 25 laboratories outside Illinois have requested certification.

Addendum

The expanded rules were published as proposed rules in the *Illinois Register* and were subject then to public comment required by the Illinois Administrative Procedures Act of 1977. Approval of the Joint Committee on Administrative Rules (JCAR) of the legislature is also a part of the procedure for final promulgation. A very powerful industrial lobby prevailed upon the members of JCAR to withhold its approval. The IEPA withdrew the rules for further study and formulation of alternate methods of application of use.

The rules for certification of laboratories for the analysis of potable water are still in effect, and the program is on-going.

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The U.S. Army Environmental Hygiene Agency Analytical Quality Assurance Program

REFERENCE: Sneeringer, P. V., Belkin, F., Puzniak, R. W., and Costick, S. A., "**The U.S. Army Environmental Hygiene Agency Analytical Quality Assurance Program,**" *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 116–119.

ABSTRACT: The U.S. Army Environmental Hygiene Agency supports the worldwide health and environment programs of the Army through consultations, supportive services, investigations, and training. To aid in this mission, USAEHA maintains an Analytical Quality Assurance Program for its Aberdeen Proving Ground and Regional Laboratories. The program encompasses the analytical areas of air pollution chemistry, water and waste water chemistry, industrial hygiene chemistry, toxicology, clinical chemistry, and radiochemistry. The program includes standardized quality control procedures, regular inspections and audits, and peer review.

KEY WORDS: U.S. Army, laboratory certification, quality assurance, peer review

The mission of the U.S. Army Environmental Hygiene Agency (USAEHA) includes support of the worldwide health and environment programs of the Army through consultations, supportive services, investigations, and training. To aid the performance of this mission, USAEHA maintains an Analytical Quality Assurance Program for its Aberdeen Proving Ground–Edgewood Area and Regional Division Laboratories. Assurance of high-quality analytical data is provided to management and survey officers who must interpret health and environment data. The program encompasses the analytical areas of air pollution chemistry, water and waste water chemistry, industrial hygiene chemistry, toxicology, clinical chemistry, and radiochemistry, and is coordinated by the Analytical Quality Assurance Office (AQAO) of the Di-

NOTE: The opinion or assertions contained herein are the private views of the authors and are not to be construed as reflecting the views of the Department of the Army or the Department of Defense.

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rectorate of Laboratory Services. To preclude hindrance of mission accomplishment, AQAO is organizationally placed so that it is independent of all laboratories and equivalent to them in organizational status.

To perform this mission, AQAO is staffed with a small number of chemists, a biologist, and technicians, and is provided laboratory space and instrumentation sufficient for preparation and confirmatory analyses of standard audit solutions. Chemicals obtained from the National Bureau of Standards or highly reputable companies are used for preparation of audit solutions. State-of-the-art equipment in spectrophotometry and gas chromatography is utilized for analyses. Whenever possible, reference standards obtained from the Environmental Protection Agency are analyzed simultaneously to support the validity of the true values assigned to the audit samples.

Authority for establishment of the USAEHA Analytical Quality Assurance Program originates from USAEHA Regulation 702-1. The regulation delineates the responsibilities of all organizational elements impacted upon by the Analytical Quality Assurance Program. Quality assurance procedures are established for all USAEHA programs involving analytical testing. For each such program, an appendix is added to the regulation that includes quality assurance criteria, quality control systems, and review procedures specific for that program.

In general, quality assurance criteria are accuracy and precision requirements for analytical procedures and are obtained from current literature, government regulatory agency handbooks, or determinations at USAEHA. Final criteria are arrived at by combined efforts of laboratory personnel, program managers, and AQAO. Two standard deviation limits are established for most analytical procedures.

In order to achieve the criteria, quality control systems are developed and implemented by the laboratories. Guidelines are well established for these systems in publications of government regulatory agencies. The systems focus on daily analyses of quality control solutions and plotting or tabulating results versus control limits. Contingency plans are formulated in the event plotted points or tabulations fall outside of the statistical control limits.

Various procedures are utilized to review the quality control systems to determine if compliance with respective criteria is being sustained. These procedures include injecting blind chemical controls among incoming samples, inspections and audits of the laboratories by AQAO, and peer review of the laboratories by other government agencies and professional societies.

All samples incoming to USAEHA for analysis are directed to AQAO for administrative processing. AQAO logs in the samples, distributes them to the proper laboratory, receives the data back from the laboratory, and routes it to respective customers. This practice allows AQAO to intermingle controls with the samples unbeknownst to laboratory analysts, and thereby obtain an unbiased evaluation of the laboratory performance. If the controls were identified, the laboratory could spend an inordinate amount of time on

them or purposefully utilize their best analyst. Either practice could produce a false representation of analytical quality. Control data are statistically evaluated and formally reported to the director of laboratory services and respective laboratory supervisors. Results exceeding quality assurance criteria are immediately reported to laboratory supervisors who initiate corrective action. Such action may include repeat analyses or collection of new samples. The centralized sample and data routing also provides customers, USAEHA management, and survey officers with a single point of contact for tracking samples and identifying their status. Such a process also lends itself to automation, which is currently being studied. Computerized storage and retrieval of information regarding samples and data will significantly increase the efficiency of processing.

AQAO inspects the analytical laboratories and the Regional Division Laboratories annually to determine if the quality control systems are being maintained. An exception to this is the Toxicology Laboratory, where federal law requires AQAO to conduct almost daily inspections. Reports of findings are forwarded through channels to the laboratory supervisors and corrective actions are taken. Since geographical separation precludes injecting blind controls among samples incoming to the Regional Division Laboratories, formal audits are conducted. Chemical standard solutions are forwarded to the Regional Division Laboratories for analyses twice a year. The results are statistically evaluated and forwarded to the Regional Division Laboratories with recommendations for improvement and additional audit solutions if required.

Where appropriate, peer review of USAEHA analytical operations is sought and coordinated by AQAO. In accordance with the Safe Drinking Water Act (Public Law 93-523), the Environmental Protection Agency and the State of Maryland inspect and audit annually the Water and Waste Water Laboratory, Radiochemistry Laboratory, and Pesticide Laboratory. Under the Clinical Laboratories Improvement Act (Public Law 90-174), the federal Center for Disease Control inspects the Clinical and Radiobioassay Laboratories on an annual basis. The Clinical and Hematology Laboratories are audited on a bimonthly basis by the College of American Pathologists. The Industrial Hygiene Laboratory participates in the Laboratory Accreditation Program of the American Industrial Hygiene Association (AIHA). Participation requires a triennial inspection of the USAEHA Industrial Hygiene Chemistry Laboratory by AIHA and quarterly auditing of the laboratory by the National Institute for Occupational Safety and Health. The Toxicology Laboratory undergoes a triennial inspection by the American Association of Laboratory Animal Care to maintain accreditation status. Also, it is anticipated that the Toxicology Laboratory will be inspected by the Environmental Protection Agency to determine compliance with their regulations for Good Laboratory Practices (Toxic Substances Control Act, Public Law 94-469).

In addition, AQAO provides quality assurance support to other Army organizations, including the U.S. Army Environmental Engineering Agency in Sagami, Japan, the U.S. Army 10th Medical Laboratory in Landstuhl, West Germany, and those Army installations conducting chemical analyses in support of National Pollutant Discharge Elimination System Permits in accordance with the Clean Water Act (Public Law 95-217). Technical audits of analytical performance are conducted twice a year. Statistical evaluations of audit results are reported along with follow-up audit samples if necessary. Laboratory consultation visits are performed to provide assistance in resolving technical problems and in development and implementation of quality control systems.

John M. Scanlon[1] *and Joseph F. Lamond*[2]

The U.S. Army Corps of Engineers Laboratory Evaluation Program

REFERENCE: Scanlon, J. M. and Lamond, J. F., **"The U.S. Army Corps of Engineers Laboratory Evaluation Program,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 120–127.

ABSTRACT: The U.S. Army Corps of Engineers has been evaluating contractor quality control laboratories, commercial laboratories being used by either the corps of engineers or its contractors, and government quality assurance laboratories for a quarter of a century. All of the corps division laboratories (New England, Ohio River, South Atlantic, Missouri River, Southwest, North Pacific, South Pacific, and the Waterways Experiment Station, acting as the division laboratory for the Lower Mississippi Valley Division) are evaluated by the Cement and Concrete Reference Laboratory sponsored by ASTM Committees C-1 on Cement and C-9 on Concrete and Concrete Aggregates and located at the National Bureau of Standards. In turn, representatives of these division laboratories evaluate the above-mentioned laboratories being used by construction contractors for quality control at corps projects. In addition, corps government quality assurance laboratories normally located at project sites are evaluated to verify that the procedures being used by government technicians and engineers comply with the specified standard. The Corps of Engineers Laboratory Evaluation Program does not certify; it only evaluates to verify that the capability exists, that the laboratory employees know how to perform, and that the necessary facilities and laboratory equipment are available to permit the performance of the tests and inspections correctly.

KEY WORDS: certification, inspection, laboratory, project, quality assurance, quality control, verification

Test results of materials, elements, and structures can only be meaningful if the sampling, testing, and analysis are performed under the jurisdiction of standard procedures. In the United States and a number of other countries, these standards are developed by ASTM. Employees of the U.S. Army Corps of Engineers responsible for establishing standards, testing procedures, and specifications for materials to be used in construction of corps projects work very actively in various ASTM technical committees for the purposes of contributing to the usefulness of the standards developed by all consumers and

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especially to cause the standard to be developed in such a way that our construction or supply specifications can refer to the ASTM standards in toto without adding exceptions. If the standards developed by ASTM are such that the corps must refer to it with exceptions or in an extreme case not be able to use it at all, it becomes not only very costly to write a corps standard but much confusion with contractors results because of their inexperience in using such a standard. Whether the standards referenced in corps specifications are federal, military, corps, or ASTM, it is still important that the laboratories evaluating materials by these standards have the personnel, equipment, and facilities to permit the materials to be evaluated as specified by the standard. Due to this fact, the corps recognized over a quarter of a century ago that a system had to be developed that could provide relative assurance that the test results obtained could be relied upon to represent the properties of the materials incorporated in the projects.

History

On 16 June 1775, a day recognized as the founding date of the U.S. Army Corps of Engineers, General George Washington appointed ex-British Colonel Richard Gridley, a 65-year-old Boston native, who gave up extensive British land grants and pensions to be the first chief of engineers. By midnight, Gridley and his men were at work, and a well-designed earthwork fortification was completed by dawn of the next day—the 17th—to protect American soldiers in the historic battle of Bunker Hill.

From this beginning, the corps has gone on to win 150 battle streamers in its traditional role, and, when called upon by the demands of an expanding nation, to become a major civil works engineering resource for the country and the biggest developer of the nation's water resources. Today, the corps is the world's largest engineering organization. The corps established the U.S. Military Academy on a permanent basis in 1802, which for the next 18 years was the first and only engineering school in America. Army engineer officers began establishing science courses in other colleges as early as 1820, though mostly after 1840. By 1860, they had helped establish science or engineering colleges or departments in at least 13 universities, including Yale, Harvard, Michigan, and the U.S. Naval Academy, which was founded in 1845. Additional information pertaining to the history of the Corps may be found in *Historical Highlights of the United States Army Corps of Engineers* (EP 360-1-13, April 1973).

Organization

The functions of the Corps of Engineers are assigned to 14 separate divisions, of which there are eight that have division laboratories, as follows:

1. New England Division (NED), Waltham, Mass.
2. South Atlantic Division (SAD), Atlanta, Ga. (see Fig. 1).

FIG. 1—*South Atlantic Division Laboratory in Marietta, Ga.*

3. Ohio River Division (ORD), Cincinnati, Ohio.
4. Missouri River Division (MRD), Omaha, Neb.
5. Lower Mississippi Valley Division (LMVD), Vicksburg, Miss. (see Fig. 2).
6. Southwest Division (SWD), Dallas, Tex.
7. South Pacific Division (SPD), San Francisco, Calif.
8. North Pacific Division (NPD), Portland, Ore.

Each division is composed of from one to five districts. A division laboratory maintains assigned capabilities to perform evaluations of various construction materials, as shown in Table 1.

Districts do not have district laboratories unless these laboratories serve as the project laboratory for two or more construction projects. Project laboratories are normally located on the project site and are authorized to perform testing such as is shown in Table 2. In addition to government project laboratories, the contractors normally have a quality control laboratory at the project site; this laboratory permits the contractor to control his production so that the end result will most likely comply with the requirements of the project specifications. The government laboratory technicians have the responsibility to verify that the end product does actually comply with these requirements.

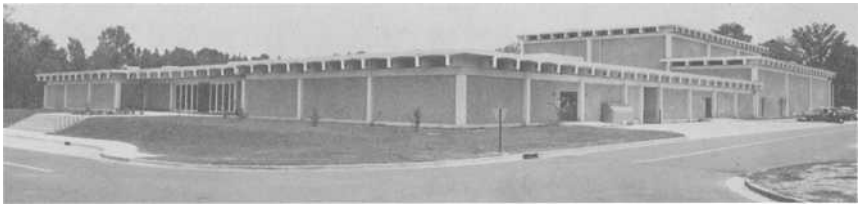

FIG. 2—*Concrete Technology Division, U.S. Army Engineer Waterways Experiment Station, in Vicksburg, Miss. This facility serves as the LMVD laboratory as well as the corps' Concrete Research Center.*

TABLE 1—*Division materials laboratory authorized testing and evaluation capabilities.*

Material or Process	MRD	NED	MPD	ORD	SAD	SPD	SWD	WES	CERL[a]
Concrete materials									
Cement and pozzolans	...	...	...	...	...	...	...	X	...
Curing compounds	...	...	...	X	...	X	...	X	...
Joint sealants	...	...	...	...	...	X	X	X	...
Joint seals	...	...	...	...	...	...	...	X	...
Waterstops	...	...	...	...	...	...	...	X	...
Other concrete materials	X	X	X	X	X	X	X	X	...
Epoxy resins	...	...	...	X	...	X	...	X	...
Soils	X	X	X	X	X	X	X	X	...
Asphaltic materials									
Bituminous designs	X	X	X	X	X	X	X	X	...
Bituminous materials	X	X	X	X	X	X	X	X	...
Other pavement materials	X	X	X	X	X	X	X	X	...
Building materials	X	X	X	X	X	X	X	X	...
Paint	X	X	X	X	X	X	X	X	X
Water/wastewater	X	X	X	X	X	X	X	X	...
Rock testing									
Structures foundations	X	...	...	...	...	...	...	X	...
Riprap suitability	X	X	X	X	X	X	X	X	...
Aggregate suitability	X	X	X	X	X	X	X	X	...
Tunnelling performance	X	...	...	...	...	...	...	...	...

[a] Construction Engineering Research Laboratory, Champaign, Ill. CERL does not serve as a division laboratory, but provides testing and evaluation for paint.

TABLE 2—*Testing authorized at project laboratories.*

Concrete
Air content
Slump
Compressive strength
Flexural strength
Sieve analyses of aggregate
Aggregate material finer than No. 200 sieve
Flat and elongated particles
Specific gravity of aggregates
Absorption by aggregates
Free moisture content of aggregates
Concrete mixer performance (except cement content)
Masonry
Relative humidity of concrete masonry units
Soils
Water content
Classification
Compaction
Field density
Unconfined compression
California bearing ratio
Plate bearing
Bituminous materials
Stability and flow values
Sieve analysis of aggregates
Water content of aggregate from hot bins
Extraction tests
Density of specimens and finished pavements
Bituminous materials
Percentage of fractured faces of aggregates

Laboratory Evaluation Requirements

The U.S. Army Corps of Engineers is a charter member supporting the Cement and Concrete Reference Laboratory (CCRL), established in 1929 by ASTM and administered by the National Bureau of Standards. As a consequence of this sponsorship, all of the Corps of Engineers division laboratories are evaluated at least every two years to verify that:

1. The equipment complies with the appropriate ASTM standard.
2. The procedures and techniques being used by Corps Division Laboratory technicians are in compliance with procedures and techniques envisioned by the standard.
3. The laboratory facilities comply with the standards.

In order to assure that the techniques, equipment, and facilities are maintained in compliance with requirements, the professional staff has an individual assigned as a quality assurance inspector who randomly evaluates the

techniques, equipment, and facilities used during everyday operations. In addition, the division laboratories receive concrete reference samples twice a year from the CCRL, prepare the necessary specimens, perform the necessary tests, and send the results to CCRL, where the results are compared on a statistical basis with results obtained by hundreds of other laboratories. The Waterways Experiment Station (WES) also participates in the Cement Reference Sample and Masonry Cement Reference Sample Programs in the same manner. The preparation and testing of these reference samples are performed by different technicians each time. On critical tests, two technicians may perform the same test on the same material and at the same time, neither knowing that the results should be similar; the quality assurance inspector evaluates these results and maintains such records to verify competence of the technicians.

Although Engineer Regulation (ER) 1110-1-8100, Laboratory Investigations and Materials Testing, has required division laboratory staffs to periodically evaluate project laboratories since about 1950, it was not until 1966 when ER 1110-1-261, Control of Field Testing Procedures, was distributed that the procedures were formalized. Presently, this regulation is ER 1110-1-21, Control of Field Testing Procedures, and division laboratory directors are required to send one or more representatives to visit each project laboratory or other laboratory doing testing for a project, at least once prior to initiation of the testing and at least once every two years thereafter:

1. The personnel assigned to a project laboratory have to be verified to be fully qualified to perform all tests required by ER 1110-1-8100.
2. The Division Laboratory Director will establish a statistically significant schedule of certification of all equipment required to perform standard tests.
3. All field testing procedures shall fully conform to those in the standard referred to in the project specifications.
4. Records of all technical training of technicians shall be maintained for each project.

Typical Laboratory Inspections

Although the staff of each division laboratory establishes its own independent procedures for carrying out the requirements of the engineering regulation, the procedures vary only slightly. In the Lower Mississippi Valley Division, which obtains its division laboratory services from the WES, three teams of inspectors visit each laboratory performing either engineering services, quality control, or quality assurance for a project. These three teams include highly trained technicians who maintain a high level of expertise in concrete technology, soil mechanics, and water and wastewater quality. In order to prevent duplication in evaluating the same equipment, each team

provides the other two teams with their reports; for example, if the soil mechanics team verified all balances, the other two teams would ignore the balances on that particular project unless the requirements for balances were more stringent.

Quality control procedures for individual water analyses are located in the chemical section of the division laboratory, referencing one of the following standard testing procedures: *Standard Methods for the Examination of Water and Wastewater*, (published jointly by the American Public Health Association, the American Waterworks Association, and the Water Pollution Control Federation), the U.S. Environmental Protection Agency's *Methods for Chemical Analysis of Water and Waste* (EPA 600-4-79-020), or any of the many standards under the jurisdiction of ASTM Committee D-19 on water.

Very seldom is more than one day required to evaluate the capabilities of one project laboratory. Following the project laboratory inspection, a complete narrative report is furnished to the division, district, and project Engineer. After about one month, a report is furnished to the division laboratory relating how each of the discrepancies was corrected. Typical discrepancies include:

1. Too large an aggregate sample either being used in a test or contained on any one sieve.
2. Concrete compression machine exceeding the required 1% accuracy.
3. Slump cones being too thin.
4. Testing standards not available for review by project staff.
5. Sieve openings too large.
6. Curing temperature out of acceptable range.
7. Weight of compaction rammer being out of acceptable range.
8. Procedures for determining saturated surface dry condition incorrect.
9. Leaking concrete molds.
10. Not waiting at least 24 h for proctor materials to obtain uniform moisture.

When the program first started in 1966, pages and pages were written on discrepancies, but due to the efforts of all concerned, very seldom do we now find more than two or three items to be concerned with at any one project. In the beginning project engineers disliked division laboratory personnel coming to their project, but now they request the evaluations and pride themselves in having excellent capabilities.

The Corps of Engineers quality assurance program in the division laboratories is inspected by CCRL. The division laboratories inspect the project laboratories and contractor laboratories. Since 1966, the Corps of Engineers has had a quality assurance program for inspecting laboratories. Therefore, at the present the Corps of Engineers has not established a policy on the use of the U.S. Department of Commerce National Voluntary Laboratory Accredi-

tation Program (NVLAP). However, the NVLAP program, when used by a commercial laboratory, will complement and assist the Corps of Engineers quality assurance program. The present NVLAP program is for fresh concrete, whereas the Corps of Engineers has a quality assurance program for concrete, soils, rock, water, and miscellaneous materials. Therefore, the Corps of Engineers may not for their own laboratories be involved in the NVLAP program for fresh concrete.

Conclusions

The Corps of Engineers is very interested in accreditation programs for nongovernment laboratories; such a program would assist corps division laboratories in evaluating private and possibly contractor quality control laboratories. The corps laboratories will not presently request accreditation for its division and research laboratories under NVLAP because we feel that our system may presently be more strict than the NAVLAP system, and because we only evaluate a laboratory for its capability for performing tests that we desire to be performed.

Diana Kirkpatrick[1] *and Jeffrey Horlick*[1]

Proficiency Testing: An Essential Element of Laboratory Performance Evaluation and Accreditation

REFERENCE: Kirkpatrick, D. and Horlick, J., "**Proficiency Testing: An Essential Element of Laboratory Performance Evaluation and Accreditation,**" *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814*, Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 128–140.

ABSTRACT: The National Voluntary Laboratory Accreditation Program (NVLAP) is administered by the Department of Commerce to accredit testing laboratories upon request. Accreditation is currently available for laboratories that test carpet, thermal insulation materials, and freshly mixed field concrete. Decisions to accredit laboratories are based on evaluations conducted by the National Bureau of Standards which include questionnaires, on-site examination, and proficiency testing.

It was recognized early that while questionnaires and site visits could provide valuable insight into a laboratory's ability, a true measure of its capability could only be determined through proficiency testing.

This paper discusses the design and operation of the proficiency testing portion of the evaluation of laboratories that test thermal insulation materials and carpets.

KEY WORDS: accreditation, laboratory performance, laboratory evaluation, thermal insulation, proficiency testing

In 1976 the U.S. Department of Commerce initiated a program to accredit testing laboratories upon their request. The program is entitled the National Voluntary Laboratory Accreditation Program (NVLAP). The task of evaluating laboratories applying for NVLAP accreditation rests with the National Bureau of Standards (NBS). To this end, the NBS Office of Testing Laboratory Evaluation Technology uses a three-part evaluation approach that includes questionnaires, on-site examination, and proficiency testing. Although a laboratory's facilities, equipment, and personnel may be assessed through questionnaires and on-site examination, the actual ability of a laboratory to produce reliable testing results can only be verified by examining

Updated with additional data on carpet test methods from "Proficiency Testing: An Essential Element of Laboratory Accreditation," D. Kirkpatrick and J. Horlick, *ASTM Standardization News*, Vol. 8, No. 12, Dec. 1980, pp. 14–17, 48.

[1] National Bureau of Standards, Washington, D.C. 20234.

its performance through proficiency testing. Thus for certain designated test methods, proficiency testing is a required part of the NVLAP accreditation process. This paper will be limited to a discussion of the proficiency testing portions of two operational Laboratory Accreditation Programs (LAPs): thermal insulation materials and carpet.

Laboratory Accreditation Program for Thermal Insulation Materials

The insulation LAP was the first NVLAP program to become operational. In order to create a viable program, the nature of the proficiency testing portion of the insulation LAP was examined in depth in the developmental stages of the LAP at meetings of NVLAP staff and representatives of industry, ASTM committees, and the testing community. The purpose of the meetings was to establish the important components of a proficiency testing program. Among the components considered were:

1. The testing areas (such as thermal measurements, fire tests, etc.) that were in need of proficiency testing.
2. The types of test equipment for which proficiency testing was needed.
3. The types of materials most desirable as specimens for each test area and test method, including their immunity from problems associated with handling, shipping and storage.
4. The parameters for each test that best characterize the laboratory's performance.

These issues were examined in depth by the National Laboratory Accreditation Criteria Committee for Thermal Insulation Materials. This advisory committee was established by the Department of Commerce to assist in the development of criteria for assessing laboratories in the insulation LAP. Public comment also provided input when the proposed LAP was published in the *Federal Register* in March of 1977 [*1*].

Several conclusions were drawn from the information generated from these sources. These conclusions, which formed the basis for the proficiency testing portion of the LAP, included the following:

1. A variety of types of materials should be used in successive proficiency testing rounds for each test area. This variety of specimen material would allow participating laboratories to become familiar with the characteristics of many materials, including some outside their normal scope of operation.
2. For thermal resistance measurements, low-density materials should be provided in a range of densities. These low-density materials would reveal measurement problems related to radiative thermal components and specimen compressibility. Also, problems associated with packing density and specimen preparation techniques would be revealed through the use of loose-fill materials.

3. A statistical package would have to be developed for data analysis for each test method.
4. A collection of precharacterized, reusable proficiency materials would be acquired for use as test specimens over several years.

The insulation LAP began its third year of operation in 1981 and is providing a variety of materials to participating laboratories for proficiency testing in the areas of thermal conductivity measurements and flammability properties measurement. The proficiency testing materials are produced according to NVLAP specifications. Generally, a special run is requested and the entire lot of material is tested for uniformity during its manufacture. Check tests may be conducted to assure the material's conformance to NVLAP specifications. These tests are conducted when possible by NBS personnel or when necessary by a qualified outside laboratory. Once the material's conformance to NVLAP specifications and its uniformity have been assured, it is ready to be packaged and shipped to NVLAP proficiency testing participant laboratories. So far, the preparation, packaging, and shipping of thermal insulation proficiency samples have been handled under contract. Precharacterized low-density fiber glass batts, a variety of loose-fill cellulosic materials, and rigid foam board have been used as proficiency samples for thermal properties tests. These materials were selected to determine a laboratory's ability to make thermal resistance measurements, to examine their sample preparation techniques, and to reveal problems in dealing with very compressible materials. Similarly, several cellulosic loose-fill materials were selected for flammability and smoldering combustion tests. Flammability testing results also reflect the participant's sample preparation techniques as part ot the testing procedures.

The frequency of proficiency testing is annual or semiannual, depending on the particular test method. Currently, specimens for most proficiency tests are provided twice a year. Certain exceptions may occur since a minimum number of participants is required to allow for meaningful data analysis in those instances when the material has not been precharacterized. When there is an insufficient number of laboratories enrolling for a particular test method, the proficiency testing requirement may be waived for that testing round. This requirement will be discussed in the section on data analysis.

Insulation LAP Proficiency Tests

Test results for the thermal insulation proficiency tests will be presented and discussed in two parts: (1) an analysis of the thermal properties measurements utilizing the ASTM Test for Steady-State Thermal Transmission Properties by Means of the Guarded Hot Plate (C 177) and the ASTM Test for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter (C 518), and (2) an analysis of data from laboratories that partic-

ipated in 25-foot tunnel tests according to the ASTM Test for Surface Burning Characteristics of Building Materials (E 84) and the flooring radiant panel and smoldering combustion tests according to HH-I-515D, Federal Specification for Cellulosic or Wood Fiber Loose-fill Thermal Insulation.

Each proficiency testing participant received an information package containing detailed instructions for specimen preparation, conditioning, and mounting. Data sheets for each test with step-by-step directions for conducting the test were included. Cutting instructions were furnished where test specimens had to be prepared from a larger sample of material.

Although tests are generally conducted in accordance with the applicable test method, NVLAP routinely specifies temperature and relative humidity conditions, test density, thickness, and other parameters dictated by the material in question. These parameters are specified to ensure uniformity in procedures and test conditions among the participants. NVLAP has endeavored to design the proficiency testing so as to minimize possible sources of confusion and error for the participants. In addition to actual test data, participants are asked to furnish copies of any charts or graphs generated as a part of the test. They are also asked to comment on any unusual events observed during the test. In one instance, this information allowed a reconstruction of the test to explain an unexpected anomaly in the test results. This test reconstruction led to acceptance of test data from several laboratories that otherwise might have been rejected.

Insulation LAP data were analyzed to determine consistent performance among participating laboratories. In addition, both thermal and flammability test data were analyzed to determine compliance with the accuracy requirements specified in the *Federal Register* notice of 18 Jan. 1979 [*2*].

Thermal Resistance Measurements

During the first year (Rounds 1 and 2) of proficiency testing for the two ASTM test methods C 177 and C 518, three versions of these tests were offered, depending on the materials to be tested [*3*]. The three versions required the testing of batt and blanket, board and block, or loose-fill materials. This was done in an attempt to provide flexibility to the participant who tested only one or two types of materials. This approach is no longer in use. Currently only one type of specimen is provided per test method. The discussion of the data that follows is presented for three material categories with each of the rounds of proficiency testing described separately. Data are grouped by either C 177 or C 518 under each category and are presented in Tables 1, 2, and 3 with the following statistical parameters included:

- *N*, the number of laboratories participating in a given test method.
- **Mean,** the average of the test values from all participants. For materials that were not precharacterized, the mean is used in place of a target value.

TABLE 1—*Proficiency testing results for board and block.*

Parameter	C 177 and C 518	C 177	C 518
	ROUND 1		
Mean[a]	0.2647	0.2673	0.2639
Std. Dev.[a]	0.0078	0.0067	0.0082
N	27	7	20
%CV	2.95	2.49	3.09
	ROUND 2		
Mean[a]	0.2543	0.2550	0.2541
Std. Dev.[a]	0.0040	0.0055	0.0034
N	26	7	19
%CV	1.56	2.17	1.32

[a] Values given for thermal conductivity are in Btu · in./h · ft^2 · °F; 1 Btu · in./h · ft^2 · °F = 0.1442 W/m · K.

- **Standard Deviation** (Std. Dev.), an indication of the spread of results from the mean among the participants.
- **Percent Coefficient of Variation** (%CV), a measure of the dispersion of the data; %CV = (standard deviation/mean) ×100

Examination of the tables shows no significant variation in test values as a function of test method or apparatus used.

Board and Block Specimens

A single specimen of polystyrene beadboard was sent to each participant for use in thermal resistance measurements. Participants were asked to test the material using either ASTM C 177 or C 518 and to identify which method had been chosen. Results are shown in Table 1. Tests were conducted at a mean temperature of 24°C (75°F). In Round 1 (spring 1979), 28 laboratories reported data, but one was excluded from the analysis because of late reporting. The analysis, based on data from 27 participants, gave an average thermal conductivity of 0.0385 W/m · K (0.2673 Btu · in./h · ft^2 · °F) for C 177 with a standard deviation of 0.000965 (0.0067). For C 518 the average thermal conductivity was 0.0380 W/m · K (0.2639 Btu · in./h · ft^2 · °F) with a standard deviation of 0.00118 (0.0082). In Round 2 (fall 1979), on a different material, the average thermal conductivity by C 177 was 0.0367 W/m · K (0.2550 Btu · in./h · ft^2 · °F) with a standard deviation of 0.000793 (0.0055). Measurements by C 518 gave an average thermal conductivity of 0.0366 W/m · K (0.2541 Btu · in./h · ft^2 · °F) with a standard deviation of 0.0004899 (0.0034).

Loose-Fill Specimens

In Round 1, thermal resistance tests were conducted on a loose-fill cellulosic material with two specimens. Although this material was *not* an insula-

TABLE 2—*Proficiency testing results for loose fill.*[a]

	Mean	Standard Deviation	*N*	%CV
	ROUND 1			
C 177 and C 518	0.2767	0.0062	15	2.24
C 177	0.2797	0.0073	5	2.62
C 518	0.2753	0.0053	10	1.94
	ROUND 2			
C 177 and C 518 Material A	0.2797	0.0037	13	1.32
C 177 and C 518 Material B	0.2754	0.0023	13	0.82
C 177 Material A	0.2808	0.0022	4	0.78
C 177 Material B	0.2760	0.0024	4	0.87
C 518 Material A	0.2793	0.0042	9	1.50
C 518 Material B	0.2752	0.0023	9	0.84

[a] Values given for thermal conductivity are in Btu · in./h · ft^2 · °F; 1 Btu · in./h · ft^2 · °F = 0.1442 W/m · K.

tion product, it was similar to cellulosic insulation products in its thermal properties. Fifteen laboratories reported data, each laboratory making one determination on each of the two specimens provided. Results are shown in Table 2. For this material, the average thermal conductivity for C 177 was 0.0403 W/m · K (0.2797 Btu · in./h · ft^2 · °F) with a standard deviation of 0.001052 (0.0073). For C 518 the average thermal conductivity was 0.03967 W/m · K (0.2753 Btu · in./h · ft^2 · °F) with a standard deviation of 0.000764 (0.0053). In Round 2, two different but very similar cellulosic materials were provided to participants for thermal conductivity measurements. The C 177 average thermal conductivities were 0.04046 and 0.03977 W/m · K (0.2808 and 0.2760 Btu · in./h · ft^2 · °F), with corresponding standard deviations of 0.000317 and 0.000346 (0.0022 and 0.0024). For C 518 measurements, the average thermal conductivities were 0.0402 and 0.03966 W/m · K (0.2793 and 0.2752 Btu · in./h · ft^2 · °F), with corresponding standard deviations of 0.000605 and 0.000331 (0.0042 and 0.0023).

Batt and Blanket Specimens

Low-density fiber glass batts from a collection of precharacterized material at NBS were provided to the participants for Rounds 1, 2, and 3. Each batt in the collection had a different premeasured thermal conductivity. Each participant was sent batts in two different thermal conductivity ranges. The test results are presented in Table 3, which shows these two thermal conductivity ranges identified as Materials A and B. The data shown are expressed as a percent deviation of each laboratory's value from the predetermined thermal conductivity. The data are presented in this manner so as not to reveal the actual value of the specimens so that they may be used in future rounds of testing. The data presented in Table 3 are grouped according to whether the reported test values fell within ±2%, ±4%, or ±6% of the actual premeasured thermal conductivity. Performance guidelines published in the

TABLE 3—*Proficiency testing results for batts.*

Round and Material	Number of Laboratories with Test Value Within Indicated Percent of Reference Value											
	±2%			±4%			±6%			>±6%		
	C 177	C 518	Combined	C 177	C 518	Combined	C 177	C 518	Combined	C 177	C 518	Combined
Round 1												
Material A	2	15	17	0	7	7	1	2	3	3	0	3
Material B	1	16	17	2	7	9	1	0	1	2	1	3
Round 2												
Material A	2	12	14	2	8	10	2	1	3	2	1	3
Material B	5	12	17	2	7	9	0	2	2	1	1	2
Round 3												
Material A	4	8	12	4	7	15	2	3	5	0	1	1
Material B	5	16	21	2	4	6	1	2	3	2	1	3

Federal Register [2] with the criteria for the thermal insulation materials LAP specify good performance as falling within a ±4% range. A value within the range of ±6% was considered acceptable. A deviation beyond ±6% represents poor proficiency and may indicate that the laboratory is not properly following the standard procedure or has an instrument calibration problem.

Flammability Tests: Insulation LAP

Proficiency testing samples were offered for three flammability test methods in Rounds 1 and 3. These methods were the ASTM E 84 7.6-m (25-ft) tunnel and the flooring radiant panel and smoldering combustion tests of Federal Specification HH-I-515D. Under the same rationale as was described for the thermal measurements section, the 7.6-m (25-ft) tunnel test was initially offered for each of three materials (batt, board, and loose fill). However, because of the limited number of laboratories enrolled for the tunnel tests, all three versions of this test were eventually conducted on the same material, a cellulosic loose fill. This same material was also used for the flooring radiant panel and smoldering combustion tests. No flammability test methods were offered in Round 2.

The loose fill cellulosic material selected for Round 1 and provided for the three test methods was chosen to produce definite and not borderline results. This cellulosic material was not an insulation product, but was chosen for characteristics similar to thermal insulation products combined with an unfamiliar appearance. This material presented a considerable specimen preparation challenge to the laboratories. For Round 3, the proficiency sample material was an actual insulation product that had been specially formulated for NVLAP.

Table 4 gives the test results for the group of laboratories that performed the E 84 tunnel tests in Rounds 1 and 3. Table 5 gives the test results for the group of laboratories that performed the smoldering combustion tests in Rounds 1 and 3. Table 6 gives the test results for the group of laboratories that performed the flooring radiant panel tests in Rounds 1 and 3. In Round 1, the data for all 13 laboratories was off scale, with a value of less than 0.12 W/cm^2. The insulation material used in Round 3 gave on scale results.

TABLE 4—*ASTM E 84 tunnel proficiency testing results.*

Parameter	Round 1	Round 3
Mean flame spread[a]	69.3	21.5
Standard deviation	4.1	1.4
N	7	6
%CV	5.9	6.3

[a] Flame spread index—average of three replicates.

TABLE 5—*Smoldering combustion proficiency testing results.*

Parameter	Round 1	Round 3
Mean weight loss, %[a]	82.5	0.51
Standard deviation	2.0	0.27
N	12	11
%CV	2.38	53

[a] Average of two replicates.

Additional Test Methods

In Round 3, proficiency samples were provided for two additional test methods for the first time. These methods were settled density as referenced in the current version of HH-I-515D, Amendment 1, and the ASTM Test for Thermal Conductance and Transmittance of Built-Up Sections by Means of the Guarded Hot Box (C 236). For the settled density test method, a loose fill cellulosic material was used. This same cellulosic material was also used for the flammability tests; because it was for this purpose, no thermal conductivity measurements were made on the material. Because of the very limited nature of the results available from the single experience in Round 3, test results for this method will not be discussed until more data have been analyzed. For the guarded hot box method, foil-faced rigid fiber glass specimens were provided. Instructions were given for the cutting and construction of a 51-mm (two-in.) thick assembly that served as the test artifact. Since participating laboratories have had difficulty in meeting the schedule for performing this test, an extension was granted for the reporting of data. Thus, no data for this method are presented in this paper.

Laboratory Accreditation Program for Carpet

Background

The carpet LAP was requested by the Department of Housing and Urban Development (HUD). The request for the carpet LAP was made under Option 7b of the NVLAP procedures. This option permits a federal agency to request a LAP and eliminates the necessity for a separate finding-of-need by

TABLE 6—*Radiant panel proficiency testing results.*

Parameter	Round 1	Round 3
Mean[a]	0.12	0.20
Standard deviation	...	0.03
N	13	13
%CV	...	14

[a] Critical radiant flux—average of three replicates.

the Secretary of Commerce. A notice of HUD's request for a carpet LAP was published in the *Federal Register* [*4*]. Under Option 7b, the federal agency that requests the LAP may recommend evaluation criteria. HUD's criteria recommendations were consistent with the criteria for the insulation LAP. The proposed carpet LAP was published for public comment in the *Federal Register* [*5*]. During the public comment period, a public hearing regarding the content of the carpet LAP was requested and the hearing was held on 26 Nov. 1979. As a result of this hearing, several test methods were added to the LAP and proficiency testing was expanded to include more tests of interest to industry and the testing community.

Carpet Test Methods

The carpet LAP embodies tests for colorfastness, durability, and flammability. As with the insulation LAP, samples are sent to participants on a semi-annual basis for a number of test methods available in the LAP. In Round 1 (summer 1980), each participant was provided a single sample, 1.2 by 1.8 m (4 by 6 ft), from which individual test specimens were cut in accordance with a detailed cutting diagram. The cutting diagram was part of an information package containing testing instructions and data sheets sent to each participant.

The specific tests or portions of tests for which there were proficiency testing requirements were as follows:

- A xenon arc colorfastness test of the American Association of Textile Chemists and Colorists (Colorfastness to Light: Water-Cooled Xenon-Arc Lamp, Continuous Light, AATCC 16E).
- The ASTM Test for Critical Radiant Flux of Floor Covering Systems Using a Radiant Heat Energy Source (E 648).
- Pile weight and pile thickness tests from ASTM's Testing Woven and Tufted Pile Floor Covering (D 418).
- The ASTM Test for Tuft Bind of Pile Floor Coverings (D 1335).
- A delamination test (Adhesion of Plied [Double Texture] Fabric, Federal Test Method 191-5950).

Each of these tests was conducted in accordance with the requirements of the test method, except for variations in the number of replicate measurements, which were requested to increase the sample size.

By designating the area of the carpet sample from which individual specimens for each of the tests were taken, an attempt was made to reduce the potential spread in the data due to the variability of the carpet across its width.

For each of the tests, Table 7 presents a summary of the mean, number of participants, the standard deviation, and the coefficient of variation (%CV). Since the AATCC xenon arc colorfastness test and the ASTM E 648 radiant panel test were both pass/fail tests, only the counts of laboratories reporting

TABLE 7—*Proficiency testing results for carpet.*

Characteristic	Test Method	Units	Mean	Std Dev	Number of Laboratories	Laboratories in Mean	%CV
Colorfastness to light	AATCC 16E	pass/fail analysis	...	...	18	18 pass	...
Radiant panel test	ASTM E 648	pass/fail analysis	...	...	12	12 pass	...
Pile weight—coated							
Weight of specimen	ASTM D 418	oz/yd^2 [a]	74.07	0.91	17	17	1.23
Pile weight	ASTM D 418	oz/yd^2 [a]	31.31	1.03	17	15	3.30
Pile thickness							
Thickness of specimen	ASTM D 418	in.[b]	0.363	0.009	17	17	2.53
Pile thickness	ASTM D 418	in.[b]	0.221	0.011	17	15	5.19
Tuft bind	ASTM D 1335	lbf[c]	6.23	0.78	17	17	12.48
Delamination	Fed. Test 191-5950	lbf[c]	7.79	1.05	17	17	13.46

[a] 1 oz/yd^2 = 0.034 kg/m^2.
[b] 1 in. = 25.4 mm.
[c] 1 lbf = 4.45 N.

and passing are reported for either. It should be noted that the analysis of the carpet data was based on comparisons with the mean of the data for all participants and that there were no established precharacterized or target values that could be used for comparative purposes. As the carpet LAP continues, a data base will be developed so that statistically valid accuracy and precision figures can be derived. When available, these figures will be provided to interested standards writing groups for consideration and possible inclusion in relevant standards and test methods.

Conclusion

The results of proficiency testing for the first two years of NVLAP operation have shown that by judicious selection of test specimen materials, reasonably well-behaved results can be generated to assess laboratory performance. It should be noted that due to the limited nature of the proficiency testing data obtained thus far, and since proficiency testing represents only one element of the total NVLAP evaluation process, the identification of certain laboratories as outliers this time did not necessarily mean that those laboratories would not receive initial accreditation. Laboratories that produce outlying test results will be examined more closely in successive rounds of proficiency testing to determine whether their testing reflects a consistent pattern of poor performance unworthy of accreditation.

Based on the data presented in this paper, the completion of several tours of on-site laboratory inspections, and the evaluation of all questionnaires, 30 laboratories were accredited by NVLAP for the testing of thermal insulation materials. The list of 30 laboratories accredited to test thermal insulation materials was published in the *Federal Register* [*6*]. A notice of the renewal of accreditation for 30 laboratories, the accreditation of seven new thermal laboratories, and the initial accreditation of 23 carpet laboratories was also published in the *Federal Register* [*7*].

Proficiency testing programs for thermal insulation and carpet are being updated continually in an attempt to realize the goals of NVLAP and the needs of the participating laboratories. NVLAP's goals include the upgrading of professional and technical competence of testing laboratories, the granting of recognition of a laboratory's competence through accreditation, and the provision of a national voluntary system in cooperation with the private sector to examine laboratories upon request. In addition, it is the aim of NVLAP to benefit the public interest by helping to assure consistent quality test results and to avoid possible misrepresentation.

In summary, on-site visits, questionnaires, and other evaluation techniques generally provide a valid indication of whether or not a laboratory can perform acceptably. A true measure of a laboratory's capability is obtained only through a long-term analysis of its performance. The relatively small values for dispersion and spread in the NVLAP test data provide con-

firmation that a laboratory's capability is clearly evidenced by proficiency testing. Based on the experience of the first three rounds, proficiency testing will continue to be an important part of the NVLAP process.

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[4] *Federal Register*, Vol. 44, No. 118, 18 June 1979, p. 35 000.
[5] *Federal Register*, Vol. 44, No. 190, 28 Sept. 1979, pp. 56 230–56 261.
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H. James Barth[1]

Performance Evaluation in the U.S. Department of Agriculture's Food Safety Inspection Service Science Laboratories

REFERENCE: Barth, H. J., **"Performance Evaluation in the U.S. Department of Agriculture's Food Safety Inspection Service Science Laboratories,"** *Evaluation and Accreditation of Inspection and Test Activities," ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 141–144.

ABSTRACT: Laboratory performance evaluation of the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) Science chemistry sections is administered by the quality assurance coordinator, who operates interlaboratory check sample programs (known and blind), uses the accredited laboratory program and contract laboratory generated check samples as an outside data source, and conducts on-site laboratory audits. USDA-FSIS-Science laboratory chemistry sections have improved their ongoing analytical capability by the adoption of a formal Quality Control and Quality Assurance Program. Each chemistry section has appointed a Laboratory Quality Control Officer; keeps a Laboratory Standards Book, laboratory performance charts, analyst performance charts, and critical control points evaluation for each analytical procedure; maintains sample tracking control; and operates an intralaboratory check sample program with the associated feedback and corrective actions being taken and recorded.

KEY WORDS: quality assurance coordinator, laboratory quality control officer, Laboratory Standards Book, interlaboratory check samples, intralaboratory check samples, laboratory and analyst performance charts, critical control points, laboratory audits

The laboratory chemistry sections in the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) provide analytical support to the meat and poultry inspection regulatory program. This support must demonstrate that the highest possible level of analytical capability and laboratory competence is being achieved.

Laboratory Quality Control Officer

Each chemistry section has a laboratory quality control officer (LQCO) who is responsible for maintaining the overall laboratory quality control

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program. The USDA-FSIS-Science chemistry section quality control program includes the maintenance of a laboratory standards book, the operation of an intralaboratory check sample program, the maintenance of laboratory and analyst performance charts, adherence to determined analytical critical control points, and a quarterly quality control report submitted by the laboratory quality control officer. In this report, the quality control status of the laboratory is reported to the laboratory director and to the quality assurance coordinator.

Laboratory Standards Book

The laboratory standards book is considered a primary laboratory quality control tool. It is a permanently bound book with sequentially numbered pages and is expected to contain all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments that relate to the accuracy of the analytical procedures performed in the laboratory. Entries must be dated and signed by the analyst performing the operation and countersigned by the laboratory quality control officer, who is required to recheck each entry for accuracy. Immediate corrective action is taken when any item fails to meet acceptable criteria.

Interlaboratory Check Samples

The interlaboratory check sample program, which is administered by the quality assurance coordinator, is composed of three kinds of check samples: known check samples that arrive at the laboratory identified as check samples, blind check samples that arrive at the laboratory identified as usual laboratory samples, and a contract laboratory check sample. A contract laboratory check sample is a known check sample and serves as an outside source check on the laboratories. The summarized, statistically analyzed results of each type of check sample are immediately provided to each participating laboratory so that any necessary corrections may be made. Laboratories that fail to meet acceptable limits are notified in writing and must respond in writing explaining what corrections were made.

Intralaboratory Check Samples

The LQCO is responsible for maintaining known and blind intralaboratory check samples for each analyst in the laboratory. Usually, the LQCO obtains a completed sample, replaces its identification with a new one, and returns it to the work flow for a second analysis. Because the analyst cannot predict which samples will be selected for this second analysis, the first sample analysis is considered to be blind. The results of the first and second analysis are immediately made known to both the first and second analyst, who are required to plot the results on their own continuing performance chart. The LQCO and analysts interpret these charts in combination with the

results from the interlaboratory check samples in order to more accurately determine the need for corrective action.

Laboratory and Analyst Performance Charts

The LQCO is responsible for maintenance of laboratory performance charts for each analytical procedure performed in the laboratory. The use of the cusum chart (cumulative sum) provides the LQCO with rapid insight to the continued quality of the laboratory performance (see Fig. 1). Analyst performance charts are plotted by each analyst so that any necessary corrections can be made immediately (see Fig. 2).

Critical Control Points

Critical control points are those places in an analytical procedure that, if varied by more than a predetermined amount, will result in a significant change in the final answer. Critical control points are determined in an analytical ruggedness test.

The LQCO is responsible for ensuring that the analysts in the laboratory are observing the critical control points in each procedure and taking corrective action when deviations from the critical control points are observed.

Laboratory Audits

Laboratory audits are a quality assurance function. One announced and one unannounced laboratory aduit is presently being conducted yearly by

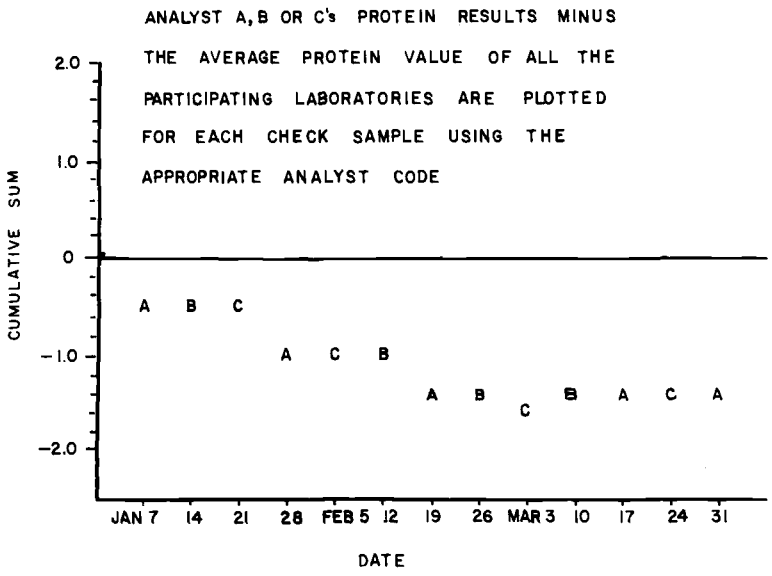

FIG. 1—*Laboratory performance chart: protein analysis.*

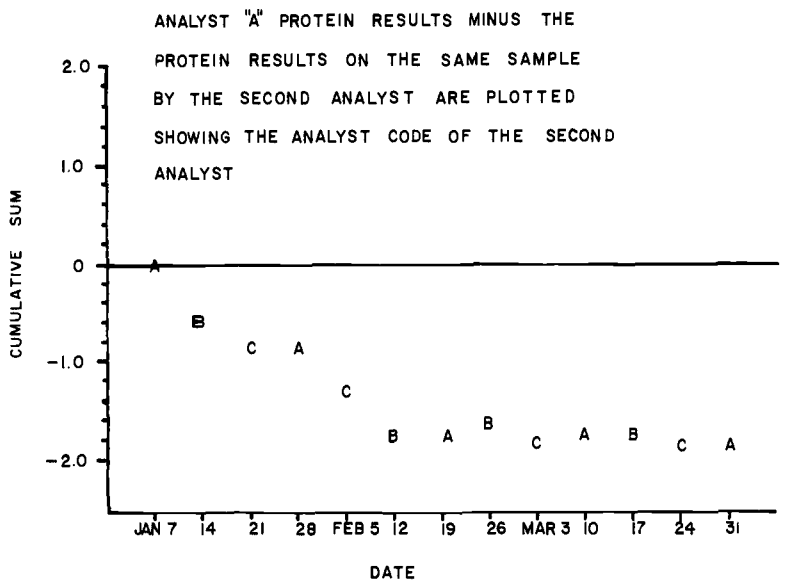

FIG. 2—*Analyst A personal performance chart: protein analysis.*

different laboratory auditors. Different auditors are employed because one may see a need for corrective action which another auditor might fail to recognize. The laboratory auditors are members of the Planning, Review, and Evaluation Branch, Chemistry Division, Science, who have many years of experience in chemistry laboratories of the same kind as they are now expected to audit. A standardized checklist is used by the laboratory auditors as a guide. The auditor interviews each analyst, asking probing questions about the particular procedure the analyst is currently performing, and requests the analysts to provide their personal performance charts and quality control records. The LQCO must also produce the laboratory performance charts and quality control records for appraisal by the laboratory auditor. Audit check samples are selected, at the time of the laboratory audit, from previously analyzed samples, and are split between two other laboratories for analysis. The results of the completed analyses are statistically analyzed and are included in an overall laboratory audit report that contains any necessary suggestions to correct observed deviations from accepted laboratory practice.

Summary

The FSIS-Science laboratory performance evaluation is an ongoing composite of several approaches. It relies heavily on a strong laboratory quality control program, interlaboratory and intralaboratory check samples, and laboratory audits and audit check samples. New ideas and procedures will be added in the future to further strengthen the program.

International Evaluation and Accreditation

David H. Stanger[1]

The Development of National Laboratory Accreditation Schemes with International Acceptance in Mind

REFERENCE: Stanger, D. H., "**The Development of National Laboratory Accreditation Schemes with International Acceptance in Mind,**" *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 147–152.

ABSTRACT: The development of the United Kingdom's National Testing Laboratory Accreditation Scheme is used as an example of the progress being made to effectively coordinate existing approval agencies so as to minimize the burden on laboratories being accredited while maximizing the benefits derived from accreditation schemes. Also discussed are the support required from governments and the role of the International Laboratory Accreditation Conference.

KEY WORDS: laboratory accreditation, International Laboratory Accreditation Conference, National Testing Laboratory Accreditation Scheme (United Kingdom)

The main thrust of this paper will be to identify the progress being made to effectively coordinate existing approval agencies so as to minimize the burden on laboratories being accredited while maximizing benefits derived from accreditation schemes, thus promoting uniformly acceptable standards of laboratory accreditation in the interests of national and international trade.

The views expressed in this paper are those of the owner of an independent testing laboratory that has provided a materials consulting and laboratory testing service throughout the world since 1874 and will include comment on the following topics:

- The support required from governments, with particular reference to the custodians of national standards.
- The development of the National Testing Laboratory Accreditation Scheme (NATLAS), the British accreditation scheme first announced by the British government on 30 June 1980.
- The role of the International Laboratory Accreditation Conference (ILAC).

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The Role of Governments

At the time of the first conference of ILAC in Denmark in 1977 there existed only three operational national accreditation systems, in Australia, Denmark, and New Zealand, with the National Voluntary Laboratory Accreditation Program (NVLAP) in formation by the U.S. Department of Commerce. It was of particular significance that during ILAC/80 eleven countries reported current developments of their individual national accreditation schemes. Written reports were received by the conference from Canada, France, Indonesia, Japan, Mexico, West Germany, New Zealand, the United Kingdom, and Czechoslovakia.

Recognizing that the legislation concerning trade between nations continues to become more complex, it is of even greater importance to prove product performance. This, in part, can be provided by the production of an authoritative laboratory report. It is therefore in the interest of nations to form schemes that will allow laboratories to apply for national recognition. With national support, laboratories will be able to play a significant part in the development of international trade.

Firstly, it is of fundamental importance that nations drafting national accreditation regulations and procedures compile their documents with international acceptance in mind. It is an opinion that incorporation of the International Organization for Standardization (ISO) Guide 25 (Guidelines for Assessing the Technical Competence of Testing Laboratories) would be the cornerstone for achieving that acceptance.

Secondly, the area of support that laboratories seek from government is for funding to launch national accreditation schemes. Laboratories will join national schemes for commercial reasons and, therefore, do recognize that they will be required to share the financial burden. However, in the initial stages of the development of a national scheme, it is essential that governments provide adequate funds to cover the initial administrative costs.

Thirdly, the point where government, and only government, can play a leading role is the establishment of national standards of measurement. Within the United Kingdom, the National Physical Laboratory is responsible for this duty and, in turn, provides substandards through various organizations. In years gone by, minimal demands have been made on those bodies holding the national standards but national accreditation schemes are now demanding, rightly, traceability back to national standards. It is therefore beholden upon governments to ensure that a commercially oriented service is provided by the custodians of national standards to support the national laboratory accreditation scheme.

NATLAS

As was stated at the beginning of this paper, the secretary of state for industry, Sir Keith Joseph, announced in the House of Commons on 30 June

1980 the government's intention to launch the National Testing Laboratory Accreditation Scheme. Prior to that date, the secretary of state had at his disposal the Advisory Council for Calibration and Measurement. The secretary of state extended the terms of reference of the Advisory Council to incorporate the development of a National Testing Laboratory Accreditation Scheme. The Advisory Council formed a Steering Committee and at the time of compiling this paper (27 January 1981) the Steering Committee had met on six occasions. In addition, specialist subcommittees have convened covering criteria to be met by laboratory assessors, the training requirements for laboratory assessors, and the criteria to be met by testing laboratories.

The work of the Steering Committee was presented to the Advisory Council during February 1981 and the scheme was launched by the British government in October 1981.

It is true to say that the Steering Committee has been very conscious of the fact that for the scheme to be successful a number of parameters must be met, which, in turn, would encourage laboratories to apply for accreditation. The scheme must be designed to limit costs for all parties concerned; be designed with international acceptance in mind (in this regard, the definitions and terms of ISO Guide 25 have been adopted). The scheme will invite existing accrediting bodies to initially provide assessors for the national scheme, with the ultimate aim that NATLAS shall take over the duties of the existing accrediting bodies. Recognizing that the scheme is voluntary, only time will establish the true commercial value of NATLAS and whether the existing agencies are prepared to hand over the duties they currently cover to a national scheme. The draft documents so far produced leave absolutely no doubt that the working arrangements within laboratories must certainly have a more formal approach than exists at present.

It is to be borne in mind when compiling criteria for an accreditation scheme that the levels of manpower and facilities vary considerably from one laboratory to another. This can best be illustrated by the staffing levels existing within testing laboratories both in the United Kingdom and the United States, where the numbers of staff range from two to 900, with 60% of the laboratories employing under 25 staff per laboratory. With these data in mind, it is essential that accrediting authorities tailor their regulations and administrative requirements to a level that, on the one hand, provides an acceptable standard for a national scheme and, on the other hand, does not burden laboratories with excessive administrative functions.

ILAC

As a result of discussions between Denmark and the United States, ILAC/77 was held in Copenhagen, resulting in the formation of three task forces. These task forces reported to ILAC/78, which was held in Washington, D.C., from which this second conference gave terms of reference to

three other task forces and called upon their chairmen to produce formal reports for evaluation by a conference to be held in Paris in 1980.

At the request of the Australian delegation and their National Association of Testing Authorities (NATA), a meeting took place in Australia in October 1979, to coincide with the retirement of Mr. H. F. Monaghan, who had been registrar of NATA for 30 years; thus ILAC/79 was held to review the work of the three task forces. ILAC/80, held in Paris in October 1980, received the full reports of the three task forces. The terms of reference of the three task forces were established during ILAC/78 and, in part amended during ILAC/79 and were as follows.

Task Force A

This task force was directed to continue its study of the legal data it had received and to examine the extent to which national testing laboratory accreditation systems could grant accreditation to foreign laboratories. It was also asked to examine the reasons for granting or withholding accreditation of foreign laboratories, and any difficulties that may have arisen in such granting or withholding of accreditations. In addition, the task force was asked to list the legal problems that may be created by international recognition of testing laboratory accreditation systems.

At the Sydney conference, Task Force A was instructed not to investigate the issues of product liability or the implementation of international agreements or technical barriers to trade. As a direct result of pressure from many delegations, the recommendation from Task Force A that a model law be designed was withdrawn during the debate on its report. It was generally agreed that the contents of that report would be of value to countries developing bilateral agreements and some delegates wished to see the report distributed to all major international bodies. The conference noted that there appears to be no "forbidding" law, but there exist many legal problems when entering into bilateral negotiations.

Task Force B

ILAC/79 asked Task Force B to continue its work in the light of the discussion at the conference, and further "to review and, where necessary, to revise criteria for entry into the Directory of National Testing Arrangements and Testing Laboratory Accreditation Systems, noting reasons for adoption of those criteria.

"To advise NATA on preparation of a second draft of the Directory, for consideration by ILAC/80.

"To include in its report to ILAC/80 on those matters, referred to:

(i) Problems encountered in collecting and presenting Directory information.

(ii) Estimates of costs and size of the Directory.
(iii) Proposals for maintenance and dissemination of the Directory.

and further, that Task Force B be asked to note that responsibility for comparison of criteria for accreditation of laboratories used by national testing laboratory accreditation systems has been allocated to Task Force C."

After a number of delegations, including those of France, Italy, the Netherlands, and West Germany had expressed views that might have deferred the production of the Directory, the conference agreed that the Directory should be published on a commercial basis in time for distribution at ILAC/81 and that entries were to be submitted by 1 Feb. 1981 to the editorial committee who, in turn, would act as the liaison to the publishers.

The debate left unresolved the commercial use of the title "ILAC."

Task Force C

ILAC/79 redefined the task force's terms of reference as follows:

(a) To undertake a comparison of criteria used by a representative selection of testing laboratory accreditation systems in assessment of testing laboratories, as a basis for a recommendation to ILAC/80 on minimum criteria for international recognition of test reports.

(b) To recommend a basis for proposals by ILAC for further development of ISO Guide 25 and the ASTM Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies (E 548).

(c) To provide the chairman of ILAC with guidance and assistance in the nomination of qualified persons to participate in the work of ISO/CERTICO (Committee for Certification of International Standards Organizations) in the development of definitions required for testing laboratory accreditation purposes (ILAC/79 Resolution 3.2.).

The task force considered its terms of reference and interpreted paragraph (a) to be an instruction to develop a framework under which laboratory accreditation organizations would be able to study and compare themselves systematically with other systems and thus develop mutual recognition with these other bodies. Such recognition would, in turn, lead to international recognition of test reports, but the task force did not consider its task to be that of developing criteria for the acceptance of test reports as such.

Apart from that amendment, which was regarded as a clarification only, the task force accepted its terms of reference.

Summary

The delegates at ILAC/80 were in general agreement with the framework for the comparison of criteria for laboratory accreditation systems and rec-

ommendations were made for their work to be further developed and extended into the areas of quality control manuals and calibration.

For those directly involved with the services provided by test laboratories, encouragement can be drawn from the fact that ILAC/80 received more delegations than ever before. With the arrival of China, Czechoslovakia, and Bulgaria, the conference enjoys the attendance of delegations from all parts of the world. The active participation of an ever-increasing number of international bodies makes a valuable contribution towards the development of the objectives of ILAC.

That ILAC/80 set aside a complete session for the announcement of new national laboratory accreditation schemes or the development of existing ones is a further indication of the increasing importance being given by nations to laboratory accreditation.

It will only be those who actually attended ILAC/80 in Paris or ILAC/79 in Sydney, Australia, who can be fully aware of the fragile and, on occasions, highly charged environment within which ILAC operates. The vast majority of delegations endorse the continuation of ILAC in its present non-incorporated status; however, the total lack of rules, including voting procedures, makes progress at all times difficult and all too frequently impossible when delegations adopt a "negative" position.

The British accreditation scheme, NATLAS, is being developed within an acceptable time frame and, rightly, considerable emphasis is being placed on the standard required of assessors. On a worldwide basis, capacity within laboratories in the private sector can, as has been proved in the past, be capable of rapid expansion. Governments must be encouraged to recognize and utilize the special value of independent testing laboratories within their international trade policies.

Alan Twomey[1]

Interlaboratory Comparisons as Used in the Accreditation of Laboratories in New Zealand's Dairy Industry

REFERENCE: Twomey, A., **"Interlaboratory Comparisons as Used in the Accreditation of Laboratories in New Zealand's Dairy Industry,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 153–161.

ABSTRACT: With the increase in the diversity of dairy products and their specifications, the laboratories of New Zealand dairy companies are accredited as the government's agent to test their products to establish their quality for export. In order for governmental bodies like the Dairy Division to accredit these factories and to guarantee their results, all laboratories seeking this status are required to participate in the interlaboratory comparison program.

The interlaboratory comparison program sends up to 9 different dairy products a month to over 60 dairy company laboratories in New Zealand for the entire dairy season. The activity is coordinated at the national coordinating laboratory while the agency-certified laboratories are under the direct control of 4 regional reference laboratories, depending on their geographical position.

The agency-certified laboratories analyze the product, the results of which are sent to the coordinating laboratory via the regional reference laboratories. The regional reference laboratories scan for gross errors and scrutinize the agency-certified laboratories results using preliminary means.

The national coordinating laboratory analyzes these results for statistics (bias, variability, and consistency) and returns the results to the agency-certified laboratories and the regional reference laboratories. Control charts of their performance are also distributed to aid the quality control function of the agency-certified laboratories.

KEY WORDS: dairy industry, interlaboratory comparisons, quality control, statistical analysis

The necessity for the New Zealand dairy industry to diversify its product range and change from traditional markets in the United Kingdom to a new market area created the need for a new quality control system. Traditionally analysis and certification of all exported dairy products was performed by the New Zealand government.

The bulk of the load has now been shifted to the manufacturing companies,

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who perform the analyses while the government oversees their work and guarantees the results.

A system of accreditation was devised to cover 9 basic dairy products having 202 specifications and requiring 20 different analyses. The system is based on method standardization, laboratory inspection and licensing, analytical performance evaluation based on production, analytical comparisons of "official" samples, and an interlaboratory comparison program (ILCP).

Interlaboratory Comparison Program

The main objective of the interlaboratory comparison program is to assist the New Zealand Dairy Division agency certification scheme in its function of maintaining and monitoring the analytical accuracy and integrity of agency-certified laboratories.

The ILCP accomplishes this by providing:

1. Information on analytical performance of participating laboratories to supplement data obtained by routine product analysis comparison.
2. An independent external monitoring system whereby participating laboratories can accurately assess their own analytical performance.
3. An effective mechanism for the early detection of and response to analytical problems.
4. A constant surveillance of national analytical standards in order to maintain uniformity within the Ministry of Agriculture and Fisheries Dairy Division and within industry, and provide impetus to improve analytical standards.
5. A wealth of statistical data giving an in-depth insight into the nature of analyses, together with their variances, reproducibilities, and limitations.

During 1980 and 1981, 65 dairy factory laboratories and 7 Governmental dairy laboratories participated in the ILCP. Nine different dairy products were analyzed and over 80 000 analyses were performed.

The ILCP operates on a monthly basis during the entire dairy season, which allows a periodic check on the analytical performance of agency-certified laboratories.

Historical Aspects of the Interlaboratory Comparison Program

When the ILCP was introduced to the dairy industry in 1977, considerable opposition and uncertainty was generated. This was because of the increased workload imposed on the factories by the program and also because somebody was monitoring the analytical capability and integrity of agency-certified laboratories. These negative attitudes were due to the failure of the Dairy Division to impress on the producers the relevance of the program as a quality control check for the manufacture of a high-quality product. The value of an independent body to assess the performance of dairy product laboratories is

vital to the credibility of their results and analysis. For a national program to work successfully, the input and cooperation of the industry was essential. Therefore we had to do considerable groundwork to establish a working group, determining the range of analyses and the required accuracy, selecting analytical methods, estimating within-laboratory precision by statistical analysis, setting up quality control charts, checking between-laboratories bias, and providing feedback of information to participating laboratories.

Once the program had been running for a period, constant improvements were made to overcome the shortcomings and inefficiencies of the system. Some early faults involved:

1. Dispatch of samples, sample integrity, types of products, and range of attributes.
2. Computation of results and the selection of an appropriate statistical method.
3. Feedback of results; turnaround time is an important factor for management of agency-certified laboratories.

For systems such as the ILCP to be successful, the communication between participating laboratories and reference laboratories must be clear and direct. The system must be simple and the results of the analysis understood and used as a management tool.

The Interlaboratory Comparison System

The three elements involved in the ILCP are agency-certified laboratories (ACL), regional reference laboratories (RRL), and the national coordinating laboratory (NCL). Their relationship is shown in Fig. 1.

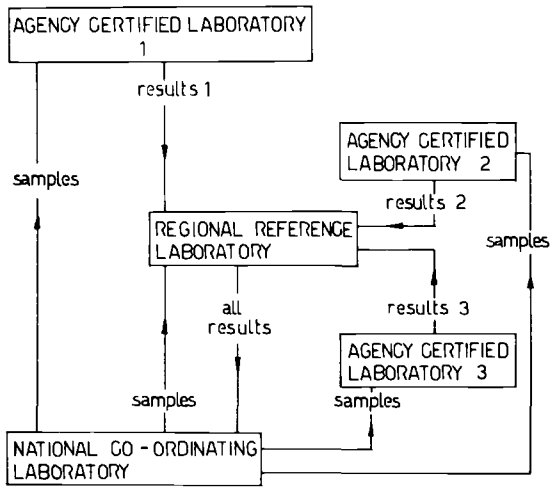

FIG. 1—*The interlaboratory comparison system.*

Staff and Their Functions in the ILCP

The national coordinating laboratory has a number of scientists and technicians to carry out the functions of the ILCP. This involves policy making, planning, and the maintenance of the program. The NCL is also responsible for the data analysis of all the results generated and communicates this information to the ACLs and RRLs.

The regional reference laboratories have a scrutiny officer to organize the ILCP and communicate with the ACLs from his region. He is also responsible for the distribution of control charts from the results of the ILCP and any follow-up actions in his region. The ACLs perform the tests in the ILCP and the laboratory managers communicate the results to the RRLs. The managers ensure that the tests are performed under routine conditions following standard methods and that the results are timely.

ILCP Operation

The ILCP operates on a monthly basis during the entire dairy season. During the first week of the month, samples are dispatched to all regional reference laboratories. The samples are tested and results obtained.

Two weeks later, the same samples are dispatched to all agency-certified laboratories, with the results due back to the regional reference laboratory within two weeks.

Meanwhile, the results from the RRLs are scrutinized for fit by the NCL and a set of preliminary means (see below) is released to the RRLs.

The RRLs use these preliminary means as a quality control check on the ACL results. When all the ACL results are handed in, they are then sent to the NCL for data analysis and computation. A computer printout of the results with national averages, regional laboratory averages, and factory performance will be distributed to all participating factories.

Maintenance of the Program

There are nine different dairy products handled in this program (Table 1), and considerable planning is required in the acquisition, pretesting, blending, packaging, and storage of the products. It is important to ensure that the composition characteristic of the products are accurate and the products are homogenous, and also that there is a reasonable range of variables in the analysis.

TABLE 1—*Products dispatched in the ILCP.*

High-Fat Products	Low-Fat Products	Protein Products
High-fat milk powder	buttermilk powder	casein
Butter	skim milk powder	caseinate
Anhydrous milk fat (AMF)		lactalbumin
		cheese

The products, with the exception of butter, cheese, and AMF are sacheted in 170-g and 90-g lots in plastic-coated aluminum foils.

Initial Quality Control Check (Preliminary Means)

The ILCP is an information generation system and the use of computers to process data helps in the reduction of turnaround time. At present we have access to computers only at the NCL; this results in a turnover time of about five to six weeks in the ILCP. In the near future, an interactive computer terminal system of data entry will be available at the RRLs; this will significantly reduce the editing and transmission times for the information flow. However, to overcome the present difficulties the RRLs use a preliminary means scheme, whereby each RRL will pretest the next month's ILCP samples in advance and thus obtain a preliminary mean. The means are then scrutinized for closeness of fit by the NCL. A preset limit (obtained from the past season's analysis of the test) is used, and the raw data are subjected to transformation to ensure a normal distribution of data. If the standard deviations of the RRLs are acceptable then the preliminary means are released. Thus when the ACLs perform the tests and send the results to the RRLs, an immediate feedback of information to the ACLs is effected by using the preliminary means system.

Typical preset limits used to obtain the preliminary means are listed in Table 2.

Data Analysis and Statistical Evaluation

Once the data of the ACL arrive at the RCL the results are processed by the data entry staff. For the chemical tests the data are analyzed separately for each product, but for the microbiological tests, the data are combined across products. Each factory's performance for each test is measured by calculating three statistics, bias, variability, and consistency.

The results for each factory are compared with the results from the four RRLs for the corresponding sample. The results are transformed where appropriate to make the distributions of the data more nearly normal (Gaussian) and the variability independent of the mean.

The difference between the factories' results (transformed if necessary) and the average of the four RRL's results is scaled by a standard deviation

TABLE 2—*Regional reference laboratory preliminary means for high-fat milk powder.*

Test	Type of Transformation Used with Raw Data	Preset Limit Standard Deviation
Fat	square root	0.04
Moisture	square root	0.043
Acidity	square root	0.015
Solubility index	square root	0.07

that has been determined from the between-RRL results over many samples and several years.

These differences for the various samples, called standardized deviations, are combined across samples to obtain measures of the average bias and the variability of each factory's results for each test relative to the RRL's results.

Bias

The measure of bias printed is actually a measure of the significance of the test of the hypothesis that the bias is zero. Hence it measures the confidence one has that there is bias rather than the size of the bias. The statistic used is $3n^{1/2} \times$ average of standardized deviations (n = number of samples), which has as its distribution three times a standardized normal distribution (when the true bias is zero). The multiplying factor of 3 was simply used so that a test significant at the 0.1% level would have a value of 10 or greater and therefore stand out.

Consistency

Because of the problem that one grossly biased value among a series of good results would have an unduly large effect on the bias measure, a non-parametric test was also used. This test simply looks to see whether or not the standardized deviations for a particular factory for a particular test are too often positive or too often negative. The statistic used is

$$3(P - N)/(P + N)^{1/2}$$

where

P = Number of positive deviations.
N = Number of negative deviations.

This has approximately a null distribution of three times a standardized normal distribution.

Variability

As well as looking to see whether a factory is obtaining a biased result on average over several samples, the scheme looks at the variability among the standardized deviations to obtain a measure of the variability of the factory's results relative to the RRL results. The obvious measure for this is the sum of the squared deviations about their mean. The sum of squares S will have a chi-squared distribution, assuming the data are normal and the standard deviation of the factory's results equals the fixed standard deviation used in calculating the standardized deviations. For ease of interpretation, this sta-

tistic is transformed into one that has roughly three times a standardized normal distribution. The transformation used is

$$3[(2S)^{1/2} - (2n - 3)^{1/2}]$$

where n is the number of samples.

Coliforms and Fungi

For all the chemical tests and the standard plate counts, one of three transformations (none, square root, log) was found to normalize the data. But for the 0, 1 coliform data and the fungi data, no such transformation was possible.

For the coliform data, a standardized deviation for each sample is calculated as

$$\frac{[(m + 1)x - S]}{[s(m + 1 - S)]^{1/2}} \qquad (S \neq 0, m + 1)$$

where

m = Number of laboratory results (=4 usually).
x = Factory result (0 or 1).
s = Sum of laboratory results and factory result—number of positives out of $m + 1$

If $S = 0$ or $m + 1$ (if all results are the same), the sample is excluded.

This can be shown to have approximately a standardized normal distribution. It can be thought of as the difference between the factory result and the average of the RRL results standardized by the standard deviation of this difference conditioned on the observed s. These standardized deviations are used as stated previously.

The inconsistency of the fungi data meant that a nonparametric approach was necessary. The result for each factory is ranked with the corresponding results from the RRLs. The difference between the rank for the factory and the average for the RRLs is again standardized by the standard deviation for this difference to produce a statistic

$$\frac{(2r - m - 2)}{[4R - (m + 2)^2]^{1/2}}$$

where

r = rank of factory result,
m = number of RRLs, and
R = average of squared ranks of all $m + 1$ results.

Again the standardized deviation has an approximate normal distribution.

Examples of typical information given in computer printouts are depicted in Tables 3 (chemistry) and 4 (microbiology).

Control Charts

The results of these samples are plotted on a control chart to give trends depicting performances of the various factories. The action limits for the tests are dependent on the tests and these are given in a manual called the *Standard Operating Procedures for Agency Certification.*

Follow-Up Action

When a participating laboratory shows a consistent bias or gross deviation in any tests or a series of tests, follow-up action is taken up by the RRL staff. Methodology, test techniques, and other factors are inspected; ILCP has been successful in many cases in detecting and offering solutions to these problems.

TABLE 3—*Typical chemistry data from ILCP.*[a]

Sample	Fat			Moisture			WPNI[b]			Acidity			Solubility		
Sample 1															
ACL result	1.4			3.8			6.5			0.125			0.1		
RRL average	1.3			3.8			6.4			0.129			0.1		
National average	1.1			3.7			6.0			0.125			0.1		
Sample 2															
ACL result	1.0			4.3			2.0			0.135			0.2		
RRL average	0.9			4.3			1.8			0.140			1.1		
National average	0.8			4.2			1.8			0.135			1.1		
Sample 3															
ACL result	1.0			4.2			3.5			0.125			0.4		
RRL average	0.9			4.1			3.4			0.129			0.4		
National average	0.8			3.9			3.3			0.124			0.3		
Sample 4															
ACL result	1.2			4.4			5.7			0.125			0.1		
RRL average	0.9			4.4			5.6			0.129			0.1		
National average	0.9			4.3			5.3			0.124			0.1		
Sample 5															
ACL result	1.2			5.0			5.0			0.130			0.1		
RRL average	0.7			5.0			4.3			0.132			0.1		
National average	0.8			4.8			4.4			0.129			0.2		
Month[c]	B	V	C	B	V	C	B	V	C	B	V	C	B	V	C
This	12	5	7	1	−5	3	9	3	7	−3	−7	−7	−12	23	−3
Overall	24	−5	20	12	−11	13	13	19	9	−1	−19	−5	−3	14	1

[a] Data given are for Region 2, Factory 2, 1979, Month 8.

[b] WPNI = whey protein nitrogen index.

[c] For this month, number of samples = 5. Overall = cumulative data for the entire dairy season; number of samples = 44. B = bias, V = variability, and C = consistency.

TABLE 4—*Typical microbiology data from ILCP.*[a]

Sample	SPC			Coliform			Fungi		
Sample 16									
ACL result	200			0			3		
RRL average	140			0000			1		
National average	93			0/30			1		
Sample 17									
ACL result	180			0			10		
RRL average	140			1000			1		
National average	138			4/30			1		
Sample 18									
ACL result	160			0			8		
RRL average	140			0000			1		
National average	106			0/30			1		
Month[b]	B	V	C	B	V	C	B	V	C
This	1	−4	5	−1	0	−3	8	−5	5
Overall	8	1	6	−4	−4	−7	−1	0	−2

[a] Data given are for Region 3, Factory 632, 1980, Month 4.
[b] For this month, number of samples = 3. Overall = cumulative average for the entire dairy season; number of samples = 16. B = bias, V = variability, and C = consistency.

Conclusion

In conclusion, the ILCP plays an important role in the accreditation of dairy laboratories in New Zealand by monitoring the performance of these factories. The performance of individual analysis is depicted as bias, variability, and consistency and accumulated for the entire season. Using information from other sources (factory inspection, official samples) the Dairy Division can piece together a complete picture of the ability of any ACL to perform agency-certified analyses.

To effect a quick feedback to all participating laboratories, a preliminary means system is used that is based on the scrutinized average result of the four regional reference laboratories. This permits the agency-certified laboratories to know their performance in about ten days. Timely management information is the key to success in any quality control system. The ILCP is an accepted quality control tool in the New Zealand dairy industry and is effective in the detection of analytical errors in participating laboratories.

John E. Roué[1]

The Standards Council of Canada's Program for Accreditation of Testing Organizations

REFERENCE: Roué, J. E., **"The Standards Council of Canada's Program for Accreditation of Testing Organizations,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 162–169.

ABSTRACT: The constitution and objectives of the Standards Council of Canada (SCC), which is a statutory corporation established by an act of the Canadian Parliament in 1970, are briefly reviewed. The relationship of the council and accredited organizations in the National Standards System (NSS) is noted. The council-approved document, Criteria and Procedures for Accreditation of Testing Organizations (CAN-P-4), is reviewed and discussed in some detail. Results obtained from a limited program of accreditation of testing organizations that was established to validate procedures and obtain cost estimates are noted and the current status of an approved national program reviewed. Reference is made to other Canadian as well as foreign national laboratory accreditation programs and the role of the International Laboratory Accreditation Conference (ILAC) is noted. The paper concludes with a brief review and summary of the Standards Council's national program, noting in particular any changes that may be dictated by experience gained in the initial implementation phase.

KEY WORDS: accreditation, Canada, laboratories, standards, Standards Council of Canada, testing

The Standards Council of Canada (SCC) is a statutory corporation created by an act of Parliament in 1970 (the Standards Council of Canada Act). However, it is important to emphasize that it is not a government agency nor are its employees public servants. In effect, the council is independent of government in its policies and operation, although it is financed by a grant from the federal government and reports to Parliament through the minister of industry, trade, and commerce.

The council consists of 57 members, 6 of whom are from federal government departments, 10 from provincial governments (one from each province), and 41 from the private sector. These latter members are nominated by a wide variety of national associations (industrial, professional, consumer, etc.) who have interests in the field of standardization.

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The prime objective of the council (as stated in the Standards Council Act) is to foster and promote voluntary standardization "as a means of advancing the national economy, benefiting the health, safety, and welfare of the public, assisting and protecting consumers, facilitating domestic and international trade, and furthering international cooperation in the field of standards."

An important consideration made clear in the Act is that the Council will "to the greatest extent practicable make use of the services and facilities of existing organizations in Canada engaged in standards formulation testing and certification."

The council was not created with the intent of duplicating the expertise and facilities of existing organizations. It does not itself prepare, write, or publish standards. These functions are performed by the Standards-Writing Organizations (SWOs), which are accredited by the council in accordance with approved criteria. Similarly, while the council does not operate certification programs or possess testing laboratories, it is empowered to accredit organizations in these areas in accordance with criteria that it develops.

Council policy decisions are implemented by an executive director and staff, who are also responsible for all administrative and operational matters.

National Standards System

A brief reference may help to clarify the relationship of the testing accreditation program to the National Standards System (NSS). The NSS is formally defined as "a federation whose components are accredited standards-writing, certification, and testing organizations, the Canadian committees concerned with international standardization, and the Standards Council of Canada. The system provides a coordinated approach to the development and advancement of voluntary standardization in the national interest."

Thus, the major components of the NSS are:

The Standards Council of Canada.

The Canadian National Committee of the International Organization for Standardization (CNC/ISO).

The Canadian National Committee of the International Electrotechnical Commission (CNC/IEC).

Accredited standards-writing organizations (SWOs).

Accredited certification organizations (COs).

Accredited testing organizations (TOs).

Background of Program

Before discussing the details of the Standards Council's accreditation program for testing organizations, and the criteria it has developed, it might be helpful to give a brief review of the background of the program with references to its scope and limitations.

The objective is to provide an accreditation program in support of product and technical testing in all fields. However, it should be noted that the National Research Council of Canada is responsible for maintaining Canada's national metrological standards, while the Department of Consumer and Corporate Affairs is responsible for regulating and inspecting measuring devices used in trade.

Several federal government departments conduct programs to determine if manufacturing and service organizations are qualified in accordance with legislated requirements or, in other cases, with specific contract specifications. The Department of Health and Welfare is an example of the first case in its administration of the Food and Drug Act. Under the act the manufacture of drugs is strictly regulated and the production and testing facilities, as well as the qualifications of employees, must meet certain requirements. The Department of National Defence (DND) is an example of the second case. Manufacturers wishing to bid on certain types of defense contracts must apply to the department to have their testing facilities inspected and, provided they meet the requirements specified by the department, are then listed in a directory of DND-recognized facilities.

The Department of Supply and Services also operates a laboratory qualification program, which is limited to laboratories capable of testing products to federal government procurement specifications.

With respect to the activities of these federal government programs for laboratory "qualification" (accreditation), it is noted that the SCC act does not give the Standards Council authority in any area expressly provided for in existing legislation.

In addition to government activities in laboratory qualification there are also some programs operated by nongovernment agencies. One example is the standard Qualification Code for Concrete Testing Laboratories (CSA A283-1974). This standard was developed by the Canadian Standards Association, which is an accredited standards-writing organization of the National Standards System.

One point to be stressed is that the council program for the accreditation of testing organizations envisages testing as a function in itself. The purpose is to develop a voluntary accreditation program that will identify those organizations that are competent in their fields of testing and also promote a general improvement of testing services in Canada. The concept is to provide a system that will permit competent organizations in all fields of testing to qualify for national accreditation. This would include calibration services, testing for product development, research, and control monitoring as well as testing in support of certification programs. It is anticipated that the program will eventually minimize duplication in the area of laboratory accreditation programs.

While it is noted that the program will be eventually financially self-

supporting, it is realized that this goal cannot be achieved in the early stages. This point is discussed later.

Accreditation Criteria and Procedures

At its 21st meeting on 5 June 1978, the council approved a policy document entitled Criteria and Procedures for Accreditation of Testing Organizations (CAN-P-4, June 1978). This document was developed by the Council's Advisory Committee on Certification and Testing (ACCT).

The ACCT consists of 24 members, including the chairman, who is normally a member of Council. Its terms of reference, *inter alia*, are to advise the council on policy matters regarding certification and testing, including the implementation phases of the accreditation programs in these areas. Its membership includes representatives of federal and provincial government departments and regulatory agencies. From the private sector representation is provided from certification, testing, and consumer organizations as well as from various industrial and trade associations.

CAN-P-4 consists of a foreword, preface, nine sections, and three annexes. The sections cover scope, applicability, definitions, eligibility, application, procedure for accreditation, maintenance of accreditation, withdrawal of accreditation, and criteria and requirements for accreditation of testing organizations. The annexes provide details of application procedures, withdrawal of accreditation, and fields of testing.

Section 9, on testing organizations, includes the following seven criteria:

Criterion 1—The organization shall have the ability to operate and maintain a testing capability to perform the tests and examinations for which it is requesting accreditation.

Criterion 2—The organization shall be managed by staff with knowledge of standards and related matters of philosophy, policy, and techniques and shall be structured administratively so as to be capable of maintaining records and providing adequate reports.

Criterion 3—The organization shall have technical expertise and professional competence in the pertinent field of testing and examination for which accreditation is sought.

Criterion 4—The organization shall be adequately equipped with facilities to carry out tests and examinations in the pertinent fields of testing. This does not preclude appropriate use of outside facilities.

Criterion 5—The organization shall have documented and acceptable procedures for:

(*a*) Maintaining records and reporting test data.
(*b*) Maintaining appropriate confidentiality.
(*c*) Maintaining appropriate standards of accuracy.

(*d*) Calibration of test equipment.
(*e*) Tracing all calibrations to the appropriate national standards.
(*f*) Consideration and settlement of complaints or appeals.
(*g*) Monitoring the test work done by its testing personnel.

Criterion 6—The organization shall be prepared to allow examination of records and procedures in the fields of testing for which accreditation has been granted or is being sought and to allow verification of the accuracy of results by the Standards Council of Canada.

Criterion 7—The organization, if dependent upon manufacturing or supplier interest, shall have an established and acceptable system of independent surveillance.

CAN-P-4 is, in essence, a generic document in that its criteria and requirements must be met by any applicant seeking accreditation regardless of the field, or fields, of testing in which it is engaged. *Field of testing* is defined as "a range of related testing activities as defined by the Standards Council of Canada." In Annex C to CAN-P-4 the fields are listed as chemical, electrical, mechanical, nondestructive, and physical testing. It is recognized that as the program develops there may be a need to increase the number of fields.

The "field" approach was selected as being the most flexible to accomodate the program concept and to minimize the administrative procedures involved in the evaluation and assessment of applications and facilities.

Implementation of the Program

In approving CAN-P-4 the council also authorized the Advisory Committee on Certification and Testing to proceed with the development of evaluation procedures and to conduct a limited program, primarily to verify the procedural aspects and to obtain realistic cost estimates. From those organizations expressing an interest in participating in this program a representative sample of four was selected and evaluation in accordance with the provisions of CAN-P-4 commenced. In June 1981, the council approved the accreditation of two testing organizations—one in the mechanical and chemical fields (textile technology) and one in the electrical field (electronic components).

Based on the response to the program and the experience gained from the limited program, the council approved a national program in October 1980. In approving this program the council directed that a conservative approach be taken consistent with existing resources. Thus, the program will be initiated with a low growth rate and will be reviewed in all its phases before the end of the fiscal year 1983–1984 in order to recommend improvements as requisite. Subsequent to the announcement of the national program a number of applications were received and several other testing organizations have expressed an intent to apply.

Accreditation of testing organizations is a two-level procedure. As mentioned before, the first level consists of compliance with CAN-P-4, which is basically a generic document. The second level is defined by supplementary documents related to that portion of the specific field (or fields) for which the applicant has requested accreditation. These supplementary documents may be established standards, specifications, or specific requirements. It will be the responsibility of the applicant organization to supply this documentation and in so doing to identify those portions of the fields of testing concerned for which it claims competence and for which it is requesting accreditation. Evaluation for both levels will be in accordance with the procedures developed by ACCT.

It is intended that a directory of accredited testing organizations will be published. This directory will list details of those fields (including classes of tests) for which each organization has been accredited. In addition, notices of accreditation will be included in the council's quarterly publication *Consensus*.

Program Administrative Procedures

For the purposes of the limited program, the Advisory Committee on Certification and Testing (ACCT) established a three-member Testing Accreditation Subcommittee (TASC), which was responsible for the review and evaluation of applications for accreditation and for making recommendations to the advisory committee. The TASC was also authorized to arrange for the services of specialist assessors as requisite. Although no problems were encountered in obtaining qualified assessors it was found that a three-member committee was too small, particularly if the question of conflict of interest arose. Approval was therefore obtained to increase the membership to a minimum of five (with a maximum of twelve). In addition to eliminating the problem mentioned above, this will allow for a wider range of professional expertise which, augmented by the assessors' specialized knowledge, will give a broader and more balanced approach to the committee's recommendations.

As part of its task the TASC also developed two preliminary documents—Guidelines for Application (CAN-P-1510) and Administrative Procedures (CAN-P-1511) for use in connection with the limited program. The reconstituted TASC has under development a document (CAN-P-1510A) that combines these two preliminary documents. Other documents under development include a revised Guidelines for Assessors and an informational publication that will describe the program in general terms.

Consideration was given to the formation of a separate accreditation subcommittee for each field (five) but it was decided that for administrative and financial reasons this approach was not justified, particularly in the initial stage of the national program. However, this, among other aspects of the program, will be reviewed at a later date.

Financial forecasts for the program have been based on the premise that the assessors will be available on an actual expense basis—that is, that it will not be necessary to pay consultant fees. So far this approach has proven satisfactory. With reference to the assessors it is noted that the individuals selected for a particular evaluation must be acceptable to the testing organization concerned.

One administrative matter under review relates to the approval procedures. At present there exists a four-level committee structure through which recommendations for accreditation must be processed:

1. Testing Accreditation Subcommittee (TASC)—five to twelve members.
2. Advisory Committee on Certification and Testing (ACCT)—24 members.
3. Executive Committee (EC)—nine members of the Standards Council.
4. Standards Council—57 members.

This, of course, is a time-consuming process, added to which is the fact that council meets only twice a year. However, as the program develops and all levels concerned have obtained more experience in the process it may be possible to reduce this rather lengthy administrative channel by a suitable delegation of authority.

The question of fees was the subject of considerable discussion. The current agreed schedule is that application and annual maintenance fees of $500 each will be charged. These fees will be levied on an application basis, regardless of the number of fields covered in any one application. While the object is to have the program operate on a self-supporting basis, it is considered that this ideal will not be reached for some time to come. Once again, this is a matter that is being kept under review.

Future of Program

The council's national program for accreditation of testing organizations is still in its embryonic stage. While the experience gained from the limited program has been of considerable value, it is recognized that there is much to be learned and a flexible rather than a rigid approach is indicated. The basic document, CAN-P-4, may require amendment in the light of further experience. The growing trend towards the harmonization of accreditation criteria in order to facilitate the recognition of test data on an international basis may also generate changes.

It is anticipated that the program will assist in identifying those organizations that have demonstrated competence to perform tests in support of such activities as research, product development, contract monitoring, and certification programs. Objectivity, impartiality, and accuracy are the major elements to be considered in establishing the credibility of an organization that provides such testing services. The establishment of a list of organizations

that have demonstrated their ability to comply on a continuing basis with common agreed criteria and procedures that encompass those elements will, it is believed, considerably enhance their status and recognition both nationally and internationally, as well as being of considerable value to potential users of their services.

The program for accreditation of testing organizations is a part of the National Standards System which is, by definition, a voluntary federation of organizations. The success of this program will depend to a large extent on the response this program receives from both the participating testing organizations and the users of their services. While it is still too early to determine this response or to assess the impact on national testing activities, surveys have indicated that there is a large potential interest.

Other Programs

In conclusion, the work of others involved in the field of laboratory accreditation should be acknowledged. The pioneer work done by the National Association of Testing Authorities of Australia (NATA) and their counterparts in the Testing Laboratory Registration Council of New Zealand (TELARC) is noted specifically in this respect. In the U.S. close association has been maintained with the U.S. Department of Commerce (DOC) and the National Bureau of Standards (NBS) and the National Voluntary Laboratory Accreditation Program (NVLAP). The work of the American Association for Laboratory Accreditation (AALA) has been also noted, as well as that of the National Conference of Standards Laboratories (NCSL) in the field of metrology.

In the United Kingdom the programs operated by both the British Standards Institution (BSI) and the British Calibration Service (BCS) have provided much useful background information. Liaison has also been maintained with the Executive of the National Testing Laboratory Accreditation Scheme (NATLAS), sponsored by the U.K. Department of Industry.

Other national programs have been monitored through the International Laboratory Accreditation Conference (ILAC) in whose work SCC has participated since the first conference (ILAC 77) in Copenhagen. Membership has also been provided on one of the ILAC task forces. The requirements for international acceptance of test data resulting from the General Agreement on Trade and Tariffs (GATT) Agreement on Technical Barriers to Trade have been also recognized.

John H. Garside[1] *and John A. Gilmour*[2]

Developments in Australia and New Zealand Laboratory Evaluation Criteria

REFERENCE: Garside, J. H. and Gilmour, J. A., **"Developments in Australia and New Zealand Laboratory Evaluation Criteria,"** *Evaluation and Accreditation of Inspection and Test Activities, ASTM STP 814,* Harvey Schock, Ed., American Society for Testing and Materials, 1983, pp. 170–179.

ABSTRACT: Laboratory accreditation on a national scale was first developed in Australia in 1947 and subsequently adopted in neighboring New Zealand in 1972. Broad statements of basic criteria for accreditation have remained constant ever since, but the interpretation and implementation of those criteria are evolving processes. Criteria are developed by consensus procedures to meet the needs of new fields of testing, new test methods, new measuring equipment, and new technology in both the laboratory and in industry. The basic approach to laboratory assessment by a process of peer review does not change, but as criteria develop the exact nature of the assessment procedure varies to accommodate that development.

KEY WORDS: laboratory accreditation, National Association of Testing Authorities, Testing Laboratory Registration Council, accreditation criteria

It has been said that laboratory accreditation is an idea whose time has come.

The idea itself, however, is anything but new. Types of approved test houses have existed throughout the world for many years, serving special industries, groups of people, or interests. Examples of such specialized schemes include approval and quality assurance programs operated by automotive manufacturers and military purchasing authorities. The term *accreditation* as now used, however, implies a more precisely defined evaluation process than was used in most of these laboratory approval or registration systems.

The idea of establishment of a national laboratory approval system for Australia was first proposed in the early 1920s, at the time of formulation of the nation's first science policy. The original concept envisaged a network of government-operated laboratories that would provide for any necessary of-

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ficial testing. For various reasons, no action was taken until the early 1940s, when, as an emergency measure, the Approved Wartime Test House Scheme was introduced. This scheme permitted routine testing of war materials in laboratories other than the official defense establishments and other government laboratories that had become severely overloaded as wartime production soared. This scheme was truly a laboratory accreditation system.

After the war, the Munitions Supply Department stated that the Approved Wartime Test House Scheme had enabled it to exercise adequate control of the quality of materials bought in or manufactured by its own plants. The success of the scheme demonstrated the possibilities of a broadly based laboratory accreditation system incorporating industrial and commercial laboratories. So, in 1947, the National Association of Testing Authorities (NATA) was formed and embarked upon an experiment in laboratory accreditation that had a number of novel features.

Firstly, this Australian system was designed to provide a national testing service that would serve the needs of government, industry, and commerce, and would have no scientific, technological, or industrial boundaries. If the community had a need for a certain type of laboratory service, then the system could provide the necessary accreditation.

Secondly, there would be no geographic limitations within Australia. The system had to operate uniformly throughout a country approximately the size of the United States and comprising six states and two territories.

Thirdly, the system was to be based on a unique method of assessment of the competence of laboratories by a comprehensive examination of laboratory operations by independent experts. The assessment was to take the form of a true peer group review with an emphasis on evaluation of management. The word *accreditation*, currently enjoying considerable popularity in the context of this and similar conferences, was not used in 1947, but the concept on which NATA was based contained all those elements regarded as so essential today.

That the time has come for the idea is obvious by the international interest shown in the International Laboratory Accreditation Conferences (ILAC) of 1977, 1978, 1979, and 1980. What was a bold experiment in 1947 is now widely accepted as an obvious solution to a general problem.

In terms of development of secondary industry, New Zealand has tended to lag behind Australia by about 15 to 20 years. It wasn't until the early 1960s, therefore, that New Zealand seriously began to broaden its industrial activity to complement its efficient and, at that time, extremely profitable agricultural industries.

Government scientific and technological advisers realized that in any modern industrial environment, quality control by manufacturers must be an integral part of all production units and that the marketplace was showing more and more interest in the quality of goods. These same advisers were

quick to perceive that NATA had had a tremendous impact on the development of measurement science and quality control practice in Australia.

By the early 1970s there was widespread agreement that a NATA-style organization would be valuable to New Zealand. So, in late 1972, the government established its Testing Laboratory Registration Council, TELARC. It was anticipated that TELARC would bring to New Zealand the same benefits and advantages brought to Australia by NATA.

The two organizations do have some subtle differences, but in all essential matters they are identical and the following sections of this paper apply equally to both countries unless specific mention is made to the contrary.

Basic Criteria

In 1947 the NATA Council defined the basic criteria against which laboratories would be assessed. These are directed to judging technical competence only. NATA firmly believes that competence is independent of ownership and government and institutional laboratories are not regarded necessarily as having special competence not available in commercial enterprises. These basic criteria are formally defined as:

- The person in direct charge of the laboratory and all officers having technical supervisory responsibilities in the conduct of the laboratory must be properly qualified for, and have had adequate experience in, the testing work concerned.
- The other members of the laboratory staff must be suitably qualified for the work on which they are engaged, and the proportion of partially trained members may not be more than that which is appropriate for such a laboratory.
- The laboratory practice, including the supervision of staff, the checking of calculations and results, and the keeping of records must be satisfactory.
- The laboratory equipment and facilities must be adequate for the performance of the testing work concerned and appropriately housed and maintained.
- The measuring and testing equipment maintained by the laboratory together with any appropriate auxiliary equipment must, at a sufficiently recent date, have been calibrated in terms of the relevant national standards and found satisfactory.

As fundamental statements of the elements essential for technical competence these basic criteria are appropriate. They are applied to all laboratories operating in all fields of testing, but require detailed interpretation and definition that is very dependent on the technical sophistication of the testing work involved before they can be implemented in practice.

Fields of Testing

Testing is divided into nine fields, namely:

- *Acoustic and vibration measurement*—measurement of noise and vibration; tests on acoustic and vibration characteristics of materials, assemblies, and structures; acoustic performance tests.
- *Biological testing*—biological, microbiological, and biochemical testing and measurement, including examination of foods, drugs, and pharmaceuticals and tests for medical and veterinary purposes; tests on biocides; tests on industrial cultures; examination of plants and animals for freedom from disease.
- *Chemical testing*—all methods of chemical analysis and detection, chemical tests on all materials, associated physical tests (such as determination of viscosity), testing and calibration of chemical and associated physical testing equipment.
- *Electrical testing*—measurement of electrical quantities, including frequency and time interval; calibration and testing of electrical and electronic components, instruments, and equipment, including industrial equipment and domestic appliances; tests on telecommunication equipment; high-voltage and high-current tests.
- *Mechanical testing*—measurement of strength of material and assemblies; aerodynamic, hydraulic, and pneumatic tests; calibration and testing of mechanical equipment (including pressure gages, flow meters, accelerometers, and the like); metallographic tests.
- *Metrology*—precise measurement of mass, length, and time and their immediate derivatives; calibration and testing of metrological equipment; examination of limit gages; testing of machine tools; assessment of geometric form; examination of gears and components.
- *Nondestructive testing*—examination of articles and structures by techniques such as radiography, ultrasonics, penetrants, magnetic particles, and eddy currents.
- *Optics and photometry*—optical and photometric tests, measurement of color, calibration and testing of optical and photometric equipment, tests on luminaires, spectrophotometry.
- *Thermal testing*—heat, temperature, and thermal conductivity tests; fire tests; tests on heat-actuated devices; calibration and testing of heat-measuring equipment; heat transfer measurement; thermal and solar radiation measurements.

Due to the limited numbers of laboratories in New Zealand, particularly in some fields of testing, TELARC consolidated these nine fields into six by combining acoustics and vibration measurement, optics and photometry,

and thermal testing into a single field called physical testing and by incorporating nondestructive testing into the field of mechanical testing. More recently TELARC has established a separate field for medical testing, which is an area not covered specifically by NATA. In all other respects the definitions of the fields of testing are identical for both organizations.

Criteria Committees

For each broad field of testing a committee of independent technical advisers is appointed. These committees are known as Registration Advisory Committees (RACs) and their essential functions are to:

- Advise the council on precise criteria for accreditation within the specific field of testing.
- Recommend changes to criteria from time to time in the light of scientific and technological developments.
- Recommend suitable individuals for appointment as assessors.
- Review assessors' reports and make recommendations to council on accreditation of laboratories.
- Generally supervise, on behalf of the council, the day-to-day assessment work in the specific field of testing.

Members of committees are appointed by the council and chosen for their own personal expertise and not as representatives of organizations. They are drawn from government establishments, academic institutions, research organizations, consultants, and industrial and commercial enterprises.

There are, therefore, nine (in NATA, seven in TELARC) criteria committees that are responsible for developing the basic criteria into precise statements that apply to particular groups of laboratories and for ensuring that these criteria statements are updated from time to time.

There are also a number of subcommittees that deal with subsections of the major fields. For example, the field of chemical testing has subcommittees working on specific criteria for laboratories engaged in testing of inorganic materials, organic materials, fuels and lubricants, surface coatings, the environment, foods, and drugs.

Laboratory Assessment

The concept of the assessment of a laboratory is that of a peer group review and is made in terms of the state of the art for the particular industry, scientific discipline, or technology. As has already been indicated, the fundamental criteria against which the review is conducted are independent of the sophistication or complexity of the work of the laboratory, but criteria development by RACs and implementation by assessors are not.

A laboratory assessment takes the form of detailed discussion between lab-

oratory staff, the assessors, and staff of NATA or TELARC, together with an inspection of the premises and laboratory equipment, including an examination of all calibration information. The assessors normally witness the laboratory staff performing routine testing tasks, including field work where appropriate.

Discussions commence with consideration of the scope of the work of the laboratory. The assessors try to reach some appreciation of the particular problems faced by the laboratory staff in their day-to-day work, so that the assessment is directed to that particular laboratory and this is reflected in terms in which accreditation is finally granted. The terms of accreditation are tailor-made for each laboratory.

Staffing is a recurring topic and during the later tour of inspection the assessors talk to the individuals. At the outset, however, the concentration is on:

- Qualifications and relevant experience of the supervisory staff.
- Lines of responsibility in technical areas.
- Training programs within the laboratory.

The assessors inspect the test equipment used in the laboratory. Special attention is paid to the following areas:

- Standards of measurement—mass, volume, temperature, force, length, electrical quantities, etc.
- Specific items of equipment required by particular test methods.
- Instrumentation and sophisticated measuring equipment.
- General purpose equipment—glassware, thermometers, ovens, water baths, balances, etc.

In addition, the assessors also investigate the training of staff in the use of their equipment and provisions made for the routine maintenance and recalibration of equipment.

The laboratory accommodation is assessed to ensure that it has sufficient space and physical facilities to cope with the range and volume of work normally undertaken. The assessors consider noise levels, lighting, storage space, convenience of layout, sample receiving areas, ventilation and safety, etc.

The assessors spend much of their time in an examination of the laboratory's management procedures. They are given free rein to probe those areas where they believe there may be problems. The following areas are selected for specific investigation:

- Collection of samples—transport, handling, and storage.
- Receipt of samples and their identification.

- Nonacceptance criteria for samples.
- Specification of tests to be carried out.
- Allocation of work to staff—instructions to staff and supervision of staff.
- Quality control programs.
- Recording of test results.
- Checking of calculations.
- Reporting of test results—precision and accuracy data.
- Security of the system—retention of test records.

All these are fruitful areas for discussion, but one of the most informative is the records system and hence assessors usually explore this aspect of laboratory management very thoroughly.

At each phase of the inspection, the assessors discuss the practice adopted by the laboratory and talk to individual staff members in an attempt to assess attitudes that may reflect on the work of the establishment. The assessors also investigate the test methodology adopted by the laboratory. Laboratories are expected to work to well-defined procedures, either in the form of standard methods of test or methods manuals that have been prepared by the laboratory staff.

Laboratories producing their own manual would be expected to follow normal good practice by including in their methods manual:

- Adequate identification of method and date of issue.
- Source of reference.
- Equipment to be used.
- Step-by-step description of method.
- Calibration and controls.
- Treatment of results.

A laboratory may be asked to arrange check tests on samples provided, or to participate in interlaboratory test programs.

This basic assessment process has been used since the very beginning, but naturally as new criteria are used the assessment itself must be modified or extended. The constant element is the peer review for compliance with the specified criteria, whatever they may be.

Assessors

The technical aspects of assessment of laboratories are performed by members of panels of assessors recruited from similar backgrounds to RAC members. The essential requirements are that assessors be individuals with recognized knowledge and reputation in a particular area of testing or technology. They must be people with status within the scientific and technological communities.

In addition to their technical attributes, assessors are also required to be people of integrity, with an ability to communicate with the people that they are likely to be called upon to assess. Before being invited to join the panel of assessors each assessor is either interviewed by a senior member of staff or a member of the appropriate Registration Advisory Committee, or is appointed on the personal recommendation of a member of the committee.

For a specific assessment, assessors are chosen whenever possible on the basis of commercial impartiality and objectivity. The laboratory under assessment is free to veto the use of any nominated assessor. If the laboratory does not believe that it is likely to receive an objective assessment from someone within its own country then TELARC and NATA are quite prepared to bring the necessary assessors from overseas, and consequently there is considerable interchange of assessors between the two organizations.

Following the assessment, the assessors either jointly or individually prepare detailed reports on their visit to the laboratory. They are asked to critically appraise all elements of the laboratory management and technical operations and their reports reflect this appraisal.

Reassessment

Laboratories are assessed at intervals not exceeding two years. The actual period between successive reassessments may be very much less than this two-year interval, depending on the original assessment report, the stability of the laboratory staff, or requests for some variation of accreditation by the laboratory.

In between formal assessments, the staff of each organization maintain a high level of personal contact with laboratories within each system.

Criteria Development

The criteria defined and used by the committees are not static. Committee members and assessors are mostly laboratory managers who are concerned with developments in techniques and equipment for the better management of their own establishments. As they learn, so do the accreditation systems, and therein lies one of the great strengths of the systems: Australasian criteria development goes hand in hand with development of the appropriate state of the art in a particular area of testing.

The constant assessment activity and the review of assessors' reports is another mechanism for updating criteria, as it provides information on any inadequacies in the current criteria.

The systems therefore consist of interactive groups of people, all having input into the criteria development process—laboratory personnel, assessors, technical group members, registration advisory committees, and finally members of council who promulgate the criteria. There is a general review of all criteria every four years.

Proficiency Testing

Proficiency testing is an integral and expanding part of the NATA and TELARC accreditation programs. In both organizations special criteria committees have been established to advise the other committees on the planning, execution, and analysis of proficiency testing exercises and to monitor the effectiveness of exercises that originate outside the control of NATA and TELARC.

Participation in appropriate interlaboratory tests on a continuing basis can be mandatory and the performance of any particular laboratory is taken into consideration by the relevant RAC in determining compliance with the criteria for registration. Both NATA and TELARC view proficiency testing as making an important contribution in their overall assessment procedures.

New Developments

As has been mentioned, TELARC has now defined a separate field in which to deal with the accreditation of hospital, private, and public medical testing laboratories. Some of these laboratories are among the largest and most complex testing laboratories in New Zealand. Others, while modest in size, may specialize in particular areas that involve complex methodology.

The field of medical testing has been divided into various subfields that identify specialist disciplines that require individual assessment by appropriately experienced assessors, such as microbiology, hematology, clinical biochemistry, etc.

To meet the need created by the establishment of this field, new criteria have to be developed. The New Zealand committee, while remaining within the basic guidelines applying to all fields, has taken advantage of material published by other medical laboratory accreditation programs such as that operated by the College of American Pathologists, and has been able quickly to develop detailed criteria for this field. The program has the support of the various national medical and paramedical societies and associations as well as the New Zealand Department of Health.

In other fields the major recent developments in criteria have been related to the introduction of computers into the laboratory and of on-line instrumentation into the production process. In this latter case, the testing is taken out of the formal laboratory environment and located on the factory floor. The testing, however, must be just as valid as more conventional testing and may be accredited in the same way, criteria must be developed to recognize this new situation.

Computers have not only transformed some laboratory operations but have also changed the concept of records systems and authentication of test reports. Laboratory accreditation systems must not inhibit such developments but must develop criteria against which the security and integrity of the new systems can be judged. Along with computer technology there has

been growth in the area of automation of testing and accreditation procedures must allow for this.

New areas of conventional testing open up fairly regularly. For example, offshore oil production has led to a need for underwater ultrasonic examination of welded structures. Accreditation of the testing services performing these tests is required and NATA in particular has had to develop criteria to cope with this demand.

Conclusion

Criteria for the accreditation of testing laboratories in Australia and New Zealand are constantly being developed to meet new needs such as:

- New fields of testing.
- New tests.
- New equipment.
- New technologies.

It is clearly an evolving process and in some areas what was acceptable ten years ago is not acceptable today.

The process by which all new criteria are developed is by consensus among laboratory managers and technicians and scientific experts in all sectors of the community. There is also increasing input from new foreign accreditation systems, which are bringing a fresh approach to the work. The long-term objective of both NATA and TELARC is to develop criteria for accreditation that are in harmony with criteria developed by kindred organizations in other parts of the world. Although much new thought is being injected into the subject, however, the basic elements of people, hardware, facilities, and management are unchanged.

Summary

Summary

The papers in this book have been divided into four sections: concepts, applications, government programs, and international experiences. The emphasis is on practical aspects of evaluation and accreditation for testing and inspection agencies and laboratories.

Concepts

The concepts section leads with a paper by **Dymond** describing early development of ASTM Standard E 548, Recommended Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies. This work reflected the original concern to provide a base for the development of later specific evaluation criteria. The author describes the development by a task force of a framework, in the form of a triangle, defining the need for additional criteria on evaluation systems and evaluators, with supporting lower level details for disciplines or fields and a base for detailed methods of test, inspection, and evaluation. This framework constitutes an original approach being emulated internationally. He mentions the related work of the International Organization for Standardization (ISO) and the International Laboratory Accreditation Conference (ILAC). Of further importance is work addressing relationships between testing laboratories and inspection agencies. The author identifies the similarity in the practices of evaluators and financial auditors, especially for independence and uniformity in application of judgements and use in supporting systems.

The paper by **Berman** describes the more recent work of ASTM Committee E-36 in developing revisions of its Standard E 548-79. Assuring the competence of laboratories is the purpose of over 70 formal systems that evaluate and accredit more than 60 000 laboratories in the United States. The need for systems reciprocity is identified to reduce unnecessary time and costs. The author describes the work done in the committee to develop generic criteria for evaluators and evaluation systems. Certain specific criteria are identified in areas of building components, manufactured buildings, sampling and analysis of water and wastewater, and sampling and analysis of atmosphere and emissions. The ongoing work of the committee, in international areas is described.

Author **Locke** compares five laboratory accreditation criteria in six basic categories. A brief analysis of each criteria points up alleged strengths and

weaknesses. Comparisons and resolution of differences could result in universal criteria. The author suggests the need to resolve differences to permit harmony between systems and originators of differing requirements. Documents explored by the author are ASTM Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies (E 548), National Voluntary Laboratory Accreditation Program (NVLAP) General and Specific Criteria for Accrediting Testing Laboratories, ISO Guidelines for Assessing the Technical Competence of Testing Laboratories (Guide 25-1978), ISO/CERTICO Guide 25/2 Proposal, and the Organization for Economic Cooperation and Development's (OECD) Principles of Good Laboratory Practice for Testing Chemicals. Six basic categories include organization, human resources, material resources, operating procedures, record keeping, and other areas, including quality systems.

Applications

The applications section of the book starts with a paper by **Graham** describing coal industry testing to support the commercial requirements of a corporation, customer requirements, and regulatory requirements for environmental policies. Accuracy of determinations at lower concentrations and quality certification effects are described for economical concerns. Details are provided on the use of early coal exploratory findings, core sampling, and special analysis sampling before property options are taken or additional exploration is conducted. Developmental core sampling is described as it relates to final mining prediction of product quality for the company and customers. Actual production processes and facilities are related to consensus contracts, advertising, incentives, and, possibly, dispute settlements. Company and national exchange programs are described for commercial product handling and test methods, using survey visits and improvements in understanding of intent to reduce expenses of exchange sampling. Details are described for composite, in-plant, and split and reservesplit sampling. Interesting concepts are described for correlating findings with customer product Btu values and fly ash results. The program recognized possible opportunities in using NVLAP and further improvements in voluntary standards and their government acceptance.

Woodall describes how a coal-using public utility applies evaluation of internal and external laboratories to improving the productivity of purchasing and quality processes, and in satisfying regulatory requirements for environmental protection and billing rates. Personnel qualification variations are discussed relating to confidence of expected laboratory performance. The author suggests reaching agreement on the actual methods used by a specific laboratory through discussion and sampling rather than by relying on broad accreditation because laboratories are used for various applications and therefore have differences in management philosophy and operating approaches.

Harris and Castino present key elements of laboratory accreditation programs, which include needs for contracts, follow-up, and handling of appeals and legal matters. They describe some laboratory management activities for random unannounced inspections and countercheck testing. Possible deficiencies are noted for questionnaire responses or rule evaluations when standards of laboratory performance are established and evaluated. Critical elements are identified for laboratory accreditation programs, especially the need to identify specific criteria applicable to the test program for which the laboratory seeks accreditation. The importance of audit programs is identified along with the need for understanding of the laboratory's documented supporting quality assurance program. The authors note the importance of criteria requirements' not leveling or lowering laboratory implementation of its activities, simply because its program was more extensive than stipulated.

Author **Gaft** presents examples of an innovative self-evaluation program for a corporate central research and investigative laboratory of multiple disciplines. He describes a system's achieving, through awareness and auditing, improvement of laboratory operations and a reduction of 83% in significant discrepancies on laboratory reports. Details are provided of quality assurance techniques and measurement of laboratory output.

The **Barton** paper discusses the impact of computerized systems in water quality laboratories to automate surveillance for regulatory requirements of the U.S. Environmental Protection Agency (EPA) and the U.S. Geological Survey (USGC). Laboratory development activities include analytical methods and validation; sewage treatment processes; baseline water standards; routine surveillance; and pollution action data collection. Scientific insight is still required as the final judge of quality.

Fargo describes corporate laboratory management and quality assurance activity for internal control and for future product liability protection. An interesting approach is the development of relationships between a corporate central laboratory and specialized satellite laboratories, including thermal, sound, fire, chemical, electrical, physical, metallurgical, rheological, and air handling laboratories. Computerized control is described for laboratory management, based on ASTM E 548 and specific test method standards. Reference is noted for the Standards Section of the General Agreement on Tariffs and Trade (GATT).

Government Programs

The section of the book dealing with government programs includes various federal and state programs. **Unger** describes the evolution of NVLAP procedures in the National Bureau of Standards (NBS), noting that since 1929 the NBS has been involved in developing criteria for evaluating testing laboratories and in providing on-site examinations, proficiency test samples, and calibration standards. The author details the federal development proc-

ess of criteria committees and discusses the problems encountered. Approaches are described to develop priorities, cooperation, and acceptance.

The paper by **Federline** describes the basis for NVLAP and the relation of criteria to peer review. Flexibility for state-of-the art laboratory technology is described relating to flexibility for diverse testing of thermal insulation, carpet, and concrete. Details relate to application examination, on-site inspection, and proficiency testing. Examples of technique are provided for laboratory improvement.

The paper by **Rutherford** gives details on a proposed U.S. Nuclear Regulatory Commission (USNRC) program for safety-related equipment in nuclear generating stations. Alternatives are described for use of NRC facilities, NRC direct contracting, or NRC review and witnessing of vendor tests. Short- and long-range options consider sampling and accreditation with use of qualification standards and improvement of test standards, specifications, procedures, and acceptance standards. Audits and independent qualification tests of important equipment are considered. The needs for a laboratory accreditation system are described with considerations for such a system.

Schwager describes the certification programs of the State of Illinois Department of Health and the Illinois Environmental Protection Agency for operation of environmental laboratories for analysis of contaminants in potable water. Common language requirements are noted for laboratories, environmental engineers, and specialists in regulatory, emergency, and decision-monitoring areas. Certification is required for laboratories engaged in any type of environmental work. A memorandum of agreement is described that combines the needs of various certification programs while retaining specialization and meeting primary enforcement implementation in bacteriological, radiological, and milk laboratory programs. A state certification office is described to facilitate implementation with savings, improvement of work quality, and meeting of various levels of federal and state stringency.

Sneeringer et al describe the U.S. Army Environmental Hygiene Agency (USAEHA) program of consultation, laboratory service, investigation, and training (as requested) for preventive medicine programs throughout the world. A wide range of disciplines comes under an USAEHA Analytical Quality Assurance Program based on federal law and army regulations. The Analytical Quality Assurance Office (AQAO) adds quality assurance criteria to each regulation, including necessary audit activity, and requires that samples be taken and subsequent controls be used. Continuing inspections are conducted by federal and state agencies as well as by professional organizations. The list of references is valuable for all chemical organizations.

The **Scanlon and Lamond** paper describes the U.S. Army Corps of Engineers' continuing evaluation program for contractor quality control laboratories, commerical laboratories, and government quality assurance laboratories. Use of ASTM standards eliminates the need for exceptions and variations, utilizing existing wide understanding. Use of the Cement and

Concrete Reference Laboratory (CCRL), established by ASTM and administered by NBS, aids in verification of equipment, procedures, and techniques. Quality assurance is performed on an assigned, continuing basis for concrete technology, soil mechanics, and water and wastewater treatment. With skilled personnel evaluation usually takes no longer than one day and includes a supporting complete narrative report for follow-up action. The program has reduced exceptions to no more than two or three items per project. Pride has now been developed so that those being appraised now request appraisals and pride themselves in having excellent capabilities for specific tests.

A paper by **Kirkpatrick and Horlick** describes the NVLAP program for thermal insulating materials with use of proficiency samples. Stress is on handling and preparation of samples and quality measurements through proficiency testing. Use of a voluntary system, in cooperation with the private sector, raises and helps assure the quality of test results. Questionnaires and on-site visits supplement the proficiency testing for a true measure of actual performance. Dispersion and spread values are used to confirm laboratory capability. Details are given for tests of insulating materials and carpets relating to specific ASTM standards, actual values, and relative laboratory performance.

The **Barth** paper describes the U.S. Department of Agriculture (USDA) program of the Food Safety and Quality Service (FSQS) supporting the Meat and Poultry Inspection regulatory program. The adoption of a formal quality assurance and quality control program is continuing to improve analytical capability through samples checked by outside data sources and on-site laboratory audits. Each chemistry section has a Laboratory Quality Control Officer (LQCO), keeps a laboratory standards book with performance charts and evaluations of critical control points for each analytical procedure, maintains sample tracking control, and operates an interlaboratory program to check samples and provide feedback and corrective action records. Standardized checklists are maintained for laboratory audits as a guide. Emphasis is placed on interlaboratory and intralaboratory check samples.

International Experiences

The international experiences discussed in this book show the wide effect of accreditation on standards development and commerce throughout the world, with examples from Britain, New Zealand, Canada, and Australia. **Stanger** provides in his paper an overview of the British development of the National Testing Laboratory Accreditation Scheme (NATLAS) and its relation to the ILAC. The role of government is discussed; various levels of government are increasing their use of voluntary systems combined with regulations. A detailed review of three ILAC task forces covers assignments in

legal data, reasons for granting and withholding accreditation to foreign laboratories, difficulties that may arise in such granting or withholding, criteria for entry into a *Directory of National Testing Arrangements and Testing Laboratory Accreditation Systems,* comparison of criteria, and work with ISO.

The **Twomey** paper describes the New Zealand dairy products program. Participation in an interlaboratory comparison program is required for laboratories seeking status to participate as accredited factories and to provide guaranteed results. A national coordinating laboratory is used with four regional reference laboratories to control agency-certified laboratories. Details are provided on statistical techniques for preliminary means, bias, variability, and consistency.

Author **Roué** provides details on the Standards Council of Canada (SCC) and the National Standards System (NSS). The document on Criteria and Procedures for Accreditation of Testing Organizations (CAN-P-4) is detailed. Relationships are noted between the Department of Supply and Services Laboratory qualification program for products to the federal government procurement specifications. Details are provided on validation procedures and techniques to obtain cost estimates.

Authors **Garside and Gilmour** provide details on developments in Australia and New Zealand where laboratory accreditation was formalized nationally in 1947 by an Australian organization, the National Association of Testing Authorities (NATA). First, the intent was to provide a national testing service to serve the needs of government, industry, and commerce, with no scientific, technical, or industrial boundaries. Second, there would be no geographic limitations within Australia. Third, the system was based on assessment of competence of laboratories by comprehensive examination of laboratory operations by independent experts. New Zealand adopted a NATA-style system in 1972, called the Testing Laboratory Registration Council (TELARC). The authors detail the basic criteria with an explanation of the "fields of testing" concept for nine fields. Registration Advisory Committees (RACs) are described with specific functions in developing criteria. Assessor activities are described with details on examination of laboratory management procedures. Criteria are provided for test or methods manuals. Details are provided for cooperation and the exchange of personnel between NATA and TELARC.

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ISBN 0-8031-0253-4