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Testing Laboratory Performance: Evaluation and Accreditation

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Testing Laboratory Performance: Evaluation and Accreditation

Proceedings of a National Conference
held at the National Bureau of Standards,
Gaithersburg, Maryland, September 25-26, 1979

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PREFACE

TESTING LABORATORIES ARE BEING SUBJECTED TO EVER INCREASING NUMBERS OF EXAMINATIONS, AUDITS, AND INSPECTIONS TO ENSURE THEIR TESTING CAPABILITY. TO DATE, OVER 60 PROGRAMS, BOTH PUBLIC AND PRIVATE, HAVE BEEN IDENTIFIED WHICH EVALUATE TESTING LABORATORIES AND BESTOW ACCREDITATION IN ONE FASHION OR ANOTHER FOR TESTS CONDUCTED.

THE PAPERS IN THESE PROCEEDINGS WERE PRESENTED AT A NATIONAL CONFERENCE ON TESTING LABORATORY PERFORMANCE EVALUATION AND ACCREDITATION HELD AT THE NATIONAL BUREAU OF STANDARDS ON SEPTEMBER 25-26, 1979. THE PURPOSE OF THE CONFERENCE WAS TO PROVIDE A FORUM FOR THE DISSEMINATION OF INFORMATION AND THE DISCUSSION OF TECHNIQUES AVAILABLE FOR EVALUATING THE PERFORMANCE OF TESTING LABORATORIES, AND ALSO TO PROVIDE INFORMATION ON THE OPERATIONAL ASPECTS OF SOME EXISTING AND PROPOSED ACCREDITATION PROGRAMS AND SYSTEMS.

THE CONFERENCE WAS ORGANIZED THROUGH THE OFFICE OF TESTING LABORATORY EVALUATION TECHNOLOGY AT THE NATIONAL BUREAU OF STANDARDS BY DR. GERALD A. BERMAN WHO SERVED AS PROGRAM COORDINATOR AND GENERAL CHAIRMAN. THE PROGRAM CONSISTED OF 29 PAPERS WHICH ADDRESSED VARIOUS TECHNIQUES FOR EVALUATING THE PERFORMANCE OF TESTING LABORATORIES, QUALITY CONTROL ASPECTS OF THE TESTING FUNCTION, EXISTING AND PROPOSED ACCREDITATION PROGRAMS AND SYSTEMS, AND INTERNATIONAL COORDINATION.

EXCEPT FOR SOME EDITORIAL CHANGES, THE PAPERS IN THESE PROCEEDINGS ARE PRESENTED AS SUBMITTED BY THE AUTHORS AS CAMERA-READY COPY.

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SESSION I

OVERVIEW OF EVALUATION AND ACCREDITATION

CHAIRMAN: DR. GERALD A. BERMAN
NATIONAL BUREAU OF STANDARDS

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USER EXPERIENCES WITH LABORATORY ACCREDITATION

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Laboratory accreditation serves a two-fold purpose in the marketplace. This relatively new technical function can provide increased confidence in the capability and reliability of testing laboratories by customers of their services. The function can also serve as a marketing tool for laboratory managers. In this sense there is an analogy with product certification. Although laboratory accreditation may eventually become a leveling force, much as accreditation of hospitals and academic departments within colleges has become, the enterprising laboratory manager should not regard accreditation as a least common denominator activity at this time. Experience of testing laboratories in several disciplines where accreditation has been available or required are reviewed. Long range roles for the accrediting function are discussed.

Key words: Accreditation; certification; colleges; confidence; criteria; evaluation; hospitals; inspectors; marketing; qualification; re-examination; technicians.

1. Introduction

Accreditation of testing laboratories by Third-party organizations is a relatively new function in the marketplace for technical services. For purposes of this presentation, Laboratory accreditation shall be characterized as including technical and administrative evaluations with periodic re-examinations. Although some accreditation activities have considerable historical continuity, most of those activities stimulating interest in laboratory managers are of recent origin. The characteristics of laboratory accreditation activities mentioned here are not exhaustive, but need not be in order to review the perception of this new function among its users.

2. User perceptions of laboratory accreditation

The direct users of laboratory accreditation are the testing laboratories themselves. The beneficiaries include several levels of users of laboratory services. These will be discussed under trends.

Informal surveys and discussions with laboratory managers reveal that those who have no prior experience are wary of the cost/benefit factor. Industry executives presently seem suspicious that accreditation will have a least common denominator or leveling effect. This reaction has been noted with regard to other forms of standardization especially so among scientist/businessmen. Laboratory managers who are looking to the future see accreditation as a long range marketing tool. They know that it will be difficult to implement on a broad basis, difficult to achieve, and difficult to market of itself. In a complementary sense, these same industry leaders realize that the ability to compare competing service organizations, the presence of external monitors for laboratory quality control, and published statements about the capabilities of testing laboratories based on common factors will provide a new discipline as the economy relies increasingly on scientific testing.

3. Analogy with product certification

The modern marketplace demands both products and services. Each category is becoming more complex as it responds to marketplace needs. Consumers, be they residential, industrial, commercial, or institutional, increasingly need evidence to support their confidence in the products and services which they purchase.

The response to this need for product confidence has been product certification. This activity is conducted by independent laboratories, trade associations, model code bodies and certification councils operating under either commercial or governmental mandate. Many of these programs provide marketing tools within certain constraints. As such activities become established and well-known, there seems to be an increasing reliance on the information which they provide to consumers.

The response to the need for supporting evidence with respect to testing laboratory services is laboratory accreditation. When this activity is based on consensus criteria, evaluation by qualified inspectors, and periodic re-examination the analogy with product certification holds. The voids in completing the comparison of the two systems are accreditation of certifiers, on one hand, and qualification of inspectors on the other. With respect to product certification there tends to be some confusion between accrediting laboratories and accrediting certifiers. Evaluation of an independent laboratories technical capabilities may not include evaluation of the administrative capabilities necessary for certification. The general lack of this latter service particularly with respect to product safety certifiers has impeded the market acceptance of alternate sources of certification. Since some laboratory accreditation activities have been informal to date, only casual attention has been paid to formalizing the qualification of inspectors for particular kinds of laboratories. On the record the budding national laboratory accreditation programs appear to be making effort to document these qualifications and harmonize them.

4. Analogy with college and hospital accreditation

Institutional accreditation is not a new activity in the marketplace for services. Although the need for accreditation of testing laboratories is being established in present time, other service organizations have been subjected to such evaluation for many years. The efficacy of accreditation for colleges and hospitals is taken for granted to such an extent that many consumers of their services are almost unaware of the confidence which they obtain through accreditation. Other forces in the marketplace for health care and educational services are, however, well aware of the importance of accreditation. The many departments in a hospital, including its laboratories, must be evaluated according to criteria well-established in the medical community and be inspected by peers, on a regular basis. The insurance industry seeks this supporting evidence for its confidence in hospitals. On a periodic basis the academic departments of a college or university are evaluated by their peers. Confidence in their diplomas by major employers of their graduates is sustained through accreditation. The fact that there may be some elements of professional discipline in these fields is known. Laboratory accreditors should be aware of this risk also.

The fact that accreditation of hospitals and colleges is only barely perceived by the consuming public, except when a withdrawal makes local news, and that nearly all institutions maintain accreditation once it is obtained makes some managers of commercial testing laboratories believe that the accreditation activity has a levelling effect thus detracting from their innovation. This belief should not become a value assumption because the effect is still manageable at this point in time while policies and criteria are still being formulated.

5. Typical markets where laboratory accreditation is necessary or useful

Laboratory accreditation has been established in certain disciplines for a number of years. Several of these programs will be discussed in detail during the conference, but I wish to establish the rather high degree of user satisfaction with these programs in the markets which they now serve. The shortcomings of any particular program as viewed by laboratory managers will not be reviewed in the presentation.

Accreditation of a construction materials testing (CMT) laboratory by the Cement and Concrete Reference Laboratory (CCRL) Program is now often specified in construction contracts. This recognition has come about in part through the recommendation by those laboratories which have passed this muster. CCRL accreditation represents a kind of industry-wide quality assurance which establishes confidence among both laboratories and their customers.

The College of American Patholigists (CAP) Accreditation Program is basically oriented toward clinical service laboratories. Some time after its establishment, the program was expanded to admit the development laboratories of medical device manufacturers. In the experience of one particular firm, this accreditation enabled it to participate in collaborative reference studies to confirm performance of a new product. The other CAP-accredited laboratories would have been less interested in participating in that exercise had the manufacturer not also been CAP-accredited.

In the discipline of non-destructive testing (NDT), full-scale laboratory accreditation is not yet feasible; however, certification of NDT technicians has been the basis for reliability on the technology for several years. Laboratories offering NDT services are expected to maintain staff certification, and testing contracts so specify. This particular approach has provided mobility among technicians at the working level during a period of rapid growth in the discipline. Some form of technician certification ought to be coupled with laboratory accreditation so that personnel changes can occur with minimum effect on the organization's accreditation.

While most accreditation programs are national in coverage, some activities are conducted on a regional or local basis generally because of marketing needs. Examples include state and municipal level recognition of laboratories to inspect and test specialized electrical installations or pressure vessels not previously code-certified. These activities respond to the needs of laboratories as well as the regulated parties although not as formal as they should be, regional accreditation programs through their existence and user satisfaction demonstrate the high potential value of this vital new service in the contemporary economy.

6. Future trends

The most significant trend yet to come in the field of laboratory accreditations is the mechanism for identifying and responding to the critical mass of interest for the development of criteria for accreditation of a given class of laboratories. One hopes that with maturation of this activity, the process of accreditation will eventually become straight forward dependent on the specific criteria applicable to particular laboratories. This condition applies whether the basis of accreditation is by product or by discipline or a combination.

The process of criteria development must anticipate customer expectations for the conduct of laboratory services, much the same as this sort of reasoning is being applied to the development of product standards. Involvement of regulatory authorities who are likely to recognize accreditation in their jurisdictions will also become increasingly important as more aspects of product performance and safety become subject to demonstrated scientific testing.

Accrediting organizations must not be aloof from the impact of their activities, I believe they have a responsibility to assist in promoting their activities through public awareness of the criteria and wide dissemination of their directories. They must also grow out of the fear of advertising by accreditees. It is unnecessary, in my opinion, to believe that a person contracting for laboratory services is going to be duped into thinking that an accreditation will cover up otherwise incompetent conduct. In this regard laboratory accreditors can learn a great deal from the experience of college and hospital accreditors. From the user's standpoint, international cooperation is a vital counterpart to a domestic program. Without it, much of the progress in international trade accomplished through the multilateral trade negotiations will be set back.

In conclusion, laboratory accreditation can serve as a stimulus to the market for testing services for a long time before it dampens the field through over-regulation.

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LABORATORY ACCREDITATION -- STATE-OF-THE-ART IN 1979

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

Key words: Laboratory accreditation; state-of-the-art in 1979.

1. Introduction

In a way, this whole conference is on the state-of-the-art in laboratory accreditation. General descriptions of laboratory accreditation models will be presented. Descriptions of evaluation technology which form part of laboratory accreditation models will be presented. Specific accreditation systems will be described. Future concepts will be presented. And finally, the program will conclude with a briefing on an upcoming conference focusing on international coordination of other accreditation systems.

The state-of-the-art I intend to present will deal with the laboratory accreditation systems in existence in the United States at this time.

2. Definitions

Before describing the extent of laboratory accreditation in the United States, I would like to start with a definition. Laboratory accreditation is the formal determination and recognition that a testing laboratory has the capability to carry out specific tests or types of tests. Under this definition laboratory accreditation does not include the development or promulgation of test methods or standards. Laboratory accreditation under this definition also does not include the act of certifying that a product meets a standard since such a certification requires attention to many more aspects in the production process than simply to the testing function.

3. Need for Laboratory Accreditation

Laboratory accreditation systems have been developed to improve the ability of testing organizations to meet a wide variety of needs. First, there is the need of government to assure compliance to health and safety standards. Then there is the need of procurement authorities to determine that a product received meets the requirements specified in the purchase request. Producers and manufacturers often must establish the specific characteristics and performance of their products as measured by some test method. Health service agencies need accurate testing information to diagnose potential problems and take corrective actions. Consumers are more and more interested in specific performance characteristics and ways to measure differences among products. General contracting groups such as in the building trades must meet certain specifications which require definitive test information. Finally, many certifying agencies have been established to attest to the accurate performance of products and testing is an integral part of that determination.

The main objective of laboratory accreditation systems is to facilitate trade both nationally and internationally. Over and above this objective, however, laboratory accreditation is used to meet other objectives, including ensuring validity of test data, promoting wide acceptance of test data, providing more efficient use of testing facilities, giving credibility to more use of testing laboratories, giving additional status to competent laboratories, promoting good testing practices, improving test methods, and providing information about accredited laboratories. Such programs inherently will upgrade the quality of measurement in testing laboratories. They will emphasize the need for calibration services, provide models for good laboratory management performance, and aid in the improvement of quality control in manufacturing. In addition, laboratory accreditation will be an aid to the reduction of defective products and a reduction in personal injury, property damage, and product liability suits.

4. Approaches to Laboratory Accreditation Systems

There are two basic approaches to accreditation of laboratories. First is the approach where laboratories are accredited to test specific products in conformance to standards using test methods pertinent to that product. Such product-focused systems are designed for the users of laboratories, particularly for those desiring a certification that products meet certain standards. These systems typically identify the testing methods to be included in the program before accepting applications for accreditation. The programs provide accreditation for only a limited number of test methods although they effectively serve the needs of laboratories for recognition to a particular set of clients.

Second is the approach where laboratories are accredited to conduct tests in broad technical areas or groups. This discipline-focused approach accepts a laboratory's statement of tests it can perform and then develops procedures to verify the laboratory's capability to perform the tests. The general area of accreditation is announced, but the specific tests to be verified will depend upon the laboratory's testing programs and the accreditor's ability to examine the skills of the laboratory to perform those testing programs. Such programs are advantageous to the laboratories since accreditation can be granted for a large spectrum of test methods but are often difficult for users of laboratories to use since the accredited tests may often not be in the language of the product performance characteristics.

5. Operation of Laboratory Accreditation Systems

Most laboratory accreditation systems contain the following features:

A. They obtain objective information about the testing laboratory's capabilities either through a questionnaire or an application form.

B. Each laboratory is visited and its operations reviewed by an evaluation team.

C. Proficiency tests are established for certain tests and the laboratory required to participate so that performance of the various laboratories can be compared.

D. After evaluation of the results of the first three features, a formal recognition of the laboratory's capability is granted.

E. The laboratory's performance is reassessed periodically to assure continued compliance with the criteria.

F. The accreditation system makes known to potential users the capabilities of potential laboratories in its system.

6. Laboratory Accreditation Programs in the U.S.

Mr. Charles Hyer, in a study performed for the Department of Commerce in 1978, examined 56 public laboratory accreditation programs in existence in the U.S. These programs were equally divided among Federal agencies, state and local agencies, and trade associations. The rapid increase in the establishment of these programs is illustrated in Exhibit 1. Apparently laboratory accreditation programs fill a need because the programs have been established recently at an increasing rate. The number of laboratories formally recognized by these systems is growing at an even faster rate as shown in Exhibit 2. In this Exhibit the number of laboratories granted accreditation in 1978 was plotted versus the year the accreditation program began. Typically, these programs require several years before significant numbers of laboratories become accredited. With the large number of programs initiated in the mid-70's, it would appear that the number of laboratories accredited will be increasing very rapidly in the 80's.

With the increasing number of accreditation programs, we are beginning to observe a situation where laboratories are accredited by more than one system. This overlap and duplication in the examination of laboratories is just beginning to be felt. For example, one laboratory provides operating space for numerous different accreditation agents at its facility, and this operating space is almost continually utilized. In other cases, we know of laboratories being accredited by 30 or 40 systems. It would appear that this overlap and duplication is costly and burdensome and will grow substantially in the coming years, and it is one reason why some sort of a national coordination of laboratory accreditation systems appears to be desirable.

7. Toward "Nationally Recognized" Laboratories

Another factor leading to the promulgation of laboratory accreditation systems is the enactment of laws and statutes which specify that testing must be done by "nationally recognized" laboratories. Private groups may very well develop systems which can be recognized nationally by Federal agencies, or Federal agencies and private groups may develop systems which warrant national recognition. The demand for national recognition, however, will tend to increase the pressure for the development of broad-based laboratory accreditation systems capable of multiple product testing and evaluation, or at a minimum, effective coordination of such systems in the interest of economy.

Each laboratory accreditation system has its own specific criteria which it will use to evaluate the testing laboratories. We have examined many of these criteria; and although it can be said that in general the criteria specify similar requirements, the laboratories find that fulfilling the requirements of these criteria calls for individual effort for each specific criterion. With the increase in laboratory accreditation systems there will be a similar increase in the work that laboratories must perform in order to be accredited by these various systems. Accordingly, some attempt needs to be made to arrive at universally acceptable criteria for application in potentially duplicative, and perhaps conflicting, programs. We believe that this is an appropriate subject for the next national conference on laboratory accreditation.

8. International Implications

International laboratory accreditation conferences have been held in 1977 and 1978. A third one is scheduled for October of this year and a fourth one is planned for the fall of 1980. The purpose of these International Laboratory Accreditation Conferences (ILAC) is to examine ways in which laboratory accreditation systems in the various participating countries can be multilaterally recognized. If such recognition can be established, then products tested in one country may be

accepted in another country without retesting. The formal international recognition of accreditation programs will, of course, depend on treaties or other arrangements made among the participating countries. In the interim, ILAC is attempting to prepare a Directory of Laboratory Accreditation Systems throughout the world. In an attempt to assure some sort of minimum acceptable characteristics of these accreditation systems, ILAC will be specifying minimum criteria which are to be met by a laboratory accreditation system in order for that system to be listed in the Directory. Some programs already in existence in the United States may not be accepted for listing in this Directory because they do not meet the criteria being suggested. More on this matter will be presented in the last session of this conference. Suffice it to say that international coordination of laboratory accreditation is of growing interest.

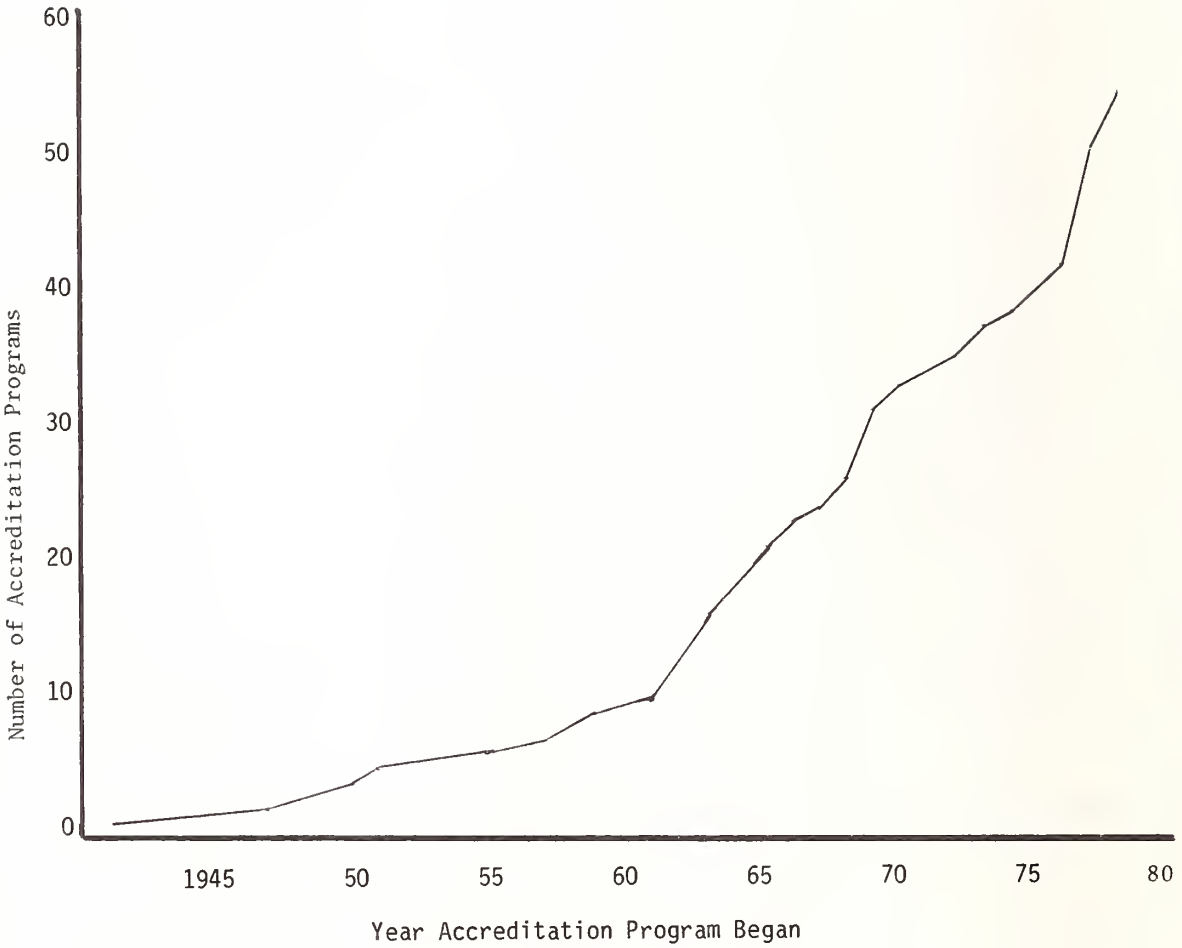
9. Summary

U.S. laboratory accreditation systems are growing rapidly in number as are the number of laboratories actually recognized. There are a number of forces in existence both nationally and internationally which are beginning to focus on the need to coordinate these systems. The key to such coordination will be the development of a universally acceptable criteria for evaluating the testing laboratories, a public and private sector coordinating body to promote acceptance of the criteria, and the consolidation of accreditation systems.

EXHIBIT 1

NUMBER OF ACCREDITATION PROGRAMS IN THE U.S.

Ref.: C. W. Hyer, "Principal Aspects of
U.S. Laboratory Accreditation Programs," January 24, 1979



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GENERIC STANDARD BASIS FOR LABORATORY ACCREDITATION

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The paper provides an overview of generic criteria for laboratory capability evaluation. The new American National Standard, ANSI/ASTM E 548-79, Standard Practice for Use in the Evaluation of Testing and Inspection Agencies, is reviewed. It provides generic criteria for evaluation of an agency for intended purpose, agency organization, human resources, material resources, and quality systems. New work is also reviewed relating to generic criteria development for accreditation systems and accreditors. Examples are provided of voluntary standards for specific disciplines and product areas. Discussion is provided of work in similar national and international areas, including mandatory use. Additional opportunities are given of appropriate survey and audit techniques for use in evaluation and accreditation.

Key words: Accreditation systems; certification; evaluation of inspection organizations; evaluation of testing organizations; inspection standards; laboratory accreditation; laboratory evaluation; regulatory liability; test standards; voluntary consensus standards.

1. Introduction

Generic criteria are required to permit development of a uniform base in preparing specific working requirements to evaluate testing and inspection agencies. These generic criteria are provided in ANSI/ASTM E 548-79, Standard Practice for Use in the Evaluation of Testing and Inspection Agencies (Ref 1). This standard serves as a starting point to achieve effective and efficient review of test and inspection organizations and relates to criteria for the evaluators and the evaluation system. In addition the generic criteria are useful in developing a base for laboratory accreditation activity.

2. Needs

Business, legal, and standards practice usually require final product or service to be evaluated for performance against established requirements and compliance criteria. However, in many areas it may be desirable for additional information to be known about an actual test or inspection process, through evaluation of agencies or activities involved in earlier decision making processes.

In normal commercial practice this flow of information and evaluation is considered in the regular contract base, the need to know, and with full regard for associated proprietary information. However, with expanding national and international trade, and involvement of third parties in commerce, it is desirable for ground rules to be defined to aid in evaluations and possible accreditation, especially with indirect and complex procurement arrangements. Also, it may well be important for regulatory requirements to relate their specific criteria to such defined normal commercial practice. Such action may result in the least adverse effect on commerce and productivity with reduction in possible regulatory liability (Ref 2).

Thus the need for the formation of ASTM Technical Committee E-36, on Criteria for the Evaluation of Testing and Inspection Agencies, and with the development of ASTM E 548-79 Standard Practice Generic Criteria.

3. Considerations

With the disengagement in the 1960's of the Department of Defense from on-site test and inspection, there was a formal trend to improving visibility of quality and reliability information for products and services from suppliers. An example of action taken to improve this flow of data and accountability was the Electronic Industries Association development of Standard EIA-1000, EIA Standard Procedure and Questionnaires for Electronic and Electrical Parts Suppliers Quality and Reliability Assurance (Ref 3). This provided a base for buyers to obtain quick answers on questions before purchasing electronic parts. The system was voluntary and also included provision for sharing of system reports.

Recognizing a need for furthering this evaluation in many test and inspection areas, ASTM Technical Committee E-36 was formed to prepare standard consensus generic criteria. These criteria were to be used by others in preparing specific requirements for qualification and accreditation of testing and inspection agencies. The Committee Scope included preparing generic standards on its own and preparing specific standards when not in area of interest of other technical committees and when coordination is needed with them. Also the Committee Scope included standard nomenclature and definitions, aiding and advising ASTM technical committees in the preparation of standards, correlation and consolidation of similar standards prepared by separate committees, and instituting cooperation between these technical committees in areas of common interest.

Further, the Committee was to encourage, secure, and promote cooperation between ASTM and other organizations including those that may accredit testing and inspection agencies. And, the Committee was to advance, improve, standardize, and unify such standards, including liaison with government and other organizations.

This presentation is not intended as a formal report on the work of ASTM E-36. Rather it is intended for those not familiar with the voluntary consensus system to aid in the understanding of the responsive nature of this work and its subsequent value through application of specific criteria for products and services in the voluntary syste and also as appropriate in the mandatory reg ulatory system. Therefore this is not a ful report and those parties interested in more factual details should refer to the writer and the Committee.

4. Test and Inspection Agencies

The generic criteria in Standard E 548-79 replaces the earlier edition of Standard E 548-77. For actual use this standard should be interpreted by a technical standard for each specific product, service, or test method. This is obvious since no single standard could be directly applied with full value in all possible applications and conditions. For example certain industries have special practices and requirements which must be placed into perspective. Even with such additional work there is much to be gained through the consideration of outline format, applicable terms, definitions, and possibly wording generated in the generic standard. Final decision for application must rest with the technical committee responsible for the final document.

Likewise care must be used if the standard is applied in normal direct negotiations and in dealings between buyers and sellers where there may be special economic and proprietary concerns.

5. E 548-79 Criteria

Although only the actual Standard may be used for full and proper understanding, this paper calls attention to certain areas which are covered in detail in E 548-79.

First, the purpose for evaluation should be identified and considered in developing any specific document from this generic base. Obviously this purpose must identify the system in which the specific document will be used and criteria relating to evaluator or accreditor. Without this understanding it would be impossible to properly apply specific requirements in the test and inspection environment.

Likewise the specific criteria must be clear in relating to possible implications in past, present, and future tense of the application.

Second, the agency organization should be considered for necessary identification, affiliation, history, services, and past recognition achievements. Here the intent is to provide only that information which must be considered necessary in specific applications.

Third, the human resources of an agency should be presented to relate personnel, responsibility, and authority with appropriate job descriptions and identification of means for maintaining personnel qualifications, work experience, training history, and facts on ensuring continued competence of personnel.

Fourth, the material resources of an agency should be identified relating to actual equipment and facilities, calibration standards, and other information necessary to ensure update and service.

Fifth, the quality system of an agency should identify the procedural systems affecting the quality of services with details on rationale of the metrology system and support activities of calibration, traceability, data analysis, feedback, and necessary survey and audit activities with periodic on-site reviews.

In summary, the standard provides a comprehensive format and approach, useful internally as well as by prospective outsiders, where there is proper specific standard consideration.

6. Evaluation System

Obviously the proper application of E 548-79 requires a full understanding for the associated evaluation system and if applicable the full details on any additional accreditation system.

Although not covered in detail in the standard it is assumed there would be proper consideration given in the system to both prevent the generation of incorrect reports and to provide effective and efficient action should there be any questions or need for control.

7. Evaluator Criteria

Likewise, the standard does not identify requirements for the evaluator and any associated accreditors. Here again it is expected such activities will be properly qualified and under supervision to assure effective and efficient operation, both for the evaluator and the agency being evaluated.

8. Specific Criteria

The continuing effort of Technical Committee E-36 has indeed been rewarding. Through this voluntary consensus base there have been developed various specific criteria standards. For example, in the Manufactured Housing area there are ASTM Standards E 542 and E 651. In the government voluntary area there is the Department of Commerce National Voluntary Laboratory Accreditation Program (NVLAP). And in addition there are several possible mandatory government applications in development, all based on E 548-79. However, the subject of this paper is generic criteria and further details must be the subject of other presentations.

9. International Applications

The work of E-36 has received aid from abroad, both in the preparation of the E 548-79 and in its application in other national criteria standards and evaluation systems. It is expected this cooperation will continue. There is also some similar effort in international standards bodies and in ad hoc activities. Again, these are beyond the scope of this paper except to note that this cooperation is expected to aid development of further generic and specific criteria in areas of products, services, and evaluation or accreditation systems.

10. Evaluation Effectiveness and Efficiency

The development of E 548-79 has been accomplished with full appreciation of demands for possible reviews, paperwork, and delays in the effectiveness and efficiency of normal productive operations. Recognition of the need for criteria to be cost effective requires full consideration by users of the standard and in development of any associated specific criteria.

Special attention has been given to setting up a structure that will be flexible with time and changing conditions, especially with the possible mandatory adoption of the criteria in regulatory processes. It is strongly recommended that similar consideration be given by others in generating specific criteria since such systems may not provide for detailed understanding and periodic reviews required under the ASTM voluntary consensus system.

Likewise it is expected this document will find good application in normal survey and audit activities for quality assurance programs and in other technical management areas.

Similar applications may also be found in the growing requirements for current good laboratory practice, current good manufacturing practice, and in reasonable testing programs.

The intent of this standard has been to provide another viable tool in the process of applying standards in improving the productivity of the world. To this end, Technical Committee E-36 extends a cordial invitation for all interested to participate in the ongoing work of the Committee and in developing new projects which might fall within the scope of the Committee.

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LABORATORY PERFORMANCE EVALUATION SERVICES OF THE U.S. NATIONAL BUREAU OF STANDARDS

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This paper describes the principal services provided by the U.S. National Bureau of Standards that allow laboratories to assess and maintain at a high level the quality of their measurements. The NBS programs described in some detail in this paper include: Standard Reference Materials, Calibration Services, Measurement Assurance Program Services, and Collaborative Reference Programs. The paper deals with the basic aims and objectives of these services. A brief description of each service is provided, along with indications of how these services have improved the performance of laboratories. Also discussed are general concepts regarding the assurance of measurement accuracy and compatibility among laboratories on a national and/or international scale.

Key words: Calibrations; Collaborative Reference Programs; laboratory performance; measurement assurance; measurement evaluation technology; measurement services, physical standards; proficiency testing; Standard Reference Materials; testing; traceability.

1. Introduction

Our society today relies on accurate measurements for realizing equity in the marketplace, for industrial quality control, for equitable enforcement of and compliance with government regulations related to the environment, health and safety, and for scientific research. In order that the uncertainty of measurements be sufficiently small so that correct decisions can be made based on measured data, measurement quality assurance must be built into the measurement system.

There is an increasing demand for the accreditation of laboratories that are capable of performing reliable measurement services in all areas of the measurement field. Accredited laboratories and the accrediting authority must be particularly sensitive to the need for measurement quality assurance. Calibration and standardization of laboratory equipment and procedures are essential to obtain the reliable measurements necessary for modern technology and to assure that, for fair trade and commerce, credible testing laboratories can be identified and called on to determine if the quality of the product adequately reflects the specification requirements. Table 1 lists the principal factors that a laboratory should consider incorporating into an overall system of quality assurance.

A key responsibility of the National Bureau of Standards (NBS), as stated in the act of Congress that establishes NBS and subsequent amendments to that act, is to establish and maintain national standards of measurement, coordinate these standards with those of other nations, and provide means and methods for making measurements consistent with those standards. In other words, provide a complete and consistent national system of physical measurements.

"Agreed upon" standards are necessary for making accurate measurements. As a familiar example, consider the prototype mass standards K4 and K20 kept by NBS which are the U.S. standards for the kilogram. By mutual agreement of the measurement community, mass measurements in the U.S. are ultimately referred to these national standards of mass.

One often hears of requirements to the effect that "measurements or a reference standard must be traceable to the National Bureau of Standards". Presumably the intent of such traceability citations is to insure that measurements are sufficiently accurate that proper decisions can be made. In a recent article, Belanger has described the confusion that can result when differing interpretations of traceability are adopted by various parties[1]. If it is required that the measurements made by an accredited laboratory be "traceable" to NBS, then it is clear that the laboratory, the accrediting party, and the customer must agree on the definition of traceability and on the criteria as to what constitutes adequate traceability.

NBS prefers a definition of traceability that focuses on the uncertainty of the measurements being performed.[1] It is clear that NBS must provide convenient mechanisms by which parties outside NBS can verify that their measurements are accurate at some desired level of uncertainty relative to national standards. Such mechanisms are needed whether or not one has accredited laboratories.

Laboratories that must make quality measurements consistent with national standards have available a wide variety of NBS measurement services from which to choose. Table 2 shows the measurement transfer mechanisms employed by NBS. This paper focuses on those services of NBS that directly facilitate the making of accurate measurements by laboratories throughout the U.S.

2. Calibration Services

The calibration of working standards is a service that has been offered to the public by NBS ever since it was formed. Today, in a typical year, NBS provides a total of several thousand calibrations for approximately 1000 different organizations - including industrial standards laboratories, Department of Defense and other Federal agency calibration activities, state and local weights and measures activities, universities, hospitals, utility companies, etc. NBS currently offers calibration services for mass, volume, density, temperature pressure, dc and low frequency electrical measurements, rf and microwave measurements, radiation, and a variety of other measurements. The array of services is constantly changing since each year NBS generally initiates calibration services to reflect new needs associated with emerging technologies. Also, to make way for new services, NBS regularly phases out services that have become less important to the measurement community because of changing technology, services offered by the private sector, or declining requirements.

It is clear that NBS does not have the personnel to calibrate all standards in the U.S. of a given type that require calibration nor would it be possible for us to offer high level calibration services for all conceivable measurement quantities for which accurate measurements are needed. Accordingly, NBS tries to provide a mix of services that is responsive to the most important needs of the measurement community and where possible to provide those services to high level laboratories that can in turn provide calibration services and thereby transfer accuracy to lower level field measurements. It is the policy of the Federal government not to compete with private sector services. Accordingly, NBS' services are limited to those special high level calibrations which are not readily available elsewhere and high accuracy calibrations required for direct traceability to national standards.

NBS publishes a catalog of calibration services, NBS Special Publication 250, "Calibration and Related Measurement Services of the National Bureau of Standards". An appendix to SP 250 is issued each June and December giving up-to-date prices and

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[1] In reference[1] traceability is defined as follows: "Traceability to designated standards (national, international, or well-characterized reference standards based upon fundamental constants of nature) is an attribute of some measurements. Measurements have traceability to the designated standards if an only if scientifically rigorous evidence is produced on a continuing basis to show that the measurement process is producing measurement results (data) for which the total measurement uncertainty relative to national or other designated standards is quantified."

information on new services that are about to be offered or services that are slated for phase-out. Both of these documents are available from the Office of Measurement Services at NBS.

Laboratories, whether formally accredited or not, wishing to maintain a high level of quality control over their measurements can effectively utilize NBS calibration services, and many do so. In recent years, NBS and its calibration customers have come to recognize that the use of standards calibrated by NBS is by itself no guarantee that the laboratory is performing adequate measurements. Even if a particular lab has a standard accurately calibrated by NBS, it probably will not be able to make accurate measurements unless the operators are skilled, the environment is adequately controlled and the measurement procedures are technically sound. Recognizing this fact, laboratory accreditation procedures generally address all of these factors.

In the section which follows, special NBS services that allow our customers to control their total measurement process are described[2].

3. Measurement Assurance Programs

NBS has developed special services called Measurement Assurance Program (MAP) Services to aid laboratories in establishing their measurement uncertainty and maintaining it at an acceptable level. NBS currently provides these services for measurements of mass, temperature (platinum resistance thermometers), dc voltage, dc voltage ratio, capacitance, resistance, electric energy (watt-hour meters), laser power and energy, and, on a trial basis, gage blocks.

The techniques used in MAP's are familiar techniques to those experienced in the quality assurance field. Unlike a calibration which only checks the standard or instrument, the MAP is designed to assess the performance of the entire measurement process. A key element of MAP is the availability of a suitable transport standard. The MAP transport standard is a device, artifact, or material[2] that is stable, rugged, and well-characterized, and whose value is accurately known relative to national standards at NBS. This standard is sent to the participating laboratories where it is measured as an unknown or "blind" sample. Since NBS measures the item before it leaves the Bureau and after it returns, its value while in the participant's laboratory should be accurately known. Any bias or offset (systematic error) associated with the measurements made by the MAP participant can be ascertained from the data returned to NBS.

Since an objective of the MAP is to establish the total uncertainty of the measurement process in the participating laboratory, it is also necessary for the laboratory to have suitable working standards upon which measurements can be made at appropriate intervals to establish the process precision and insure that it remains within acceptable limits. NBS provides advice on applicable quality control techniques such as the keeping of control charts to monitor the random error (precision) of the process and make sure that the process remains in a state of statistical control. Knowing both the systematic error or bias by means of data taken on the NBS transport standard and the random error established by the measurements made in the laboratory over a suitable period of time,it is possible for NBS to issue a test report that quantifies the total measurement uncertainty of the participant. NBS provides consulting help to new MAP participants in identifying problems and generally insuring that their accuracy objectives are met.

NBS disseminates measurement assurance services in two ways. Most users deal with NBS on a one-on-one basis, but NBS and our customers are increasingly interested in using a group or regional approach. This second approach[3] has been particularly successful in the case of dc voltage, and so NBS is looking for opportunities to utilize the same approach for other quantities. The regional or group MAP involves a group of laboratories in one part of the country (e.g., Southern California) interacting with NBS as a group through one laboratory designated as the "pivot" laboratory. There appear to be a number of advantages both to NBS and to our customers from the use of the more efficient group or regional approach, including lower costs to the participants, faster turnaround time, and in the long run, less frequent need for interacting with NBS to verify measurement accuracy.

The net result of a MAP is that a rigorous uncertainty statement can be developed for the performance of the measurement system. Additionally, it provides a mechanism for noting changes with time or out-

[2] Standard Reference Materials can be used as the basis for a MAP when coupled with appropriate methods and data analysis.

of-control conditions. Should some organization, either private or governmental, wish to institute a laboratory accrediation program for calibration laboratories, data from a MAP (assuming an NBS service is available for the measurement quantity of interest) can provide an excellent tool for assessing laboratory performance. Note that the MAP approach is a "systems" type approach and that it has much in common with the philosophy of the Standard Reference Materials Program as described in the section which follows.

4. Standard Reference Materials

Standard Reference Materials (SRM's) have been produced, certified and issued by NBS since 1950[4]. SRM's are well-characterized, homogeneous, stable materials (or simple artifacts) with specific properties measured and certified by NBS. Over 1,000 different SRM's are now available from NBS [5]. The SRM inventory can be categorized into three basic types of certified reference materials. These categories are: 1) materials certified for chemical composition or purity, 2) materials certified for one or more fundamental physical or chemical properties such as pH or melting point and 3) materials or artifacts certified for other properties usually associated with special engineering type applications, e.g., sieve sizing or color fading. Many of the SRM's in this latter category are certified on a method-dependent rather than absolute basis. SRM's are widely used throughout the world in a variety of measurement applications including development and evaluation of measurement methods, assurance of long-term measurement compatibility among different laboratories and establishment of measurement traceability to NBS.

During fiscal year 1978, NBS distributed 37,000 SRM units to over 10,000 users throughout the world. Foreign laboratories represent over 20 percent of SRM users. The four major SRM user categories are: 1) industrial research and quality control laboratories[6], 2) environmental analysis and monitoring laboratories[7], 3) laboratories performing clinical or health related measurements[8,9,10] and 4) laboratories engaged in basic scientific and/or metrological research (e.g., establishment of an accurate temperature scale)[11,12].

One of the most significant outputs of the NBS SRM program during the last 10 years, has been the development of a greater understanding of the role of SRM's in total measurement systems. The NBS Office of Standard Reference Materials (OSRM) has placed an increased emphasis on utilizing a "systems approach" to accurate measurement, whereby NBS SRM's together with standardized well-characterized test methods (reference methods) are used to transfer accuracy and establish measurement traceability throughout large multi-laboratory measurement networks. As indicated earlier, the systems approach in the SRM Program shares many common features with MAP activities. A large number of articles and monographs have been published by J.P. Cali [13-15] and other members of the OSRM staff [16-18,6,7,8] concerning the systems approach to accurate and compatible measurements.

The systems approach to measurement compatibility recognizes the fact that SRM's provide a highly useful and important, but by no means sufficient mechanism for achieving measurement compatibility on a national or international scale. Measurement compatibility means that all measurement stations within a given measurement network obtain values within agreed-upon measurement uncertainties, when measuring a specific property of the same material. The systems approach to measurement compatibility is illustrated in Figure 1 and described extensively in the review paper by Uriano and Gravatt[16].

Figure 1 represents a hierarchical system of analytical methods and reference materials each coupled to the other in the manner shown. The function of each component (I to VI) is to transfer accuracy to the level immediately below it and to help provide traceability to the level immediately above it, thus helping to assure measurement compatibility in the overall system.

As we proceed from bottom to the top of the measurement hierarchy, accuracy requirements increase at the expense of decreased measurement efficiency. At the top of the hierarchy are the so-called definitive methods of analysis or test, which give the most accurate values obtainable.[3] Unfortunately most definitive methods (e.g., gravimetric techniques for preparing analyzed gas SRM's [16]) are usually time consuming, sophisticated methods and thus are not economically acceptable for widespread and routine field use. Definitive methods, however, are used

[3] For definitions and more detailed discussion of definitive, reference and field methods, see ref. [16].

whenever possible to certify NBS SRM's. SRM's then can be used to transfer accuracy further down the measurement hierarchy, e.g., to verify the accuracy of or calibrate reference methods.

Reference methods, which may be automated comparative methods (e.g., nondispersive infrared spectrometry for measuring carbon monoxide in air) can then be used directly in the field or alternatively as a basis for developing or evaluating other methods. Reference methods are also commonly used for producing secondary reference materials, which in turn are directly used in routine field measurement applications. Examples of reference methods are the Environmental Protection Agency reference methods for monitoring the ambient air criteria pollutants[20]. The Annual Book of ASTM Standards lists hundreds of standard test methods, which can be designated as reference (or in some cases definitive) methods. For example, the ASTM E-350 series of Standard Methods for chemical analysis of a variety of iron and steel products[21] constitutes an excellent example of reference methods[16]. In fact, the systems approach to compatible measurement historically originated in the metals industries[4,13], where NBS SRM's and ASTM standard methods both play a critical role in assuring measurement compatibility.

The accurance of numerous field methods can in principle be traced back to a definitive method in such a hierarchical accuracy-based measurement system. In such a system, SRM's and other reference materials play a necessary, role in the transfer of accuracy. However, SRM's, by themselves, cannot assure high quality measurements. As in the case of MAP's, good methods, good laboratory practices, well-qualified personnel as well as proper intra-laboratory (internal) and inter-laboratory (external) quality assurance procedures are just as important as the reference materials.

Variations of the idealized accuracy-based measurement system are now in place in many industrial areas and are being implemented in the areas of clinical and environmental analysis[7,10]. Many other areas are also beginning to utilize this approach. An excellent illustrative example of the systems approach to measurement compatibility, which involves both SRM's and ASTM standard methods, is represented by the recent Department of Commerce National Voluntary Laboratory Accreditation Program (NVLAP) for testing the properties of thermal insulation materials[22]. This is the first NVLAP program being implemented by the Secretary of Commerce. A number of NBS SRM's and ASTM Standard Methods are cited in the criteria [22] for accrediting laboratories, covering such properties as particle size and thermal resistance.

Figure 2 schematically illustrates the thermal resistance measurement system. NBS is in the process of developing a series of high and low density fiberglass SRM's[4] certified for thermal resistance (R-values) as a function of temperature and density. The NBS SRM's are certified by a definitive method (The NBS Guarded Hot Plate Method). Having been certified, the SRM's can then be used to control the accuracy of reference methods such as the ASTM Guarded Hot Plate Method (ASTM C177) or for direct calibration of comparative reference methods such as the Heat Flow Meter Method (ASTM C518). Thus the NBS SRM's and ASTM methods are intended for direct, continuous use in intra-laboratory quality assurance programs.

NBS is also developing a set of thermal insulation test specimens for use in proficiency testing, i.e., an external or interlaboratoty quality assurance program. This will provide a mechanism for directly monitoring (auditing) the performance of participating laboratories on a periodic basis. The audit program provides the measurement system with an appropriate feedback and traceability mechanism.

Table 3 contains a summary of the most common uses of SRM's in measurement applications. The reader is referred to various papers cited previously[11,13-17] for other specific examples of the use of SRM's. The review paper[16] cited previously also discusses the relative roles of various organizational components (e.g., voluntary standards organizations, national standards laboratories, regulatory agencies) in assuring measurement compatibility.

5. Collaborative Reference Programs

NBS has been involved for many years in programs for proficiency assessment of laboratories in cooperation with private industry and standards organizations. These programs were initiated to assist laboratories in determining the accuracy level and

[4] The first of these SRM's, (SRM 1450 - High Density Fiberglass) is now available from NBS[5].

precision of their testing and in improving their testing performance. The programs are sponsored by a variety of organizations and are conducted under a variety of procedures. Each field of testing has its special problems and each sponsoring organization its own goals. Hence, no two of the existing programs are identical, but each has been designed to meet the specific needs.

In 1936, the first collaborative reference sample program was initiated for cement as part of the NBS Research Associate Program of the Cement Reference Laboratory of the American Society for Testing and Materials (ASTM) Committee C-1. In 1966, this program was revised to essentially its present form wherein two pairs of samples for physical tests and two pairs of samples for chemical analyses are distributed each year. Similar programs for bituminous, soils, aggregates, and portland cement concrete and bituminous concrete were then established in rapid succession, the last in 1974. These programs are under the sponsorships of ASTM and the American Association of State Highway and Transportation Officials, respectively.

In 1969 a bimonthly program for paper and board testing was initiated under the sponsorship of the Technical Association of the Pulp and Paper Industry and a program for control of the quality of shipping container components was established for the Fourdrinier Kraftboard Institute. This later program involves weekly testing and monthly reports by the participants. A quarterly program for the rubber industry was started in 1970 with the help of ASTM Committee D-11, and a color and appearance program, of interest to many industries and users, was established for the Manufacturers Council on Color and Appearance. This quarterly program presently includes tests for gloss, color and color difference, and retroreflectivity.

The Collaborative Reference Program (CRP) provides a participating laboratory with a means for checking periodically the level and uniformity of its testing performance in comparison with that of other laboratories. A major feature of all CRPs is the periodic distribution to the participating laboratories of suitably selected and prepared samples. The participants are instructed to test the samples in accordance with standard test methods and supplemental instruction provided by NBS. They are also requested to report any deviations from the standard procedure, as for example, when the conditions in the test room are not strictly in compliance with the requirements of the standard. Special data forms are provided to the laboratories for reporting results to NBS.

The test results are analyzed at NBS in accordance with the Youden two-sample procedure[23] using special computer programs. The results of the analysis are presented using tables and Youden's graphical technique, as shown in Figure 3. In this diagram, each point represents a laboratory and the ellipse represents the bounds within which 95 percent of the points for similar laboratories are located.

6. Technical Support for the National Voluntary Laboratory Accreditation Program

In February 1976, the Department of Commerce (DoC) established the National Voluntary Laboratory Accreditation Program (NVLAP). The purpose of this program is to give recognition, through accreditation, to laboratories that have the capabilities to correctly perform specific tests according to identified standard methods. There are three (3) different procedures for instituting laboratory accreditation programs under NCLAP. Procedure (A) is for the general public and it requires that four distinct phases be accomplished, i.e., finding of need, establishment of a criteria committee, development of criteria, and the examination for accreditation. Procedures (B) and (C) are for the use of Federal agencies and private consensus organizations (consensus by DoC definition[5]) respectively. Both (B) and (C) permit by-passing the requirements for "finding of need" and the establishment of a criteria committee. NBS provides technical support to this program by assisting in the development of both general and specific criteria and by evaluating the capabilities of laboratories that request accreditation [24,25]. The examination methodology covers three phases: 1) Questionnaire, 2) On-site inspection; and 3) Proficiency testing.

For proficiency testing the "true" or target test result for any particular test is obtained by one of the following ways:

(1) Manufacturer. For some properties of a sample, it is possible to determ

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5 Section 7c.3(b) of Federal Register, Volume 44, Number 81, April 25, 1979, Page 24274-24282 (15 CFR Part 7c) lists six criteria that "private sector organizations" must meet in order to be in this category.

what the test result should be from information on how the sample was made. However, each case has to be thoroughly examined before manufacturing information can be used as the basis for determining the target or "true" values. This approach is often useful in proficiency testing programs requiring qualitative responses or identifications only (e.g., is starch present or not).

(2) Reference Laboratory. Sometimes a single laboratory, such as the National Bureau of Standards, has sufficiently high competence and national recognition that it can be used to provide the target or "true" test result. This is particularly useful when the laboratory has the capability of and has agreed to carefully verify the correctness of every important dimension of its apparatus and every step in its application of the standard test method.

(3) Group of Reference Laboratories. When no single laboratory can be given national recognition as having sufficiently high competence to set the national standard, it sometimes is possible for a proficiency test coordinator to use the results from a number of reputable laboratories. This would be accomplished by pooling their results (after a suitable statistical check on the agreement among the results) in order to establish the target or "true" test result.

(4) Reference Method. Under NVLAP procedures, the standard test method will usually also be the reference method. However, in some cases the standard test method may be so broadly written as to permit a wide variety of test equipment and testing protocols. If in such a case a particular protocol and equipment combination is recognized as a reference method (or can be shown through error analysis to yield results well within the required precision and accuracy), then the results obtained with that method by one or more "reference" laboratories are used to establish the target test result.

(5) Participants. If there is a sufficient number of participating testing laboratories and an insufficient number of reference laboratories, then the test results of the participating laboratories are sometimes pooled by a proficiency test coordinator to establish the target result for the individual participants. It is important that the pooled test results include only test data from laboratories known (on the basis of all available information) to be following the standard test method. This is determined not from the test data, but from an inspection report and from information submitted originally and with the test data.

(6) Previous Proficiency Test and Inter-laboratory Data. Sometimes the same samples are used as were used in a previous proficiency test. If so, the new target test result is based on a weighted pooling of current and previous test results.

7. Summary

The recognition of the need for a consistent measurement system led to the formation of the National Bureau of Standards and in particular NBS' responsibility for "The custody, maintenance, and development of the national standards of measurement, and the provision of means and methods for making measurements consistent with those standards." The laboratory performance evaluation services of NBS benefit all segments of our society through the promotion of quality measurements relative to national standards whether the concern is for fair trade in the marketplace or determining the pull of gravity in a scientific investigation.

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SESSION II

EVALUATION TECHNOLOGY

CHAIRMAN: DENNIS H. GALLAGHER
LEEDS AND NORTHROP

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THE MEASURING PROCESS AND LABORATORY EVALUATION

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Graphical review of the theory of the measuring process. In view of the theory, what should be examined in the evaluation of laboratories? What might questionnaires and inspection reveal? How good are various types of proficiency tests?

Key words: Collaborative reference program, test method; interlaboratory testing; laboratory evaluation; linear model; measuring process; proficiency testing; Youden two-sample analysis.

1. What is a Measuring Process?

A measuring process involves a relationship between the quantity of some property of a material, product or system and an indicating device sensitive to that property. A simple familiar example is the thermometer which indicates the temperature of the surrounding material by the expansion of mercury in glass. Another example is the voltmeter whereby the voltage is indicated by the angular deflection of the needle.

Ideally there should be a stable linear relationship between the quantity being measured and the response of the indicating device. However, even in such a simple example as the mercury-in-glass thermometer the relationship is not exactly linear nor is it stable especially before the glass has been adequately "aged." Non-linearity, however, is not a serious problem if the device can be calibrated simply or a simple theory relates measurement and quantity. Examples of non-linear relationships are ohmeter needle deflection vs electrical resistance and transmittance as a measure of concentration.

Generally, the relationship between the measurement and the quantity being measured may be represented graphically by a monotonically increasing or decreasing curve (Figure 1).

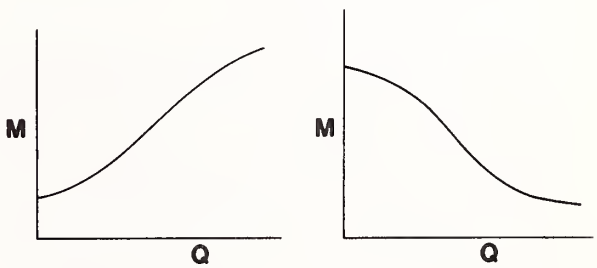

Figure 1. Relationship Between Measurement (M) and Quantity (Q) Being Measured

One essential requirement is that the relationship between measurement and quantity be monotonic. The situation shown in Figure 2 is unacceptable because of its ambiguity: the measurement M could mean that the quantity is either Q_1 or Q_2.

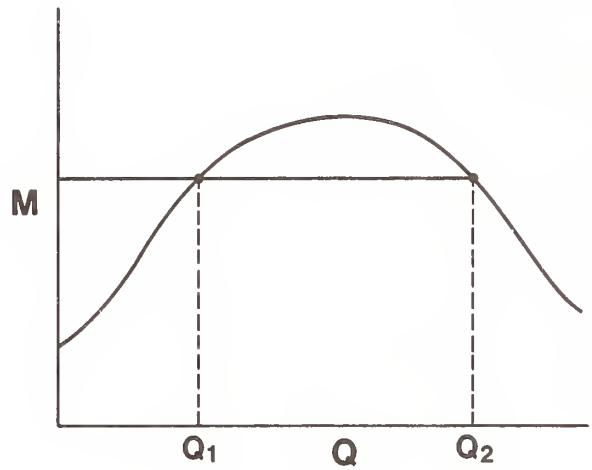

Figure 2. Ambiguous Relationship: Does Measurement (M) Indicate Quantity Q_1 or Q_2?

A measuring process usually is defined by a protocol or standard test method such as an ASTM standard. In addition to sampling error, a realization of a measuring process involves four elements:

(1) The clarity and specificity of the test protocol;

(2) An observer or operator and his or her interpretation of the protocol;

(3) The type, condition, and calibration of the instrument and equipment used;

(4) The environment (temperature, humidity, air polution, air movement, atmosphere pressure, vibration, gravity, intensity and wave-length distribution of illumination, etc.).

Consider a single laboratory and for the moment one operator and one set of test equipment. Over a short period of time the environment will usually remain reasonably constant. Then for a series of samples covering the test range of interest and ignoring sample variability and other sample problems, measurement of the samples will result in a curve relating the measurements to the quantity being measured (Figure 3).

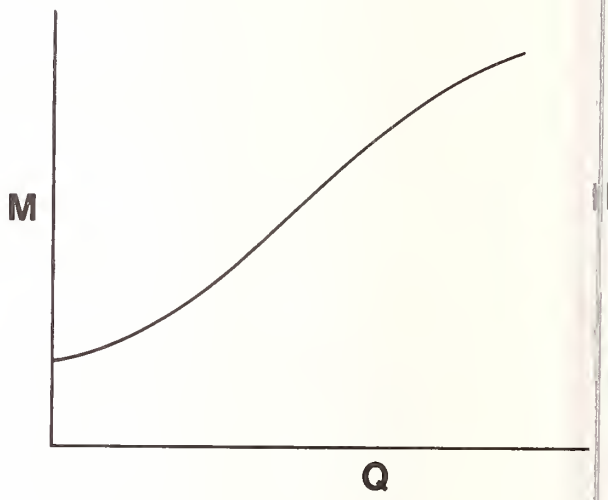

Figure 3. Monotonic Relationship Between Measurement (M) and Quantity (Q)

If a second and a third series of samples identical to the first series are measured in the same laboratory but by different operators, or on different days, or using different sets of equipment, then a family of closely related curves will be obtained (Figure 4).

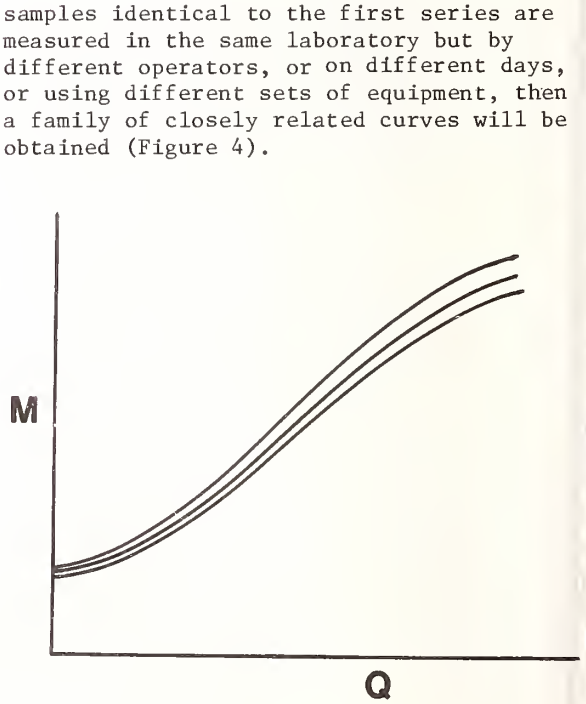

Figure 4. Varying Conditions Within a Laboratory

If similar series of tests are made in a second laboratory, a second family of curves relating measurements to quantity will be obtained (Figure 5).

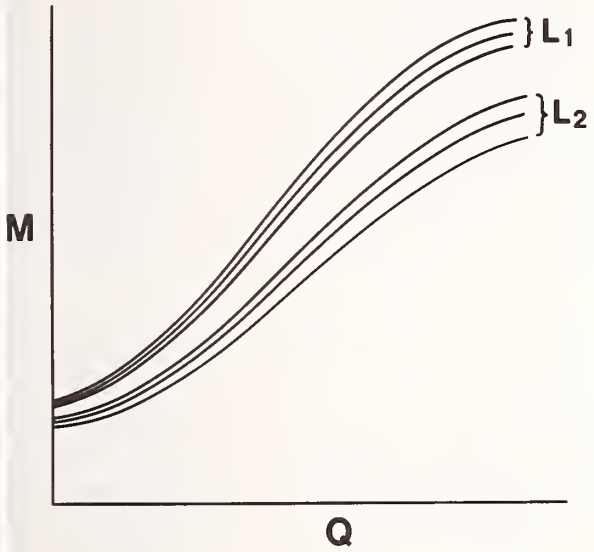

Figure 5. Varying Conditions Within and Between Laboratories

An independent measure of Q may be available in some cases, from the manufacturer of the samples (for example, concentration) or from results obtained by a superior reference method. An alternative approach - and in most cases the only available approach - is to represent the quantity being measured by the average value obtained by a number of laboratories all applying the specified measuring process. By so doing the curves representing each laboratory usually are linearized (Figure 6).

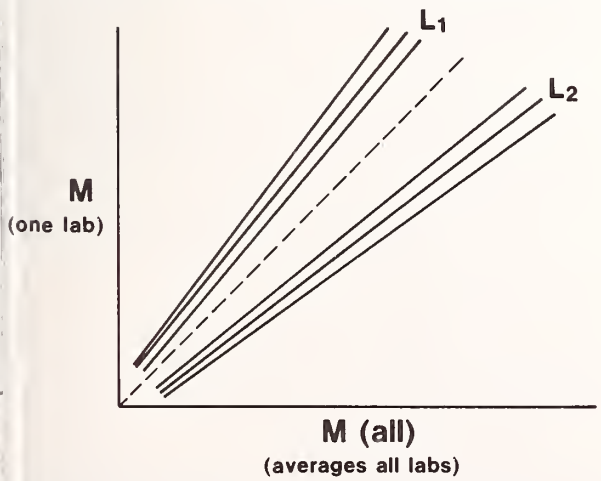

Figure 6. Linearization of Curves When Plotting One Laboratory Against Averages of All Laboratories

If a laboratory's results agree exactly with averages over all laboratories, the laboratory would be represented by a 45° line through the origin (Figure 7A). Generally a laboratory can have a zero error (e.g., for a chemical method, failure to make a blank correction) (Figure 7B), an amplification error (Figure 7C), or both (Figure 7D).

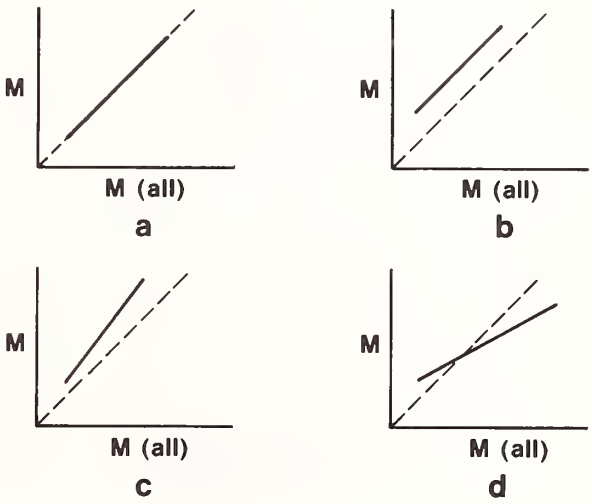

Figure 7. Possible Situations: a) Laboratory Agrees with Averages Over All Laboratories; b) Laboratory Has Zero or Constant Error; c) Laboratory Has Amplification or Proportional Error; and d) Laboratory has Both Errors

This representation of the results of an interlaboratory testing program (or "round robin" as it sometimes is called) is known as the linear model [1, 2, 3][1]. The deviation of the line from 45° through the origin is a systematic error consisting of two components: the zero error and the amplification error.

When the procedure followed by a laboratory differs appreciably from the standard procedure, some non-linearity may be expected. Also, even if approximately linear, serious laboratory-material interaction may occur. What is meant by laboratory-material interaction in the linear model?

[1] Figures in square brackets indicate the literature references at the end of the paper.

When the actual values obtained by a laboratory for several materials are plotted against the average values obtained by many laboratories, the plotted points for the laboratory usually do not fall exactly on the best fitting line for the laboratory (Figure 8).

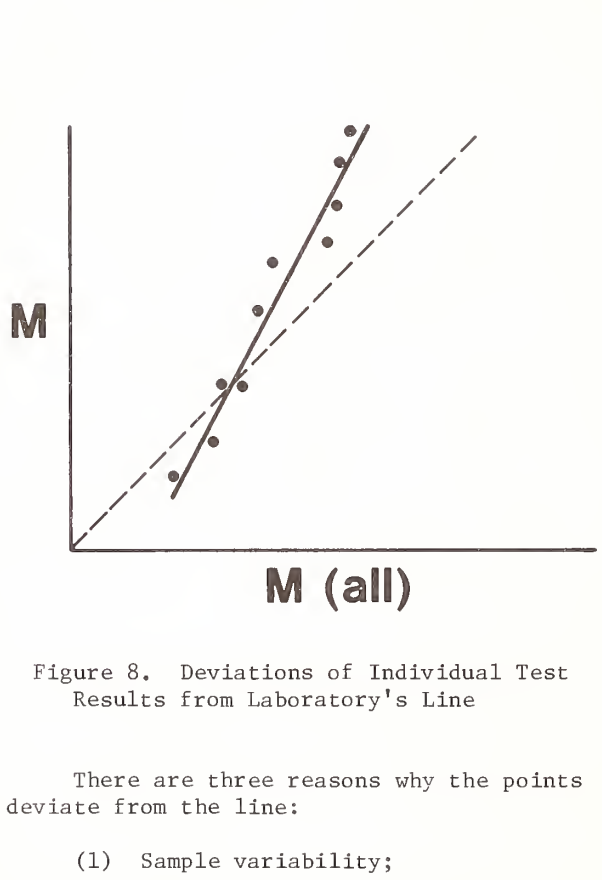

Figure 8. Deviations of Individual Test Results from Laboratory's Line

There are three reasons why the points deviate from the line:

(1) Sample variability;

(2) Moment-to-moment instrument/ environment/operator variability;

(3) Laboratory-material interaction.

The first two of these may be considered random effects and theoretically can be reduced as small as desired by replication (i.e., by replicating the measurements on a series of test pieces and averaging the test observations). However, when this is done, the points often still do not fall on the line because of laboratory-material interaction.

It is easier to give an example of this interaction than to define it precisely. Consider two materials that would give exactly the same test value if a certain interpretation of the test protocol is followed exactly. Also, suppose that the first of these materials is quite sensitive to relative humidity but the second is not. If a laboratory fails to control relative humidity sufficiently close to a required level (perhaps because of its interpretation of the protocol), it could obtain the correc test value (or at least a value close to its line) for the second material but not for the first. It can be said then, that there is an interaction between the sensitivity of the material to relative humidity and the failure of the laboratory to control relativ humidity close enough. The distance of the plotted point from the line for this laboratory and material will remain large no matte how much replication is involved.

No matter how well the test protocol is standardized and how well the laboratories follow the protocol, some laboratory-materia interaction will be present, just as there will almost always be some systematic laboratory error and some random replication error. Standardization does not result in perfection, hopefully it does result in the reduction of these errors to the level where they have no practical significance.

2. Evaluation of Laboratories

In view of the theory of the measuring process, what is it that should be examined in the evaluation of laboratories? Ideally the examination of a laboratory with regard to its capability to perform a specific test method should provide information on its systematic (zero and amplification) errors, its ability to replicate its own measurement and how that varies with test level, its residual or interaction errors for each class of materials, and the likelihood that the laboratory's quality of performance will be maintained. The last is a question of being in statistical control.

For the purpose of laboratory accredita tion, the capability of a laboratory to perform may be examined by three methods:

(1) Information gathering, such as a questionnaire completed by the laboratory and evaluated by experts;

(2) On-site inspection of the laboratory;

(3) Proficiency testing.

As used here a proficiency test is any means by which the actual testing performance of a laboratory is determined.

The capability to perform might be examined exclusively by proficiency testing in the form of a periodic interlaboratory (or round robin) testing program in which a number of materials are distributed simultaneously to each of the laboratories desiring accreditation or continued accreditation. If a sufficient number of materials and replicate test specimens of each material are distributed to each laboratory and this is repeated, say, every few weeks, a very complete picture of the laboratory's performance would be obtained, including information on systematic, random and interaction errors and the stability of the laboratory's performance over a period of time. Unfortunately, such a proficiency testing program is likely to be very expensive both to administer and in testing time for each laboratory.

At the other extreme, in order to assure control over the four elements that enter into each realization of the measuring process, all laboratories that wish to be accredited could be required to have exactly the same equipment, calibrated frequently by the same calibration service. Also, all personnel (testing technicians and supervisors) could be required to have the same training, perhaps in a special course established by the accrediting authority. Even then, it might be necessary to be concerned with environmental factors such as gravity and barometic pressure. Can a laboratory located in Denver obtain the same test results as one located close to sea level? Obviously if all laboratories are using identical equipment and identically trained personnel, it is more likely that they will obtain equivalent test results, with relatively small systematic and interaction errors. Again, unfortunately, such requirements are likely to be expensive and moreover tend to freeze the state-of-the-art.

Between these extremes are various possible combinations and types of requirements, questionnaires, inspections and proficiency testing, the best combination varying with the nature of the test method, the number of laboratories and so forth. For example, with heavy dependence on an extensive questionnaire to determine details concerning a laboratory's personnel, equipment, quality control procedures, adequacy of financing, and so forth, and on a thorough inspection by trained inspectors, a single proficiency test sample might be used. From the information obtained about test equipment and procedures by the questionnaire and inspection, experts should be able to judge the likely performance of the laboratory. The test result obtained by the laboratory in testing the proficiency sample will either verify this judgment or it will not. If not, the result cannot distinguish between a systematic deviation, a random error, an interaction, or a poor sample. A disqualified laboratory will certainly claim the last.

One combination that should work well in many situations includes for each test method:

(1) A small number of pertinent questions about the equipment and its calibration, with the response of the laboratory evaluated by experts. The experts may generate additional questions either for mail response or for the inspection.

(2) A quick inspection to verify the existence of the claimed equipment and calibration records, the general condition of the equipment, and one or two critical dimensions, the last being especially important if equipment design requirements have been changed over the years.

(3) A periodic proficiency test, the size and frequency of which depending on the cost of testing and samples, and the likely stability of the equipment. The proficiency test should include at least two test samples, one each of two very similar but not identical materials. Such a minimal proficiency test provides for each laboratory just one degree of freedom for calculation of systematic plus interaction error and, if the materials are sufficiently similar, approximately one degree of freedom for replication error. This minimum program cannot provide information on how the systematic error varies with test level nor how much interaction error is present.

The above two-sample proficiency test was recommended by Dr. Jack Youden [4, 5] and is used in some of our Collaborative Reference Programs which were established to help a participating laboratory evaluate its performance in comparison with that of other laboratories. The Youden approach has been very successful because of its easily understood graphical presentation (Figure 9) in

which each laboratory is represented by a point on the graph, the point being at the intersection of the coordinates of the laboratory's results for the two samples. As the points for 95% of similar laboratories should fall within the ellipse, the performance of a laboratory with a point appreciably outside the ellipse is very questionable.

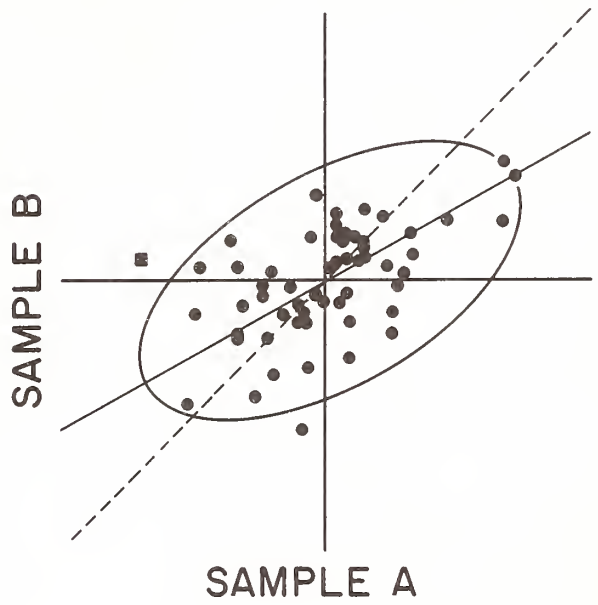

Figure 9. Youden Two-Sample Diagram

What has been presented here is quite simplified compared with the real world of laboratory evaluation, but an understanding of the theory of the measuring process as presented here, or a suitable extension of it for a specific testing situation, is very helpful in the design of appropriate examination procedures for the evaluation of laboratories.

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INTER-LABORATORY ROUND ROBINS FOR DETERMINATION OF ROUTINE PRECISION OF METHODS

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Attention is directed to the importance of determining precision of test methods under routing conditions of use. Comparisons of precision values obtained under very limited conditions have a very narrow range of usefulness. Such "ideal" precision values lead to incorrect use of "checking limits" in attempts to control performance of operators and of laboratories and of statistically invalid rules for retesting, rejection of results, and initiation of third-party referee testing. Measures of precision under routine conditions, both within-laboratory and between-laboratories, are necessary to identify the contribution of the test method to the total variability of measurement in research, manufacturing, and in exchange of materials and goods in commerce.

Key words: Accuracy; between-laboratory precision; components of variance; "duplicity"; ideal conditions; measurement process; "omnifariousness"; precision; round robin; routine conditions; variance model; within-laboratory precision.

1. Introduction

An essential preliminary to the planning of an inter-laboratory round robin is agreement on the uses to be made of the resulting precision information. This is so because there are many suitable models on which design of the round robin may be based. Proper use of the information depends on the components that have been included in the model. If, for example, within-laboratory precision is determined by one operator, using one instrument, making repeated tests on a standard sample within a short period of time, ideal conditions may have been represented, but the result will be of little use in describing agreement of test results when the test method is used in research, manufacturing, or in the exchange of materials in commerce. Precision obtained under ideal conditions has limited, tightly circumscribed uses in the development of test methods, comparison of competing methods, and in evaluating modifications to methods. However, the best possible agreement of results under ideal conditions has little relevance to agreement among measurements in routine use of test methods.

2. Measurement as a Process

The measurement of a property of a material should be looked upon as a process. The major elements in the process are materials, methods, instruments (or reagents), operators, time, environmental conditions, and laboratories.

A variance model is applied to the process. The total variance is made up of components due to the elements which make up the process. The process may be truncated at any point. The model may be as simple as the one representing the ideal conditions

mentioned in the Introduction; a standard sample, tested two or more times by the same operator, using the same instrument over a very short period of time. The resulting precision information is useful only for describing this particular, truncated measurement process. It is not applicable for any comparison with measurements made by other operators using other instruments at different times.

On the other hand, the model may involve all the recognized elements or variables; two or more samples of a material, each tested more than once by each of two or more operators using different instruments (of the same or different design), at different times, under different environmental conditions and in different laboratories. The model may call for omitting any component, or can combine components in any mix. It is extremely important to know exactly what model is used in a round robin program.

The way components are combined determines how precision information may be used to test the reality of observed differences. In practical applications of a test method, we are interested in the total contribution of the measurement process to the apparent variations in observations made on the product. We know that in use of the method operators vary, instruments vary, that materials are not perfectly homogeneous and, perhaps most obviously of all, that it is difficult to repeat results time after time. The extent to which each of these elements does vary in the measurement process must be taken into account.

3. Control of the Elements of the Process

Control is partly in the hands of the planners of the round robin, partly within each of the participating laboratories, and partly in the purview of the laboratories as a group.

In the first instance, the planning group needs assurance that the material distributed for test is as homogeneous as possible. Evidence of this homogeniety may be provided by assurance that the production process was in statistical control. Even with that assurance, samples for test should be distributed at random.

3.1 Operator Control

Operator control is maintained through plotting a control chart for each operator in the laboratory. It is sometimes suggested that this control chart be based on duplicate tests run periodically on routine samples. A control chart for the range of duplicates is kept. The operator is considered to be in control when all ranges ar within the control limits. This gives one measure of operator performance, that is, how well results can be duplicated, on the average, when measurements are made within a very short period of time. One danger is that the results may not be independent. A more serious deficiency in this approach is that, as experience invariably demonstrates the real problems that operators have are with changes that occur in performance of the test over time. These changes are due to differences in set-up and calibration of instruments, changes in reagents, temperature or humidity changes, fluctuations in laboratory services (water, electricity, etc.) or other uncontrolled or unrecognized variables.

Therefore, it is recommended that oper ator control be based on control charts for averages, as well as ranges, of periodic replicate tests on portion of a standard sample. Incidentally, a standard or a spiked sample is also useful in measuring the accuracy of a method. Whereas precisio refers to mutual agreement among repeated measurements, accuracy refers to the agreement of the average of observations with a standard or accepted value. The standard deviation provides an inverse measure on precision; the constant error, or bias, is an approximation of the accuracy.

3.2 Instrument Control

Instrument control is achieved by regular recalibration of instruments and throu development and use of standard curves. Al so, it is possible to follow the success of these activities by maintaining a control chart on the instrument, handled in a way similar to the operator control chart.

3.3 Time Control

The effects of time may be evident in uneven performance by the operator or by an instrument but must also be watched as a phenomenon affecting everything that goes on in the laboratory. Points out of contro on the operator control chart for averages may be due to an operator fault or to some environmental change. The grouping of test replicates and their spacing in time should be based on a rationalization of possible occurrences in the laboratory environment. The control plan must be developed with ful attention to the theory of statistical control.

Experience has shown that in a well-run laboratory, good operator and instrument control are achievable. Time control may be more difficult. It is not possible to tell exactly how much variability is due to operator and instrument unless these components are included in the round robin model. It is often assumed that they are controlled and that their contribution to the total variance is small. The assumption is made that this small variance is due to system causes that are built into the test method at the time it was developed. Smaller operator or instrument variability (after all points out of control have been assigned a cause and the causes removed) would require further developmental work on the method. Round robin models intended to produce information useful in routine application of the method should usually include performance of the method on more than one day, i.e., time should always be one component in the model.

3.4 Inter-laboratory Control

Inter-laboratory control is attained by use of a standard sample testing program or the exchange of samples in a proficiency testing program. Such programs are widely used among laboratories belonging to one organization or an association of organizations. Unfortunately, they do not exist widely among independent laboratories joining together in a round robin with the explicit purpose of measuring precision of test methods.

To an extent, use of a pre-test before running the main round robin will serve the purpose of control. However, control is an ongoing activity and short-term attempts to locate and correct causes of large inter-laboratory differences are only partially, or even only marginally effective. There are no short-cuts to good control.

4. Avoiding the Pitfalls

The shortcoming of the standard material, one operator/instrument, short period of time model is that it results in what W. J. (Jack) Youden dubbed "chemist's duplicity". Such a model usually results in a more optimistic level of precision than when the model calls for independent observations performed on different days. The within-laboratory part of the "duplicity" model is usually accompanied by a between-laboratory part. The between-laboratory part then confounds all differences between operators, instruments, and time with real laboratory differences. This is an "omnifarious" model which leads to an impossible situation when it comes to analyzing the reasons for differences between laboratories.

The "duplicity model" may be useful in comparing one method with another or measuring the effect of a modification of a method. Care must be taken that exactly the same model is applied to both trials. Also, this model may be useful in maintaining the precision of a method (determining whether it has changed), but, again, the model must be strictly followed each time it is checked.

The problem with publishing the ideal precision in a method is that there is an implication that any single pair of results run in any lab at any time should have as good a result. It becomes particularly reprehensible when precision information of this sort, whether expressed as a standard deviation or as a "checking interval" is used to try to control an operator or a laboratory. See Section 3 on control of the elements of a measurement process. At best, these numbers can be used only as a very rough guide as to whether a new operator or a new laboratory is in the general region of precision achieved in good laboratories. Even as a rough guide, the limitations of this model must be recognized.

Unfortunately, when "checking intervals" are presented in a method, users of the method are encouraged, in a completely indefensible way, to use the intervals to call for retesting, for accepting the retest with or without regard for the original result, or for justifying comparative testing programs or the employment of a referee laboratory. None of these things are indicated on the basis of such extenuated evidence.

With so little to recommend the practice of using minimum models, it is hard to explain why more attention has not been given to precision in the routine use of methods.

5. A Useful Routine Precision Model

Prerequisites for a precision model for use in round robin testing include existence of a test method which has gone through a shakedown period in one laboratory, ruggedness testing to demonstrate that it is not sensitive to minor perturbations in test conditions, and which exhibits control within laboratories. It is also desirable that it have been incorporated in an inter-laboratory proficiency testing program.

Because statistical control of the method has not always been recognized as a requirement in all laboratories, it is desirable that a preliminary round or rounds be run to familiarize all participants with the method and to work out any bugs which still exist.

Assuming that attention has been given to such preliminaries, a number of laboratories, not less than six and preferably at least 10 should have agreed to praticipate in the round robin. Homogeneous samples of material must have been obtained and distributed at random among the participating laboratories.

If the method is to be used to test more than one material, a number of different materials should be sampled so that the whole range of use of the test will be represented. Structural differences in materials, interferences of possible contaminants, and other things that could account for a variable response should be considered in selecting the materials. If the test applies to only one material, samples should be supplied at different levels of content of the property to be measured, for example, at different concentrations. Precision may be constant at all levels, may be proportional to the level, or may respond non-linearly (logarithmicly, exponentially, etc.) At least three levels, and preferably more, are necessary to measure curvature.

Assuming that operators and instruments are controlled and their contribution to the total variation in the measurement process is small, a useful model is to have one operator in each laboratory make duplicate determinations on each sample on each of two days. The within-laboratory precision will be made up of components due to the duplicates and due to days. The between-laboratory precision will be made up of the within-laboratory precision plus the component due to laboratories.

At least the within-laboratory and between-laboratory standard deviations should be presented. If for either of the categories of precision, the values are the same (not significantly different) for all materials or for all levels of a material, only a single value need be reported for within- and one for between-laboratory precision. If the standard deviations are proportional to the level, the precision may be reported as the coefficient of variation; the standard deviation divided by the average times 100. If the precision varies with material or level, a table may be prepared grouping materials or levels with the same (not significantly different) precision. If the precision is related to the level curvilinearly, the results may be presented as a curve.

6. Conclusion

The degree of skill employed in planning a round robin is indicated by how well the planner has succeeded in avoiding "duplicity" and "omnifar-ousness". The model should be directly aimed at the purpose to which the precision information is to be put, how and in what environment the test method is to be used. Since standard methods of test are intended for use in all kin of practical situations, it is imperative that inter-laboratory round robins be plann for determination of precision of methods u der routing, not ideal conditions.

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MONSANTO'S ANALYTICAL TESTING PROGRAM

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Recognizing the need to ensure the validity of environmental data, Monsanto has charged its Environmental Analytical Sciences Center (EASC) with ensuring that all analyses for monitoring the environmental effects of its operations are credible. Thus far, the effort has focused on the credibility of the industrial hygiene analyses performed throughout the company. Since round-robin testing programs are an effective tool to demonstrate the validity of analytical measurements, the EASC established a Monsanto Analytical Testing Program. Under this program, modeled after NIOSH's PAT Program, the EASC periodically supplies standard samples of compounds of interest to various company laboratories. Standard samples of materials, unavailable elsewhere, are prepared on sampling substrates commonly employed by Monsanto laboratories.

Two compounds of major interest to Monsanto are acrylonitrile (AN) and styrene monomer (SM). Two methods are employed for workplace monitoring of these compounds. Some sites employ a modification of the standard NIOSH method using charcoal tubes as the sampling medium. In this method the sample is desorbed with a solvent prior to gas chromatographic determination. The remaining sites employ sample collection tubes packed with either Porapak N or Chromosorb 101. In this method the sample is thermally desorbed from the porous polymer tubes and injected directly into a gas chromatograph. Generating standard samples of AN and SM on these two substrates requires different approaches. The charcoal tube standards are generated on a high-flow manifold at collection rates of between 100-1000 cc/minute using a high-rate permeation source. Porous polymer tube samples are generated on a low-flow collection manifold (10-20 cc/min.) using low-rate permeation tube devices.

This paper describes the Monsanto Analytical Testing Program, the standard generation system employed, and the problems encountered in generating known standards. The steps involved in documenting the composition of the standard samples and the results of several round-robin evaluations will also be presented.

Key words: Acrylonitrile; industrial hygiene; proficiency testing; round-robin standards generation.

Good laboratory practices regulations promulgated by the FDA [1][1] and proposed by the EPA [2] will affect the way health effects testing laboratories conduct analyses. The EPA and OSHA have also expressed concern about the quality of data being submitted by environmental and industrial hygiene testing laboratories. GLP regulation, laboratory certification and accreditation schemes have come into being as a result of concerns of these governmental agencies.

Because most of Monsanto's plant laboratories submit industrial hygiene and environmental data to state and Federal agencies, it is important that these data comply with GLP concepts and be based on sound scientific procedures. To assure that its plant laboratories produce data of documented validity, Monsanto began an aggressive good laboratory practice program by establishing a good laboratory practices group in the Environmental Analytical Sciences Center (EASC) at Dayton in January 1978.

The programs established by this group includes:

1. Preparing a manual spelling out the essential elements of Good Laboratory Practices.

2. Encouraging each plant laboratory to prepare a GLP manual which describes their site program.

3. Encouraging a voluntary GLP laboratory audit program.

4. Field validation and audit of automatic continuous area monitors used to analyze plant environments.

5. Helping plant laboratories work towards American Industrial Hygiene Association accreditation. The ultimate goal is to have one plant lab accredited in each of the five Monsanto operating companies (two have AIHA accreditation at this time).

6. Setting up a standards preparation laboratory which tailors standards to specific needs of Monsanto plants.

7. Interlaboratory proficiency testing of plant labs by holding round-robin test of compounds of interest to Monsanto. This program has been dubbed the Monsanto Analytical Testing (MAT) program, and is modeled after the National Institute of Occupational Safety and Health's Proficiency in Analytical Testing (PAT) program.

1. The MAT Program

One of the minor elements of a comprehensive GLP program is laboratory participation in round-robin studies. However, the majority of round-robin studies available are not applicable to Monsanto Company laboratories. That is, the types of contaminants, samples matrices and sampling substrates available are not relevant to the majority of analyses encountered by Monsanto environmental laboratories. To fill this special need, the EASC established a standards generation facility. The mission of the facility is to prepare environmental standards that are pertinent to the analyses commonly performed within the company.

Participation in the program is completely voluntary. Results are reported in a coded format to ensure anonymity. All supporting data relating to the homogeneity and stability of the standard samples is reported to participating laboratories with the results of the study. The philosophy of result reporting is one of supplying the laboratories with sufficient data to enable them to make a judgement about their laboratory's performance rather than grading or ranking laboratories.

To date the effort has focused on the credibility of the industrial hygiene analyses performed throughout the company. Two compounds of major interest to Monsanto are acrylonitrile (AN) and styrene (SM). Both of these compounds are monitored intensively at various plants throughout the company. Some laboratories may analyze up to 100 samples per month. It is thus important to demonstrate the validity of these analyses, not only from the viewpoint of worker safety, but also to provide a measure of data validity since decisions concerning plant operating procedures are sometimes based upon industrial hygiene measurements.

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[1]Figures in brackets indicate the literature references at the end of the paper.

Within Monsanto, two distinct methods are employed for workplace monitoring of AN. Some sites employ a modification of the standard NIOSH method using charcoal tubes as the sampling medium. Other sites employ sample collection tubes packed with either Porapak N or Chromosorb 101. The charcoal tube method samples a larger volume (≈20 L) of air and employs solvent desorption (usually 2% acetone in CS_2). The porous polymer tube method samples a much smaller volume of air (∿3 L) and employs thermal desorption of the sample directly into a chromatograph. Sampling an atmosphere of 2 ppm AN, which is the threshold limit value (TLV), the charcoal and the porous polymer tube methods collect about 86 and 13 µg of AN, respectively.

2. Generation of Standard Samples Containing Acrylonitrile

Standard samples are prepared by drawing a known volume of a dynamically generated atmosphere of AN through the sampling tubes. The AN atmosphere is generated with a Kin-Tek Precision Calibration System equipped with a permeation source. Pure air is supplied with an Aadco Model 737 pure air generator. The AN contaminated air stream moves from the permeation device and is diluted with additional air before it passes through a glass mixing chamber to a multiport glass manifold. (See Figure 1). The diluted air stream is drawn through sampling tubes attached to the glass manifold by a sampling plenum. The sampling plenums were constructed in a similar manner to those used by the National Bureau of Standards [3].

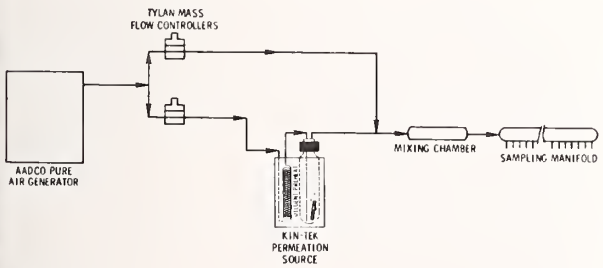

Figure 1. Schematic of Standards Generation System

In the case of charcoal tube samples, the sampling plenum consists of three sets of flow limiting orifices (hypodermic needles). Four matched orifices comprise each set. The orifices within each set were selected such that the individual flowrates do not vary by more than ±2% from the set averages. The average flowrates of the three sets of orifices are 0.933, 0.440 and 0.110 L/min. Using this apparatus (Figure 2), three different loadings of AN on the charcoal tubes can be obtained simultaneously. For this study, the desired amounts of AN loaded onto the sample tubes are approximately 11, 43, and 90 µg of AN; simulating the amounts that would be collected from 20 L of air containing approximately 0.2, 1.0 and 2 ppm of AN respectively.

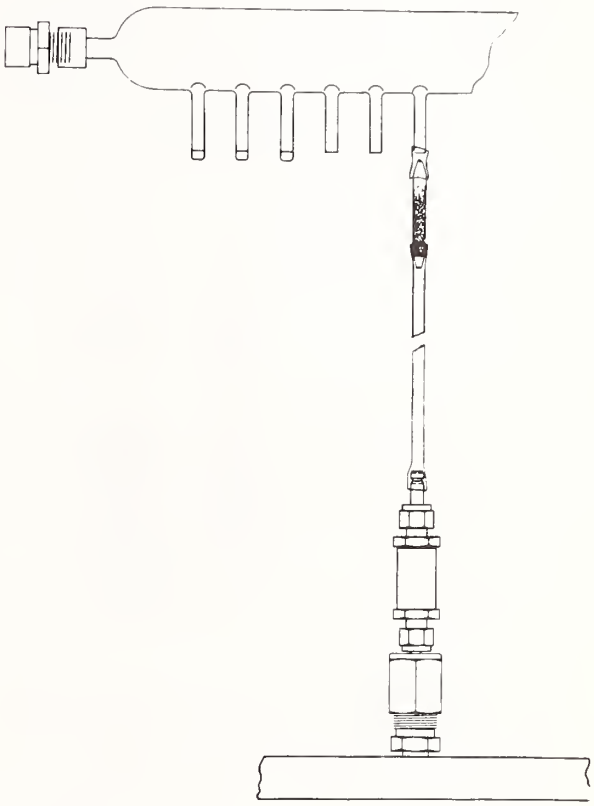

Figure 2. Charcoal Tube Sampling Plentum (one orifice assembly shown)

For porous polymer tube samples, the sampling plenum (Figure 3) consists of twenty flow-limiting orifices (33 gage hypodermic needles) carefully selected to provide flowrates of within ±1.5% of one another. Figure 4 shows the construction of an individual orifice assembly. The average flowrate of these matched orifices is 12.28 mL/min.

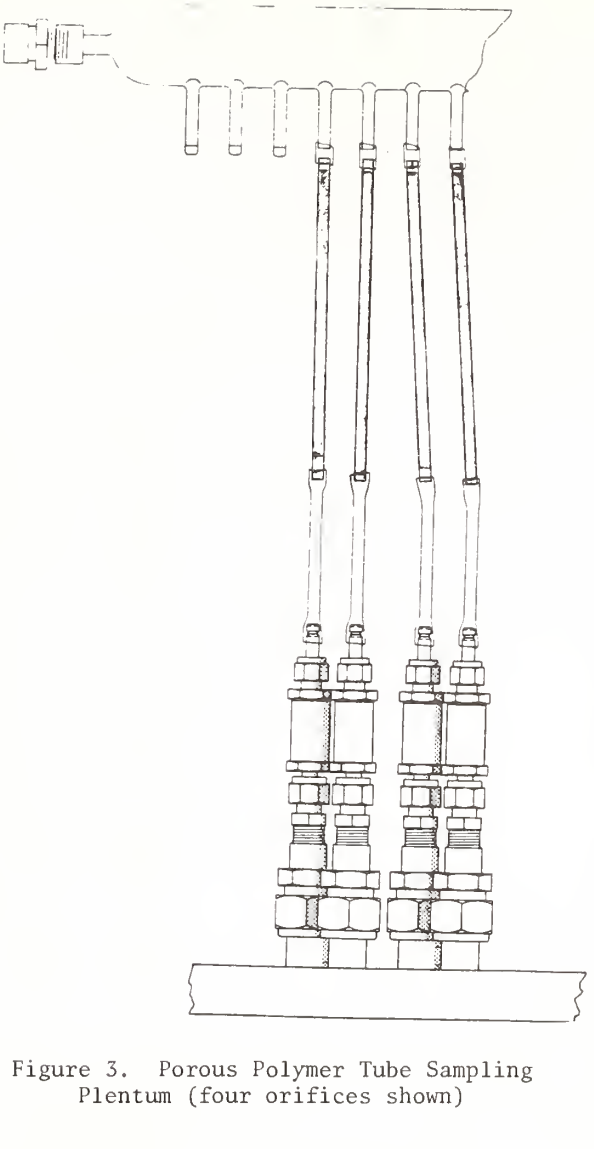

Figure 3. Porous Polymer Tube Sampling Plentum (four orifices shown)

A lower flowrate is required for polymer tube samples since the pressure drop across the packed tube increases dramatically with increasing flowrate. At a flowrate of less than approximately 35 mL/min the pressure drop across a tube becomes negligible in comparison to the pressure drop across the orifice. A constant flowrate is obtained regardless of the flow characteristics of the sample tube. Varying amounts of AN are deposited on the tubes by varying the collection time. Usually, the collection time is adjusted to obtain either 6 or 13 µg of AN, simulating the amounts that would be collected from 3 L of air containing approximately 1.0 or 2.0 ppm of AN, respectively.

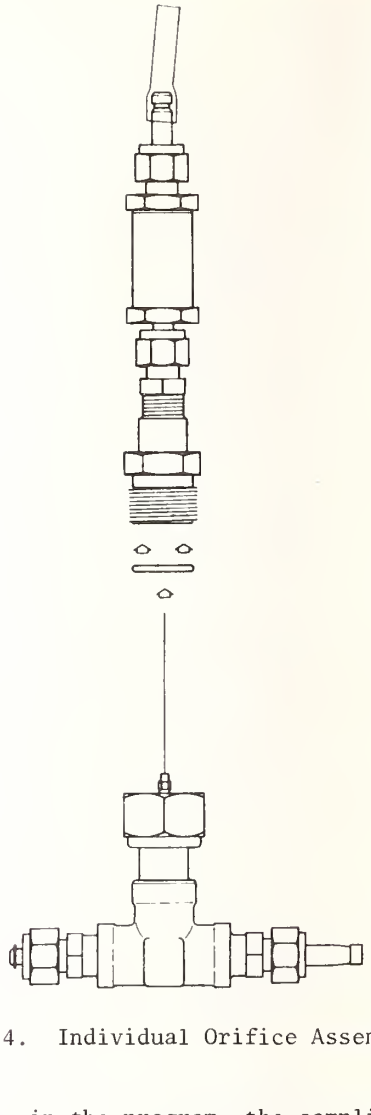

Figure 4. Individual Orifice Assembly

Early in the program, the sampling plenum was constructed with fine metering valves in place of hypodermic needle orifices. This configuration was abandoned because the metering valves were found to require periodic calibration and readjustment in order to maintain a set flowrate variability of not greater than ±2%. However, this type of apparatus will hold its calibration for several days and was used to produce the first set of porous polymer tube samples used in MAT Round 1.

3. Standard Generation Protocol

Before standard samples can be employed in a round-robin study, an assessment of sample integrity must be undertaken. EASC uses the following general protocol to ensure the production of acceptable standards:

A. Determine the precision and accuracy of the analytical technique employed for sample quality control. This determination is made at each contaminant level.

B. Determine the reproducibility of the generated standards by producing and analyzing several sets of standards at the desired loading levels. If possible, verify the accuracy of the generated standards by using an independent method(s) or standard(s) to determine the contaminant loadings. Ideally, the independent method(s) or standard(s) should have clear traceability to the National Bureau of Standards. If no independent method or standard is available, have a set of standards analyzed by a different laboratory to verify loadings.

C. Determine the stability of the generated standard over at least a two week period. Ideally, the standard should be stable at room temperature for at least two weeks. However, in some cases, sample preservation steps (e.g., refrigeration) may be necessary.

D. Based upon the observed contaminant loadings obtained in step B and/or C, calculate the average observed loading at the 99% confidence level.

4. Results of the Acrylonitrile Round-Robin Studies

Two AN round-robin studies have been completed. Six laboratories participated in the AN on Porapak N study. Ten laboratories were involved in the AN on charcoal round-robin. While the majority of participants were Monsanto Company Laboratories, four laboratories outside of the company participated in the charcoal tube study. In both studies, each laboratory received three samples and a blank. Two of the samples were identical, simulating samples contaminated to the action level (one-half the TLV level). The third sample simulated a sample contaminated to the TLV level. The duplicate loadings were submitted to serve as a rough check on intralaboratory precision. The results of the two studies are given in Tables 1 and 2. For both studies, the data indicate individual laboratories have a good degree of intralaboratory precision. The average relative deviation from the average of the two identical samples was 1.5% for the Porapak N round-robin participants and 2.2% for the charcoal round-robin participants.

The interlaboratory agreement was not as good. Laboratories in the Porapak N study had relative standard deviation of 19.3% and 17% for samples similating the action and TLV levels, respectively. Laboratories participating in the charcoal study displayed a slightly larger standard deviation of 24.5% and 25.4% for samples representing the Action and TLV levels, respectively.

The theoretical and average observed loadings of the sample tubes for each study can also be found in Tables 1 and 2. Since EASC's standard generation facility has just completed modifications to permit the independent verification of the contaminant loadings, these values were supplied to MAT 1 and 2 participants as an estimate of the sample loadings. Future round-robin samples will have a more definitive number attached to them. This will be accomplished by analyzing the contaminant air stream as the samples are being prepared.

References

[1] Nonclinical Laboratory Studies, Good Laboratory Practices Regulations, Federal Register, Vol. 43, No. 247, December 22, 1978.

[2] Good Laboratory Practice Standards for Health Effects, Federal Register, Vol. 44, No. 91, May 9, 1979.

[3] Cadoff, B. C., Hughes, E. E., Alverez, R., and Taylor, J. K., Preparation of Charcoal Sampling Tubes Containing Known Quantities of Adsorbed Solvents, National Bureau of Standards, Department of Commerce, Report Number NBSIR, 74-530, July 1974.

Table 1. Participant's Results, MAT Round 1
Acrylonitrile on Porapak N Tubes

AN Reported, µg

Laboratory	Sample X	Sample Y	Sample Z	Blank
1	6.69	6.51	13.19	0.01
2	5.75	6.0	12.25	0.08
3	4.4	4.2	8.9	0
4	1.675*	4.854	10.46	0.027
5	4.33	4.45	9.37	0.01
6	6.68	6.61	13.36	0.00

$\overline{X}_{(x\&y)} = 5.50$ $\overline{X}_{(z)} = 11.2$

$\sigma = 1.06$ $\sigma = 1.9$

rel. σ = 19.3% rel. σ = 17%

Summary of supporting information for samples:

	X&Y	Z
Theoretical loading (µg)	6.94	13.74
EASC average observed loading (µg)	5.92±0.34†	11.26±1.34†

†99% confidence interval based on the analysis of 9 tubes
*data point omitted from calculation of mean; rejection based on Q test at 90% confidence level

Table 2. Participant's Results, MAT Round 2
Acrylonitrile on Charcoal Tubes

AN Reported, µg

Laboratory	Sample X	Sample Y	Sample Z	Blank
1	26.62	26.39	62.15	00.00
2	35.1	35.8	82.4	0.4
3	40	40	95	ND
4	29	27	63	
5	35.5	42.9	79.3	ND
6	31.6	31.5	77.5	0.0
7	39.0	39.8	89.6	000
8	50.3	48.5	110.0	0.0
9	33.5	33.6	78.0	ND
10	18.22	20.04	38.71	00.00

$\overline{X}_{(x\&y)} = 34.22$ $\overline{X}_{(z)} = 77.57$

$\sigma = 8.38$ $\sigma = 19.68$

rel. σ = 24.5% rel. σ = 25.4%

Summary of supporting information for samples:

	X&Y	Z
Theoretical loading (µg)	43.36	99.91
EASC average observed loading (µg)	40.71±0.88*	98.14±1.18*

ND - not detected
*99% confidence interval based on analysis of 24 tubes

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LABORATORY EVALUATION TECHNIQUES - US ARMY CALIBRATION PROGRAM

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The US Army utilizes three principal techniques in the evaluation of its calibration laboratories: Technical Measurement Audits, Technical Inspections and Certification of Technicians. Each major calibration laboratory is subject to each of the above techniques or a combination thereof contingent upon its mission and location within the Department of Army logistical complex. Each of the techniques is administered or managed by the US Army Metrology and Calibration Center (USAMCC) at Redstone Arsenal, Alabama.

Technical Measurement Audits are objective in nature while Technical Inspections and Certification of Technicians rely heavily on subjective considerations. The combination establishes a comprehensive quality assurance program for calibration.

Key words: Audit; calibration; calibration laboratory; certification; evaluation; inspection.

1. Introduction

US Army calibration laboratories are operated in accordance with regulatory requirements and technical guidance provided from higher echelon activities. The regulatory requirements and technical guidance assure, in theory, that the calibration laboratories perform at a level sufficient to meet mission requirements. In practice, adherence to regulatory requirements and/or higher echelon technical guidance does not in itself assure quality performance. Additionally, laboratory personnel are always subject to ignore the requirements and guidance. In order to assure satisfactory performance, the US Army periodically evaluates its laboratories, utilizing principally three different techniques: Technical Measurement Audits, Technical Inspections, and Certification of Technicians. The techniques employed are used to confirm that the laboratories are capable of and perform at a level sufficient to fulfill mission requirements.

There is no attempt to use any of the aforementioned techniques to rank or rate the laboratories against one another. The primary intent is to confirm performance at a predetermined level. It constitutes a pass-fail evaluation.

The primary responsibility for the establishment, performance, and/or monitoring of the evaluation processes rests with the US Army Metrology and Calibration Center (USAMCC) at Redstone Arsenal, Alabama. The USAMCC is tasked with program management and technical guidance for the total US Army Calibration System. The evaluations serve as the means to determine the effectiveness of the program management and the validity of the technical guidance.

2. Technical Measurement Audits

In essence, a Technical Measurement Audit is a "hands on" performance test of a calibration laboratory's ability to provide

precision measurements. Unless problems are encountered, audits are conducted entirely via mail. The USAMCC provides a primary or reference lab standard, with the certified value unknown to the audited laboratory, to the audited laboratory for calibration. The value measured by the laboratory is then compared to the primary certified value of the standard. The emphasis is on the accuracy and precision of measurement. Management and administrative practices are of peripheral concern only.

Parameters currently maintained in the audit program are: DC Voltage, AC Voltage, Resistance, Capacitance, Attenuation, VSWR, Microwave Power, Absolute Pressure, Gage Pressure, Length, and Mass. The standards for the various parameters are supported by the US Army Standards Laboratory (ASL), the Army's primary level calibration laboratory, located at the USAMCC. There are no rigid intervals of calibration. The audit standards are calibrated as deemed necessary.

Each audit package is composed of no more than one DC and low frequency, one microwave and one physical parameter. (For the remainder of this paper, audit package refers to the hardware-audit primary or secondary reference standards; and accompanying forms and instructions shipped to the audited facilities.) The audit packages are tailored to the capability of the audited facility. Upon receipt of the package, each facility is allowed ten working days to perform the measurements at the points specified and place the audit package and report of measurement in the mail to the USAMCC. The report of measurements must include all raw data, manner of reduction (computations), calibration procedure (to include traceability of laboratory standards) and name of the technician peforming the audit.

Upon receipt of the report of measurement at the USAMCC, an analysis of the results is performed. The analysis addresses the absolute difference between the mean value of the standard as measured by the audited laboratory and the certified value as provided by the ASL, and statistically measures the dispersion (standard deviation) about the mean value provided by the audited laboratory. If both the mean value and standard deviation are judged acceptable and the administrative requirements of the audit have been met, the audited laboratory is notified by letter and no further action is taken. Because US Army laboratories utilize US Army Technical Bulletins describing step by step calibration procedures, little effort is expended toward analysis of the procedure unless unsatisfactory results ar obtained.

In the event that an audited laboratory's results are unsatisfactory (either mean value or standard deviation), that laboratory will be required to cease suppo in the affected parameter or downgrade the capability until the source of error is lo cated and the conditions surrounding that error rectified. Initial effort, (joint b tween the facility and the USAMCC) as a re sultant of unsatisfactory performance, is directed toward cross checking of the audi facility's standards within house, recompu tation of data, recertification of audit standards and confirmation that the proper procedure was followed in total. In genera the initial effort locates the source of problem. If the problem cannot be isolate to drift in a standard (audit or laboratory standard), computational error, or error o omission in the procedure, then the effort to locate the problem is expanded to inclu examination of the technical correctness o the procedure, actual capability of the lab oratory's standards, training of the techni cian, competence of the technician or satis factory support of the laboratory's standar by the supporting activity. Concurrent wit the attempt to isolate the problem, the audited activity must analyze potential im pact upon supported items caused by such unsatisfactory measurements. Corrective action is taken as required to assure validity of calibration of supported equipment.

Subsequent to the location of cause of the problem, a reaudit utilizing different serial numbered audit standards is conducte to confirm alleviation of the problem. Rea sons for past failures in the audit "run th full gamut". Although rare, the reason for failure in an audit is sometimes never ascertained. Extensive investigation leads t no conclusions. If a reaudit is then performed satisfactorily, the laboratory resumes full operations.

Upon conclusion of an audit, the commander of the installation at which the lab oratory is located is provided a report by letter from the USAMCC. The report provide quantitative results (difference, standard deviation), a finding of AGREEMENT/NO AGREE MENT (satisfactory or unsatisfactory) for each parameter audited, complete discussion (to include corrective action) or any problems encountered and comments concerning a facility's ability to react to and rectify problems in the event of a NO AGREEMENT finding.

Every effort is made to convince laboratory personnel that audits are for their benefit as well as a test of their ability. Excluding computational errors as a source of failure, there have probably been as many failures due to conditions external to the audited laboratory's control as there have been directly attributable to the audited laboratory. When personnel view the audit in this manner and perform it as routinely as a normal calibration then the results truly reflect the ability of that laboratory to meet its mission requirements. In reality, because of potential consequences of a failure, a significant number of laboratories over-emphasize the audit by utilizing only certain technicians, increasing the number of measurements, utilizing multiple methods and increasing time spent. While an audit in this instance can check standards, procedure, certain personnel, etc., it does not verify the everyday quality of the laboratory.

Technical measurement audits are conducted quarterly at eleven Army Area Calibration Laboratories (responsible for geographical area support), semiannually at twenty-three Army Internal Calibration Laboratories (responsible for single installation support) and annually at the NATS Supply Center, Luxembourg (as a courtesy).

3. Technical Inspections

Technical inspections are on-site inspections of installation calibration programs. They differ from audits in their scope and the fact that they encompass laboratory customers as well as the laboratory. While audits are based almost exclusively on quantitative or objective judgments, inspections require a significant degree of subjective evaluation.

The USAMCC conducts technical inspections annually at the ASL, six Continental US (CONUS) Area Calibration Laboratories, twenty-five CONUS Internal Calibration Facilities, approximately one-third of the fifty-two Transfer Teams in CONUS, and contractor facilities as the need arises. In addition, the USAMCC has been tasked to expand the Technical Inspections to include calibration activities in Europe and the Pacific Theater.

Each inspection team is composed of one civilian team chief and two to four civilian and/or military team members. Technical (hardware) expertise is usually provided by Senior NCO's. Inspections require from three to five days each, dependent upon size of the installation to be inspected. Transfer teams, as small mobile operations, are generally inspected in one to two days by two Senior NCO's.

Technical inspections address two principal areas: (1) The capability of the installation or activity to accomplish its assigned calibration mission to include the availability of technical skills, technical information, measurement methods and accuracy of measurements, and (2) Compliance with prescribed policies and procedures. Specifically the inspection team reviews: (1) Administrative and management practices, (2) Availability, maintenance and use of current, approved calibration procedures, (3) Control of forms, records, reports and applicable procedures, (4) The internal quality assurance surveillance program, (5) Control, maintenance and operation of the calibration recall system, (6) Environmental and safety controls, (7) Knowledge of and compliances with appropriate references, (8) Training program, (9) Maintenance practices, and (10) Technical capability of calibration technicians in the maintenance and use of measurement standards, use of hand tools, use of calibration procedures, and performance of calibration.

The most time consuming facet of the technical inspections (other than time required visiting customer/owner areas) is the review of the technical capability of the calibration technicians. This is accomplished through "end-item checks." Calibration technicians perform a "hands on" calibration for validity of calibration of an item recently calibrated while an inspection team member observes the performance "over the shoulder." Such a check encompasses many of the ten specific areas of review listed previously, i.e., use of approved calibration procedures, use of proper forms, observance of proper safety practices, etc. as well as the technical capability of expertise of the technician.

Inspection findings are divided into two categories: Deficiencies and Observations. Deficiencies are shortcomings that affect the technical capability of the laboratory, safety or health hazard or conditions that if allowed to continue would lead to technical problems or health or safety hazards. Observations indicate conditions that are contrary to prescribed regulations and policy or good management practice but would not be of sufficient impact as to be classified a deficiency. As the findings are made during the inspection, every effort is made by the inspection team to assist in alleviating the shortfall or initiating requisite action.

Selected activities receive an overall rating of satisfactory or unsatisfactory at the conclusion of the inspection based upon severity of observations and deficiencies. An unsatisfactory rating may be the basis for discontinuing calibration operations until the adverse conditions are corrected. Satisfactory ratings may be accomplished by directed corrective action, while unsatisfactory ratings necessitate a reinspection.

An unsatisfactory rating may be given when any of the following adverse conditions are noted: (1) An invalid calibration of a measurement system, (2) A safety or health hazard, (3) Damage to measurement standards, TMDE or property, (4) An adverse impact on the combat effectiveness of a weapon system or tactical organization due to calibration support, (5) Invalid calibration of a critical nuclear weapons TMDE, (6) Calibration of TMDE or measurement standards when not in the prescribed environment, and (7) Loss of traceability to national standards.

At the conclusion of the inspection, the commander of the installation or activity is informed of the findings. Upon return to the USAMCC, the inspection team prepares and forwards a comprehensive report, including required corrective action when appropriate, to the installation commander. The commander in turn outlines corrective action taken or to be taken. The next inspection will confirm whether or not the corrective action was accomplished.

4. Certification of Technicians

Certification of technicians is a relatively new program and is currently restricted in its application. Calibration technicians are encouraged to voluntarily enroll in a skill certification program consisting of a combination written and "hands on" performance examination to verify their skills.

Each participating installation is responsible for developing and maintaining a plan for certifying its calibration technicians. The installation in a joint effort with the USAMCC establishes a set of standards that are definitive and contain the essential elements in sufficient detail to adequately evaluate the individual technician's performance.

The standards stress three basic aspects: (1) Core knowledge, (2) Speciality knowledge, and (3) Demonstrated ability. Core knowledge addresses the basic skills and knowledge necessary to perform in a functional area, i.e., interpretation of drawings and schmatics, use of basic test equipment, etc. Specialty knowledge refer to the specialized skills and knowledge necessary to perform duties as stated in t job description. Demonstrated ability is the "hands on" application of core and spe cialized knowledge.

The actual evaluation for certificati consists of a written examination (prepare by the USAMCC) encompassing both core and specialized knowledge, a "hands on" profic ency examination administered by a compete individual or individuals and an experienc profile that clearly identified and compar a technician's actual experience and train ing with the program requirements. The re sults of the evaluation are reviewed by th installation's Certification Review Commit tee who in turn recommend: (1) Approval o certification of the technician, (2) Furth development and training of the technician or (3) Withdrawal/reinstatement of the cer fication of the technician.

Current policy dictates a three year interval for recertification of a technici who routinely performs within the area for which certification was awarded. If the technician is reassigned to another area o does not routinely perform in that area, then a two year interval is invoked.

5. Summary

The laboratory evaluation techniques described above provide a comprehensive examination of the ability of US Army Calibration Laboratories to fulfill their mission requirements. Implementation of the techniques requires considerable managerial or program, and technical expertise and a degree of common sense. The techniques, if employed conscientiously will confirm the ability/inability of an army laboratory to perform satisfactorily. To this author's knowledge, utilization of a combination of the above techniques has not failed to vali date the status (satisfactory or unsatisfac tory) of a calibration program correctly. The techniques are sound. The effectivenes of the program, as with any quality assurance program, rests with management's abili ty or desire to correct detected shortcomings.

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THE VALUE OF SPLIT SAMPLE PROGRAMS FOR CONTRACTUAL ACCEPTANCE OF IN-HOUSE LABORATORY PROCEDURES

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Because coal is heterogeneous, special procedures are necessary for the determination of the quality. Commercially, the amount of coal to be sampled in a year for a contract may be a million tons. Both the seller and the buyer need a proven system for contractual acceptance of the determined quality. The necessity for including both the automatic sampler and the laboratory in such a system is discussed and the resulting split sample program is shown to be a natural development. The program serves the primary purpose of determining the quality but it also serves as a continuous evaluating system of the in-house laboratory procedures.

Key words: Heterogeneous; in-house; laboratory; preparation; riffle; sample; standards.

1. Introduction

Almost every news report refers to coal as America's "Energy Ace in the hole." This major energy source is used primarily as a fuel for the generation of electricity. In recent years, the advancements made in increasing efficiencies in utilizing this fuel have been, in part, due to the construction of larger steam generating stations. To supply such users the increased tonnage necessary, more efficient coal handling methods, also, have been developed. Unit trains with dedicated equipment hauling as much as ten thousand tons are common. The mines have installed facilities for rapid loading of these trains, often loading at the rate of five thousand tons per hour. The generating stations have installed facilities for rapid unloading of these trains and some installations can unload such a ten thousand ton train in less than an hour.

But coal is a most heterogeneous fuel and special attention and special equipment is necessary for the correct sampling. Contracts requiring the delivery of a million tons a year are common and these contracts usually include a premium/penalty quality clause guarantee. For such a clause to be meaningful, both sampling equipment operation and the laboratory procedures must have contractual acceptance by both the supplier and user. The split sample program with in-house laboratory analyzing is one satisfactory and successful solution. It is also a most exacting and demanding program.

2. Sampling System

It is preferable that coal be weighed and sampled at the same point in time. If there is a lapse in time between these two events, consideration should be given by both the purchaser and seller to changes in moisture during this interval and the consequent shift in relationship of moisture to the true quality of the coal at the instant when ownership of the coal transfered from one to the other [1]. The standard operating condition is for the train to be weighed at the loading site, therefore it is preferable for the sampling to be done at the loading site.

The specifications for such a sampling system are normally those that meet the A.S.T.M. Standards D-2013, "Preparing coal samples for analysis" [2] and D-2234, "Collection of a gross sample of coal" [3]. It is not unusual for the specifications to be such that even more increments are taken than are required to meet these standards. The design may require as many as three or four sample cutters in series. This is necessitated by the large primary increment. At a 5000 tons per hour loading rate for 3" x 0 coal, the primary increment can be as much as thirty-three (33) tons per hour. A typical three stage sampler is shown in Figure 1. Such a sampling system with associated conveyors, feeders, crushers, etc. is a large material handling installation and is expensive.

2.1 Sampling System Example

If a coal handling installation sampling 3" x 0 washed coal loading at the rate of 5000 tons per hour is used as an example, what are some of the basic components? Such an installation requires a primary cutter with an opening of 9-inches to travel at the rate of 18-inches per second at 75-second intervals. Each increment is 1400 pounds. This is thirty-three tons per hour.

A large feeder discharges this coal increment to a secondary cutter, also with an opening of 9-inches. This will divide the initial increment to about 5000 pounds per hour.

This secondary sampler product is then crushed to a top size of number 8 standard sieve size. The crusher product is fed to a tertiary sampler with an opening of 1¼-inches. Even with three sample cutters operating in series, the tertiary product can be as much as 30 kilograms per hour.

3. Sample Preparation

The final amount of product from the automatic sampler is too much for the laboratory and the amount is divided, with enclosed rifflers, until the desired sample of about 1000 g is available [4]. There are usually at least three such samples retained: one is for the seller, one is for the purchaser, and one is retained as a referee sample. Each of these is immediately sealed in a heavy vapor-impervious bag and properly identified.

4. Sample Handling

Prompt movement of the split samples of coal to the laboratories is important. Although the coal sample is sealed in a heavy vapor-impervious bag, it is essential that the sample be analyzed as soon as possible because deterioration is a problem. At one time, A.S.T.M. Standards referred to deterioration of coal samples and warned of time elapse not to exceed 30 days [5]. This has since been removed from the standards becau such a definite time implied and was often assumed that the deterioration was not serious for these 30 days.

5. Sampling System Acceptance

The acceptance of an automatic samplin system is equally important to both the sel and the buyer. Both recognize the apprecia economic importance of its use. Both are d pendent on it for a representative sample. It must function as designed and installed. It must be able to sample a whole consignme at approved intervals. It must function in manner that the increments and the resultin samples are free of contamination. It must be dependable as an operating piece of equi ment.

It is important to the seller because the quality of the product must be known be fore it can be offered in the market place. It is important to the purchaser because th quality of the product will be based on the split sample. Improper operation can resul in a bias sample and only extensive manual sampling may determine the effect on the sa ple. Contracts include specific statements allowing for observation and inspection.

Such a method for procuring a split sample then becomes a contractual accepted procedure.

6. Analytical Procedures

The analytical procedures followed by the laboratories determining the quality fo contractual acceptance are those included i the contract. The contract may state simpl "All sampling and testing will be in accordance with current applicable A.S.T.M. Stan dards [6] or it may detail specific conditions that must be considered as critical f analyzing for full compliance. Other recog nized standards, such as Bureau of Mines an International Organization for Standardization, are also designated as applicable.

The parameters considered important fo the particular coal's use are included in t contract and these are checked by the labor tories. The results are empirical and are reproducible by carefully adhering to definite prescribed methods and standards [7].

Laboratories testing the same coal sample but using different standards may report results that do not agree. Such differences are not to be interpreted as a fact that one laboratory is reporting incorrect results. Each can be correct for the method and standard used. Such differences, however, are expected to be constant. Such possible differences are the reasons the standard to be used must be included in the contract.

7. Laboratory Acceptance

The criteria for acceptance of any laboratory as reputable is difficult to define free of ambiguities. The personnel must be trained and experienced. The equipment for the tests must be available and calibrated. Precision and accuracy, both, must be expected. These are obvious and no laboratory would be expected to be accepted without such. Then what criteria are recognized as establishing contractual acceptance of in-house laboratory procedures when the split sample program is used?

7.1 Representative Sample

The split sample is the sample representing the whole consignment. It is the sample taken by the automatic sampler. It is the sample that is divided without human choice in its division. It is the proper size and amount for the laboratory.

7.2 Sample Preparation

The split sample will be prepared in an identical manner for each consignment.

7.3 Routine Testing

The number of such samples supplied to each of the two in-house laboratories each year is large. If the average train weight is 10,000 tons, then one hundred samples can be expected for a million ton a year contract. Each sample, then, is handled and tested according to the standards in a routine manner.

7.4 Continuous Checking

As the number of samples in the program increases, the statistical variations permitted will be predictable. Each laboratory's results will serve as a constant check on the performance of the other laboratory.

7.5 Continuous Cross-check

Few sellers supply coal to but one buyer and few buyers receive coal from but one seller. It follows then that there is a constant cross-checking of in-house laboratory performance and procedures with the split sample program.

7.6 Criteria for Accreditation

Such is the criteria for contractual acceptance of in-house laboratory procedures. It can be considered as volunteer laboratory accreditation by contractual compliance.

8. Precautions for a Successful Split Sample Program

8.1 Sampler Agreement

The automatic sampling system's specifications and design should be agreed upon as acceptable by both the coal buyer and the coal seller. Its operation will meet such specifications.

8.2 Handling Agreement

The sample preparation and handling of the product from the automatic sampler will be under the supervision of trained personnel and will be performed according to standards agreed upon by both the coal supplier and coal buyer.

8.3 Sample Delivery

The sample will be dispatched to both laboratories without delay in the most efficient manner.

8.4 Statistical Analysis

A statistical analysis of the comparative results as well as interpretation of variants must be continuous.

9. Round Robin Testing

The fuel laboratories in the coal industry do not rely on just split samples for checking. Round robin samples are also used. These samples are specially prepared from a single "unknown" sample. Care is taken to divide the original sample into as many equal parts as needed by continually mixing and separating the particals. Because of the heterogeneous characteristics of coal, the sample is normally reduced to at least 2.50 millimeter and usually to an even smaller 250 micron size. Such crushing, mixing and separating is expected to loose some of the original total moisture, an important parameter in all commercial coal quality evaluations. This loss does not negate the sample as useful for checking but instead it becomes exactly that, a sample useful for verifying the results obtained by routine laboratory procedures between comparing laboratories.

The value of such checking of routine laboratory procedures decrease, though, if special handling, not routine handling, is initiated by the personnel.

Special handling is expected to be used if a proposed procedural change is being considered or new equipment is being standardized.

A standardized sample is a sample with known values for such round robin testing.

10. Summary and Conclusions

10.1 Sampling is more than just a basic adjunct to coal testing.

10.2 A split sample representing the coal at the moment when the ownership transfers from the supplier to the buyer at the time of weighing is the only sample that represents the true quality purchased.

10.3 A program of continuous analysis of split samples will serve as a program of continuous monitoring of procedures between laboratories. Such a program promotes routine treatment of all samples.

10.4 Round robin samples are essential for establishing technics and standardizing equipment but the split sample program is essential for establishing the quality.

10.5 As the number of such split sample agreements increases for the same supplier or for the same buyer, each in-house laboratory is more recognized for its professional competency because of the increase in opportunities for multiple acceptance.

10.6 The value of split sample programs for contractual acceptance of in-house laboratory procedures is that it shows that such a program must be recognized as a logical criteria for continuous satisfactory laboratory accreditation for purpose of commerce.

References

[1] 1978 Book of A.S.T.M. Standards, American Society for Testing and Materials, Part 26, pp. 314-315.

[2] Ibid., pp. 279-293.

[3] Ibid., pp. 310-326.

[4] Ibid., Table 1, p. 285

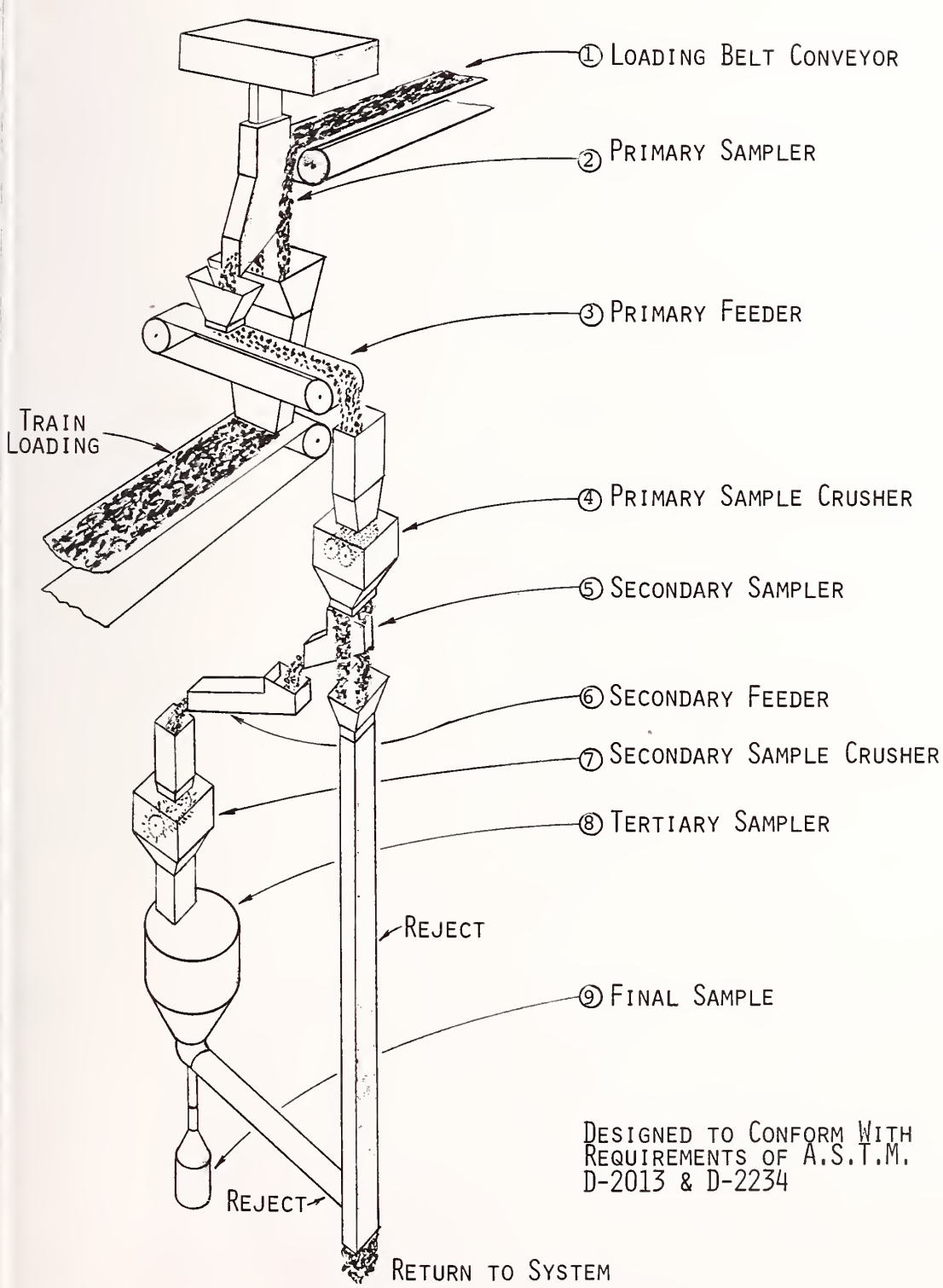
[5] 1972 Book of A.S.T.M. Standards, American Society for Testing and Materials, Part 19, p. 28.

[6] Mullins, R. A., The Determined Value c Unit Train Coal, presented at American Chemical Society Coal Seminar, Charleston, W. Va. October 14, 1977.

[7] Op cit., Ref. 1., p. 189.

FIGURE 1. OLD BEN COAL COMPANY

TYPICAL THREE STAGE SAMPLER



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SESSION III

HEALTH SERVICES ACCREDITATION PROGRAMS

CHAIRMAN: ROBERT D. MEDZ
U. S. ENVIRONMENTAL PROTECTION AGENCY

ational Bureau of Standards Special Publication 591, Proceedings of the National Conference n Testing Laboratory Performance: Evaluation and Accreditation, held at NBS, Gaithersburg, D, September 25-26, 1979. Issued August 1980

SUMMARY OF EVALUATIONS OF CLINICAL LABORATORIES PARTICIPATING IN THE CENTER FOR DISEASE CONTROL EVALUATION PROGRAM

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During the period from 1969 to 1979, the Center for Disease Control has provided for the evaluation of about 1,000 interstate clinical laboratories for licensure purposes, and has provided a performance evaluation program to an additional 1,700 clinical laboratories that were not required to participate by the CLIA '67 law. Licensed laboratories are required to use personnel who meet personnel standards, to meet applicable standards for internal quality control of tests, and to perform satisfactorily in various proficiency testing programs. In most cases the personnel and internal quality control were not evaluated for nonlicensed participants. A review of the data suggests that some laboratories meet or exceed most of the standards, but that a disturbing number of laboratories do not. The demonstration of specific poor performance is often a sufficient stimulus to improvement; in some cases regulatory authority seems necessary to bring about improvement. This paper will provide data based on the CDC program.

Key words: Clinical Laboratories Improvement Act of 1967; CLIA '67; Clinical laboratory evaluation; Evaluation, qualifications of laboratory personnel; Evaluation, internal quality control; Evaluation, performance; Checklist; Proficiency testing; Improvement.

1. Introduction

From 1969 through 1978, the Center for isease Control (CDC) conducted a clinical aboratory evaluation and improvement pro- ram as a part of its responsibility for icensing laboratories operating in inter- tate commerce. The 950 interstate aboratories were expected to meet tandards for personnel, for internal uality control systems, and for perform- nce. Approximately 1,800 additional aboratories participated as nonlicensed olunteers in the performance evaluation art of the CDC program. As of 1978, the ealth Care Financing Administration (HCFA) as given regulatory responsibility for licensing interstate laboratories as well as for certifying for payment those laboratories that serve Medicare patients; CDC continues to evaluate performance of nonlicensed participants. In addition, CDC now is responsible for conducting an independent assessment of the HCFA evaluation system and surrogate systems, offering advice and constructive criticism where needed.

The purpose of this paper is to describe the methods, selected observations, and impact of the evaluation and improvement program operated by CDC from 1969 through 1978.

2. Materials and Methods

There are standards currently applicable for clinical laboratory personnel which specify minimal qualifications for the laboratory director, technical supervisor, general supervisor, and technologists. These standards indicate education, experience and training requirements for each position category.[1] Personnel submit information along with an annual application for licensure which is verified by an in-house study before a license is issued to the laboratory.

There are also standards currently applicable for a quality control system for clinical laboratories. The quality control system includes procedures covering a range of items from equipment calibration and maintenance to validation of methods, surveillance of results, remedial action for defects, written procedures manuals, records, and specimen handling and tracking.[2] A detailed checklist is used by CDC Examiners to assure that each laboratory's quality control system is uniformly examined. The importance of this checklist in assuring an objective and complete on-site evaluation cannot be over-emphasized. A copy of one page from a CDC checklist is shown in Attachment 1.

Proficiency test samples for assessing a laboratory's performance are prepared and distributed by CDC in the categories of microbiology, dianostic immunology, clinical chemistry, pharmacology, and toxicology.[3] Figure 1 shows some of the samples which are mailed.

Performance of participants is assessed for summary purposes in relation to the performance of reference laboratories. Generally, participants in the qualitative tests are assessed in terms of the percentage that reported the correct identification of each of the test organisms; in quantitative tests, the parameters provided by the reference laboratories are used as the targets for participants. The number of clinical laboratories that received samples in 1978 is shown in Table 1.

3. Results and Program Impact

As an example of the impact of the program Figure 2 shows the progressive degree of adoption of a particular standard by 172 laboratories in the CDC program from 1969 through 1976. Note that at the outset only about half of the laboratories had an acceptable preventive maintenance program; by 1976 95% had a routine program. Figure shows the percent of bacteriology laboratories that were checking their media in 1969, and the progressive improvement over time. Figure 4 shows that the more recentl enrolled laboratories as a group adopted this bacteriology quality control standard promptly with less necessity for reiteration by CDC examiners.

Another analysis of program impact is afforded by the data presented in Table 2. The percentages of laboratories licensed in 1971 (the class of 1971) that met several selected quality control standards for each year from 1971 through 1977 are shown. For comparison, the data for the more recently enrolled class of 1977 are also presented. Obviously, there was some improvement in the degree of adoption of these quality control standards.

In Figure 5, the performance of all participants enrolled in bacteriology is shown, regardless of when participating laboratories came into the program. The newest enrollees will have little or no experience with the program, whereas others will have had the benefit of program stimulation for years. Because samples in each shipment are not identical the challange varies from shipment to shipment. However, the standard test organisms are recycled regularly so in eve year participants will have at least sever opportunities to isolate and identify the most important pathogens. The results ind cate that in most years from 10 to 20% or more of the participants make grades of le than 75 on the shipment consisting of five or more samples and as a consequence their efforts often reflect their best performan this measurement suggests that efforts to stimulate improvement should be continued.

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[1] An abstract of the qualification requirements for clinical laboratory personnel (CLIA '67) can be obtained from the author.

[2] A summary of the standards for internal quality control (CLIA '67) can be obtained from the author.

[3] A description of the proficiency tes program and shipping schedule can be obtained from the author.

Evidence of improvement in bacteriology is presented in Table 3. Eleven laboratories that entered the program in 1972 in bacteriology were followed through 1978. Only 7 offered services in gonorrhea diagnosis in 1972, and of these, 3 performed satisfactorily -- a pattern that has persisted through 1978.

The degree of improvement is obviously related to how poor performance was when the improvement stimulus was initially applied. Figure 6 shows that laboratories testing relatively few specimens for gonorrhea performed the poorest but benefited most from the program stimulus. In contrast, the high-volume and larger laboratories performed so well initially that improvement is much more difficult to demonstrate.

Laboratory performance in detecting hepatitis B surface antigen in sera is shown in Table 4. The progressive abandonment of the less sensitive second-generation test is indicated; this was stimulated by the program's demonstration that the test was less sensitive than the third generation test.

The difference in variances between tests for rheumatiod factor before and after the program provided standardization is shown in Figure 7. Note that this program effort resulted in a considerable improvement from a very wide variance between laboratories to a variance of only 0.93.

Program stimuli have a multiplier effect in most disciplines. For example, demonstration of poor performance can be expected to stimulate individuals to improve their performance and to help the staff justify substituting more accurate and precise procedures for archaic procedures. A case in point is the erythrocyte count (Figure 8); as laboratorians have improved their individual performance, they have also replaced the less reliable procedures with more accurate and precise procedures. We recommend as a guiding principle "If it's worth doing, it's worth doing well."

The final example of program impact concerns the stimulating effect of a notice to a laboratory that its license is to be revoked because of poor performance. A study of grades laboratories made in bacteriology for five shipments before and five shipments after receiving such notices shows that their average grades increased by 8.9 points. Concurrently, the average grades of a randomly selected sample of laboratories that did not receive a notice declined 1.4 points. This suggests that laboratories that are not motivated by the simple demonstration of poor performance are motivated by the threat of license revocation.

MATERIALS CFR 74.20(c) 405.1317 (a)(3)		NO (Code)	COMMENT
14. The following are labeled (identity, titer or concentration, recommended storage, preparation or expiration date)	Antimicrobials	☐ 01080	
	Antisera	☐ 01081	
	Control Organisms	☐ 01082	
	Media (tubes, plates, kits)	☐ 01083	
	Disc	☐ 01084	
	Strips	☐ 01085	
	Reagent Solutions	☐ 01086	
15. Materials in use are "in-date", reactive, and not deteriorated	Antimicrobials	☐ 01087	
	Antisera	☐ 01088	
	Control Organisms	☐ 01089	
	Media (tubes, plates, kits)	☐ 01090	
	Disc	☐ 01091	
	Strips	☐ 01092	
	Reagent Solutions	☐ 01093	

TESTING OF REAGENTS CFR 74.20(a) 405.1317(a)(1) 405.1317(b)(1)		Positive Reaction NO (Code)	Negative Reaction NO (Code)	Written Q.C. NO (Code)	COMMENT
16. The following reagents (in use as individual biochemical tests or as a part of a commercial system) are tested each day of use to demonstrate a positive and negative biochemical reaction	Catalase	*☐ 01094	*☐ 01095	*☐ 01096	
	Coagulase	*☐ 01097	*☐ 01098	*☐ 01099	
	Ferric Chloride	*☐ 01100	*☐ 01101	*☐ 01102	
	Indole	*☐ 01103	*☐ 01104	*☐ 01105	
	Methyl red	*☐ 01106	*☐ 01107	*☐ 01108	
	Nitrate	*☐ 01109	*☐ 01110	*☐ 01111	
	Oxidase	*☐ 01112	*☐ 01113	*☐ 01114	
	Voges-Proskauer	*☐ 01115	*☐ 01116	*☐ 01117	
17. The following disc and/or strips are tested when each new vial is opened and each week of use to demonstrate positive and negative biochemical reactions.	Bacitracin	*☐ 01118	*☐ 01119	*☐ 01120	
	Optochin	*☐ 01121	*☐ 01122	*☐ 01123	
	ONPG	*☐ 01124	*☐ 01125	*☐ 01126	
	X	*☐ 01127	*☐ 01128	*☐ 01129	
	V	*☐ 01130	*☐ 01131	*☐ 01132	
	XV	*☐ 01133	*☐ 01134	*☐ 01135	
18. The following antisera are tested when each new vial is opened and each month of use to demonstrate positive and negative agglutination reactions	*E. Coli*	*☐ 01136	*☐ 01137	*☐ 01138	
	Hemophilus	*☐ 01139	*☐ 01140	*☐ 01141	
	Herella	*☐ 01142	*☐ 01143	*☐ 01144	
	Salmonella	*☐ 01145	*☐ 01146	*☐ 01147	
	Shigella	*☐ 01148	*☐ 01149	*☐ 01150	
	Streptococcal	*☐ 01151	*☐ 01152	*☐ 01153	
STAINS CFR 74.21(a) 405.1313(b)(1)(i)					
19. The following stains are tested each day of use to demonstrate expected staining characteristics.	Capsule	*☐ 01154		*☐ 01156	
	Flagella	*☐ 01157		*☐ 01159	
	Methylene Blue	*☐ 01160		*☐ 01162	
	Spore	*☐ 01163		*☐ 01165	
20. Gram stain is tested when prepared and each week of use to demonstrate expected staining characteristics (positive and negative reactions)		*☐ 01166	*☐ 01167	*☐ 01168	

21. Each batch of the following media, if used by the lab, is tested for the following characteristics

GROWTH MEDIUM	Support Growth NO (Code)	Sterility No (Code)	Written Q.C. NO (Code)	COMMENT
Blood Agar	*☐ 01169	*☐ 01170	*☐ 01171	
Brain Heart Infusion Agar/Broth	*☐ 01172	*☐ 01173	*☐ 01174	
Chocolate Agar	*☐ 01175	*☐ 01176	*☐ 01177	
Heart Infusion Agar	*☐ 01178	*☐ 01179	*☐ 01180	
Motility	*☐ 01181	*☐ 01182	*☐ 01183	
Mueller Hinton	*☐ 01184	*☐ 01185	*☐ 01186	
Nutrient Agar/Broth	*☐ 01187	*☐ 01188	*☐ 01189	
Thioglycollate Broth	*☐ 01190	*☐ 01191	*☐ 01192	
Tryptic Soy Agar/Broth	*☐ 01193	*☐ 01194	*☐ 01195	
Todd Hewitt Broth	*☐ 01244	*☐ 01246	*☐ 01247	

ATTACHMENT 1. EXAMPLE OF ONE PAGE OF A CHECKLIST USED BY CDC EXAMINER DURING ON-SITE LABORATORY EVALUATION

FIGURE 1. PROFICIENCY TESTS SAMPLES PREPARED AND DISTRIBUTED BY CDC

NUMBER OF LABORATORIES IN CDC PROFICIENCY TESTING PROGRAM, BY CATEGORY, 1978

CATEGORY	NUMBER OF LABORATORIES
MICROBIOLOGY	1,229
Bacteriology	872
Special Gonorrhoeae Testing	353
Mycobacteriology	410
Mycology	438
Parasitology	676
Virology	107
Antimicrobial Susceptibility Test	872
DIAGNOSTIC IMMUNOLOGY	986
Immunology	771
Hepatitis B Antigen	371
Syphilis Serology	552
CHEMISTRY	1,555
Chemistry Profile	1,079
Endocrinology	708
Pharmacology-Digoxin	523
Toxicology-Drugs of Abuse	455
Toxicology-Blood Lead	238
HEMATOLOGY	1,187
IMMUNOHEMATOLOGY	700
CYTOPATHOLOGY	475

TABLE 1

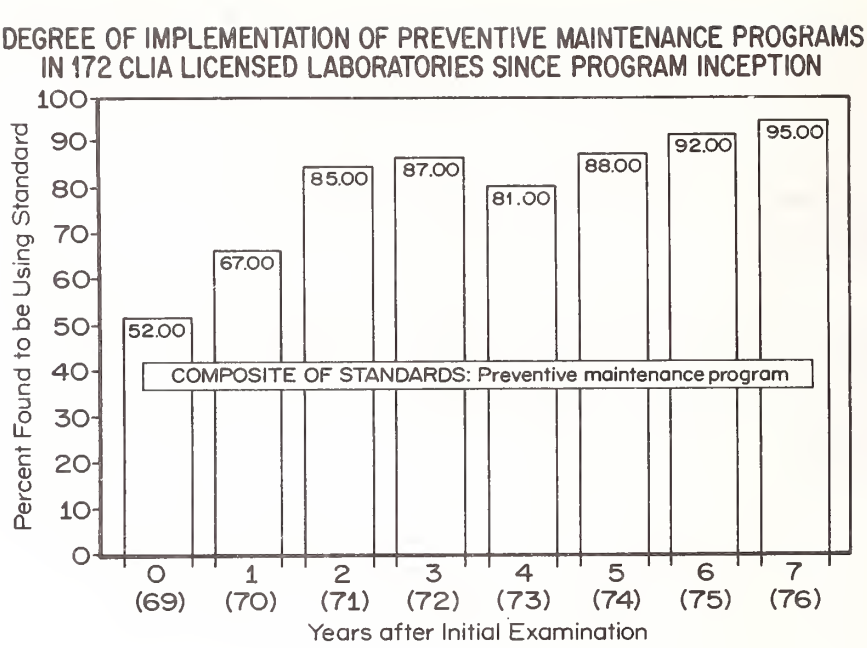

FIGURE 2

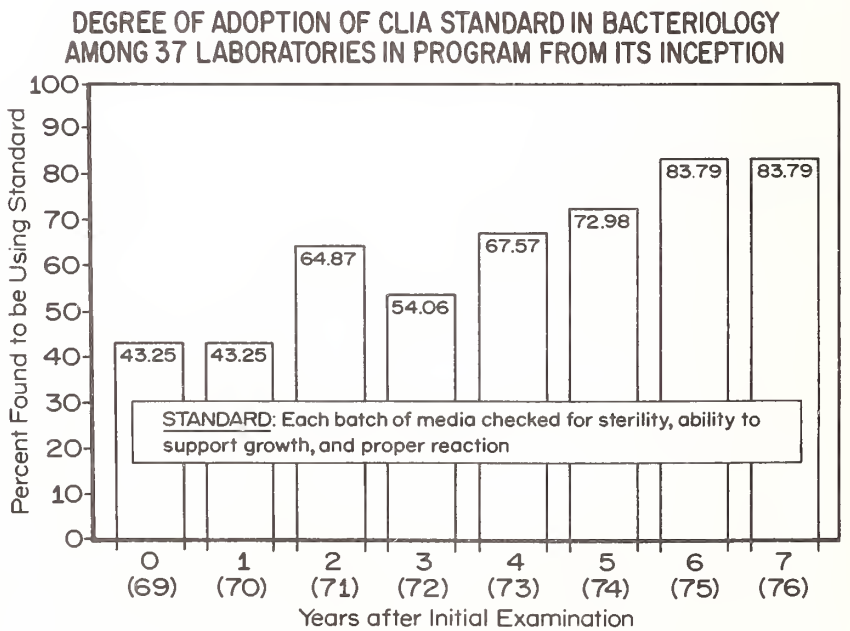

FIGURE 3

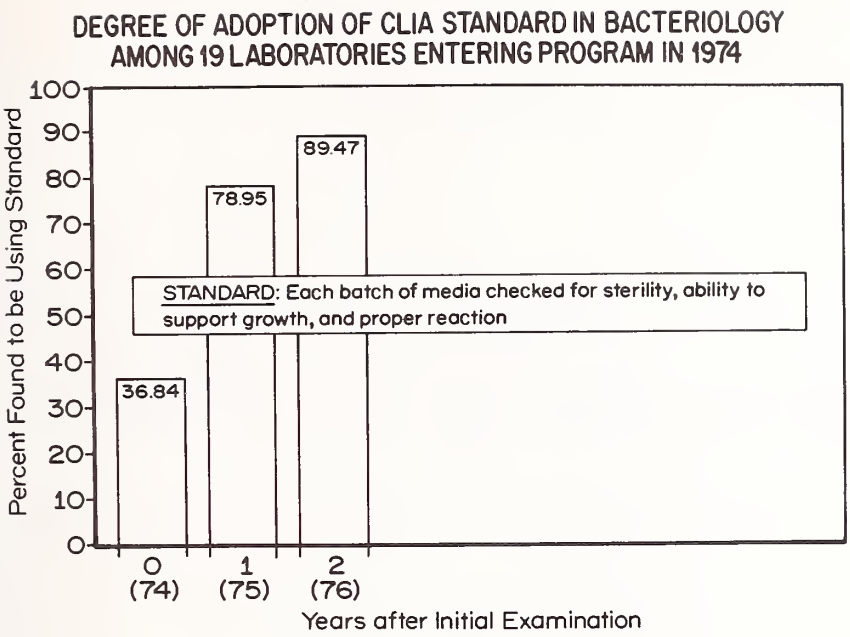

FIGURE 4

DEGREE OF ADOPTION OF QUALITY CONTROL STANDARDS BY CLASS OF 1971 LABORATORIES AND BY CLASS OF 1977 LABORATORIES

Category and standard	Percent of Class of 1971 labs met standards on date shown '71	'72	'73	'74	'75	'76	'77	Percent of Class of 1977 met standards
Bacteriology								
Reagents checked	14	18	27	45	64	70	82	43
Autoclave checked	43	64	91	82	100	90	100	100
Indate reagents used	29	55	64	91	82	100	100	100
Serology								
Tests controlled	33	60	64	64	70	90	91	57
Chemistry								
Controls, pregnancy test	38	83	100	92	91	91	92	100
Immunohematology								
Serum, cells checked	50	45	82	73	100	100	100	83

TABLE 2

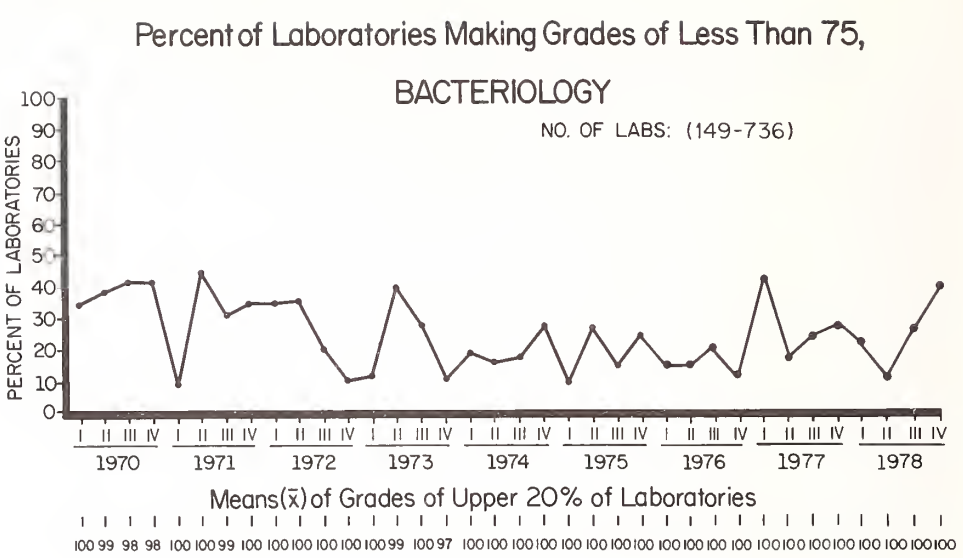

FIGURE 5

SUCCESS OF CLASS OF 1971 LABORATORIES COMPARED TO CLASS OF 1977 LABORATORIES IN ISOLATING AND IDENTIFYING *NEISSERIA GONORRHOEAE* FROM MIXED CULTURES

Laboratory Number	Performance of 1971 labs on date shown '72	'73	'75	'76	'76	'77	'78	Lab Number	Performance of 1977 labs in '78
04–60	NE*	S	S	S	S	S	S	01–26	S
12–31	NE	U	S	NP	S	S	S	04–40	NE
13–13	NE	S	S	S	S	S	S	04–70	U
14–05	NE	U	S	S	S	S	U	10–30	S
20–36	S	S	S	S	S	S	S	14–25	S
22–14	U	U	S	S	S	S	S	15–24	S
29–07	U	U	S	S	S	S	S	19–68	S
32–12	NP	NP	S	S	S	S	S	26–16	S
40–04	S	S	S	S	S	S	S	29–66	NE
41–17	S	U	U	S	S	S	S	35–07	U
45–16	U	U	S	S	S	S	S	35–21	S
								36–40	S
								37–94	S
Percent S	43	36	91	91	100	100	91		82

*NE, not enrolled for gonorrhea; S, satisfactory; U, unsatisfactory; NP, did not return results

TABLE 3

PERFORMANCE OF LABORATORIES RELATED TO DAILY TESTING LOAD-*NEISSERIA GONORRHOEAE*

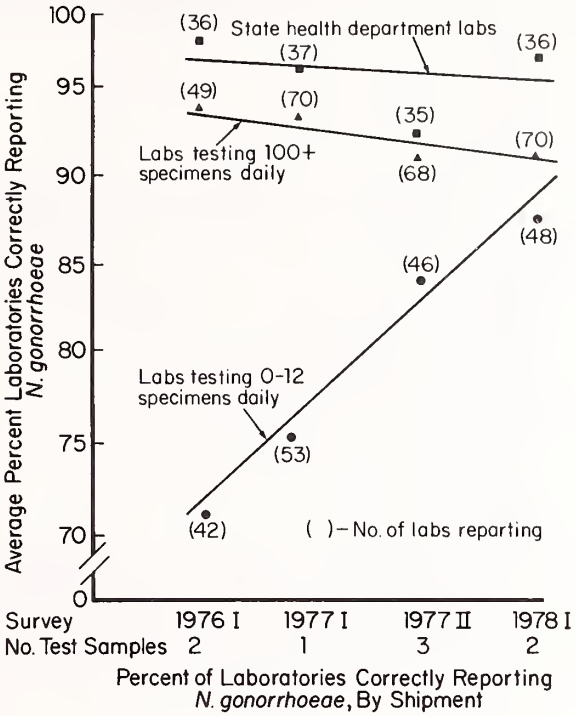

FIGURE 6

SENSITIVITY OF SECOND AND THIRD GENERATION TESTS FOR DETECTING HEPATITIS B SURFACE ANTIGEN POSITIVE SERA

Year	Results on Proficiency Testing Samples			
	2nd generation tests		3rd generation tests	
	# Labs	% Correct	# Labs	% Correct
1975	114	79	206	99
1976	90	60	238	99
	53	62	251	95
1977	48	66	274	98
	48	80	273	99
1978	27	97	281	99
	33	79	276	96
1979	5	60	322	99
Average Percent Correct		72		98

TABLE 4

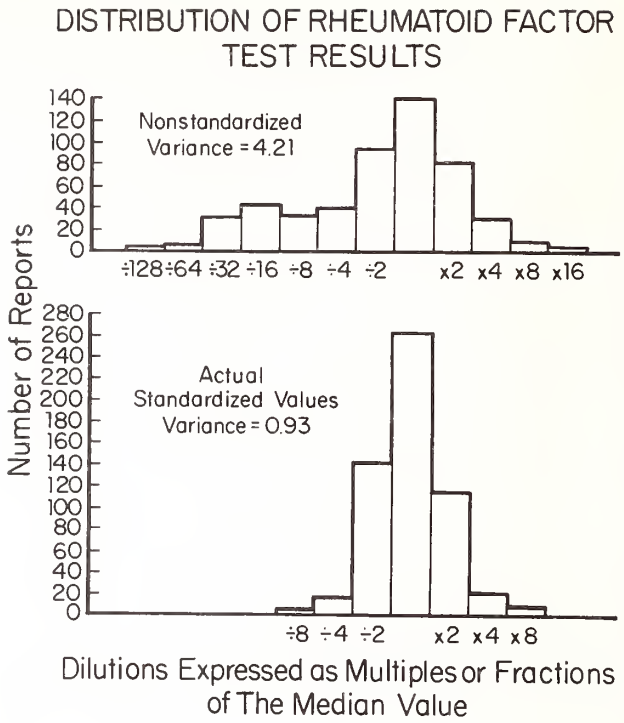

FIGURE 7

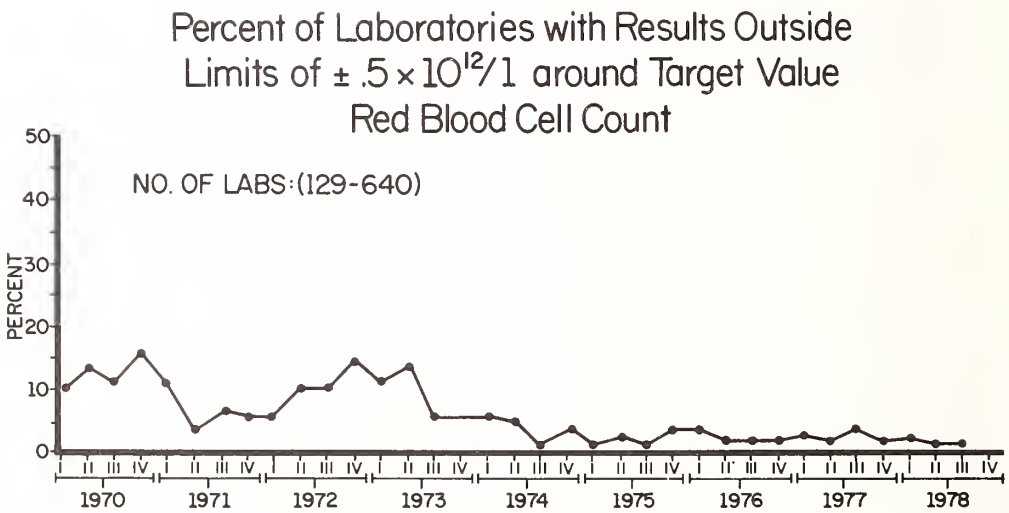

FIGURE 8

National Bureau of Standards Special Publication 591, Proceedings of the National Conference on Testing Laboratory Performance: Evaluation and Accreditation, held at NBS, Gaithersburg, MD, September 25-26, 1979. Issued August 1980

EVALUATION AND APPROVAL OF LABORATORIES IN CONNECTICUT IMPORTANCE OF VOLUNTARY STANDARDS

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The Laboratory Division of the Connecticut Department of Health Services is responsible for licensure, registration, performance evaluation and approval of hospital, indpendent clinical, water, waste water, food, dairy, air and a variety of other laboratories which perform tests of public health significance. Of the almost 400 facilities, more than three-quarters of these participate in proficiency testing and are inspected yearly.

The philosophy of performance evaluation and approval in Connecticut has evolved from one of complete authority and control by the state to one which is based increasingly upon cost effectiveness, consistency, enforceability and participant input. Dependence on voluntary standards now extends from granting equivalence for inspections conducted by qualified professional groups to accepting proficiency testing results from well conceived programs. Most success in acceptance of equivalent programs has been attained with clinical laboratories and least progress has been made with environmental laboratories. This difference probably is attributable to the newness of environmental as opposed to clinical laboratory legislation and the availability of acceptable programs.

Using the evaluation and approval of recombinant DNA laboratories in Connecticut as an example, the advantages of using existing regulations and voluntary standards are discussed as a model of efficiency.

Key words: Clinical laboratories; cost effectiveness; environmental laboratories; licensure; performance evaluation; physician's office laboratories; proficiency testing; public health; recombinant DNA; registration and approval; voluntary standards.

1. Introduction

Responsibilities of State Agencies for regulation of laboratories are increasing more rapidly than the funds available to fulfill these responsibilities. An innovative approach is needed to assure quality of laboratory results without excess expenditure of taxpayers funds.

After almost ten years of a traditional regulatory program in which state resources were required to maintain complete responsibility for inspection and proficiency testing programs, the Connecticut Health Laboratory has initiated a system involving voluntary standards and participation by non-governmental organization in the inspection and proficiency testing process. Specifics of the Connecticut program including advantages, limitations and the need for continued review and change are covered in this report.

2. Scope

In Connecticut, the Laboratory Division of the Department of Health Services is responsible for licensure, registration, inspection, proficiency testing, and approval of all laboratories performing tests of public health significance on or for Connecticut citizens. Included are hospital and independent laboratories, water, waste water, diary, food and air testing laboratories, blood banks and plasmapheresis centers. Recombinant DNA laboratories, academic laboratories and laboratories using dogs for teaching and research are also included. The Department of Health Services has primary enforcement responsibility for approval of laboratories included under Medicare, the Clinical Laboratories Improvement Act (CLIA), the Safe Drinking Water Act (SDWA) and National Polution Discharge Elimination Systems (NPDES) legislation. About 400 separate facilities, as well as the proficiency testing specimens required to determine quality of the work done by them, are the responsibility of ten professional and four non-professional employees. These regulatory responsibilities cannot be discharged effectively without at least tacit acceptance of the basic principles of voluntary standards.

3. Clinical Laboratory Regulation

At the request of the Connecticut Society of Pathologists and members of the State Advisory Committee on Clinical Laboratory Regulation the Laboratory Division began looking at alternatives to state sponsored inspection and proficiency testing programs. Hospital and independent clinical laboratories had long been subjected to a multiplicity of programs required by federal, state and peer review groups. After carefully reviewing the inspection and accreditation program of the American Association of Blood Banks (AABB) an agreement for alternate year inspections by the state and AABB was concluded in November of 1977. The most significant reasons for this decision were:

1. The AABB program was more thorough than ours.

2. Funding was not available to provide an equivalent program.

A somewhat different agreement was reached with the College of American Pathologists (CAP) in December of 1978. In essence, the State of Connecticut accepted the biennial inspection of member hospital laboratories in lieu of the yearly state inspection. However, CAP agreed to a 10% reinspection by the state. About one half of the 50 hospitals are accredited by CAP leaving the state with about twenty five annual surveys and reinspections. It is expected that some agreement soon will be worked out with the Joint Commission on the Accreditation of Hospitals (JCAH) because of the recent "deemed status" granted to this organization by the federal government to approve hospital laboratories for Medicare purposes. It was not altruism which prompted this arrangement. Rather, it was the increasing realization that federal funding would not always be available, that regulation is not one of the more popular items competing for state funds, that these institutions are providing quality laboratory services as evidenced by eight years of acceptable proficiency testing results and that redundancy in inspection was creating more problems than it was solving.

Much of the impetus for statutory change (which in January 1,1980 will enable acceptance of proficiency testing programs other than those provided by the state) originated from the sub-committee for Microbiology which functions as part of our mandated Advisory Committee for Clinical Laboratory regulation. This advisory committee includes peer review and has provided a perspective unavailable to many regulatory agencies. Input from hospital and independent laboratory microbiologists has resulted in an appreciation of the differences in problems encountered in different settings as well as common problems resulting from inspection and proficiency testing. The disadvantages usually expected from this "fox in the chicken coop" approach have not materialized.

Another problem area which was improved by a change in statute was licensure of physician's office laboratories. Previously a combined practice of two or more practitioners required licensure. Only a single physician who performed tests in the course of his practice was exempted. This law was unreasonable and unenforceable. The new law establishes a licensure requirement for practitioners which is based on volume and complexity of testing as defined in regulations. We feel that this is a more logical and economical approach than requiring licensure for all practitioners performing tests or basing an exemption on the number of practitioners involved such as the arbitrary five limit suggested by a recent version of the proposed CLIA.

Peer review is not without problems. Most peer reviewers are not thorough enough in covering details. This thoroughness is

criticized frequently as nit-picking. Any professional has available to him textbooks, journals, seminars and continuing education courses to satisfy his intellectual requirements. However, he does not always have and needs periodic scrutiny to make certain that he and his employees are properly taking and labeling specimens, updating specifications, recording information necessary to achieve adequate quality control, protecting themselves from biological and chemical danger and accurately reporting results. Some of the most astute laboratory scientists are remiss at keeping records of their own work and helpless at requiring others to do so. There is no better way to be assured that records will be kept properly than to convince the laboratory director or supervisor that his errors and omissions will be discovered.

Additional problems in peer review are created by differences in the frequency of inspections. An unfair burden is placed on independent laboratories which are required to be inspected yearly under the same Medicare regulations which allow on-site inspection by JCAH and CAP, biennially. Inequities also exist in the criteria used during inspection. A classic example with which our group has been wrestling for some time is the Medicare requirement for use of quality control organisms on a daily basis for antibiotic susceptibility testing [1] which is less stringent for CAP approved laboratories [2].

Application of the term "voluntary" to proficiency testing and laboratory inspection has resulted in some differences in interpretation. The pathologist who participates in the CAP proficiency testing program may make the interpretation that he participates in the program of his own volition, that he can withdraw at any time and that there are no penalties if his performance is not within the prescribed limits. However, when a governmental agency accepts such a program to meet requirements for regulatory purposes the only voluntary thing about it is that he has chosen this route rather than be subjected to the alternative state program. It is incumbent upon the agency granting equivalent status to differentiate between the good and poor performer and to use this information to require improvement or to prevent any damage from poor results. Input and compliance are the keys to voluntary standards. Particpants must have the opportunity not only to criticize the standards currently in use and to make suggestions for change but also to make compromises and to adhere to the standards once adopted.

A cost effective program for determining quality of laboratory performance will be forthcoming when proficiency tests can be conducted without prior warning and when the correct response has been established well in advance of the actual test. Several years ago when this suggestion was made to Center for Disease Control by our group it was considered to be impractical. However, in the recent Public Health Service publication "Proposed Interim Proficiency Testing Program for Medicare Laboratories" [3] methods for reference laboratories were recommended for the chemistry program. It is expected that additional definitive and reference methods [4] will be established by groups such as The National Committee for Clinical Laboratory Standards (NCCLS).

At the Connecticut State Health Laboratory it is our opinion that a better appraisal of laboratory performance in clinical chemistry can be obtained by two unannounced proficiency tests than by the six announced tests currently recommended in the above reference by the Public Health Service. Three specimens, two unknowns (normal and abnormal) and one specimen with known values would be used. All specimens would be assayed using reference methods. Statistically significant target values and acceptable ranges would be established in advance. After a suitable period to allow all laboratories to adjust their procedures to obtain values comparable to those from the reference methods, the specimen with assigned values would be discontinued. A similar approach could be used for categories other than chemistry.

After all the time and effort that has been directed to performance evaluation through proficiency testing, a serious problem still remains. Little progress has been made in development of a system to determine integrity of the specimens. Until such a system is developed, no assessment can be made of the significance of specimen handling (including methods for obtaining, processing and transporting the specimen) on quality of laboratory performance.

4. Environmental and Public Health Laboratories

The most complex regulatory problems now exist in the environmental area. Some of the precise methodological requirements of the Safe Drinking Water Act and the Water Pollution Control Act are difficult to comprehend. Good proficiency test specimens for volatiles and chlorinated hydrocarbons are hard to find and we now prepare them in-

house. We have not yet had the opportunity to to consider the problems involved in determining quality of air analysis. Even the variety of analyses performed in different laboratories is surprising. For example, there are 19 laboratories in Connecticut approved to perform tests required under the Safe Drinking Water Act, ten approved under NPDES and 48 approved for both. Of the 48 having combined approval, 8 of these are approved to do food and one of these also performs tests for pollutants in air. Four laboratories are approved to perform tests only on domestic waste water. Eight laboratories in Connecticut are approved to perform tests on milk as required by State and Interstate Milk Shippers regulations. Most of the requirements for inspection and proficiency testing of laboratories in these specialties currently are prescribed with very little leeway for application of voluntary standards.

5. Recombinant DNA Laboratories

Laboratories which lend themselves best to voluntary standards are the academic, quality control and Recombinant DNA Laboratories. They require registration because of their use of organisms of public health significance. Recombinant DNA laboratories fit into this category because E. coli is included in the public health code as one such organism. They are registered under existing regulations because those involved finally agreed that this was a lesser evil than a whole set of new state statutes and regulations which could differ substantially from existing federal requirements. The only state requirement is that these facilities adhere strictly to NIH guidelines, whether or not their work is federally supported, and that they keep the state informed of changes in projects and advisory committee members. They have been inspected yearly and found not only to obey the guidelines but also to be an excellent source of information on laboratory safety. This model of simplicity in laboratory regulation is also a model for the application of voluntary standards in an area which the public considers to be critical for protection of their health and safety.

I am grateful to John Redys, Director of the Laboratory, and members of the regulatory staff for critically reading the manuscript and to Phyllis Botticello for assisting in its preparation.

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THE LABORATORY ACCREDITATION PROGRAM OF THE AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

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The accreditation program for laboratories will be described along with the program to assist accredited laboratories to maintain their accreditation through continued demonstration of competence and performance. An Industrial Hygiene Laboratory is a laboratory that analyzes samples taken to assist in the recognition, evaluation and control of the workplace environment. The factors which are used to determine whether a laboratory qualifies for accreditation as an industrial hygiene laboratory will be described in detail. Such factors include personnel qualifications, quality control and proficiency testing, facilities, recordkeeping, analyses performed, safety and analytical procedures. A description of the accreditation process will be provided along with steps that are taken to assist laboratories not maintaining acceptable standards of performance. The role of the coordinator, the site visitor, the accreditation committee and the AIHA Board of Directors will be outlined and possible changes in the program will be discussed. The effectiveness of the program in improving industrial hygiene laboratories will be reviewed.

Key words: Accreditation; Accreditation Committee; American Industrial Hygiene Association; coordinator; industrial hygiene laboratories; laboratory; PAT; performance; personnel; proficient; quality control; reaccreditation; site visit

The first step in discussing the laboratory accreditation program of the American Industrial Hygiene Association is to define the term industrial hygiene and briefly describe an industrial hygiene laboratory. Industrial hygiene is that science and art devoted to the recognition, evaluation and control of those environmental factors or stresses, arising in or from the workplace, which may cause sickness, impaired health and well being, or significant discomfort and inefficiency among workplace employees.

The industrial hygienist depends on the industrial hygiene laboratory, a laboratory that analyzes samples taken to assist in the recognition, evaluation and control of the workplace environment for data. The laboratory is critical for determining existing potential health hazards and measuring the effectiveness of control measures implemented in previously identified problem areas. The laboratory data is interpreted by the industrial hygienist who must then relate the findings to standards set by the Occupational Safety and Health Administration (OSHA) - with advice from the National Institute for Occupational Safety and Health (NIOSH). It is important, therefore, that the laboratory provide data that can be trusted.

An examination of these definitions shows a definite need for some method of insuring the validity of the data such as accreditation of the laboratories. Accreditation means professionalism to those

laboratories involved in the program. It is a mark of competence demonstrating that the laboratory measures up to the strictest possible standards. The sole aim of the American Industrial Hygiene Association accreditation program is to assist industrial hygiene laboratories in achieving and maintaining the highest possible level of professional performance.

If a laboratory is not accredited, there is no assurance that the data or information that it generates is reliable. The accreditation program has helped laboratories find areas where improvement was needed and has assisted laboratories in development of quality control programs that insure valid data. All laboratories participating in the accreditation program will probably agree that the program has been beneficial. Accreditation is a statement to both the public and to workplace employees who are affected by the results that a laboratory has met certain standards set by recognized professionals in the field. A laboratory accreditation program is and will continue to be an effective tool in the continued improvement in the performance of the industrial hygiene laboratory.

How does the accreditation process work?

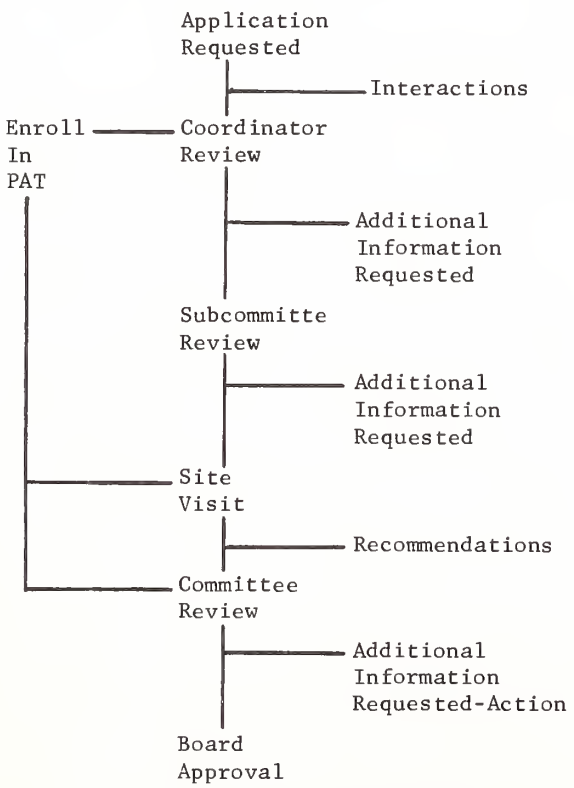

Figure 1. Flow Chart for Laboratory Accreditation Process

The flow chart in Figure 1 shows the variou steps in the process leading to accreditation along with those places where assistance can be provided. First is the reques for the application which is filled out an sent to the laboratory coordinator at the American Industrial Hygiene headquarters i Akron, Ohio. The coordinator who is employed by the Association reviews the application, mainly for completeness and then sends the application to two members of the Laboratory Accreditation Committee for a thorough review. The Laboratory Accreditation Committee is a committee of qualified volunteers who are appointed annually by the AIHA Board of Directors. The laboratory is simultaneously enrolled in the NIOSH Proficiency Analytical Testing program, better known as PAT. This program requires bi-monthly evaluation of supplied contaminants. Satisfactory performance judged against the results of all participating laboratories is required to become accredited and to remain accredited.

The first aspect of the application which is considered important are the qualifications of personnel. The director of the laboratory must be a Diplomate of the American Board of Industrial Hygiene o have six years experience in industrial hygiene chemistry after completing a medica degree or an academic degree in one of the basic sciences. The committee must judge whether or not the applicant meets the six years experience standard. The entire work experience of the individual is considered to make certain that the laboratory is unde the control of trained, competent, practicing industrial hygiene chemists.

This requirement is noteworthy for the following reasons. Historically there has been good corelation between the ease with which a new laboratory has met this experience criteria and measurements of performance subsequently achieved and maintained. The experience requirement has often been a big hurdle for many laboratories - particularly those where the industrial hygiene function has been a non-specific entity of a larger general chemistry laboratory.

The laboratory supervisor should have a doctorate degree in a related science or a medical degree with an additional two years experience in related procedures. Otherwise, he should have a master's degree plus four years experience or a baccalaureate degree and six years experience in related procedures. There are also requirements spelled out for the technologists and

technicians. The titles often do not match those used internally within the various organizations seeking accreditation, however, the program is more concerned with the function of the individuals rather than with the title.

The area of personnel qualifications most often raises questions such that the laboratory may have to provide additional detailed information prior to review. The subcommittee review may also suggest that someone else may be more appropriate as director until specific requirements are attained by the named individual. At the time of the site visit, suggestions again may be made with regard to improving qualifications and helping the individuals to become more familiar with industrial health. Suggestions which are made are not binding on management but are offered so that personnel structures will compare with those of other accredited laboratories.

Closely related to the importance of having trained industrial hygiene chemists is the decision to accredit only laboratories performing a significant amount of industrial hygiene work. This sounds straightforward but is difficult to administer in practice. Many laboratories are involved with water chemistry, air pollution, solid waste or toxicology. There are also laboratories that want to be accredited under the program that do not have any identifiable industrial hygiene program. To measure the involvement of a laboratory in industrial hygiene the application requires a statement of work load in terms of origin and purpose encompassing the past year's testing.

A second area of importance is in regard to the laboratory quality control program. In committee review, the quality control program is given equal weight with the qualification of the personnel. If a laboratory does not have a good quality control program, it will be very difficult for any laboratory to obtain accreditation. The requirements include a statement of policy with regard to quality control and a manual which contains all quality control work. Preferably, someone should be designated as the laboratory quality control coordinator, although for smaller laboratories this individual may serve in a multiple capacity. Control charts should be in use for those analyses most commonly encountered and spiked samples should be used for infrequently performed analyses. The quality control policy should state what action is taken when a result is found outside the expected range. Participation in other proficiency testing programs and exchange of samples with other accredited industrial hygiene laboratories is encouraged.

The application also requires a detailed description of other factors:

1. Facilities
2. Record keeping system
3. Type and amount of analysis performed
4. Safety program
5. Analytical procedures

The act of answering the queries is, itself, beneficial. Many interested laboratories, in an effort to respond, have recognized certain benefical changes which subsequently have been instituted. In a few instances, applications have been delayed until changes have been made. As stated before, the purpose of the program is to assist laboratories in achieving and maintaining a high level of professional performance.

After an application has been reviewed and accepted by the subcommittee, and a laboratory has completed two PAT rounds successfully, an on-site visit is scheduled to verify the material presented and to examine the operation of the laboratory. The site visitor is an expert in the field of industrial hygiene and his objective is simply to offer constructive advice.

The site visitation is an important aspect of the accreditation process. Site visitors are selected based on their expertise in laboratory operations. Site visits, which are scheduled at mutually convenient dates, are usually conducted and completed in one day. If deficiencies are noted, recommendations are made to the laboratory regarding changes which should be made.

Information from the application review, site visit report and performance in the PAT program are submitted for final committee approval. The committee may request additional information or make further recommendations to the applicant. In some instances, a second site visit may be required to insure that major recommendations have been carried out. After approval by the committee, summary sheets are submitted for approval by the Board of Directors of the American Industrial Hygiene Association.

Accreditation is granted for a period of

three years. During this period, a laboratory is required to participate in the PAT program and advise the committee on an annual basis of any major changes that occur. A current list of accredited laboratories appears in the Journal of the American Industrial Hygiene Association.

The reaccreditation process operates in a similar fashion except for a certain simplification of the procedure. The reaccreditation application basically requests information on the changes and improvements that have occurred over the three year period. The subcommittee review is not needed and the site visit is conducted with all the accumulated information over the three year period, including previous site visitor's and committee recommendations, performance in the PAT program, changes in personnel and any other changes of significance that may affect the performance of the laboratory. The committee then reviews the entire package and passes its recommendation on to the AIHA Board of Directors.

As has been stated the purpose of the program is to assist laboratories in upgrading performance. The first place for providing assistance is during the coordinator review of the application. The coordinator's job is to insure that the application is filled out completely and correctly. He may recommend greater emphasis in some areas and less in others not only to assist the laboratory but to help the committee better understand the nature of a particular laboratory operation. He serves as the communicator, relaying recommendations of both the committee and site visitors and notifying the laboratory when a final decision is made.

The subcommittee review points out areas where more information may be needed and suggests potential trouble spots that the site visitor may need to discuss with the laboratory.

The site visitor prepares a written report with recommendations for improvement which is part of the total package for committee review. These recommendations must be answered with specific statements of action that will be taken by the laboratory.

The results of the PAT program are used to determine a laboratory's proficiency for those analyses performed. Extra sets of samples are available for laboratories having difficulties. Also, exchanging samples with other laboratories is suggested as a help in resolving difficulties.

A meeting of laboratory directors is held annually at which time problems and progress are discussed. Also, a quarterly newsletter is published for information exchange among laboratories. The newslette carries items of interest submitted by laboratories, new products available, and summary information on PAT data.

Although the program has been in operation for over six years changes are under investigation to insure continued improvement. Most of the laboratories that would be classified as industrial hygiene laboratories are accredited. The committee must now deal with what it considers borderline laboratories to insure that these are not excluded simply because they are not strictly industrial hygiene laboratories. Other changes or items under committee review are:

1. The definition of proficient and non-proficient to conform with the definition used by NIOSH.
2. The requirements for laboratory director and supervisor which would leave no questions regarding who would or would not qualify.
3. Additional procedures for assisting laboratories that are having difficulties with the PAT program to insure proficient analyses not only for those analytes in the PAT program but for al analytes.
4. The possibility of an interim accredita tion for those laboratories that may nc exactly meet the requirements but whicl obviously have analytical capability.

Response to the accreditation program has been excellent. The list of about one hundred thirty (130) accredited laboratories is still growing with no sign of decrease ir the rate of growth.

In summary, most laboratories agree the accreditation program has been beneficial tc them. It is a statement to both the public and employees that a laboratory has met standards as set by recognized professionals in the field. The laboratory accreditation program is and will continue to be an effective tool for the improvement in performance of the occupational health laboratory.

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COLLEGE OF AMERICAN PATHOLOGISTS INSPECTION AND ACCREDITATION PROGRAM

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COLLEGE OF AMERICAN PATHOLOGISTS

The College of American Pathologists Inspection and Accreditation Program is a professional, voluntary, peer-review program of laboratory improvement. The standards are developed by a Commission of volunteer pathologists and the program is operated by this Commission, with support from the College's central office and computer center. Biennial inspections are conducted by volunteer pathologists. Each pathologist is assisted by a team of his choosing, representative of the size and complexity of the laboratory to be inspected. The standards include requirements on quality control, safety, environment, instrument maintenance and personnel. An inspection checklist is used to assure that all areas are examined. Proficiency testing is a prerequisite and results are an integral part of the accreditation decision. Emphasis is placed on the educational aspects of the program. CAP accreditation is accepted by the Joint Commission on Accreditation of Hospitals, the Center for Disease Control, and some states. Accreditation by CAP assures the physician and patient that test results are reliable.

Key words: Accreditation; College of American Pathologists; criteria; inspection; inspector's manual; pathology; proficiency testing; standards.

1. Description

The College of American Pathologists Inspection and Accreditation Program was developed almost 20 years ago with the primary objective of improving the quality of clinical laboratory services and assuring the accuracy and reliability of test results. Although the program has grown in complexity and effectiveness, the goal still remains one of laboratory improvement through peer-review and education. The College of American Pathologists Inspection and Accreditation Program is a professional, voluntary, peer-review program with about 1800 laboratories currently participating. This represents more than 10 percent of the labs in the country.

2. Development and Operation

The program is under the direction of a Commission on Inspection and Accreditation; a group comprised of a chairman and ten regional commissioners. Each commissioner is a highly qualified pathologist who has been appointed by the President of the College. The commission meets at least quarterly to review its current standards and to examine new or problem areas that may exist. Each regional commissioner is assisted by state commissioners in carrying out the operations within individual states. The state commissioner's duties may vary according to the responsibilities delegated by the regional commissioner, but in most cases, his major responsibility is to assist in the recruiting, training and assigning of inspectors.

Each inspector is a board-certified pathologist who has attended a recent inspector's workshop or received on-the-job training during an inspection with an experienced inspector. Each inspector is assisted by a team of specialists, chosen by the pathologist-inspector, based on the size and complexity of the lab which they are assigned to inspect. For example, in a two or three hundred bed community hospital, the inspector might select a chemist, a chief technologist and possibly a supervisory technologist. In a university setting the team may include several other pathologists and a number of doctoral level assistants. The team is usually chosen from within the inspector's own institution, but this is only because of the logistics involved in recruiting inspectors. We are currently developing a computer program to provide a data base on inspectors, and hopefully, this will make it easier for an inspector to recruit assistants from other laboratories in his or her area.

The commissioners and inspectors, through daily contact with the many laboratories in the program, are continuously aware of the expanding technology and changing needs within the practice of laboratory medicine. Inquiries are addressed to the College from laboratories all over the country, questioning the scientific relevance of certain requirements, or seeking advice on acceptable methods for meeting the requirements. All of these inquiries are reviewed by the commission and are often referred to one of the College's resource committees. The resource committees are comprised of pathologists with expertise in special areas such as toxicology, parasitology and so on. The resource committees review the questions referred by the commission and offer their expert knowledge in resolving these issues. In many cases, the questions raised by the participants or inspectors point up outdated aspects of the program, which are then promptly changed. Such input also adds to the further development of the program by calling attention to details that might ordinarily be overlooked.

3. Standards and Criteria for Accreditation

The standards required to achieve accreditation are very comprehensive, addressing all aspects of quality control, such as methodology, reagents, control media, equipment, proficiency testing, specimen handling, and reports. They also include requirements on safety, instrument maintenance, personnel, laboratory environment and facilities. In order to assure that all of these requirements are met uniformly in each laboratory, the commission has developed Inspection Checklists containing more than 1700 questions on all areas of the lab. Today's checklists are computerized to allo for constant updating, as the state-of-the-art continues to expand. These checklists serve as an aide to the inspector, since there are so many requirements, and it is very possible to overlook something without such a guide. However, in a peer-review pr gram, the real emphasis is on the professional judgement of the inspector. Through his knowledge of the I&A Standards and his experience as a pathologist, the inspector evaluates, not only the routine systems of quality control within the laboratory, but also the effectiveness of various approache the underlying attitudes and the management principles which determine how well the lab oratory is serving the patient.

4. Proficiency Testing

One of the major requirements for achieving and maintaining accreditation, is the successful participation in an interlab oratory comparison program. Laboratories i the College's I&A Program are required to participate in the proficiency testing programs offered by the College. The College refers to its proficiency testing programs as Survey Programs (not to be confused with inspection). The College Survey Program is the most widely accepted program of its kin with more than 9000 laboratories enrolled, providing the largest data base for interlaboratory comparison in the world. At the time of the on-site inspection, the proficiency test results are reviewed by the inspector. The regional commissioner again reviews the results as part of the overall review of the inspection report. All unacceptable results (those outside the limits established by the comparison) must show evidence of review and corrective action. Once the laboratory is accredited, a semi-annual summary of survey results is generated by the computer and sent to the lab. Copies of this report are also sent to the regional commissioner for review. This assures that an accredited laboratory is continuously being monitored for proficienc in specimen identification.

5. Education

Continuing education through peer-review and professional consultation is an integral part of a program such as the College's I&A Program. The inspector and members of the team bring with them the knowledge and experience they have gained through past inspections, as well as their

own professional experiences. This provides the setting for an exchange of knowledge that is beneficial for both the laboratory being reviewed and those performing the review. In recognition of this fact, the American Medical Association has authorized the issuance of continuing medical education credit to pathologists practicing in CAP accredited labs and to each pathologist who inspects for the College. One of the best examples of the educational process involved is seen in the summation conference. During this conference the inspection team meets with the laboratory director and the staff to go over the findings of the inspection. The Inspector's Manual [1] that is provided to the inspector each time he agrees to perform an inspection, states that "The summation conference is an appropriate time to present the objectives of the inspection and accreditation program and discuss improvement of the laboratory in educational terms."

6. Government and Professionel Relations

There are many programs, both governmental and professional, that conduct inspections in the lab. For many years, the College has worked to eliminate duplicate inspections through close liaison with other groups. The College has maintained an equivalency with the Clinical Laboratory Improvement Act of 1967 since its implementation. This equivalency enables a laboratory accredited by the College to apply for an exemption from licensure and to substitute its College inspection in lieu of federal inspection. The College also had formal agreement with three states, Georgia, Connecticut, and Tennessee, to substitute CAP inspection for state inspection and negotiations are currently underway in several other states. In addition, the College has recently entered into an agreement with the Joint Commission on Accreditation of Hospitals, whereby hospital based laboratories accredited by CAP are not inspected by JCAH. The College also maintains liaison with many of the specialty societies within the laboratory field, such as the American Association of Blood Banks and the American Association of Clinical Chemists.

7. Inspection Process

A laboratory achieves accreditation from the College through the following steps: First they phone or write our office to request an application. We send the lab a packet of material consisting of a Long Form Questionnaire, the Inspection Checklists, which I showed you earlier, a booklet of Standards and a covering letter instructing the lab on how to complete the information required. The Long Form Questionnaire contains questions on test volume, instrumentation, methodology, and quality control. We also ask that the lab provide a personnel form on all professional and supervisory personnel, a sketch of the laboratory and copies of proficiency test results for the past year. This data provides information to the inspector before his visit, which indicates what will be involved in the inspection. In this way he can also select an appropriate team. It also supplies information to our office which is kept in a permanent file.

The checklists give the lab a chance to review the requirements in each section before submitting the forms for inspection. Since the standards are stringent, it often takes several months for the laboratory preparing for its first inspection to institute all of the quality control measures that are required for accreditation. Procedure manuals need to be updated, documentation reviewed, and checks made for health records, safety manuals and maintenance records. Often the lab preparing for its initial inspection will send a representative to one of the Laboratory Improvement Seminars that are presented throughout the year by the commission.

Once the completed forms are received in our office, a notice is sent to the commissioner informing him that the lab is ready for inspection. The commissioner then appoints an inspector to visit the laboratory and notifies us so that we can send the data on the lab to the inspector. The inspector reviews the data and contacts the lab to arrange for an inspection date. All inspection visits are announced. The inspection is normally scheduled about five weeks from the time the lab submits the completed forms.

The inspector and the team then visit the laboratory. They hold a preliminary orientation meeting with the lab director and department heads. In a hospital lab, the inspector also meets with the hospital administrator and chief of staff. The inspection team then goes through the lab and completes the inspection checklists. After the inspection, the inspection team and laboratory staff assemble for the summation conference, mentioned earlier.

After the on-site visit, the inspector sends his report to the College computer center where a computerized list of

deficiencies is generated. This computer report, along with the inspector's written comments is sent to the regional commissioner with the rest of the file. The commissioner then reviews the report and sends a copy to the lab director with appropriate comments, requesting that the deficiencies be corrected and that documentation be provided for each corrective action. The lab is given 30 days to respond to the report.

Once the commissioner receives the response from the lab, he carefully reviews the entire report, and once he is satisfied that each deficiency has been adequately corrected and documented, he sends his recommendation to accredit the lab to our office, and an accreditation letter is sent to the laboratory under the chairman's signature. A certificate is also ordered at this time. Formal approval is made by the entire commission at its next regularly scheduled meeting. If the lab fails to meet the standards required for accreditation, it is advised on ways to correct the deficiencies and invited to re-apply after one year. Each year there are approximately twelve to sixteen labs that are denied accreditation.

Each step of this process is monitored on our computer and a weekly report is sent to our office so that we can keep track of all the labs being inspected. Once the laboratory is accredited, this information is entered on the computer and the time is automatically set so that the lab receives reinspection forms 90 days before its accreditation is due to expire. The accreditation, by the way, is valid for a two year period. During the interim year, between on-site visits, the lab is sent a set of the Inspection Checklists and asked to perform a self inspection. This enables the lab to evaluate its current status and correct any deficiencies that may have cropped up since the last inspection. A copy of the self inspection report is sent to the inspector who is assigned to perform the next on-site visit, so that he can check to see that the deficiencies noted in the interim year have been corrected.

Our data shows that each subsequent inspection uncovers fewer and fewer deficiencies. This is a clear indication that the program is meeting its primary goal of laboratory improvement.

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LABORATORY ACCREDITATION FOR TOXICOLOGY FACILITIES

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Certification of toxicologists and accreditation of toxicology laboratories have been the subject of concern to the Society of Toxicology since 1973. Numerous committees have studied the problem and all came to the conclusion that such programs would greatly enhance the science of toxicology. This paper describes certification and accreditation programs for toxicologists and toxicology laboratories.

Key words: Accreditation; certification criteria; evaluation; toxicology laboratories.

1. Introduction

For some years, there has been concern on the part of the regulatory agencies in the Federal government about the standards of performance of laboratories submitting data on chemicals that must receive approval prior to shipment in interstate commerce. Congressional committees and consumer organizations have been quick to blame toxicologists for having inadequate performance standards. When certain laboratories were charged with failure to meet good laboratory practices, the credibility of toxicologists suddenly came under fire. Officials of the Food and Drug Adminstration and the Environmental Protection Agency testified before Congressional committees that data from toxicology laboratories could not be relied upon and something would have to be done to ensure the quality of performance by laboratories submitting data to regulatory agencies. The Society of Toxicology became deeply concerned about these charges and responded by supporting and sponsoring a certification and accreditation program.

2. Certification

In June, 1979, the American Board of Toxicology was incorporated in the District of Columbia. It is now in the process of preparing a "self-evaluation examination" program which will be available to anyone who wishes to test his or her skills on competence in toxicology. The examination will be graded and persons found to be deficient in any area(s) will then have an opportunity to take refresher course(s) in preparation for a full-fledged examination for certification. The response to participate in this program has been most encouraging and indicates that toxicologists regard toxicology as requiring a high degree of professionalism. The Board is totally independent of the Society of Toxicology and elects its own officers and Directors. It did however receive substantial financial support from the Society to help defray expenses in getting the program underway.

3. Accreditation

The development of reliable toxicological information depends upon the caliber of the laboratories from which basic data are obtained.

In July, 1979, the Toxicology Laboratory Accreditation Board was incorporated in the District of Columbia to provide a program for laboratory accreditation. The Board consists of twelve members, with approximately equal representation from industry, government, academia, and consulting laboratories. The Board is independent of the Society of Toxicology, but received a grant in support of the organizational work.

The purpose of the Toxicology Laboratory Accreditation Board is to encourage, promote, and maintain high standards of performance in toxicology through a system of accreditation by (1) recognizing those laboratories demonstrating competence in various aspects of toxicology; and (2) promoting good laboratory practices in toxicology. The Board will accredit a toxicology laboratory in specific functional areas for which the laboratory requests accreditation and demonstrates that it meets the standards and requirements for accreditation. Any laboratory applying for accreditation must designate on the application those functional areas for which accreditation is desired. For each area, the toxicology laboratory may receive full accreditation, provisional accreditation, or accreditation withheld. To receive full accreditation, an applicant must have completed and prepared reports or publications of studies in the functional area for which accreditation is sought. Failure to obtain full accreditation in one functional area will not normally influence the action of the Board in considering other areas within the same laboratory. A list will be published annually, specifying functional areas in which full accreditation has been granted. Provisional accreditation will be granted to a laboratory which meets all requirements in staff, facilities and procedures but has not demonstrated proficiency. Within a limited period of time (to be determined by the Board), the laboratory must meet the deficiency provision to become fully accredited or provisional accreditation will be revoked.

A laboratory that has been fully accredited and subsequently found to have serious deficiencies will be notified of those deficiencies and given the status of probationary accreditation. Within a specified period of time (to be determined by the Board) the deficiencies must be corrected or accreditation will be revoked. Laboratories from which accreditation is withheld will be given a report listing th deficiencies and the laboratory may reappl (no earlier than six months) before consid eration will be given for accreditation. Laboratories applying for accreditation wi be required to pay a nonrefundable applica tion fee, the amount being determined at t time of application, the size of the labor tory, number of professional and technical staff, number of animals housed, and an es mate of the time required for the site vis To help defray expenses of the Board, accr ited laboratories will be required to pay an annual fee.

It is anticipated that toxicology lab oratories will seek accreditation for the following reasons: (1) to serve as eviden that an accrediting organization of profes sional peers considers the laboratory cap able of performing toxicological investi- gations, (2) to provide outside consultati with the assurance that the procedures to followed are consistent with the "state of the art" and, (3) to serve as a means of determining whether facilities and equipme or procedures could be improved upon.

The Board is currently in the process of preparing a manual on procedures for accreditation which will include instructions for filing applications, payment of fees, and preparations for site visits. The site visit team will consist of two or more individuals, including experts in the area for which accreditation is being soug The review will be based on guidelines for good laboratory practices, as established by the Board. Particular attention will b given to such things as qualifications of personnel, adequacy of facilities and equi ment, scientific soundness of protocols, conduct of study, appraisal of the results and the program for quality assurance.

It is hoped that the establishment of the Toxicology Laboratory Accreditation Board will lessen the need for government intervention. It is essential that person working in laboratories be given freedom t pursue new ideas while at the same time wo under self-imposed high standards. The Accreditation Board fulfills this need be- cause it is a voluntary program.

SESSION IV

ACCREDITATION SYSTEMS AND CONCEPTS

CHAIRMAN: JOHN A. GRANT
AMOCO OIL COMPANY

tional Bureau of Standards Special Publication 591, Proceedings of the National Conference
Testing Laboratory Performance: Evaluation and Accreditation, held at NBS, Gaithersburg,
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LABORATORY PERFORMANCE EVALUATION AND ACCREDITATION - IT'S ALL IN THE IMPLEMENTATION

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Based on many years of experience in the development of product evaluation information under Federal, State and local Codes and Standards and related in-house studies of associated accreditation programs, the critical features of these programs have been identified in terms of the degree to which they are likely to achieve their objectives. Most accreditation programs place heavy emphasis on written documentation of conformance to established criteria and in-house quality assurance programs, stressing test equipment calibration and maintenance, with limited attention to the critical control features and measures of the extent of in-house implementation. A review of the critical features of laboratory accreditation programs indicates that these programs must include: (1) "hands-on" proficiency of personnel, (2) feedback mechanisms for program improvement, (3) procedures-in-case-of non-compliance and/or errors, (4) random unannounced inspections of test facilities and (5) independent countercheck reference testing. Accreditation programs lacking in one or more of these critical features can drift to a "least common denominator" modus operandi and fall short of original objectives.

Key words: Countercheck reference tests; critical control features; feedback; implementation; inspections; laboratory accreditation; laboratory performance evaluation; noncompliance; proficiency.

Introduction

Virtually all laboratory accreditation programs currently sponsored by Federal, State, and local regulators place heavy emphasis on written documentation of conformance to established criteria and in-house quality assurance programs, generally stressing test equipment calibration and maintenance. In most cases limited attention is given to critical control features of laboratory quality assurance programs which, if given higher priority in evaluating the

performance of individual programs would provide for an overall higher level of accuracy and uniformity of test results and/or product certifications.

We believe that a review of key elements of laboratory evaluation and accreditation programs is necessary to fully appreciate the significance of the phrase: "It's all in the implementation." These include: "hands-on" proficiency of personnel, feedback mechanisms for program improvement, procedures-in-case-of non-compliance and/or errors, the importance of random unannounced inspections of test facilities and the need for independent counter-check reference testing.

Consideration must be given to current laboratory accreditation programs that appear to be drifting into the "least common denominator" modus operandi with accredited laboratories marginally satisfying established criteria. Accredited laboratories unwilling to lower their performance standards to this "least common denominator" can, by choice, restrict their involvement in particular areas of product testing and certification or withdraw from the entire accreditation program. Emphasis upon implementation of the essential criteria identified as a result of these considerations must be stressed in order to minimize inequity and improve the overall effectiveness of any laboratory accreditation program.

Studies of Accreditation Programs

Underwriters Laboratories is currently involved in a number of laboratory accreditation programs covering a wide spectrum of products and services. This involvement has provided opportunities to study the key features of each program and evaluate strengths and weaknesses. These programs are all related to UL's activities concerned with the evaluation and testing services of materials, products, and systems for public safety. These programs are sponsored or managed by all segments of government -- Federal, State, and municipal -- and, in some cases, by private organizations.

The High Velocity-Short Range Progra

The nature of accreditation criteria and their implementation vary greatly among programs. Some are limited to the most basic elements necessary to accredit a facility: place of business, chief person to contact at the facility, financial status, staff size, and the nature of services provided, accompanied with a prepaid fee. In these cases, the accreditation process is simple, and limited in scope. Problems, if any, usually relate to some minuscule detail overlooked in the application process. We refer to these program as "High Velocity-Short Range" programs.

The Paper Based-Middle Range Progra

Other accreditation programs, however, are supported by a set of "rules and regulations" or accreditation criteria, varying in detail, and covering a broad range of information about the operation and qualifications of the laboratory seeking accreditation. Ownership and management structure, resumes of key personnel and their reporting relationships, details of the physical plant and test equipment, record keeping, report format and in-house review procedures, certification mark or label control, feedback and corrective action procedures, test equipment standardization and calibration, laboratory quality control procedure and freedom from conflict of interest are among the details usually included

in these criteria. Applications for accreditation usually must be accompanied by voluminous paper detail, documenting or responding to, in one form or another, the established criteria. Accreditation under these types of programs, what we term "Paper Based-Middle Range" programs, is based primarily upon a review of the paper submitted by the applicant and the prepayment of fees. Again, any problems usually relate to overlooked paperwork detail.

These paper based programs are numerous; an example which typifies them occurred several years ago. UL made application for accreditation under the designated Rules and Regulations. On the surface, the program appeared to be detailed, broad scoped and comprehensive. We proceeded with some apprehension as to whether or not we could readily meet all the criteria that had been established while at the same time being pleased that the authors of the program showed such initiative in the development of comprehensive quality assurance criteria for accreditation for all applicants. We made considerable effort to gather all the voluminous paper required to respond to the criteria and furnished the several copies required along with the accreditation fee. Subsequently, after one or two trips to the accrediting organization office to discuss certain details, we were accredited and began to implement our services under that accreditation. Based upon the number of hurdles we had overcome to gain accreditation initially, we fully expected a continuing and fruitful dialogue with the accreditation program administrators concerning the implementation of the program. Instead, our <u>total</u> involvement with the administrators for the past 2-3 years has been an annual letter reminding us that continued accreditation was contingent on the payment of the renewal fee.

Multi-Faceted-Broad Range Programs

Finally, there are accreditation programs that involve the full range of elements including: a comprehensive application to establish qualifications, initial and follow-up on-site inspections, a required in-house quality assurance program, proficiency testing and at least an announced intent at the equitable implementation of the originally established accreditation criteria, including deaccreditation procedures.

These are the types of programs that must serve as the foundation upon which the laboratory accreditation programs are built, if indeed the overall concept is to succeed. In fact, it is only through the use of the multi-faceted-broad range approach that the overall need for the establishment of individual laboratory accreditation programs can be supported. If high velocity-short range or paper based-middle range programs continue to be the trend, the entire concept of laboratory accreditation will no longer be supportable.

The Accreditation Panacea

Many accreditation programs depend upon the occurrence of nonconformances in the field to trigger actions by the accreditor to seek correction on the part of one or more participating accredited laboratories, or to begin deaccreditation proceedings. In many respects this "de facto accreditation" system has merit. With one essential difference it is this type of system which the work of third party laboratories has been judged, accepted for many years and continues to be judged and accepted in numerous product testing areas, long before formal accreditation programs came into vogue. It is the system under which UL has grown and gained National and Inter-

national acceptance. The essential difference in the emerging system of accreditation is that participating laboratories initially receive an aura of high competence and performance capability under a cloak of accreditation. Whether or not the aura is deserved or later grows depends upon the nature of the accreditation process. A superficial and ineffective accreditation program can lead to acceptance of the "least common denominator" modus operandi, wherein the accredited laboratory marginally satisfying the criteria sets the level of performance toward which laboratories accredited under the program migrate or feel pressure to follow the downward trend. The sinking ship analogy may fit in this situation; one either elects to say on board and ride it down with the others, or take to the lifeboats, salvaging what you can in the process.

Critical Control Features

Based upon many years of experience and related in-house studies, it is recommended that five "critical control features" be included in laboratory evaluation and accreditation programs and implemented in conjunction with such programs. These features are: (1) "hands-on" proficiency of personnel, (2) feedback mechanisms for program improvement, (3) procedures-in-case-of non-compliance and/or errors, (4) random unannounced inspections of test facilities and (5) independent countercheck reference testing. While each of these elements is individually treated in greater detail herein, it is vital that they be implemented collectively; only in this way will the overall benefit to a given program be realized through the synergistic effect produced.

(1) Hands-on Proficiency of Personnel - The present emphasis on evaluation and accreditation of laboratories based upon review of paper documentation of qualificatio should be reversed. On-site evalua tion should include the witnessing of the conduct of tests or the performance of service by those personnel that are actually engaged in th work. Objective evaluations, including oral interviews designed to elicit the level of familiarity with the test method and equipment should be held with involved personnel at both supervisory and technic levels.

(2) Feedback Mechanisms for Program Improvement - Few existing accreditation programs include mechanisms for feedback from other laboratories or users of the product or service. Such mechanism should be developed and their use encouraged. Feedback mechanisms could include a system for categori ing and analyzing complaints, perio seminars with accredited laboratory personnel and users, periodic infor mational letters or bulletins to participants that call attention to any emerging sub-standard features of the program with recommendations or directives for corrective action and frequent in-depth analysis by the administrators, with input solicited from the participants, to determine if the program is meeting its objectives. To be successful, however, the utilization of feedbac mechanisms must be for the purpose of improving the program, rather that solely being the source of implementing punitive actions.

(3) Procedure-In-Case-Of Non-Compliance or Errors - This contro feature is perhaps of the greatest overall importance to the effective ness of an accreditation program. If the actions taken to correct a non-compliance, either under the accreditation program or the in-house quality assurance programs o the participating laboratories, represent long-term procedures

wherein the non-compliance (i.e., laboratory program defect, incorrect test data generation, etc.) is allowed to continue until a resolution is found or on a so-called temporary provisional basis, which in reality becomes a permanent condition, then meaningful procedures in-case-of non-compliance exist in name only.

Effective procedures-in-case-of non-compliance are based upon the premise that actions associated with a proven non-compliance must cease. This means, for example, that an accredited laboratory ceases to conduct certain tests under the banner of the accreditation until the non-compliance is resolved; this means that manufacturers of the products so tested cease using the non-complying product performance test data in conjunction with the marketing of the product; this means that if the non-compliance continues, deaccreditation follows expediciously.

Indeed the strength and substance of the answer to the question "what happens in case of non-compliance?" represents the strength and substance of the entire accreditation program. This question must be asked of all participants in any accreditation program and the answer carefully analyzed by the accrediting organization. Organizations utilizing multi-faceted broad range accreditation programs will recognize the weak, non-substantive answers as being characteristic of ineffective in-house laboratory quality assurance programs.

(4) Unannounced Inspection of Test Facilities - It is recognized that the initial on-site evaluation of personnel and test equipment should be announced. Laboratories may need a reasonable amount of time to determine that the facilities are, in fact, ready for accreditation under particular criteria of a given program. Once accredited and providing services under the program, laboratories should be subject to random, unannounced on-site inspections. They serve as a means for early detection of substandard performance, disclosure of major changes in key personnel and significant variations in major test equipment and serve as a countercheck that important recommendations for improvement have been implemented. Most importantly, this unannounced visit permits the examiner to make a more accurate evaluation of the laboratories' day-to-day operations and avoid one-time demonstrations capability that can be associated with announced facility inspections.

(5) Independent Countercheck Reference Testing - Another very effective mechanism for monitoring the work of laboratories is to continually subject the results of a wide spectrum of their work to review and countercheck. Anonymity among participating laboratories is a necessary requirement, as is the need for reporting the results to participants. Given the opportunity to compare the results of their work with other laboratories, program managers are much more likely to correct non-complying performance. Similarly, they are in a much better position to demand that accreditors take action to correct deficiencies indicated through interlab reference specimen testing.

Summation

UL's experiences with accreditation programs have not been entirely on the negative side. We are currently participating in some accreditation programs that have been carefully and knowledgibly conceived and uniformly and equitably implemented.

The success or failure of any laboratory accreditation program ultimately depends upon the persistence and judgment of the administrators to implement the program in a uniform, equitable manner with insistence upon compliance with all features of the program's criteria.

It is perhaps appropriate to close with a quote by Elbert Hubbard, who wrote the famous "Message to Garcia." In his published notebook he said: "We shall never get the right idea of work until we see at the bottom of it is public service."

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LABORATORY ACCREDITATION BY DISCIPLINES

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Abstract

In Laboratory Accreditation Programs by Discipline - the laboratories are accredited for performance of groups of tests or specific tests within a discipline of testing. Individual laboratories may be accredited in more than one discipline and for one or more classes within each discipline. The evaluation process for discipline accreditation covers the technical and ethical competence of the personnel, and the equipment and quality control procedures for the discipline/groups of tests that are enumerated in the laboratory's application for accreditation.

Key words: Classes of tests; directory of accredited laboratories; discipline; laboratory accreditation.

1. Introduction

The principles of "accreditation by disciplines" are not generally understood, although they are utilized successfully by the largest national system, Australia's National Association of Testing Authorities (NATA). They are also utilized by the American Association for Laboratory Accreditation (AALA), and are acceptable to the National Voluntary Laboratory Accreditation Program (NVLAP) under their optional procedures (15 CFR Part 7c) for private sector organizations.

2. Nine Technical Disciplines

The NATA and AALA systems have nine technical disciplines as follows:

1. Acoustical and Vibration Measurement
2. Biological Testing
3. Chemical Testing
4. Electrical Testing
5. Thermal Testing
6. Mechanical Testing
7. Metrology
8. Non-destructive Testing
9. Optics and Photometry

Each discipline has sub-disciplines referred to by NATA as sections and/or classes of tests, and by AALA as groups of tests. A group of tests within the electrical discipline may cover a type of test such as high voltage testing or be by broad product classification such as batteries.

NATA divides the Non-destructive Testing discipline into seven sections:

Radiographic examination of metals
Radiographic examination of non-metals
Radiographic examination of components and assemblies
Ultrasonic examination of metals
Ultrasonic examination of non-metals
Ultrasonic examination of components and assemblies
Other non-destructive tests

Each section is divided into classes of tests. Applications for accreditation may be made for one or more classes of tests or for one or more items within a class of

tests. Examples of the breakdown of two NATA sections within the Non-destructive Testing discipline are as follows:

Radiographic Examination of Components and Assemblies
- Aircraft structures
- Components and assemblies (applicant to specify)

Ultrasonic Examination of Non-metals
- Ceramics and refractories
- Plastic laminates
- Plywood
- Other specified non-metals

The above examples help illustrate that a laboratory is evaluated for accreditation by sub and sub-sub disciplines, not for all the testing within the discipline. The laboratory specifies the extent of its capabilities in its application and requests accreditation accordingly.

3. Evaluation Process for Discipline Accreditation

All valid laboratory accreditation programs involve an on-site evaluation of the capabilities at the laboratory. After the laboratory's application has been reviewed and deemed to provide adequate information, trained, professionally qualified inspectors are assigned to visit the laboratory to evaluate its technical competence to perform the types of tests indicated in the application.

The evaluation covers the personnel, equipment, organization, laboratory and quality control procedures for the discipline and all involved types of tests. Since discipline accreditation is more broad-range than accreditation "by product-by standard" the review of personnel and adequacy of procedures must be very extensive. Demonstrations of typical tests during initial evaluations and follow-ups are required.

The initial inspection of the laboratory requires a minimum of one day and up to several days dependent upon the size of the laboratory and the number of classes of tests in each discipline. A similar amount of time is required to evaluate the same laboratory for a single product being tested per one or a limited number of standards.

4. Discipline Standards and Accreditation Criteria

The NATA program has a separate booklet that provides information on requirements for registration in each discipline. Each booklet describes the coverage of the discipli and the classes of test, the application a evaluation procedure and other pertinent i formation.

The AALA program is similar and each discipline accreditation program is based upon voluntary consensus standards that have been and are being developed in ASTM and other standards writing organizations. These separate discipline standards follow the generic criteria that are provided in ASTM Standard E-548 "Standard Practice Generic Criteria for Use in the Evaluation of Testing and/or Inspection Agencies" and ISO Guide 25 "Guidelines for Assessing the Technical Competence of Testing Laboratori

5. Directory of Accredited Laboratories

An important function of all laborato accreditation programs is to make availabl to all interested parties on a current bas a directory of accredited laboratories, wi clear designations of the discipline and types of tests covered by the accreditatio The user of the accreditation program must be made aware of the basis of the evaluations, the extent and limitations of the listings, and the reevaluation procedures. This full disclosure is important since th user of the accreditation and testing serv ices must determine if the accreditation process is adequate for his use or whether he wants to add additional requirements to satisfy his specific needs.

In addition to the above information, the NATA Register of Laboratories details the terms of the accreditation and lists the signatories. The terms of accreditati are those classes of test applicable to th work of the laboratory, modified by ranges of measurements where they are applicable, and by statements of uncertainty of measu- ment where they are applicable. The approved signatories are the laboratory offi cers to whom the Council has given specif approval to sign NATA endorsed test documents. Endorsed test documents may be signed by these signatories. If any of th leaves the laboratory, he is automatically terminated. The NATA Directory is in the form of loose-leaf sheets, with one or mo sheets for each laboratory. Updating she s are distributed frequently.

6. Conclusion

There are hundreds of laboratory accreditation programs covering specific, limited areas of test; they are operated numerous organizations, such as corporati s, trade associations and government agencie

nd are generally limited to their own use uch as for a product certification program. s a consequence of these splintered and un- oordinated accreditation programs, most aboratories in the U.S., especially the ulti-discipline laboratories doing testing or fees, are inspected many times every year. his becomes expensive and represents un- ecessary duplication of efforts.

The only national systems in the U.S., hat have as their objective providing ac- reditation in all or most test areas, are VLAP (government operated) and AALA (private ector program).

It is important to recognize that ac- reditation by discipline is a broad-band pproach and as such permits a greater ortion of the total accreditation assign- ent to be done in a shorter period and in more efficient manner.

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ACCREDITATION PROGRAM FOR CANADIAN TESTING ORGANIZATIONS

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The paper briefly describes the constitution, role and responsibilities of the Standards Council of Canada, which is the accrediting authority for the national voluntary accreditation program for testing organizations in Canada. It also touches on the composition of the National Standards System (NSS), a federation of independent autonomous organizations working towards the further development and improvement of voluntary standardization in the national interest. This system, which is under the aegis of the Standards Council, will include accredited testing organizations as one component.

The document, "Criteria and Procedures for Accreditation of Testing Organizations" (CAN-P-4) was approved and published by Council in 1978. A limited (pilot) accreditation program is being conducted this year (1979) in order to evaluate implementation procedures and estimate costs for a national program. It is hoped that this limited program will provide sufficient information for Council to make decisions in 1980 concerning a national program.

Key words: Accreditation; Canada; Laboratories; Standards; Standards Council of Canada; Testing.

1. Introduction

This presentation describes the Standards Council's accreditation program for Canadian testing organizations but first it may be of interest to provide some information on the constitution of the Council. The Standards Council of Canada was created by an Act of Parliament in 1970 (The Standards Council of Canada Act). Its membership consists of 16 Federal and Provincial officials and 41 representatives from private organizations which have interests in the field of standardization. However, it is important to emphasize that the Council is not a government agency nor are its employees public servants. In effect, it is independent of government in its policies and operation although it is financed by a grant from the Federal Government.

The prime objective of the Council (as stated in the Standards Council Act) is to foster and promote voluntary standardization.

The Act also states that the Counci in carrying out its objectives, may "accredit, in accordance with criteria a procedures adopted by the Council, organ zations in Canada engaged in standards formulation, testing and certification..

The Council was not created as a su organization duplicating existing expert e and facilities. It does not itself prep e write or publish standards. These funct ns are performed by the Standards-Writing Organizations (SWOs) who are accredited the Council in accordance with approved

criteria. Similarly, the Council does not plan to certify products or operate testing laboratories but is implementing programs to accredit both Certification and Testing Organizations.

2. National Standards System (NSS)

The National Standards System 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".

The programs for accreditation of certification and testing organizations are now in the implementation phase and the current status of the testing program will be described later.

3. SCC - Organization

And now before introducing the main topic of my presentation, I feel it might be of some value to briefly describe the SCC organization. The Council itself meets only twice a year and the responsibility for its affairs between these meetings is delegated to a nine member Executive Committee. This Committee meets six times a year.

The day-to-day work of the Council is planned and co-ordinated by a permanent staff of approximately sixty. Four branches headed by Directors are responsible to the Executive Director. Three of these branches are located at the Council Headquarters in Ottawa with one (the International Standardization Branch) situated in Mississauga, Ontario (near Toronto).

The specialized professional expertise and experience is provided to Council by various Advisory Committees. Thus the Advisory Committee on Certification and Testing (ACCT) is the body responsible for supplying advice and guidance to Council on these activities. The ACCT is a 24 member body which was formed in 1974 and since that time has operated under the chairmanship of Mr. J.E. Elliot, Director of Engineering, Vehicle Quality and Safety, Chrysler Canada, Ltd.

4. Accreditation of Testing Organizations

The document "Criteria and Procedures for Accreditation of Testing Organizations" (CAN-P-4) was approved at the Twenty-First Council Meeting on June 5, 1978. Before discussing this document a résumé of the background of the program including a brief outline of its scope might be in order.

One point which I would like to stress is that the Council program for the accreditation of testing organizations envisages testing as a function in itself and not solely in its relationship to certification programs. The goal 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. Such a program would permit competent organizations in all fields of testing to qualify for national accreditation. This would include calibration services, testing for product development, research and contract monitoring as well as testing in support of certification programs.

It is planned 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 other Federal Government departments conduct programs to determine if manufacturing and service organizations are qualified in accordance with legislated requirements or, in other cases, to specific contract specifications.

In addition to these government activities there are also some non-government agencies operating qualification programs. 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. The program is operated by the Certification branch of that organization.

4.1 CAN-P-4

Reference was made above to the approval by Council of a criteria and procedure policy document for the accreditation of testing organizations. This document was published in September, 1978, with the title "CAN-P-4 - Criteria and Procedures for Accreditation of Testing Organizations".

In addition to approving the draft CAN-P-4, Council also authorized the Advisory Committee on Certification and Testing (ACCT) to proceed with the development of implementation procedures, the investigation of legal aspects and the implementation of a limited program to estimate costs. The first two activities have been completed and the implementation of a limited program has been initiated. This limited program is essentially a pilot project and on its completion (the evaluation of a small number of representative testing organizations) recommendations will be made to Council concerning the implementation of a national accreditation program.

In format CAN-P-4 consists of a Foreword, Preface, nine Sections and three Annexes.

There are seven criteria which are summarized below:

Criterion 1: Ability to operate and maintain an adequate testing capability.

Criterion 2: Staff-administrative competence.

Criterion 3: Staff-technical competence.

Criterion 4: Adequate facilities.

Criterion 5: Documented and acceptable procedures for maintenance of records.

Criterion 6: Willingness to allow examination of records, etc.

Criterion 7: Independence of operation.

CAN-P-4 is, in essence, a "generic" type document in that its criteria and requirements must be met by any applicant for 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" and in Annex "C" to CAN-P-4 they are listed as - Chemical, Electrical, Mechanical, Non-Destructive and Physical.

4.2 Implementation of the Accreditation Program

Accreditation of testing organizations is a two-level procedure. The first level consists of compliance with CAN-P-4 and the second level is defined by supplementary documents related to that portion of the specific field for which the applicant has requested accreditation. These supplementary documents may be National Standards of Canada, other established standards or a client's specifications. It will be the responsibility of the applicant to supply this documentation and identify those portions of the field (or fields) of testing for which it claims competence.

It is realised that while a small testing organization would probably be interested in being accredited for a small portion of a specific field, a large organization might well request accreditation in several fields.

The evaluation of a testing organization is conducted by a Testing Accreditation Sub-Committee (TASC) of the Advisory Committee on Certification and Testing (ACCT). This sub-committee consists of a chairman and two members and it is authorized to request assistance from specialists when necessary. After the evaluation is completed the TASC makes its recommendation through ACCT to Council. The Standards Council is the approving authority for accreditation.

5. Other National Programs

There has been a considerable amount of documentation generated in the past few years by other countries regarding laboratory accreditation.

Some national accreditation programs are already in operation and the Standards Council has been able to take advantage of the previous effort which has been expended by others in this area.

Specifically, I would like to refer to the work done by the U.S. Department of Commerce and the National Bureau of Standards in the development of their NVLAP

program. Other sources from the U.S. are ASTM, which produced its Standard Recommended Practice E-548-76, and the American Council of Independent Laboratories (ACIL) which has also been active in this area. The program of the American Association for Laboratory Accreditation is also being noted with interest.

From the U.K. we have also benefited by the work done by the British Standards Institution (BSI) and the British Calibration Service (BCS). Their procedures and documentation have been of considerable assistance to us.

We have drawn on the Australian experience where the National Association of Testing Authorities (NATA) has had a laboratory registration program in existence for over thirty years - indeed it is probably the pioneer in this respect. A more recent national scheme is that of New Zealand where the Testing Laboratory Registration Council (TELARC) has been in operation for the past few years.

On the international scene the Council has participated in the 1977 and 1978 International Conferences on Recognition of National Programs for Testing Laboratories (ILAC) and will be represented at ILAC 1979.

6. Conclusion

It is anticipated that the program for accreditation of testing organizations will assist in identifying those organizations which have demonstrated competence. Objectivity, impartiality and accuracy are the major elements to be considered in establishing the credibility of an organization which provides such testing services.

A Directory of organizations which have demonstrated their ability to comply on a continuing basis with common agreed criteria and procedures will, it is believed, considerably enhance their national status and recognition. It also should be 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 it receives from both the participating organizations and the users of their services. It is still too early to determine this response or to assess the impact on national testing activities.

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ECONOMIC EFFECT OF LABORATORY ACCREDITATION

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A fear of some commercial laboratory owners about national accreditation is that laboratories remaining unaccredited will be able to charge lower prices and, thus, garner the majority of the testing business. This study determined average prices for tensile tests of metals, relative amounts of these tensile tests performed in "well-accredited" and "poorly-accredited" laboratories; and determined the effect of being accredited, under today's systems of accreditation, on the quantities of tensile testing business obtained by commercial laboratories. In geographic regions where being "accredited" is recognized as important by a major segment of manufacturing industry, most of the tensile testing, regardless of price, is performed in "well-accredited" laboratories. In geographic regions where no strong segment of consuming industry requires "accreditation", most of the tensile testing is done in laboratories "poorly accredited" by today's systems. Thus, if the consuming industry recognizes the value of accreditation, there will be an economic advantage for accredited laboratories: they will be able to charge more and also may gain more testing business. In regions where no strong segment of industry recognizes the value of accreditation, accredited laboratories will suffer economically. The economic effect of any proposed laboratory accreditation program should be studied prior to initiating the program.

Key words: Accreditation; costs; economic; prices; testing.

1. Introduction

The owner or manager of a commercial laboratory is always prey to the suspicion that competitors charging lower prices will garner most of the available business. Many types of testing are looked upon by consuming industries and governmental agencies as commodities: quality is either taken for granted or not cared about.

Everybody says laboratory accreditation costs money. All laboratory owners seem to say they spend great quantities of time preparing documentation and undergoing inspections. Presumably, there would be a economic effect of national accreditation.

The Federal Register of April 2 1979 published a comment by the Depa ment of Commerce, page 24276, that said quite strongly that there is no need to study the economic impact of accreditation programs, because thos requesting the accreditation progra

will already have considered the economic impact. My interest was piqued. I had neither heard nor read of factual economic studies.

I proposed to Dr. Berman that the economic impact of accreditation on tensile testing ought to be studied, and I proposed to do so on a large number of laboratories. I suggested that I would come here today to report on data and results of which I had, at that time, no knowledge. I see, as a matter of fact, that I am the only speaker in the entire program discussing economics.

2. The Study

The tensile test of a metal is a pull in a testing machine of a sample that has already been prepared to a specific shape and size. Preparation charges for test samples vary and are often quoted as a fixed price. However, the price of the test alone is almost always quoted on a fixed price basis.

Within certain bounds, the test must be performed approximately the same way by almost all laboratories. Properly done, about 5 to 7 tensile tests per hour are possible. Shortcuts, which sometimes lessen quality, enable as many as 10 to 12 tests per hour to be done. This lowers cost and can lower price. The price any one commercial laboratory charges for a tensile test can be quoted; is likely to reflect the way the laboratory does the test; and also may reflect competitive conditions the laboratory faces.

I sent questionnaires to over 100 commercial laboratories in the eastern United States and asked the prices they charged for tensile tests. I also asked questions which would indicate whether or not each laboratory was in a condition that would probably enable it to pass an accreditation inspection. A copy of the questionnaire is attached to the written copy of this talk. As you might expect of a novice, I didn't ask exactly the right questions; and I had to telephone a great many laboratories both to get answers and to form opinions as to their accreditation status.

I divided "accreditation status" into 2 categories: "good" and "fair". Laboratories that had quality-control manuals and had already been approved by accreditation systems that I believed to be thorough (such as the aircraft engine industry), I considered to be in the "good" category. Laboratories without quality-control manuals or which had been inspected only by customers such as welding fabricators in the nuclear industry, who often perform "less-than-rigorous" inspections, I considered to be in the "fair" category. I have personally visited a number of the laboratories in this study and I talked by telephone to many more. While there may be disagreement with my definition of accreditation categories, I am quite certain that I placed most of the laboratories in the proper category.

3. The Data

In the eastern United States, with perhaps not enough laboratories reporting, Table 1 shows the average price overall for tensile tests, and the average prices charged by "fair" and "good" categories of laboratories. The "good" and "fair" are within 12% and 2%, respectively, of the overall average. All prices over $25. and all laboratories doing under 5 tests per week are excluded.

Table 1. Average Price Per Test
Eastern U.S.
(Incomplete Data-41 Laboratories)

Overall	$12.12
22 Accredited "Good"	11.86
16 Accredited "Fair"	13.53

Now, here is a rule of thumb regarding pricing: an industrial customer, who has been regularly using a certain vendor, will not shift to another vendor on a price basis alone if the reduction of price is less than 10%. In the laboratory industry, users seem to require even greater reductions of price to induce them to change from one commercial laboratory to another. The data of Table 1 doesn't show enough variation of price to cause shifts of customers. Oddly, the

"good" category seems to charge a lower average price.

Table 2, in which the volume of tests performed in various laboratories is considered, throws a different light on the subject. Here we see that most of the tensile tests in the eastern United States are performed by the "good" category at

Table 2. Price and Quantity
Eastern U.S.

Tests Per Day	Average Price	Where Done
20 or more	$11.58	100% in Good
10-20	8.78	60% in Good
5-10	12.45	60% in Good
Under 5	13.70	30% in Good

prices lower than the eastern average. Although not shown in the table, 2/3 of all tests done in the eastern United States are priced below average and half of all the tests done are performed in the "good" category laboratories.

These broad-scale geographic data must be considered with caution. They cover too much territory geographically, whereas most tensile testing of metals is done on a regional basis. Probably most commercial laboratories are regional: serving a small geographic region. In the eastern United States, probably very few tensile test samples travel more than 100-150 miles. The foregoing data overlooks regional competition, and the data to follow provides substantiation.

In New England, Table 3, there are 5 "good" and 6 "fair" laboratories

Table 3. Average Price Per Test
New England-11 Laboratories

Overall Eastern	$12.12	
Overall N.E.	7.75	
5 "Good"	11.50	(+48%)
6 "Fair"	7.92	(-2%)

performing tensile tests. See how much higher, 48%, the average price charged by the "good" laboratories is than the overall average. The "fair" laboratories are almost at the average. This is a situation in which price differentials might induce movements of customers from higher priced to lower priced laboratories.

So, what do we find? Table 4 shows that most of the tensile testing in New England is performed at a price above the New England average

Table 4. Price and Quantity
New England

Tests Per Day	Average Price	Where Done
20 or more	$ 9.85	100% in Good
10-20	10.40	60% in Good
5-10	---	---
under 5	5.50	0% in Good

of $7.75 and most of it is performed in "good" category laboratories. In fact, 60% of all the tensile testing is performed in the "good" laboratories at above the overall average price.

In New England, most of the purchasers of tensile testing are willing to pay higher prices in order to have their tests performed by "accredited" laboratories. New England, incidentally, is the headquarters of two of the nation's largest aircraft engine manufacturers Pratt & Whitney and General Electric. Both companies have very strong laboratory inspection and accreditation systems. Subcontract vendors to these two companies abound, and they are forced to use accredited laboratories for their testing. Many other industries in New England recognize that accreditation by Pratt & Whitney and General Electric means a laboratory does good work.

For the Metropolitan New York City area, which includes New York City, Long Island, and northeastern New Jersey, Table 5 shows the average price charged by "good" category laboratories to be higher than the overall average; while the average price charged by "fair" laboratories is significantly lower than the

overall average. Here, again, the price discrepancy seems great enough to warrant purchasers moving from the higher priced to the lower priced laboratories. Yet, Table 6, we find that all laboratories doing more than 10 tests per day are in the "good" category. In fact, 70% or more of all the tensile tests done in this region are at above the average price for the region and are performed in "good" category laboratories.

Table 5. Average Price Per Test
Greater Metropolitan New York
7 Laboratories

Overall National	$12.12	
Overall	13.86	
5 "Good"	15.50	(+12%)
2 "Fair"	9.75	(-30%)

Table 6. Price and Quantity
New York Area

Tests Per Day	Average Price	Where Done
20 or more	$15.00	100% in Good
10-20	15.00	100% in Good
5-10	12.33	33% in Good

The Metropolitan New York region is complex and less well understood. There is a significant aircraft industry accreditation program, and there may be a "rub-off" factor. There may also be a transportation problem: users hesitating to entrust samples to a slow and difficult shipping situation, and, hence, using the nearest laboratory.

Within the region, there is one small geographic area in which two laboratories are "good" and one laboratory is "fair". One "good" laboratory and the "fair" laboratory compete "head-on" at the same low price. The "good" laboratory does about 50% more tests than the other. Surprisingly, the third laboratory, which is also "good", charges 70% more than the other two and still obtains 30%-50% of the tensile testing business in the area. This seems to indicate that purchasers of tensile testing in this sub-area value accreditation more than price.

In another small geographic area near New York, of five laboratories performing tensile tests, two are "good". Complete data on volume of tests was not obtained, but one "good" laboratory, charging a price 60% of that charged by the others, was doing the heaviest volume of tensile testing found in the eastern United States.

This seems to indicate that a well-accredited laboratory that is able to charge a lower price can attract a very significant volume of the tensile testing market.

The Philadelphia area, Tables 7 and 8, shows a complete reversal of anything discussed so far. Here,

Table 7. Average Price Per Test
Greater Philadelphia Area

Overall National	$12.12	
Overall	10.33	
3 "good"	15.00	(+45%)
3 "fair"	5.70	(-45%)

Table 8. Price and Quantity
Philadelphia Area

Tests Per Day	Average Price	Where Done
20 or more	---	---
10-20	6.50	0% in good
5-10	---	---
less than 5	12.25	75% in good

there is a severe price discrepancy between the "good" and "fair" categories. The price discrepancy appears great enough to make users of tensile testing move to the lower-priced laboratories. The "good" category laboratories have only 25% of the tensile testing market in the region that extends from Baltimore to central New Jersey and westward halfway across Pennsylvania.

This region contains a heavy foundry industry, diverse mundane manufacturing industries, and no strong aircraft or nuclear industry that relies heavily on independent testing laboratories. This is a region in which a tensile test is a

commodity. Price, therefore, is a very strong consideration. Published advertisements and visits to laboratories indicate that sub-standard techniques may be in use and, thus, may hold down cost.

4. Conclusion

There is an economic effect of laboratory accreditation. In geographic regions where most consumers of tensile testing believe accreditation means quality, the laboratories that seem to be best qualified are getting the major share of the business. This is so regardless of whether they charge higher or lower prices. In geographic regions where consumers of tensile testing are not aware, on a widespread basis, of accreditations and possible variations of quality, the laboratories charging the lowest prices are getting most of the business.

Thus, if industry is aware of the value of laboratory accreditation, the economic effect of national accreditation will be good for accredited commercial laboratories: they will obtain more business and at higher prices. If industry does not care about laboratory accreditations and quality, the lion's share of the business will go to lower-priced laboratories, whether they are accredited or not.

Organizations desiring a national laboratory accreditation procedure for a given test or category of tests must study the potential economic effect. This should be done by gathering data on a regional basis in order to avoid disruptions, "splitting the market" for the test, in some regions.

A "split" market" would mean that some commercial laboratories in a region would forego either the accredited or the unaccredited portion of their business. The effect would be to lessen the capacity for doing that type of test in the region. Since commercial laboratories are an integral part of much manufacturing industry, a decrease of testing capacity could be disruptive to industry.

The economic effect of a laboratory accreditation program cannot be taken for granted. The potential economic effect must be studied regionally to be sure that requesters of a LAP from one region do not disrupt the market for testing in another region.

5. Appendix - Questionnaire Sent to Laboratories

What do you charge for performing a tensile test (not including machining) of a standard metal sampl

Do you perform your tests or keep your records in accord with requirements of any industry, government agency, company or anyone (do not include ASTM). (If you follow only ASTM, your answer should be "no".)

IF YES

Are you regularly (at least once each year) inspected by the accrediting agency?

If yes, do they give you a certificate or place you on an "approved list"?

If yes, how many different accreditations like the above do you undergo for tensile testing?

Do you have a typed or written manual that describes the following: how you perform a tensile test, how you prepare and maintain test records, how you check the quality of your tensile tests, who in your laboratory is qualified to perform tensile tests?

SESSION V

QUALITY CONTROL

CHAIRMAN: EDMOND G. FRANZAK
SANDIA LABORATORY

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THE ROLE OF THE QUALITY CONTROL MANUAL IN THE INSPECTION AND TESTING LABORATORY

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An indispensable tool for every testing laboratory is an adequate quality control manual. Such a document is a cornerstone of the laboratory's credibility and an important ingredient in its assessment for accreditation.

Several years ago, the American Council of Independent Laboratories (ACIL), an organization with a long history of interest in laboratory accreditation, made a significant contribution in this area. ACIL commissioned its Laboratory Accreditation Committee to develop a guidebook on laboratory quality control. The committee's product was published by ACIL in 1976; its title is "Manual of Practice: Quality Control System: Requirements for a Testing and Inspection Laboratory."

In this paper, ACIL will review the development of the manual and its contents. Included in it are sections on Organization; Operational Procedures; Personnel; Equipment and Calibration; Reference Samples; Recommended Personnel Basic Requirements; Inventory of Standards and Equipment Requiring Calibration; and Sources of Reference Samples.

The paper will also assess the impact of this manual on the laboratory community. Samples of adaptations of the manual's guidelines by individual laboratories in various disciplines will be presented. Also, reference to the manual by other bodies, such as Government agencies, will be discussed.

Finally, the paper will estimate the importance of quality control manuals and programs in the day-to-day operation of a laboratory and in relation to the broader issues of evaluating and accrediting testing laboratories.

Key words: Calibration; equipment; evaluation; laboratory; manual; personnel; quality assurance; quality control; systems.

Dating back to the sixties and early seventies the independent laboratories, especially those involved with the aerospace industry, were in quite a dilemma. (Although the term "independent" is used in this paper when referring to laboratories, the principles of Quality Control apply to all types of laboratories.) The laboratories began to feel the pinch when multitudinous clients and governmental agencies began their own methods and interpretations of Quality Control Programs and audits of testing laboratories. The laboratories also began to get requests for "Who certifies you?" or "Who accredits you?" or "What national agency qualifies you?". Some laboratories were hiring people strictly for the purpose of working with auditors. It was at this point nearly a decade ago that a group of us in the American Council of Independent Laboratories decided that something must be done to develop a uniformity in the system. When the concept of a laboratory qualification or accreditation program was presented, naturally a committee was formed to develop the idea. Many people in the laboratory business said that it was impossible to accredit laboratories or to develop criteria due to the great diversity of laboratories and types of testing and inspection. However, in developing the concept, it became so simple that it seemed ridiculous that there are, in essence, just three main ingredients in an accreditation program for a laboratory, or really any type of service. They are: People, Equipment and a Quality Control Program. It is not necessary to accredit to every specification, or to every material, or even to every product. This is the muddle in which we have been involved. As we progressed, it became more clear that the backbone of any accreditation program was to be the Quality Control Aspect.

It soon became quite apparent that in order to have an accreditation program, it was necessary to have an "accreditor" and "accreditees". The accreditees we had, they were the members of ACIL but the accreditor was lacking. If we, the ACIL, were to be the accreditation agency, then in essence, it would be a self-certification program and lack the meaning that was wanted and needed.

The emphasis was then switched, by the committee and council, to attempt to develop a Quality Assurance System that would be uniform for testing laboratories regardless of field of operation and be readily adaptable for an accreditation system.

The Quality Assurance System

The Quality Assurance System was then examined and the keys to the concept were established.

These keys were:

Laboratory Organization
Operational Procedures
Personnel
Equipment and Calibration
Reference Samples

Let us examine each of these keys in some detail:

Laboratory Organization

A look at the Laboratory Organization provides an excellent perspective of the Quality Assurance Program. It gives: the type of work that can be performed, the geography covered, the function of the main laboratory and branches, historical data, structure or organization for capabilities, a look at the operational and support departments, and indication of services available.

Operational Procedures

Operational Procedures are a vital part of the Quality Assurance System. Written procedures describing such items as workflow routes; sources utilized for inspections; listings of certifications, qualifications and laboratory approvals by other agencies; detailed procedures for conducting tests analyses, inspections, etc.; and detailed procedures for sampling or selecting specimens for testing, are all a necessary part of operations.

Personnel

Personnel is a major key to establishment of a Quality Assurance System in a laboratory. It would really be great if we could all have a cadre of perfect personnel but I don't think that anyone has achieved this perfect work force. Personnel management systems therefore needed, are Job Responsibility Mandates (job descriptions), Job Training Programs, Personnel Classifications and Personnel Biographies.

Equipment and Calibration

In order to establish credibility in the field of testing, all equipment used must be accurate, reliable and dependable. This constitutes the physical facilities of the laboratory. A complete list or inventory of all equipment requiring calibration or standardization must be maintained; sources for calibration and required frequency must be kept updated constantly and those environmental conditions required must be met.

Now this is where, as they say, the rubber meets the road. The keystone to all systems, Quality Assurance, Quality Control, Accreditation, etc., etc., is DOCUMENTATION. Unless it's recorded, it has no value. Records must be maintained and corrective actions verified. Suitable records shall be maintained for calibratable laboratory standards and test equipment, whether used internally or externally. Each inventory listing should contain the following:

1. The name of the manufacturer.
2. The equipment model and serial number.
3. The properties subject to standardization.
4. The range of operation and the range of calibration.
5. A reference to a recognized calibration procedure.
6. The frequency of calibration.
7. Allowable tolerances or maximum sensitivity.
8. The source of verification.
9. A chronological history of repairs, modifications or substitutions.
10. Traceability of reference standards to the National Bureau of Standards or accepted values of natural physical constants.

The proof of adequacy of standards, and test equipment in particular - capability for accuracy - stability and suitability - shall be established by each laboratory. Subsequent to the cross-referencing of test equipment and calibration standards, the necessary sources and required frequency for verification shall be established. The success of the calibration system is primarily dependent upon the quality control supervisor who is responsible for scheduling calibrations or standardizations. An individual selected for this position should be personally responsible and able to delegate authority, but not responsibility, to subordinates. Determination of realiztic calibration intervals is dependent upon the basis of stability of the instrument or standard, its purpose and degree of usage.

Certain calibrations and test methods require controlled environmental conditions to insure the accuracy of results. Dependent upon the physical property and degree of sensitivity of the calibration or test, certain environmental factors such as temperature, humidity, cleanliness, vibration, voltage, radio frequency interference, pressure and atmosphere must be controlled. The extent of the control required however should be specified.

Written procedures and documented evidence of calibrated standards and test equipment provide the basis for a sound Quality Control Program. Procedural detail may be individually derived by each laboratory or may be altered to conform to established recognized standards. Primarily the scope of the operation must satisfy the referee or inspector, as well as conform to the Client's requirements. Sufficient detail should be incorporated into an in-house procedure so as to make the document instructional to internal personnel as well as meaningful to external referees. The following information is pertinent to such a document:

1. Type of calibration or standardization being performed.
2. Specifics such as calibration points or intervals, accuracy required, governing specifications, etc.
3. Necessary standards and equipment.
4. Record of test data.

5. Equipment condition.

6. Final disposition.

Measuring and test equipment shall be calibrated by the laboratory or an external commercial facility, either of which must utilize reference standards whose calibration has been certified as being traceable to the National Bureau of Standards or has been derived from accepted values of natural physical constants. Certificates or reports shall attest to the fact that the standards used in obtaining the results have been compared at planned intervals with a standard traceable to the national standard or with independently reproduced standards.

To assure continuity of satisfactory operations, provisions must be made for the prevention of equipment and personnel inaccuracies. A documented system of existing practices including periodic inspections or operational checks to insure stability between calibrations shall be established to assure uniformity of performance and to serve as a basis for alteration of standardization intervals.

Records provide objective evidence that calibration schedules are complied with and that the accuracy of the equipment or standards is being maintained. Proof of performance should include reference standard certificates, data sheets containing actual values of both present and prior calibrations, a summary of routine maintenance and repairs made and the final calibration form which suitably cross-references the equipment to the reference or transfer standard.

Reference samples

After all the personnel, equipment and calibration systems are in order and are being documented, then the job of Quality Assurance is still not completed. It is a well known fact in statistical analyses that variables do occur, that makes results fall outside of accepted limits. We must therefore establish confidence limits. The true indication of a good Quality Control Program is in the results obtained; accurate, reliable, repeatable results. This is in effect "the proof is in the pudding", and is determined by objective and competent personnel using standard methods and accurate equipment, instruments, and materials to ascertain the repeatability and accuracy of the laboratories' test results. This proof is obtained by the use of reference samples an/or inspection services. There is a need in this area for the establishment of "round-robin" testing and comparative results. There are many organizations capable of originating and performing this service, but at this time more is needed.

Impact of the Manual on the Laboratory Community

To the uninitiated in the ways of Quality Control the first impact upon starting is ghastly horror. It is "horrendous" job to develop a Quality Assurance Program starting from point zero. It is a lot of work and takes considerable time. It is costly, and there is no use kidding you about it. Those who have done it know only too well what a project it is. Furthermore, it is a continuing job, an ongoing project that needs constant attention. Once established, however, the Quality Assurance Program can be and is very beneficial. Its use can be beneficial in sales of services, it is irreplaceable in accreditation programs and benefits are boundless in loss prevention programs.

The Quality Control Manual is an instruction kit that you have written for yourself to guide your laboratory operation in the production of quality work. I have seen some of the manuals produced by laboratories and they are excellent. When completed, a Manual may well be considered to be a proprietary document, due essentially to the cost that it has taken to produce it. Many are also considered to be proprietary due to the content that a laboratory has included for its own use but not intended for public dissemination. I do not feel that I am at liberty to even suggest the names of laboratories that I know, that have completed their manuals, but if you inquire you might find some laboratory that is willing to share its manual with you.

Use of the Manual of Practice

I personally feel extremely pleased that the Manual of Practice, Quality Control System has been accepted by many laboratories and also by many agencies now writing accreditation criteria. It has become the backbone of many systems now in operation. I come from a genera-

tion of laboratory personnel who needed no quality control because they were the experts - their word was final - if they said so, that was it. Well, times have changed - thank God. And now when we say it, we have the documentation to prove it, we have the system to back us up.

The use of the Quality Assurance System in day-to-day operations of the laboratory is of the utmost importance. Operational checks of equipment before the day's work begins, the check of instruments and the constant use of standards have done more to upgrade testing and inspection services than we can realize. And this is only the beginning.

The broader impact of the Quality Assurance System is in the accreditation process. The certification or accreditation of laboratories or inspection agencies is a failure without recourse to the Quality Assurance System. Studies have shown that a good Quality Assurance System, with proper documentation, provides the basic need for the accreditation audit needed.

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LABORATORY QUALITY PROGRAM REQUIREMENTS

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The need for quality control of laboratory results was identified early by The National Institute for Occupational Safety and Health when a great disparity of analytical results was noted among 14 industrial hygiene laboratories. The result was a four pronged attempt to improve performance: 1 - An educational program was developed; 2 - An inter-laboratory proficiency program, PAT, was started; 3 - A laboratory quality control manual and a standard for laboratory control were developed; 4 - A laboratory accreditation program was developed by AIHA under contract.

The Environmental Protection Agency, the Occupational Safety and Health Administration, the Food and Drug Administration, the American Society for Testing Materials and others have described similar programs in various standards and regulations. Finally the American National Standards Institute (ANSI) Z-1 Committee on Quality Assurance and its Systems and Procedures Sub-Committee have agreed that there is a need for a generic Quality Control Standard for laboratories which will differ from a manufacturing quality control standard. A laboratory quality control standard is being drafted by a writing committee under the aegis of the Biomedical Division of the American Society for Quality Control.

Key words: Accuracy; control chart; control limits; corrective action; data validation; precision; proficiency analytical testing; quality control; statistical quality control.

1. Introduction

Under the Occupational Safety and Health Act of 1970, the National Institute for Occupational Safety and Health was given the responsibility for organizing the analyzing and the reporting of samples collected by OSHA Compliance officers in the detection of contaminants in industrial atmospheres.

Under the provisions of Section 7(c)(1) of the above Act, contracts were let by OSHA with 12 state industrial hygiene laboratories to assist in handling the work load.

Early in the program, to determine the level of agreement among 14 laboratories, 12 state and 2 NIOSH, known samples of contaminants were sent to the participating organizations. Not surprisingly, 14 different results were reported.

Accordingly, a number of steps were taken in an effort to improve laboratory performance by obtaining better agreement among laboratory results. To put it another way, a concerted effort was made to improve the quality of laboratory product, the "product" being reports of analytical results. It was sought, therefore, to improve precision and accuracy of method determination reports, while not providing methods evaluation information.

2. Quality Improvement Measures

Over a period of time NIOSH has taken the following steps to improve laboratory performance quality:

2.1 Proficiency Analytical Testing Program

NIOSH started the Proficiency Analytical Testing Program in May, 1976 known as PAT.[1] The Chemical Reference Laboratory, in Cincinnati, by contract prepares known samples of contaminants -- asbestos, lead, silica dust, cadmium and zinc, and one of eight solvents on charcoal collection tubes. These are mailed at two month intervals to participating laboratories. Results are returned to the CRL. There they are tabulated and forwarded to the participant laboratories.

Each round has four sets of samples (subgroups) plus one blank. We are currently preparing control charts similar to (Figure 1) for each laboratory and each contaminant. Plotted control limits help give an indication of drift tendencies, and a picture of whether or not labs were running their determinations out of control. Current data are used to determine statistically valid control limits.

In addition, selected labs under contract have been given "hands-on" assistance in setting up and maintaining a quality control program. This assistance was given by a consulting firm under contract to NIOSH.

2.2 NIOSH Laboratory Quality Control Manual

In order to improve and make consistent the quality of results obtained by the laboratory the NIOSH Industrial Hygiene Service Laboratory Quality Control Manual (Technical Report #78)[2] was published and widely distributed. This draft manual, which identifies and describes eleven elements of a laboratory quality control program serves two purposes. It assists small laboratories in setting up a quality program, including preparation of a quality manual, and it provides text material for courses given by the Training and Manpower Development Division of NIOSH.

We have found that even in a very small organization, four or five people can successfully conduct a viable quality program.

2.3 Laboratory Accreditation

NIOSH has also contracted with the American Industrial Hygiene Association to support preparation and validation of an accreditation program for industrial hygiene analytical laboratories. This accreditation includes among other things, the need to establish and maintain a quality control system within the laboratory.

2.4 Quality Training

The Training and Manpower Development Division of NIOSH periodically offers a course to assist interested laboratories in obtaining accreditation. A substantial portion of this three-day presentation is devoted to quality control matters, as can be seen from the following course subjects covered:

- History of Laboratory Accreditation
- The Current Program
- Criteria for Accreditation
- Accreditation Applications
- Proficiency Analytical Testing
- Intralaboratory Quality Control
- Frequency Distribution and Measures of Control Tendency and Variability
- Measuring Variability
- The Normal Curve and Analysis of Control
- Control Charts
- X - R Control Charts
- Problem Session - Control Charts
- Problem Session Review - Control Charts
- Specific Applications of Quality Control Charts
- Special Situation Control Charts
- Data Tests and Other Statistical Techniques

2.5 Laboratory Quality Control Specification

NIOSH has developed a Laboratory Quality Control Specification entitled, "Industrial Hygiene Laboratory Quality Program Requirements".[3] It identifies 22 elements needed in a laboratory quality control program as follows:

- Statement of Objectives
- Policy Statements
- Organization

Quality Planning
Standard Operating Procedures
Recordkeeping
Chain-of-Custody Procedures
Corrective Action
Quality Training
Document Control
Calibration
Preventive Maintenance
Reagent and Reference Standards
Procurement and Control
Sample Identification and Control
Laboratory Analysis and Control
Interlaboratory and Intralaboratory
Testing Programs
Handling, Storage and Delivery
Statistical Quality Control
Data Validation
System Audits

It can readily be seen that though there are some similarities to a manufacturing quality control system, many of these elements are peculiar to the laboratory environment.

2.6 Other Laboratory Quality Control Activity

While NIOSH was engaging in these attempts to improve laboratory quality, other organizations were concerned about similar problems and undertook various steps to alleviate them. The U.S. Environmental Protection Agency Quality Assurance and Environmental Monitoring Laboratory is publishing a monumental three-volume "Quality Assurance Handbook for Air Pollution Measurement Systems"[4] Volume I - "Principles" is in print and it identifies and discusses in detail 23 elements of Quality Assurance as follows: Volumes II and III are in preparation.

ELEMENTS OF QUALITY ASSURANCE

Document Control and Revisions
Quality Assurance Policy and Objectives
Organization
Quality Planning
Training
Pre-Test Preparation
Preventive Maintenance
Sample Collection
Sample Analysis
Data Reporting
Procurement Quality Control
Calibration
Corrective Action
Quality Costs
Interlaboratory and Intralaboratory
Testing
Audit Procedures
Data Validation
Statistical Analysis of Data
Configuration Control
Reliability
Quality Reports to Management
Quality Assurance Manual
Quality Assurance Plans for Projects
and Programs

The Mine Safety and Health Administration is carrying out an active interlaboratory test program to standardize the accuracy of reference standard gas concentrations used in calibrating laboratory gas chromatographs.

In September 1973, The Occupational Safety and Health Administration published Title 29 Code of Federal Regulations, Part 1907 :Accreditation of Testing Laboratories This regulation, now temporarily revoked, a double requirement for quality control. First, testing laboratories, testing and approving a wide range of safety and health related equipment from ladders to fire extinguishers, must demonstrate existence of a satisfactory quality control system in order to gain accreditation. In turn, the accredited testing laboratory must demand that its clients, who are manufacturers of products over which OSHA excercises surveillance, have an effective quality control system, ensuring this by periodic quality surveys and audit of off-the-shelf purchases of their products.

While these and other government agencies were developing and attempting to use these relatively new laboratory quality control techniques, two other groups were beginning to exhibit interest in this area. The first was what was formerly the Biomedical Control Technical Committee of ASQC. (Now the Biomedical Division). Early in 1973, NIOSH established liaison with this organization which now has a laboratory quality control writing committee of which the author is a member. NIOSH has solicited and received from this committee outstanding interest and assistance in the preparation of the Laboratory Quality Control Specification noted above.

A primary interest of this ASQC committee is in the preparation of a laboratory quality assurance standard and work is proceeding to this end.

Secondly, the organization meeting of the American National Standards Institute Committee Z-1 on Quality Assurance was held on February 5, 1975. Within the Z-1 Committee there is the systems and procedures sub-committee. One of the functions of this committee is to identify the need for one or more generic ANSI standards for the management of the quality system.

The American Society for Testing Material has published in draft a "Recommended Practice for Laboratories Engaged in Sampling and Analysis of Atmospheres". Its requirements for Laboratory Quality Control are similar to those of the NIOSH quality specification.

I am sure that all present are familiar with the NAVLAP provisions for laboratory quality control.

The FDA regulations 21 CFR 1000 "Diagnostic Radiology Facilities Quality Assurance Programs" and 21 CFR 82 "Medical Devices" provide typical examples of regulatory requirements for laboratory quality control.

Since laboratories of all kinds fall generally under the service industry category, NIOSH feels that its "Specification for an Industrial Hygiene Laboratory Quality Control System" can with some judicious editing and pruning, be made applicable to the operations of any type of laboratory and, by extension, to any type of service industry.

The foregoing has been an explanation of the efforts of various governmental industrial and standards publishing individuals and groups to develop and agree upon an acceptable quality control system standard for laboratories of every kind. Once one has accepted the basic premise that all laboratories receive samples of some kind from some source; must identify and keep track of them; analyze or test them; report on results; keep adequate records; maintain the accuracy of test and analytical equipment by systematic calibration and carry out all or most of the quality control elements listed as necessary above, then it seems "as follows night, the day" that a laboratory quality control system standard is not only necessary but feasible and finally, inevitable.

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[1] Ratliff, T.A. "Quality Control in Occupational Safety and Health," Annual Technical Conference Transactions, American Society for Quality Control, 1974, pp. 129-131.

[2] Industrial Hygiene Service Laboratory Quality Control Manual, Technical Report #78, National Institute for Occupational Safety and Health, Cincinnati, Ohio, 1974.

[3] NIOSH Specification for Industrial Hygiene Laboratory Quality Program Requirements, National Institute for Occupational Safety and Health, Cincinnati, Ohio, 1976/

[4] Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I- "Principles", U.S. Environmental Protection Agency, Quality Assurance and Environmental Monitoring Laboratory, Research Triangle Park, N.C., 1975.

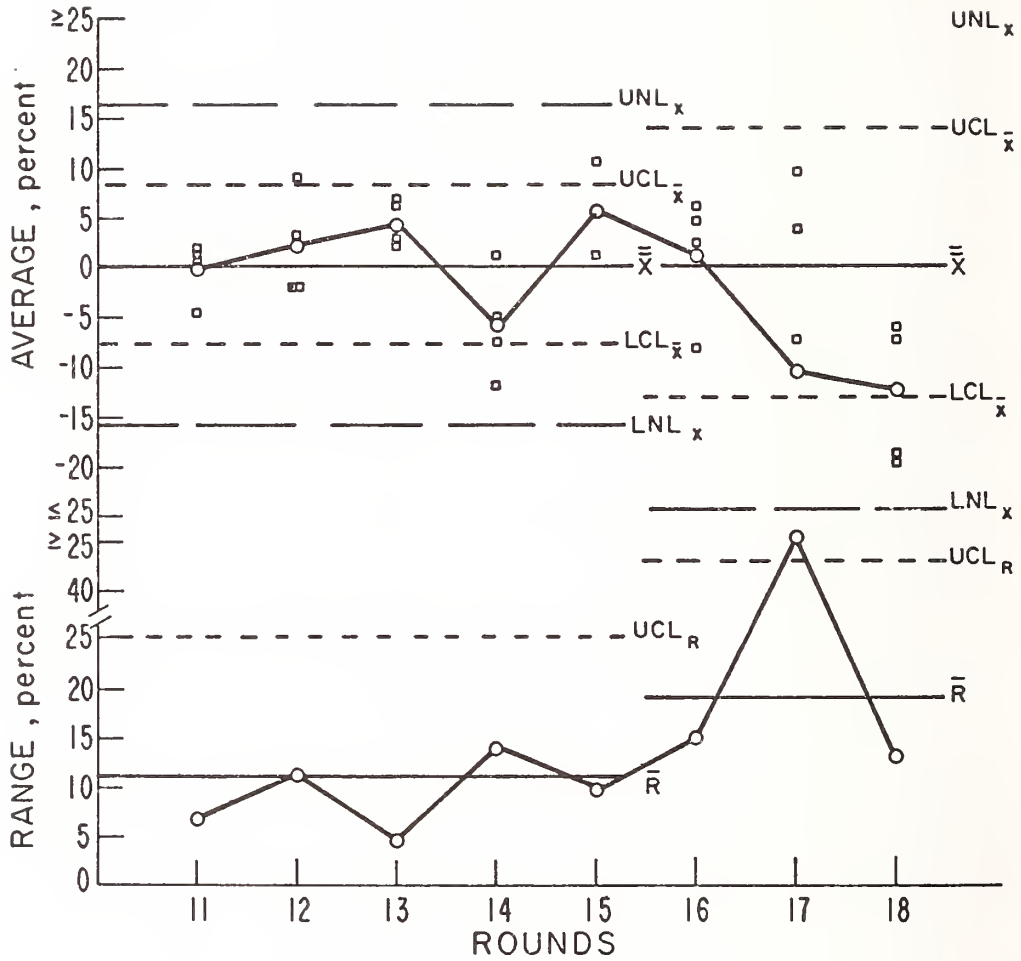

Figure 1 - Sample Control Chart For Each Laboratory
For Each Contaminant

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QUALITY CONTROL PROCEDURES IN A LABORATORY TESTING CEMENT FOR COMPRESSIVE STRENGTH

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This paper describes an in-house quality control system used by the Joint Research Laboratory (JRL) of the National Ready Mixed Concrete Association and the National Sand and Gravel Association (NRMCA-NSGA). The system is used to control the quality of the results of compressive strength tests of portland or blended cements by ASTM Method C109 but can also be used for other physical and chemical tests of cement and concrete.

Key words: Cement and Concrete Reference Laboratory; cement and concrete testing; compressive strength; control charts; in-house quality control; quality control system.

Introduction

The NRMCA-NSGA Joint Research Laboratory routinely participates in the Cement Reference Sample Program of the NBS Cement and Concrete Reference Laboratory (CCRL) in which pairs of cement samples are distributed twice a year. In addition the JRL has obtained a large number of sealed samples of a local cement which are tested as a "standard" or "reference" cement whenever an "unknown cement" is tested and when the CCRL samples are tested. The paper describes the system used to control the quality of tests for cement compressive strength by ASTM C109. The system can also be used for other physical and chemical tests of cement.

Control charts are maintained of the deviation of JRL results from the average of other laboratories participating in the Cement Reference Sample Program and of the deviation of the reference cement from established averages. The data generated demonstrate that in the JRL the most troublesome variations are those which occur over long periods of time. Standard deviations of tests made within a period of several days are approximately half as large as the standard deviations of tests made over a period of several years. Tests of standard cement made at the same time as the CCRL reference samples show excellent correlation. That is, if the standard cement results are high, results on the CCRL reference samples will also be high relative to the average of all laboratories in the program.

CCRL Cement Reference Sample Program

Since 1965 the CCRL has distributed pairs of cement samples every six months to a group of 120 to 180 participating laboratories. Each laboratory is asked to perform physical and chemical tests in accordance with designated ASTM Standard methods. The cement reference sample program is described in papers by several authors.[1,2,3,4][1] Results are reported to the CCRL and in a short time each laboratory receives a consolidated report giving the average values, multi-lab precision, single lab precision and other statistical data along with scatter diagrams for each test. Further, each laboratory receives a numerical rating from 5 to 1 depending upon the deviation of its result from the average of all other laboratories.* The rating scale is in multiples of the multi-lab standard deviation in accordance with the schedule in Table 1.

Use of the Cement Reference Sample Data

Although the cement reference sample data have been useful in the development of precision statements in several ASTM methods and in evaluating methods and procedural variations there has been little written describing how a laboratory can use the data to improve its own performance or control test procedures, aside from the examination of the scatter diagrams and the tabulation of the numerical ratings from 5 to 1 described earlier.

Table 1 summarizes the ratings of the JRL (Laboratory 112) for 3 and 7 day compressive strength for C 109 mortars.

In the CCRL program two samples of cement are distributed to participants twice a year. For compressive strength each laboratory is asked to prepare a single batch of C 109 mortar with each cement and to mold six 2 inch cubes for test in compression.

For all samples except numbers 9-12, three cubes are broken at 3 days and three at 7 days. Samples 9 to 12 were Type III cement and the test ages were 1 and 3 days. Since the JRL does not perform all of the physical and chemical tests the samples are large enough for the main operator to mix two batches from each sample. Generally one additional operator makes an additional batch as a part of a continuing operator training program. Only the results of the first batch mixed are reported to the CCRL.

In 1968 the JRL secured a supply of carefully blended cement and sealed a large number of samples in metal cans to provide a additional "standard cement," Lot 4538. Thi cement is tested with each CCRL sample and whenever an important unknown sample is received for testing.

Table 2 is the detailed compressive strength data for tests of samples 51, 52, and the standard cement. Generally, Batch A is mixed on one day and Batch B on the follo ing day. Method C 109 defines a "test" as th average of tests of 3 cubes and although va ues for individual cubes are reported to the CCRL only the average values are used in the CCRL reports and tabulations. Table A is a summary of the deviation of the JRL test values from the average for all participati laboratories. Table B is a similar tabulation for the standard cement, Lot 4538. Tables A and B are appended to this paper.

Table 3 is a summary of various averages and standard deviations calculated fro the strength deviations in Tables A and B. Figure 1 shows a good correlation between t deviations from the CCRL sample averages an the deviations of tests of Lot 4538 standar cement mixed at the same time. The Lot 453 deviations are calculated from the average used for that lot. Plotted values are for tests of individual batches. The line show is drawn through an overall average CCRL deviation of -10 psi and an average Lot 453 deviation of -75 psi and is parallel to the line of equality. No regression analysis has been made.

The overall variation is calculated as the standard deviation of the individual batch deviations in the respective tables taking into account the sign of each deviation. The average deviation, -26 and +6 psi for the CCRL samples are negligible and near zero.

For Lot 4538 the deviation averaged - and -74 psi. These are barely of statistical significance. The corresponding averages were zero after sample 40. The overal standard deviations range from 182 to 229 ps The differences between standard deviation for CCRL and Lot 4538 samples are not significant. Further, although the 7-day values appear larger they are not significantly higher than the 3-day values. A representative value for the overall long-term standard deviation would be about 212 psi.

[1]Figures in brackets indicate the literature references at the end of the paper.
*Using CCRL multi-lab standard deviation.

The short term batch-to-batch standard deviation from batches mixed on consecutive days can be estimated from the range of strength test results obtained on Batches "A" and "B" (or the range of the deviations). These ranges and their averages are given in Tables A and B. Table 3 gives the standard deviations and averages values for the CCRL and Lot 4538 tests. Again the values for 3- and 7-day tests are not significantly different, and a standard deviation of 98 psi is representative of the short term variation at either age.

The short term or between batch standard deviation ranges from 2.5 to 3.8 percent of the average for Lot 4538 and can be compared to the single laboratory standard deviation contained in the precision statement for Method C 109 of 3.8 percent. Note that the C 109 precision statement was derived from the cement reference sample program data.

The overall standard deviations are roughly 7 and 5.5 percent of the average and are similar in size to the C 109 multi-laboratory coefficient of variation of 7.3 percent.

Construction of Control Charts

As noted in the previous section the overall or long term standard deviation is over twice the day-to-day standard deviation and even if the day-to-day component could be eliminated the remaining long term standard deviation would exceed 170 psi. In marked contrast with typical cement company laboratories which test cement every day the JRL often tests only a few cements in the 6 month interval between reference samples. Presumably this relatively small amount of practice makes it difficult to avoid the long term procedural variations.

Until additional analysis was undertaken for this paper the JRL maintained control charts on the average deviation of two batches with 3s and 2s control limits based on the overall standard deviation. Limits were symmetrical about the average deviation.

At the present time a decision has been made to maintain:

a. Separate 3-and 7-day control charts for the reference samples. (Deviation from CCRL average.)

b. A control chart for 3-and 7-day tests of Lot 4538. (Deviation from Lot 4538 average.)

c. A difference 2 sigma limit for acceptable agreement between duplicate batches applicable to all usual cements.

d. A difference 2 sigma limit for acceptable agreement between the three cubes that are averaged to constitute a test.

Control Charts for Reference Samples

Figures 2 and 3 are the control charts for tests of cement reference samples. Strength is expressed as a deviation from the CCRL average for all laboratories. Each point represents the average for two batches. The chart line connects the average deviation obtained on each pair of samples distributed in the program. Three sigma control limits are given for the average deviation for the two batches mixed for each sample and the average of the pair of samples distributed at a given time (4 batches). The standard deviation used is that for batches mixed over a short period. The limits are computed respectively as:

$$0 \pm 3s/(2)^{\frac{1}{2}} \text{ for 2 batches}$$

$$0 \pm 3s/(4)^{\frac{1}{2}} \text{ for 4 batches}$$

Note that laboratories which do not have enough cement to test duplicate batches can likely estimate the short term standard deviation from the range of deviations of the pair of samples mixed in the program. Suitable values could also be derived from duplicate batches of a reference cement or even from the C 109 precision statement.

Figure 4 is the control chart for 3 and 7 day tests of the standard cement Lot 4538. Again construction is similar and the short term standard deviation, averaged for 3-and 7-day tests, is used.

Examination of Control Charts, Figures 2, 3 and 4

1. Low results were obtained on reference samples 5 and 6 and this is the primary reason why the standard Lot 4538 cement was used with sample 7 and all later samples.

2. Samples 11 and 12 produced markedly divergent results, but the reference cement tests were normal. It is clear now that the sample numbers were interchanged since the average for the sample pair is reasonably good.

3. No ready explanation is available for the high results on samples 17 and 18 and only moderately high results on Lot 4538.

4. High results were produced in all tests of samples 21 and 22.

5. Unfortunately no reference cement was tested in the period from sample 29 to 34. During this period the laboratory was in temporary quarters before moving into new facilities in 1974.

6. Samples 31 and 32 produced low 7-day strength and high 28-day strengths. No good explanation was discovered.

7. Starting with sample 39-40 a formal control chart procedure and on-going analyes were implemented. Agreement between batches and samples greatly improved. Strength levels in all tests decreased progressively through samples 51-52. Procedures were thoroughly reviewed. Training started on a new backup operator. Tests demonstrated that cube density had decreased and that increased tamping pressure would increase both density and strength. When samples 53 and 54 were tested the Lot 4538 strengths and densities returned to normal levels. The report on the averages for the CCRL samples will not be available until early October and, therefore, these deviations are not available in Figures 2 and 3.

Use of Standard Cement Lot 4538 Data to Correct Tests of Unknown Cements

Figure 5 is a plot of the Cement Reference Sample Deviations (Table A) minus the Lot 4538 deviations (Table B) for batches mixed at the same time. In each instance, the deviations are the average for two batches or rounds.

Figure 1 showed that the strength levels on the reference samples correlate well with levels on the Lot 4538 cement tested at the same time. This suggests that when unknown cements are tested the results can be corrected by the amount that Lot 4538 tests, made at the same time, are high or low.

Figure 5 is a test of this hypothesis and except for a couple of early results the systematic variation of results shown in the control charts is eliminated. Table 4 provides the averages and standard deviations of these "corrected" deviations along with the JRL deviations in tests of the CCRL reference samples and Lot 4538. The period included is from sample 15 through 52.

The "corrected deviations" average 93 and 119 psi at 3 and 7 days, respectively. These arise because during the period the average strength of the Lot 4538 tests was 93 and 113 psi less than the values used in computing the Lot 4538 deviations.

3 days: 3045 - 93 = 2952 psi
7 days: 4230 - 119 = 4111 psi

Therefore, when an unknown cement is tested the best estimate of its 3 day strength would be:

$$X_{corr} = X_v - (X_r - 2952)$$

where

X_{corr} is the estimated 3 day strength

X_v is the result of testing the unknow cement

X_r is the strength of Lot 4538 mixed a the same time.

(In each instance results are the average o tests of two batches.)

The standard deviations of the correct values in Table 4 are dramatically improved The 95 percent confidence limits on tests corrected in this manner should be about ± 250 psi.

Within Batch and Batch-to-Batch Surveillanc

The control charts described employ av erages of 2 and 4 batches of mortar and are designed to control the troublesome long term variations. Control charts for ranges within and between batches could be maintained but the JRL has decided to use D2S limits for the three cubes averaged for a test and for the two or three batches generally mixed.

The range of the three cubes tested fr a batch at a given age in the reference sam ple program were extracted and expressed as standard deviation percent. The average 3 and 7 day coefficient of variations were 2.1 and 2.8%, respecrively. The precision statement for ranges between 3 cubes is:

> "The range between 3 cubes made fr a single batch of C 109 mortar tested at 3 or 7 days should not exceed 7 or 9 percent of their average, respectively (D2S). The corresponding value for the range of 3 cubes tested at 28 days is likely somewhat larger than that for 7 day tests, but the 7-day values will be used until additional data is developed.[5]"

No corresponding precision statement for agreement of tests of 3 cubes is given in ASTM Method C 109.

The precision statement for agreement of batches made within a period of several days is derived from the between batch standard deviations in Table 3. The standard deviation chosen is 3.0 percent and is applied for all ages. Note that the C 109 precision statement uses a single-laboratory standard deviation of 3.8 percent. The JRL precision statement is:

> "The range between batches (rounds) of C 109 mortar made by a single operator should not exceed the following at 3 or 7 days: (Comparable ranges for tests at 1 day are likely somewhat larger and those at 28 days somewhat smaller.)
>
> | | Range, % of Average, D2S |
> |---|---|
> | Range of 2 rounds | 8.4% |
> | Range of 3 rounds | 9.9% |
> | Range of 5 rounds | 11.7% |
>
> Note that the D2S values should be exceeded about 1 time in 20 in the long run."

Summary

The Joint Research Laboratory has participated in the cement reference sample program for the past 13 years. For most of this time a laboratory standard cement has been tested with the reference samples and when other cement samples are tested.

To control the results of ASTM C 109 compressive strength test results the laboratory has developed:

a. Difference 2 sigma limits for the range of the three cubes tested at each age.

b. Difference 2 sigma limits for the range between batches (rounds) mixed within a short period.

c. Control charts for the deviation of the reference sample results from the grand average of all laboratories on each sample.

d. Control charts of the deviation of the laboratory standard cement from its established average.

The procedure of expressing the JRL reference sample results as deviations from the grand average for participating laboratories permits the use of simple, familiar, easily understood statistical procedures, calculations and control charts.

A study of the reference sample data demonstrates that in the JRL multiple batches can be tested to reduce short term testing variations to the desired levels. However, C 109 mortars tested at intervals of 6 months or more can be expected to show larger variations or bias which will be characteristic of the particular day or week on which they are tested.

If the "standard cement" yields a high result on a given day, the CCRL reference sample mixed on that day will be similarly high. Using the standard cement deviations to correct the CCRL reference samples mixed on the same day significantly improves agreement with the CCRL averages. It appears that if the laboratory standard cement is mixed each day an unknown cement sample is tested the JRL can use the standard cement results to estimate the strength that would be obtained if the 100 to 200 CCRL laboratories had tested the cement. The 95 percent confidence limit on such an estimate would be approximately ± 250 psi.

References

[1] Crandall, J. R. and Blaine, R. L., "Statistical Evaluation of Interlaboratory Cement Tests," Proc. ASTM V 59, 1959, pp 1129-54.

[2] Youden, W. J., "Statistical Aspects of the Cement Testing Program," Proc. ASTM V 59, 1959, pp. 1120-28.

[3] Arni, H. T., "Precision of Air-Permeability, Turbidimeter and No. 325 Sieve Fineness Data," ASTM STP 473, Fineness of Cement, 1968, pp 20-44.

[4] Mandel, John and Lashof, T. W., "Interpretation and Generalization of Youden's Two Sample Diagram" Jour. Quality Tech., V. 6N1, Jan. 1974, pp 22-36.

[5] ASTM C 670-77, "Recommended Practice for Precision Statements for Test Methods for Construction Materials."

Table 1. Summary of JRL Ratings on Compressive Strength

Included are the ratings for 3 and 7 day strength of 46 CCRL samples that have been tested.

Rating No.	Deviation from Av, Standard Deviation(1)	Expected % of Labs	JRL, % of Samples
5	0 - 1	68.3	73.9
4	1 - 1.5	18.3	14.1
3	1.5 - 2.0	8.8	7.6
2	2.0 - 2.5	3.3	3.3
1	+ 2.5	1.2	1.1

(1)Using CCRL Multi-lab Standard Deviation.

Table 2. Typical JRL Compressive Strength Data
(Cement Reference Sample Program, CCRL)

Sample No.	Operator	Batch	Test Age, Days	C 109 Cube Compressive Strength, psi 1	2	3	Av.(2)
51	WDH	A(1)	3	2990	2990	2900	2960
			7	4415	4260	4560	4410
		B	3	3060	2940	3040	3015
			7	4370	4435	4315	4375
52	WDH	A	3	3280	3365	3480	3375
			7	4200	4200	4210	4205
		B	3	3435	3320	3430	3395
			7	4160	4370	4350	4295
Standard (Lot 4538)	WDH	A	3	2490	2540	2480	2505
			7	3670	3730	3770	3725
		B	3	2565	2625	2700	2630
			7	3635	3780	3735	3715

(1)Reported to CCRL.
(2)Only the average value for tests of 3 cubes is used in scatter diagrams and computations by CCRL.

Table 3. Summary of JRL Averages and Standard Deviations (J-146)

Item		Test Age 3 Day	Test Age 7 Day
1. Overall Variations			
1.1 CCRL Deviations (From the CCRL Average)			
(to No. 52)	N	82	84
	$\bar{X}$, psi	-26	+ 6
	s, psi	182	227
1.2 Lot 4538 Deviations (From the Average Used for Lot 4538)			
(to No. 54)	N	38	38
	$\bar{X}$, psi	-78	-74
	s, psi (%)	208 (7.0)	229 (5.5)
Average Strength psi		2967	4156
2. Between Batch Std. Dev., psi (%) (by range)			
2.1 Samples 1-40			
	CCRL	95	131
	Lot 4538	114 (3.8)	124 (3.0)
	Av.	104	128
2.2 Samples 1-52			
	CCRL	83	111
	Lot 4538	91 (3.1)	105 (2.5)
	Av.	87	108

Table 4. Correction of JRL Deviations of CCRL Samples Using Lot 4538 Data -- Samples 15-52

Data for samples 7-12 are not included because of difficulties experienced early in the program.

Item	No. Values	Average Deviation	Std. Dev., psi
3 Day Tests			
Deviation			
(a) CCRL	30	-20	179
(b) 4538	15	-113	200
(c) Corrected	30	+93*	126
7 Day Tests			
Deviation			
(a) CCRL	30	21	207
(b) 4538	15	-98	233
(c) Corrected	30	+119*	121

*(c) = (a) - (b)

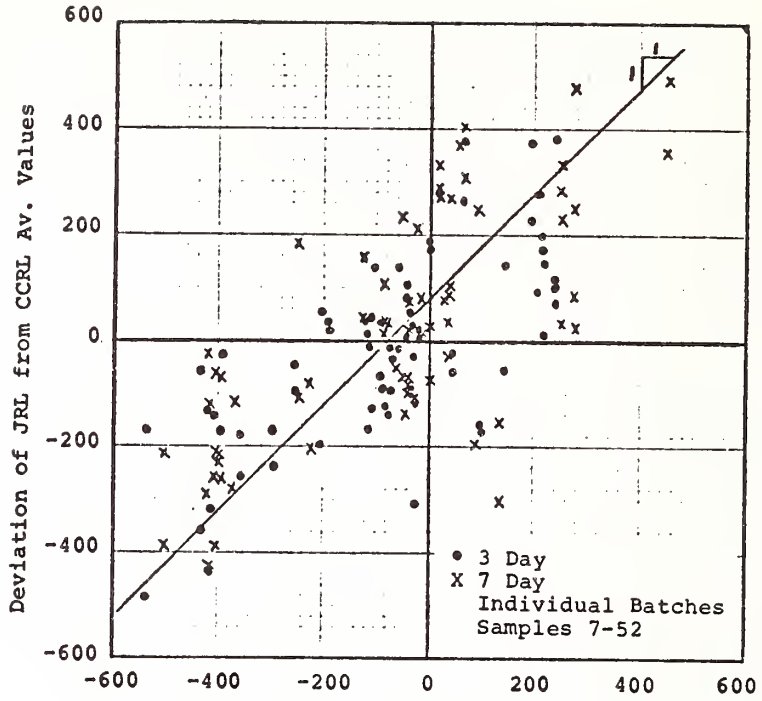

Figure 1. Comparison of Compressive Strength Deviations on Lot 4538 with Deviations in CCRL Cement Reference Sample Program (Series J-146)

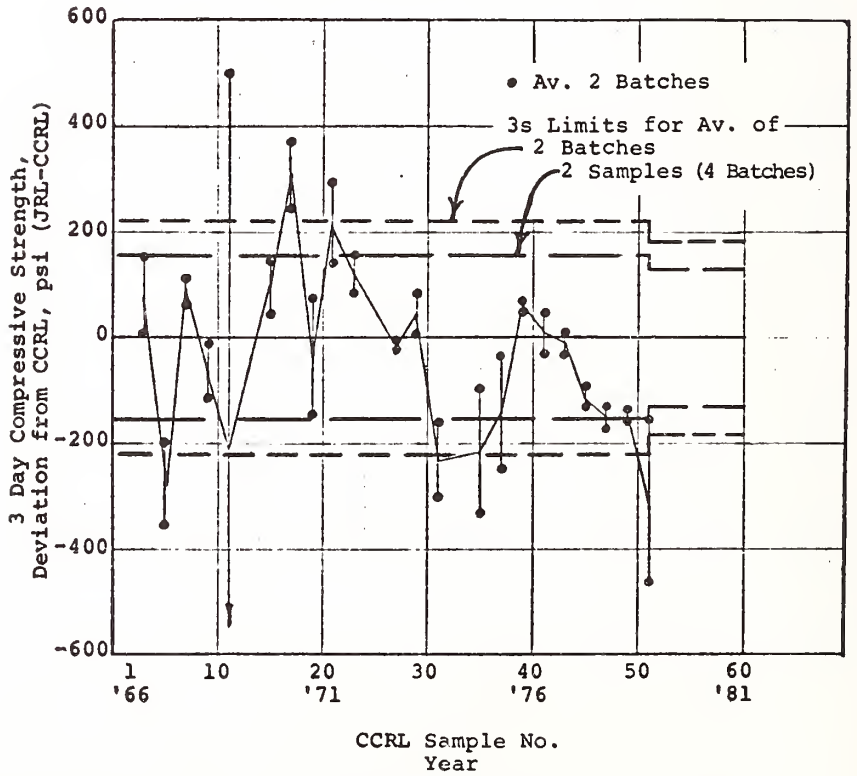

Figure 2. Control Chart for 3 Day Strength, Cement Reference Samples -- JRL (Series J-146)

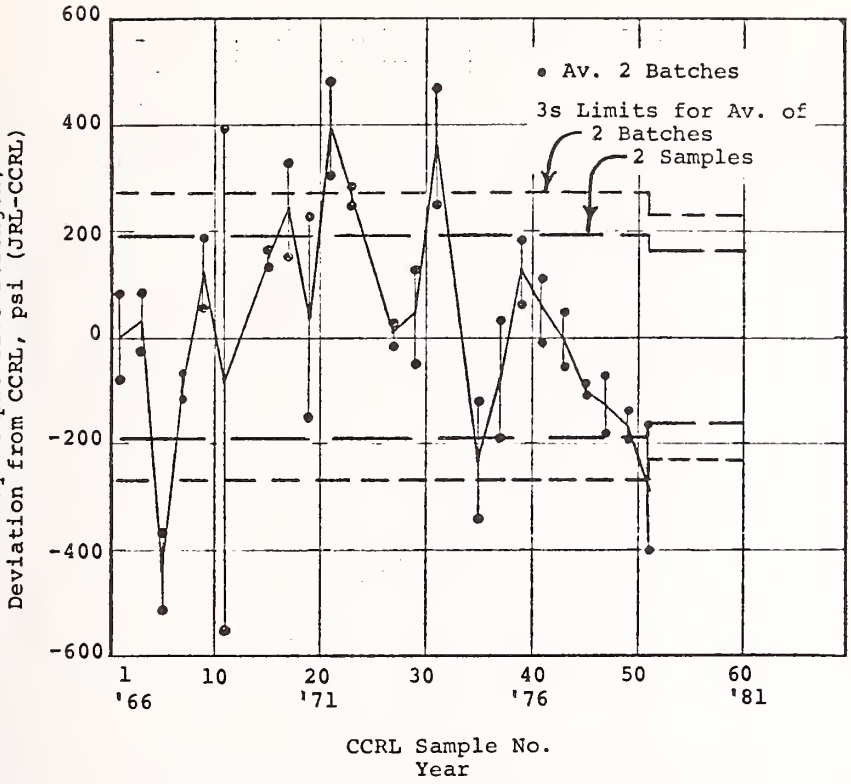

Figure 3. Control Chart for 7 Day Strength, Cement Reference Samples -- JRL (Series J-146)

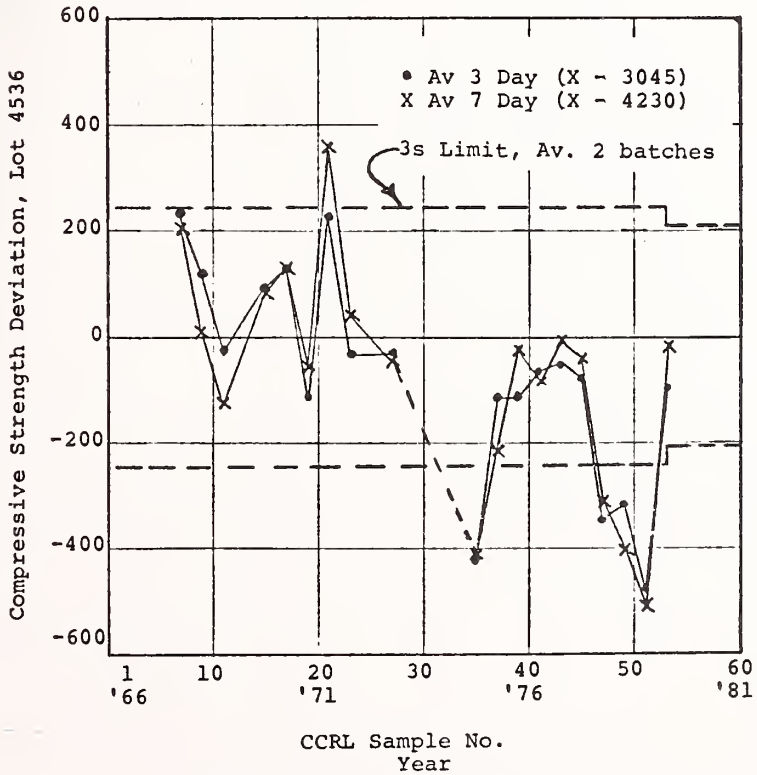

Figure 4. Control Chart for Tests of Cement, Lot 4538 (Series J-146)

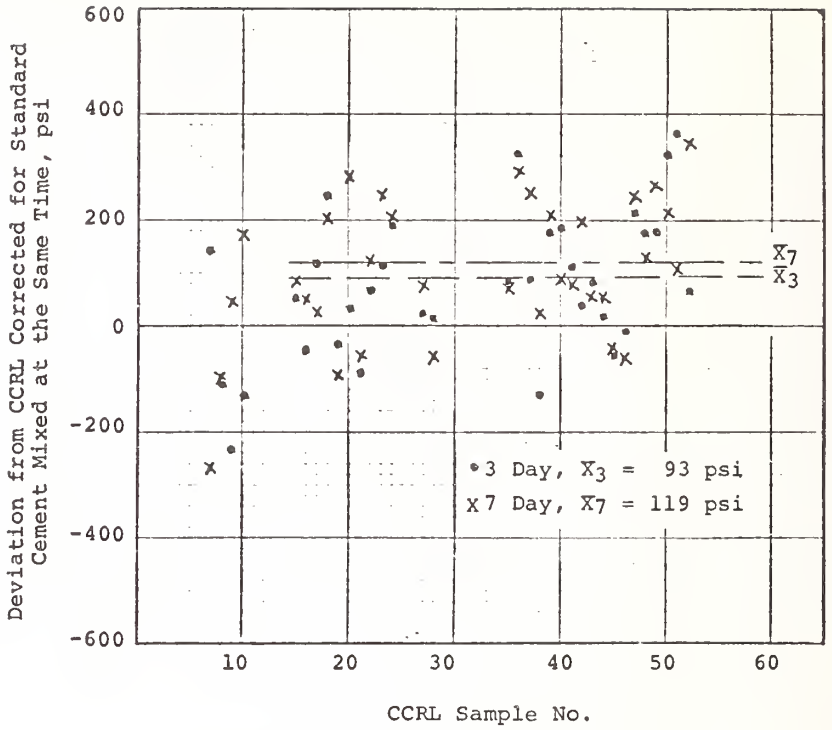

Figure 5. Reference Sample Program Results Corrected for Standard Cement Results (Series J-146)

Appendix A

Table A. Deviation of JRL Results from Average Compressive Strength in the Cement Reference Sample Program

h test is the average of results from 3 cubes from a batch of ASTM C 109 mortar. The de-
tion is the difference between this test result and the average for all participating labs.

ple o.	Oper-ator Date	3 Day Strength Tests Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Batch Range, psi	7 Day Strength Tests Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Batch Range, psi
	ACE	20	---			-157	-3	-80	154
	(8/66)	150	---			12	155	+84	143
								+ 2	
	ACE	144	165	154	24	34	137	86	103
	(3/67)	69	-66	2	139	-141	89	-26	230
				78				30	
	WDH	-121	-270	-196	149	-363	-365	-364	2
	(8/67)	-375	-337	-356	38	-711	-321	-516	390
				-276				-440	
	WDH	118	13	66	105	-147	23	-62	170
	(2/68)	71	166	118	95	136	81	109	55
				92				23	
	WDH	-170	-55	-112	115	80	35	56	45
	(8/68)	-166	144	-11	310	7	367	187	374
				-62				122	
	WDH	-749	-1034	-916	235	-362	-752	-557	390
	(2/69)	559	459	509	100	354	424	389	70
				-203				- 84	
	(8/69)								
	WDH	279	19	149	260	286	51	168	235
	(2/70)	96	6	51	90	33	238	136	205
				100				152	
	JK	265	230	248	35	79	229	154	150
	(8/70)	379	374	376	5	336	331	334	5
				312				244	
	JK	-125	-165	-145	40	-198	-108	-152	90
	(2/71)	138	13	76	125	247	212	230	35
				-34				39	
	WDH	109	174	142	65	354	249	302	105
	(8/71)	387	197	292	190	493	478	486	15
				217				394	

(con't.)

Table A (con't.)

Sample No.	Operator Date	3 Day Strength Tests: Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Batch Range, psi	7 Day Strength Tests: Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Ba Ra
23	WDH	-13	187	87	200	170	405	288	
24	(2/72)	139	179	159	40	182	312	247	
				123				268	
25									
26	(8/72)								
27	WDH	-59	41	- 9	100	24	39	32	
28	(2/73)	-22	- 7	-14	30	-73	37	-18	
				-12				7	
29	WDH	2				-49			
30	(8/73)	84				131			
31	WDH	-159				472			
32	(2/74)	-302				247			
33									
34	(8/74)								
35	WDH	-359	-319	-339	40	-287	-392	-340	
36	(2/75)	-58	-138	-98	80	-28	-208	-118	
				-218				-229	
37	WDH	-116	54	-31	170	-113	187	37	
38	(8/75)	-304	-194	-249	110	-280	-105	-192	
				-140				-78	
39	WDH	84	34	59	50	268	103	186	
40	(2/76)	103	28	66	75	101	31	66	
				62				126	
41	WDH	57	37	47	20	-64	56	- 4	
42	(8/76)	7	-63	-28	70	74	159	116	
				10				56	
43	WDH	-7	28	10	35	-81	-31	-56	
44	(2/77)	-35	-30	-32	5	19	84	52	
				-11				- 2	
45	WDH	-136	-126	-131	10	-66	-96	-81	
46	(8/77)	-92	-92	-92	0	-139	-74	-106	
				-112				94	
47	WDH	-24	-234	-129	210	-65	-75	-70	
48	(2/78)	-172	-167	-170	5	-158	-203	-180	
				-149				-125	

(con't.

Table A (con't.)

Sample No.	Operator Date	3 Day Strength Tests Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Batch Range, psi	7 Day Strength Tests Deviation, psi (JRL-CCRL) Batch A	Batch B	Av.	Batch Range, psi
49	WDH	-179	-94	-136	85	-215	-65	-140	150
50	(8/78)	-258	-48	-153	210	-221	-156	-188	65
				-144				-164	
51	WDH	-486	-431	-458	55	-387	-422	-404	35
52	(2/79)	-166	-146	-156	20	-210	-120	-165	90
				-307				-284	
53	WDH				365				65
54	(8/79)				195				200
Av. Range, $\bar{R}$									
1-40					108				148
1-54					94				125

*Sample numbers were probably interchanged. Excluded from calculations.

Appendix B

Table B. Deviation of Lot 4538 Tests from Established Average Values

Tests of C 109 mortars made with carefully preserved samples of cement, Lot 4538. Values are expressed as the test value minus 3045 psi at 3 days and the test value minus 4230 psi at 7 days.

Sample No.	Operator Date	3 Day Strength Tests Deviation, psi (X-3045) Batch A	Batch B	Av.	Batch Range, psi	7 Day Strength Tests Deviation, psi (X-4230) Batch A	Batch B	Av.	Bat Ran ps
1									
3									
5									
7	WDH (2/68)	240	220	230	20	135	275	205	14
9	WDH (8/68)	95	145	120	50	-15	35	10	5
11	WDH (2/69)	160	-225	-32	385	45	-295	-125	34
13									
15	WDH (2/70)	210	-20	95	230	250	-80	85	3
17	JK (8/70)	65	195	130	260	15	250	132	2
19	JK (2/71)	-105	-115	-110	10	-90	-25	-58	
21	WDH (8/71)	240	215	228	25	450	275	362	1
23	WDH (2/72)	-60	0	-30	60	15	65	40	
25									
27	WDH (2/73)	45	-110	-32	155	0	-85	-42	
29	WDH								
31	WDH								

(con't.)

Table B (con't.)

Sample No.	Operator Date	3 Day Strength Tests Deviation, psi (X-3045) Batch A	Batch B	Av.	Batch Range, psi	7 Day Strength Tests Deviation, psi (X-4230) Batch A	Batch B	Av.	Batch Range, psi
33									
35	WDH (2/75)	-430	-410	-420	20	-420	-405	-412	15
37	WDH (8/75)	-25	-205	-115	180	-175	-250	-212	75
39	WDH (2/76)	-40	-190	-115	150	40	-85	-22	125
41	WDH (8/76)	-40	-90	-65	50	-40	-125	-82	85
43	WDH (2/77)	-70	-30	-50	40	-40	35	- 2	75
45	WDH (8/77)	-75	-80	-78	5	-45	-35	-40	10
47	WDH (2/78)	-395	-295	-345	100	-395	-225	-310	170
49	WDH (8/78)	-355	-275	-315	80	-400	-405	-402	5
51	WDH (2/79)	-540	-415	-478	125	-505	-515	-510	10
53	WDH (8/79)	-95	-95	-95	0	-125	85	-20	210
Av. Range, $\overline{R}$									
1-40					129				140
1-53					102				118

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STANDARD THERMAL PERFORMANCE TESTING PROCEDURES

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Formal standardized procedures for thermal performance tests were established at the Johns-Manville R&D Center as part of a program to assure reliability of test data. A number of requirements had to be met by the procedures. While the tests are based on ASTM and other similar recognized standard methods, the procedures had to be sufficiently detailed to insure consistently reliable results by all operators, some of whom may not have had long-term experience in thermal testing. Likewise, the procedures had to cover a wide variety of types and forms of materials, test equipment and temperature ranges. A complicating factor was the inter-relation between general lab procedures applicable to all activities, procedures for checking general purpose equipment and specific thermal test equipment, thermal test methods, and test specimen preparation procedures for specific types of materials.

This paper describes the formats for a series of formal cross-referenced standardized procedures for thermal performance tests. The paper also details some of our experiences in preparing and implementing these test procedures.

Key words: Laboratory test procedures; quality assurance lab test; standard test methods; thermal performance test.

1. Introduction

The basic objective of a quality assurance program for a testing laboratory is to insure the consistent reliability of the test results obtained. This was also the objective of the program at the Thermal Conductivity Laboratory, or K-LAB, at the Johns-Manville Research and Development Center in Denver, Colorado.

The K-LAB performs a wide variety of thermal performance tests. The scope includes various types and forms of materials, which may be tested individually or in combination with other materials and at various temperatures. Samples submitted for test include materials from regular plant production for routine quality control, new products under development, and competitive product In addition, a limited amount of outside c contract testing is performed. Thermal te procedures involve establishing steady-sta heat flow under prescribed conditions, and then measuring the heat flux and the surfa temperatures. Related properties, such as physical dimensions and density, are also determined because of their influence on thermal performance.

The K-LAB has long operated under informal standard thermal test procedures. Many of these served as the basis for star dard test methods, subsequently published s ASTM, ANSI, or ISO standards. Formerly, te testing quality assurance relied on the sk and long-term experience of the K-LAB ope tors with their testing equipment. While

test procedures generally followed the requirements of the published standard test methods, there were many minor deviations where experience had demonstrated published test criteria were either too lax or overly restrictive, or special needs had to be met.

The incentive for the J-M K-LAB to establish formal test procedures came from several directions. There was need for further improvements in precision and accuracy. The volume of testing had increased. Laboratory personnel have been added, promoted, and transferred, resulting in a transient personnel situation. The requirements of the national and state thermal test laboratory certification and accreditation programs were another factor. An internal requirement in establishing the formal K-LAB standard procedures was that they be compatible with other J-M and R&D systems already in existence. For example: The R&D Information Center had previously established procedures to be followed in recording data in permanent lab notebooks, and also had general formats for reports. Thus, the K-LAB procedures had to complement the other systems.

2. Standard Procedures

Thermal performance testing was analyzed carefully to identify areas where standard procedures were needed to meet testing quality assurance requirements. The task was to separate common activities of the various steps in testing, and to rearrange them in logical combinations that would lead to the preparation of cohesive standard procedures. For example, many of the details of laboratory operation apply to all activities irrespective of the complexity of the test procedure involved or the type of material being tested. Certain pieces of laboratory equipment, such as temperature indicators and recorders, are in general use rather than being associated with a particular piece of thermal test equipment. Further, except for physical size consideration, the steps involved in the preparation of specimens for testing is more a function of the character of the material being tested than the particular piece of thermal test equipment that will be utilized.

What evolved was a plan for six classes of standard procedures, with the recognition that extensive use of cross referencing would be utilized. These are enumerated in Table 0.

Table 0 - Classification of Thermal Test Procedures

1. General lab operation
2. Check adjunct apparatus
3. Check thermal test apparatus
4. Thermal test methods
5. Test specimen preparation
6. Standard reference check specimens

The first area covers the general operation of the K-LAB, including as standard procedures, authorization of tests, handling of samples received, retention of data and information, and reporting of test results. The nature of thermal testing requires the use of both common or general test equipment that might be used in several test procedures, and specific test equipment for only one type of test. Checking procedures for general or adjunct test equipment are covered in the second area, while specific test apparatus are in the third area. The actual testing procedure to be followed in conducting a specific test is covered in the fourth area. Procedures for the preparation of specimens for the test are covered in the fifth area. This is divided by types of materials, i.e., batts and blankets, rigid board and block, pipe insulation, and refractory materials. In the sixth area, the preparation and handling of standard reference check specimens is covered.

The decimal system was utilized to classify types of procedures within a class, and sections within a particular procedure.

Thus, as shown in Table 0, the number 4 identifies a procedure as a thermal test method. The number 4.3 is a thermal test method for a specific piece of test apparatus, in this case, the high temperature calorimeter complying with ASTM-C182; the number 4.3.7 is a section within that test method.

Details of the formats used in each of the areas follow.

3. Formats

The first area of standard procedures deals with laboratory operation. This has

been divided into two procedures; 1.1 covers the general mechanics of the K-LAB operation, while 1.2 details reports. Because of the importance of the proper written communication of technical data by testing laboratory, reporting procedures were put into a separate procedure. In this procedure, general requirements to be met by all reports, in addition to specific formats for the five types of reports issued by the K-LAB, are covered. Table 1 details the format for 1.1 and 1.2 procedures.

Table 1 - Format - Laboratory Operation Procedures

1.1 General K-LAB procedures

1.1.1 Scope - applicability, categories of procedure

1.1.2 Hazards - general caution

1.1.3 Index - procedures

1.1.4 Test Authorization

1.1.5 Assignment - assignor, responsibility

1.1.6 Schedule - priority of tests

1.1.7 Test Data - reference to permanent notebook records

1.1.8 Report - reference to 1.2

1.1.9 Sample disposition - retention

1.1.10 K-LAB information - types of records, retention

1.2 K-LAB reports

1.2.1 Scope - all written communication of thermal performance data

1.2.2 Types - description, distribution limits

1.2.3 Style - no set writing style, units (US vs. metric)

1.2.4 General requirements - applicable all reports

1.2.5 Format - test report

1.2.6 Format - development report

1.2.7 Format - external report

1.2.8 Format - memo report

1.2.9 Format - letter report

An essential part of the quality assurance program of any testing laboratory is the periodic checking and calibration of testing equipment used. Calibration record of all testing equipment in the Material Performance Section or physical testing group at the J-M R&D Center, which includes the K-LAB, have been put on computer. A typical print-out, (Figure 1), describes the equipment including its range, usual location and person responsible. Calibration information includes who usually performs the work, recommended frequency, dates of past calibrations and the next due date. In periodic review of the computer files, attention can be focused on equipment past its normal check or calibration date.

Standard pieces of laboratory equipment, such as scales and balances, are serviced routinely by an outside contractor, frequently the manufacturer's local representative. No attempt is made to dictate checking procedures for this equipment. Primary electrical and temperature standard and measuring equipment are sent out periodically to a qualified local metrology laboratory with standards traceable to NBS. Again, no attempt is made to dictate procedures followed. Only for that test equipment which is checked and calibrated by K-LAB staff have standard procedures been written. Those pertaining to adjunct test apparatus are covered by the 2.x series of procedures (see Table 2 for format details). Similarly the procedures for checking thermal test apparatus are in the 3.x series (see Table 3).

Table 2 - Format - Adjunct apparatus check

2.x.1 Scope - type(s) apparatus covered

2.x.2 Hazards - general caution, and specific hazards (if any)

2.x.3 Apparatus - description of apparatus checked

2.x.4 Frequency - frequency of checks

2.x.5 Test equipment - list of test equipment

2.x.6 Procedure - detailed check/calibration procedure, precautions, record, explanatory drawings

Table 3 - Format - Thermal test apparatus check

3.x.1 Scope - type(s) of thermal test apparatus covered

3.x.2 Hazards - general caution, and specific hazards (if any)

3.x.3 Standard Test - reference to standard test method, such as ASTM, and list of exceptions (if any)

3.x.4 Apparatus - description of apparatus checked

3.x.5 Frequency - frequency of checks (may be various levels of detail)

3.x.6 Log - permanent records to be kept

3.x.7 Procedure - test equipment and standards required, detailed check/calibration procedure, precautions, explanatory drawings (daily checks of thermal test equipment are covered as part of area 4 on thermal test methods).

The procedures to be followed in actually conducting a thermal performance test are described in the 4.x series. When the program is completed a separate procedure will have been prepared for each type of thermal test apparatus. Details of the format for 4.x procedures are shown in Table 4.

Table 4 - Format - Thermal test methods

4.x.1 Scope - type(s) apparatus covered, materials typically tested, temperature range and size and other limits.

4.x.2 Hazards - general caution, and spefic hazards (if any)

4.x.3 Standard test - reference to standard test method such as ASTM, and list of exceptions (if any)

4.x.4 Specimen - test specimen description, and reference to standard procedures 5.x on preparation

4.x.5 Apparatus and equipment - list of test equipment required

4.x.6 Procedure - Initial startup, daily checks of apparatus, detailed test procedure, precautions, data requirements (including examples) and daily shut down

4.x.7 Calculations - equations, procedure, hand calculator program (if used) and example

4.x.8 Figures - explanatory drawings

Procedures describing the preparation of thermal test specimens are divided by type of material to be tested, with separate procedures for batt/blanket, loose-fill, and rigid board and blocks. Because of special requirements, separate procedures were also prepared for pipe insulation and for refractory materials. Details of the format 5.x procedures for test specimen preparation are included in Table 5.

Table 5 - Format - Test specimen preparation

5.x.1 Scope - type of material covered

5.x.2 Hazards - general caution, and specific hazards (if any)

5.x.3 Standard test - reference to standard test methods, such as ASTM, and list of exceptions (if any)

5.x.4 Apparatus and equipment - list of all equipment required

5.x.5 Procedure - selection, I.D., cutting to size, drying and other pre-test conditioning, physical measurements, data requirements, and precautions

5.x.6 Calculations - equations, procedure, hand calculator program (if used), and example

5.x.7 Figures - explanatory drawings

Preparation of procedures for the last area, the preparation and checking of standard reference test specimens, has been held in abeyance. An increasingly important portion of thermal performance testing relies on heat flow transducers to determine thermal flux. In the past, NBS has made available a moderately heavy density glass fiber board in 1 inch thickness only, as a standard thermal reference material (SRM). This standard was adequate for calibration of heat flow transducers when thermal testing accuracy requirements were far less stringent than today. Current technology has shown that many discrepancies can occur when an apparatus calibration based on the current NBS thermal SRM is extended to materials of different characteristics than the standard, and especially when extended

to the greater thicknesses common in today's insulation standards.

NBS now has a program under way to develop equipment which will permit them to offer a wider variety of thermal SRM's. Our need for 6.x procedures will be inversely related to the success and timing of the NBS program.

4. Observations

The preparation and implementation of standard thermal performance test procedures has required a large investment in time on the part of the personnel involved. This was not unexpected, as the need for accuracy and completeness of presentation was recognized early. Limited availability of time necessitated establishing priorities, so that the more important procedures were attacked first. K-LAB personnel had to continue regular testing activities at the same time.

The question of how much detail to include in a standard procedure requires judgement. A fine balance is required between providing sufficient detail to cover all requirements, and overloading a procedure with the "obvious." One device which worked well in the preparation of an initial draft, was for an experienced operator to use a pocket dictating machine to record every step he followed as he went through a test. This was edited to insure essential details were covered and non-essential ones eliminated.

You will note reference in each procedure to the hazards involved. While not particularly dangerous as such, thermal testing does involve possible personal contact with elevated temperature surfaces, high voltages, dusts, and cutting devices such as a band saw. Over the years, the R&D Center has maintained an enviable safety record within Johns-Manville. This has been achieved only by constant attention to the hazards involved and careful work habits on the part of the personnel.

The availability of computer-controlled drafting facilities expedited the preparation of explanatory diagrams. These were prepared quickly, were of excellent clarity, and in contrast with photographs showed only those details considered pertinent. Figure 2 is an example of a computer drafted diagram.

The obvious benefit of improved testing precision and accuracy has been realized by all operators having standard procedures available. A perhaps not so obvious benefit was the critical analysis of each step during the preparation of a standard procedure. The following questions were asked many times: Is this step really necessary? Is there a better way in terms of improved accuracy or reduced operator time?

We plan continued efforts to complete the balance of the standard procedures. In the future, we also plan periodic review, to insure that the standard procedures represent the best methods for achieving reliable test results and that the operators are following the methods established.

The author is deeply appreciative of the K-LAB staff for their helpful comments on the general plan, and for their assistance in preparing most of the actual procedures. Without their extra efforts the program could not have reached its present stage.

STANDARDIZATION/CALIBRATION COMPUTER RECORD - 83 DATE 8/24/79

EQUIPMENT DESCRIPTION - BALANCE

MANUFACTURER - SARTORIUS

MODEL/SERIAL NUMBER - MOD3716/SER2611008

JM RESEARCH ID -

LOCATION - 302

JM EMPLOYEE RESPONSIBLE - D OBER

VARIABLE 1	VARIABLE 2	VARIABLE 3
WEIGHT		
RANGE OF OPERATION 0-1200 GM		
RANGE OF STANDARDIZATION 0-1200 GM		
INSTRUMENT RESOLUTION .01/.1 GM		
ALLOWABLE ERROR TOLERANCE ON READINGS .01/.1 GM		

STANDARDIZATION INTERVAL - 12MONTHS

DATES OF STANDARDIZATION (YMMDD) - 905 808 705

RESULTS OF MOST RECENT STANDARDIZATION - SATISFACTORY

DATE OF NEXT STANDARDIZATION (YMMDD) - 005

NAME OF PERSON OF SERVICE PROVIDING MOST RECENT STANDARDIZATION - QA BALANCE SERVICE

SERVICE CONTRACT (Y OR N) - Y

TRACEABILITY TO NBS OR OTHER AUTHORITY AS REQUIRED -

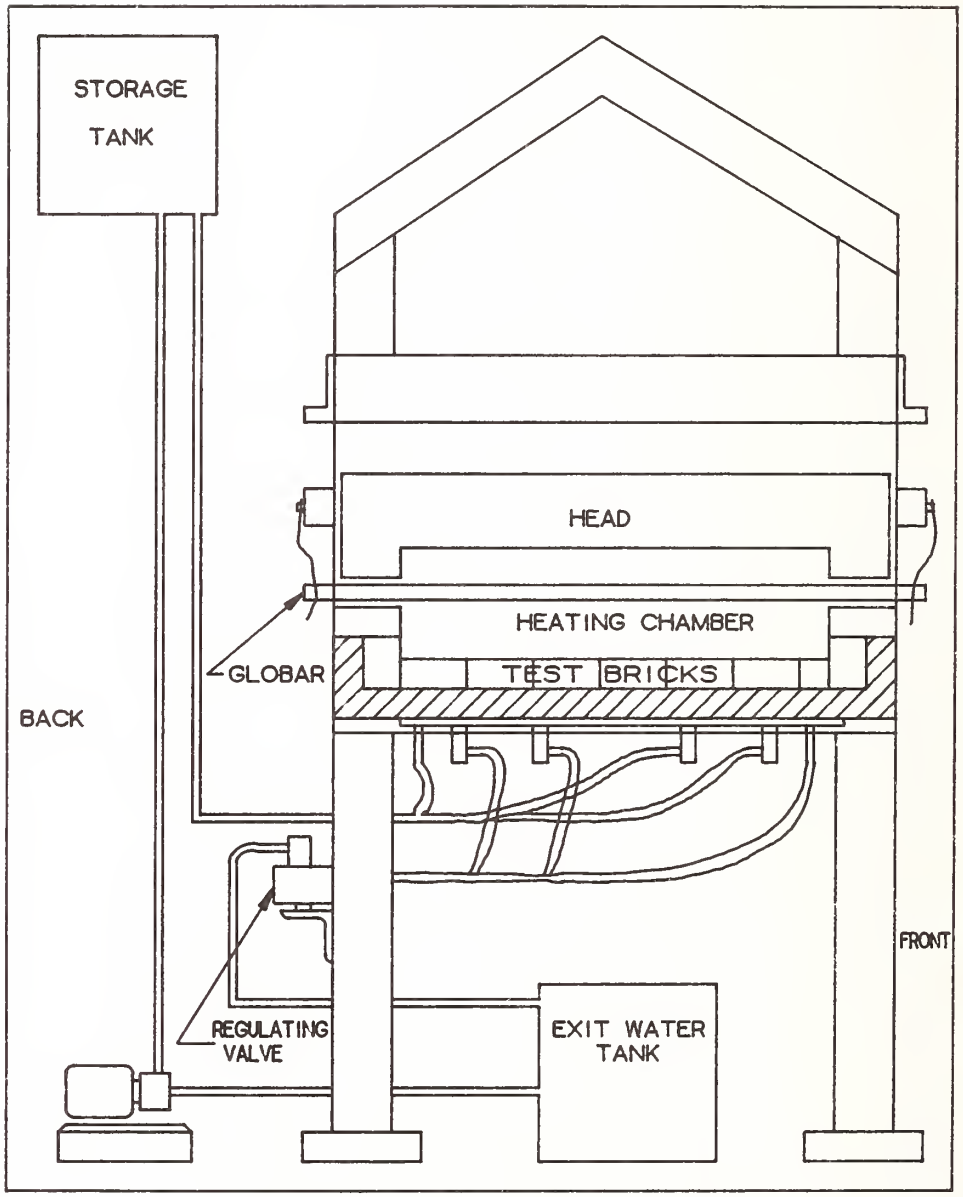
Figure 1 - Example of Computer Calibration Record

Johns-Manville

TEST METHOD
JM-1074

PRODUCT	TEST METHOD NO.
Insulating Firebrick, Castables Refractory Fiber	493-4.3
TEST: Thermal Conductivity using J-M Calorimeter	PAGE NUMBER

THIS METHOD IS THE SAME AS THAT SPECIFIED IN THE FOLLOWING STANDARD SPECIFICATIONS:



APPROVALS:

Director R&D, Applied Technology Date

X - INDICATES CHANGE

THIS PAGE SUPERSEDES | DATE ISSUED

Figure 2 - Example of Computer Drafted Diagram

National Bureau of Standards Special Publication 591, Proceedings of the National Conference on Testing Laboratory Performance: Evaluation and Accreditation, held at NBS, Gaithersburg, MD, September 25-26, 1979. Issued August 1980

LABORATORY PERFORMANCE EVALUATION A NEW LOOK AT QUALITY ASSURANCE IN THE TESTING LABORATORY

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Safety and liability laws, consumer awareness and Federal laws governing test requirements necessary to qualify a component for use in Nuclear reactors has caused a new look at laboratory performance. The independent laboratory is preferred by legal departments since it avoids the connotation of conflict of interest in any litigation which might result if a component fails. Quality Assurance organizations have revised their methods of audits and approach to the control requirements needed by independent test laboratories. This reexamination has shown that in many cases laboratory performance has not been what the laboratory customer expected. This paper presents not only the requirements for nuclear qualification but assesses those performance standards currently found in test laboratories. Further and most important, it presents several solutions to the problems. These are solutions that have been used successfully. They require, as most human endeavors, understanding and cooperation as well as acceptance of certain responsibilities on both the laboratory and the laboratory customer.

Key words: Advent of safety, liability and Federal Nuclear laws requiring tests; consumer awareness and legality; customer and laboratory responsibilities; inadequacies of test laboratories; Institute of Electrical and Electronic Engineers Specifications; laboratory capabilities; laboratory performance evaluation; manufacturers response to laws and consumers; one way to solve the problem; pretest quality planning; tests required for nuclear or safety related products; what the laboratory customer expects in a test.

1. Introduction

1.1

The advent of the safety and liability laws and Federal laws governing safety related products for Nuclear applications has caused Quality Assurance organizations to revise quality programs in the area of qualification testing of products.

1.1.1

Included in these laws is Title 10, Code of Federal Regulations, Part 50, appendix B, commonly referred to as 10CFR50, which is applicable to all activities affecting the safety related functions of nuclear power plants and describes the quality program requirements for design, construction, and operation of these structures, systems and components. In addition, ANSI N45.2 was prepared for general industry use as a guide, for implementation of 10CFR50, appendix B. The design control requirements of these documents includes methods of design verification, one of which is qualification testing.

1.2

Cursory discussions with legal experts leads to the conclusion that qualification tests by an independent test laboratory is preferred, since it precludes allegations in litigation regarding conflict of interest in test results. Therefore, the independent laboratory performance becomes extremely important.

1.3

Qualification testing of safety related products is specified by the Institute of Electrical and Electronic Engineers specifications, IEEE-323 and 344.

1.3.1

In addition, revised laws for product safety and liability have resulted from consumer awareness and have necessitated changes in manufacturers' thinking regarding product qualification.

1.3.1.2

As a result, qualification testing of new products, review and possible requalification of existing products has become mandatory in many company operating policies.

1.3.1.3

Such has been the case at ITT Barton whose written policy is to perform qualification testing on every product we sell.

1.3.1.4

In addition, the testing imposed by the Institute of Electrical and Electronic Engineers specifications IEEE-323 for safety related products such as instruments used in Nuclear power plants is stringent. I will briefly discuss these tests in order that you will be more able to appreciate the serious nature of what I have to say relative to the subject of laboratory performance.

2. Test Classification

2.1

The IEEE-323 specification defines a Class 1E safety related product as, "The safety classification of the electric equipment and systems that are essential to emergency reactor shutdown, containment isolation reactor core cooling and containment and reactor heat removal or otherwise are essential in preventing release of radioactive material to the environment."

2.1.1

Each type of Class 1E power equipment must be qualified by analysis, successful use under similar conditions, or by actual test to demonstrate its ability to perform its function under normal and Design Basis Events (DBE's).

2.1.2

Design Basis Events are earthquakes, high radiation levels and loss of coolant accidents.

2.1.3

Most manufacturers of Class 1E safety related products qualify by a combination o analysis and testing.

3. Test Requirements

3.1

Specification IEEE-323 requires ageing or simulated end of life test typically 10 to 40 years, as the first of a series of tests that must be performed sequentially. ITT has found that very few laboratories have this capability or specialized knowledge.

3.1.2 Ageing

3.1.2.1

The ageing requirement exists so that by test it can be proven that an instrumen to be used in nuclear applications can ope ate within design parameters and operation accuracies for 39 years, 364 days, 23 hour and 59 minutes and then suffer a Design Basis Event such as an earthquake or loss of coolant accident and the instrument wil still operate during and after the Design Basis Event.

3.1.3 Radiation

3.1.3.1

It follows, therefore, after completi of ageing tests the instrument is subjecte to the next IEEE-323 test of Gamma Radiation at the level of 200 x 10^6 Rads. For comparison, the human body limit of Gamma radiation if 400 Rem. The radiation tests insure that materials such as wiring and

electronic components will not fail due to accumulative Gamma radiation absorbed over the life of the instrument and therefore, will still perform the intended function at end of life during a Design Basis Event.

3.1.4 Seismic

3.1.4.1

The next test in sequence is the Seismic simulation test specified in IEEE-344 and is conducted on a biaxial seismic simulator. Testing consists of 5 operational basic earthquake or OBE tests of approximately 35 seconds during which the instrument operation and outputs are remotely recorded. These OBE tests are followed by one SSE or Safe Shutdown Earthquake test of approximately 35 seconds but at higher response acceleration in peak G's. Frequencies are enveloped from 1 Hz to 100 Hz at nominal peak response acceleration of 2 to 15 G's and are conducted in both horizontal and vertical axes.

3.1.5 Loss of Coolant Accident

3.1.5.1

The last test is again contained in IEEE specification 323 and is called the LOCA or Loss of Coolant Accident test. Here the specimen is subjected to saturated steam at 320°F and left to operate while recording outputs and operational functions hopefully within design limits for as much as 100 days. The specimen under test is sprayed with a caustic solution during the 1st 24 hours of LOCA test.

3.1.6 Test Laboratory Performance

3.1.6.1

Although we have had many successful tests at such laboratories, we have also experienced such problems as inadequate test planning, test set-ups that fail during test, inadequate audit of test functions by laboratory personnel, missing or erroneous log keeping and data recording and even the destruction of our test specimen. ITT Barton and other quality assurance organizations have reexamined test laboratory relationships with prospective customers by improving communications through mutual understanding of what is expected during the conduct of a test. Responsibilities are incumbent on both parties. Although there are several solutions, an approach which has been successful is pre-test quality planning.

3.1.6.2 Pre-test Quality Planning

3.1.6.3

A joint meeting, prior to entering into any contract, which must include technical, purchasing/contracts and quality assurance personnel during which the following subjects, at a minimum must be discussed:

- Referenced quality program requirements.
- Errors and omissions in proposed p.o. and specifications.
- The technical approach to test methods.
- Instrumentation requirements.
- Test set-up adequacy.
- Test set-up check-out prior to test start.
- Test process checklists.
- Test deviations.
- Test data recording and retention.
- Test reports.

3.1.6.4

Contractor responsibility must embrace the philosophy to assist the laboratory in achieving timely and specified performance results.

3.1.7 Laboratory Performance Requirements

3.1.7.1

The laboratory customer is purchasing expertise, not just facilities and test personnel assistance. The experience of the laboratory can do much to prevent aborting tests, assuring required test conformance, reducing costs, and improving laboratory competitiveness.

3.1.7.2

Instrumentation and test set-ups must provide the intended results. Assurance of this results from set-up check-out, prior to notification to contractors that the laboratory is ready. Such action insures minimum costs to both laboratory and contractors.

3.1.7.3

In complex tests such as those referenced in IEEE-323, which include simulated life ageing, gamma radiation, seismic and loss of coolant accident (LOCA), simulation requires quality control improvement. The

use of process control checklists has been successful. These lists are orderly checks of test set-up, instrumentation operation, test sequences and ancillary and monitoring equipment to observe and record data and specimen performance.

3.1.7.4

Contractor responsibilities include pre-test quality planning for the same reasons mentioned. Quality personnel must be involved at the earliest possible time.

3.1.7.5

Test deviations in laboratory instrumentation and test specimen failures require immediate verbal notification and laboratory quality procedures should require written, timely submission of details, including cause and corrective action, with provision for contractor engineering and quality personnel approval signatures as applicable.

3.1.7.6

In testing to verify design of safety related devices under 10CFR50, reporting of defects and non-conformances as required by 10CFR21 will be imposed and provides severe penalties for failure to report. Laboratory customer quality personnel must monitor to assure performance to requirements by laboratory personnel, instrumentation and test specimens.

3.1.7.7

Test data are the end product purchased by the contractor. Data must be complete, accurate and legible. A chronological test log must be maintained by laboratory personnel with entries of time, date and signatures.

3.1.7.8

There must be a pre-stated mutual agreement for data retention. Some data are required to be held for years and contractual relief to the laboratory should be given in writing. Original data being turned over to the contractor one year after approval of final test report has worked well.

3.1.7.9

Retained data in the laboratory must be protected and considered proprietary. Pass or fail information and results are of value to contractor competition.

3.1.7.10

Review of test data must be made at pre-determined intervals consistent with the agreed upon test plan.

4. Conclusion

4.1

Therefore, inclusion of those items presented and in particular, the pre-test quality planning efforts will assure that products tested will conform to advertised performance specifications and/or contractual obligations.

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SESSION VI

EVALUATION PROGRAMS AND SYSTEMS

CHAIRMAN: JOHN R. DISE
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A MEASUREMENT ASSURANCE PROGRAM - THERMOMETER CALIBRATION

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The platinum resistance thermometer (SPRT), calibrated in accordance with the specifications of the International Practical Temperature Scale of 1968 (IPTS-68), is the international standard for temperature measurement in the range 13.81 K (-259.34°C) to 903.89 K (630.74°C) to which the United States subscribes. Such SPRT's are used to calibrate other SPRT's, "industrial resistance thermometers", or other types of thermometers, or used directly where highly accurate temperature measurement is desired. There are many laboratories in the United States that calibrate SPRT's and other resistance thermometers at various levels of accuracy. A measurement assurance program (MAP) on the calibration of SPRT's has been developed at the National Bureau of Standards. In the program, three pre-calibrated SPRT's are shipped to a participating laboratory for calibration. Upon return, the SPRT's are recalibrated at the NBS and shipped to the next laboratory. The two NBS calibrations (before and after) are compared with those of the participant. This paper describes the results of the MAP measurements on the SPRT's.

Key Words: Calibration; check thermometers; fixed points; International Practical Temperature Scale of 1968; measurement assurance program; platinum resistance thermometer; reference thermometer; thermometer.

1. Introduction

The National Bureau of Standards (NBS) has the responsibility to establish, maintain, and develop the standards for temperature measurements for the nation's industrial and scientific communities and, in cooperation with other national laboratories, to establish international uniformity of temperature scale. The dissemination of these standards and the methodology of temperature measurements is achieved through appropriate publications, consultations, calibration services, Measurement Assurance Programs (MAP), and temperature measurement seminars[1]. The International Practical Temperature Scale of 1968 (IPTS-68) is the present basis for internationally uniform values of temperature [1,2].[2] The IPTS-68 is based on the assigned values of the temperatures of specified, reproducible equilibrium states of pure substances (defining fixed points) and on standard instruments calibrated at these temperatures. Between the fixed-point temperatures, interpolation equations relate the

[1]Because of the increased interest in thermometry the last few years, these precision thermometry seminars are now being held twice a year at the NBS, in March and in September.

[2]Figures in brackets indicate the literature references at the end of this paper.

indications of the standard instruments to temperature values of the IPTS-68. The platinum resistance thermometer is the specified standard instrument from 13.81 K (-259.34°C) to 903.89 K (630.74°C), the platinum-10% rhodium alloy versus platinum thermocouple from 903.89 K to 1337.58 K (1064.43°C), and the optical pyrometer above 1337.58 K. The assigned values of temperatures of thirteen equilibrium states that define the IPTS-68 are given in table 1 (the states and values with asterisks). For the specified interpolation equations of the various temperature ranges, see reference [2].

As part of the study of properties of substances or of the direct investigation of other suitable thermometric reference points, temperatures of various equilibrium states other than those of the defining fixed points are constantly being published. (Research is conducted at the NBS to improve the realization of the defining fixed points, as well as other suitable fixed points.) Most of the temperatures of the equilibrium states are obtained with thermometers that have been calibrated in terms of the IPTS-68. Recently the Consultative Committee for Thermometry (a subcommittee of the International Committee of Weights and Measures) published a compilation of such measurements for secondary thermometric reference points between 13 and 3700 K [3]. Values up to the gold point (1337.58 K) from the compilation are included in table 1. The vapor pressure versus temperature relation for some substances given in the compilation are excluded from table 1. These secondary reference points may be employed to check the calibration of thermometers calibrated in terms of the IPTS-68 or used to calibrate such thermometers or other thermometers for use over a limited temperature range. [In the calibration of thermometers other than those specified by the IPTS-68, the temperature intervals of calibration must be small enough so that the temperature unit (i.e., the size of the degree) of the thermometer scale is the same as that of the thermometer specified by the IPTS-68.]

This paper is a brief report of the MAP involving the calibration of platinum resistance thermometers in accordance with the specification of the IPTS-68. (Henceforth, a platinum resistance thermometer that meets the IPTS-68 specifications for a standard will be referred to as SPRT). The range of calibration of the SPRT that will be discussed is from the oxygen point [i.e., 90.188 K (-182.962°C)] to 903.89 K. This is the range where most of the temperature measurements are made and where the long-stem SPRT is normally used. Also, for convenience, this MAP concerning the calibration of SPRT's will be referred to as SPRT-MAP. Since the calibration of the SPRT can be accidentally changed during use, procedures for continued testing of the integrity of the measurement process (internal MAP) is described as part of the SPRT-MAP.

SPRT's are delicate instruments. They must be handled in a manner that avoids tapping or bumping against table tops or other objects. They should not be vibrated. When used properly, they will give accuracie of ± 1 mK over most of the specified tempera ture range. Such SPRT's are used to calibra other SPRT's, industrial type platinum resistance thermometers (PRT), or other types of thermometers (e.g., thermistors, mercury thermometers, quartz thermometers, thermocouples, etc.) or used directly where the highest accuracy of temperature measurement is required (e.g., standard cell baths, length standards, electric power, calorimetry, etc.). Hence, the SPRT is the standard to which temperature measurements over a broad range is referred. A MAP is needed at every level of thermometry accurac whether the accuracy that is claimed is in the calibration laboratory or in the user laboratory or plant. Although this paper deals with SPRT-MAP, the concept, the repeated check measurements, and the documen tation of the MAP are applicable to other levels of thermometric accuracy.

To disseminate the IPTS-68 to the thermometry community, SPRT's of various laboratories are calibrated at the NBS in accordance with the IPTS-68 at the specified fixed points (oxygen point, triple point of water, tin point, and zinc point). There are a number of standards laboratories in the United States that calibrate SPRT's at accuracy levels of 0.01 to 0.001 K for in-house use or for other organizations. Their SPRT calibrations are traceable to the NBS through their reference SPRT's that have been calibrated at the NBS. These laboratories have one or more of the specified fixed points, or have baths that are controlled near the fixed-point temperatures, for calibration of the SPRT's. The operatic of the fixed points is checked or standardiz using the NBS calibrated reference SPRT. Where baths are used, the reference SPRT is used to calibrate the test SPRT's directly. These reference SPRT's are handled extremely carefully, e.g., some are "hand carried" between the NBS and the standards laboratories. However, in spite of careful documentation of traceability of the reference SPRT to the NBS, the calibration may change or there may exist unknown weak links in the measurement process of the laboratory itself. The SPRT-MAP has been designed to

TABLE I

Some of the Reference Points of Thermometry[a,b]

Equilibrium[c,d,e] State	Temperature T(K), IPTS-68	Equilibrium[c,d,e] State	Temperature T(K), IPTS-68
e-H_2 (TP)*	13.81*	Hg (TP)	234.308
n-H_2 (TP)	13.957	Hg (FP)	234.314
e-H_2 (BP)*,33,330.6 Pa	17.042*	Ice Point	273.15
e-H_2 (BP)*	20.28*	H_2O (TP)*	273.16*
n-H_2 (BP)	20.397	Phenoxybenzene (TP)	300.010
O_2 (tr,α-β)	23.867	Ga (MP)	302.921
Ne (TP)	24.562	Steam Point*	373.15*
Ne (BP)*	27.102*	Benzoic acid (TP)	395.52
O_2 (tr, β-γ)	43.801	In (FP)	429.784
O_2 (TP)*	54.361*	Sn (FP)*	505.1181*
N_2 (TP)	63.146	Bi (FP)	544.592
N_2 (BP)	77.344	Cd (FP)	594.258
Ar (TP)*	83.798*	Pb (FP)	600.652
Ar (BP)	87.294	Hg (BP)	629.81
O_2 (CP)*	90.188*	Zn (FP)*	692.73*
CH_4(TP)	90.686	S (BP)	717.824
Kr (TP)	115.770	Cu-Al eutectic (MP)	821.41
Kr (BP)	119.800	Sb (FP)	903.905
Xe (TP)	119.388	Al (FP)	933.607
Xe (BP)	165.090	Cu-Ag eutectic (FP)	1052.7_5
CO_2 (SP)	194.674	Ag (FP)*	1235.08*
CO_2 (TP)	216.580	Au (FP)*	1337.58*

[a]Reference points with asterisks (*) are the defining fixed points of the IPTS-68.

[b]Reference points listed without the asterisks (*) were taken from reference [3]. Where more than one value was given, the average was taken. Values only up to the gold point 1337.58 K are given here; for values above this temperature, see references [2,3].

[c]Except for triple points and where pressures are indicated, the values of temperature are for equilibrium states at a pressure of 1 standard atmosphere (101,325 Pa).

[d]TP = triple point, BP = boiling point (vanishingly small vapor fraction), CP = condensation point (vanishingly small liquid fraction), FP = freezing point, SP = sublimation point, e-H_2 = equilibrium hydrogen, n-H_2 = normal hydrogen, tr = solid phase transition, and MP = melting point.

[e]The Ar (TP) may be used as an alternative to the O_2 (CP) and the Sn (FP) may be used as an alternative to the steam point to obtain the IPTS-68 in terms of the SPRT.

compare the output, i.e., a standards laboratory's SPRT calibrations, with those of the NBS.

2. IPTS-68 in the SPRT Range

The SPRT temperature scale of the IPTS-68 is based on the resistance ratio W(T) defined by

$$W(T) = R(T)/R(273.15K), \qquad (1)$$

where R(T) is the SPRT resistance at IPTS-68 temperature T (kelvins) and R(273.15 K) is the resistance at 273.15 K (0°C). [The Celsius temperature t(°C) is defined by t = T - 273.15.][3] The SPRT resistor must be "annealed pure platinum", supported in a "strain-free" manner, and have a value of W(100°C) not less than 1.39250. The resistor must be hermetically sealed inside a protective sheath filled with dry gas. The interpolation equations are expressed in terms of W. Hence, to determine the value of temperature on the SPRT scale, the resistance of the SPRT must be measured at the temperature of interest and at 0°C.

2.1 Interpolation Equations

From 0°C to 630.74°C (903.89 K), the values of IPTS-68 temperature are defined by

$$t = t' + 0.045\left(\frac{t'}{100°C}\right)\left(\frac{t'}{100°C} - 1\right)\left(\frac{t'}{419.58°C} - 1\right)\left(\frac{t'}{630.74°C} - 1\right)°C, \qquad (2)$$

where t' is defined by

$$W(t') = R(t')/R(0°C) = 1 + At' + Bt'^2. \qquad (3)$$

Equation (3) is equivalent to

$$t' = \frac{1}{\alpha}[W(t')-1] + \delta\left(\frac{t'}{100°C}\right)\left(\frac{t'}{100°C} - 1\right), \qquad (4)$$

where

$$\alpha = A + B \times 100°C \qquad (5)$$

and

$$\delta = -\frac{B(100°C)^2}{A + B \times 100°C}$$

Equation (2) is independent of the SPRT; it is intended to adjust the SPRT temperature scale, given by equation (3), to be closer to the thermodynamic temperature scale. The thermometer constants R(0°C), A, and B are determined from calibration at the triple point of water, the steam point or the tin point, and the zinc point. (Henceforth, the triple point of water will be abbreviated TP). The constants α and δ are derived from the constants A and B according to equations (5) and (6), respectively. When the steam point (100°C) is used in the calibration, the constant α can be obtained directly from equation (4), i.e.,

$$\alpha = [W(100°C)-1]/100°C = [R(100°C) - R(0°C)]/R(0°C) \times 100°C \qquad (7)$$

After the thermometer constants A and B are obtained, tables of W(T) at integral values of t are calculated for the SPRT from 0°C to 631°C using equations (2) and (3).

Below 0°C, the W(T) relation of the SPRT is given by

$$W(T) = W^*(T) + \Delta W(T) \qquad (8)$$

where W*(T) is the reference function defined by

$$T = \sum_{j=0}^{20} a_j[(\ln W^*(T) + 3.28)/3.28]^j \ K \qquad (9)$$

and $\Delta W(T)$ is a deviation function which is a polynomial in T. The coefficients a_j of equation (9) are given in reference [2]. The reference function was developed from the results of comparison of SPRT's against gas thermometers. The range from 13.81 to 273.15 K (0°C) is divided into four subranges, each with its specified deviation function. The deviation function for the subrange 90.188 K (-182.962°C) to 273.15 K,

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[3]Henceforth, temperatures will be expressed interchangeably in °C and K, based on the definition.

the range included in the SPRT-MAP, is given by

$$\Delta W(T) = b(T-273.15\ K) + e(T-273.15\ K)^3(T-373.15\ K) \quad (10)$$

where the constants b and e are determined from calibration at the TP and the measured deviations ΔW at the steam point (100°C) and at the oxygen point or the triple point of argon. If the tin point instead of the steam point is used, W(100°C) for the SPRT should be calculated from equations (2) and (3). (Note that for the tin point, t = 231.9681°C but t' = 231.9292°C). After the thermometer constants b and e are obtained, tables of W(t) are calculated for the SPRT from -183°C to 0°C using equations (10), (9), and (8).

2.2 Fixed Points

Of the four fixed points of the IPTS-68 that are involved in the SPRT-MAP, the TP is the most important. Although R(0°C) for the resistance ratio W may be obtained from measurements at the ice point, in routine measurements it is most accurately obtained from the resistance measurements at the TP, R(TP). In an intercomparison of fifteen TP cells at the NBS, the averages of readings on each cell were all within a range of ±0.1 mK [4]. Also, in another test, the range of readings obtained over three days on each of eight TP cells was 0.01 mK [5]. In terms of the resistance value at 0°C, 0.01 mK corresponds to 4×10^{-8} R(0°C).

The freezing points of tin and zinc are realized at the NBS by using samples of these metals that are nominally 99.9999 percent pure. These samples are issued as NBS Standard Reference Materials SRM-740 and SRM-741, respectively. The freezing points of cells that have been assembled using these metals have been found to agree within ±0.1 mK [6,7]. During the freezing process the furnaces are controlled about 1 K below the freezing point to give a complete freeze duration of 14 to 16 hours. Normally, the SPRT's are calibrated during the first 50 percent of the freeze, during which time the temperature change is not more than 0.2 mK.

At the NBS, the SPRT's are calibrated at the oxygen point by a comparison method in terms of reference standard SPRT's, using a copper block apparatus that is maintained during the measurements as nearly isothermal as possible close to the oxygen point. The results of repeated measurements over a two-year period on "check SPRT's" show the standard deviation of the oxygen-point calibration to correspond to ±0.16 mK. (See the section on check SPRT's.) This oxygen-point calibration can be compared to the calibration methods used by many standards laboratories, where the SPRT's are calibrated in baths that are controlled close to the fixed points in terms of reference SPRT's.

3. Internal MAP

In addition to international comparison of temperature scales by interchanging calibrated SPRT's, the NBS maintains an internal SPRT-MAP. This consists of a bank of fixed-point cells (TP, tin point, and zinc point), which have been tested and found to yield temperatures that agree within ±0.1 mK (see section 2.2), and a bank of reference standard SPRT's (for the oxygen point and for temperatures between 13 and 90 K). The results of the measurements with these cells demonstrate that the fixed points used at the NBS are highly reproducible and, since materials of exceptionally high purity are used, the temperatures obtained are close to those of pure substances. As part of this internal SPRT-MAP, measurements are obtained with check SPRT's whenever the fixed-point devices are used in SPRT calibration. The following is a brief description of the internal SPRT-MAP at the NBS (for details, see references [8,9,10]).

3.1 Check SPRT's

In a calibration laboratory it is extremely important that the laboratory's own measurement errors be small enough so that the results of the users of the calibrated instruments would not be affected by those errors. This means that the measurement process of the calibration laboratory must always be under control and must produce results that always lie within these allowable limits of measurement error. (At the NBS, procedures are constantly being sought to improve its measurement accuracy and to eliminate possible accidental calibration errors.) In order to establish the validity of a single calibration on a new SPRT, i.e., that the variability of the measurements is within the allowable limits of measurement error and that the calibration process is under control, there must be redundant measurements of a control or check SPRT. (A check SPRT is defined herein as an SPRT used to monitor the measurements at a temperature.) Any abrupt shift in the calibration of the check SPRT would indicate that there may be problems with the fixed-point devices or with the measurement instrument, possible change in the

calibration of the reference SPRT or the bath temperature control is not operating properly, or that the check SPRT was accidentally "bumped." The long record of measurements on the check SPRT gives information on the limits of calibration error of any new SPRT.

The procedure that is employed at the NBS to monitor the calibration of every batch of SPRT's is as follows. Different long-stem type check SPRT's are assigned to the zinc-point, tin-point, and oxygen-point calibration measurements. To obtain the corresponding values of W at these fixed points, the resistances of the check SPRT's are also measured in the TP cell with every measurement obtained at the zinc, tin, or oxygen point. In the cases of the zinc and tin point measurements, the freeze is initiated using the check SPRT and the first equilibrium readings are obtained on the check SPRT. This is followed by calibration of the test SPRT's (usually six). After all of the test SPRT's are calibrated, the check SPRT is read again in the freezing-point cell. The second reading with the check SPRT for the given freeze must not differ from the first by more than 0.5 mK. Usually the difference is not more than 0.1 or 0.2 mK because the calibrations are made during the first 50 percent of the freeze (see section 2.2). Also, the readings should be consistent with those obtained in earlier freezes. (For those laboratories that employ NBS calibrated SPRT's to standardize the freezing points of tin and zinc before calibrating the test SPRT's, the reference SPRT's can serve as their check SPRT's.) With the oxygen-point calibration apparatus, a second reference standard SPRT is calibrated in terms of the working reference standard SPRT in the same manner as the test SPRT's. The standard deviations of the values of W of the check SPRT's obtained over a two-year period were ±0.28 mK, ±0.30 mK, and ±0.16 mK for the zinc, tin, and oxygen point calibrations, respectively.

3.2 Secondary Reference Points

Secondary reference points have many applications. If the calibration of a reference SPRT is uncertain, rather than to be recalibrated, it can be tested at one of the secondary reference points in the range where temperature measurements are to be made. To detect any possible accidental calibration errors at the defining fixed points (e.g., transcription error) in routine calibrations, measurements at one or more of the secondary reference points could be included as part of the calibration process. Although the calibration would not be in accordance with the IPTS-68 specifications, SPRT's may be calibrated at the secondary reference points for limited interpolation use. Differences between such secondary calibrations and the IPTS-68 calibration should be expected, depending upon the error in the temperature value of the fixed point; upon variations in the realization of the fixed point, e.g., sample purity or technique; and upon differences in the SPRT's. To minimize the error in realization of the secondary fixed points, sealed secondary reference cells are being developed at the NBS [11,12].

The selection of a secondary reference point, instead of a defining fixed point for testing the calibration of a SPRT, is expected to be based on its greater convenience and its temperature being in the region where measurements are to be made. However, the TP is a highly reproducible and easily realized defining fixed point; measurements at the TP should detect any large changes in the calibration of the SPRT. (In the calibration of SPRT's at the NBS the readings are obtained in the following order: R(TP), R(Zn), R(TP), R(Sn), R(TP), $R(O_2)$, and R(TP). When the SPRT's are to be used only above -50°C, the last two readings are omitted. Over a two-year period the average of the standard deviations of three or four R(TP) readings of SPRT's that were calibrated was about ±0.1 mK, which indicates the stability that could be expected in SPRT's over a short time interval [10].)

4. SPRT-MAP

It is essential that a laboratory engaged in the calibration of SPRT's have at least two reference SPRT's and several check SPRT's to monitor the calibration process. Before one of the reference SPRT's is sent to the NBS for calibration, it should be calibrated in terms of the second reference SPRT (or else the calibrations of the SPRT's should be compared.) Upon return of the first reference SPRT from the NBS, it should be calibrated again in terms of the second reference SPRT. If the SPRT's were handled with sufficient care during use, the two calibrations, before and after, should agree within the measurement uncertainties. (In a series of tests over six years, where SPRT's were exposed intermittently to -180, 0, 100, 232, 420, 450, and 480°C, the calibrations at the fixed points did not change by more than 1 or 2 mK.) Also, if the second reference SPRT had previously been calibrated in accordance with the IPTS-68 (or at the NBS), the two calibrations should agree with the new NBS calibration

Accidental agreement of the two user-laboratory calibrations can result if the same error is made in both calibrations, e.g., the fixed point may be 0.01 K colder than the assigned value. However, the comparison with the NBS calibration should reveal this error, i.e., the measured value of W and the value of W given in the NBS calibration will be different for the "temperatures." When the second reference SPRT is sent to the NBS for calibration, similar comparison calibrations should follow. Hence, by such procedures a "do-it-yourself" internal MAP can be established. Obviously, more calibrated reference SPRT's can be used to improve the comparison statistics of the reference SPRT's. In the calibration of test SPRT's, check SPRT's must be employed to monitor the calibration process each time. The results on the check SPRT's can also support the stability of calibration of the reference SPRT, particularly if the two SPRT's are of the same quality. (Hence, as previously stated, the measurement results on the check SPRT's serve to monitor the complete calibration process.)

The SPRT-MAP service provided by the NBS requires calibration of three NBS owned SPRT's. The participating laboratory is requested to calibrate the SPRT's by procedures that are normally employed in the laboratory for the calibration of SPRT's or in measurements using SPRT's. (Some laboratories use SPRT's principally to calibrate thermometers other than SPRT's and only rarely calibrate SPRT's.) Work sheets that accompany the SPRT's request information on temperature standards that are employed (i.e., fixed points and reference SPRT's with their calibration constants), geometry and other data on the fixed point devices and baths that are important in temperature measurements (e.g., immersion depth, use of aluminum or graphite bushing, temperature equalization blocks in baths, etc.), the pertinent measurement data, and the final calibration tables that are normally furnished to "customers." Immediately upon receipt of the SPRT's, and just prior to shipment of the SPRT's back to the NBS, the laboratory must determine the R(0°C) of the SPRT's at two currents (1 and 2 mA). These measurements in conjunction with the calibration data will show (1) whether the SPRT's were harmed during shipment, (2) whether the SPRT's were carefully handled by the laboratory, (3) whether the measurement procedure of the laboratory is standard, and (4) whether the resistance unit is close to our national unit of resistance. When the calibration is completed, the SPRT's are returned to the NBS for recalibration and shipment to the next participating laboratory. The SPRT-MAP comparison is usually reported back to the participating laboratory within three to six weeks after receipt of the calibration results, depending upon the calibration situation at the NBS and other factors.

The laboratories that have participated thus far in the SPRT-MAP are AVCO (Systems Division), Boeing Aerospace Company, Duke Power Company, Leeds and Northrup Company, Pratt and Whitney Aircraft, Rockwell International (Autonetics), Rosemount, Inc., Sandia Laboratories, U.S. Air Force Aerospace Guidance and Metrology Center, U.S. Army White Sands Missile Range, U.S. Army Metrology and Calibration Center, U.S. Navy Eastern Standards Laboratory, and U.S. Navy Western Standards Laboratory. Two of the laboratories have completed their second SPRT-MAP. The range of accuracies that was desired by the laboratories was about ±0.01 to ±0.001 K; a few laboratories felt that accuracies within ±0.1 K were satisfactory in some of their applications.

As part of the SPRT-MAP, calibration tables of W(T) at integral values of temperatures were received from the participating laboratories. The values at -183, 100, 232, and 420°C were compared with those obtained at the NBS. The values at these temperatures are sufficiently close to the fixed points (oxygen, steam, tin, and zinc points, respectively) to consider them equivalent to those obtained at the assigned temperatures of the fixed points. Figure 1 shows the

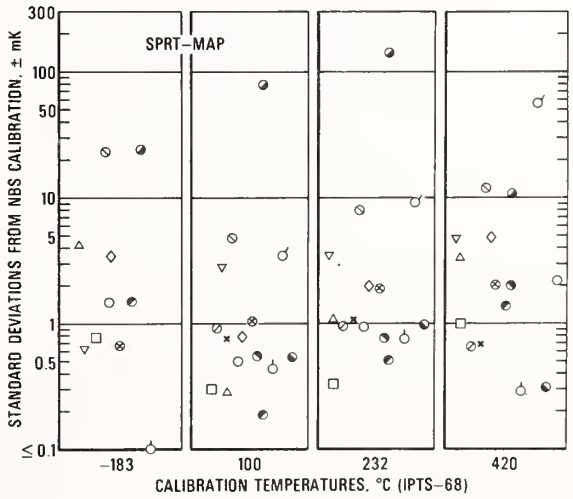

Figure 1. Standard deviations of calibrations of various laboratories from the National Bureau of Standards calibration of three SPRT's near the fixed points.

standard deviations of each of the various laboratories from the NBS calibrations for the three SPRT's at the above temperatures. Most of the standard deviations are shown to be within ± 5 mK, but there are some deviations that are substantially larger. Very few laboratories made measurements at the steam point (the measurements with the tin point cell being easier); however, the calibration values at the steam point are compared for all of the laboratories.

Many of the laboratories have been shown to be performing excellent measurements; the SPRT-MAP results have added confidence to their work. Where problems occurred, such as adjustments for differences in barometric pressure on the freezing point or for radiation losses, they were readily detected and corrected. The SPRT-MAP work sheets helped to document better the measurement process. Where the SPRT-MAP showed that the measurements are not up to expectation, it has helped to indicate possible improvements in the measurement process.

5. Conclusion

To maintain high quality measurement assurance in SPRT calibration, it is essential to have

1.) temperature standards (fixed points or reference SPRT's) that are compared regularly in terms of the national standards,

2.) redundant sets of measurements to test continuously whether the calibration process is under control (e.g., measurements on check SPRT's that are always included in the group of SPRT's being calibrated),

3.) comparison of the calibration (i.e., the output) with the NBS.

All three support each other to attain measurement assurance.

For users of calibrated SPRT's (i.e., those who are not necessarily involved in the calibration of SPRT's) the calibration of the SPRT may be checked by employing one or more of the many fixed points listed in table 1 in the temperature range of interest. Such measurements also provide more detailed measurement assurance.

6. Future Thermometry MAP

A number of improvements will be made in the current SPRT-MAP service provided by the NBS, particularly in the area of providing a documentation of the SPRT-MAP concept and measurement procedure to serve as a guide for maintaining a good SPRT-MAP. (For details of the measurement process reference should still be made to [6,7,8, 9,10].) The document will show samples of good work sheets to help formulate a suitable measurement process. The document will include samples of internal MAP for continuous monitoring of the process (see section 3.). Most of the laboratories that have participated thus far in the SPRT-MAP follow internal MAP procedures. To reach a broader thermometry community, an industrial platinum resistance thermometer MAP is being developed to serve those that use industrial type PRT's instead of SPRT's. The MAP procedures are expected to be very similar to those of the SPRT-MAP.

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THE CERTIFICATION OF BUILDING PRODUCTS IN THE UNITED STATES

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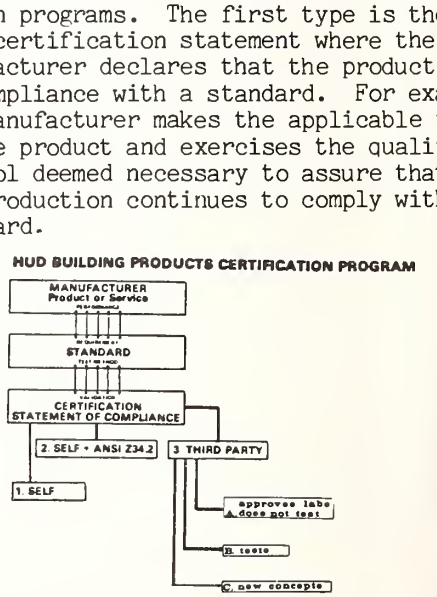
Based on a survey of certification for building products United States, HUD has developed qualifications and procedures for administrators in carrying out certification programs. In addition, a glossary of terms, used in the HUD Certification of Building Products Program, has been developed. In the United States, manufacturers provide certification of a product to a particular standard while adminstrators provide a validation of the manufacturer's certification. Several examples of certifications will be discussed. As an adjunct to certification, HUD and specific program administrators, have developed basic criteria to be used by administrators in approving laboratories. An example of the use of these criteria in the carpet program will be extensively discussed. It is anticipated that a NVLAP for the testing of carpet will be developed. Finally, HUD's view on administrators. building products, future certification and laboratory accreditation programs in the United States and international certification will be presented.

Key words: Building products; certification; laboratory accreditation.

Presently, there is an intense interest in the certification of building products by code officials, architects, and government agencies associated with the building industry. The purpose of this paper is to provide an understanding of the Department of Housing and Urban Development's certification of building products programs and to provide some basis for the establishment of a national policy in the United States for certification of building products and for other products when the system can be determined applicable.

Certification, of a product to a standard, refers to the authentication, or attesting by a manufacturer or vendor, that the product being sold complies with a particular standard. It is important to note that the manufacturer or vendor is the only one that can make this declaration or certification.

Figure I illustrates three types of statements of compliance found in certification programs. The first type is the self-certification statement where the manufacturer declares that the product is in compliance with a standard. For example the manufacturer makes the applicable tests on the product and exercises the quality control deemed necessary to assure that the production continues to comply with the standard.



The second type is similar to the first, except more formal, and extensive records are kept in accordance with established pratices. such as the American National Standards Institute Standard Z 34.2 (which requires recording of the frequency of testing, description of the manufacturing process and/or quality control programs.)

The third type of statement of compliance is the administrative type where neutral third parties actually collect, review and file test reports; check the manufacturer's quality control program and validate the manufacturer's certification.

Third party organizations or administrators are sometimes used to conduct certification programs to validate the manufacturer's declaration of certification. Such programs involve required test frequencies and plant visits to assure that quality control procedures are being followed. The administrator/validator does not certify products, but rather gives a testimonial based on test records and inspections that the manufacturer is complying with the provisions of the standard. The administrator/validator allows the use of his registered mark or label for as long as the product complies with the standard and withdraws the use of the mark or label when noncompliance is established. This clear distinction between producer and the administrator's involvement is important. The producer is ultimately responsible for the certification of the product and the administrator is responsible for the conduct or operation of the specified certification program. Minimum requirements for testing frequencies, plant visits, etc. are set forth in the certification program and can be increased in intensity at the discretion of the administrator relative to the producers ability to comply with the standard. The public is informed of complying products through the periodic issuance of a directory, listing or marking of products. Noncomplying products are deleted from such issuances. Thus, it is only the producer or vendor that assumes the risk, the liability and the profit from the sale of the product. It should be pointed out, however, that in some foreign countries, the government itself acts as the administrator or may grant a waiver to administrators relieving them of any liability responsibilties. In these cases the administrator can also certify the product along with the producer.

Appendix I contains a list of some of the third party organizations validating building products.

Generally, there are three classes of administrator type certification programs. The first class only serves as the manager or administrator of the program but does not do any testing. In this case, the administrator approves other laboratories to do the testing and makes audits to verify the quality control level in the plant. The second class of administrators do not approve other test laboratories but does all of the testing itself. Finally, class three administrators are characterized by having an open system where a nonprofit organization is chartered to sponsor a program and the administration is put out for bid. An example of this type of program is the Safety Glazing Certification Council (SGCC) program and the Insulating Glass Certification. Council (IGCC) program for insulating glass. In some instances, there are combinations of types within a sample certification program.

Certification programs, involving administrators or third party type, generally perform the following ten duties:

1. Administrates a program relating to a specific standard;
2. Obtains a license agreement between the manufacturer and the administrator;
3. Approves laboratories for testing;
4. Reviews initial test data and quality control data of manufacturers to determine acceptance;
5. Issues notices of validation;
6. Allows the use of administrators' labels on manufacturers products;
7. Issues a directory or listing or prod ucts in the program when applicable;

8. Samples and periodically visits the plant to determine continuing compliance with the standard;

9. Decertifies products that do not comply with the standard after intiial acceptance;

10. Maintains an appeal process or challenge procedures in cases of dispute.

In order to clarify many of the other terms used in certification, a list of terms used in the HUD Building Products Certification Programs appears in Appendix II.

The use of certification programs is growing in acceptance because they are meeting the needs of the vaious segments of the building industry. One of the main purposes of any certification program is to provide some assurance to the user that the product actually delivered complies with the designated standard and continues to do so on an ongoing basis.

For manufacturers, certification removes the likelihood of unfair competition based on spurious claims and provides for a fair and equitable basis for marketing a product. Certification programs also assist the acceptance and establishment of new products. Many times, new products, without a long history of performance, are not accepted by users. Certification can provide some information and assurance that the product at least complies with a standard and that a quality control program exists for continued production. Often this assurance can be used in place of a long history of usage. Obviously, however, certification programs can never guarantee 100 percent assurance or performance but can provide users with some degree of confidence that the product complies with the standard and will perform satisfactorily provided that the reference standard is meaningful.

Certification programs also provide manufacturers with a creditable assurance for their products that they alone could not provide. These programs can, in addition, provide some assistance to manufacturers' quality control programs and prevent confusion and misrepresentation to consumers with regard to claims made for the product. In addition, certification programs used in conjunction with viable standards reduce the chances of premature failure thereby enhancing cost effectiveness and conserving energy when a product fails and has to be replaced. Not only is the cost of the produce and labor involved but also the loss of energy used to manufacture the product. Consumers also benefit directly because it aids in making value judgment choices and reducts the need for duplicate evaluations by different users, by providing impartial and accurate information on the product. Many times these judgment choices involve concerns for health and safety.

A classic example of the use of certification program in achieving many of the benefits described above, is the HUD Carpet Certification Program. Originally, 60 percent of the carpet provided to HUD-insured mortgage homes did not comply with the existing standard even though manufacturer declared their carpets complied with the standard. After one year, many of these carpets deteriorated and necessitated costly replacement. Many honest and reputable carpet manufacturers lowered their quality levels because they could not compete on an equitable basis with manufacturers that did not actually comply with the standard. The purchase of carpet was particularly difficult for users, because at the time of delivery it was impossible to visually determine if the carpet was in compliance with the required standard. With the advent of a carpet certification program, the percentage of carpet in the HUD program not complying was reduced to less than seven percent. Most of the seven percent noncomplying carpets, however, involved only a few factors which were of a marginal failure nature, consequently, the amount of carpet that would constitute any major failure would be negligible. It appears this level of compliance cannot be lowered without a more intensive testing and monitoring program which would be extremely expensive for manufacturers and consumers. We do not believe this is necessary.

Basically, the cost of the carpet certification program to the manufacturer has been less than a cent per square yard of carpet. The program is generally accepted by the carpet industry with about 80% of the mills participating. Many skeptics thought the program would stifle innovation by imposing new demands for rigid quality controls but each year the number of qualities in the program continues to grow. Architects, designers and others are finding the benefits of this program are many are using the administrator directories in choosing a carpet.

In balance, carpet manufacturers have been pleased with the results of the program because they can compete on a fair and equitable basis. Concomitantly, the growth of carpet sales has continued. Consumers are also content with the program because they can determine characteristics of any carpet in the program by checking the marked number on the back with the listing in the administrator's directory. In addition, a challenge procedure and the testing of field samples has added creditability and prestige to the program.

One of the key elements, and the most expensive part for an administrator to carry out in a certification program, is approval or accreditation of testing laboratories. Generally, the following criteria are used for approving or accrediting laboratories in conjunction with a proficiency or collaborative reference program and an initial audit visit.

1. Description of the laboratory including name and address along with an organizational chart of the laboratory;

2. Declaration by the laboratory of its ability and services to be offered;

3. Possession of a laboratory operations control manual;

4. Submission of the name and qualification of responsible personnel including a record of training and an examination of competency;

5. Description and photograph of equipment including calibration, verification and maintenance records;

6. Examination of the laboratory for environmental and safety concerns;

7. Possession of sample test reports including procedures for testing and copies of all relevant standards;

8. Possession of a record of an appeals process available to users in cases of dispute.

Our programs require that the laboratories be approved only for the particular tests they are able to conduct. This follows the NVLAP concept which the Department of HUD has encouraged and supported by submitting a carpet laboratory approval program for the Department of Commerce action.

Internationally, there are several groups engaged in certification activities. The International Standards Organization (ISO) has established a technical committee (Certico TC 149) to address the concerns of certifying products on a world wide basis. This Committee has issued several documents including guides for the principles and practices of certification along with guidelines for assessing the technical competency of testing laboratories. One of the goals of Certico is to develop a universal system for the acceptance of products complying with ISO standards. This system would remove trade barriers and reduce the need for redundant testing by several countries. Presently the committee is work-in four areas: (1) Self and third party certification; (2) Quality assurance; (3) Marking; (4) Basic documents.

It is anticipated that a product for international certification will be suggested in the coming year. Along with Certico, an ad hoc committe on International Laboratory accreditation (ILAC) is developing procedures for accrediting laboratories. Their efforts currently are confined to (1) legal problems of accrediting laboratories; (2) organizing a directory of organizations accrediting laboratories; and (3) obtaining a list of terms and needs of laboratory accreditation. Finally, there is an effort by the United Nations (UN) to develop harmonization and

control rules for buildings and building products. While efforts of these organizations are long term, it appears they are progressing at a rapid rate. It is anticipated, however, that the immediate form for certifying products internationally will be bilateral memoranda of agreement letters.

Looking at the future of certification in the United States, it appears there is a need for a national policy for the certification of products. One method to initiate this effort, is to obtain an intergovernmental agency agreement on a standard criteria for the certification of products. It is very frustrating for manufacturers and consumers to determine the necessary requirements for a particular product. For example, insulating materials must comply with the requirements of HUD, DOC, CPSC, DOD, DOI, etc. What is needed is a single document that contains all of the requirements necessary for certification. It is HUD's belief that the responsibility for building products rests with HUD. This does not mean that the functions of the other agencies are usurped, but rather there should be some focal point on certification for manufacturers of building products. Equally, in the private sector, there should exist the development of a national certification committee to provide for a unified approach on the certification of products.

We believe a viable single system for certification and laboratory accreditation can be established through a quasi private sector-government endeavor that would be recognized and used nationally. Further, it would provide a base for international recognition of these programs.

APPENDIX I

PRIVATE BODIES WITH CERTIFICATION PROGRAMS

AAMA	*	Architectural Aluminum Manufacturers Association
ADL	*	Associated Dallas Laboratories
AGA		American Gas Association
AHAM		Association of Home Appliances
APA	*	American Plywood Association
ARDL	*	Akron Rubber Development Laboratory
ARI		Air-conditioning and Refrigeration Institute
ARL	*	Applied Research Laboratory
ASSE		American Society of Sanitary Engineers
AWIA	*	American Wood Inspection Agency
AWW	*	A.W. Williams Inspection
AWWI	*	American Wood Window Institute
BHMA		Builders Hardware Manufacturers Association
CLFMI		Chain Link Fence Manufacturers Institute
EPTL	*	El Paso Testing Laboratory
ETL	*	ETL Testing Laboratories
HPMA	*	Houston Chemical Service
HVI		Home Ventilating Institute
IAPMA		International Association of Plumbing & Mechnical Officials
IGCC		Insulating Glass Certification Council
ITL	*	Industrial Testing Laboratory
JPMA		Juvenile Products Manufacturers Association
MEA	*	Metallurgical Engineers of Atlanta
NAHB	*	National Association of Home Builders
NPA	*	National Particleboard Association
NSF		National Sanitation Foundation
NWMA	*	National Woodwork Manufactures Association
PFS	*	Plywood Fabricator Service
PTL	*	Pittsburgh Testing Laboratory
RIS		Redwood Inspection Service
SL	*	Skeist Laboratories
SPIB	*	Southern Pine Inspection Bureau
SW	*	Southwestern Laboratory
TCA		Tile Council of American
TECO	*	Timber Engineering Company
TPIT	*	Timber Products Inspection & Testing Services
UL		Underwriters Laboratories
UST	*	U.S. Testing
WCLI	*	West Coast Lumber Inspection Bureau
WGS	*	Williams Grademarking Services
WHL	*	Warnock Hersey
WQA		Water Quality Association
WSC		Water Systems Council
WWPA	*	Western Wood Products Association

* Registered in the HUD Building Products Certification Program

APPENDIX II

HUD BUILDING PRODUCTS CERTIFICATION PROGRAM

DEFINITION OF TERMS

Acceptance Sampling Plan - A specific plan that states the sample size (number) and the associated acceptance and rejection criteria.

Accreditation Agency - An organization that conducts and administers an accreditation system and recognized to have the competency to evaluate that testing facilities are adequate to conduct tests.

Accredited Test Facility - A test facility which has been approved by an accreditation agency.

Accreditation - A public declaration by a national agency that a testing laboratory has the qualifications necessary to perform a specific testing activity.

Administrator - Designated by the sponsor of a certification program to perform the executiv duties required to manage the affairs of that program.

Agency - An organization designated by some authority to engage in testing, inspection, and/or administering certification programs.

Applicant - The person or (organization) requesting accreditation of its certification program.

Approval - The acceptance of a testing laboratory or administrator by an approving body.

Association Test Facility - A test facility organized and operated by a trade or professiona organization and providing test services for products.

Audit - A formal verification.

Authority - The responsible person in charge of the work or the authorized representative.

Calibration - The comparison of two objects, one of which is of a known or accepted values, to determine any deviation from the one being compared.

Certification of Approval - A seal, statement of conformance, label, classifiction, directo listing, endorsement or other affirmation that a product complies with applicable standards.

Certification - The procedures by which products or services become certified.

Certification Mark - The sponsor's or validator's sign or symbol that identifies a product or service as being certified. The certification of compliance is by the producer or vendo

Certification Program - An organized system where products or services may be certified to specific standards on a uniform equitable basis.

Certified - Attested by the producer or vendor under the procedures of a certification program as satisfying the requirements of the referenced standard.

Certifier - The producer or vendor who certifies that the products or services meet the requirements of a referenced standard.

Collaborative Reference Testing - A program where a uniform material or a products of controlled characteristics, is distributed to participating laboratories. The laboratories test the materials or products and submit the test results for evaluation.

Commercial Test Facility - Provides a test service under contract or on a fee basis.

Competence - Requisite abilities including requirements such as training, experience, initiative, supervision needed and communication skills.

Compliance Assurance - The process of appraising the manufacturers quality control program in conjunction with monitoring, auditing and inspecting the product or services being offered.

Conformity Certification - The action of certifying by means of a certificate or mark that a product or service conforms to a standard.

Consensus - Substantial agreement of those concerned with the scope and provisions of a standard as judged by a recongized authority. Consensus implies more than the concept of a sample majority, but not necessarily unanimity.

Criteria - Detailed requirements for examining and evaluating a laboratory or an administrator to assure competency.

Evaluation - A formal judgment of the ability of a testing laboratory or administrator to perform satisfactorily based upon analytical data or other judgment factors.

Evaulation Team - A group of individuals recognized as competent and equipped to evaluate testing facilities or act as a referee on technical questions.

Field Inspector - A trained person capable of obtaining samples representative of production and knowledgable in the evaluation of quality control records, test methods and instrument calibration.

Independent Test Laboratory - A testing laboratory which has no orgnization tie or financial interest in the manufacture, vending or promotion of the specific product or services being tested.

Inspection - The process of measuring, examining, gaging, or comparing the product or service with the specified requirements.

Inspection Level - The relative sample size or number for a given amount of production.

Label - A sticker, nameplate, or similar printed statement appearing on a product or packaging material which provides instructive or required information.

Laboratory Accreditation - An authoritive action for evaluating test facilities and approving those judged competent to perform specific tests.

Laboratory Environment - The aggregate of all conditions, such as temperature, humidity, and lighting, that may influence the testing or performance of the product.

Laboratory Evaluation - A process of inspecting, examinining or assessing the organization to determine its capability and competence to carry out specific tests.

Laboratory Evaulation Criteria - Statements prescribing the organizational resources, the equipment and facilities, the operational procedures, and the minimum techical performance levels required of a testing laboratory for accreditation.

Laboratory Examination - The process of inspecting and obtaining information in order to judge the laboratory's capability for performing specific tests.

Licensee - The manufacturer or vendor authorized by contract to use the sponsor's or administrator's certification mark for validation purposes.

Logo - A symbol, label, hallmark or statement, authorized by sponsor or administrator indicating certification or compliance with the specified standard by the producer or vendc

Mandatory Standard - One which is established by law and the observance of which is compulsory.

Manufacturer - See Producer.

Manufacturer's Test Facility - A test facility organizationally affilated with a manufactur and providing test services on the product and services of that manufacturer.

Monitoring - The act of observing and reviewing certification programs.

Person - Any individual, consumer, organization, educational intitution corporation. societ Federal, state or local government agency.

Prerequisite Testing - Preliminary testing carried out before a formal collaborative or other testing program is carried out.

Procedural Guide - A description of the certification program containing the administrativ testing program, standard reference, and other information necessary to carry out a laboratory or administrator function.

Producer - A person or orgnization that produces, manufactures, assemblies, or packages a product or offers a service that is capable of being tested for conformance with the applicable standard.

Product - Any manufactured item, construction, material or service described by a specific standard.

Product Certification - Attesting product conformance to a referenced standard using an organized program.

Proficiency Testing - A systematic testing program where a sample is measured by a number of laboratories or a random series of samples tested to determine the accuracy of measurement.

Qualified Personnel - Competent persons adequately trained in the applicable test procedur equipment operations, and calibration methods.

Quality Assurance - A systematic approach for all actions necessary for the manufacture of a product or performance of a service to comply with a designated standard.

Quality Control A means by which a manufacturer achieves conformity to a given standard to prevent the production of defective items.

Reassessment - Repetition of the complete examination and evaluation initially required of a laboratory or an administrator seeking accreditation.

Redactory or Technical Library - A library of standards, codes and other technical information necessary for carrying out a testing procedures, and verifying that the product complies with standard.

Reference Facility - Recognized as professionally competent properly equipped and staffed to evaluate the technical content and adequacy of a test method and acts as a referee on technical questions.

Reference Material - A material, substance or device whose intrinsic properties are used for physical comparison.

Self-Certification - The certifiction of a product by a producer or vendor of the product being certified.

Sponsor - An organization under whose authority a certification program is developed, promulgated, and financed and with whose name the certification program is identified. It may also own or be in process or registering a certification mark.

Standard - A rule for course of action established by an authority, custom, or general consent. It would include a physical embodiment of a unit of measurement.

Technician - An employee assigned to perform the actual operations of a testing or isnpection program.

Testing - An evluation or a determination of a physical or performance characteristic for the purpose of establishing conformance to a standard.

Testing Agency - An organization staffed and equipped for measuring, testing, or inspecting products.

Test Data - The quantitative and qualitative information derived from testing.

Test Method - A description of the procedures, equipment, and methodology for determining if a product is in conformance wholly or partially to a standard or parts of a standard.

Testing Facility or Laboratory - A person or organization whose functions include testing, analyzing, or inspecting products or services. This also includes the physical plant required to house the test equipment and records.

Third Party Certification - The certification of a product by an organization which has no organizational tie or financial interest in the manufacture, vending, supplying or promotion of the product being certified.

Traceable to a Primary Standard A documented chain of comparisons connecting a working standard to a primary standard being maintained by some responsible organization.

User - An organization or activity which makes use of a test laboratory or an accreditation agency.

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LICENSING PROGRAMS FOR FIELD TECHNICIANS AND CONCRETE LABORATORIES IN MASSACHUSETTS

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The state-wide licensing of field concrete technicians and concrete testing laboratories has been in effect in Massachusetts since January, 1975. As of this date there are twenty licensed concrete testing laboratories and approximately 1250 licensed field concrete technicians. Prequalifying agencies were designated by the State Building Code Commission to insure a proper mechanism to license technicians and laboratories. Proven test methods, procedures, and standards were adopted, wherever possible, to give the programs credence and to ease their implementation. The need, development, operation, rules and regulations, and evaluation of the programs are set forth.

Key words: Accreditation; concrete testing laboratories; field concrete licensing; prequalifying agency; testing agency.

1. Introduction

The first known state-wide licensing programs for field concrete technicians and concrete testing laboratories were implemented in January, 1975, by the promulgation of the Massachusetts State Building Code under the jurisdiction of the State Building Code Commission as authorized by the Massachusetts legislation (Chapter 802 of the Acts of 1972).

Prior to this time there were no requirements for licensing or for accreditation of field concrete technicians or concrete testing laboratories in the Commonwealth. Also there were no uniform building code requirements throughout Massachusetts, which proved a hardship to the design and construction industry.

Since the implementation of the programs, almost five years ago, twenty concrete testing laboratories and over 1250 field concrete technicians have been licensed by the state.

2. Need for Concrete Accreditation Programs

The recommended practices of the American Concrete Institute and other nationally recognized agencies state that inspection agencies should be hired primarily on their capabilities and qualifications, and not on a cost basis. Unfortunately, this credo often gets lost in the shuffle and inspection contracts often go to the lowest bidder, who may or may not be qualified, unless there is an effective accreditation or licensing program.

The final acceptance or rejection of concrete in a structure is normally based on the strength of the concrete meeting or exceeding a specified criteria in the project specifications which is based on the compressive strength of cylindrical concrete specimens, presumably fabricated, handled, cured, tested, etc. in accordance with American Society for Testing and Materials (ASTM) standards, some twenty-eight days after the concrete is incorporated into the

structure. If the procedures of the ASTM standards are not followed (i.e., specimens are improperly fabricated, handled, cured, tested, etc.), the cylinder will normally indicate a lower strength or strength potential than concrete properly incorporated into a structure.

Low or improper strength results, in some cases caused by improper inspection or testing procedures, often causes delays in construction, load tests, lawsuits and other fallout which adds to the cost of construction and imposes economic hardships on all concerned with the project.

Other concerns over the reliability of the concrete test results as they relate to public safety and structural integrity are simultaneously brought into focus.

Based on economics and safety it is, therefore, important and essential that all field concrete technicians and concrete testing laboratories be accredited or licensed to ensure that they are qualified to perform the required tests in accordance with the applicable standards and specifications.

3. Implementation Mechanism

There is some law which recognized the impetuous not to change an unsatisfactory condition until motivated by disaster. In Massachusetts this motivating disaster was the January, 1971 collapse of a sixteen story reinforced concrete apartment structure under construction at 2000 Commonwealth Avenue in Brighton which resulted in four fatalities. The resulting press coverage and public concern lead the Massachusetts Legislative to propose legislation which would prosecute field inspectors for not performing all the tests required to prevent such an occurrence in the future.

The construction industry in general, including design professional, suppliers, and testing agencies felt that the proposed legislation was too vague, took a negative approach to the situation, and would have established an unneeded commission, which is the apparent legislative procedure for dealing with a crisis. The Massachusetts Construction Industry Board (MCIB, incorporated as The Massacusetts Concrete Industry Board before broadening its scope) was formed to speak for the industry. The State Building Code Commission, MCIB, and other concerned agencies and individuals proved successful in preventing the passage of these bills based on their commitment to provide positive action in state-wide programs.

The field concrete technician and concrete testing laboratory licensing programs were adopted or developed by the Commission as a result, based on the developmental work of MCIB and assistance of the National Bureau of Standards (Contract No. 5-35-776) [1] Code.

4. Development

The provisions of the licensing programs were based on nationally recognized standards, practices, and procedures, wherever possible, to provide efficient and reliable programs, free of specialized encumberances and related specialized costs.

Key to the programs was the establishment of a prequalifying agency, recognition of established testing agencies to examine and evaluate applicants, and the adoption of the testing agencies proven testing programs.

4.1 Concrete Testing Laboratories

The Commission designated the Cement and Concrete Reference Laboratory (CCRL) as the prime testing agency to examine and evaluate laboratories desiring to be licensed.

The designation of the nationally recognized CCRL lent credence to the program. No new agency or new testing procedures had to be established. Periodic reevaluation, contained in the program, was made to conform to the normal CCRL inspection tour cycle.

The New England Division, Corps of Engineers, also has been designated as a testing agency to perform timely examination and evaluation as required between CCRL's normal inspection tours. Due to the nature of their work and reputation, there is no conflict of interest. Their performance and fees are compatible with CCRL.

The Construction Materials Safety Board (CMSB) was established by the Commission to act as the prequalifying agency to examine, or cause to be examined, the testing agency examination and evaluation, and to make its recommendation to the Commission for appropriate action.

CMSB also reviews application for materials, devices, products and methods of construction not included in the State

Building Code. It is made up of nine members consisting of representatives of the Commission, engineering, architecture, testing laboratories, construction, and university faculty. The CMSB performs its services voluntarily. It generally meets one-half day per month. Administrative and secretarial duties are performed by Commission staff.

The Laboratory Accreditation Sub-Committee was formed by CMSB to act on its behalf to perform the detailed evaluation of the testing agency's report and subsequent examination and evaluation of the laboratory's affidavits, where applicable, certifying correction of deficiencies cited in the testing agency's report. In some instances the Sub-Committee requires additional proof of deficiency correction prior to making its recommendation to CMBS.

The Laboratory Accreditation Sub-Committee is made up of five members consisting of representatives of a federal laboratory, state laboratory, private laboratory, material supplier and Commission Staff. The makeup of this Sub-Committee provides expertise required for evaluation. The Sub-Committee performs its services voluntarily. It generally meets one-half day per month. Administrative and secretarial duties are performed by the Commission staff.

4.2 Field Concrete Technicians

The Commission designated MCIB as the testing agency to examine and evaluate all persons desiring to be licensed as concrete field technicians. MCIB submits all examination results and evaluations to the prequalifying agency for their action.

MCIB was incorporated in 1973 to foster the development of quality construction and to promote and support high standards of quality. Its membership includes individuals, firms and organizations concerned with construction, design, teaching, testing, and production.

MCIB developed an accreditation program [2] for field concrete technicians as part of its commitment to public safety and the legislature. Previous work of the National Ready Mixed Concrete Association was beneficial. MCIB began its examination and accreditation of field concrete technicians in the summer of 1973.

MCIB established a certification committee to be responsible for the examination and evaluation and its reliability. No new agency had to be established and the Commission adopted a proven working program.

CMSB was established as the prequalifying agency to examine the evaluation of the testing agency. The Commission staff normally acts in its behalf in the field of concrete technicians programs.

5. Operation of the programs

The mechanism for the operation of the licensing programs is relatively efficient.

5.1 Concrete Testing Laboratory

1. The laboratory makes application to the Commission staff.

2a. The laboratory requests testing agency (CCRL or New England Division, Corps of Engineers) examination through Commission staff which sometimes directs the laboratories to the testing agency directly.

2b. The results of the testing agencies examination are forwarded to the prequalifying agency (the Laboratory Accreditation Sub-Committee of CMSB) through the Commission staff within ten days of receipt by the laboratory.

2c. Any laboratory deficiencies cited in the testing agency's report are to be corrected within two months and the prequalifying agency shall be so notified by affidavit submitted through the Commission staff.

2d. The prequalifying agency normally meets within the month to approve results and/or corrections to any deficiencies so cited, requests for more information, or recommends denial based on the results and lack of sufficient information received.

3a. The laboratory sends the prequalifying agency a notarized statement that key positions are filled by qualified personnel along with their resume, through the Commission staff. The key positions are the director of testing services, supervising laboratory technician, and supervisory field technician. One person may fill more than one position if qualified.

3b. The prequalifying agency approves the personnel criteria, requests more information, or recommends denial based on the information submitted.

4. The laboratory sends in the licensing fee (of one hundred dollars per

year) to the Commission staff.

5. Upon completion of the prequalifying agency's examination, and receipt of the licensing fee, action is taken by the Commission on the issuance of the concrete testing laboratory license.

6. The licenses require renewal annually. The laboratory shall send the prequalifying agency (a) an affidavit that the compression testing machines have been calibrated and verified with equipment traceable to the National Bureau of Standards. (b) A notarized renewal form indicating key personnel along with updated resumes. (c) The licensing fee.

7. The prequalifying agency and Commission take appropriate action on the license renewal.

8. The laboratory shall notify the Commission within seven days of any vacancy of any key position and take appropriate action to obtain approval of a person to fill that position.

5.2 Field Concrete Technician

1. The person requests an application form from the Commission staff.

2. The person makes application for examination by the testing agency (MCIB), and includes the examination fee (currently thirty-five dollars).

3. The MCIB Certification Committee notifies the applicant of the next field concrete technician examination. (Special mini-examinations can be held in case of determined hardship).

4. The Certification Committee arranges for the concrete, place of tests, equipment, and jurors.

5. The applicant performs physical tests on items b through f and demonstrates knowledge of items a and g.

a. ASTM C172: Sampling Fresh Concrete.

b. ASTM C143: Test for Slump.

c. ASTM C31: Making and Curing Test Specimens in the Field.

d. ASTM C231: Test for Air Content - Pressure Method.

e. ASTM C173: Test for Air Content - Volumetric Method.

f. ASTM C138: Test for Weight per Cubic Foot (Density).

g. ASTM C192: Storage and Transportation of Test Cylinders.

6a. The applicant fails the examination if he has failed two of the performance tests, b through f above.

6b. The applicant is given a "partial" if he fails one of the performance tests and must take a retest on that performance test, in order to pass.

7. Three jurors independently grade the applicant as to pass or fail on each test. The jurors are accredited field concrete technicians and normally represent three different disciplines to provide knowledgeable and unbiased results. The jury system is the backbone for the reliability of the program.

8. At least two members of the Certification Committee are present at the examination to independently evaluate the applicant as to passing or failing. If the Committee is not in concurrence with the pass or failure of the candidate, the jurors are consulted which normally results in resolution of the situation. If the situation cannot be resolved it is forwarded to the Board of Trustees of MCIB for their action.

9. At least two members of the Board of Trustees of MCIB, being elected officials of that Board, review the examination results for final evaluation and forward the results to the prequalifying agency. MCIB also notified the applicant of MCIB accreditation or failure.

10. The accredited applicant sends in a picture with his application form and licensing fee (currently twenty dollars for two years) to the Commission staff.

11. The Commission staff normally acts on behalf of the prequalifying agency (CMSB) and forwards the results to the Executive Director of the Commission.

12. The Executive Director issues the licenses for those who qualify upon approval by the Commission.

13. Renewals are issued bi-annually by the Executive Director upon receipt of the

renewal licensing fee (currently twenty dollars).

14. Concrete Field Technicians working for government agencies are exempted from license fees.

6. Rules and Regulations

The Commission publishes "Rules and Regulations for the Licensing of Concrete Testing Laboratories" [3] and "Rules and Regulations for Concrete Testing Personnel" [4] which should be referenced for details. Many of the requirements contained therein have already been addressed. Other highlights of these regulations are presented.

6.1 Concrete Testing Laboratories

1. All laboratories including branch and project laboratories engaged in the testing of concrete for use in structures subject to construction control by the State Building Code shall be licensed. Structures not subject to control by the Third (Latest) edition of the code are:

1. Any building containing less than thirty-five thousand (35,000) cubic feet of space;

2. Any single or two family house or any accessory building thereto;

3. Any building used for farm purposes; and

4. Retaining walls less than ten (10) feet in height.

2. Except as modified by the rules and regulations, all concrete testing laboratories shall conform to designated provisions of "Inspection on Testing Agencies for Concrete, Steel and Bituminous Materials as Used in Construction," ASTM E329-72.

The personnel qualification requirements are broken down into the three categories established by ASTM E329-72, that of director of testing services, supervising laboratory technician, and supervising field technician. One person who is qualified may fill more than one position. The ASTM E329-72 criteria have been broadened for the director to recognize practical expertise as follows:

The testing services of each laboratory (main, branch or project) shall be under the direction of a Director of Testing Services who shall be a full-time resident employee of that laboratory and shall be qualified in accordance with any one (1) of the following three (3) sets of requirements:

a) He shall be a Professional Engineer, registered in the Commonwealth of Massachusetts with at least five (5) years of experience in responsible charges of work related to Structural Engineering, Construction Engineering or Construction Materials Testing. He shall be subject to demonstrate his ability to interpret the results of tests of concrete and concrete aggregates as stated in ASTM E329-72; or,

b) He shall have a Bachelor's Degree in Engineering from an accredited institution and an additional total of three (3) years experience performing tests on concrete and concrete materials which shall include two (2) years as a laboratory technician or supervisor. He shall be subject to demonstrate his ability to interpret the results of tests of concrete and concrete aggregates as stated in ASTM E329-72; or,

c) He shall have at least eight (8) years experience including five (5) years experience as a laboratory technician or supervisor and shall be subject to demonstrate his ability to interpret the results of tests of concrete and concrete aggregates as stated in ASTM E329-72.

4. On structures subject to construction control, affidavits must be submitted with the building permit application to show that the laboratory is licensed.

5. Provisions are provided for penalties and revocation of licenses for false report or cause.

6. Any aggrieved laboratory has the right to appeal to the State Building Code Appeals Board in lieu or prior to any court action.

6.2 Field Concrete Technician

1. All field concrete technicians engaged in the testing and/or inspection of concrete in structures subject to construction control (See 6.1 item 1) shall be licensed.

2. Provisions are made for revocation of license for non-compliance with the rule and regulations, Code, or standards of good practice.

3. Any aggrieved person has the right to appeal to the State Building Code Appeals Board.

7. Evaluation of the Field Concrete Technician and Concrete Testing Laboratory Programs.

This evaluation is conducted on the eve of five years of operation of the field concrete technician and concrete testing laboratory programs.

7.1 Positive Aspects

1. Parties of firms involved with or licensed by the program believe in its merits and it has received the overall support of the industry.

2. The operational mechanism and rules and regulations have had only minor modifications during the five-year period. This indicates good development and implementation of the programs.

3. No complaints have been received on the caliber and performance of agencies (CCRL: New England Division, Corps of Engineers; or MCIB) or the prequalifying agency (CMSB). Their results are evaluated as reliable and above reproach.

4. Several complaints have been received by MCIB on the evaluation of the field concrete examination by applicants. All except one were withdrawn upon showing the applicants the grading on the jurors data sheet. In the one exception, the Board of Trustees of MCIB voted to overrule the findings and the jurors committee's recommendations. In this case it appears that the applicant was arrogant and may have invited harsh critique in some judgmental areas by the jurors. It was also alleged that one juror was not present during part of one test and relied on another juror for his grading. The aggrieved applicant was able to convince the Board, a juror, and a Certification Committee member of his thorough knowledge and ability to perform the tests during this hearing, which is what it is all about.

5. The use of the appeals provision to appear before the State Building Code Board of Appeals has not been used and no litigation has been entered against any portion of the programs. This indicates no major grievances.

6. The modifications of the ASTM E329-72 of the personnel qualifications for director of testing services has allowed several experienced and capable persons to continue to act in or move into this capacity. This would not have been possible under that standard as written.

7. A better appreciation of the performance criteria and test limitations has been realized. Many take the examination, pass the technician examination and are accredited by MCIB for educational or other appreciative reasons. Many accredited technicians live outside of and do not practice in Massachusetts. Many accredited technicians are in related industry and not testing.

8. Experienced and practicing technicians had a failure rate of one-third on the examinations held during the implementation of the program. This leads to the supposition that at least one-third of the field tests were performed improperly prior to the program and indicates its need and benefit.

7.2 Areas of Concern

1. The major area of concern has always been that of monitoring and enforcing the programs.

Project affidavits are required to be submitted with the building permit application to indicate that technicians and laboratories are licensed on structures subject to construction control. This places the responsibility of providing required services on the person who signs the affidavit subject to persecution if the terms of the affidavit are not carried out. The responsibility of ensuring that the project affidavit and its intent are carried out primarily rests with the local municipal building official and/or the state inspector who reviews the application and issues a building permit. Building officials and their staff are not always cognizant of all details of the Code let alone ancillary rules and regulations. In many instances they do not have the time or staff to effectively monitor all phases of all the construction projects in their jurisdiction. One municipal building official did shut down a project on which an unlicensed technician was performing as a licensed field concrete technician. This project was shut down for approximately twenty four hours until a licensed technician was present at the site.

The program further relies on the voluntary self-policing action of the industry as a whole. Suppliers and contractors should want to see qualified technicians

and laboratories on the project so as not to have the tests indicate lower potential of concrete strength than that incorporated into the structure. Other licensed laboratories and technicians should want to see only qualified personnel and firms active to enhance their chances at obtaining work and also enhance the professionalism of their field. Sometimes it proves difficult to volunteer.

Rumors have been heard of violations:

a. Licensed laboratories have sent out unlicensed technicians to projects when licensed technicians are not available, in order to cope with the variable work loads typical to the testing industry.

b. Field equipment has been used that is not in satisfactory condition to pass CCRL inspection, and which may not provide reliable results within designated accuracies, during heavier than normal work activity.

c. Licensed technicians do not always conform to the recommended testing standard provisions or to project specifications. The going technician pay scale (currently averaging in the range of four to five dollars per hour) may not always invite dedicated personnel.

d. The morale and professionalism of the licensed technicians is not as high as it was during the early stages of accreditation and licensing.

e. One laboratory does not have a full-time director of testing services.

Rumors are difficult to investigate. Formal written complaints have been the designated mechanism to initiate investigation. Only a few formal written complaints have been received and these were rated invalid based on investigation by state inspector of the Department of Public Safety.

More attention to monitoring and enforcement of the programs by local and state inspection agencies is required to alleviate concern over rumors and to take action on any proven violations.

2. The staff of the Commission has been honestly criticized in not taking timely action on applications and other matters, this is especially true during times of code rewrite and specialized projects. This is not the fault of the program but one of work loads and/or administration. Sufficient time and staffing should be allotted to the program in order to readily process the administration and secretarial work on a weekly basis.

3. No training program is part of the field concrete technician licensing program. Some applicants cannot find a satisfactory way to prepare for the performance examination. Several firms provide training services (for a fee on the order of fifty dollars). Some do a good job but others do not allow enough time to sufficiently train the applicant, which can cause an economic hardship (around eighty five dollars) on the applicant without the desired results. The MCIB Certification Committee is taking this matter under advisement.

4. Not all of the Massachusetts State Agency Testing laboratories participate in the program. The proficient agencies, the Metropolitan District Commission, the Massachusetts Bay Transportation Authority, and the Mass Port Authority do participate. Notable in its absence is the Department of Public Works.

5. High competition for work, amongst the laboratories, reportedly leads to economic magic, by some, in order to break even on some projects or to survive. The programs to date do not appear to have fully alleviated the cost shopping practice.

7.3 Cost of the Program on the Technician and Laboratory

1. The field concrete technician must pay thirty five dollars to be examined and twenty dollars bi-annually for licensing. This is considered reasonable.

2. The only cost incurred by the concrete testing laboratories for the program is the one-hundred dollar annual licensing fee. The one-thousand dollars for the bi-annual to tri-annual CCRL inspection and the approximate two-hundred dollar fee for annual compression testing machine calibration are considered as normal operating overhead for proficient laboratories.

7.4 The Cost to Administre the Program

The cost to the Commonwealth to administer the program is minimal. The economical administration of this program rests with the self-sufficiency of the testing agencies and the voluntary services of the prequalifying agency.

7.4.1 Concrete Testing Laboratory

1. CCRL, the designated testing agency, derives its own funds to operate its function.

2. The Concrete Sub-Committee of CMSB, the prequalifying agency, volunteers an average of two man-days per month for its half day monthly meetings.

3. The Commission staff averages three to four man-days per month to administer the program. The time spent is higher during CCRL inspections and annual renewals but tends to be less during other periods.

7.4.2 Field Concrete Technician

1. MCIB, the designated testing agency, derives its own funds to operate its function by the thirty five dollar examination fee, which was established on a break-even basis. The normal cost of these examinations is in the order of two-thousand dollars to process around thirty candidates. The concrete and examination facilities are normally donated. The biggest expenditure is for a fifty dollar honorarium to each juror. Other expenditures include coffee, lunch, and administration costs.

2. The Commission staff acting for CMSB, the prequalifying agency, averages three to four man-days per month to administer the program.

7.5 Summary

The programs have provided sense of pride and professionalism amont the technicians, better appreciation of the tests, and more reliable results. They have been universally accepted within Massachusetts, and other states have developed programs based on them. They have proven efficient and economical to administer.

Uniform criteria has been established throughout the State. The programs are worthwhile and have been proven successful, but require more vigilant monitoring and enforcement to sustain or improve upon their rated merits. Other planned programs are just as essential.

8. Other Related Programs

The implementation of the field concrete technician and concrete testing laboratory programs are a couple of positive steps in ensuring quality concrete construction. Other programs should be considered to ensure qualified personnel are on the project to oversee proper incorporation of the concrete and related materials into the structure to realize construction and specified results. Other programs under consideration in Massachusetts are:

Plant Concrete Technician
Field Concrete Inspection
Laboratory Concrete Technician
Construction Supervisors

The programs are currently being deferred in favor of other projects and budgetary considerations. It is hoped that these programs can be developed and implemented without the need for a disaster triggering mechanism.

9.0 Acknowledgements

To those who have forwarded these programs, with no personal recognition or economic reward, for the privilege of sharing in the effort to improve quality standards in construction.

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THE CRIME LABORATORY ACCREDITATION PROGRAM OF THE AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS (ASCLD)

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The American Society of Crime Laboratory Directors (ASCLD) has formulated a crime laboratory accreditation program with the following objectives: 1) to improve the quality of laboratory services provided to the criminal justice system, 2) to offer to the general public and to users of laboratory services a means of identifying throughout the nation those laboratory facilities which satisfy accreditation criteria, 3) to develop and maintain criteria which can be used by a laboratory to assess its level of performance and strengthen its operation, and 4) to provide an independent, impartial and objective system by which laboratory facilities can benefit from a total organizational review.

A significant part of the program is the Standards Manual, which identifies the principles and standards, discusses them and lists evaluation criteria for each of the following areas: 1) laboratory management and operation, 2) personnel qualifications, 3) procedures and instruments/equipment, and 4) physical plant and security.

A pilot program is currently under way to test the on-site evaluation aspect of the accreditation program. Four crime laboratories of varying size, geographic location, and organizational placement have volunteered to serve as "test sites" for this phase of the program

Key words: Accreditation; American Society of Crime Laboratory Directors (ASCLD); certification; management; on-site visit; personnel qualifications; physical evidence; proficiency testing; standards.

1. Introduction

The National Advisory Commission on Criminal Justice Standards and Goals made the following recommendation in 1973 in the volume titled POLICE [1][1]:

"(Recommendation 12.1, Certification of Crime Laboratories)

"It is recommended that a national program be established to insure that all tests and analyses performed by state, regional, or local laboratory facilities are procedurally sound and scientifically valid. The program should provide for the certification (sic) of those facilities whose testing procedures and scientific analyses meet the minimum standards set by the agency administering the program.

"1. An existing national agency or organization should be designated to administer the program. This body should develop minimum standards by which it can measure every crime laboratory's level of proficiency.

"2. The national agency or organization should conduct periodic evaluations of every state, regional, and local laboratory to determine its level of proficiency in performing laboratory tests. In conducting the evaluation, it should rate the laboratory only on the basis of those tests which it actually performs in rendering services.

"3. The national agency or organization should, on the basis of the evaluation, certify every laboratory that meets or exceeds the designated minimum standards in all the tests which it performs."

The results of a LEAA-funded proficiency testing research program added objective substantiation to the intuitive feeling of many practitioners that some forensic science laboratories, for varying reasons, were not performing all physical evidence examinations at a level consistent with the state-of-the-art in the criminalistics profession [2]. One general finding of the report was that "a wide range of proficiency levels among the participating laboratories exists, and in general, there are several evidence types with which the laboratories are having serious difficulties."

[1]Figures in brackets indicate the literature references at the end of the paper.

1.1 Definition

The National Advisory Commission on Criminal Justice Standards and Goals, as previously noted, used the term "certification" in reference to the process by which a facility, in this instance a crime laboratory, is evaluated to determine whether or not it meets minimum standards of performance. Clearly, the proper term is "accreditation", defined as: "....a procedure by which a non-government agency determines that a program of study or an institution meets prescribed standards. The institution may, for example, be a college, a university, or a hospital." [3]

2. The ASCLD Crime Laboratory Accreditation Program

The American Society of Crime Laboratory Directors (ASCLD) was organized in 1973. One of its principal objectives is to promote, encourage and maintain the highest standards of practice in the field of crime laboratory services. The Committee on Laboratory Standards and Evaluation has progressed toward that goal by developing a Standards Manual and by working to establish an accreditation program that will be financially self-supporting and, consistent with the definition of accreditation, be peer administered.

The ASCLD accreditation program is totally neither product oriented nor discipline oriented. The crime laboratory's "products" that are tested (specifically, they are identified, sometimes quantitated and often compared) include an almost infinite variety of items that potentially may become physical evidence in a criminal, or civil, investigation and trial. Most commonly, the items tested include firearms, documents, bloodstains, seminal stains, drugs, poisons, hairs, fibers, paint, glass, flammables, explosives, and soils. Less common, but by no means unusual, are metals, vegetation, paper, wood, plastics and saliva.

The term "discipline", as applied to a crime laboratory, is not clearly defined. Within the criminalistics profession, it is consistently applied to sub-specialties that are actually groupings of physical evidence types. For example, personnel certification efforts now in progress have defined the four sub-specialties, or "disciplines", of firearms and toolmark examination, serology, drug (controlled substance) identification, and "trace evidence" (hair, fiber, glass, paint, soil, etc.)

ASCLD is using neither the relatively narrow product-focused approach that determines only a crime laboratory's capability to test a specific item of physical evidence (e.g., a bloodstain) to some specified standard using a definitive test method, nor the equally restrictive discipline-focused approach used by the National Association of Testing Laboratories in Australia (such as chemical testing or instrumental analysis). Rather, it has selected a broad accreditation program that identifies principles and standards for each of the following four areas of a crime laboratory's operation: 1) laboratory management and operations, 2) personnel qualifications, 3) procedures and instruments/equipment, and 4) physical plant and security.

2.1 Laboratory Management and Operations

The Laboratory Management and Operations section of the Standards Manual covers the managerial functions of planning, organizing, directing and controlling. The planning function, for example, is defined as the analysis of relevant information from the present and the past and an assessment of probable future developments so that a course of action (plan) may be determined that enables the organization to meet its stated objectives. The objectives are then outlined in terms of principles and standards, followed by a brief discussion and by the listing of evaluation criteria. The latter are intended for use by the laboratory for self-assessment and/or by the site evaluation team during its visit. The criteria are 1) does the laboratory have a stated list of objectives? 2) have the objectives been communicated to all employees? and 3) do the objectives appear relevant to the needs of the community serviced by the laboratory?

The functions of organizing, directing and controlling are handled in the same manner; i.e., with a statement of the principle(s) involved, an enumeration of the standards as they apply to the particular function or sub-function, a brief discussion of each standard, and a listing of the evaluation criteria for each function or sub-function.

2.2 Personnel Qualifications

The qualifications of both the professional, and, to a limited extent, the support personnel within a crime laboratory, are considered and judged "in context" with the situation in which the individual works. Most important, therefore, is the existence in the laboratory of a system such that "reliability is assured with respect to procedures, equipment, processing and interpretation of results and that the examinations are as complete as adequate laboratory equipment permits and the case situation warrants." If, for example, in a particular type of examination there is close supervision by a qualified forensic scientist, the need for a highly qualified person doing the work is reduced, assuming that court requirements are satisfied.

Qualifications are considered in the ASCLD program for personnel in the following categories: 1) management, 2) controlled substances identification, 3) toxicology, 4) trace evidence examinations, 5) serology, 6) firearms/toolmark examination, 7) document examination, 8) latent fingerprint examination, and 9) non-testifying support personnel. Using serology to illustrate the principles and standards as stated, the former require that the forensic serologist should have knowledge of basic biological sciences sufficient to understand the basis of forensic serological tests and sufficient knowledge of chemistry to prepare test specimens and solutions and to understand the mechanisms involved in the testing procedures. In addition it is recommended that the forensic serologist have adequate knowledge of the statistics (population frequencies of blood groups) in the discipline and have sufficient mastery of the techniques and procedures so as to be able to produce reliable results. The standards are stated as follows: "1) The forensic serologist should have completed the science requirements for a baccalaureate degree in a natural science or in criminalistics, 2) The forensic serologist should have education and experience/training commensurate with the analyses and testimony provided, 3) Those persons conducting serological examinations should have successfully completed an extensive series of proficiency tests, and 4) It is

recommended that those persons conducting serological investigations meet the qualifications of an appropriate peer group certification board, if and when such a board is formulated. (Crime Laboratory Accreditation Program - rev. 5-15-79.)

Standards No. 3 and No. 4, in regard to proficiency testing and certification, are restated for every one of the personnel categories. Because certification is a voluntary effort, however, there is a statement in the introductory part of the personnel qualifications section to the effect that absence of certification of an individual does not necessarily imply that the person is unqualified.

2.3 Procedures and Instruments/Equipment

The thrust of this aspect of the ASCLD program is stated simply. Are the procedures and instruments/equipment used by the laboratory either generally accepted in the field, or supported by adequate scientific data, and are materials necessary to conduct these analyses and/or examinations available? Thus, the criteria for evaluation require that a crime laboratory use scientifically acceptable procedures and prescribed controls and standards, together with instruments and equipment that are adequate in specifications, checked for calibration and maintained in good working order.

Unlike testing laboratories, crime laboratories do not generally have, nor are required to use, "standard", "accepted" or "recommended" methods. Criminalistics is a relatively new discipline and is comprised of many identifiable forensic science subspecialties such as serology, firearms identification and questioned documents identification. Also, methods and procedures are to some degree dependent on the requirements of the laws and regulations of the jurisdiction(s) served by the crime laboratory, and criminalists are concerned that courts may discredit a scientific examination, however valid, if it were not carried out by a "standard" method. Finally, many criminalistic examinations, whether an identification of an unknown or the comparison of two or more items to determine common origin, are so dependent on varying quantities of the physical evidence available, or so affected by the possibility of contamination, that standardization of the procedure, method or test is difficult.

The Forensic Sciences Foundation is currently carrying out a LEAA-supported project entitled "Criminalistics Methods of Analysis Feasibility Study". Its purpose is to develop and test a mechanism for determining the acceptability of alternative scientific methods. Should a workable mechanism be developed, perhaps one that would include a compendium of acceptable scientific methods, the procedures section of the ASCLD accreditation program could benefit from it. It should be emphasized again, however, that the procedures or methods used by the crime laboratory are but one aspect of the accreditation program; management practices, personnel qualifications, physical plant, and evidence security are equally important.

2.4 Physical Plant and Security

Space considerations, design considerations, security and personnel safety are the elements of this fourth section of the accreditation program. Adequate and proper space, including bench areas, storage areas, and clerical and other support space is an obvious necessity for efficient operation of any laboratory. It lowers the risk of mishandling or contaminating physical evidence and keeps personnel morale at a level conducive to high productivity. Proper design of the crime laboratory also facilitates its operation. For example, inadequacy or misplacement of utilities can hinder or even prevent certain instruments from functioning properly.

The need for physical evidence security and integrity sets a forensic science laboratory apart from other types of laboratories. It is, in fact, a serious enough element within the accreditation process that failure to meet the standards for "chain of evidence" or integrity of evidence would undoubtedly cause a crime laboratory to fail.

To ensure that laboratory personnel work in a safe environment, standards for safety equipment, for the handling of carcinogenic/toxic/dangerous materials, and safety procedures and rules must be established and adhered to.

3. Pilot Program for On-Site Evaluation of Crime Laboratories

After final review of the Crime Laboratory Accreditation Program by the ASCLD Board of Directors, a pilot on-site evaluation test was designed and completed. Four laboratories of varying size (from four to more than forty professional personnel), differing geographic location, and organization placement ranging from local to regional to state, volunteered to serve as "test sites". The site evaluation teams consisted of four (at one site, three) crime laboratory directors. The make-up of the teams varied only slightly; many of the team members participated in more than one site evaluation as either part of the inspection team or as a "host" laboratory.

The report of the on-site evaluation sub-committee has not been completed. Tentative conclusions suggest that many of the evaluation criteria must be re-written in a form that is more objective and more readily capable of measurement. The on-site visit protocol must be standardized in terms of procedure, the time spent on each section of the evaluation criteria, and the training of the on-site visit team members. A comprehensive and well-planned on-site visit is an absolute necessity in a meaningful laboratory accreditation program.

4. Implementation of the ASCLD Accreditation Program

Acceptance of the Standards Manual, as distributed, by the membership of the American Society of Crime Laboratory Directors at its October, 1979 meeting will signal the Laboratory Evaluation and Standards Committee to request approval to prepare a proposal for implementation of an accreditation program. To be considered and developed, then, would be such factors as 1) the composition and bylaws of the Laboratory Accreditation Board, 2) the length of accreditation period(s), 3) the method of application for accreditation, including the types of supporting documents that should be submitted prior to the on-site visit, 4) the procedure for on-site visits, 5) re-accreditation, 6) a "scoring" system, pass/fail or otherwise, and 7) financial support of the program.

5. Summary and Objectives of Accreditation

Accreditation of a forensic science laboratory involves the assessment of a number of factors, including the management of the laboratory, the general overall competency of the staff, suitability of the working environment and the evaluation of the procedures used in the course of its operation. A fundamentally sound and objective accreditation program will benefit the criminal justice system, specifically the users of crime laboratory services, by 1) improving the quality of laboratory services provided by the criminal justice system, 2) offering to the general public and to users of laboratory services a means of identifying those laboratory facilities which satisfy accreditation criteria, 3) developing and maintaining criteria which can be used by a laboratory to assess its level of performance and strengthen its operation, and 4) providing an independent, impartial and objective system by which laboratory facilities can benefit from a total organizational review.

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CERTIFIED LABORATORY PERFORMANCE EVALUATION

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The USDA-FSQS-Science Certified Laboratory Program commenced in late 1962 in response to the meat food industry for more rapid analytical results on official samples. Initially, non-government Chemistry laboratories that requested certification and that met our requirements were certified for moisture, protein, and salt determinations. In 1969, with the advent of the cooked sausage regulations, the Certified Laboratory Program was extended to cover fat determinations in addition to the previously mentioned determinations.

Presently, the Certified Laboratory performance evaluation is an ongoing program. Analytical results are compared between the Certified Laboratories and the USDA Laboratories. These analyses are monitored using computer generated reports. Each USDA Certified Laboratory Reviewer is responsible for verifying these reports for accuracy and following up on unacceptable analytical variations. In addition, the Certified Laboratory Reviewer makes an unannounced on-site review of each Certified Laboratory per year. Review reports contain information regarding all aspects of the Certified Laboratory's analytical operation and include recommendations for necessary corrective action including decertification if necessary.

Key words: Accuracy and precision of the checking authority; laboratory procedures; reliability of the sample collection; tools for laboratory evaluation.

1. Introduction

Certified Laboratory Performance evaluation is a multiphase operation. In order to provide a fair evaluation of a laboratory's ongoing performance a procedure had to be devised to consider three main points:

1. Accuracy and precision of the checking authority
2. The reliability of the sample collector
3. The actual laboratory procedures both administrative and analytical

To ignore any one of these points would result in a loss of integrity of the overall laboratory evaluation program.

2. Accuracy And Precision Of The Checking Authority

The continued accuracy of the USDA-FSQS-Science Laboratories is monitored with known check samples and blind check samples. In addition, the Laboratory Quality Control Officer maintains laboratory control charts and requires that each analyst maintain his own quality control charts. These charts are regularly reviewed by the laboratory Quality Control Officer to determine that work is maintained to established performance standards.

Certified Laboratory evaluation begins with the sample collector who selects the split samples used to check the certified laboratory's continued analytical capability. Proper training of the sample collector includes sample selection, preparation, handling, labeling and mailing procedures. Improperly prepared samples may introduce sample variability, exceeding analytical variability, yielding analytical results whose variability could not be blamed on the laboratory. We cannot realistically measure analytical variability under these conditions.

3. Laboratory Procedures

Laboratory Quality Control is stressed at all times, and includes a careful critical points evaluation of sample receipt, record keeping, sample preparation, in-laboratory sample tracking, analutical procedures, calculations, and reporting of results. Standard solutions and laboratory equipment are to be regularly checked and records of such checks are to be recorded in detail in the Laboratory Standards Book. We require the laboratory to determine sample acceptability upon sample receipt. Sample acceptability includes sample integrity, proper identification, and sufficient amount of sample for the requested analysis. Complete sample information must be kept in a sample record book.

4. Tools For Laboratory Evaluation

The primary tool for ongoing laboratory performance evaluation is the companion sample computer program. Companion samples are split samples analyzed by both the Certified and the assigned USDA-FSQS Laboratories. Companion sample results are stored by computer operation for each laboratory. This processed data provides a profile of the continuing laboratory performance.

To keep data errors to a minimum, each Certified Laboratory Reviewer is provided with a copy of the weekly summary of newly matched data (between the Certified Laboratory and the USDA-FSQS-Science Laboratory). The computer highlighted data that exceeds the accepted limits of analytical variation is rechecked to determine the accuracy of the USDA-FSQS-Science Laboratory or Certified Laboratory data as well as correctness of data entered into the data base. In addition, the Certified Laboratory Reviewer contacts the Certified Laboratory to discuss the possibility of analytical problems occurring when the computer report shows a bias developing.

The Certified Laboratory Reviewer makes an annual unannounced on-site review of each Certified Laboratory and of the Inspectors who utilize the Certified Laboratory. Review reports contain information regarding all aspects of the Certified Laboratory's analytical and administrative operation and provide recommendations for necessary corrective actions including possible decertification.

The Certified Laboratory coordinator maintains an overall laboratory performance file showing original certification results, ongoing laboratory performance, review reports, computer generated data reports, and any correspondence regarding recommendations for corrective action.

5. Summary

By constantly pursuing any area where errors may occur, by continuously monitoring the check samples from the Certified Laboratory and finally by maintaining a good Certified Laboratory Review Program, a good measure of laboratory performance can be achieved.

SESSION VII

INTERNATIONAL COORDINATION

CHAIRMAN: HOWARD I. FORMAN
U.S. DEPARTMENT OF COMMERCE

National Bureau of Standards Special Publication 591, Proceedings of the National Conference on Testing Laboratory Performance: Evaluation and Accreditation, held at NBS, Gaithersburg, MD, September 25-26, 1979. Issued August 1980

PROPOSED U.S. POSITION PAPER FOR THE THIRD INTERNATIONAL CONFERENCE ON RECOGNITION OF NATIONAL PROGRAMS FOR ACCREDITING TESTING LABORATORIES (ILAC) SYDNEY, AUSTRALIA, OCTOBER 22-26, 1979

OFFICE OF PRODUCT STANDARDS
U.S. DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20230

The Third International Conference on Recognition of National Programs for Accrediting Testing Laboratories (ILAC/79) will be held in Sydney, Australia, October 22-26, 1979. ILAC is an informal assemblage of nations and international organizations whose objective is to examine ways in which accredited laboratories in each country could be internationally recognized. The primary work of ILAC/79 was performed by three Task Forces which have -- (1) analyzed legal problems raised by the recognition of nationally recognized laboratory accreditation systems; (2) drafted an international directory of organizations which operate accreditation systems; and (3) developed a description of the needs, objectives, and effects and consequences of laboratory accreditation and prepared a list of basic terms and definitions. The Task Force reports are summarized in this position paper; proposed U.S. positions with respect to these Task Force reports are also included. The preconference briefing is being held as part of this national conference to inform all interested parties about the content of ILAC/79 deliberations and to receive comments and suggestions from the participants with respect to the position the U.S. should take at ILAC/79.

Key Words: Definitions; directory of accreditation systems; international; laboratory accreditation; legal constraints.

1. Introduction

The first International Laboratory Accreditation Conference (ILAC/77), held in Copenhagen in October 1977, designated task forces to explore relations with ISO, to study legal problems associated with accreditation, and to consider the preparation of an international registry of accrediting organizations. The second Conference (ILAC/78), held in Washington in October 1978, established Task Forces A, B, and C to continue and extend the work of the original task forces (i.e., Task Forces 1, 2, and 3), and to report on that work at the third Conference (ILAC/79) to be held in Sydney, Australia, in October 1979.

Task Force A was to make an analysis of the legal problems raised by the recognition of national laboratory accreditation systems, based, among other things, upon the answers to a questionnaire which was reviewed and approved at ILAC/78.

Task Force B was to decide on information to be sought from accrediting organizations which would, in turn, be assembled by the Australian delegate into a draft directory of organizations or bodies which operate accreditation systems. The Task Force would analyze the problems encountered in collecting and presenting the information, including costs and size of the

task, and make proposals for the maintenance and dissemination of the directory.

Task Force C was to prepare, in cooperation with ISO and other concerned international organizations, a paper on needs, objectives, and effects and consequences of laboratory accreditation, and to prepare a list of basic terms and their definitions relative to laboratory accreditation.

These task force reports constitute the main items on the agenda of the third Conference (ILAC/79) to be held in Sydney in October 1979.

This position paper is based on the reports of Task Forces A, B, and C. The proposed draft directory of organizations and the subsequent analysis of costs, size, maintenance, and dissemination of the directory have not as yet been made available to ILAC delegates.

Comments on this position paper and on the Task Force reports should be made at the preconference briefing session to be held at 2 p.m. on September 26, 1979, at the National Bureau of Standards, or should be submitted in writing on or before October 5, 1979, to Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, U.S. Department of Commerce, Washington, D.C. 20230; (202) 377-3221.

2. Overall U.S. Position

The United States supports the informal assemblage of nations and international organizations represented by ILAC, and the objectives and work of ILAC as reflected in the activities and reports of ILAC's various task forces.

3. Report of Task Force A

3.1 Summary

In response to the questionnaire distributed by Task Force A, over 600 pages of information from 18 countries were received and analyzed. Task Force A considered not only specific legal constraints to the formal, national recognition of accreditation systems but also relevant factors bearing on the activity of testing laboratories.

The main points made by Task Force A in its report are:

A. In many instances, mandatory requirements for testing products prescribe that only specific laboratories named in the law or regulation may carry out tests relevant to these requirements. Accordingly, it may be necessary for such laws or regulations to be amended to allow other testing laboratories which have been accredited under a recognized accreditation program to carry out the appropriate tests on the products covered by those laws or regulations.

B. Some accreditation bodies apparently are able to accredit foreign testing laboratories; but either the extent of such accreditation is not clear, or their specific authority to provide such accreditation is not clear.

C. As a general rule, countries do not impose on laboratories in foreign countries requirements or obligations which materially differ from those imposed on their domestic laboratories.

D. There is relatively little evidence of specific laws or regulations which immunize an accrediting body from liability or acts of negligence. No court decisions whereby accrediting organizations or testing laboratories were found liable for any act of negligence in accrediting a testing laboratory were reported.

E. Full reciprocity for acceptance of accredited laboratories among countries should be based on requirements such as: the need for comparable standards and procedures; the need for procedures to insure continuing product compliance; the need for the accrediting body to be independent of the laboratories it accredits; the need for test reports to be in the language of the country extending acceptance of the accreditation program; and the need for reciprocity to be open only to countries extending mutual reciprocity.

3.2 Recommendations of Task Force A

That Task Force A be continued and be assigned the following tasks (to be reported at ILAC/80 in Paris):

A. Look further into the existence of legal reasons preventing the formal accreditation of foreign testing laboratories. To assist in this task, request the delegations responding to the Task Force A questionnaire to provide further information on the following items:

   i. For those accreditation programs which do not permit accreditation of foreign testing laboratories, list major reasons for refusing to do so and indicate what needs to be done to eliminate such restrictions.

   ii. For those accreditation programs which accredit foreign testing laboratories, identify any major difficulties which may have arisen from such accreditation, and list accredited laboratories together with the extent to which such laboratories have been used.

B. Identify the possible extent of unstated but real problems of those accreditation systems which do not provide accreditation to foreign testing laboratories. Include, particularly, problems associated with the difficulty in instituting liability proceedings against a foreign testing laboratory, and problems in use of public funds to pay for such accreditation such as cases where the agency is not willing to use such funds to accredit foreign testing laboratories.

C. For those laws and regulations silent on foreign laboratory accreditation programs, ask the reporting country to specify how the laws may be amended, revised, or otherwise interpreted to provide for recognition of such programs. Task Force A recognizes that appropriate criteria for evaluating laboratories are essential to the operation of a recognized accreditation program and that ILAC may wish to compile suggested criteria.

D. If ILAC should undertake to compile appropriate criteria, Task Force A should be invited to examine those criteria to identify any legal problems or recommend what laws need to be enacted or amended to allow use of such criteria.

E. Task Force A was presented with the possibility that mandatory testing systems may be an important source of technical barriers to trade. Task Force A should determine the likelihood of this possibility and propose ways and means for eliminating or minimizing that possibility.

3.3 U.S. Position

Concurrence with recommendations A, B, and C of Task Force A, since these are logical extensions of the work already begun and appear to be necessary to more completely utilize the data already collected. Concur also with recommendation D, suggesting that the chairman of the next scheduled ILAC Conference be authorized to request assistance from Task Force A whenever, in his judgment, there is the need suggested in recommendation D.

The U.S. strenuously objects to recommendation E of Task Force A. ILAC is an informal assemblage of nations and international organizations primarily interested in developing arrangements whereby testing laboratories and their data in one country will be recognized and accepted as valid in another country. Some participants in ILAC may be government officials having responsibility for, or for other reasons are concerned with, international trade negotiations. Some of those officials have indicated a desire to use ILAC as a forum to discuss issues which are not basic to ILAC's principal purposes and objectives, particularly issues concerning matters which have for many years been the subject of discussions in the multilateral trade negotiations (GATT Agreement), and which will continue to be discussed in the context of the implementation of those trade negotiations.

The U.S. sees no logical reason why ILAC's forum, which is intended to be a

temporary one with plenary sessions held only once annually, should be used to discuss any of the same issues that are, by formal agreement of the nations involved, subject to disposition by the terms of that Agreement. The lack of logic in having ILAC spend any of its limited time on such matters is even more apparent in view of the fact that ILAC has no means by which it can resolve any such matters.

For a more detailed explanation of this position, reference is made to a letter of June 19, 1979, which Dr. Forman, Head of the U.S. Delegation to ILAC/79, sent to the ILAC/78 Heads of Delegations from the European Common Market Countries.

4. Report of Task Force B

4.1 Summary

Task Force B developed an outline for the provisional directory shown in Annex 1 of its report. That outline proposes a "foreword" describing the background of ILAC, the purpose and layout of the directory, methods for collecting information, and methods for collecting updated information in the directory. The outline proposes "Part I" of the directory to include one-page summaries of the general testing arrangements in each of the countries represented in ILAC. The outline proposes "Part II" of the directory which would contain one-page summaries of each of the accreditation programs existing in each of the countries represented at ILAC.

To be eligible for inclusion in Part II of this directory an accrediting organization must operate its accreditation system to meet the following conditions:

(i) It must be actively engaged in the accreditation of laboratories.

(ii) It must specify accreditation of the testing laboratories in terms of well-defined fields of testing, scientific disciplines or technologies, or specific products or tests.

(iii) Its technical criteria for accreditation must be formulated by persons possessing the necessary technical competence in the relevant field of testing.

(iv) Its criteria for accreditation must be published and be generally available.

(v) It must only accredit laboratories in respect of tests performed in accordance with test specifications agreed between the laboratory and the accrediting organization.

(vi) Its evaluation of laboratories must be in terms of criteria which provide that:

(a) Laboratory structure and management are clearly defined and are organized in such a way that the integrity of its staff and operation is assured;

(b) Laboratory staff are suitably qualified and experienced and technically competent for the work in which they are engaged;

(c) Laboratory equipment is appropriate for the tests undertaken and that it is properly installed, maintained, and calibrated at intervals prescribed by the accrediting authority. Adequate records of calibration and servicing must be maintained;

(d) The testing environment and laboratory accommodation are appropriate for the tests undertaken;

(e) Laboratory practices such as--
sampling (where appropriate)
sampling identification
test methods and procedures
supervision of staff
keeping of records
checking of results and calculations are satisfactory;

(f) The laboratory records system is secure and contains full details of all tests undertaken;

(g) Test documents present accurately, clearly, and unambiguously the test results and all relevant information.

(vii) (No item vii was included in the Report.)

(viii) It must assess laboratories using teams of impartial experts who have expertise in the area of testing in which accreditation is sought.

(ix) Its assessment must be completed by a formal report by the assessors.

(x) It must reassess its accredited laboratories at regular and reasonable intervals.

(xi) It must publish a list of laboratories which it has accredited. Entries in Part II are to be made in terms of nine fields of testing (chemical, electrical, etc.).

4.2 Recommendations of Task Force B

Task Force B agreed to meet in Sydney immediately prior to ILAC/79 to update its report, and to meet again after ILAC/79 to expedite the work and take into account the comments made at ILAC/79.

4.3 U.S. Position

Task Force B should be encouraged to continue the development of the directory. A plan for developing and distributing the directory in final form should be prepared by the Task Force for presentation at ILAC/80. The draft directory should be distributed to all ILAC representatives as soon as possible for comments. The task force should resolve all the issues raised by the comments and, alternatives for presentation at ILAC/80 for resolution.

The "Conditions for Entry in Part II of Directory" presented in Annex III of the Task Force report and reprinted above represent criteria for evaluating accreditation organizations. Although these conditions appear to be reasonable, there are many which will be subject to interpretation (e.g., "(vi)(e)...laboratory practices such as sampling...are satisfactory."). The U.S. believes that ILAC/79 or ILAC/80 should vote on each condition listed in Annex III before these conditions are put into effect in the final directory.

5. Report of Task Force C

5.1 Summary

Task Force C presented a report on the needs, objectives, and effects and consequences of laboratory accreditation (Appendix 1 of the Task Force C report). The intent of the report was to discuss why laboratory accreditation is desirable, what it can hope to achieve, and the impact such accreditation would have on the community which utilizes such a system.

Appendix 2 to the report includes a set of definitions of basic terms used in laboratory accreditation. Definitions compatible with ISO definitions were used wherever possible.

5.2 Recommendations of Task Force C

The Task Force submitted the following recommendations:

A. ILAC/79 should encourage all nations to develop national systems for accreditation of their testing laboratories along lines which generally will be recognized and utilized by other nations.

B. Work begun in providing the definitions shown in Appendix II of the Task Force report should be continued in an attempt to arrive at a comprehensive set of definitions. ISO should be invited to present such a set of definitions to ILAC/80, but if ISO does not accept this invitation by January 1, 1980, ILAC should request that Task Force C continue the work.

C. A thorough comparison of the criteria used by the major accreditation systems should be undertaken by Task Force C for ILAC/80 leading to minimum criteria for multilateral recognition.

D. Each country should establish a central inquiry point to provide information on accreditation systems and accredited laboratories.

5.3 U.S. Position

Suggest that the report and Appendix 1 be incorporated as the introduction to the proposed directory and that the definitions, Appendix II, be included in the appropriate section of the directory. Further suggest that Task Force B be given the responsibility for receiving suggested revisions to the definitions and for preparing a set of final definitions for use in the directory.

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KEY WORDS *(six to twelve entries; alphabetical order; capitalize only the first letter of the first key word unless a proper name; separated by semicolons)*

ccreditation; audit certification; laboratory accreditation; laboratory performance valuation; quality control; testing laboratories.

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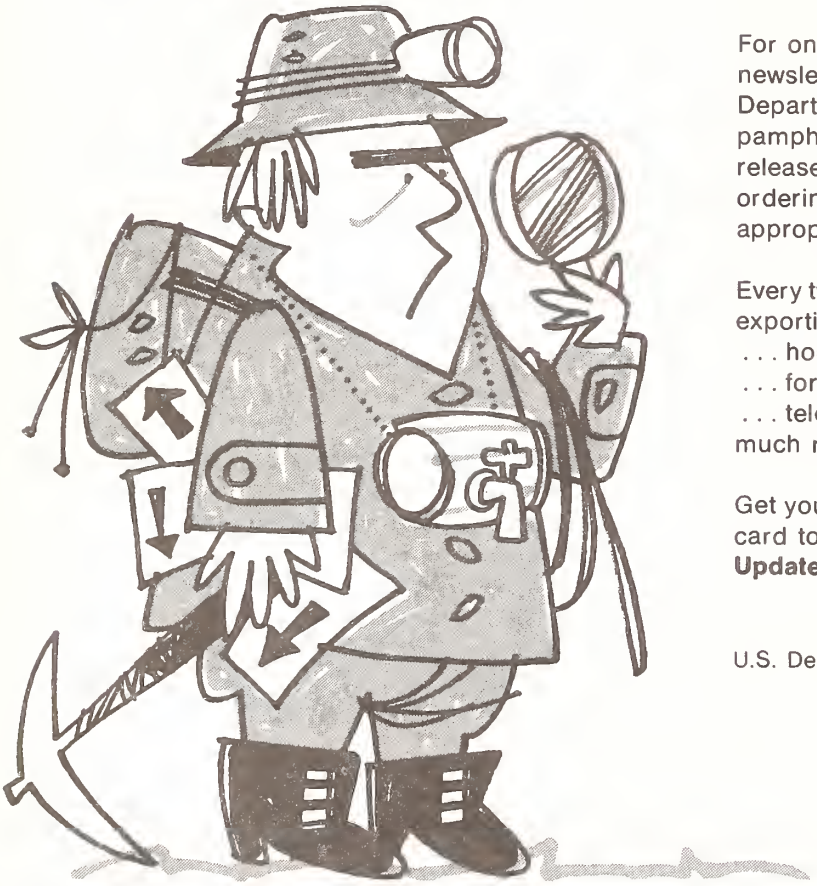

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