Accreditation Practices for Inspections, Lests, and Laboratories

Harvey E. Schock, Jr., editor

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Each paper published in this volume was evaluated by three peer reviewers. The authors addressed all of the reviewers' comments to the satisfaction of both the technical editor(s) and the ASTM Committee on Publications.

The quality of the papers in this publication reflects not only the obvious efforts of the authors and the technical editor(s), but also the work of these peer reviewers. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution of time and effort on behalf of ASTM.

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Foreword

This publication, Accreditation Practices for Inspections. Tests. and Laboratories, contains papers presented at the symposium on Accreditation Practices: Inspection and Tests, which was held in Baltimore, Maryland, 18 May 1988. The symposium was sponsored by ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. Harvey E. Schock, Jr., Product Assurances, presided as symposium chairman and was editor of this publication.

Contents

| Overview | vii |
|--|----------|
| General Concerns for Laboratory Accreditation | |
| Status of Laboratory Accreditation and Related Practices in Standards— H.E. SCHOCK, JR. | 3 |
| LABORATORY ACCREDITATION PROGRAMS AND TECHNIQUES | |
| Advantages of Laboratory Accreditation—R. L. GLADHILL Discussion | 19 23 |
| Accrediting Component and Materials Suppliers Laboratories—J. W. LOCKE | 24 |
| Activities of the Construction Materials Reference Laboratories Related to Laboratory Accreditation—J. H. PIELERT | 30 |
| National Aerospace and Defense Contractors Accreditation Program— W. T. KAARLELA | 37 |
| Related Contributions to Laboratory Accreditation | |
| Operator Errors in the Measurement of Microindentation Hardness — G. F. VANDER VOORT | 47 |
| Evaluation of Accreditation Systems and Their Demands on the Independent Testing Laboratory-D. H. STANGER | 78 |
| Interlaboratory and Intralaboratory Proficiency Testing—J. HORLICK | 85 |
| Towards a New Standard for Laboratory Accreditation Terminology—P. S. UNGER | 95 |
| Laboratory Accreditation in International Commerce | |
| Laboratory Accreditation in Canada: Update—g. c. hysert and m. archambault | 103 |
| Accreditation of Medical Laboratories in Australia-J. A. GILMOUR | 110 |
| The NAMAS Accreditation System—J. D. SUMMERFIELD | 116 |
| Laboratory Accreditation and Quality System Accreditation—A Merging of the Ways—M. R. BELL | 120 |

Overview

This book is a followup to Evaluation and Accreditation of Inspection and Test Activities, STP 814. The rapidly growing number of international bilateral agreements of recognition between laboratory accreditation programs of various countries highlights the need for improved understanding of impacts on commerce. This advanced use of accreditation is supported by new techniques for performing actual assessment to improve the effectiveness and efficiency of accreditation systems.

STP 1057 is divided into four sections:

- Section 1, General Concerns for Laboratory Accreditation
- Section 2, Laboratory Accreditation Programs and Techniques
- Section 3, Related Contributions to Laboratory Accreditation
- Section 4, Laboratory Accreditation in International Commerce

Section 1, General Concerns for Laboratory Accreditation

Schock offers a listing of concerns related to improving laboratory accreditation. Identified are opportunities for assessment, control, and accreditation. An appendix provides examples of ASTM laboratory accreditation standards in basic, specific, and related areas. The listing includes ASTM standards E 548 and E 994. Also provided is a listing of various international guides and publications.

Section 2. Laboratory Accreditation Programs and Techniques

Gladhill documents advantages of laboratory accreditation using specific standardized test methods for determining competence by a qualified evaluation agency, with public statement of fact. This requires accreditation agency freedom from conflict of interest with fair unbiased opinions and operation on a totally fee-reimbursable basis. Criteria for evaluation must be publicly available with continuing technical assistance between laboratories and accrediting body. Accreditation is not a product certification and accrediting agencies do not certify specific individual products tested by a laboratory. Laboratory capability requires a continuing good quality system in the laboratory. Proficiency testing programs must provide confidence for continuing calibration. Specific accreditation programs should be reviewed in advance to determine suitability for acceptance by appropriate governmental and regulatory bodies to eliminate duplicate evaluations and accreditations, especially for international trade areas. Accreditation program data are helpful in test method standards development and updating equipment.

Locke describes laboratory accreditation for testing where products are accepted based on factory quality control competence. This uses coordination of laboratory accreditation with quality systems for products under just-in-time procurement. Especially important is testing as a major component in a process establishing product quality where accreditation deals with measurement processes and statistical measurement control to assure manufacturing process control with end-item testing. Accreditation is discussed using departures from standards if reasons are known for individual aspects of test areas. Accreditation programs are reviewed for individual product performance requirements of purchasers for the acceptance of test data. Various approaches to captive and purchased laboratory services are reviewed for procurement item testing and special concerns for individual aspects of fatigue testing. Pielert reviews the development of a coordinated national system for construction materials testing laboratories. This includes developing a manual of professional practice for quality in construction projects, including design, regulation, laboratories, and construction site activities. Included is special attention to improving the quality of materials used in highways. Attention is directed to updated standards for variations in laboratory approaches for differing types of specific construction materials. The legal and liability concerns are also addressed. Details are provided on soils, cement, concrete, asphalt, aggregates, and special materials programs.

Kaarlela provides information on a new accreditation program for suppliers in the aerospace industry. Included is a summary of present overlapping accreditation activities with summary of simplified coordinated third-party concept for improved effectiveness and efficiency. Highlighted are activities to interrelate cost and quality. Details are provided of accreditation program organization and its relation with the ultimate customer. Pilot programs are discussed with use in demonstrating and assuring applicability in services, materials, mechanical hardware, electronics, and functionally critical products. Special attention is given to selection and training of assessors and inspectors for continuing verification of product and process. Identified are future activities required in standards bodies to consider new accreditation approaches.

Section 3. Related Contributions to Laboratory Accreditation

Vander Voordt recognizes the important problem of human variability and performance in identifying operator errors in measurements. His round-robin study is a classic in identifying problems in microindentation hardness across 24 laboratories. Details are provided on problems with test methods, operator variability, and actual measurements. ASTM Standard E 691 is applied for interlaboratory test programs. Within and between laboratory precision results are reviewed. In addition to operators, problems were identified with materials and machines. Calibration problems are reviewed together with data variability and handling of outliers.

Stanger provides a wealth of personal experience as a laboratory operator in several countries. Requirements are reviewed as imposed on laboratories in obtaining accreditation and in relating to national quality programs. Examined are demands and attendant costs. Various quality systems standards and accreditation system practices are discussed relating to laboratories. Practical problems are identified in calibration, logo usage, assessor training, and related costs. Time cycle problems are reviewed with their lengthy impact on introducing new programs and applying to new sites. Detailed laboratory operator information is provided on United Kingdom accreditation programs. Technical details are provided on specific compliance relating to various guides and standards imposed on laboratory owners. Despite extensive demands, the author identifies benefits of operating under accreditation.

Horlick identifies proficiency testing in determining operational competence of a laboratory for specific products, test methods, and defined laboratories. Proficiency testing is identified as a condition for initial and continuing accreditation. Each field of testing and each test method within a field has unique proficiency testing requirements. Important information is provided on proficiency results for standards preparers to improve test methods. Information use is also reviewed for an assessor to augment evaluation of its own quality program and to obtain thirdparty assistance if problems are discovered. Definite rules are reviewed for handling confidentiality of proficiency testing results. Test methods are reviewed for economic and technical concerns, legislative and regulatory importance, ability to indicate characteristics of laboratory operation, and ability to provide insight into laboratory competence. In addition, within laboratory testing is reviewed as part of laboratory quality assurance programs. Extensive details are provided on the actual operation of proficiency testing programs and selection of artifacts and reference materials. Unger summarizes standards development for terms used in laboratory accreditation and related quality areas. Included is information on avoiding use of the term certification. The importance of terms and their definitions is reviewed in laboratory accreditation to permit improvement, as the usage of descriptive terms varies considerably. Identified is the issue of how a laboratory accreditation system is structured. Information is provided on defining quality for laboratories. Also identified are some new areas requiring definitions.

Section 4, Laboratory Accreditation in International Commerce

Hysert and Archambault in their paper provide important information on requirements and criteria for testing and calibration laboratories, each of which are accredited separately. Discussion is provided on an important proposed national calibration network. Information is provided on the coordinated Crown Corporation national Canadian program at federal, provincial, and private levels, each with their own activities. Details are provided on structuring of the accreditation system and the benefits of actual operation. The paper provides good details and specific references. Availability of an excellent video, LAB BENCH, gives both an excellent introduction to laboratory accreditation with considerable basic training for both laboratory operators and assessors.

Gilmour utilizes over 40 years of Australian NATA experience to develop a new medical laboratories accreditation program with intergovernmental transprofessional committees and their special document guidelines and questionnaires for each discipline of pathology. Reviewed is a management approach using a full-time staff professional pathologist with on-site team peer reviewers. Described is the application of full continuity for the staff person in large hospital assessment where team members may change over a 14-day assessment. One of the benefits of the program is improved professional experience for assessors and the complementary roles for various involved organizations. Also reviewed are general practice areas where proficiency testing is used extensively. The program extends to accrediting media suppliers with further expansion planned for total traceability of end test results as a further step to accreditation of quality assurance and product certification.

Sommerfield describes the governmental service providing a unified link between government and industry for laboratories, calibration, and quality assessment. This provides for government and other organizations requiring contractors applying products or services holding NAMAS accreditation as an assurance of consistency and quality. Described are mutual recognition agreements with programs of other countries for testing and calibration. Fees are discussed. Covered are permanent and site laboratories including those for EEC/Directive noise measurements. Cooperation between accreditation systems and accredited laboratories is discussed as a means of minimizing development and other costs. Plans are discussed for free access of goods meeting required standards for the European Internal Market of 1992.

Bell introduces the New Zealand Council TELARC Code for both laboratory accreditation and quality system accreditation for quality assurance in laboratories and accreditation of quality control laboratories within industry. Assessment of supplier quality management systems is described to determine compliance with established criteria. The growth of quality systems standards is discussed as contrasted to quality program contract requirements for suppliers. Similarity of assessor staffs and personnel is discussed for laboratory accreditation as contrasted to quality system accreditation, suggesting possible combining of the two activities. Possible superficiality of quality management system assessment and extension to laboratories is discussed relative to specialized laboratory accreditation for laboratories. Identified are needs to develop quality management systems requirements for testing laboratories, as contrasted to using quality systems requirement standards developed for manufacturing areas. Also considered is the need for special training of laboratory assessors for quality management areas of laboratories. TELARC provides combined assessment with requirements, criteria, and advisory comments. Recommendations are offered for international cooperation for assessors of quality management systems.

ASTM Committees

Persons desiring to participate in the development of basic standards for laboratory accreditation are cordially invited to attend meetings of ASTM Committee E-36. This Committee is working on special standards for quality systems of testing laboratories, proficiency testing in laboratories, remote site laboratories, and general updating of basic standards to consider new national, regional, and international requirements. Additional work is planned to help identify and improve use of common concerns through a modular approach to standards writing. This will consider areas and elements of assessment for testing and inspection areas in laboratories and in industry as related to possible requirements in other surveys and audits. Through a modular approach, it is expected improvements will be achieved in assessor and auditor training, operation, and control. Liaison Committee E-36.40 is available to answer questions on possible interfaces of E-36 work with other standards writing bodies and users of accreditation standards.

In addition, attendance is invited at meetings of other ASTM technical committees developing standards for detailed processes, materials, products, services, test methods, and specific laboratory accreditation requirements.

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