MEDICAL DEVICES: MEASUREMENTS, QUALITY ASSURANCE, AND STANDARDS

ASTM SPECIAL TECHNICAL PUBLICATION 800

C. A. Caceres, Clinical Systems Associates, Inc.;
H. T. Yolken, National Bureau of Standards;
R. J. Jones, American Medical Association; and
H. R. Piehler, Carnegie-Mellon University,
editors; with the assistance of J. W. Schick

1916 Race Street, Philadelphia, Pa. 19103

Library of Congress Catalog Card Number: 82-072890

NOTE

The Society is not responsible, as a body,
for the statements and opinions
advanced in this publication.

ASTM Publication Code Number (PCN)
04-800000-54

Printed in Ann Arbor, Mich.
Jan. 1983

The very idea of a specification involves the existence of a mass of common knowledge in regard to any material, which knowledge is more or less available to both producer and consumer. If the manufacturer or producer have opportunities which are not available to the consumer of knowing how the variation of certain constituents in the product will affect that product during manufacture, so also does the consumer (if he is philosophic and is a student) have opportunities not available to the producer of knowing how the same variation of constituents in the product will affect that product in service. And, it is only by the two working together, and combining the special knowledge which each has, that a really valuable specification can be made.

Excerpted from "The Making of Specifications for Materials," by Dr. Charles B. Dudley, Presidential Address delivered before the American Society for Testing and Materials, 1903.

A Note of Appreciation to Reviewers

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

ASTM Committee on Publications

List of Contributors

Authors

M. Anbar, PhD—Department of Biophysical Sciences, State University of New York at Buffalo, Buffalo, New York

A. D. Bernstein, DSc—Department of Surgery, Newark Beth Israel Medical Center, Newark, N.J.

G. N. Bowers, MD—Clinical Chemistry Laboratory, Hartford Hospital, Hartford, Conn.

S. Boyarsky, MD—Division of Urology, Washington School of Medicine, St. Louis, Mo., and chairman, Biomedical Engineering Committee, American Urological Association, Baltimore, Md.

P. G. Brown—Deputy Director, American Society for Testing and Materials, Philadelphia, Pa.

J. M. R. Bruner, MD—Anesthesia, Massachusetts General Hospital, Boston, Mass.

C. A. Caceres, MD—Clinical Systems Associates, Inc., Washington D.C.

W. T. Cavanaugh—President, American Society for Testing and Materials, Philadelphia, Pa.

G. B. Devey—Technology consultant, Washington, D.C.; formerly Section Head, National Science Foundation, Washington, D.C.

F. J. Doyle, PEng—Canadian Standards Association, Rexdale, Ontario, Canada

H. Eden, MD—Biomedical Engineering and Instrumentation Branch, DRS, The National Institutes of Health, Bethesda, Md.

J. O. Galante, MD—Committee F4 on Medical and Surgical Materials and Devices of the American Society for Testing and Materials, Chicago, Ill.

G. S. Hammer—Technology consultant, Bethesda, Md.; formerly Manager for Technical Development, Association for the Advancement of Medical Instrumentation, Roslyn, Va.

D. C. Hanlin—Research assistant, Clinical Systems Associates, Inc., Washington, D.C.

J. D. Hoffman, PhD—National Measurement Laboratory, National Bureau of Standards, Washington, D.C.

E. Horowitz, PhD—Center for Materials Research, Johns Hopkins University, Baltimore, Md.

M. F. Houston, MS—Medical Device Standards/Biomedical Engineering, Bureau of Medical Devices, Food and Drug Administration, Silver Spring, Md.

R. J. Jones, MD—American Medical Association, Chicago, Ill.

K. S. Kagey, MD—Private practitioner, Shrewsbury, Mass.

A. R. Kahn, PhD—Applied Electronics Consultants, Inc., Madison, Wis.

W. H. Kirchhoff, PhD—Office of Environmental Measurements, National Bureau of Standards, Washington, D.C.

P. G. Laing, MD—Committee F4 on Medical and Surgical Materials and Devices, American Society for Testing and Materials, Pittsburgh, Pa.

E. Lautenschlager, PhD—Northwestern University, Biological Materials, Chicago, Ill.

A. D. Lewis, PE—Assistant Director for Construction-Medical Design and Engineering, Office of the Assistant Secretary of Defense (MRA and L), Washington, D.C.
G. C. Macks—Office of Clinical and Management Systems, Clinical Center, National Institutes of Health, Bethesda, Md.
R. S. Melville, PhD—Bureau of Medical Devices, Food and Drug Administration, Silver Spring, Md.
E. Mueller—Bureau of Medical Devices, Food and Drug Administration, Washington, D.C.
V. Parsonnet, MD—Department of Surgery, Newark Beth Israel Medical Center, Newark, N.J.
H. R. Piehler, PhD—Engineering and Public Policy, Carnegie-Mellon University, Pittsburgh, Pa.
L. Podolsky, DSc—Consulting engineer, Pittsfield, Mass.
W. Raythen—Electrophysiology technician, Department of Medicine, Newark Beth Israel Medical Center, Newark, N.J.
W. Rowe, PhD—Institute for Risk Analysis, American University, Washington, D.C.
J. W. Schick—Research assistant, Clinical Systems Associates, Inc., Washington, D.C.
F. E. Scire—Surface Characterization, National Bureau of Standards, Washington, D.C.
W. S. Staewen—Clinical Engineering, Sinai Hospital, Baltimore, Md.
E. C. Teague, PhD—Surface Characterization, National Bureau of Standards, Washington, D.C.
H. Turndorf, MD—New York University Medical Center, New York, N.Y.
D. Vahey—Battelle-Columbus Laboratories, Columbus, Ohio
B. C. Wang, MD—Anesthesiology, New York University Medical Center, New York, N.Y.
C. C. Watts, MD—Division of Neurosurgery, University of Missouri-Columbia Health Sciences Center, Columbia, Mo.
H. T. Yolken, PhD—Office of Health Measurements and Technology, National Bureau of Standards, Washington, D.C.
P. J. Zalesky, PhD—Research and Development, Meadox Medicals, Oakland, N.J.

ASTM Editorial Staff
Janet R. Schroeder—Editorial Director
Kathleen A. Greene—Manager, Acquisitions and Review
Rosemary Horstman—Managing Editor
Helen M. Hoersch—Senior Associate Editor
Helen P. Mahy—Senior Assistant Editor
Allan S. Kleinberg—Senior Assistant Editor
Virginia M. Barishek—Assistant Editor

Contents

Introduction

The American Medical Association (AMA), the National Bureau of Standards (NBS), and the American Society for Testing and Materials (ASTM) sponsored a conference, "Medical Devices: Measurement, Quality Assurance, and Standards," held on 24-25 Sept. 1981 at NBS in Gaithersburg, Md. The objective of the conference was to provide physicians, scientists, and members of industry and government with a comprehensive overview of the role and impact of medical device standards and measurements on health care.

The Sponsors

Perhaps the most notable observation to be made regarding the participants in planning the conference is the wide spectrum of philosophies represented by academia, the private practitioner, the medical community, the engineering community, professional standards-development organizations, and small and large medical device businesses.

The three sponsor organizations represent a spectrum of special interests; each has individual philosophies on and approaches to standards development. The AMA represents the grass roots, practicing physician. The NBS provides its inherent and widely recognized professional and technical capabilities, particularly in the area of development of reference materials and methods. ASTM enjoys a worldwide reputation in many areas for its effective consensus standards-setting techniques.

While the individuals on the Task Force for the conference project are representative members of these well-known organizations, as *individuals* they identified with the need for standards development and joined together out of that common interest. It is hoped that the efforts resulting from this conference and this text will encourage increased interaction among other health and medically oriented professional groups.

The Consumer View

One central theme of the conference was to address the need to integrate the physician's views with business and standards-development organizations. Health care devices and related technologies cannot be developed in a vacuum, nor can standards affecting that technology. Traditionally, physicians have taken a passive role in standards development. When individuals have at-

tempted to become involved, results have been mixed. Yet, health care practitioners are the real consumers of today's medical technology.

Often small groups work without substantial external input and develop partisan recommendations, suggesting action or inaction depending on the purposes of the group. Or, they may duplicate the work of other groups, but yield results of a different slant. Often, standards have been stimulated and developed by manufacturers, or they have been initiated and developed in response to government mandate or lawsuits.

Inherent to the successful development of usable guidelines for standards efforts are *communication* between the fields of expertise, *a common basis* for scientific development and acceptance of data, *a response mechanism*, and an *information dissemination* mechanism.

Conference participants cited four recommendations in response to the needs for improved communication, accurate measurements, and clinical evaluations:

1. Standards-development organizations need to become more acutely aware of prioritization factors, such as indications of current practices in the medical fields, establishment of levels and classifications of activities (such as pre-standard guidelines versus definitive standards), timeliness, cost-effectiveness, and the economic-societal-market impacts of standards activities.
2. Improved reference measurements and methodology should be definitively integrated with the measurement/diagnostic needs of the medical fields.
3. Improved data bases and information networks should be developed and should reflect consumer needs as they relate to human factors, environment of use factors, and routine patterns of use.
4. Current and improved medical practices are dependent on a systematic approach to providing therapies, future device development, and modification of current devices. Related standards activities should embrace a systems approach so that efforts are compatible with that which is already in place in society's health care establishments.

Using this Text

This book was designed to provide the reader with the greatest amount of educational value possible while consuming the smallest amount of the reader's time. This is of the utmost importance to the professional whose time is limited.

Several functional features of this text are provided to help the reader read selectively. The *Overview* is a synopsis of the thematic sections contained in this text. The Overview is followed by a *Guidelines* section consisting of conceptual discussion chapters. The Guidelines section is then followed by a *Case Study* section. This arrangement will help direct the reader to the topics of greatest interest to the individual.

In the development of this text, several individuals in addition to the authors supplied the editors with many excellent references. The *Selected References* section is divided into key areas, and then subdivided into journals, textbooks, proceedings, and standards. The referenced materials were carefully chosen to complement the topics covered in this text.

The *Index to Key Concepts* is an index based on several broad concept/application areas. Each key concept in this section is followed by pertinent chapter numbers, as well as by a list of subtopics and the page numbers where discussion may be found. Thus, at a glance, the reader is directed to specific areas of interest and interrelated topics. In addition, there is a separate alphabetical index.

The opinions and views expressed in all the chapters contained in this text are those of the authors and are not to be construed as the views of their employment or professional membership affiliations, the National Bureau of Standards, the American Medical Association, or ASTM.

Preface: Standards Development in the Medical Device Field

The insights, discussion, and recommendations presented in this text are representative of many individuals' contributions. However, coordination of this endeavor is due to joint participation by three primary organizations: the National Bureau of Standards, ASTM and the American Medical Association. The following comments express the views of the authors affiliated with these organizations.

The Clinician's View of Standards

Richard J. Jones, M.D., American Medical Association

The American Medical Association (AMA) has always recognized the important role that medical devices play in the practice of medicine, in the care of patients. For many years, until 1954, the AMA had a Department of Medical Instrumentation which reviewed the characteristics of medical devices or instruments and approved or disapproved their use. Since then, many physicians have continued to be active in working with device manufacturers and FDA advisory panels.

The AMA has assumed the role of an observer. As an organization, it has rarely contributed to the process of writing standards for medical devices. However, it has been active for many years in developing its own position on the use of drugs, has contributed much to the drug regulation and approval process, and has maintained representation on the Medical Device Standards Management Board of the American National Standards Institute.

In recent years, as the inclination to strengthen the regulatory process has grown, many members of the medical profession have expressed alarm at the threat to innovation and scientific progress. While formal research programs in major institutions or those funded by granting agencies may be able to tolerate fairly elaborate rules and regulations, the innovative approach to patient care is a more fragile thing.

In the United States we have a highly trained cadre of scientifically oriented physicians who are capable of and do make critical scientific judgments—tempered by the humanitarian traditions of the profession—every day in their practice. They are aware of the pitfalls of "clinical impressions," have a rudimentary understanding of statistics and epidemiology, and have often contrib-

uted in some measure to the medical scientific literature. When faced with a difficult medical problem where applications of new devices or new combinations of old devices may make a difference in patient outcome, such men and women should not be constrained by governmental regulations established by agencies that have no responsibility for the welfare of individual patients and are under no threat of malpractice litigation if the judgment is poor.

There is much discussion now about the need for medical device standards. Should they be mandatory or voluntary? Should they be standards of manufacture, performance, safety, efficacy, or use (labeling standards)? Is it even reasonable to attempt any such thing as standards development in such a dynamic field as medicine, where advances are being made so rapidly that in the years it takes any group to "hammer out" a standard, it may become outdated? None of these questions has been completely resolved; thus, discussion between all parties, including the physician-users, should be given wide currency.

There has also been much said about the dangers of medical technology run rampant and the plight of the uninformed physician who finds him or herself at the mercy of new instruments and their technicians. This reinforces the need for the physician to become better informed in this area so that he or she can further contribute to the development of new and innovative techniques for successfully dealing with patients' problems.

Standards and Medical Care

J. D. Hoffman, National Measurement Laboratory, National Bureau of Standards

The marvelous complexity of the human body and our increasing knowledge of how the body functions has led to techniques of diagnosis and treatment that are growing in sophistication. This trend will persist as the electronic and computer revolution continues its amazing acceleration.

Yet, for all the complexity of tools serving modern medicine, the needs of the physician are quite straightforward. First, safety must be a major consideration in the design and use of every medical device. Secondly, a device should not only do no harm, it should also do some good. This is an area of some complexity, involving both clinical trials as well as the reliability of the device in question.

Finally, in the case of measuring or diagnostic medical devices, the dominant theme is accuracy. The most sophisticated and expensive measurement tool is of little worth—in fact, it may be dangerous—if the numbers it produces are wrong. And, numbers, the products of measurement, are crucial indicators of physiological states or effectiveness of treatment. In addition to diag-

nostic medical devices, measurement accuracy is important in the design, evaluation, and manufacture of a wide variety of medical devices. Safety, effectiveness, and accuracy are key concepts, bonding all pursuits in the fields involved in standardization—medicine, scientific research, practical engineering, and standards writing.

Voluntary standards, generated by the open participation of all involved parties, can benefit both manufacturer and user. But, progress in the area of medical device standards requires close cooperation of all involved sectors. Without cooperation there is the real danger that standardization could stifle innovation or add unnecessary expense and delay to the application of medical devices.

A System for Voluntary Standards

W. T. Cavanaugh, President, ASTM

As an organization, ASTM has, for over 80 years, become a system to manage the development of consensus standards. What benefits have groups involved in the ASTM voluntary standards system seen?

First, *voluntary* standards have become public demonstrations to consumers of an effort to meet an evident responsibility.

Second, they are evidence of efforts to arrive, through consensus deliberations, at a definable and known quality in a product.

Third, they are evidence of efforts to assure freedom of competition, but above a baseline level of quality in performance.

Fourth, they are evidence of efforts to assure "due process" responsibility in the event of failure.

Finally, they are evidence of efforts to establish a methodology to cope with needed changes and improvements at the same time that previously established performance levels are maintained.

Industrial and commercial groups have long benefited from standards in these five ways. Various medical professional groups, working with the ASTM system, have also become aware that similar benefits can accrue to them. This volume is, in part, evidence of that fact.

In a technologic era the physician has become, in a number of ways, dependent on devices, systems, and processes. Many of these have had excellent standards developed through stimuli of industry. It has become apparent, however, that the majority of standards needed must come through grassroots stimuli by physicians, who are, in fact, entrusted by the public to assure quality and accessibility of all health and medical services.

It is with that viewpoint in mind that ASTM has sought to work with physician groups to generate standards needed by the practicing clinician so that he

or she can obtain optimal products for the care of patients. In many instances we feel that the standardization process has, additionally, solved problems of cost control and stimulated new and useful product lines.

The interest shown and efforts initiated by these three groups has been a welcome opportunity to create, through this text and other activities, a step for future activity in standards, when needed by physicians, to assure patients that their services are augmented by medical devices commensurate with all that the state of the art allows.