Methods for Quality Control in Diagnostic Microbiology

Editors: J. Michael Miller, Ph.D.
Berttina B. Wentworth, Ph.D.

American Public Health Association

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and
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Washington, D.C.

ISBN 0-87553-121-0

2/852M

PREFACE

"Quality control-QC"—For many laboratorians these words mean an intrusion into worktime and into laboratory budgets. If everyone were equally convinced of the value of well controlled procedures in microbiology, we might have less difficulty in accepting quality control as an important prerequisite to clinically relevant laboratory results. And quality control IS critical to good patient care.

This is a book for those who believe in good quality control. It is designed for use at the bench, and is intended to be a "how-to-do" book, addressing real laboratory problems, with directions for quality control in all areas of the microbiology laboratory. We hope it will meet the needs of those who wish to develop and implement a quality control program as well as those who wish to improve an existing one.

Quality control for microbiology has had an interesting history over the past fifteen to twenty years. Although some hospitals recognized the need for quality control and had wisely begun to design and implement programs, passage of the Clinical Laboratory Improvement Act (CLIA) in 1967 was responsible for development of most of the quality control methods in use today. To meet the mandate of CLIA, microbiologists met to formulate the beginnings of quality control standards, albeit without a data base from which to work. Nevertheless, the procedures they derived had a sound scientific basis.

Although we believe that quality control is as important today as it was then, we recognize that it is time to assess the true value of the methods in use. Nonproductive quality control should be eliminated, not when it is inconvenient and costly, since productive quality control may be both of these, but when careful data analysis shows it to be unnecessary.

Specimen quality must become a priority item in quality control. Emphasis on collection of quality specimens should begin in schools of medicine and schools of medical technology. Laboratories should not report the results of testing inappropriate specimens or specimens of poor quality without explaining the errors inherent in such testing.

Laboratories must look at all aspects of their operation,—personnel, equipment, instrumentation, safety, and technical procedures,—in formulating a total quality control program.

We wish to thank June Sumpter for her invaluable assistance in the preparation of this book and Dr. Adrienne Ash of the American Public Health Association for her able assistance in its production.

J. Michael Miller
Berttina B. Wentworth

CONTRIBUTORS

Marilyn S. Bartlett, M.S.
Associate Professor, Indiana University School of Medicine, Indianapolis, Indiana

Carl H. Blank, Dr. P.H.
Chief, Consultation and Educational Resources Branch, Division of Laboratory Training and Consultation, Laboratory Program Office, Centers for Disease Control, Atlanta, Georgia

Jean H. Bowdre, Ph.D.
Associate Director, Clinical Microbiology/Immunology Laboratory, North Carolina Memorial Hospital, Chapel Hill, North Carolina

Linda S. Burton, B.A., MT(ASCP)
Technologist, Clinical Microbiology Laboratories, Emory University Hospital, Atlanta, Georgia

Robert M. Gay, M.D.
Associate Pathologist and Director, Clinical Microbiology Laboratory Services, The Moses H. Cone Memorial Hospital, Greensboro, North Carolina

Kathleen L. Harper, M.S.
Indiana State Board of Health, Indianapolis, Indiana

Edward O. Hill, Ph.D.
Professor, Department of Pathology and Laboratory Medicine, Emory University School of Medicine and Director, Clinical Microbiology Laboratories, Emory University Hospital, Atlanta, Georgia

Kenneth W. Jernigan, B.S., M.P.H.
Laboratory Field Services, California State Department of Health Services, Berkeley, California

George E. Kenney, Ph.D.
Professor and Chairman, Department of Pathobiology, School of Public Health and Community Medicine, University of Washington, Seattle, Washington

Karl T. Kleeman, Ph.D.
Rex Hospital Laboratory, Raleigh, North Carolina

Gretchen G. Landon, B.S.
Nevada State Health Laboratory, Nevada Department of Human Resources, Reno, Nevada

J. Michael Miller, Ph.D.
Bacteriology Training Section, Division of Laboratory Training and Consultation, Laboratory Program Office, Centers for Disease Control, Atlanta, Georgia

Patrick R. Murray, Ph.D.
Associate Professor, Departments of Medicine and Pathology, Washington University School of Medicine, St. Louis, Missouri

Mark A. Neuman, Ph.D.
Associate Director, Clinical Microbiology and Immunology, Department of Laboratory Medicine, Naples Community Hospital, Inc., Naples, Florida

Regina Reed, M.M.Sc.
Technical Specialist, Clinical Microbiology Laboratories, Emory University Hospital, Atlanta, Georgia

Raymond L. Schrunk, M.B.A.
Management Development and Consultation Division, Laboratory Program Office, Centers for Disease Control, Atlanta, Georgia

Anne R. Towne, MT(ASCP)
Supervisor, Bacteriology Section, Laboratory Services, The Moses H. Cone Memorial Hospital, Greensboro, North Carolina

William M. Wagner, Sc.D.
Division of Laboratory Training and Consultation, Laboratory Program Office, Centers for Disease Control, Atlanta, Georgia

Berttina B. Wentworth, Ph.D.
Laboratory Director, Bureau of Laboratory and Epidemiological Services, Michigan Department of Public Health, Lansing, Michigan

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CHAPTER 1

PROCEDURE MANUAL

J. Michael Miller, Ph.D.

INTRODUCTION

The most important written document in a microbiology quality control program is not one of the texts or journals available for reference and technical information; it is the standard procedure manual compiled by laboratorians for use in the laboratory. There are a number of excellent sources that describe the process of procedure manual development.[1,2,3,4] The procedure manual is written primarily for inexperienced laboratory personnel who may be unfamiliar with the procedures used in the laboratory but it is also important for the experienced laboratorian. The most valuable role of the procedure manual is communication. Lack of communication is a major cause of laboratory stress.[5] There is often a lack of communication between physician and laboratorian, each misunderstanding the unique needs of the other; between the nursing staff and the laboratory; and even between laboratory staff members who work different shifts.

Lack of communication results in a frustrated laboratory staff; poorly selected, collected, and transported clinical specimens; and concerned physicians who rightfully question the accuracy and relevancy of the results reported on their specimens. It is incumbent upon the laboratory to initiate and open channels of communication to all those using the services of the laboratory. The greatest communication tool for the laboratorian is an up-to-date procedure manual.

All accrediting agencies require that a complete and current procedure manual be available for use in the laboratory. Federal regulations list seven important points regarding the manual.

1. Each laboratory (e.g., bacteriology, mycology, parasitology) must have a procedure manual.
2. The procedure manual must be located in each corresponding workbench area.
3. The procedure manual must have the technical supervisor's written attestation that the manual is reviewed annually.
4. The technical supervisor's review of the manual must be dated.
5. The manual must contain only those procedures currently in use in the laboratory.
6. All changes made in the manual must be documented and dated.
7. All changes must have written approval of the technical supervisor designated by initials and date.

The procedure manual should be so well planned and designed that it serves as the "communicator" for the laboratory. In that regard, it must describe the potential daily problems encountered in the laboratory as well as their solutions. In addition to routine technical procedures and differential tests, the manual must address accepted, abbreviated techniques unique to a particular laboratory. For example, if *Escherichia coli* is isolated from urine and the routine procedure of the laboratory is to use

the minimum criteria of "lactose fermenter on MacConkey agar, oxidase negative, and spot-indole test positive" as the presumptive identification for the organism, this procedure should be clearly defined in the manual and separated from the more extensive biochemical identification afforded by "kits" or conventional media. The manual should contain the unique laboratory policies pertaining to specimen handling on all shifts, as well as telephoning, errors, personnel responsibilities, referrals, and other special problems.

One design of the manual may include five major sections. Large laboratories may consider these as five separate manuals. They are (1) quality control, (2) specimen collection, (3) technical procedures, (4) laboratory safety, and (5) preventive maintenance. In designing and writing the manual, consider each as a separate section to be written fully, accurately, and in depth before the next section is begun.

DO'S AND DON'TS OF WRITING PROCEDURE MANUALS

Do determine that the finished product will be an accurate reflection of the service and needs of the laboratory.
Do work on one section at a time before moving to the next section.
Do enlist the aid of all laboratorians involved in microbiology.
Do set a reasonable time limit for each section to be completed.
Do designate one person to coordinate the total effort.
Do set aside special times for work on the manual in which interruptions will be minimal.
Don't panic over the potential size of the manual.
Don't try to write the manual alone.
Don't set a time limit for the total manual to be completed—it is never "complete."
Don't wait until the month before "inspection" to begin reviewing or writing the manual.
Don't try to work on the manual in a place where interruptions will make concentrating impossible—work in a library or in a quiet office.

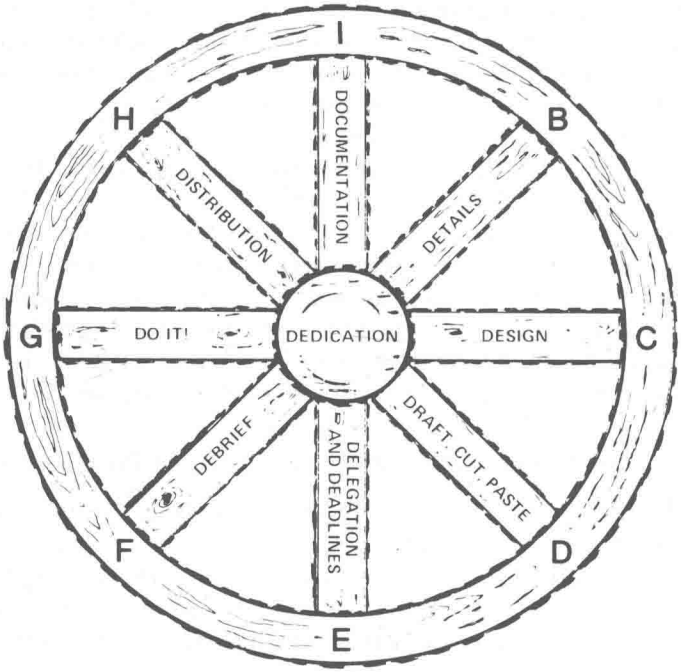
PROCEDURE MANUAL DEVELOPMENT

As illustrated in Figure 1:1, the development of a good procedure manual is a continuing process, one which is never "complete." There are eight steps involved in developing the manual, and all are important.

Dedication.

The central issue at the onset is the dedication of those involved in the manual's development. If all concerned laboratorians are involved in developing and writing the manual, each worker will feel responsible for

THE CONTINUING PROCESS OF PROCEDURE MANUAL DEVELOPMENT



the finished product. The unalterable goal should be to develop the best possible manual for the microbiology laboratory. Do not try to write the manual during other routine laboratory activities.

Details and Design.

The one person assigned the responsibility of leading the "procedure manual team" becomes the coordinator of the project. It should be the responsibility of the coordinator to suggest a format to be used throughout the manual and to provide a sample outline for each participant to follow. After a format is selected, each participant should write the assigned portion to conform to the sample outline. The coordinator is also responsible for the overall organization of the manual and should make sure that all of the laboratory's policies and procedures are included in the final product. The coordinator should ensure that an inexperienced technologist can understand the laboratory policy by reading the procedure manual. After these policies and procedures are listed and reviewed by the laboratory director, the next step in the process may begin.

Draft, Cut and Paste.

The manual cannot be written on the basis of only experience, without references. For each portion of the manual, bring the necessary refer-

ences to the work table. References in microbiology should include professionally recognized microbiology manuals, current journals, [describing procedures chosen by the laboratory to be included in routine work], technical newsletters, manufacturers inserts [from which data may be taken] and the old procedure manual if one is being updated. Each procedure in a part of the manual can then be written, using these materials. Photocopy those portions of the literature that are relevant to the procedure or test being described. Carefully record the sources of the material in the reference list. One may choose an introductory paragraph from one source, a procedural outline from another and specimen criteria from yet another. These "pieces" are then "cut and pasted," with a record of the corresponding references, before the text of the procedure or test is typed in its final form.

Delegation and Deadlines.

Each person who works in the microbiology laboratory should have some part, however small, in the development, writing, and decision making processes of the manual. Assign each person a single test or procedure and explain the format concept of the manual. Establish a reasonable timetable for each small portion to be completed and provide a time during the work-day for writing. In a group meeting, explain how to use references, where the references are and how the "cut and paste" process can save time.

Debrief.

As a rough form of each portion of the manual is completed, review the written procedure to ensure that it is accurate, complete, properly referenced, and a true description of the actual process at the bench. Allow other members of the laboratory staff to review the work of the group. Make additions and corrections to the rough copy as necessary.

Do It!

As a portion is completed and each contribution is reviewed, have the corrected copies retyped and prepared for a final review. When a section is finally completed, have it printed for insertion in the manual, or use a typed version. After it is inserted in the manual, however, corrections or changes must be initialed and dated by the technical supervisor.

Distribution.

The original or master copy of the manual must remain with the laboratory supervisor, but a copy of each appropriate section must be retained in the corresponding workbench area of the laboratory. For example, if anaerobic bacteriology is performed in the laboratory, a copy

of the anaerobic procedures section of the manual should remain in the anaerobe laboratory. The same is true with mycology, parasitology, virology, or other specialty areas that larger laboratories often have. Each section of the manual (e.g., quality control, specimen collection) should be designed and written so that it can stand alone as a complete unit.

The specimen collection portion should be so well written and complete that it could be given, in its entirety, to the hospital nursing service to aid them in preparing the specimen collection portion of their manual, since the procedures described in the microbiology manual should be the standard to which the corresponding portion in the nursing manual conforms. The specimen collection portion of the microbiology manual should be provided to all hospital floors for staff reference, either in booklet form or as rolodex-type files. Infection control personnel should at least be familiar with the specimen collection portion of the manual.

Documentation.

Not only is the use of references very important when preparing the manual, but when a new technology becomes available or a more efficient method is described for a laboratory procedure, a change in protocol is more likely to be implemented if the value of the change can be documented from the literature. The mere fact that a procedural change was described in a lecture or a workshop may not justify a change in the current procedure and further documentation is required in addition to protocol changes. The laboratory must validate any change in methodology before incorporating the change into its daily procedure.

The manual must be reviewed annually; this review must be documented. If a procedure has been altered, the entire process described in Figure 1:1 should be followed to make the change in the manual. The annual review of the manual need not be a traumatic event, occurring just before the laboratory is "inspected;" the review should be continuous. The manual should be reviewed one part at a time. For example, a different section could be reviewed each quarter. During the review, each person in the laboratory should be assigned a part of each section to determine any needed changes. If a great deal of effort went into the initial development of the manual, little effort should be required for the annual review.

The procedure manual is most conveniently maintained in a looseleaf notebook for easy insertion of pages. Each procedure, test, or topic should begin on a new page so that changes can be made easily. Select a numbering system that will provide easy reference but that will allow additional pages to be inserted without disrupting the number sequence. Bartlett [1] suggests assigning each part of the manual a certain number of pages without overlapping numbers. As an example, quality control may be assigned page numbers 1-99, and the specimen collection and handling

section, 100-199. Larger laboratories will have more voluminous manuals because the services provided by virology and mycology sections, or other branches within the laboratory, may require separate segments to address each discipline.

The format should be basically the same for each discipline. If the laboratory does not use conventional biochemical methods (e.g., multiple-tubed biochemicals) to identify bacterial isolates, it is not necessary to include conventional charts in the main body of the manual; however, these lengthy reference procedures should be a part of the manual appendix.

Manufacturer package inserts may not be substituted for a written procedure; neither may reference texts substitute for a written protocol.

Materials such as flow charts and manufacturer package inserts may, however, be used as supplements to the written procedure. A table of contents, carefully and completely designed, should be included.

FORMAT OF THE PROCEDURE MANUAL

No required format is available, although the National Committee for Clinical Laboratory Standards (NCCLS) has published a suggested guideline[6] that could be used by most laboratories. Some directors of larger laboratories have published procedure manuals describing the microbiology techniques used in their hospitals.[4,7] Other outlines of manual formats are also available.[1]

Quality Control Section.

When the quality control (QC) section of the manual is complete, its contents may be referenced, where appropriate, in subsequent parts of the manual. Items to be included in the QC section are:

1. General laboratory policies for:
   a. Laboratory organization: levels of authority and responsibility.
   b. Selection and revision of procedures used in microbiology.
   c. Purchasing and inventory.
   d. Accession of specimens: the method for tracing a specimen from the patient through its circuit in the laboratory.
2. Quality control policies and procedures for:
   a. Internal quality control—for preventive maintenance of equipment and for the laboratory's safety program. A large laboratory may require separate manuals for preventive maintenance and laboratory safety; a small laboratory, however, may be able to incorporate these two programs within the internal QC section of the manual. Internal, blind proficiency testing performed in the laboratory should be described.
   b. External quality control—for receiving, processing and preparing reports on subscription survey and proficiency testing specimens.

c. Reports and records—what they are, where they are kept and for how long, who completes the records and who checks them.
d. Stock cultures.
e. Antibiotic susceptibility testing—the disk diffusion and minimum inhibitory concentration procedures used in the laboratory and QC procedures associated with them. This procedure may be referenced in subsequent parts of the manual. The method for recognizing and correcting an out-of-control result should be described.
f. Reagents and antisera.
g. In-house products.
h. Miscellaneous functions (may be placed in appendix).
   (1) How to set up the CO_2 incubator.
   (2) How to set up the anaerobic system, including holding jars.
   (3) How to operate the autoclave.
   (4) Media preparation and labeling with medium name, lot number, and date prepared.
   (5) Disposal procedures.
   (6) Decontamination and spill cleanup.

Many of the topics listed above are discussed in subsequent chapters of this book. Large laboratories may require more items than those listed.

The Specimen Collection Section.

William H. Ewing has wisely written that "From the standpoint of effectiveness of the laboratory, nothing is more important than the adequacy and condition of the specimen received for examination. If specimens are not properly collected and handled, or are not representative, the laboratory can contribute little or nothing to any investigation or to the welfare of the patients." Because of the critical importance of the quality of the specimen, the specimen collection manual must be explicit in its description of the needs of the laboratory regarding clinical specimens submitted for examination. The manual must address at least the following items:

1. Laboratory policies regarding time of operation, after-hours arrival of specimens and reference cultures.
2. Specimen collection technique. The use of detailed charts is helpful and will be discussed in other chapters of this book. Firm policies on the selection, collection and transport of the specimens to the laboratory must be presented.
3. Criteria for rejection. Clinically relevant results are not obtained from specimens that have been improperly selected, collected or transported to the laboratory. The action to be taken on unacceptable specimens must be described. After these policies are established by the laboratory director and included in the procedure manual, the