A document-management process is vital for ensuring that staff access and use only the most current versions of documents, and that everyone is following the same process sequence and procedure instructions. By doing so, performance variations that can affect the quality of laboratory services and results are greatly reduced or actually eliminated.

Laboratory Documents: Development and Control; Approved Guideline — Fifth Edition (GP2-A5), published by Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) in March 2006, presents the components of writing and managing documents for the clinical laboratory and describes what laboratories need to do to meet published regulations and accreditation requirements, as well as international standards.

Establishing a quality-management system (QMS)

As stated in the newly published CLSI guideline: “This edition of GP2 is applicable to any laboratory, regardless of size, scope, or specialty (including point-of-care testing), wherever the laboratory may be in the transition of its quality program from traditional quality-control (QC) and quality-assurance (QA) practices to the concepts of quality-management systems.”

To establish a complete QMS, an organization needs to define the infrastructure known as the quality-system essentials (QSEs) necessary to provide quality care to patients. The 12 QSEs are the foundational building blocks that support the organization’s work operations, also called “path of workflow.”

Every service has a defined path of workflow, which represents the sequence of activities from the initiation of a request for a service, through the provision of that service, and any necessary follow-up. In the clinical laboratory, the path of workflow begins with an order for a laboratory examination (test), proceeds to provision of the report and any necessary follow-up consultation. Each healthcare organization can use the same QSEs to manage its respective path of workflow, thus developing one universal set of policies, processes, and procedures for the QSEs that apply to all the services in the entire organization. Laboratory Documents: Development and Control (GP2) is the backbone of the QSE “Documents and Records.”

Practical application for laboratorians, manufacturers, and educators

According to the guideline, “GP2-A5 is intended for use by the following: administrative and technical personnel who develop laboratory documents; manufacturers; and educators.” But, are these audiences actually using this guideline in day-to-day practice? It seems that the answer is a resounding “yes.”

In 1999, two organizations, Capital Health Laboratory Services-UAH and Mayo Clinic Department of Laboratory Medicine and Pathology (DLMP), were both introduced to the CLSI quality-management system model — including GP2, as well as complementary documents, Continuous Quality Improvement: Integrating Five Key Quality System Components (GP22) and Application of a Quality-Management System Model for Laboratory Services (GP26). Both organizations first implemented the QSE “Document and Records” using GP2, and both organizations had similar positive outcomes.

Joan Carlson, MLT, BSc(MLS), senior manager of quality systems/operations for the Capital Health Laboratory Services-UAH site, explains, “The first thing we tackled was redesigning document management completely around GP2, which took about three to four months. Implementation and conversion of existing documents, albeit for a large reference laboratory, took approximately two years, including time to create process documents, which was a new and exciting aspect to us.”

At the Mayo Clinic DLMP, GP2 has been important to the work of Kris Arney, quality management, who had a similar experience with implementing the first QSE, “Documents and Records.” Arney explains, “By implementing format management and standardizations, all of our employees are assured of having the most recent documents to perform their laboratory testing. In addition, we use these to train all our staff. Finally, these documents are available to inspectors who come to the DLMP to ascertain if we are meeting our regulatory require-
ments. It took three years to fully implement this QSE. This implementation required substantial education, provided by our quality-assurance staff. Also, the QA office performed internal audits to determine if the DLMP laboratories were meeting these QSE requirements. The benefits far outweighed the good deal of effort.”

When asked about the practical use of the CLSI document, Arney says, “GP2 is very valuable for establishing document management. It helps define the different types of documents, and how and when to use them. It helped us establish the format for our documents and the process for implementing document control, master index, and master files.”

She adds, “CLSI documents provide instructions, guidelines, and examples of how to implement in laboratories. When in doubt, consult the CLSI documents. They help provide the expertise, and then it becomes the norm. They are always accessible for our staff to review or consult, and are accessed as a daily resource. They help our laboratories meet the regulatory requirements.”

For laboratorians, GP2-A5 explains how to flowchart work processes, how to identify the procedures that support those processes, and provides examples of those processes and procedures. For manufacturers, GP2-A5 describes how to reorganize operators’ manuals for setting up and operating their automated instruments in more of a laboratory-workflow sequence and presents analyte information in a more reader-friendly tabular format. For educators, GP2-A5 provides the tools to give students in medical-technology-training programs an overview of how the work really happens in a laboratory, not by individual analytes but by sequences of work activities — each of which needs to have structure.

Renamed and reorganized for a clear focus

Previous editions of the CLSI document were titled Clinical Laboratory Technical Procedure Manuals and focused on elements to include in laboratory-examination procedures. This edition has been renamed and reorganized to provide:

- the use of process flowcharts to depict the linkages between laboratory procedures;
- writing guidelines for process and procedure documents for the pre-examination, examination, and post-examination activities that represent the laboratory’s path of workflow;
- writing guidelines for process and procedure documents specifically for multitest automated analyzers;
- writing guidelines for procedures for laboratory information systems; and
- an introduction of the management and control of laboratory documents after they are approved for use.1

“Now, using this updated version of the GP2 guideline, laboratory documents will more accurately represent the way work actually sequences through the laboratory.”

“What is most important for laboratories to know is that this current CLSI guideline — and the previous version, GP2-A4 — were a radical departure from other versions of this document over the years,” says Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ)CQMgr, quality systems consultant. Berte, who is a member of CLSI committee that developed the document, further explains, “What the laboratory is currently calling standard operations procedures (SOPs) from GP2 versions A1 to A3 were based on individual analytes. Now, using this updated version of the GP2 guideline,

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laboratory documents will more accurately represent the way work actually sequences through the laboratory. Work does not happen one analyte at a time. GP2 readers no longer have to make the mental leap from reading an old SOP approach based on a single analyte and then walking over to the instrument and trying to figure out how to make that instrument run 50 analytes on one sample.”

Arney concurs, “The distinction of the GP2-A5 is that this edition discusses the use of flowcharts as a valuable tool to help develop and define a process. Flowcharts identify a series of procedures that define who, how, what, where, and when something happens; this defines the process. Also, flowcharts are helpful if you want to improve a process that is not working well. By examining a process from beginning to end, redundancy, hand-offs, and duplications can be discovered. The flowchart can then be revamped to address these issues. Flowcharts can also be beneficial in developing training modules.”

Beyond the major difference of including process flowcharts to depict linkages between laboratory procedures, GP2-A5 also provides a generic flowchart for setting up and running an automated analyzer. This flowchart allows a laboratory to write specific procedure instructions for any given analyzer used in the laboratory, in conjunction with information from the manufacturer’s operator manual.

Newly included guidance on how to format computer instructions is based on the way the computer presents the information to the reader; for instance, scrolling, clicking (in a Windows-based environment), or entering information with a cursor and prompt.

Finally, an expanded section on developing and controlling laboratory documents has been added. This new information is derived from the initial guidance given in CLSI document, A Quality Management System Model for Health Care (HS1). The issues regarding document development, approval, and control were drawn from HS1 and...
According to Berte, the distinguishing highlights of GP2-A5 include “more detailed information about laboratory processes, more examples of process flowcharts, and more guidance about the procedures that support them. There is also additional information about automated analyzers, laboratory information systems, and document control.”

**A resource for compliance**

While individual countries have specific regulatory and accreditation requirements, a common goal among all of them is to define, document, and train for their particular organizations’ activities. GP2-A5 is a guideline for how to implement requirements that have been established by regulatory and accrediting organizations and international standards for laboratory documents and procedure manuals.1

CLSI has developed the “how to” tools for implementation of quality requirements prescribed by the International Organization for Standardization (ISO). ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence*, defines standards for quality management in the medical-laboratory environment. The U.S. government regulatory requirements, such as the CLIA ’88 legislation, and various U.S. accreditation agencies are incorporating requirements from ISO 15189:2003 into their programs. GP2-A5 includes requirements of the ISO 15189:2003 standard for pre-examination, examination, and post-examination laboratory documents.

Moreover, all future CLSI quality-management-systems documents published will include guidance on how to meet the requirements of the international standard, where appropriate, explains Jennifer McGearry, MT(ASCP), MSHA, CLSI director of standards and quality.

**Role of laboratories and healthcare organizations**

Laboratories and healthcare organizations that build accreditation requirements into their daily practice will be well prepared for inspections and assessments. Berte notes, “If laboratories follow the guidance presented in GP2-A5, they will meet the regulatory and accreditation requirements for laboratory documents.”

Arney says, “CLSI documents help provide a place to start when developing a new process. They provide terminology, definitions, and valuable expertise.”

Overall, Carlson explains, “The GP2 guideline is well-written and easy to understand. I believe using this guideline to create documents will not only assist the laboratory staff in meeting the most rigorous standards of any inspection or accreditation organization but also — and most importantly — allow those who use them to respond positively to the benefits they get.”

Melissa J. D’Archangelo is a marketing and communications consultant based in Chester Springs, PA.

**References**


**Related Documents**

CLSI offers a collection of products to support the implementation of a complete quality-management system. For more information, visit [www.clsi.org](http://www.clsi.org). Related documents that complement the new GP2 standard include:

- A Quality Management System Model for Health Care; Approved Guideline — Second Edition (HS1-A2);
- Application of a Quality Management System Model for Laboratory Services; Approved Guideline — Third Edition (GP26-A3); and

CLSI welcomes comments and questions about the documents; this feedback serves as the basis for updated document editions. All comments and responses are formally addressed and published in the next edition of the document. For more information about Clinical and Laboratory Standards Institute references and best practices, visit [www.clsi.org](http://www.clsi.org) or call 610-688-0100.