

# Quality Qorner

## Break the Old Paradigm—Once and for All!

I must have pushed your hot button about laboratory documents in the May Quality Qorner with Myth #2, “Our SOPs meet inspection,” because I received lots of comments and questions from several readers. Here is an example: “In one lab section, the SOPs are so long they are in a 8-inch binder that can hardly be opened and filled with information the techs will never use... basically the SOPs are useless and everyone uses package inserts for procedures or if any questions arise. How can you have an SOP that follows format but is useful to the techs?”

It appears there is still a lot of confusion about requirements for laboratory documents. This whole thing pushes my hot button, too! Despite all the changes made since 2002 in the CLIA regulation, CLSI guideline GP2, and the CAP General Checklists, not enough laboratory professionals seem to be aware that we are no longer strapped with an “NCCLS format.” Let me explain why and what your laboratory should do about it.

The original 1980 NCCLS guideline, GP2, Clinical Technical Procedures Manuals, contained a list of suggested contents for technical procedures *manuals*. Somehow the idea about information that should be contained in the manuals got corrupted into a standard required format for *each procedure*. Early on, blood bankers, histotechnologists, cytotechnologists, and microbiologists recognized “the NCCLS format”—about quantitative manual testing by analyte—as unusable in their respective settings. The “format” actually did not work for automated testing procedures either, because analyzers do not test the analytes manually, one at a time, in alphabetical order, although laboratory manuals are often organized this way. In addition, the “format” was completely irrelevant to preanalytical sample collection and processing, as well as to computer procedures.

Complicating the issue for many years was the CAP General Checklist requirement that laboratory *procedures* were “in substantial compliance with NCCLS document GP2.” Hundreds of deficiencies were cited over the years for not following the “format” supposedly “required” in NCCLS guideline versions GP2-A1, -A2, and -A3. Laboratories brave enough to write documents to meet the needs of the staff that did the work (instead of the desire of the inspectors) were forced to cave in and revert, or waste space and staff patience with a series of “Not Applicable” sections in each document, or (like my transfusion service) argue fervently that the checklist item misinterpreted the guideline’s intent. As clearly stated in the Introduction section of those 3 versions, GP2 provided guidance for manuals, not a standard for a single document—all of which was completely optional.

Due to our firmly entrenched (but erroneous) paradigm that published requirements are for individual documents, laboratory professionals continue to misinterpret CLIA requirement 493.1251 (2003) to be applicable to individual procedures. To the contrary, the CLIA requirement clearly states, “...the procedure *manual* must include the following...”

As a result of the dawning awareness, first experienced by the blood bankers, that quality management systems are based on work processes, a small group of interested parties convened to revise NCCLS guideline GP2-A3 in 2000; version GP2-A4 was published in 2002. This version presented a radical departure from a perceived procedure-based document “format” to the concept of

documenting preanalytic, analytic, and postanalytic work processes, then writing procedures that provided instructions for the individual activities in those work processes. The guideline suggested that preanalytic information be contained in separate manuals, for use by laboratory and non-laboratory sample collection personnel who are closest to the patient. The guideline also offered a process for setting up and operating automated analyzers—supported by information from the operators’ manuals—and suggested that analyte-specific information could be contained in ready-reference tables instead of individual multi-page “procedures.”

The CAP removed the checklist requirement to be in compliance with “the format” in 2003. Yippee!! We were finally free from the trap of writing documents to please inspectors in an outline that did not work! Now the task is to get the inspectors to understand that there is no more “format!” A reader complained to me last month that the inspectors wanted to cite their transfusion service as deficient for not having documents in “the NCCLS format.” This supervisor challenged the inspector to show where it said they had to do that. She then showed them a copy of GP2-A4 and the different types of documents it contains; the inspector begrudgingly removed the deficiency. *Message to laboratory inspectors:* Wake up! Just because your laboratory lives in the old paradigm when it does not have to should not constrain others that have chosen to follow the updated guidance!

Speaking of updated guidance, how does your laboratory know when CLSI (formerly NCCLS) guidelines have been revised and are available? Is your laboratory an institutional member of CLSI? If not, it should be! Why? Because your laboratory will benefit from the efforts of hundreds of volunteers who write guidance documents and provide examples to share with laboratories like yours. For a few hundred dollars per year, your laboratory will have access to a searchable database of *all* CLSI guidelines and standards on all topics and specialties. As an active member of CLSI, your laboratory can participate as writers, advisors, observers, and commenters on drafts of new guidelines and revisions of older ones. There is no reason not to be current.

I strongly urge your laboratory to obtain a copy of the just-released CLSI GP2-A5, now entitled, “Laboratory Documents: Development and Control.” The guideline contains several examples of laboratory process and procedure documents that more accurately reflect the way work actually happens in the laboratory. You can obtain one at [www.clsi.org](http://www.clsi.org).

It is time now to release my hot button and take a deep breath of fresh Colorado spring air. Keep the e-mails coming!

### *This Month's Quality Quote:*

“Few people read business documentation for recreation. They read it for solutions, which they want quickly.” —*Adrienne Escoe*

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