

# Quality Qorner

## Low Carb Documents

My local newspaper ran a column after the holiday season by a woman who is a former mayor and state representative and has been actively involved in the community for a long time. She included a poem by an anonymous author entitled, "Twas the Month After Christmas" that began like this:

*"Twas the month after Christmas and all through the house  
Nothing would fit me, not even a blouse.  
The cookies I'd nibbled, the eggnog I'd taste,  
All the holiday parties had gone to my waist..."*

The poem continued in its traditional style and it was as if I had written it about my tasty holiday experience! It ended with the line, "Happy New Year to all and to all a good diet!"

I've been trying hard to make low carb living part of my lifestyle. It's definitely a struggle at holiday time, but for the rest of the year it's doable...and desirable. A low carb diet pares us down to eating essential, healthful foods that are good for us and keep our bodies healthy.

As a long-time inspector, assessor, consultant, and reader of laboratory documents, it's apparent to me that laboratory documents need to go on a "low carb diet." Just as unused carbs turn into fat that's unhealthy for our bodies, unused laboratory documents turn into fat procedures manuals that are unhealthy for laboratory staff.

It's not healthy to have:

- procedures that are so lengthy as to be incomprehensible;
- procedures that are missing essential "how to do it" steps but instead include unnecessary information;
- documents that provide details about individual analytes but don't describe how to do the work;
- procedures that describe actions that others take but not the information the reader needs to know right then;
- procedural revisions sitting in a big in-pile in the supervisor's office because it's so much work to rewrite them; and
- procedures manuals that are only trotted out when the inspectors come.

I could list many more problems with the way laboratory procedures manuals have been historically written and organized, but I'm sure you know well what I mean. So the challenge is how to put our laboratory documents on a low carb diet, trim the fat down to lean muscle, and make them healthy.

Food is made up of proteins, carbohydrates, and fats, each with an important role in maintaining the human body. However, there can be too much of a good thing; extra pounds result from accumulation of unused carbohydrates and fat. Using this analogy, we could say that the "meat" of a laboratory document—that is, the information needed to fulfill the document's purpose—is the protein and that untimely, surplus or out-of-place information is the carbs and fats that need elimination to make the document function more effectively. Continuing with the analogy, if a vital amine (aka, "vitamin") is missing from the food in our diet we can suffer dire consequences. Likewise with laboratory documents; when vital information is

missing from procedural instructions, errors and omissions occur that can compromise patient safety.

Probably everyone reading this has purchased a diet book at some time or another—I've found the "South Beach" ones to be particularly useful. Fortunately, there is a new diet book for laboratory documents that has reorganized protein, carbs, and fat into palatable document "recipes." Just as recipes can be organized into categories such as appetizers, entrees, and desserts, laboratory documents can be categorized into policies, processes, and procedures.

The first edition of NCCLS guideline GP2 was released more than 25 years ago with a "recipe" for the contents of a laboratory procedure that was based on individual analytes. However, not all laboratory procedures are analytic. For example, neither the entire preanalytic portion of the laboratory's path of workflow nor the related laboratory computer system procedures are about testing. As a result, the original recipe did not fit all types of laboratory documents and the added carbs and fats have made the documents extremely unwieldy. Therefore, in 2002, the NCCLS (now the Clinical and Laboratory Standards Institute, CLSI) began a recipe makeover.

A hard-working group of volunteers has just updated guideline GP2 into the new edition that is being released by CLSI this month. GP2-A5 was renamed *Laboratory Documents: Development and Control*.<sup>1</sup> This guideline represents the ultimate low carb diet for laboratory policy, process, and procedure documents. Laboratories that actually went on this document diet and have seen the results contributed the examples in the appendices. You won't believe the difference! Talk about slimmed down!

As individuals, we all know that we should eat better and get more fit and trim, likewise we all know that our laboratory documents should follow the same advice. However, it's what we do about what we know that actually makes the difference.

*"Every last bit of food that is bad must be banished  
till all the additional ounces have vanished..."*

1. CLSI. *Laboratory Documents: Development and Control*; Approved guideline GP2-A5. Wayne, PA: Clinical and Laboratory Standards Institute, 2006. Available at: [www.clsi.org](http://www.clsi.org)

*Lucia Berte is a quality systems consultant in Westminster, CO who subjects herself and her clients to low carb (document) diets. References furnished on request.*



Send comments/questions to [lberte@att.worldnet.net](mailto:lberte@att.worldnet.net).

Lucia M. Berte  
MA, MT(ASCP)SBB, DLM;  
CQA(ASQ)CQMgr