

A close-up photograph of a man in a dark suit, white shirt, and patterned tie. He is looking down at a document he is holding, with a focused and slightly smiling expression. The background is blurred, suggesting an office setting. The lighting is warm, highlighting his face and the texture of the paper.

Get a Grip on Document Control

An auditor's secrets for maintaining and improving process media

by Mary McAtee

Every year I perform gap analyses on organizations that are building compliant quality management systems. A client I recently visited was well along the path of documenting the company's system. The quality manager and a very enthusiastic administrator spent a couple of hours taking me through their methodology for developing documentation. They had created an impressive style guide that defined text layout, font styles and format. The templates they had created for procedures and work instructions were logical and well thought out. The process for document issuance and recall appeared relatively bulletproof—even if a bit labor-intensive.

To see how this system behaved in action, I selected the contract review procedure and a rather complex setup document for a spray paint apparatus to follow through to the point of use. Each document contained sophisticated, exacting language and nearly five pages of text.

My first stop was the legal department, where I observed that all the attorneys were able to produce the latest revision of the document and demonstrate their understanding of its content. The quality assurance manager beamed like a proud papa as the neat binder of documents was produced for my inspection.

Then I stopped at the first of four paint stations on the shop floor. I asked the operator how he knew which setup parameters and acceptance criteria to use. He rummaged through a toolbox and produced a laminated piece of cardboard coated with various hues of over spray. The card contained a meticulous, hand-drawn table, matching paints, PSI settings, materials, nozzle types, bake times and finish criteria. I flipped through the work instruction and chuckled appreciatively. The operator had accurately reduced five pages of verbose text to a concise table that he could refer to at a glance and apply to his task at hand.

The operator at the second station was using an older revision of the correct document. She hadn't switched to the new version because the changes were minor, and she'd spent an hour highlighting sections and annotating her Spanish version to make it easier to use. I will spare you what we found when we contacted the other two sites using the same document.

Later, as I sat down with a very deflated QA manager in the conference room, I commented on how lucky he was that he had people who cared enough to document what they were doing. During the ensuing discussion, we came to some common but painful conclusions:

- The documents were written as a required step in the compliance process, not as a value-added proposition.
- The documents' style, format and vocabulary were rigid and identical for executives, engineers, administrators and machine operators.
- Process owners weren't included in the writing process or, except for managers, in reviewing the documents.
- The change process wasn't accessible

to the people most affected by document inadequacies.

■ The change process was adequate for more static processes, such as contract review, but couldn't support the rapid demands of manufacturing—especially across various facilities.

I would safely bet a business lunch that most managers couldn't walk around their shop floors without finding a controlled document violation of some sort. In fact, the registrars I speak with tell me controlled document violations are their most common finding.

Developing an effective, value-added controlled document system requires planning and monitoring just like any other element of a quality system.

First is intent. Why are you making the considerable investment in a document control system? There appears to be a direct relationship between the return an organization can expect from the system and the imagination and creativity of those who developed it. If the intent was to make sure the minimum requisite documents were written and accessible, you can expect a minimum return. If, on the other hand, your team asked itself how each system element could best serve the particular process, the returns would be enormous.

Allow for improvement over time

Developing reliable and consistent process execution is critical for effective production planning. It's the bedrock of any meaningful continual improvement effort.

To begin, try to separate redesigning processes from documentation. If you see obvious flaws or opportunities for improvement, act on them. Just remember, dismantling and reassembling each process as you document it generally causes more problems than it solves. This path is akin to designing each room of a house as you build it. Typically, this method yields a never-ending documentation timeline with new methods and processes that haven't been properly validated and are unfamiliar to the system's users.

Document your processes as they exist now and accept that you'll be including some warts and flaws with them. But always predicate this approach on developing and tracking pertinent system metrics that will permit you to identify flaws and

drive ongoing process improvement. You'll find that a measured number of cogent document changes over time will improve your documentation faster than trying to write perfect documents at the outset.

Involve the right people

Make sure the people who will be using the documents are involved in writing and reviewing them. The line manager's or engineer's expertise may be one or two levels above the information needed to document a process. The

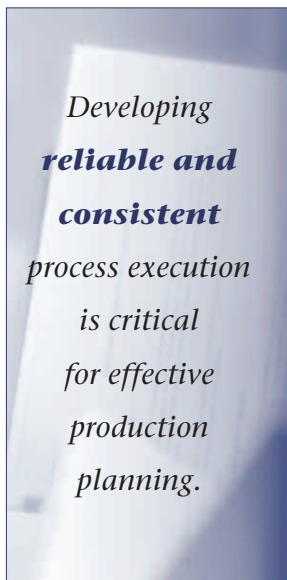
engineer will know the proper PSI setting for the paint station, for example, but it's likely only the operator can tell you that the system drifts and the settings need to be checked and adjusted every hour.

Don't be afraid to have operators document exactly what they do and how they do it. Someone else can polish the language and format if needed. Getting end users' perspectives will reduce the number of edit cycles required before a document's initial release. User acceptance of these documents also increases if they've had a hand in creating them.

Consider document ergonomics

Documents are tools and should be subject to the same initial selection criteria. For example, when you design or purchase a gage or tool, it's to fill a defined need with very specific criteria. Is the tool accurate enough for its intended use? If used correctly, will it give repeatable, reproducible results? Is the tool's design and configuration appropriate for its intended use? Can the user read all the indicators easily while using it? Have personnel been taught how and when to properly use the tool? Is there a defined storage container or location that protects the tool while ensuring accessibility?

All of these criteria apply to documents as well. Every one should have a



purpose, and you should anticipate very specific returns when it's used. Layout, and even the media used to access a document, should be relevant to its use. Design documents that communicate content accurately and quickly. I've found that line workers prefer using short, succinct flow-chart and table documents rather than flipping through pages of text. They need to find the information quickly and get back to the task at hand.

Operators and inspectors usually welcome color photographs of defects and acceptance criteria. Clearly defined criteria make operators more autonomous and can significantly reduce the time material sits awaiting additional evaluation by a material review board or additional parties.

Invest in accessibility

Those of us who've been around long enough remember the old half-door on the documentation room. You waited there to request authorized copies of a document or to initiate change requests. If the door was closed, it meant the nice little old person (or the crabby little old person) was retrieving outdated documents and issuing new ones. That door was closed a lot of the time.

The fast-paced, lean environments of most of today's global manufacturing organizations demand real-time access to current, accurate information that's subject to frequent changes. Consequently, document binders on the shop floor generally aren't an effective means of access. Posting controlled documents at various workstations merely increases the retrieval and change-management nightmare.

Providing electronic access to documents at the point of use is the optimum solution. This ensures real-time access to the most current documents for all interested parties. The hardware options are abundant and include PDAs and touch screens for very basic use. Exploiting the Web to access documents online overcomes distribution problems involving time and distance from facility to facility.

A little investment analysis will tell you that electronic document access becomes almost absurdly cost-effective when weighed against scrap, rework and customer satisfaction costs associated with outdated document use, or employing people to manage your paper system.

Two of my clients have convinced me that electronic document access is a matter of desire and can be implemented in any environment by a motivated organization. The first client, a high-speed injection molding and assembly job shop, is driven by ever-changing customer requirements and quick turnaround demands. The second is a meat-processing facility that is, by nature, continually cold and wet.

Both places employ a diverse, multilingual and not terribly computer-literate work force. Each has made extensive use of flowcharts with process symbols, along with detailed illustrations and photographs, to minimize text in multiple languages. This approach also requires far less training for new employees and readily supports changes in process requirements.

Both clients use touch-screen technology, but the meat-packing firm has taken it even further. Because of the mobile nature of its process work flow, it uses rugged, moisture-proof wireless computers mounted on forklifts and rolling workstations.

Both organizations are confident that savings in other areas have more than offset their investments.

Manage document changes efficiently

If I asked you what the average cycle time is for processing document changes within your organization, would you know? Change requests awaiting approval in a supervisor's in basket and later distributed by hand cost companies both time and money. Ensuring that nothing is missed or forgotten in a manual system requires more expense, and the process is still prone to lapses.

Developing or purchasing an electronic change request/management system is a prudent investment. These systems can reduce the cycle time for incorporating and

distributing changes from weeks to a couple of days. Many of these systems permit end-users to initiate change requests for various process documents. This results in more accurate document content and almost always reduces compliance audit findings.

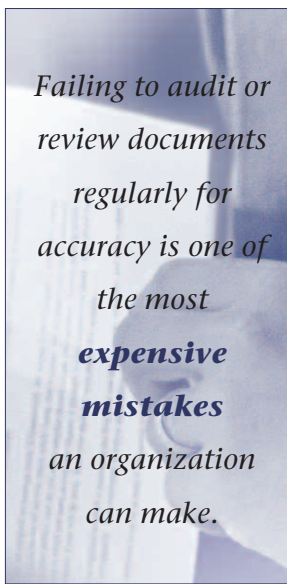
Keep content current and accurate

Failing to audit or review documents regularly for accuracy is one of the most expensive mistakes an organization can make. All too often, and despite the work that went into creating the documents, they aren't reappraised until they wind up in an auditor's hands. Consider placing key process documents on a scheduled review cycle as part of your internal assessment program. This will ensure that you get the maximum benefits from the document and reduce unpleasant audit surprises.

Demand value and return from your documentation system, then develop metrics to determine if you're getting that value and return. Put an effective and inclusive document control process in place that will help you get there; it's potentially one of the best investments you can make for your organization.

About the author

Mary McAtee is a mechanical engineer and longtime quality professional. She began her career as a reliability engineer in the defense industry more than 25 years ago. After spending several years as a contributing member of the Joint Electronic Defense Engineering Council, she became interested in ISO compliance standards. McAtee has been a lead assessor since 1991 and was one of the first TickIT assessors in the United States. She has assisted several organizations in their quest for registration and is currently the director of implementation services at Quality Systems International, an IBS America Co. E-mail her at mmcatee@qualitydigest.com. **qd**





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