

# Quality Management Systems: Module 1

**DAVID KORCAL:** In a good procedure, I want to see that they're indicating what personnel can do the different steps of that procedure. So they're going to define who can do a corrective action, who do they need to communicate to, who can do root-cause analysis-- who's been trained on root-cause analysis, in other words, or determining what that initiating cause is. So there will be that assignment of responsibility in that procedure.

Beyond that, it's going to spell out the different steps. We obviously need to identify the problem. We need to communicate that we bring in the appropriate resources to fix the problem. And we fix that initial problem. If a client didn't get a report, we're going to get that client their report. All right. There may be a fax board problem that's causing all our faxes not to go out. But we're going to at least resolve that client's problem.

So we're going to fix the initial problem. And then we're going to move on and say, hey, is this problem systematic or not? And so that step's got to be in there, that we're going to look at that initiating cause. And then finally, once we've chosen and implemented what we feel is the right fix for this or the right corrective action for this, we're going to monitor it. We're going to look and see, does that procedure say we want to monitor this corrective action to see if there's a re-occurrence? All right.

If we get a lot of reoccurring problems after we've put in the right corrective action or what we think is the right corrective action, we may not have gotten it. We might have to go back to the drawing board and select a different corrective action for that process.

Well, that quite often starts with a disconnect, I think, between the procedure and the staff. It might be that the procedure doesn't have a lot of detail in it. It might be the staff is unaware of the procedure. But if you look, what you'll see is probably a procedure that doesn't have as much detail or is maybe even completely missing, that would be one lab maybe that's just getting into the quality systems and hasn't got a policy and procedure on corrective action yet.

But it might be-- start there. And then there may not be any training going on. And so when you interview the staff and are asking about corrective action process, you might get blank stares or, yeah, I think we have a process for that, or those types of responses. And so there's a disconnect. So they're not being trained on their own system procedures or these overarching procedures that kind of form the basis of our quality system.

And so then that translates into records. You start looking at the records generated from that type of a process. And there are going to be few and far between. There's not going to be a lot of detail. A lot of them will just fix the initial problem or the problem at hand. They won't go into looking for the root cause or initiating cause of that problem. So that's kind of the things that we'll see in labs that are-- haven't made that transition from just having the paperwork or

the structure in place to actually implementing it and putting it into action and really reaping the benefits of a good-quality system.

Quite frequently, if we look at a real sketchy document, it might just reiterate the standard, whatever standard they're following, or-- I mean the corrective action portion. And that corrective action portion may say that you need an individual who-- you need to define who can initiate a corrective action and who can stop work and start work and those types of buzzwords. And you'll see those steps in the procedure. But you won't see any explanation beyond that in the procedure. So it might go from identify the problem, fix the initial problem, do root-cause analysis, monitor, and close the corrective action. And that would be a sketchy procedure.

A more detailed procedure is going to flesh those areas out. And it's going to go into detail about who can identify the initiating problem, who do they need to communicate that to. We want to see that they're communicating to their supervisor, those sorts of things-- fixing the initial problem, obviously.

But then what has to be raised? Severity of the problem. We had clients who were impacted by this problem. Maybe that's one where we want to see in the procedure that they're going to contact those clients and let them know that there was a problem with their work. We're going to want to see that they're doing something above and beyond in those particular areas. Those have to get looked into a little deeper.

We have to start doing a full-fledged corrective action on those processes-- and then when it gets to a root cause, just defining what it is, letting people understand that it's not a narrow view of this. We want to broaden it. And we want to look and say, hey, this might be across the laboratory. A client didn't get their report. But what happens if none of our clients are getting their faxed reports-- so instead of just looking at this one client's problem, expanding that view to the laboratory as a whole and just defining that. And then, as a good friend of mine said, adding in some of the tools that might be used for a root cause, as well, into that procedure would be a good addition to that as well.

And then when you get to monitoring, flesh that a little more. What types of things can be used for monitoring-- ongoing quality control. You can design matrices that would be different test points during that next couple of months to monitor that. Maybe it's the fax error log for those reports that aren't getting out that you're going to then monitor over a period of time.

And I think one of the things that corrective actions does as opposed to anything else in the quality system is it brings to light for those folks who have to sit down and work through a problem the importance of keeping good records. And it becomes very glaring when they're trying to troubleshoot a control problem on a piece of equipment. And they go, OK, well, when did we open that bottle of calibrator?

Well, and then the bottle's not dated with an open date. So that record isn't there. And now there's a hole. And they go, oh, you know what? I understand now why we date these-- because I really need that information now.

I think in the labs that I've gone to where I see a good understanding of corrective actions is it starts with a good procedure that spells out the steps of that lab's corrective action process. And it's got enough detail so that folks really have a good understanding of that and look at that from a number of different ways.

We can interview staff as we're going through the laboratory and see if they've got a good handle on that process and that procedure. And then we can turn to the records and look at the records that are being generated from that procedure. And that would be your corrective action forms that actually detail what you did when a problem arose in the laboratory.

This is something-- because we all know problems happen. It's just a fact of life. And a lot of times, we fix the problem and move on. And we forget to do the detail work, the documentation of that, and actually looking beyond just fixing the initial problem.

So does this lab have a good understanding of that? The good ones seem to. And they'll generate a lot of records from that. And when we review those records, we find that there's a lot of good detail in those records, that they've looked beyond just fixing the initial problem. They've looked at trying to address the initiating cause, or we call it the root cause, what really started that whole chain of events that led to that problem.

So that's the good labs. There seems to be good understanding by the staff. They got a good procedure. And then because of that, they end up with decent records.