

4.10 – Corrective Action

This section describes the interpretation and application of section 4.10 of the 15189 standard.

What is the intent?

The intent of this clause is to ensure the following:

- The laboratory has a plan in place to respond to complaints or other nonconformances.
- The employees have a means to communicate quality issues directly to management, and management acts on this information.
- The focus is on the process, not the person.
- The laboratory takes action based on the root cause, and not just the symptoms.



What are the key requirements?

- Develop a procedure for an investigation process to determine underlying cause(s) of the problem.
- Determine if the problem is random or chronic.
- Document changes made in response to the problem and evaluate effectiveness.
- Get participation of key players.

The laboratory is an extremely busy environment. Even with an attentive management team and well implemented QMS, “things happen” that fall outside of the expectations and sometimes may not be detected until later down the path.

How do we then control deviations that actually occur? The answer of course depends on the seriousness, the severity, and the risk of recurrence of the deviation. The response needs to be a measured and should be commensurate with the deviation in question.

15189 Walkthrough Course – Sample Content

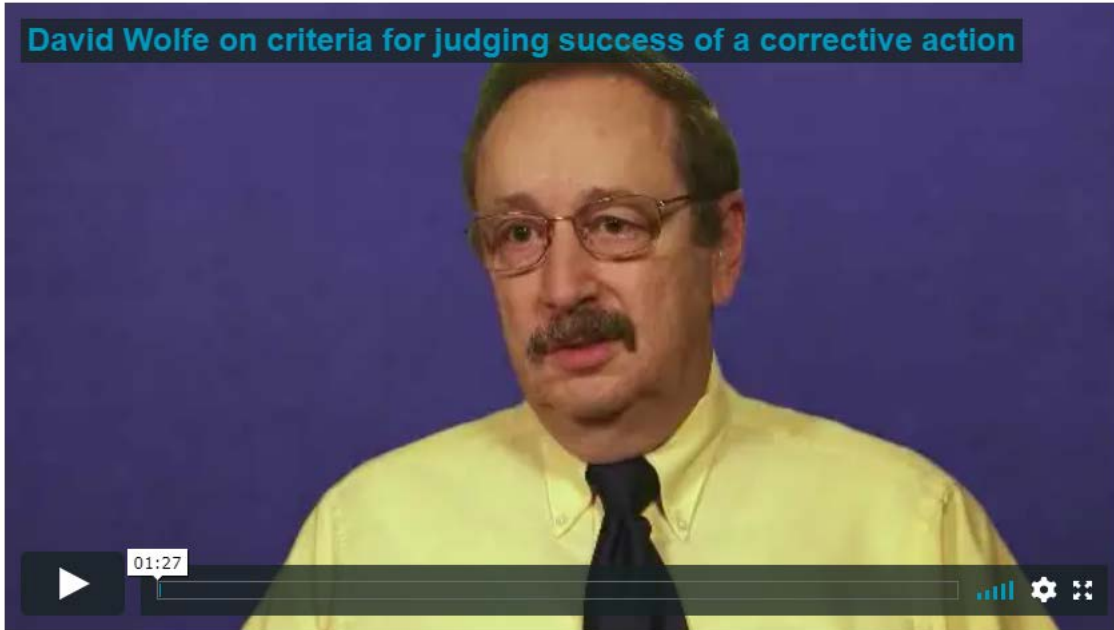
- Some deviations need only a correction or remedial action; others may need a small investigation.
- Still others may need root cause analysis and input from subject matter experts.
- Root cause analysis helps identify what, how, and why something happened.
- Once a root cause analysis is made and the underlying cause is identified, the team devises an appropriate corrective action plan, begins the implementation of the plan, and develops monitoring mechanisms to track and measure effectiveness of the actions taken to prevent further recurrences of the deviation.



[Article on root cause analysis pitfalls from ISMP \(Institute for Safe Medication Practices\)](#)

What are the benefits?

- Surfacing of issues becomes quicker.
- It enables better follow through on employee concerns.
- A more transparent organization is formed in which value is placed on identifying issues, not hiding them.
- Complaints and issues raised by all sources—employees, vendors, and customers—are placed before management. Management acts promptly on all concerns.
- Corrective action takes you beyond “putting out the fires” and establishing mechanisms to prevent fires.
- Cost-savings are realized, because fires translate to cost. Corrective action is an investment up front for compliance to ISO; however, it will pay off in the long run.



Question: *What is the difference between corrective and preventive action?*

Corrective Action

- An action to eliminate the cause of a detected nonconformity
- An action taken to prevent recurrence
- An action based on root cause analysis

Preventive Action

- An action to eliminate the cause of a potential nonconformity
- An action taken to prevent occurrence
- An action based on data analysis and/or risk analysis

15189 Walkthrough Course – Sample Content

5.7, 5.8 & 5.9 – Post-examination/Reporting of Results/Release of Results

This section describes the interpretation and application of sections 5.7, 5.8, and 5.9 of the 15189 standard.

What do we look for?

Assessors review:

- Protocols to ensure accuracy of results
- Patient reports that include all required information
- Corrected reports
- Comments indicating quality of specimen if less than adequate
- Reporting units and normal ranges
- Agreed upon time frame for receiving reports between laboratory and requestor
- Validation records from instrument interface to final report destination
- Protocols for establishing and calling critical results
- Use of calling criticals as a quality indicator
- Retention and storage guidelines for specimens
- Safe disposal of specimens procedures
- Procedures for transcribing and releasing results from referral labs
- Problem reports
- TAT reports

How do we audit?

- We check the thoroughness of root cause analysis in generating corrective actions for problems to which they are related.
- We review TAT.
- We verify corrected reports.
- We look at the critical results that were called.
- If there was an instrument problem noted in Section 5.3I, we will check to see if customer was notified regarding delay.
- If numerous corrected reports were from a particular testing operator, we will check training and competency records.
- If corrected reports were due to a miscalculation of values, we will check validation records between instrument and/or computer calculations and manual calculations.
- We will check if corrected reports clearly indicate original and corrected results on same report.
- We will check mechanism to ensure terminated employees' computer access has been removed, disallowing access to patient records.
- We will ask staff to retrieve results and generate a report.

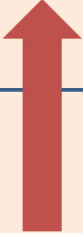


Example of 5.7/5.8/5.9 technical problems that may stem from QMS problems

Example: A physician called to complain about delayed TAT for his patients' results. The physician states this is the second time she has called.

15189 Walkthrough Course – Sample Content

Laboratory management is responsible for ensuring that the appropriate individuals receive result reports within an agreed-upon time interval. So, delayed TAT violates technical requirement clause 5.8.1. However, if a root cause analysis would have been performed after the first instance, the second would likely not have occurred. Performing root cause analysis is part of the identification and control of nonconformities (4.9) and corrective action (4.10). This also demonstrates a failure to fulfill a service agreement between the laboratory and clinician (4.4).

Symptom / Technical Problem 	Repeated delays in TAT	5.8.1
System Cause	Lack of root cause analysis Ineffectual corrective action Lack of process for ensuring service agreements are honored	4.9 4.10 4.4