



## SQA Advisory: No. 15

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TOPIC: Determining the Root Cause

Introduction: Arriving at the root cause of an unanticipated, negative event is difficult however, paramount to ensuring that a proper correction is implemented.

Discussion: When unanticipated, negative events occur in an organization it is important to correct them. It is recognized that these events may be minor or major in nature but categorizing them this way does not preclude the need to fix the problem and prevent recurrence. The focus for correcting the problem must be on the system that yielded it in addition to the negative event itself. Far too often, organizations focus only on the event and how to fix it but fail to analyze the cause of the event to the extent that they can be certain their correction will prevent recurrence. This is true even if the correction appears to be systemic. Without the actual cause, the wrong system may be changed. Furthermore, if a problem is categorized as being “minor”, a focus only on the event is typical.

SQA Position: Root cause is viewed as the fundamental reason for a problem that, if eliminated or controlled, will ensure that the problem never returns.

There are a lot of available investigation tools for determining root cause. They include Pareto analysis, cause and effect analysis, regression analysis, fault-tree analysis, 5-whys, etc. When applied to a problem for the purpose of finding the root cause, these tools are helpful. This is only a small sample of the many tools available.

Below are some other ways to recognize root cause.

- The root cause is not another statement of the problem. For instance, the root cause of an uncontrolled drawing is not a “drawing that was missed, overlooked or uncontrolled.”
- When the root cause is identified it can be used to “turn on” and “turn off” the problem like a switch.
- The root cause points to a system and not the single lapse in a system. Using the previous example of the uncontrolled drawing, the root cause would not state “The computer database of drawings did not contain this one so it was kept in a file on the production floor.” Clearly, one must ask “why?” to this and doing so would go deeper into the problem and closer to the real root cause.

SQA corrective action forms have been revised to help an organization recognize the real root cause. The revision will add 3 yes or no questions that require the respondent to answer. They are:

1. Does the statement of root cause simply repeat the problem found in the nonconformity?
2. Can the problem be turned on and turned off by manipulating the stated root cause?
3. Does the root cause address a process or system?

Beginning immediately, all submitted corrective action responses will be thoroughly reviewed for their stated root cause. In the past this review was primarily limited to the assigned lead auditor however, there will be added oversight at the SQA office.

Given the short lead-time associated with responding and closing corrective actions and the potential rejection of the root cause response, it is imperative that this statement is correct.