Job Aid 2: Appropriateness Criteria 4-11

*…….. Corrective action to be taken shall be determined and documented.* ISO 15189: 4.9 Identification and control of nonconformities

*…….. Corrective action shall be appropriate to the effects of the nonconformities encountered.* ISO 15189: 4.10 Corrective action

These key ISO sentences ensure that the laboratory can apply common sense to the control of nonconformities. It puts the action to be taken, into context, for the laboratory and their customers. Therefore, laboratory management must take responsibility to define criteria for…

**WHAT IS APPROPRIATE?**

or suggestions for when to institute Root Cause Analysis (RCA), the first step in the Corrective Action (CA) process.

1. Immediate CA qualifiers (ensures the system remains responsive to urgent problems)
   * Sentinel event – an occurrence involving death or serious injury to customers or personnel. It is called *sentinel* because the magnitude of the event signals the need for immediate investigation and response.
   * Event involving high cost.
   * Event involving high risk.
     + *Near-miss* (a process variation that did not affect the outcome, but for which a reoccurrence carries a significant chance of a serious adverse outcome)
     + Event that scores *highest risk* in a risk-based scoring system (e.g. amended results)
   * Nonconformities identified through the audit process.
2. CA targeted by management (analysis is essential to understanding which processes have the most important problems so the problems can be prioritized for solutions)
   * Periodic Analysis of aggregate data from NCE log
     + Reveals patterns and trends of nonconformities at a process or system level
     + Does not replace individual event investigation
     + The quality of the aggregate analysis is dependent on the quality of the data for analysis.
       - NCE log event classifications are carefully selected to optimize tracking, sorting, and correlating of data
       - NCE log remains up-to-date
   * CA considerations when periodically reviewing NCE reports
     + Needs of the customer
     + Compliance with legal or regulatory requirements
     + Frequency of the NCE occurrence
     + Cost/benefits tradeoff