

SLMTA 2 Job Aid 1: Risk-based Scoring

Improvement activities shall be directed at areas of highest priority based on risk assessments. ISO 15189: 4.12 Continual improvement

Risk-based scoring serves as a filtering system to determine if an individual event requires immediate entry into the corrective action (CA) process or requires continued monitoring and surveillance. This semi-quantitative scoring system allows a laboratory to measure the magnitude, or impact, of the individual event taking into account the frequency of the event to guide appropriate actions. Even though there is a level of subjectivity and professional judgment involved, this risk-based scoring provides a way to prioritize actions and direct resources to where they will be most effective.

1. Classify the impact, or severity, of the event as *Catastrophic, Major, Moderate, Minor*. Since the *frequency* category does not reflect the number of patients affected by the occurrence, capture the number of customers affected when applying the *severity* category. Your site may further define the different severity levels based on the extent of injury, cost, or risk.
2. Classify the frequency of an occurrence or the probability of a potential occurrence as:
 - *Frequent* – likely to occur immediately or within a short period of time. Definition examples that can be used include, but are not limited to, *happens once per week, happens several times a year, more than 1 occurrence per 1000 opportunities*.
 - *Occasional* – probably will occur (e.g. happens once per month, may happen several times in 1-2 years, less than 1 occurrence per 1000 opportunities)
 - *Uncommon* – possibly will occur (e.g. happens once every few years, may happen sometime in 2-5 years, or less than 1 occurrence per 10,000 opportunities)
 - *Remote* – unlikely to occur (e.g. once in life of the system, may happen sometime in 5-30 years)
3. Determine the risk-based score from the table where:
 - Highest risk – 3 – corrective action needed to eliminate the root cause
 - Intermediate risk – 2 - short-term correction to fix or contain the problem, effectiveness measured through monitoring until the occurrence becomes significant
 - Lowest risk -1 - no action necessary except remedial action to fix the consequences of the problem; effectiveness measured through monitoring until the occurrence becomes significant

Risk-based Metrics:	Impact (Severity)				
		Catastrophic	Major	Moderate	Minor
Frequency (Probability) of Occurrence	Frequent	3	3	2	1
	Occasional	3	2	1	1
	Uncommon	3	2	1	1
	Remote	3	2	1	1

SLMTA 2 Job Aid 2: Appropriateness Criteria

..... *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)
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