Job Aid 1: Risk-based Scoring 4-10

*Improvement activities shall be directed at areas of highest priority based on risk assessments and the opportunities identified.*  ISO 15189: 8.6.1 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)** |
| **Frequency (Probability) of Occurrence** |  | Catastrophic | Major | Moderate | Minor |
| Frequent | 3 | 3 | 2 | 1 |
| Occasional | 3 | 2 | 1 | 1 |
| Uncommon | 3 | 2 | 1 | 1 |
| Remote | 3 | 2 | 1 | 1 |