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| **Job Aid 1 Risk Register Process**  |
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| **ISO 15189:2022 Clause 8.5.2** *The laboratory shall prioritize and act on identified risks. Actions taken to address risks shall be proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.The laboratory shall record decisions made and actions taken on risks and opportunities.The laboratory shall integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness* |
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| **RISK IDENTIFICATION**: Identify risk/s and include enough detailed information in order to assess the risk. Where do you identify risks? E.g. NCE Trends, Customer complaints, audits, staff and user feedback, EQA results or post Management Review. |
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| **RISK ASSESSMENT**: Score the Frequency of occurrence or Probability of a potential occurrence using the following |
| **Frequent** (4) – likely to occur immediately or within a short period of time. Examples that can be used include, but are not limited to, happens daily or once per week, happens several times a year, more than 1 occurrence per 1000 opportunities. |
| **Occasional** (3) – 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** (2) – 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** (1) – unlikely to occur (e.g. once in life of the system, may happen sometime in 5-30 years) |
| Score the **impact or severity** of the event, to judge this, use numbers of patients affected as the mitigation of risk is primarily to patient care and use the following scoring. Take the context into consideration.  |
| Catastrophic (4)  |
| Major (3)  |
| Moderate (2)  |
| Minor (1)  |
| **RISK CONTROL** **PRIORITY** will be calculated which determines the action to be taken.  |
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| 9-16 High Risk corrective action needed to eliminate the root cause. Perform a root cause analysis. (Red = unacceptable risk) |
| 4-8 intermediate Risk: short-term correction to fix or contain the problem, effectiveness measured through monitoring until the occurrence becomes insignificant. (Yellow = acceptable risk if risk is reduced as far as reasonably possible) |
| 1-3 Low Risk: no action necessary except immediate correction to fix the consequences of the problem; effectiveness measured through monitoring until the occurrence becomes insignificant. (Green= broadly acceptable risk) |
| **RISK MONITORING** |
| Monitoring the effectiveness of the action taken to mitigate the risk. |
| **METHOD**: How is the laboratory going to monitor the action? Use the evaluation processes that are already available such as quality indicators, review of technical records, monthly laboratory statistics of customer complaints, audits. Use a contingency plan if required. |
| **TIMEFRAME**: Set a timeframe for monitoring e.g Monthly or 3 monthly, annually.  |
| **RESIDUAL RISK STATUS**: Has the action been effective? If yes and completely removed then no further monitoring is required or although mitigation effective, laboratory decides to continue to monitor.If action not effective, reevaluate by performing RCA or go back to planning in PDSA or perform a risk/benefit evaluation. |
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| **OPPORTUNITIES** |
| These may arise from the same sources of evaluation of the Management System or a SWOT analysis can be performed. |
| The laboratory may decide to have one improvement and opportunity register which includes actions from MRM, improvement projects, identified through risk process or any event during the period of review.Opportunities include – expanding the scope of testing, expanding the scope of accreditation, automating pre analytical systems, purchasing new equipment.  |
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