|  |  |
| --- | --- |
| **Initial Report**Section filled out by reporting party | **Description of Potential Nonconformity** |
| Click or tap here to enter text.*\*Can also include here how the issue was identified, what lead to the detection/discovery of this issue, explain why the activity/behavior could be a potential nonconformity and with what consequence/impact.* |
| **Initial Assessment of Potential Nonconformity**Section filled out by investigating/researching party | **Nonconformity Type (select all that apply)** |
|

|  |
| --- |
|[ ]  Training |
|[ ]  Personnel |
|[ ]  Technical |
|[ ]  Administrative |

 |
| **Source of Nonconformance** |
| Click or tap here to enter text.*\*Where is the nonconformity coming/originate from? SME? Support? Management? Parent agency? Internal/External? Etc.* |
| **Person(s) Impacted (select all that apply)** |
|

|  |
| --- |
|[ ]  Management |
|[ ]  Scientist |
|[ ]  Technician |
|[ ]  Support staff |

 |
| **Policy/Procedure/Standard Affected** |
| Click or tap here to enter text. |
| **Involved Individual(s)** |
| Click or tap here to enter text. |
| **Affected Evidence/Assignment(s)/Case(s)** |
| Click or tap here to enter text. |
| **Risk Evaluation**Section filled out by designated responsible party | **Determine Severity (S) OR Impact Analysis on Previous Work** |
| Choose an item. |
| **Gauge the Likelihood of Reoccurrence (O)** |
| Choose an item.  |
| **Ability to Detect the Incident/Issue (D)** |
| Choose an item. |
| **Assessment and Evaluation Results**Section filled out by designated responsible party | **Risk Priority Number (RPN) = S x O x D OR Significance of Nonconformance** |
| Click or tap here to enter text.*\*Here, lab can enter in the parameters for when action(s) must be taken given the RPN. For example,**Lab can determine that regardless of what the RPN is, if the S/O/D factor is 9-10, then action must be taken. Lab can determine and set ranges for when action is not necessary, recommended, strongly desired, etc. based on Lab’s risk tolerance.**This is a good resource to learn a little bit more about the FMEA model:* [*https://www.iqasystem.com/news/risk-priority-number/*](https://www.iqasystem.com/news/risk-priority-number/)  |
| **Determination of Acceptability of Nonconforming Work** |
| Click or tap here to enter text. |
| **Categorize Nonconformance Elements (select all that apply)** |
|

|  |  |  |
| --- | --- | --- |
|[ ]  Personnel related |[ ]  Measurements related |[ ]  Isolated incident |
|[ ]  Equipment |[ ]  Methods/Procedures |[ ]  Systemic |
|[ ]  Materials/Chemicals |[ ]  Environment related |  |  |

*\*Selected elements should have been addressed above* |
| **Considerations** |
| Click or tap here to enter text. |
| **Actions Taken**Section filled out by responsible/designated party | **Action(s) Taken** |
| Click or tap here to enter text.*\*Does work need to be halted, repeated, reports withheld, or no actions necessary? Corrections made for above affected work? Proceed to corrective action on systemic/significant behavior/errors?* |
| **Has the Customer been Notified?** |
| Choose an item.*\*Retain notification record* |
| **Corrective Action** |
| Choose an item.**See Corrective Action #:** Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Quality Assurance Manager approved:** |  |
| **Date approved:** |  |
| **Approved by:**  |  |
| **Title of approver:** |  |
| **Date approved:**  |  |