|  |
| --- |
| **FSOP050.1****CORRECTIVE AND PREVENTATIVE ACTION REPORT (CAPA)** |

|  |  |  |
| --- | --- | --- |
| **CAPA Number :** |  | **Location of Adverse Event/Non-conformity :** |
|  |  |  |

|  |
| --- |
| 1. **Details of the adverse event/non-conformity** *(i.e. Problem definition statement, description of the event, non-conformity)***:**
 |
|  |
| **Detected/observed by:** | **Date:** |

|  |
| --- |
| 1. **Disposition:** (*immediate remedial action taken; include an assessment of impact***):**
 |
|  |
| **Risk to Project - Impact Categorisation: Minor Major**  |
| Proposed by: | Date: | Implementation date: |

|  |
| --- |
| 1. **Investigation: Details of findings and causes with supporting evidence if applicable:**

*(There is always a prexisting condition and an action (or catalyst) that when combined result in a* *problem. Always look for at least 2 causes of any problem)* |
| Investigated by: | Date started: | Date finished: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Details of Corrective/Preventative Action(s),** including consequences, quality improvement

suggestions, SOP changes, verification testing (\*indicate as CA or PAe.g. PA/23/001)

|  |  |  |  |
| --- | --- | --- | --- |
| **Number\*** | **Action** | **Responsible Person** | **Implementation Date** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

 |
| **Submitted to Quality Manager:** | **Date:** |

|  |
| --- |
| 1. **Verification of validity of Corrective and/or Preventative Action**
 |
| **Corrective Action:**Addresses the root cause?Prevents recurrence? Valid Invalid. Issue new CAPARemarks: | **Preventative Action:**Addresses the root cause? Prevents occurrence? Valid Invalid. Issue new CAPARemarks: |
| Signature (QM):  | Date: | Signature (QM): | Date: |

|  |
| --- |
| 1. **Follow up of Corrective/Preventative Action taken**
 |
| **Implementation of corrective action(s) is:**Implemented Not implemented. Issue new CAPARemarks: | **Implementation of preventative action(s) is:**Implemented Not implemented. Issue new CAPARemarks: |
| Signature (QM): | Date: | Signature (QM): | Date: |

|  |
| --- |
| 1. **Verification of Effectiveness of Implemented Corrective/preventive Action**
 |
| **Corrective Action is:**Effective Not effective. Issue new CAPARemarks: | **Preventative Action is:**Effective Not effective. Issue new CAPARemarks: |
| Signature (QM): | Date: | Signature (QM): | Date: |

Instructions:

1. The person observing or detecting the adverse event or non-conformity shall fill in section A
2. The affected person shall fill in sections B, C, D
3. The Quality Manager (QM) or Management representative shall fill in sections E, F, G