**UK NEQAS for H&I Unsatisfactory Performance**

You may use this form as a template to aid your CAPA response to your Unsatisfactory Performance Notification. **NOTE:** You will still need to complete the CAPA on the Participant’s Portal, however you can use this template to copy/paste your answers to prevent data loss in case of timeout of the Portal.

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| --- | --- | --- | --- |
| Scheme\*: |  | Date issued\*: |  |

*\*The above information will be pre-populated in the Participant’s Portal, however you may find it useful to record it here for your records.*

**1. DESCRIPTION OF NON-CONFORMITY** *Include a description of what happened and include all relevant information in sufficient detail to describe the issue(s) that led to unacceptable performance.*

**2.** **IMMEDIATE CORRECTIVE ACTION** *What immediate action has been taken following your laboratory’s performance issue(s)? (e.g. corrective/observations/recalibration/re-analysis/ review of IQC).*

**3. INVESTIGATION** *Consider any applicable evidence: Documents Analysed e.g. SOPs, training records, packing slips, raw data, etc. People Interviewed. Contributory Factors: Were there extenuating or unusual circumstances?*

**4. ROOT CAUSE ANALYSIS** *Please identify the root cause of the recent performance issue(s) (e.g. malfunction of equipment, staff training or competency issue, reagent storage conditions not met).*

**5. CONSEQUENCES/RISKS** *Consider how the non-conformance could also affect clinical testing and reporting as well as the degree of severity of the risk.*

**6. CORRECTIVE/PREVENTATIVE ACTION** *What procedures have been implemented to prevent re-occurrence of the performance issue(s)? (e.g. issue corrected results for samples/training of staff/dissemination of knowledge/SOP changes).*

**7. ACTION PLAN** *How will you follow-up on these actions? What procedures will be used to review performance to ensure your corrective/preventative actions have been implemented successfully and effectively?*

**8. LESSONS LEARNT** *e.g. showing good practice being implemented.*

**Attachments**

*Supporting documents can be uploading in the Participants Portal if applicable.*