The laboratory is expected to use its own quality management system documentation for the conduct of:

* root cause analyses
* the risk assessment of non-conformities
* corrective actions and preventive actions

This checklist is to be used to ensure the submission is complete. This checklist does not replace the laboratory’s own quality management system. Refer to ISO/IEC 17025:2017. Attach evidence using your Company’s Quality Management forms. Please place all forms into a single PDF file.

Program and corrective action details (All Fields MUST be completed)

|  |  |
| --- | --- |
| Laboratory Name |  |
| IFM Customer Number (Cnnnnn) |  |
| Program Name / Topic |  |
| What reason did the laboratory participate? | Routine 3 rounds,  Repeat due to previous outlier(s),  Additional QC round |
| Has the laboratory participated in this topic before? | Yes  No |
| If yes, identify the most recent previous round? |  |
| What was the outcome of the most recent  previous round? | No Outliers  Outliers |
| If outliers, what corrective actions were  performed for the most recent previous round? |  |
| How was the success of the corrective actions for  the most recent previous round determined? |  |
| Relevant NCB |  |
| Name of Submitter (for correspondence) |  |
| Email of Submitter (for correspondence) |  |
| Summary of the determined root cause (200 character limit) |  |
| Summary of the implemented action related to the root cause that prevents re-occurrence (500 character limit) |  |

# **Root Cause Investigation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Clause | Topic | Completed | Evidence is attached | |
| Page # | Paragraph # |
| 8.7.1 b | Root cause analysis report is appended |  |  |  |
| Evaluation of depth of this issue. (Do similar nonconformities exist, or could something similar potentially occur again?) |  |  |  |
| The above was performed by:  Quality Manager  Laboratory Manager  other Senior Staff | | | | |

# **Risk and Impact** of **Nonconforming Work** according to ISO/IEC 17025:2017 (clause 7.10)

|  |  |  |
| --- | --- | --- |
| Clause | Summary | Confirmed |
| 7.10.1 b and c | An evaluation of the significance of the PTP outlier has been made, including impact analysis in the context of measurements/results reported to customers. |  |
| 7.10.1 e | Consideration has been given to notifying customers and recalling work |  |
| 7.10.2 and 8.7.3 | The PTP outlier has been registered in the quality management system |  |
| Quality management system reference number/identification for the PTP outlier |  |
| 7.10.3 and 8.5.1.c, 8.7.1.e | Once the root cause has been established, the risks of recurrence of this or a similar deficiency have been evaluated and acted on.[[1]](#footnote-1) |  |
|  | An impact statement/risk analysis has been provided to the NCB(s). |  |
| Comment (optional): | | |
| The above was performed by:  Quality Manager  Laboratory Manager  other Senior Staff | | |

# **Development and Implementation of** **Corrective Actions, Plans to Monitor the Success of Actions and Further Preventive Actions** according to ISO/IEC 17025:2017 (clause 8.7)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Clause | Topic | Completed | Evidence is attached | |
| Page # | Paragraph # |
|  | If the corrective action report is in a language other than English, an English language summary is provided. |  |  |  |
| 8.7.1 b | The implemented actions address the identified root cause and are designed to prevent re-occurrence of the nonconformity.  (The type of action and its urgency also relates to the risk assessment.) | Yes  No  Comment | | |
| 8.7.1 c | Description of the implemented corrective actions are appended |  |  |  |
| Evidence that the corrective action has been implemented is appended. (Show evidence of implemented action, highlighting the changes.) |  |  |  |
| 8.7.1 d | Describe the reason it is considered the implemented action will be effective |  | | |
| Date (including planned future actions/reviews), when this matter will be finalised |  | | |
| 8.7.1 f | Changes to management system - Has a document, procedure or policy been updated? (Attach evidence, clearly highlighting the change.) | Yes  No  Comment | | |
| 8.7.2 | Corrective action(s) are appropriate to the effects of the nonconformity |  | Provide your brief reasoning. | |
| The above was performed by:  Quality Manager  Laboratory Manager  other Senior Staff | | | | |

1. Impact and risk evaluation cannot be conducted until the root cause of the deficiency has been established. Even errors of small magnitude could be considered significant if found to have occurred as a result of certain systematic causes. The magnitude of conferred risk is not necessarily equivalent to the magnitude of the error in the reported result. [↑](#footnote-ref-1)