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| **1** | Organisation: |  | Nonconformity no: |  |

Note 1: Section 2 and 3 can be omitted if done previously and the content is still valid – ref. proposed action plan

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| **2** | Correction  *Immediate fix/disposition of an existing nonconformity with completion dates. Attach supporting documents.* |  |

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| **3** | Root cause analysis:  *Describe results of root cause analysis and check applicable key factor(s) that best define the root cause.* |  | **Check applicable key factor(s):**  Personal competence  Adequate procedure(s)  Available resources  Organisation culture/attitude  Human error |
| Risk assessment and mitigation *(if appropriate)* |  | |

Note 2: Investigate how /why this happened – Identify and justify which root cause(s), if removed or changed, will prevent recurrence.

Note 3: Use the organisation procedures for risk assessment and list conclusion and mitigation (if applicable)

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| **4** | Corrective Action:  *Effective solutions to prevent recurrence with completion date(s). Attach supporting documents.* |  |

Note 4: A report of final resolution of corrective action must be submitted to ICETRA (the applicable inspector) within the date specified as [Due date] in the nonconformity report.

Note 5: The corrective action should detail the root cause analysis, specify correction measures (immediate fix) and how the corrective action arrangements prevent recurrence of similar deficiencies and re-establish compliance with requirements.

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| **5** | Acceptance of corrective action |  | |
| *Quality/Compliance manager or his/her deputy accepting the proposed corrective action. Name and date:* | | | *Signature:* |

**For ICETRA use only**

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| **6** | ICETRA acceptance/rejection of the corrective action | Accepted | | Rejected |
| *Comments/explanations (if applicable)* | | | | |
| *Inspector name and date:* | | | *Signature:* | |