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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:* |