Title: Deviations

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Document History

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<td>1</td>
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<td>Reference to clinical incidents at 1.1, 2, 3.6 and 3.7</td>
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1. Scope

1.1 Deviations are defined as unpredicted events which affect (or may affect) the integrity of results and/or the Quality Management System (QMS). This includes non-conforming work and any clinical incidents. The purpose of this procedure is to describe the methods and responsibilities for reporting and investigating Deviations within the University of Aberdeen ISO/IEC 17025:2017 compliant QMS.

1.2 Non-conforming work may include critical equipment or environmental conditions which are out with specified limits.

1.3 A Deviation may be an unexpected event or a planned event.

2. Responsibilities

All staff involved in testing: Raise Deviation reports as appropriate.
Technical Manager: Manage non-conforming work using the Deviation process and authorise corrections and any CAPA.
Quality Assurance Manager (QAM): Manage the Deviations system and escalate as appropriate.
Named clinician: Review of any clinical incidents which may occur.

3. Procedure

3.1 Any member of staff member may raise a Deviation report.

3.2 Upon discovery of a Deviation, the employee shall:

- Inform the Technical Manager, or nominated deputy.
- Agree if the Deviation is unexpected or planned.
- Obtain a non-conformance number from the QAM on the same day, or as soon as possible, providing brief details.

3.3 The member of staff raising the Deviation shall detail the event in a Deviation Report form (TMP-QA-86) with the Technical Manager, or nominated deputy.

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Key to symbols: ⚠️ = Important point to note  🟢 = Warning
3.4 In the Deviation Report form the employee and Technical Manager shall complete in the following in the ‘details’ section:

- A description of the Deviation and include details of samples, customer, work area(s) involved, procedure/process being deviated from, equipment details, etc. as applicable.
- Impact analysis on any previous test results which may have been affected.
- Document any investigative action taken.
- Identify any action to be taken (including halting or repeating testing, withholding or recalling test reports).
- Record details and attach copies of relevant documentation and evidence.

3.4 In the ‘Corrective Action’ section the employee and Technical Manager shall detail:

- Any corrective actions indicating responsibilities and time-scales. Where a Deviation involves a specific operator the proposed CAPAs shall be discussed, agreed and documented with that operator.

3.5 Completion of the above shall be within ten days of Deviation being identified. The QAM shall record the Deviation in Q-Pulse.

3.6 To complete ‘Follow up’, the Technical Manager and QAM (with input from the named clinician if appropriate) shall review and assess the technical content of the Deviation report. This will encompass:

- Establishing if Deviations of this nature have occurred previously, or could recur, cross referencing any Deviation report(s) and determine if the Deviation will have any impact on any other test results, or opinions and interpretations, issued previously.
- The QAM will categorise the root cause identified, in order to identify any trends.
- The QAM will identify if customers or regulatory authorities should be informed of the Deviation.

3.7 The QAM and Technical Manager (with input from the named clinician if appropriate) shall review the effectiveness of corrective actions identified.

3.8 The Technical Manager shall authorise and justify the acceptability (if appropriate) of any non-conforming work and the resumption of testing (if halted).

3.9 The QAM and Technical Manager (and named clinician, if appropriate) shall sign and date the Deviation Report and assess any impact of the Deviation on testing activity. Deviation reports shall be retained in Q-Pulse.

4. Abbreviations and definitions

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<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>Corrective Action</td>
<td>Action to prevent recurrence of an identified Deviation</td>
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<tr>
<td>Preventive Action</td>
<td>Action to prevent occurrence of a potential event</td>
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<td>QAM</td>
<td>Quality Assurance Manager</td>
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<td>QMS</td>
<td>Quality Management System</td>
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5. Related documentation and references

TMP-QA-86 Deviation Report

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