QMS Self-Assessment Process

PURPOSE

The purpose of this process is to ensure the effective implementation and maintenance of the Division’s Quality Management System by conducting regular audits on all aspects of the QMS.

RESPONSIBILITY

Responsibility for this process lies with the Division’s Quality Team. All area / line managers within the Division are responsible for implementing the procedure.

PROCEDURE

1. Each year the Quality Team compiles an annual internal audit schedule for the Division’s Quality Management System. The schedule sets out:
   a. Processes to be audited
   b. Units to be audited for identified processes
   c. Assigned auditors (in pairs)
   d. Provisional dates (months) for audits

Each process (QMS Process, Key Business Process and Quality Manual) should ideally be audited once a year. Issues such as the importance of activities, auditor holidays, busy periods of work, activities that can only be audited at a specific time of the year due to the nature of the task(s) etc. are taken into account in scheduling. Auditors should never audit their own areas and areas should be audited by different auditors each time.

2. The Quality Team will incorporate any agreed changes to the audit schedule, will publish the schedule on the shared server and will advise each auditor of its issue. It is the responsibility of all auditors to check the audit schedule. Auditors are responsible for arranging directly with area /line managers the appropriate time to carry out the audit, and should arrange audit times around the activity in order to witness the actual activity being carried out wherever possible.

3. Prior to the audit, auditors must read the previous Audit Report (where applicable), making note of any areas that require checking or particular attention, and checking that the actions from the last audit are complete. Audit Reports are filed on the Division’s share server.

4. Before the audit, the auditor(s) should develop a checklist using previous Audit Reports, procedures for the areas etc., and note any particular questions they would like to ask. Where possible, auditors should also decide upon samples, check records, etc. prior to the audit so
they are aware of what they wish to focus on. However, for some procedures, this will not be possible until during the actual audit.

5. Auditors should conduct the audit on the agreed dates, taking note of any areas for improvement that are identified on the checklist. The following is recommended to be discussed during an audit, in addition to any prepared questions/ appropriate questions
   a. Receive a demonstration of how a procedure is carried out (i.e. “show me”)
   b. Ascertain whether the procedure is effective and efficient
   c. Invite auditees to make suggestions for areas for improvement at the end of the audit

6. On completion of the audit, auditors must complete the Audit Report. The Audit Report should include objective evidence of deviation from implemented procedures / working guidelines or other applicable documents and all supporting information.

7. The Audit Report is sent via email to the Quality Team leader. All other documentation, including the paper trail, is given to the Quality Team leader for filing. If any urgent action is required, the Quality Team leader will ensure appropriate action is taken, informing relevant staff as appropriate.

8. A copy of the completed Audit Report is sent to the auditees and their area / line manager by the Quality Team leader.

9. Follow-up actions are tracked by the Quality Team.

DOCUMENTATION
• Internal Audit Checklist Template
• Internal Audit Report Template

RECORDS
All audit records (reports and paper trails) are maintained by the Quality Team. Records of Improvement Action Items resulting from the audits are logged in the Division Action Plan on the shared server.

APPROVALS AND REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Date</th>
<th>Approved by:</th>
<th>Details of Change</th>
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<tbody>
<tr>
<td>1</td>
<td>15 Sept 2016</td>
<td>David Mahedy, Director</td>
<td>Initial release</td>
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