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1 Internal Auditing

1.1 Introduction & Purpose

The purpose of this procedure is to define your organization's process for undertaking QMS audits, process audits, and supplier and legislation audits in order to assess the effectiveness of the application of our quality management system and its compliance to ISO 9001:2015. This procedure also defines the responsibilities for planning and conducting audits, reporting results and retaining associated records.

1.1.1 Process Activity Map

1.1.2 References

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS EN ISO 9000:2015</td>
<td>Quality management systems</td>
<td>Fundamentals and vocabulary</td>
</tr>
<tr>
<td>BS EN ISO 9001:2015</td>
<td>Quality management systems</td>
<td>Requirements</td>
</tr>
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<td>BS EN ISO 9004:2000</td>
<td>Quality management systems</td>
<td>Guidelines for performance improvements</td>
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<tr>
<td>BS EN ISO 19011:2018</td>
<td>Auditing management systems</td>
<td>Guidelines for auditing</td>
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</table>

1.1.3 Terms & Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>ISO 9000:2015 Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformity</td>
<td>Fulfilment of a requirement (3.6.4)</td>
</tr>
<tr>
<td>Non-conformity</td>
<td>Non-fulfilment of requirement (3.6.9)</td>
</tr>
<tr>
<td>OFI</td>
<td>Opportunity for improvement</td>
</tr>
<tr>
<td>Corrective action</td>
<td>Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence</td>
</tr>
</tbody>
</table>
1.2 Application & Scope

By applying the principles of auditing, outlined by ISO 19011:2018, your organization ensures that all internal audits are conducted with due professional care, integrity and independence. All conclusions derived from the audit are based upon objective and traceable evidence. Your organization’s arrangements for conducting internal audits at planned intervals, include the following audit criteria:

- Our own requirements, e.g. policies, processes, procedures, instructions, specifications;
- Customer requirements, e.g. flowed down by contract;

1.3 Responsibilities

It is the responsibility of the Quality Manager to coordinate the internal audit programme in order to:

- Obtain audit results;
- Report audit performance;
- Monitor trends, e.g. repeat audit findings or acknowledged improvement;
- Determine the root causes of non-conformities;
- Provide the results of audits to top management;
- Track how long corrective actions remain open, versus planned closure;
- Review the effectiveness of corrective actions taken.

The Internal Auditors are required to:

- Review relevant management system documents and records;
- Review and prepare the Internal Audit Checklist;
- Arrange audit appointment;
- Conduct opening meeting;
- Sample and observe process inputs/activities/outputs;
- Record objective evidence to verify process compliance or non-conformance;
- Conduct the closing meeting;
- Provide input for improvement of the audit programme and audit process.

The Auditees are required to undertake timely corrections to fix any immediate problems and corrective actions to prevent recurrence:

- Ensure corrective actions are implemented and are closed-out within the agreed timeframe;
- Minor areas of non-conformance are taken care of immediately;
- Ensure the status of corrective actions and any non-conformances are kept up-to-date.

1.4 Internal Audit

1.4.1 Internal Audit Programme

The Quality Manager is required to prepare and distribute the Internal Audit Programme that is dependent upon the size and complexity of operations, including the identification and frequency of each audit, e.g. monthly, quarterly, annually:

- Determine the status and importance of each process;
- Establish audit frequency based on the status and importance of each process;
actions are completed. A member of the audit team will then sign off the audit report. An audit summary is prepared as an input for management review.

1.7 Forms & Records

All documentation and records generated by the internal audit process are retained and managed in accordance with the *Documented Information Procedure*. Retention of documented information to show that the audit programme has been effectively implemented include the audit programme, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, audit performance metrics.

<table>
<thead>
<tr>
<th>Title &amp; Description</th>
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<tbody>
<tr>
<td>Internal Audit Report.docx</td>
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<tr>
<td>Internal Audit Feedback.docx</td>
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<tr>
<td>Internal Audit Programme.xlsx (Includes the process matrix and the 10-year &amp; 2-year audit programmes)</td>
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<tr>
<td>Gap Analysis Checklist.docx</td>
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<td>Process Audit Template.xlsx</td>
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<td>Supplier Audit Checklist.docx</td>
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<td>Supplier’s Self-Assessment.docx</td>
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<td>Internal Audit Checklist.xlsx</td>
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<tr>
<td>Corrective Action Report.docx</td>
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<td>Corrective Action Log.xlsx</td>
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