Company

ISO 9001:2015

**Prepared by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_, FQM Auditor**

**Approved by:\_\_\_\_\_\_\_\_\_\_\_\_\_,**

**Date:**

1. **Introduction**
2. **Scope**

This Internal Audit focused on all relevant aspects of the business processes within the company’s management system and against the International Standard ISO 9001:2015.

1. **Objective**

To review and confirm that the company operates their business management system in compliance with the appropriate ISO 9001:2015, and demonstrate an evidence based assessment of the company’s performance in using the system.

1. **Executive Summary**

The opening meeting was conducted at \_\_\_\_am and the closing meeting was conducted and findings agreed at \_\_\_\_pm.

The policies, processes and procedures were reviewed in depth together with an appropriate random check of controlled records to verify that operational activities were in accordance with the written systems and that the company was in compliance with the requirements of the International Standard.

1. **Review Findings**

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| **Responsible** | **Observations** | **By Date** |
|  | OFI x |  |
|  | NC x |  |

**Date of audit**

**Auditor**

***Name Date***

***Insert Signature Here***

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| **AUDIT CHECKLIST/RESULTS PAGE 1 of 11** | | | |
| **ISO 9001** | **Context of the Organisation** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 4.1  4.2  4.3 | **Context of the organisation and its scope**  Can the organisation demonstrate that it has considered a range of internal and external issues relevant to its purpose and strategic direction that affect its ability to achieve the intended results of its QMS?  Have interested parties or stakeholders been identified?  Has the scope been determined and does it consider the products and services of the organisation? |  |  |
| 4.4 | **Management system and its processes**  Has the organisation considered:  -Inputs, outputs and interactions of the processes?  -The effective operation and control of these processes?  -Assigning responsibilities and authorities for these processes?  -The risks and opportunities in relation to planning?  -Change Management of these processes?  -Retaining and Maintaining documented information to support the operation and demonstration of the processes? |  |  |

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| **AUDIT CHECKLIST/RESULTS PAGE 2 of 11** | | | |
| **ISO 9001** | **Leadership** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 5.1  5.2  5.3 | **Does the management team:**  Demonstrate commitment to the effectiveness of the system?  Demonstrate Quality objectives?  The Quality requirements are integrated into the business?  Are resources available to run the QMS?  Communicate the importance of the QMS?  Ensure the QMS achieves its intended results?  Promote improvement?  **Does the management team:**  Ensure customer, statutory and regulatory requirements are determined, understood and met?  Ensure the risks and opportunities with respect to products and services and enhanced customer satisfaction are determined and addressed?  Maintain focus on customer satisfaction?  **Policy**  Has the organisation established, implemented and maintained quality policy?  Is it appropriate to the context of the organisation and include a commitment to improvement?  **Roles, Responsibilities and Authorities**  *Management have assigned roles to ensure:*  The processes deliver the intended outputs? And the QMS meets the requirements of the relevant standard?  The QMS performance is measured and opportunities for improvement are promoted? |  |  |

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| **AUDIT CHECKLIST/RESULTS PAGE 3 of 11** | | | |
| **ISO 9001** | **Planning** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 6.1  6.2  6.3 | **Addressing Risks and Opportunities**  Has the organisation considered issues and stakeholder needs to achieve intended results, enhance desired effects, reduce undesired effects and achieve improvement?  Are all risks and the actions taken proportionate to the potential impact?  Integrates and implemented in to the QMS?  Evaluate the effectiveness of these actions?  **Objectives**  Aligned to the policy?  Consider compliance obligations?  Measureable? Monitored?  Relevant? Communicated?  Do the plans consider and demonstrate; What, When, Who and evaluation of?  **Planning of changes**  The purpose and consequences?  The impact on the QMS?  Resources and responsibilities?  Demonstration of processes / procedures? |  |  |

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| **AUDIT CHECKLIST/RESULTS PAGE 4 of 11** | | | |
| **ISO 9001** | **Support: Resources** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 7.1 | **Has the organisation:**  Considered the capabilities and constraints of internal resources?  Used and controlled external providers?  Demonstrated the infrastructure in place for effective operation of its processes, including; buildings, equipment, software, transportation, IT?  Provided the necessary environment for the effective operation of its QMS regarding Social / Psychological / Physical requirements?  The resources to undertake the desired monitoring and measurement?  Ensured any equipment used for monitoring and measurement is calibrated, safeguarded and information recorded against recognised standards? |  |  |
| 7.2  7.3  7.4 | **Can the organisation:**  Demonstrate it has identified the necessary competences of persons to ensure effectiveness?  Demonstrate they have taken the necessary steps to record the education, training and experience?  Demonstrate the effectiveness of the actions taken to acquire and retain the necessary evidence?  *Demonstrate that they have made persons aware of:*  The policies and objectives?  Their effect and interaction with the QMS?  *Demonstrate an effective communication programme:*  What, When, With, How, Who?  Does it include external communication? |  |  |

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| **AUDIT CHECKLIST/RESULTS PAGE 5 of 11** | | | |
| **ISO 9001** | **Support: Documented Information** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 7.5 | **Has the organisation:**  *Demonstrated that documented information necessary for the QMS has:*  Identification and description?  Set format?  Reviewed and approved?  Effective for the QMS to function as required?  Considered its compliance obligations?  **Can the organisation demonstrate:**  That documented information is available and suitable for use?  It is protected from improper use?  *That its control of such address:*  Distribution, access, retrieval and use?  Storage and preservation?  Control of changes?  Retention and disposition?  Information external to the organisation which is necessary for the operation of the QMS and is identified? |  |  |
| **AUDIT CHECKLIST/RESULTS PAGE 6 of 11** | | | |
| **ISO 9001** | **Operations: Planning, Control and Requirements** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 8.1  8.2 | **Can the organisation demonstrate:**  Effective planning and control of their operations to meet the requirements for the provision of products and services?  *Effective communication with customers that:*  Handle the enquiries, including complaints?  Provide the necessary information?  Outline handling customer property?  Establish contingency actions where required?  **Has the organisation ensured that:**  Products and services have the applicable statutory and regulatory requirement defined?  It can meet the claims of the products and services it offers?  *Prior to commencement of the contract they have:*  Reviewed customer specific requirements?  Identified requirements for the intended use?  Reviewed variations of requirements?  Documented the necessary information related to above? |  |  |
| **AUDIT CHECKLIST/RESULTS PAGE 7 of 11** | | | |
| **ISO 9001** | **Operations: Design and Development** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 8.3 | **Can the organisation demonstrate:**  The internal and external resources needs for the design and development of products and services taking into account the nature, duration and complexity of the design.  The process stages for review, verification and validation of design?  The responsibilities and authorities?  The involvement of customers and/or end users?  Information is recorded to confirm the process?  **Has the organisation ensured that:**  It can meet the claims of the products and services it offers?  *Prior to commencement of the contract they have:*  Identified the possible consequences of failure?  **Can the organisation demonstrate:**  Controls are in place for verification and validation?  Outputs meet the input requirements?  Measurement and acceptance criteria?  Actions to control change and prevent adverse impacts?  **Documented information retained for all above** |  |  |
| **AUDIT CHECKLIST/RESULTS PAGE 8 of 11** | | | |
| **ISO 9001** | **Operations: Control of External Processes, Products and Services** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 8.4  8.5  8.6  8.7 | **Can the organisation demonstrate controls for:**  Effective management of external products and services incorporated with or provided directly to clients?  Ensuring the external services remain within the company’s QMS processes?  Verifying the externally provided products and services?  *Records retained outline:*  Processes, methods, Equipment, Competences and Monitoring communication with external providers?  Monitoring, measurement, competence and validation information?  **Has the organisation ensured that:**  Unique identification of products and services are recorded to enable traceability?  *Post-delivery activity considers:*  Statutory and regulatory requirements?  Potential undesired consequences?  Customer feedback?  *Nonconforming outputs are controlled by:*  Correction / Segregation / Authorisation?  With supporting documented information which describes the actions taken and authority obtained? |  |  |
| **AUDIT CHECKLIST/RESULTS PAGE 9 of 11** | | | |
| **ISO 9001** | **Performance Evaluation: Monitoring, Measurement and Audit** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 9.1  9.2 | **Has the organisation identified:**  What needs to be measured, when and how?  The methods of analysis evaluation to ensure valid results?  **Can the organisation demonstrate:**  They evaluate the keep records of performance and effectiveness of the QMS?  Customer perception and satisfaction?  *That the information measured provides results in:*  Effectiveness of planning?  Actions taken to address risk and opportunity?  External providers?  The need for improvement in the QMS?  **Are Internal Audits:**  Planned / scheduled at regular intervals?  Meeting QMS and standards requirements?  Confirming the QMS is implemented and maintained?  *Considering:*  Criteria and Scope? Frequency? Methods? Responsibilities? Planning?  Previous results reviewed? Reported?  Legislation?  Appointing competent auditors with impartiality?  *Demonstrating:*  Methods of reporting to relevant stakeholders?  Actions taken without delay?  Retained documented information in relation to the audit programme? |  |  |

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| **ISO 9001** | **Performance Evaluation: Management Review** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 9.3 | Does the organisation review the QMS at planned intervals?  **Does the management review consider:**  The status of previous actions?  Changes in internal and external issues?  The performance and effectiveness of the QMS:  -Customer satisfaction and feedback?  -The extent to which objectives have been met?  -Conformity of products and services?  -Nonconformities and corrective actions?  -Monitoring and measurement results?  -Audit results?  -The performance of external providers?  -The adequacy of resources?  -The effectiveness of actions taken to address risks and opportunities?  -Opportunities for improvement?  **Do management review outputs include:**  Opportunities for improvement?  Any need for changes to the QMS?  Resource needs?  Training and Competence needs?  Supplier changes? |  |  |
| **AUDIT CHECKLIST/RESULTS PAGE 11 of 11** | | | |
| **ISO 9001** | **Improvement** | **NC / OFI** | **EVIDENCE, COMMENTS, OBSERVATIONS** |
| 10.1  10.2  10.3 | **Do opportunities for improvement include:**  Improving products and services?  Consideration for future needs?  Correcting and preventing undesired effects?  Improving the performance of the QMS?  **Can the organisation demonstrate:**  Its actions taken to control and correct non-conformities?  *That it has evaluated the need for action to eliminate, thus preventing a recurrence by*:  Reviewing and analysing the nonconformity?  Determining the root causes?  Determining if similar issues could occur?  **Can the organisation demonstrate:**  Action taken was effectively implemented?  It has reviewed the effectiveness of the action?  If risks and opportunities have changed as a result?  Any changes made to the QMS as a result of the actions to address non-conformances?  **How does the organisation demonstrate:**  Its commitment to the continual improvement of the suitability, adequacy and effectiveness of the QMS? |  |  |