Company X

ISO 9001:2015

Internal Audit

Checklist and Report

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

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

**Date:**

1. **Introduction and Scope**

This Internal Audit focused on all relevant aspects of the business processes within the company’s management system against clauses 4 to 7 of the International Standard ISO 9001:2015.

1. **Objective**

To review and confirm that the company operates their management system in compliance with clauses 4 to 7 of 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. Findings from the Internal Audit are outlined below.

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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| **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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| **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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| **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? |  |  |