Instructions: Complete this form using the instructions in blue text for each section. If you have an assigned on-site consultant, they will lead you through this process. Periodically (annually or as changes occur) you will review and update information. Retain this document as a record of QMS planning in your Quality Management System.

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Plan** | | | |
| **Process Name** | Quality Management | **Process Owner** | Management Representative |
| **Associated Process Documents & Records** | Quality Manual, QMS Plans and forms | **Quality Objectives Supported** | * Program Win Rate – over 40% * Time to fill Open Positions - * Retention rate - * Invoice Accuracy – less than 1% * Customer Satisfaction – zero complaints |
| **Key Resources** | Management representative, Internal auditors, CORE system, corporate electronic and paper files | **ISO 9001:2015 Clauses** | 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 6.1, 6.2, 6.3, 7.1, 7.2, 7.3, 7.4, 7.5, 8.1, 8.4, 9.1, 9.2, 9.3, 10.1, 10.2, 10.3 |
| **Outsourced Processes and Controls** | External auditor | **Risks or Opportunities to consider** | Listed, progress tracked and reviewed as necessary in QMS Plan document |

**Process Diagram**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Corporate policies and processes,  Previous Management Review minutes and agenda’s  Upstream Process = NA | * Internal audit forms and records * Improvement suggestions * Management Review agendas and minutes * ISO 9001:2015 standard | 1. Define Key Processes & Quality Objectives 2. Provide document and records Control 3. Conduct internal audits 4. Determine and initiate improvements 5. Issue and complete Corrective/ Preventive Actions 6. Hold Management Review meetings | Quality Manual,  QMS Plan, Internal Audit records,  CAPAs,  Management Review minutes,  Controlled Docs & Records | Executive Management,  Corporate staff,  Operational staff, Customers  Downstream Process = All processes | Internal audit, Management Review meetings |

Instructions: For this section, the Process Owner and Auditor(s) will fill this in together and note any actions needed.

**Process Review**

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Owner:** | Deanna Eaton | **Associated CA’s or NC’s reviewed:** |  |
| **Auditor(s):** | Brenda Walguanery | **Documents and Records Reviewed (including previous audits):** |  |
| **Date Reviewed:** |  | **Date of Next Review:** |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Owner Questions** | **Yes** | **No** | **Notes/Action Needed** |
| 1. Is the Process Plan and Diagram (from pages 1-2) still current? (4.4.1) |  |  | If no, list actions being taken: |
| 1. Have there been any major changes since the last review? (4.4.1) |  |  | If yes, list actions being taken: |
| 1. Are the process measures still valid? (4.4.1, 7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Are measure targets being met? (4.4.1, 7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Are resources still adequate for the process? (7.1) |  |  | If no, list actions being taken: |
| 1. Are there any new risks in the process to consider? (6.1) |  |  | If yes, list actions being taken: |
| 1. Are any resources used for monitoring and measurement of the process fit for their purpose? (7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Is there any key knowledge about the process to capture? (7.1.6) |  |  | If yes, list actions being taken: |
| 1. Are there any process improvements needed or opportunities to take advantage of? (4.4.1, 6.1, 10.3) |  |  | If yes, list actions being taken: |
| 1. **List any additional actions items such as:** documents or records to update; training or communication to be done. |  |  |  |

**Process Audit**

Instructions: For this section, the Auditor(s) will complete as they conduct the audit. Evidence listed should be specific and detailed. Each question should note either “OK” if all requirements were found to be compliant or “NC” if there was a nonconformity.

Process Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 4.4.2a  7.5.2  7.5.3 | 1. Specific to the Quality Management process - what controlled documents are in use?  Check for appropriate:   * identification and format * review and approvals * availability and suitability * protection and access * storage and retention * change control   **Look for:** Look at several documents. List names of specific documents reviewed and their revisions in use. Check for all of the bulleted requirements above. |  |  |
| 4.4.2b  7.5.2  7.5.3 | 2. Specific to the Quality Management process - what records are kept?  Check for appropriate:   * identification and format * review and approvals * availability and suitability * protection and access * storage and retention * change control   **Look for:** Look at several records. List names, dates and other identifiers of specific records reviewed that are in use. Check for all of the bulleted requirements above. |  |  |

Competence, Awareness and Communication

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 5.2 | 3. Verify that the quality policy has been reviewed by top management.  **Look for:** Management Review meeting minutes and note the date of review. Ensure that any posted copies of the quality policy are properly controlled. |  |  |
| 7.2 | 4. What evidence shows that employee competence levels have been determined for those working in this process, including internal auditors?  **Look for:** Job descriptions, job postings, manager’s knowledge and experience, competency charts, certificates of completion. Be sure to confirm training certificates for all internal auditors. Check recently hired employees, if any. |  |  |
| 7.3  7.4 | 5. How does the organization determine internal and external communications? How are requirements for awareness (7.3) communicated to employees?  **Look for:** Meeting records, the Communication and Awareness Plan |  |  |

Process Conformity

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 4.1 | 6. Is the Quality Management process being followed as defined in the Quality Manual and related documents?  **Look for:** Read the appropriate Quality Manual sections shown under “ISO clause” (to the left) before completing the questions in this section. List the Quality Manual Revision. |  |  |
| 4.1  4.2 | 7. Verify the organization determined, monitored and reviewed relevant external and internal issues related to the context of the organization.  Verify the organization determined, monitored and reviewed the requirements of interested parties.  **Look for:** The QMS Plan document exists and is periodically reviewed. Actions listed in the QMS Plan are completed as planned. |  |  |
| 4.3 | 8. Verify the scope of the QMS has been defined and documented.  **Look for:** Ensure the Quality Manual defines the scope of the QMS including justifications for any requirements that don’t apply. |  |  |
| 4.4  8.1 | 9. Verify the organization established, implemented, maintained and continually improve the processes needed for the Quality Management System.  **Look for:** Process Plan documents exists and are periodically reviewed and audited. List names, revisions and review dates of several Process Plans. |  |  |
| 5.1 | 10. How does Top Management demonstrate leadership and commitment to the QMS and customer focus?  **Look for:** Top management’s attendance in Management Review meetings and review of quality objectives, QMS training, employee meetings, etc. |  |  |
| 5.3 | 11. How are responsibilities and authorities assigned, communicated and understood?  **Look for:** Organization charts, roles defined in Quality Manual or other documents |  |  |
| 8.4 | 12. What controls are in place for suppliers and purchased products and services?  Ensure there is criteria for evaluation, selection, monitoring and re-evaluation of suppliers.  Verify that purchases are approved.  Verify that received items are checked against purchasing documents.  Verify that suppliers are reviewed on an ongoing basis.  **Look for:** Approved supplier list, purchase order approvals, drawings or instructions sent with service orders, receiving inspection/verification. Check Management Review minutes for review of suppliers. |  |  |
| 8.4 | 13. Are there any outsourced processes (by external providers) for the Quality Management process? If yes, how are they controlled?  **Look for:** Verify that any outside suppliers used during the process were properly selected, controlled and evaluated. Ensure they are listed above in the Process Plan on Page 1. |  |  |
| 9.2 | 14. What evidence shows that the planning of the internal audit program includes:   * Audit intervals or frequency * Methods * Responsibilities * Planning requirements * Reporting * Audit criteria and scope * Objective, impartial auditors?   **Look for:** Review the Quality Manual, Internal audit schedule and forms. Check for all bulleted requirements above. |  |  |
| 9.2.1 | 15. What evidence shows that the last internal audit:   * Was conducted according to the schedule * Used objective auditors * Reported the findings to top management * Took appropriate actions?   **Look for:** Audit schedules, audit reports, management review minutes, corrective actions |  |  |
| 9.3.1 | 16. Are management reviews (MR) occurring at the planned interval?  **Look for:** Compare the frequency noted in the Quality Manual with actual meeting frequency. |  |  |
| 9.3.2  9.3.3  9.1.2  9.1.3  6.3  7.1 | 17. Are all Management Review agenda items covered during the cycle audited?  **Look for:** Management Review minutes cover all bulleted requirements at least once in the minutes. Ensure there are no blank fields. |  |  |

Process Evaluation

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 4.4.1  6.2  9.1.1 | 18. Have all Measurements found in the Quality Manual Plan been reviewed as required?  **Look for:** Review Key Measurements and note the date of the last review. |  |  |
| 8.7 10.2 | 19. How are Nonconformances and Corrective Actions addressed?  Verify that risks are updated as part of planning, as needed.  **Look for:** Review any NC’s and CA’s opened and closed since the last audit. Ensure they are filled out completely. |  |  |
| 10.1  10.3 | 20. Are there any suggested process improvements?  **Look for:** Type in suggestions for improvement from the auditee(s) or from the auditor or type “No suggestions for improvement at this time.” |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Audit findings summary** |  | | |
| **Corrective Actions Issued** |  | | |
| **Auditor Name**  **(Sign-off)** |  | **Date** |  |
| **Process Owner Name**  **(Sign-off)** |  | **Date** |  |