# STEP ONE: Audit Planning

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| --- | --- | --- | --- |
| **Process to Audit (Audit Scope):** | | | |
| **Audit Date(s):** | **Lead Auditor:** | | |
| **Audit #:** | **Auditor(s):** | | |
| **Site(s) to Audit:** | | | |
| **Applicable Clauses of [Standard] Standard(s):** | | | |
|  | |  | |
| **Applicable Documents to Audit** | | | **Rev.** |
| [Quality Manual Doc Title] | | |  |
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# STEP TWO: Compare Documentation vs. Requirements

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| **Compare the [Short Client Name] documentation with the applicable clauses of [Standard].** | | |
| **Question** | **Y/N**  **(or N/A)** | **Evidence or Notes Sheet Ref. #** |
| In general, does the [Short Client Name] documentation address (and not contradict) the applicable requirements of [Standard]? |  |  |
| Are the documents properly controlled, and are only the latest versions available for use? |  |  |
| Do the documents address any applicable statutory, regulatory and/or customer requirements? If there are no such additional requirements, indicate “N/A.” |  |  |
| **Indicate any suggestions for improvement related to the documentation:** | | |
|  | | |

# STEP THREE: Compare Actual Practice vs. Requirements

| **Compare the requirements of [Standard], the [Quality Manual Doc Title] and other documentation against what employees are actually doing in everyday practice.** | | | |
| --- | --- | --- | --- |
| **Requirement**  **Reference** | **Question** | **Y/N**  **(or N/A)** | **Evidence or Notes Sheet Ref. #** |
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# STEP FOUR: Issues from Prior Audits and/or [CAR Form Abbreviation]s

| **Review previous audits for this process. Review previous [CAR Form Abbreviation]s issued against this process, or as a result of previous audits for this process. Add additional checklist questions here, based on the previous audits, [CAR Form Abbreviation]s or other documents or requirements, as you see fit.** | | |
| --- | --- | --- |
| **Reference** | **Issue to Follow Up** | **Closed / OK?** |
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# STEP FIVE: Verify the Overall Effectiveness of the Process

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| --- | --- | --- |
| **Review the applicable procedure(s) for this process and answer the questions below.** | | |
| **Question** | **Y/N**  **(or N/A)** | **Evidence or Notes Sheet Ref. #** |
| Are the procedure steps accurate and complete as compared to true practice? |  |  |
| Are there sufficient check steps (inspections, tests, reviews, approvals, sign-offs, etc.) that ensure the process outputs meet requirements before passing onto the next process? |  |  |
| Does the process appear to adequately meet the requirements of [Standard] and the [Short Client Name] documentation? |  |  |
| Does the process appear to adequately meet any applicable customer or regulatory requirements? (Indicate “N/A” if there are not such requirements applicable to this process.) |  |  |
| **Indicate any problems you uncovered with the process, or findings related to other [Standard] clauses not specifically called out in the checklist portion:** | | |
| **Provide brief details on any areas that you found were well-implemented, particularly effective or worth noting as positive traits of the process.** | | |
|  | | |

# STEP SIX: Process Effectiveness Assessment Report (PEAR):

If the audit is for a top-level QMS process, complete this section; otherwise it may be skipped.

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| **Process Implementation Status** | Practice **fully** matches requirements &/or procedures |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | **2** |  |  | **4** |  |  | **5** |
| Practice **partially** matches requirements &/or procedures |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | **2** |  |  | **3** |  |  | **4** |
| Practice does **not** match requirements &/or procedures |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | **1** |  |  | **2** |  |  | **2** |
|  |  | Objectives not met, no actions taken | | | Objective not met, but corrective actions are underway | | | Objectives are fully met | | |
|  |  | **Process Performance** | | | | | | | | |

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| --- | --- |
| **Final PEAR Score:** |  |

# STEP SEVEN: Summarize Findings for [CAR Form Abbreviation] System

Based on the findings and nonconformities you have recorded in the previous sections, summarize the necessary actions needed. For type, choose one of the following:

**C** =Corrective action needed (existing noncompliance)

**P** = Preventive action needed (potential noncompliance)

**OFI** = Opportunity for Improvement

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **[CAR Form Abbreviation] #** | **[Standard] Clause** | **Describe finding as you want it to appear in the [CAR Form Abbreviation] system.** | **Type** | **Major /**  **Minor** |
|  |  | Requirement:  Evidence:  Rationale for Finding: |  |  |
|  |  | Requirement:  Evidence:  Rationale for Finding: |  |  |
|  |  | Requirement:  Evidence:  Rationale for Finding: |  |  |
|  |  | Requirement:  Evidence:  Rationale for Finding: |  |  |
|  |  | Requirement:  Evidence:  Rationale for Finding: |  |  |

# STEP EIGHT: Review Audit Report and Submit

All auditors on the audit team must submit their audit reports for summary and review by the Lead Auditor. Lead Auditor: review the completeness of this report prior to submitting it to the [Specific Title for ISO MR]. Be sure findings show objective evidence, that everything is written clearly, and that all checklist questions are answered.

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| --- | --- |
| Audit report reviewed and ready for submission: |  |
| Signature of Lead Auditor |
|  |
|  | Date |

# NOTES PAGE

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| --- | --- |
| **Your Note reference #** | **Notes, evidence, findings, comments, etc.** |
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