Key Process Audit Checklist

What is the Process being audited?
Observe all aspects of the process being done. Ask questions about how the process gets done by the people doing the process.

Who is the Process Owner?
What role, responsibility and authority?

What are the applicable ISO 9001 clauses that affect this process?
Make sure the audit checklist asks appropriate questions from these ISO clauses.

What risks were identified to the process? Where are they found? How important are they? Are they listed? What was done to deal with the risks? (Action?) What records exist when actions are required, and how do we see actions were completed?

What is the Process being audited?

What measurement or performance indicators exist? What monitoring or measuring is there?
How is the performance and trends?
What goals are there?
Any customer feedback?
How effective is the process?
Are employees and management aware of negative trends and is anything being done?

What other Processes does this one link to or interact with? What examples can be followed into other processes?
Follow audit trails from this process into other processes to assure the linkage, sequence and interaction are working as intended.

Who is involved with this process? (Departments and job functions)
Who is the Process Owner?
What role, responsibility and authority?

What training and skills are required?
Any special skills, certifications or training needs?

What are the applicable ISO 9001 clauses that affect this process?
Make sure the audit checklist asks appropriate questions from these ISO clauses.

What Inputs are required to do this process? Are these good and correct?
What comes from internal and external customers?

What Outputs come out of this process?
What gets delivered to internal and external customers
What current records and historical evidence can you see to prove effectiveness of the process?
Are records adequate per plan?

What procedures or work instructions exist for this process?
Get copies of all appropriate documentation and review.
Do the people clearly demonstrate that they can do their jobs per the documented procedures and work instructions?

What current records and historical evidence can you see to prove effectiveness of the process?
Are records adequate per plan?

Collect documents looked at, it’s number and revision date. Verify against master documents.
Any obsolete documents in use?
Are all documents used for production controlled?
Are documents populated and signed as required?

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