

Process Auditor's Pocket Reference

1. Process name, location, owner, organizational application
2. Purpose of process; objectives; monitoring & measurement
3. Is process in value stream?
4. **Process** objectives, quality objectives; monitoring & measurement, yields, criteria & methods for operation and control, analysis
5. **Product** quality objectives; monitoring & measurement, conformity
6. How does organization know process operation is OK?
7. How does organization know process control is OK?
8. Inputs: material, information, cust. require'ts, process trigger
 - Input name/description, source
 - Input acceptance criteria, control methods
 - Feedback loop to supplier
 - Information control
9. Process outputs: material and information
 - Output name/description (don't forget data & records), user
 - Acceptance criteria, critical characteristics, control methods
 - Feedback loop from customers (internal & external)
10. Tools/equipment; maintenance and calibration; availability
11. Environment and infrastructure: suitable?
12. Personnel/training needs identified; qualifications verified
13. Process steps/tasks/activities; procedures, work instructions, conformance; critical parameters.
14. Additional process controls; validation
15. Product identification, traceability, handling, etc.
16. Information/document controls, records & controls
17. Process CA/PA; effectiveness; verification