

Layered Audit Process

1. PURPOSE:

The purpose of this procedure is to define the process for performing and documenting layered audits. The purpose of performing layered audits is to a) verify compliance to the documented manufacturing/assembly process to assure the production system is working optimally, b) involve various levels of management in the audit process, c) remove roadblocks to correcting potential issues which are identified by the audit and d) lead to standardized work practices.

2. **DEFINITIONS**:

<u>Layered Audit:</u> An audit that is performed by various levels (layers) of management to assure conformance to Quality system requirements.

<u>Error Proofing Verification</u> — Checking operation of devices that prevent the manufacture or assembly of non-conforming product. For the purposes of this procedure, devices which detect and stop the transfer of non-conforming product, e.g. 100% in-line inspection equipment) is included. If possible, proper functioning of the error-proofing device should be verified during the layered audit. The intent is to ensure error proofing devices with the potential to fail, wear, misalign, mis-locate or otherwise become out-of-adjustment, be switched off, disabled, bypassed or removed, are verified and or mastered. The minimum requirement during the management layered audit is to check the verification log sheet (because error-proofing verification is often performed by a different person than the manufacturing system or process control audit. Layered audits should ensure that error-proofing verification frequency is adhered to, and that alternate inspection is in place if error proofing is not functioning properly.

FCL - Formal Customer Complaint

3. RESPONSIBILITIES:

3.1 It is the responsibility of the Director of Operations (Manufacturing) to ensure that resources exist to carry out the requirements listed in this procedure. It is recommended that plant Quality personnel provide on the job training as required to personnel who will b conducting these audits (i.e. walk the process using the audit checklist as a guide).3.2 It is the responsibility of the Plant Manager to ensure that the audits are conducted as prescribed in the procedure.

4. COMMON PROCEDURE REQUIREMENTS

In general, this process is designed to allow for various levels of plant leadership to assess adherence to procedures, work instructions, control plans, etc. and correct non-conformances on a real time basis. Layered audits may also be conducted to verify



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compliance to other specific DBS or Customer/regulatory requirements (eg. PFMEA audits, control plan audits, production part approval compliance audits, and preventive maintenance audits).

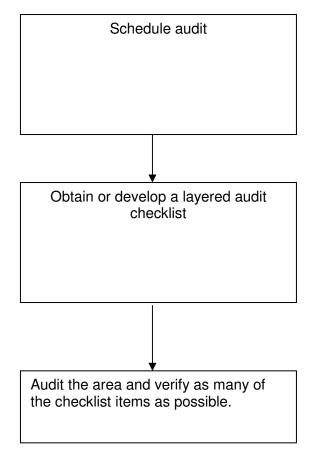
Various layers of management shall conduct the Layered Audit:

Operations Supervisor – The Operations Supervisor shall audit a specific process operation, line, or cell once per shift.

Middle Management – Middle management (eg. General Supervisor) will select at random and audit one line, cell, or department at a minimum of once per week. Middle management will also assure that checklists are being completed by the operations supervisor and that open issues are closed.

The Plant Manager and/or Plant Manager's Staff will audit one line, cell, or department at a minimum of once per month. Plant Manager will also assure that checklists are being completed by the middle management and open items are being closed.

Process Flow Diagram for Layered Audits



An audit schedule must be developed to track progress of layered audit cycle completion. See Appendix B for example of audit schedule. Select an area that has not been audited recently based on the audit schedule.

The checklist should be developed using input from a cross-functional team. Checklists must include the following minimum requirements:

- Review error-proofing verification records
- Review FTQ tracking, reporting, and reaction
- Verify that the operator is following standardized work
- Verify that the operator is trained/certified.

Other items should be included in the checklist based on Quality system or Customer Satisfaction issues. Examples include:

- Rework or repair instructions available and being followed
- Gages calibrated
- Preventive maintenance complete
- Material properly identified
- Proper process settings

An example checklist is included in this procedure as Appendix A.



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Document results as satisfactory or unsatisfactory

Correct all non-conforming items within area of responsibility. Note the corrective action taken and date on the checklist.

Relay all other unsatisfactory items to the responsible personnel and note who was contacted on the checklist

Monitor and report layered audit results

Review documentation, observe activities, and interview manufacturing personnel (without impacting production).

Provide a brief description of the nonconformance on the checklist. Items not audited should be noted as "Not Reviewed".

Corrections should be made and put in place immediately

If unsatisfactory items have the potential to place the product quality at risk, immediate action must be taken by manufacturing to correct the situation. Issues that cannot be corrected immediately should be tracked throughout the plant corrective action process or through the internal audit process and escalated as required. Communicate non-conformances to Manufacturing Engineering for feedback into FMEAs if appropriate.

Layered audit results will be reviewed by management on a periodic basis. The effectiveness of the layered audit process will be evaluated by tracking/reviewing layered audit schedule adherence and first time conformance results (number of items conforming during the audit vs number of items checked – see example Appendix C). Repeat issues should be identified and addressed.



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APPENDIX A – LAYERED AUDIT CHECKLIST EXAMPLE

	Process Element	Υ	N	Corrective Action/Comments	Date Corrected
Со	mmunication				
•	Are employees aware of any recent Formal Customer Complaints (FCC's) / quality issues?				
Wo	rkplace Organization & Environment				
•	Is in-process & outgoing material properly identified				
•	Is traceability in place where required?				
•	Is FIFO used?				
•	Is nonconforming or suspect product identified and placed in a designated area?				
•	Are proper containers used in production, including outgoing material? Is workplace clean and orderly?				
Se	i-Up				
•	Are Visual Aids (required by the Control Plan) available?				
•	Are Change Over instructions followed?				
	Operator Certification/Standardized Work				
•	Are Operators following standardized work?				
•	Are Operators certified on the job?				
Co	ntrol Plan				
•	Are control plan checks made at the proper frequency, with the correct sample size and on the correct form?				
•	Are product/process checks within specification? If not, are reaction plans being followed?				
•	Are significant process events recorded?				
First Time Quality					
•	Are alarm limits being used?				
•	Is a reaction plan available and being followed?				
Ме	asurement Systems				
•	Are Error Proofing devices, gages and fixtures verified?				
•	Are all gages (required by the Control Plan) available at the workstation? Are the gages numbered, calibrated and match the Control Plan?				
Со	ntainment/Rework				
•	Is containment information documented when the product is nonconforming?				
•	Is rework/teardown completed per instructions with proper identification?				
P.N	M. Activities				
•	Are Preventive Maintenance activities complete to schedule?				



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APPENDIX B - AUDIT SCHEDULE EXAMPLE

Management		Dept 30	35	40	45	50	55
Category	Frequency						
Supervisor 1	Once/shift	Mon	Tue	Wed	Thur	Fri	Mon
Supervisor 2	Once/shift				Mon	Tue	Wed
General	1/week					Thu	
Supervisor							
Plant	1/month						Tue
Manager/Staff							

APPENDIX C – LAYERED AUDIT FIRST TIME CONFORMANCE TRACKING EXAMPLE

