

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:

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

Error Proofing Verification – 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 be 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

Layered Audit Process

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

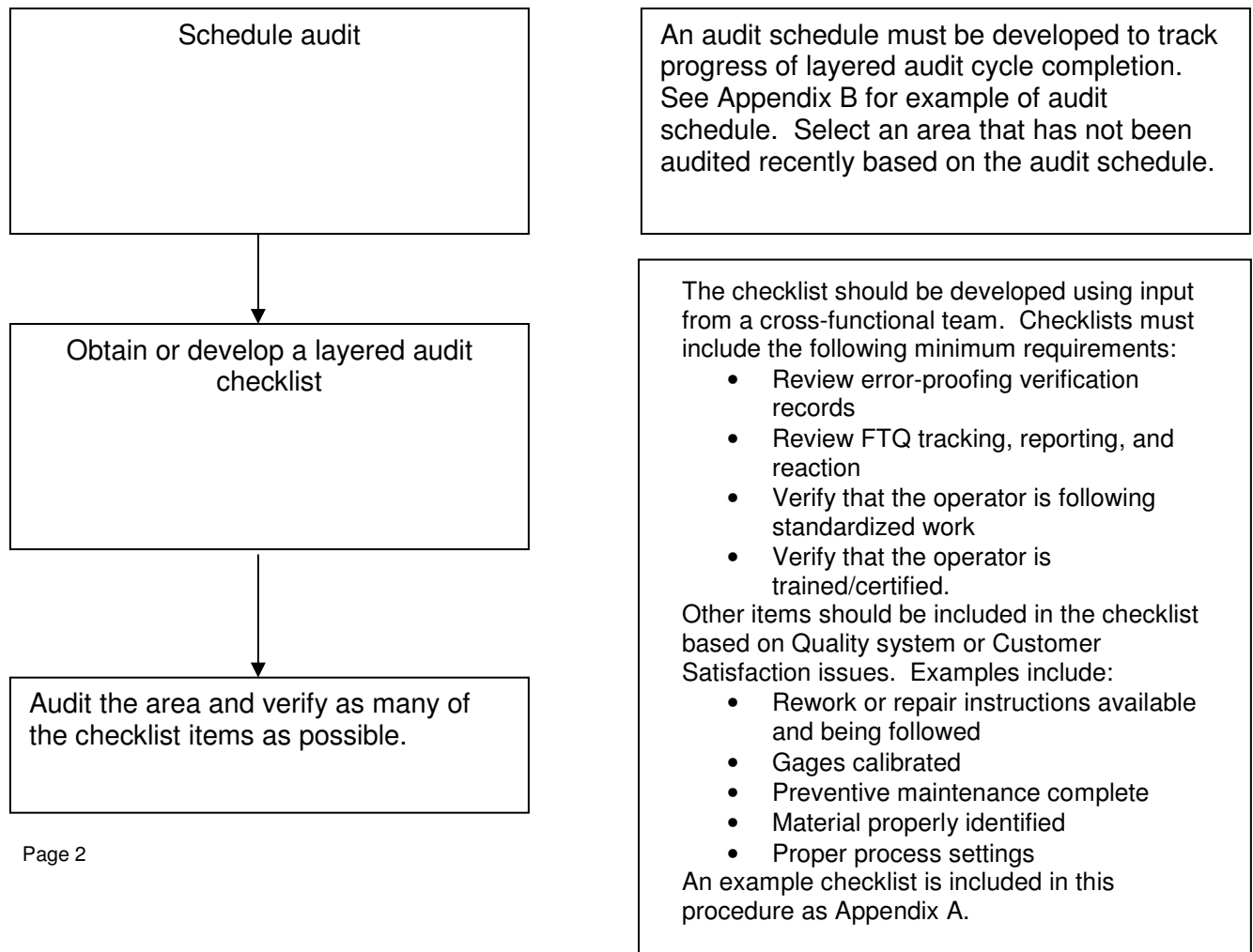
Various layers of management shall conduct the Layered Audit:

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

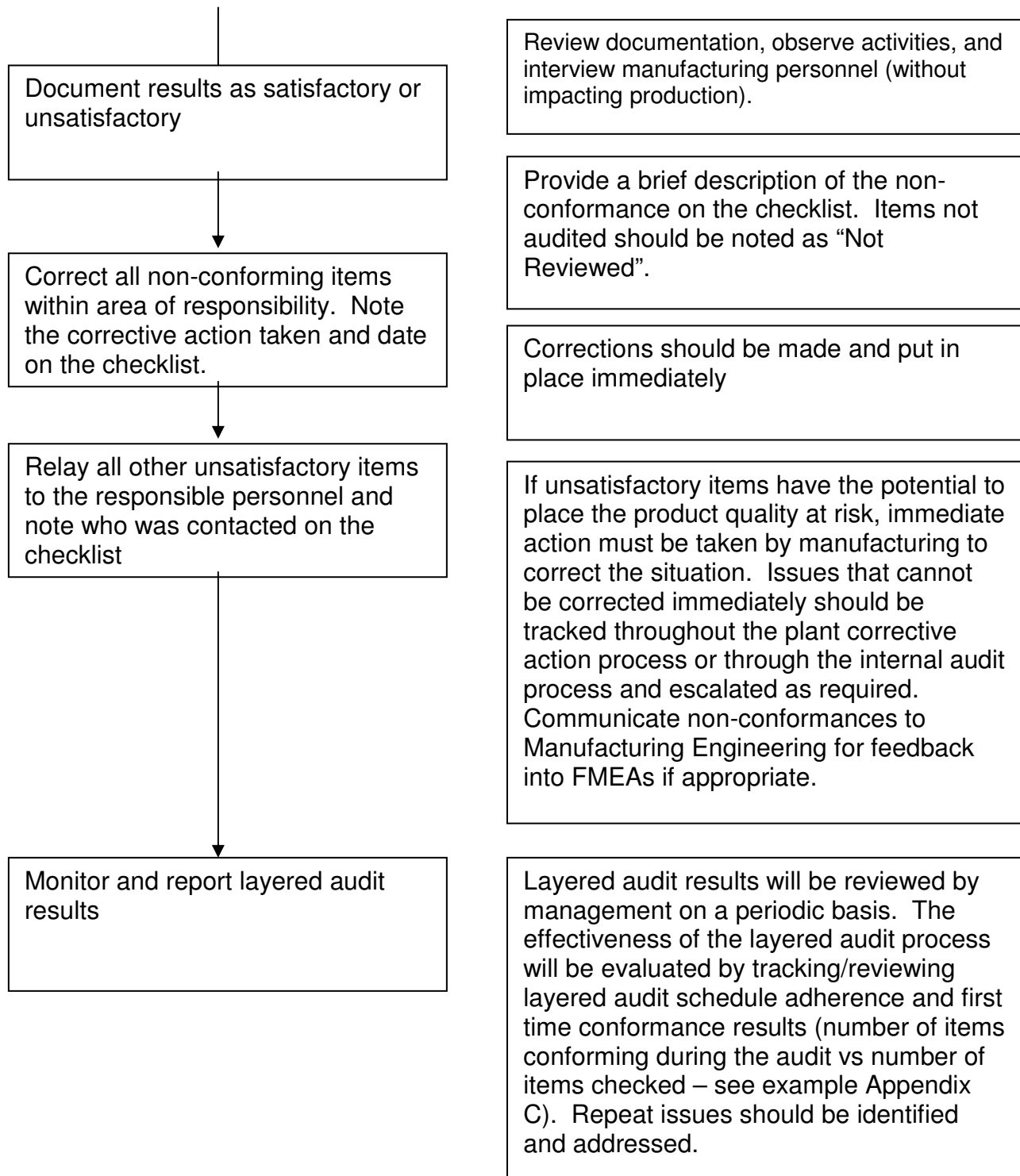
Middle Management – Middle management (eg. General Supervisor) will select at random and audit one line, cell, or department at a minimum of once per week. Middle management will also assure that checklists are being completed by the operations supervisor and that open issues are closed.

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



Layered Audit Process



Layered Audit Process

APPENDIX A – LAYERED AUDIT CHECKLIST EXAMPLE

Process Element	Y	N	Corrective Action/Comments	Date Corrected
Communication				
<ul style="list-style-type: none"> Are employees aware of any recent Formal Customer Complaints (FCC's) / quality issues? 				
Workplace Organization & Environment				
<ul style="list-style-type: none"> Is in-process & outgoing material properly identified 				
<ul style="list-style-type: none"> Is traceability in place where required? 				
<ul style="list-style-type: none"> Is FIFO used? 				
<ul style="list-style-type: none"> Is nonconforming or suspect product identified and placed in a designated area? 				
<ul style="list-style-type: none"> Are proper containers used in production, including outgoing material? 				
<ul style="list-style-type: none"> Is workplace clean and orderly? 				
Set-Up				
<ul style="list-style-type: none"> Are Visual Aids (required by the Control Plan) available? 				
<ul style="list-style-type: none"> Are Change Over instructions followed? 				
Operator Certification/Standardized Work				
<ul style="list-style-type: none"> Are Operators following standardized work? 				
<ul style="list-style-type: none"> Are Operators certified on the job? 				
Control Plan				
<ul style="list-style-type: none"> Are control plan checks made at the proper frequency, with the correct sample size and on the correct form? 				
<ul style="list-style-type: none"> Are product/process checks within specification? If not, are reaction plans being followed? 				
<ul style="list-style-type: none"> Are significant process events recorded? 				
First Time Quality				
<ul style="list-style-type: none"> Are alarm limits being used? 				
<ul style="list-style-type: none"> Is a reaction plan available and being followed? 				
Measurement Systems				
<ul style="list-style-type: none"> Are Error Proofing devices, gages and fixtures verified? 				
<ul style="list-style-type: none"> Are all gages (required by the Control Plan) available at the workstation? Are the gages numbered, calibrated and match the Control Plan? 				
Containment/Rework				
<ul style="list-style-type: none"> Is containment information documented when the product is nonconforming? 				
<ul style="list-style-type: none"> Is rework/teardown completed per instructions with proper identification? 				
P.M. Activities				
<ul style="list-style-type: none"> Are Preventive Maintenance activities complete to schedule? 				

Layered Audit Process

APPENDIX B – AUDIT SCHEDULE EXAMPLE

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

APPENDIX C – LAYERED AUDIT FIRST TIME CONFORMANCE TRACKING EXAMPLE

