Manufacturing Standard Operating Procedure

Department: Manufacturing Operations | Version: [1.0]

Document ID: [SOP-DEPT-###] | Effective Date: [MM/DD/YYYY]

1. Purpose

This Standard Operating Procedure establishes guidelines for manufacturing operations to ensure consistent product quality, operational efficiency, and compliance with safety and regulatory requirements.

2. Scope

This procedure applies to all manufacturing personnel, quality control staff, maintenance technicians, and supervisors involved in production operations.

This procedure applies to:

- Production floor operators and technicians
- Manufacturing supervisors and team leads
- Quality assurance and quality control personnel
- Maintenance and engineering staff
- Warehouse and material handling personnel

Exclusions:

[Describe any activities, processes, or personnel NOT covered by this SOP]

3. Definitions

The following terms have specific meanings within this procedure. Defined terms are capitalized when used throughout this document.

Term	Definition
Batch/Lot	Quantity of product manufactured under identical conditions

CAPA	Corrective and Preventive Action - systematic problem resolution process
First Pass Yield	Percentage of units passing quality inspection on first attempt
GMP	Good Manufacturing Practice - quality guidelines for production
NCR	Non-Conformance Report - documentation of quality deviations
OEE	Overall Equipment Effectiveness - production efficiency metric
SPC	Statistical Process Control - quality monitoring methodology
Takt Time	Available production time divided by customer demand rate

4. Responsibilities

The following roles and positions have specific responsibilities for this procedure:

Role/Position	**Responsibilities**
[Plant Manager]	Will provide resources and ensure compliance with quality and safety standards
[Production Manager]	Will oversee daily operations, scheduling, and production targets
[Quality Manager]	Will maintain quality systems and authorize product release
[Shift Supervisor]	Will coordinate production activities and enforce procedures on the floor
[Operators]	Will follow work instructions, operate equipment safely, and report issues
[Maintenance]	Will maintain equipment per schedule and respond promptly to breakdowns

5. Production Procedures

5.1 Pre-Production Setup

- ☐ Review production schedule and work order requirements
- ☐ Verify raw materials availability and quality certification
- ☐ Complete equipment startup checklist and safety verification
- ☐ Confirm tooling, fixtures, and calibration status are correct
- ☐ Review quality specifications and control point requirements
- ☐ Ensure all required PPE is available and in good condition

5.2 Production Execution

1. Follow work instructions exactly as documented without deviation
2. Perform in-process quality checks at specified intervals
3. Document production counts, times, and any deviations accurately
4. Report equipment issues or abnormal conditions immediately to supervisor
5. Maintain clean and organized work area per 5S standards
6. Segregate and identify any non-conforming material immediately

5.3 End of Shift Procedures

- ☐ Complete production log with accurate counts and batch information
- ☐ Document any quality issues or non-conformances encountered
- ☐ Perform equipment shutdown procedures per checklist
- ☐ Clean work area and return tools to designated locations
- ☐ Complete shift handoff report with key information for next shift
- ☐ Secure any sensitive materials or work-in-progress

6. Quality Metrics Dashboard

Track and monitor the following quality metrics. Review during daily/weekly production meetings:

Metric	Target	Current	Trend	Action Required
First Pass Yield	>98%		Up/Down/Stable	
Defect Rate (PPM)	<500		Up/Down/Stable	
OEE	>85%		Up/Down/Stable	
Scrap Rate	<2%		Up/Down/Stable	

Customer Complaints	0		Up/Down/Stable	
On-Time Delivery	>95%		Up/Down/Stable	

Note: Metrics not meeting targets require documented action plans within 5 business days.

7. Continuous Improvement Log

Document improvement ideas, Kaizen events, and implementation status:

Date	Improvement Description	Category	Owner	Status

7.1 Improvement Categories

- Safety: Workplace safety and ergonomic improvements
- Quality: Product or process quality enhancements
- Efficiency: Productivity improvements and waste reduction (Lean)
- Cost: Cost savings and resource optimization
- Environment: Environmental impact reduction

8. Preventive Maintenance Schedule

All production equipment must be maintained according to the following schedule. Overdue maintenance must be escalated to the Maintenance Manager immediately.

Equipment ID	Equipment Name	PM Frequency	Last PM Date	Next PM Due	Assigned To
[ID-001]	[Equipment Name]	Daily			[Technician]

[ID-002]	[Equipment Name]	Weekly			[Technician]
[ID-003]	[Equipment Name]	Monthly			[Technician]
[ID-004]	[Equipment Name]	Quarterly			[Technician]
[ID-005]	[Equipment Name]	Annually			[Technician]

WARNING: Never operate equipment that has missed scheduled maintenance or failed inspection. Tag equipment out of service and notify Maintenance immediately.

9. Non-Conformance Report (NCR)

All quality deviations must be documented using this Non-Conformance Report process:

1. Identify and immediately quarantine non-conforming material
2. Complete NCR form with detailed description of the non-conformance
3. Notify Quality and Production supervisors within 2 hours
4. Conduct root cause analysis (5-Why, Fishbone, or approved method)
5. Determine disposition: Use As-Is, Rework, Scrap, or Return to Vendor
6. Implement corrective actions to prevent recurrence
7. Verify effectiveness of corrective actions within specified timeframe

9.1 NCR Disposition Options

☐ Use As Is (requires documented engineering justification and approval)
☐ Rework (specify approved rework procedure)
☐ Repair (specify approved repair method)
☐ Return to Vendor (complete RMA documentation)
☐ Scrap (complete scrap documentation and cost allocation)

9.2 NCR Log

NCR #	Date	Description	Disposition	CAPA #	Status

10. Emergency and Exception Procedures

10.1 Emergency Response

In case of emergency, follow the procedures below. Safety of personnel takes priority over all other considerations.

1. Ensure immediate safety of all personnel in the area
2. Contact emergency services if required (911 or local emergency number)
3. Notify supervisor/manager immediately
4. Follow facility emergency evacuation procedures if applicable
5. Document the incident using the Incident Report form

10.2 Exception Handling

When standard procedures cannot be followed due to unusual circumstances:

1. Assess the situation and identify the specific deviation required
2. Obtain verbal approval from [Supervisor/Manager] before proceeding
3. Document the exception, including justification and approver
4. Complete the Exception Request Form within 24 hours
5. Submit for formal review during the next scheduled procedure review

WARNING: Exceptions should only be made when necessary and must be properly documented. Repeated exceptions may indicate the need for procedure revision.

11. Related Information

The following documents and references relate to this procedure:

Category	Reference
Related Policies	Quality Policy, Health and Safety Policy, Environmental Policy
Related SOPs/Procedures	SOP-MFG-002 Equipment Calibration, SOP-MFG-003 Material Handling, SOP-MFG-004

	Lockout/Tagout
Related Forms	Production Batch Record, NCR Form, CAPA Form, PM Checklist, First Piece Inspection Form
External References	ISO 9001:2015 Quality Management, OSHA 29 CFR 1910, GMP/cGMP Requirements (if applicable)

12. Document Control

SOP Owner	[Production Manager / Quality Manager]
Approved By	[Plant Manager / Director of Operations]
Contact Email	[manufacturing@company.com]
Contact Phone	[(XXX) XXX-XXXX]
Review Schedule	Annual or upon process changes, equipment modifications, or quality issues

13. Revision History

Document all revisions to maintain a complete audit trail:

Version	Date	Changes
1.0	[MM/DD/YYYY]	Initial release

14. Authorization and Approval

Name	Role	Signature	Date
	Prepared By		
	Reviewed By		

	Approved By		

15. Documentation of Training

I have read and understand the content of this Standard Operating Procedure. I have received training specific to the procedures, hazards, and emergency protocols described herein.

Note: All personnel who will perform tasks covered by this SOP must sign below prior to conducting any work. Additional signature pages may be attached as needed.

Printed Name	**Signature**	**Date**
[Manager/Supervisor]		