

Standard Operating Procedure (SOP)

Start-up Quality Control Checks and Documentation

Purpose:

This SOP details the procedures for **start-up quality control checks and documentation**, including pre-start equipment inspections, verification of calibration and settings, initial product quality assessments, and thorough record-keeping. The purpose is to ensure that all production processes meet quality standards from the outset, minimizing defects and maximizing operational efficiency through consistent monitoring and accurate documentation.

Scope

This SOP applies to all production lines and personnel involved in start-up activities at [Facility/Department Name].

Responsibilities

- Quality Assurance (QA) Staff:** Oversee and verify QC checks, calibration records, and documentation.
- Operators:** Perform start-up inspections and complete required records.
- Maintenance Team:** Ensure equipment calibration and readiness before start-up.
- Supervisors:** Review and approve QC documentation and ensure compliance.

Procedure

- Pre-Start Equipment Inspection**
 - Visually inspect all equipment for cleanliness, integrity, and readiness.
 - Check for proper installation of guards, safety devices, and emergency stops.
 - Complete the *Pre-Start Equipment Inspection Checklist* (see Appendix A).
- Verification of Calibration and Settings**
 - Ensure all measurement and control instruments are within calibration dates.
 - Verify equipment settings (temperature, pressure, speed, etc.) match production specifications.
 - Document calibration verification in the *Calibration Log*.
- Initial Product Quality Assessment**
 - Run a short batch or sample production as per SOP XX-XXX.
 - Conduct required quality checks (dimensions, weight, visual appearance, other key criteria).
 - Record results on the *Start-up Product Quality Checklist* (see Appendix B).
- Documentation and Record-Keeping**
 - Ensure all checklists and logs are completed, signed, and dated.
 - File records according to the document control procedure.
 - Report any deviations or non-conformances using the *Non-Conformance Report* form.

Documentation

| Document | Description | Retention Period |
|--|--|------------------|
| Pre-Start Equipment Inspection Checklist | Record of visual inspections and equipment readiness | 1 year |
| Calibration Log | Verification of equipment calibration status | 2 years |
| Start-up Product Quality Checklist | Initial product quality assessment results | 1 year |
| Non-Conformance Report | Documentation of out-of-spec results or deviations | 3 years |

Revision History

| Date | Version | Description | Approved By |
|--------------|---------|-----------------|--------------|
| [YYYY-MM-DD] | 1.0 | Initial release | [Name/Title] |

Appendices

1. **Appendix A:** Pre-Start Equipment Inspection Checklist (template)
2. **Appendix B:** Start-up Product Quality Checklist (template)
3. **Appendix C:** Non-Conformance Report Form (sample)