STANDARD OPERATING PROCEDURE

(SOP)

SOP Title:	[Enter procedure title - be specific and descriptive]
SOP Number:	[SOP-XXX-000]
Department/Area:	[Manufacturing / Quality Control / Operations / etc.]
Effective Date:	[MM/DD/YYYY]
Review Date:	[MM/DD/YYYY]
Version/Revision:	[Version 1.0]
Supersedes:	[Previous version number or "N/A" if new]

1. PURPOSE

[Clearly state why this SOP exists and what it aims to accomplish. Example: This SOP defines the standard procedure for calibrating digital torque wrenches to ensure measurement accuracy and maintain quality standards in assembly operations.]

[Include what problem this procedure solves or what outcome it ensures.]

2. SCOPE

[Define where and when this SOP applies. Be specific about boundaries.]

- **Applies to:** [List departments, roles, or equipment covered]
- **Locations:** [Specify facilities or work areas]
- **Frequency:** [How often this procedure is performed]
- **Does NOT apply to:** [List any exclusions or exceptions]

3. RESPONSIBILITIES

Role/Position	Responsibilities

[Operator/Technician]	• Perform procedure according to this SOP • Report deviations or issues • Complete required documentation
[Supervisor/Manager]	• Ensure staff are trained on this SOP • Monitor compliance • Approve deviations when necessary
[Quality Assurance]	• Audit procedure compliance • Review and approve SOP changes • Verify documentation completeness
[Add other roles]	[Define their specific responsibilities]

4. SAFETY PRECAUTIONS & WARNINGS

■ SAFETY WARNINGS - READ BEFORE PROCEEDING

Personal Protective Equipment (PPE) Required:
[ ] Safety Glasses [ ] Gloves [ ] Lab Coat [ ] Steel-Toe Boots [ ] Hearing Protection
[ ] Respirator [ ] Face Shield [ ] Other: _____

Hazards & Risks:
• [List all potential hazards: chemical, electrical, mechanical, etc.]
• [Specify injury risks if procedure not followed correctly]
• [Note any environmental or equipment damage risks]

Emergency Procedures:
• Emergency Contact: [Phone number]
• First Aid Location: [Specify location]
• Emergency Shutdown: [Describe procedure]
• Spill Kit Location: [If applicable]

Critical Safety Rules:
• [List non-negotiable safety requirements]
• [Example: "Never bypass safety interlocks"]
• [Example: "Always work in pairs when handling heavy components"]

5. DEFINITIONS & REFERENCES

Term	Definition
[Technical term]	[Clear definition of term as used in this procedure]
[Abbreviation]	[What the abbreviation stands for and means]
[Specialized term]	[Explain in plain language]
[Add more as needed]	[Definitions help ensure consistent understanding]

Related Documents & References:

• [List related SOPs, work instructions, or technical manuals]
• [Include regulatory standards or compliance requirements]
• [Reference manufacturer specifications if applicable]

6. MATERIALS & EQUIPMENT

Category	Item	Specifications/Notes
Equipment	[Equipment name]	[Model, serial number if specific]
	[Tool name]	[Size, type, calibration requirements]
Materials	[Material/supply name]	[Grade, quantity, storage requirements]
	[Consumable item]	[Lot tracking requirements if applicable]
Software	[Software/system name]	[Version, access requirements]
Documentation	[Forms/logs required]	[Document numbers, where to find]

7. PREREQUISITES

[List everything that must be completed or verified before starting this procedure:]

[ ] Personnel performing this procedure must be trained and qualified

[ ] [Required certifications or competencies]

[ ] [Environmental conditions: temperature, humidity, cleanliness]

[ ] [Equipment must be calibrated and operational]

[ ] [Previous process steps must be completed]

[ ] [Required approvals or permits obtained]

[ ] [Add additional prerequisites as needed]

8. PROCEDURE

Follow these steps in order. Do not skip steps unless explicitly instructed to do so based on conditions noted.

STEP 1: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram showing what this step looks like]
Action: [Describe exactly what to do in clear, specific language]
Parameters/Settings: • [Specify measurements, temperatures, pressures, etc.] • [List any equipment settings] • [Include acceptable ranges or tolerances]
Important Notes: • [Highlight critical points about technique or sequence] • [Warn about common mistakes] • [Note timing requirements if applicable]
Acceptance Criteria: [How to verify this step was completed correctly]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 2: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]

Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 3: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 4: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 5: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 6: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 7: [Concise step description]

VISUAL REFERENCE

[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 8: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 9: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]

Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

STEP 10: [Concise step description]

VISUAL REFERENCE
[Insert photo or diagram]
Action: [What to do]
Parameters: [Settings, measurements, or specifications]
Notes: [Important points or warnings]
Acceptance Criteria: [How to verify completion]
[ ] Step Complete: [Initials: _____ Time: _____]

Continue adding steps as needed. Each step should be numbered sequentially and include visual references, clear actions, and verification criteria.

9. QUALITY CONTROL & VERIFICATION

Verification Point	Method	Acceptance Criteria	Frequency	✓
[What to check]	[How to check it]	[What result is acceptable]	[When to check]	[ ]
[In-process check]	[Visual/measurement]	[Spec/tolerance]	[Each unit/batch]	[ ]
[Final inspection]	[Test procedure]	[Pass/fail criteria]	[100% or sample]	[ ]
[Documentation]	[Record verification]	[Complete and accurate]	[Each procedure]	[ ]

10. DOCUMENTATION & RECORDS

Required Records:
• [List all forms, logs, or data that must be recorded]
• [Specify batch records, equipment logs, test results, etc.]
• [Note any electronic system entries required]

Document Type	Retention Period	Storage Location
[Batch records]	[Specify years/period]	[Physical or digital location]
[Equipment logs]	[Specify period]	[Location]
[Quality data]	[Specify period]	[Location]
[Training records]	[Specify period]	[Location]

11. DEVIATIONS & TROUBLESHOOTING

Handling Deviations:

• Any deviation from this SOP must be documented and approved by [specify role]
• Use Deviation Form [specify form number] to record and justify deviations
• Investigation required for any out-of-specification results

Common Issues & Solutions:

Problem	Possible Cause	Corrective Action
[Describe issue]	[Why it might occur]	[Steps to resolve]
[Common error]	[Root cause]	[Solution or workaround]
[Equipment problem]	[Likely cause]	[Troubleshooting steps]

12. SPECIAL CONSIDERATIONS & NOTES

Environmental Considerations:
[Temperature, humidity, cleanliness requirements]

Regulatory/Compliance Notes:
[FDA, ISO, OSHA, or other regulatory requirements]

Best Practices:
[Tips from experienced operators, efficiency improvements]

Training Requirements:
[Specific training or certification needed to perform this SOP]

Additional Notes:

[Space for other important information not covered above]

13. REVISION HISTORY

Version	Date	Description of Changes	Author	Approver
1.0	[MM/DD/YY]	Initial release	[Name]	[Name]

APPROVAL SIGNATURES

The signatures below indicate that this SOP has been reviewed and approved by the appropriate authorities.

Role	Name (Print)	Signature	Date
Prepared By: [Title/Department]			
Reviewed By: [Title/Department]			
Approved By: [Title/Department]			
Quality Assurance: [Title/Department]			

TRAINING RECORD

All personnel must be trained on this SOP before performing the procedure. Maintain records below or in training management system.

Employee Name	Employee ID	Training Date	Trainer Name	Trainer Signature

HOW TO USE THIS SOP TEMPLATE

1. Replace all bracketed text [like this] with your specific information
2. Insert actual photos/diagrams in the visual reference sections for each step
3. Add or remove sections as needed for your procedure complexity
4. Ensure all safety warnings are comprehensive and clearly visible
5. Have SMEs (Subject Matter Experts) review for technical accuracy
6. Test the SOP with actual operators before final approval
7. Update the document control section with each revision
8. Ensure all approvers sign before implementation