

STANDARD OPERATING PROCEDURE BLUEPRINT

A reusable SOP shell plus writing rules so every process document looks the same, is auditable, and actually gets used on the floor.

PART A — HOW TO USE THIS BLUEPRINT

ISO 9001 does not require a document titled “SOP.” It requires documented information where it is necessary for the effectiveness of the QMS (clause 7.5) and wherever a clause says “maintain” or “retain.” This blueprint is the house standard for any process you decide to document as an SOP.

Write for the person who will do the work on a busy Tuesday — not for the auditor. The auditor will follow the same document.

When you need an SOP vs. a work instruction vs. a record

Type	Use when	Typical owner
SOP (this blueprint)	A process with multiple roles, handoffs, decisions, or ISO/customer requirements (e.g., contract review, receiving, CAPA, calibration).	Process owner + Quality
Work instruction	One job at one station. Step-by-step, photos, torque values, inspection points. Referenced by the SOP.	Supervisor / manufacturing eng.
Form / record	Evidence the process ran as planned. Do not rewrite the SOP onto the form.	Process owner
Quality manual / process map	How processes interact. The SOP sits under one box on the map.	Management representative

Writing rules (enforce these in review)

1. One process per SOP. If you need “and then we also do purchasing,” that is a different SOP.
2. Start each step with a verb and name the role: “Quality Inspector records the results on Form F-075.”
3. Put numbers, specs, and set points in the step or in a referenced WI — not in a paragraph of prose.
4. Show the decision: IF nonconforming THEN hold and open NCR. Do not hide branches in a note.
5. Name the record produced by the step. If no record is produced, say so.
6. Do not copy ISO clause text into the SOP. Map the clause in the header and write what your plant actually does.
7. Keep the current approved copy where the work happens. Obsolete copies are a finding waiting to happen.
8. Review on a defined cycle or when the process, risk, or customer requirement changes — not only when an auditor is coming.

ISO 9001 clauses this blueprint supports:

Clause	How the SOP helps
4.4	Describes a QMS process: inputs, outputs, sequence, criteria, resources, responsibilities, risks.
5.3	Assigns authority and responsibility for the process.
6.1 / 6.2	Captures process risks/opportunities and objectives / measures.
7.1–7.3	Lists competence, infrastructure, and awareness needed to run the process.
7.5	Is itself controlled documented information (identification, review, version, obsolete).
8.x	Operational planning and control for that process (the numbered steps).
9.1	Defines what is measured and where the data lives.
10.2	Tells the reader what to do when the process output is nonconforming.

Delete Part A when you issue a live SOP, or keep a separate “SOP on SOPs” (document control procedure) and issue only Part B.

PART B — FILLABLE SOP (issue this page forward)

Replace every prompt in [brackets]. Remove unused optional rows. Add your logo in the header if required.

1. DOCUMENT CONTROL BLOCK

Document title	[Process name] Standard Operating Procedure
Document number	SOP-XXX
Revision	0
Effective date	[YYYY-MM-DD]
Review due	[YYYY-MM-DD]
Process owner	[Title]
Prepared by / date	
Reviewed by / date	
Approved by / date	
ISO 9001 clauses	[e.g. 8.4 Control of externally provided processes]
Related customer / regulatory reqs	[or None]
Classification	☐ Uncontrolled copy if printed ☐ Controlled only in [system name]

2. PURPOSE

State why this process exists in one to three sentences. Example: "To review customer requirements before committing to supply, so the organization only accepts work it can meet."

3. SCOPE

In scope	[Sites, products, shifts, process start/stop]
Out of scope	[What this SOP does not cover, and which document does]
Applies to	[Roles / departments]

4. REFERENCES

Type	Number / title	Use
Standard	ISO 9001:2015	QMS requirements
Internal SOP		
Work instruction		
Form / record		
Customer spec		
External spec / law		

5. DEFINITIONS AND ABBREVIATIONS

Term	Meaning in this SOP

6. RESPONSIBILITIES AND AUTHORITIES

R = Responsible (does the work) A = Accountable (yes/no authority) C = Consulted I = Informed

Activity	[Role 1]	[Role 2]	[Role 3]	[Role 4]	Quality / MR
Initiate process					
Perform process steps					
Verify / inspect					
Handle nonconformance					
Approve exceptions					
Retain records					
Review / improve process					

Authority to stop the process / withhold release: [Title]. Authority to approve a deviation: [Title].

7. INPUTS, OUTPUTS, AND INTERACTIONS

Process inputs	[Info, material, customer reqs, previous process output]
Process outputs	[Product, service, data, record, next-process input]
Upstream processes	[SOP numbers]
Downstream processes	[SOP numbers]
Support processes	[IT, calibration, training, maintenance]

8. RESOURCES AND COMPETENCE

Equipment / software / infrastructure	[List; include calibrated devices]
Materials / environment	[ESD, FOD, cleanliness, temperature if relevant]
Competence required	[Training / qualification codes]
How competence is demonstrated	[OJT sign-off, test, certificate]

9. RISKS, OPPORTUNITIES, AND CONTROLS

Risk or opportunity	Level (H/M/L)	Control already in this SOP	Residual / further action

10. PROCEDURE

Numbered steps. One action per step. Name the role. Name the record. Attach a simple flowchart if the path branches.

Step	Role	Action (verb first). Include IF/THEN decisions.	Record / system / WI
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

Add rows as needed. If a step is performed only under a condition, write the condition in the Action cell.

11. NONCONFORMING OUTPUT AND ESCALATION

How nonconforming output is identified	[Hold tag, system block, red bin]
Immediate action	[Contain, notify, segregate]
Record to open	[NCR / 8D / customer notice]
Who may disposition	[Title — and when customer approval is required]
When to stop the line / stop shipment	[Criteria]

12. RECORDS AND RETENTION

Record / form	Where stored	Retention	Owner	Disposition after retention

13. PROCESS MEASURES AND OBJECTIVES

Measure / KPI	Target	Source data	Frequency	Who reviews

14. TRAINING AND COMMUNICATION OF THIS SOP

Who must be trained before working	[Roles]
Training method	[Read & sign / OJT / classroom]
Record of training	[Training Manager / matrix / form]
How changes are communicated	[Alert, toolbox, system pop-up]

15. REVISION HISTORY

Rev	Date	Author	Description of change (what and why)
0	[effective]		Initial release

16. APPROVAL SIGN-OFF (issue of this revision)

Role	Name	Signature	Date
Author / process owner			
Quality / document control			
Approver (authority)			

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Blueprint only. Adapt to your QMS. Do not treat this file as a controlled SOP until you assign a number, complete the content, and approve it in your document-control process.