HEALTHCARE POLICY AND SOP REVIEW TEMPLATE

Policy and SOP Review Checklist

Review healthcare policies and SOPs for current requirements, clear ownership, safe instructions, controlled approvals, version integrity, staff access, implementation, review cycles, and verified corrective-action closure.

FACILITY / LOCATION	AUDIT DATE	AUDITOR	APPROVER

Adapt review intervals, approval authorities, evidence sources, document templates, training rules, retention periods, emergency-change processes, and exception controls to current facility policy and applicable local requirements.

1. Audit setup, policy scope, ownership, and governance

1 **Confirm the facility, audit date, auditor, document-control owner, clinical-governance lead, department owners, approvers, and escalation contacts for the policy and SOP review.**

METADATA + SIGN-OFF

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Identify who can approve, restrict, or rapidly revise a high-risk document.

2 **Define the policy families, SOPs, work instructions, protocols, forms, clinical pathways, emergency procedures, and support documents included in the audit scope.**

DOCUMENT SCOPE CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Include policies, SOPs, protocols, work instructions, forms, pathways, and linked documents that staff actually use.

3 **Verify every sampled document has a named owner, accountable department, approval authority, effective date, review date, version, and controlled-document identifier.**

CRITICAL | OWNERSHIP + CONTROL CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Check owner, approver, version, effective date, review date, and controlled identifier together.

4 **Review previous document-control findings, overdue reviews, conflicting procedures, obsolete copies, policy-related incidents, survey findings, and overdue corrective actions.**

PREVIOUS FINDINGS REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use repeat issues to target high-risk services, policy families, and weak document-control processes.

5 **Confirm the organization has identified the current legal, regulatory, accreditation, professional, payer, manufacturer, and facility requirements relevant to each sampled document.**

CRITICAL | REQUIREMENTS MATRIX CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Do not assume one external requirement applies to every service or jurisdiction.

6 **Capture the audit start time, departments sampled, document sample, evidence method, and any exclusions or restrictions on confidential or sensitive content.**

CRITICAL | SAMPLE + EVIDENCE SETUP

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Record the sample and evidence method without exposing unnecessary confidential information.

2. Regulatory, accreditation, evidence, and source requirements

7 **Verify each sampled policy or SOP cites or can be traced to the current external requirements, evidence, standards, manufacturer instructions, or internal controls that justify the procedure.**

CRITICAL | SOURCE REQUIREMENT CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Trace the active instruction to the current authoritative requirement or approved evidence source.

8 **Confirm superseded laws, standards, guidance, or manufacturer instructions have been identified and do not remain embedded in active procedures.**

CRITICAL | OBSOLETE SOURCE REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Look for withdrawn guidance, superseded standards, and outdated manufacturer instructions.

9 **Check the document review process includes a reliable method for detecting material changes in applicable regulations, accreditation expectations, safety alerts, and professional guidance.**

CRITICAL | CHANGE-DETECTION PROCESS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Confirm someone is responsible for watching material changes in the sources that govern the document.

10 **Verify jurisdiction-specific requirements are distinguished from organization-wide standards so staff are not directed to use rules that do not apply to their location or service.**

JURISDICTION APPLICABILITY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Separate site-specific or jurisdiction-specific requirements from enterprise-wide rules.

11 **Confirm high-risk clinical and operational procedures are reviewed by suitably qualified subject-matter experts before approval or reapproval.**

SUBJECT-MATTER REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use reviewers with enough expertise to challenge high-risk clinical content.

12 **Check the evidence or source record is retained well enough to explain why a requirement was added, changed, removed, or retained during review.**

SOURCE TRACEABILITY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Keep enough source evidence to explain why the document changed.

3. Document structure, clarity, identifiers, and controlled format

13 Verify every sampled document uses the approved template or minimum structure, including title, purpose, scope, responsibilities, procedure, references, approvals, and revision information as applicable.

CRITICAL | CONTROLLED TEMPLATE CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use the approved document structure so staff can find critical information consistently.

14 Confirm titles, document codes, versions, dates, page identifiers, and linked forms are consistent across the controlled document and the document-management system.

CRITICAL | DOCUMENT ID + VERSION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Match title, code, version, dates, and linked records across the document and system.

15 Check instructions use clear, actionable language with defined decision points, limits, escalation triggers, and exceptions rather than ambiguous or conflicting wording.

CRITICAL | INSTRUCTION CLARITY REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Test whether a user can act on the instruction without guessing what it means.

16 Verify abbreviations, terminology, clinical terms, units, thresholds, roles, and definitions are standardized and understandable to the intended users.

CRITICAL | TERMINOLOGY STANDARDIZATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Standardize terms, abbreviations, units, thresholds, and role names.

17 Confirm tables, diagrams, checklists, attachments, forms, and links referenced by the SOP are current, accessible, and correctly matched to the active version.

CRITICAL | LINKED DOCUMENT CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Open referenced forms and links rather than assuming they are still valid.

18 Check critical warnings, contraindications, patient-safety steps, required approvals, and stop-work or escalation criteria are visible where staff need them.

CRITICAL WARNING REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Make stop-work, escalation, contraindication, and safety-critical steps easy to see.

4. Clinical accuracy, patient-safety controls, and operational feasibility

19 **Verify the procedure reflects current approved practice and does not conflict with other active policies, clinical pathways, order sets, equipment instructions, or emergency procedures.**

PRACTICE ALIGNMENT CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Compare the SOP with current practice, linked systems, and other active policies for conflicts.

20 **Confirm patient identification, consent, medication, infection prevention, equipment, communication, documentation, and other relevant safety controls are included where the process requires them.**

CRITICAL | PATIENT-SAFETY CONTROL REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Check only the safety controls relevant to the process being reviewed.

21 **Check required staffing, qualifications, supervision, equipment, supplies, environment, and technology are realistically available for staff to perform the SOP as written.**

OPERATIONAL FEASIBILITY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Verify the resources required by the SOP actually exist where the work is performed.

22 **Verify thresholds, dose or concentration limits, time windows, monitoring frequency, acceptance criteria, and escalation rules are correct and clearly stated where applicable.**

CRITICAL | LIMIT + THRESHOLD CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Confirm every critical value, limit, time window, and monitoring frequency is correct.

23 **Confirm the policy defines what staff must do when the standard process cannot be followed, including interim controls, authorization, documentation, and escalation.**

EXCEPTION PROCESS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Define what staff do when the normal process cannot be followed safely.

24 **Check high-risk steps have enough verification, cross-checking, documentation, or independent review to prevent foreseeable errors or unsafe variation.**

HIGH-RISK VERIFICATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use independent checks or other safeguards where a foreseeable error could cause serious harm.

5. Roles, responsibilities, approvals, and multidisciplinary review

25 **Verify the document clearly assigns responsibilities to the correct professions, departments, supervisors, approvers, and support functions.**

CRITICAL | RESPONSIBILITY MATRIX

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Assign every action to the role that truly owns it in practice.

26 **Confirm the approval workflow matches facility governance requirements and includes the required clinical, operational, quality, safety, legal, pharmacy, infection-control, or other reviewers where applicable.**

CRITICAL | APPROVAL WORKFLOW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Include the reviewers required by governance and by the risks in the procedure.

27 **Check approval dates, reviewer names or roles, meeting or committee evidence, and electronic approvals are complete and traceable.**

CRITICAL | APPROVAL EVIDENCE

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Retain traceable evidence of who reviewed and approved the document and when.

28 **Verify delegated approval authority is current and does not allow unauthorized staff to approve, release, or materially change controlled procedures.**

CRITICAL | DELEGATED AUTHORITY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Do not allow expired or informal delegation to become an approval shortcut.

29 **Confirm multidisciplinary documents are reviewed by all materially affected services rather than only by the document owner.**

CRITICAL | MULTIDISCIPLINARY REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Ask every materially affected service to review shared procedures.

30 **Check disagreements, unresolved risks, conditional approvals, and exceptions are documented and escalated before the revised document becomes effective.**

UNRESOLVED RISK ESCALATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Resolve or formally escalate material disagreement before release.

6. Implementation, staff access, training, and competency

31 **Verify the current approved policy or SOP is available at the point of use in the format staff are expected to access during work.**

CRITICAL | POINT-OF-USE ACCESS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Test the exact pathway staff use to find the current document during work.

32 **Confirm obsolete, uncontrolled, draft, locally saved, printed, or bookmarked versions are removed, disabled, or clearly marked so they cannot be mistaken for the current procedure.**

OBSOLETE COPY CONTROL

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Remove or clearly mark local files, printouts, drafts, and bookmarks that point to old versions.

33 **Check affected staff receive appropriate communication before or at the effective date when a new or revised document changes their responsibilities or workflow.**

CRITICAL | CHANGE COMMUNICATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Communicate material changes before staff are expected to work differently.

34 **Verify training, read-and-understand acknowledgment, competency assessment, simulation, or supervised practice is completed when the risk or complexity of the change requires it.**

TRAINING + COMPETENCY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Match implementation effort to the risk and complexity of the change.

35 **Confirm staff can explain the key requirements, escalation triggers, and current version for sampled high-risk procedures without relying on outdated local practice.**

CRITICAL | STAFF KNOWLEDGE TEST

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use a practical scenario to test whether staff know the current critical requirements.

36 **Check agency, temporary, rotating, trainee, remote, and contractor personnel receive the policy access and instruction required for the work they perform.**

EXTERNAL STAFF ACCESS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Include agency, temporary, rotating, remote, and contractor staff where the SOP applies to them.

7. Version control, change management, distribution, and archiving

37 **Verify each revision has a unique version, effective date, revision summary, approval record, and clear relationship to the superseded version.**

VERSION HISTORY CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Every revision should be uniquely identifiable and traceable to the version it replaced.

38 **Confirm material changes are assessed for downstream impact on forms, training, competencies, order sets, signage, equipment settings, software, contracts, and related policies.**

CRITICAL | CHANGE IMPACT ASSESSMENT

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Check whether a document change requires updates to forms, systems, training, signage, or equipment settings.

39 **Check controlled distribution reaches every applicable location, department, digital library, workstation, device, or printed point-of-use copy before the new version is relied on.**

CRITICAL | CONTROLLED DISTRIBUTION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Confirm all controlled locations receive the active version before go-live.

40 **Verify superseded documents are archived according to retention requirements and remain retrievable for investigations, claims, audits, or historical review when required.**

CRITICAL | ARCHIVE + RETENTION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Archive superseded documents so they remain retrievable when retention rules require it.

41 **Confirm archived and draft versions are access-controlled so users can distinguish them immediately from the current approved version.**

DRAFT / ARCHIVE CONTROL

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Prevent users from confusing drafts or historical documents with the active procedure.

42 **Check emergency or rapid policy changes use a documented interim approval, communication, review, and expiry or formalization process.**

CRITICAL | EMERGENCY CHANGE PROCESS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Rapid changes still need defined approval, communication, expiry, and formal review.

8. Implementation verification, linked records, and real-world adherence

43 **Observe a representative workflow and verify staff practice is consistent with the current approved policy or SOP.**

CRITICAL | LIVE WORKFLOW OBSERVATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Observe the actual process rather than relying only on document review.

44 **Confirm records, forms, logs, checklists, electronic fields, labels, and evidence generated by the process match the requirements in the current procedure.**

CRITICAL | RECORD / FORM ALIGNMENT

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Compare the records staff create with what the current SOP requires.

45 **Check local workarounds, verbal rules, unofficial job aids, or department customs do not conflict with the controlled document.**

CRITICAL | WORKAROUND CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Treat recurring unofficial workarounds as evidence that either practice or the document needs correction.

46 **Verify recurring deviations, near misses, complaints, incidents, audit findings, or staff questions are reviewed for possible policy ambiguity or implementation failure.**

CRITICAL | DEVIATION TREND REVIEW

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use incidents and repeated questions as signals that the document may be unclear or impractical.

47 **Confirm the document owner receives enough operational feedback to know whether the procedure is practical, understood, and consistently followed.**

OWNER FEEDBACK LOOP

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Document owner review should include feedback from the teams who actually use the procedure.

48 **Check corrective actions address both non-adherence and any underlying document problem, such as unclear wording, missing resources, obsolete links, or unrealistic workflow.**

CRITICAL | SYSTEM CORRECTIVE ACTION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Fix the document and the system cause, not just the individual non-compliance event.

9. Review cycle, triggered review, metrics, and exception management

49 **Verify every sampled policy or SOP is within the review interval required by applicable rules, accreditation, facility policy, risk, or document type.**

REVIEW-DATE COMPLIANCE

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Apply the review interval required for the specific document and setting.

50 **Confirm overdue reviews are visible in a controlled register with owner, risk level, due date, escalation status, and interim decision on whether the document remains safe to use.**

CRITICAL | OVERDUE REVIEW REGISTER

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Overdue documents need visible ownership, risk assessment, and escalation rather than silent rollover.

51 **Check significant incidents, regulatory changes, new technology, product changes, service redesign, audit findings, or repeated deviations trigger an out-of-cycle review when appropriate.**

TRIGGERED REVIEW CHECK

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use material change and safety events to trigger review before the routine due date when needed.

52 **Verify document-control metrics track overdue reviews, approval cycle time, implementation completion, obsolete copies, policy-related findings, and other meaningful risks.**

DOCUMENT CONTROL METRICS

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Track measures that reveal document-control risk, not just the number of policies reviewed.

53 **Confirm approved exceptions or deviations specify scope, justification, risk controls, authorization, start date, end date, affected locations, and required follow-up.**

EXCEPTION AUTHORIZATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Exceptions need scope, rationale, controls, authorization, dates, and follow-up.

54 **Check temporary exceptions are closed, renewed, or incorporated into a formal revision before their authorized period expires.**

TEMPORARY EXCEPTION CLOSURE

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Do not allow temporary deviations to continue indefinitely without formal resolution.

10. Findings, corrective actions, verification, and sign-off

55 **Calculate the overall policy and SOP review result and summarize critical gaps, overdue reviews, conflicting instructions, obsolete content, and implementation risks.**

AUDIT SCORE + SUMMARY

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Separate immediate patient or operational risk from underlying document-control causes.

56 **Create immediate containment for any policy gap that could expose patients, staff, or operations to unacceptable risk, including temporary instruction, restriction, or escalation where needed.**

CRITICAL | CRITICAL CONTAINMENT ACTION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Record any temporary instruction, restriction, or escalation used before normal work continued.

57 **Assign each finding an owner, priority, due date, root-cause requirement, corrective action, document revision task, and closure-evidence rule.**

CRITICAL | CORRECTIVE ACTION ASSIGNMENT

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Use short deadlines for immediate risk and realistic deadlines for permanent document correction.

58 **Escalate overdue, repeated, high-risk, legally significant, or patient-safety-related document findings to the required governance level.**

CRITICAL | GOVERNANCE ESCALATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Escalate high-risk, repeated, legal, or patient-safety findings to the appropriate governance level.

59 **Verify closure through approved revision, source validation, communication, training, removal of obsolete copies, observation, record review, or repeat audit as appropriate.**

CRITICAL | CLOSURE VERIFICATION

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Do not close a finding until the revised document and its implementation are objectively verified.

60 **Record the final audit decision, remaining exceptions, next review date, auditor, document-control or governance approval, date, time, and signature.**

CRITICAL | APPROVAL + SIGNATURE

Compliant | Needs attention | Critical gap | N/A

◇ Execution tip: Keep unresolved high-risk instructions restricted until every release condition is documented and approved.