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HEALTHCARE COMPLIANCE DOCUMENTATION AUDIT TEMPLATE

Compliance Documentation Audit Checklist

Audit healthcare compliance documentation across licenses, policies, staff credentials, clinical records, equipment evidence, emergency records, quality systems, retention, access, and corrective closure.

FACILITY / DEPARTMENT	DATE / SHIFT	DOCUMENT GROUP / SCOPE	AUDITOR / REVIEWER

1. Audit scope, compliance register, document owners, and escalation

1 **Confirm the facility, department, audit date, auditor, compliance lead, document-control owner, and escalation contacts are recorded.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

2 **Define the document groups in scope, including licenses, policies, clinical records, staff files, equipment records, safety records, emergency plans, quality evidence, and external certificates.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

3 **Verify the organization maintains a current register or other controlled method showing required compliance documents, owners, review dates, expiry dates, and storage locations.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

4 **Confirm document ownership and approval authority are defined for clinical, operational, safety, facility, equipment, HR, quality, and regulatory records.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

5 **Review recent survey findings, expired certificates, missing records, overdue policy reviews, incomplete training evidence, documentation incidents, and open corrective actions.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

6 **Escalate immediately when a missing, expired, falsified, inaccessible, or uncontrolled document could affect legal authorization, patient safety, critical operations, or regulatory compliance.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with the compliance register and clear document ownership.

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2. Licenses, registrations, certificates, permits, and accreditation evidence

7 Verify required facility licenses, operating registrations, permits, certificates, and approvals are current and match the legal entity, site, and services provided.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

8 Check expiry dates, renewal submissions, conditions, restrictions, and responsible owners for sampled licenses and certificates.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

9 Confirm required professional, laboratory, pharmacy, radiation, waste, fire, lift, pressure-system, or other regulated certificates are available where applicable.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

10 Verify accreditation certificates, survey outcomes, conditions, waivers, corrective plans, or other external compliance evidence are controlled and retrievable.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

11 Check superseded, expired, suspended, or replaced licenses and certificates are clearly archived and not displayed or relied upon as current evidence.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

12 Escalate expired, missing, suspended, materially restricted, or incorrect authorization that could affect the facility's ability to provide a regulated service.

CRITICAL | DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Treat expired legal authorization as a high-priority gap.

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3. Policies, SOPs, forms, version control, and controlled documents

13 **Verify required policies, SOPs, work instructions, clinical protocols, forms, checklists, and emergency procedures have a clear owner and approval status.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

14 **Check each sampled controlled document has a title, unique identifier where used, version or revision status, effective date, approval, and review date.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

15 **Confirm obsolete versions are removed from active points of use and retained only through the approved archive or records process.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

16 **Check staff can access the current approved version at the location and time it is needed, including during downtime or emergency conditions where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

17 **Verify changes are reviewed, approved, communicated, and linked to training or implementation actions when the revision affects staff duties or safety controls.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

18 **Escalate uncontrolled, conflicting, obsolete, unapproved, or inaccessible procedures that could lead to unsafe or noncompliant practice.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only current approved versions should be in active use.

4. Staff credentials, training, competency, and personnel compliance records

19 Verify sampled staff files contain the licenses, registrations, certifications, privileges, role qualifications, and other credentials required for assigned duties.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

20 Check credential expiry dates, renewals, restrictions, primary-source or other required verification, and escalation of lapsed credentials are controlled.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

21 Confirm mandatory orientation, annual training, emergency preparedness, infection prevention, safety, privacy, equipment, and role-specific training records are complete where required.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

22 Verify competency assessments, supervised practice, authorization, or reassessment evidence is available for activities that require documented competence.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

23 Check contractor, agency, locum, volunteer, student, and outsourced-worker documentation meets the organization's requirements before applicable work begins.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

24 Escalate missing or expired credentials, privileges, mandatory training, or competency evidence when the person is performing work that requires current authorization.

CRITICAL | DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on staff authorization without current evidence.

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5. Clinical records, consent, patient documentation, privacy, and access controls

25 **Verify sampled clinical records are complete, legible, attributable, dated or timed where required, and organized so relevant care information can be retrieved.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

26 **Check required consent, authorization, patient-rights, procedure, medication, assessment, discharge, transfer, or other clinical documentation is present where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

27 **Confirm corrections, late entries, amendments, and electronic changes preserve authorship, date, and an appropriate audit trail rather than obscuring the original record.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

28 **Verify access to patient information is restricted to authorized users and that records are protected from inappropriate disclosure, alteration, loss, or destruction.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

29 **Check downtime, scanning, upload, filing, interface, or document-indexing processes do not create missing, duplicate, misfiled, or inaccessible patient records.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

30 **Escalate missing critical clinical documentation, invalid or absent required consent, unauthorized access, or record integrity issues that could affect patient care, privacy, or legal evidence.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Protect record integrity, confidentiality, and retrievability.

6. Equipment, maintenance, calibration, utilities, and facility compliance records

31 **Verify medical equipment inventories and sampled asset records show inspection, preventive maintenance, service, repair, and current operational status as required.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

32 **Check calibration certificates, reference standards, test results, due dates, failed-calibration actions, and traceability are available for equipment requiring measurement assurance.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

33 **Confirm electrical, generator, UPS, fire-system, HVAC, medical-gas, water, lift, pressure-system, or other facility maintenance and test records are current where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

34 **Verify defective or out-of-service assets have traceable restrictions, repair records, verification evidence, and authorized return-to-service status.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

35 **Check vendor and service reports identify the correct asset or system, work performed, results, technician or provider, date, deficiencies, and follow-up actions.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

36 **Escalate missing safety-critical maintenance, calibration, test, or repair evidence when equipment or a facility system remains in use without acceptable assurance.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: No safety-critical asset should rely on missing maintenance evidence.

7. Infection prevention, sterilization, cleaning, waste, and medication-control documentation

37 **Verify infection-prevention policies, surveillance records, audits, exposure follow-up, hand-hygiene monitoring, and outbreak documentation are maintained where required.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

38 **Check sterilization, disinfection, reprocessing, load records, indicator results, equipment checks, recalls, and traceability documentation are complete where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

39 **Confirm environmental cleaning schedules, terminal-cleaning records, isolation-area logs, housekeeping audits, and corrective actions can be retrieved for sampled areas.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

40 **Verify biomedical or regulated-waste segregation, storage, collection, transport, manifest, vendor, or disposal records are maintained where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

41 **Check medication storage, refrigerator temperature, controlled-drug, pharmacy, expiry, recall, or other medication-control records are complete where required.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

42 **Escalate documentation gaps that prevent traceability of sterilization, infection-control response, waste disposition, medication control, or another high-risk compliance process.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve traceability for high-risk infection and medication controls.

8. Safety, emergency preparedness, incidents, drills, and risk documentation

43 Verify current emergency plans, hazard assessments, response procedures, continuity arrangements, and escalation contacts are approved and accessible.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

44 Check emergency training, drills, exercises, after-action reviews, corrective actions, and required evidence of staff participation are documented.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

45 Confirm occupational injury, illness, exposure, sharps, incident, near-miss, security, fire, utility, or other safety records are completed under the applicable program.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

46 Verify fire, life-safety, evacuation, egress, emergency-lighting, alarm, suppression, essential-power, and related inspection or test records are current where applicable.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

47 Check risk assessments, permits, contractor controls, incident investigations, root-cause reviews, and corrective-action records are linked to accountable owners.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

48 Escalate missing emergency, incident, or safety documentation when it prevents verification of a critical control, required response, or corrective closure.

CRITICAL | DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Emergency and incident evidence must support readiness and follow-up.

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9. QAPI, audit evidence, committee records, CAPA, vendors, and external review

49 **Verify the quality program maintains evidence of audits, indicators, improvement projects, adverse-event review, performance monitoring, and governing or leadership oversight where required.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

50 **Check committee minutes, management reviews, safety meetings, infection-control reviews, medication reviews, or other oversight records document decisions and assigned actions.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

51 **Confirm internal and external audit findings are linked to corrective and preventive actions with owners, due dates, evidence, and effectiveness review.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

52 **Verify complaints, grievances, patient feedback, vendor issues, supplier performance, service-level failures, and recurring nonconformities are documented and trended where applicable.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

53 **Check contractor and vendor files include required agreements, insurance, credentials, licenses, service evidence, privacy or security terms, and compliance documentation where relevant.** DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

54 **Escalate repeated overdue actions, unverified corrective closure, missing governance evidence, or unresolved external findings that create material compliance risk.** CRITICAL DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close audit findings with accountable CAPA and effectiveness evidence.

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10. Retention, security, retrieval, gaps, corrective actions, and final sign-off

55 Verify retention periods are defined by document type using applicable legal, regulatory, accreditation, contractual, clinical, privacy, and organizational requirements.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.

56 Check records are protected against unauthorized alteration, loss, inappropriate destruction, ransomware, environmental damage, or access failure through approved controls and backups.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.

57 Test retrieval of sampled current and archived documents to confirm the correct version and supporting evidence can be produced within the required operational or audit timeframe.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.

58 Record each documentation gap with document type, affected site or department, risk level, owner, due date, immediate control, and required closure evidence.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.

59 Create corrective actions for missing records, expired approvals, weak version control, incomplete training evidence, record-integrity problems, retention gaps, or recurring retrieval failures.

DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.

60 Record the final audit result, critical open gaps, overdue actions, document restrictions, next review date, auditor, compliance owner, document-control owner, and management sign-off.

CRITICAL | DOCUMENTATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Make retention, retrieval, and corrective closure auditable.