HEALTHCARE CALIBRATION INSPECTION TEMPLATE

Calibration Inspection Checklist

Audit calibration control across device identity, reference standards, traceability, as-found accuracy, tolerance, adjustment, certificates, failed calibration handling, and return to service.

FACILITY / DEPARTMENT	DATE / SHIFT	DEVICE GROUP / SAMPLE	AUDITOR / REVIEWER

1. Audit setup, calibration governance, device scope, roles, and escalation

1 Confirm the facility, department, calibration review date, auditor or technician, equipment owner, biomedical or clinical engineering lead, and escalation contacts. — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Define ownership before sampling.

2 Define the device groups, clinical services, measurement functions, calibration population or sample, and time period included in the inspection. — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use a risk-based sample where permitted.

3 Verify the organization has current policies for calibration, inspection, maintenance, equipment inventory, out-of-service control, and return-to-use approval. — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Keep current procedures available at the asset.

4 Confirm calibration intervals and activities follow manufacturer instructions, applicable legal or accreditation requirements, or a documented risk-based equipment-management program where permitted. — CRITICAL — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Document the basis for every interval.

5 Review recent out-of-tolerance results, overdue calibrations, repeated drift, device failures, complaints, service events, and open corrective actions relevant to the scope. — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Start with recent failures and overdue work.

6 Confirm staff know when a device must be removed from clinical use, who can authorize calibration or adjustment, and how a serious accuracy concern is escalated. — CRITICAL — CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Escalation rules should be known before testing.

2. Equipment inventory, identification, criticality, due status, and service history

7 Verify each sampled device has a unique asset identifier and matches the equipment inventory, manufacturer, model, serial number, location, and responsible department. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Match physical device to the inventory record.

8 Record the measurement function, clinical use, operating range, resolution, relevant accessories or probes, and patient-risk significance of inaccurate measurement. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Clinical criticality should influence review depth.

9 Check the current calibration status, last calibration date, next due date, service provider, maintenance strategy, and any active restriction or hold status. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Check due date and active restrictions together.

10 Identify devices used for diagnostic, therapeutic, monitoring, laboratory, environmental, or facility measurements and apply the correct calibration requirements for each category. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use device-specific calibration requirements.

11 Confirm devices that are new, recently repaired, relocated, upgraded, or modified receive the required inspection and testing before initial or resumed use. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: New or repaired devices need controlled release.

12 Escalate missing asset identity, unclear ownership, overdue calibration, conflicting due dates, or devices in service without enough evidence to confirm current status. CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not rely on a label alone.

3. Reference standards, traceability, calibration method, environment, and uncertainty

13 **Identify the reference standard, calibrator, simulator, test set, phantom, reference thermometer, pressure source, electrical standard, or other equipment used for the calibration.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Record the exact reference used.

14 **Verify reference standards have current calibration status and documented metrological traceability appropriate to the measurement being made.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Traceability needs documented links.

15 **Check the calibration method or work instruction is approved, current, suitable for the device, and consistent with manufacturer or authorized technical requirements where applicable.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use the approved method revision.

16 **Confirm the selected test points cover the clinically or operationally relevant range and include the required zero, low, mid, high, alarm, or functional points as applicable.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Choose points that represent real use.

17 **Verify environmental conditions such as temperature, humidity, warm-up time, stabilization, electrical supply, vibration, or setup do not invalidate the calibration result.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Stabilize the setup before reading.

18 **Record or review measurement uncertainty, acceptance decision rules, correction factors, or other technical information when required by the calibration program or external laboratory scope.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Apply uncertainty rules where required.

4. Pre-calibration inspection, as-found condition, setup, and baseline readings

19 **Inspect the device for physical damage, contamination, broken seals, damaged probes or sensors, loose connectors, worn cables, depleted batteries, or other conditions that could affect measurement.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Preserve the condition before adjustment.

20 **Verify accessories, leads, probes, cuffs, sensors, test adapters, fixtures, software versions, and configuration settings required for calibration match the device and approved method.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use the correct accessories and setup.

21 **Confirm the device is cleaned, electrically safe where required, warmed up, stabilized, zeroed, or otherwise prepared according to the approved procedure before testing.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Complete required safety preparation first.

22 **Record as-found readings before adjustment so the device condition at the time of inspection remains traceable.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: As-found data supports impact review.

23 **Check initial readings for drift, instability, hysteresis, nonlinearity, noise, intermittent faults, error codes, or other abnormal behavior that may require investigation.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Investigate unstable readings, not only failures.

24 **Remove the device from service when physical condition, setup, self-test failure, unstable output, or other pre-calibration findings make a valid calibration unsafe or unreliable.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Unsafe setup means stop the calibration.

5. Accuracy, repeatability, range, alarms, and performance verification

25 **Compare device readings with the approved reference at the required calibration points and record both reference and device values.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Record reference and device values together.

26 **Calculate or record error, deviation, correction, or percent difference using the approved method and compare it with the acceptance tolerance.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use the approved error calculation.

27 **Repeat selected points when required to assess repeatability, stability, drift, or measurement consistency rather than relying on a single reading.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Repeatability can reveal hidden instability.

28 **Verify zero, span, low-range, mid-range, high-range, and clinically significant operating points as applicable to the device and measurement function.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Cover clinically important parts of the range.

29 **Test alarms, limits, displays, indicators, outputs, data transmission, recording functions, or control responses where calibration depends on associated performance.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Calibration may include associated alarms and outputs.

30 **Classify each tested point as within tolerance, needs investigation, or out of tolerance and prevent release when any safety-critical acceptance criterion fails.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Failed acceptance criteria block release.

6. Tolerance, adjustment, as-left results, failed calibration, and impact assessment

31 **Confirm tolerance limits are defined from approved manufacturer specifications, technical standards, clinical requirements, or the organization's authorized calibration procedure.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Tolerance must come from an approved source.

32 **Adjust or recalibrate the device only when the procedure permits it and only by qualified personnel using controlled settings, tools, software, or service access.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only qualified personnel should adjust settings.

33 **Record as-found results before adjustment and as-left results after adjustment so the amount and direction of correction remain traceable.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Keep as-found and as-left evidence.

34 **Repeat the required calibration points after adjustment and confirm the device now meets all applicable acceptance criteria before release.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Re-test after every accepted adjustment.

35 **When a device is found out of tolerance, identify the period since the last known acceptable result and assess potentially affected measurements, patients, products, tests, or processes as required.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Assess what may have been affected.

36 **Quarantine, repair, replace, downgrade, or permanently remove devices that cannot meet tolerance or whose calibration integrity cannot be restored with approved methods.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Do not release a device that cannot meet tolerance.

7. High-risk clinical equipment, specialty measurements, and risk-based controls

37 **Identify calibration tasks involving high-risk or life-supporting equipment and confirm the required manufacturer, regulatory, accreditation, or hospital-specific controls are applied.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Critical devices need the correct technical program.

38 **Verify devices used for infusion, ventilation, physiologic monitoring, laboratory measurement, sterilization monitoring, environmental control, or other critical functions receive the correct technical tests for their intended use.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Test what matters to intended clinical use.

39 **For imaging or radiologic equipment, apply the manufacturer and applicable regulatory maintenance and calibration requirements rather than a generic alternate schedule where stricter rules apply.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Apply stricter imaging rules where required.

40 **Check medical laser or other specially regulated equipment follows the required manufacturer service and calibration instructions and is handled only by qualified personnel.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Special equipment may require manufacturer service.

41 **Confirm devices included in any alternate or risk-based maintenance program are eligible, clearly identified, supported by documented risk assessment, and maintained to the approved program.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: AEM eligibility and rationale must be documented.

42 **Escalate any situation where a device's clinical criticality, regulation, manufacturer requirement, or lack of maintenance history makes the proposed calibration approach inappropriate.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Escalate when the proposed method is not permitted.

8. Calibration certificates, labels, external providers, records, and traceability

43 **Verify calibration certificates identify the correct device, date, method or service performed, reference standards, results, acceptance status, and service provider.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Match the certificate to the exact asset.

44 **Check external calibration providers are approved for the required scope and competence, and review accreditation or quality evidence where the organization requires it.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Use providers approved for the required scope.

45 **Confirm certificates or records include traceability information and enough detail to reconstruct the calibration result, especially for critical measurements.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Keep enough evidence to reconstruct the result.

46 **Apply or update calibration labels with asset ID, calibration date, next due date, status, and other required information without obscuring safety labels or controls.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Labels must match the record.

47 **Update the equipment-management system, maintenance record, asset register, or quality record with the new calibration result and next due date.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Update the system before release.

48 **Escalate missing certificates, incorrect asset numbers, incomplete results, expired reference standards, conflicting labels, or records that cannot support traceability.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Incomplete traceability needs correction.

9. Post-calibration release, overdue devices, recalls, trends, and program review

49 **Verify the device passes required functional, safety, alarm, or performance checks after calibration before it is returned to clinical or operational use.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Post-calibration testing confirms real readiness.

50 **Confirm any out-of-service tag, system hold, quarantine status, or physical restriction is removed only after authorized review and documented release.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Only authorized staff remove restrictions.

51 **Review overdue calibration by risk level and prevent continued use when the organization's policy, manufacturer requirement, or applicable regulation does not permit an overdue condition.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Overdue use must follow the controlling rules.

52 **Check service bulletins, safety notices, recalls, software changes, field corrections, or manufacturer updates for any effect on calibration method, interval, or acceptance limits.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Review bulletins that change limits or methods.

53 **Trend out-of-tolerance rates, repeat adjustments, device drift, overdue work, failed standards, vendor issues, and repeat repairs to identify systemic improvement needs.** CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Trend drift and repeated failures.

54 **Review calibration intervals and methods when performance history shows excessive drift, repeated failures, low-risk stability, or other evidence that requires a controlled program decision.** CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Change intervals only through a controlled decision.

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

55 Record each calibration finding with device ID, issue type, risk level, immediate control, accountable owner, due date, and approved evidence requirement. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Every critical finding needs one owner.

56 Create immediate containment for every critical out-of-tolerance result, failed reference standard, unsafe device condition, missing traceability record, or unauthorized calibration status. CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Contain risk before root-cause work.

57 Assign corrective actions for repair, recalibration, impact assessment, certificate correction, provider review, process change, training, or program improvement as required. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Match actions to the actual failure mode.

58 Verify closure through repeat calibration, independent review, repair evidence, updated certificate, corrected inventory status, impact-assessment completion, or other approved proof. CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Close only with objective verification.

59 Escalate overdue, repeated, high-risk, or patient-impacting calibration findings to the required biomedical engineering, quality, clinical, laboratory, or management level. CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Escalate repeated or patient-impacting failures.

60 Record the final calibration inspection result, devices remaining restricted, open actions, next review date, auditor or technician, reviewer approval, date, time, and sign-off. CRITICAL CALIBRATION

Compliant | Needs attention | Critical gap | N/A

Execution tip: Final sign-off should show remaining restrictions.