NABH BIOMEDICAL AUDIT READINESS CHECKLIST

Complete documentation guide for Indian hospitals

10 document categories • All ME chapter requirements • Audit-ready format

25+	12,000+	10
hospitals live on Vajra	assets tracked	document categories

Prepared by Vajra — Proteger AI Private Limited, Bangalore
April 2026 • Version 1.0

How to Use This Checklist

This checklist maps every documentation requirement from the NABH Management of Equipment (ME) chapter into a hospital-actionable format. It is structured across 10 document categories — from asset inventory to regulatory approvals — covering all items NABH assessors look for during accreditation and re-accreditation.

Use it as a pre-audit gap analysis tool, a monthly compliance review, or an onboarding guide for new biomedical staff. Each item has a checkbox for status tracking and a note field for observations.

NOT STARTED | IN PROGRESS | COMPLETE | N/A

Before your audit	Run through every section. Mark status. Any item showing NOT STARTED or IN PROGRESS is your action list.
During onboarding	Use as a training guide for new biomedical engineers — each item shows exactly what documentation is needed.
Monthly review	Review Section B (Maintenance) and C (Calibration) every month to confirm schedules are on track.
Post-audit	Use non-conformance feedback to update item notes with corrective actions and target completion dates.

Important note on NABH scope: This checklist covers biomedical equipment management documentation only. IT assets, facility infrastructure, and clinical records are governed by separate NABH chapters and are outside the scope of this document. For AERB-regulated equipment (X-ray, CT, MRI), refer to Section J for the applicable regulatory documentation.

A ASSET & INVENTORY

Master Biomedical Asset Register

Complete list of all biomedical equipment with serial no., model, manufacturer, dept., acquisition date, cost.

Auditor note: Must be updated within 30 days of any new procurement or disposal.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Department-wise Equipment List

Individual equipment lists per department (ICU, OT, ER, Radiology, etc.).

Auditor note: Assessors verify that all departments are covered, not just high-value equipment areas.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Equipment Classification (Critical / Non-Critical)

Each asset categorised by risk level. Critical equipment requires enhanced PM and response protocols.

Auditor note: Classification criteria should align with NABH ME chapter definitions.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Equipment Life Cycle Records

Records from procurement through commissioning, service history, and eventual condemnation.

Auditor note: Demonstrates full asset traceability — required for NABH ME element on lifecycle management.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Asset Tagging / Unique ID Records

Physical ID tags (QR codes, asset labels, barcodes) linked to digital records.

Auditor note: Each tag must map to a specific asset entry in the master register by unique ID.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

B MAINTENANCE RECORDS

Annual Preventive Maintenance (PM) Planner

Documented PM schedule for the full calendar year, equipment-wise with planned service months.

Auditor note: Based on manufacturer recommendations. Must exist at the start of each year.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

PM Checklists (Equipment-wise)

Standardised checklists for each equipment category defining what is inspected during every PM.

Auditor note: Equipment-specific, not generic. OEM checklists acceptable if adopted formally.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

PM Completion Records

Signed records confirming PM was completed — date, technician name, findings, actions taken.

Auditor note: Both planned and actual dates must be recorded. Unsigned records are non-conformances.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Breakdown Maintenance Register

Log of every equipment failure: date, complaint, equipment ID, downtime, resolution, root cause.

Auditor note: Must include all incidents — even minor ones. Unrecorded breakdowns are a critical gap.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Daily Rounds

Daily equipment readiness records, especially for critical care (ICU, OT, Emergency).

Auditor note: Signed by biomedical engineer or designated technician. Gaps in daily rounds are flagged.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

PM & BM Log (Monthly)

Monthly consolidated log combining all PM activities and breakdown incidents for that month.

Auditor note: Required per department. Assessors often request the past 12 months during audit.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

C CALIBRATION & QUALITY

Calibration Master List

Comprehensive list of all equipment requiring periodic calibration with due dates and calibration agency.

Auditor note: Must distinguish between NABL-accredited lab calibrations and OEM calibrations.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Calibration Schedule

Planned calibration dates for the year, equipment-wise.

Auditor note: Schedule must be realistic and achievable. Assessors check adherence to this schedule.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Calibration Certificates (NABL / OEM)

Valid calibration certificates linked to specific equipment by serial number.

Auditor note: Certificate validity dates must be current. Expired certificates = immediate non-conformance.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Calibration Status Labels

Physical labels affixed to equipment showing last calibration date and next due date.

Auditor note: Labels must be visible, legible, and consistent with certificate records.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

D SAFETY & RISK

Electrical Safety Test (EST) Reports

Annual or biannual ESTs for all electrically operated equipment — documenting earth continuity, insulation, leakage.

Auditor note: Especially critical for ICU, OT, and life-support equipment. Must be performed by qualified personnel.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Earth Resistance Test Reports

Reports confirming earth resistance is within safe limits for critical areas.

Auditor note: Tested independently from EST. Frequency as per IS/IEC standards applicable to the facility.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Leakage Current Test Reports

Records of chassis leakage current measurements for electrically sensitive equipment.

Auditor note: Critical for patient-connected equipment. Limits as per IEC 60601 standards.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Medical Device Incident Register

Log of any adverse events or near-misses involving medical equipment.

Auditor note: Mandatory under CDSCO regulations and NABH patient safety standards. Must be kept even if no incidents occurred (as nil record).

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

E INSTALLATION & COMMISSIONING

Installation & Commissioning Records

Records confirming equipment was correctly installed, tested, and verified before clinical use.

Auditor note: OEM commissioning report preferred. In-house records acceptable with authorised signatures.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Equipment Acceptance / Handover Records

Signed records transferring equipment from vendor/supplier to hospital — confirming it meets specifications.

Auditor note: Must match procurement order specifications. Signed by biomedical engineer and authorised hospital representative.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

F AMC / CMC / WARRANTY

AMC Agreements

Signed Annual Maintenance Contracts covering all equipment without active warranty.

Auditor note: Must specify scope of coverage, response times, and exclusions. Expired AMCs without renewal = gap.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

CMC Agreements

Comprehensive Maintenance Contracts (parts + labour) where applicable.

Auditor note: Distinguished from AMCs (labour only). Assessors verify high-value equipment is covered.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Warranty Documents

Active warranty certificates from OEM/vendor for recently procured equipment.

Auditor note: Warranty period, coverage, and vendor contact must be on file. Equipment beyond warranty needs AMC.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Service Visit Reports

Reports from every vendor/AMC service visit — date, engineer name, work performed, parts replaced, sign-off.

Auditor note: Must be filed per equipment. Verbal service visits with no documentation are non-conformances.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

G TRAINING

User Training Records (Biomedical / Vendor)

Attendance registers and training content records for all equipment training conducted.

Auditor note: Covers both clinical user training (nurses, doctors) and biomedical engineer training. Dated and signed.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

H EMERGENCY & CRITICAL CARE

Critical Equipment List

Formally designated list of life-critical equipment requiring priority maintenance and zero-downtime protocols.

Auditor note: Must be approved by clinical and biomedical leadership. Used to prioritise response in breakdowns.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

ICU / OT Equipment Readiness Records

Pre-session/pre-shift checklists confirming all critical equipment is functional and ready for patient use.

Auditor note: Signed by biomedical engineer or qualified technician. Daily records expected for ICU and OT.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

I CONDEMNATION & DISPOSAL

Condemned Equipment Register

Log of all equipment formally taken out of service — equipment ID, condemnation date, reason, approving authority.

Auditor note: Equipment removed from service without formal condemnation creates inventory discrepancies.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Condemnation Approval Records

Signed approval from authorised committee/personnel confirming condemnation decision.

Auditor note: Committee composition and authority must align with hospital policy. One-person decisions are not sufficient.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Scrap / Disposal Certificates

Documentation confirming equipment has been physically disposed of in compliance with e-waste regulations.

Auditor note: E-Waste (Management) Rules 2022 apply. Certificate from authorised recycler required.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

J REGULATORY (BIOMEDICAL SCOPE)

AERB License & Approvals (X-ray, Radiology)

Valid AERB registration/license for all X-ray machines, CT scanners, fluoroscopy units, and radiation-emitting devices.

Auditor note: AERB licenses are time-limited. Expired license = immediate regulatory non-conformance. Renewal must be tracked proactively.

Status

[ ] Done [ ] Partial [ ] N/A

Notes: _____

Is Your Hospital Audit-Ready?

Vajra automates every item in this checklist — PM scheduling, calibration alerts, incident logging, NABH report generation, and complete asset traceability. Trusted by 25+ hospitals across India.

Book a Free Demo	Website	Email	WhatsApp
vajra.software/#demo	vajra.software	contact@vajra.software	+91 97900 72534