HEALTHCARE REPROCESSING AUDIT TEMPLATE

Sterilization and Disinfection Checklist

Audit device classification, point-of-use care, cleaning, high-level disinfection, sterilization cycles, indicators, complex devices, sterile storage, recalls, and corrective actions.

FACILITY / DEPARTMENT	AUDIT DATE	AUDITOR	APPROVER

Use with current regulations, facility policy, validated processes, approved chemicals, and manufacturer instructions for each device and system.

1. Audit setup, reprocessing scope, classification, and governance

1 **Confirm the facility, sterile services or reprocessing area, audit date, operating status, auditor, reprocessing lead, IPC contact, and escalation contacts.** METADATA + SIGN-OFF

Compliant | Needs attention | Critical gap | N/A

Tip: Identify who can stop a process, quarantine a load, remove equipment from service, start a recall, and authorize release after a critical reprocessing failure.

2 **Define the reusable devices, procedure areas, collection routes, cleaning stations, disinfectors, sterilizers, storage areas, shifts, and outsourced processes included in the audit.** SCOPE CHECKLIST

Compliant | Needs attention | Critical gap | N/A

Tip: Sample the full decontamination life cycle from point of use and dirty receipt through cleaning, inspection, processing, storage, distribution, and release.

3 **Verify current reprocessing policies, device and equipment manufacturer instructions for use, approved chemical instructions, validation records, and escalation procedures are available to staff.** CRITICAL DOCUMENT VERIFICATION

Compliant | Needs attention | Critical gap | N/A

Tip: Use the current approved instructions for the exact device, accessories, detergent or disinfectant, packaging system, and processing equipment.

4 **Confirm devices are classified by infection risk as critical, semicritical, or noncritical and assigned the required sterilization or disinfection level before processing.** CRITICAL SPAULDING CLASSIFICATION

Compliant | Needs attention | Critical gap | N/A

Tip: Critical items require sterilization before patient use; semicritical items require at least high-level disinfection unless sterilized; noncritical items use the approved lower-level process.

5 **Review recent sterilization or disinfection failures, wet packs, damaged instruments, positive biological indicators, recalls, complaints, infection concerns, and overdue corrective actions.** PREVIOUS FINDINGS REVIEW

Compliant | Needs attention | Critical gap | N/A

Tip: Use repeat failures to target specific devices, loads, sterilizers, shifts, packaging methods, chemical processes, or staff competency gaps.

6 **Capture the audit start time, sampled workflow areas, equipment identifiers, and approved reference evidence without including unnecessary patient identifiers.** TIMESTAMP + EVIDENCE

Compliant | Needs attention | Critical gap | N/A

Tip: Record enough context to verify where, when, and on which equipment the observation occurred while protecting patient privacy.

2. Point-of-use care, collection, transport, and dirty-area receiving

7 **Verify reusable devices receive the required point-of-use treatment so gross soil is removed and organic material is not allowed to dry before cleaning.**

CRITICAL | POINT-OF-USE CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Follow the device instructions for use; avoid unapproved soaking or chemicals that can damage the device or interfere with later processing.

8 **Confirm contaminated devices are transported promptly in closed, leak-resistant, puncture-resistant where required, clearly designated containers that protect staff and the environment.**

CRITICAL | CONTAMINATED TRANSPORT

Compliant | Needs attention | Critical gap | N/A

Tip: Separate sharps and fragile items appropriately and prevent open hand-carrying of contaminated instruments through clean or public areas.

9 **Verify dirty receiving and decontamination areas are physically or operationally separated from clean assembly, packaging, sterile storage, and released supplies.**

CRITICAL | DIRTY-TO-CLEAN FLOW

Compliant | Needs attention | Critical gap | N/A

Tip: Observe staff and material movement to confirm contaminated items do not cross back into clean workflows.

10 **Check received sets and devices are identified, counted where required, linked to the correct tray or case, and inspected for missing, damaged, or single-use components before cleaning.**

RECEIVING + TRACEABILITY

Compliant | Needs attention | Critical gap | N/A

Tip: Resolve missing components, sharps, and damage before the set progresses into the clean side of the workflow.

11 **Confirm staff handling contaminated instruments use task-appropriate PPE and safe work practices for sharps, splashes, chemicals, and heavy or awkward devices.**

CRITICAL | DECONTAMINATION PPE

Compliant | Needs attention | Critical gap | N/A

Tip: PPE selection should reflect the actual exposure risk and chemical safety information for the task.

12 **Verify contaminated devices do not remain unprocessed beyond the approved time or condition and that delays trigger the specified pre-cleaning, soaking, or escalation process.**

CRITICAL | PROCESSING DELAY CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Track delayed trays and devices because dried soil can make cleaning more difficult and undermine later disinfection or sterilization.

3. Cleaning, decontamination, rinsing, and drying

13 **Confirm each device is disassembled, opened, unlocked, or otherwise prepared for cleaning exactly as required by the device manufacturer instructions.** CRITICAL DEVICE PREPARATION

Compliant | Needs attention | Critical gap | N/A

Tip: Hidden joints, ratchets, channels, detachable parts, and lumens must be exposed to the cleaning process where the instructions require it.

14 **Verify detergents or enzymatic cleaners are approved for the device and process and are prepared at the required concentration, temperature, water quality, and change frequency.** CRITICAL CLEANING CHEMISTRY

Compliant | Needs attention | Critical gap | N/A

Tip: Check product label or IFU requirements rather than using a single dilution or temperature for all devices.

15 **Observe manual cleaning technique for adequate friction, brushing, flushing, immersion or other required steps while controlling splashes and aerosols.** CRITICAL MANUAL CLEANING

Compliant | Needs attention | Critical gap | N/A

Tip: Use the correct brush or accessory size and replace worn or contaminated cleaning tools according to the approved process.

16 **Verify ultrasonic cleaners, washer-disinfectors, and other automated cleaning equipment are loaded, operated, tested, maintained, and used according to manufacturer instructions.** CRITICAL AUTOMATED CLEANING

Compliant | Needs attention | Critical gap | N/A

Tip: Check cycle selection, spray-arm or connector function, detergent supply, load configuration, and any required routine performance tests.

17 **Confirm channels and lumens are flushed, brushed, connected, irrigated, and rinsed as required so all internal surfaces receive the complete cleaning process.** CRITICAL LUMEN + CHANNEL CLEANING

Compliant | Needs attention | Critical gap | N/A

Tip: Trace one complex device through every channel step and confirm the correct adapters, volumes, tools, and sequence are used.

18 **Inspect sampled devices after cleaning for visible soil, residue, moisture, corrosion, damage, and cleanliness; repeat cleaning before further processing when acceptance criteria are not met.** CRITICAL CLEANLINESS INSPECTION

Compliant | Needs attention | Critical gap | N/A

Tip: Sterilization or high-level disinfection should not be used to compensate for inadequate cleaning.

4. Inspection, function checks, assembly, packaging, and labeling

19 **Inspect instruments and reusable devices under suitable lighting and magnification where required for cleanliness, integrity, alignment, sharpness, insulation, corrosion, and other defects.**

CRITICAL | POST-CLEAN INSPECTION

Compliant | Needs attention | Critical gap | N/A

Tip: Remove damaged, pitted, cracked, misaligned, or otherwise unsafe devices from service according to the approved pathway.

20 **Verify devices are function-tested and assembled in the correct configuration with approved accessories, lubricants, protectors, and set contents before packaging.**

CRITICAL | FUNCTION + ASSEMBLY

Compliant | Needs attention | Critical gap | N/A

Tip: Confirm moving parts, ratchets, hinges, cutting edges, electrical insulation, and detachable components are fit for safe use.

21 **Confirm the selected wrap, pouch, rigid container, tray, filter, seal, and packaging method are compatible with the device and chosen sterilization process.**

CRITICAL | PACKAGING COMPATIBILITY

Compliant | Needs attention | Critical gap | N/A

Tip: Packaging must allow sterilant penetration and drying while maintaining package integrity through handling and storage.

22 **Verify external process indicators and internal chemical indicators are placed and interpreted according to the packaging system, sterilization method, and facility procedure.**

CRITICAL | CHEMICAL INDICATOR SETUP

Compliant | Needs attention | Critical gap | N/A

Tip: An indicator shows exposure to specified conditions; it does not by itself prove sterility.

23 **Check package labels provide the required load, cycle, sterilizer, date, contents, assembler or traceability information without damaging package integrity.**

LABEL + TRACEABILITY

Compliant | Needs attention | Critical gap | N/A

Tip: Use labels and marker methods approved for the packaging system and facility traceability process.

24 **Confirm prepared packs are dry, correctly sealed, not compressed or overfilled, and protected from tears, punctures, open seals, or other defects before loading.**

CRITICAL | PACKAGE INTEGRITY

Compliant | Needs attention | Critical gap | N/A

Tip: Do not send a compromised or wet package forward for processing or release.

5. Disinfection level, chemical processing, and high-level disinfection

25 **Verify the selected disinfection level matches the device classification, intended patient contact, manufacturer instructions, and facility policy.**

CRITICAL | DISINFECTION LEVEL

Compliant | Needs attention | Critical gap | N/A

Tip: Semicritical devices require at least high-level disinfection unless they are sterilized; noncritical devices use the approved lower-level process.

26 **Confirm devices are thoroughly cleaned and rinsed as required before entering a chemical disinfection or high-level disinfection process.**

CRITICAL | PRE-DISINFECTION CLEANING

Compliant | Needs attention | Critical gap | N/A

Tip: Residual soil can reduce the effectiveness of chemical disinfection and must be corrected before processing continues.

27 **Verify high-level disinfectant or chemical sterilant concentration, minimum effective concentration testing where applicable, temperature, exposure time, expiry, and reuse life are controlled per instructions.**

CRITICAL | CHEMICAL PROCESS CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Record the exact product and test result and follow the manufacturer instructions for the full validated exposure conditions.

28 **Check basins, automated endoscope reprocessors, processors, lids, adapters, tubing, and circulation systems are clean, functional, maintained, and used within validated operating conditions.**

CRITICAL | PROCESSOR READINESS

Compliant | Needs attention | Critical gap | N/A

Tip: Confirm the processor cycle and connections are compatible with the exact device being reprocessed.

29 **Verify all required device surfaces and internal channels are fully exposed to the disinfectant for the complete contact time without trapped air or incomplete immersion where applicable.**

CRITICAL | FULL CONTACT VERIFICATION

Compliant | Needs attention | Critical gap | N/A

Tip: Trace a sampled device to confirm every channel or surface receives the required chemistry and exposure.

30 **Confirm post-disinfection rinsing, drying, handling, transport, and storage prevent residual chemical exposure and recontamination before the device is used or stored.**

CRITICAL | POST-HLD HANDLING

Compliant | Needs attention | Critical gap | N/A

Tip: Use the specified rinse water quality, drying method, handling precautions, and storage configuration for the device.

6. Sterilization method, cycle selection, loading, and processing

31 **Confirm critical reusable devices are sterilized before use and that the selected sterilization method is compatible with the device, packaging, and manufacturer instructions.** CRITICAL STERILIZATION INDICATION

Compliant | Needs attention | Critical gap | N/A

Tip: Use steam sterilization whenever it is appropriate for heat- and moisture-compatible devices; use validated alternatives only when required.

32 **Verify the correct validated cycle, exposure parameters, drying phase, and load type are selected for the device and sterilizer rather than relying on a generic cycle.** CRITICAL CYCLE SELECTION

Compliant | Needs attention | Critical gap | N/A

Tip: Match the exact cycle to the sterilizer, load, device, packaging system, and manufacturer instructions.

33 **Inspect sterilizer load configuration for correct spacing, orientation, tray placement, pouch position, weight, and absence of overloading that could impair air removal, sterilant contact, or drying.** CRITICAL LOAD CONFIGURATION

Compliant | Needs attention | Critical gap | N/A

Tip: Observe a live load and compare it with the sterilizer and packaging instructions for use.

34 **Confirm hinged instruments are open or unlocked and multipart devices are arranged as required so sterilant can reach all surfaces and retained moisture can drain or dry.** CRITICAL DEVICE CONFIGURATION

Compliant | Needs attention | Critical gap | N/A

Tip: Do not tightly close or assemble devices in a way that prevents the validated sterilization process from reaching internal surfaces.

35 **Verify immediate-use steam sterilization is not used as a substitute for adequate inventory, routine convenience, or poor scheduling and that each use meets the approved indication and traceability process.** CRITICAL IMMEDIATE-USE CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Review the reason, device, cycle, transfer method, patient use, and any required documentation for each sampled immediate-use event.

36 **Confirm implantable items and other high-risk loads are managed under the facility's current release criteria, including required biological monitoring and quarantine where applicable.** CRITICAL HIGH-RISK LOAD RELEASE

Compliant | Needs attention | Critical gap | N/A

Tip: Do not release a high-risk load before all required monitoring and authorization criteria have been satisfied.

7. Sterilizer monitoring, indicators, load release, and records

37 **Review mechanical cycle records for each sampled load and confirm time, temperature, pressure or other required physical parameters met the validated acceptance criteria.** CRITICAL MECHANICAL MONITORING

Compliant | Needs attention | Critical gap | N/A

Tip: Investigate incomplete printouts, alarms, aborted cycles, parameter excursions, or missing records before load release.

38 **Verify an external chemical indicator is present on each package or container and internal chemical indicators are used and interpreted according to current procedure.** CRITICAL CHEMICAL INDICATORS

Compliant | Needs attention | Critical gap | N/A

Tip: A failed or questionable indicator requires the affected item or load to be held and investigated rather than released.

39 **Confirm biological indicators are used at the required frequency and for the required load types, incubated and interpreted correctly, and linked to the sterilizer and load record.** CRITICAL BIOLOGICAL MONITORING

Compliant | Needs attention | Critical gap | N/A

Tip: Follow current facility policy and applicable standards for frequency, implant loads, test packs, incubation, documentation, and response.

40 **Verify dynamic-air-removal steam sterilizers receive the required air-removal test, such as a Bowie-Dick test, at the defined frequency and after relevant maintenance or relocation when required.** CRITICAL AIR-REMOVAL TEST

Compliant | Needs attention | Critical gap | N/A

Tip: A failed air-removal test requires the sterilizer to remain out of routine use until the cause is resolved and acceptance criteria are met.

41 **Confirm loads are released only after staff review the full set of required mechanical, chemical, biological, package, drying, and cycle acceptance criteria.** CRITICAL LOAD RELEASE

Compliant | Needs attention | Critical gap | N/A

Tip: Release authority and exceptions should be explicit; do not use a single indicator as the only basis for routine load release.

42 **Verify sterilization records are complete, legible, retrievable, retained for the required period, and traceable to the sterilizer, cycle, load contents, operator, and any required patient or procedure record.** STERILIZATION RECORDS

Compliant | Needs attention | Critical gap | N/A

Tip: Test the traceability chain from a sampled package back to its load record and from a sampled load forward to distributed items where required.

8. Complex devices, endoscopes, specialty items, and single-use controls

43 **Verify complex reusable devices follow the exact manufacturer reprocessing instructions for disassembly, cleaning, connectors, brushes, adapters, leak testing, disinfection or sterilization, drying, and storage.**

CRITICAL | COMPLEX DEVICE IFU

Compliant | Needs attention | Critical gap | N/A

Tip: Do not assume a process validated for one model or accessory is suitable for another device with different channels, materials, or design.

44 **Where applicable, confirm flexible endoscopes receive required pre-cleaning, leak testing, manual cleaning, channel brushing and flushing before high-level disinfection or sterilization.**

CRITICAL | ENDOSCOPE PRE-CLEAN + LEAK TEST

Compliant | Needs attention | Critical gap | N/A

Tip: A failed leak test or damaged channel requires the device to be removed from normal processing and managed according to manufacturer instructions.

45 **Verify automated endoscope reprocessor connectors, channel adapters, cycle selection, chemistry, alarms, and documentation match the exact endoscope and processor instructions.**

CRITICAL | AER CONNECTION + CYCLE

Compliant | Needs attention | Critical gap | N/A

Tip: Incorrect channel connection can leave internal surfaces inadequately processed even when the machine completes a cycle.

46 **Confirm processed endoscopes and other complex devices are thoroughly dried, handled with clean technique, and stored in a configuration that protects them from contamination and retained moisture.**

CRITICAL | DRYING + STORAGE

Compliant | Needs attention | Critical gap | N/A

Tip: Observe drying and storage rather than relying only on a completed processor cycle.

47 **Verify reusable accessories, valves, caps, brushes, water bottles, tubing, and detachable components are processed or replaced at the required interval and are not omitted from the device workflow.**

CRITICAL | ACCESSORY CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Trace the accessory set as carefully as the main device because small components can carry the same contamination risk.

48 **Confirm devices labeled for single use are not reprocessed unless reprocessing is specifically permitted under applicable law and the facility uses an authorized, validated process.**

CRITICAL | SINGLE-USE DEVICE CONTROL

Compliant | Needs attention | Critical gap | N/A

Tip: Quarantine any item whose reuse status, labeling, or reprocessing authorization is unclear until it is resolved.

9. Sterile storage, distribution, package integrity, traceability, and recall

49 **Inspect sterile storage for cleanliness, controlled access, suitable temperature and humidity where specified, protection from moisture, dust, crushing, splash, pests, and excess handling.** STERILE STORAGE

Compliant | Needs attention | Critical gap | N/A

Tip: Separate sterile supplies from sinks, floors, dirty returns, chemicals, and other contamination sources according to facility requirements.

50 **Verify staff inspect package integrity, dryness, seals, indicators, labeling, and any event-related or facility-defined shelf-life criteria before an item is issued or opened for use.** CRITICAL PRE-USE PACKAGE CHECK

Compliant | Needs attention | Critical gap | N/A

Tip: Treat a wet, torn, punctured, opened, crushed, or otherwise compromised package as nonsterile.

51 **Confirm sterile items are transported in clean, protected carts or containers and remain separated from contaminated devices during internal or external distribution.** CRITICAL STERILE TRANSPORT

Compliant | Needs attention | Critical gap | N/A

Tip: Inspect the full route from sterile storage to the point of use and backhaul of contaminated items.

52 **Verify inventory rotation and stock handling prevent unnecessary compression, repeated handling, expired or out-of-policy stock, and storage practices that could compromise sterile barrier systems.** INVENTORY ROTATION

Compliant | Needs attention | Critical gap | N/A

Tip: Use the facility's approved event-related sterility or shelf-life policy and the packaging manufacturer's requirements.

53 **Test traceability from a sampled sterilized item or set to the processing load and, where required, to the patient, procedure, location, or clinical use record.** CRITICAL END-TO-END TRACEABILITY

Compliant | Needs attention | Critical gap | N/A

Tip: Traceability should support rapid identification of all potentially affected items if a later processing failure is discovered.

54 **Confirm a written recall process can identify, stop use of, retrieve, quarantine, document, reprocess, and communicate about items from suspect sterilization or disinfection loads.** CRITICAL RECALL READINESS

Compliant | Needs attention | Critical gap | N/A

Tip: Review one recent recall or run a documented traceability test to confirm the process works in practice.

10. Quality assurance, failures, competency, corrective actions, and sign-off

55 **Calculate the overall sterilization and disinfection compliance result and summarize critical failures, repeat gaps, affected devices, loads, equipment, and workflow stages.** AUDIT SCORE + SUMMARY

Compliant | Needs attention | Critical gap | N/A

Tip: Separate immediate device or patient risk from underlying process, equipment, training, staffing, documentation, or supply causes.

56 **Create immediate containment for every critical processing failure, including holding affected loads or devices, removing failed equipment from service, and starting recall or escalation when indicated.** CRITICAL IMMEDIATE CONTAINMENT

Compliant | Needs attention | Critical gap | N/A

Tip: Document what was stopped, quarantined, recalled, reprocessed, or restricted before normal work continued.

57 **Investigate failed cycles, positive biological indicators, failed chemical indicators, wet packs, processor alarms, or recurring defects using the approved failure-management pathway.** CRITICAL FAILURE INVESTIGATION

Compliant | Needs attention | Critical gap | N/A

Tip: Review operator technique, load configuration, utilities, equipment maintenance, consumables, indicators, chemistry, and manufacturer support as applicable.

58 **Assign each finding an owner, priority, due date, root-cause requirement where appropriate, corrective action, and objective closure-evidence rule.** CRITICAL CORRECTIVE ACTION

Compliant | Needs attention | Critical gap | N/A

Tip: Use urgent deadlines for immediate risk and realistic deadlines for permanent fixes such as repair, validation, workflow redesign, or competency improvement.

59 **Verify reprocessing staff competency is current for their assigned tasks and that closure is confirmed through repeat observation, records, test results, maintenance evidence, or a focused repeat audit.** CRITICAL COMPETENCY + CLOSURE

Compliant | Needs attention | Critical gap | N/A

Tip: Do not close a critical action based only on a written comment; verify that the process now performs as required.

60 **Record the final audit decision, remaining restrictions, next review date, auditor, reprocessing or IPC approval, date, time, and sign-off.** CRITICAL APPROVAL + SIGNATURE

Compliant | Needs attention | Critical gap | N/A

Tip: Keep affected devices or equipment restricted until every release criterion and required approval has been met.