SPD assessment preparation

LRS SPS LLC - Sterile Processing Solutions

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A source-linked preparation guide for sterile processing teams at U.S. healthcare facilities and surgical centers.

Introduction

A practical review guide for sterile processing teams preparing for a facility inspection or operational assessment.

Scope note

This resource is for preparation. It does not certify compliance, determine which rules apply to a facility, or replace an inspection, accreditation survey, or operational assessment.

Facility pathway note

Requirements vary by facility type, state and local law, CMS participation, accreditation program, construction date, adopted standards, and manufacturer instructions. Identify the rules that apply to your facility before treating any checklist item as mandatory. CMS survey checks below are specifically labeled for participating ambulatory surgery centers (ASCs); professional and accreditation topics can depend on the facility's pathway. CDC recommendations are evidence-based guidance and are not automatically regulations.

ASCA checklist note

ASCA lists the CDC Infection Prevention Checklist for Outpatient Settings as a tool for reviewing infection-prevention policies, procedures, supplies, and staff adherence to safe practices.

Six assessment domains

01 Equipment Validation, Maintenance, and Monitoring

Review the evidence that equipment and each sterilization process perform as intended.

Dynamic-air-removal testing

If the facility uses a dynamic-air-removal sterilizer, check that an air-removal test (Bowie-Dick) is performed daily in an empty sterilizer before processing, as applicable to the equipment and adopted process.

Status: CDC evidence-based recommendation
Citation IDs: [10]

Biological indicator schedule and records

For a CMS-participating ASC, verify a biological indicator is used at least weekly for each sterilizer and with every load containing implantable items, with results documented. Follow any additional applicable requirements.

Status: CMS ASC survey check

Citation IDs: [5]

Inspection, maintenance, and manufacturer communication

Review routine equipment inspections, preventive maintenance, service records, and a clear path for raising process or device concerns with the manufacturer. Use manufacturer recommendations and the facility's applicable standards to set the work and frequency.

Status: Pathway-specific consideration
Citation IDs: [2], [6]

Cleaning verification and reusable-device end of life

Where the facility's adopted standard and validation protocol call for it, include residual protein, hemoglobin, and total organic carbon (TOC) in cleaning assessment. Evaluate reusable-device condition and end of life using risk and observed function; do not substitute an unsupported universal cycle count.

Status: Pathway-specific consideration
Citation IDs: [2], [3]

02 Staffing, Competency, and Professional Development

Make role expectations, demonstrated competency, and ongoing learning easy to review.

Role-based training and competency evidence

Keep current role descriptions, orientation, competency assessments, and follow-up training records for staff performing reprocessing tasks. Align requirements with facility policy, applicable law, and the standards or accreditation program the facility follows.

Status: Pathway-specific consideration
Citation IDs: [4], [7]

Certification and continuing education

Check which credentials are required by the facility's jurisdiction, employer, contract, or accreditor; do not assume an HSPA credential is universally required. For HSPA-certified staff, track renewal and continuing education, including updates to standards and guidance.

Status: Pathway-specific consideration
Citation IDs: [4]

Patient-safety leadership and mentoring

Identify experienced sterile-processing leaders who can observe work, coach staff, respond to questions, and mentor developing team members. Include communication with infection prevention, clinical teams, and equipment support where relevant.

Status: Pathway-specific consideration
Citation IDs: [4], [7]

03 Point-of-Use, Decontamination, and Cleaning

Follow the device instructions from point of use through inspection and cleaning.

Pre-cleaning before sterilization

For a CMS-participating ASC, check that items are pre-cleaned according to the manufacturer's instructions or, when instructions are not provided, evidence-based guidelines before sterilization.

Status: CMS ASC survey check

Citation IDs: [5]

Inspect for soil and repeat cleaning as needed

For a CMS-participating ASC, verify devices are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization. Record and resolve recurring cleaning issues under the facility's quality process.

Status: CMS ASC survey check

Citation IDs: [5]

Point-of-use soil management and transport

Maintain a point-of-use soil-management process and transport workflow that protects staff and devices and follows applicable IFUs. Joint Commission guidance for immediate-use steam sterilization (IUSS) states that cleaning and transport steps are not omitted when IUSS is used.

Status: Pathway-specific consideration

Citation IDs: [7], [8]

Central processing and quality control

CDC recommends performing most cleaning, disinfection, and sterilization of patient-care supplies in a central processing department to make quality control easier. Review any processing performed elsewhere for consistent training, monitoring, and handling controls.

Status: CDC evidence-based recommendation

Citation IDs: [10]

04 Preparation, Packaging, and Sterilization

Check that each item follows its instructions and that load monitoring is complete.

Chemical indicator placement

For a CMS-participating ASC, verify a chemical (process) indicator is placed correctly, as described in the manufacturer's instructions, in the instrument packs in every load.

Status: CMS ASC survey check

Citation IDs: [5]

Device instructions and the full reprocessing cycle

Review the complete facility workflow from decontamination and cleaning through inspection, sterilization, and storage. Check device and equipment IFUs at the relevant steps; use the appropriate validated process for each device and intended use.

Status: Pathway-specific consideration

Citation IDs: [1], [3], [7], [8]

Evidence-based disinfection and sterilization

Confirm procedures use an evidence-based approach and follow applicable device instructions, adopted standards, and facility policies. For outsourced or centralized services, include processing controls and instrument integrity during interfacility transport in the review.

Status: Pathway-specific consideration

Citation IDs: [7], [8], [10]

05 Environment, Capacity, and Emergency Readiness

Check work-area conditions, procedure capacity, and the limits around emergency processing.

Distinct conditions by processing area

Review the applicable temperature and humidity parameters separately for decontamination, prep and pack, and sterile storage. If the facility declares conformance with a standard, confirm that each location performing sterile processing follows that standard consistently. The governing facility standard and local requirements determine the values; do not treat one area's target as universal across the SPD.

Status: Pathway-specific consideration

Citation IDs: [1], [3], [8]

Anesthetizing-location humidity and records

For CMS-participating ASCs, review operating-room temperature, humidity, and airflow against nationally accepted guidelines, applicable IFUs, and state or local rules; keep records of the facility's monitoring and adopted range. CMS's ASC survey manual cites ASHRAE 170's 20–60% RH range as an example. Separate CMS hospital/CAH guidance describes a 35% baseline and an elected categorical waiver allowing eligible hospitals and CAHs to use a 20% minimum, and recommends an upper RH of 60% or less. CMS clarifies that ASCs do not need that waiver to use lower RH, but must follow IFUs for OR supplies and equipment. Do not apply the hospital/CAH waiver as an ASC requirement.

Status: CMS ASC survey check

Citation IDs: [6]

Instrument availability for expected volume

For a CMS-participating ASC, compare instrument-set quantities with expected daily procedure volume and the time needed for appropriate cleaning and sterilization.

Status: CMS ASC survey check

Citation IDs: [6]

Emergency equipment and non-routine use

CMS requires a CMS-participating ASC to have equipment for rapid emergency sterilization available on-site when sterility has been compromised. Emergency sterilization is not the routine method between cases. CDC says implant flash sterilization is limited to unavoidable cases and must not be used for convenience, time-saving, or insufficient instrument inventory.

Status: CMS ASC survey check

Citation IDs: [6], [7], [11]

06 Records, Traceability, and Sterile Storage

Make load documentation, package condition, and storage controls reviewable.

Load-level records and monitoring results

For a CMS-participating ASC, maintain current documentation for each sterilization device, including results from each load. Prepare a way to relate processed sets to the relevant load record under the facility's applicable standards and policies. This guide does not assert that bidirectional patient-level tracking is required.

Status: CMS ASC survey check
Citation IDs: [5], [8]

Storage conditions and shelf-life policy

Use the facility's approved storage and shelf-life policy, manufacturer labeling, and applicable requirements. Under CDC's event-related guidance, shelf life depends on packaging quality, storage, transport, handling, and events that compromise package integrity; do not apply a universal fixed duration without a basis.

Status: CDC evidence-based recommendation
Citation IDs: [8], [11]

Protect the sterile storage area

CDC recommends a well-ventilated sterile storage area protected from dust, moisture, insects, and temperature or humidity extremes. Check that facility conditions also follow applicable construction rules and manufacturer storage instructions.

Status: CDC evidence-based recommendation
Citation IDs: [8], [11]

Labels and pre-use package integrity

CDC recommends labels identifying the sterilizer, cycle or load number, sterilization date, and expiration date when applicable. Inspect packages before use; torn, wet, punctured, or otherwise compromised packages should be reprocessed. CMS's ASC worksheet also asks facilities to reprocess compromised sterile packages.

Status: CMS ASC survey check
Citation IDs: [5], [11]

References [1]–[11]

[1] AAMI: Understanding What Sterile Processing Needs from HTM Professionals

Overview of reprocessing stages and area-specific environmental parameters.

AAMI article
https://aami.org/news/htm-sterile-processing-maintenance-ifus-infection-control/

[2] AAMI: Study Illuminates Industry Blind Spot for Reusable Device End of Life

Discusses ST98 residual-soil measures, risk-based end-of-life evaluation, inspection, and communication.

AAMI article
https://aami.org/news/new-study-medical-device-reprocessing-end-of-life/

[3] AAMI: Sterilization Standards FAQs

AAMI reference point for locating applicable sterilization standards and topics.

AAMI standards FAQ
https://aami.org/standards/faqs/sterilization-standards-faqs/

[4] HSPA: Certification, continuing education, and leadership

HSPA resources describe certification renewal, continuing education, current practice updates, and leadership development topics.

Certification renewal and continuing education
https://myhspa.org/certification/renew-your-certification/

Certified Healthcare Leader exam content outline
https://myhspa.org/wp-content/uploads/2023/05/CHL_Exam_Content_Outline-1.pdf

[5] CMS: QSO-22-16-ASC: Infection Control Worksheet

CMS survey worksheet for ASC infection-control practices, sterilization indicators, load records, and package integrity.

CMS QSO-22-16-ASC PDF
https://www.cms.gov/files/document/qso-22-16-asc.pdf

[6] CMS: State Operations Manual, Appendix L, and CMS RH waiver memo

ASC requirements for records, procedure-volume equipment, emergency equipment, and RH; the separate waiver memo clarifies its eligibility.

CMS State Operations Manual, Appendix L
https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r137soma.pdf

CMS memo S&C-13-25-LSC & ASC
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-13-25

CMS memo 15-27-Hospital, CAH & ASC on RH and IFUs
https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/survey-and-cert-letter-15-27

[7] The Joint Commission: Instrument Reprocessing — Immediate-Use Steam Sterilization

Joint Commission FAQ on IUSS, IFUs, cleaning and transport steps, avoiding convenience use, and staff competency.

Joint Commission standards FAQ
https://www.jointcommission.org/en-us/knowledge-library/support-center/standards-interpretation/standards-faqs/000001153

[8] The Joint Commission: Centralized processing, sterile storage, and applicable standards

Joint Commission materials on interfacility transport, evidence-based processing, storage integrity, and applicable law and standards.

Centralized Sterilization Services Certification
https://www.jointcommission.org/en-us/certification/centralized-sterilization-services

Temperature and humidity requirements for sterile storage
https://www.jointcommission.org/en-us/knowledge-library/support-center/standards-interpretation/standards-faqs/000001430

[9] ASCA: CDC Infection Prevention Checklist for Outpatient Settings

ASCA's listing explains that the checklist supports infection-prevention policies, procedures, supplies, and systematic review of staff practices.

ASCA public resource library entry
https://www.ascassociation.org/viewdocument/infection-prevention-checklist-for-outpatient-settings-cdc

[10] CDC: Sterilizing Practices

CDC evidence-based recommendations on central processing, process verification, Bowie-Dick tests, and the reprocessing cycle.

CDC Sterilizing Practices
https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html

[11] CDC: Recommendations for Disinfection and Sterilization in Healthcare Facilities

CDC guidance on implant flash sterilization, sterile storage, load labels, shelf life, and package inspection.

CDC Summary Recommendations
https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html