Identification of Best Practice Standards in CSPD Relating to Infection Control

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- Review of ANSI-AAMI and CDC standards/guidelines for Central Sterile Processing Departments (CSPD).
- Review of AORN/IASHCSMM/CBSPD recommended guidelines and best practice standards for CSPD
- Review of The Joint Commission (TJC) and CMS survey requirements for CSPD.
- Utilization of Survey Readiness Audit Tools.
- Summary of “Top Survey Hit List”
- Open Forum Questions.

OBJECTIVES
SECTIONS I - V

- Know what the standards and guidelines are relating to infections control for the CSPD's processing of instruments, scopes and equipment.
- To become aware that organizations such as AORN, IAHCSMM and CBSPD develop their best practice standard from; AAMI, CDC, CMS, OSHA, State agency's and manufactures.
- Keep in mind that TJC utilizes the federal, state, regulatory, governing organizations and industry standards in development of their performance measures for surveying healthcare.
- Be prepared for TJC survey by completing; gap analysis, risk assessments and tracers quarterly for SPD processes such as sterilization, HLD and disinfection.

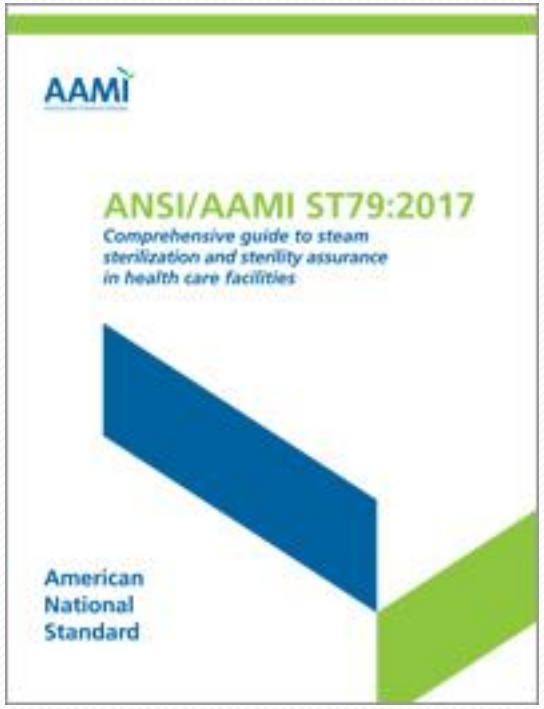
SECTION - I

- Review of ANSI–AAMI and CDC standards/guidelines for Central Sterile Processing Departments (CSPD)

ANSI/AAMI

The compressive guide to steam sterilization and sterility assurance in heath care facilities

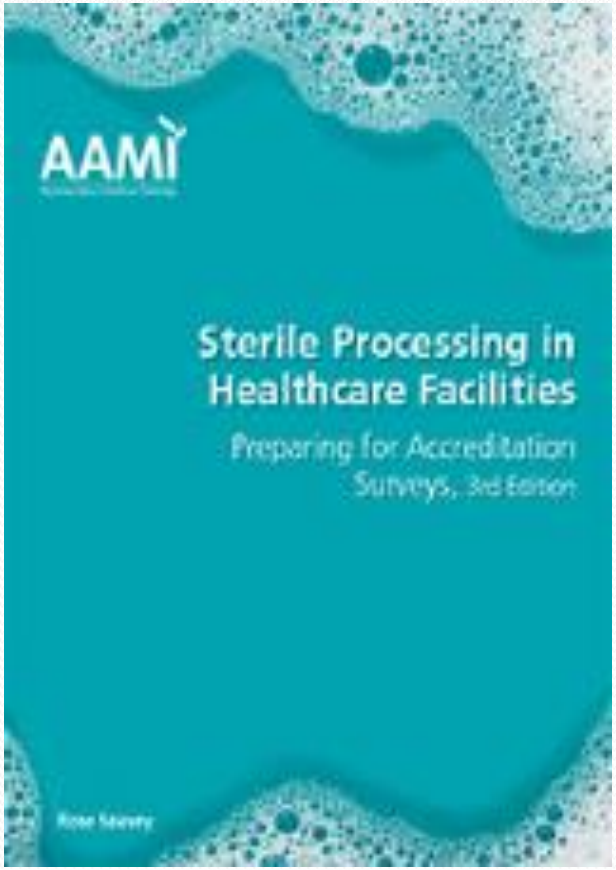
(You need this book)



ANSI-AAMI GUIDELINES

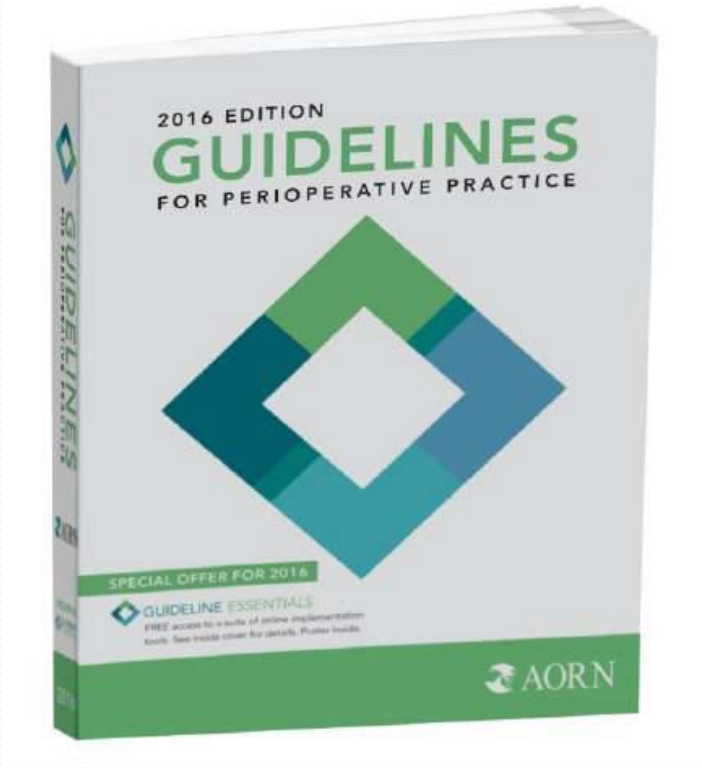
- **AAMI; www.aami.org make sure your hospital is a member.**
- **Go to the website; http://my.aami.org and have their books in your IC library (purchase the on-line ones);**
- **ST90: 2017**
  - Processing of health care products-Quality management systems for processing in healthcare facilities
- **ST91;2015**
  - Flexible and semi-rigid endoscope processing in health care facilities

- This book provides valuable tools for preparing for accreditation surveys and maintaining compliance with accreditation requirements as they relate to sterile processing.
- New to this third edition are best-practice audit tools for immediate-use steam sterilization (IUSS) and high-level disinfection (HLD), and an instrument integrity checklist.
- It has also been updated to reflect the 2017 revision of ANSI/AAMI ST79 and current TJC accreditation standards related to sterile processing.
- TJC's new SAFER matrix scoring methodology is also discussed.

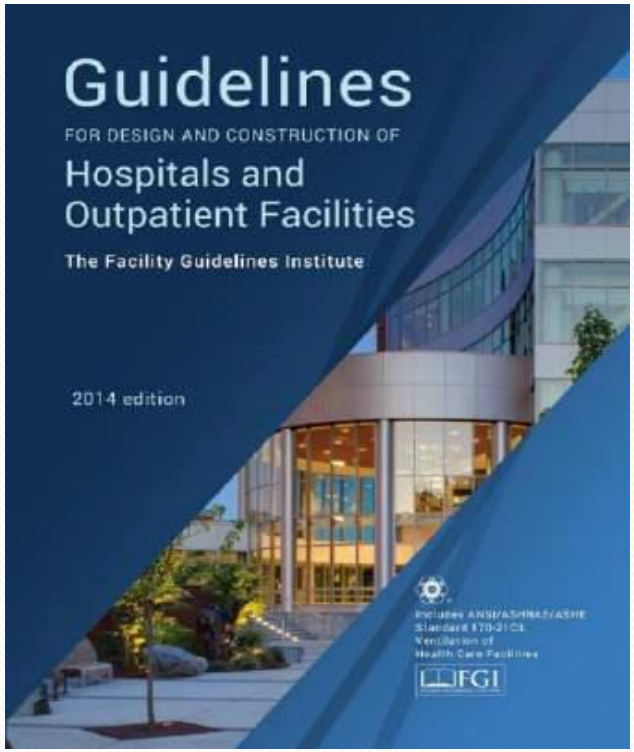


STANDARD FOR PARAMETERS

AORN



FGI/AIA



JOINT TASK FORCE

CDC

- CDC-2008 Guidelines now has revised statement in 2017
  - Endoscopes manual cleaning must be done and verified before HLD or Sterilization.
  - Follow the manufactures IFU for testing, manual cleaning (with recommended brushes) for channels and elevator sites (ERCP scopes), rinsing and HLD or sterilization.
  - Transporting of scopes;
    - From the clean storage cabinet to patient use in a secure, rigid container that is clearly marked CLEAN.
    - After patient use flushing and Point-Of-Use Pre-Cleaning and placed in a secure, rigid container that is clearly marked RED Biohazard.
    - Traceability/Trackability to patient's

CDC

- CDC-2008 Guidelines now has revised statement in 2017
- Storage cabinets;
  - Scopes and channels dry
  - Accessory items (caps) kept with the correct scope.
  - Temperature and Relative Humidity same as clean storage area. Keep a manual log if no electronic data
  - Hanging properly, tips not touching the bottom of the cabinet
  - Hang time between cleaning (now not surveyed due to varied definitions) but preferred

SECTION - II

- Review of AORN/IASHCSMM/CBSPD recommended guidelines and best practice standards for Central Sterile Processing Departments (CSPD)

AORN

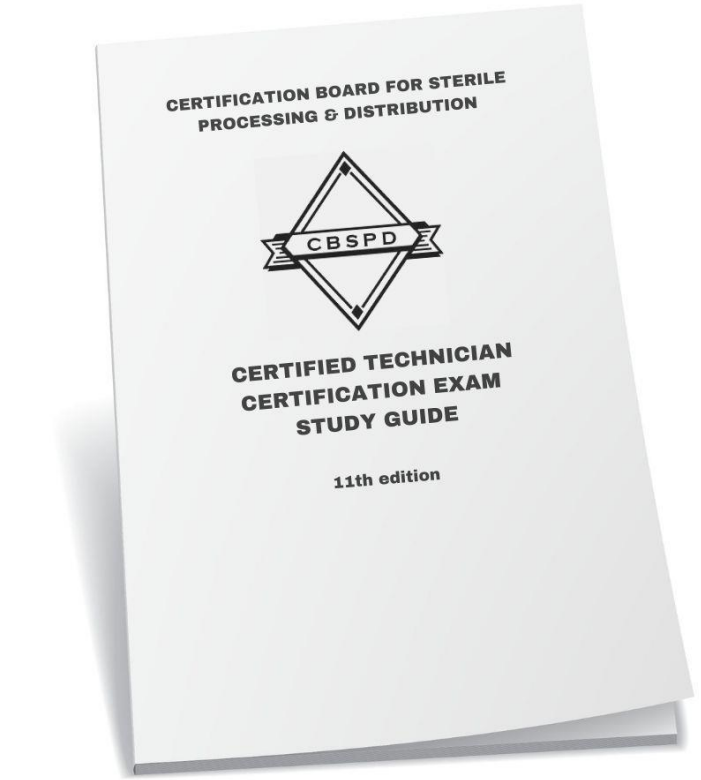
- 2019-Guidelines
  - Long sleeves covering arms (prevent shedding of skin and hair) in the Prep/Assembly and Sterilization area
  - Peel Pouches (PP) are to have the instruments in the open position for sterilization. Do not place a PP in a tray unless it is approved
  - Environmental cleaning same as the OR.
  - Case Cart closed or covered and identified as CLEAN/Soiled.
  - Wrapper/PP expiration dates.
  - Transport of soiled instrument in the open position with pre-enzymatic spray or gel (moist for 72 hrs usage) and in closed container

IAHCSMM/CBSPD

- Central Service Training Manual, Eighth Edition
  - Certification are;
    - CHL -Leadership/Management
    - CRCST -Technician
    - CIS -Instrument Specialist
    - CER -Endoscope
    - CER -Education (no new testing)

- Certification Board For Sterile Processing & Distribution;
  - Certification are;
    - CSPM -Leadership/Management
    - CSPDT -Technician
    - CSIS -Instrument Specialist
    - CFER -Endoscopes
    - CASSPT -Ambulatory Surgery Technician

TRAINING MANUALS

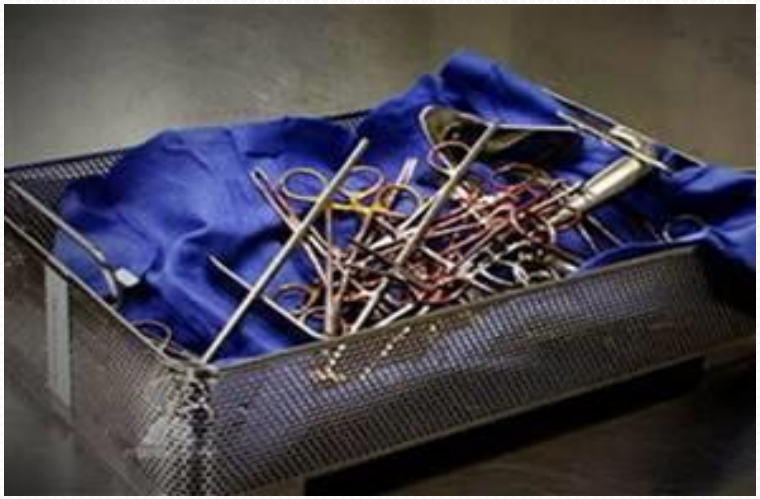


ENVIRONMEMTAL PARAMETERS

LOCATION	PRESSURE	TEMPERATURE	RELATIVE HUMIDITY	AIR EXCHANGE
Decontamination Area	NEGATIVE	60 - 65 F DEGREES	30 - 60 % (40 % Average)	10 / HOUR
Prep/Pack Assembly Area	POSITIVE	68 - 73 F DEGREES	30 - 60 % (40 % Average)	10 / HOUR
Sterile / Clean Storage	POSITIVE	65- 75 F DEGREES	30 - 70 % (50 % Average)	4 / HOUR
Sterilizer Access Room	NEGATIVE	75 - 85 F DEGREES	30 - 60 % (50 % Average)	10 / HOUR
Staff Locker Area	NEUTRAL	68 - 75 F DEGREES	30 - 60 % (45 % Average)	4 / HOUR

ROOM PRESSURE INDICATORS

POINT-OF-USE INSTRUMENT PREPARATION



DECONTAMINATION AREA

PPE

DECONTAMINATION AREA

Head cover

Mask

Face shield

Gown

Plastic Apron

Gloves

Shoe covers

SECTION - III

- Review of The Joint Commission (TJC) and CMS survey requirements for Central Sterile Processing Departments (CSPD)

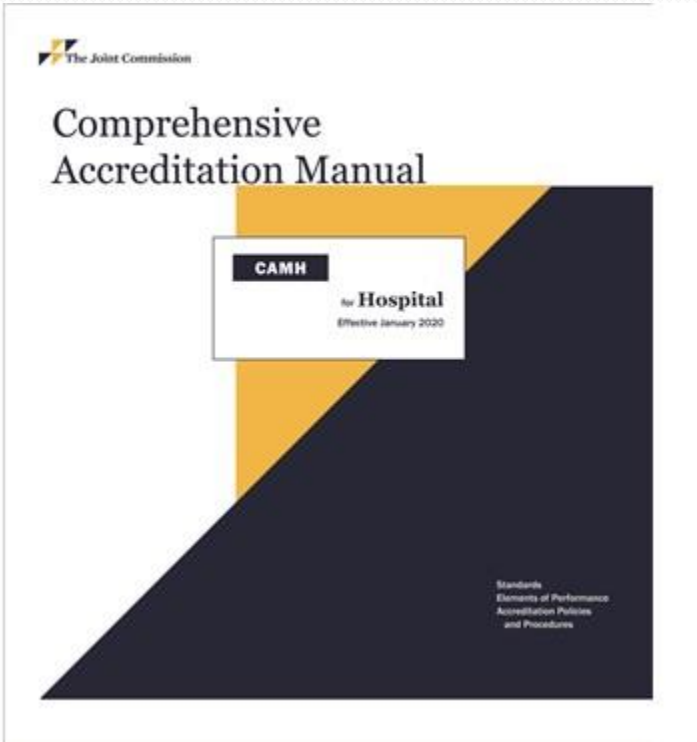
TJC Survey

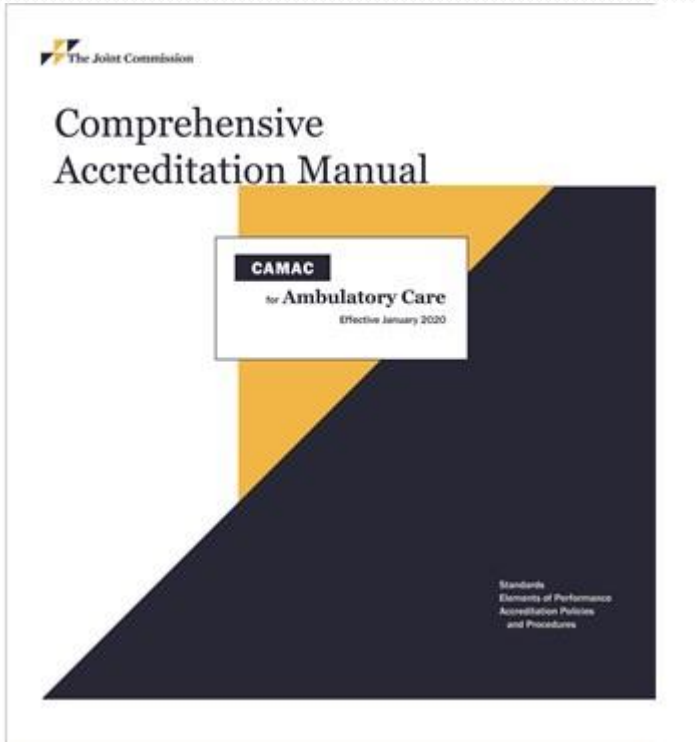
- They utilize their standards and elements of performance.
- Standards; will provide directions on performance expectations and rational as to why it is important.
- Elements of Performance; are provided with the standards as to how the organization is to meet them.
- Standards that that they will review in CSPD are;
  - Environment of Care
  - Human Resource
  - Infection Prevention and Control
  - Process Improvement
  - Leadership

TJC Survey

- Standard relating to HLD and Sterilization;
  - IC.02.02.01; Healthcare organizations are required to reduce the risk of infections associated with medical equipment, devices (instruments) and supplies.
  - Use of evidence-based guidelines (EBG) and policy's from professional organizations and regulatory agencies.
  - Now listed as High Survey Enhancement on September, 1st, 2018 and non-compliance scores will be given for not following the manufactures IFU for:
    - Instruments/Scopes; packaging, storage, use, transporting, cleaning and processing by HLD or Sterilization in an open position. **(AUDITS)**
    - CSPD Processing equipment; sterilizer (steam and Gas Plasma), ultrasonic cleaners, AERs, cart washers, washer/disinfectors, monitors, rigid containers, Peel Pouches, Blue-Wrappers, Biological and Chemical Indicators etc.
    - Quality Controls are being done; TOSI/Verify, Sonic Check, BI-Controls

TJC MANUAL


The Joint Commission
Comprehensive
Accreditation Manual
CAMH
for Hospital
Effective January 2020
Standards
Elements of Performance
Accreditation Policies
and Procedures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FEDERAL AGENCY REGULATIONS

- The Center s for Medicare and Medicaid Services (CMS) have developed Conditions of Participation (CoP) and Conditions for Coverage (CFC) regulations.

  - **CoP / CFC** = Are rules governing the eligibility of someone or of an entity to be involved in a particular activity or organization. **CMS** has described its compliance relationships with healthcare facilities as **requirements** that hospitals must meet to **participate in** the Medicare and Medicaid programs for qualifying for payment.
  - These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries.
  - CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CFCs.
  - CMS contracts with state's department of health such as NY-DOH to survey facilities in order to begin the payment program.

FEDERAL AGENCY REGULATION

- CMS Surveyor worksheet for infection control is broken down in to five module;

  - Module 1: Infection Control / Prevention Program
  - Module 2: General Infection Control Elements
  - Module 3: Equipment Reprocessing
    - High Level Disinfection and Sterilization
  - Module 4: Patient Tracers
  - Module 5: Special Care Environments

CMS SURVEY TOOL

Centers for Medicare & Medicaid Services
Hospital Infection Control Worksheet

- Name of State Agency:_____
- Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the Infection Control
- Condition of Participation. Items are to be assessed by a combination of observation, interviews with hospital staff, patients and their family/support persons, review of medical records, and a review of any necessary infection control program documentation.
- **During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.**
- The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

CMS SURVEY TOOL

Module 3: Equipment Reprocessing

Section 3.A; Reprocessing of Semi Critical Equipment

- Semi critical equipment are objects that contact mucous membranes or non-intact skin and require, at a minimum, High-Level Disinfection prior to reuse (e.g. some endoscopes, speculums, laryngoscope blades) “Probes”
- Items processed by CSPD or any department performing HLD and Sterilization.
- Surveyors may ask to see policies to verify they are meeting current best practice standards by federal or professional organizations.

RULES

- Regulatory Agencies that CSPD rules are judged on;
  - City/County Health Department
  - State Department of Health
  - CMS
  - CDC
  - OSHA
  - FDA

GUIDELINES

- **ANSI-AAMI** (Association for the Advancement of Medical Instruments)
- Professional Organizations;
  - **AORN** (Association of peri-Operative "Periop" Registered Nurses)
  - **SGNA** (Society Gastroenterology Nurses and Associates)
  - **IAHCSMM** (International Association of Healthcare Central Service Materiel Management)
  - **CBSPD** (Certification Board for Sterile Processing and Distribution)

SECTION - IV

- Utilization of Survey Readiness Audit Tools , do MOCK Survey's and unannounced Tracers in Central Sterile Processing Departments (CSPD)

ACCREDIDATION ORGANIZATIONS

- AO's used for
  - The Joint Commission (THC)
  - Accreditations Associations for Ambulatory Health Care (AAAHC)
  - Accreditation Commission for Health Care (ACHC)
  - American Associations for Accreditation for Ambulatory Surgery Facilities Health Care (AAAASF)
  - Healthcare Facilities Accreditation Program (HFAP)
  - Center for Improvement in Healthcare Quality (CIHQ)
  - The Compliance Team (TCT)
  - State Health Departments (DOH)

SECTION - V

- Summary

SUMMARY OF

- Top Survey Hit List;

1. Infection Control
2. High-Level Disinfection
3. Life Safety Codes
4. Human Resource
5. Leadership
6. Quality Performance Improvement
7. High Risk Equipment/Surgical Items
8. Point-of-Use Pre-Cleaning
9. Transporting of Clean/Sterile and Soiled Instruments/Scope items
10. Loaner Items

SUMMARY OF

- Top Survey Hit List:
  1. Patient Portable Use Mobile Medical Equipment
  2. Employee Persona Protection Equipment
  3. Peel Pouches (instruments in the open position)
  4. Storage Carts Clearances (top/bottom) lower solid shelf
  5. Inspections of trays after having been assembled
  6. Case Cart
  7. QC and BI Testing (Positive results)
  8. Implant Trays/Items
  9. Recalled Trays
  10. Departments with soiled reusable instruments

QUESTIONS

REFERENCES

- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)
- The Joint Commission Comprehensive Accreditation Manual, Hospitals (2019)
- The Joint Commission Tracer Observation Form for High-Level-Disinfection (20017)
- TJC *The Source* The Joint Commission Compliance Strategies, High-Level Disinfection, February, 2019
- AORN's *Guidelines* for Perioperative Practice (2019)
- IAHCSMM, Central Sterile Technician Manual, Eighth Edition

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