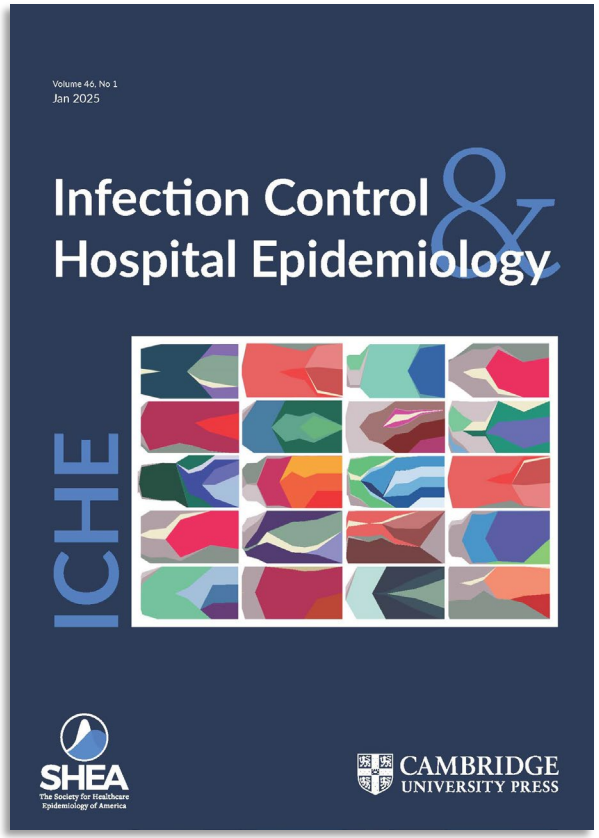
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*Infection Control & Hospital Epidemiology* publishes scientifically authoritative, clinically applicable, peer-reviewed research on control and evaluation of the transmission of pathogens in healthcare institutions and on the use of epidemiological principles and methods to evaluate and improve the delivery of care. Major topics covered include infection control practices, surveillance, antimicrobial stewardship, cost-benefit analyses, resource use, occupational health, and regulatory issues.

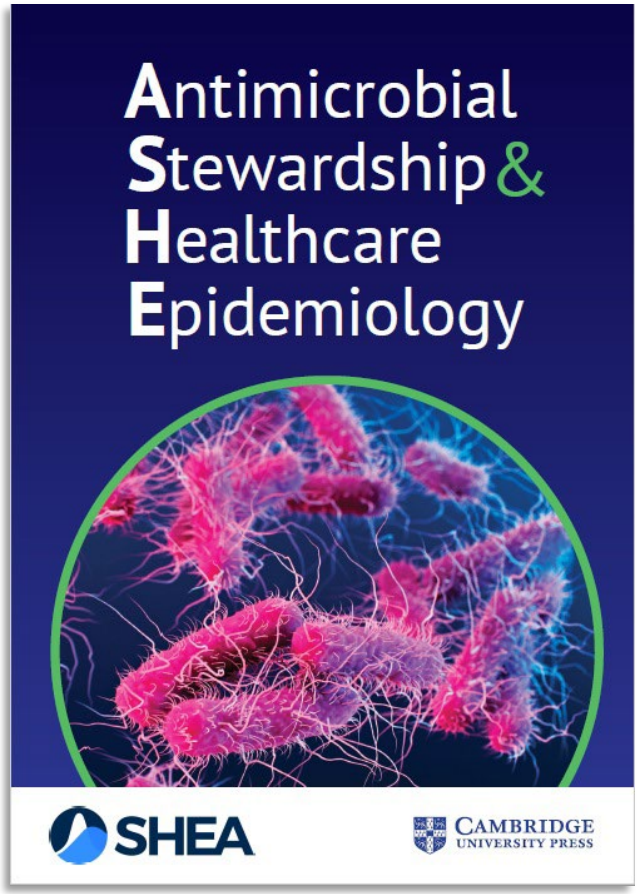
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**November 19, 2026 | 2:30 – 3:30 pm ET**
**January 27, 2027 | 4:00 – 5:00 pm ET**

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# Housekeeping

- Technical difficulties? Visit: https://support.zoom.us
- Webinar recording, PowerPoint presentation, and references available on learningce.shea-online.org
- Streaming Live on SHEA's Facebook page
- Zoom Polling, Q&A & Chat



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# November Town Hall Panelists:



**Dr. Bernard Camins**
*Mount Sinai*



**Dr. Katie Passaretti**
*Advocate Health*



**Dr. Tom Talbot**
*Vanderbilt University*

# Invited Panelist:



**Tanya Stellges**
*Vanderbilt Health*



**Sharon Wright, MD, MPH**
*Beth Israel Lahey Health*

# Nationwide Chlorhexidine Shortage

**Sharon B. Wright, MD, MPH, FIDSA, FSHEA**
**Chief Infection Prevention Officer**

Beth Israel Lahey Health

# All CHG products are either on allocation and backorder currently, with no clear date for return

- Sage/Stryker 2% CHG wipes
- Hibi Hubs bathing system
- HibiClens (4% CHG liquid)
- Other aqueous CHG brands





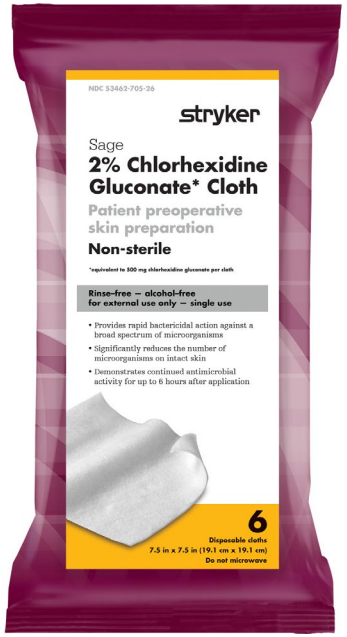


Click to see full view



# Shortage is driven by Sage/Stryker CHG wipe manufacturing issues

- Sage/Stryker 2% CHG wipes manufacturing stopped, with no clear timeline for return
- Backorder on Sage/Stryker (only manufacturer) led to rapid run on other CHG products (e.g., HibiClens)
- Many products now on allocation, limiting ability to source large volumes



# Considerations for use of limited deployment of CHG resources at your facility

- Who
  - CHG bathing daily for patients in ICUs
  - CHG bathing for Oncology patients (with or without CVCs)
  - Pre-operative CHG bathing (inpatients and outpatients)
  - Daily CHG bathing for Med/Surg patients with CVCs in place
- How
  - Product(s)
  - Frequency
  - Alternate sources/vendors/products

# SPD & Infection Prevention: Bridging Gaps and Strengthening Practices

November 2026 Town Hall

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# Colorado hospitals cited for contaminated equipment, including 3 instances of 'immediate jeopardy'

Contaminated equipment was what led officials at the Rocky Mountain VA Medical Center in Aurora to reschedule hundreds of dental and surgical procedures earlier this year. VA officials told The Denver Gazette on Wednesday that the source of the contamination has been identified as flecks of plastic.

https://denvergazette.com/news/health/colorado-hospitals-cited-contaminated-equipment/article_57f7dee8-492c-11ef-a694-eb8dec077c50.html

# Surgery crisis persists at HCA's North Florida Hospital



Gary Nelson Mar 21, 2024 10:50 pm

At least three surgeons "unloaded" on hospital administrators Thursday after work was halted because of "residue" on instruments that were purportedly cleaned and sterilized.

The clamps and other surgical tools had an orange or black film on them that left smudges on gloves and gauze. Mainstreet obtained photos of the dirty tools but is not releasing them to protect the identities of those who took them.

https://www.mainstreetdailynews.com/business/surgery-crisis-hca-north-florida-hospital

# California hospital staff call for halt of surgeries over bizarre particles

Hospital officials said the equipment is sterile, while staff questions safety.

BETH MOLE – JUN 8, 2023 11:05 AM | 101

More than 70 staff members of a San Diego-area hospital are calling for a halt of all surgeries at the facility due to unidentified black, brown, and gray specks on surgical trays, the San Diego Union-Tribune reported.

The objecting staff have signed a petition to spur hospital officials to pause procedures until the issue is resolved. But officials at the facility, the Kaiser Permanente Zion Medical Center, have rejected the call, according to the Union-Tribune. A spokesperson for the facility did not respond to voicemails from Ars.

Haynes added that management had assured staff that the particles—whatever they are—are sterile. Surgical equipment goes through a two-step process before use: a wash and then a trip through an autoclave, a pressurized steam machine used for sterilization. But Haynes argued that simply being sterilized doesn't mean it's fit for surgery.

"The fact that a contaminant is "safe" (not a microbe) doesn't mean that contaminant is implantable," she said.

# HOSPITAL REFUSES TO PAUSE SURGERIES AFTER FINDING UNKNOWN CONTAMINANTS ON EQUIPMENT TRAYS

THE SHOW MUST GO ON.

"Sterilization guidelines," Haynes reminded, "are that anything non-sterile (or) non-sterilizable found inside a surgical tray renders that tray contaminated."

In spite of this seemingly massive concern, however, administrators at Kaiser, a giant nationwide healthcare provider, are refusing to do more than investigate the matter, saying in a statement to employees that the newspaper reviewed that the hospital will "continue to schedule surgeries at Zion that can be safely performed."

https://futurism.com/neoscope/hospital-surgical-contaminants
https://arstechnica.com/health/2023/06/calif-hospital-staff-call-for-halt-of-surgeries-over-bizarre-particles/

# SPD (& HLD) and Infection Prevention

- Top non-compliant elements of performance cited during surveys for 2023 for accreditation programs

## Hospital

- IC.02.02.01, EP 2: The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

## Ambulatory Care

- IC.02.02.01, EP 2: The organization implements infection prevention and control activities while doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

## Critical Access Hospital

- IC.02.02.01, EP 2: The critical access hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

## Office-Based Surgery

- IC.02.02.01, EP 2: The practice implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

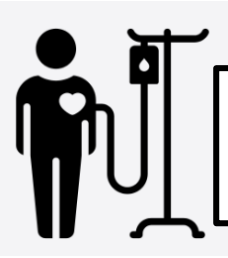
https://www.jointcommission.org/en-us/knowledge-library/newsletters/joint-commission-online/03-apr-24



Instrument/ Device transport



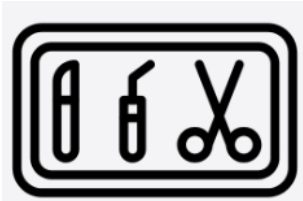
Training & Competency



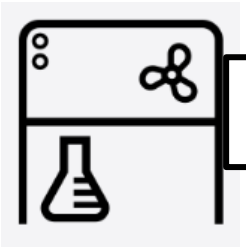
Pt specific Instrument Issues (e.g., CJD)



Equipment PM



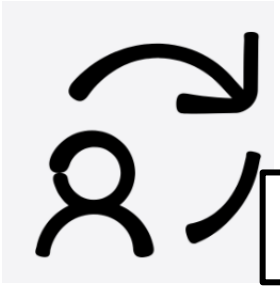
Instrument/ Device Storage



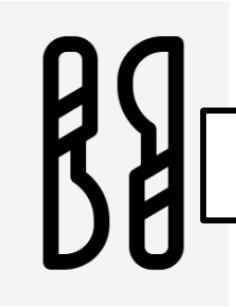
Environmental/ Life Safety Issues



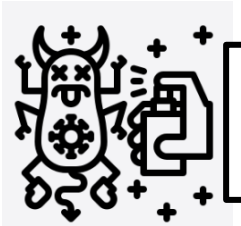
Water Quality



Quick Turnover (IUSS)



Single Use Devices



Instrument/Device Cleaning & Decontamination



Delayed Reprocessing



Quality/Efficiency Metrics



Assessment of Cleanliness

*Infection Control & Hospital Epidemiology* (2025), **46**, 561–583
doi:10.1017/ice.2025.41

SHEA

## SHEA Expert Guidance

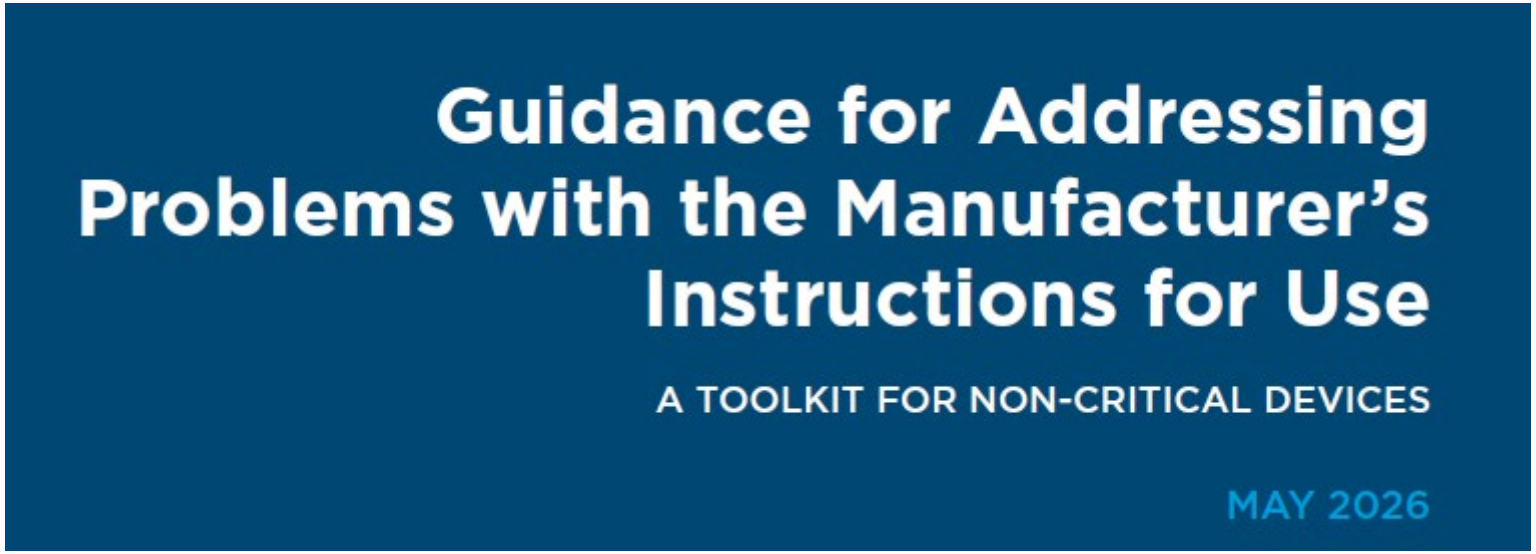
# Multisociety guidance for sterilization and high-level disinfection

Erica S. Shenoy MD, PhD[1,*], David J. Weber MD, MPH[2,*], Kathleen McMullen MPH, CIC[3], Zachary Rubin MD[4], Priya Sampathkumar MD[5], Joshua K. Schaffzin MD, PhD[6], Emily Sickbert-Bennett PhD, MS, CIC[2], Laraine Washer MD[7], Deborah S. Yokoe MD, MPH[8], Audrey H. Calderwood MD, MS[9], Raymond Chinn MD[10], Michelle Day RN, MSN, CGRN[11], Sylvia Garcia-Houchins RN, MBA, CIC[12], Waleed Javaid MD, MBA, MS[13], Susan Klacik BS[14], Erin Kyle DNP, RN, CNOR[15], Rekha K. Murthy MD[16], Amber Wood MSN, RN, CNOR, CIC[15] and William A. Rutala PhD, MPH, CIC[2]

[1]Harvard Medical School, Massachusetts General Hospital, Mass General Brigham, Boston, MA, USA, [2]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA, [3]Mercy, St. Louis, St. Louis, MO, USA, [4]Los Angeles Department of Public Health, UCLA Health, Los Angeles, CA, USA, [5]Mayo Clinic, Rochester, MN, USA, [6]University of Ottawa Faculty of Medicine, Children's Hospital of Eastern Ontario, Ottawa, ON, Canada, [7]University of Michigan Medical School, Ann Arbor, MI, USA, [8]University of California San Francisco (UCSF) School of Medicine, UCSF Medical Center, San Francisco, CA, USA, [9]Dartmouth Health, Lebanon, NH, USA, [10]County of San Diego Health and Human Services Agency, San Diego, CA, USA, [11]Hartford Hospital, Hartford, CT, USA, [12]Nash Healthcare Consulting, El Paso, TX, USA, [13]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [14]Healthcare Sterile Processing Association (HSPA), Chicago, IL, USA, [15]Association of periOperative Registered Nurses, Denver, CO, USA and [16]Cedars Sinai Medical Center, David Geffen UCLA School of Medicine, Los Angeles, CA, USA

# The Challenge of MIFUs

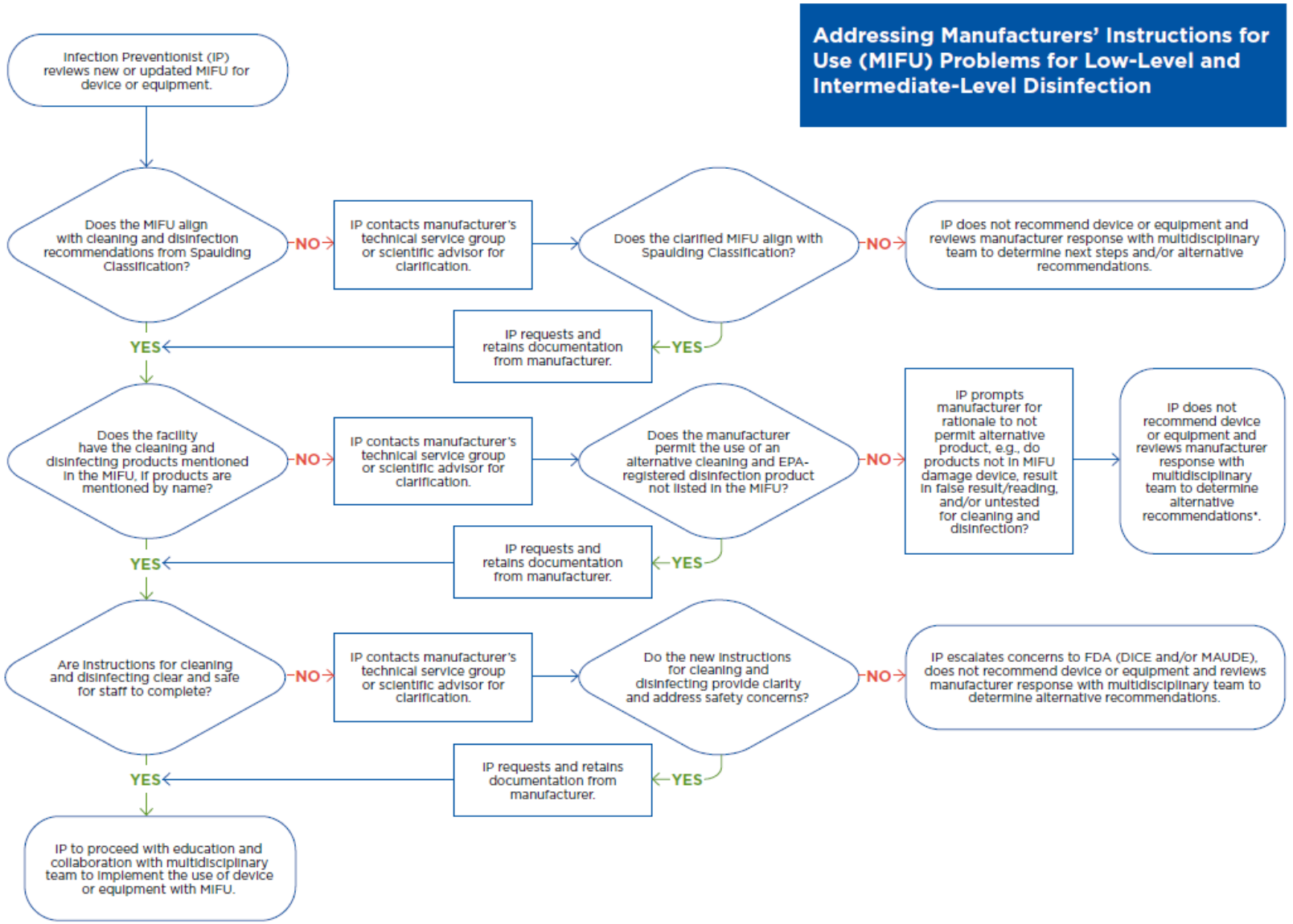
APIC
Association for Professionals in Infection Control and Epidemiology




https://apic.org/a-resource-for-addressing-discrepancies-in-the-manufacturers-instructions-for-use-of-non-critical-devices-mifus/

# Algorithm for Problematic MIFU

The following algorithm has been created based on the guidance for addressing MIFU problems. If the problem in the MIFU cannot be resolved, a multidisciplinary team may be necessary to conduct a risk assessment for the device or equipment to implement alternative recommendations.






https://apic.org/a-resource-for-addressing-discrepancies-in-the-manufacturers-instructions-for-use-of-non-critical-devices-mifus/

**SHEA Expert Guidance**

# Multisociety guidance for sterilization and high-level disinfection

- **When facing a conflict between the reusable medical device's MIFU and the accessory used for processing**
- **If the manufacturer of a device did not validate the process, but the manufacturer of the accessory specifically validates its process for that device (or vice versa)**
- **If the MIFU refers to consumable products (e.g., detergents, brushes) by name or with general attributes**
- **If the MIFU contains ambiguous language**
- **If the MIFU uses terms without providing the definitions or sufficient detail to allow for implementation**
- **If the MIFU is unclear or so complex that it cannot be implemented**
- **If the MIFU is not available**
- **If a facility is technically not able to implement the MIFU**
- **If the facility cannot implement the MIFU due to irresolvable challenges and it has no further options for recourse**

# One Health System's Approach to Sterilization and HLD Quality

**Tanya Stellges, BS CRCST**

**Director, Sterilization and HLD Quality Program, Vanderbilt Health**

VANDERBILT HEALTH

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# Vanderbilt Health Sterilization & HLD Quality Program

- Created in recognition of the importance of adherence to all recommended instrument sterilization/HLD practices to reduce patient/employee harms, more detailed assessment of such practices by external regulatory agencies
- Designed to serve as a partnership w/ operational leaders/end users (i.e., surgeons and proceduralists), while being a separate and distinct entity to the clinical programs
- **Key Steps:**
  - *Formation of Formal Oversight Committee*
  - *Centralization of Instrument Sterilization Practices*
  - *Hiring of an Infection Preventionist with an SPD Background*
  - *Standardization of HLD Practices & Training Program*
  - *Development of SPD/HLD Focused Environment of Care Survey Tools*
  - *Development of Quality Metrics*

# Vanderbilt Health Sterilization & HLD Quality Program Framework

## Assess Current State

- Builds relationships and identify key areas.
- Identify all locations performing reprocessing activities
- Inventory device types, workflows, and operational models
- Establish program scope and stakeholder ownership

## Establish Standards & Governance

- Gain operational support and begins defining expectations
- Define organizational expectations based on AAMI, AORN, SGNA, and regulatory requirements
- Develop system-wide policies and procedures
- Create committee and workgroup structure for review and approval

## Develop Measurement & Accountability

- Framework for Standardization
- Create comprehensive auditing tools aligned with standards
- Conduct baseline assessments across all sites
- Establish key performance indicators (KPIs) and reporting mechanisms

## Implement Oversight & Compliance

- Operational Accountability
- Review findings through governance committees
- Approve organizational standards and policies
- Define accountability structure for compliance and corrective actions

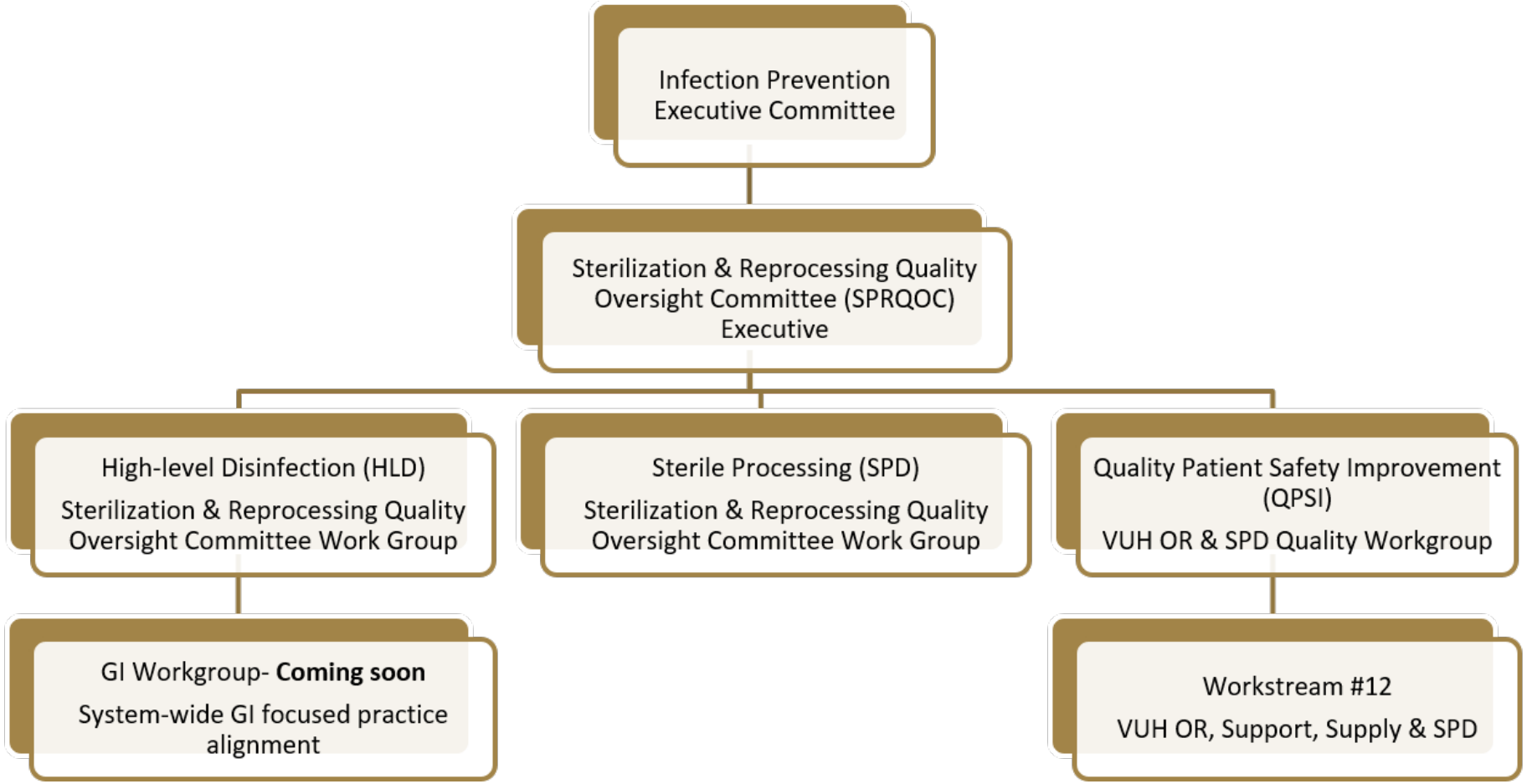
## Drive Standardization & Improvement

- Supports Sustainability
- Prioritize gaps and opportunities identified through audits
- Implement standardization initiatives across locations
- Monitor performance trends and sustain improvements

# Overview Scope of Practice & Sterile Processing HLD Sites

| Setting #1 | Setting #2 | Setting #3 | Setting #4 |
|---|---|---|---|
| Clinics performing HLD onsite<br>**Not performed in SPD* | Clinics sending instruments/medical devices to SPD | Clinics performing HLD & sending instruments/medical devices to SPD | Sterile Processing Sites |
| Total Sites= 85 | Total Sites= 310 | Total Sites= 29 | Total Sites=14 |

# Systemwide Quality Oversight Committee



# Sterilization & High-Level Disinfection Quality Program Overview

## 1. New Acquisition, Programs, Site Assessments, Audits & EOCs

- Onboarding on new program, & sites to ensure compliance
- Risk Assessment & mitigation
- Site practice and documentation assessments
- Environmental of Care (EOC)
- Action plan monitoring & recommendations
- Initiated in response to regulatory findings and/or trends

## 2. Regulatory Compliance Monitoring

- Assessment of space requirements
- Water quality compliance
- Practice and documentation assessments
- Review reprocessing equipment (preventative maintenance, repairs, etc.)
- Environmental monitoring

## 3. Quality Support

- Process mapping
- Data analysis
- Event analysis, RCA & ACA
- Investigation of devices and instruments to determine infection risks
- Facilitation of workgroups
- Comprehensive assessment and monitoring action items

## 4. Metrics- Development & Monitoring

- Quality metrics oversight for SPD and HLD sites
- Data analysis to identify trends and focus improvement (EOCs, Censitrac, Veritas, etc.)
- Support with operational metrics to determine continued sustainability

## 5. Safety Rounding & Rounding

- Focused rounding in high risk HLD reprocessing sites
- Rounding in VUH Perioperative and VUH/VCCOC sterile processing
- Quality rounding in regional reprocessing & Ambulatory surgery centers
- Safety rounding

## 6. Validation & Documentation

- Management of Policies, Standard Operating Procedures (SOPs)
- SBARs, Project planning, etc.
- Manufacture Instructions for Use (MIFU)
- Safety Data Sheet (SDS) Validation of devices/scopes
- Reprocessing & chemical validation

## 7. Specialized Education, & Training

- HLD Champion Training
- Maintain a list of users and site performing reprocessing
- Development of specialized training to support operational leaders with compliance.

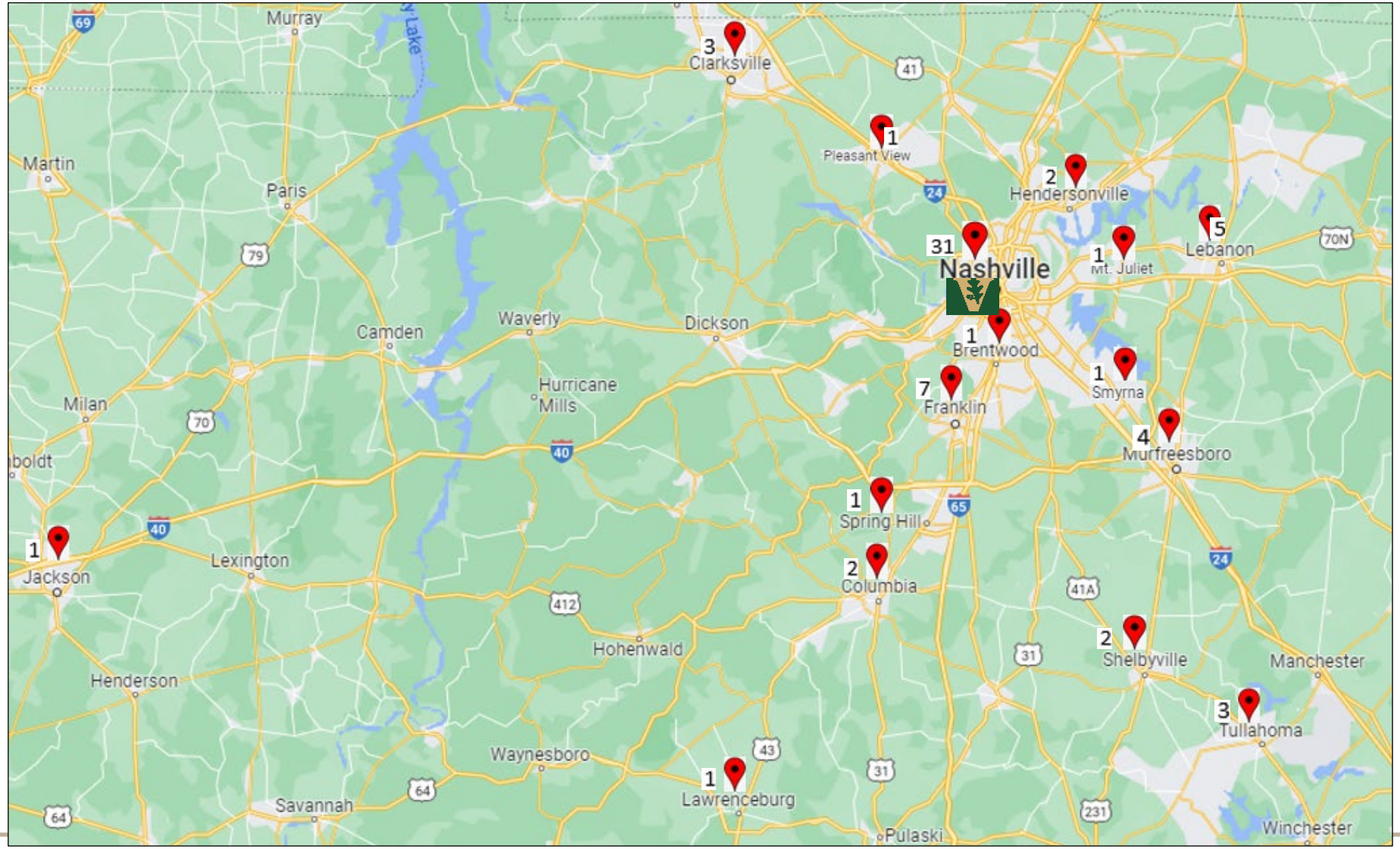
## 8. Special Projects & Support

- Assigned based on organizational need
- Reassess regularly based on current findings
- Implementation of new systems
- System-wide support for reprocessing areas

# High-Level Disinfection Quality Program

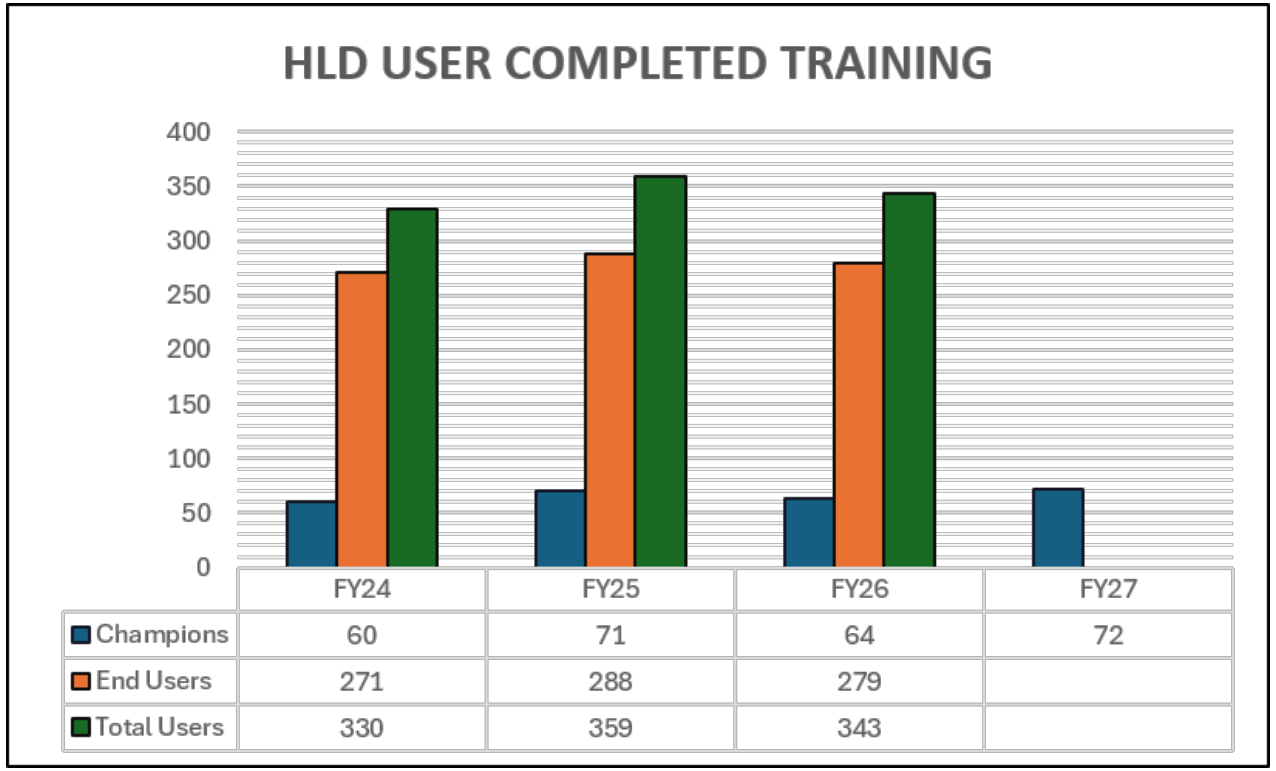
# Vanderbilt Health HLD Locations (2024)

| City | Locations Performing Onsite HLD |
|---|---|
| Nashville | 35 |
| Franklin | 10 |
| Lebanon | 7 |
| Murfreesboro | 5 |
| Tullahoma | 3 |
| Clarksville | 4 |
| Hendersonville | 5 |
| Shelbyville | 3 |
| Columbia | 2 |
| Brentwood | 3 |
| Spring Hill | 2 |
| Smyrna | 1 |
| Lawrenceburg | 1 |
| Jackson | 1 |
| Pleasant view | 1 |
| Mt. Juliet | 1 |
| **Grand Total** | **78** |



# Total HLD Chemistries & Champion Training Vanderbilt Health

| | |
|---|---|
| Trophon (AER) | 40 |
| Steris System 1E/Endo (AER) | 12 |
| Revital-Ox Resert (Manual) | 7 |
| Tristel OPH (Manual) – VEI | 5 |
| Medivators (AER) | 3 |
| TEE Clean (AER) | 2 |
| Cidex OPA (Manual); OER Pro (AER); Revital-Ox (Manual) | 1 |
| Revital-Ox Resert (Manual); TD-100 (AER) | 1 |
| Cidex OPA (Manual); Medivators (AER) | 1 |
| Revital-Ox Resert (Manual); Revital-Ox Resert (AER) | 1 |
| Cidex OPA (Manual) | 1 |
| OER Mini (AER) | 1 |
| OER Pro (AER); Revital-Ox Resert (Manual) | 1 |
| OER Pro (AER) | 1 |




**Number of users trained** decreased from **359** in **FY25** to **343** in **FY26**

**Champions trained** increased from **64** in **FY26** to **71** in **FY27**

**End users trained** decreased from **288** in **FY25** to **279** in **FY26**

**Percentage of champions identified vs. champions completing training** increased from **83%** in **FY26** to **87%** in **FY27**

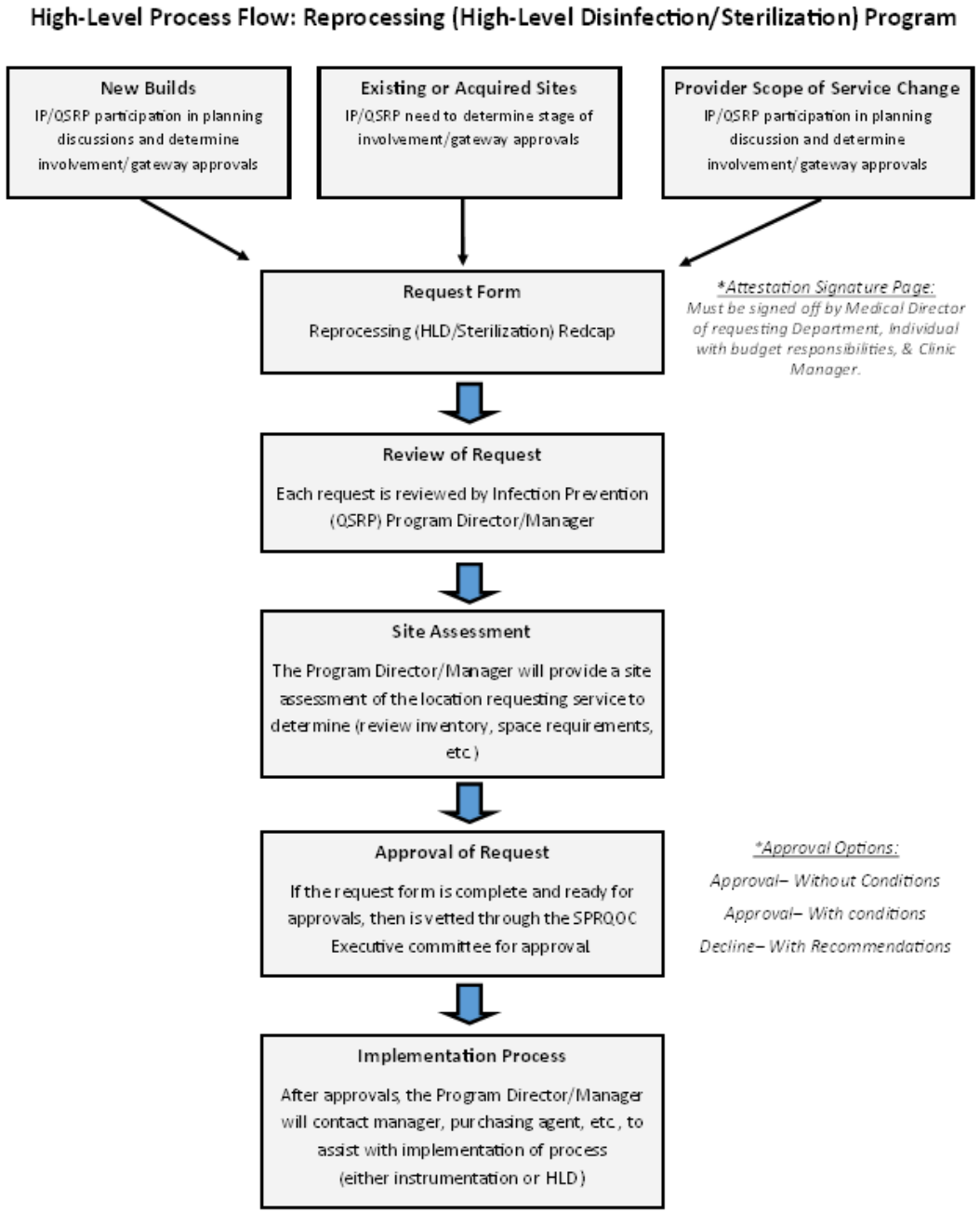
**New chemistry** added - OER

# Defining the
# High-Level Disinfection/Sterilization Request Process

**Action Items:**

- Establish point of involvement
  - New builds= VOS Planning team
  - Acquired sites= VOS Planning team
  - Existing site= Clinic Manager
  - Provider Scope of service change=
    - Clinic Manager
    - Accreditations & Standards team (TJC only)

- Utilization of Ambulatory leadership meetings to establish awareness of program & request form.
  - Ambulatory Leaders Meeting (Monroe Carell & Adult)
  - Ambulatory Leaders Meeting (VIP/Regionals)
  - Newsletter
  - Ambulatory Website/IP Website
    - Creation of algorithm with defining scope of practice change & reprocessing with QR code or link to RedCap survey



# Censitrac - Ambulatory Clinics HLD

**Total sites for Phase 1 (Trophon) Implementation = 31**

**Total sites for Phase 2 (Revital-OX/Steris/OER) =16**

## Sept 2022

-SPD Steering Committee Approval

-Health IT Project Approval

-TCO & PEER approved.

-Approval for hardware purchase.

## March 2025

-BAA agreement completed with Vendor and privacy office.

- Deep drive of cloud version of application completed.

## Dec 2025

-Rework of site and hardware needs.

-Onsite review of hardware needs and purchase.

-Project manager assigned by Vendor.

## Dec 2026

-Completion training and implementation for sites utilizing Trophon.

Development of Steris and Revital-OX standardized training.

## July 2027

-Completion training and implementation for sites with continued monitoring.

-Transition GI sites to new platform 2384

-Development of HLD specific quality metrics to track compliance.

## Aug 2024

-Censis BAA with privacy office and vendor.

**-Project placed on HOLD**

## Sept 2025

-Project restart with Heath IT.

-Submission of quote to Censis for facility IDs.

- Contract approved by vendor and PO cut.

-Reconciliation of sites with hardware needs.

## Sept 2026

-Completion of off-site hardware needs.

- Weekly meetings to development of standardized training and workflows for each chemistry.

-Start up of operational leader and vendor meetings to prepare of onsite training.

## Jan 2027

-Monitoring of implemented system for compliance.

-Completion of standardized training and workflows for Steris & Revital-OX users

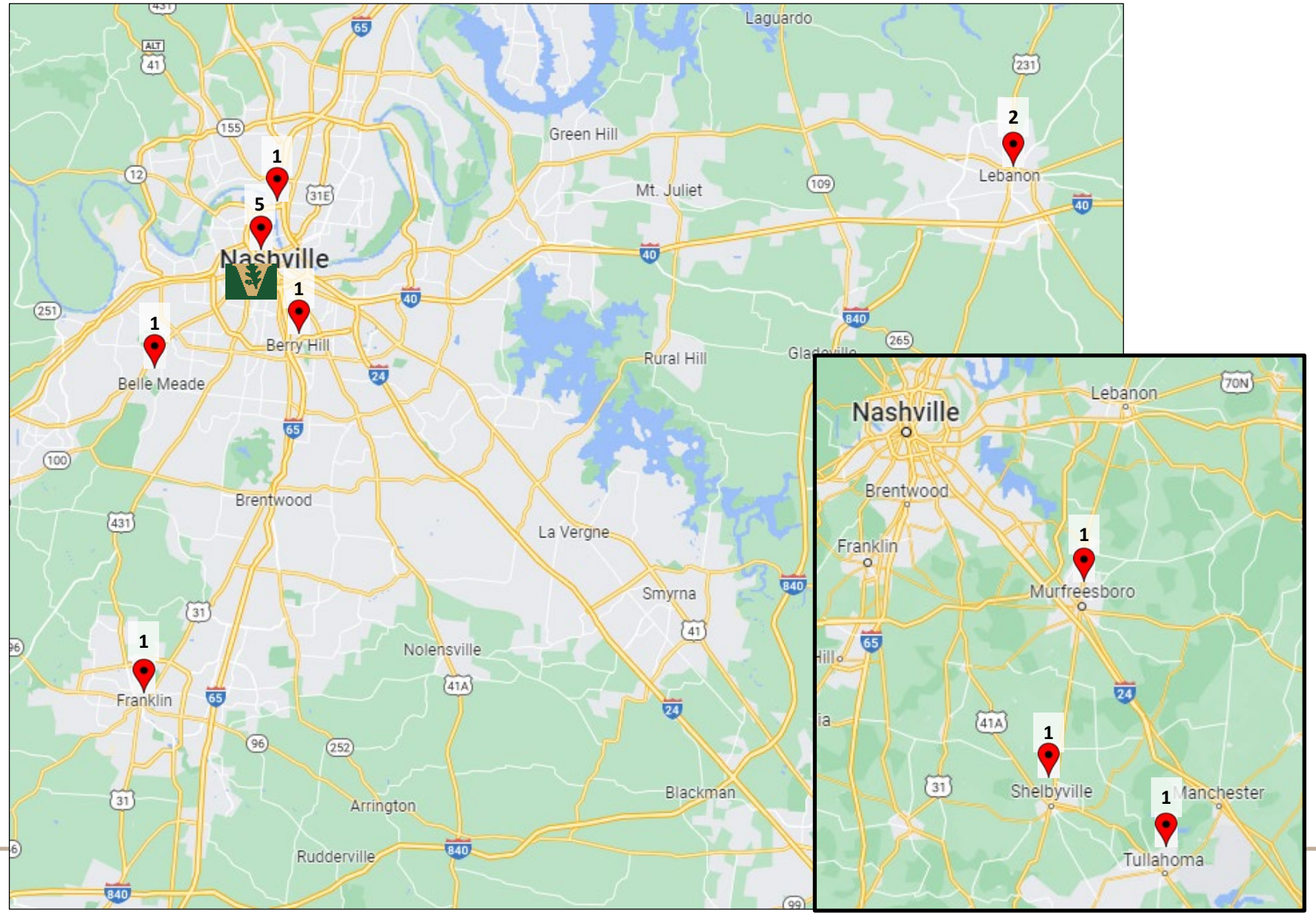
-Assess training and implementation with upcoming JC survey

**Once completed, we will work with VIS for standardization*

# Sterilization Quality Program

# Vanderbilt Health SPD Sites

| Sterile Processing Locations | # sites |
|---|---|
| VUH (Main Campus) | 2 |
| Monroe Carell (Main Campus) | 2 |
| FEL (Main Campus) | 1 |
| VCCOC (Briley) | 1 |
| OHO (100 Oaks) | 1 |
| VHBM (Belle Meade) | 1 |
| VSCF (Franklin) | 1 |
| VCSC (VCH Murfreesboro) | 1 |
| VBCH (Shelbyville) | 1 |
| VTHH (Tullahoma) | 1 |
| VWCH (Wilson County) | 1 |
| VWCH ASC (Wilson County) | 1 |
| **Grand Total** | **14** |



# Standardized  Protocols, Auditing, Event Review & Tracking

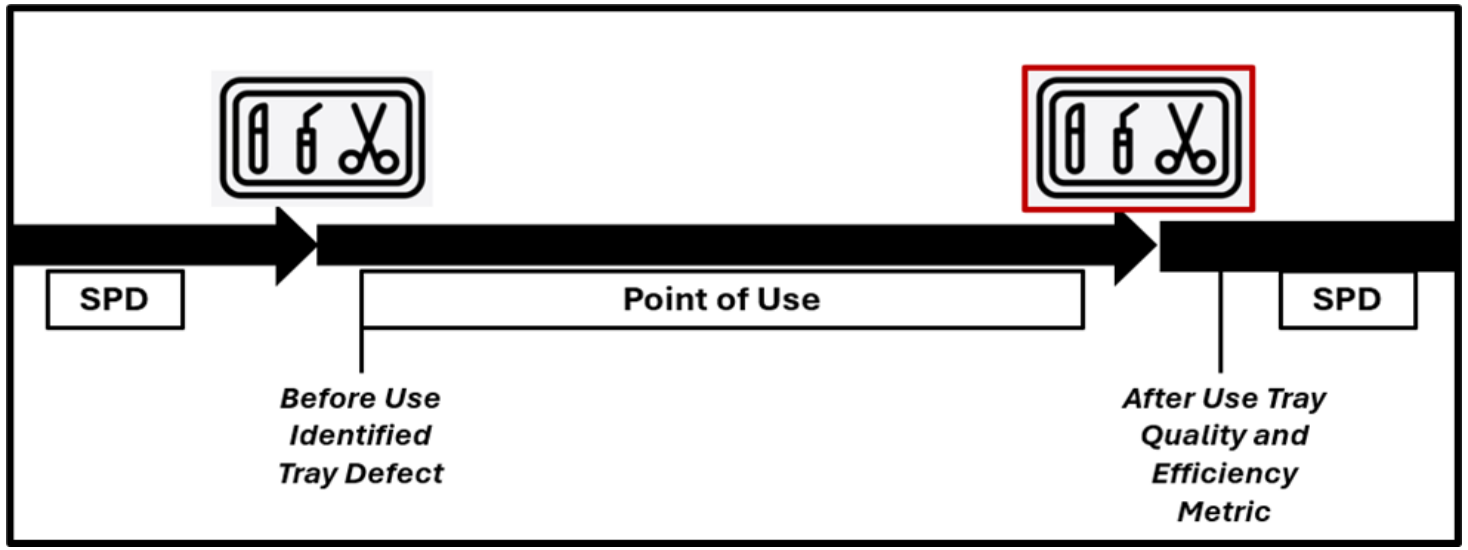
- Established standardized environment of care auditing tool aligned with AAMI Standards
- Auditing to capture compliance with documentation and practice compliance
  - To identify areas of opportunity and focus improvement
- Quality reporting of defects, event review and data analysis
- Standard Operating procedures and policies
  - Standardized documents overseen by Infection prevention Sterilization and HLD quality team.
- SSI Event review of instruments utilized in procedure to validate sterilization parameters and qualification testing.

# Quality Metric Development

| Metric Name | Definition |
|---|---|
| **Immediate Use Steam Sterilization (IUSS) Rate** | Total IUSS cycles performed/ surgical case volume |
| **IUSS Proportion of Events Due to Bioburden** | Proportion of all IUSS cycles that were due to the presence of bioburden in the instrument tray |
| **Tray Defect Rate** | Number of Instrument pans or devices with a reported defect from the end user (i.e., missing instruments, damaged instruments, assembled wrong, etc.)/ surgical case volume |
| **Instrument Spray Compliance Rate** | An audit of instruments verified visually at receipt in SPD to determine if the instrument tray was sprayed with the purpose of retaining moisture (to prevent bioburden hardening). Percent of audited trays that had evidence of instrument spraying/ total trays assessed. |
| **Instrument Spray Compliance Assessment Rate** | Percent of all instrument trays received with SPD that were assessed for spray compliance. |
| **Biological Indicator Fail Rate** | Percent of all sterilization cycles with a failed biological indicator |
| **Chemical Indicator Fail Rate** | Percent of all sterilization cycles with a failed chemical indicator |
| **Bowie Dick Fail Rate** | Percent of all sterilization cycles with a failed Bowie Dick test (where indicated) |

# Tray Defect Metric Revision and Standardization

- July 2025:  Agreement to standardize tray defect reporting with Sterilization/HLD Quality program as the central assessor of the metrics (aligns with other quality reporting, e.g., CLABSI assessment).
- Revised metrics related to where occurred in cycle of use
  - Broken into 2 metrics: **Before Use** and **After Use**
  - Better reflects where in the instrument tray flow opportunities arise



# Lessons Learned

- Alignment and standardization of practices has **reduced variability** in practice, **improved efficiencies** across the system, **focused training** and education, and allowed for **resource sharing**
- Presence of dedicated personnel solely focused on instrument and device quality has **allowed in depth auditing** of instrument sterilization and HLD practices across the system to identify potential areas for improvement
- Program members **serve as a bridge to facilitate** robust reviews of quality issues (move from “us vs. them” dynamic to open dialogue of barriers and opportunities in a collaborative manner)
- Team members are housed and meet regularly with other IP personnel - allows for a **synergistic approach** between the teams, **aligning both instrument and device quality work with general IP improvement** in surgical and procedural areas

