WHAT IS REALLY IN ANSI/AAMI ST 58: 2013 CHEMICAL STERILIZATION AND HIGH-LEVEL DISINFECTION IN HEALTH CARE FACILITIES???

Presented by Advantage Support Services, Inc.

Objectives:

- Explanation of the Purposes of ST58
- A brief history of ANSI/AAMI Guidelines that led to ST58
- Review of most common variances in compliance with ST58 and interactive discussion of the operational impact of recommendations in ST58
- Deliver recommendations for realistic implementation plans
- Question and Answer session
- Summary

Cellphones are welcome here!!!

Audience:

Please text COOLPINE859 to 22333 and join the session!

Question #1

Does your facility have ST58 in SPD?

A. YES
B. NO
C. I don't know what ST58 is

RESULTS

Which one is ST58?

Is it the one about the most commonly used sterilization method?

Nope:

That's *ANSI/AAMI ST79:2017: Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities (Contains Amendments)*

Ohhhhhh, I know, it's the one about Flexible Scope processing, right?

Nope:

That's *ANSI/AAMI ST91: 2021: Flexible And Semi-Rigid Endoscope Processing In Health Care Facilities*

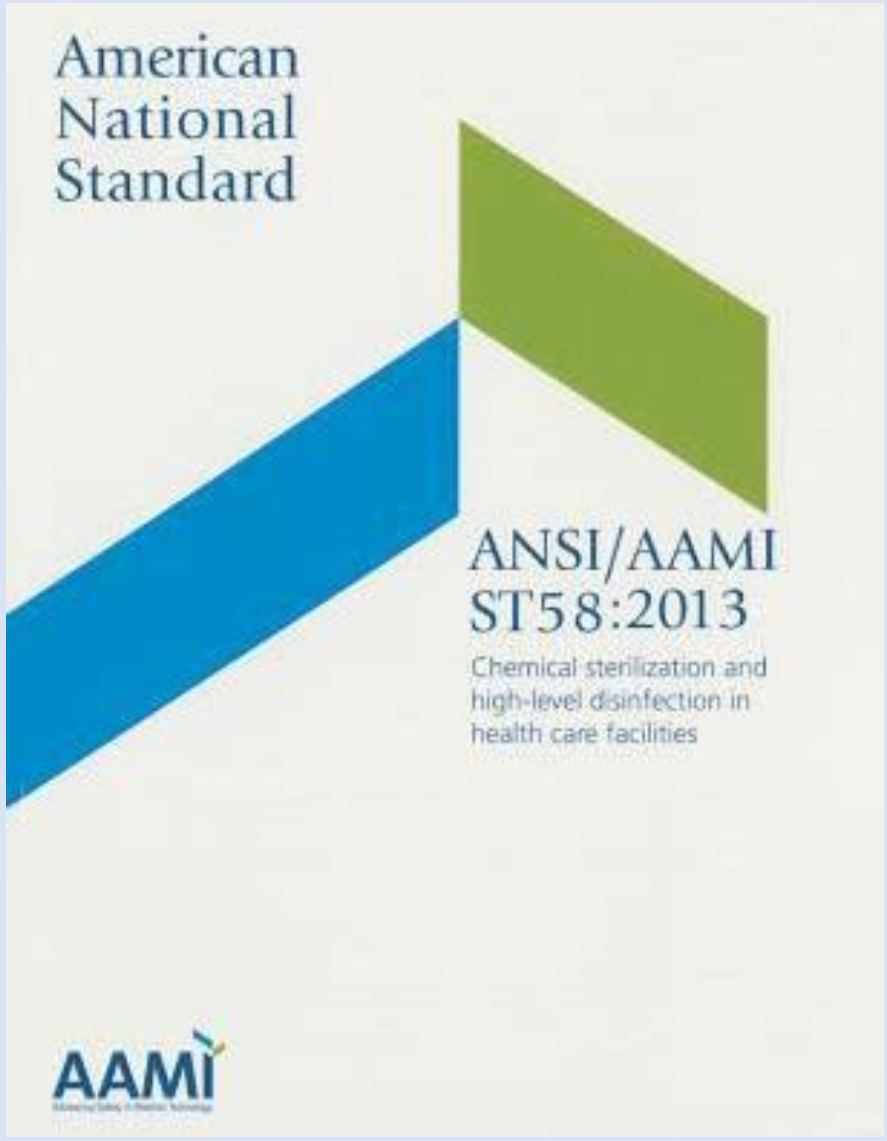
Soooooooo, it's gotta be the one for ETO???

Nope:

That's *ANSI/AAMI ST41: 2008 (R2018): Ethylene Oxide Sterilization In Health Care Facilities: Safety And Effectiveness*

Presented by Advantage Support Services, Inc.

ST58 is…



This recommended practice specifically addresses:

a) work area design considerations for processing areas in which liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems are used;

b) staff qualifications, education, and other personnel considerations;

c) criteria for selecting liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems;

d) decontamination and preparation of instruments;

e) safety and efficacy considerations in the use of liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems;

f) storage and transport of sterilized or disinfected devices;

g) quality control methods; and

h) quality process improvement.

Why do I suddenly need to know about ST58 now?

When your goal is Minimum Compliance, each Accreditation Survey is a **GAMBLE**.

"Todays price is not yesterday's price" - Joseph Antonio Cartagena A.K.A. "Fat Joe"

Information is more accessible, Standards are digital and training for Surveyors is much more focused on SPD, with more than 72% of Surveys resulting in a finding for SPD.

Aiming for Best Practice means that even if you fall short, you are still in compliance.

If your facility is performing Chemical High Level Disinfection (HLD) or Sterilization without having and knowing ST58, you are taking a chance with your patient care.

A brief history of ANSI/AAMI Guidelines that led to ST58

The first edition of **ANSI/AAMI ST58**, Safe use and handling of glutaraldehyde-based products in health care facilities, was published in **1996**.

The second edition incorporated **AAMI TIR7, Chemical sterilants and high-level disinfectants: A guide to selection and use**, was published in **2005**.

A brief history of **CURRENT** ANSI/AAMI ST58 Guidelines

Key updates to the current **third edition** *(that was updated in 2018)* include:

- additional and current workplace safety information
- new and updated annexes specific to vapor monitoring
- expansion of the types of sterilization processes described to address new systems available to the health care user
- improved guidance for workplace design
- alignment of recommendations to companion health care facility documents, including **ANSI/AAMI ST79: Steam** and **ANSI/AAMI ST41: Ethylene Oxide Sterilization In Health Care Facilities: Safety And Effectiveness**
- a revised product testing selection to simplify recommendations
- expanded recommendations for personnel training
- and updated quality process recommendations.

Matching intended use to IFUs and 510Ks

Follow the IFUs is drilled into our heads, but as professionals we have to remember that if it sounds too good to be true, it probably is.

The **Spaulding Category**[3] has to allow Chemical Disinfection, not just the IFUs.

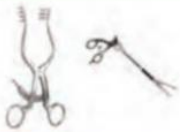
Consider the case of **Steris1's** in December 2009.

We have to be more "Truth Seeking" professionals.

When IFUs and actual use do not match, take a look at the **510K**.

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act).

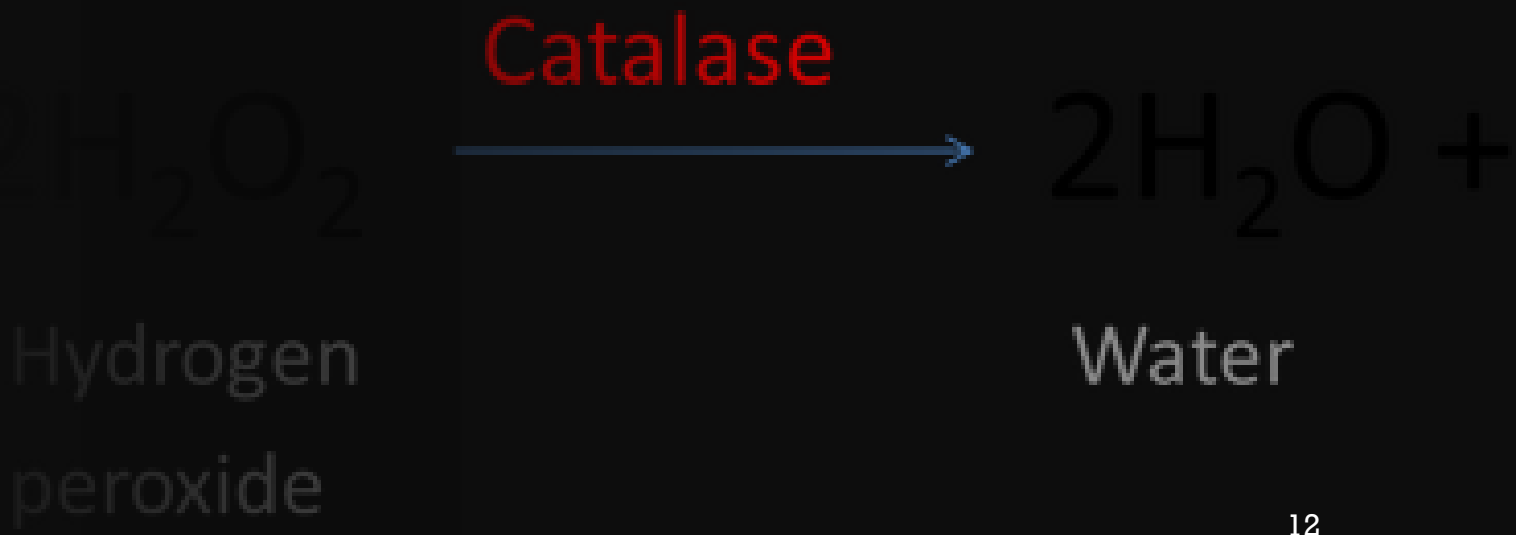
Several high-profile incidents have shown us that the IFUs that manufacturers provide us, do not ALWAYS match what they submitted to the **FDA**!!!

Patient Contact	Examples	Device Classification	Minimum Disinfection Level
Intact Skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous Membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, vascular system		Critical	Sterilization

Operational Application: Using the Annexes

A. **Microbial lethality, materials compatibility, and toxicity**
B. **Glutaraldehyde solutions**
C. **Hydrogen peroxide solutions**
D. **Ortho-phthalaldehyde solutions**
E. **Peracetic acid–hydrogen peroxide solutions**
F. **Sodium hypochlorite solutions**
G. **Chemical vapor sterilants using alcohol and formaldehyde**
H. **Hydrogen peroxide gas sterilization**
I. **Ozone sterilization**
J. **Government regulation**
K. **Occupational exposure to bloodborne pathogens (29 CFR Part 1910.1030)**
L. **User verification of cleaning processes**
M. **Example of documentation of premature release of implants**
N. **Gas and vapor monitoring**

Review of the **MOST** common variances in compliance with ST58



Common variances in compliance with ST58: Work Area Design: Ventilation

3.4 Ventilation of processing areas and equipment:
3.4.1 General considerations:

- Proper ventilation will help ensure an irritation-free, safe, and comfortable work environment. Chemical odors could be the first indication that the ventilation might not be adequate… Therefore, the ventilation system should be designed to control potential airborne concentrations of chemical sterilants, and measures should be taken to ensure that it is operational at all times.
- The need for local exhaust ventilation can be assessed through environmental monitoring during manipulation and use of chemical sterilants/high-level disinfectants (including dispensing, pouring, and disposal).

SPD LEADERS AND TEAM MEMBERS MUST HAVE REAL-TIME ACCESS TO THE LATEST VENTILATION MEASUREMENTS!!!

Common variances in compliance with ST58: Work Area Design: Chemical Storage

3.6 Storage of chemical sterilants/high-level disinfectants

- Prior to use, the IFU, the SDS, and the chemical sterilant/high-level disinfectant product label for the specific product should be consulted for storage instructions. In general, however, unused chemical solutions should be stored in tightly closed containers in a cool, secure, properly marked, well-ventilated area; they should not be stored under sinks.
- **The area under sinks is an uncontrolled environment and is not suitable for storage.**

Common variances in compliance with ST58: Personnel Considerations

4.2.2 Processing personnel

The responsibility for performing chemical high-level disinfection and sterilization processes should be assigned to:

Qualified individuals who have:

- demonstrated knowledge of and **DOCUMENTED COMPETENCE** in all aspects of decontamination, assembly, and sterilization

4.3.1 Processing personnel engaged in sterile processing and chemical high-level disinfection should receive both an initial orientation and on-the-job training.

- Vendor specific initial training in the operation of the specific high-level disinfection or chemical sterilization system used by the processing department; Participation in in-service programs designed specifically for the personnel performing chemical sterilization and disinfection processes; and
- Further, it is recommended that such personnel should successfully complete a **CENTRAL SERVICE CERTIFICATION EXAMINATION** within **two years** of employment and should maintain that certification throughout their employment.

Common variances in compliance with ST58: Personnel Considerations: Supervisory

4.2.1 Supervisory personnel: Successful completion of documented specialized training, such as a sterile processing management; participation in continuing education programs and courses; demonstration of comprehensive knowledge of pertinent state and federal regulations, particularly OSHA regulations;

- Supervisory personnel should maintain competency throughout their tenure by:

- participating in facility and departmental **IN-SERVICE AND TRAINING PROGRAMS**;
- **DEMONSTRATE** (***v. give a practical exhibition and explanation of how a machine, skill, or craft works or is performed***) and improve their expertise through participation (as a member or resource person) in committees within the health care facility (e.g., risk management, hazardous materials, quality improvement, infection prevention and control, safety, standardization, product evaluation, policies and procedures)
- **QUALITY IMPROVEMENT ACTIVITIES**.

Personnel Considerations: PPE

4.4.3 Skin protection (liquid)

- Skin should be protected against contact with chemical solutions. Gloves impervious to the chemical should always be worn if there is any possibility of contact with a chemical solution, including the handling of the LCS/HLD solution containers, bottles, or cassettes. The forearms should be protected by elbow-length gloves or by protective sleeves made of a material impervious to the chemical See **Annexes B-I.**

4.4.4 Respiratory protection

- Standards set by OSHA for respiratory protection and hazard communication (29 CFR 1910.134 and 29 CFR 1910.1200, respectively) require the use of appropriate respirators by all employees who could be overexposed to chemical vapor during routine or emergency work procedures (see **Annex J.6**).

A.4 Toxicity

- Health care personnel must be protected from hazards associated with occupational exposure to LCSs/HLDs and gaseous chemical sterilants. Patients must be protected from the potentially harmful effects of exposure to LCS/HLD Before clearing an LCS/HLD or gaseous chemical sterilization system for marketing, the FDA evaluates information provided by the manufacturer on the safety of the product. The FDA must also clear the manufacturer's labeling for the product, which includes written IFU with adequate warnings and precautions.

Question #2

RESULTS

Is Face Protection provided at your facility for unloading Chemical HLD and changing Chemical Cups or Cassettes as required by the MIFUs for this Equipment?

A. Yes

B. No

C. Yes, but nobody uses it

Cleaning devices prior to Chemical HLD or Sterilization

6.6 Cleaning and other decontamination processes:
6.6.1 General considerations

To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process, whereas others must be prepared for and subjected to terminal sterilization or high-level disinfection.

1. Chemical Sterilization and HLD ≠ Handwashing
2. Handwashing items whose IFUs recommend Automated Washing is **UNDER PROCESSING**.
3. Automated cleaning is preferred to manual cleaning due to the reproducibility and control of the process.[2]

vs.

Quality Control: IFUs and Material Compatibility

Annex A.3 Materials compatibility: A.3.1 General considerations

That is, the chemical sterilant/high-level disinfectant should not alter the material of a device in such a way that the device will not be safe or will not function as intended.

Annex A.3.3 Effects on metals

Metals, although not necessarily heat-sensitive, might be exposed to chemical sterilants/high-level disinfectants as components of reusable, heat-sensitive devices.

DO NOT USE CHEMICAL STERILIZATION AND HLD TO REDUCE IUSS:

- Material Compatibility and IFUs typically does not allow it
- Sterilization performed outside of SPD often falls short of documentation requirements.

TIP: When the IFU allows both Steam and Chemical HLD or Gaseous Sterilization, Check with Manufacturer for which method impacts materials the most.

CMS audit regulations state…*"If manufacturer's instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the practice should be citied as a violation of 42 CFR 416.44(b)(5)."*

Quality Control: Equipment Malfunction

9.5.2 Gaseous chemical sterilizer malfunction; 9.4.3 Automated processing equipment malfunction;

- If the physical-monitoring records indicate any malfunction or suspicious operation, the cycle load should be considered nonsterile and not used.
- The department head or designee should be notified.
- The manufacturer's written IFU should be reviewed for troubleshooting information.
- After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the sterilizer manufacturer's written IFU, and the sterilizer should be removed from service.
- All items should be completely repackaged, all wrappers and disposable products should be replaced, and new process indicators should be used.
- Items from aborted cycles should be removed from packaging while wearing PPE, cleaned if needed to remove residual chemicals, repackaged, and reprocessed according to manufacturer's written IFU.

Quality Control: Recall

9.8 Product recalls: 9.8.2 Recall procedure

A recall procedure should:

a) be written,
b) outline the circumstances for issuing a recall order,
c) designate the person or people authorized to issue a recall order, and
d) designate the person or people responsible for reporting on the execution of a recall order.

9.8.3 Recall order

A recall order should:

a) include all items processed back to the last negative BI (if applicable);
b) be immediately communicated to affected departments and followed by a written order;
c) identify products to be recalled by lot number (if applicable), product or patient name, or other information;
d) identify the people or departments to whom the order is addressed;
e) require the recording, in terms of kind and quantity, of the products obtained in the recall; and
f) specify the action to be taken by the people receiving the order (e.g., destruction or return of product).

9.8.4 Recall summary report

A summary report of a recall order should:

a) identify the circumstances that prompted the recall order;
b) specify the corrective actions taken to prevent a recurrence;
c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and
d) provide verification that the recalled items were reprocessed or destroyed, as appropriate.

9.2.2 Cycle documentation and record-keeping:

Knowing the contents of the lot or load enables personnel to decide how critical a recall might be.

TIP: A written step by step Algorithm for recall is a time saving and compliance ensuring step that helps the whole department!!!

Quality Control: Evacuation Plan

9.5.2 Gaseous chemical sterilizer malfunction

- If the physical-monitoring records indicate any malfunction or suspicious operation, the cycle load should be considered nonsterile and not used.
- The department head or designee should be notified.
- The manufacturer's written IFU should be reviewed for troubleshooting information.
- After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the sterilizer manufacturer's written IFU, and the sterilizer should be removed from service.
- All items should be completely repackaged, all wrappers and disposable products should be replaced, and new process indicators should be used.
- Removing a load from an aborted cycle can present a risk of exposure of workers to residual sterilant.
- The manufacturer's written IFU should be followed, appropriate safety precautions should be observed, and personnel should wear appropriate PPE.
- Items from aborted cycles should be removed from packaging while wearing PPE, cleaned if needed to remove residual chemicals, repackaged, and reprocessed according to manufacturer's written IFU.

Quality Control: Biological Load Testing Frequency and Qualification Testing

9.5.4.3 Frequency of use of biological indicators and process challenge devices

- A PCD with the appropriate BI should also be used at least daily**, but preferably in every sterilization cycle (see 9.5.4.5).**

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a sterilization cycle **could vary from one cycle to another**.

Process challenge devices containing appropriate BIs should be used for sterilizer **qualification testing during initial installation of the sterilizer; after relocation, major repairs or malfunctions of the sterilizer; and after sterilization process failures.**

9.5.2 Gaseous chemical sterilizer malfunction

- After a major repair of a sterilizer, it should be **requalified** according to the manufacturer's written IFU, which should include the appropriate BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run (see 9.5.4.4). The BI test results should be obtained and be determined to be satisfactory before the sterilizer is returned to service.

References: **4** & **5**

Quality Control: Gas and Vapor Monitoring

Annex N.1 General considerations:

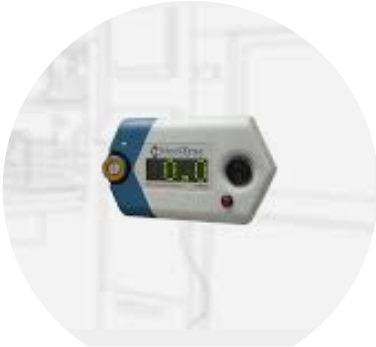
- To ensure a safe work environment and to establish compliance with regulatory limits and voluntary guidelines on occupational exposure to the gases and vapors of chemical sterilants/high-level disinfectants, several air sampling and monitoring techniques are currently in use.

- OSHA has established **PELs** for many compounds. Even if the health care facilities are not specifically required by law to monitor the vapor concentration, OSHA can enforce PELs by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards that are causing or likely to cause death or serious physical harm to employees.

- OSHA will typically use commonly accepted standards, such as ACGIH® TLV® exposure limits to determine whether the exposures are deemed harmful levels.

- Monitoring may be used to demonstrate compliance with the accepted exposure standard.

Question: If Monitoring is not used, how does a facility demonstrate compliance with Exposure Standards?



Note 3—The term **"monitor"** has several meanings in common usage and refers more to the intent to provide ongoing exposure measurements rather than a single gas concentration measurement (sampling). The term **monitor** therefore includes methods such as exposure badges and diffusion tubes as well as continuous monitors. Most of these technologies provide one data point for the gas concentration collected over a sampling period (e.g., 8 hours) and often that result is only known after a subsequent laboratory analysis. The term **"continuous monitor"** refers to an instrument that measures the gas concentration in real time and provides the gas concentration continuously over time.

Quality Control: My facility does not have Gas and Vapor Monitoring

Erin Brockovich was an unemployed single mother becomes a legal assistant and almost single-handedly brings down a California power company accused of polluting a city's water supply.

You **DESERVE** Vapor Monitoring for Glutaraldehyde, Peracetic Acid, and Hydrogen Peroxide exposure.

How long are you going to allow your facility to continue not to monitor chemicals that the Federal Government has established as hazardous to your health?

Remember: There was a time that Smoke Detectors were optional when building a house.

Question # 3

Does your facility provide "Continuous Monitoring" for H2O2 Sterilization, Chemical HLD, and Peracetic Acid?

A. Yes for all three
B. Yes for some, but not all
C. NO for all three

RESULTS

Quality Control: Recordkeeping for Chemical HLD

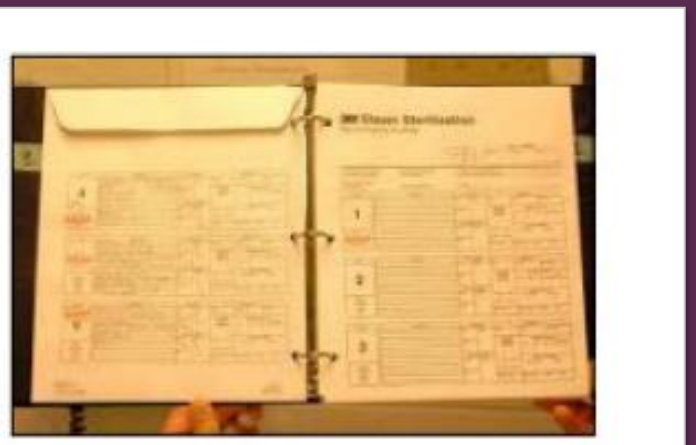
9.2.2 Cycle documentation and record-keeping

For each chemical sterilization or high-level disinfection cycle, the following information should be recorded and maintained:

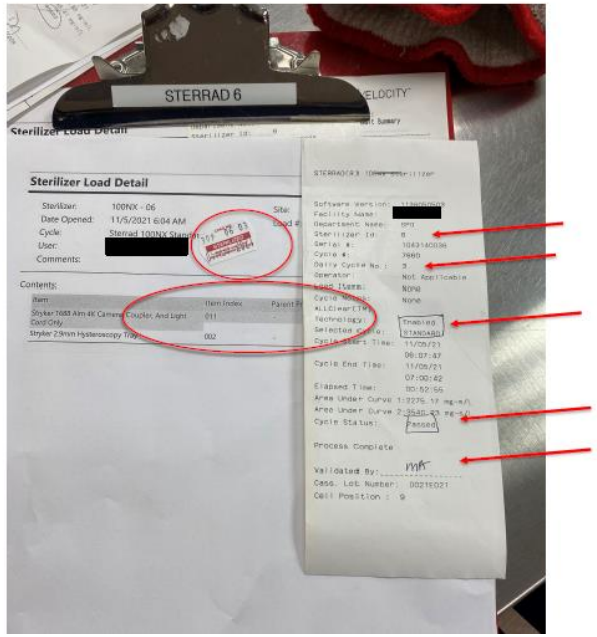
a) the assigned lot number, including chemical sterilizer, processor, or soaking container identification and cycle number; **b)** the specific contents of the lot or load, including quantity, department, and a description of the items; **c)** the patient's name and medical record number, if available; **d)** the procedure, physician, and—if applicable—serial number or other identification of the item; **e)** the shelf-life date, if applicable, the lot number, and the date that the original container of LCS/HLD was opened; the use-life of the open container; the date that the product was activated or diluted; the date that the activated, diluted, or ready-to-use solution was poured into a secondary container; and the reuse-life of the solution; **f)** the exposure time and temperature, if not provided on the physical monitors; **g)** the date and time of cycle; **h)** the time, temperature, and—if applicable—chemical concentration of the exposure phase of the chemical sterilization or high-level disinfection cycle; **i)** the name or initials of the operator;

DO NOT RELY ON THE LOAD RECEIPT ONLY IF THIS INFORMATION WHEN USING MANUAL METHODS OR EQUIPMENT THAT DOES NOT PROVIDE ALL OF THE INFORMATION ABOVE. MAKE A LOG!!!

TIP: KEEP THE SUPPLIES AND CONDUCT ANNUAL TRAINING FOR MANUAL PROCESSING FOR DOWNTIME PURPOSES.



Rationale: Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record, they are also needed to detect malfunctions as soon as possible, so appropriate corrective actions can be taken



Quality Control: Recordkeeping and Load Release for Chemical Sterilization

9 Quality control: 9.1 General rationale:

This section covers product identification and traceability, documentation and record-keeping, monitoring of chemical sterilization and high-level disinfection processes, product testing, product recalls, and quality process improvement.

- I l ❤ ve the Manual and Electronic documentation set ups for Steam Sterilization.
- I do not particularly enjoy the Manual and Electronic documentation set ups for Steam Sterilization. 😠

Sterilization Documentation does not change per Sterilization Method.

TIP: Create a Log Sheet that matches the Steam Sterilization Records and configure Electronic Documentation to match Steam Sterilization.

Quality Control: Lot Labeling before the Sterilization Cycle

9.5.4.5.2 Routine test procedure with BIs

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD should be labeled with appropriate sterilizer and lot information

What's the real reason facilities label AFTER the cycle???

Annex H.3 Effective use of hydrogen peroxide gas sterilizers

To ensure efficacy when using a hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

- b) No cellulose-based products should be included inside or outside the package to be sterilized. (Cellulose based products such as towels, gauze, or paper are absorptive and can interfere with the sterilization process. These types of materials can cause cycle cancellation.)
- f) Devices should be packaged in **Tyvek®-Mylar®**

Quality Control: Regularly Scheduled Documented Product Testing

9.7 Product testing: 9.7.1 General considerations:

Product testing consists of a series of procedures used to verify that manufacturer's written IFU can be successfully performed in the user facility. Product testing can only be used to verify the information provided in the manufacturer's written, validated IFU. Not all medical devices processed need to be product tested. Instead medical devices are typically placed into product families. The most challenging device to process from each family can be identified as the **MASTER PRODUCT**, which represents the entire **family of devices during testing.**

9.7.2 Gaseous chemical sterilization processes

For product testing devices that use gaseous chemical sterilization processes, BIs and CIs should be placed within the product test samples (known as Master Products) The number of BIs and CIs used within each product test sample will depend on the size and configuration of the package being tested. Medical device manufacturers can assist in identifying where to place BIs and CIs. Document the placement of the BIs and CIs (e.g., digital photo) and label each to determine where the positive BIs and/or unresponsive CIs were located to assist in a thorough investigation to determine the reasons for the failures.

Examples of placement of BIs and CIs for product testing are as follows:

a) For an instrument set, the BIs and CIs should be placed at each end of the tray and among the instruments that are placed in stringers.

b) For rigid sterilization container systems and other containment devices, the BIs and CIs should be placed in areas recommended by the containment device manufacturer.

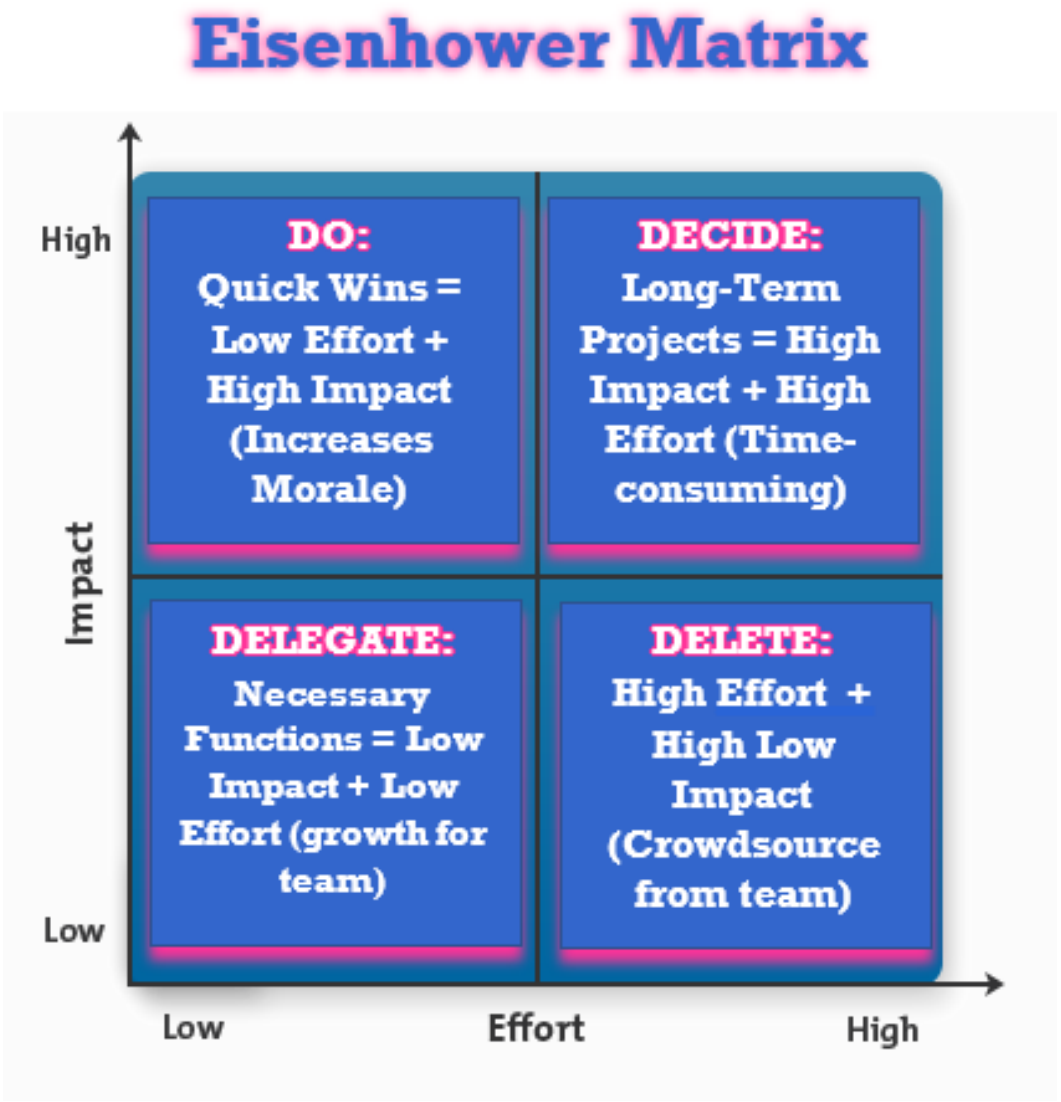
The test protocol, test results, and any corrective actions taken should be **DOCUMENTED** and **MAINTAINED** as part of the sterilization log or **QUALITY ASSURANCE PROGRAM DATA**. Documentation of product testing activities should be maintained, including:

- the date the testing was performed, the name of the master product, product family name, identification of the locations of BIs and CIs within the master product, and test results.

Rationale: Process challenge devices used for sterilizer efficacy and routine testing present a known challenge to the sterilization process. However, PCDs do not reflect the items routinely processed in a health care facility. Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process.

Developing an Action Plan:

1. Print out this Presentation
2. Bug your leadership to get a copy of ANSI/AAMI ST58:2013 (R2018)
3. Chemical Sterilization And High-Level Disinfection In Health Care Facilities
4. Perform a Self- Assessment of your facility's practices
   A. Be honest about opportunities
   B. Use an Eisenhower Matrix to prioritize
5. Advocate the evidence-based opportunities to your leadership
6. Work cross-functionally with Infection Prevention for their clinical expertise
7. Reach out to Human Resources for unaddressed Health and Safety concerns



Summary

There is no perfect SPD, but familiarity and Continuous Quality Improvement **(CQI)** activities based on the standards in ST58 can ensure that you are delivering the highest quality of processed medical devices to YOUR patients.

"Perfection is not attainable, but if we chase perfection, we can catch excellence." - Vince Lombardi, **NFL Hall of Famer, Two-time Superbowl Winning coach of the Green Bay Packers**


Q
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References:

1. American National Standard/Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58:2013/(R)2018 Chemical sterilization and high-level disinfection in health care facilities.

2. https://www.sehd.scot.nhs.uk/publications/sspr/sspr-14.htm

3. https://www.courtemanche-assocs.com/high-level-disinfection-hld/

4. https://www.asp.com/products/terminal-sterilization/sterrad-velocity-biological-indicator-system

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6. https://www.imdb.com/title/tt0195685/

7. https://www.mindtools.com/pages/article/newHTE_95.htm

IN CLOSING

Thank you for allowing us to present at your Chapter meeting.

We would love to continue the conversation and consideration to help reach your personal and facility's goals.

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