CRITERION

"THE OFFICIAL NEWSLETTER OF THE CBSPD, INC."

Volume 21, Issue 1 - Summer 2017

Message from the Chairman of the Board:

A summit was held with AAMI, FDA Center for Devices and Radiological Health, CDC, American Hospital Assoc. and Joint Commission last September addressing the topic of Preventing Device-Related Healthcare-Associated Infections (HAI). As a follow-up to a summit held in 2011, which addressed strategic initiatives to improve safe reprocessing of reusable medical devices, this event was to be a first step in gaining the consensus needed to take a systems approach to combating HAIs.

As a representative of the CBSPD and my hospital, I had the pleasure of being one of the 100 stakeholders attending the summit. In addition to the organizations who supported the summit, other areas represented were stakeholders from Sterile Processing, Operating Room, Infection Prevention, Healthcare Technology Management and clinicians.

Issues discussed were broken down into three categories:

1. People - who are responsible for the manufacture of, use of, and reprocessing of medical devices and equipment.
2. Places - where devices are used and reprocessed.
3. Things - the devices and equipment.

The conclusion from the summit? Healthcare-Associated Infections are not isolated events. They are system failures, which must be combated through a committed team effort. (More information can be found at http://www.aami.org/productspublications/articledetail.aspx?ItemNumber=3865)

Programs such as this recognize and support the importance of what we do in our jobs, as we see the expectations of Sterile Processing personnel growing and putting higher demands on all of us who do this important job. This is why it is so important to have standardized knowledge that certification provides as well as ongoing education.

This issue of the newsletter contains ballots for the CBSPD Board of Director positions. The open positions are Ambulatory Surgery, Flexible Endoscope Reprocessor, Surgical Instrument Specialist and Technician. Please exercise your right to vote after reviewing the candidates' information. You may only vote on the ballots for the certification you hold.

Wishing all of you a happy and safe summer.

Karen Swanson, LPN, CSPM, CFER

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Report on the Association for the Advancement of Medical Instrumentation (AAMI) - *Nancy Chobin, RN, CSPM, CFER*

AAMI met March, 2017 in Baltimore, Maryland. The following updates are provided:

Working Group 40 (Steam Sterilization Hospital Practices).

This Committee is responsible for ST-79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. All comments were reviewed at this meeting and with several conference calls afterwards. The Committee has resolved all comments and the document has gone to the AAMI Board and then will go to the ANSI Board for approval. It is estimated the revised, long awaited ST-79 will be available by August. Keep checking the CBSPD and AAMI webpages (www.aami.org) for more information.

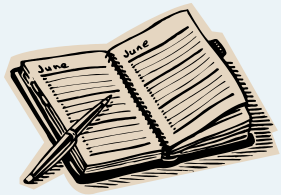
In October AAMI will meet in in Baltimore, Maryland.

Working Group 84 (Flexible Endoscope Reprocessing)

The Committee met in March and had a conference in May to continue to discuss the over 400 comments received to update the document. The Committee will reconvene in October with a one and a half day session to attempt to get the document completed.

AAMI/ANSI ST-81 – Information to be Provided by Device Manufactures

The Committee met in March. The original document was reaffirmed (meaning it is still needed). The Committee is working on standardized instructions for use that would apply to all companies (i.e. a hemostat from any instrument manufacturer would have the same instructions). However, this is in its early stages and the Committee has much more work to do.



Technical Information Report (TIR) for Low and Intermediate Level Disinfection in Healthcare Settings for Medical Devices and Patient Care Equipment and Sterile Processing Environmental Surfaces.

This Committee met in March and is finalizing this document.

WG 86 – Quality Systems for Device Reprocessing

This group met in March, and is finalizing their document which identifies the practices needed for a quality system. It is anticipated this will be published sometime this fall.

The CBSPD will be conducting a survey regarding certification. Please watch for notification on our website if you'd like to participate.

If you would like to have the survey mailed to you, please contact the CBSPD office at 908.236.0530 or email your request to: mailbox@sterileprocessing.org

Is It True?

It is amazing how rumors get started and spread so quickly! A rumor that has been out there for many years, but seems to have strengthened over the past year or two, is CBSPD and IAHCSMM are merging. Let us put this to rest by saying this is NOT TRUE. The CBSPD is a viable organization committed to providing competency based certification exams internationally since 1991. We hold ourselves to the highest standards in the industry and maintain our accreditation with the National Commission for Certifying Agencies (NCCA).

The annual CBSPD Board of Directors Meeting takes place in October, in New Jersey.

Voting for Nominees to the Board of Directors

Voting is now open for four positions on the CBSPD Board of Directors: Technician, Ambulatory Surgery Representative, Surgical Instrument Representative and Flexible Endoscope Representative. The nominees are certified through the CBSPD in that specific certification, and are employed in that exact position in a healthcare facility.

The elected candidate will be required to submit verification of employment and position held on facility letterhead verified by HR. In addition, the candidate's employer must provide a letter stating the individual will be granted the time off for the annual Board meeting in October. If the candidate cannot verify that he/she works in the specified position required for the Board vacancy, then the position will be forfeited and awarded to the candidate who placed second.

Please note, you must only vote for a candidate that represents your job title (i.e. if you're an Ambulatory Surgery Tech, you can only vote for those nominees, etc., AND you MUST be CBSPD certified in order to vote.) You may mail in a ballot or fax it.

Technician Nominees

Jimir Medina Arjona - Florida

- 10 years experience in sterile processing Tech in three different hospitals in Florida.
- Board Certified since 2012
- Management Certified 2/2017
- Working by self in Surgery Center as instrument Tech I
- Background in healthcare for 15 years in Cuba
- Proud to be US citizen
- Wants to serve on board and be part of organization, because he chose Sterile Processing as his career.

Markita Carter - Florida

- Sterile Processing Technician Lead Tech. Is currently a Lead Tech.
- She has been in the sterile processing field for 21 years this February.
- She shows passion for what she does. She puts forth her best efforts in ensuring sterile processing is done correctly and in a timely manner.
- She would be a good fit for the Board, because her faithfulness and eagerness shows that she loves what she does.
- Her time and attendance is wonderful. Last year in 2016, Markita had perfect attendance and one 8 minute tardy.
- Choose Markita Carter for the Board and you won't be disappointed.

Deborah Hager - New York

- I think that coming from a small hospital I have a lot to offer as a board member due to my ten years of experience in Sterile Processing. A rural hospital has different challenges than a larger hospital, and it would make a well-rounded team to have all demographics represented. Thank you for consideration.

Robert Shrum - Michigan

- Over 10 years experience working in sterile processing.
- MEMS, Military Emergency Management Specialist.
- Michigan Army National Guard; Battalion Medic incharge 119th Field Artillery
- Michigan Army National Guard; State Medical Command Det 6, Detroit MI. Medical Administrator.
- Michigan Air National Guard; 110 Tactical Hospital, acting 1st Sergeant, administer enlisted personnel.

GI Scope Nominees

Michael Bravata - New Jersey

- I have been a Flexible Endoscope Reprocessor for twelve years.
- I started working one day a week in Essex Endoscopy Center and advanced to five days a week in less than one year. I was only hired to be a reprocessor as my abilities demonstrate I am a strong willed learner. I was responsible for all documentation and departmental paperwork and also did the medical billing.
- In 2009, I was certified with the CBSPD and recertified 2014. At the same time, I was employed full-time at St James Hospital as an emergency room clerk until 2008 when they were in the process of closing.
- I then started working at Clara Maass Medical Center, which is now Robert Wood Johnson Barnabus Health (RWJBH) in the emergency room as a unit clerk. Last year, I began working full time in the endoscopy department as their certified scope reprocessor. Being certified was a major factor in their decision to hire me.
- I am knowledgeable with Pentax and Olympus scopes and Custom Ultrasonic, Evotech and Medivators AER.

Michael Bravata - New Jersey - cont.

- I keep current in reprocessing by subscribing to Healthcare Purchasing, Healthmark Digest, Case Medical and 3M webinars. I am current on all my competencies and responsible for ensuring that the employees in the department are current also.
- My background is very extensive and will be an asset to the CBSPD.
- Currently, I am in college obtaining a BA degree in hospital administration, with this education and the experience working with the CBSPD will provide a decisive factor in the medical/GI field.
- When asked why is this important for me to become a board member, I am a professional who likes to make a difference and uphold duties entrusted to me. My position is of great importance; every scope is reprocessed in compliance with the guidelines of the hospital, scope manufacture and the CBSPD. I know that the best person for this position will be me. I take pride in my job and look forward to my daily responsibilities. I have read the job description and looked forward to the challenges of the tasks; it will truly be an honor working with a distinguished group of professionals.

Christopher Franklin - Indiana

- I am a passionate sterile processing and endoscopy tech, with a constant drive to learn and do more for this industry.
- I have 6 years experience working in sterile processing and one year working exclusively in endoscopy. I am currently employed at IU Health Methodist Hospital in downtown Indianapolis as a full-time endoscopy tech.
- My responsibilities are to oversee the reprocessing of all endoscopes in the endoscopy unit. I also provide training and in-services on endoscope handling, reprocessing, and repair reduction strategies.
- I hold 3 certifications from the CBSPD, including CSPDT, CSIS, and CFER. I am certified in basic life support and have also completed the Society of Gastroenterology Nurses and Associates (SGNA) GI Technical Specialist program. Most recently I have been enrolled in the 2 year SGNA Infection Prevention Champions program and serve as the representative for my facility.

Christopher Franklin - Indiana - cont.

- In my free time, I also run a website devoted to uniting sterile processing professionals and provide them with the tools and information necessary to excel in their careers.
- My goal with this site is to help in the efforts of reducing the number of HAI's as they pertain to sterile processing.
- I believe that given the opportunity to serve such a renowned organization, I could bring my knowledge, experience, and organization and the individuals that it certifies, that expertise to help advance and grow the CFER program and the rapidly evolving endoscopy field. To be chosen as CFER Board member, would truly be an honor and allow me to further my involvement in a career that I am so genuinely passionate about. Thank you for your kind consideration.

Fanny Lazo - New York

- I have known Ms. Lazo for 9 years. She was the first employee hired when I started East Side Endoscopy, an ambulatory surgery center located in New York City.
- ESE is a joint venture among local gastroenterologists, Beth Israel Medical Center and Physicians Endoscopy with 4 procedure rooms. Approximately 11,000 procedures are performed annually at the Center.
- As lead technician, Ms. Lazo's primary responsibilities were to manage a staff of 8 full time technicians and medical assistants, support physicians during procedures oversee purchasing and most importantly direct the decontamination and scope-reprocessing department.
- From "Day 1," Fanny demonstrated her commitment to excellence setting the standard for the role of technicians in the procedure room and the critical importance of endoscopic reprocessing as it pertains to infection prevention, the delivery of quality healthcare and ensuring patient safety.
- Among her many contributions during her tenure at East Side Endoscopy, Fanny oversaw the testing and introduction of the 3M Clean-Trace ATP testing device technology, led the way for all technicians to obtain CFER certification and was instrumental in developing an observation tool for remote auditing of the scope decontamination process which will be presented at the 2017 DDW conference.

Fanny Lazo - New York - cont.

- In my 25+ years of experience in gastroenterology/ endoscopy, Fanny is by far the most proficient endoscopy technologist with whom I have worked. She possesses a superior knowledge of all things endoscopy including procedure room technique, the equipment and supplies utilized as well as the decontamination and scope reprocessing process.
- Your organization and its members will benefit enormously with Fanny Lazo as a Board member, whom I am certain will serve to advance the mission of your organization and its members.

Surgical Instrument Specialist Nominee

Natoria Pettyjohn - Delaware

- Nominating myself to act as the Surgical Instrument Representative.
- I have been working in the hospital field for over ten years.
- I started as a Unit Secretary, surgical technologist and now Sterile Processing Technician.
- I love learning new things and gathering information for my co workers.
- I also previously travel to different hospitals as a travel sterile processing technician.
- I understand how you have to learn quickly especially in a new role or atmosphere.

Ambulatory Surgery Tech Nominees

Still open! Vote for a certificant who you think will be a valuable asset to our organization!

All ballots must be received in the CBSPD office by **Monday, August 28th and no later.** Any ballots received after this date will not be counted.

Certificants who win the election will be notified by phone by a CBSPD representative. **You will be asked to provide the specified documents (verification of job from employer and time granted off to attend BOD Meeting) to our office before we publicly announce the results.**

FINAL winners will be announced on Thursday, September 7th on our website and Facebook page.

OFFICIAL CBSPD BALLOT

SELECT OR WRITE IN A NAME

TECHNICIAN Nominees:

Jimir Medina Arjona _____
Markita Carter _____
Deborah Hager _____
Robert Shrum _____

Surgical Specialist Nominee:

Natoria Pettyjohn _____

GI SCOPE Nominees:

Michael Bravata _____
Christopher Franklin _____
Fanny Lanzo _____

AMBU Tech Nominee(s):

Write in a name: _____
_____

ALL BALLOTS MUST BE RECEIVED IN THE CBSPD OFFICE BY MONDAY AUGUST 28, 2017.

Mail to: CBSPD, 148 Main St., Suite D-1, Lebanon, NJ 08833 Or Fax to: 1-908-236.0820.

Important: ONLY CBSPD OFFICIAL BALLOTS WILL BE ACCEPTED.

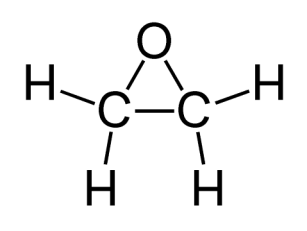
LOW-TEMPERATURE STERILIZATION

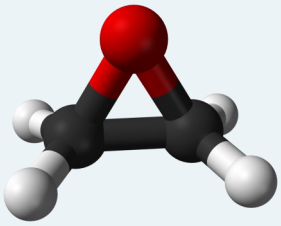
Karen Swanson, LPN, CSPM

Many items to be sterilized cannot withstand the high temperatures of steam sterilization due to the materials they are made of. There are multiple options to be used as alternatives to steam sterilization. Each has its own technology and restrictions.

Ethylene Oxide (ETO)

Ethylene Oxide (ETO) is one of the oldest low-temperature alternatives to steam sterilization. Though there has been a decrease in the use of ETO in healthcare facilities, manufacturers of medical and surgical supplies continue to use Ethylene Oxide as the main method of sterilization. ETO is the most stable of the low-temperature sterilants. It penetrates complex devices and long lumens without breaking down. Unlike other methods, there are no restrictions on lumen sizes.





ETO is liquid that become a gas at room temperature. In both states, it is flammable and explosive. The risk of fire and explosion can be eliminated by mixing ETO with hydrochlorofluorocarbon (HCFC) or carbon dioxide (CO2). It is completely soluble in water at 10ºC (50ºF). It is colorless and odorless in low concentrations.

ETO is highly toxic and can cause severe burns to the skin and irritation of mucous membranes and the respiratory tract. Because of the long term health effects of excessive exposure to ETO, OSHA has established limits on occupational exposure to ETO gas.

Two types of ETO are used in healthcare facilities: undiluted, 100% ETO, which is provided in single-dose cartridges; and EO mixtures consisting of EO and either HCFC or CO2. Most commonly used in healthcare facilities is 100% ETO. It is supplied in single-dose cartridges which is easier to handle than large tanks. The ETO mixtures are supplied in large tanks. Areas for the storage of these tanks must meet the OSHA regulations, building codes and must be well ventilated.

The parameters of ETO sterilization are gas concentration, exposure time, humidity, temperature, and in the case of sterilizers that use EO mixtures, pressure. The process used to kill microorganisms is called alkylation, which is the removal of hydrogen from the chemical structure of the microorganism. Alkylation interferes with the normal metabolism of the microorganism, causing it to die. In order for the ETO to penetrate the cell walls, the microorganisms must be hydrated.

The exposure time is related to the concentration of Ethylene Oxide, temperature and humidity. These times and temperatures will vary according to the sterilizer manufacturer.

Sterilizers using 100% ETO have exposure cycles that range from:

37ºC (99ºF) for 3 to 4 hours, with ranges of 30% to 80% relative humidity38ºC (100ºF) for 4.5 hours at 80% relative humidity 55ºC (130ºF) for 1 hour, with relative humidity ranging from 30% to 80%.

Exposure cycles for sterilizers using ETO and HCFC are:

38ºC (100ºF) for 6 hours, with relative humidity ranges of 30% to 70%.55ºC (130ºF) 2hr 10 min, with relative humidity ranges of 30% to 70%.

Exposure cycles for sterilizers using ETO and carbon dioxide are:

38ºC (100ºF) for 7.5 hours, with relative humidity ranges of 30% to 80%.55ºC (130ºF) 2hr 10 mi) 3 hours, with relative humidity ranges of 30% to 80%.

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Ethylene oxide sterilization cycles should be monitored every load with a process challenge device (PCD) containing a biological indicator containing Bacillus atrophaeus and a chemical indicator. Placement of the PCD in the load is dependent on the sterilizer manufacturers' instructions. Incubation of the biological indicator is according to the BI manufacturers' instructions. Internal and external chemical indicators specific to ETO sterilization should be used for all packages to be sterilized.

Unlike other low-temperature methods, implants can be sterilized in Ethylene Oxide sterilizers. Implants should be quarantined until the results of the biological indicator have been determined to be negative.

All items sterilized in ETO must be subjected to an aeration process to remove the ETO residuals from the packages. This process protects the employees and patients from the harmful residuals. Aeration takes place in the same chamber after the sterilization process has been completed. The sterilizer must have dedicated exhaust must be and provide continuous, filtered air washes. Aeration times are affected by heat; the higher the heat the shorter the aeration time. According to ANSI/AAMI ST41, typical times and temperatures are 122ºF (50ºC) for 12 hours, 130ºF (54ºC) for 10 hours, or 140ºF (60ºC) for 8 hours. Because the devices release ETO at different rates, the device manufacturers' instructions for aeration should always be followed.

All items to be sterilized in ETO must be cleaned and free of water, saline and body fluids. Reaction of the ETO with these can be produce Ethylene glycol or Ethylene chlorohydrin residual which can be toxic.

ETO has been classified by OSHA and ACGIH as a carcinogen and a reproductive hazard. It is regulated by OSHA, EPA, and FDA. OSHA (29 CFR 1910.1047) specifies requirements for employee monitoring, installation of the sterilizer, engineering controls, medical surveillance, emergency situations and measures to prevent employee exposure to ETO. If appropriate precautions are taken, EO can be used safely.

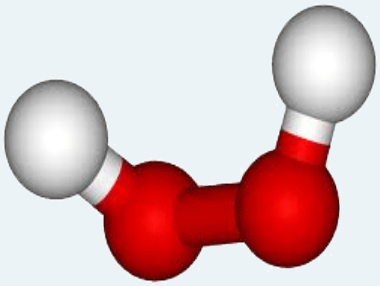
HYDROGEN PEROXIDE LOW TEMPERATURE STERILIZATION METHODS

Hydrogen Peroxide Low Temperature Sterilization methods provide effective sterilization without the hazards or extended aeration times associated with ETO sterilization. Many items previously sterilized in ETO are now sterilized using hydrogen peroxide in various forms. Only devices that have been validated by the specific device manufacturer for this process should be sterilized by hydrogen peroxide methods discussed here. If this information cannot be verified with the medical device manufacturer, the sterilizer manufacturer should be consulted.

Low-temperature gas plasma- LTGP - (STERRAD ®)

uses a combination of hydrogen peroxide vapor and gas plasma to effectively and safely sterilize packaged devices. The only hook-up needed is an electrical outlet.

Approved items include single-channel flexible endoscopes, semi-rigid ureteroscopes, cameras, light cords, batteries, power drills and rigid endoscopes, including hysteroscopes and choledocoscopes. Implants are not cleared for sterilization using LTGP. All items must be cleaned and dried prior to packaging. The following devices and materials should not be processed in any LTGP sterilizer: devices with dead-end lumens, cellulose-based materials (e.g. cotton, paper, gauze), liquids, items that do not meet the lumen length/ diameter criteria, any organizing trays that contain cellulose based materials, load-control stickers (unless they are made of Tyvek® plastic), count sheets (unless they are made of Tyvek® plastic), traditional adhesive labels (e.g. dust cover labels) and implants.



The parameters for LTGP sterilization are time, temperature, and hydrogen peroxide gas plasma. Cycle time varies with the sterilizer model. Cycle temperature varies from 113°F to 131°F (45ºC to 55°C), depending on the sterilizer model. The sterilant is provided in a multi-dose cassette containing 10 single ampules of liquid hydrogen peroxide (H2O2) at a nominal 59% concentration.

There are currently three models of the STERRAD® sterilizers. Each has different capacities, but all are limited in the ability to sterilize devices with long and narrow lumens or dead-end channels. Devices sterilized in these sterilizers and various cycles must be validated by the device manufacturer. Each model's instructions for use must be carefully followed, including weight limits in the load.

STERRAD 100S®

Operates at a cycle time of approximately 55 minutes. Instruments with lumens are restricted to size and length. Only those devices validated and cleared for use in the STERRAD® 100S can be processed in this sterilizer.

STERRAD® NX®

has two cycles: Standard and Advanced. It has the ability to sterilize a variety of instruments and accessories, including single-channel flexible endoscopes, semi-rigid ureteroscopes, rigid endoscopes, including hysteroscopes and choledocoscopes. Only those devices validated and cleared for use in the STERRAD® NX® should be processed in this sterilizer.

The **Standard cycle** sterilizes general surgical instruments requiring low temperature sterilization in a 28 minute cycle. Lumens are restricted to size and length.

The **Advanced cycle** sterilizes general surgical instruments and single lumen flexible endoscopes that meet the lumen restrictions and have been validated by the scope manufacturer for this sterilization process. There is a limit of 10 lumened devices per cycle. When sterilizing flexible scopes, only one flexible scope can be processed in the load, and is the only item in the load. The cycle is 38 minutes.

STERRAD® 100NX®

has a greater capacity to sterilize a variety of instruments and accessories, including single-channel flexible endoscopes, semi-rigid ureteroscopes, including hysteroscopes and choledocoscopes. The STERRAD® 100NX® provides four cycles: STANDARD, FLEX, DUO, and EXPRESS.

The **Standard cycle** can sterilize general surgical instruments and lumened medical devices in 47 minutes.

The **Flex cycle** can sterilize single-channel flexible endoscopes in 42 minutes.

The **DUO cycle**, is designed for most flexible endoscopes in approximately 60 minutes

The **EXPRESS cycle** is used to process general and delicate instruments without lumens, rigid and semi-rigid telescopes/endoscopes (including da Vinci® 3-D Endoscopes) and rechargeable batteries in 24 minutes.

Biological indicators specific to the LTGP process containing Geobacillus stearothermophilus should be used for routine monitoring of the LTGP cycles. For the STERRAD® 100NX® DUO cycle, a BI test pack is used. ANSI/AAMI ST58 recommends BI testing at least daily, but preferably for each load. . If testing is performed daily, each type of cycle (STANDARD, ADVANCED, FLEX, DUO) being used should be tested with a BI or BI test pack, as applicable. It is not required to quarantine loads until the BI results are known but will help reduce the possibility of recalls.

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Low-temperature hydrogen peroxide-LTHP -(Steris V-PRO™)

Low-temperature hydrogen peroxide (LTHP) uses vaporized hydrogen peroxide (59%) as the sterilant. It is used for sterilizing heat or moisture-sensitive devices such as cameras, light cords, flexible endoscopes, non-lumened endoscopes and batteries. Only an electrical outlet is needed for installation of the sterilizer.

All items must be thoroughly cleaned, rinsed, and dried before being packaged. Trays for containing items should be perforated. Tyvek® pouches or additional absorbent materials should not be added to trays unless their use has been validated by the packaging manufacturer and FDA-cleared for that use.

The parameters for LTHP sterilization are time, temperature and hydrogen peroxide concentration. The hydrogen peroxide is provided in a cup. The contents of the cup is used to sterilize multiple cycles.

There are currently three models of the V-PRO™ sterilizers. Each has different capacities, including weight limits for load contents.

V-PRO™ 1 Plus

has a large capacity chamber and can sterilize lumened items in a 55 minute cycle and non-lumened devices in 28 minutes. Lumen restrictions apply to this method.

V-PRO™ maX

has a 28 minute non-lumened cycle; a 35 minute flex cycle that can sterilize up to 2 flexible endoscopes or 1 flexible endoscope and 24 lbs of non-lumened instruments; and a 55 minute cycle capable of sterilizing up to 20 stainless steel lumened items.

V-PRO™ 60

has a 28 min non-lumen cycle; a 38 min flexible endoscope cycle (only 1 scope); and a 60 min lumen 12 stainless steel lumens.

Biological indicators specific to the LTHP process containing Geobacillus stearothermophilus should be used for routine monitoring of the LTHP cycles. ANSI/AAMI ST58 recommends BI testing at least daily, but preferably for each load. If testing is performed daily, the BI should be used in the shortest cycle that will be run that day. Monitoring every load with a BI and quarantining the load until the BI results are known to be negative reduces the potential for recalls; however, AAMI does not require BI monitoring of each load. It is not required to quarantine loads until the BI results are known but will help reduce the possibility of recalls. The BI PCD for routine monitoring consists of a BI and a CI inside a Tyvek® pouch, and it is placed in the center of the top shelf of the sterilizer.

Geobacillus stearothermophilus

Biological indicators specific to the LTHP process containing Geobacillus stearothermophilus should be used for routine monitoring of the LTHP cycles. ANSI/AAMI ST58 recommends BI testing at least daily but preferably for each load. If testing is performed daily, the BI should be used in the shortest cycle that will be run that day. Monitoring every load with a BI and quarantining the load until the BI results are known to be negative reduces the potential for recalls; however, AAMI does not require BI monitoring of each load. It is not required to quarantine loads until the BI results are known but will help reduce the possibility of recalls. The BI PCD for routine monitoring consists of a BI and a CI inside a Tyvek® pouch, and it is placed in the center of the top shelf of the sterilizer.

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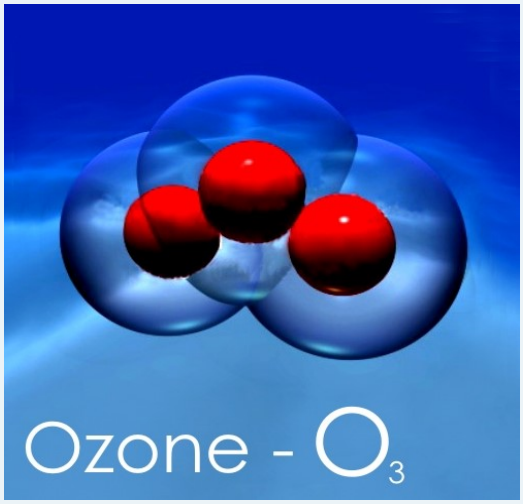
Hydrogen peroxide-ozone Sterilization (STERIZONE® VP4 – Getinge)

Hydrogen peroxide–ozone sterilization is a low-temperature method that uses both vaporized hydrogen peroxide (H2O2) and ozone (O3) in a multi-phase process that sterilizes at temperature of 41°C or 105.8°F . The complete cycle time is dependent on the composition of the load. The same cycle is used for all loads. Electrical power and oxygen are needed.



Unlike the Sterrad ®and V-PRO™ sterilizers, items to be sterilized in the STERIZONE® VP4 Sterilizer do not need to be "bone dry " eliminating this extra preparation step.

The STERIZONE® VP4 Sterilization System can sterilize general instruments, single-channel flexible endoscopes, and rigid and semi-rigid channeled devices such as single-channel and double-channel semi-rigid endoscopes. Either dedicated or mixed loads of general instrumentation, rigid endoscopes, and flexible endoscopes, including video gastroscopes and colonoscopes can be processed. Unlike the other hydrogen peroxide sterilization systems, the chamber can accommodate up to 75 pounds of instrumentation. A loading cart and rack are available for this sterilizer as well.

Acceptable packaging materials include sterilization pouches made of nonwoven polyethylene with polyester/LDPE and transparent film; aluminum containers using disposable polypropylene filters recommended for use with vaporized hydrogen peroxide sterilization processes; nonwoven polypropylene wraps; and metal and plastic trays.

The system uses a specially designed 280 mL bottle containing 50 weight-percent H2O2 solution. The amount of sterilant per cycle is based on the composition, weight and temperature of the cycle.

The BI PCD is a specially designed diffusion-restricted container that holds the proprietary Biological and chemical indicators. Biological indicators specific to the STERIZONE® VP4 process containing Geobacillus stearothermophilus should be used for routine monitoring cycle. ANSI/AAMI ST58 recommends BI testing at least daily, but preferably for each load. Monitoring every load with a BI and quarantining the load until the BI results are known to be negative reduces the potential for recalls; however, AAMI does not require BI monitoring of each load.

ROUTINE MONITORING FOR ALL LOW TEMPERATURE STERILIZATION METHODS

A chemical indicator specific to the low temperature sterilization process being used should be placed inside and outside each package. AORN 2016 states the external CI should be read before the package is stored, issued or opened in the OR and the internal CI should be read in the OR before the package is placed on the sterile field. The CI manufacturer's instructions for use (including interpretation of the color change or the migration of the chemical) and storage (including the expiration date) should always be followed.

SAFETY PRECAUTIONS FOR HYDROGEN PEROXIDE MUST BE CAREFULLY OBSERVED. Excess exposure can be hazardous to humans. Contact with hydrogen peroxide solution is corrosive and extremely irritating to skin, eyes, nose, throat, lungs and the gastrointestinal tract.

Continuation from Page 11

Contact with the eyes can cause irreversible damage, including corneal ulceration and blindness. Inhalation of vapors or mists can be severely irritating to the nose, throat, and lungs; pulmonary symptoms. Personnel should always wear PPE polyvinylchloride or nitrile gloves when removing items from the sterilizers and when handling the sterilants. Always refer to the sterilizer manufacturers' instructions for handling sterilants.

Ozone is a skin, eye and inhalation hazard.

Hydrogen peroxide should only be used in a well-ventilated area. Personnel should avoid breathing vapor or mist. In case of a hydrogen peroxide spill, personnel should ensure that the spill area is ventilated, flood the spill with large amounts of water, and distribute chemical spill sorbent pads. All contaminated materials should be disposed of according to the facility's hazardous waste policy. Personnel should wear safety goggles and nitrile gloves when handling hydrogen peroxide solutions.

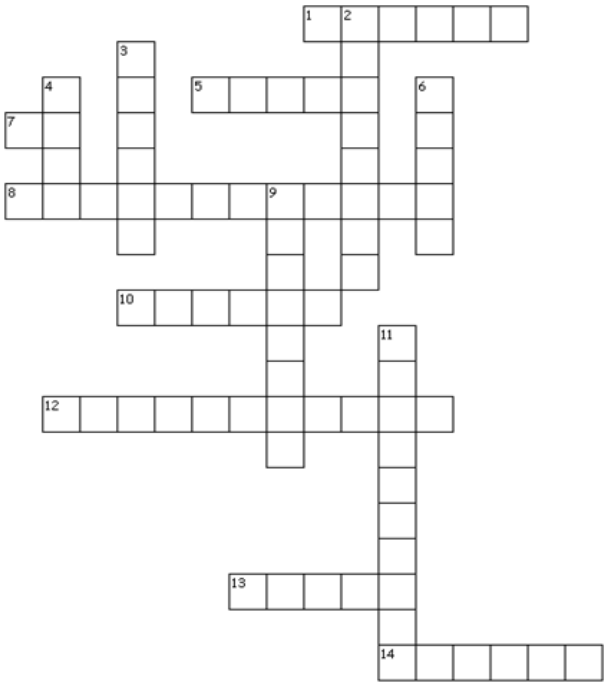
References:

Association for the Advancement of Medical Instrumentation. Chemical Sterilization and High-Level Disinfection in Health Care Facilities. ANSI/AAMI ST58:2013. Arlington (VA): AAMI, 2013.

Association for the Advancement of Medical Instrumentation. Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. ANSI/AAMI ST41:2008/(R)2012. Arlington (VA): AAMI, 2008.

The Basics of Sterile Processing. Sterile Processing University, 6th edition.

Fun with Low Temperature Sterilization



Across

1. ETO items must be clean and free of water, ____, and body fluid prior to sterilizing.
5. Manufacturer's IFUs on indicators should include interpretation of _____.
7. ETO should have a _____ on every load
8. Caution Cancer and _____ Hazard
10. LTGP is Low Temperature Gas _____
12. Low _____ Sterilization
13. Hydrogen Peroxide _____ Sterilization (O3)
14. External CI should be read prior to them being ____, issued, or opened.

Down

2. ETO items must be subjected to _____ after sterilization.
3. H2O2 method is without _____ and extended aeration time.
4. Major advantage to newer low temp sterilization methods over ETO is turnover _____.
6. Sterilizer use can be dependent on length and diameter of _____
9. All items should have a ____ indicator
11. ETO biological contains Bacillus

POST TEST

1. The oldest low-temperature sterilization process is

A. low-temperature gas plasma.
B. hydrogen peroxide -ozone.
C. ethylene oxide.
D. low-temperature hydrogen peroxide.

2. The process used to kill microorganisms in ethylene oxide sterilization is called

A. passivation.
B. condensation.
C. expiration.
D. alkylation.

3. Exposure time in Ethylene Oxide is related to temperature, humidity and

A. sizes of lumens.
B. gas concentration.
C. hydrogen concentration.
D. cleanliness of the item to be sterilized.

4. The sterilant used for LTGP is provided in a(n)

A. multi-dose cup.
B. multi-dose cassette.
C. metal cartridge.
D. tank.

5. All packages to be sterilized in a low-temperature sterilization cycle should contain

A. biological indicators.
B. internal chemical indicators.
C. paper count sheets.
D. process challenge devices.

6. Which of the following is not an acceptable packaging material for hydrogen peroxide sterilization processes?

A. Paper tray liners
B. Tyvek pouches®
C. Plastic trays
D. Polypropylene wrappers

7. The biological indicator used for ethylene oxide sterilization should contain

A. Geobacillus stearothermophilus
B. Geobacillus subtilis
C. Bacillus anthracis
D. Bacillus atrophaeus

8. The biological indicator used for all hydrogen peroxide sterilization processes should contain

A. Geobacillus stearothermophilus
B. Bacillus atrophaeus
C. Geobacillus subtilis
D. Bacillus anthracis

9. ANSI/AAMI ST58 recommends biological monitoring in hydrogen peroxide sterilizers be performed

A. once a week.
B. monthly.
C. at least daily.
D. in every load containing an implant.

10. When handling hydrogen peroxide solutions, personnel should

A. wear goggles and gloves.
B. wear an OSHA approved respirator.
C. dilute the solution with ammonia.
D. contact the poison control center.

CBSPD Has Approved this In-Service for 1 CEU

KEY: 1. C, 2. D, 3. B, 4. B, 5. B, 6. A, 7. D, 8. A, 9. C, 10. A

CBSPD - ITEM REVIEW COMMITTEE REPORT

June, 2017

The Item Review Co-Chairs continued to review all the CBSPD Item Banks for updating of references and verification of test specifications assigned to each question. Updating included retiring old questions or questions not currently relevant to the practice. We used the criterion that with 100 questions on each exam, every question must be one that tests the candidate's ability to provide safe practice.

The Flexible Endoscope Reprocessing Item Bank was completely reviewed in preparation for the new examination that was administered in February, 2017. Additional, new questions were written and approved by the Item Review Committee.

The Ambulatory Surgery Sterile Processing Item Bank – was completely reviewed and updated. New questions are being written in preparation for a new exam which will be administered in November, 2017. This exam will be based on the updated Job Analysis Survey performed in 2016. An Item Review meeting to review and approve the new questions is planned for early July.

After the Ambulatory Surgery Bank is completed, the Technician Bank will then be reviewed.

The Committee is seeking new Item Writers and Reviewers. If you have the time and would like to write and/or review questions for the CBSPD Item Banks, please contact us for further information. You can earn CEUs towards your recertification and you learn as you write! We hold Item Writing Workshops via the internet to teach you the process. Join us in this rewarding process!

If interested, please email:

mailbox@sterileprocessing.org

Answers to:

Crossword Puzzle

Across

1. ETO items must be clean and free of water, SALINE, and body fluid prior to sterilizing.

5. Manufacturer's IFUs on indicators should include interpretation of COLOR.

7. ETO should have a BI on every load

8. Caution Cancer and REPRODUCTIVE Hazard

10. LTGP is Low Temperature Gas PLASMA

12. Low TEMPERATURE Sterilization

13. Hydrogen Peroxide OZONE Sterilization (O3)

14. External CI should be read prior to them being STORED, issued, or opened.

Down

2. ETO items must be subjected to AERATION after sterilization.

3. H2O2 method is without HAZZARD and extended aeration time.

4. Major advantage to newer low temp sterilization methods over ETO is turnover TIME.

6. Sterilizer use can be dependent on length and diameter of LUMEN

9. All items should have a CHEMICAL indicator

11. ETO biological contains Bacillus ATROPHAEUS

Sterile Processing University, LLC.

Sterile Processing University provides textbooks, workbooks and on-line courses to meet the educational needs of sterile processing and flexible endoscope reprocessing personnel. All materials are routinely updated to ensure the most current information is provided. In addition, all educational materials are based on scientific data, recommended practices, regulations, etc. which includes the Association for the Advancement of Medical Instrumentation standards.

Online Continuing Education Programs - SPD offers a full line of Continuing Educational programs at a nominal fee. All are approved for Continuing Education points from the Certification Board for Sterile Processing.

Textbooks available:

The Basics of Sterile Processing Textbook (6th edition). This book is for sterile processing technicians and Ambulatory Surgery sterile processing technicians.

The Basics of Sterile Processing Workbook (6th edition). To be used in conjunction with the textbook and offers hundreds of study questions and quizzes.

The Basics of Flexible Endoscope Reprocessing Textbook (2nd edition) Is intended for those individuals who are responsible to reprocess flexible endoscopes.

The Basics of Flexible Endoscope Reprocessing Workbook (2nd edition) To be used in conjunction with the textbook and offers hundreds of study questions and quizzes.

Management Basics for Sterile Processing Textbook- (3rd edition) This book contains 17 chapters on all management concepts for the sterile processing manager or supervisor and includes performance appraisals, interviewing, safety, labor laws, budgeting, career ladders, etc.

Instructional CS - NOTE TO EDUCATORS - SPU offers an instructional CD in Power Point to facilitate teaching a Central Service/SPD course. The CD follows the course content for the **The Basics of Sterile Processing**. If you previously purchased a CD, you are eligible for an upgrade.

On-line courses available: If your technicians so not have access to a formal course, the following courses are available on line. There is no time limit so they can learn at their own pace. A quiz is given after each chapter is completed and there is s final exam at the completion of the course.

Basics of Sterile Processing Technician course - conforms to the 6th edition of The Basics of Sterile Processing (2016).

Basics of Sterile Processing Ambulatory Surgery Technician course - conforms to the 6th edition of The Basics of Sterile Processing (2016) and includes only those areas of practice that relate to the Ambulatory Surgery practice setting

The Flexible Endoscope Reprocessor course - conforms to the 2nd edition of the Basics of Flexible Endoscope Reprocessing.

Sterile Processing Policies, Procedures and Forms - ***SPU offers policies, procedures and documentation forms on line! Pick a la carte or all the policies and forms. All policies are reference to AAMI standards and federal regulations where applicable.***

Visit: www.SPDCEUS.com for all your sterile processing education needs. SPU…Quality education at affordable prices!

CBSPD Inc.
Oasis Commons
148 Main Street
Suite D-1
Lebanon, NJ 08833
USA

May 2016 - May 2017

CBSPD Certification Exam Stats

(Passing names listed at

***www.sterileprocessing.org/new_members.htm*)**

Technician: Total Sat for Exam = 5,231;
Total Passed = 3,218 (62%); Total Failed = 2013 (38%)

Management: Total Sat for Exam = 127;
Total Passed = 61 (48%); Total Failed = 66 (52%)

Instrument Specialist: Total Sat for Exam = 103;
Total Passed = 70 (68%); Total Failed = 33 (32%)

Ambulatory Surgery: Total Sat for Exam = 122;
Total Passed = 70 (57%); Total Failed = 52 (43%)

GI Scope: Total Sat for Exam = 1070;
Total Passed = 706 (66%); Total Failed = 364 (34%)

****Reminder to All Upcoming**

October/November 2017 Re-certs**

Why retake the exam when after working full time for 5 years, you only need 10 points of education per year to re-certify (except for Supervisors/Managers)?

If you became certified or re-certified in October 2012, you are due for re-certification in October 2017. Please have your completed re-certification packet with payment into the CBSPD office no later than 9/19/17.

If you became certified or re-certified in November 2012, you are due for re-certification in November 2017. Please have your completed re-certification packet with payment into the CBSPD office no later than 10/24/17.

The CBSPD e-mails and mails out re-certification packets 6 months before your certification is due to expire. If you have not received your packet yet, please contact our office to update your address and/or print one out from our downloads page at

www.sterileprocessing.org/download.htm