Executive Summary Walter Reed National Military Medical Center (WRNNMC)
Sterile Processing Department (SPD) Audit

This report provides evaluation and analysis of processes and environmental quality controls related to WRNNMC SPD. An audit was conducted 15 January 2015 utilizing a modified version of SPS Medical's Sterilization Audit Checklist. Overall results of the audits were commendable and all staff members were knowledgeable about SPD and immediate-use sterilization processes and very respectful during the entire survey process. Despite the overall positive results, there are some areas for improvement. Recommendations were referenced by AAMI, AORN, and OSHA guidelines.

General Findings

***** Indicates issues that remain unchanged from last audit**

- ***In all areas of SPD, manufacturers' instructions for use (IFU) are not being referenced, therefore not being followed throughout the sterilization process, including immediate use sterilization.
  - ***Recommendation:*** Educate staff on the importance of IFUs and on the use of OneSource. Ensure all personnel have access to OneSource. Also, hardcopies of IFUs should be maintained and accessible during information technology (IT) outages. IFUs not found in OneSource should be requested from and provided by the manufacturer (AAMI ST79, Policies, procedures, and manufacturers' written IFU, 7.2, pp. 53; AAMI ST79, Test container system, 10.10.3.2.5.2, pp. 12; AORN, 2014, pp. 579).
- ***Several staff members working in the department with home laundered scrub hats.
  - ***Recommendation:*** Educate staff on SPD standard operating procedures of wearing hospital laundered attire. Hospital laundered attire minimizes the introduction of microorganisms and lint to items being processed in SPD (AAMI ST79, Attire 4.5.1, pp. 39-40).
- ***Paper signs posted in several areas (prep and pack, sterile storage areas).
  - ***Recommendation:*** Put paper signs in document protectors or laminate the documents and limit the number of signs posted to only those messages that are necessary to support the work being accomplished. Placing the paper signs in document protectors or laminating the signs allows for proper cleaning (Personal communication, V. Greenfield, 18 September 2014).
- ***Transport containers (e.g. bags, carts and/or containers) are not labeled biohazard. The carts were coming from the operating room without biohazard signs.
  - ***Recommendation:*** Labeling the transport container communicates to others that items are potentially infectious. OSHA requires labeling of all containment systems. Example: Green "Clean" and red "Biohazard" flipping magnets can be used on metal carts for labeling (AORN, 2014, pp. 544; OSHA, 29 CFR 1910.1030 (d) (2) (xiii) (A)).

- Improvement from last audit (18 September 2014): Sterile items and unsterile items are no longer in the same area of the sterile storage, sterile supply storage, assembly, and decontamination areas.
  - ***Recommendation was followed:*** Separate sterile and unsterile items to prevent the potential for contamination (AORN, 2014, pp. 120).

Decontamination Area

- ***Staff members were inconsistent in wearing complete personal protective equipment (PPE). Ancillary and SPD staff were frequently seen without masks and heavy duty gloves when cleaning instruments, which is not appropriate for proper protection when performing this function.
  - ***Recommendation:*** Enforce the use of PPE during instrument decontamination per SPD policy. Educate staff on the potential of punctures in gloves and cross-contamination of microorganisms and the requirement to wear heavy duty, waterproof gloves. (AAMI ST79, Decontamination area, 4.5.2, pp. 40).

- A standard ultrasonic cycle is currently being used for all instrument trays.
    - ***Recommendation:*** The ultrasonic cleaner and instrumentation IFUs identify specific cycles times or settings and should be followed (AORN, 2014, pp. 546).

Prep and Pack

- ***Brushes found in the assembly area work stations.
    - ***Recommendation***: Remove all brushes and ensure staff understands cleaning only happens in the decontamination area to prevent cross contamination in the assembly area (AAMI ST79, Cleaning, 7.5.1, pp. 55).
- The solution that is used for flushing lumen instruments were not properly labeled; pure 70% alcohol or mixed 50/50 with water were used for the purpose of drying.
    - ***Recommendation***: Deionized or distilled water should be used to flush all instruments with lumens that will undergo steam sterilization to support steam contact for the sterilization process. Instruments with lumens that will undergo Sterrad for sterilization should be dried with compressed medical grade air. Follow MFG's IFUs (AAMI ST79, Devices with lumens, 8.3.8, pp. 75).
- ***In regards to routine maintenance of rigid containers, staff did not check the condition of the gaskets nor were they aware they needed to do so.
    - ***Recommendation***: Follow each MFG's IFU for routine maintenance required to ensure rigid containers are in proper functioning order (AAMI ST79, Rigid sterilizer container systems, 5.2.3, pp.43; AORN, 2014, pp.567).
- Improvement from last audit (18 September 2014): Count sheets were not placed within rigid trays and containers. Currently, the count sheets are placed in plastic sleeves that are attached outside of the rigid trays and containers.
    - ***Recommendation was followed***: Place count sheets into a peel pack and tape to the outside of blue wrap or outside of the rigid container. Use of nontoxic ink for labeling is recommended to avoid toxins being deposited on packs or instruments (AAMI ST79, Package labels, 8.3.2, pp. 68).
- Improvement from last audit (18 September 2014): Several staff members were no longer using alcohol instead of Caviwipes to wipe down work areas.
    - ***Recommendation was followed***: Ensure Caviwipes are available at every station and educate staff why alcohol is not used and the sporicidal effects of Caviwipes (AAMI ST79, Housekeeping procedures, 3.4, pp. 35).

Sterilization

- Heavy instrument sets are not being weighed.
    - ***Recommendation:*** Weigh heavier trays to ensure the 25-pound weight limit is not exceeded. Proper weight will facilitate the process of sterilization and prevent ergonomic issues. Break down, reconfigure sets heavier than 25-pounds and validate those sets for sterilization (AORN, 2014, pp. 579; AAMI, Preparation of and assembly of surgical instrumentation, 8.4.2, pp. 75).
- Sterilizer logbooks were organized and maintained for each sterilizer in the sterile processing section. Each workstation had its own monitor and computer access.
    - ***Sustain:*** Proper documentation ensures that the sterilization process is monitored, aids in recall process, and establishes accountability. Having both manual and digital system provides checks and balances, and provides evidence of the department's quality control program.
- Improvement from last audit (18 September 2014): SPD staff did know about the process of sending a positive BI to the lab.
    - ***Recommendation was followed***: The microbiology laboratory should perform a presumptive identification according to the BI MFG's written IFU to determine whether the recovered microorganism is indeed the test microorganism that was on the BI spore strip or is laboratory containment (AAMI ST79, Microbiological testing, 10.7.5.2, pp. 115).

Sterilization Storage & Housekeeping

- Work area was cluttered. One of the staff members stated the work area is cleaned weekly and shelves are cleaned everyday by housekeeping or SPD night shift staff.
    - ***Recommendation:*** Surfaces such as walls, shelving, air intake and return ducts, should be cleaned on a regularly scheduled basis. Floors and horizontal work surfaces should be cleaned at least daily (AAMI ST79, Housekeeping procedures, 3.4, pp. 35).
- ***Several wrapped instrument trays were stacked on storage shelves.
    - ***Recommendation:*** Compression of wrapped instrument trays can compromise sterility and cause contamination. Adjusting the shelving width and height to accommodate various sizes of instrument trays and/or obtaining more storage shelves can decrease the practice of stacking wrapped instrument trays (AAMI ST 79, Sterile Storage, 8.9.2, pp. 88).
- Several wrapped instrument sets did not have sterility maintenance covers (dust covers) per institution policy.
    - ***Recommendation:*** Enforce or rewrite current policy. (AMMI, Sterility maintenance covers, 8.9.1, pp. 87).

Management & SPD Training

- Currently, 100% civilian and 3% military SPD staff members are certified. It is commendable that military staff is going through weekly training to prepare for the certification exam. However, the job descriptions for the Officer in Charge (OIC) and the Non-commissioned Officer in Charge (NCOIC) did not address certification.
    - ***Sustain:*** Initial and continuing education, maintaining weekly training, and experienced staff are vital in all aspects of instrument processing and steam sterilization. Continuing education and central service certification for sterile processing personnel should continue to be promoted and facilitated by management.
    - ***Recommendation***: Job descriptions for both management and personnel should reflect certification recommendations. Central service management certification should be attained by management (AAMI ST79 Supervisory personnel, Sterile processing personnel, pp. 37-38; AORN, 2014, pp. 592).
- ***SPD training records audited. Currently, when staff are not present for in-services (i.e., equipment, new process, mandatory hospital training), no follow up sessions are being offered as reflected in training records.
    - ***Recommendation:*** Videotape in-services or voice record to ensure staff that are not present or on off shifts receive the training.

Policies and Procedures

- Out of 30 policies reviewed, five did not meet AORN/AAMI recommendations and twelve of the written policies were not being followed in practice. This shows improvement in practice because during the last audit on `8 Sept 2014, sixteen of the written policies were not being followed in practice.
    - ***Recommendation:*** Educate staff on policies and procedures and ensure adherence.
- There were no SOPs on weight of instrument sets, laundering policy that supports personnel wearing their own hair covers, and use of biohazard signage when transporting contaminated instruments from the operating room to the decontamination area in SPD.
    - ***Recommendation:*** Create policies in accordance with AAMI and AORN recommended practices.

Summary

After the completion of the audit, it is apparent that the leadership and staff have a comprehensive grasp on sterile processing operations. This is evidenced by a commendable overall result of this audit. However, despite positive results, there are areas for improvement. One of the critical findings is a lack of referencing of IFUs throughout the sterilization process. Not following and enforcing established policies and procedures is another critical finding. It is important to continue to focus on observed areas of excellence such as quality assurance, maintaining established policies and procedures, and the initiative to promote professional development by achieving certification in sterilization services. I recommend you use this audit sheet in preparation for Joint Commission and to perform quarterly audits in SPD.

Report prepared by Maj David Bradley, USUHS CNS Student
22 January 2015

Attachments:

1. SPD Policy Review
2. SPD Sterilization Audit Checklist

References

Association for the Advancement of Medical Instrumentation [AAMI]. (2014). *ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA: AAMI.

Association of periOperative Registered Nurses [AORN]. (2014). *Perioperative standards and recommended practices for inpatient and ambulatory settings* (2014 ed.). Denver, CO: AORN.

SPD Sterilization Audit Checklist

AAMI standards state the delivery of sterile health care products for use in patient care depends not only on the efficacy of the sterilization process itself but also on: efficient facility design, proper training of personnel, good infection prevention and control practices, effective quality control and process improvement systems, and appropriate documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on who it was used. Use this Sterilization Audit Checklist to review your facility's compliance with best practices (as defined by AAMI standards) and to make quality improvements.

Date: 15 January 2015 ***Auditors: Maj Bradley***

Facility: Walter Reed National Military Medical Center ***Location: Sterile Processing Department***

Contacts: MAJ Jade Hamel

Decontamination Area – **Facility Design, PPE & Procedures**

		Yes	No	DNO
1.	Is the area separate from clean activities and accessible by a door and pass through window?	☑	☐	☐
2.	Are doors and pass-through windows kept closed to confine airborne contaminants?	☐	☑	☐
3.	Is the area clean and free of improper items, e.g. debris, shipping boxes, fans, food, drinks?	☐	☑	☐
4.	Is there negative pressure and a minimum of 10 air exchanges to the outside w/o recirculation?	☑	☐	☐
5.	Is temperature (60-65^{o}F) and humidity (30-60% RH) controlled and recorded daily?	☐	☑	☐
6.	Are floors, walls, ceilings and work surfaces made of proper materials to withstand frequent cleaning?	☑	☐	☐
7.	Are floors, walls, ceilings and work surfaces cleaned frequently?	☑	☐	☐
8.	Is there an appropriate eye wash station (e.g. hands free and able to flush both eyes)?	☑	☐	☐
9.	Is there a proper hand washing station conveniently located in the area?	☑	☐	☐
10.	Are personnel washing hands when leaving the area?	☑	☐	☐
11.	Do all personnel wear appropriate PPE and remove PPE properly?	☐	☑	☐
12.	Are the manual cleaning sinks 3-sections to allow for soaking, washing and rinsing?	☑	☐	☐
13.	Are instruments sorted upon arrival by their different cleaning instructions for use (IFU)?	☐	☑	☐
14.	Is detergent type, dilution, water quality/temperature and brushes per the instrument MFG's IFUs?	☐	☑	☐
15.	Are sterilization containers cleaned between use and with proper detergent per the MFG's IFU?	☐	☑	☐
16.	Are ultrasonic cleaners used and for proper time according to the instrument MFG's IFUs?	☐	☑	☐
17.	Are all mechanical cleaners being tested, i.e. at least weekly, preferably daily?	☑	☐	☐
18.	Are mechanical cleaners loaded properly to allow for effective cleaning?	☑	☐	☐
19.	If the mechanical cleaners have a printout, is it located on the clean side?	☑	☐	☐

DNO = Did Not Observe

(2)Window from decontamination room to assembly room found wide open and door not closed. Having the window and door open effects the negative pressure.. (AAMI ST79, Functional workflow patterns, 3.2.3, pp. 23).
(3)Sharps container under 3 vessel sink area, and dirty towels (x3) found in sterilizer access area. Ensure access areas behind the sterilizers are regularly cleaned and sharp containers are accounted for and disposed of properly (AAMI ST79, Decontamination area, 3.3.7.1, pp. 31).
(5)Humidity was documented at being 3%. Follow up stated "will continue to monitor". Document steps taken with follow up and ensure humidity is within normal limits (30-60%) (AAMI ST79, Relative humidity, 3.3.6.6, pp. 29).
(11) Staff members not wearing complete personal protective equipment such as masks and heavy duty gloves when cleaning instruments. Enforce the use of PPE during instrument decontamination per SPD policy. Educate staff wearing heavy duty, waterproof gloves while handling contaminated items greatly decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross contamination (AAMI ST79, Decontamination area, 4.5.2, pp. 40).
(13-16) Staff knew how to access OneSource, but did not know if IFUs were followed for detergent type, dilution, water quality/temperature and brushes per the instrument MFG's IFUs. Staff member are unaware of how to change ultrasonic settings. Have in-service covering IFUs-ensure all staff receive training (AAMI ST79, Training and continuing education, 4.3.1, pp.38).

Incidental findings
-Wood used to elevate sinks, which is not cleanable, and clutter found near computers suggesting proper cleaning is difficult to do for housekeeping (AAMI ST79, Housekeeping procedures, 3.4, pp. 35).
-Signs posted without document protectors.

Prep & Pack – **Inspection, Assembly & Packaging**

	Yes	No	DNO
1. Personnel wearing facility-donned scrubs, hair covers, no jewelry or artificial nails?	☐	☑	☐
2. Floors, walls, ceilings and work surfaces are made of proper materials and frequently cleaning?	☑	☐	☐
3. Is every instrument visually inspected for cleanliness and function?	☑	☐	☐
4. Are dirty instruments returned to decontamination for re-cleaning?	☑	☐	☐
5. Are cleaning brushes only being used in decontamination area and not the clean assembly area?	☐	☑	☐
6. Is compressed, medical grade air available and used to dry instruments (i.e., lumens)?	☑	☐	☐
7. Are instruments sets being assembled correctly and in appropriate trays?	☑	☐	☐
8. Are misc. items (e.g. towels, count sheets, tray liners, tape) being used properly (i.e., no count sheets inside sets)?	☑	☐	☐
9. Are paper plastic pouches, wraps and/or containers being used correctly?	☑	☐	☐
10. Are packaging materials and container accessories being inspected prior to use?	☐	☑	☐
11. Are all instrument sets (including loaners) at or below the maximum weight of 25 lbs.?	☐	☑	☐
12. Is there a lot control label placed properly on all packages prior to sterilization?	☑	☐	☐
13. Are internal chemical indicators/integrators being used and placed properly with all packages (i.e., each level of multiple trays, corners of rigid containers)?	☑	☐	☐

(1) Staff members observed wearing artificial nails and home laundered hair covers. Staff unsure how often hair covers need to be changed (AAMI ST79, Attire, 4.5.1, pp. 39-40). Recommend not wearing artificial nails and using disposable hair covers. If home laundered hair covers are allowed, a policy needs to be in place stating how these items will be cleaned that is in compliance with AAMI and AORN standards.
(5) Brushes were located at workstations. Recommend that all brushes be removed from the assembly area. If additional cleaning is necessary, return the instruments to the decontamination area to prevent cross contamination (AAMI ST79, Training and continuing education, 4.3.1, pp.38).
(10) Staff did not check the gaskets. Follow the MFG's IFU for maintenance of rigid containers (AAMI ST79, Rigid sterilizer container systems, 5.2.3, pp.43; AORN, 2014, pp.567).
(11) Staff do not weigh instruments to ensure set weight limit is 25 lbs. Proper weight of sets promotes sterilization and/or drying and protects workers from injuries caused by lifting (AAMI ST79, Weight and density of sets, 8.4.2, pp.76).

Incidental findings

-The solution used for flushing the instrument lumens was not properly labeled. Could not determine if solution was 70% alcohol or mixed 50/50 with water for drying. AAMI ST79, recommends deionized or distilled water be used if the lumens need to be flushed and sterilized immediately. No documentation found in AAMI ST79, if alcohol can be used to flush in order to dry lumens. Instruments going through steam sterilization should not be flushed with a drying agent (lumens should remain moist). Follow MFG's IFUs (AAMI ST79, Devices with lumens, 8.3.8, pp. 75).

Sterilization – **Steam, Low Temperature & QA**

	Yes	No	DNO
1. Are steam sterilizers being loaded properly (i.e., light items on top, heavy items on bottom; pouches on edge; and trays less than 25 lbs)?	☑	☑	☐
2. Are steam sterilizer cycles selected in accordance with instrument MFG's IFUs?	☐	☑	☐
3. Are MFG's IFUs readily accessible for personnel who are processing instruments?	☑	☑	☐
4. When IUSS occurs, is it performed correctly, i.e. approved container, cycle, indicators?	☑	☐	☐
5. Are all instruments and packaging systems used in low temperature processes validated?	☑	☐	☐
6. Are terminally processed loads allowed to cool to room temperature before handling (i.e., at least 30 minutes before stored or used)?	☑	☐	☐
7. Is each sterilizer cycle printout reviewed and initialed before load removal?	☑	☐	☐
8. Does each sterilization package have an external and internal chemical indicator?	☑	☐	☐
9. Are biological indicators (BIs) used daily and with every load containing an implant?	☑	☐	☐
10. Do personnel activate and incubate BIs properly, i.e. MFG's IFU and to national standards?	☑	☐	☐
11. Is an unprocessed BI from the same lot being incubated daily in each incubator?	☑	☐	☐
12. Are pre-vacuum steam sterilizers tested daily for air removal using a Bowie-Dick type test pack?	☑	☐	☐
13. Are positive BIs sent to microbiology laboratory for gram staining to protect against false +?	☑	☐	☐

14. Are all sterilization records complete, accurate and presentable? ☑ ☐ ☐
15. All sterilizers retested (all modes, 3 consecutive times) after installation, major repairs or failures? ☐ ☑ ☐

(1) Sterilizers are being loaded properly, however; sets are not being weighed. Recommend staff create a SOP for the weighing of sets (AORN, 2014, pp. 579; AAMI ST79, Preparation of and assembly of surgical instrumentation, 8.4.2, pp. 75).
(2) & (3) SPD staff could not locate the MFG's IFU in OneSource (AORN, 2014, pp. 579).
(4) IUSS is not performed in the SPD (see IUSS audit tool).
(15) SPD staff verbalized the process of retesting the *Noncompliant* sterilizer is not done in all modes for 3 consecutive cycles include Bowie-Dick tests (AAMI ST79, Qualification testing, 10.8.1, pp. 122).

Sterile Storage & House Keeping

	Yes	No	DNO
1. Are sterile items located in a clean, separate and enclosed storage area?	☑	☐	☐
2. Is temperature (75°F max) and humidity (30-70% RH) controlled and recorded daily?	☐	☑	☐
3. Is storage shelving appropriate, i.e. bottom shelves covered, all smooth surfaces, clean?	☐	☑	☐
4. Is ceiling or ceiling tiles made of an appropriate construction (e.g. not particulate-fiber shedding)?	☑	☐	☐
5. Are sterile wrapped packages placed flat on storage shelves and not stacked?	☐	☑	☐
6. Does each sterile package have a load label with sterilizer no., load no. and date of processing?	☑	☐	☐
7. Is an "event-related" sterility assurance policy being used along with IFU?	☑	☐	☐
8. Are floors cleaned and disinfected at least daily for all instrument reprocessing areas?	☑	☐	☐
9. Are work surfaces (and frequently touch items) cleaned and disinfected daily for all areas?	☐	☑	☐
10. Are walls, equipment, ducts, light fixtures and storage shelves on a routine cleaning schedule?	☐	☑	☐

(2) Humidity was documented at being 3%. Follow up stated "will continue to monitor". Document steps taken with follow up and ensure humidity is within normal limits (30-60%) (AAMI ST79, Relative humidity, 3.3.6.6, pp. 29).
(3) Shelves covered with dust; staff unaware if it gets cleaned by night shift or housekeeping. Surfaces such as walls, shelving, air intake and return ducts, should be cleaned on a regularly scheduled basis (AAMI ST79, Housekeeping procedures, 3.4, pp. 35).
(5) Instruments are stacked. Shelving is modular and is able to support additional shelves. Recommend purchasing extra shelves to prevent stacking of instruments (AAMI ST79, Sterile Storage, 8.9.2, pp. 88).
(9) & (10) Area cluttered and staff member said the counter gets wiped weekly. Floors and horizontal work surfaces should be cleaned at least daily with Cavicide (AAMI ST79, Housekeeping procedures, 3.4, pp. 35).

Incidental Findings
-Items in the storage area with dust covers were ripped (holes, not completely sealed). Items should be repackaged with new dust covers to prevent tearing of blue wrapper.
-Unorganized storage of instruments on the back shelf in sterile storage.
-Sign posted without document protectors.

Management & SPD Training

	Yes	No	DNO
1. Are Policies & Procedures updated to best practices and followed (i.e., loaners, hand hygiene, product recall?	☐	☑	☐
2. Is there a formal, written RECALL POLICY in place in case of sterilization failure?	☑	☐	☐
3. Is there a Soiled Instrument Transport Checklist in place at point of use?	☐	☑	☐
4. Is there an Instrument Tray Audit program in place to inspect instrument sets for accuracy?	☐	☑	☐
5. Are reusable instrument MFG's required to provide a validated IFU before purchase, loan or trial?	☑	☐	☐
6. Have all sterile processing personnel certified and are CE training records up to date?	☐	☑	☐
7. Is temperature (75°F max) and humidity (30-70% RH) controlled and recorded daily?	☑	☐	☐

(1) Policies have not been updated, but are in the process of being updated. Recommend updating and creating policies in accordance with AORN and AAMI recommendations.
(3)Currently there is not a Soiled Instrument Transport Checklist in place. Recommend creating a checklist at the point of use.
(4)Instrument Tray Audit program is not in place to assess for instrument accuracy. The random checking of the trays provides a means of ensuring that each patient has a complete and sterile tray.
(6) There were inconsistencies with documentation of competencies in the training records. Recommend reviewing training records and document all elements listed.

Policy # / Title	Written Policy Supports Standards			Practice Compliance With Standards		
	Yes	No	Policy element	Yes	No	**Clinical Compliance Observation**
7. SPD workflow	X		States unassigned personnel will don the appropriate PPE	X		IN COMPLIANCE with standards
8. Traffic control in SPD	X		Supports items being placed in trash and regulated waste.		X	Dirty towels found in access area behind sterilizers.
9. Attire and personal appearance	X		States need to wear proper PPE, staff members will tuck in their scrub tops and strings, and non-disposable hair covers must be changed daily.		X	Staff in Decon without mask, multiple staff without scrub tops tucked in. Staff in Decon wearing sterile gloves vs. rubber gloves. AAMI ST79 4.5.2, pp 40 recommends heavy-duty gloves to reduce the risk potential for puncture.
10. Food control in SPD	X		States food or gum is not permitted in SPD	X		IN COMPLIANCE with standards
11. Disposal and handling of sharps	X		Sharps containers less than ¾ full	X		All sharp containers within compliance of policy
16Staff Orientation	X		IN COMPLIANCE with standards		X	Inconsistencies with documentation with competencies in SPD.
17. Clinic staff orientation	X		IN COMPLIANCE with standards	X		IN COMPLIANCE with standards
21. Procedures for decontamination section	X		Safety shoes (steel toed) are required when working in this area, white T-shirt tucked in.		X	Some staff did not have on white t-shirts and none of staff had on steel toe safety shoes in Decon. Personal clothing that extends above the scrub top neckline or below the sleeve of the surgical attire should not be worn (AORN, 2014, pp. 53).
22. Decontamination and handling	X		Doors will remain closed.		X	Door and window to decon open.

23.	Processing of loaner equipment	X		For all scheduled elective procedures, loaner instruments, sets and/or non-stocked implants should be received in SPD 48-72 hours prior to case.		X	Conflicting SOPs: Under J on page 74, policy states: All sets are to arrive 24 hours prior to case Staff member stated loaner sets are processed that show up with only 24 hours' notice
24.	Policy and procedure for the use of Renuzyme plus enzyme detergent solution		X	Latex exam or surgical gloves shall not be used as personal protective equipment *Policy does not support manufacturers IFUs concerning temperature, concentration, soaking time.		X	Some staff was just wearing surgical gloves and not the thick utility gloves.
26.	Cleaning of cannulated instruments	X		Has no mention of preventing aerosolization. ST79 7.5.3.2 Immersible devices should be cleaned under water to minimize aerosolization.	X		IN COMPLIANCE with standards
27…	Cleaning and processing flexible scopes		X	No mention of following manufacturer's instruction for use (AAMI, ST58. Manufacturers' written IFU, 7.2.2, pp. 39)	X		Flexible scopes cleaned and processed at clinics
28.	Cleaning and care of air-powered or battery operated	X		Staff very thorough with proper cleaning and care of air powered or battery operated equipment	X		IN COMPLIANCE with standards

equipment						

Policy # / Title	Written Policy Supports Standards			Practice Compliance With Standards		
	Yes	No	Policy element	Yes	No	Clinical Compliance Observation
29…. Laparoscopic instrument decontamination	X		IN COMPLIANCE with standards	X		IN COMPLIANCE with standards
31. Assembly procedures	X		IN COMPLIANCE with standards	X		Censitrac used extensively and questions elevated to supervisor if assembly issues came up
32. Inspection of instruments		X	Cutting into a piece of ordinary absorbent cotton can test		X	No testing materials present at assembly stations
33. Laparoscopic instrument testing	X		IN COMPLIANCE with standards		X	Last check on Micromed PD-8K by biomed was done in 2012. Items should be tested every year.
36. Labeling package	X		Ensure all personnel label packages correctly	X		All package are label before the sterilization
37. 3M ATTEST RAPID READOUT STEAM PACK 1296/1296F (CHALLENGE PACK) BIOLOGICAL INDICATOR		X	After the completion of the cycle, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest biological pack. Open test pack and allow biological indicator to cool outside of the pack for an additional 10 minutes prior to crushing.	X		IN COMPLIANCE with standards
39. Biological monitoring	X		BI is placed in the autoclave every load	X		IN COMPLIANCE with standards
40. Bowie-Dick test	X		Performed on the Night Shift as the first load in the sterilization process	X=		Did not observe the procedure, but the staff was able to verbalize the procedure and the documentation was completed in the log book accordingly
41 …..Chemical indicator	X		All staff assigned to SPD is responsible for being knowledgeable regarding chemical indicators.	X		Class I indicator (card for rigid containers and tape for wrapped sets) was placed on outside of all packs and instrument sets

42. Indicators (Class 5 integrators)	X		Ensure the insertion of class 5 indicators all sterilization packs and	X		IN COMPLIANCE with standards

Policy # / Title	Written Policy Supports Standards			Practice Compliance With Standards		
	Yes	No	Policy element	Yes	No	Clinical Compliance Observation
			instrument sets			
43. Care and operation of steam sterilizers		X	No mention of testing proper operation of steam sterilizer in policy after sterilizer installation, relocation, malfunctions, and major repairs		X	SPD staff verbalized the process of retesting the sterilizer is not done in all modes for 3 consecutive cycles include (AAMI ST79, Qualification testing, 10.8.1, pp. 122).
45. Unloading procedures for sterilizer	X		Ensure all personnel adhere to safe practice in unloading of sterilized items from the sterilizers. Observation: properly unloading the instrument sets or packs after completion of sterilization process and cooling down	X		IN COMPLIANCE with standards
47. Wet loads	X		IN COMPLIANCE with standards	X		IN COMPLIANCE with standards
48. Load control monitoring	X		All sterilized items shall have a label with a lot or load number: Observation: Lot stickers were noted all packs and instrument sets and showed proper documentation.	X		IN COMPLIANCE with standards
49. Storage of sterile supplies	X		IN COMPLIANCE with standards		X	Humidity is annotated at 3% several times, per SOP and AAMI ST79, humidity should be 35-70% (AAMI ST79, Relative humidity, 3.3.6.6, pp. 29).
53. Event related sterility/sterile packaging and shelf life	X		Monitor quality of trays. Perform monthly audit of 25 trays Verbal: Staff member unaware of monthly audit on trays		X	Management was not aware of monthly audits of 25 trays

References & Resources:

AAMI ST79. (2013) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

AORN Perioperative Standards and Recommended Practices, 2014 Edition.

The Joint Commission Position Statement on Steam Sterilization, 2009.

www.iahcsmm.org

www.sterileprocessing.org

**** The above form was modified by Dr Linda Wanzer to include the SPD Policy Review**

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References

Association for the Advancement of Medical Instrumentation [AAMI]. (2014). *ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA: AAMI.

Association of periOperative Registered Nurses [AORN]. (2014). *Perioperative standards and recommended practices for inpatient and ambulatory settings* (2014 ed.). Denver, CO: AORN.

Executive Summary Walter Reed National Military Medical Center (WRNNMC)
Immediate-Use Steam Sterilization (IUSS) Audit/ Point of Use Cleaning Audit

This report provides evaluation and analysis of processes and environmental quality controls related to WRNNMC main operating room. Audits were conducted 21-22 January 2015 utilizing modified version of SPS Medical's Sterilization and Point of Use Cleaning Audit Checklists. Overall results of the audits were commendable and all staff members were knowledgeable about immediate-use sterilization/point of use cleaning processes and very respectful during the entire survey process. Despite the overall positive results, there are some areas for improvement. Recommendations were referenced by AAMI, and AORN guidelines.

General Findings

MOR Immediate Use Steam Sterilization

IUSS was performed 20 times in the autoclaves for December 2014. There were a total of 858 surgical cases performed in December of 2014, yielding an average of 2.33%.

> ***Recommendation:*** Continue practice of minimal use of IUSS. "Immediate use steam sterilization should be kept to a minimum and should be used only in selected clinical situations and in a controlled manner" (AORN, 2014, pp.581-583. Recommendation VII, Sterilization).

Some documentation of IUSS cycles performed was incomplete (some missing patient's information, some missing loading or operator names).

> ***Recommendation:*** "Documentation of cycle information provides a means for tracking items that are processed using IUSS to individual patients and for quality monitoring" (AORN, 2014, pp. 583, Recommendation VII.g, Sterilization).

Staff member wasn't aware flash containers need to be cleaned according to MFR IFUs.

> ***Recommendation:*** "IUSS containers should be cleaned, inspected and maintained according to the manufacturer's written instructions" (AORN, 2014, pp. 582-583, Recommendation VII.e.1, Sterilization).

Flash sterilization being done on hardware that is removed on a semi regular basis per staff member. Documentation states decontamination and reason is terminal cleaning.

> ***Recommendation:*** "Decontamination should be performed in an area intended, designed and equipped for decontamination activities" (AORN, 2014, pp. 582, Recommendation VII.a.1, Sterilization and Disinfection). Terminally cleaning removed hardware to return to patients does not fall under selected clinical situations. "Immediate use steam sterilization should be kept to a minimum and should be used only in selected clinical situations and in a controlled manner" (AORN, 2014, pp.581-583. Recommendation VII, Sterilization).

MOR Point of Use Cleaning

There is no policy on point of use cleaning of instruments.

Recommendation: A policy should be written and followed for point of use cleaning. "Instruments should be maintained as free of gross soil as possible during the surgical or other health care procedure. Cleaning and decontamination should begin as soon as possible after items have been used" (AAMI ST79, 2014, pp.48, Handling, collection, and transport of contaminated items). "Preparation for decontamination of instruments should begin at point of use" because this improves the efficiency and effectiveness of the decontamination process (AORN, 2014, pp. 487, Recommendation V.a., Care of instruments).

No sterile water on back table in the Operating Rooms. (50% of the rooms audited (9 out of 18) did not have sterile water on back table. Only normal saline was on the back table to clean the instruments.)

Recommendation: Instruments should be wiped with sterile surgical sponges moistened with sterile water during the procedure to remove gross contamination. Saline, blood, body fluids, and debris are corrosive and may cause pitting, rusting, and corrosion when allowed to dry in or on the instruments (AORN, 2014, pp. 542, Recommendation IV.a., Care of instruments). Make sure instruments are cleaned with sterile water at the point of use to prevent the formation of biofilm (AAMI ST79, 2014, pp.47-48, 6.3 Care and handling if contaminated reusable items at point of use).

Incidental finding: Only 1 out of the 9 rooms audited had unlabeled normal saline irrigation fluid/medication observed on the back table. When reported to staff, staff immediately corrected the situation.

Recommendation: As soon as the medication is received on the back table (sterile field), the person receiving should label the medication with its name, strength, and concentration to avoid medication administration errors. Providing preprinted labels may help with compliance (AORN, 2014, pp. 293, Recommendation IX.c., Medication safety).

Report prepared by Maj David Bradley, USUHS CNS student

23 January 2015

References

Association for the Advancement of Medical Instrumentation [AAMI]. (2014). *ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA: AAMI.

Association of periOperative Registered Nurses [AORN]. (2014). *Perioperative standards and recommended practices for inpatient and ambulatory settings* (2014 ed.). Denver, CO: AORN.

Immediate-Use (aka Flash) Sterilization Audit Checklist

AORN standards state flash sterilization should only be used when there is insufficient time to terminally sterilize reusable medical devices. Flash sterilization should not be used as a substitute for sufficient instrument inventory as it may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process. Use this Flash Sterilization Audit Checklist to review your facility's compliance with best practices (as defined by AORN standards) and to make quality improvements.

Date: 22 January 2015 Auditors: Maj Bradley

Facility: Walter Reed National Military Medical Center Location: Main Operating Room

: CDR Malionek

	Yes	No	DNO
20. Flash sterilization is kept to a minimum and not used as a substitute for sufficient instrument inventory?	☐	☑	☐
21. Device mfg's validated instructions for use (IFU) for decontamination available and followed?	☑	☐	☐
22. Only FDA cleared sealed containers used for flash sterilization (instead of an open tray)?	☑	☐	☐
23. All items are placed in the flash container in a manner that allows steam to contact all surfaces?	☑	☐	☐
24. The weight of the flash container and flashed items is always less than 25 lbs?	☐	☑	☐
25. Class 5 chemical integrating indicators are used inside each tray with every flash cycle?	☑	☐	☐
26. Device mfg's IFU for sterilization (cycle type, exposure time and temperature) is always followed?	☑	☐	☐
27. Personnel are educated regarding the different types of flash cycles, i.e. gravity and prevacuum?	☑	☐	☐
28. Personnel understand that items incompatible with the available sterilizer cycles are not be flashed?	☑	☐	☐
29. Personnel understand that "single use devices" are not to be flash sterilized?	☑	☐	☐
30. Measures are taken to prevent contamination during transfer of the items to the sterilization field?	☑	☐	☐
31. Flashed items are for "immediate use" only and never returned to inventory for use at a later time?	☑	☐	☐
32. Flash containers are disassembled and cleaned after each use and according to the mfg's IFU?	☐	☑	☑
33. A Bowie-Dick test is performed daily or each day the pre-vacuum cycle is to be used?	☑	☐	☐
34. BI testing is performed daily inside a flash container at the shortest time for each cycle type used?	☑	☐	☐
35. Personnel understand that implantable devices are flashed in emergency situations only?	☑	☐	☐
36. Flash cycles containing an implant are always monitored with a Class 5 integrator and a BI?	☑	☐	☐
37. Class 5 integrator and BI results are recorded with all items traceable to the individual patient?	☐	☑	☐
38. Sterilizer printouts are removed and initialed after every cycle to verify all parameters were met?	☑	☐	☐
39. Maintenance records are kept for each sterilizer with date and complete description of service?	☑	☐	☐

DNO = Did Not Observe

(1) Flash sterilization being done on hardware that is removed on a semi regular basis per staff member. (AORN, 2014, pp.581-583. Recommendation VII, Sterilization).

(5) Staff member unsure of weight limit of 25 pounds. (AAMI ST79, Weight and density of sets, 8.4.2, pp.76).

(13) Staff member stated she wasn't aware flash containers were cleaned after each use according to MFR IFU. (AORN, 2014, pp. 582-583, Recommendation VII.e.1, Sterilization).

(18) Item "flashed" was missing patient information, reason for sterilization or who retrieved item to take to room. (AORN, 2014, pp. 583, Recommendation VII.g, Sterilization).

OR Policy Review – related to Immediate Use Sterilization

Policy # / Title	Written Policy Supports Standards			Practice Compliance With Standards		
	Yes	No	Policy element	Yes	No	Clinical Compliance Observation
6-03 Immediate Use Steam Sterilization (IUSS)	X		Ensure documentation is complete with patient name, reason for sterilization, and who retrieved item from sterilizer to take to operating room.		X	In the month of January, up to the date of the audit, six items logged was missing patient information, reason for sterilization, or who retrieved item from sterilizer to take to operating room.

References & Resources:

AAMI ST79. (2014) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

AORN Perioperative Standards and Recommended Practices, 2014 Edition.

**** The above form was modified by Dr Linda Wanzer**

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Point of Use – Instrument Preparation & Transport Audit Checklist

Date: 22 January 2015 *Auditors: Maj Bradley*

Facility: Walter Reed National Military Medical Center *Location: Main Operating Room*

Contacts: CDR Malionek

	Yes	No	DNO
1. Is sterile water on the back table and is it labeled?	☐	☑	☐
2. Has staff received training and that training documented in accordance with POU policy, AAMI, & AORN recommendations? (AAMI ST79, Service personnel, 4.3.2, pp. 39)	☑	☐	☐
3. Are instruments wiped of gross soil with sterile surgical sponges and sterile water? (AAMI, handling, collection, and transport of contaminated items, 6. 2., p. 47; AORN, 2014, Care of instruments, p. 543)	☐	☑	☐
4. Are lumens irrigated with sterile water throughout the procedure to remove gross soil? (AAMI, handling, collection, and transport of contaminated items, 6. 2., p. 47; AORN, 2014, Care of instruments, p. 543)	☐	☑	☐
5. Are sharps separated from other instruments and placed into a puncture proof container? (AAMI, Standard/ transmission-based precautions, 4.6., p. 41; AORN, 2014, RP V, Sharps safety, p. 364; OSHA, 29 CFR 1910.1030)	☑	☐	☐
6. Are multi-part instruments opened, disassembled and arranged within their original set? (AORN, 2014, RP V, Care of instruments, p. 543)	☑	☐	☐
7. Are hinged instruments kept fully open using stringers, racks and/or instrument pegs? (AORN, 2014, RP V, Care of instruments, p. 543)	☑	☐	☐
8. Are light instruments placed on top of heavy instruments or placed in separate containers? (AORN, 2014, RP V, Care of instruments, p. 543)	☑	☐	☐
9. Are microsurgical instruments segregated into the separate containers? (AORN, 2014, RP V, Care of instruments, p. 543)	☑	☐	☐
10. Is pre-soak solution or wet towels soak with water being used to keep instruments moist? (AORN, 2014, RP V, Care of instruments, p. 544) Enzymatic solution by elevator	☑	☐	☐
11. Are instruments contained properly during transport to Decontamination area? (AORN, 2014, RP V, Care of instruments, p. 544)	☑	☐	☐
12. Are transport containers (e.g. bags, carts and/or containers) labeled biohazard? (AORN, 2014, RP V, Care of instruments, p. 544; OSHA, 29 CFR 1910.1030)	☐	☑	☐
13. Is the water or cleaning solution used to keep the instruments moist, contained or discarded before transport? (AORN, 2014, RP V, Care of instruments, p. 544)	☑	☐	☐
14. Are instruments being transported as soon as possible to prevent blood from drying? (AORN, 2014, RP V, Care of instruments, p. 544)	☑	☐	☐
15. Is the outside of the transport container free of bio-burden? (AORN, 2014, RP V, Care of instruments, p. 544)	☑	☐	☐

Noncompliant

(1) (3)& (4) No sterile water on the back table ("We use sterile water for big cases"). Ensure instruments are cleaned with sterile water at the point of use to prevent the formation of biofilm (AAMI ST79, Care and handling of contaminated reusable items at point of use,6.3, pp. 48).

(12) No biohazard label on transport containers(OSHA, 29 CFR 1910.1030 (d)(2)(xiii)(A)

OR Policy Review – related to Point of Use Cleaning

Policy # / Title	Written Policy Supports Standards			Practice Compliance With Standards		
	Yes	No	Policy element	Yes	No	Clinical Compliance Observation
There is no policy on point of use cleaning of instruments		X	(AAMI ST79, 2014, pp.48, Handling, collection, and transport of contaminated items).“		X	* Nine rooms audited out of 18 did not have sterile water on back table. Only normal saline was on the back table to clean the instruments.

References & Resources:

AAMI ST79. (2014) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities AORN Perioperative Standards and Recommended Practices, 2014 Edition.

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