Sterile Processing Site Assessment

Standard American Medical Center

This document is only intended as a sample of work highlighting technical observations, assessment and writing skills. The name of the facility which was assessed for this report, as well as the sponsoring company have been changed.

SITE ASSESSMENT COMMITTEE

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DISCLAIMER

The recommendations in this document are based on the professional experience of the XYZ Consulting Education Team. All advice communicated in this document should be considered peer-to-peer advice only and should not be considered as indirect recommendation from any regulatory or standards-based organization or legally binding. Additionally, great effort has been taken to include advice in all applicable topics. However, it is possible that some topics or themes have been omitted due to oversight. The document should not be considered as an all-inclusive review of policies and procedures.

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PART ONE: WRITTEN POLICY REVIEW

General Recommendations

- We recommend that all policies and procedures relevant to Sterile Processing be placed into a single PDF document complete with a table of contents. This would be in lieu of individual files for each policy. Placing all applicable policies in a single document allows technicians to keyword search or find SPD-specific policies quickly. We also recommend that this electronic document be made accessible to all staff.
- There are no indications of periodic policy review on the documents which were reviewed. Policies should be reviewed on a periodic timetable by a committee. We suggest a statement in each header or footer that says “This policy is scheduled for review on XX date”.
- We recommend that all policies contain a named individual for final approval. Currently the approver is a position title or un-named group such as “Perioperative Directors”.
- The “Author” field should have names and credentials associated with the committee or reference another document that lists these individuals and credentials.

Recommended New Policies

- Sterrad
- HLD
- High-priority or one-of-a-kind sets
- Releasing implants before bio result
- Set Assembly
- Repair and PM
- Use of tracking systems

Biological Monitoring

- This policy file should be called “Load Recall” and not “Biological Monitoring”. This will assist people who need to search for the load recall policy during emergent situations as such a policy needs to be fast and accessible.
- Under procedures for both causes: we suggest adding a process for immediate notification of OR personnel (including the surgeon) in cases where the load was partially distributed for use prior to discovery of the wet packs. Having a tracking system that communicates to the operating room can be very helpful here and should be referenced if possible.
- The references under the root cause appear to be referencing AAMI standards, however this is not implicit throughout the document and should be declared as the source for each reference.
- Under documentation: If a tracking system is in use, it should be indicated here and specified.
- “Wet Pack” or “Wet Load” could also be keywords for this policy (if a single electronic policy compilation is adopted).

Bloodborne Pathogen Exposure Control Plan

- This information appears to be taken directly from OSHA’s Bloodborne Pathogen Standard. It meets all requirements.

CJD Precautions

- This policy is out of date and should be revised. CDC has an update that is relevant to the "definitions" section. This information can be found: http://www.cdc.gov/ncidod/dvrd/cjd/qa_cjd_infection_control.htm and here: http://www.cdc.gov/ncidod/dvrd/cjd/
- Another good resource: http://www.who.int/csr/resources/publications/bse/whocdscsraph2003.pdf
- Under F. Iatrogenic CJD transmission: The statement "No such cases have been reported since 1976" is incorrect. There have been incidents since the publishing of this policy.
- Under the procedure, there is no indication of explicit communication procedures between OR and CSPD staff regarding potential or known CJD contaminated instruments

EtO Safety

- We recommend that the Central Service Technician Manual (IAHCSMM) not be used as a reference for an official hospital policy.
- From Aeration procedure, we recommend removing step 5 and step 6 completely. Current OSHA standard mandates that aeration must occur in the same container as ETO sterilization: http://www.epa.gov/oppsrrd1/reregistration/ethylene_oxide/ethylene_oxide_fs.html

Immediate Use Steam Sterilization

- We recommend revising the Information portion of point 1 in Decontamination to:
    - "If item is to be processed for IUSS by the Operating Room staff, it must be cleaned and decontaminated and prepared per the facility's cleaning procedures in accordance with current CSPD standards and device IFUs. This includes proper cleaning agents, dilutions, and instruments."
- We recommend removing or clarifying step 10 under decontamination. Perhaps re-word this to state that a visual check to confirm the absence of condensation should be done prior to transferring IUSS devices to the sterile field.
- Be sure to include tracking system procedures in the physical monitoring section if applicable. We recommend using an electronic tracking system for record keeping related to IUSS.
- Daily autoclave maintenance should also be depicted in the policy (unless otherwise indicated in a different policy).

CSPD Sterilization Protocol

- This policy is missing a disclaimer that the use of textile materials in sets for sterilization is not recommended (see http://csao.net/files/pdfs/AORN%20Recommended%20Practices%20for%20Selection%20and%20Use%20of%20Packaging%20Systems%20for%20Sterilization.pdf).
- Under Saturated Steam: The sterilization cart/buggy should not be under any form of cooling ventilation while in the cool down process. If a sheet or cover is to be used, we recommend this be added to the policy.
- Add under "Caution" that this may be an indication of a wet load and should be investigated as such.
- In number 5 of Saturated Steam section: This should be a class V indicator.
- For number 6, we recommend doing a daily bio test to prevent recalls on items over a longer period of 24 hours (in the event of a negative test). This includes all SPD and flash sterilizers.
- For low-temperature, we recommend that a new policy be developed and devoted to this topic and only referenced here.

    - Under this description: “items with restrictions based on lumen, diameter and length” should be confirmed in IFU valid for low-temperature sterilization.
- Remove reference to the Central Service Technician Manual (IAHCSMM).

PART TWO: OBSERVATIONS

General Department Observation

Commendations

Layout of the department and physical work space is very commendable. There appears to be adequate space for all functions and department operations, which is often a rarity for Sterile Processing departments across the country. The “red line” is appropriately placed, along with available jumpsuits, shoe covers and hair coverings for visitors.

The posted Shift Report Communication sheet is also to be commended. Additionally, the Communication Log book, staff bulletin boards (with department statistics) in the office area is very thorough and well done.

In our initial discussion with the department manager, Sally Joe, we learned that “left over” sets at the start of the day shift had been reduced considerably under her leadership. This was accomplished by eliminating specialized positions, cross-training and rotating staff so that they could complete all duties as needed. This is an achievement that we commend and suggest that it be shared with all Standard facilities.

We learned that the department staffing model uses staggered shifts which is extremely effective for on-going coverage and positive communication flow.

We observed that the department phone did not ring more than 2-3 times. This demonstrates that technicians have a strong drive for high quality customer service. Technicians were also observed to be extremely helpful to OR staff and fellow team members within the department.

Assembly

Commendations

Work stations appear generally to have a universal layout. From a psychological perspective, this is a benefit because a technician can sit at any work station and know that all supplies and equipment are universally located instead of having to re-adjust mentally to a unique set-up if working at various stations.

Supplemental instrument lubrication was observed at nearly every work station, which is to be commended.

The use of white bath towels or washcloths were not observed anywhere in the department. This is a common problem in many departments and is commendable that none were found.

Suggestions

Distilled water was observed at one station, but no brushes for lumens were observed. One station also had a cup of alcohol and syringe. We didn’t observe the alcohol being used, so we can’t confirm what this was for. So, we simply point out as a reminder that for instruments with lumens or cannulas, only distilled (or sterile, deionized, etc.) water should be used for flushing/brushing at the assembly area. Alcohol should only be used during the final steps of processing flexible scopes.

The peel pack station is very well organized. However, it was observed that the lower shelf at the station has dust accumulation. We also observed some dust build up in other areas of clean assembly (see photo section). We recommend establishing a rotating cleaning schedule and documentation log for this and other

“out of sight” areas. The department management team can decide what items should be cleaned, what degree of cleaning needs to be performed and how often.

Very few tip guards were found at each work station. In some cases, there were no tip guards. We recommend that a variety of sizes of tip guards be placed at each work station. The purpose is to protect delicate or sharp instruments during set transport. Additionally, tip guards within sets help to minimize injury or possible break in aseptic technique by the surgical tech who unpacks the set in the O.R.

Testing materials were not found at the work station (theraband, plastic dowel rods, etc.). One technician mentioned that scissors are not tested due to concerns about latex contamination, which is a valid concern. We recommend that scissor testing be resumed using non-latex test material. XYZ Consulting can assist in providing ordering information for these materials. We also recommend that all other instrument testing supplies be well stocked at each assembly station. XYZ Consulting can also provide mini testing cabinets for each station and provide an in-service on the proper testing materials and how to use them.

Magnification tools were not observed at any of the work stations. We recommend that some form of magnification tool (simple magnifying lens at minimum) be present at each work station. Inspection of micro instruments under magnification is critical since these instruments are used by the surgeon under magnification. Defects or bioburden which are obvious to the surgeon are not often visible to the processing technician unless magnification is used during the inspection process.

Decontamination

Commendations

The pass-through window was observed to be closed when not in use. Instruments passed through the window were never observed to be blocking the window or causing it to remain open. This is often overlooked in other facilities.

The CleanOp/Mojave drapes for decontamination tables are excellent. We encourage their continued use (or any other similar product).

Negative air pressure was assessed and found to be adequate using a simple “Kleenex” test.

Ergonomic standing mats are in place and being used. The mats are perforated, which is very appropriate for the decontamination area.

Rigid endoscopes were observed to be well protected for transport in dirty case carts, as well as during the decontamination process.

70% isopropyl alcohol is used to disinfect hand wash items before passing through the window. This disinfection process before passing an item to the clean area is often overlooked at many facilities. Keep in mind however that for alcohol to be effective, it must have a minimum wet contact time of five minutes.

Suggestions

Respiratory protection is a concern for decontamination technicians. Nearly all technicians that were observed used the mask/face shield combination product, but had the mask portion covering only their chin. The mask needs to be worn completely covering the nose and mouth. If breath fog builds up on the visor, then an alternate product (or combination of products) needs to be explored. It is vital that the respiratory tract be protected in decontamination areas due to aerosolization of pathogenic microorganisms and other particles (see Rationale paragraph of AAMI ST79, 3.3.7.1).

It was observed that the emergency eye wash station became blocked by case carts during the shift. A clear pathway to the eyewash station should always be maintained. The eye wash station was also quite dirty and the protective faucet caps were not in place.

We observed inspection logs for environmental controls in decontamination. While it is a positive sign that such logs are kept, we recommend that these sheets not be stored in decontamination due to cross contamination issues that may result when the logs are eventually archived with other files. Any forms, posters, etc. that are stored in decontamination should be considered contaminated.

The door pressure test is important, but the log should describe specifically what method is used to test this and what parameters indicate a "pass" or "fail" for this test. If an electronic device is used to indicates a simple pass/fail (similar to a sterilization biological incubator), we recommend that the log indicate that the test was done electronically, the result it provided and what the device tests (specific parameter).

The temperature of the decontamination area at 18:30 on 2-18-14 was out of acceptable range at 74.7 degrees Fahrenheit. Temperature and humidity must remain in the acceptable range. While building facilities personnel may also monitor temperature and humidity in other ways, AAMI ST79 indicates that monitors (or immediate and relevant data) be accessible to CSPD staff inside the actual work areas (note highlighted text):

> *"Special considerations apply to the decontamination area. The following are some of the key issues to be considered [list ranging from a. to mm.]: What environmental controls will be required? (Environmental conditions [temperature and humidity] should be displayed accurately within the decontamination area.)" (3.2.2.2, point w).*

> *"An independent humidity monitor should be located in each area that requires controlled relative humidity. Relative humidity should be recorded daily. Processing personnel in each work area are responsible for monitoring and recording the relative humidity to ensure that the correct relative humidity is being achieved." (3.3.6.6, paragraph 1).*

Sink water (which was dirty) was left standing at a decontamination station while no technician was present. If a technician leaves for break or to work in another area, sinks should be drained. The Getinge ultrasonic also had grossly contaminated water which was left standing. Ultrasonic water should be drained and replaced when visibly soiled/cloudy. In three separate observation sessions, we did not observe technicians using the ultrasonic machines at any time.

Proper brushes for working channels of flexible ureteroscopes could not be found in the decontamination area. When a technician was asked if she could find a brush for the scope, she was not able to find any appropriate brush in the sink area or decontamination supply cart. Flexible ureteroscopes are also not being properly leak tested in decontamination. Follow-up regarding proper care and handling of flexible scopes will be discussed outside of this report through the XYZ Consulting national endoscope specialist, Jon Fish.

While hand sanitizer is acceptable for technicians after they "doff" soiled PPE and before they leave the decontamination area, an actual hand wash sink would be preferable.

For other environmental concerns in the decontamination area, please see the photos section at the end of this report. The decontamination area of the CV area will be discussed in a separate section.

CV Decontamination & Processing Area

Commendations

The CV-CSPD technician, Jason, should be commended for his passion, dedication to quality and strong concern for patient safety.

Suggestions

In general, the physical layout of the CV clean work room, sterile storage and decontamination room pose significant problems for infection control, patient safety and staff safety. Our overall recommendation is for management of both CSPD and OR to consider the discontinuation of decontamination and reprocessing services in this area due to the issues detailed below. If this is not possible, we have provided some suggestions for immediate action.

We did not observe any negative air pressure in decontamination (or positive pressure in the assembly area). This is a concern not only for the outside hallway, but also for the clean processing (and sterile storage) in the room adjacent. The autoclave that is installed between decontamination and this clean/sterile storage area is not sealed into the wall because autoclaves typically do not have a decontamination room where the chamber is located. In other words, there are sufficient gaps between the wall/floor and the autoclave unit or simply due to the design of the autoclave. It is possible that airflow may be able to pass back and forth from decontamination through these gaps unless there is appropriate negative pressure. Another concern is that if the decontamination negative air pressure is not adequate, this contaminated air could be entering the immediate area where sterile sets are being pulled from the autoclave through these natural gaps.

We did not observe any temperature or humidity indicators in this decontamination area. Even though the temperature and humidity could not be assessed by evidence, the room "felt" far above acceptable ranges for temperature and humidity. This is most likely due to the autoclave chamber portion and steam pipes being located in the decontamination area. For references regarding temperature and humidity in AAMI ST79, please see the CSPD "Decontamination" section above.

The PPE for this decontamination area is inadequately placed. PPE should be located outside of (or just within the door of) the decontamination suite. It was reported (although not directly observed) that nursing staff often enter the decontamination area without donning any PPE and then returning to the restricted area of the O.R. There are many cross-contamination possibilities if this is happening (i.e., aerosolized particles on nurses scrubs, shoes stepping into contaminated floors, etc.). We recommend that immediate action be taken to keep nurses or other staff out of the decontamination area unless they fully don PPE before entering, "doff" PPE when leaving, exchange head covering and scrubs before they return to the restricted area of the O.R.

Under the autoclave (in decontamination) near the floor, there appears to be some type of condensation or other leak which has built up over time into a slimy, semi-liquid type substance. Since bacteria often proliferate in warm, dark, moist areas it is quite possible that this substance may have a colonized pathogenic microorganisms since it appears to have built up over time. We strongly recommend (at minimum) that the autoclave panels be removed and the entire floor surface immediately surrounding the internals of the autoclave be cleaned and disinfected. Since this autoclave leads directly from decontamination into a clean area, it may be worthwhile to culture this fluid, especially if it is found to be pooling/spreading to the clean area underneath the autoclave.

There is no ultrasonic machine in this decontamination suite. We highly recommend that such a machine be installed and used. CV instruments are usually quite bloody and skipping ultrasonic cleaning for such instruments is strongly discouraged. A related concern is that the CV technician does not arrive until 12:00pm each day. If a CV procedure (first case) ends at 9 or 10am, this means that the instrumentation is sitting

without being processed for two or more hours. When the instruments do begin the decontamination process, it is likely that bioburden has been allowed to dry. Cleaning then becomes extremely difficult, especially since there is no access to an ultrasonic machine.

The CV technician reported that he performs a TOSI washer test monthly. AAMI ST79, 7.5.3.3 recommends that a TOSI test be performed weekly at minimum, but preferably daily.

There are concerns with case carts blocking proper egress in the event of a fire or other emergency. This is problematic in the confined space of decontamination (which also serves as dirty case cart holding) but also cleaned case carts which are stored in the hall way. Please consult with a facilities safety officer to determine if it is acceptable to store clean cast carts and other equipment on both sides of the hallway. Additionally, the fire escape plan map which is posted in the outer hall, is located behind a supply cart (full of supplies) and can't be seen quickly should an emergency occur.

Since there is no cart washer in this area, carts are disinfected with 70% isopropyl alcohol. However, the minimum wet contact time of five minutes required for disinfection was not observed. The technician sprayed the entire cart, then wiped it down. The internal sections of the cart were not observed to be disinfected. Due to the large surface area of the cart, we recommend using some other type of disinfectant that has a shorter required contact time.

A used flexible scope for CV was found to be bagged and placed on a decontamination table. The first concern is with the care and handling of the scope. Endoscopes should always be transported in some type of protective case. A plastic bag does not provide adequate protection from damage during transport. The second concern is with cross-contamination. The bagged scope was being stored in the decontamination area for an unknown amount of time and placed on a contaminated surface. Since the scope isn't processed in this area, it will eventually be retrieved for processing elsewhere, but the outer bag should now be considered contaminated.

As shown in the photo section of the main CSPD work station, wood-based storage and tables should not be used in a sterile storage area. The CV clean room cabinets should be replaced with plastic or stainless steel cabinets. The assembly table was covered with a surgical blanket. The blanket could be an issue with lint transfer to instruments and we recommend that it should be removed. If the decision is made to keep the blanket on the assembly table, it should be exchanged after every shift. The work station in the CV assembly area could also be improved ergonomically. We recommend a proper chair (instead of a rolling stool) with lumbar support. An alternative would be placing a standing floor mat. To increase productivity, we also recommend that a printer be placed with the computer in this area.

It is our opinion that the instrument sets in should not be stored in this work area, particularly wrapped items. Humidity in this area is probably much higher than it should be due to the confined space and a washer disinfector being open after each wash cycle. As with all work areas, temperature and humidity parameters/data should be visible at any time and logged daily by the technician.

Steam Sterilization

Commendations

Placing barcode labels on the sides as well as the top of wrapped items is excellent. The set can be identified regardless of how it is placed on storage shelves.

The laminated "HOT" and "Quarantined Load" signs are also excellent. We observed one steam load that had a handwritten card with the time that the load was removed from the autoclave, which is evidence of great communication.

Suggestions

See photo section regarding completing a load record sheet. All other steam sterilization processes appear to be in order and appropriate.

Gas Plasma Sterilization

NOTE: Ethylene Oxide processes were not observed and are therefore not included in this report.

Commendations

Exam gloves were available for changing hydrogen peroxide cartridges. These cartridges can and do leak, so it is vital that skin is protected.

Suggestions

We recommend that eye protection also be made available when changing a hydrogen peroxide cartridge.

Regarding all sterilization records, we recommend that instead of leaving a form field blank if the count is zero (peel-pack count, set count, etc.) that some type of written notation (such as 0, X, Ø) be made to indicate that none of the specific item type were present on that particular load. See the photo section for an example of one record sheet where blanks were left. Leaving blank areas causes a degree of uncertainty for a record which should be complete and accurate. All other gas plasma sterilization processes appear to be in order and appropriate.

Sterile Storage, O.R. Core & Materials Management

NOTE: In-depth assessment of the materials management processes are beyond the scope of this particular assessment report. However, we were able to observe and report on some areas. Overall, we strongly recommend pursuing additional in-depth observation and analysis of the entire perioperative process and flow with the XYZ Consulting team.

Commendations

Once again, we commend the strong customer service of the CSPD team. The core technicians whom we observed always went out of their way to provide excellent service to the O.R.

Core techs were observed to be very hard working and using their time as effectively as possible. Even though there are several weaknesses in the entire process of pulling case carts and assisting the O.R., they used their time wisely and should be commended for their dedication.

Suggestions

There were some observed inconsistencies in the use of transport trays and shelf liners in sterile storage (see photo section). For example:

- Some wrapped sets are stacked on top of each other with transport trays sandwiched between, while other multiple stacks of wrapped items do not use transport trays at all.
- Some wrapped items are stored on wire shelves (no shelf liner) while some rigid containers are stored on shelves with liners. Shelf liners are not necessary for storage of rigid containers.

We observed that vendor consigned (loaner) sets had tracking sheets taped to the outer wrap with autoclave tape. Using autoclave tape is not recommended because this tape is only intended to be used for sealing a wrapped set for sterilization. Another problem with using autoclave tape in lieu of regular tape is that it tends to curl up fall off the package when it has not gone through a steam cycle. This results in the tracking sheet falling off the set and getting lost. We recommend using clear plastic “packing sheet” envelopes to affix the tracking sheet to the loaner set (after sterilization). Steve Lennon from Standard Good Samaritan can connect you with the supplier of these sleeves/envelopes.

There are concerns regarding FIFO (first in, first out) of both instruments and disposable supplies. Even though instrumentation does not "expire", it is best practice to rotate sets and instruments using FIFO. It may be worthwhile to compile a set/instrument utilization report to determine the frequency of set turnovers. Concerns related to FIFO of instrumentation are primarily targeted around items that are stored in bins, items that have multiple quantities, items that can't be shelved in an orderly way or that typically have low utilization. For example, we found a peel-packed "Custard Cup" on the top of the storage bin dated 13 Apr 2013 and another "Custard Cup" at the very bottom of the same bin dated 21 Dec 2010. On a shelf, we found a standard basin in front dated 13 Sep 2013. In the back of the same shelf was a standard basin dated 21 Feb 2012.

We observed a general inconsistency with set/instrument shelf labeling of par levels. Some set storage shelves had par level indications on the shelf label while others did not.

We observed several large/heavy sets that were being stored on the top shelf (see photo section). For example, DeMayo knee positioners, Bookwalter table posts and laparoscopic retractor trays are all quite heavy but are being stored on the top shelf. We recommend that these items be relocated to shelves at waist level to reduce the risk of employee injury (both immediate and long term injury). This is also a concern for wrap integrity. When heavy wrapped sets are placed on shelves above waist level, the temptation is to slide the set out without picking it up because the item is too heavy to lift overhead. Sliding wrapped sets (rather than lifting them directly off of the shelf) can cause tears in the wrap. This also relates to the concern about the inconsistency of tray liners and transport trays mentioned above.

We have several concerns that an appropriate FIFO process of disposable items is not being done. We observed one materials technician emptying a new box of 5mm laparoscopic cannulas on top of the existing pile (which was already quite full). We observed another technician unpacking drapes on a nearly empty shelf, but he did not move the "old stock" to the front and just placed the new drapes in front of the "old" product (see photo section). While the current insufflation tubing does not have an expiration date, we found product with a manufacturing date of July 2012 in the back/bottom of the bin and a manufacturing date of October 2013 on top/front of the bin.

Another concern related to disposable items is that some items were significantly over par level. For example, the Seprafilm Bioresorbable bin had a shelf label with a maximum quantity of 16, but we found more than 30 individual items in the bin. There were also many supply shelf labels that had a max/min quantity of 0. We were able to discuss some of these topics with the Senior Supply Chain Manager, Wayne Segree.

The "breakdown" room is also an area of concern. Unboxed sterile goods were being stored in carts next to outside shipping containers. Also, a styrofoam drink cup was placed in a bin with sterile goods (see photo section). It was reported (although not observed) that this storage area is unrestricted (plain clothes access is allowed) even though there were un-boxed sterile supplies in the room.

It was reported (although not directly observed) that items that are pulled as "hold" items are rarely used and that these items are also stored redundantly in the O.R. core as well as the surgical procedure room. We recommend an in-depth analysis of the frequency of use of these "hold" items. Depending on the results of that analysis, it may not be necessary for CSPD technicians to pull "hold" items that are rarely used and are readily available in the O.R. area (if needed).

While observing a technician pulling (or "picking") supplies for the next day's cases, she was interrupted several times to assist the O.R. This interrupted her work flow in gathering supplies for cases. This position is also responsible for pulling supplies and instruments for add-on cases. In order to improve efficiency and provide better service to the O.R., it may be worth exploring dividing this current position into two separate roles (one person dedicated to O.R. needs and another person dedicated to pulling cases).

Several peel-pack bins in the O.R. were completely empty while others seemed to be overflowing (see photo section). Typically, we found that commonly used instruments had very small bins and were often the items which were depleted. Items which were less commonly used had larger bins and supply. When a core technician was asked about the peel-pack inventory process for the O.R., she said that there is no formal process. Individual instruments are taped for identification as a "peel-pack" item and are processed as they are used. During this time, we observed the O.R. asking for a specific peel-pack item but all O.R. storage areas had been depleted. We recommend that a deeper analysis and investigation be conducted to improve this process.

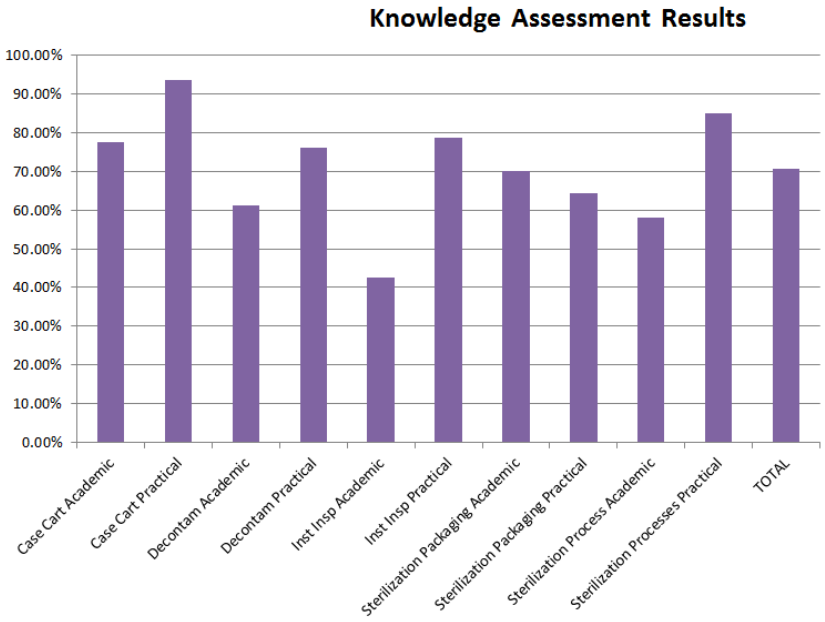
There are several problem areas with the preference card process and the cards themselves. Some of these are noted in the photo section. However, an in-depth analysis for improving these problem areas are beyond the scope of this project. We strongly encourage the perioperative management team to consider a full analysis with the support of the XYZ Consulting Perioperative Optimization team.

Immediate-use Steam Sterilization (IUSS) records in the CV area were observed to be inconsistent or incomplete. Some examples of this are:

- One form field did not have an answer to the question "parameters met?".
- One form field did not have the name of the person loading the autoclave.
- One form field indicated that parameters were met and bio was run, but a note written in the margin said that the set was not sterilized with no other explanation.
- There does not appear to be a field on the form to document if the biological result was negative or positive.
- Handwritten markings on the ticket printout were inconsistent.

One suggestion for improving the quality of the IUSS documentation would be to designate someone to routinely audit these forms and report inconsistencies to the O.R. manager and CSPD manager. Another suggestion is to create an "ideal example" of a record sheet and ticket printout to use for staff education (informally by posting the example sheet or formally through an IUSS in-service).

PART THREE: ASSESSMENT EXAM

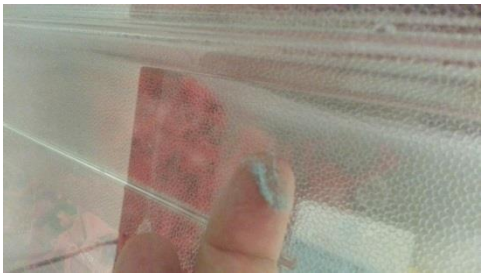


Assessment exams were given via the online XYZ Consulting Assessment Module during the assessment period. An overview graph of exam results (average scores in each category) is shown below. A more complete report of individual and composite results will be sent to the leadership team in a separate document.

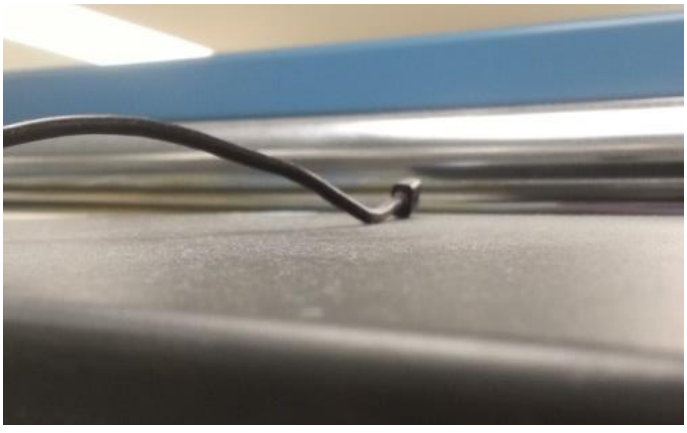
PART FOUR: OBSERVATION PHOTOS

The purchase of new work stations with stainless steel surfaces is completely justified. Wood-based work surfaces should not be used in the CSPD.

Additionally, the overhead lights on the current work stations can't be dusted properly. The "grill" itself collects dust which is difficult to remove, but dust has also collected behind the light "grill" (difficult to see in this photo).



Dust build up on supply shelf below peel-pack station.



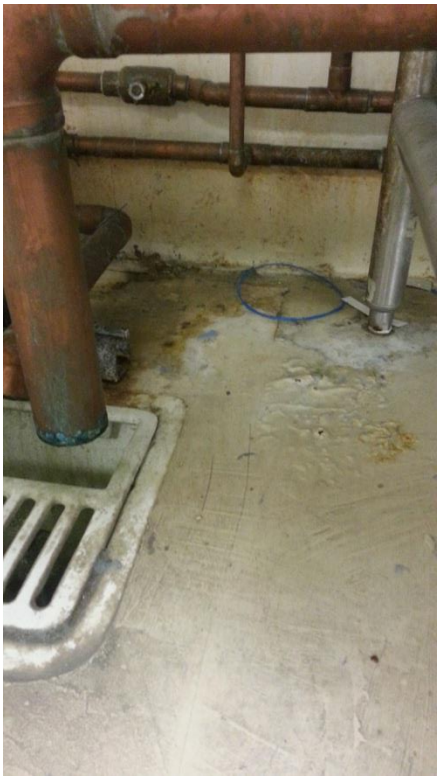
Dust build up on top of a work station computer. For more information, see the section labeled "Assembly".

Items which are large and/or heavy should be placed at waist level to reduce risk of employee injury. This example is of a very heavy DeMayo Knee Positioner on the top shelf. Other similar heavy items were found on top storage shelves, such as Bookwalter table posts.

General inconsistency with the use of transport trays, shelf liners and stacking wrapped sets. Some sets have a tray liner while stacked, others do not. Some shelves had liners, but transport trays are still used. Some shelves with liners were used to store rigid containers but not wrapped sets. Other shelves are not lined but wrapped items are stored without transport trays.

There are two marked water fill levels in decontamination sinks. It is difficult to know which one line to use or what the purpose of each one is. Water level lines may not even be necessary with automatic dosing machines (please check with dosing manufacturer). If possible, these adhesive labels should be removed because they are likely to be harboring bioburden over time. If water level markers are needed, they should be laser etched or marked with permanent marker.

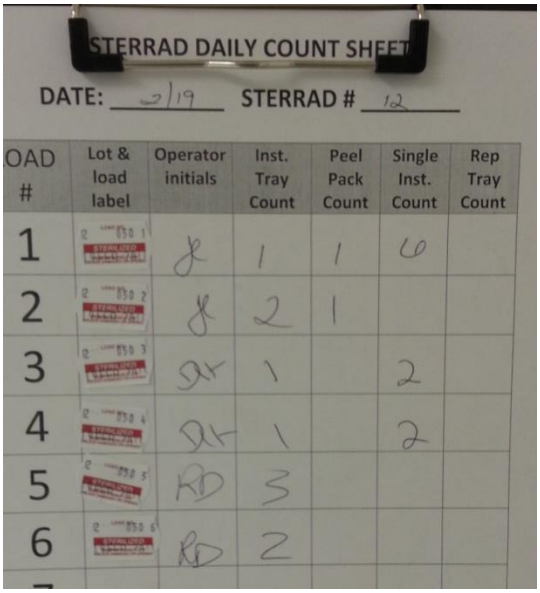
Delicate micro instrument found on decontamination floor. We did not observe the instrument being dropped, so we can't confirm how long ths instrument has been here. Could easily be stepped on and destroyed.



Regarding environmental/facilities upkeep in the decontamination area, we first recommend that the floor be re-surfaced. Areas with worn, chipped/cracked or bare floor are areas where biomaterial can “hide” and bacteria can replicate. We also recommend a more diligent effort be made to clean ALL areas of decontamination routinely, not just the areas of common use/traffic. Ideally, documentation logs should be kept for routine and deeper cleaning to ensure that it is being performed regularly.

Decontamination brushes should be disinfected regularly. A good time to do this is at the end of the day. Some brushes can be sent through the washer/disinfectors, but check with the brush manufacturer for specific instructions. When brushes have worn, bristles spread out (such as the blue brush in this photo), they should be replaced. Lumen brushes (particularly for flexible scopes) should be replaced more often to prevent scratching the lumen or working channel (refer to flexible brush manufacturers instructions for use).

Keeping computer related items clean in decotamination (and preventing cross-contamination and harboring of pathogenic microbes) can be a challenge. The plastic cover for this keyboard is worn and cracked. We recommend using a “washable” (impervious) keyboard for decontmination. Computer mice are difficult to shield/cover, so one suggestion is the use of touch screen capable monitors (which can be covered with disposable plastic). If this is not possible, consider discarding the mouse on a quarterly or biannual basis.



STERRAD DAILY COUNT SHEET

DATE: 2/19 STERRAD # 12

OAD #	Lot & load label	Operator initials	Inst. Tray Count	Peel Pack Count	Single Inst. Count	Rep Tray Count
1		JL	1	1	0	
2		JL	2	1		
3		SH	1		2	
4		SH	1		2	
5		RD	3			
6		RD	2			

For sterilization records, consider using some type of notation (0, X, etc.) if the count is zero. This is preferred over leaving the form field blank.

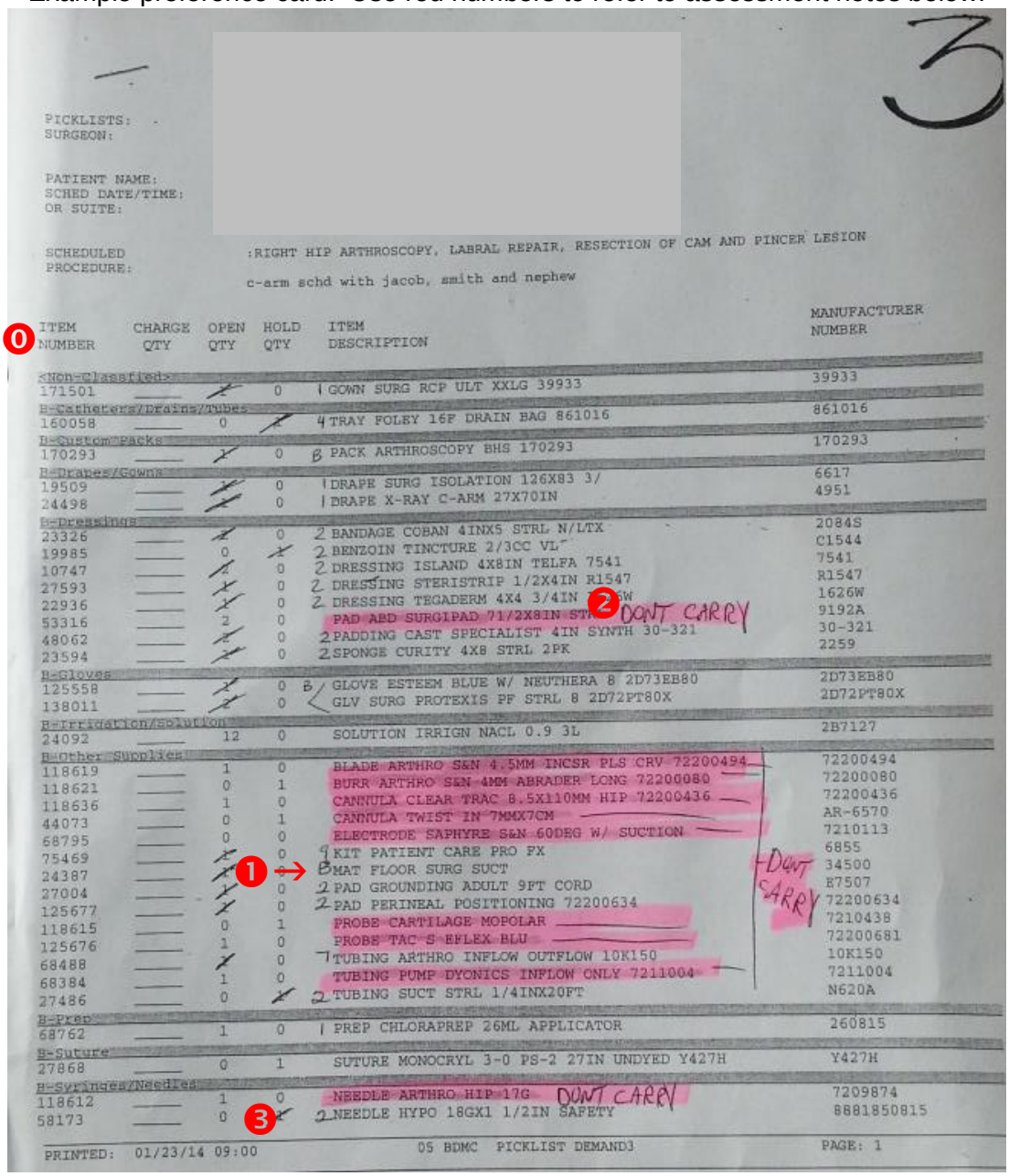
To be clear, these are two different supply shelves (not a “before and after”). We provide the two photos only as a reference point. In this example, the supply shelf shown on the left appeared very similar to the supply shelf shown on the right before it was stocked. We observed that the technican placed new product in front of older product instead of roatating the old product to the front and placing newer product in the back. Additionally, there was so much new product that the technician had a difficult time trying to fit it all onto the cart. We recommend a deeper investigation into utilization, min/max levels and re-order points.

External (outside) shipping containers being stored in the same room (some cases in or near the same bin) as unboxed sterile supplies. Even though there are unboxed sterile supplies, this room is reported to be unrestricted (street clothes permitted). Drink cup placed in the same bin as (and on top of) unboxed sterile supplies.

Examples of depleted peel-pack stock in the O.R., usually occurring with commonly used instruments. Note that the "Crile" bin also has some dust build up. Cleaning logs for sterile storage carts may need to be initiated.

Examples of peel-pack bins where inventory could possibly be reduced (if their utilization is found to be low) to make room for additional inventory of instruments with higher utilization.

Example preference card. Use red numbers to refer to assessment notes below.



PICKLISTS:
SURGEON:

PATIENT NAME:
SCHED DATE/TIME:
OR SUITE:

SCHEDULED PROCEDURE: :RIGHT HIP ARTHROSCOPY, LABRAL REPAIR, RESECTION OF CAM AND PINCER LESION

c-arm schd with jacob, smith and nephew

ITEM NUMBER	CHARGE QTY	OPEN QTY	HOLD QTY	ITEM DESCRIPTION	MANUFACTURER NUMBER
<Non-Classified>					
171501	____	1	0	1 GOWN SURG RCP ULT XXLG 39933	39933
B-Catheters/Drains/Tubes					
160058	____	0	1	4 TRAY FOLEY 16F DRAIN BAG 861016	861016
B-Custom Packs					
170293	____	1	0	8 PACK ARTHROSCOPY BHS 170293	170293
B-Drapes/Gowns					
19509	____	1	0	1 DRAPE SURG ISOLATION 126X83 3/	6617
24498	____	1	0	1 DRAPE X-RAY C-ARM 27X70IN	4951
B-Dressings					
23326	____	1	0	2 BANDAGE COBAN 4INX5 STRL N/LTX	2084S
19985	____	0	1	2 BENZOIN TINCTURE 2/3CC VL	C1544
10747	____	1	0	2 DRESSING ISLAND 4X8IN TELFA 7541	7541
27593	____	1	0	2 DRESSING STERISTRIP 1/2X4IN R1547	R1547
22936	____	1	0	2 DRESSING TEGADERM 4X4 3/4IN [illegible]W	1626W
53316	____	2	0	PAD ABD SURGIPAD 71/2X8IN ST[illegible] DONT CARRY	9192A
48062	____	1	0	2 PADDING CAST SPECIALIST 4IN SYNTH 30-321	30-321
23594	____	1	0	2 SPONGE CURITY 4X8 STRL 2PK	2259
B-Gloves					
125558	____	1	0	8 GLOVE ESTEEM BLUE W/ NEUTHERA 8 2D73EB80	2D73EB80
138011	____	1	0	GLV SURG PROTEXIS PF STRL 8 2D72PT80X	2D72PT80X
B-Irrigation/Solution					
24092	____	12	0	SOLUTION IRRIGN NACL 0.9 3L	2B7127
B-Other Supplies					
118619	____	1	0	BLADE ARTHRO S&N 4.5MM INCSR PLS CRV 72200494	72200494
118621	____	0	1	BURR ARTHRO S&N 4MM ABRADER LONG 72200080	72200080
118636	____	1	0	CANNULA CLEAR TRAC 8.5X110MM HIP 72200436	72200436
44073	____	0	1	CANNULA TWIST IN 7MMX7CM	AR-6570
68795	____	0	0	ELECTRODE SAPHYRE S&N 60DEG W/ SUCTION	7210113
75469	____	1	0	1 KIT PATIENT CARE PRO FX	6855
24387	____	1	0	8 MAT FLOOR SURG SUCT	34500
27004	____	1	0	2 PAD GROUNDING ADULT 9FT CORD	E7507
125677	____	1	0	2 PAD PERINEAL POSITIONING 72200634	72200634
118615	____	0	1	PROBE CARTILAGE MOPOLAR	7210438
125676	____	1	0	PROBE TAC-S EFLEX BLU	72200681
68488	____	1	0	1 TUBING ARTHRO INFLOW OUTFLOW 10K150	10K150
68384	____	1	0	TUBING PUMP DYONICS INFLOW ONLY 7211004	7211004
27486	____	0	1	2 TUBING SUCT STRL 1/4INX20FT	N620A
B-Prep					
68762	____	1	0	1 PREP CHLORAPREP 26ML APPLICATOR	260815
B-Suture					
27868	____	0	1	SUTURE MONOCRYL 3-0 PS-2 27IN UNDYED Y427H	Y427H
B-Syringes/Needles					
118612	____	1	0	NEEDLE ARTHRO HIP 17G DONT CARRY	7209874
58173	____	0	1	2 NEEDLE HYPO 18GX1 1/2IN SAFETY	8881850815

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0. Item numbers on the product may change, but is usually not updated on the preference card. The main method to make a product description change or item number change is to post a communication note on the wall (see image below).
1. Supply storage is not set up in a logical “track” formation to match the preference card. There are <u>no bin locations</u> on the preference card. The handwritten numbers here are from a seasoned technician who has memorized what aisle they are located on. She will sometimes write in aisle numbers for new technicians who are learning how to pull cases, but only if she has time to do so.
2. Several items are not carried anymore, but remain on the preference card. A new technician pulling/picking cases has no way of determining if an item truly should be selected or not (simply “tribal knowledge”). This is demonstrated in the photo with pink highlights. The highlights are only for demonstration purposes. Preference cards with “don’t carry” items are not highlighted and look like any other item needing to be pulled/picked.

Additionally, there are items on the card that are in stock, but it’s unnecessary to pull them because

they are stored and supplied from other patient care areas when needed. The technicians sometimes end up pulling/picking these items because they are on the preference card, but the items always get returned because they aren't needed. It has been reported that the item remains on the preference card to remind the nursing staff to charge for the item.

3. Related to item #2, "hold" items are pulled in CSPD for the case cart, but a large majority of these hold items are rarely used and have to be returned and re-stocked. It was reported by staff that many of these "hold" items on the preference card already exist in "back-up" supply in the O.R. core as well as in room cabinets (triple redundancy).

Example of wall/poster communication of item conversion. This poster (or similar) is the primary way technicians know that a change has been made to a preference card. Lawson number, item description, manufacturer and reference number on the preference card are typically not updated. If they are updated, it is not in done in a timely fashion.