Testing of routinely sterilized products should be part of a healthcare facility’s quality control program, and ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, recommends that quality assurance testing of routinely processed items be performed on an ongoing basis. The standard provides information on where to place biological indicators (BIs) and chemical indicators (CIs); the placement of packs throughout the load; and criteria for acceptance of test results. However, ST79 does not provide specific information on how to conduct this testing. These decisions are up to the discretion of the individual hospital and depend on what the hospital actually sterilizes.

Resurrection West Suburban Medical Center in Oak Park, IL, used a science-based approach similar to that used in industry for validation of sterilized products. All sterilized items were reviewed and assigned to product families. Master products for each of the product families were identified and used to conduct product quality assurance testing; BIs and CIs were placed in designated locations within the master product. Finally, each sterilizer cart was loaded with the master product in designated locations, while the remainder of the cart was filled in with routinely sterilized product. A sterilization cycle was run with the parameters designated for that product family.

It was decided that product quality assurance testing would be conducted on the following schedule: 1) initial testing would be conducted and then repeated on a quarterly basis for one year; 2) after one year of achieving satisfactory results, testing would be repeated semi-annually for a second year; and 3) if results remain satisfactory at that point then testing would continue to be conducted on an annual basis. Product testing would also be performed when major changes were made in packaging; wraps; or load configuration such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper. The test program includes both BI and CI testing and an evaluation of post-sterilization moisture content (i.e., the occurrence of “wet packs”). A product quality assurance testing protocol was developed and presented to the hospital’s Infection Control Committee for approval.

Program Development
To determine which products could be used as master products, the different products that are sterilized were grouped into product families. Initially, product families were determined by the Central Sterile Processing Department (CSPD) manager and were later refined with input from members of the CSPD. In developing the product families, we looked at various sterilization features, including multiple layers, close tolerances between layers, mated surfaces, accessory items, lumens, density/metal mass of the items, and whether surface contact only was needed or whether the steam needed to penetrate through the material of the device (and potentially packaging) to sterilize it. Packaging was also looked at in determining how to define different product families, and manufacturer recommendations for different instruments and trays were compared to actual practice in the CSPD. All product families were tested with the one standard cycle used in the CSPD.

Once the product families were developed, master products were identified for each product family. Each master product was studied to determine placement of BIs and CIs. These samples were seeded with BIs and CIs placed in difficult-to-sterilize areas (the most resistant to steam penetration) throughout the master product. The product families and subfamilies are outlined with each protocol below.

After both steam sterilization and flash sterilization, testers allowed packs to cool for 30 minutes before opening. After opening, they evaluated the insides of packs/trays to determine if there was any moisture present. If moisture was present, testers determined the cause and repeated the tests after the cause of moisture had been rectified.
CSPD Protocol for Product Quality Assurance Testing

One basic sterilization cycle is run on the steam sterilizers in the CSPD: 270°F, 10 minutes exposure, 20 minutes dry time. Other cycles available on the sterilizers are not normally used and therefore were not tested. Three basic steam sterilization cycles are run in surgery: flash sterilization of a single item, flash sterilization of several instruments, and express sterilization. The flash sterilization cycles are gravity flash cycles while the express sterilization cycles are pre-vacuum cycles.

Seven product families/subfamilies were identified in the CSPD. For each one, testers:

- Ran the designated cycle three consecutive times.
- Checked CIs at end of each cycle and recorded results. All CI results must be positive.
- Incubated BIs per procedure, or sent BIs to test lab, and recorded results after designated time interval. All test BI results must be negative. Control BI results must be positive.
- Investigated any unacceptable results and determined cause of problem. Based on analysis, changes were made in product design, loading configuration, or test protocol and either tests were rerun or sterilization of the product with the problem features was stopped.

Specific details of the product families/subfamilies are as follows:

**Peel Pouches with Instruments:** small quantities of instruments packaged in a plastic or metal tray with a lid; the tray is then placed in a paper-plastic peel pouch that is sealed for sterilization. This product family is represented by placing two instruments in a micro-instrument tray with a mat and lid. The tray is then placed in the pouch and sealed.

- Before placing the microtray inside the peel pouch, place BI and one CI inside the microtray.
- Place five pouches in the following locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

**Genesis Sterilization Containers:** basic surgical instrument trays that contain numerous hand-held surgical instruments. Items may be wrapped in a towel, and/or packed in a paper/plastic peel pouch. The tray is packaged in a rigid sterilization container. This product family is represented by a minor tray with the retractors wrapped in a towel and the tissue forceps placed in a sealed peel pouch.

- Place six BIs and six CIs in designated locations within the master product.
- Place five trays in the following locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

**Wrapped Instruments (subfamily: procedure tray):** basic surgical instrument trays that may contain additional accessories such as basins and towels. These trays have an open top and are wrapped with a spun-bonded poly-olefin two-ply wrapper. This product family is represented by a vaginal delivery tray.

- Place six BIs and six CIs in designated locations within the master product.
- Place five trays in the following locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

**Wrapped Instruments (subfamily: implant tray):** implant trays containing screw/plate cases and possibly additional instrumentation. These trays may have a lid that is closed. The tray and its container are then wrapped with a two-ply spun-bonded poly-olefin wrapper. This product family is represented by implant trays containing screw/plate cases.

- Place six to seven BIs and six to seven CIs in designated locations within the master product. Dry spore strips are used for areas where the tolerances do not permit placement of a self-contained BI without damage to the BI.
- Place three trays in the following locations: one end of top layer, opposite end of bottom layer, and center of middle layer of carriage. In subsequent cycles trays will be moved so that test trays are also placed at the top and bottom locations that were not covered in the first cycle of tests. After completion of tests at least one tray should have been sterilized in one of the cycles in each of these locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

**Wrapped Instruments (subfamily: complex orthopedic tray):** three layers with molded forms for the
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Placement of instruments with a lid that locks into place. The tray and its container are wrapped with a two-ply spun-bonded poly-olefin wrapper. This product family is represented by simulated instrument trays.

- Place nine BIs and nine CIs in designated locations within the master product (see Figure 1). Dry spore strips are used for areas where the tolerances do not permit placement of a self-contained BI without damage to the BI.

- Place three trays in the following locations: one end of top layer, opposite end of bottom layer, and center of middle layer of carriage. In subsequent cycles trays will be moved so that test trays are also placed at the top and bottom locations that were not covered in the first cycle of tests. After completion of tests at least one tray should have been sterilized in one of the cycles in each of these locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

Wrapped Instruments (subfamily: power instrumentation): power instrumentation in a metal case with a locking lid, wrapped with a two-ply spun-bonded poly-olefin heavy duty wrapper. This product family is represented by the Stryker 5000 and Stryker 4100.

- Place eight BIs and eight CIs in designated locations within the master product. Dry spore strips are used for areas where the tolerances do not permit placement of a self-contained BI without damage to the BI.

- Place three trays in the following locations: one end of top layer, opposite end of bottom layer, and center of middle layer of carriage. In subsequent cycles trays will be moved so that test trays are also placed at the top and bottom locations that were not covered in the first cycle of tests. After completion of tests at least one tray should have been sterilized in one of the cycles in each of these locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

Wrapped Instruments (subfamily: basin sets): basin set with smaller basins nested inside larger basins, towels used as wicking material between basins and wrapped in a two-ply spun-bonded poly-olefin wrapper.

- Place one BI and one CI between each layer of the basins for a total of four BIs and four CIs. Due to close tolerances (mated surfaces) between basin layers, dry spore strip BIs are used.

- Place five basin sets in the following locations: both ends of top layer, both ends of bottom layer, and center of middle layer of carriage.

Results/Conclusions for CSPD Steam Sterilizers
Product quality assurance testing was conducted on the CSPD sterilizers in fall 2007. All BI and CI results for CSPD steam sterilizers designated were acceptable as outlined in the protocol for:

- Peel pouches with instruments: both CSPD steam sterilizers.
- Genesis sterilization containers: both CSPD steam sterilizers.
- Wrapped instruments (subfamily: basin sets): in steam sterilizer 2.
- Wrapped instruments (subfamily: procedure tray): both CSPD steam sterilizers.
- Wrapped instruments (subfamily: power equipment): both CSPD steam sterilizers.

No problems were noted with moisture in the packs. Therefore all products identified as belonging to these product families were approved for sterilization in the CSPD sterilizers with the following parameters: 270°F, 10 minutes exposure, 20 minutes dry time.

Figure 1. Placement of BIs and CIs in a complex orthopedic tray.
Initial testing of the Wrapped Instruments (subfamilies: implant tray, basin sets, and complex orthopedic tray) revealed some problems with moisture being present either on the outside of the wrapper, inside the tray, or in the towel under the tray. These issues were investigated and it was determined that the problems were caused by operator error. In some cases sterilization containers had been placed on top of the wrapped trays and trays had been moved from the sterilizer cart prior to completion of the cool-down period. In cycles where these operator error issues did not exist, there were no problems. All employees were retrained in proper unloading of steam sterilizer procedures. BI and CI results were acceptable for these product families/subfamilies and all parameters were met during the sterilization cycles.

Initial testing of the Wrapped Instruments (subfamily: complex orthopedic tray) revealed 17 positive test BI results on the early read out of the BIs. After 48 hours incubation of the BIs, only one BI showed a positive visual result. Upon removal from the product many of the test BI vials were misshapen and the caps barely depressed when the vials were activated. It was theorized that due to close tolerances, the BIs had been damaged during the sterilization process. These tests were rerun using dry spore strips instead of self-contained BI vials. Subsequent results showed all test BIs to be negative and all test CIs to be positive as they should be. All cycle parameters were also acceptable in these cycles.

Based on results of the investigations and repeated testing, these product families/subfamilies were accepted for sterilization in the CSPD sterilizers with the following parameters: 270°F, 10 minutes exposure, 20 minutes dry time.

Operating Room Steam Sterilization Protocol for Product Quality Assurance Testing
There are three basic steam sterilization cycles that are run in surgery: gravity flash sterilization of a single item, gravity flash sterilization of several instruments, and express sterilization. Five product families have been identified in the operating room. The testing followed the same parameters noted above; specifics to each family are noted.

  • Place a BI and CI in the tray as representative of the product family.
  • Sterilize the tray at 270°F, 3 minutes exposure, 0 to 1 minute dry time.

Gravity Flash Sterilization of Multiple Instruments: multiple instruments in an unwrapped, open sterilization tray.
  • Bury a BI and a CI among the instruments in the tray.
  • Sterilize the tray at 270°F, 10 minutes exposure, 0 to 1 minute dry time.

Express Sterilization of Peel Packed Items: two single hand-held instruments placed into a peel pouch and then the pouch is sealed.
  • Place a BI and a CI in the peel pouch with the instruments prior to sealing the pouch.
  • Sterilize the peel pouch at 270°F, 4 minutes exposure, 3 minutes dry time.

Express Sterilization of Wrapped Instrument Tray with Lid: an eye instrument tray with the lid closed. This tray is wrapped with a single ply of light weight spun bonded poly-olefin wrapper.
  • Place three BIs and three CIs in designated locations in the tray. The lid is closed and the tray is wrapped.
  • Sterilize the tray at 270°F, 4 minutes exposure, 3 minutes dry time.

Express Sterilization of Complex Orthopedic Tray: a three-layer complex, plastic molded orthopedic tray without a lid. This tray is wrapped with light weight single-ply spun bonded poly-olefin wrapper.
  • Place nine BIs and nine CIs within the contents of the tray, three on each layer.
  • Sterilize the tray at 270°F, 4 minutes exposure, 3 minutes dry time.

Results/Conclusions for OR Steam Sterilizers
The initial round of product quality assurance testing of the OR steam sterilizers was conducted in summer 2007 with a second round that fall. A series of three replicate cycles for each of the different types of cycles that are used for sterilization of actual products were run in each of the OR steam sterilizers. The following results were obtained for all of the steam sterilizers in the OR:
  • All sterilization parameters on the three-minute flash sterilization cycle for a single unwrapped

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item were within acceptable limits.

- All test BI results for three-minute cycles were negative and all test CI results were positive.
- All sterilization parameters on the 10-minute flash sterilization cycle for an unwrapped instrument tray were within acceptable limits.
- All test BI results for the 10-minute cycles were negative and all test CI results were positive.
- All sterilization parameters on the express sterilization cycle for peel pouched instruments were within acceptable limits.
- All test BI results for the express sterilized peel pouched instruments were negative and all test CI results were positive.
- All sterilization parameters on the express sterilization cycle for wrapped eye instrument tray were within acceptable limits.
- All test BI results for the express sterilization cycle for wrapped eye instrument tray were negative and all test CI results were positive.
- All sterilization parameters on the express sterilization cycle for wrapped complex orthopedic instrument tray were within acceptable limits.
- All test BI results for the express sterilization cycle for wrapped complex orthopedic instrument tray were negative and all test CI results were positive.
- All control BI results were positive.

Since all product quality assurance test results were acceptable, these sterilizers are acceptable for sterilization of all of these product families.

Conclusion

New and loaner instrumentation will be evaluated against the product families identified. If possible, these instruments will be assigned to one of the established product families. If this is not possible, a new product family will be defined and this instrumentation will be used as the master product for testing of the new product family. When new or loaner instrumentation is assigned to an existing product family, the new product will be evaluated to determine if the master product used for testing covers this new product. If the current master product does not cover the new product, then testing will be repeated using the new product as the master product. Testing will also be repeated under the following circumstances:

- when major changes are made in packaging; wraps; or load configuration such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper. Other changes in product will be evaluated to determine if and the extent of product quality assurance testing that will need to be performed. In some circumstances a paper analysis of the changes may be adequate without repeating of actual test cycles.

Donna Swenson, BS, CSPDM, CRCST, CHL, has been actively involved in the industrial and healthcare sterilization/sterile processing fields for many years. She is currently the co-chair of AAMI’s Industrial Moist Heat Sterilization Committee and is one of the U.S. delegates to ISO/TC 198WG3 Moist Heat Sterilization of Medical Devices. Swenson also serves on several other AAMI committees. She is the central sterile processing manager for Resurrection West Suburban Medical Center in Oak Park, IL. She also serves as adjunct faculty for the Resurrection Learning Institute.