CRCST SELF-STUDY LESSON PLAN

LESSON NO. CRCST 121
(Technical Continuing Education-TCE)

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LEARNING OBJECTIVES:

1. Explain the difference between product validation and verification
2. Tell when product testing is necessary
3. Discuss how to create product families
4. Review procedures to test the cleaning process
5. Review procedures to test the sterilization process

Yesterday's Central Sterile Supply Department (CSSD) technicians spent much of their time cutting and rolling bandages, and cleaning and sterilizing gloves, bedpans and reusable needles and syringes. Their counterparts today process laparoscopes, robotic instrumentation, neurological cages, and complex loaner instruments used in all surgical specialties. In addition to the ever-increasing complexity of instrumentation, many types of microorganisms are becoming more resistant and difficult to kill. These and other trends have brought the priority of product testing to the forefront of our profession.

As with all CSSD processes, the need to correctly perform product testing is extremely important. This lesson reviews basic protocols that should be incorporated in the product testing procedures used by all healthcare facilities.

Objective 1: Explain the Difference between Product Validation and Verification

Product testing is of two types: validation is done by the manufacturer to establish evidence with a high degree of assurance that a product complies with a regulation, specification or conditions that were imposed at the start of the product's development phase. In other words, validation is done to confirm that the product is functioning as it was designed to function and complies with the FDA 510(k) submission requirement. Note: A 510(k) is a premarket (before-market) submission from a manufacturer to the U.S. Food and Drug Administration. Its purpose is to demonstrate that a device to be marketed is at least as safe and effective as (substantially equivalent to) a legally marketed device that is not subject to premarket approval for manufacture.

The manufacturer's validation covers all phases of the product handling process, including cleaning, testing and sterilization. It also includes sterilization testing utilizing half-cycles, confirming a sterility assurance level of 10^{-6} sterilant concentration, and meticulously documenting all phases of the testing process. In almost all healthcare facilities, complying with these testing parameters is, at best, very difficult and probably impossible.

In contrast to validation by the manufacturer, verification is a hospital-based process of establishing evidence that provides a high degree of assurance that a product accomplishes its intended requirements at the specific facility. Its purpose is to ensure the vendor-documented results can be obtained in that CSSD. For example, can a specific tray validated by the manufacturer to be sterilized in the four-minute cycle be sterilized in that cycle with the facility's sterilizers?

Objective 2: Determine When Product Testing is Necessary

The need for product testing should be strongly considered when evaluating new types of instrumentation if they differ significantly from those currently being processed. Testing should be done during product evaluation prior to purchase to avoid obtaining a product that cannot be effectively cleaned and sterilized within the facility.

Testing should be done periodically on routinely-processed reusable sets. Testing should also be performed when changing packaging materials, and new container systems most certainly should be thoroughly tested prior to purchase. When changing types of flat wrappers or peel packaging products, it is important to retest the sterilization process to confirm that the results are the same as those that occur with the previously used products.

Manufacturer's changes from the FDA-approved Instructions for Use (IFU) may also trigger product testing, depending on the types of changes made, such as changes

in the cleaning process or the product's sterilization parameters.

Installation of new decontamination and sterilization equipment, or major repairs done to existing decontamination and sterilization equipment require that the equipment be tested before it is placed into service.

CSSD personnel should not permit reconfiguration of a manufacturer's organized instrument set, such as screw and plate sets or orthopedic loaner sets. Doing so will require that the set be revalidated by the manufacturer because it no longer matches the set configuration submitted to the FDA.

Testing should occur whenever there is any doubt about the effectiveness of the cleaning and sterilization process. The facility's Infection Control and Prevention Committee should be actively involved in determining the need for and frequency of product testing.

Objective 3: Discuss How to Create Product Families

Because it is not possible to test every reusable item processed in a CSSD, product families can be created and tested. Family items should be similar in nature, such as lumened instruments or orthopedic reamers and graters. Families can also be instrument sets for the same surgical specialties, such as cardiothoracic, orthopedic, neurology, and general.

After product families are selected, each set within each family should be evaluated for complexity of instrumentation and required decontamination and sterilization processes. The most difficult-to-clean sets should be selected for verification of the cleaning process.

Examples of these sets include instruments with small, long lumens and multiple-piece instrumentation, such as flexible endoscopes and laparoscopic instrumentation that cannot be completely disassembled. Instruments with small crevices or serrations or other difficult-to-reach areas should also be evaluated, as should instruments that require manual cleaning with no additional mechanical cleaning.

The most difficult sets to sterilize in each type of sterilization process should be selected for sterilization verification. These sets include complex instruments, such as flexible endoscopes, power equipment and multiple-part instrumentation that cannot be completely disassembled. Sets containing instruments with small lumens or sets requiring extended sterilization cycles should also be considered.

Objective 4: Review Procedures to Test the Cleaning Process

Product verification requires that the facility's testing process be very carefully followed. Before the testing process begins, ensure that there are sufficient amounts of the recommended cleaning chemicals that will be needed. A meeting with laboratory personnel is essential if some instrumentation will need to be sent to the laboratory for culture to verify bioburden reduction as a result of the cleaning process.

The cleaning verification process requires that the Manufacturer's IFU be carefully followed as the instruments are cleaned. CSSD personnel should document each step in the cleaning process, including use of the required chemicals in the proper concentration and for the soak times required for manual cleaning. If mechanical cleaning is done, it is important to document the cycles utilized, the times in each phase of the cycle, the chemicals and chemical concentrations used, and the temperatures of each phase in the cycle.

As soon as the cleaning process is complete, test the most difficult-to-clean instruments in the set with the selected testing product. Culture swabs should be obtained from areas of the instrument that the commercial product cannot reach, such as the center of long lumens or inside the casing of some power surgical instrumentation.

Handle the culture swabs carefully to prevent cross contamination. For example, ensure swabs do not touch the sides of the culture tube while placing them inside the tube.

Swabs should be immediately sent to the laboratory for culture. In some instances, it may not be possible to safely swab the instruments without potentially contaminating the swab. Then the instruments themselves may need to be protected while being transported to the lab to obtain the culture swabs. When sending instruments to the lab for testing, be sure to protect them from contamination by placing them inside a pre-sterilized transport container, such as a flash pan.

Some commercially-prepared test materials may also require lab processing in compliance with the manufacturer's instructions. Procedures for transporting them include protecting the instrument in a pre-sterilized container or placing the test product inside of vendor-provided transport envelopes.

There are no current benchmark standards for acceptable levels of bioburden after cleaning; however, the desired testing results are a reduction of soil and microbes to levels that are safe to handle.

The testing process should be repeated at least three consecutive times with desired results for a successful test process. When repeating this process, ensure that the same type of instrumentation is utilized for the tests. If the desired results are not obtained, the cleaning and testing processes should be reviewed and, if necessary, the manufacturer should be contacted for more information and guidance.

Objective 5: Review Procedures to Test the Sterilization Process

Just as with testing for the cleaning processing, the facility's testing procedures and the manufacturer's IFU for sterilization must be very carefully followed.

Before beginning the sterilization testing, ensure that there are sufficient quantities of biological indicators (BIs), chemical integrators (CIs), and sterilant, if applicable. Biological indicators may need to be purchased in glassine packages, not the customary ampules, because the ampules cannot be placed into small areas such as lumens. Chemical integrators should be Class 3 or higher to properly monitor the sterilization process.

Laboratory personnel should be consulted as some instruments may need to be inoculated with cultured spores in areas where the biological ampule or the glassine spore strips cannot be placed.

Begin the sterilization verification process after the instruments have been properly cleaned and assembled. Note: These instruments may be the same instruments used in the cleaning process or they may be instruments that are easier to clean, but difficult to sterilize per the manufacturer's IFU. Place the BIs and CIs throughout the tray as follows:

Continued

- Instrument sets (wrapped)
  - In the most difficult area of the set for the sterilant to reach
  - In the densest part of the instrument set
  - At opposite ends of the tray
  - Among the instruments placed on stringers
  - Inside lumens
- Instrument sets (containers)
  - In the most difficult area of the set for the sterilant to reach
  - Each corner and in the center of the container
  - In the densest part of the instrument set
  - Among the instruments placed on stringers
  - In other areas recommended by the container's manufacturer
  - Inside lumens
- Instrument sets (vendor multi-layered)
  - In any area determined by the manufacturer to be the greatest challenge to the sterilization process
- Basin sets
  - Do not use BIs in the ampule because the ampule will increase the space between the basins and permit more steam penetration.
  - Place glassine-packaged BIs and CIs in the areas where air pockets could form

Document where each BI and CI is located within the set. Place completed sets on a sterilization cart. The sets should be placed in various areas of the sterilizer carriage or chamber along with other instrument sets in such a way that the contents are representative of a normal load. Sterilize the load using the cycle program recommended by the manufacturer.

When the cycle is complete, allow the items to cool properly. Remove the test items from the sterilizer's carriage or chamber. If the sets contain items inoculated with a cultured spore, do not open the set until someone is available to swab the inoculent for culture to avoid contamination by the air in the room or by personnel accidently touching the products.

Process the BIs following the manufacturer's recommendations. BIs should be incubated the entire recommended time (24-48 hours), and rapid readings that give 1- to 3-hour readings should be used as a guide only. Glassine-packaged BIs should be aseptically transferred to the transport envelope and delivered to the laboratory to be processed.

Each step of the sterilization process should be documented, including the type of sterilizer used, cycle run, length of each cycle phase, and type of BI and CI used. The CI results should be also be documented.

The sterilization testing process should be repeated at least three consecutive times utilizing the same instrumentation. Meticulous cleaning should occur between tests. Results are considered successful when all biological indicators are negative for growth.

Conclusion

With today's complex instrumentation and the increasing need to turn instrumentation around quickly, it is important for CSSD personnel to know they are providing clean, sterile instruments to the Operating Rooms. Product testing is necessary for this assurance. Even though testing is time-consuming and expensive, it is necessary to help ensure the consistently best outcomes for our patients.

References

ANSI/AAMI ST79:2010 & A1:2010 Section 7.5

ANSI/AAMI ST79:2010 & A1:2010 Section 10

ANSI/AAMI ST79:2010 & A1:2010 Annex D

IAHCSMM Central Service Technical Manual. Seventh Edition Chapters 9, 11, 12, and 15

Young, Martha. *Verification, Validation: What's the difference?* OR Manager Vol. 27, No. 03. March, 2011.

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Quiz No. CRCST 121 (CIRCLE THE CORRECT ANSWER)

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Objective 1

1. Validation testing is done in a facility's CSSD department.
   a. True
   b. False

2. When are manufacturers required to validate medical devices?
   a. Before FDA approval
   b. Annually
   c. Every five years
   d. A and C

3. The purpose of a 510(k) is to demonstrate that a device to be marketed is substantially equivalent to:
   a. Other instruments developed by the manufacturer
   b. All other instruments in the marketplace
   c. Legally marketed devices not subject to market approval
   d. Any device that costs no more than device covered by the 510(k)

Objective 2

4. Product testing should occur
   a. During the evaluation period before new product purchase
   b. After changes to FDA-approved Instructions for Use
   c. Before installing new decontamination and sterilization equipment
   d. All the above

5. Product testing should be done _____ product evaluation.
   a. Before
   b. During
   c. After
   d. A and B above

6. It is acceptable to reconfigure the contents of orthopedic loaner sets as long as the set has been cleared by the FDA.
   a. True
   b. False

7. Changes in the manufacturer's Instructions For Use (IFU) always require product retesting.
   a. True
   b. False

Objective 3

8. Instrument sets with small lumens and complex instruments should be selected for testing.
   a. True
   b. False

9. Which is true about a product family?
   a. Instruments should be similar in nature
   b. Instruments should be from the same manufacturer
   c. Instruments should be those with which CSSD personnel have processing experience.
   d. None of the above is correct

10. It is not necessary to test instruments requiring extended sterilization cycles.
    a. True
    b. False

11. Which factor is <u>not</u> a reason for product testing?
    a. Complex instruments
    b. Change in purchasing group
    c. Change in packaging material
    d. Multiple-part instruments

Objective 4

12. The cleaning product testing process should
    a. Comply with the manufacturer's Information For Use (IFU) document
    b. Be performed by persons trained by the manufacturer
    c. Be done in the Operating Room immediately after the item is used
    d. All of the above are acceptable

13. What should be done if it is not possible to safely swab instruments without potentially contaminating the swab?
    a. A different instrument should be tested
    b. A manufacturer should be contacted for suggestions
    c. The FDA should be contacted
    d. Instruments should be transported to the lab for culture swabs

14. Which is true about benchmark standards for acceptable levels of bioburden?
    a. They have been developed by FDA
    b. They must be developed by the manufacturer
    c. Standards of The Joint Commission should be used
    d. None of the above

15. How many times should the testing process for cleaning be repeated with desired results for the test to be considered successful?
    a. Two
    b. Three
    c. Four
    d. Five

16. Documentation for cleaning process testing should include the
    a. Type and concentration of chemicals used
    b. Washer cycle utilized
    c. Instrument soak time
    d. All the above

Objective 5

17. Product sterilization testing should include
    a. BIs and CIs
    b. Manufacturer's Instructions for Use (IFU)
    c. Staff in-service sessions
    d. A and B above

18. In what form should biological indicators normally be used for sterilization testing?
    a. Glassine packages
    b. Ampoules
    c. Both of the above
    d. Special FDA packaging

19. The instruments used for cleaning testing should not be used for sterilization testing.
    a. True
    b. False

20. BIs should be placed
    a. Randomly throughout the tray
    b. Outside the sterilization wrap
    c. Among the instruments placed on stringers
    d. All of the above

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