Proper use of chemical and biological indicators; SPD ceiling requirements

By ***Ray Taurasi*** - February 20, 2017

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Q I am a CRCST and work at two different hospitals; one is just a part time position. One facility says if the chemical indicator fails but the BI passes then it's OK to release the load. I strongly disagree with this practice but since I have nothing in writing, the manager says he sees no reason to change their practice. We do follow AAMI standards but I still need some clarification on this issue.

A As you know chemical indicators are just one of the tools used to verify the efficacy of the sterilization process. Other tools include administrative, and mechanical. Administrative controls include supervision, documentations, policies, procedures and the like. Mechanical controls are devices which monitor and record the mechanical performance of the sterilizer through the cycle including, temperature, and time. Chemical and biological indicators are considered process controls which mean they tell us that a package has been exposed to some parameter(s) of the sterilization process. There are six different classes or types of chemical indicators which provide information relative to the sterilization process.

- **Class 1**—This process indicator demonstrates only that the item has been exposed to the sterilization process. An external process indicator (e.g., autoclave tape, indicator labels) is intended to visibly distinguish processed from unprocessed packages. It does not establish whether the contents are sterile or if the adequate sterilization parameters have been achieved. Generally, external process indicators are not sensitive enough to determine whether the inside of the package or its contents have met the performance requirements necessary for sterilization.
- **Class 2**—this indicator is designed for specific performance tests, such as the Bowie-Dick test, which assesses steam penetration and air removal within the sterilizer chamber.
- **Class 3**— is a single parameter indicator that only responds to one of the critical parameters required for a specific sterilization process. For example, steam sterilization has three parameters: saturated steam, time, and temperature. The class 3 indicator may only respond to one of these parameters such as temperature or steam. The manufacturer of the indicator must specify the parameter and clearly indicate this on the product labeling.
- **Class 4**—is a multi-parameter indicator and is designed to react to two or more of the critical parameters. It indicates exposure to a sterilization cycle at stated values.
- **Class 5**—is an integrating indicator which is designed to react to all required parameters of a particular sterilization process and at a greater than specific range. The performance and confidence level of an integrator is compared to the inactivation of a test organism.
- **Class 6**—is an emulating indicator which is designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specific sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.

All chemical indicators and biological indicators must be utilized in accordance with the device manufacturer's instructions for use. Any package with a failed chemical indicator should not be used. The cause for the failed chemical indicators should be investigated. If the failure seems to be isolated to the one package then possible causes might include product defect, inappropriate placement or use in package, and inadequate exposure.

Biological indicators are actual challenge control devices which verify that a sterilization cycle achieved all parameter requirements to destroy all viable living organisms including spores, which are contained in the BI.

Prior to the release of the contents of a sterilization load, all monitoring controls, administrative process and mechanical should be assessed to ensure they have satisfactorily met performance requirements.

It is important to note that a passed chemical and or biological indicator does not guarantee that all contents are sterile. These devices do ensure that if contents were adequately cleaned, prepared, inspected, and packaged in accordance with policies, procedures and manufacturer's IFUs then the sterilization process was adequate to achieve sterility.

Q Like many sterile processing departments we are located in the bowels of the oldest part of the hospital. We have outgrown the space that we have and need additional space to hold sterile supplies and instrument sets for case cart assembly. We have been given some additional space in a room across the hall which was previously used to store old, obsolete furniture and equipment. They painted the walls and resurfaced the floors but the ceiling is mostly open with exposed pipes, electrical wiring, and duct work. I asked that the entire ceiling be enclosed but was told that was unnecessary and the cost would be prohibitive, especially since we would likely be moving to another area in the future. There has been some discussion of moving us to a new space in

the next phase of the building project. The building project hasn't even been approved yet so any move will be a year or two away. Can you provide any documentation or advice that could support me in convincing the powers that be that we need to address the ceiling issue?

A Your concerns relative to an open and exposed ceiling are legitimate; such conditions are not acceptable for a sterile storage holding area. A finished ceiling with enclosed fixtures limits condensation, dust accumulation, and other possible sources of contamination, which could compromise the sterile integrity of sterilized packages. This of course could pose a very serious risk to patient care and safety resulting in nosocomial infections. It is imperative that the room be maintained in the highest degree of cleanliness, and be restricted to traffic and appropriate personnel. The same conditions that apply to an operating core should be enforced in sterile processing. AAMI standards for the design and maintenance of a sterile storage area state: "Processing area ceilings should be constructed to create a flush surface with recessed, enclosed fixtures. Pipes and other fixtures above work areas should also be enclosed. Ceilings should be constructed of non-particulate, non-fiber-shedding materials."

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