

Center for Medicaid and State Operations/Survey & Certification Group

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DATE: September 4, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Flash Sterilization Clarification - FY 2010 Ambulatory Surgical Center (ASC) Surveys

*****Memo revised to correct regulation citation and contact information*****

Memorandum Summary

Flash Sterilization Clarification: State survey agencies (SAs) using the new survey process in FY 2009, including completing the Infection Control Surveyor Worksheet, have experienced challenges in evaluating use of “flash sterilization” by ASCs. Attachment 1 clarifies what this term means, and how to distinguish appropriate from inappropriate use of flash sterilization.

Background

We are clarifying the issue of the Infection Control Surveyor Worksheet and flash sterilization. This is an area in which technological changes require changes in the way surveyors assess compliance of sterilization practices in ASCs. Attachment 1 is a set of bullets the Centers for Medicare & Medicaid Services (CMS) has developed with assistance from the Centers for Disease Control & Prevention and the Food and Drug Administration. They have been informally distributed to FY 2009 ASC-HAI volunteer SAs, and will be reviewed at the October 20-22 surveyor training.

Questions concerning this memorandum should be addressed to Marilyn Hanchett at Marilyn.hanchett@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

“Flash” Sterilization & ASC Surveys

In reviewing some of the ASC Infection Control Surveyor Worksheets submitted by States that have voluntarily implemented the new survey process in FY 2009, CMS has noted that issues concerning the use of “flash” sterilization in ASCs need some clarification. Please note that the Surveyor Infection Control Worksheet does not use the term “flash sterilization.” However, question E in the sterilization section of the Worksheet is the pertinent question related to this issue, and some surveyors have entered comments referring to observing flash sterilization.

After consulting with the CDC and FDA, we are providing the following interim guidance about flash sterilization. Please pass this information on to your surveyors. This subject will be addressed in more detail at the October ASC training, but it is important enough that we want to ensure that the States using the infection control surveyor worksheet on a voluntary basis in FY 09 receive clarification as soon as possible.

It is crucial that everyone have a common understanding of what is meant by “flash” sterilization, since there have been technological changes that require a more nuanced understanding of this term. Flash sterilization has traditionally referred to a very short sterilization cycle for a very small and unwrapped load. One of the major concerns with this process has been that, because the load was unwrapped, the sterility of the device could not be maintained after it was removed from the sterilizer. However, as sterilizers have improved their ability to allow for steam penetration, it has become possible to effectively sterilize wrapped or “contained” (e.g., in specialized metal containers, pouches or cassettes) loads in short cycles.

Sterilization of unwrapped/uncontained loads should not be routine practice in ASCs but should be used only for an urgent and unpredicted need for a specific device (e.g., when an instrument is dropped). Routine sterilization of unwrapped/uncontained loads continues to be inappropriate and should be cited as a violation of **42 CFR 416.51(a)**.

Utilization of a short sterilization cycle of a wrapped/contained load may no longer be a concern so long as the ASC is following ALL manufacturers’ instructions for the devices involved. To determine whether the ASC (that employs a short sterilization cycle on a routine basis) is properly doing so, a number of factors must be considered. All sterilizers that have been cleared by FDA to run short cycles have been validated by their manufacturers to perform effectively in those cycles for defined validation loads. The critical determinants in determining whether a sterilization cycle is likely to be effective are found in the manufacturer's instructions for the various devices involved.

Surveyors should utilize the following questions to assess the appropriateness of the ASC’s sterilization practices:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?

4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?

If an ASC is *properly* using short sterilization cycles for wrapped/contained loads, then it should not be cited for a violation of the ASC infection control requirements.

Note the emphasis on the manufacturer's instructions for use, which have been validated by the manufacturer and reviewed and cleared by FDA. Unfortunately, many facilities are not aware of and do not necessarily follow the manufacturer's instructions. Following the manufacturer's instructions is critical, especially for short sterilization cycles. It takes time for steam to penetrate a sterilizer load and to achieve an acceptable sterility assurance level (SAL), which is typically 10^{-6} . The weight and complexity of the materials in the load, the presence or absence of fabric, the presence or absence of lumens, etc. will influence outcome. Loads in short cycles must comply with the sterilizer manufacturer's instructions. If loads do not comply (e.g., too heavy, too complex, etc), sterility cannot be assured.

If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC's practices should be cited as a violation of [42 CFR 416.51\(a\)](#).

Of course, no item can be successfully sterilized if it has not first been thoroughly cleaned, so surveyors should also observe whether adequate pre-cleaning is being performed with water and detergent or water and enzymatic cleaners prior to sterilization. Cleaning can be either manual or mechanical.

If further questions arise please do not hesitate to email Marilyn.hanchett@cms.hhs.gov.