Routine Biological Control Spore Testing of Autoclave Units

Policy Objective: To describe \the requirements for spore testing and the procedure for handling a positive spore test result.

Background: Biologic spore test products vary, and are designed for use based on specific autoclave type. The usual autoclaves found on site include: steam sterilizers, Ethyl Oxide sterilizers, or dry-heat sterilizers. Biologic control testing challenges the sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile.

Autoclaves will be maintained according to manufacturer's guidelines. If the manufacturer's guidelines are not present on site, a qualified technician will service the autoclave annually. A dated sticker on the autoclave or a service receipt is acceptable documentation of appropriate maintenance.

Procedure:

1. Spore testing of sterilization loads must be completed at least monthly, but may be run more often depending on procedures performed at the site.

2. Specific spore test must be used according to the manufacturer's recommendation and must be appropriate to the type of autoclave that is being tested.

3. If a positive test occurs, the autoclave must be taken out of service immediately until an inspection is completed and a negative retest occurs.

4. Appropriate actions for a positive spore test are:
   a. **R**eport the problem
   b. **R**epair/service the autoclave
   c. **R**etrieve **all** instruments sterilized during the positive spore test timeframe, this includes all instruments sterilized since the last negative spore test
   d. **R**etest the autoclave, confirm a negative test
   e. **R**e-sterilize all retrieved instruments

5. Documentation of all biological spore testing is to be maintained to include:
   a. Date of test
   b. Test results
   c. Type of spore test used
   d. Person performing/documenting test results.
   e. Actions taken for any/all positive spore tests

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