AUTOCLAVE VERIFICATION AND VALIDATION FOR SURVIVAL SURGICAL EQUIPMENT

Overview/Purpose

In accordance with the Guide, “sterilization methods should be selected on the basis of the physical characteristics of the materials to be sterilized and sterilization indicators should be used to validate that materials have been properly sterilized. “ The purpose of this policy is to ensure verification and validation when an autoclave is the selected method of sterilization for survival surgery equipment or instruments.

Moist heat in the form of saturated steam under pressure is the most widely used and dependable method of sterilization. Moist heat destroys microorganisms by the irreversible coagulation and denaturation of enzymes and structural proteins.
Temperatures in the range of 121°-132°C (250° - 270°F) must be maintained for a minimal time to kill microorganisms. Steam sterilization is nontoxic, inexpensive, rapidly microbicidal and sporicidal.

Definitions

1. **Verification** - Verification of autoclave function includes the use of chemical control indicators (e.g. autoclave tape or steam or autoclave indicator strips) to ensure the appropriate temperature has been reached during the cycle.

2. **Validation** - Validation of autoclave function includes the use of biological controls (e.g. Verify®, 3M™ Attest™) to confirm lack of microbial growth. Biological controls use heat resistant microorganisms to determine the effectiveness of steam sterilization. Biological controls are sensitive and accurate and require a period of incubation to validate the effectiveness of the autoclave cycle.

Requirements

1. A chemical control indicator must be used for verification of all items being sterilized for survival procedures or surgeries. Chemical control indicators provide instant notification of failures to reach the required autoclave cycle temperatures.
    a. A chemical control indicator must be present on the outside package of all items being autoclaved. Most surgical peel pouches have a built-in chemical control indicator.
    b. An additional chemical control indicator must be present on the inside of surgical packs prior to autoclaving to ensure adequate steam penetration.
    c. The autoclave date must be present on the outside package or pouch.
    d. Unused autoclaved items must be resterilized within 1 year from the date of initial sterilization, or if the outer covering is compromised.
    e. If chemical control indicators fail to reach the required autoclave cycle temperature, items must be resterilized prior to use.

2. Autoclave validation must be performed semiannually.
    a. Documentation of semiannual validation must be available and accessible for review.

Applicable Regulations

1. Animal Welfare Act Regulations (AWAR, 9 CFR, Chapter 1, Subchapter A)
2. Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals
3. National Research Council *Guide for the Care and Use of Laboratory Animals,* Eighth Edition. National Academy of Sciences, 2011
4. The Federation of Animal Science Societies *Guide for the Care and Use of Agricultural Animals in Research and Teaching*

Additional Information/Guidance

1. Fox, James, et al. Laboratory Animal Medicine 2nd edition. Academic Press 2002.
2. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
3. http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html

History of Revisions

050-00 - new policy approved 10/18/13
050-01 - revised to clarify verification and validation, the requirement for initials to be included on the outside package of autoclaved items was removed, unused autoclaved items must be resterilized within one year; approved 11/18/16