Monitoring of Steam Autoclaves Used for Surgical Instrument Sterilization

PURPOSE
Survival surgical procedures in animals require the use of sterile surgical instruments (1, 2, 5). The use of a steam autoclave is one approved sterilization method. The purpose of this standard operating procedure is to provide guidance on appropriate monitoring and servicing of the steam autoclave used to sterilize instruments and devices used in survival surgeries or other percutaneous procedures. Autoclave monitoring is an essential component of quality control for steam autoclave performance and is important to prevent surgical-induced infections (3, 4, 7, 8). The use of sterile instruments for survival surgeries is an expectation of NIH/OLAW (1). The procedures outlined below do not apply to monitoring procedures for autoclaves used for biohazardous waste decontamination. For more information on the requirements for autoclaves used for biohazardous waste, contact EH&S at 2-6025 or ehsbio@colorado.edu

DEFINITIONS

- **Steam autoclave**: Equipment generating adequately timed temperatures, pressure, and saturated steam for sterilization of equipment and supplies.
- **Sterilization**: Complete killing of all living organisms, including bacterial and fungal spores (2-4, 7, 8).
- **Monitoring**: Quality control procedures to ensure steam autoclave performance is satisfactory in the sterilization of surgical instruments. This includes the use of indicators of autoclave performance and documenting regular autoclave maintenance according to the manufacturer’s instructions (3, 4, 6-8).

PROCEDURES FOR ENSURING STERILIZATION OF EQUIPMENT

There are three parameters of steam sterilization: adequate steam saturation, temperature and time. It is necessary to ensure all parameters are met to ensure sterility (3).

A. **Types of indicators used in monitoring and recommended procedures**:

1. **Class I or Process Indicators**: These include autoclave tape or autoclave pouches. These react only to the temperature component of steam sterilization, do not guarantee sterility, and indicate an item as processed or unprocessed. These indicators may be placed on the inside or the outside of the autoclave package (3). Class I indicators may already be incorporated into sterilization pouches.

2. **Biological Indicators**: Biological indicators use live bacterial spores and are considered the highest and most reliable level of sterility assurance. Biological indicators also include the use of positive controls. Biological indicators must be placed centrally within both a table-top and full-size autoclave (3-5, 7, 8).

3. **Class V Integrating Indicators**: Class V integrating indicators measure three parameters necessary to achieve sterility in a steam autoclave, but do not use bacterial spores. Positive controls are not used with this type of indicator. Class V indicators should be placed in a sterilizing pouch, sealed and placed in the middle of a table-top autoclave load. If a full-sized autoclave is used, they should be wrapped with every item (3-5, 7, 8).

B. **Frequency of monitoring**:

1. It is required that a Class I indicator (autoclave tape) be used on each item (or pouch) being sterilized, and that the date of sterilization be written on the indicator strip prior to the pouch/item being sterilized in the autoclave. This is a visual indicator that a pack/pouch/item reached an appropriate temperature. In place of Class I indicators, sterilization pouches with “built-in” indicators do not need to have separate indicator tape placed on them.
2. Biological or Class V integrating indicators must be run at least once every month that a tabletop autoclave is used. If a large departmental autoclave generally used for biowaste is used to sterilize instruments and equipment for surgeries, a biological or class V integrating indicator must be used in each load.

C. Reporting Negative Results:
1. If a processed biological indicator has viable spores, all items in loads since the last negative biological indicator must be reprocessed. If any items processed since the last negative biological indicator were used on animals, the attending veterinarian must be contacted and animals monitored for illness or infection.
2. If a Class V indicator rejects a load, the cycle must be repeated with a new Class V indicator. If the indicator rejects both autoclave cycles, all items in loads since the last accepted load must be reprocessed in a validated autoclave with new Class V indicators. If the above-mentioned items were used on animals, the attending veterinarian must be contacted and animals monitored.
3. In the case of any failed test, appropriate servicing of the autoclave should be done and validation of sterilization should be made prior to use in aseptic procedures.

AUTOCLAVE MAINTENANCE
Every autoclave must have routine and preventative maintenance performed at a frequency recommended by the manufacturer \((3,5,7,8)\). Routine and preventative maintenance is important for ensuring both proper sterilization and personnel safety. Records of all maintenance and replacement of autoclave components should be kept for each autoclave and be made readily accessible if requested. If the autoclave is shared amongst several users and not a departmental autoclave, the records should be kept in proximity of the autoclave. Users of shared tabletop autoclaves are responsible for determining how best to accomplish routine maintenance, monitoring and record keeping.

RECORDKEEPING
Recordkeeping is the responsibility of the operator(s) of the autoclave. Records must minimally include monthly biological indicator or class V indicator results, documentation of autoclave maintenance along with the manufacturer’s recommendations, and any actions taken if biological or class V indicators failed. Records should be kept close to each autoclave for reference.

Maintenance records for departmental autoclaves (those used for biowaste processing) must be kept at the department level and/or with the Environmental Health and Safety Office; however, all biological indicator or Class V indicator results for these larger autoclaves should be kept with the autoclave.

REFERENCES AND NOTES
5. American Association for Laboratory Animal Science. https://www.aalalearninglibrary.org/Pages/Courses/Lessons.aspx?intCourseID=3294&intTrackID=0

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