QAM-I-110

Operation and Calibration of the Autoclave

Revision 11

Approval:

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Laboratory Manager Date

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Texas Institute for Applied Environmental Research

1. Applicability and Purpose

i. This procedure applies to the operation and calibration of the autoclave for sterilization. The purpose of this procedure is to provide a method for the operation and calibration of the Market Forge Co. STM-E autoclave. The guidelines assure quality of data and uniformity of techniques between analysts.

2. Definitions

i. DI (deionized) water- Water that has passed through anion and cation exchange resin bed cylinders that remove most ions.
ii. Refer to QAM-Q-101, “Laboratory Quality Control” for standard QA/QC definitions.

3. Equipment, Reagents, and Standards

i. Equipment
   a. Market Forge Co. STM-E autoclave
   b. NIST traceable Type K thermocouple and meter- the thermometer on the autoclave is not recorded and is for information only.
   c. Registering thermometer that holds record of maximum temperature.
   d. Temperature sensitive tape
   e. ProSpore Ampule containing *Geobaccilus stearothermophilus* spores, or equivalent
ii. Reagents: none
iii. Standards: none

4. Procedure

i. Calibration
   a. The performance of the autoclave is initially evaluated by establishing its functional properties and performance, i.e. heat distribution characteristics with respect to typical uses and timer calibration checks. This is done with a temperature indicator and documented in the autoclave logbook.
   b. Autoclaves should meet specified temperature tolerances of 15 lbs. per square inch pressure and 121°C ± 2 temperature for one hour. Every time the autoclave is used, the temperature and pressure are recorded in the autoclave logbook or E-log. Temperature is measured

with a maximum registering thermometer placed in the autoclave, not the thermometer on the face of the autoclave. The pressure is recorded from the gauge on the autoclave. If temperature and pressure do not reach specified tolerances, a corrective action report (CAR) is completed and the autoclave is placed out of service until it is repaired. A CAR is not required if the autoclave is only used for deactivation of live bacteria waste only, and these levels are not attained.

c. The pressure and temperature meters on the autoclave are calibrated periodically by the Tarleton State University Maintenance Department or outside contractor. The timer calibration is performed by TIAER laboratory personnel at least annually. This action is recorded in the Maintenance Logbook, QAM-Q-103-1. Again, this may not be necessary if the autoclave is used for waste sterilization only.

d. Calibration Checks

   i. Demonstration of sterilization temperature is provided by use of a thermocouple, or maximum registering thermometer, and an internal pressure meter with every cycle. Appropriate biological indicators may be used (when in use) to determine effective sterilization. Indication may also be done by melting of plastic Petri dishes or other means.

   ii. Sterilization indicator tape may be used on all reagents and equipment to show that they have been autoclaved. This tape is not required on petri dishes to be disposed of, and does not ensure that the sterilization has met the time, temperature and pressure requirements. The tape is initialed and dated for newly autoclaved bottles.

   iii. Timer calibration check: once temperature and pressure have reached operation levels, compare the autoclave timing mechanism to a National Metrology Institute traceable laboratory timer or clock.

   iv. Weekly, when in use, a Prospore Ampule (or equivalent) is included with the contents and incubated. Change of color of the ampule contents

during incubation is indicative that the autoclave is not sufficiently sterilizing contents.

ii. Operation

a. Fill bottom of the sterilizing chamber with approximately six quarts of DI water or just below the ledge at the bottom of the door opening. Be certain that the drain valve is closed.

b. Load the autoclave in a manner that protects the items being sterilized and allows airflow around the objects. Ensure that caps on plastic bottles are left loose to avoid collapse of the container upon cooling. Latch and lock the autoclave door.

c. Set the exhaust selector switch. All items other than liquids may be sterilized with the selector at FAST. Liquids require a SLOW exhaust.

d. Turn the timer to the desired length of the sterilizing period stated in the SOP for the analysis. The timed cycle starts only after the pressure-temperature combination has been reached. The pilot light indicates that the unit is up to temperature and pressure and the timer is running.

e. When the sterilizing cycle is complete and the timer has returned to zero, two more minutes will elapse before the indicator light shuts off and the exhaust cycle will be complete.

f. When opening the door, allow a few seconds for the steam to escape from the chamber before opening it completely. (Release the handle to avoid possible contact with the remaining steam.)

g. Temperature sensitive tape may be used with the contents of each run to indicate autoclave contents have been processed.

h. Records of autoclave operations are maintained for every cycle. Records include date, contents, maximum temperature reached, maximum pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analysts initials. All data are recorded in the Autoclave Log or E-log, Attachment 1.

5. Quality Control and Safety Aspects

i. All aspects of this procedure comply with QAM-Q-101, "Laboratory Quality Control" and QAM-S-101, "Laboratory Safety".

ii. Autoclave maintenance, either internally or by service contract, is performed annually. This includes a pressure check and calibration of temperature device (Tarleton Maintenance or outside vendor). Records of the maintenance are maintained in the Laboratory Manager's file and noted in the Autoclave Logbook or E-log comments section.

iii. The autoclave mechanical timing device is checked quarterly against a timer that has been calibrated or verified using a recognized National Metrology Institute traceable reference at least annually, bracketing the range of use. The actual time is documented and recorded in the Autoclave Logbook comments section. Acceptance limits are ± 2 minutes for a 60 minute period or ± 1 minute for a 30 minute period. If the autoclave is used for waste sterilization only, servicing, limits and checks are not required.

iv. Safety guidelines for individual samples are followed and bacteria waste is handled safely.

v. Be aware that quick release of steam may occur in the operation of the autoclave. Ensure sufficient distance from the exhaust to avoid burns or injury. Do not touch the device while it is hot.

6. References

i. "Market Forge C. Service and Parts Manual, 17-0188A," Everett, Massachusetts.

ii. The National Environmental Laboratory Accreditation Conference Institute (TNI) standard, 2016.

7. Attachments

i. Autoclave Logbook (or E-log), QAM-I-110-1

Attachment 1
Example Autoclave Logbook

Autoclave Logbook

Date	Initials	Max Temperature	Max Pressure	Sterilization Time	Total time		Contents
		°C	psi		Time in	Time out	
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