Biological Safety Series

June 2019

Autoclaves:

Validation and Monitoring

Occupational Health and Safety Service
HSD164B (rev 2)

UNIVERSITY OF CAMBRIDGE

Validation and Monitoring

Validation: Establishing documented evidence that a disinfection process will consistently inactivate target organisms under defined conditions of use.

Monitoring: To observe or record the activity or performance of a device.

Calibration: The act of checking or adjusting (by comparison with a standard) the accuracy of a measuring instrument.

Introduction

Autoclaves can be used for numerous laboratory and medical applications, for example, media preparation, sterilisation of fluids, instruments, fabrics and waste disposal (ie 'discard' cycle).

Microbiological laboratory waste, clinical samples and genetically modified microorganisms (GMOs) and licensed materials including plants and soils **must** be made biologically inactive before disposal.

COSHH and GM risk assessments require the assessor to provide specific information for autoclaving. The choice of temperature and cycle time will depend on the load type (liquid/solid) and type of the biological organism.

Commissioning

A qualified engineer must commission all newly installed autoclaves. Part of this process is to validate the autoclave to ensure it will perform as expected.

All autoclaves **must** be annually inspected by a representative for the University's insurers to comply with the Pressure Systems Safety Regulations (PSSR) 2000 (https://www.safety.admin.cam.ac.uk/subjects/workplace/pressure-equipment and http://www.hse.gov.uk/pubns/indg178.pdf).

Bureau Veritas (BV) acts as the Competent Person to carry out this inspection. Departments must register all autoclaves on the BV SWIFT database (see leaflet on waste inactivation: https://www.safety.admin.cam.ac.uk/publications/biological/hsd173b-waste-inactivation-validation).

How do you validate?

Thermocouple 'mapping' should be used. This involves placing multiple (usually 12+) independent thermocouples at various sites (including the most inaccessible) within both 'typical' and 'difficult to penetrate' simulated loads. This will produce a recording output for these runs to determine if all sites maintain the required temperature for the required time. This is not something that can be carried out in-house but it must be carried out by a competent trained person with specialist equipment.

Benchtop autoclaves are not recommended for waste inactivation, as these cannot usually be validated.

When do you validate?

As a general rule, autoclaves used for the inactivation of biological materials **must** be validated **annually**, or more frequently where risk assessment determines this necessary. Re-validation is required when typical load volumes, type of materials (eg solid/liquid/fabric) and equipment are changed or following recommissioning after maintenance work. **Rarely**, there **may** be very specific situations where, following risk assessment, validation can be done less frequently, eg where an autoclave is used solely for the inactivation of non-GM HG1 microorganisms. This approach **must** be fully documented, requires robust monitoring, and stipulation of validation frequency.

The maintenance engineer can usually do the validation as part of an annual maintenance contract (Record retention for report: 5 years).

Conditions needed for inactivation

Microorganisms are typically inactivated by autoclaving under conditions that maintain 121ºC for at least 15 mins with full steam penetration (holding-time). This time might be increased with particular organisms (e.g. spore-forming bacteria), large liquid volumes or where steam penetration is difficult. The successful sterilisation of some materials via autoclaving can also be hindered by pockets of trapped air within the load or insufficient steam access to the load through incorrect loading of the autoclave. The service engineer should be consulted to determine an appropriate holding time for these particular loads. The minimum 15 mins **excludes** the time required to reach 121ºC.

TSE agents (prions) require different treatments:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/260961/report.pdf

Monitoring

Each run must be monitored by the user to ensure the correct temperature and pressure has been reached and maintained for the correct duration.

The use of 'autoclave tape' is not a suitable means to show that this has occurred. Autoclave records (paper or electronic) for the destruction of waste containing GMOs, HG2 (or above) and SAPO agents must be retained and archived for auditing purposes.

'Modern' autoclaves have the possibility to electronically download autoclave cycles and might have a 'Pass/Fail' error alert. Older autoclaves have a built-in thermocouple linked to a chart or digital recorder which monitors each run and provides a printout that can be kept as a record. If the autoclave lacks this, there are two options:

- Install a suitable digital recorder linked to a thermocouple that can be fitted to many (not all) older or small autoclaves, but make sure it provides a continuous printout, recording the temperature throughout the run **or:**
- Place a suitable commercially available autoclave 'indicator' in each load and keep a log-book that records the results of each run.

New: In some cases (eg licenced activities), further records with information such as operator, type of load and cycle number are required for audit purposes.

Autoclave indicators

Some commercially available indicators (including standard autoclave tapes) **are not adequate** for monitoring inactivation of GM waste because they change colour either at temperatures considerably lower than 121ºC, or within minutes of reaching 121ºC and are unable to detect steam penetration. Thence they do not confirm that the appropriate conditions have been maintained for a sufficient time.

Only TST (Time, Steam, and Temperature) Class 6 (emulating) indicators are suitable for monitoring the performance of a particular cycle. They must conform to **ISO 11140-1 Part 1 Class 6** standard and are validated for set autoclaving parameters. These indicators are sold by Steris, Fisher Scientific, PMS Medical, to name a few.

Self Contained Biological Indicators (SCBI) can be used to monitor the effectiveness of the sterilisation process eg Steris Verify-STEAM or 3M Attest.

You are advised to speak to the autoclave manufacturer for advice on the correct product for the desired cycle conditions. **The use of biological or chemical indicators is not acceptable for validation** (used for monitoring only).

If you use an autoclave to inactivate biological material, all waste cycles must be validated at least annually.

Human tissue waste should be incinerated.

Companies providing validation services and monitoring supplies

(Note these are examples only. There are other companies providing this service)

Steris
https://www.steris-healthcare.com/

LTE Scientific Ltd
Greenbridge Lane
OL3 7EN
Tel: 01457 876221
Email: info@lte-scientific.com

Astell
19-21 Powerscroft Road
DA14 5DT
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ESTS (GB) Ltd
7 Low March Ind. Estate
NN11 4SD
Tel: 01933 270999
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