University Occupational Health and Safety Guidance Notes

SAFE USE OF AUTOCLAVES

1. PURPOSE 2
2. SCOPE 2
3. ABBREVIATIONS 2
4. SPECIFIC RESPONSIBILITIES 2
4. SELECTION AND INSTALLATION 2
5. MAINTENANCE AND VALIDATION 3
6. GENERAL RISK ASSESSMENT 4
7. STANDARD OPERATING PROCEDURES 4
8. LOADING AND UNLOADING PROCEDURES 5
9. INFORMATION, INSTRUCTION, TRAINING AND SUPERVISION 6
10. EMERGENCY PROCEDURES 6
11. COMPLIANCE 6

1. PURPOSE

The purpose of this document is to provide guidance on the safe use of autoclaves used to make biological waste safe (sterilisation of waste contaminated with infectious or potentially infectious substances). It should be used in conjunction with the Occupational Health and Safety Biological Safety Standard.

2. SCOPE

This document applies to staff responsible for the management of autoclaves within departments, and staff and post graduate students who are required to use autoclaves for the purpose as described.

3. ABBREVIATIONS

CL	Containment Level
PI	Principal investigator
SOP	Standard Operating Procedure
WSE	Written Scheme of Examination

4. SPECIFIC RESPONSIBILITIES

3.1 Departmental Biological Safety Co-ordinator (or other nominated person)

Autoclaves within departments should be under the managerial control of a responsible person as nominated by the Head of Department who should:

- Ensure that the autoclave is managed safely and operated only by trained and competent individuals;
- Arrange for maintenance/servicing of departmental autoclaves;
- Co-ordinate with Estates Services to engage with the University Engineers Insurers Surveyor to carry out examinations under the WSE.

3.2 Estates Services

Autoclaves must have a WSE at commissioning, and must be examined according to this scheme by a competent person thereafter at appropriate regular intervals. At the University of Strathclyde this is done through the University's Engineering insurers, therefore in this respect all autoclaves/pressure vessels must be registered with the University Engineers Insurers Surveyor.

3.3 Principal Investigators

PIs must ensure that disinfection protocols are in place and displayed within their laboratories. Where sterilisation by autoclave is required they must ensure that the waste is handled, stored and transported to the autoclave in a safe and secure manner. PIs must ensure that:

- Risk assessments identify waste decontamination and disposal methods;
- Autoclaves used for inactivating waste have been appropriately validated;
- All personnel working under their supervision are given sufficient information, instruction and training regarding waste segregation, decontamination and disposal; and
- Procedures for the use of autoclaves are followed.

3.4 Autoclave users

All users of autoclaves should be sufficiently trained and instructed in their use.

4. SELECTION AND INSTALLATION

Autoclaves are required in the building at CL2, and within the laboratory or laboratory suite at CL3. The selection of autoclave will be dependent upon its intended use. For CL2 laboratories generating a small amount of waste a small benchtop autoclave with integral heater for steam generation may be appropriate although this type of autoclave cannot be as easily validated as the larger vacuum pulsing autoclaves that are sufficient at CL2 and also CL3. The British Standard BS 2646-3: 1993 *Autoclaves for Sterilisation in Laboratories* and BS EN 12347: 1998

Performance criteria for steam sterilisers and autoclaves should always be consulted to ensure that installation and servicing meet British Standard specifications.

5. MAINTENANCE AND VALIDATION

5.1 Written Scheme of Examination

Under the Pressure Systems Safety Regulations 2000, users and owners of pressure systems must ensure that a WSE is in place before the system is operated for the first time. The WSE is drawn up at installation by the competent person (University Insurance Engineer) and identifies the parts of the system that require subsequent examination and the maximum interval between these checks. The system then must be examined in accordance with the WSE. An autoclave **must not** be operated without a WSE.

WSEs, validation and maintenance documents and cycle records should all be kept for audit purposes or for inspection by regulatory bodies.

5.2 Maintenance

In addition to the WSE autoclaves must be maintained to ensure the safe operation and condition of the system so that they do not give rise to risks to health and safety. The requirement for maintenance of the system should not be confused with the requirement for examinations under the written scheme, although an issue identified under an examination may require maintenance work to rectify the issue. The frequency of maintenance should be assessed and a suitable maintenance programme planned by engaging with a service provider. The service plan may take into account:

- The age of the system;
- The operating/process conditions;
- The working environment;
- The manufacturer's/supplier's instructions;
- Any previous maintenance history;
- Reports of examinations carried out under the WSE by the competent person;
- The results of other relevant inspections (e.g. for maintenance or operational purposes);
- Repairs or modifications to the system; and
- The risks to health and safety from failure or deterioration.

5.3 Validation, calibration and monitoring

5.3.1 Calibration

Calibration of the autoclave is required and is usually done as part of the service/maintenance agreement. Calibration will check that the control panel of the autoclave is functioning correctly and is displaying the operating parameters correctly.

5.3.2 Validation

If an autoclave is being used for a waste cycle (make safe/destruct cycle) where the load contains pathogens or genetically modified material then validation is require in order to demonstrate an effective 100% kill. Validation in this respect is carried out by 12 point thermocouple testing using user defined mock loads. This test method is described in The British Standard BS 2646-3: 1993 *Autoclaves for Sterilisation in Laboratories*.

Validation must be carried out by a competent person using calibrated thermometric test equipment working to national standards. The use of biological or chemical indicators for this purpose is not adequate. Benchtop autoclaves cannot be easily validated and therefore should be avoided for make safe cycles. Further information can be obtained by contacting the service engineer.

Validation of autoclaves used to make waste safe should be at least annually at the time of service, and at other times such as re-commissioning or where the load significantly changes. Validation records should be kept for a minimum of 5 years. HSE inspectors are likely to request validation records and WSEs during inspections or investigations.

5.3.3 Routine monitoring

Autoclave performance should be monitored by users. Where the autoclave is used to make waste safe it should have the facility to either print out or electronically save the record of each 'run' to indicate successful decontamination of the load. A written autoclave log book should be kept alongside the machine. Records should be kept for a minimum of 5 years.

Spore strips or chemical or physical indicators can be used to test the autoclave at frequent intervals but these do not replace validations requirements. Autoclave tape should not be used as a means of monitoring the performance of the autoclave, it is solely to indicate that the load has been processed.

6. GENERAL RISK ASSESSMENT

A suitable and sufficient risk assessment must be completed by a competent person before using an autoclave and thereafter reviewed at appropriate intervals. All users must read and sign the risk assessment before use. The main hazards associated with the use of autoclaves include:

- Pressurised steam;
- Scalding from the heat of surfaces and liquids;
- Manual handling whilst loading/unloading;
- Exposure to infectious substances in the load;
- Exposure to hazardous substances/vapours/liquids due to failure of the cycle;
- Failure to make safe the infectious load.

7. STANDARD OPERATING PROCEDURES

The risk assessments should identify the need for documented SOPs or protocols. SOPs in turn should identify the treatment options and operating parameters/conditions known to kill the agents that are suspected or known to be present in the load. Where materials cannot be autoclaved then SOPs should specify the disinfectants and disinfection methods that are to be used. SOPs should take into account:

- The type of solid and liquid wastes that are to be autoclaved;
- The containers (which allow steam penetration) that are to be used;
- The sterilising cycle required (e.g. temperature and holding time);
- Whether biological or chemical indicators are to be used and their location in the load;
- The loading and unloading procedures;
- The checks to be made and recorded by the users and others;
- The emergency procedure in the event of a malfunction or failure; and
- Subsequent handling and disposal of the autoclaved waste.

Effective sterilisation by autoclaving depends on:

- Installation and commissioning using test loads (worst case scenario load) to validate load temperatures and other operating conditions;
- Effective removal of air from the vessel and all parts of the load including the use of containers that allow steam penetration;
- Achieving and maintaining suitable load temperatures and holding times and the ability to validate these under operating conditions by independent thermocouple tests rather than by the use of biological and chemical indicators;
- Regular through examination and testing by a competent person under a WSE including the checking of safety valves, steam pressure indicating valves and in the case of bench top autoclaves water level indicators.

For CL3 labs (operating as derogated CL3 labs at the University of Strathclyde), direct access to a dedicated waste treatment autoclave in the laboratory or laboratory suite is recommended. If this is impracticable, the standard operating procedure should specify the conditions under which the removal of waste to an autoclave outside the laboratory or to a suitable clinical or animal incinerator is permitted, e.g. the use of robust, leak-proof and sealed inner and outer container. This may be subject to HSE approval.

Autoclave cycles will vary dependent on several factors. Typical minimum sterilisation temperatures and holding times are indicated in the Table 1.

Process	Sterilisation temperature	Sterilisation time (holding time)*
Liquid sterilisation**	121°C - 124°C 115°C - 128°C	15 mins 30 mins
Equipment sterilisation	121°C - 124°C 126°C – 129°C 134°C - 138°C	15 mins 10 mins 3mins
Make waste safe (inactivation of materials for discard or re-use)	121°C – 124 °C 134°C 134°C	15 mins 3mins 18 mins (material infected with TSEs + incineration)***

Table 1. Minimum recommended parameters for sterilisation by autoclave.

The following points should be noted in determining the correct:

- Loads that contain a range of items/containers may not heat uniformly. Short holding times may therefore be subject to proportionate variations which should be avoided.
- *Time held at sterilisation temperature, as determined at validation, does not include warm up and cool down.
- **** Liquid media may be sensitive to sterilisation at a lower temperature, however a longer holding time must be used.
- *** Any material infected with Transmissible Spongiform Encephalopathies (TSEs) must be sent for incineration following autoclaving.

8. LOADING AND UNLOADING PROCEDURES

Written procedures for the safe loading and unloading of the autoclave should be included in the general risk assessment. Standard operating procedures should be available made available to users and a copy kept next to the autoclave.

8.1 Loading the autoclave

Procedures for loading an autoclave should include:

- Ensure appropriate PPE is worn;
- Any material that is awaiting autoclaving should be stored securely and safely;
- A labelling system should be used to identify the waste generator and the contents of the waste;
- Autoclave bags should be packaged so as to allow steam penetration into the load. Bags should not be sealed;
- Ensure that loads are handled in accordance with good manual handling techniques;
- Some chemicals (including disinfectants) or other substances may produce harmful vapours when autoclaved, or they may be corrosive to the autoclave. The risk assessment should take into account these possibilities and report items that must not be autoclaved.

8.2 Unloading the autoclave

Procedures for unloading an autoclave should include:

- Ensure appropriate PPE is worn;
- Warning lights should be checked prior to opening an autoclave;
- If a fault is indicated attempts to open the autoclave should only be made under the authority of the responsible person;
- Do not attempt to override the door interlocks;

- Stand clear when opening the door as hot liquid or vapour may escape;
- Ensure that loads are handled in accordance with good manual handling techniques;
- Autoclaved waste should be disposed of appropriately. Any reusable waste containers should be safely emptied and reclaimed.

9. INFORMATION, INSTRUCTION, TRAINING AND SUPERVISION

All staff who are involved in the management of the maintenance/testing of autoclaves should have knowledge of operation and sterilisation processes.

All autoclave users should be provided with adequate information, instruction and training. Training should, at a minimum, include:

- Standard operating procedures;
- Proper use of PPE;
- Safe loading and unloading procedures;
- Proper use of autoclave log books and cycle record keeping; and
- Emergency procedures.

10. EMERGENCY PROCEDURES

Procedures should be established to deal with a failure in the autoclave run which results in an unsterilized load or partially sterilised load to enable the waste to be repackaged for transfer to another autoclave or to an incinerator. The SOP should specify the conditions, e.g. the use of robust, leak-proof and sealed inner and outer container, under which the removal of waste to an autoclave outside the laboratory or an alternate mechanism for treatment should be carried out, for example through the Clinical Waste Service (Estates Services), but this should only be required in extreme cases and must be discussed with the Biological Safety Adviser. Where materials cannot be autoclaved then SOPs should specify the disinfectants and disinfection methods that are to be used.

There should be appropriate monitoring or indicating devices to warn the user to shut down the autoclave safely if critical operating conditions are not achieved.

11. COMPLIANCE

This guidance aims to meet the requirements of:

- Control of Substances Hazardous to Health Regulations (2002)
- Health and Safety at Work Act (1974)
- Management of Health and Safety at Work Regulations (1999)
- Manual Handling Operations Regulations (1992)
- Pressure Systems Safety Regulations (2000)
- Provision and Use of Work Equipment Regulations (1998)
- Health Technical Memorandum 07-01: Safe management of healthcare waste (2013)