Arrangements for the Maintenance and Testing of Laboratory Autoclaves

Royal Free NHS Trust & Royal Free and UC Medical School (Hampstead Campus)

This document has been produced by the Safety Office, Royal Free in consultation with the Works Department and the Safety Advisory Unit at UCL. The purpose of these arrangements is to ensure that laboratory autoclaves comply with the appropriate standards and that users understand their responsibilities. For this reason, laboratory autoclaves have been categorised as follows:

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<th>LABORATORY AUTOCLAVES</th>
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<tr>
<td>AUTOCLAVE TYPE</td>
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<tr>
<td>TYPE A</td>
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<td>TYPE B</td>
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<td>TYPE C</td>
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**Type A Autoclaves.**
Autoclaves for patient-related¹ use come under this category. Because of the potential risk of infection involved, autoclaves in this category need to comply with Health Service Technical Memorandum HTM 2010 which is based on the British Standard BS 3970. This standard has been incorporated as a Trust document “Procedure Note Sterilization” (see references) and is available on the Trust Freenet and RF Campus Safety Web Page.

¹ Patient-related means either instrumentation etc. that could come into contact with a patient or where patient test results are reliant on the autoclaving procedure.
**Type B Autoclaves.**
Autoclaves for the sterilization of materials and goods which may be contaminated with organisms categorized in Hazard Groups 2 and 3 come under this category. These autoclaves will need to comply with BS 2646. A summary of what the user needs to know in terms of maintenance requirements for these type of autoclaves is listed in appendix I.

**Type C Autoclaves.**
Autoclaves which are used in low risk environments, for example, where containment level 1 work is carried out come under this category. These autoclaves do not need to comply with BS 2646 or BS 3970 – but will need to meet the requirements of the Provision and Use of Work Equipment Regulations (PUWER) 1998 (see Appendix II) and/or The Pressure Systems Safety Regulations 2000 (Appendix III).

**Genetic Modification Work**
Persons carrying out genetic modification work involving GM material where a risk assessment has established that there is a potential threat to the environment, for example should there be an accidental release, would need to use Type B autoclaving facilities where autoclaving is required.

**References**
- NHS Estates 94/95: Health Service Technical Memorandum (HTM) 2010 “Sterilisation”.
- The Genetic Modifications Regulations 2000 – Approved Code of Practice.
  (The above Approved codes of Practice are available from the Safety Office, RFH).

Appendix I - Maintenance requirements for laboratory autoclaves in accordance with Part 4 of BS 2646 - “Guide to Maintenance”:

**Maintenance Schedules**
Part 4 of the British Standard outlines the following as minimum maintenance routines for laboratory autoclaves:

1. **Minimum daily maintenance schedule**
2. **Minimum weekly maintenance schedule**
3. **Minimum quarterly maintenance schedule**
4. **Minimum annual maintenance schedule and inspection**

1. **Minimum daily maintenance schedule**
The standard recommends that the following checks and activities be carried out daily by the operator:

   (a) visual checks for steam and water leaks and checking, for example, that the steam pressure from supply is correct.
   (b) checking for cleanliness of autoclave parts, for example, internal chamber, fittings, door seal etc. and cleaning where necessary.
   (c) inspecting chart recordings for unusual traces and reporting any abnormalities.

2. **Minimum weekly maintenance schedule**
The standard recommends that the following checks be made weekly by the responsible person:

   (a) operation of indicator lamps
   (b) temperature and pressure gauges and correlation of temperature gauge against pressure gauge during a cycle.
   (c) Inspection of chart recordings for abnormalities.

**Minimum quarterly maintenance schedule**
The standard recommends that the following checks be made every 3 months by a maintenance/service engineer:

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2 The operator is defined in the British Standard as the person trained to use the autoclave. In everyday language this equates to the user or person who is using the autoclave.

3 The responsible person is defined in the standard as the person responsible for the operating policy of autoclaves within the laboratory. In relation to the Trust and School (RFH Campus) this equates to the manager or head of department.
(a) check control instrumentation as it may require recalibration or replacement.
(b) check valves, for example, if there is a steam-pressure reducing valve present – does it need cleaning or replacement?
(c) check joints in piping
(d) check the chamber for corrosion and wear.
(e) inspect all electrical heat terminal points.
(f) check for cleanliness of water and steam line main strainers – if fitted.
(g) check pipework and drains to waste to ensure they are clear and operating.
(h) check for correct functioning of door interlocks.

4. Minimum annual maintenance schedule and inspection
The following checks and activities should be undertaken annually by a maintenance/service engineer:

(a) check service history for recurring faults and corrective action;
(b) Inspect and remove any scale from the chamber by a method approved by the manufacturer.
(c) Check the water-level control and indicator systems;
(d) Check condition and operation of temperature indicator and pressure gauges.
(e) Test the operation of safety valve(s) and door interlocks under operating conditions.
(f) During a cycle with the chamber empty, check all control functions including correlation of pressure and temperature gauges against known references.
(g) Test all functions under working conditions to the satisfaction of the responsible person.
(h) Carry out thermometric tests of typical laboratory loads as during original commissioning and validation.

Documentation of maintenance work
The following documents should be available:

(a) Instruction Manual
(b) Maintenance Log
(c) Autoclave Process Record
(d) Permit to Work Certificates

(a) Instruction Manual
The manual should include a maintenance schedule covering for example, safety features provided; spare parts list, operation instructions etc.

(b) Maintenance Log
A log of all work carried out on the autoclave, including breakdown maintenance; planned maintenance and any defects noticed during use, maintenance or repair should be kept. The person carrying out the work should sign the log.

4 The maintenance/service engineer is defined in the standard as the person who performs maintenance or service work on the autoclave. In relation to the Trust & UC Medical School Royal Free Campus, this person may be contracted to the laboratory from outside or maybe someone within the Works Dept.
(c) Autoclave Process Record
The user of the autoclave is responsible for recording each operating cycle of the autoclave.

(d) Permit to Work Certificate
The use of permit to work certificates is recommended prior to the commencement of work on autoclaves by service / maintenance engineer. If this is not possible, the British Standard states that it is essential that the engineer is informed of any hazard(s) involved and any necessary safety precautions e.g. personal protective equipment.

Staff and Training
- All staff involved in maintenance of autoclaves should have knowledge of their operation and knowledge of the sterilization process.
- Training should be provided for all staff concerned with the planned maintenance of laboratory autoclaves and a record kept of training.
- Routine tasks may be carried out by local laboratory or maintenance staff who have had formal training.
- Training should be periodically reviewed.

Testing of Autoclaves
Tests for safe function and performance need to be carried out as specified in Part 5 of BS 2646. Test instruments should also meet the criteria outlined in Part 5 of the standard.
Appendix II

Basic Requirements of the Provision and Use of Work Equipment Regulations (PUWER) 1998

General Requirements of PUWER
There is a general duty to carry out a risk assessment of the risks to people’s health and safety from equipment used at work, so that the risks can be prevented or controlled.

PUWER also requires that equipment provided for use at work is:

• suitable for the intended use and for the conditions in which it is used;
• safe for use, maintained in a safe condition and inspected by a competent person to ensure this remains the case;
• used only by people who have received the relevant information, instruction and training;
• accompanied by suitable safety measures, for example, protective devices, markings and warnings.

Risks created by the use of the equipment should be eliminated or where possible controlled by:

• taking appropriate “hardware” measures, for example, providing suitable guards, protection devices, markings and warning devices, system control devices, for example, emergency stop buttons, and PPE (personal protective equipment).
• taking appropriate "software" measures such as following safe systems of work and providing adequate information, instruction and training.

A combination of these measures may be necessary depending on requirements of work, your risk assessment and practicability of such measures.

Maintenance
Work equipment should be maintained so that it is safe and so that its performance does not deteriorate to the extent that it puts people at risk. The frequency at which maintenance activities are carried out should also take into account the:

(1) intensity and frequency of use and maximum working limits;
(2) operating environment;
(3) variety of operations i.e. is the equipment performing the same task all the time or does this change?
(4) risk to health and safety from malfunction or failure.
**Maintenance management**

For maintenance to be effective, it needs to be targeted at the parts of work equipment where failure or deterioration could lead to health and safety risks. Maintenance should address those parts which have failed or are likely to deteriorate and lead to health and safety risks.

Appropriate techniques for maintenance management should be selected through risk assessment and used independently or in combination to address the risks involved. A number of maintenance management techniques could be used, for example:

(a) planned preventive;
(b) condition-based;
(c) breakdown.

Maintenance procedures should be carried out in accordance with any manufacturer’s/suppliers recommendations which relate to the equipment. PUWER also recommends that a record be kept of maintenance for high-risk equipment, for example in the form of a maintenance log.
Appendix III

Requirements under The Pressure Systems Safety Regulations 2000

Autoclaves come under the definition of a pressure system\(^5\) under the Pressure Systems Safety Regulations 2000 and so the following requirements apply:

**Written Scheme of Examination**
A written scheme of examination is required for most pressure systems before operation. The scheme will need to be drawn up or certified as suitable by a competent person\(^6\). It must specify the nature of the examination and how often the system is to be examined.

All protective devices must be included in the scheme. It should also include pressure vessels, and/or parts of pipework that could give rise to danger, if they were to fail.

**Maintenance**
Regulation 12 of these Regulations builds on the more general duties in the HSWA 1974 and Regulation 5 of the PUWER 1998, which require that work equipment is maintained so that it does not give rise to risks to health and safety.

Under the Pressure Systems Safety Regulations, all pressure equipment and systems should be properly maintained. There should be a maintenance programme for the system as a whole. It should take into account the system and equipment age, the environment and its use, for example:

1. Tell-tale signs of problems with the system should be looked for e.g. if a relief valve repeatedly discharges at the wrong setting, this could be an indication that the system is not working properly.
2. Signs of wear and corrosion should be looked for.
3. Where protective devices have to be isolated for maintenance, alternative arrangements to ensure safety levels are not exceeded without detection should be made.
4. Ensure there is a safe system of work, so that maintenance work is carried out properly and under suitable supervision.

The need for maintenance should not be confused with the requirement for examinations under the written scheme. They are two separate issues although problems identified during an examination under the written scheme may require maintenance to correct.

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\(^5\) A pressure system is defined as a system comprising a pressure vessel, its associated pipework and protective devices under the Pressure Systems Safety Regulations 2000.

\(^6\) The competent person carrying out examinations under a written scheme does not necessarily need to be the same one who prepares or certifies this scheme as suitable. A competent person may be:

(a) A company’s own in-house inspection department;
(b) An individual person (e.g. a self-employed person);
(c) An Organisation providing independent services.
Further details can be found in the Approved Code of practice to the Regulations (see references).

**Training**

Everybody operating, installing, maintaining, repairing, inspecting and testing pressure equipment should be provided with suitable training, and have the necessary skills and knowledge to carry out their job safely. Additional training or re-training may be required if the job changes; the equipment or operation changes or where skills have not been used for a while.

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