Autoclaves: Safe systems and compliance

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An Autoclave uses beyond atmospheric **pressure** and elevated **temperature** to sterilize items as well as carrying out ‘make-safe’ procedures to inactivate all biological agents

Legal Requirements

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Autoclave use must conform to

Workplace (Health, Safety and Welfare) Regulations 1992
Safe working environment

Provision and Use of Work Equipment Regulations 1998 (PUWER)
Safety standards of work equipment including suitability, training, safety and maintenance

Pressure Systems Safety Regulations 2000 (PSSR)
Pressure systems and their hazards in the workplace and examination

Guidance detailing safe autoclave use and maintenance

British Standards – BS 2646-1
Autoclaves for sterilization in laboratories
Design, construction, safety and performance

British Standards – BS 2646-3
Autoclaves for sterilization in laboratories
Safe use and operation

HSE: PM73 (rev 3)
Safety requirements for autoclaves

HSE: The Management and Operation of Microbiological containment laboratories

Health Technical Memoranda (HTM)

HTM provide guidance for the healthcare setting in maintaining high standards along with infection prevention and control. The requirements of this standard changes the frequency and type of tests carried out including weekly and quarterly checks

Work at the University which is research only purposes and not based in the healthcare setting are not required to follow HTM standards. BS 2646 and HSE's PM 73 (rev 3) are sufficient

Provision and use of work equipment regulations 1998 (PUWER)

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PUWER

Suitability, safety and maintenance

Manufacturers must supply machinery which is safe and –

- Ensure the technical file is available
- Provide operating instructions
- Provide a Declaration of Conformity
- Carry out or arrange a Conformity assessment including Installation Qualification Test after installation and
  Performance Qualification Test before use

PUWER: Maintenance Planning

PUWER requires inspection of work equipment at appropriate times and sufficient intervals to ensure the equipment is maintained in a safe working condition and that any deterioration can be detected and remedied in good time

Planning for routine maintenance is not only required by the regulations but a pro-active way to approach safety

Planned Preventive Maintenance advantages:

- Safer operation
- Reduction in downtime of machinery
- Reliability of machinery to carry out inactivation
- Reduces and controls some of the risks identified in the risk assessment

Training and Supervision

PUWER requires people who use work equipment to receive sufficient training in how to use the equipment, the risks associated with usage and precautions that must be taken

Training should be recorded
Refresher training should also be carried out along with information and instruction when:

- There are changes in work activity
- Changes of Supplier and Autoclave
- Changes to the process
- Adjustments made to Programmes

Pressure Systems Safety Regulations 2000

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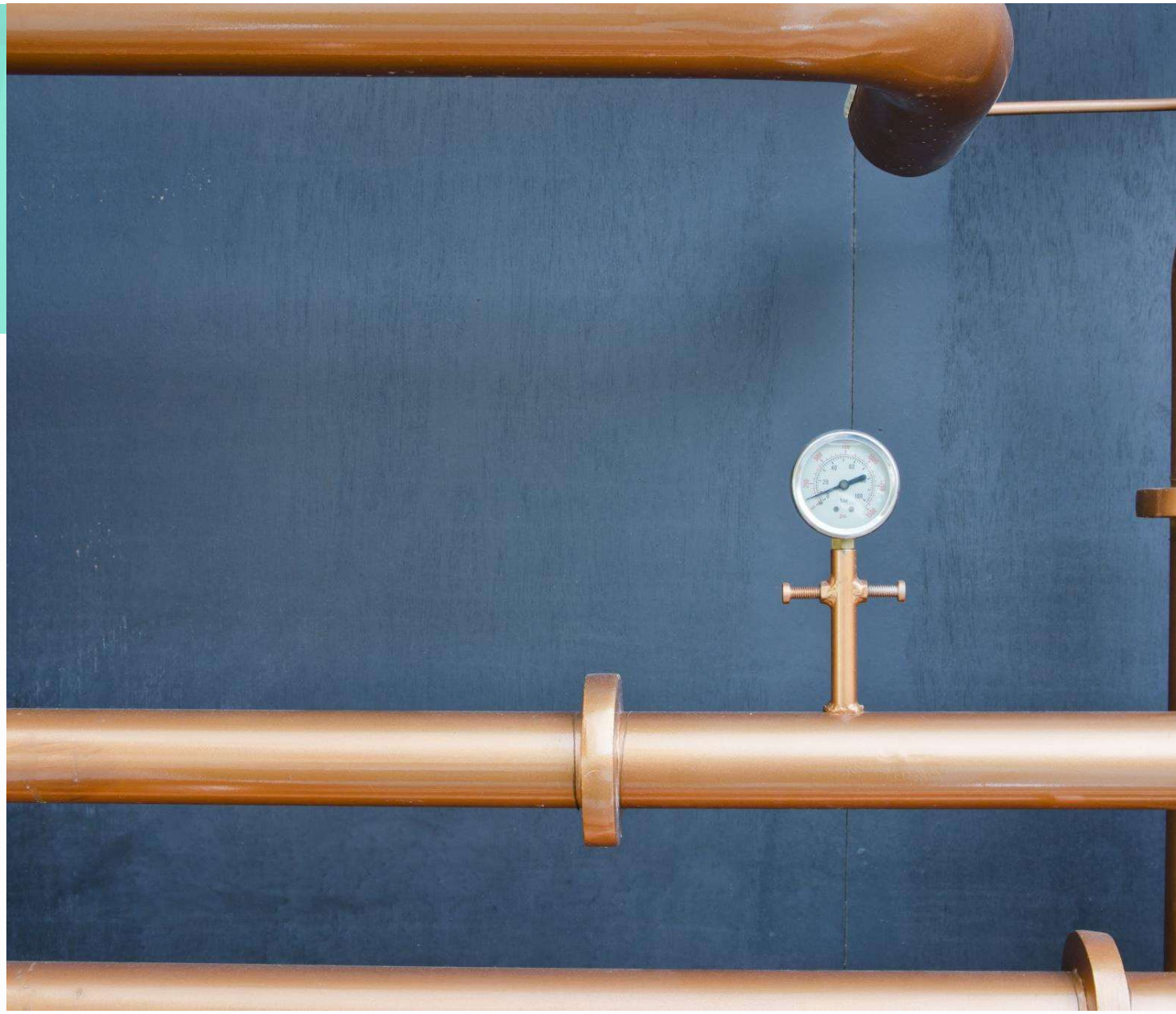


PSSR

Requires a Written Scheme of Examination

The Responsible person/ user must:

Establish clear and safe operating limits

Develop a Written Scheme of Examination before use

Plan periodic maintenance to maintain the system

Provide operating instructions

Written Scheme of Examination

This must be developed before a Pressure system can be used

The nature and frequency of examination must be specified

The periodic examination should be carried out by the competent person and given to the user or owner of the autoclave within 28 days

Documentation must be kept in the autoclave records

Documentation

Responsible Person(s) overseeing Autoclave provides:

- Written Scheme of Examination
- SOP/ Relevant Sections of Manufacturer's Manual
- Documentation provided by Manufacturer
- Risk Assessment
- Contingency Plan

Operator/user log:

- Daily Checks/ Autoclave process record
- Reporting faults/ malfunction and actions taken
- Performance Monitoring

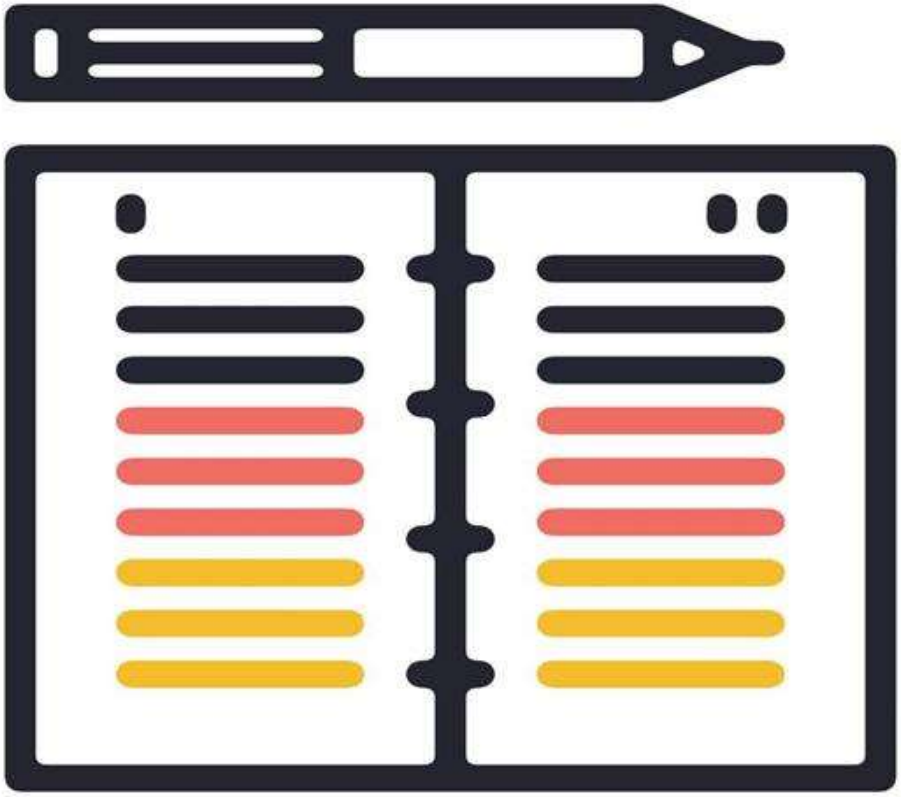
Service Provider:

- Installation Qualification
- 6 Months/ Yearly Checks
- Faults/ Malfunctions

SOP for autoclave use should cover

- The type of waste to be autoclaved
- Containers that are to be used
- The required cycle(s) with temperature and time settings
- If biological or chemical indicators are to be used and where they should be placed in the load
- Checks to be carried out and recorded by operators/users
- Loading and unloading procedures
- The handling and disposal of autoclaved waste
- Instructions of actions operators/users must take if a malfunction or failed run occurs
- Details of the maintenance regime

Visual Checks



Daily Records

Visual checks

Visual checks should be carried out before using an autoclave

The format can be a quick tick sheet

It is not a requirement to record visual checks however it should be documented as carried out in your daily records

Visual Checks

- Check inside the chamber. Is it free from debris and without damage?
- Is the door seal without defects and shows no signs of damage? Clean the door if needed
- Check the locking security of the door(s). Are inter-locking doors working as they should be? Are the securing bolts tight? Check the welds are not cracked and the hinges are adequately greased
- Check all services on the autoclave appear as they are programmed to and are available. Is the autoclave working in a safe and effective manner?
- Check the feed water
- Check for any signs of leaks
- Check for signs of corrosion

Daily Records

- Record the cycle
- Confirm that visual checks have been carried out
- Record the time a cycle is commenced
- Materials loaded
- Programme used
- Operator name or I.D

Pass or failed cycle
Any other faults and actions taken

Autoclave Accidents and Incidents at the University

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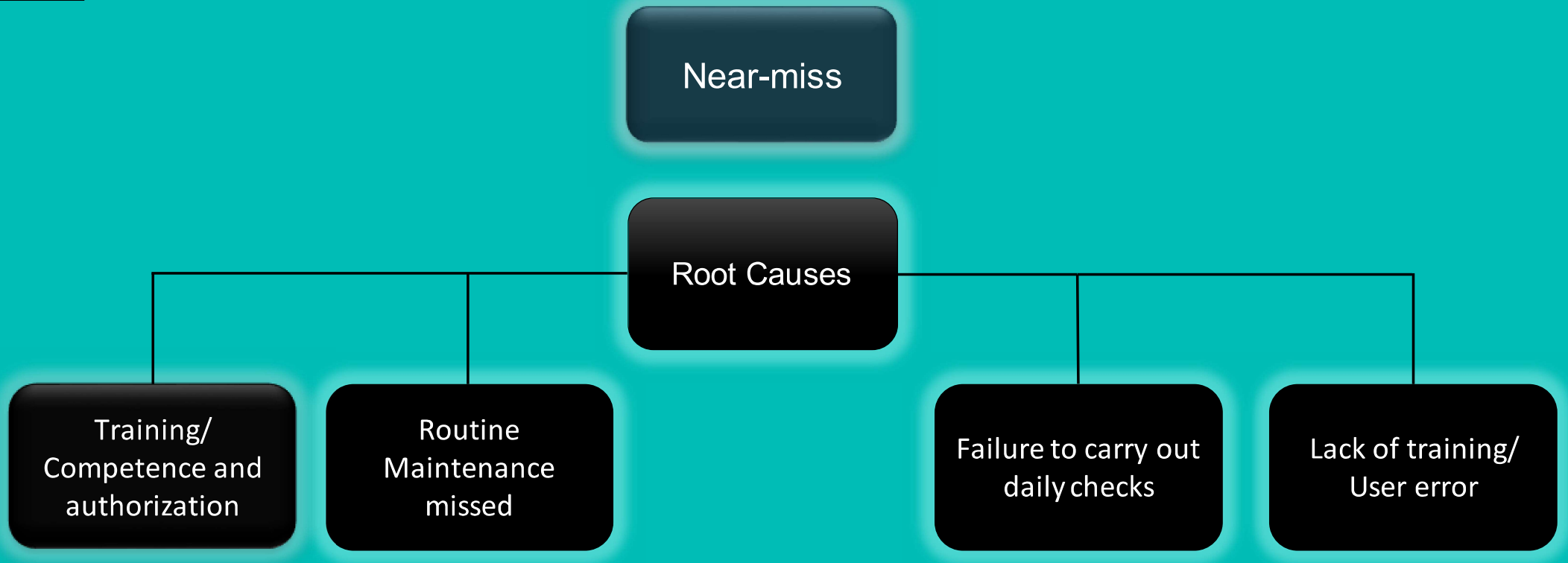
AssessNET reports



HSE Report

An incident occurred after 2008 which involved an operator using an autoclave when the door inadvertently opened and released uncontrolled stored energy

This was a fatal accident

Roles and Responsibilities

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Responsible Person(s)

Instruction and Training should be carried out and documented before anyone works with an autoclave. The responsible person(s) oversees training and instruction. They decide when operators/users are competent

Agree a frequency to review autoclave operation, cycle logs and plant history file

They plan or oversee a contingency plan and emergency procedures for autoclaves

They establish who has access to key and codes which can override safety controls

They ensure servicing and maintenance is carried out

They make the decision to take autoclaves out of service

Risk Assessment

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General hazards

Biological

- Spillages
- Failure of a cycle/fail to make-safe

Physical

- Pressure Vessel hazard
- Temperature

Operational

- Manual or automated system controls
- Loading and unloading
- Deterioration:
  - Corrosion
  - Build up

Contingency Planning

- Consider what to do if cycles fail, whether you can repeat the cycle or have access to another autoclave
- Spillages and the procedures to follow to contain release if it occurs before inactivation
- Factors requiring autoclaves to be taken out of service
- Response time of the Service Provider

Thank you for listening