

Safety requirements for autoclaves

Guidance Note PM73(rev3)



Introduction

- 1 Autoclaves are pressure vessels with lids or doors, arranged for regular access. They are used in a variety of processes, where products are placed inside the vessel and subjected to greater than atmospheric pressures and, in most cases, elevated temperatures.
- 2 This guidance covers industrial autoclaves used in workplaces. It is aimed at all employers, supervisors and managers responsible for the safe operation and maintenance of these devices. It specifically addresses the risks associated with safeguarding, training and maintenance.
- 3 The guidance can also help Notified Bodies (responsible for conformity assessment) and Competent Persons (devising written schemes of thorough examination) to assess the autoclave and identify measures for risk reduction.
- 4 This guidance has been prepared in response to two fatalities in the UK since 2008. One incident involved a walkway collapsing while production staff were loading the autoclave. In the other incident, an employee was struck by the vessel door when it opened, while still under pressure.

Risks from autoclaves

- 5 Autoclaves are high-risk equipment. Their use is covered by the Provision and Use of Work Equipment Regulations 1998 (PUWER)¹ and the Pressure Systems Safety Regulations 2000 (PSSR).²
- 6 The most serious risks come from the uncontrolled release of stored energy, which happen when safety critical parts fail. This can cause violent ejection of:
 - components/pieces of equipment;
 - the pressurising medium;
 - the vessel contents.

What you need to do

- 7 You must reduce the risks outlined above by taking appropriate safety measures. What is required depends largely on the size of the autoclave, its operating pressure and the kind of pressurising medium.
- 8 You can determine the measures appropriate for your particular situation by weighing up the risk factors described in this guidance.

9 The starting point is to identify the safety critical parts of the autoclave system, including those where a single fault leads to total disengagement or loss of system integrity.

10 The nature of the autoclave, how it is installed and what it is used for may highlight other hazards such as:

- inadvertent opening/failure of the lid/door mechanism while under pressure;
- overloading the supporting framework;
- corrosion/erosion;
- fragile containers, in autoclaves for sterilising, shattering if exposed to a sudden temperature change.

Determining risk factors

11 You must assess the following key issues:

- control of automated and manual systems;
- inadvertent pressurisation with a person inside the autoclave;
- inadvertent pressurisation of blowdown, drain and transfer lines;
- a door or lid opening violently under pressure;
- verifying nil pressure before opening the vessel;
- location;
- instruction and training;
- thorough examination;
- maintenance and inspection.

Control of automated and manual systems

12 Autoclave control can be fully manual but programmable electronic systems (PESs) are becoming increasingly commonplace in autoclave control. The monitoring and control facilities these systems provide may be very sophisticated. They can allow for automatic shutdown and remote monitoring, as well as a facility to indicate that a fault has been detected, at a remote location away from the autoclave. You must have the following control safeguards in place.

13 In automated autoclave systems, you must configure all safety devices so that, in the event of a dangerous situation, the autoclave will fail-safe with a means of dissipating residual energy (ie the pressurising medium within the autoclave). These dangerous situations include:

- loss of power;
- loss of pressure;
- over-pressure;
- over-temperature;
- emergency stop activation;
- interlock/sensor discrepancy.

14 When any automated system is placed in a safe condition, the inlet valves should close and the exhaust valves open, which is established industry practice. There must be gauge points on or near the valves to allow verification that there is no longer pressure in the lines.

15 There must also be isolation of pressure to the autoclave. This should normally be achieved with fail-to-safe automated valves or manually-operated valves, using

double isolation valves when transferring and isolating relevant fluids, which is the established industry standard.

16 To prevent risks from interlock/sensor discrepancy on automated process controls, you should verify the function of the interlock or safety device. Established industry practice for this is to continually monitor interlock and safety devices with independent sensors so that, in the event of a discrepancy, the autoclave is placed in a safe condition and a fault condition is reported immediately.

17 Manually-operated autoclaves rely on operator procedure to verify the safe condition of the plant and that interlocking and safety devices are functioning correctly. Visible door position indicators and additional gauge points are also advisable, to further reduce the risk, by allowing the operator to cross-check the status of the autoclave.

Inadvertent pressurisation with a person inside the autoclave

18 If the autoclave is large enough for an operator to enter, fit the autoclave door with a device to prevent the door from closing and the cycle from starting with the operator inside.

19 Where full-body access inside the autoclave is possible, it is also advisable, depending on the process, to reduce the risk further by providing a safety alarm or pull cord inside the vessel to automatically engage the emergency stop circuit.

Inadvertent pressurisation of blowdown, drain and transfer lines

20 To prevent inadvertent pressurisation or scalding at adjacent autoclaves, you must install independent drain and blowdown lines wherever possible. Where this is not possible, there must be additional safety devices to make sure only one autoclave blowdown valve can be in the open position at any one time.

21 Where the exhaust of relevant fluid from one autoclave is reused in another autoclave, it is essential to provide a valve in the transfer line. This must be interlocked with the door-locking mechanism of the autoclave that the relevant fluid is being supplied to.

Door/lid opening violently under pressure

22 You should take several factors into account when you are assessing the suitability of door/lid opening and closing mechanisms, especially those fitted with a mechanism that allows rapid opening (called quick-opening doors), where exposure can occur quickly.

23 This can also apply to smaller vessels if the initial 'cracking' of the door seal is likely to lead to dangerous emissions of vapour, scalding liquid or fragments of product container, which have shattered in the autoclave. Paragraphs 24-29 explain the precautions you must take.

24 The autoclave should not be capable of being pressurised unless the door/lid is completely closed, the securing mechanism fully engaged and the chamber sealed. This is normally achieved by interlocking between the door-securing mechanism and the pressurising system. Where pressure is applied:

- from an external source, eg steam, air or other gas, the interlock should be between the door-securing mechanism and the pressurising fluid inlet valve;
- by boiling liquid in the vessel, the interlocking arrangement should be between the door-securing mechanism and the source of heat;
- by a pump, the pump should not be able to pressurise the system unless the door-securing mechanism is fully engaged.

25 As part of any automated door-opening system, the door position monitoring must be verified. You can ensure this by installing more than one position sensor. It is also advisable to include a visual indicator to allow the operator to physically check the door position.

26 The autoclave should be vented to reduce the internal pressure to atmospheric conditions before the door-securing mechanism can be disengaged.

27 Take care to make sure the door/lid does not open violently due to any residual pressure in the vessel. A suitable device for this purpose is a safety catch robust enough to prevent single component failure of the normal door-locking assembly and which has to be released independently after:

- the door-securing mechanism has been disengaged; and
- the door seal has been broken.

The purpose of a safety catch is to prevent risk from residual pressure inside the vessel. However, as the extent of residual pressure cannot be determined, it is recommended that the safety catch is capable of withstanding energy release from catastrophic failure (ie normal working pressure). Safety catches can be automatically or manually engaged.

28 Where there is a danger of the door seal sticking, with residual pressure remaining, the door mechanism should break the seal before the locking device is disengaged in such a way that the door remains captive. Where this is not possible, movement should be restricted, so the door opens not more than 8 mm after it has been partially released. A suitable device for this is a safety catch that:

- has to be released independently of the door being unlocked; and
- may not be fully released until the door has been 'cracked' open and the seal broken.

29 To further reduce the risk of harm from hot product, it is advisable to prevent the door/lid from being opened until the temperature of the autoclave contents have been reduced to a safe level. This may be achieved by using an interlocking arrangement, incorporating temperature-sensing devices located in the parts of the vessel expected to remain at the highest temperature at the end of the cycle.

Verifying nil pressure before opening the vessel

30 All autoclaves must include a correct and suitable pressure indicator installed where the operator can see it easily. This should usually be on or near the autoclave.

31 On larger autoclaves the residual pressure may not be enough to register on an indicator gauge. But, acting over the surface area of a large door, this residual pressure can exert a considerable force that is released violently, if the door is opened suddenly. Normal industry practice is to prevent this by installing a vent

valve (also referred to as a test cock) to verify there is nil pressure. The test cock may be manually operated, or form part of the automated process control.

32 On automated systems the vent valve is opened with a 'test sequence' button. This must be a hard-wired circuit, with independent sensors used to confirm nil pressure in the autoclave. Integration with the door position interlocks (as part of the door-opening sequence) is also established practice.

33 On manual systems, there is a reliance on hearing the pressure release (air systems) from the vent valve and/or visual means, eg steam. The vent valve outlet should always be arranged, so that any discharge will not injure someone carrying out the test.

Location

34 Several aspects of location of the autoclave are important. These include:

- access;
- control position;
- outlets;
- loading arrangements.

Paragraphs 35-39 explain the action you need to take.

35 The operator needs safe access, taking account of relevant general hazards, such as:

- working at height;
- hot surfaces;
- poor visibility;
- awkward reaches.

36 To reduce risks to other people besides the operator further, install the autoclave so its door/lid faces away from main thoroughfares wherever possible.

37 Position controls for the autoclave so they are remote from potential energy release created from failure of the door and from pressure relief, blowdown or drain outlets.

38 Situate the outlets remotely or install additional pipework to the discharge from these devices, to a place where it will not be a hazard.

39 Where trolleys are used to load product into the autoclave, avoid using pedestrian access platforms for this purpose. Provide dedicated trolleys and rails strong enough to support the product's weight. In all circumstances, do not exceed the maximum load of the trolley, rails and access platforms.

Instruction and training

40 The training and instruction given to operators should cover all the procedures and information they need to operate the system safely. It should also cover any special procedures to follow in an emergency. You also need to give existing staff regular refresher training.

41 Do not allow anyone to enter the confined space of an autoclave, unless you have assessed the risks to health and safety, put a suitable safe system of work in place and provided training in confined space entry for the people involved. There is further information on work in confined spaces in the HSE leaflet *Safe work in confined spaces*.³

42 Supervisors are crucial in making sure operators follow agreed safe systems of work. They also need to be competent to carry out their duties effectively and may themselves require refresher training, if there are changes to the way you work.

Thorough examination

43 A competent person should examine autoclaves containing a 'relevant fluid' (as defined under PSSR), periodically, under a Written Scheme of Examination (WSE).

44 Under PSSR, it is the autoclave user's responsibility to make sure the WSE is prepared and in place before the autoclave is put into use. The WSE should include:

- those parts of a system that must be formally examined;
- the nature of examination required;
- details of any preparatory work required;
- the maximum interval between examinations;
- details of those certifying the WSE and when it was completed.

See *Written schemes of examination: Pressure Systems Safety Regulations 2000* for more information.⁴

45 The autoclave user must provide information, such as operating and maintenance records, to enable the competent person to establish how the autoclave is being used and target their examination accordingly.

46 You should adopt a similar regime of examination under PUWER for vessels containing a non-relevant fluid.

Maintenance and inspection

47 Do not confuse the need for maintenance with the requirement for thorough examination under the written scheme. They are two separate issues, although problems identified during an examination under the WSE may require maintenance to correct.

48 Under PSSR, the user must inform the competent person of any significant repairs or modifications to the system.

49 Make suitable and effective arrangements to make sure the autoclave is properly maintained. Where the manufacturer or supplier has provided maintenance instructions for all or part of the system, these will form the basis of the maintenance programme. If they are not comprehensive enough to cover the on-site operating conditions, they should be supplemented as appropriate. Paragraphs 50–57 explain the arrangements you need to include.

50 You need planned preventive maintenance on the autoclave system, carried out at regular intervals by an experienced person, properly trained and competent to recognise defects.

51 There should be an appropriate monitoring scheme to keep all safety-critical parts of the autoclave, including all those where a single component failure can lead to danger, in efficient working order. This will normally include daily (or shift) checks to ensure that all the critical safety devices are working effectively, carried out by operators who have had the necessary training.

52 Keep a comprehensive maintenance history, with suitable and sufficient records of maintenance inspections, tests, faults, repairs and modifications to help identify and address problems before they develop and to inform the competent person of any significant repairs or modifications to the system.

53 Take appropriate actions arising from problems identified during operation of the system and assessed for their impact on the safety of the system. For example: make frequent checks in processes where accumulations of deposits of process waste materials may cause protective devices and other safeguards to become ineffective. This applies particularly to door interlock devices, tap-in points and vent lines.

54 Where the vent line requires regular rodding to clear the build-up of detritus:

- you need to provide safe access to the rodding point; and
- the rod should be long enough to clear the bore through to the autoclave chamber.

55 Make sure that door-locking assemblies are in good working order, regularly check that all securing bolts are tight, welds are not cracked and that the tightening mechanism (eg wedge or castellations) is to the correct tolerance. It is widely believed that vibration causes bolt loosening (referred to as self-loosening). In such applications, use a suitable thread locking device (also referred to as free spinning, friction locking, or chemical locking devices) to prevent self-loosening.

56 On three-part door-locking assemblies, the rotating ring is a safety critical part (as it is a single component used to retain the door against the vessel rim). You must target maintenance to ensure the ongoing integrity of this connection. Dimension checks, in combination with close visual inspection, should form part of periodic inspection, to make sure that the ring is not running eccentrically.

57 Ensure that door assemblies are adequately greased. Consult the manufacturer about any particular recommendations, eg use of high-temperature grease to the injection points and manually applying graphite paste to the door seal face.

References

1 *PUWER 1998: Provision and Use of Work Equipment Regulations 1998. Open learning guidance* (Second edition) HSE Books 2008 ISBN 978 0 7176 6285 2

2 *Safety of pressure systems. Pressure Systems Safety Regulations 2000. Approved Code of Practice L122* HSE Books 2000 ISBN 978 0 7176 1767 8 www.hse.gov.uk/pubns/books/l122.htm

3 *Safe work in confined spaces* Leaflet INDG258 HSE Books 1997 (Priced pack ISBN 978 0 7176 1442 4) www.hse.gov.uk/pubns/indg258.pdf

4 *Written schemes of examination: Pressure Systems Safety Regulations 2000* Leaflet INDG178(rev1) HSE Books 2002 (Priced pack ISBN 978 0 7176 2269 6) www.hse.gov.uk/pubns/indg178.htm

Further reading

HSE's pressure systems web pages: www.hse.gov.uk/pressure-systems/index.htm

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

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