REGULATORY REQUIREMENTS FOR AUTOCLAVES

1. INTRODUCTION

The University of Melbourne owns and controls a variety of autoclaves across various Schools, Faculties and Departments. Autoclaves contain at least one pressure vessel. Some of these pressure vessels have regulatory requirements under the *Occupational Health and Safety Regulations 2017* (Vic).

This document outlines the specific regulatory requirements for:

- design approval.
- risk assessment.
- maintenance.
- inspection; and
- training.

2. KEY REGULATORY REQUIREMENTS

A pressure vessel is defined in *AS/NZS 1200 Pressure equipment*. It is categorised as a hazard level A, B, C or D or E. These hazard levels are mainly determined according to maximum volume, operating pressure, type of fluid/gas and type of door closure as outlined in *AS 4343 Pressure equipment – Hazard levels*. AS 4343 provides the following examples to describe the hazard levels:

Hazard level A (high hazard) — applies to large vessels, (e.g., 4000 tonne ethane vessels, 7000 tonne butane or propane vessels, 25 000 tonne ammonia vessels, 200 tonne chlorine vessels and large power boilers)

Hazard level B (medium hazard) — applies to most shop fabricated boilers and pressure vessels.

Hazard levels C and D (low and extra low hazards, respectively) — applies to small pressure equipment or equipment with low hazard contents (e.g., small air receivers).

Hazard level E (negligible hazard) — applies to all negligible-hazard pressure equipment not classified in hazard levels A, B, C and D. This equipment is usually exempt from special regulatory control but is covered by general plant safety regulations.

Table 1 provides a brief outline of regulatory requirements for autoclaves, based on their hazard level.

REGULATORY REQUIRMENTS					
Hazard Level	Design Approval (2.1)	Risk Assessment (2.2)	Maintenance (2.3)	Inspection (2.4)	Training (2.5)
A	✓	✓	✓	✓	✓
B	✓	✓	✓	✓	✓
C	✓	✓	✓	✓	✓
D	✓	✓	✓	✓	✓
E		✓	✓		✓

✓	Required
✓	May be required
	Not required

Table 1: Regulatory requirements for autoclaves, based on their hazard level

2.1 Design approval

The design of pressure vessels (high-risk plant) must be registered with WorkSafe (or the Regulatory equivalent) prior to use in the workplace. This registration is undertaken by the manufacturer/designer of the pressure vessel. The pressure vessel is given a unique design approval number that is included on a name plate. Therefore, autoclaves will have a nameplate with an approval number.

Autoclaves with a hazard level of A, B, C and D require design approval.

2.2 Risk assessment

All high-risk plants require hazard identification and risk assessment prior to use. The University Health & Safety: Plant risk assessment form can be used for this purpose.

The first page of the risk assessment can be used to document the regulatory requirements highlighted in Table 1:

- design approval number outlined in Section 2.1 – indicated by the **red rectangle** in Appendix A.
- scheduled maintenance and inspection requirements outlined in Section 2.3 and Section 2.4 – indicated by the **green rectangle** in Appendix A;
- training requirements outlined in Section 2.5 – indicated by the **blue rectangle** in Appendix.

Associated with the risk assessment will be the Health & Safety: Standard operating procedure (SOP) that outlines the safe use of the plant. Along with instructions for the safe operation of the autoclave, the SOP should include the requirements for preoperational checks by the user.

For more general information on risk assessment methodology refer to Health & Safety: Risk assessment methodology.

Autoclaves with a hazard level of A, B, C, D and E require a risk assessment.

2.3 Maintenance

The frequency of scheduled maintenance (also referred to as inspection) is determined by the manufacturer's recommendations and, in many cases, the volume of use and type of activity[1].

Taking into account the above, local areas should consult the manufacturer/supplier (such as the operating manual) for the frequency. After the frequency has been determined this should be recorded. For example:

- a plant risk assessment.
- a cyclic events checklist;
- a set of instructions for autoclaves; or
- a plant risk register.

Autoclaves with a hazard level of A, B, C, D and E require scheduled maintenance.

[1] Additional requirements, such as OGTR or Import Permit Condition should also be considered when determining the frequency and type of servicing requirements.

2.4 Inspections

AS/NZS 3788 Pressure equipment – In-service inspection states that scheduled inspections:

- verify that fabrication and operation comply with design conditions.
- verify that pressure equipment is safe and fit for service under the specified operating conditions until the next planned inspection.
- verify that maintenance, repairs, and alterations are carried out in a manner which maintains the integrity of the pressure equipment.
- indicate repairs, replacements or alterations which may be needed; and
- assess the remaining safe life of the pressure equipment.

PLEASE NOTE:

Scheduled inspections are undertaken by a consultant, for all registered pressure vessels across Schools, Faculties and Departments within the University. These inspections are in line with AS/NZS 3788.

The service is provided at cost to the Faculty or Department by:

Frank Busch Inspection Pty Ltd.

- Tel: 03 9384 2800; or
- email office@busch.net.au

2.4.1 Scheduling

Scheduled inspections consist of three components:

- internal inspection.
- external inspection; and
- pressure relief valves.

Scheduled inspection intervals are determined by the MPa.L (mega Pascals per litre) of the pressure vessel, the fluid type, and the contents, not by the hazard level. Additionally quick released opening autoclaves may affect the scheduling requirements. Table 2 represents the inspection intervals for most autoclaves.

INSPECTION INTERVALS				
MPa.L	**Commissioning inspection required**	**First yearly inspection**	**Inspection interval (years)**	
			External	**Internal**
≤ 100 MPa.L	No	No	–	–
≥ 100 MPa.L	Yes	No	2 years	4 years
Pressure relief valve	Yes	Yes	4 years	

Table 2: Scheduled inspection intervals for autoclaves.

The MPa.L for the autoclave should be determined and recorded. For example, on the plant risk assessment.

Autoclaves with a hazard level of A, B and C generally have an MPa.L ≥ 100 and therefore require scheduled inspections as listed in Table 2. Some autoclaves with a hazard level of D may also require the scheduled inspections listed in table 2. If uncertain of the MPa.L of an autoclave, the local area should arrange for a competent person to determine this and the inspection requirements.

After the frequency has been determined this should be recorded. For example, on the plant risk assessment, in a cyclic events checklist or in the plant risk register.

2.4.2 Records

Records of all inspections and maintenance should be kept for the life of the autoclave (for the duration that the autoclave is in control of the University). The Occupational Health and Safety Regulations 2017 require the following:

> *An employer or self-employed person must keep a record of any inspection and maintenance carried out on the following plant for the period that the employer or self-employed person has management or control of the plant:*
>
> - *pressure vessels with a hazard level A, B or C as determined by AS 4343 Pressure equipment*

2.5 Training

Ensure all staff and/or students using and operating the plant, including autoclaves, have received training in its safe operation. A record of training must be made and should be kept by the local area.

Autoclaves with a hazard level of A, B, C, D and E require appropriate training.

For use in conjunction with the Health & Safety: Regulated plant requirements.
For further information, refer to Plant and electrical equipment or contact your Health and Safety Business Partner.

3. APPENDIX A: PLANT RISK ASSESSMENT FORM

THE UNIVERSITY OF MELBOURNE

HEALTH & SAFETY
PLANT RISK ASSESSMENT FORM

Ra No.:	Date:	Version No.:	Review Date:	Authorised by:

STEP 1 – ENTER INFORMATION ABOUT THE ACTIVITY/TASK, ITS LOCATION AND THE PEOPLE COMPLETING THE RISK ASSESSMENT

Location name:	Building No.:	Room No.:	Date:	Assessed by:	HSR/Employee represenative:

Users of the plant:	**Plant (Manufacturer's name and model no.):**		
	Serial No.:		
Purpose of plant:	**Does the plant require licensing/registration?**	Yes ☐ No ☐	Licensing/Registration No.:
	Additional information for pressure vessels. (Refer to AS 4343)	Design approval no.:	Date of manufacture:
		Class (A, B, C, D E):	Number of pressure chambers:

Description of how plant is used:

Does the operator require a licence or competency?		
	☐ External licence	Specify:
	☐ Internal competency	Specify:
	☐ No specific competency	

Workplace conditions (Describe layout and physical conditions - including access and egress)

Consider operation outside of normal conditions • Cleaning • Non-standard use • Breakdown & repair • Maintenance • Commissioning • Decommissioning • Emergency situations	
List systems of work for using the plant: • Training • SOPs • Manufacturer's information and instructions • Inspections • Emergency situations	
Is there past experience with the activity/task that may assist in the assessment? • Existing controls • SOPs • Standards • Industry standards • Incidents & near-hits • Legislation & Codes • Training • Incident Investigation • Guidance material	