

# Standard Operating Procedure

<b>Task/Activity/Equipment:</b> General procedures for autoclave sterilisation of biohazard waste	
<b>Purpose:</b> To outline the standard precautions and procedures for autoclave sterilisation of biohazard waste including GMO and microbiological waste.	
<b>Location:</b> Flinders University	<b>Reference Number:</b> IBC-SOP-31 <b>Version:</b> 1.0
<b>Written by:</b> Dr Jess Hall, Biosafety Specialist	<b>Reviewed by:</b> Institutional Biosafety Committee
<b>IBC approval date:</b> May 2023	<b>Revision required date:</b> May 2028
<b>Replaces the version:</b> Not applicable (1st version)	
<b>Changes to the last approved version:</b> Not applicable (1st version)	

## 1. POTENTIAL HAZARDS

Infectious substances	Pressure vessels (autoclaves)
Risk group 1 or 2 microorganisms	Burns and scalds from steam, hot fluids, materials, and surfaces.
Genetically modified organisms	Manual handling of containers.
Diagnostic specimens	Slips and trips from poor housekeeping

## 2. TERMS & ACRONYMS

DAFF	Department of Agriculture, Fisheries and Forestry
GMO	Genetically Modified Organism
OGTR	Office of the Gene Technology Regulator

## 3. RELEVANT LEGISLATION, GUIDELINES & STANDARDS

- *Gene Technology Act 2000*
- *Gene Technology Regulations 2001*
- OGTR Guidelines for Certification of a Physical Containment Facility (PC1, PC2)
- *Australian/New Zealand Standard 2243.3 Microbiological Safety and Containment*

## 4. SWP SCOPE AND COVERAGE

Autoclaves operate at high temperatures and pressures and all users must be aware of the hazards. All pressure vessels and boilers must be regularly inspected and certified every 2 years, and an inspection, service and repair record must be maintained. Yearly calibration of the autoclave must be undertaken by the manufacturer, and service, calibration and repair records must be maintained. Copies of these records must be made available within the autoclave facility.

All users must be trained\* in the safe operation of the autoclave prior to first use. This will provide an understanding of the appropriate conditions for load sterilisation, and an appreciation of the hazards associated with heat, steam, and pressure.

\*Training sessions will be conducted by competent, authorised persons from the associated College or facility to ensure that all relevant new staff students are trained.

5. HAZARDS		
Hazards Identified	Rating	Safety Measures
Burns & scalds from steam, hot fluids & materials	M	Training; containment baskets; protective gloves/clothing/footwear, safety glasses or face shield, mandatory signage
Burns from radiant heat and hot surfaces	M	Training; containment baskets; protective gloves/clothing/footwear; mandatory signage
Manual handling of containers	M	Use trolleys & baskets
Pressure vessel rupture	M	Pressure vessel certification and regular maintenance
Poor housekeeping – trips	M	Keep autoclave facility clear
Poor housekeeping – slips from spills/leaks	M	Hazard signage; mop, bucket & DAFF approved disinfectant to clean spills
Exposure to hazardous workplace substances	M	Fume extraction: training ('no hazardous chemicals to be autoclaved')
Exposure to biological hazards	M	Wear gloves when handling waste; transport waste in sealed containers; have DAFF approved disinfectant available in facility; biological spore test sterility check must be included with each kill-cycle load; temperature probe must be used with each kill-cycle load; weekly cleaning of autoclave chamber with disinfectant solution; biannual servicing of the autoclave.

6. PRE-OPERATIONAL SAFETY CHECKS
<ul style="list-style-type: none"> <li>Do not use defective or faulty equipment.</li> <li>Ensure that the annual calibration of the autoclave is up to date, prior to use.</li> <li>All operators must be trained and signed off in an authorised training session conducted by competent, authorised persons.</li> <li>If GMOs or biosecurity material is to be autoclaved, operators must be trained and approved to handle such material.</li> <li>Operators must wear protective clothing, safety glasses and enclosed footwear.</li> <li>Use heat-insulating/moisture-proof gloves provided for use when loading the autoclave.</li> <li>Ensure that no chemical hazards that may present a risk when heated or held under pressure are present. This includes bleach, which may produce hazardous vapours when autoclaved.</li> <li>Ensure that goods that are autoclaved are not in direct contact with the autoclave chamber surface.</li> <li>Following repair or service of the autoclave, the first cycle run must be validated using biological indicators and temperature probe monitoring prior to use for the treatment of biosecurity waste.</li> </ul>

7. PREPARATION OF GOODS FOR AUTOCLAVE STERILISATION	
1	Goods must be packaged and prepared for autoclaving whilst within a containment facility.
2	Enclose disposable waste in an autoclavable biohazard waste bag (look for the biohazard symbol on the bag) placed inside of a second autoclavable biohazard waste bag. Seal the external bag with pressure indicator tape.
3	The outside of the bag should be sprayed with disinfectant following packaging and should be placed into an enclosable tub or container before transport to the autoclave facility. The outside of the tub or container should then also be sprayed with disinfectant.
4	Transfer bags onto a solid stainless-steel tray or stainless-steel enclosure (no lid) to confine spillage prior to autoclaving.



**Figure 1: Autoclave bag placed on tray.**

5	Snip/slash hole through both layers of biohazard bags to allow penetration of steam and displacement of air.
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## 8. LOADING AUTOCLAVE, INCLUDING BIOLOGICAL INDICATORS FOR TEST CYCLES

6	Autoclave test cycles must include two biological indicators (e.g., 3M Attest 1262 Biological Indicators) in each processed load. This testing must be undertaken monthly.
7	Label the indicators for individual identification, then place in the following locations: <ul style="list-style-type: none"> <li>• In the bottom shelf of the autoclave, directly above the drain point. This represents the 'coldest' part of the load.</li> <li>• In an item representative of the densest item being sterilised – e.g., within a large Schott bottle of water if sterilising liquids, or within a jar of clean soil if sterilising soil.</li> <li>• A third unprocessed indicator will also be required as a control but should not be autoclaved.</li> </ul>
8	Wheel trolley to autoclave and load per operating conditions for the autoclave.
9	Position free temperature probe (thermocouple) in your representative load item.
10	Start the appropriate autoclave cycle per operating conditions for the autoclave.
11	Enter details of the cycle into the Waste Processing Logbook.

## 9. UNLOADING AUTOCLAVE

12	Check printout to ensure that cycle has passed. Where a test cycle is being completed, retain a copy of the printout, sign as 'Unloaded by....' and record in the Waste Processing Logbook.
13	Where cycle has passed, commence unloading per step 3 below. Where cycle has failed, reprocessing of waste is required, following conditions outlined under 'Preparation of goods for autoclave sterilisation'.
14	Wear safety glasses or face shield and heat proof gloves when unloading goods.
15	Open door of autoclave following operating conditions for the autoclave.
16	Unload trolley from autoclave as trained.
17	Wearing heat proof gloves, carefully remove temperature probe and replace inside the autoclave – CAUTION, HOT
18	Wearing heat proof gloves, unlock and remove the trolley – CAUTION, HOT
19	Wearing heat proof gloves, remove sterilised items– CAUTION, HOT
21	Wearing heat proof gloves, collect biological indicators and mark as processed – CAUTION, HOT
22	Where autoclave test cycle is run with biological indicators, 'crush' indicator ampules and place into indicator incubator. <ul style="list-style-type: none"> <li>• Include a control indicator (i.e., an un-autoclaved indicator tube) from the same batch of indicators as used in the autoclave load. Clearly mark the control indicator as such.</li> </ul>

	<ul style="list-style-type: none"> <li>After 48 hours, check indicator results and record in waste processing logbook.</li> </ul>
23	Dispose of waste via biohazard / clinical waste stream for offsite incineration.

## 10. RECORD KEEPING REQUIREMENTS

The following waste management records must be maintained, retained for the specified period, and be made available upon request and at each OGTR or IBC audit:

- Autoclave cycle records (load validation records) – retain records for a minimum of 18 months.
- Copies of autoclave printouts for test cycles – retain records for a minimum of 18 months.
- Records of biological indicator tests undertaken monthly – retain records for a minimum of 18 months.
- Records relating to inspection, servicing, and certification of the autoclave – retain records for a minimum of 5 years.

The Waste Processing Logbook must be completed for each test load processed, at least once per month.

## 11. FORBIDDEN ACTIVITIES

1	<p>Decontamination must not be performed in the autoclave if:</p> <ul style="list-style-type: none"> <li>the autoclave is defective, malfunctioning or out-of-service; and/or</li> <li>the results of each monitoring test and the results of the yearly servicing and calibration for the autoclave are not recorded and available.</li> </ul>
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## 12. APPLICABILITY

These procedures are applicable to persons involved in autoclave sterilisation of biohazard waste including GMO and microbiological waste derived from research activities at Flinders University.

## 13. CONTACTS

Biosafety Officer	Belinda Cox	<a href="mailto:ibcadmin@flinders.edu.au">ibcadmin@flinders.edu.au</a> ph. (08) 82013436
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