

Biological Risk Management and Containment

Calibration, Testing and Certification of Containment Equipment

Monitoring and Measuring Performance

Containment Laboratory Reference

Version 2.1- September 2024

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This document was updated from Version 2 which was reviewed and approved n February 2021.

Record of Amendments to Version 2.1

Date	Page number	Nature of amendment
Sept 2024		Minor edits to wording throughout document
Sept 2024	5	Section 3.3 rewritten to provide equal emphasis to both testing methodologies
Sept 2024	8, 9	New record templates provided for autoclave testing methodologies



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1. Who is this reference document for?

This document is intended for **principal investigators (PIs), designated persons in charge, designated laboratory person (DLPs)**, technical staff and students who require access to laboratories within University of Auckland containment and transitional facilities.

2. Biological safety cabinets (BSCs)

2.1 Testing and calibration of BSCs

BSCs at the University are tested annually against the relevant Standard appropriate for the BSC. These standards include Australian/New Zealand standard (AS/NZS), European or National Science Foundation (NSF) testing procedures. Testing is performed by an International Accreditation New Zealand (IANZ) accredited testing company.

BSCs are to be tested as soon as possible after being moved. BSCs are not to be used if they do not have current certification.

3. Autoclaves

In the University we have multiple types of autoclaves. For the BRMC purpose, we only refer to the ones used for waste decontamination. The autoclaves (mostly the benchtop type) that are used for glassware sterilisation or other purposes do not have to meet all the requirements below, but they still need appropriate maintenance as defined by the university's <u>Machinery and Plants Safety</u> standard.

3.1 Safety testing of autoclaves

Autoclaves are tested annually under the requirements of the Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) Regulations 1999, and receive a safety test certificate. Testing is performed by an IANZ-accredited testing company. The safety test certificate is to be posted beside the autoclave. For

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more information, please refer to the BRMC guidance Use of Autoclaves to Treat Biohazardous Waste.

3.2 Autoclave temperature probe and pressure transducer calibration

Autoclave temperature probes and pressure transducers are calibrated annually, and calibration certificates are to be retained as part of approved autoclave documentation.

3.3 Autoclave prevacuum testing

Prevacuum autoclaves must be tested regularly while operational. There are two options:

- 1. Biological Indicators on a monthly basis, as described below and in the BRMC guidance *Use of Autoclaves to Treat Biohazardous Waste*, OR
- 2. Helix tests on a weekly basis, which test for the removal of air from the autoclave chamber before the sterilisation cycle by the placement of a steam process indicator at the end of a long thin piece of tubing. Documentation of test results is to indicate the type of test used, expiry date and lot#.

The results are to be documented in a folder beside the autoclave. See Appendix 1 for the format for recording these results.

3.4 3.4 Biological indicator testing

Bio-indicator tests are to be performed monthly at a minimum as per the instructions outlined in the BRMC guidance *Use of Autoclaves to Treat Biohazardous Waste.* Biological indicators are to use an accredited biological indicator containing > 10^5 *Geobacillus stearothermophilus* spores. The tests may either be configured for rapid results (i.e. $3M^{TM}$ AttestTM 1292) or use conventional indicator systems (i.e. $3M^{TM}$ AttestTM 1292). Documentation of test results is to indicate the type of bio-indicator test used, the lot of indicators and the incubation times used.

The results are to be documented in a folder beside the autoclave. See Appendix 1 for the format for recording these results.

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4. Room Pressure

Testing and calibration of directional airflows, negative pressure and air pressure gauges

4.1 PC2 Laboratories

Directional airflows into PC2 laboratories are verified at the time of monthly laboratory inspection by designated persons in charge. Verification can be undertaken with the use of a simple tell-tale (strip of tissue) and recorded as a simple yes/no for directional airflow.

Measurement of speed of airflows in each entrance can be estimated using a wire anemometer (a device used for measuring the speed of wind), although this is not mandatory.

Where magnehelic gauges* are present, the readings should be documented on monthly lab inspection result sheets.

4.2 PC3 Laboratories

Directional airflows into PC3 laboratories shall be measured by a pressure differential gauge. The gauge reading will be verified and documented on the monthly laboratory inspection sheets by designated persons in charge. The gauge used shall be calibrated and tested by an IANZ-accredited supplier at two-year intervals.

* A magnehelic gauge is an instrument that measures the static pressure in a heating, venting and cooling or HVAC system.

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5. Definitions

Designated laboratory person (DLP) means the trained person in each research group who has been given the authority to receive purchase requests made in SciTrack and to make a formal request for a purchase order via PeopleSoft. In containment and transitional facilities DLPs will have additional training to enable them to scrutinise documentation for restricted items and provide support to researchers.

Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager or an appointed delegate.

Principal Investigator (PI): In the context of hazard containment and transitional facilities, a principal investigator is the holder of an independent grant administered by the University and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader." The PI is responsible for assuring compliance with applicable University standards and procedures, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks, they retain responsibility for the conduct of the study.

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6. Appendix 1: Autoclave Validation

Helix test

To be undertaken on first run after any required warmup cycle at the beginning of each week. The sections in yellow can be prefilled on the template with information specific for each facility.

- Record the test detail
- Record the identity of the autoclave (eg, Bldg-Room, unit #, or UOA asset #)

	UNIVERSITY OF AUCKLAND Wapper Taumata Rea			
Verification:	Helix cat <mark>#:</mark>	Lot #:	Expiry:	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	
Date	Autoclave ID	Cycle number	Result	Operator Signoff
			Pass / Fail	

Biological indicator

To be undertaken at a minimum of once per month. Please refer to the BRMC Guidance *Use of Autoclaves to treat Biohazardous Waste* for more information

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The sections in yellow can be prefilled on the template with information specific for each facility.

- Record the type of BI (eg, 3M[™] Attest[™] 1262, 1292)
- Record the identity of the autoclave (eg, Bldg-Room, unit #, or UOA asset #)
- The cycle type will refer to the options available in that facility

Start/Finish dates (highlighted in green) are only required for BIs that take multiple days to process (eg 3M[™] Attest[™] 1262). Additional information required by individual facilities should be recorded in extra columns.

AUTOCLAVE VALIDATION - BIOLOGICAL INDICATOR (BI) RECORD						UNIVERSITY OF AUCKLAND Wapaga Taumata Rau		
Verification:	3M Attes	t BI cat#	:		Lot #:		Expiry:	
Date	Autoclav	/e ID		Cycle ty	Cycle type		BI position in load	
BI incubation	Start date	Start time	Finish date	Finish time	Positive Growth	Negative Growth	Result:	Pass / Fail
Sample								
Positive Control							Operator Signoff:	
Date	Autoclava ID			Cycle type PI pecition is		BI position in load		
Date				cyde type				
BI incubation	Start date	Start time	Finish date	Finish time	Positive Growth	Negative Growth	Result:	Pass / Fail
Sample								
Positive Control							Operator Signoff:	
Date	Autoclave ID			Cycle type		BI position in load		
BI incubation	Start date	Start time	Finish date	Finish time	Positive Growth	Negative Growth	Result:	Pass / Fail
Sample								
Positive Control							Operator Signoff:	

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