Biological Risk Management and Containment

Monitoring and Measuring Performance

(Internal Verification and Reporting)

Containment Laboratory Guidelines

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1. Contents

2. Who are these guidelines for?

These guidelines are intended for **principal investigators (PIs), designated persons in charge, designated laboratory person (DLPs)** and technical staff within the Containment Facilities.

3. Objectives

Regular internal **verification** is an integral part of any risk management system. The purpose is two-fold:

1) To ensure that systems and procedures outlined in containment guidance are fit for purpose and achieve the desired results; and if not, appropriate improvements are identified
2) Ensure that the BRMC is complied with
3) To identify risk and ensure appropriate risk mitigation procedures are put in place
4) Make improvement recommendations where weaknesses or inefficiencies are observed

4. Structure

The University is a complex environment with staff hierarchies that differ through the faculties to suit local operational needs. In order to achieve the objectives above, the University Internal Verification consists of several layers of checks done with a periodicity that goes above and beyond than the 6-monthly required by section 8.11.2 of the 154-03-02 Standard. This is to ensure that issues are identified in a promptly manner and constantly through the time. The University Internal Verification includes:

1) Monthly laboratory inspections of each lab by designated laboratory persons (DLPs) or laboratory users
2) Three-monthly inspections
3) 6 monthly scoped inspections
4) Unannounced laboratory checks

The results of verification exercises are as follows:

1) Where **non-conformances** are identified they are documented and corrected
2) The root cause of non-conformance is also identified (where appropriate), documented and corrected
3) Exemplars identified as the result of monthly inspections, internal verifications are noted in the facility's verification register and used as models for improvement (i.e. good practices are shared across the University community)

The findings of the internal verification exercise and any critical non-conformances are to be reported to the Delegated Operator (Deputy Vice-Chancellor (Research)) and senior management / faculty executive leadership teams, with recommendations as to how systems and resources might be improved.

The findings of the internal verification exercise are to be discussed amongst **designated persons in charge** shortly after its completion to ensure immediate non-conformances are addressed and closed out.

5. Monthly laboratory inspections

Monthly laboratory inspections are to be undertaken by DLPs, laboratory users or as per delegation of Technical Managers. These are designed to ensure that the physical structure of laboratories is maintained to a high standard and individuals are routinely observing good laboratory practice.

The focus of monthly inspections is to ensure:

- Laboratory users are making all efforts to meet the University of Auckland Biological Risk Management and Containment Standard (i.e. the requirements of AS/NZS 2243.3 at a minimum)
- A high standard of laboratory cleanliness
- All equipment testing has been undertaken before due date

Monthly inspections can be made using a purpose-designed checklist (see Appendix 1), which can be completed online or in hard copy. Completed inspection checklists should be filed electronically.

A dedicated checklist (*Appendix 3*) is to be used for ancillary areas such as walk-in cold-rooms, centrifuge rooms and rooms with low temperature freezers. It is recommended that a PC1 laboratory inspection checklist is used in incubation rooms.

Minor non-conformances are to be noted and closed out on the checklists. Non-conformances along with close out actions to the designated person in charge. Repeated or major non-conformances are to be documented in Damstra.

6. Three monthly inspections

Three monthly inspections include:

- the reconciliation of facility and MPI import records
- tracking of medical waste processes
- verification of central HSNO approval register (Infonetica).

7. Twice a year scoped internal verifications

Internal verification is undertaken in each facility by designated persons in charge and is designed to ensure that systems and processes (including monthly laboratory inspections) are regularly checked and are fit for purpose. Internal verification exercises are conducted twice per year, and they can last from 2 to 3 months depending on scope. Also, considerations are made around University operations and available resources. Their duration and depth do not allow for a simple '6-monthly' cut off but the whole internal verification system meets and exceeds the AS/NZ 2243.3, section 8.11.2 requirement.

Six-monthly internal verification exercise of selected outcomes out of the 22 defined in *Appendix 2* will be undertaken by the Technical Management Team, Hazards and Containment Manager and Biological Safety Adviser. Selected outcomes are chosen by the Hazard and Containment team and the Technical Management team on the basis of previous external and internal non-compliances, reported incidents, to monitor ongoing improvement projects and AS/NZ 2243.3, section 8.11.2 requirements. In order to fulfil the last point at least one outcome related to the registers and one related to the training programme must be chosen.

At the discretion of the designated person in charge, facility verifications can be undertaken by a designated person in charge from another location or facility.

Exemplars, non-conformances, corrective actions and close out are to be noted in the facility verification register.

8. Unannounced laboratory checks

Unannounced laboratory checks or inspections can be conducted by the designated person in charge, technical managers, hazards and containment manager or biological safety adviser, to confirm that monthly laboratory inspections are being undertaken and are appropriately calibrated.

9. Focus of internal verification

The 22 outcomes are designed to addresses the following areas:

1) Imports
2) Transfers
3) Location data in SciTrack or laboratory Excel spreadsheets
4) Repairs and renovations
5) Knowledge of HSNO approvals and additional controls
6) Physical state of the laboratory and work practices
7) Training and induction
8) Documentation of approved autoclaves
9) Medical waste processes

Items 1 to 6 are part of the internal verification exercise conducted by designated persons in charge. Items 7 to 9 are to be conducted by either technical managers or hazards and containment managers.

10. Internal verification findings

Designated persons in charge are to document findings in accordance with the agreed focus, within the agreed time period.

Areas of good practice are to be noted, as well as non-conformances and areas that could be improved. It is to document the following:

- Location
- Research group involved
- Positive comments as well as non-conformances
- Exemplars
- Classification of non-conformances
- Date the corrective action was notified to the research group
- Date the corrective action was closed

It can be kept in a form of file in a shared folder or in Damstra when the functionalities allow.

11. Internal verification findings

Containment team is to discuss internal verification to discuss findings, recommendations and approvals. Findings of the Hazards and Containment Manager on other verification inputs will be provided. The focus of this meeting is to determine underlying causes and eliminate these where possible. Any action, follow up correspondence and/or follow up inspections are to be agreed at this meeting. Underlying issues and risks that are identified are to be documented in the internal audit report.

12. Facility verification report

A report is to be written within one week of the internal verification findings by the Hazards and Containment Manager, who will ensure agreement of content with technical managers as appropriate. This report is to be circulated to the operator and relevant faculty senior leaders.

13. Classification of non-conformances

Non-conformances identified by monthly laboratory checks are to be corrected and noted on the checklists. Non-conformances identified by unannounced laboratory visits or an internal verification exercise should be documented in Damstra**.** Non-conformances identified in the twice-yearly internal audit are to be documented into the Facility register. Corrective actions and close out is also to be documented. Containment team defines the severity of a non-conformance.

Classification

Minor non-conformances are typically those that are unlikely to immediately affect containment, and these are to be immediately rectified. Examples of minor non-conformances are:

- Minor faults in the structural integrity of the laboratory (cracks in walls, floor and bench surfaces)
- Lack of cleanliness and clutter on benchtops
- Laboratory coats and PPE not being worn
- No expiry dates on decontamination agents
- Inaccurate location data for restricted biologicals
- Ceiling tiles and wall panels not reinstated by contractors
- Lack of HSNO/HRMO approval synopsis

Major non-conformances are typically those that are likely to immediately affect containment and may cause or lead to a biosecurity risk, signal possible noncompliance with statutory obligations or continued minor non-conformances.
Major non-conformances can include:

- GMO work being undertaken by a research group that does not have unambiguous HSNO approval (i.e. existing HSNO approvals need amendment to provide clear and unequivocal coverage)
- Procurement of restricted goods without appropriate permits or transfer documentation
- Restricted material not stored in an appropriately identified area
- Imports and transfers that do not appear on the central register and/or in SciTrack

Critical non-conformances are typically those that are likely to immediately compromise containment and/or is a serious risk to biosecurity, the environment, or the health and safety of people and communities. Critical non-conformances could include:

a. Conducting work with GMOs in areas that are not included in the containment facility

b. Significant structural repairs or renovations that are likely to compromise the containment boundary being undertaken without notification to MPI

c. Transfer of restricted import or GMO without MPI approval

d. GMO work being undertaken by a research group that does not have HSNO approval (EPA and MPI notification required).

Notification requirements

Critical and major non-conformances are to be reported to MPI within 24 hours by the Operator or by the Hazards and Containment Manager (after consultation with Dean, Operator and Associate Director Health, Safety and Wellbeing).

In the event of item d. (i.e. unauthorised GMO work being conducted) and where this work has been conducted in containment, there must be an appropriate investigation to ensure accuracy of any reporting. It is envisaged that the initial internal investigation would be undertaken within 24 hours. Once the investigation has established that the GM work is unauthorised, MPI will be notified as soon as possible (and within 24 hours) by the Operator or by the Hazards and Containment Manager (after consultation with the Dean, Operator and Associate Director Health, Safety and Wellbeing). The incident may also be the subject of internal disciplinary processes.

For suppliers' non-conformances (item c) both supplier and MPI will be notified by the Hazards and Containment Manager or by delegated signatory within 24 hours.

Critical non-conformances are to be documented in the facility's verification register and if appropriate, the underlying issues and risk register. Corrective actions and close out are also to be documented.

14.Incidents and Risk register

The Hazards and Containment Manager and the Biological Safety Adviser are to document consistent minor and major non-conformances identified either as part of a three- monthly verification, as part of unannounced inspections, or as a result of incidents occurring, to identify underlying issues and mitigating actions that have been taken. The register is to document the following:

- Date of verification or unannounced inspection

- Location
- Underlying cause or problem
- Actions taken to address the underlying cause

The risk register is available on Damstra.

15. Documentation

The facility is to have the following registers:

- Facility verification register (central HSW sharefolder)
- Risk register (Damstra)
- Approved autoclave register
- Repairs and renovations register
- Import and transfer registers
- HSNO register (Infonetica and central HSNO register)
- Canvas training
- Specialist training registers (e.g. PC2 lab)

16. Definitions

Verification means a process that uses objective evidence to confirm that specified requirements have been met. There are many ways to verify that requirements have been met: for example, inspections, testing, alternative calculations, examination of relevant documents and direct observation of practice.

Non-conformance means a deviation from a procedure, standard, specification or expectation. (A non-conformity may also be termed a "defect"). Non-conformances are classified as minor, major or critical.

Damstra is the incident management system which is used to log incidents Health and Safety related. Thanks to its capacity to track and assign actions it is also used for containment incidents or observations, even when they are not health and safety related.

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.

Vault is the old brand name of Damstra and it is often still used as it does appear in the software as well.

Appendix 1: Monthly laboratory inspection checklist example for PC1 and PC2 laboratories

Containment Laboratory Monthly Inspection Checklist (PC1)					
Building:		**Level**		**Room**	
Name:				**Date**	
Date(s) fume cupboard(s) test due:					
Date(s) biological safety cabinet(s) test due:					
Synopsis of HSNO approvals is available for each lab group					
1	All hand wash basins are clean and have adequate soap and handtowels. If a hand-wash station is used then adequate ethanol based hand-wash is present				
2	Wall surfaces are sealed and easily cleaned				
3	No unsealed penetrations in ceilings - ceiling tiles in place				
4	Floor is sealed and seamless				
5	Floors clean with no stains or old spills				
6	Under-bench areas are clear – no chilli bins, cardboard, permeable material including spill sheets (incontinent pads) on floor				
7	Benches are clean and free of clutter (i.e. equipment on bench clearly in use and not being allowed to accumulate)				
8	All cultures stored on benches are contained appropriately				
9	Writing materials/books well separated from experimental areas or in clear file.				
10	Approved disinfectants readily available (at least one per lab group) and properly labelled				

11	No lab coats on lab chairs or in offices	
12	All excess lab coats have been returned to the laundry	
13	All chairs and stools have impervious coverings (no cloth fabric) and coverings are intact	
14	Fume cupboards and chemical storage cabinets are clean and tidy and all chemicals identified	
15	Biological safety cabinets are free of clutter	
16	Paper and cardboard rubbish removed daily	
17	Biohazard and laboratory waste not accumulating and taken to loading dock promptly	

Corrective actions:

Corrective actions completed:

Containment Laboratory Monthly Inspection Checklist (PC2)

Building:		**Level**		**Room**	
Name:				**Date**	

Date(s) fume cupboard(s) test due:		
Date(s) biological safety cabinet(s) test due:		
Synopsis of HSNO approvals is available for each lab group		
Directional inward flow confirmed or Magnehelic gauge reading		
List of pathogenic bacteria handled in laboratory (if applicable)		
List of persons in laboratory who have received PC2 laboratory instruction		
1	All hand wash basins clean and have adequate soap and hand towels	
2	Wall surfaces are sealed and easily cleaned.	
3	No unsealed penetrations in ceilings and ceiling tiles in place	
4	Floor is sealed and seamless	
5	Floors clean with no stains or old spills	
6	Under-bench areas are clear – no chilly bins, cardboard or permeable material on floor	
7	Benches are clean and free of clutter (i.e. equipment on bench clearly in use and not being allowed to accumulate)	
8	All cultures stored on benches are contained appropriately	
9	Writing materials/books well separated from experimental areas or in clear file.	

10	Keyboards have disposable covers	
11	Approved disinfectants readily available (at least one per bench) and properly labelled	
12	Dedicated PC2 lab coats	
13	All excess lab coats have been returned to the laundry after autoclaving	
14	All chairs and stools have impervious coverings and coverings are intact	
15	Fume cupboards and chemical storage cabinets are clean and tidy and all chemicals identified	
16	Biological safety cabinets are free of clutter	
17	Biohazard waste in bin with autoclave bag and not accumulating	
18	Biohazard and laboratory waste taken for autoclave/disposal promptly	

Corrective actions:

Corrective actions completed:

Appendix 2: Verifiable Outcomes and their Verification

	Verifiable Outcome	How and When Verified*	Relevant section of MPI standard 154.03.02	Verification method
1	Laboratories meet requirements of Physical Containment Levels 1 and 2 [as defined in AS/NZ 2243.3 (2002). Benchtop decontamination agents have instructions. Class 2 Biosafety cabinets and Fume cupboards are tested annually	Monthly DLP Inspections 6-monthly Internal verification	8.2 and 8.3.3	Lab inspections
2	Signage at the perimeter of the Containment Facility is reviewed yearly to ensure fitness for purpose.	Yearly internal verification	Control #5 on APP 202708	Inspection of signage
3	Repairs to laboratories are documented and follow the *Expert User Guidelines*	6-monthly Internal verification	6.1.3	Verify Lab repair database for last 3 months follows guidelines
4	Delegated Authorities are reviewed every 6 months	6-monthly Internal verification	7.2.2	Review delegated authorities.

5	Importation databases are reconciled with MPI records. Use of Permits to Import is documented as per *Expert User Guidelines*.	3-monthly verification	8.4.1	Reconciliation with MPI records for last 3 months. Check all documentation including use of import permit database is present.
6	Problems with suppliers are identified and documented in an Incident Register	6-monthly Internal verification	UoA requirement	Verify Incident database for last 3 months is complete
7	Those undertaking research involving GMOs understand the applicable HSNO approval(s) and any additional controls.	6-monthly Internal verification	8.4.2; 7.2.3	Ask to a representative sample of people in labs about HSNO approvals
8	Central registers for HSNO approvals are up-to-date	6-monthly Internal verification	7.2.5	Verify facility databases are up-to-date
9	Research work involving RG2 microorganisms is covered by UABSC approval and this is documented in a transparent manner	6-monthly Internal verification	UoA Policy	Check facility databases are up-to-date
10	Details of developed GMOs and storage location are documented in a robust and accurate manner	6-monthly Internal verification	8.4.2	Track up to 3 GMOs (per research group) which were developed in last 4 months. If no new GMOs, older GMOs can be tracked.

11	Details of imported and transferred risk goods along with storage location are documented in a robust and accurate manner. ***Packaging for transfer is documented.***	6-monthly Internal verification	8.4.1	If applicable, track up to 5 items (per research group) imported or transferred.
12	All persons with access to Containment laboratories have completed online training	6-monthly Internal verification	7.2.3	Verify all Canvas non-completers have no access to containment laboratories
13	All persons with access to Containment laboratories are inducted	6-monthly Internal verification	7.2.3	Reconcile lab lists with induction lists
14	Contractor induction is documented in a robust and accurate manner	6-monthly Internal verification	7.2.3	Examine contractors induction for last 5 months
15	All persons in Containment laboratories working with specific biological hazards are trained in those hazards.	6-monthly Internal verification	UoA requirement	Select up to 3 people known to work with RG2 pathogens and verify training
16	All persons using autoclaves are trained	6-monthly Internal verification	7.2.3	Check autoclave training database
17	All Technical Team Leaders are trained	6-monthly Internal verification	7.2.3	Check Floor managers training database
18	All DLPs are trained	6-monthly Internal verification	7.2.3	Verify DLP training database

19	s52 Unwanted Organisms permissions are documented in a robust manner	6-monthly Internal verification	7.2.5	Verify UOR database for each facility
20	Approved autoclaves and their testing regimes are documented in a robust manner. Autoclave temperature probes are calibrated annually.	6-monthly Internal verification	8.3.3	Verify autoclave documentation
21	Medical Waste Contractors are able to track and trace medical waste	6-monthly Internal verification	8.3.3	Take at least 6 bins and track through contractors
22	Emergency Plans are up-to-date. Emergency and Contingency plans are tested regularly.	yearly Internal verification	8.9	Hazard floor plans available to the Emergency services.

*please note that frequency will be decided as described at section 7.1. Only the selected outcomes on the basis of specified criteria, will undergo internal verification. At least one orange (registers) and one green (training programme) must be chosen every 6-months to meet AS/NZ 2243.3, section 8.11.2 requirements

Appendix 3: Monthly laboratory inspection example checklist for ancillary rooms (Centrifuge rooms, cold rooms and -80 freezer rooms)

Containment Laboratory Monthly Inspection Checklist (Ancillary Room)					
Building:		**Level**		**Room**	
Name:				**Date**	
1	Wall surfaces are sealed and easily cleaned				
2	No unsealed penetrations in ceilings and walls - ceiling tiles in place				
3	Floor is sealed and seamless				
4	Floors clean with no stains or old spills				
5	No chilly bins, cardboard or permeable material on floor				
6	Benches (if present) are clean and free of clutter **				
7	All chairs and stools (if present) have impervious coverings (no cloth fabric) and coverings are intact**				
8	Biohazard waste, paper and cardboard not accumulating and removed daily				
9	No spill sheets (incontinent pads) on floor				
10	There is a high standard of overall tidiness.				

******* put **N/A** if not present or not applicable*

Corrective actions: **Corrective actions completed:**

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