Biological Risk Management and Containment

Monitoring and Measuring Performance

(Internal Verification and Reporting)

Containment Laboratory Guidelines

Version 3- February 2021

Approved by: Vice-Chancellor
Document Owner: Associate Director, Health, Safety and Wellbeing
Content Manager: Manager, Hazard and Containment

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This document was originally Version 2 which was extensively reviewed and approved in February 2021.

Record of Amendments to Version 3

Date	Page number	Nature of amendment

Contents

1. Who are these guidelines for?

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

2. Verification and identification of risk

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) To identify risk and ensure appropriate risk mitigation procedures are put in place

Verification consists of:

1) Monthly laboratory inspections of each lab by designated laboratory persons (DLPs) or laboratory users
2) A broader three-monthly internal verification exercise (that includes observational tours)
3) Unannounced laboratory checks
4) Identification of underlying issues in order to ensure the reasons are addressed
5) Identification of exemplars (practices or facilities)

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)

Risks are identified as a result of the following:

1) Identification of underlying issues as a result of verification and subsequent analysis of the reasons behind these underlying issues in order to ensure the identified risks

are addressed. These underlying issues are to be documented in the underlying issues and risk register

2) Identification of external risks posed by suppliers and outside agencies, usually through due diligence undertaken as a result of SciTrack requisitioning and purchasing processes. Supplier non-conformances are to be documented in the underlying issues and risk register and may also be noted in the facility's verification report
3) Identification of risks associated with importation as a result of import reconciliation (refer to expert user guidelines "Importing Restricted Biologicals"). Import non-conformances may also be noted in the facility's verification report
4) Identification of risks by anyone in the organisation either spontaneously or as result of verification meetings. These risks are to be documented in the underlying issues and risk register and may also be noted in the facility's verification report

A visual representation of the internal verification system is in Appendix 1.

The information inputs and flows within the verification system are represented graphically in Appendix 2.

The findings of the internal verification exercise and any critical non-conformances are to be reported to the Licenced Operator (Deputy Vice-Chancellor (Research))and senior management /faculty executive leadership teams, with recommendations as to how systems and resources might be improved. Reports are also to be sent to the University of Auckland Biological Safety Committee (UABSC) to ensure that organisational improvements can be adopted.

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.

In addition, designated persons in charge are to ensure programmed maintenance and testing are undertaken at least two weeks before the date of the internal verification.

3. Monthly laboratory inspections

Monthly laboratory inspections are to be undertaken by DLPs or laboratory users. 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 Appendices 5 and 6), which can be completed online or in hard copy. Completed inspection checklists should be filed electronically.

A dedicated checklist (Appendix 6) is to be used for ancillary areas such as walk-in cold-rooms, centrifuge rooms and rooms with low temperature freezers. A PC1 laboratory inspection checklist is to be used in incubation rooms.

Minor non-conformances are to be noted and closed out on the checklists. The DLP is to report repeated or major non-conformances along with close out actions to the designated person in charge. Repeated or major non-conformances are to be documented in the facility's verification register.

4. Unannounced laboratory checks

Unannounced laboratory checks or inspections are to 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. Non-conformances (no matter how minor) are to be noted and documented in the facility's verification register.

5. Facility internal verification exercise

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 to be conducted in April, August and December of each year.

Facility verification exercises will be undertaken by either two designated persons in charge or one designated person in charge and one DLP, who are both familiar with the laboratory group.

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.

6. Focus of internal verification

Internal verification 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.

Designated persons in charge for each facility are to meet with the technical manager at least two weeks before the internal verification exercise and decide on how items 1-6 above will be verified. Length of verification will be determined in this meeting so that observational tours can be conducted within an agreed timeframe. The focus of verification may also be determined by:

- Findings of monthly laboratory inspections
- Previous laboratory inspections and internal verification
- Unannounced laboratory visits

The internal verification focus is to be formally documented and any checklists and documentation circulated at least one week prior to the laboratory visits.

7. Internal verification findings and facility verification register

Designated persons in charge are to document findings in accordance with the agreed focus, within two weeks of the internal verification exercise.

Verification findings are to be noted in an electronic facility verification register. Areas of good practice are to be noted, as well as non-conformances and areas that could be improved. The facility verification register is to document the following:

- Location
- Research group involved
- Positive comments as well as non-conformances
- Exemplars
- Classification of non-conformances (minor or major)
- 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.

8. Other verification inputs

The Hazards and Containment Manager is to undertake checks every three months on:

1) Training and induction
2) Documentation of approved autoclaves
3) Medical waste processes

9. Internal verification findings meeting

Designated persons in charge are to meet within two weeks of the 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 underlying issues and risk register.

10. Facility verification report

A report is to be written within one week of the internal verification findings meeting by the Hazards and Containment Manager, who will ensure agreement of content with all designated persons in charge and technical managers. This report is to be available in the containment facility and be circulated to the operator and faculty administration.

11. Classification of non-conformances

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.

Minor non-conformances identified by monthly laboratory checks are to be corrected and noted on the checklists. Minor non-conformances identified by unannounced laboratory visits or an internal verification exercise are to be documented in the facility's verification register, and if appropriate, the underlying issues and risk register**.** Corrective actions and close out is also to be documented.

Major non-conformances are typically those that are likely to immediately affect containment, signal possible noncompliance with statutory obligations or continued minor non-conformances.
Major non-conformances 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)
- Use of suppliers who are unable to confirm or identify restricted goods in their inventories

- Lack of HSNO approval synopsis
- Location data that has not been updated within two weeks of receipt
- Imports and transfers that do not appear on the central register and/or in SciTrack

Such 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 is also to be documented.

Critical non-conformances are typically those that are likely to immediately affect containment and/or signal noncompliance with statutory obligations. Critical non-conformances are:

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

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

c. Transfer of restricted import or GMO without MPI approval (this includes supplier non-conformances)

d. GMO work being undertaken by a research group that does not have HSNO approval.

Critical 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.

All non-conformances, whenever Minor, Major or Critical should be entered on the accident/incident reporting platform (Damstra).

12. Corrective actions

Corrective actions are to be written up in the facility's verification register and undertaken within two weeks of notification, or by negotiation with the designated person in charge.

Failure to complete or demonstrate significant progress towards completing corrective actions within two weeks will result in escalation to the line manager.

13. Underlying issues 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.

14. Identification of risk

While the underlying issues and risk register will be the major source of risk identification, reconciliation of outside databases such as the three-monthly import reconciliation exercise (refer to the guidelines *Importing Restricted Biologicals*) should also be used. Lab personnel are also to be enrolled in identification of risk.

15. Documentation in each facility

Each facility is to have the following registers as soft copy or access to:

- Facility verification register
- Risk register (Damstra)
- Approved autoclave register.
- Repairs and renovations register

And the following electronic registers:

- Import and transfer registers
- 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.

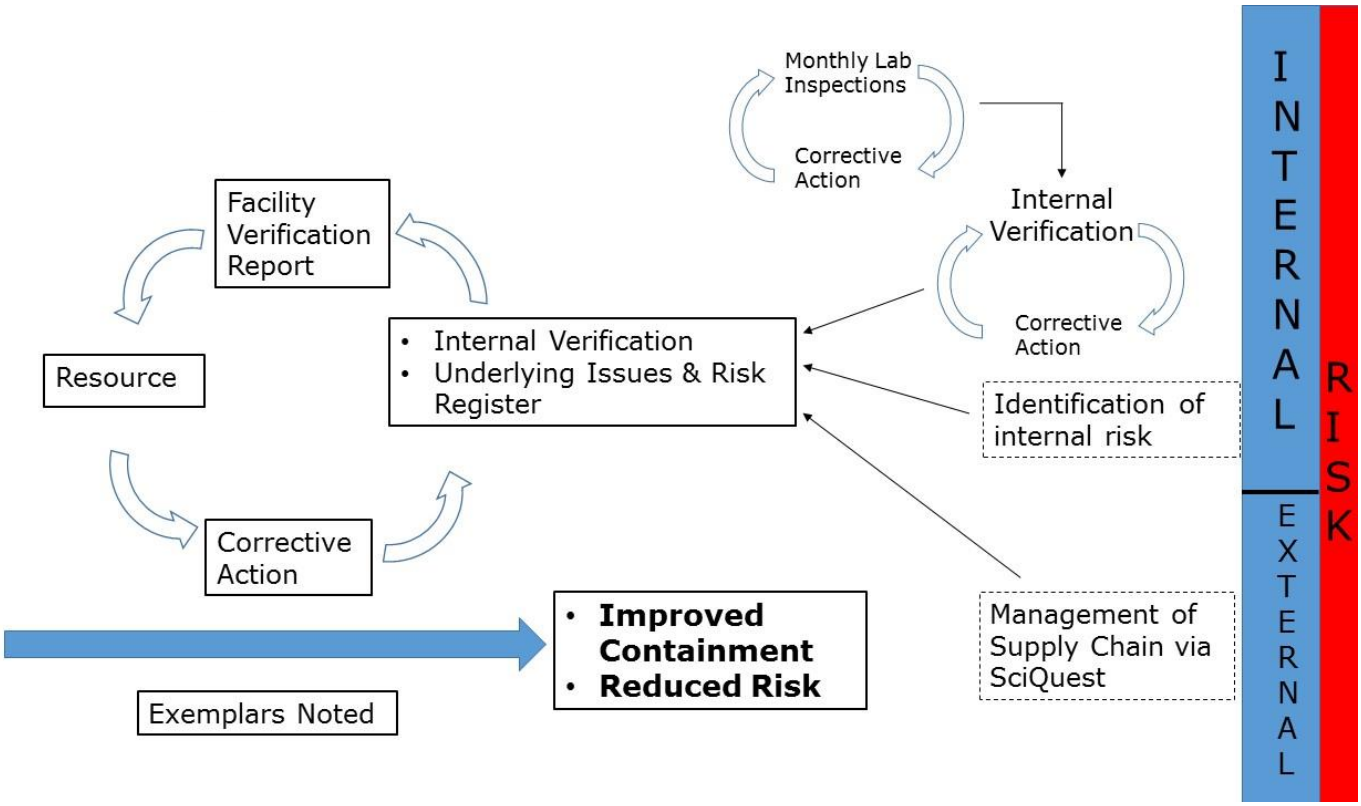
Non-conformance means a deviation from a procedure, standard, specification or expectation. (A non-conformity may also be termed a "defect"). Non-conformances are classified as minor, major or critical.

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.

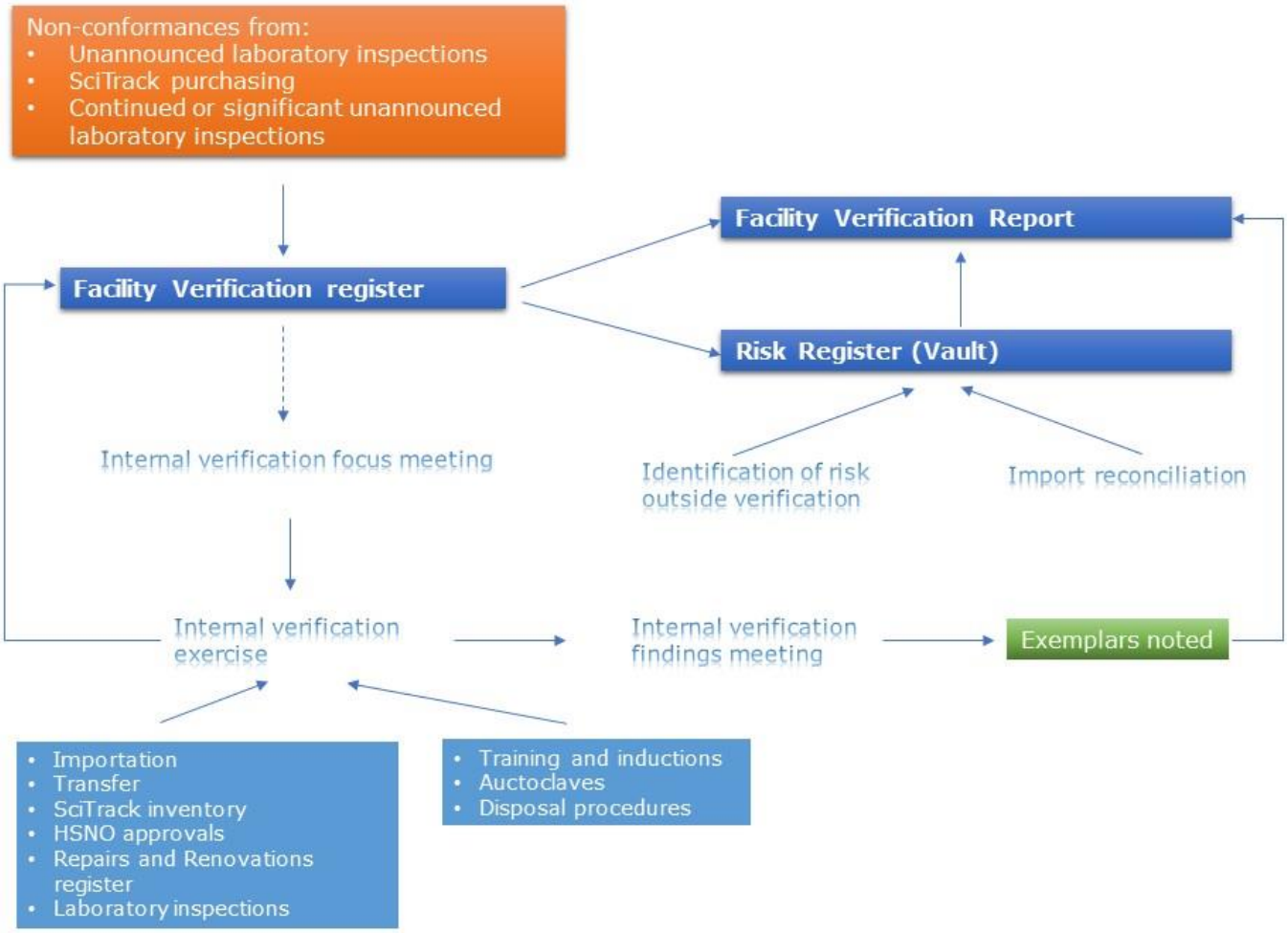
Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager or an appointed delegate.

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.

17. Appendix 1: The internal verification model applied to continual improvement in containment as per ISO 9001



18. Appendix 2: Information inputs into internal verification and reporting systems



19. Appendix 3: Monthly laboratory inspection checklist 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:

20. Appendix 6: Monthly laboratory inspection 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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