Internal Audit Report – Final

1903 Biosecurity and Biological Agents

11 March 2020

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Activity	Date
Terms of Reference Issued	20 June 2019
Fieldwork	1 July 2019
Draft Report Issued	31 January 2020
Close Out Meeting	24 February 2020
Final Report Issued	11 March 2020
Report Tabled at Audit Committee	20 March 2020

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1903 Biosecurity and Biological Agents

Context

Biological agents are used in research programs at UNSW. UNSW are required to comply with legislative and regulatory requirements which set out regulations and practices relating to the procurement, importation, storage, handling, transport and disposal of biological agents. The purpose of this engagement was to ascertain the adequacy of processes and controls in place to achieve compliance with biosecurity legislation and containment requirements relating to non-Genetically Modified Organisms (non-GMO). The review focused on the School of Biological, Earth and Environmental Science (BEES), the School of Biotechnology and Biosciences (BABS), the School of Medical Sciences (SOMS), the School of Chemical Engineering, the Graduate School Biomedical Engineering (GSBME) and The Kirby Institute as case studies to understand the processes and controls within Faculties/Schools to manage biological agents and biohazards.

Strategic Area

Research / Operating Environment

Review Summary

Fundamental Improvements are Required

UNSW has placed significant focus on establishing key controls for managing highly regulated research areas. This has resulted in a greater focus on research involving gene technology, and less focus on establishing robust process for the management of non-genetically modified (GMO) biological agents.

Internal Audit identified that the University is unclear on the extent of non-GMO biological agents being used and stored on-site within PC1 and PC2 facilities (excluding facilities within The Kirby Institute). This is impacting the ability of UNSW to understand the true risk exposure of such materials to the University and broader community and to ensure appropriate risk-based controls are in place. Whilst it is acknowledged that the importing of biological agents is regulated by the Department of Agriculture, Water and Environment (DAWE), robust controls are required to ensure non-GMO biological agents are appropriately managed once on-campus, in accordance with the import permit requirements (e.g. use of quarantine facilities) or the microorganism risk group rating requirements (per Biosafety regulations).

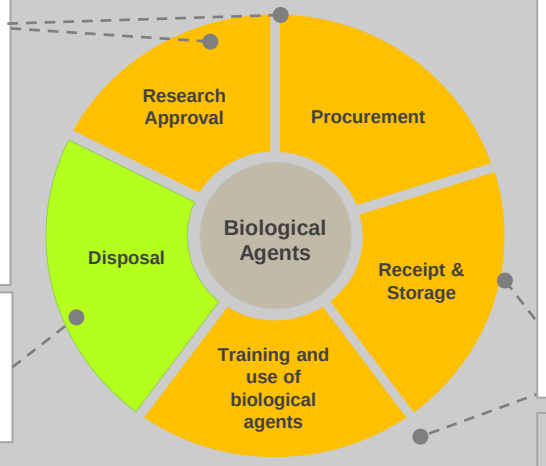
Internal Audit also identified that review and approval processes are not occurring in-line with University policy and procedures. The University also does not have a clear procedure which considers both biosecurity and biosafety and training requirements are inconsistent across the sample schools, with content not always adequately covering the establishment of better practice laboratory techniques.

The issues noted above may impact the University's ability to attest to compliance with key legislation and to demonstrate that a clear process exists with appropriate due diligence to manage potential non-compliance and work health safety risks to both the University and the broader community.

The findings are set out below against the areas reviewed as part of the Internal Audit and detailed in the report:

- ✓ RECS and WH&S have a good working relationship in the management of biological agents and biohazards and have identified improvement opportunities to strengthen the control environment.
- ! The University is currently unable to confirm the extent of non-GMO biological agents on-site **(Finding 2.1)**
- ! Controls for the acquisition of non-GMO biological agents including review and approval processes are not consistently in line with UNSW policies and procedures **(Finding 2.2)**
- ! The current Biosafety Procedure does not define responsibilities for all processes and is not in line with legislation, regulations and standards **(Finding 2.4)**

- ✓ The process to destroy and dispose of Biological Waste is defined in UNSW's Laboratory Hazardous Waste Disposal Guidelines.
- ✓ Clear ownership for the management of the disposal services has been assigned to Estate Management.



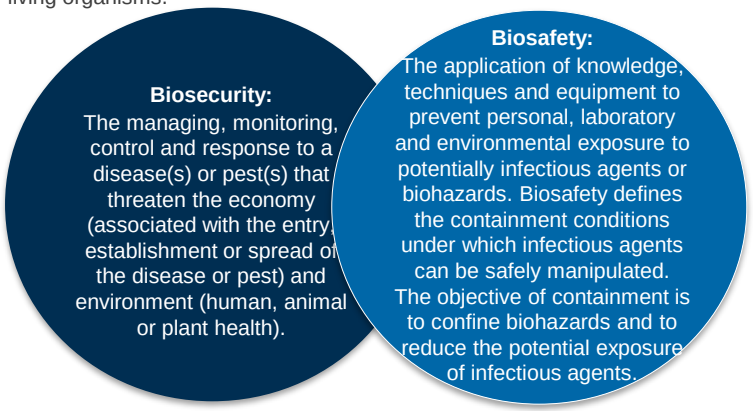
- ✓ A sample storage database is currently used by one case study school and is in development within another case study school.
- ✓ A centralised import application process has been implemented within one of the case study schools
- ✓ Competency based training is currently being piloted within one of the case study schools.
- ✓ Annual refresher training is required to be completed by all staff and students working in laboratories within one of the case study schools.
- ✓ Within one of the case study schools a weekly stand up is conducted for all staff and students working in laboratories to discuss current works and projects.
- ! Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures **(Finding 2.3)**
- ! Biosafety training and awareness is not standardised and is incomplete, increasing the risk of incidents and inappropriate use of equipment and materials **(Finding 2.5)**

Management will take steps to update current policy and procedure requirements and develop a risk based plan to undertake a University wide inventory exercise.

1. Executive Summary

Background and Context

Biological hazards are organic substances (including pathogenic micro-organisms, pests and diseases) that may pose a threat to the health and wellbeing of humans and other living organisms.



Biosecurity Legislation and Standards

In order to protect Australia's environment from foreign pests and diseases, the Department of Agriculture, Water and Environment (DAWE) regulates the importation of some products subject to biosecurity import conditions through the Biosecurity Import Conditions system (BICON). BICON houses the Australian Government's Biosecurity import conditions database for more than 20,000 plants, animals, minerals and biological products and specifies what import conditions exist and whether an import permit is required. BICON is also the vehicle by which import permits, as approved by DAWE, are accessed to allow the importing of biological products.

The ***Biosecurity Act 2015*** is focused on managing diseases and pests that may cause harm to human, animal or plant health or the environment.

***AS/NZS Standard* 2243.3:2010 Safety in the Laboratories (Series): Part 3: Microbiological safety and containment** is intended to assist in addressing the obligations under occupational health and safety legislation to take care of both people in the workplace. This Standard is intended to cover safety and containment aspects of work with microorganisms, including genetically modified microorganisms. This Standard is not intended to provide for compliance with a specific act or regulation, however, it should be noted that this Standard is recognised in common law as defining current knowledge in microbiological safety practice.

The Work Health and Safety Act 2011 protects workers and other persons against harm to their health, safety and welfare through the elimination or minimisation of risks arising from work.

Refer to **Appendix A** for a register of relevant Biosafety Legislation.

Management of biological agents at UNSW

The management of biological agents and biohazards within UNSW is a decentralised process (refer to **Appendix B**).

At UNSW, work with genetically modified organisms (GMO) is governed by the UNSW Gene Technology Research Committee (GTRC). The focus of the GTRC is to ensure the reduction of possible harm to the health and safety of people and the environment through research activities that use GMO's.

The UNSW ***H323 Biosafety Procedure*** provides a structured approach to protect the environment from accidental release and to prevent exposure of workers and students in these areas to hazards presented by biological material. This procedure was written to help staff and students meet various related legislative and regulatory requirements. The key components of this process is outlined below:

Acquisition Review & Approval

- All research and teaching involving biological agents must have **documented approval** from a UNSW approved authority.
- Schools or researchers apply directly to DAWE for **import permits**. Where a School has an existing import permit, materials can be added onto the goods list (where appropriate). For material procured locally, a researcher can purchase without additional approval.
- Import permits indicate whether materials need to be stored and handled under an **Approved Arrangement** (AA). UNSW has centralised the management of all Biosecurity sites with one annual licence fee to cover multiple AAs. Applications for new AAs and subsequent monitoring of DAWE inspections is managed by RECS.

Storage of Material

- All purchased and imported biological materials should be **receipted** to ensure that the correct order has been received before being made available for use.
- AS/NZS 2243.3 identifies the work practices that are applicable for **training, transport, containment and documentation**.
- Heads of School (HoS) are responsible for identifying **training needs** to ensure appropriate use, storage and management of biological materials and equipment.

Disposal

- UNSW Estate Management manage a biological waste contractor to **safely and appropriately remove biological waste**.

Reliance is placed on individual Schools, Principle Researchers and/or Supervisors to ensure research and teaching involving the use of biological agents is conducted in accordance with Biosafety Legislation, Regulations, Australian Standards, Codes of Practice and University policies and procedures. Applications for the import of biological products are submitted through BICON and are the financial and legal responsibility of the importer.

1. Executive Summary

Background and Context

Physical containment is the term used to describe procedures and structures designed to reduce or prevent the release of viable organisms into the outside environment. The physical containment level used relates to the risk group classification of the microorganism, i.e. Physical Containment Level 2 for risk group 2. There are four classifications of Physical Containment Facilities and are identified by the 'PC' prefix followed by numbers 1 – 4. Biosecurity containment refers to the level of quarantine containment (Approved Arrangements) required (BC1 – BC4) and is stated on the import permit.

The internal audit was performed through a review of relevant documentation (including enterprise and Faculty/School level policies and procedures) and walkthrough meetings with key stakeholders including Faculty/School management and operational staff to understand processes followed to manage biosafety. The following six schools were selected in collaboration with key stakeholders as part of the scoping process and through self-nomination, in order to validate the execution of UNSW's process. Site visits were conducted within the following laboratories to evidence signage, use of personal protection equipment (PPE) , cold storage, sample management and waste disposal practices.

- School of Biological, Earth and Environmental Sciences (BEEs) – 1 AA and 1 PC2 lab
- School of Biotechnology and Biosciences (BaBS) – 2 AA and 1 PC2 lab
- School of Medical Sciences (SoMS) – 1 AA and 1 PC2 lab
- School of Chemical Engineering (School of Chem Eng) – 1 AA and 1 PC2 lab
- Graduate School of Biomedical Engineering (GSBME) – 1 PC2 lab
- The Kirby Institute - Internal Audit conducted a walkthrough meeting with PC3 laboratory staff within The Kirby Institute, however, a physical inspection was unable to be performed due to access restrictions based on the nature and risk rating of the laboratory

Across the University there are 16 registered Approved Arrangement facilities and 177 PC1 and PC2 laboratory and one PC3 laboratory registered within ARCHIBUS (Estate Management's enterprise facilities management system). Refer to Appendix C for a full listing, including location.

The University (including staff and students) has a duty of care to ensure due diligence in relation to WH&S responsibilities. This includes making sure UNSW has suitable safe systems of work in place for working with and monitoring biological agents. The absence of a robust end-to-end process could lead to hazards and associated risks not being identified or managed meaning UNSW could be at risk of:

- breach of legislative requirements, in particular the Biosecurity Act 2015 and WH&S Act 2011;
- inability to meet or demonstrate their obligations as a Person Conducting a Business or Undertaking (PCBU);
- reputational damage;
- inability to meet or demonstrate their obligations in accordance with the Work Health Safety Act 2011; and
- increased incidents as a result of inadequate safety and risk management controls.

Summary of Findings

The table below summarises the number of findings identified and their associated rating. Please refer to the Detailed Findings section for further details.

Report Rating: **Fundamental Improvements are Required**	Control Issue Rating					
	Very High	**High**	**Moderate**	**Minor**	**Low**	**Opportunity for Improvement**
# of findings reported	-	-	3	2	-	-
# of agreed actions	-	-	4	2	-	-

The diagram on the following page provides further details on the issues identified across the end-to-end process including a summary of the sample testing observations against each stage within the end-to-end process.

Details relating to better practice considerations have been included in Appendix D, based on research conducted across Australian universities.

1. Executive Summary

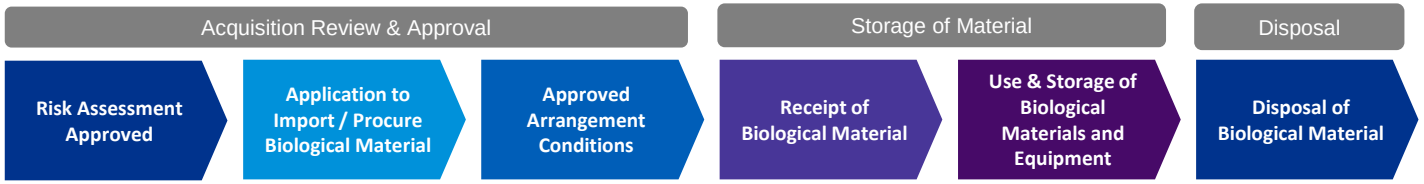
Below is a summary of the outcomes of the review against the current UNSW high-level process in the management of biological agents. Results of testing at a sample of schools highlights compliance against each stage of the biosafety process.

Biological Agents and Biohazards

Biological Agents Governance

- ✓ RECS and WH&S have a good working relationship in the management of biological agents and biohazards and have identified improvement opportunities to strengthen the control environment
- ! The current risk exposure is unknown for non-GMO biological agents and biohazards (Finding 2.1)
- ! The current Biosafety Procedure does not comprehensively articulate the end-to-end process and responsibilities, increasing the risk of non-compliance with legislation, regulations and standards (Finding 2.4)

Biological Agents Process per Biological Agents Policy



- ✓ A centralised import application process has been implemented within one of the case study schools.
- ✓ Within one of the case study schools a weekly stand up is conducted for all staff and students working in laboratories to discuss current works and projects.
- ! Controls for the acquisition of non-GMO biological agents including review, approval and receipt processes require improvement (Finding 2.2)

- ✓ A sample storage database is currently used by one of the case study schools and is in development within another case study school.
- ! Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures (Finding 2.3)

- ✓ The process to destroy and dispose of Biological Waste is defined in UNSW's Laboratory Hazardous Waste Disposal Guidelines.

Sample School Compliance Testing Results

School of Biological, Earth and Environmental Sciences	✗	✗	✓	✗	✗	✓
School of Biotechnology and Biosciences	✗	✓	✓	✗	✗	✓
School of Medical Sciences	✗	✗	✓	✗	✗	✓
School of Chemical Engineering	✗	✓	N/A – AA not currently utilised	✓	✓	✓
Graduate School of Biomedical Engineering	✗	✓	N/A – No AA facility	✓	✗	✓
The Kirby Institute	✗	✓	N/A – No AA facility	✓	✓	✓

Biological Agents Training and Awareness

- ✓ Competency based training is currently being piloted within one of the case study schools.
- ✓ Annual refresher training (theory based) is required to be completed by all staff and students within laboratories within one of the case study schools.
- ! Biosafety training and awareness is not standardised and is incomplete, increasing the risk of incidents and inappropriate use of equipment and materials (Finding 2.5)

1. Executive Summary

Summary of Findings

Below is a summary of the three moderate-rated findings

- 2.1 The University is currently unable to confirm the extent of non-GMO biological agents on-site;
- 2.2 Controls for the acquisition of non-GMO biological agents including review and approval processes are not consistently in line with UNSW policies and procedures;
- 2.3 Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures;

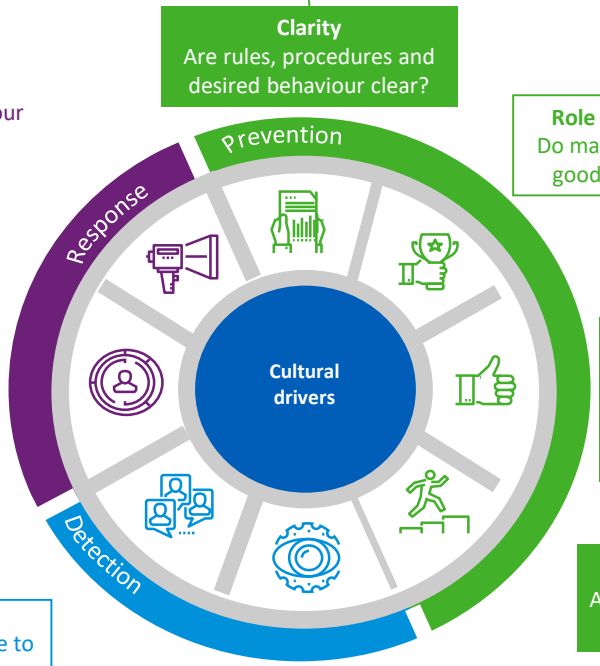
Management awareness of findings

Management were aware of all issues identified within this Internal Audit report.

1. Executive Summary

Summary of Soft Controls Analysis

A soft controls root cause analysis has been performed to identify the behavioural drivers relating to each finding contained in this report. The diagram below provides a summary of the root cause/s of behaviour identified for the noted observations which requires management focus. By addressing the behavioural root cause, the overall quality of the soft controls environment will be improved.



! **Controls for the acquisition of non-GMO biological agents including review and approval processes are not consistently in line with UNSW policies and procedures** ***(Finding 2.2)***

There is a lack of clarity amongst HoS regarding their key responsibilities within the Biosafety Policy.

Clarity
Are rules, procedures and desired behaviour clear?

✓ Some Heads of School are openly role modelling the importance of WH&S practices and the appropriate management of research. There has been a focus in some schools in establishing a more open culture in relation to research WH&S, especially regarding PHD students whereby one school is establishing a program to better support PHD students in executing WH&S processes.

Role Modelling
Do managers set a good example?

Enforcement
Is desired behaviour rewarded and undesirable behaviour sanctioned?

Accountability
Are people being held accountable by others in the organization for misconduct?

Commitment
Do employees feel motivated and engaged to follow the rules?

! **The University is currently unable to confirm the extent of non-GMO biological agents on-site** ***(Finding 2.1)***

Priority has been placed on establishing processes and governance mechanisms for research areas that have key legislative requirements (e.g. Approved Arrangements under the Biosecurity Act 2015 and Gene Technology).

Achievability
Are activities/targets realistic?

! **Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures** ***(Finding 2.3)***

There is currently limited capacity in the WH&S and RECS team to further increase and expand the current monitoring of facilities.

Discussability
Do people feel comfortable to voice their opinion, raise issues and discuss dilemmas?

✓ Faculty WH&S representatives are focused on raising issues regarding process improvements and non-compliance.

Transparency
Are people's behaviours visible to others?

2. Detailed Findings & Agreed Management Actions

2.1 The University is currently unable to confirm the extent of non-GMO biological agents on-site	Management aware of finding	**Moderate** Substantial/Possible/ Immediate

Outlined in the AS/NZS Standard 2243.3, the appropriate undertaking and review of risk assessments prior to work with biological matters is considered a key requirement. Despite the Australian Standards not being governed by legislation, the requirements are recognised under common law for microbiological safety practice.

The University is currently unable to confirm the extent of non-GMO biological agents on-site (excluding the PC3 facility within The Kirby Institute) due to a lack of visibility over the current holdings of non-GMO biological material stored within UNSW laboratories. Specifically, Internal Audit notes that current processes don't allow for a central view of acquisitions, usage and storage of biological agents. Refer to finding 2.2 and 2.3 for further details.

Without visibility, an appropriate review of risk cannot be completed and the current risk exposure to the University is not fully known.

Soft Controls Root Cause:
Commitment – Priority has been placed on establishing processes and governance mechanisms for research areas that have key legislative requirements (e.g. Approved Arrangements under the Biosecurity Act 2015 and Gene Technology).

Why is this important?
As the current risk exposure for UNSW is unknown, UNSW may not have identified or be mitigating key risks that may lead to loss of the Approved Arrangement license including:

- Breaches of legislative requirements including the Biosecurity Act 2015 and the Work Health Safety Act 2011
- Inability to demonstrate obligations in accordance with key Acts
- Increased incidents as a result of inadequate safety and risk management controls.

The University currently holds one Approved Arrangement license and, if compromised, the University will be unable to hold biological agents requiring quarantine.

[R1] **Moderate**

A) UNSW Safety and Wellbeing will update current policy and procedural requirements to ensure all materials are registered (excluding SSBA's monitored by RECS) and communicate to Heads of School the responsibility of all laboratories to regularly undertake inventory checks and to maintain a complete register of all substances stored within each laboratory.

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment
Completion Date: 30 September 2020

B) Develop a plan to undertake a University wide risk based inventory exercise to take stock of all the biological materials (and related import permits, where applicable) being stored within each laboratory.

HOS will be required to coordinate the undertaking of an inventory exercise with relevant laboratory registers updated. Outcomes of the stocktake will be endorsed by HOS and will be provided to the Biosafety Coordinator for central storage. Findings and exposures are to be reported to relevant areas for inclusion in their respective risk profiles.

Inventory stocktake guidelines will also be developed to ensure consistency across facilities.

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment
Completion Date: 30 September 2020

C) The outcomes of the stocktake (Refer to R1-B) the risk profiles of DVCR, RECS, WHS and schools will be verified to ensure they reflect the level of risk exposure as informed by the outcomes of the inventory exercise.

Responsibility: Trudy Devitre, Director Risk Management with support from Adam Janssen, Senior Manager, Health Safety and Environment and Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 31 March 2021

2. Detailed Findings & Agreed Management Actions

2.2 Controls for the acquisition of non-GMO biological agents including review and approval processes are not consistently in line with UNSW policies and procedures	Management aware of finding	Moderate Substantial/ Possible /Immediate

Review and approval

Under the UNSW Biosafety Procedure the Head of School (HoS) is responsible for ensuring research and teaching utilising biological agents is appropriately approved per table 1, listed below:

- Microorganism Risk Group 1 – 2 – Approval by HoS/Supervisor.
- Microorganism Risk Group 3 – 4 – Approval by HoS, UNSW GTRC and DVC(R).
- Import or Export of Biological Material – HoS and Department of Agriculture, Fisheries and Forestry (DAFF)

Note: DAFF is identified as approver for biological imports within the current procedure, however DAWE were appointed as Biosecurity administrators in 2013.

At the six schools sampled (one laboratory within each School):

- Evidence of the appropriate approval of research using non-GMO biological products prior to procurement could not be obtained for five schools and five HoS advised they do not undertake this process.
- Research using non-GMO agents within the PC3 laboratory are required to notify the laboratory manager, however the HoS does not provide formal approval.
- Researchers are responsible for applying for import permits in one school and researchers are responsible for ensuring appropriate use of general import permits in five schools.
- Compliance with import permits and conditions is the responsibility of researchers in all schools without a mechanism to monitor compliance.

Additionally, the GTRC does not include biosecurity and biosafety in its Terms of Reference (ToR) and therefore this level of approval is not in place.

In the absence of preventative review and approval controls, the University may be unaware of how key risks are being appropriately managed. As an example, Internal Audit was notified of an incident relating to the exposure of a student to a non-GMO substance which caused serious health concerns. The use of the substance was ordinarily considered 'low risk' through standard procedures, however the student utilised the substance using a 'high risk' method which caused exposure.

Soft Controls Root Cause:

Clarity – There is a lack of clarity amongst HoS regarding their key responsibilities within the Biosafety Policy.

Why is this important?

Without effective controls in place to manage acquisition of biological agents, UNSW is unable to confirm what biological agents are being procured, received and assess the risks associated with holding them on-site and associated usage.

[R2] **Moderate**

A) The current review and approval processes will be reviewed, amended and documented to ensure a holistic, practical, risk based approval approach for all research and teaching involving the use and management of non-GMO biological material is undertaken as part of the updated of the policies and procedures.

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment with support and input from Ted Rohr, Director Research Ethics and Compliance Support and Trudy Devitre, Director Risk Management
Completion Date: 30 September 2020

B) Communicate the revised review and approval process requirements to all HoS

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment with support and input from Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 30 September 2020

C) Following the undertaking of the inventory exercise (Ref to [R1-B], UNSW will conduct a review to determine if a new governance mechanism is required to provide oversight over research and teaching relating to the use of biological materials and compliance with relevant policies and processes.

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment with support and input from Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 31 March 2021

2. Detailed Findings & Agreed Management Actions

2.3 Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures	Management aware of finding	Moderate Medium / Likely /Immediate

Storage and Registers of biological material

There was an inability to validate that procured biological agents are stored and used in accordance with import permits, legislative requirements and standards at the 5 Schools sampled. This was due to:

- Complete registers of stored biological agents were not always complete as required within the Biosafety Policy (excluding the PC3 laboratory within The Kirby Institute).
- Registers are required to be provided to the Biosafety Coordinator however this does not always occur.
- There is a reliance on researchers and supervisors to complete registers or notify Laboratory Technical Staff on amendments required to the registers, without robust mechanisms to ensure compliance and accuracy (excluding the PC3 laboratory within The Kirby Institute).
- Instances of cold storage samples were sighted without labels within the PC2 laboratories, impacting the identification of the owner, contents or expiration date.
- RECS are reliant on the Principle Researchers notifying them of any quarantine facility requirements which may not always occur.

Inspections of facilities are performed by the WH&S team, however these are ad-hoc and records of inspections undertaken do not include 3 of the Schools sampled.
Additionally, DAWE conducts inspections annually on AA facilities however these inspections are focused on the physical premises, storage and disposal but do not consistently cover how items are being used. It is acknowledged that RECS are intending to compliment DAWE inspections by reviewing the management of goods within the laboratory to ensure a complete inspection of all AA facilities.

Soft Controls Root Cause:
Achievability – There is currently limited capacity in the WH&S and RECS team to further increase and expand the current monitoring of facilities.

Why is this important?
There is a risk that biological agents are inappropriately handled and stored on campus, resulting in exposure impacting the health of the UNSW staff and broader community and potentially Australia's agriculture environment.

[R3] **Moderate** – As part of the revised procedure (refer to Finding 2.2), the Head of School's will be required to ensure up-to-date registers are provided to the Biosafety Coordinator on a half-yearly basis (risk based).

Responsibility: Aaron Magner, Director UNSW Safety and Wellbeing supported by Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 30 September 2020

[R4] **Moderate** – Management will define, as part of the process updated in Finding 2.3, the requirement for risk based, regular and/or periodic inspections on facilities to ensure compliance with WH&S legislation and AS/NZS Standard 2243.3 requirements. The process will require the following:

- Audits to be conducted on non OGTR certified and DAWE regulated facilities within a defined time period and based on risk, including consideration of different audit types, for example self declaration, health check or full detailed inspection; and
- Outcomes of audits will be articulated in a report which includes root cause analysis and presented to an appropriate governance mechanism (including reporting on the closure of actions as a standing agenda item of the Committee).

In determining a three-year audit plan, resource requirements, consideration of responsible stakeholders and potential constraints will be articulated and presented to the Division of Research and WH&S leadership to ensure adequate resourcing is allocated to the undertaking of the audit plan. Additionally, where facilities will not be included as part of the audit plan reasoning will be documented.

Responsibility: Aaron Magner, Director UNSW Safety and Wellbeing
Completion Date: 30 September 2020

Opportunity for Improvement – Management might find it useful to investigate the use of a Bioagents Inventory Management System (i.e. Jagger) which would restrict the ability to apply for an import permits and procure biological material without appropriate approval and will maintain and inventory of goods.

2. Detailed Findings & Agreed Management Actions

2.4 The current Biosafety Procedure does not define responsibilities for all processes and is not in line with legislation, regulations and standards	**Management aware of finding**	**Minor** Medium/Possible /Short Term

On review of the Biosafety Procedure, the following was noted:

1. There are missing elements within the procedure, including:

- Biosecurity compliance management processes (as required in the Biosecurity Act), including inspections, audits and fit-and-proper person tests have not been defined.
- Processes relating to spills are not embedded within the current procedures.
- There is no or outdated references to the Biosecurity Act 2015, Quarantine Act 1908 and DAWE.
- Roles and responsibilities of WH&S and RECS are managed through a Service Level Agreement (SLA) however this is not articulated within the current procedure.
- Responsibilities have not been specifically articulated for Researchers, the Biosafety Coordinator, laboratory and general staff and students.

2. Broader UNSW policies and procedures which compliment processes for managing biological agents aren't linked, including:

- Information on the application of import permits and the use of approved arrangements is located on the RECS intranet but not referenced in policy documentation.
- Policies relating to immunisations, protective equipment, disposal and signage, exist in isolation of the Biosafety Procedure.
- Processes relating to incident management do not reference broader UNSW incident management processes.

It is noted that the procedure is dated 2016 and was due for review in March 2019, however this has not yet occurred. In considering better practice procedures, Internal Audit would suggest a combined Biosafety and Biosecurity Manual which clearly aligns UNSW processes with legislation/standards, together with mechanisms to facilitate and monitor compliance. Refer to **Appendix E** for a suggested table of contents, as an example for consideration.

Why is this important?

- The University is unable to confidently ensure that UNSW processes are aligned with legislative requirements, potentially resulting in breaches to legislation; and
- In the instance of an incident or non-compliance, the University is unable to demonstrate that a clearly documented end-to-end processes is available to staff to reference.

[R5] Minor –

A) Update the Biosafety Procedure to be in accordance with the Biosecurity Act, WH&S Act and AS/NZS Standard 2243.3 (including approval, sourcing and procurement through to disposal and relevant roles and responsibilities) and ensure the design of the procedure considers the end-user in mind. The revised procedure will cover the end-to-end process, referencing both biosafety and biosecurity and related policies and procedures. Process maps and approval flows will also be included to clearly provide direction. The revised process will be communicated and training on responsibilities will be embedded within specific training programs, including the PC2 laboratory training. The process will also be made available on both the WH&S and RECS intranet sites.

Responsibility: Adam Janssen, Senior Manager, Health Safety and Environment supported by Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 30 September 2021

B) Highlight specific obligations that arise under the Biosecurity Act 2015 (Cth) to ensure that the appropriate University Compliance Owner is assigned to each obligation (in accordance with the Legislative Compliance Procedure), and ensure that each obligation is recorded in the University's Legislation Register.

Responsibility: Paul Serov, Compliance Manager with support and input from Adam Janssen, Senior Manager, Health Safety and Environment and Ted Rohr, Director Research Ethics and Compliance Support.
Completion Date: 30 September 2021

C) University Compliance Owners assigned to obligations under the Biosecurity Act 2015 (Cth) (as agreed in action B) to update existing internal controls (eg. Biosafety Procedure) and establish new internal controls necessary to effectively manage the obligation and give assurance under the existing legislative compliance certification program (in accordance with the Legislative Compliance Procedure). This will include the requirements for annual compliance declarations to be completed for key roles within the revised procedure (i.e. Principle Researchers, HoS etc.) to specify compliance with biosecurity and biosafety responsibilities to the relevant Compliance Owner.

Responsibility: University Compliance Owners assigned to obligations under the Biosecurity Act 2015 (Cth) – As assigned in action R5-B.
Completion Date: 30 September 2021

2. Detailed Findings & Agreed Management Actions

2.5 Biosafety training and awareness is not standardised and is incomplete, increasing the risk of incidents and inappropriate use of equipment and materials	**Management aware of finding**	**Minor** Medium/Possible /Short Term

Biosafety training and education programs are executed at a local school level with varying levels of training requirements noted, as follows, across the 5 sample schools:

- Users in 1 of the 5 schools are required to provide evidence of 'Biosafety Awareness for working in PC2 facilities' training completion as well as signatures from their laboratory space manager, their supervisor and the laboratory technical manager before a request is submitted for swipe card access into the laboratory;
- Another school allowed users to work in a laboratory without completion of the 'Biosafety Awareness for working in PC2 facilities' training, provided they were accompanied by a supervisor who was working side by side on the same bench, however, this is not always monitored; and
- 'Biosafety Awareness for working in PC2 facilities' training can be provided up to three months after users have worked in a laboratory for three of four schools.

Furthermore, the 'Biosafety Awareness for working in PC2 facilities' training is presented by the Biosafety Coordinator from the UNSW WH&S team and this training is focused on raising compliance awareness with the AS/NZS Standard 2243.3 rather than standard laboratory operating procedures which could result in poor laboratory techniques and misuse of equipment.

In line with better practice, Internal Audit notes that 1 of the 5 schools is piloting a competency-based training approach, where students must demonstrate their ability to perform key tasks correctly before moving on to the next training module.

Why is this important?

In the absence of standardised training requirements, researchers and students accessing laboratories may not have the appropriate level of skill and knowledge needed to identify and manage key risks and use equipment and materials in a safe manner. This may potentially result in WH&S incidents or non-compliance with key legislative requirements.

[R6] Minor – Following the establishment of the revised procedure and process (Refer to R5), the University will undertake a training needs analysis and develop a training matrix which identifies role specific and risk based mandatory research related training requirements to be completed by all staff and students. It will be the responsibility of all HOS to ensure training delivery is in accordance with the developed training matrix.

The training analysis should require certification of successful completion to be provided to an appropriate governance mechanism once staff and students have received a 100% pass on the competency assessment.

As part of establishing training requirements consideration will be given to laboratory access restrictions based on the completion of training requirements.

Responsibility: Aaron Magner, Director UNSW Safety and Wellbeing with support and input from Ted Rohr, Director Research Ethics and Compliance Support
Completion Date: 30 September 2021

Appendix A – HS430 Register of Biosafety Legislation

The table below outlines the Biosafety Legislation, Standards and Related Codes of Practice that should be followed.

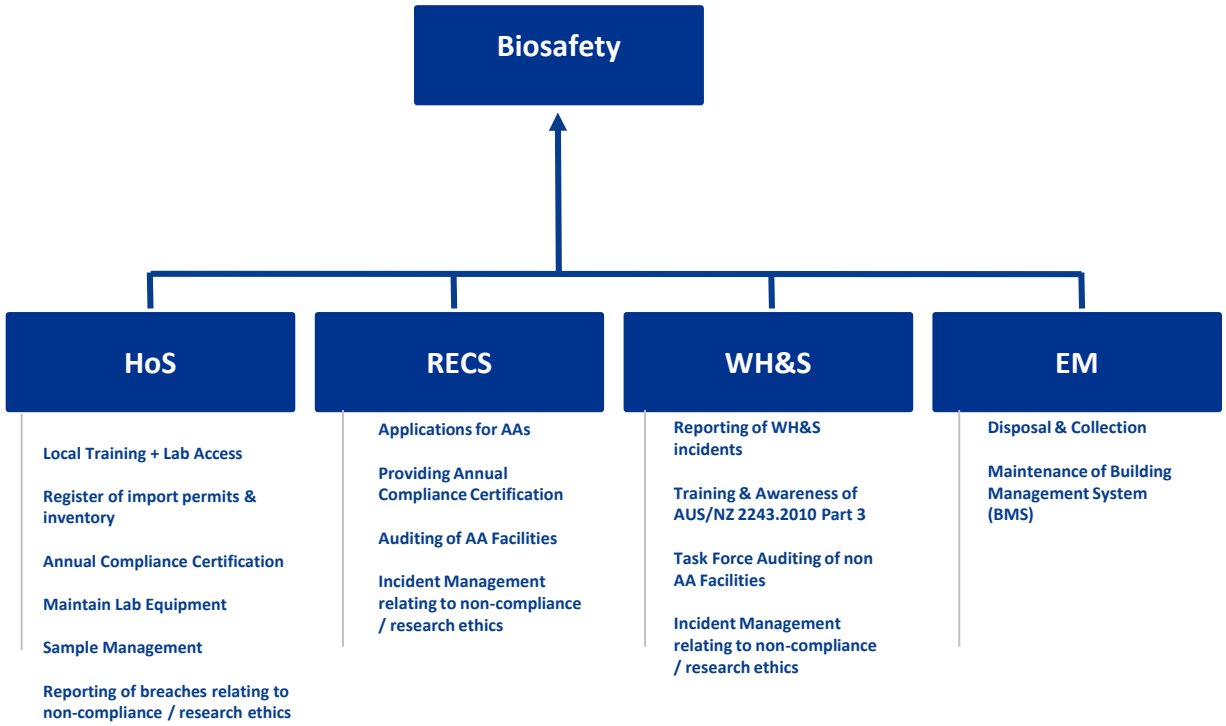
HS430 Register of Biosafety Legislation, Standards and Related Codes of Practice	UNSW SYDNEY

Legislation (Commonwealth)
Biosecurity Act 2015
Biosecurity (Consequential Amendments and Transitional Provisions) Regulation 2016
Crimes (Biological Weapons) Act 1976
Crimes (Biological Weapons) Regulations 1980
Weapons of Mass Destruction (Prevention of Proliferation) Act 1995
Gene Technology Act 2000
Gene Technology Regulation 2001
Prohibition of Human Cloning Act 2002
Research Involving Human Embryos Act 2002
National Health Security Act 2007
The National Health Security Regulations 2008
Legislation (NSW and ACT)
Work Health and Safety Act 2011 (NSW)
Work Health and Safety Regulation 2017 (NSW)
Work Health and Safety Act 2011 (ACT)
Work Health and Safety Regulations 2011 (ACT)
Anatomy Act 1977 (NSW)
Animal Research Act 1985 (NSW)
Animal Research Regulation 2010 (NSW)
Biological Control Act 1985 (NSW)
Gene Technology (NSW) Act 2003
Human Cloning and Other Prohibited Practices Act 2003 (NSW)
Human Tissue Act 1983 (NSW)
Human Tissue and Anatomy Legislation Amendment Bill 2002 (NSW)
Protection of the Environment Operations Act 1997 (NSW)
Environment Protection Act 1997 (ACT)
Public Health Regulation 2012 (Part 8 Disposal of bodies) (NSW)
Public Health Act 2010 (NSW)
Research Involving Human Embryos (NSW) Act 2003 (NSW)
Standards
Australian/New Zealand Standard AS/NZS 1336: Eye and Face Protection - Guidelines
Australian/New Zealand Standard AS/NZS 1715: Selection, Use and Maintenance of Respiratory Protective Equipment
Australian/New Zealand Standard AS/NZS 1270:2002 (R2014) Acoustics - Hearing protectors
Australian/New Zealand Standard AS 2030.1 Gas Cylinders – General Requirements
Australian/New Zealand Standard AS/NZS 2161.1: Occupational Protective Gloves - Selection, Use and Maintenance
Australian/New Zealand Standard AS/NZS 2243: Safety in Laboratories 9 Part set, especially Part 3: Microbiological safety and containment (Part 7, electrical Aspects now obsolete)
Australian/New Zealand Standard AS 2252.1: Biological safety cabinets - Biological safety cabinets (Class I) for personnel and environment protection
Australian/New Zealand Standard AS 2252.2: Controlled environments - Biological safety cabinets Class II - design
Australian/New Zealand Standard AS 2252.3: Controlled environments - Biological safety cabinets Class III - design
Australian/New Zealand Standard AS 2252.4: Controlled environments - Biological safety cabinets Classes I

and II - Installation and use (BS 5726:2005, MOD)
Australian/New Zealand Standard AS 2252.5: Controlled environments – Cytotoxic drug safety cabinets (CDSC) – Design, construction, installation, testing and use.
Australian/New Zealand Standard AS 2252.6: Controlled environments – Clean work stations – Design, installation and use
Australian/New Zealand Standard AS/NZS 2982: Laboratory design and construction
Australian/New Zealand Standard AS/NZS 3816: Management of clinical and related wastes
Australian/New Zealand Standard AS/NZS 4187: Reprocessing of reusable medical devices in health service organisations
Australian/New Zealand Standard AS 4775: Emergency eyewash and shower equipment
Australian/New Zealand Standard AS/NZS 4815 Set: Sterilising Medical instruments – Set
Australian/New Zealand Standard AS 4834: packaging for surface transport of biological materials that might cause disease in humans, animals and plants
Australian/New Zealand Standard ISO 13994 Clothing for protection against chemicals
Security Sensitive Biological Agent (SSBA) Standards: for the handling, storage, disposal and transport of SSBAs and suspected SSBAs
Codes of Practice
safe work australia: – National Code of Practice for the Control of work-related exposure to hepatitis and HIV (blood-borne) viruses: [NOHSC:2010(2003)] (Archived – for reference only)
NHMRC: National Statement on Ethical Conduct in Human Research (2007 – updated in 2015)
NHMRC: Australian code for the care and use of animals for scientific purposes 8th edition (2013).
SafeWork NSW: First aid in the workplace code of practice (July 2015)
Australian Transport Council: Australian Code for the Transport of Dangerous Goods by Road & Rail (2015)
Other
Australian Government: National Waste Policy (2009)
NHMRC: The Australian Immunisation Handbook 2010
NHMRC: Human Research Ethics Handbook 2001
NHMRC: Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)
WHO: Guidance on regulations for the transport of Infectious Substances (2015 - 2016)
DAWR: Australian Biosecurity Import Conditions (BICON)
SafeWork NSW: Personal Protective Equipment
EPA NSW: Waste and recycling
EPA NSW: Environmental guidelines: Use and disposal of biosolids products
OGTR: Guidelines for certification of Physical Containment facilities
OGTR: Guidelines for the Transport, storage and disposal of GMOs
safe work australia: – Guidance on the Interpretation of Workplace Exposure Standards for Airborne Contaminants (2013)
safe work australia: – National Hazard Exposure Worker Surveillance: Exposure to biological hazards and the provision of controls against biological hazards in Australian workplaces March 2011
safe work australia: –National Occupational Health and Safety Commission – Diseases Acquired from Animals (Archived – for reference only)

Appendix B – Key Responsibilities

The table below outlines key responsibilities in the management of biosafety and biosecurity across the UNSW.



Appendix C – Listing of UNSW Laboratories and Approved Arrangements

The tables below outline the total number of laboratories and Approved Arrangements registered within ARCHIBUS (UNSW's enterprise facilities management system). It is noted that the details within ARCHIBUS may not reflect the current total number of laboratories and Approved Arrangements as advised by Senior Manager, Health and Safety.

UNSW Laboratories – PC1, PC2 and PC3

Lab Type	Div/Fac Name	Building Name	Total
PC1	DVC (Research)	Lowy Cancer Research Centre	1
	Faculty of Engineering	Science & Engineering (SEB)	8
	Faculty of Science	Rupert Myers	2
PC1 Total			11
PC2	DVC (Research)	Lowy Cancer Research Centre	14
		Science & Engineering (SEB)	1
		Wallace Wurth	2
	Faculty of Engineering	Chemical Sciences	4
		Hilmer Building	1
		Science & Engineering (SEB)	5
		Tyree Energy Technologies Building (TETB)	1
	Faculty of Medicine	Lowy Cancer Research Centre	75
		Research and Education Centre	1
		Shared Health Research & Education Campus	1
		Wallace Wurth	49
	Faculty of Science	Biological Sciences - North	7
		Mathews	1
		Rupert Myers	2
		Science & Engineering (SEB)	1
PC2 Total			165
PC3	Faculty of Medicine (The Kirby Institute)	Wallace Wurth	1
PC3 Total			1
Grand Total			**177**

UNSW Approved Arrangement – BC1 and BC2

Containment Level	AA Class	School	Building Name	Total
BC1	5.11, 5.12		Clinical Sciences Building, Prince of Wales Hospital	1
	5.11, 5.12	Biological Resources Centre (BRC)	St George Hospital Research Institute	4
	5.11	BEES	Biological Science - South	1
	5.12	BRC	R2 Building, Randwick Campus	5
BC1 Total				11
BC2	5.2	Chemical Engineering	Science and Engineering Building	1
	5.2	SoMs	Lowy Cancer Research Centre	1
	5.2	BABS	Biological Sciences – South	1
		BABS	Biological Sciences – North	1
BC2 Total				4
NA	7.5	BRC	Wallace Wurth Building	1
Grand Total				**16**

Appendix D – Better Practice Considerations

The table below outlines Biosafety and Biosecurity best practice across Australian universities.

Biosafety Task	UNSW Process	Best Practice
Review of Applications		Biosafety Applications are required to be submitted for all research or teaching that involves the use of biological material. Work is prohibited to commence before the application is reviewed and approved by the Institutional Biosafety Committee (IBC). Low risk projects (work involving biological material unlikely to cause human or animal disease or harm the environment) require the submission of an application, however, these are treated as a notification. This process has been omitted from UNSW's current research governance and approval processes.
Application of Import Permits		Researchers are unable to apply for import permits directly through the Department of Agriculture Water Resources and the ability to submit an application on BICON is restricted and linked through an Electronic Inventory Management System.
Reporting, Monitoring and Compliance Activities:		For all ongoing projects that have been approved by the Institutional Biosafety Committee, investigators must complete: Annual Progress reports during the life of the project and a final report is to be completed on completion of the project. Applications for storage of biological agents must be made before expiry of the current IBC project approval. Annual Reports for all IBC projects are due by mid-December each year.
		A central register is maintained with all import permits that have been issued to the University at both the University level and the local level.
		An inventory list of all agents utilised by each department that it uses, handles or stores is maintained at the local level.
Incident Reporting		All biohazardous incidents (and near misses) or non-compliant (or suspected non-compliant) incidents involving regulated biologicals must be immediately reported to the IBC. The committee will formally investigate and seek a written explanation of the incident from the relevant persons using the IBC Incident Report Form.
Facility Audits		All facilities should be inspected at least annually to ensure its containment requirement still complies with Australian Standards 2243.3:2010. Root cause analysis completed for all instances of non-compliance identified. Facility managers will work to remediate any corrective actions arising from the audits, however, will provide status to the IBC if requested. In cases of repeated instances of non-compliance, the audit frequency may increase.
Risk Management		Risk Management Assessment must be completed and approved for all actitives that involve biological agents. Risk Assessments must be reviewed a) Each time changes are made to the task, procedure; or equipment; b) Following an incident that involved the use of biologicals and/or animals; or c) At least every 3 years.
		Safe Work Instructions (SWIs) and Standard Operating Procedures (SOPs) should outline the safe way to undertake a task and may be developed for techniques, processes and equipment to minimise any risk to individuals when working with biohazardous materials.
Storage		Regular maintenance will be performed on laboratory equipment as per manufacturer standards and guidelines. Repairs will be scheduled on as needed basis. A register of maintenance and inspection requirements for laboratory equipment is maintained.
		Sample Inventory Management/Classification System has been implemented to ensure value/risk classification, contents, owner and expiry date are all clearly identifiable.
Disposal		Hazardous waste collection and disposal must be environmentally responsible and comply with Federal and State legislation and any other regulatory requirements. All records in regard to waste transportation, facility receipt and disposal are to be retained for 5 years.

Key: Not Implemented | Partially Implemented | Fully Implemented

Appendix D – Better Practice Considerations

The table below outlines Biosafety and Biosecurity best practice across Australian universities.

Biosafety Task	UNSW Process	Best Practice
Training & Awareness		Mandatory biosafety training is required for anyone working with biological material and access to the laboratory is not provided until all training has been completed. This training is delivered through online modules and at the conclusion, users are required to complete an online quiz with a pass rate of 100%. The IBC requires a copy of the certificate once training has been successfully completed. Training courses must be refreshed every three to five years (depending on the course). 100% pass on the competency assessment is required for successful completion of the course. 1. Organisational Training - Organisational biosafety training is provided by Research Services. The following training courses cover legislations and procedures in biosafety: a) OGTR Compliance – Compulsory for personnel working with GMOs, or within an OGTR certified containment lab. b) Biosafety Compliance – Compulsory for personnel working with biological risk group agents, or within containment labs. c) Import, Export Transport and Packaging of Biological Material – Compulsory for personnel working with quarantined goods or importing, exporting or transporting biological material. d) Biosafety Cabinet training – Compulsory for personnel using a biosafety cabinet. e) Autoclave training – Compulsory for personnel using an autoclave. f) Biosafety Spills Training – Recommended for personnel working with biological hazards, or within a biological containment lab.
		2. Lab Specific - Lab-specific training is provided by the area lab technician and authorised trainers. A record of training is maintained by the Lab Technical Manager, and may be audited by the IBC at any time. Personnel must indicate to the certification holder that they understand their training by signing the training declaration. NB: The Biosafety Team has prepared a number of Lab Safety Guidelines & Checklists to assist in training. Compulsory for personal entering the lab including environmental services, engineering, security, IT and administrative personnel. Training must be arranged prior to commencing work in the lab with the area technician. Topics Include: a) General lab induction b) Operational procedures c) Lab safety rules d) Emergency procedures e) Procedures for handling and disposal of waste f) Location of emergency stations and protective equipment g) Specific lab induction - High risk areas (e.g. tissue culture labs & animal houses) have specific induction processes where personnel are trained by an authorised trainer to use the facility. h) Specific equipment induction - An equipment specific training program must be in place in every laboratory (e.g. centrifuge, autoclave, BSC II cabinet etc..). Personnel must be trained by an authorised trainer before they use any equipment.
		3. Project Specific - It is the responsibility of the project supervisor/subject coordinator to: a) ensure personnel under their supervision attend the required safety training appropriate for the work performed b) ensure that all staff/students are aware and compliant with the relevant OGTR regulations and biosafety guidelines in relation to using biohazards agents and GMOs in their particular projects train (or organise the training of) staff/students in project specific activities assess the competency of staff in project-specific activities. c) Training records must be maintained by the primary investigator and may be requested by the IBC at any time.

Key: Not Implemented | Partially Implemented | Fully Implemented

Appendix E – Suggested Table of Contents - Biosafety and Biosecurity Manual

The table below outlines key definitions and acronyms used in relation to biosafety and biological agent management.

Table of Contents

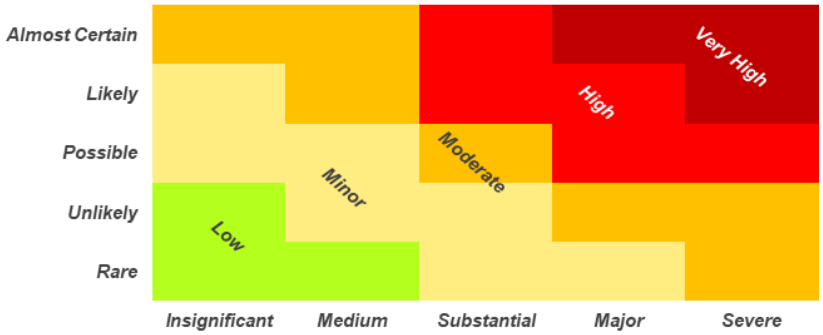
Appendix F – Ratings and Definitions

Overall Report Rating	
Immediate Attention Required	The risks associated with the control issues identified indicate that there are significant gaps in the control environment and design of controls. This will severely impact the achievement of process objectives and presents a major risk to the area under review. Issues identified require immediate management attention.
Fundamental Improvements are Required	Isolated high and/or moderate control issues have been identified where internal controls may not be appropriately designed or operating effectively. This represents a risk that some key process objectives may not be achieved and will require short term remediation action from management to ensure that risks are appropriately managed.
Some Improvement Required	Adequate control environment in most areas. Isolated moderate and/or minor control issues have been identified which may require remediation action from management to ensure that risks are appropriately managed.
Satisfactory	Satisfactory control environment. Only isolated minor and/or low issues have been identified which require corrective action.
Not Rated	Applies to focused reviews where a rating may not be representative of the overall control environment; high level or specific reviews where only a small section of an area/process is examined; and investigations which are not rated.

Issue Risk Ratings	Assessment of Issue	Velocity	Suggested Resolution Timeframe
Very High	The issue identified is severe and exposes the University to an unacceptable level of risk. The issue reflects a poorly controlled process/entity where non-achievement of key objectives is likely or almost certain. Immediate management action and escalation of the issue is required to manage associated risks related to a process/area of operation.	Immediate Short Term Long Term	3 months 3 months 6 months
High	The issue identified is critical to a process and exposes the University to a high level of risk. The current control environment is not adequate to manage the risk concerned, where key controls are either absent or not operating reliably and effectively. It is likely to impact the achievement of key objectives of a process/area of operation.	Immediate Short Term Long Term	3 months 3 months 6 months
Moderate	The issue identified is an important part of the overall controls framework to effectively manage risks associated with a process/area of operation. The controls need to be working effectively to ensure that the right level or balance of controls is in place.	Immediate Short Term Long Term	6 months 6 months 12 months
Minor	The issue identified represents isolated control gaps or deficiencies which do not threaten the achievement of objectives in a process/area of operation. These issues, if left unaddressed in the long term, may result in potential deterioration of the control environment or lead to systemic breakdown of controls.	All Velocities	18 months
Low	The issue identified represents isolated irregularities in the effectiveness of existing controls which can be addressed through business as usual management activities. There is no impact to objectives in a process/area of operation.	All Velocities	18 months
Opportunity for Improvement	Opportunities to improve operations that do not have a control implication.	N/A	N/A

UNSW Risk Management Framework

Below are the University's risk rating matrix and the relevant definitions.



Likelihood

The likelihood rating indicates the potential for an occurrence.

Likelihood	Description
Almost Certain	Expected (90+% chance) to occur in most circumstances.
Likely	Will probably occur (61-90% chance) i.e. More likely to occur than not.
Possible	Possible occurrence (21-60% chance).
Unlikely	Remote chance of occurring (1-20% chance).
Rare	May occur in exceptional circumstances (<1% chance).

Velocity

The velocity rating identified the potential speed at which the impact will materialise and impact the University.

Velocity	Description
Immediate	The impact of the risk will affect the University's operations, its reputation and/or ability to operate immediately.
Short Term	The impact of the risk will take up to six months to be realised and thus provides some lead time to convene a working party to prepare for and manage the expected impact.
Long Term	The impact of the risk will take over six months to be realised and provides substantial lead time to establish a working team to plan and execute mitigation activities to manage the expected impact.

Risk Consequence

The consequence table defines the nature of a potential impact that results from a risk being realised. The rating is determined by the highest rated impact irrespective of impact type.

Impact Type Consequence	Academic (Research & Teaching)	Facilities & Operations	People & Community	Financial	Global Standing	Partners & Authorities
Severe Long term or widespread impact requiring Senior Executive and Council time and effort over multiple months and deviation from strategic plan.	• Systemic academic or research fraud • Loss of signature high profile research capability • Closure of signature course • Multiple (>10) students suspended or unenrolled from courses • Multiple (>10) student's degrees are retracted • Compromised student and research data • Multiple academic research papers are retracted	• Loss of critical facilities (i.e. labs) for 1+ year • Critical IT systems not available for greater than 6 months and irretrievable loss of this stored data • Data integrity/loss and IP loss associated with sensitive research and commercial endeavours • Large scale release of sensitive and personal information to public domains • Inability to deliver key project benefits/Critical operations unable to be performed	• VC and/or key Executive resigns • Board restructure • Pervasive loss of University community confidence • Reckless, work-related harm to people/Multiple work-related deaths or serious permanent disabilities • Widespread, permanent environmental harm • QILT rankings drop • Significant personal liability and/or potential custodial sentence of directors and/or employees	• Fraud event ($1M) • Misappropriation of $1M funds including Philanthropic donations • Financial loss including teaching revenue exceeding $50M and/or have the potential to incur additional costs in more than the current year • Key 3rd Party withdrawal of funding	• Engagement with partners/entities not aligned with RAS – connection with tobacco and gambling industries etc. • Legal action with material basis of negligence • International and widespread prolonged (>1 month) adverse media, including social media • Global Higher Education community raise concerns over UNSW actions • Loss of provider status	• Total loss of confidence by Government/Student Community/Authorities/Funding and Research Bodies • Key strategic partner/alliance ceases engagement with UNSW
Major Impact requiring Senior Executive management and oversight and notification to Council.	• Withdrawal of or conditions imposed on Research funds • Unable to continue research and/or teaching in a FOS • Withdrawal or retraction of publications • Retraction of a student qualification • Loss of a defined group of students and research projects' data	• Partial loss of a critical facility between 6 months to 1 year • Loss of central teaching or research facilities for 3 terms • Regulatory sanction/suspension of licence/accreditation conditions • Loss of critical IT system for 1-2 terms • Sensitive and personal data released to public • Major project benefits are no longer viable/Critical operations compromised	• Faculty Dean, VP or DVC termination • Single work-related death or permanent disability • Long term damage to the environment • Ongoing disruptive Industrial action (>1 month) • Widespread Student and/or Staff body protest/outcry • Community outcry and action/staff performance across the University eroded	• Financial loss including teaching revenue, between $20M - $50M	• International and widespread short-term (1 month) adverse media including social media • Suspension or conditional Provider Status • Loss of standing in the Australasian Research and Academic Community visible to global partners	• Investigation by ACNC, ATO, ANSTO or AONSW • Targeted enquiry or investigation by Authorities • Widespread disaffected student community • Corporate partners (existing and potential) disassociate themselves from UNSW • Legal dispute with Corporate partner (e.g. IP and commercialisation rights) • Major partner disengages
Substantial Impact requiring Executive oversight and HOS, Director action	• Capability to complete research or teaching commitments is undermined impacting quality, cost and timeframes • Unable to continue research and/or teaching in a FOS for a term • Erosion of student GPA and progression rates • Loss of a student cohort or research project's data • New course unable to be progressed or introduced • Load sharing to support signature course and/or research	• A building is not able to be occupied for approximately 1 month during teaching year • Loss of central teaching or research facilities between 1-2 terms • Core IT systems are inconsistently available to staff and students throughout the terms • Irretrievable loss of non-research data • Project/operations cost/time over-runs	• Key person loss • Staff performance issues (>1 area of the University) • Work-related injury requiring hospitalisation • Localised environmental harm lasting >1 week • Industrial action (up to 1 month) • A student group lodges complaints • A Community group voice concerns • Legal action from a group of students, staff or community group	• Financial loss between $5M - $20M • Costs and/or loss unable to be consumed in the current Divisional or Faculty budget	• Adverse state-based and social media traffic (mainly spurious) lasting 2 weeks • Persistent short-term Media enquiries over the events • Australian Higher Education Community query UNSW Research and Academic Integrity • Pursuit of a new opportunity is compromised	• Authorities and government register strong concerns/threaten investigation • Corporate partners (existing and potential) voice strong concerns • Breach of contracts • Enforceable penalties or civil action • Increased partner complaints
Medium Localised impact for a Divisional Unit or School	• Program development deferred or not progressed • Capability to complete research or teaching commitments is compromised in the short term • Increased reliance on unexperienced casual teaching staff	• Compromised access to research equipment and/or facilities for 1 month • A building is not able to be occupied for 1-2 weeks during term • Basic IT systems availability is unstable for staff and students for less than 1 month	• Localised staff performance issues • Community member, staff or student legal action • Student groups register separate concerns • Work-related injury/illness requiring medical/health professional intervention • Localised environmental harm <1 month	• Financial loss between $50k - $5M • Costs and/or loss unable to be consumed in the current Unit or School budget • Unauthorised spend up to $500K	• Active adverse student social media traffic (mainly spurious) lasting 2 weeks • External queries over UNSW Research and Academic Integrity • One-off adverse media report with local coverage or intra-industry knowledge of incident	• Authority formally seeks clarification • Issue of infringement notice
Insignificant Issue that is managed as part of BAU	• Unit development is postponed or not progressed • Casual teaching staff are unable to be sourced impacting quality • Research data or samples impacted but recovered within 3 days	• Facilities are unable to be occupied for the day • Localised user group unable to access IT systems (<3 days) • IT systems do not operate efficiently • Operational performance impacting day-to-day activities or project	• Disaffected group of students and/or staff • Minor work-related incident requiring first aid treatment only • No material environmental harm – on-site, immediately contained, no ongoing impact	• Financial loss less than $50k • Unauthorised spend up to $50k	• N/A	• Authority registers issue only • Minor complaints that can be managed within the business unit