Biosafety - Internal Certification of Containment Laboratories Procedure

Section 1 - Summary

(1) This Procedure ensures that the University is compliant with Australian Standards for containment laboratories and outlines:

a. The management process for determining the appropriateness of facilities used for work with biohazardous agents and ensuring microbiological safety.
b. The internal certification process and routine monitoring required at all containment facilities at Victoria University (VU).
c. The structural and behavioural requirements for certification of biological containment laboratories at the University.

Section 2 - TEQSA/ASQA/ESOS Alignment

(2) HESF: 2.3 Wellbeing and Safety

Section 3 - Scope

(3) This Procedure applies to all work areas of the University where biological risk group agents or samples that might reasonably contain biological risk group agents are used, stored, handled, transported and disposed.

Section 4 - Definitions

(4) Institutional Biosafety Committee (IBC) – The IBC provides on-site scrutiny of low-risk contained dealings that do not require case-by-case consideration by the Regulator through independent assessment of NLRD proposals on behalf of their organisation, ensuring compliance with legislative requirements.

The IBC is required to comprise a range of suitable experts and an independent person. The objective of the IBC at VU is to protect the health and safety of members of the Australian community and its environment in the following ways:

a. identifying risks posed by, or as a result of, work within the University with agents that are potential biosafety and biosecurity concerns;
b. managing those risks by regulating 'dealings' and certifying facilities.

(5) Physical Containment Level 1 (PC1) – A PC1 laboratory or facility is suitable for work with microorganisms that have been designated Risk Group 1. In addition, samples originally designated Risk Group 2 that have subsequently been fixed or inactivated may be handled in PC1 Facilities.

(6) Physical Containment Level 2 (PC2) – A PC2 laboratory or facility is suitable for work with biohazardous material that have been designated Risk Group 2 or lower.

(7) Physical Containment Levels 3 (PC3) and 4 (PC4) – At present, VU does not have PC3 or PC4 facilities; therefore Risk Group 3 and Risk Group 4 biohazards must not be handled within VU facilities.

(8) Risk Group 1 Biohazard – Risk Group 1 microorganisms and other biological agents that are of low risk to the individual or workgroup and community, are unlikely to cause human, animal or plant diseases and are already present and widely distributed in the environment.

(9) Risk Group 2 Biohazard – Risk Group 2 microorganisms and other biological agents are of moderate risk to the individual or workgroup, limited risk to the community, may cause infection to humans, animals, plants, invertebrates or the environment, yet effective treatment is available. Risk Group 2 microorganisms are already present but not widely distributed in the environment.

(10) Risk Group 3 and 4 Biohazards – At present, VU does not have PC3 or PC4 facilities; therefore Risk Group 3 and Risk Group 4 biohazards must not be handled within VU facilities.

(11) Office of the Gene Technology Regulator (OGTR)– The OGTR operates within the Australian Government Department of Health and Aged Care to provide administrative support to the Gene Technology Regulator in the performance of the functions under the Gene Technology Act 2000. The OGTR provides assessment and certification of biocontainment facilities handling certain types of genetically modified organisms or materials.

(12) Department of Agriculture, Fisheries and Forestry (DAFF) – The Department of Agriculture, Fisheries and Forestry (DAFF) protects Australian agriculture. The DAFF asses and issue permits for the importation of biological goods, and provide assessment and certification of quarantine approved premises (Approved Arrangements) for the handling of imported biologicals.

Section 5 - Policy/Regulation

(13) See Biosafety Policy.

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
IInstitutional Biosafety Committee (IBC)	The IBC is responsible for certifying all work areas within VU where hazardous biological material is used and/or stored. Areas that are not externally certified by DAWE or the OGTR must be internally certified by the VU IBC. The IBC will be responsible for the certification of both new areas and refurbished existing facilities.
College or Institute	The College or Institute is responsible for appointing the Chief/Principal Investigator.

Roles	Responsibilities
Chief/Principal Investigator (C/PI)	To apply for certification the C/PI must complete the Internal Certification Application Form and submit this to the IBC for assessment. The C/PI is responsible for contacting the IBC to arrange for a preliminary inspection of any existing work area that is to be internally certified. Once certified, it is the responsibility of the C/PI to ensure that the area is maintained to the standard and requirements of the physical containment level through appropriate procedures, behaviours and maintenance, which are assessed by annual inspection by the IBC.
Deputy Vice-Chancellor, Research & Impact	Determine if a facility is to be closed if serious non-compliances are observed.

Part B - Operating Procedures

Certification

(14) All work areas where hazardous biological material is used, that are not externally certified by DAWE or OGTR, must be internally certified by the VU IBC.

(15) The IBC will issue the requirements for internal certification and make these available on the Biosafety intranet site. These requirements are based on the Australian/New Zealand Standard (AS/NZS) 2243.3 - Safety in Laboratories, Part 3: Microbiological Safety and Containment, and AS/NZS 2982 - Laboratory Design and Construction.

(16) A formal certification process will be conducted by the IBC, a representative of the IBC, or an individual that the IBC considers to be "competent" at preforming inspections.

(17) To apply for certification the Chief/Principal Investigator or Research Institute must complete the Internal Certification Application Form and submit this to the IBC for assessment. Note that all forms and other detailed information are located on the Biosafety intranet site under Lab Facilities - Certification Process.

(18) There may be circumstances where a specific requirement or proposed usual condition for a PC level or facility type may not be applicable. Where alternate facility design or proposed work practices can be shown to provide the necessary containment or risk management for the dealings to be conducted in that facility, a request for an exemption from the requirement or condition in question may be made on the Internal Certification Application Form. Conditions may be imposed on the certification relating to the exemption. Such conditions might, for example, restrict the types of dealings that can be conducted in the facility, or include the imposition of additional physical containment and/or procedural requirements.

(19) The facility Internal Certification Application Form will be assessed by the IBC, a representative of the IBC, or an individual that the IBC considers to be "competent" at preforming the inspection.

(20) The work area will be approved if the requirements for certification are met, as detailed in the Internal Lab Certification Checklist and are appropriate for the level of risk presented by the biological agents used and procedures conducted within the facility.

(21) Once approved, the Institute will be provided with a letter that outlines the certification requirements and signage for the door that indicates the level of containment that the work area provides and the expiry date of the internal certification certificate. The certification sign must be displayed at all times.

(22) Internal Certification is valid for a period of five years.

Part C - Inspections

Existing Facilities

(23) Certified work areas can be randomly inspected at any time by the IBC, a representative of the IBC, or an individual that the IBC considers to be "competent" at preforming inspections.

(24) Once certified it is the 'owning' Research Institute's responsibility to ensure that it is maintained to standard.

(25) Certified areas must be inspected annually by the Research Institute using the Basic or Expanded Internal Certification Laboratory Inspection Forms.

New Facilities and Refurbishment of Existing Facilities

(26) The IBC must be informed of any Commissioning of New Areas or Refurbishing of Existing Facilities.

(27) The Research Institute shall complete the Internal Certification Application Form for all facilities that need to be certified.

(28) The Research Institute must contact the IBC to arrange for a preliminary inspection of any existing work area that is to be internally certified. During this initial inspection, any non-compliance will be reported to the Institute for remedy.

(29) If it is a new facility, the plans must be submitted to the IBC for assessment before going to tender. It is strongly recommended that the IBC remain engaged throughout the project design phase and that any issues arising that may impact internal certification of the facility be immediately brought to the attention of the IBC.

(30) Upon completion of any new building works the IBC must be contacted to inspect the facilities.

(31) Inspections will be undertaken by the IBC, a representative of the IBC, or an individual that the IBC considers to be "competent" at preforming the inspection.

Non-compliance

(32) To retain certification, the work area must meet all of the requirements of certification for the level of containment for which it is certified.

(33) Where any non-compliances are identified by a College or Institute, or through an IBC-led inspection, the IBC will issue an inspection report that will outline the action that must be taken to address these non-compliances. Work Areas will be given a timeline with which to demonstrate compliance. Laboratory certification will be revoked if compliance cannot be rectified within the timeframe given.

(34) The IBC can recommend to the Deputy Vice-Chancellor, Research & Impact that a facility be closed if serious non-compliances are observed. The laboratory will remain closed until compliance can be demonstrated.

Varying, Suspending or Surrendering an Internal Certification

(35) Changes to the type of biological hazards used or work conducted by the workgroup in a certified facility, may necessitate changes to the requirements that a facility must meet in order to ensure the appropriate level of containment and the safety of the workgroup within the work area. Certification can be varied, suspended or surrendered on completion of an Internal Certification Application Form.

a. Variation - The IBC will assess the variation and determine whether re-inspection of the work area is required.
b. Suspension - Certification can be suspended to allow for laboratory maintenance or renovation to be performed,

or if there are repeated or serious non-compliance that are not resolved in a timely manner. During such time, work with biological hazards is not permitted in the work area. Re-inspection of the facility may be necessary to confirm that the certification requirements are still being met.

c. Surrender - Certification can be surrendered if a laboratory or facility is no longer used for infectious agents. In such a case, all signage must be removed upon surrender so that it is clear that work involving biological risk agents can no longer be conducted in the work area.

(36) Changes to work practices that result in an increased level of containment shall warrant re-inspection and new certification of the work area.

Section 7 - Supporting Documents and Information

(37) A copy of the legislation relevant to the handling of genetically modified organisms (GMOs) and imported biologicals can be found on the Biosafety intranet site under Compliance, in addition to details of relevant Australian Standards and risk group agents.

(38) All supporting documents can be found on the Biosafety Website or by contacting the Biosafety Manager(ibc@vu.edu.au).

(39) The following Procedures may be relevant when considering internal certification of containment laboratories:

a. Biosafety - Dealings Involving Genetically Modified Organisms Procedure
b. Biosafety - Dealings Involving Risk Group Agents Procedure
c. Biosafety - Importing and Exporting Biological Material Procedure
d. Biosafety - Non-Compliance and Adverse Incidents Procedure

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