Biosafety - Certification of Biocontainment Facilities Procedure

Section 1 - Summary

(1) This Procedure ensures that the University is compliant with relevant regulatory requirements (including Australian Standards and Gene Technology Regulations 2001 (Cth)) 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 certification process and routine monitoring required at all biocontainment 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 of.

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 Office of the Gene Technology Regulator (OGTR) through independent assessment of Notifiable Low Risk Dealings (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 activities involving 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.

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(6) Physical Containment Level 2 (PC2) – A PC2 laboratory or facility is suitable for activities involving 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) Regulated biological material (RBM): RBM is biological material governed by a regulatory scheme or recognised set of guidelines or standards, including RG2 (or above) material, GMOs, biosecurity-controlled material, and Security Sensitive Biological Agents (SSBAs).

(9) Risk Group 1 (RG1) Biohazard – Risk Group 1 (RG1) microorganisms and other biological agents that are of low risk to the individual, workgroup and community, are unlikely to cause human, animal or plant diseases and are already present and widely distributed in the environment. RG1 material is considered unregulated.

(10) Risk Group 2 (RG2) Biohazard – Risk Group 2 (RG2) microorganisms and other biological agents are of moderate risk to the individual or workgroup, and of limited risk to the community. They may cause infection to humans, animals, plants, invertebrates or the environment, yet effective treatment is available. RG2 microorganisms are already present but not widely distributed in the environment. RG2 (and above) material is considered regulated.

(11) Risk Group 3 (RG3) and 4 (RG4) 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.

(12) Office of the Gene Technology Regulator (OGTR)– The OGTR operates within the Australian Government Department of Health 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 dealing with certain types of genetically modified organisms or materials.

(13) Department of Agriculture, Fisheries and Forestry (DAFF) – The Department of Agriculture, Fisheries and Forestry (DAFF) protects Australian agriculture, water resources, and the environment. The DAFF asseses and issues permits for the importation of biological goods and provides assessment and certification of quarantine approved premises (Approved Arrangements) for the handling of imported biologicals.

Section 5 - Policy/Regulation

(14) Biosafety Policy.

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Institutional Biosafety Committee (IBC)	The IBC is responsible for certifying all work areas within VU where Regulated Biological Material (RBM) is used and/or stored. Areas that are not externally certified by DAFF or the OGTR must be internally certified by the VU IBC. The IBC will be responsible for the certification of both new facilities and refurbished existing facilities.
Senior Manager, Research Infrastructure & Biosafety	The Senior Manager, Research Infrastructure & Biosafety, is responsible for providing biosafety expertise on all new infrastructure and refurbishment projects involving biocontainment facilities, whether for teaching or research, and representing the interests of the IBC, as and when required.

Roles	Responsibilities
Institute or College	The Institute or College is responsible for appointing the Facility Contact/Manager and ensuring that certified biocontainment facilities are maintained to the required standard. For all new infrastructure and refurbishment projects, the Institute/College must ensure that the IBC is notified, and that the Senior Manager, Research Infrastructure & Biosafety, is engaged at the initial design brief development stage and space planning, and throughout the subsequent design, build, defect rectification, and commissioning stages.
Facility Contact/Manager (FC/M)	It is the responsibility of the Facility Contact/Manager (FC/M) to ensure that the facility is maintained to the standard and regulatory requirements of the physical containment level through appropriate procedures, behaviours, and maintenance, which are assessed by annual inspection of the facility against relevant criteria. To apply for certification the FC/M must complete the Certification of Biocontainment Facilities Application Form (BI006) and submit this to the IBC for assessment. The FC/M is responsible for contacting the IBC to arrange for a preliminary inspection of any facility that is to be certified, prior to the commencement of any activity in the facility. Note that a Technical Manager may be appointed as the FC/M where this is deemed appropriate based on the facility type and users.
Deputy Vice-Chancellor, Research & Impact (DVC-RI)	Determine if a facility is to be closed if serious non-compliances are observed.

Part B - Procedures

Certification

(15) The requirements/criteria for biocontainment facilities are set out in BI013 – Requirements of Biocontainment Facilities. All facilities where regulated biological materials (RBMs), i.e. RG2 materials, GMOs, and biosecurity-controlled materials, are handled or stored must be internally certified by the Victoria University Institutional Biosafety Committee (IBC) (as PC2 facilities), or externally certified by the OGTR (as PC1 or PC2 facilities) or by DAFF (as Approved Arrangements).

(16) 'General laboratories/facilities' where activities involve unregulated RG1 agents/material, must still meet the relevant AS/NZ Standards for a biocontainment facility (see points 1-46 in BI013 – Requirements of Biocontainment Facilities). This is overseen by the Institute/College, Facility Contact/Manager, and Health and Safety Advisors, and does not require IBC oversight.

(17) To apply for internal or external certification of a facility, the Facility Contact/Manager, appointed by the Institute or College, must complete BI006 – Certification of Biocontainment Facilities Application Form and submit this to the IBC for assessment. Note that all forms and other detailed information are located on the Biosafety SharePoint site under Lab Facilities - Certification Process.

(18) The requirements for external certification are detailed by the relevant regulatory body, i.e. DAFF provides Approved Arrangements for facilities handling imported biologicals, and the OGTR certifies facilities for dealings involving GMOs. Links and additional information are available on the Biosafety SharePoint site. Refer to Biosafety - Dealings Involving Genetically Modified Organisms Procedure for further information on OGTR certification processes.

(19) The requirements for internal certification, issued by the IBC, are available on the Biosafety SharePoint 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.

(20) A formal certification process is conducted by the IBC, a representative of the IBC, or an individual that the IBCconsiders to be competent to perform such inspections.

(21) 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 risk group agents and the activities to be conducted in the facility, a request for an exemption from the requirement or condition in question may be made on the BI006 – Certification of Biocontainment Facilities Application Form. Conditions may be imposed on the certification where the exemption is granted. Such conditions might, for example, restrict the types of activities that can be conducted in the facility, or include the imposition of additional physical containment and/or procedural requirements.

(22) The application will be assessed initially by the Senior Manager, Research Infrastructure & Biosafety, who may request additional information from the applicant, prior to the facility inspection being conducted, as detailed in the next section.

(23) The IBC will issue final approval on the BI006 – Certification of Biocontainment Facilities Application Form, after the requirements for certification are met, based on the application form and facility inspection report, confirming that the risk management of the regulated biological material and activities conducted within the facility are satisfactory. For external certification, approval will be advised once it is granted by the external regulatory body (i.e. OGTR or DAFF).

(24) The IBC will provide the applicant with an approval letter outlining the certification requirements, together with signage for the facility that indicates the level of containment and the certification expiry date. Biocontainment certification signage must be securely displayed at all times.

(25) Internal certification is valid for a period of five years. After this time, if certification is to be continued, the Institute or College, or Facility Contact/Manager appointed to oversee the facility, must submit a BI006 – Certification of Biocontainment Facilities Application Form, with a request for renewal. This will trigger an assessment of the facility's ongoing compliance and may include an IBC inspection by a representative of the IBC, or an individual that the IBC considers competent to perform the inspection.

Inspections – Existing Facilities

(26) The IBC can randomly inspect certified biocontainment facilities at any time, using a representative of the IBC, or an individual that the IBC considers competent to perform the inspection.

(27) Once certified, it is the Institute's or College's responsibility to ensure that it is maintained to the required standard.

(28) Certified facilities must be inspected annually by a suitably qualified representative of the Institute or College, or other delegate, using BI001 – Biocontainment Facility Inspection Form – Internal PC2, or an equivalent inspection checklist. Refer to BG028 Biocontainment Facility Inspection Guideline – Internal PC2 for further information and guidance around undertaking an internal PC2 inspection.

Inspections – New Facilities and Refurbishment of Existing Facilities

(29) The Facility Contact/Manager appointed by the Institute or College must inform the IBC of any plans to establish new facilities, or refurbish existing facilities, where biocontainment is a future or existing requirement.

(30) For all new infrastructure projects, the Senior Manager, Research Infrastructure & Biosafety, as a biosafety expert and representative of the IBC, must be engaged at the initial design brief development stage and space planning, as well as throughout the subsequent design, build, defect rectification, and commissioning stages. This ensures the appropriate design and process considerations and requirements are met from the outset, and assists in avoiding the risk of costly rectification works during the build stage or after completion.

(31) For all new and refurbished facilities, the facility design plans must be submitted to the IBC for assessment prior to going to tender.

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

(33) The Institute or College shall complete the certification steps, as detailed in the section above, for all new and refurbished facilities that require certification.

(34) Upon initial assessment and acceptance of the BI006 – Certification of Biocontainment Facilities Application Form, the Facility Contact/Manager must arrange with the IBC for a preliminary inspection of any facility that is to be certified against the BI001 – Biocontainment Facility Inspection Form – Internal PC2. Following this initial inspection, any areas of non-compliance will be reported to the Institute/College as action items for rectification.

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

Non-compliance

(36) To retain certification, the facility must continue to meet all of the requirements of certification for the level of containment for which it is certified (see BI013 – Requirements of Biocontainment Facilities).

(37) Where the Institute or College, Facility Contact/Manager, technical support personnel, OHS personnel, or through an IBC-led inspection, identify any non-compliances, these must be reported to the IBC. The IBC will then issue an inspection report that will outline the actions required to address the non-compliances. The facility will be given a reasonable timeline within which to demonstrate compliance, as determined by the IBC based on the non-compliances observed. Laboratory certification will be revoked if compliance concerns/breaches cannot be rectified within the required timeframe.

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

Varying, Suspending or Surrendering an Internal Certification

(39) Changes to the type of biological materials handled, or the type of activities conducted within a certified facility, may necessitate changes to the biocontainment requirements. These must be met in order to ensure the appropriate levels of containment and safety within the facility. Certification can be varied, suspended or surrendered using the BI006 – Certification of Biocontainment Facilities Application Form.

a. Variation - The IBC will assess the variation and determine whether re-inspection of the facility is required.
b. Suspension - Certification can be suspended to allow for laboratory maintenance or refurbishment to be undertaken, or if repeated or serious non-compliances are not resolved in a timely manner. During such times, all work with RBMs is prohibited in the facility. Re-inspection of the facility may be necessary to confirm that the certification requirements are met.
c. Surrender - Certification can be surrendered if a facility is no longer used to handle biological agents for which the biocontainment certification is required. In such case, all signage must be removed upon surrender so it is clear that activities involving RBMs can no longer be conducted in the facility. Upon receipt of the application to surrender certification, the IBC will advise on all essential processes for the downgrade of the biocontainment, including decontamination and RBM material disposal requirements.

(40) Changes to work practices that result in an increased level of containment shall require re-inspection and new certification of the facility.

(41) Where the level of certification is varied, suspended, or surrendered, signage must be securely replaced or removed immediately to ensure that activities involving RBMs is not conducted in de-certified facilities.

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Section 7 - Supporting Documents and Information

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

(43) All supporting documents can be found on the Biosafety & Biocontainment SharePoint site or by contacting the Biosafety Manager(ibc@vu.edu.au).

(44) 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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