Biosafety - Internal Certification of Containment Laboratories Procedure

Section 1 - Purpose / Objectives

(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.
c. The structural and behavioural requirements required for certification of biological containment laboratories at the University.

(2) This procedure does not address:

a. Dealings with genetically modified organisms that must be conducted in OGTR certified facilities. Procedures relating to dealings with Gene Technologies and are detailed in Dealings Involving Genetically Modified Organisms Procedure.
b. Dealings requiring Quarantine Approved Premises, as defined by the DAFF Biosecurity Act and implemented by AQIS. Procedures relating to dealings with AQIS are detailed in the Import, Export, Transport and Packaging of Biological Material Procedure.
c. Dealings requiring Department of Health and Ageing approval of premises, as defined in the Health Security Act are detailed in the Dealings Involving Risk Group Agents Procedure.

Section 2 - Scope / Application

(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 3 - Definitions

(4) Nil

Section 4 - Policy Statement

(5) See Biosafety Policy.

Section 5 - Procedures

Roles/Responsibilities

(6) Key responsibilities and accountabilities are outlined in the Biosafety Governance Procedure (pending).

Facility Classification

(7) The Australian Standards 2243.3, Safety in Laboratories, Part 3: Microbiological Safety and Containment & Australian Standards 2982, Laboratory Design and Construction , outline the requirements, both structural and procedural, which facilities should meet.

(8) Four physical containment levels, PC1 to PC4 are assigned for work with hazardous biological agents.

(9) Hazardous biological agents are classed into four risk groups, termed Risk Groups 1 - 4, based on the infectivity allergy or toxicity of the agent, ease of transmissibility, resultant effect, host range of agent, availability of vaccines/effective treatment in humans, animals or plants including:

a. microorganism (bacteria and viruses);
b. material which contains microorganisms including plant, insect and animal cell cultures, tissue samples, blood samples, soil samples, sewage samples etc.
c. prions;
d. toxins derived from biological sources, including animals, plants and microorganisms.

(10) Physical containment of hazardous biological agents involves a combination of engineering controls, safety equipment and worker practices to handle potential biohazards safely and reduce or prevent the release of viable organisms into the outside environment.

Physical Containment Level 1 (PC1)

(11) 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.

(12) Risk Group 1 microorganisms and other biological agents 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.

Physical Containment Level 2 (PC2)

(13) A PC2 laboratory or facility is suitable for work with biohazardous material that have been designated Risk Group 2 or lower.

(14) 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.

Physical Containment Level 3 (PC3)

(15) A PC3 laboratory or facility is applicable where work is conducted with microorganisms or material likely to contain microorganisms that are classified as Risk Group 3. At present, Victoria University does not have PC3 facilities; therefore Risk Group 3 biohazards must not be handled within Victoria University facilities.

(16) Risk Group 3 microorganisms and other biological agents are of high individual risk, moderate community risk and usually cause serious infection to humans, animals, plants, invertebrates or the environment. Effective treatment is available.

Physical Containment Level 4 (PC4)

(17) A PC4 laboratory or facility is applicable where work is conducted with microorganisms or material likely to contain microorganisms that are classified as Risk Group 4. At present, Victoria University does not have PC4 facilities; therefore Risk Group 4 biohazards must not be handled within Victoria University facilities.

(18) Risk Group 4 microorganisms and other biological agents are of high individual and community risk, and usually cause life-threatening human or animal disease that may be readily transmissible between individuals. Effective treatment and preventative measures are not usually available.

Operating Procedures

Certification

(19) All work areas where hazardous biological material is used, that are not externally certified by Department of Agriculture, or the OGTR, must be internally certified by the Victoria University Institutional Biosafety Committee.

(20) The Institutional Biosafety Committee will issue the requirements for internal certification and make these available on the biosafety website.

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

(22) To apply for certification the Collage must complete the Internal Certification Application Form and submit this to the IBC for assessment.

(23) There may be circumstances where a specific requirement or proposed usual condition for a PC level/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.

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

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

(26) Once approved, the College 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.

(27) Internal Certification is valid for five years.

Inspection

(28) Certified work areas can be randomly inspected at any time by the IBC, representative of the IBC, or an individual

that the IBC considers to be "competent" at preforming inspections.

(29) Once certified it is the 'owning' Colleges responsibility to ensure that it is maintained to standard.

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

(31) Commissioning of New Areas or Refurbishing Existing Facilities

(32) The College shall complete the Internal Certification Application Form for all facilities that need to be certified.

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

(34) If it is a new facility, the plans must be submitted to the IBC for assessment before going to tender.

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

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

Non-compliance

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

(38) The IBC will issue an inspection report to the College that highlights any non-compliances and the action that must be taken to address them.

(39) 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.

(40) The Institutional Biosafety Committee can recommend to the PVC (Research and Research Training) 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

(41) 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.

(42) A certification can be varied by completing an Internal Certification Application Form. The IBC will assess the variation and determine whether re-inspection of the work area is required.

(43) 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.

(44) 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 work employing infectious agents can no longer be conducted in the work area.

(45) Changes to work practices that result in an increased level of containment shall warrant re-inspection and new

certification of the work area.

Section 6 - Guidelines

(46) Nil

Section 7 - Templates

(47) Nil

Section 8 - Supporting Documents

(48) A copy of the legislation can be downloaded from the VU Governance & Secretariat Website.

(49) All supporting documents can be found on the Biosafety Website or by contacting the Manager, Research Infrastructure and Biosafety (ibc@vu.edu.au).

(50) The following Procedures have been referenced in this document:

a. IBC P002 Internal Certification of Containment Facilities Procedure
b. IBC P003 Dealings Involving Genetically Modified Organisms Procedure
c. IBC P004 Import, Export, Transport & Packaging of Biological Material Procedure
d. IBC P005 Non-Compliance and Adverse Incidents Procedure
e. IBC P006 Biosafety Governance Procedure

(51) The following Forms have been referenced in this document:

a. IBC I001-2 Expanded or Basic Internal Certification Laboratory Inspection Forms
b. IBC 1004 Internal Certification Application Form

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