Biosafety - Packaging and Transport of Biological Materials Procedure

Section 1 - Summary

(1) This Procedure explains the requirements for packaging and transporting biological material considered to be a biological hazard. Transport of material can be internal within the University, or external, to other organisations or locations.

Section 2 - TEQSA/ASQA/ESOS Alignment

(2) HESF: Standards 2.3 Wellbeing and Safety; 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity

Section 3 - Scope

(3) The transportation of biological material from one place to another (by bike, car, truck, bus, train, post, plane, ship or carrying whilst walking) is a regulated activity to ensure that materials do not:

a. become contaminated by the environment;
b. escape containment to contaminate people or the environment.

(4) This document is for use by Victoria University staff and students who need to transport biological samples. The procedures explain the requirements for transporting biological material considered to be hazardous and includes transport requirements for infectious, diagnostic, exempt and quarantine material being transported by air or surface.

(5) Prior to transportation, an assessment of the required licences, permits and/or agreements must be completed and put in place. These procedures assist staff and students to ensure that they are compliant with the requirements and safe working procedures when transporting biological material.

(6) The transport of biological material is regulated by a variety of legislation/regulations. The applicable legislation depends on whether the mode of transport is air, post, road, rail, or pedestrian, and whether the biological materials are infectious, GM or under quarantine restrictions. Relevant legislation/regulations have been inserted throughout the document and are listed under Section 6, Part B. A full list of Acts, Regulations and Standards relevant to transport of infectious agents can be found on the Biosafety Intranet page.

(7) The intent of all the transport regulations is that packaged material should not escape from the package under normal conditions of transport.

(8) The transport of live animals is not covered under transport of biological material guidelines (refer to the Animal Welfare Policy). However, any infectious tissues from animals fall under the transport regulations.

(9) For additional and related guidance concerning the handling and movement of biological material refer to the following:

a. For genetically modified (GM) material go to the Biosafety - Dealings Involving Genetically Modified Organisms Procedure and Biosafety – Labelling, Storage and Transport of Genetically Modified Material Procedure (pending).
b. For the import or export of biological material go to the Biosafety - Import and Export of Biological Material Procedure (pending).
c. For the storage and use of Risk Group agents go to the Biosafety - Dealings Involving Risk Group Agents Procedure.

Section 4 - Definitions

(10) ADG7 – Australian Dangerous Goods 7th Edition

(11) CASA – Civil Aviation Safety Authority

(12) DG/DGC – Dangerous Goods/Dangerous Goods Class

(13) GMO – Genetically Modified Organism

(14) GM – Genetically Modified

(15) IATA – International Air Transportation Association

(16) IBC – Institutional Biosafety Committee

(17) OGTR – Office of the Gene Technology Regulator

(18) UN – United Nations

(19) P – UN Packing Instruction

(20) AS 4834 – Australian Standard: Packaging for surface transport of biological material that may cause disease in humans, animals and plants

(21) AS/NZS 2243.3 – Australian New Zealand Standards: Safety in Laboratories, Part 3: Microbiological Safety and Containment

Section 5 - Policy/Regulation

(22) Biosafety Policy

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Deputy Vice-Chancellor, Research & Impact	The Deputy Vice-Chancellor, Research & Impact (DVCRI) is responsible to the Vice-Chancellor for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by International Air Transportation Association (IATA) and other transport regulatory bodies.

Roles	Responsibilities
Executive Director, Research Services	The Executive Director, Research Services, is responsible to the DVCRI to ensure that the Senior Manager, Research Infrastructure and Biosafety is competent to advise and report on the legislative requirements for the transport of biological material.
Senior Manager, Research Infrastructure and Biosafety	The Senior Manager, Research Infrastructure and Biosafety is authorised to advise on and report to the IBC on legislative requirements for all transport (external and internal) of biological material.
Directors, Executive Deans and Heads of Department	Directors, Executive Deans and Heads of Department are responsible for ensuring that all staff and students receive appropriate information and training necessary for them to transport biological material following all legislative requirements.
Manager, Technical Services	The Manger, Technical Services is responsible for ensuring that designated research spaces are adequately supported so that biological material can be transported in a compliant and safe manner. They are to ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all transport of biological material legislation and guidelines are met.
Technical Managers	Technical Managers must ensure that there will be at least one member of staff per area who has been trained and licensed to supervise all packaging of biological material, subject to IATA regulations. Technical Managers are also responsible for ensuring that IATA certification is current.
Chief Investigators	Chief Investigators (including Principal Investigators, Academic Supervisors, Research Supervisors and Unit Conveners) are responsible for the health and safety of the undergraduate and postgraduate students they supervise, in addition to volunteers and staff employed under them. They are to ensure that their students and staff are aware of and abide by VU's procedures for the Packaging and Transport of Biological Material.
Staff, Students and Volunteers	Staff, students and volunteers working with biological hazards must ensure that they follow safety guidelines and abide by VU's Procedures for the Packaging and Transport of Biological Material set out by VU and their respective Technical Manager and Chief Investigators. They must ensure that their actions do not put themselves, or any other individual at risk

Part B - Biologicals as Dangerous Goods

Classes of Dangerous Goods

(23) Dangerous goods (DG) are classified according to criteria determined by the United Nations (UN). There are nine classes of dangerous goods. Biological materials are classified as Class 6 – Toxic and Infectious Substances. There are two divisions within Class 6: 6.1 Toxic substances and 6.2 Infectious substances.

(24) Note that other dangerous goods are sometimes also transported with biological material, such as dry ice (Class 9 Miscellaneous), liquid nitrogen (Class 2 Gases), ethanol (Class 3 Flammable Liquids) or formaldehyde (Class 8 Corrosives), or the material itself may fall into another dangerous goods class.

Defining Biological Material for Transport

(as per WHO Guidance on regulations for the transport of infectious substances 2021-2022)

Cultures

(25) Culture is a method by which biological agents are intentionally propagated, under controlled conditions. Any cultured biological agent capable of causing disease in humans or animals will fall under the definition of infectious substances.

Patient specimens

(26) Patient specimens are products or materials that are collected directly from humans or animals for the purpose of

research and/or diagnostic investigations. Also referred to as patient samples, diagnostic specimens/samples. As with cultures, if a patient specimen contains biological agents capable of causing disease in humans or animals, they will be defined as infectious substances.

Biological substances

(27) Biological products are substances or materials that are derived from living organisms (e.g. bacteria, fungi, vaccines, animals, humans etc.) and are extracted and/or purified for use as a preventative, therapeutic or diagnostic tool (e.g. antitoxins, vaccines or vaccine components). It is important to note that some biological products may be governed by special requirements or licensing agreements and may therefore be subject to regulations that differ from, or be in addition to, those set out for infectious substances.

Medical or clinical wastes

(28) Waste generated in treating patients (humans or animals) and conducting laboratory activities, and that is contaminated by reagents, liquids, tissues, cultures and other products, is considered medical or clinical waste. If this waste contains biological agents capable of causing disease in humans or animals, then this medical or clinical waste is an infectious substance.

Medical devices or equipment

(29) Medical devices or equipment that have been contaminated by biological agents during patient treatment or laboratory processes, may be defined as infectious substances if the biological agents contained within them are capable of causing disease in humans or animals.

Exceptions

(30) There are some circumstances where, although the material or product being shipped falls under one of the above definitions, it will not meet the definition for an infectious substance due to the confirmed absence of biological agents, or that any biological agents present are known to be incapable of causing disease in humans or animals (i.e. non-pathogenic, inactivated or neutralized through a decontamination process). For examples, see section 4.6 of the WHO Guidance on regulations for the transport of infectious substances 2021-2022.

UN Numbers for Biological Material

(31) Most DG have a UN number assigned to them. The UN numbers that may be associated with the transport of biological material are:

a. UN2814 - Infectious Substances affecting humans
b. UN2900 - Infectious Substances affecting animals only
c. UN3373 - Diagnostic specimens
d. UN3245 - GMOs (Note that infectious GMOs should be assigned UN 2814 or UN 2900)
e. UN3549 - Medical or clinical wastes containing Category A infectious substances, affecting animals or humans
f. UN3291 - Medical or clinical wastes containing Category B infectious substances, or which are reasonably believed to have a low probability of containing infectious substances
g. UN1845 - Carbon dioxide (dry ice)

(32) See Appendices 1 and 2 of the Packaging and Transport of Biological Material Checklist for flowcharts to assist in identifying the appropriate Category and UN number for a given biological material.

Clause 6.2 Dangerous Goods – Infectious Substances

(33) These are substances that are known, or are reasonably expected, to contain pathogens. Pathogens are defined

as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals (IATA Dangerous Goods Regulations, section 3.6.2). Examples of Class 6.2 infectious substances include biological substances, cultures, patient specimens and medical or clinical waste. These can be from animal or human sources.

(34) Note: toxins from plant, animal or bacterial sources should be considered under Class 6.1 Toxic substances – refer to the Dangerous Goods Regulations for further detail or contact your trained and licensed Civil Aviation Safety Authority (CASA)/IATA member of staff.

Categories of Biological Material within Class 6.2

(35) There are three categories of biological material as defined by the IATA Dangerous Goods Regulations (i.e. international regulations). These are:

a. Category A – an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease to humans or animals. The list is not exhaustive. Infectious substances, including those containing new or emerging pathogens must NOT be transported as diagnostic specimens.

   Examples:

   i. pure Hepatitis B virus culture = Category A Infectious substance, with UN 2814.

b. Category B – infectious material that does not meet the criteria for inclusion in Category A and is known or suspected of containing less virulent pathogens. Such material is assigned to UN 3373, except for cultures of material which must be assigned to UN 2900 or UN 2814.

   Examples:

   i. blood sample containing HIV that is being sent for HIV testing = Category B Infectious substance, UN 3373, with shipping name “Biological substance, Category B”. Note that pure HIV culture = Category A.
   ii. patient blood sample suspected to contain Streptococcus A = Category B, UN 3373.
   iii. pure Streptococcus A culture = Category B, UN 2814.
   iv. pure Canine Parvovirus culture = Category B, UN 2900.

c. Exempt Category – minimal likelihood that pathogens are present. While biological materials that fit into the Exempt Category are not considered dangerous, these specimens still need to meet certain packaging and marking requirements detailed below in Section D. Note that specimens containing Risk Group 1 pathogens are not subject to the regulations.

   For examples see section 4.6 of the WHO Guidance on regulations for the transport of infectious substances 2021-2022.

   In Australia only, material equivalent to that defined in the IATA regulations as ‘Exempt Category’ is considered Category C material, as defined in the Australian Standard 4834: Packaging for surface transport of biological material that may cause disease in humans, animals and plants (AS 4834). Note that Category C:

   i. applies only to surface transport within Australia, i.e. by road and rail; and
   ii. if this material is transported by air, then the IATA regulations for Exempt Category shall be followed.

General Packaging and Labelling requirements for Class 6.2 Infectious Substances

(36) The local Technical Manager, or other staff who have completed a CASA/IATA accredited Biological Specimen Transport training course, must be consulted prior to the transport of any biological material. A list of qualified staff can be obtained by contacting the Senior Manager, Research Infrastructure and Biosafety.

(37) Infectious materials require triple packaging, where redundant layers of packaging and sufficient absorbent material can be used to control leakages and/or breaches of containment. Different types of triple containment are indicated in the appendices of the accompanying checklist.

(38) For transport by air, the packaging must be IATA approved (such packaging will be stamped with an approval). These packages have been drop tested and pressure tested and are available commercially.

(39) In addition to UN numbers assigned to DG, there are also UN Packing Instructions (P) applicable to each type of DG:

a. P620 - Category A infectious substances (UN2814 or UN2900)
b. P650 - Category B infectious substances (UN3373)
c. P621 - Medical or clinical waste containing a Category B infectious substance (assigned to UN3291)
d. P622 - Medical or clinical waste containing a Category A infectious substance affecting humans or affecting animals (assigned to UN3549)

(40) Coolants (refrigerants) are a substance that is used to maintain a cool temperature around the DG to preserve its integrity during transit. Ice blocks or gel packs may be used as a coolant – wet ice is not recommended due to potential for leaks and spills.

(41) Some coolants are themselves DG of other classes, therefore other packing requirements specific to these substances may need to be observed, such as for dry ice – contact the local Technical Manager for advice.

(42) Packages must be labelled with the appropriate UN numbering, the shipping name and include an itemised list of contents. Additional requirements for Category A infectious substances are detailed in Part C.

(43) Note: a material transfer agreement may be required for the transfer of certain biological materials between organisations. Seek assistance from Research Partnerships in Research Services.

Commercial Couriers

(44) When arranging a courier to transport any DG, including infectious or biological material, the courier company must be provided with accurate details of what is being transported. The courier company will then determine if they are able to transport the package and advise of any additional requirements prior to collecting the package.

(45) Most courier companies will package DG on behalf of the sender, where required (e.g. where a VU staff member with IATA certification is unavailable). Commercial courier companies commonly used to transport biological material include:

a. Dangerous Goods International
b. Direct Courier
c. World Courier
d. FedEx

Part C - Procedural Requirements for Transport of Category A and Category B Infectious Biologicals

General Requirements

(46) For all transport of Category A or B material by air, road or rail, Technical Manager’s must be contacted for advice and guidance. Technical Managers will be able to recommend and arrange suitable packaging and commercial

couriers, and assist in completing the accompanying Packaging and Transport of Biological Material Checklist.

(47) Consult the Packaging and Transport of Biological Material Checklist and relevant appendices for guidance and supporting information – the completed checklist must be reviewed by a Technical Manager and/or supervisor, prior to dispatch of a package.

GM Material

(48) Please refer to the Biosafety - Labelling, Storage and Transport of Genetically Modified Material Procedure.

Transport by Air

(49) To send Category A or B material by air, Technical Manager's should be contacted to arrange for a CASA/IATA approved packager to advise on how to package the material, label the package, and prepare the transport documentation.

(50) Commercial courier company (such as Dangerous Goods International (DGI), Direct Courier or FedEx) can also be used to pack and deliver. Commercial companies usually send their packages on cargo planes.

(51) Carrying biological materials on one's person onto an aircraft is strictly prohibited.

Transport by Road or Rail

(52) The Australian Code for the Transport of Dangerous Goods by Road & Rail, 7th Edition (Cth) (ADG7) requires Category A and B biological material to be packed and labelled as per the IATA air transport requirements.

(53) The use of appropriate and experienced couriers is recommended to transport all Category A and Category B biological material, even for transport between University campuses. The use of personal vehicles is strongly discouraged. Where a staff or student car is used to transport Category A or Category B biologicals for purposes of work, the car insurance company should be contacted to determine if the car insurance is valid for this purpose.

(54) The transport of DG, including Category A and Category B biological material and other DG such as dry ice, on public transport, including public or private taxis, is strictly prohibited.

Transport by Post

(55) Infectious substances are PROHIBITED by Australia Post in international mail and may only be sent domestically under very strict conditions. The University does not support the use of Australia Post for transport of biological material and in most circumstances requires the use of a commercial courier.

(56) Transport of any biological material through Australia Post will only be permitted in extenuating circumstances. If material is to be sent by post, the Senior Manager, Research Infrastructure and Biosafety must be contacted for approval.

Packaging and Labelling Requirements

(57) Category A infectious substances (UN2814 and UN2900) and medical or clinical waste (UN3291 and UN3549), require a Dangerous Goods Transport Document (DGTD) to be completed. A DGTD includes the following details:

a. Sender and Receiver information
b. Description of the DG, including UN number, proper shipping name, and primary hazard Class (i.e. Class 6.2)
c. Type and NET quantity of dangerous goods for each package
d. Handling Requirements

e. Emergency Response Information
f. Certification (Shipper's Declaration), i.e. IATA Shipper's Declaration for Dangerous Goods

(58) For additional details, see the WHO Guidance on regulations for the transport of infectious substances 2021-2022.

Part D - Transportation Requirements for Exempt/Category C Biologicals (Non-infectious)

General Requirements

(59) For all transport of Exempt/Category C material by air, road or rail, Technical Managers should be contacted for advice and guidance. Technical Managers will be able to recommend and arrange suitable packaging and commercial couriers, and assist in completing the Packaging and Transport of Biological Material Checklist.

GM Material

(60) Please refer to the Biosafety - Labelling, Storage and Transport of Genetically Modified Material Procedure.

Diagnostic Material

(61) Provided the diagnostic material does not meet the criteria for Category A or Category B, or Risk Group 2, infectious material, it may be transported as per Exempt/Category C. Some examples include dried blood spots; human or animal specimens that are not reasonably expected to contain infectious microorganisms or disease (e.g. skin, blood, body parts); soil, water and plant samples not reasonably expected to contain infectious material.

Transport by Air

(62) Although Exempt/Category C biological material is not considered a DG, the regulations indicate that an element of professional judgment is required to determine if a substance is Exempt. Depending on the type and quantity Exempt/Category C biological material, there may be additional labelling and packaging requirements – refer to the IATA Dangerous Goods Regulations.

(63) Although a Shipper's Declaration is not required, a consignment note/airway bill is required.

Transport by Road or Rail

(64) The requirements for surface transport of Exempt/Category C material are detailed in AS 4834. The appendix of this Australian Standard has a sample declaration form that can be used for Exempt/Category C material – this can be obtained from the Senior Manager, Research Infrastructure and Biosafety. Note that AS/NZS 2243.3: Safety in Laboratories, Part 3: Microbiological Safety and Containment also summarises the transport and packaging requirements detailed in AS 4834.

(65) Documentation and any coolants (e.g. ice bricks or gel packs) should go between the secondary and outer packaging. Documentation must be accessible to the transporter without opening the inner package.

Packaging Requirements

(66) A leak-proof primary receptacle must be used (e.g. capped tube). If there are multiple primary receptacles, they should be secured together (e.g. by a rubber band) to prevent damage or be individually wrapped or separated to prevent contact.

(67) A watertight and leak-proof secondary package must be used (e.g. plastic bag or screw-capped jar).

(68) Hard/solid outer packaging must be used (e.g. esky)

a. where a polystyrene esky is used, additional outer packaging of a snuggly fitting cardboard box must be used.

(69) Absorbent material in sufficient quantity to absorb the total volume of liquid specimens should be placed between the primary and secondary receptacles.

(70) Where possible, biodegradable packaging materials should be used.

(71) The package must be secured to the vehicle so that it will remain in position under adverse conditions, e.g. accidents and or during heavy braking conditions. The package should be segregated from other material and be good quality and strong enough to withstand normal transport conditions (consider vibration, heavy braking).

Labelling Requirements

(72) The outer packaging must be marked/labelled as follows:

a. Description of material, i.e. either Exempt Human Specimens or Exempt Animal Specimens.
b. Name and address of sender (do not use PO Box numbers).
c. Name and address of receiver (do not use PO Box numbers).
d. Orientation labels if the package contains liquid in volumes of 50mL or more.

Part E - Transport between VU Campuses and Sites (Low Risk Biological Material only)

General Requirements

(73) Low-risk biological material, i.e. that which does not meet the definition of infectious material Category A or Category B, may be transported in-person by any means within and between VU Campuses and sites, provided it is accompanied by an authorised person who is familiar with the contents of the package and is confident in procedures to clean up spills. Prior to transport, the local Technical Managers should be consulted, as they will be able to recommend and arrange suitable packaging, and assist in completing the required risk assessments and the Packaging and Transport of Biological Material Checklist.

(74) Transport of low-risk biohazards (experimental or waste material) by walking and carrying materials is permitted between:

a. two laboratories/storage areas in the same building separated by non-laboratory corridors;
b. two laboratories/storage areas in different buildings – package and label materials to ensure that under no circumstances will the material:
    i. become contaminated by the environment, or
    ii. escape containment to contaminate people or the environment.

GM Material

(75) Please refer to the Biosafety - Labelling, Storage and Transport of Genetically Modified Material Procedure.

Packaging and Labelling Requirements

(76) Transport of biological material between campuses and sites requires appropriate basic-triple packaging, as outlined in Appendix 5 of the accompanying checklist. The package must be labelled clearly and appropriately, as per Part D above, including all relevant DG markings.

(77) If using a commonly available solid esky, it must be clearly labelled as containing biological material and ‘no food or drink’. All applicable risk assessments must be completed prior to transport.

(78) The Senior Manager, Research Infrastructure and Biosafety must be notified of any adverse events that occur during transport.

Section 7 - Supporting Documents and Information

(79) Please see Packaging and Transport of Biological Material Checklist, with the following appendices:

a. Appendix 1: A simplified overview of the process of defining and classifying infectious substances (Source: WHO Guidance on regulations for the transport of infectious substances 2021-2022).
b. Appendix 2: Summary of biological material packaging instruction classification (Source: AS/NSZ 2243.3).
c. Appendix 3: Triple packing and labelling requirements of Category A infectious substances (Source: AS/NZS 2243.3 & WHO Guidance on regulations for the transport of infectious substances 2021-2022).
d. Appendix 4: Triple packing and labelling requirements of Category B infectious substances, or Category C biological material when transported by air (Source: AS/NZS 2243.3 & WHO Guidance on regulations for the transport of infectious substances 2021-2022).
e. Appendix 5: Examples of basic triple containment packaging materials, suitable for transporting Category B and C materials by road, or for internal pedestrian transport of biological material (Source: WHO Guidance on regulations for the transport of infectious substances 2021-2022).
f. Appendix 6: Examples of packing for transport between or within VU campuses and sites.

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Accountable Officer	Andrew Hill Deputy Vice-Chancellor, Research & Impact Andrew.Hill@vu.edu.au
Responsible Officer	Beverley Baugh Executive Director, Research Services +61 3 9919 5827
Enquiries Contact	Penelope Steer-Cope Senior Manager, Research Infrastructure and Biosafety +61 3 9919 4199