Requirements for the Identification of Genetically Modified Organisms in Storage Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines storage requirements of genetically modified (GM) organisms (GMO). It supplements the University of Queensland (UQ) Biosafety Policy and requirements specified by the Office of the Gene Technology Regulator's (OGTR) Guidelines for the Transport, Storage and Disposal of GMOs.

(2) The Procedure does not apply to the housing of whole, viable GM animals or plants.

(3) This Procedure applies to all UQ workers and Classes of Persons who are working with GMO or genetically modified microorganisms on UQ sites.

(4) UQ workers must be familiar with the relevant legislation, regulations and guidelines that apply to dealing with GMOs. It is a requirement of the OGTR that accurate storage records and labelling are in place to easily identify GMOs both inside and outside certified facilities.

(5) This Procedure provides detailed instructions and examples of labelling and storage of GM microorganisms, GM animal/plant/invertebrate/aquatic materials, and samples containing GMOs (e.g. tissues, seeds, viral vectors) in fridges/freezers, cold rooms, liquid nitrogen dewars, constant temperature rooms, and equipment, which must be adhered to for workers safety.

(6) Material covered by a licence (i.e. DNIR/DIR) must be stored, labelled and records kept as per the conditions of the licence.

Section 2 - Key Controls

(7) UQ workers must comply with the following measures when working storing GMO material at UQ:

a. follow appropriate risk management procedures and be properly trained (UQ online Biosafety training and specific training determined by the Supervisor) and assessed competent by their supervisor to work with GMOs.
b. have protocols in place for ensuring the release of viable GMOs from containment will not occur.
c. undergraduate students, volunteers and visitors must be supervised by a UQ worker authorised by UQ's Institutional Biosafety Committee (IBC) while undertaking a dealing with a GMO or GM material described in this Procedure at all times.

(8) Chief Investigators are responsible for the oversight of storing GMO material and UQ workers under their supervision.

(9) The IBC and HSW Division - Biosafety will monitor and inspect the storage of GMOs and advise UQ workers of any required changes.

Section 3 - Process and Key Requirements

Categories of GMOs

(10) GMOs are defined by the Gene Technology Act 2000 and Gene Technology Regulations 2001 as belonging to one of four main categories:

a. Exempt Dealings (ED)
b. Notifiable Low Risk Dealings (NLRD)
c. Dealing Not involving Intentional Release (DNIR) and
d. Dealings involving Intentional Release (DIR).

(11) Refer to the Low Risk Genetically Modified Dealings Procedure and the Gene Technology Regulations 2001 for further details on classification of GMOs.

Higher-level controls

(12) GM material must be classified and recorded as an ED, NLRD, DNIR or DIR before storage requirements are applied.

(13) GMOs must only be stored in locations authorised for the relevant dealing category, including certified facilities where required by the approval, certification instrument or licence.

(14) Only UQ workers listed in the Classes of Person in the Record of Assessment (NLRD) or trained in licence conditions may label and store GMOs.

(15) Storage arrangements must maintain containment and security to prevent unauthorised access, loss, damage or unintentional release.

(16) GMOs must be stored in sealed, durable and suitable containers and, where required, segregated from non-GM material and other dealing categories.

(17) Containers, secondary containment and storage units must be clearly and durably labelled so the GM material, approval basis and responsible person can be identified.

(18) Complete, current and accessible storage records must be maintained to support identification, traceability, inventory control and inspection.

(19) Contingency arrangements must be documented for equipment failure, emergencies, natural disasters and temporary relocation of GMOs.

(20) Storage of GMOs must comply with applicable legislation, OGTR guidance, certification instruments, UQ approvals and any DNIR or DIR licence conditions. Licence conditions prevail where inconsistent requirements apply.

(21) Storage arrangements, labelling and records must be monitored and reviewed to verify ongoing compliance.

(22) Actual or suspected non-compliance must be reported, investigated and managed through corrective action, including escalation where required.

Physical Storage Requirements

(23) GMOs may be stored either inside or outside of authorised physical containment facilities in accordance with;

a. the OGTR Guidelines for the Transport, Storage and Disposal of GMOs (outside);
b. the relevant OGTR - Guidelines for Certification (inside); and
c. the Institutional Biosafety Sub-Committee (IBSC) approval memo or OGTR licence (DNIR/DIR).

(24) GMOs from NLRD or DNIR that require dealings to be undertaken in a PC3 Facility must be stored within a certified PC3 facility unless an external storage location is approved in the licence conditions or the certification instrument.

(25) An approved storage location outside of an authorised physical containment facility must be secured to prevent the unauthorised access of GMOs. A secured location can be defined as either a locked storage unit, or a storage unit located in a restricted access area.

(26) GMOs must not be stored in a site that is prone to flooding or storm surges.

(27) If the facility where the GMOs are stored is susceptible to damage from natural disasters, a contingency plan must be developed to prevent the unintentional release of GMOs in the event of damage to the infrastructure.

(28) Where possible, GMO samples should be stored separately from non-GM biological materials.

(29) Where GMO samples and non-GMO samples cannot be stored separately, labelling must accurately identify all primary containers. Where this is not possible, all samples must be treated as GMOs.

(30) Different GMO categories should be physically segregated where possible.

(31) Where DNIR and DIR licence conditions conflict with clauses of this Procedure, the licence conditions will prevail.

Container Requirements

(32) PC2 GMOs must be double contained when being stored.

(33) Primary containers (e.g. tubes, vials, bags) must be sealed, leak-proof, unbreakable and of chemical-resistant material suitable for storage conditions (e.g. −80 °C, liquid nitrogen).

(34) Secondary containers (e.g. cryoboxes, sealed racks) must also be secure and unbreakable.

Labelling Requirements

(35) Labelling must allow for the easy identification of GMO and non-GMO samples.

(36) For GMOs from DNIR or DIR, the label should include words “Authorised Person Only” or similar. This is to inform people that they are not to handle the GMOs unless trained in the licence conditions.

(37) The samples should be labelled clearly showing the material is, or contains a GMO, e.g. where possible the primary container label should state “GMO”.

(38) If the primary container cannot be labelled “GMO”, the secondary container must state “GMO” and all material inside the secondary container treated as GM.

(39) The format of the label is at the discretion of the Chief Investigator; however, all GMO samples must be clearly labelled to indicate:

a. That the material is genetically modified.
b. UQ Institutional Biosafety Committee (IBC) identifier (IBC/NNNN/Org Unit/Year)
c. Type of GMO (e.g. GM bacteria, GM plant tissue).

d. Date of storage and responsible person or project.

(40) Labels must be durable and legible, suitable for the storage conditions (e.g. cold, liquid nitrogen).

(41) Where GM material from more than one category of dealing is being stored, the users must ensure that it can be easily distinguished.

(42) The storage unit (e.g. fridge/freezer/liquid nitrogen dewar) must be clearly labelled as containing GMOs and show the name and contact details of the person responsible for the dealings. The following minimum details must be clearly displayed on the storage unit:

a. Freezer/Fridge Name.
b. GMO label.
c. Name of Chief Investigator or Group.
d. IBC identifier number.
e. Contact person & details (i.e. email/phone number).
f. A biohazard label if any GM micro-organisms satisfy the criteria for classification as a Risk Group 2 or 3 organism in the AS/NZS 2243.3:2022.
g. Where the size of the storage unit does not permit complete labelling (i.e. liquid nitrogen dewar) a GMO label and biohazard label must be attached to the outside of the unit.

Contingencies

(43) Contingency plans for the relocation of GMOs in the event of a fridge, freezer or cold room failure must be prepared.

(44) Authorisation from the local facility or safety manager, must be obtained prior to writing the procedures. For GMOs under DIR or DNIR licences, consult with HSW Biosafety (biosafety@uq.edu.au) to determine the necessary requirements for incorporating the plan into the licence.

(45) This plan should include:

a. Notification of appropriate person (i.e. local safety or facility managers),
b. Selection of appropriate location(s) should be included in the dealing in UQSafe as a contingency location,
c. Appropriate packaging for transport,
d. Route of transport,
e. Persons or classes of persons authorised to transport goods,
f. Access to building, level, room and storage facility,
g. Spill procedures and record keeping requirements.

(46) The plan must ensure that all samples are transported and stored in accordance with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs.

(47) Storage records must be updated to reflect the current location of GMOs.

Record Keeping

(48) Procedures must be in place to ensure that all GMOs stored are recorded, the records are current, and can be made available to the OGTR upon request. The method of record keeping used must:

a. be easily located by others (in the event of absence of team members); and

b. be in a form that is understood by others.

(49) Each GMO sample stored must have a complete, up to date inventory entry that includes:

a. Unique sample identifier (ID) (if applicable),
b. GMO description (organism, vector, modification details),
c. IBC authorisation or OGTR licence number,
d. Researcher responsible (name/initials),
e. Date added to storage,
f. Exact storage location,
g. Storage unit (freezer, fridge, LN_2 dewar)
h. Shelf, box/rack

(50) Codes may be utilised, provided they are thoroughly explained within the record.

Section 4 - Roles, Responsibilities and Accountabilities

Institutional Biosafety Committee (IBC)

(51) The IBC oversees the management and regulation Genetically Modified Dealings at the University as described in this Procedure.

Institutional Biosafety Sub-Committee (IBSC)

(52) The IBSC will undertake duties in accordance with its Terms of Reference and the Biosafety Policy. The IBSC's responsibilities include:

a. Assisting Chief Investigators determine classification of GMO dealings.
b. Describing any labelling requirement that are in addition of those described in the OGTR Guidelines for the Transport, Storage and Disposal of GMOs or licence conditions.

Health, Safety and Wellness Division (HSW Division)

(53) The Health, Safety and Wellness Division is responsible for:

a. Providing UQ workers with education, advice and support regarding OGTR requirements and gene technology regulatory compliance obligations at UQ.
b. Assessing whether Organisational Units and UQ workers can demonstrate compliance with this Procedure and that any compliance issues identified are rectified in a timely manner.

(54) Biosafety Advisors within the HSW Division are responsible for:

a. Providing UQ workers with education, information, and support to enable them to understand their biosafety compliance obligations at UQ.
b. Inspecting and monitoring the requirements outlined in the OGTR Guidelines for the Transport, Storage and Disposal of GMOs and this Procedure.
c. Reporting breaches and contraventions of the OGTR legislation, guidelines and instruments as they relate to GMO dealings to the IBC and OGTR.

Heads of Organisational Units

(55) Heads of Organisational Units where there are GMO dealings must ensure that there are sufficient containment facilities and that are compliant with OGTR requirements, including:

a. Sufficient size, type and operational conditions for the GMOs being stored;
b. Chief Investigators follow the conditions listed on approvals, licences, guidelines and this Procedure; and
c. Report any non-compliance or perceived non-compliance to the IBC and Biosafety as soon as they become aware of it.

Chief Investigators

(56) Chief Investigators are responsible for the ongoing monitoring, management and oversight of GMO dealings, and must ensure:

a. The GMO dealing is approved by the IBSC;
b. UQ Workers are trained in the condition of the approval and adhere to this Procedure;
c. Ensure that the dealings with GMOs comply with the conditions of the IBSC's approval and that storage and labelling of GMOs is in accordance with this Procedure; and
d. Keep records of GMOs and training of UQ Workers.

UQ Workers

(57) All UQ workers undertaking GMO dealings at UQ must comply with this Procedure, understand, and comply with any additional requirements specified by OGTR or the IBC, and ensure they are:

a. Following the requirements for the facility where the dealings are being conducted;
b. Reading the GMO applications, risk assessments and understand all conditions of approvals that are in place;
c. Ensuring they are the approved class of person in the approval and that the dealing is in an approved class of facility as listed in the UQSafe application;
d. Signing or acknowledging a record that they understand their responsibilities under this Procedure and other relevant documents.

(58) Contractors, subcontractors and consultants must not label or store GMOs within UQ facilities.

(59) UQ workers handling, using, or storing GMOs at locations external to UQ, must comply with the local procedures and requirements of the external organisation.

Section 5 - Monitoring, Review and Assurance

Monitoring of storage of GMOs

(60) The storage of GMOs will be reviewed and monitored regularly by the relevant Chief Investigator or delegate to ensure:

a. compliance with regulatory requirements; and
b. that accurate records of transport are maintained.

(61) UQ’s Biosafety Advisors will:

a. Review storage labelling on containers and storage devices;

b. Review storage records during annual certified facility inspections; and
c. Monitor biosafety regulatory requirements and changes to industry codes, standards and guidelines; and revise this Procedure as required to ensure its relevancy and currency.

(62) Annual inspections of UQ's certified facilities and GMOs will be undertaken by persons authorised by the UQ IBC, to ensure that:

a. dealings, storage containers/devices and facilities meet requirements; and
b. all UQ workers storing GMOs are compliant with regulations and storage requirements.

Non-compliance

(63) If a non-compliance is detected, the Chief Investigator or their delegate must inform HSW Biosafety (biosafety@uq.edu.au) as soon as practicable and complete a BioRisk Incident Form in UQSafe.

(64) UQ workers who do not comply with the guidelines and regulations associated with GMOs may be subject to corrective actions from the UQ IBC and/or the OGTR.

(65) The UQ IBC, based on the evidence of multiple non-compliances, may refuse approval of GMO dealing applications such as ED, NLRD or GMO licences, or refer the UQ Worker(s) to another organisational unit for review.

Section 6 - Appendix

Definitions, Terms, Acronyms

Term	Definition
Chief Investigator	For the purposes of this Procedure includes Supervisors, Managers, Project Leaders and academic principal advisors that are conducting research at UQ and hold an academic or research appointment.
Classes of Persons	The role of the person authorised to undertake GMO dealings as mentioned in the Record of Assessment issued by the IBSC under Section 13B Gene Technology Regulations 2001. Roles include: - Adjunct staff - Animal technician - Associate researcher - Biosafety contact - Honours student - Lab facility manager - Master's student - Operations manager - PhD student - Postdoctoral researcher - Project leader - Radiation safety officer - Research academic - Research fellow - Teaching academic - Technical assistant - Undergraduate student - Visitor
DIR	Dealings involving intentional release. GMO that are intentionally released into the environment and outside of certified facilities.
DNIR	Dealings not involving intentional release. Dealings with GMOs in containment which do not meet the criteria for classification as exempt dealings or notifiable low risk dealings (NLRDs).

Term	Definition
GMO	Genetically Modified Organism. An organism modified as described in the Gene Technology Regulations 2001.
Housing	Kept under husbandry or cultivation conditions necessary to support life, health, growth, or reproduction.
IBC	UQ's Institutional Biosafety Committee. Oversees biosafety at the University.
IBSC	UQ's Institutional Biosafety Sub-Committee. Assesses and approves GMO dealing applications in accordance with the Gene Technology Act 2000 and Gene Technology Regulations 2001.
NLRD	Notifiable Low Risk Dealings. These GMO dealings are undertaken in containment (not released into the environment); have been assessed by the Institutional Biosafety Sub-Committee (IBSC) and pose a low risk to the health and safety of people and the environment (provided certain risk management conditions are met).
OGTR	Office of the Gene Technology Regulator (Australian Government).
Primary Container	The innermost receptacle that directly contains the GMO or GM material. Examples are sealed tube, vial, flask, or box.
Secondary Container	The outer layer of containment that encloses the primary container(s). Examples include a hard walled transport box, sealed plastic container, hard walled box.
Stored/storage	In this Procedure it is defined as kept, contained, or preserved in a manner that is primarily for holding and does not include care, maintenance, or husbandry necessary to sustain life or growth (i.e. whole, live plants or animals would not be stored but housed).
Storage Unit	A container that is used to hold GMOs contained within primary and secondary container. These may be a cupboard, fridge, freezer, etc.
UQ Workers	For the purposes of this Procedure includes: 1. staff – continuing, fixed-term, research (contingent funding) and casual staff members; 2. visiting academics and researchers; 3. affiliates – academic titles holders, visiting academics, emeritus professors, adjunct and honorary title holders, industry fellows and conjoint appointments; 4. higher degree by research students; and 5. volunteers and students undertaking work experience.

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