Australian Government

Department of Health

Office of the Gene Technology Regulator

Annual Inspection Checklist for a Physical Containment Level 2 Large Scale Facility

Checklist for annual inspection against the usual Conditions of Certification of the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility* version 3.1 – issued 28 February 2018 (the Guidelines)

Organisation Name	
Facility Name	
OGTR Certification Number	

Name(s) and signature(s) of person(s) inspecting the facility (please print name clearly)

Date of Inspection	

About this checklist

- The use of this checklist is **not** mandatory.
- Condition C15 requires annual inspection of a certified facility and recording of the extent of compliance with certification conditions. This checklist is provided to assist with these requirements, however certification holders may choose to record inspection findings in another format.
- Please **do not** send this checklist (or other record of inspection) to the OGTR unless specifically requested.
- This checklist reflects the usual conditions of certification as detailed in the Guidelines. Where the instrument of certification issued by the Regulator contains any additional conditions, exemptions or amendments to the Guideline conditions, inspection must be made against the conditions of the instrument of certification. This checklist may still be used in such cases, however the specific conditions that apply, and the extent of compliance against them, should be noted where applicable.
- If inspection identifies that the facility does not meet a condition of certification, reasons for the non-compliance and details of how it is to be rectified should be recorded. **Note that non-compliances must also be promptly reported to the Regulator under C67 of the Guideline.**
- The order of this checklist is intended to generally reflect movement through the facility as you are conducting an inspection. The colours are intended to differentiate between conditions (no highlighting) and work practices (highlighted orange), and to show where records or results may need to be kept as part of compliance with the conditions of certification (highlighted blue).
- If you do not understand the intention or details of a condition, please consult the Guidelines. If you are still unsure, please contact the OGTR on 1800 181 030 or ogtr.cdes@health.gov.au.

Current and anticipated use of the facility

Describe the dealings being undertaken (and anticipated to be undertaken in the near future), work flow, expected volumes and timelines. Any GMOs and non-GMOs in the facility. List any other relevant laboratory regulatory requirements/certifications.

Conditions of Certification for a Physical Containment Level 2 Large Scale Facility

Please indicate compliance and/or provide the specified information for each condition.

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
C1	**Work not permitted** The following work must not be conducted in this facility: a. work with any GMO that under the Act, or under the conditions of a licence, requires containment in any physical containment level higher than PC2; b. the housing/keeping/rearing of any animals, invertebrates or aquatic organisms; or c. the growing of any plants.	Only permitted work conducted		
C3	**Facility signs** Each entry point to the facility must be labelled with a PC2 Large Scale facility sign and a biohazard symbol on or next to each access door such that persons entering the facility are able to clearly see they are entering a certified PC2 facility	PC2-LS Sign (supplied by OGTR)		Location? Current?
		Biohazard sign		Location?
C2, C35-37, C51 and C68.	**Personal protective clothing** PPE must include: • protective clothing for arms and front of body (rear fastening gown preferable) • disposable gloves (only for dealings with GM viral vectors or RG 2 microorganisms) • respiratory protection (if deemed necessary in assessment mentioned in R21) Must be able to remove all PPE and decontaminate hands before leaving facility.	Laboratory coat or gown (C36)		Type
		Gloves (C36)		Used?
		Respiratory protection (C36) Risk assessment (R21)		Outcome of assessment? Used?
		Closed footwear (C36)		Used?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	PPE contaminated with GMOs must be removed ASAP and decontaminated before reuse. Facility must include designated storage or hanging facilities for protective clothing – so contaminated clothing will not cross-contaminate other surfaces and items. Documentation of risk assessment of operator exposure to aerosols (required by R21) must be kept.	Booties (C36)		
		Entry/exit procedures (C35, C37)		Details
		PPE decontamination procedures (C51)		
		Storage (C2, R8)		Location
		Records kept (C68)		Outcome
C2	**Facility Structure** Fully enclosable (relates to R1) • bounded by walls, doors, windows, floors and ceilings • doors and windows lockable or otherwise secured Any openings in walls, ceiling or roof (e.g. air vents) appropriately screened with insect-proof mesh (R2)	Fully enclosed		
		Insect proof mesh		
C5, C6, C7,C15, C33, C34	**Facility Management** Facility management requirements must continue to be met (relates to R13) Access restricted to authorised persons (e.g. by keys, access cards, combination locks, rules) when dealings being undertaken. Doors closed when dealings in progress and locked when facility unattended. Facility (including LWTS if present) must be inspected every 12 months by a competent person. Inspection	Requirements met (C5, R13)		
		Access restricted (C6)		How? List of authorised users?
		Doors closed/ locked when unattended (C33)		
		Windows closed (C34)		

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	records must be kept.	Facility inspected (C15)		At least every 12 months? By competent person? Previous inspection record(s) sighted?
		Records kept (C68)		
C2	**Facility cleanability** Surfaces are able to be decontaminated (relates to R3), i.e. • smooth • impermeable to water • resistant to damage by cleaning agents (Applies to surfaces where contamination is likely to occur e.g. walls, floors, benches, furniture, ceilings) Open spaces between and under benches etc. must be accessible for decontamination (relates to R4)	Walls (C2, R3)		
		Floors (C2, R3)		
		Benches (C2, R3)		
		Furniture, including seating (C2, R3)		
		Ceilings/other (C2, R3)		
		Accessible (C2, R4)		
C14, C68	**Pests** Effective pest prevention strategies must be documented and implemented. Records must be kept.	Pest prevention (C14)		Details. Any pests observed?
		Records kept (C68)		
C2, C68	**Hand and Eyewash** Hand washing facilities present (relates to R7): • dedicated washbasin with potable water and hands-free operation, or • other suitable means, such as hands-free	Hand wash (C2, R7)		How is it operated? Plumbed? Chemical disinfectant?
		Eyewash (C2, R7)		Plumbed or portable? Location? Maintained?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	dispensers of decontaminant solution Eye wash present – plumbed or single-use packs (R7) Emergency drench showers present. (R7)	Drench shower (C2, R7)		Location?
		Records kept (C68)		
C29, C30, C68	**Backflow Prevention** All potable water supplies protected in accordance with AS/NZS 3500.1 Applies to any device or system that could contaminate a potable water supply. Device must be tested annually and, if does not pass test, any failures must be rectified and the device re-tested until compliance is achieved. Other reticulated services (gas/air/steam) linked to primary containment device capable of forming cross-connection must undergo risk assessment to determine whether backflow prevention required. Risk assessment must be documented and kept for as long as relevant (relates to R10 and R12) If determined backflow is required, backflow prevention must be implemented. If a backflow prevention device is found to be defective and defect is not corrected, connected equipment must be clearly marked to show that it must not be used until defect corrected. Results of testing must be kept.	Present		Device type
		Tested annually (C29)		Date tested?
		Test report		Pass?
		Risk assessment (R10)		Determination?
		Equipment marked if device defective (C30)		
		Record of risk assessment kept (R12)		If yes, how achieved?
		Results kept (C68)		
C16, C40, C43, C68	**Closed systems for GMOs** • Facility must contain closed system (relates to R14) • Closed system designed to prevent the release of GMOs – including via ventilation (R15)	Reactor type		Volume, manufacturer, etc?
		Reactor decontamination method		How? In situ?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
C21, C22, C43 C23, C24, C52	• Cultures must be contained in closed systems • Closed lines used for transfer (relates to definition of closed system) • Any critical defect identified in the closed system while the facility is in operation must be reported • Records must be kept. Collection of GMOs from/addition of materials to a closed system or transfer of materials between closed systems, must be conducted in a manner that prevents release of GMOs including aerosols. **Reusable** • Decontamination must occur *in situ* • Tested for integrity before each use and after relocation/maintenance • Defective equipment must be labelled and must not be used **Note:** an N/A response to this question could mean, for example, that no reusable system in facility. **Single-use** • Able to be tested for leaks prior to loading with GMOs – i.e. filled with media to enable leak detection. Tubing/lines, fittings and filters visually inspected. • Mechanisms to secure large bio-reactor bags (if present) • Capable of being decontaminated without release of GMOs (including aerosols) • Decontamination by approved method. **Note:** an N/A response to this question could mean, for example, that no single use system present in facility.	Reactor inspection/ maintenance (C21, C23, R16)		Date?
		Closed transfer lines (C16, R14)		For transfer of viable GMOs
		Decontamination method (Reusable) (C43)		How?
		Aerosols contained (C40)		How? HEPA? 0.2 um?
		Records kept (C68)		
		Leak detection (C16, R16)		How?
		Large bio-reactor bags (C16, R17)		Secure and easy removal for decon?
		Decontamination method (Single-use) (C52)		How? Autoclave? Chemical?
C16	**Containment Equipment (other)** Other equipment used to process GMOs (e.g. centrifuges,	Present		Details

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	filtration systems) must be designed to contain GMOs (including aerosols) **Note:** an N/A response to this question could mean, for example, that no other containment equipment is used.	Designed to contain GMOs		How? HEPA? 0.2 um?
C16	**Secondary Containment Equipment** e.g. Bunding Must be sufficient to contain the volume of fluid held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers, plus the volume of any disinfectant that might be used and any expected general fluid movement (relates to R24).	Bunding		Max volume
		Other		Details e.g. type, volume
C17, C26 C42, C54, C56, C61, C67, C68	**Liquid Waste Treatment System (LWTS)** • Fully enclosed pipes, tanks and other components (relates to R25 a) • Robust construction materials capable of being decontaminated for inspection/maintenance (R25 b) • Likelihood of damage must be minimised (e.g. by location) (R25 c) • Pipes capable of being inspected and labelled appropriately. If not inspectable, must be double skinned or have leak detection mechanisms in place (R25 d) • Vents to pipes, tanks etc. filtered to prevent release of GMOs (R25 e) • Strategies in place to ensure seal integrity of LWTS and components (drain pipes, holding tanks and vent lines) (R25 f) • Screening provided to limit solids leaving the work area via the LWTS (R25 g) • Secondary containment provided (e.g. bunding) in room/s or area/s housing LWTS (R25 h): ○ sufficient to contain the volume of liquid waste held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers, plus the volume of any disinfectant that might be used and any	Fully enclosed (C17, R25 a)		Location? Authorised persons only?
		Materials (C17, R25 b)		Able to be inspected? Materials used?
		Likelihood of damage minimised (C17, R25 c)		How? By location?
		Pipes (C17, R25 d)		Labelled appropriately? Capable of inspection/double skinned/leak detection?
		Vents filtered (C17, R25 e)		0.2 µm? HEPA?
		Seal integrity (C17, R25 f)		Strategies?
		Screening for solids (C17, R25 g)		
		Bunding (C17, R25 h)		Max volume? Smooth, impermeable, able to decon?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	expected general fluid movement; and ○ smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning/ decontamination agents to be used. • Documented contingency plan and means in place to respond to leakage of waste containing GMOs/failure of LWTS. Must include details of specialised equipment to be used for responses (R25 i) • Decontamination of the LWTS: ○ carried out in a way that prevents release of GMOs ○ use a combination of time and temperature validated as effective against GMO being used • Clearly labelled to show has been monitored for effectiveness etc. as per TSD's • Results of monitoring and calibration must be kept. • Records of maintenance must be kept. **Note:** an N/A response to this question could mean, for example, that no LWTS external to facility used to treat GMOs.	Other secondary containment (C17, R25 h)		Details e.g. type, volume
		Contingency plan (C17, R25 i)		Specialised equipment?
		Decontamination – prevents release of GMOs (C42)		
		Decontamination - Validated (C54)		How?
		Monitored for effectiveness (C26)		As per TSDs?
		Labelled to show monitoring (C56)		As per TSDs?
		Results and records kept (C68)		
C16, C27, C28, C38, C39, C58, C68	**Biological Safety Cabinets** Must be present if dealings (other than those within a LWTS or closed systems) will produce aerosols containing GMOs (Relates to R22). Dealings (other than those within a LWTS or closed system) that produce aerosols containing Risk Group 2 microorganisms must be performed in a BSC or other aerosol containment device approved by the Regulator. BSCs must be inspected and tested at least once every 12 months and after relocation/maintenance/HEPA replacement. Where testing has shown a BSC is defective, it must be clearly marked to show that it is not to be used for	Present, number (C16, R22)		Type; location?
		Tested (C27)		At least every 12 months? Test date (sticker); test results (sticker); NATA accredited?
		Clearly marked if defective (C28)		
		Used for dealings that produce aerosols (C38)		

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	dealings with GMOs that produce aerosols until defect corrected. Installation and decontamination of biological safety cabinets must be in accordance with AS/NZS 2252.4. Records must be kept. **Note:** an N/A response to this question could mean, for example, that a BSC is not being used in the facility.	Installation and decontamination in accordance with AS/NZS (C39, C40)		
		Records kept (C68)		
C38	**Other aerosol containment equipment 1**	Aerosol containment details		Type, details
C38	**Other aerosol containment equipment 2**	Aerosol containment details		Type, details
C5, C59-C61, C67	**Spills** Documented procedures and means (e.g. spill kit) for cleaning up GMO spills (including large spills) must be in place.	Spill kit (C5, R13)		Location
		Documented procedures (C5, R13)		Detail
C4	**Disinfectants Used** Disinfectants effective against GMOs used in facility must be available. Containers clearly labelled with contents and expiry date (if relevant).	Available		Type
		Labelled		Expiry date?
C41-C53	**Decontamination** All decontamination procedures carried out in a manner that prevents release of GMOs (including aerosols) and by trained personnel Methods may include: a. Autoclaving or other heat treatment;	Carried out so as to prevent release of GMOs (C42)		Details
		Carried out by trained personnel (C44)		

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	b. Chemical treatment; or c. Other method approved in writing by the Regulator. GMOs and organisms infected with GMOs rendered non-viable prior to disposal. All waste decontaminated before disposal/discharge: • Liquid (floor and sink drains) (can be via procedures that ensure viable liquid effluent is not discharged down the sink) • Solid waste Work benches, surfaces and equipment where GMOs used must be decontaminated when dealings complete and before any maintenance. Equipment decontaminated prior to removal from facility Chemical treatment must be effective against particular type of GMOs being decontaminated. **Note:** an N/A response to this question could mean, for example, that the specific type of waste treatment referred to is not being used in the facility.	GMOs and organisms infected with GMOs (C49)		Details
		Floor drainage (C46)		Details
		Sink Drainage (C47)		Details
		Solid waste (C47)		Details
		Surfaces and equipment (C45, C46, C48, C50)		Details
		Chemical treatment effective against type of GMO (C53)		Details
		Results and Records kept (68)		
C25, C54-C57, C68	**Autoclave or other heat-based equipment** Temperature and time controls calibrated by qualified person at least every 12 months. Efficacy monitored either: • monthly (if used frequently) or • before or with each cycle (if used intermittently)	Calibration/testing (C25)		Date tested? NATA accredited (not mandated)? Sensors, pressure?
		Efficacy monitored (C25)		How? How often?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	by the use of: • Thermocouples; • Chemical indicators; • Biological indicators; or • Enzyme indicators. Records of calibration and monitoring must be kept for 5 years. Must be labelled to show that it has been calibrated/ monitored for effectiveness; and if it is defective. A combination of temperature and time that has been validated as effective for the decontamination of the particular type of GMOs must be used. Must be able to differentiate between processed and unprocessed loads (e.g. by autoclave tape).	Labelled as tested (C56) and if defective (C57)		
		Records of calibration and monitoring (C68e)		Kept for last 5 years?
		Validated as effective for the GMO (C54)		How?
		Differentiation of loads (C55)		How?
C62	**Labelling of GMOs** Containers of GMOs must be clearly labelled to indicate that they contain GMOs. Any unlabelled potentially viable material must be treated as a GMO and handled in accordance with the requirements and conditions specified.	Containers labelled appropriately (C62)		How? What's on a label?
C63-C65	**Removal and storage** >25L only with written permission from Regulator. ≤25L and not exempt: • In accordance with TSDs; and • to at least PC2 level facility; OR • another location for storage; OR • for decontamination (or disposal if the method of disposal is also the method of decon); OR • to another location agreed to in writing by Regulator.	Approval for >25L (C63)		Details
		≤25L (C64)		Volumes?
		Double contained (≤25L; C64)		Type? Unbreakable?
		Surfaces decontaminated (≤25L C64)		How? Before and after transport?

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	Decontaminate exterior surfaces as required by transport guidelines, before and after transport. Labelling to show name, address and contact details of sender. **Note:** an N/A response to this question could mean, for example, that viable GMOs are not removed from the facility.	Appropriate destination (≤25L; C64)		Certified facility? Storage Unit? For decon/disposal?
		In accordance with TSDs (<25L; C65)		Details
C66	**Removal of non-GMOs from the facility** Non-GMOs must not be removed from facility while dealings with GMOs are being conducted unless: a. procedures to ensure that work with the non-GMOs are not contaminated with GMOs have been documented; b. the above procedures have been implemented; and c. all primary containers and transport containers are decontaminated prior to removal from the facility. **Note:** an N/A response to this question could mean, for example, that non-GMOs are not removed from the facility while dealings with GMOs are being conducted.	Documented procedures to prevent cross-contamination		Specify procedures. Documented?
		External decontamination prior to removal from facility		Disinfectant used?
C31, C32, C68	**Training** All persons intending to undertake dealings must be trained in Conditions of Certification (Part B). Training must include (where applicable or relevant to each persons' role): • Transport, storage and disposal of GMOs dealt with in facility; • Identification of risks associated with GMOs dealt with in facility; • Spill and decontamination procedures;	All persons trained (C31)		
		Transport/storage/ disposal (C32 a.)		Details
		Identification of risks (C32 b.)		Details
		Spill and decon (C32 c.)		Details
		Emergency procedures (C32 d.)		Details

Condition number	Condition details		Complies? (Yes/No/NA)	Comments
	• Emergency procedures; • Personal protective equipment; • Reporting requirements; • Certification requirements; • Conditions of any licences and • Structure and operation of facility (including design limits). Records (including signed statements) must be kept.	PPE (C32 e.)		Details
		Reporting requirements (C32 f.)		Details
		Cert requirements (C32 g.)		Details
		Licence requirements (C32 h.)		Details
		Structure and operation (C32 i.)		Details
		Records kept (C68)		

Record keeping requirements

The Guidelines require the making and keeping of a range of records (C68). These must be made available to the Regulator on request. These record-keeping requirements are noted where relevant in the Conditions of Certification table above but this table provides a consolidated list of record-keeping requirements. Please indicate compliance with the following record-keeping requirements and/or provide the specified information for each.

Condition Number	Record	Complies? (Yes/No/NA)	Comments
C15	**Facility inspection** Facility (including LWTS, if present) must be inspected at least once every 12 months, by a competent person. A copy of the most recent inspection record must be provided to the Regulator on request.		
C25, C54	**Autoclave** Calibration of the autoclave thermometer and timers must be performed annually by a competent person. Test results must be kept and provided to the Regulator on request.		
C25, C54	**External liquid waste treatment system (LWTS) (if present)** Calibration of the thermometer and timers must be performed annually by a competent person. Test results must be kept and provided to the Regulator on request. Results of any maintenance of LWTS.		
C2, C29	**Backflow prevention** Testable backflow prevention devices must be tested at least every 12 months. Documentation of test results must be provided to the Regulator on request. Risk assessment for backflow prevention (where applicable).		
C21, C23	**Closed system for large-scale culture** Inspection and testing of the integrity of any closed system (reusable or single-use) must be undertaken before each use. Records must be kept and made available to OGTR if requested.		
C14	**Pest control** A record of pest prevention strategies/control activities must be kept and provided to the Regulator on request.		
C31	**Training records** All personnel must be trained in procedures and facility details. Records must be kept and provided to the Regulator on request.		
C27	**BSCs** BSCs must be inspected and tested every 12 months, or after relocation, maintenance, or after HEPA filters are replaced. A certificate summarizing test results and date of next test must be fixed to the cabinet.		
C36 (R21)	**Respiratory protection** Documented risk assessment of whether respiratory protection is deemed necessary.		

Further questions relevant to compliance with certification conditions

The following questions may assist you in identifying any possible issues in the facility structures or processes. Please answer yes or no to each question and where you answer yes provide further details, taking the relevant Guideline requirement and conditions into consideration.

Question	Relevant requirements/ conditions	Yes/No	Comments
Have the facility boundary or internal layout changed in the last 12 months? *Approval must be sought prior to any changes to the internal or external layout of the facility. If intended structural changes will affect containment of GMOs, a variation or suspension of the certification may be required.*	R1 C2, C18-C20		
Is there any recent damaged or unscreened holes in the facility boundary (walls/roof/floor)? *Facility boundary must be a fully enclosable space.*	R1 C2		
Is there any damage to walls/floors/roof (e.g. cracks in floor covering) especially in areas where GMOs may be present? Are there any exposed/unsealed porous surfaces? *Surfaces where contamination may occur must be smooth, impermeable to water, easily cleanable and resistant to damage. Unsealed surfaces do not generally meet this requirement.*	R3 C2		
Have you significantly changed the scale of the dealings being conducted in the facility? *Facility processes (e.g. for decontamination and spills) must be appropriate for the scale of dealings. Also consider whether any linked authorisations (DNIRs/NLRD) allow for the change in scale.*			
Do you still have effective secondary containment in place at all times when dealing with volumes of GMOs that meet the definition of large scale? *Secondary containment must be provided to retain any leakage from the closed system. It must be of sufficient capacity to retain the volume of fluid held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers plus the volume of any disinfectant that might be used. With additional capacity to prevent any expected general fluid movement from breaching the secondary containment.*	R24 C16		

Question	Relevant requirements/ conditions	Yes/No	Comments
Have you significantly changed the style of vessel/s that comprise the closed system or are any of the vessel/s now different to what was originally assessed? *This may impact containment equipment requirements or secondary containment (such as volume of bunding provided). Details of changes may be required to be provided to the OGTR (e.g. type, number, maximum volume).*	R14-21, R24, R27 C16		
Are the waste treatment procedures or equipment different to what was originally assessed? *A new waste treatment system may require commissioning data and validation prior to use.*	R25, R27f-i C17, C52		
Are all aerosols still being effectively contained, including in Closed systems and LWTS? *Approval must be sought for non-standard aerosol containment equipment.*	R15, R19, R21-R23 C16, C38, C40, C41, C42		
Have there been any spills in the facility or a release of GMOs from the facility? Have any non-compliances against the Conditions of Certification been identified in the facility? *Any spill outside the facility (including as a result of failure of the LWTS), release of GMOs from the facility or identified non-compliance must be reported to the Regulator as soon as reasonably practicable.*	C67		
Have there been any significant failures of equipment used in the facility? *A significant failure of equipment may require reporting to the Regulator e.g. if the failure is a critical defect in the closed system while the facility is in operation, or, if as a result of the failure, there is a major release of GMOs from primary containment.*	C67		