Annual Inspection Checklist for a PC3 Facility

Checklist for annual inspection against the usual Conditions of Certification as detailed in the Gene Technology Regulator’s *Guidelines for Certification of a Physical Containment Level 3 Facility Version 1.0 - 01 December 2022*

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

| Date of Inspection |  |
| --- | --- |

**Please Note**

1. The use of this checklist proforma is **not** mandatory in order to satisfy the annual inspection reporting component of Condition 15. Rather, it is provided to assist those who find it convenient to use in the annual inspection of certified facilities for compliance with the conditions of certification under Condition 15.
2. A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 15, but the proforma is **not** intended to be the **only** acceptable format for the report.
3. Please use the ‘Application Checklist’ against the requirements for certification (as opposed to this ‘Annual Inspection Checklist’) when applying for a new certification, or when seeking a variation to the requirements for certification of a facility (e.g. lifting the suspension of a certification after modifications to the facility.)
4. Please do not send this report to the OGTR unless specifically requested**.**

# Facility details

|  |  |
| --- | --- |
| Organisation |  |
| Facility details | Cert-xxx  PC3 Facility ☐ Animal room(s) ☐ Invertebrates room(s) |
| GMOs in the facility |  |
| Relevant non-GMOs present |  |
| Licences associated with facility |  |
| NLRD(s) associated with facility |  |

# Facility management

## Facility manual

Person who is responsible for training of staff: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of last review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Information required in the facility manual:

|  |  |
| --- | --- |
| Required information | Addressed |
| Facility manager’s contact details |  |
| Emergency contacts details |  |
| Copy of certification instruments and conditions of certification |  |
| Copy of licences/NLRDs |  |
| Copy of *Guidelines for the Transport, Storage and Disposal of GMOs* & *Certification of a PC3 facility* |  |
| Structure & operation of facility (including design limits) |  |
| Details of all GM and non-GM organisms used in the facility, associated risks, and risk management strategies |  |

Procedures to be included in the facility manual:

|  |  |
| --- | --- |
| Procedures | Addressed |
| Procedures for handling animals and invertebrates held within the facility, if applicable, including the procedure to be implemented in the event an animal/invertebrate escape within or outside the facility and to account of all animal/invertebrate held within the facility |  |
| Entry & exit procedures, PPE requirements and protocols for use / removal |  |
| Procedures for use and operation of BSC / other aerosol containment equipment, including the removal of gloves and over-sleeves on completion of the dealing and prior to leaving the BSC |  |
| Procedures for the use of sharps, if applicable, including circumstances in which sharps to be used |  |
| Procedures for movement of equipment out of facility, including its decontamination |  |
| Procedures and validation for use of decontamination chamber if present |  |
| Procedures for decontamination of GM organisms, including use of the autoclave |  |
| Procedures and triggers for the gaseous decontamination |  |
| Procedures for disposal of waste and effluent, including their transport |  |
| Procedures for transporting viable GMOs inside the facility, including transport of GMOs for storage |  |
| Procedures for the transport of viable material outside the facility (e.g. to another PC3 facility) |  |
| Circumstances or events which must be reported to the Regulator |  |
| **Contingency plans for:** | |
| Spills of GMOs inside and outside the facility |  |
| Accidental exposure/medical emergencies to the GMOs |  |
| Escape of animals or invertebrates containing GMOs within or outside the facility, if applicable |  |
| Alarms for fire or loss of pressure |  |
| Release of GMOs from the facility (e.g., loss, theft or unintentional release) |  |
| Failure of power or ventilation systems |  |
| Failure of autoclaves and other decontamination systems |  |
| Failure of BSCs and other aerosol containment equipment |  |
| Natural disasters and fire |  |
| Medical emergencies to persons |  |
| Security threats |  |

## Record keeping

Required to keep for \*at least 3 years of records \*\* at least 12 months of records

| **Conditions** | **Item** | **Frequency** | Completed | **Comments** |
| --- | --- | --- | --- | --- |
| C14, C15, C22 | Inspection of facility | Annually\* |  |  |
| C21 | Pest prevention strategy | Ongoing\* |  |  |
| C26  C28  C31 | BSC | Annually\* |  |  |
| C26  C28  C31 | IVCs & change stations | Annually\* |  |  |
| C26  C33  C34 | Autoclave (maintain) | Annually\* |  |  |
| C32 | Autoclave (validate) | Quarterly\*\* |  |  |
| C26  C33  C34 | LWTS | Annually\* |  |  |
| C36 | Backflow prevention device | Annually\* |  |  |
| C37  C38 | Ventilation | Annually\* |  |  |
| C68 | Gaseous decontamination | As required per C69 |  |  |
| C72 | List of all GM organisms in the facility | As required per C72 |  |  |
| C77-81 | Training/ Update training records | As required per C77-81\* |  |  |
| C83 | List of persons authorised to enter the facility | As required per C83 |  |  |
| C84 | Facility manual review | Annually\* |  |  |

## Other

|  |  |  |  |
| --- | --- | --- | --- |
|  | Section | Requirement | Comments |
| C2 | Annual shutdown | Facility inspected after annual shutdown, if applicable |  |
| C11 | Work not including | Dealings above PC3 containment  Housing of plants and aquatic animals beyond minimum time |  |
| C77  to  C80 | Training | Authorised persons re-trained on last updated procedures?  Training records updated  Training of people who are authorised but not undertaking dealings ☐ e.g. tradie |  |
| C85 | Health monitoring | Procedures developed to:  record accidents and potential exposure to GM human pathogens  respond to exposure to GM human pathogens |  |
| C4  C5 | Authorised entry | Authority to exclude people from the facility  Entry is restricted to authorised people |  |
| C21 | Pest Program | Program is proactive  reactive  Frequency |  |

# Work practices

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| C47  C48 | PPE worn | lab coat  closed footwear  eye protection  gloves  skin abrasions covered  Long hair tied/covered ☐  Optional  Mask ☐ respirator ☐ face shield ☐  PAPR ☐ booties ☐ double gloves ☐ |  |
| R16 | PPE storage | Dedicated hanging/storage for PPE  Reusable PPE are stored in a manner preventing cross contamination |  |
| C40  C41C42 | Personal effects | Food or drink not brought into/stored in the facility ☐  Personal items not taken into the facility ☐  Essential items decontaminated prior to exit ☐ |  |
| C74 | Transport of GMOs | Viable GMOs removed from the facility  If yes, purpose of transport is:   * Transport to other PC3 or PC4 facility * Export * Written permission from the Regulator   Transport conducted in accordance with the *Guidelines for the Transport, Storage and Disposal of GMOs* |  |
| C52  C54 | Aerosol containment | Aerosol generating dealings with GMOs in BSC  Centrifugation of GMOs in sealed containers ☐ |  |
| C55 | Sharps | Not used in direct connection with GMOs unless no alternatives are available |  |
| C23  C76 | Storage of GMOs | within work area only  Triple contained | Exemptions? Alternate site inspected? |

# Inspection of the physical facility

## General facility

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R2  R3 | Facility Boundary | Facility sealable for gaseous decontamination  Windows, if present, closed and sealed |  |
| C22 | **Structural changes** | Any since last inspection |  |
| C13 | Containment | Facility not used as a primary containment facility |  |
| R6 | Lifts | No lifts present |  |
| R8 | Pass through boxes /barrier autoclave | Type:  Doors unable to be opened simultaneously  Autoclave outer door opens only after successful decontamination |  |
| R10  R11 | Openings fitted with screens | Openings in walls, ceiling, or roof are screened  Screens are:  fixed and sealed against mounting  made of appropriate material  Small enough to prevent movement of invertebrates or animal |  |
| R5 | Penetrations | Sealed |  |
| R17 | Communication equipment | Primary equipment  Alternative independent back-up system |  |
| R31 | Eyewash | Plumbed  Single use |  |
| R13  R14 | Surfaces  Fixtures/fittings | Surfaces are:  smooth, impervious to water and easily cleanable  resistant to cleaning agent and decontaminants  Open spaces between and under fixtures, fittings and equipment accessible for decontamination |  |
| R9 | Decontamination Chamber | Present  Doors unable to be opened simultaneously |  |

## Entry, airlock, anteroom

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R38 | **Inward airflow** | Air pressure at the entrance of the facility or each work area |  |
| R39  R40 |  | During the normal operation, work area at least 50 Pa below the pressure outside the facility  and  When either airlock door is opened, air pressure in all work area remains at least25 Pa below the pressure outside the facility |  |
| C16 | Signage on door | OGTR sign  Biohazard sign  Emergency contact numbers |  |
| C43  C44 | Facility access | Outer facility door lockable when unoccupied |  |
| C45  C46 | Entry and exit through airlock  Emergency exits only used in an emergency if present ☐ |  |
| R7 | Airlock doors | Self-closing  Sealed  Outer door has mechanism to restrict entry  Doors unable to be opened simultaneously |  |
| C18 | Airlock | No GMO dealings other than transport  No used PPE  No handwash basins  No equipment |  |
| C19 | **Anteroom** | No GMO dealings other than transport (or autoclaving)  No used PPE  No handwash basins  No equipment |  |

## Work area

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| C17 | Emergency contacts | Visible in each work area |  |
| R30 | Hand decontamination | Present at or near the exit of work area  Hands-free operation |  |
| R15 | **GM dealing in multi room facility** | Areas where GMO dealings are conducted are clearly identified |  |
| C73 | GMO labelling | Containers labelled to indicate they contains GMOs |  |

## Aerosol containment

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R20 | BSC | Number & type |  |
|  | Powered by uninterruptable power supply |  |
| R21  C28  C29  C30  C52 |  | Decontaminated before servicing  Tested annually and after relocation  HEPA filter integrity testing  Result and date of the next test affixed to BSCs  If defective, labelled appropriately ☐ |  |
| Used for all GMO dealings producing aerosols | Any exceptions? |
| C28b  C29  C30 | IVCs and other aerosol containment devices approved in writing by the Regulator | Device type:  Decontaminated before servicing  Tested annually  HEPA filter integrity testing  Result and date of the next test affixed to equipment  If defective, labelled appropriately ☐ |  |

## Decontamination

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R12 | Liquid effluent | Decontaminated prior to discharge from sink/floor drainage exit |  |
| C59 | GMOs/organisms infected with GMOs | Rendered non-viable before removal ☐ |  |
| C60 | Items removed from facility | Decontaminated prior to removal |  |
| C57 | Work surfaces | immediately after use ☐ at end of day ☐ |  |
| C49C61 | PPE | Removed when exiting work area  Removed prior to entering the airlock  Decontaminated before reuse or disposal |  |
| C25C58 | Equipment | Equipment decontaminated before maintenance |  |
| C63 | **Other methods** | UV / Irradiation  Approved in writing by the Regulator |  |
| C70 | Spills | Spills kit present |  |

### Chemical decontamination

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| C20  C67 | Chemical decontaminants | Available supply of disinfectants  Concentration and exposure time effective against the GMOs being decontaminated  Users aware of the minimum exposure time required for effective decontamination | Present in all work areas |
| Labelled (contents, concentration, expiry date) |  |

### Gaseous decontamination

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| C68 | Gaseous decontamination | Chemical used for gaseous decontamination: |  |
| Has the chemical been validated as effective against the GMOs |  |
| Use of appropriate indicators for the validation of the decontamination |  |

### Heat decontamination

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R22 | Autoclave | present  Not in airlock |  |
| C65 |  | Type: barrier  free-standing  Doors unable to be opened simultaneously |  |
| C32 |  | Physical parameters validated at least quarterly  **Via**:  Independent thermocouples  or  Chemical indicators which use a combination of moisture, heat, and time  or  Other |  |
| C66 |  | Combination of parameters (pressure, temperature, time) validated as effective against the organism being decontaminated or suitable surrogate |  |
| C33 |  | Annual testing and maintenance completed , including:  Calibration of temperature and pressure measuring probes  Testing and confirmation that all parameters of the system (temperature, time, pressure and flowrate) are operating within the specified limits  Testing of all safety and relief components, including the autoclave safety valves  and  Maintenance of the equipment to ensure effective operating conditions |  |
| C34  C35 |  | Result and date of the next test affixed to equipment  If defective, labelled appropriately ☐ |  |
| C64 |  | Loads packed such that steam can be contact all material |  |
| Measures to differentiate loads pre and post decontamination | autoclave tape |
| Air, steam & liquid is filtered / decontaminated prior to discharge |  |
| R24  C33  C34  C60  C71 | LWTS | Present  Fully enclosed system ☐  Pipes clearly identifiable  Leak detection present  or double skin  Vents to pipes, tanks filtered  Restricted access to LWTS room  Validated to ensure that it can achieve the parameters required to inactivate the most resistant organism used in the facility ☐ |  |
|  |  | Annual testing and maintenance completed , including:  Calibration of temperature and pressure measuring probes  Testing and confirmation that all parameters of the system (temperature, time, pressure and flowrate) are operating within the specified limits  Testing of all safety and relief components, including the autoclave safety valves  and  Maintenance of the equipment to ensure effective operating conditions |  |

## Ventilation system

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R18  R19 | **Room access** | Access to ventilation equipment restricted  Ducts, and access panels clearly identifiable |  |
| R32  R36 | **Exhaust and supply system** | The facility fitted with a ventilation system establishing negative air pressure in the facility and a directional airflow into the work area(s) ☐  Exhaust & supply system interlocked |  |
| **Exhaust fitted with:**  At least one HEPA filter through which all exhaust air is filtered  Pre filter upstream  Exhaust fan downstream of the exhaust HEPA  Gas-tight air ducts between the facility and the HEPA filter housing |  |
| R33  R34  R37 | **Exhaust housing** | HEPA mounted in gas-tight housing with sealed access doors |  |
| **Design and location of the filter housing allow for**:  Easy access  Secure and damage free handling of the HEPA  In situ gaseous decontamination  Maintenance, replacement and integrity testing of the HEPA filter  If gaseous decon performed on HEPA filters, Gas tight isolating valve present on:  Air inlet duct  Upstream port  and  Downstream port  *If pressure across HEPA filter measured,* 0.2µm hydrophobic membrane filter present on facility side of HEPA |  |
| C27  R41 R42 | **Ventilation system malfunction and alarm** | Facility equipped with an audible alarm  Alarm activated when pressure in the work area(s) or airlock deviates from the set point by 15 Pa for more than 2 minutes  **In the event of failure or malfunction of the ventilation system:**  Use emergency stop button  have procedures  Notification to OGTR ☐ |  |
| R35  C25  C37 | Testing of the Ventilation system | Decontamination of the HEPA housing prior to testing or repair  **Annual testing and maintenance of the facility ventilation system including:**  Testing of the pressure differentials  Checking directional airflow  Testing of the alarm  Testing of components of the ventilation system in a system failure scenario  Calibration of transducers fitted to the air-handling system and validation of air-handling performance  Calibration of pressure gauges  The air handling control system  If applicable, the building management system  and  Integrity testing of all HEPA |  |

## Backflow prevention devices

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| R25  R26  R27  C36 | **Backflow prevention** | Water supply, connected directly or indirectly to any part of a water service, protected against backflow  If no backflow prevention devices, documentation on risk assessment/risk management plan available  If defective, labelled appropriately ☐ |  |
| R28 | **Vacuum system** | Present  if so, fitted with:  0.2 µm hydrophobic membrane filters and  liquid disinfectant traps  If central vacuum system, filter and trap on the facility side of the vacuum line  If portable pump, filter and trap located before the pump |  |
| R29 | **Piped gas** | Present in a BSC  if so,  Reverse flow prevention on outlets in BSC  or fitted with ≤0.2µm hydrophobic membrane filter |  |

## Animal work area

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| Ani-C1  Ani-C9 | Signs | Sign on outer door with special entry conditions/ animals present ☐  Documented system to account for all animals |  |
| Ani-C6 | Dealings generating aerosols | Conducted in BSC  or  in aerosol containment equipment approved in writing by the Regulator (e.g., Inhalation exposure system) |  |
| Ani-R1  Ani-C4  Ani-C5  Ani-C7  Ani-C8 | Cages/enclosure | Cages/enclosures devices appropriate for the animals being housed present (all life stages)  Animal infected with aerosol transmissible GMOs housed in sealed cages/enclosures fitted with exhaust HEPA filters (IVCs or ventilated enclosure HEPA filtered)  Cage is labelled to indicate it contains a GMO  and the number of animals within the cage/enclosure |  |
| A-R2 | Containers used for Euthanising | Container used for euthanising animal containing GM micro-organisms requiring PC3 containment and capable of being shed are:  sealed  and  fitted with a gas inlet filtered with a 0.2 µm hydrophobic membrane |  |
| Ani-C11  Ani-C12 | Decontamination | Animal carcasses decontaminated prior to removal from the facility  Equipment, cages, bedding and animal waste decontaminated prior to removal from the facility |  |

## Invertebrate work area

|  | Section | Requirement | Comments |
| --- | --- | --- | --- |
| Inv-C1  Inv-C7 | Signs | Sign on outer door with special entry conditions/ invertebrates present  Documented system to account for all invertebrates ☐ |  |
| Inv-R1  Inv-R2  Inv-R3 | Anteroom | Anteroom present for entry to the room(s) housing invertebrates  Anteroom doors self-closing doors  No dealings conducted within the anteroom  Mechanism to prevent invertebrates from traversing anteroom/airlock boundary  and  capable to be maintained in darkened/ lit state  Means present to inspect and remove invertebrates on persons exiting the anteroom |  |
| Inv-C5  Inv-C6 | Cages/enclosure | Cages/enclosures devices appropriate for the animals being housed present (all life stages)  Cage is labelled to indicate it contains a GMO  and the number of animals within the cage/enclosure |  |
| Inv-C10 | Aerosols | Dealings with aerosol transmissible GMOs dealings conducted in BSC |  |
| Inv-C11  Inv-C12 | Decontamination | Invertebrates euthanised prior to removal from the facility  Cage/containers decontaminated prior to removal from the facility |  |
| Inv-C9 | Invertebrate trap | Room fitted with a suitable invertebrate trap ☐ |  |