

## **CHAPTER 2 – REQUIREMENTS OF CERTIFICATION**

This Chapter is divided into two Parts:

General requirements (Part 1) outlines the requirements that must be complied with by the holder of any certification for a facility, irrespective of the type of facility and the containment level to which the facility is certified; and

Specific requirements (Part 2) outlines the specific requirements that must be complied with for facilities certified to varying containment levels.

### **PART 1: GENERAL REQUIREMENTS**

The holder of the certification must:

- maintain control of GMO dealings in the facility through processes appropriate to the facility's containment level and type;
- prevent release of GMOs and organisms infected with GMOs from the facility unless specifically approved (in writing) by the Regulator;
- prevent the persistence of GMOs and organisms infected with GMOs within the facility other than those being stored or used in a dealing;
- comply, and ensure all people in the facility comply with, the Specific Conditions identified in Part 2 which apply to the facility, as specified in the Regulator's instrument of certification under section 84 of the Act; and
- ensure that the facility is inspected at least once per year. A copy of the inspection report must detail the extent of compliance with the Regulator's conditions of certification and must be provided to the Regulator if requested. Any non-compliance issues must be notified to the Regulator as soon as practicable.

## **PART 2: SPECIFIC REQUIREMENTS**

### **1. REQUIREMENTS FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) LABORATORY FACILITY**

#### **General**

- 1 The work that can be conducted in a facility that is certified as a Physical Containment Level 2 (PC2) Laboratory Facility includes work with GMOs that present a low to moderate potential risk to people and/or the environment. It may include some work with plant tissue culture and some work with small animals, but must not include the housing of animals for lengthy periods or the growing of plants (except those in tissue culture or contained in a plant growth cabinet).

#### **Facilities**

- 2<sup>\*</sup> The facility must be labelled with the following adhesive signs as supplied by the OGTR:
  - (a) a Physical Containment Level 2 (PC2) sign on the outside of facility access door(s);
  - (b) a biohazard symbol on the outside of facility access door(s); and
  - (c) a PC2 Facility Practice sign prominently displayed inside the facility.
- 3<sup>\*</sup> The facility must be a fully enclosable space contained within walls, doors, windows, floors and ceilings.
- 4 Walls, floors, ceilings and benches must be smooth, impermeable to water, cleanable, and resistant to the cleaning agents and/or disinfectants used in the facility. Facility furniture, including seating, must be washable.
- 5 A wash basin must be provided for hand washing within the facility. By 30 June 2004 the wash basin must be fitted with a basin mixer of the hands-free operation type.
- 6 Water supplied to the laboratory must be provided with back flow prevention.
- 7 Eyewash facilities (either a plumbed eyewash facility or single-use packs of sterile eye irrigation fluids) must be provided within the facility. Eyewash facilities must be used and maintained in accordance with the manufacturer's instructions.
- 8 The facility must contain a pressure steam steriliser (autoclave) or have an autoclave that is accessible to facility users. If the autoclave is not located in the facility, it is preferable that it be located within the same building as the facility.
- 9 Designated storage or hanging provisions for protective clothing must be available within the facility.

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<sup>\*</sup> OGTR requirement additional to AS/NZS 2243.3:2002

- 10 A supply of disinfectants for decontamination purposes must be available in the facility. The disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.
- 11 Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

### **Personal protective clothing and equipment**

- 12 Protective clothing to protect the front part of the body must be worn by all persons performing procedures in the facility.
- 13 Closed footwear must be worn.
- 14 Gloves must be worn for work undertaken in a biological safety cabinet.
- 15 Protective clothing must be removed after completing laboratory procedures and before leaving the facility. This requirement does not apply if entering another containment facility, certified to PC2 by the Regulator, that is directly connected to the facility.

### **Containment equipment**

- 16 If procedures that generate aerosols containing GMOs are to be performed in the facility, the facility must contain a biological safety cabinet, or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.
- 17 Installation, use and decontamination of the biological safety cabinet must be in accordance with the requirements of AS/NZS 2647: "*Biological safety cabinets - Installation and use*".
- 18 The biological safety cabinet must be tested at least every 12 months by a NATA accredited organisation. The cabinet must be labelled to show its test status.

### **Work Practices**

- 19<sup>\*</sup> All requirements for a PC2 Laboratory Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.
- 20 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.
- 21<sup>\*</sup> Windows must remain closed while laboratory procedures are in progress unless they are fitted with intact flyscreens. Facility doors must be closed when laboratory procedures are in progress.
- 22 All facility personnel must be trained in the requirements of the OGTR PC2 Laboratory Facility Guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle hazardous material.
- 23<sup>\*</sup> Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.

- 24 Any procedures that generate aerosols containing GMOs must be performed in a biological safety cabinet or other equipment designed to contain aerosols specifically approved in writing by the Regulator.
- 25 Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.
- 26 Work benches, surfaces and equipment where laboratory procedures have taken place must be decontaminated immediately after any spills and when laboratory procedures using GMOs are completed.
- 27 All work surfaces and equipment, in relevant areas of the facility, must be decontaminated before maintenance is carried out.
- 28 GMOs, organisms infected with GMOs, equipment or protective clothing contaminated with GMOs, and liquid and solid wastes containing GMOs, must be decontaminated by pressure steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator. Chemical disinfectant treatment must be in accordance with Appendix E of AS/NZS 2243.3:2002. Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility. Protective clothing that has not been contaminated with GMOs may be washed using normal laundry methods.
- 29 Where a pressure steam steriliser (autoclave) is used for decontamination:
  - (a) Provision must be made to allow for the penetration of steam into the container during autoclaving.
  - (b) The coldest part of the load must be exposed to a minimum temperature of 121° C for at least 15 minutes.
  - (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of autoclave tape).
  - (d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel.
  - (e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.
- 30\* All GMOs, and waste potentially contaminated with GMOs, being transported out of the facility must be transported in accordance with the "*Guidelines for the Transport of GMOs*".
- 31\* Animals and plants not used in the work being performed in the facility must be regarded as waste on removal from the facility and decontaminated by pressure steam sterilisation (autoclaving), incineration or any other method approved in writing by the Regulator.
- 32\* GMOs or organisms infected with GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled

- temperature container). The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located, and have a biohazard symbol posted on it.
- 33<sup>\*</sup> GMOs or organisms infected with GMOs being stored outside the facility must be double-contained. The primary container must be sealed and unbreakable. The primary container must be stored in an unbreakable secondary container and clearly labelled. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.
  - 34<sup>\*</sup> Transport of material between the facility and the storage unit must be in accordance with the "*Guidelines for the Transport of GMOs*". Gloves must be worn while transferring primary containers between the storage unit and the secondary container used for transport. Any spills that occur during storage outside the facility or when transferring to the storage unit, must be reported to the Regulator as soon as practicable. The spilt material and the area must be decontaminated.
  - 35 All cultures must be clearly identified.
  - 36 All cultures of fungi and other spore-dispersing organisms must be sealed during storage.
  - 37 Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.
  - 38 Long hair must be tied back or covered with a hair net to avoid contamination.
  - 39 Mouth pipetting is prohibited in the facility.
  - 40 Only reading/writing material and computers essential to procedures performed within the facility are permitted on work benches where procedures are performed. Reading and writing material must not be used inside a biological safety cabinet. Where possible dedicated reading/writing areas should be provided and used.
  - 41 Persons who have been performing procedures in the facility must wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas.
  - 42<sup>\*</sup> The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.
  - 43 Strategies must be in place to ensure that the facility is free of pests. A record of the program and dates of specific activities must be kept and made available if requested