

SCHEDULE 6

Regulation 12(4)

CONTAINMENT MEASURES FOR MICRO-ORGANISMS OF GROUP II

1. The containment measures for Type B operations using micro-organisms from Group II shall be chosen by the user from the levels in the Table below as appropriate to the micro-organism and the operation in question in order to ensure the protection of health of the general population and the environment.

2. Type B operations shall be considered in terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow the selection and design of process, plant and operating procedures best fitted to ensure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risks of failure as the consequence of that failure becomes less tolerable.

B2 SPECIFICATIONS	Containment Levels		
	B3	B4	
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built

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B2 SPECIFICATIONS	Containment Levels		
	B3	B4	
(a) ( <del>a</del> ) Hazard signs should be posted	Optional	Yes	Yes
(b) ( <del>b</del> ) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
(c) ( <del>c</del> ) Personnel should wear protective clothing	Yes, work clothing	Yes	Yes, A complete change
( <del>d</del> ) ( <del>d</del> ) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) ( <del>e</del> ) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) ( <del>f</del> ) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) ( <del>g</del> ) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h) ( <del>h</del> ) The controlled areas should be	No	Optional	Yes

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B2 SPECIFICATIONS	Containment Levels		
	B3	B4	
maintained at an air pressure negative to atmosphere			
(i) (i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) (j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
(k) (k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7. Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means