

Note: The table below represents recommendations by the author for steam sterilisers associated with bio-containment facilities at PC2, PC3 and PC4 levels. These are recommendations only. Items that have specific mention in the AS/NZS and the regulatory guidelines are highlighted in red. Always consult regulatory authorities for requirements associated with a particular project as these can vary with time and often depend on application.

LEGEND:

A ACCEPTABLE ALTERNATIVE, PROVIDED IT IS FIT FOR PURPOSE

C CONSIDER BASED ON POTENTIAL HAZARDS

NR NOT RECOMMENDED

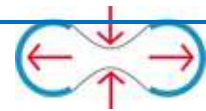
PC3_{PRI} PC3 FACILITY WHICH FORMS A PRIMARY CONTAINMENT ENVIRONMENT

R RECOMMENDED

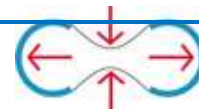
SR STRONGLY RECOMMENDED

Y REQUIRED

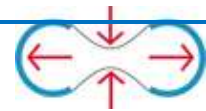
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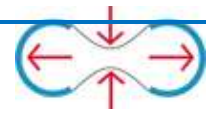
STEAM STERILISER RECOMMENDATIONS FOR CONTAINMENT APPLICATIONS							
ITEM	PC2	AS/NZS 2243.3 ISSUE				REGULATORY	
		PC3	PC3 PRI	PC4	DAFF	OGTR	
Minimum standard 316L stainless steel for chamber	R	R	R	R	R	R	
All surfaces in contact with steam or product to be corrosion resistant	R	R	R	R	R	R	
All surfaces in contact with steam or product to be minimum standard 316L stainless steel			R	R			
Barrier seal - Gas tight sealed barrier flange around steam steriliser barrier wall to seal steam steriliser to facility wall penetration		Y	Y	Y	Y	Y	
High temperature sealants used for any areas likely to be exposed to elevated temperatures	Y	Y	Y	Y	Y	Y	
All penetrations through barrier seal to be gas tight . Applies to items such as cables, instrumentation, monitoring, services to inside instrumentation panel, pressure gauges, door controls		Y	Y	Y	Y	Y	
Potted seals		A	R	R	R	R	
Gas-tight glands		A					
Penetrations of tubes or pipes through barrier seal to have mechanism in place to minimise likelihood of breach of barrier in event of damage to tube. (For containment side mounted pressure gauges, air or steam to inner doors). E.g. 0.2 micron membrane filters at the barrier, <u>or</u> rigid & properly fixed tubing <u>or</u> physical protection.		R	R	R	R	R	
Steam steriliser to be of downward displacement type (only applies if non-porous loads and loads without air pockets are exclusively required – otherwise pre-vacuum type always recommended)	A	NR	NR	NR	NR	NR	
Steam steriliser to be of pre-vacuum type	R	Y	Y	Y	Y	Y	
Cycles to include liquid, porous and instrument type options, with load probe and retained condensate temperature sensors capable of being included in validation control of cycle.	C	Y	Y	Y	Y	Y	
Include special load cycles for carcass, soil, etc., as applicable for type of facility	R	Y	Y	Y	Y	Y	
Include capability for 134 deg. C. cycle where special risks are possible, eg CJD, prions	C	C	C	C	C	C	
Post-vacuum to be provided to assist with drying	R	R	R	R	R	R	



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		PC3	PC3 PRI	PC4	DAFF	OGTR	
Steam steriliser to be provided with internal load probe for porous/liquid loads	Y	Y	Y	Y	Y	Y	
Evacuation paths to be protected by 0.2 micron steamable sterile membrane filters.	C	Y	Y	Y	Y	Y	
Filters to be of hydrophobic type. Filters are installed to protect vacuum pumps, liquid ring fluid and other components from exposure to contaminated waste material	C	Y	Y	Y	Y	Y	
Protection filters to be capable of being separately steam sterilized, or to be exposed to steam fully as part of each decontamination cycle.	C	Y	Y	Y	Y	Y	
Filters to be capable of being integrity tested	C	A	R	R	R	R	
Alternative to integrity testability is to provide two filters in series	C	A					
Cycle to incorporate condensate retention such that potentially contaminated condensate is exposed to full sterilization cycle time and temperature prior to release/discharge	C	Y	Y	Y	Y	Y	
Capability to decontaminate all potentially exposed pipes and components with liquid disinfectant or gas/vapour decontaminant in event of unrecoverable cycle failure so that maintenance/repair can be carried out safely.	C	Y	Y	Y	Y	Y	
Sensors in direct contact with chamber to be of sealed type, such as sealed diaphragm pressure sensors and non-capillary type temperature sensors	R	R	R	R	R	R	
Alternatively sensors to be provided with steamable 0.2 micron hydrophobic sterile membrane filters		A	A	A	A	A	
High temperature incineration of evacuation air			C	C			
Provide exhaust ventilation to remove heat, steam and odours	Y	Y	Y	Y	Y	Y	
Provide exhaust hoods above entry and exit doors of steam steriliser (except post-vacuum type)	R	R	R	R	R	R	
Provide exhaust grilles directly above entry and exit doors of steam steriliser (post-vacuum type)	A	A	A	A	A	A	
Provide areas for holding of material awaiting steam sterilization	Y	Y	Y	Y	Y	Y	
Areas for material awaiting steam sterilization to be secure against unauthorized access	Y	Y	Y	Y	Y	Y	



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			PC3 PRI	PC4	DAFF	OGTR	
Areas for material storage to be protected against entry of vermin	Y	Y	Y	Y	Y	Y	Y
Provide area for discharged material to cool	Y	Y	Y	Y	Y	Y	Y
Provide area for discharged material to be stored, including cold room or freezer if warranted.	C	C	C	C	C	C	C
Ensure sufficient space for accommodation, handling and movement of trolleys	Y	Y	Y	Y	Y	Y	Y
Bursting disk protection upstream of sealed bonnet chamber pressure relief valves. Space monitored and alarmed for pressure rise		Y	Y	Y	Y	Y	Y
Gas tight sealed barrier flange around steam steriliser barrier wall to seal steam steriliser to facility wall penetration		Y	Y	Y	Y	Y	Y
CONTROLS AND VALIDATION							
Physical parameter validation - temperature, time	Y	Y	Y	Y	Y	Y	Y
Calibration of all cycle-critical instrumentation	Y	Y	Y	Y	Y	Y	Y
For barrier wall steam sterilisers, interlocking of doors to prevent non-containment door being opened until a potentially contaminated chamber has undergone a successful cycle		Y	Y	Y	Y	Y	Y
SUPPORT AREAS							
Steriliser engineering space and access to be outside the containment barrier		Y	Y	Y	Y	Y	Y
Steriliser engineering space to be air conditioned or ventilated to remove heat	R	R	R	R	R	R	R
Steriliser engineering space access to be accessible by suitably qualified persons only	R	R	R	R	R	R	R
Consider rating of steam steriliser engineering space	C	C	C	C	C	C	C
Ensure drains are capable of withstanding the temperature of liquid effluent	R	R	R	R	R	R	R
Consider chilled water based heat recovery in lieu of cold water single pass systems in areas where water shortage is an issue	C	C	C	C	C	C	C



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MAINTENANCE AND ONGOING VALIDATION							
Carry out annual calibration of temperature monitoring devices that form part of cycle control. Create and maintain records of calibrations	Y	Y	Y	Y	Y	Y	Y
Carry out periodical maintenance in strict compliance with manufacturer's recommendations by suitably qualified technicians	Y	Y	Y	Y	Y	Y	Y
Ensure any repairs are carried out by suitably qualified technicians in a manner approved by the manufacturer. Update any pressure vessel testing records if required (e.g. major chamber repair)	Y	Y	Y	Y	R	R	
In event of a cycle failure necessitating emergency maintenance, ensure the facility biosafety officer is involved with the decontamination of any potentially exposed components to minimize a health or containment breach hazard	SR	SR	SR	SR	SR	SR	SR

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