

		Low Temperature Sterilization		Quarantine	Recall System	Record Keeping System	Subculture Positive
Organization	Test Pact Contents	Placement	Frequency				
<p> AAMI <i>Ethylene oxide sterilization in health care facilities</i>, ANSI/AAMI ST41, 1999 </p>	<p> Routine Pack: Before assembly, the test pack components should be held at room temperature (20-23°C {68-73°F}) and at least 35% relative humidity (RH) for 2 hours. Place one BI in a plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe. Place syringe between the folds of one cotton surgical towel, place in one peel pouch or wrapper. Or use an equivalent disposable test pack. </p> <p> Challenge Pack: Before assembly, the test pack components should be held at room temperature (20-23°C {68-73°F}) and at least 35% relative humidity (RH) for 2 hours. </p> <p> You need four clean 100% cotton surgical towels, approximately 18" in by 30" each folded in thirds, lengthwise, then in half. One adult plastic airway, one 10" section of amber latex tubing with an internal diameter of 3/16" and a wall thickness of 1/16". A CI and two 24" x 24" wrappers, 2 BIs each in a separate plastic syringe, consult manufacturer for BI placement, remove needle and tip guard. Place syringes, airway, and tubing between towel 2 and 3, over wrap and tape. Can use a disposable pack if it has been validated against the AAMI challenge test pack. </p>	<p>Place in center of full load for routine testing.</p> <p>Depends on size of sterilizer. For 3M™ Steri-Vac™ Gas Sterilizer or sterilizers <16 cu. ft., place one pack in front.</p>	<p>Should be used in each cycle.</p> <p>After the sterilizer is installed run three consecutive empty cycles.</p> <p>Periodic quality assurance testing which should be conducted at least quarterly and after major redesign, relocation or corrective maintenance, any time after major changes are made in packaging, procedures or materials, and any time that major changes are made in the composition of the load. Three consecutive cycles are run but the test pack is placed in a fully loaded chamber.</p> <p>Periodically place BIs and CIs in actual products being processed to gain confidence in the ability of the system to sterilize particular products. Identify test samples and run in a full load.</p>	<p>Each load containing implantables should be monitored and, whenever possible quarantined until BI results available.</p>	<p>Retrieve and reprocess items from the sterilization failure.</p>	<p>Yes</p>	<p>Yes</p>

Biological Indicators (BI's) - Load Control 2/05 3M Health Care

BI = Biological Indicator CI = Chemical Indicator		Low Temperature Sterilization			Quarantine	Recall System	Record Keeping System	Subculture Positive
Organization	Test Pact Contents	Placement	Frequency					
AORN <i>Standards, Recommended Practices & Guidelines, 2004</i>			<p>EO: <i>B. subtilis</i> spore testing should be performed with every load.</p> <p>Low Temperature hydrogen peroxide gas plasma: <i>B. subtilis</i> spore testing should be performed at the same interval as other sterilizers in the facility.</p> <p>Low temperature liquid peracetic acid sterilizers: <i>B. stearothermophilus</i> spore testing should be performed at least weekly and preferable daily. The product used should be designed specifically for use with the peracetic acid process. Consult the sterilizer manufacturer for product location and instructions.</p> <p>All Processes: Additional monitoring of several consecutive sterilization cycles after installation, repair, redesign or relocation of sterilizers.</p>	AAMI recommends quarantine of the implantable device until the outcome of the BI result.	Appropriate Action	Yes		
ASHCSP <i>Recommended Practice for Central Service, Sterilization, Section 6, 2001</i>	EO: See <i>Ethylene Oxide Use in Hospitals: A manual for Health Care Personnel</i> or AAMI ST41.	EO: See <i>Ethylene Oxide Use in Hospitals: A manual for Health Care Personnel</i> or AAMI ST41.	<p>EO: Should be used with each load.</p> <p>Additional testing should be performed when there is a positive biological result, upon installation of the EO sterilizer, relocation of the sterilizer, and when major repairs are performed.</p> <p>Other Low Temperature Sterilization Processes: Biological indicators designed for this process should be used.</p>		All issued and stored items from the positive biological indicator back to the last negative indicator must be retrieved and reprocessed.	Yes		
CDC <i>Guidelines for Handwashing & Hospital Environmental Control, 1985</i>			Should be used at least once a week and each load if it contains implantable objects.	Implantable objects until biological indicator is negative at 48 hours	Yes, if implantable objects.			

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JCAHO - <i>Comprehensive Accreditation Manual for Hospitals, 2005</i>			As determined by facilities policies and procedures. Policies and procedures should be based on most stringent recommended practices, laws, rules and regulations, and current scientific knowledge.					
VA <i>Handbook 7176</i>			Each Cycle		Yes	Yes		