Sterilization and High-Level Disinfection Options: Sample of Pros and Cons

5/12/2008

	Pros	Cons	Standards for Use
STERILIZATION			
Ethylene Oxide (EtO)	Low temperature, low moisture, gas sterilization for heat and moisture-sensitive instruments Used for sterilization of reusable healthcare products Can control ethylene oxide emissions in several ways: 1.Thermal oxidation 2.Catalytic oxidation (Steris Isomedix oxidizes 99.9% releasing only CO2 and water) 3.Acid-catalyzed scrubbers 4.Condensation/Reclamation system	OSHA animal studies show that EtO is a known carcinogen; it may cause leukemia and other cancers Inhalation can cause nausea, vomiting, neurological disorders In solution, EtO can severely irritate and burn the skin, eyes and lungs May damage the central nervous system, liver and kidneys or cause cataracts Must monitor occupational exposure and use special venting Instruments must be sterilized for 12 hours or more Extremely reactive and flammable **New EPA Rule** on hospitals that are "Area Sources" that own or operate an EO sterilization facility are now required to have air pollution control devices (APCD) by 12/09 and have a management practice plan to sterilize full loads. For a copy of the rule, go to http://www.epa.gov/ttn/atw/area/fr28de07b.pdf. Permissible exposure limit (PEL) is 1ppm as an 8-hour time-weighted average	National Emission Standards for Hospital Ethylene Oxide Sterilization, 40 CFR 63 Part wwwww

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Peracetic Acid (Steris P6000)	An alternative to the use of ethylene oxide Low temperature sterilizer for flexible and rigid endoscopes	Highly toxic Can burn employees from chemical vapors Wet process so 'just-in-time"; must be used in 2 hours or Must dry instruments with forced air (then only considered high-level disinfected, no longer sterile) if not used within 2 hours Some manufacturers have not approved EtO alternatives for sterilization due to materials incompatibility. Sterilant mixture contains acetic acid and hydrogen peroxide (H2O2), in addition to peracetic acid; Acetic acid - 10ppm PEL; H2O2 - 1ppm PEL (8hr TWA); no monitoring method or PEL for peracetic acid	29 CFR 1910.1000 Table Z-1
Hydrogen Peroxide Plasma Gas (ASP Sterrad and Sterrad NX)	No chance of worker exposure as cassettes are not pierced until the sterilizer is under vacuum. Requires no special ventilization Water vapor is its only waste Sterilizes devices between patient use Low temperature, terminal sterilization suited for some but not all heat and moisture sensitive items Short cycle processing time (55 minutes)	Sterrad NX limited to processing single channel endoscopes of a minimum internal diameter and of a limited length Limited to processing single channel flexible endoscopes; Instruments must be completely dried and wrapped in non-cellulose (proprietary) cloth wrap. Solid waste from this process is plastic cassettes 1 ppm PEL (8hr TWA)	29 CFR 1910.1000 Table Z-1
Vapor-Phase Hydrogen Peroxide (VPHP)	Low temperature sterilization (Steris) End-product is water vapor Self contained cartridge prevents staff exposure Can process single-channel flexible endoscopes and semi-rigid uretherscopes in 38 minutes (ASP) Short processing time (38-75 minutes depending on equipment)	New to market Incompatible with iron and some plastics (which are susceptible to the oxidation by hydrogen peroxide) Cannot sterilize highly absorptive products, such as those made from linens, powders, liquids and devices containing long, narrow or dead-end lumens. Solid waste is the plastic cartridge	

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Steam	Established and effective technology No chemicals are used Penetrates fabric Cheap	Its high temperature and moisture can not sterilize camera cords and other sensitive plastics and glues Incompatible with plastics and rubber substances Anhydrous materials can not be sterilized (oil, greases, powders) Cannot penetrate hollow needles or instruments packed in moisture resistant materials (test tube, glass)	ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
Ozone	Gas sterilizer (by TSO3) Odor is readily detected at low levels below those that cause adverse health effects All ozone is converted into water vapor FDA approved for rigid medical devices No special ventilization or utilities needed Taps into hospital's oxygen line to create ozone, so no need to purchase consumables Average cycle time is 4.5 hours to sterilize Able to process many heat-labile materials and some lumened devices and all types of urological scopes Can process ophthalmic lenses, cables and cords, power batteries and Doppler probes Water vapor and oxygen are the end-product Inexpensive to operate - cost per load $1	Toxic gas (per FDA, 21CFR801.415) Respiratory system irritant Priority pollutant contributing to the formation of smog Plastics and rubber are incompatible with ozone sterilization Not intended for use with any flexible endoscopes, glass or plastic ampoules, liquids or implants, latex and textile fabrics Might be slow getting retrofits to camera cords (replacing rubber with silicone) to make compatible Hard to get validation from manufacturers on instruments 0.10ppm OSHA permissible level of exposure (PEL) over 8 hour period, 5-day week; 4ppm immediately dangerous (note: much lower acceptable threshold level than EtO, which is 1ppm)	29 CFR 1910.1000 Table Z-1
Radiation	Both gamma and electron beam radiation are used commercially No harmful emissions Entire volume of the product is sterilized Gas-permeable packaging not needed Gamma rays can reach all areas of products	Radiation degrades some plastic gels, Teflon, rubber and polypropylene Could be harmful to products with batteries or electronic components Electron beams may not reach products that are dense or stacked below another product	ISO/TS 13409:2002

High Level Disinfection

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	Pros	Cons	Standards for Use
Glutaraldehyde (Cidex)	Commonly used for a quick-turnaround of instruments Achieves high level disinfection in 45 minutes for heat-sensitive equipment Not a human carcinogen Inexpensive	Short-term effects: Irritant (eyes, nose, throat) Long term effects: skin sensitizer; can induce asthma attacks, respiratory sensitization and dermatitis Requires special ventilation hoods and protective equipment CA exposure limit 0.05 ppm Ceiling (not to exceed at any time) OSHA has not established a PEL (permissible exposure limit) NIOSH recommends 0.2 ppm Ceiling from vapor	8 CCR 5155
Ortho-phthalaldehyde (Cidex OPA)	Achieves high-level disinfection in 12 minutes In a heat-controlled automatic endoscope reprocessor, OPA is effective in 5 minutes (versus glutaraldehyde's 20 minutes) Respiratory symptoms associated with Cidex OPA are described as mild and significantly less severe than with glutaraldehyde Quicker turn around allows greater turn-over More expensive than established glutaraldehyde solutions	Little human toxicological research on health effects Potent skin sensitizer 6500 times more toxic to aquatic life than glutaraldehyde requiring neutralization with glycine before drain disposal Allergic reaction to patients from instruments cleaned with OPA and to staff exposed California deemed Cidex OPA a hazardous waste on Jan. 2001unless treated with glycine first No established air monitoring method or exposure limit	None
Concentrated OPA (ASP Evotech)	Purportedly eliminates the need for manually brushing the endoscope channels before reprocessing, but lack of double-blind clinical studies to fully support the FDA claim Automatically neutralized before drain disposal in reprocessor Fully automated washer and disinfector System equipped with alcohol and compressed air cycle to facilitate drying	OPA disinfectant is not reused Concerns about handling of alcohol waste, whether flammable atmospheres are created in the alcohol purge phase, and whether the process lid gasket eliminates the need for local exhaust ventilization Excess concentrated OPA needs to be disposed of as hazardous waste	None
Diluted Peracetic Acid (Steris Reliance EPS)	A high level disinfector for use on flexible endoscopes only Eliminates personal contact with chemical components by using a sealed bag for both the enzymatic detergent and disinfectant Not possible to open disinfector during cycle, which eliminates skin exposure	Does not eliminate manual pre-cleaning using a brush Chemicals are not reused Waste from each cycle is reportedly non-hazardous, definitive data not received	29 CFR 1910.1000 Table Z-1

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	Pros	Cons	Standards for Use

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