<table>
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<tr>
<td><strong>STERILIZATION</strong></td>
<td><strong>OSHA animal studies show that EtO is a known carcinogen; it may cause leukemia and other cancers</strong>&lt;br&gt;<strong>Inhalation can cause nausea, vomiting, neurological disorders</strong>&lt;br&gt;<strong>In solution, EtO can severely irritate and burn the skin, eyes and lungs</strong>&lt;br&gt;<strong>May damage the central nervous system, liver and kidneys or cause cataracts</strong>&lt;br&gt;<strong>Must monitor occupational exposure and use special venting</strong>&lt;br&gt;<strong>Separate ventilation</strong>&lt;br&gt;<strong>Additional ventilation</strong>&lt;br&gt;<strong>New EPA Rule on hospitals that are &quot;Area Sources&quot; 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 <a href="http://www.epa.gov/ttn/atw/area/fr28de07b.pdf">http://www.epa.gov/ttn/atw/area/fr28de07b.pdf</a>. Permissible exposure limit (PEL) is 1ppm as an 8-hour time-weighted average</strong></td>
<td>National Emission Standards for Hospital Ethylene Oxide Sterilization, 40 CFR 63 Part wwww</td>
</tr>
</tbody>
</table>
## Sterilization and High-Level Disinfection Options: Sample of Pros and Cons

### 5/12/2008

### Standards for Use

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<tr>
<td><strong>Peracetic Acid (Steris P6000)</strong></td>
<td>Highly toxic</td>
<td>29 CFR 1910.1000 Table Z-1</td>
</tr>
<tr>
<td>An alternative to the use of ethylene oxide</td>
<td>Can burn employees from chemical vapors</td>
<td></td>
</tr>
<tr>
<td>Low temperature sterilizer for flexible and rigid endoscopes</td>
<td>Wet process so &quot;just-in-time&quot;; must be used in 2 hours or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Must dry instruments with forced air (then only considered high-level disinfected, no longer sterile) if not used within 2 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some manufacturers have not approved EtO alternatives for sterilization due to materials incompatibility.</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Hydrogen Peroxide Plasma Gas (ASP Sterrad and Sterrad NX)**        | Sterrad NX limited to processing single channel endoscopes of a minimum internal diameter and of a limited length | 29 CFR 1910.1000 Table Z-1 |
| No chance of worker exposure as cassettes are not pierced until the sterilizer is under vacuum. | 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) |                   |
| Requires no special ventiliation                                       | Water vapor is its only waste                                        |                   |
| Water vapor is its only waste                                         | Sterilizes devices between patient use                               |                   |
| 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)                             |                                                                      |                   |

| **Vapor-Phase Hydrogen Peroxide (VPHP)**                             | New to market                                                        |                   |
| Low temperature sterilization (Steris)                               | Incompatible with iron and some plastics (which are susceptible to the oxidation by hydrogen peroxide) |                   |
| End-product is water vapor                                           | Cannot sterilize highly absorptive products, such as those made from linens, powders, liquids and devices containing long, narrow or dead-end lumens. |                   |
| Self contained cartridge prevents staff exposure                     | Solid waste is the plastic cartridge                                 |                   |
| Can process single-channel flexible endoscopes and semi-rigid uretherscopes in 38 minutes (ASP) |                                                                      |                   |
| Short processing time (38-75 minutes depending on equipment)          |                                                                      |                   |
# Sterilization and High-Level Disinfection Options: Sample of Pros and Cons

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

**5/12/2008**

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<td><strong>Glutaraldehyde (Cidex)</strong></td>
<td>Commonly used for a quick-turnaround of instruments</td>
<td>Short-term effects: Irritant (eyes, nose, throat)</td>
</tr>
<tr>
<td></td>
<td>Achieves high level disinfection in 45 minutes for heat-sensitive equipment</td>
<td>Long term effects: skin sensitizer; can induce asthma attacks, respiratory sensitization and dermatitis</td>
</tr>
<tr>
<td></td>
<td>Not a human carcinogen</td>
<td>Requires special ventilation hoods and protective equipment</td>
</tr>
<tr>
<td></td>
<td>Inexpensive</td>
<td>CA exposure limit 0.05 ppm Ceiling (not to exceed at any time)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OSHA has not established a PEL (permissible exposure limit)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH recommends 0.2 ppm Ceiling from vapor</td>
</tr>
<tr>
<td><strong>Ortho-phthalaldehyde (Cidex OPA)</strong></td>
<td>Achieves high-level disinfection in 12 minutes</td>
<td>Little human toxicological research on health effects</td>
</tr>
<tr>
<td></td>
<td>In a heat-controlled automatic endoscope reprocessor, OPA is effective in 5 minutes (versus glutaraldehyde’s 20 minutes)</td>
<td>Potent skin sensitizer</td>
</tr>
<tr>
<td></td>
<td>Respiratory symptoms associated with Cidex OPA are described as mild and significantly less severe than with glutaraldehyde</td>
<td>6500 times more toxic to aquatic life than glutaraldehyde requiring neutralization with glycine before drain disposal</td>
</tr>
<tr>
<td></td>
<td>Quicker turn around allows greater turn-over</td>
<td>Allergic reaction to patients from instruments cleaned with OPA and to staff exposed</td>
</tr>
<tr>
<td></td>
<td>More expensive than established glutaraldehyde solutions</td>
<td>California deemed Cidex OPA a hazardous waste on Jan. 2001 unless treated with glycine first</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No established air monitoring method or exposure limit</td>
</tr>
<tr>
<td><strong>Concentrated OPA (ASP Evotech)</strong></td>
<td>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</td>
<td>OPA disinfectant is not reused</td>
</tr>
<tr>
<td></td>
<td>Automatically neutralized before drain disposal in reprocessor</td>
<td>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 ventilation</td>
</tr>
<tr>
<td></td>
<td>Fully automated washer and disinfecter</td>
<td>Excess concentrated OPA needs to be disposed of as hazardous waste</td>
</tr>
<tr>
<td></td>
<td>System equipped with alcohol and compressed air cycle to facilitate drying</td>
<td>None</td>
</tr>
<tr>
<td><strong>Diluted Peracetic Acid (Steris Reliance EPS)</strong></td>
<td>A high level disinfecter for use on flexible endoscopes only</td>
<td>Does not eliminate manual pre-cleaning using a brush</td>
</tr>
<tr>
<td></td>
<td>Eliminates personal contact with chemical components by using a sealed bag for both the enzymatic detergent and disinfectant</td>
<td>Chemicals are not reused</td>
</tr>
<tr>
<td></td>
<td>Not possible to open disinfecter during cycle, which eliminates skin exposure</td>
<td>Waste from each cycle is reportedly non-hazardous, definitive data not received</td>
</tr>
<tr>
<td></td>
<td></td>
<td>29 CFR 1910.1000 Table Z-1</td>
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Thanks to Erica Stewart, CIH, HEM, Kaiser Permanente, for reviewing this document.
Prepared by Practice Greenhealth

Sources:
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Steris Isomedix website, www.isomedix.com/ethyleneoxide/
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"High Level Disinfection," Infection Prevention Guidelines, Tietjen LG, W Cronin and N McIntosh. 1992
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