November 3, 2010

Ethylene Oxide Sterilization Association, Inc.
Considerations for Sterilizing Battery-Powered Devices

This document is intended to provide relevant information for ethylene oxide sterilizers and their customers regarding the use of ethylene oxide to sterilize battery devices or other devices with stored energy. This document is not a standard or industry guidance, and it creates no new legal obligations. The information provided is advisory in nature and informational in content.

Background

Ethylene oxide gas is a highly flammable/explosive substance. Unfortunate experience in the sterilization industry has shown that a relatively small amount of ethylene oxide in a single chamber, when ignited, can destroy a large facility with serious risk to human safety. For that reason, ethylene oxide sterilization facilities require absolute protection against energy discharges in the chamber. The concern with battery-powered devices or other devices with stored energy is that such energy could potentially trigger ethylene oxide ignition under certain circumstances.

It is, therefore, ABSOLUTELY CRITICAL for customers to inform the sterilization facility whether the item being sterilized has the energy potential to ignite ethylene oxide. Examples of battery-powered medical devices that might have such energy potential include:

- Penlight
- Oncology Phototherapy Catheter
- Implantable Defibrillator
- Irrigation Pumps -- various
- Spinal Cord Stimulator
- Powered Stapler
- Isolated Battery Packs
- Ozone Generator
- Implantable Neurostimulator
- Cochlear Implant
- Implantable Glucometer
- Lighted Retractor
- Powered Tissue Biopsy Device
- Powered Bone Screwdriver
- Powered Tracheotomy Device
- Implantable Pressure Monitor
- RH/Temperature Probes
- Angioballoon Inflator/Monitor
- Incontinence TENS Implant
- Needle Ossillator
- Bone Cement Mixer
- Phlebotomy Illuminator
- Pain Control Neurostimulator

Due to concerns with ethylene oxide ignition, most sterilizers do not sterilize devices with stored energy using ethylene oxide. This general policy reflects considerations of the applicable Occupational Safety and Health Administration (OSHA) regulations, Fire and Electrical Code Standards, as well as sterilization companies’ internal safety standards.
There are times, however, when ethylene oxide sterilization is the only method available for a battery-powered medical device. In those circumstances, the customer supplying the device for sterilization and the contract sterilization facility should work together to conduct a safety assessment of the device to determine whether an exemption is feasible. A written agreement that confirms each party’s understanding of the potential problems with ethylene oxide is strongly recommended. Sample language includes:

CUSTOMER understands that ethylene oxide is extremely flammable and requires absolute protection against energy discharges in the chamber. Accordingly, the customer hereby acknowledges the ethylene oxide processing is not intended for batteries or other stored energy devices and agrees these items will not be submitted for ethylene oxide processing, unless agreed to in writing per below.

COMPANY’S policy is to refuse to sterilize devices with stored energy using ethylene oxide unless device meets company’s internal safety standards for processing.

CUSTOMER has asked for an exemption for its device. If ethylene oxide sterilization is the only method available for said device, CUSTOMER understands that an ad hoc safety review must be conducted. As part of that review, CUSTOMER will need to provide detailed, documented information on the device so a safety review to justify an exemption can be completed.

Safety Assessment -- Risk Evaluation Must Be Conducted

As indicated above, in order to justify an exemption for a battery-powered device, a thorough risk review and documented, detailed safety assessment must be conducted. The evaluation should be robust enough to demonstrate that the risks of ignition of ethylene oxide are controlled sufficiently and that no one’s safety is placed at risk. In some cases, the contract sterilizer may have the technical expertise to conduct such an assessment. But in most circumstances, a third-party may be engaged to provide the safety assessment.

Customer Information Needed

Input from the customer on the device under review is imperative to the safety evaluation. If a customer cannot or will not provide the information needed for the safety review, the sterilization contractor has the right and the responsibility to refuse the product in question.

As part of the review process, the customer/device manufacturer should provide the following information:

- User documentation, such as marketing brochures or user instructions: This information is needed to understand how the device is operated, how
it is to be installed, how the energy circuit is engaged and other information.

- **Product specifications:** This provides relevant information on storage conditions, battery life, currents/voltages developed, number of pulses possible, and any other information that might be helpful.

- **Product design details,** such as AutoCAD drawing files, assembly drawings, packaging design, circuit diagrams (showing voltages, currents, switches, controllers, capacitors, resistors, voltage transformers, etc.), specifications for wiring connectors, and/or battery specifications: This information is needed to assess the energy available under various conditions of failure.

It may also be necessary to involve product engineers who are most knowledgeable about device design and testing in the evaluation process, as they can often quickly resolve any remaining questions or identify remaining information gaps.

**Questions to Address in Safety Assessment**

As noted, the safety assessment should be considered a joint project between the device manufacturer and the contract sterilizer. Questions that should be considered in the initiation of a risk review include:

- **Can the medical device exceed a known safe level of electrical potential or temperatures that could ignite ethylene oxide either by design, misassembly, or damage?**

- **If so, what are the layers within the device to avoid possible ignition during a sterilization process?**

  **NOTE:** At least two layers of protection should be identified. For example, a switch to turn the device on would be one layer and a second layer might be a battery power isolation tab that is removed prior to device usage.

- **What is the potential for the device to activate during sterilization such that operational energies, heat generated by a normal or damaged device would not initiate ethylene oxide ignition?**

  **NOTE:** This requires a detailed understanding of the device, including circuit designs, energies available, energy discharge potential, and temperatures generated under various circumstances. Customer input on these factors is essential in the review process.
Are the chemical components of the batteries compatible with ethylene oxide? An exothermic test should be conducted with the stored energy components to verify that they cannot trigger an exothermic reaction when exposed to ethylene oxide.

**Factors To Consider in the Risk Review**

- **Normal Cycle Flammability** -- The labeled Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements in the U.S. require that chambers must stay below theoretical flammability limits for ethylene oxide during processing.

- **Cycle Flammability with Stored Energy Devices** -- When stored energy devices are processed, they must meet a stricter requirement for flammability. A margin of at least 20 percent below the lower explosive limit (LEL) for ethylene oxide (empty chamber model) should be targeted.

- **Potential to trigger ethylene oxide ignition** -- Consider key factors for ethylene oxide ignition energy.

  Pure ethylene oxide vapor minimum ignition energy (MIE) is ~1,000 mJ.

  Keep in mind that small amounts of oxygen with ethylene oxide vapor makes it more sensitive. MIE ethylene oxide in air is 0.06 mJ.

  An individual can discharge energy in the range of 1-50 mJ during a commonly experienced static discharge where one experiences a shock when touching a metallic surface.

  The complete ignition curve is not available for ethylene oxide. Hydrogen is more conservative and is used in its place. Therefore, <12V @ <5A is theoretically safe. See Factory Mutual’s Hydrogen Ignition Curve (Appendix 1).

  If the energy is close to ignition curve, then consider whether the ignition risks are controlled sufficiently that the inherent risks are acceptable; evaluate all built-in safety measures and document the risk assessment in a report. Identify at least two layers of protection against accidental ignition during sterilization.

- **Brushed DC motors** -- By design, the brush/commutator interface of DC motors break an inductive circuit multiple times during every rotation of the motor. This produces virtually continuous arcing as the brushes...
reverse the magnetic field within the rotor of the motor. Depending on the
inductance of the rotor and the motor design, the energy in each circuit
breaking arc can have sufficient energy to ignite an ethylene oxide
atmosphere. These devices must be carefully analyzed and a conservative
judgment made about its potential to ignite ethylene oxide.

- Slip ring motors -- These contain windings that can have a significant
  inductance. This inductance can store a significant magnetic potential
  energy and if discharged, the resultant spark can have sufficient energy to
  ignite an ethylene oxide atmosphere. Slip ring motors do not actively
  make and break the rotor current, but imperfections in the rings and
  brushes do create tertiary sparking during operation. This sparking can
  have sufficient energy to ignite an ethylene oxide atmosphere and must be
  considered in the assessment.

- Brushless motors -- These contain windings that can have a significant
  inductance. This inductance can store a significant magnetic potential
  energy and if discharged, the resultant spark can have sufficient energy to
  ignite an ethylene oxide atmosphere. No spark is produced, but brushless
  motors in general have larger inductance than brushed motors. Discharge
  of the windings would most likely be caused by some form of upset and
  should be factored into the assessment.

- Other device factors:
  - Voltage transformers;
  - Current multipliers;
  - Capacitors that can increase the available energy;
  - Existence of battery isolation strip;
  - Sealed gas tight casing; and
  - Live wire leads.

- Impact of accidents or upset conditions -- Consider what happens if:
  - Device is misassembled (isolation tab missing);
  - Device is crushed during loading;
  - Random jostling or stray RF turns device on; or
  - Motor is jammed.

An overview of the specific criteria to consider in the safety evaluation is
included in the appended sample checklist.
As highlighted, ethylene oxide gas is highly flammable/explosive and circumstances in which ignition of ethylene oxide can occur must be avoided at all costs. If ethylene oxide sterilization is the only option for a battery-powered medical device, a thorough, detailed, and documented safety assessment must be conducted in order to justify an exemption that allows the device to be processed via ethylene oxide, despite its stored energy. The device manufacturer plays a key role in that evaluation.
### SAMPLE: POWERED COMPONENT SAFETY REVIEW CHECKLIST

<table>
<thead>
<tr>
<th>Item #:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vendor Name:</td>
<td>Power Source:</td>
</tr>
<tr>
<td>(include size if battery)</td>
<td></td>
</tr>
<tr>
<td>Sterilizer:</td>
<td>Other: ___________________________</td>
</tr>
<tr>
<td>(circle one)</td>
<td>Cycle ID: ________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Specifications and/or other design details attached?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the device exceed 5 amps at 12 volts?</td>
<td>YES*</td>
<td>NO</td>
</tr>
<tr>
<td>Does the device store any energy (e.g., capacitors)?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is there On/Off switch on the device?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is there an isolation tab to prevent the device from turning ON automatically?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Can the device activate during sterilization?</td>
<td>YES*</td>
<td>NO</td>
</tr>
<tr>
<td>Can the device exceed a known safe level of electrical potential or temperature that could ignite EO?</td>
<td>YES*</td>
<td>NO</td>
</tr>
<tr>
<td>Is the cycle non-flammable after EO inject?</td>
<td>YES</td>
<td>NO*</td>
</tr>
<tr>
<td>Is the cycle temperature acceptable for the battery?</td>
<td>YES</td>
<td>NO*</td>
</tr>
<tr>
<td>Are the cycle vacuum washes acceptable for the battery?</td>
<td>YES</td>
<td>NO*</td>
</tr>
<tr>
<td>Are the chemical components of the battery compatible with EO?</td>
<td>YES</td>
<td>NO*</td>
</tr>
<tr>
<td>Is an exothermic test required to confirm battery compatibility?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Does the device contain a motor?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>If yes, evaluate the energy that could be generated during sterilization before proceeding. Is energy &gt; 5 amps @ 12 volts?</td>
<td>YES*</td>
<td>NO</td>
</tr>
</tbody>
</table>

* Do not proceed. Device cannot be EO sterilized.
**Safety Review Conducted and Dispositioned By / Date**

<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>DATE</th>
<th>DISPOSITION (circle one)</th>
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Appendix 1: