Thermal Sterilization of EO-compatible Medical Devices

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Scope

- FDA has requested input on the subject of alternative technologies for sterilization of medical devices currently sterilized in ethylene oxide (EO) gas in an industrial setting
- This presentation explores the possibility of migrating those devices to steam or dry heat.

Basis of Presentation

- AAMI TIR17 addresses “Compatibility of materials subject to sterilization”
- The listing of materials shown as compatible with EO sterilization in Table 1 of that document is the basis of the listing and analysis presented here.
- The “rule-in/rule-out” process was based upon a compatibility in the AAMI document of “•••” or “••••”, with the latter preferred.

Background

- The decision to sterilize medical devices using EO is typically made for the following reasons:
  - Excellent product penetration
  - Reliability; established compatibility with the process and a long history of validated processing for the materials used
  - Cost; the size of industrial/contract sterilizer chambers enables economical sterilization

Materials Typically Sterilized In EO

- ABS
- PTFE
- PFA
- PCTFE
- PVF
- EFTE
- FEP
- Polyacetals
- Polyamides (nylons)
- Polycarbonates
- Polyesters
- Polyethylenes
- Polyimides
- Polyketones
- Polypropylenes
- Polysulfones
- PVC
- Epoxies
- Silicone
- Butyl
- EPDM
- Nitrile
- Styrenic Block Copolymers
- Cellulosics

Subset of Materials Which are Less Compatible with Radiation than EO

- PTFE
- PFA
- FEP
- Polyacetals
- Polyamides (nylons)
- Polypropylenes
- Silicone
- Butyl
- Styrenic Block Copolymers
- Cellulosics

Subset of Materials Which are Less Compatible with Steam or Dry Heat Than With EO

- Polyacetals
- Polyamides (nylons)- depends upon specific grade
- Polypropylenes
- Silicone-depends upon specific grade
- Butyl-depends upon specific grade
- Styrenic Block Copolymers
- Cellulosics

Potential Alternate Sterilization Methods for These Materials

• **Polyacetals**	• **Hydrogen Peroxide Vapor**
• **Polyamides (nylons)**	• **Hydrogen Peroxide Vapor (depends on grade)**
• **Polypropylenes**	• **Hydrogen Peroxide Vapor**
• **Silicones**	• **None listed**
• **Butyl rubber**	• **Hydrogen Peroxide Vapor (depends on grade)**
• **Styrenic Block Copolymers**	• **Hydrogen Peroxide Vapor**
• **Cellulosics**	• **None listed**

Thermal Sterilization vs. EO

- Thermal sterilization uses fairly small chambers
- Maintenance requirements of the equipment are similar to or less than those of EO sterilizers
- Cycles are much faster (total cycle time)
- Thermal burns and pressure vessel considerations are the only hazards

- EO uses large chambers and is well suited for bulk-quantity sterilization
- Cycles are long; conditioning and aeration add to the cycle duration
- EO is toxic

Steam vs. Dry Heat

- Steam Cycles are:
  - Relatively fast (~1-2 hours total)
  - Parametrically controllable
  - Run at 121-135°C
  - Penetrate loads well if prevacuum cycles are used
- Dry Heat Cycles are:
  - Slower (60-150 minute exposure plus heat up)
  - Less able to be parametrically controlled
  - Run at 150-170 °C
  - Potentially slow penetration through the load

Alternatives

- Material Compatibility of Mixed Materials may be questionable
- Deep vacuum for VH2O2 processing may compromise design integrity
- Some materials cannot be sterilized in these alternative methods.

Results of this Review

- There are a large number of polymers that can be migrated to thermal sterilization methods
- The details of specific device construction may constrain this migration
  - Examples of potential interferences in migration can include:
    - Physical incompatibility arising from thermally-induced effects like differential expansion of overmolded parts
    - Effects of moisture on the product, not just the heat
    - Effects of high temperature on the finished product in dry heat sterilization
- Changing the production model will be costly

Conclusions

- Some materials currently sterilized in EO cannot be migrated to radiation sterilization
- Some materials currently sterilized in EO cannot be migrated to steam of dry heat sterilization
- The effects of high-temperature sterilization can make migration of otherwise-compatible devices impossible
- The logistics and equipment for thermal sterilization differ greatly from EO and would take a lot of capital and time to implement if devices can be migrated to these methods

Thank you!

- Please feel free to contact us with any questions

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