AORN Recommended Practices for Sterilization

**RECOMMENDED PRACTICE V**
Ethylene oxide (EO) gas sterilization may be used for sterilization of heat and moisture-sensitive items.

**Interpretative statement 1**
Items should be clean and free of visible water droplets before packaging.

**Rationale**
Soil inhibits sterilization and moisture may produce toxic by-products that are not removed by aeration.

**Interpretative statement 2**
The manufacturer’s written instructions should be followed for loading the sterilizer.

**Rationale**
Sterilizers differ in design and operating characteristics. Items are placed in the sterilizer in baskets or on loading carts in a manner that allows free circulation and penetration of EO.

**Interpretative statement 3**
Documentation of cycle performance should describe the four essential parameters for sterilization:
- sterilant concentration,
- relative humidity,
- temperature, and
- exposure time.

**Rationale**
Ethylene oxide is an alkylating agent which, under the right parameters results in microbial death. Ethylene oxide is a sterilizing agent known for its hazardous and toxic nature.

**RECOMMENDED PRACTICE VI**
Items sterilized with EO must be properly aerated in a mechanical aerator.

**Interpretative statement 1**
When a combination sterilizer/aerator unit is used, both cycles must be completed before the items are removed.

**Rationale**
According to the AORN “Recommended practices for environmental responsibility in the practice setting”, EO is an occupational health hazard. It irritates the skin and mucous membranes. Personnel exposure to EO may result in cancer, reproductive abnormalities including genetic damage, and neurological disease. The Occupational Safety and Health Administration (OSHA) regards EO as a human carcinogen and a chemical that has the potential for causing adverse reproductive effects in humans. The Working Committee of the International Agency for Research on Cancer (IARC) voted to upgrade EO as a probable human carcinogen to humans. Nevertheless, it can be safely used under controlled conditions.

**Discussion**
Mixtures of EO and inert gases (e.g., carbon dioxide, fluorinated hydrocarbons) are used in health care facility EO sterilization procedures. Chlorofluorocarbons cause depletion of the ozone layer, and by the year 2000, chlorofluorocarbons no longer will be produced in the United States. Research on alternative ozone-shield-compatible, flame-retardant gases are being conducted by manufacturers and alternatives to EO have been released for marketing by the FDA. Users should be cognizant of federal, state, and local regulations regarding use.

**Interpretative statement 2**
When using a separate aerator unit, items should remain on the sterilizer cart or in a non-EO absorbent basket during transport. If a cart or table is used, it should be pulled rather than pushed during transfer, and transfer should be completed as quickly as possible. If it is necessary to handle individual items or any EO-absorbent material prior to complete aeration, butyl rubber gloves should be worn.

**Rationale**
To prevent personnel from breathing EO gas or coming into contact with EO residues, items must be handled as little as possible before aeration. Pulling rather than pushing the cart during transfer directs the flow of EO-contaminated air away for personnel.

**Butyl rubber gloves** provides protection to the skin when handling EO-contaminated items. Ethylene oxide absorbed into items represents a hazard to patients and personnel if not removed. Ethylene oxide outgases or diffuses from sterilized items over time. This process can be speeded up by raising the temperature of the item and by increasing the flow of air around the item.

**Interpretative statement 3**
Specific aeration time necessary for particular materials depends on many variables that include
- composition and size of the item,
- the preparation and packaging,
- type of EO sterilization system,
- aeration system, and
- temperature penetration pattern of the aerator chamber.

**Rationale**
Adequate aeration time must be allowed following sterilization so that residual EO can be reduced to a level safe for both patients and personnel.
STRAVING FOR EXCELLENCE IN ST. AUGUSTINES CSSD

Steri-view recently visited St. Augustines Hospital in Durban and spoke to the CSSD Unit Manager, St. Gail Grundling about the challenges that she has faced over the years in building up her department to the efficient, smooth running operation that it is today. Grundling, who is Theatre trained, starting working in the St. Augustines CSSD over 11 years ago for "selfish reasons" in that she found that the unsociable Theatre hours involved made it very difficult to spend enough time with her family.

Grundling reminisced: "In those days conditions were far from ideal as the CSSD was housed in the old mortuary, my desk was a mortuary slab, we shared the room with the ETO sterilizer and autoclaves were some distance away down the passage. Fortunately a custom designed CSSD was built one year later which incorporated the required safety and work flow features that are necessary in a modern CSSD".

“We are all under constant pressure to reduce operating costs throughout the hospital and the big challenge that I face in this regard is to ensure that the same standards of patient care are delivered if we consider using an alternative, less expensive product. While we very seldom come in direct contact with patients, we are constantly aware of the dangers that they face should any non-sterile item from our CSSD be used in their treatment. As there are very few SABS standards for the products commonly used in the CSSD, I have had to rely very much on my suppliers to provide me with information as to their product specifications and the relevant international standards that they comply with. I would never consider using a product, the quality of which the manufacturer does not fully warrant and which complies with the relevant performance standards".

“I have managed to establish good sterilization procedures for my department over the years and I am pleased to say that St. Augustines CSSD is quite often used as a referral point for other hospitals in the area. I am always pleased to receive calls from other CSSD Managers to discuss problems that they are encountering and also to share views on new ideas that they may have on sterilization topics as unfortunately we do not have the necessary forum for such interchange of ideas in Kwazulu-Natal".
Interpretative statement 4
Items should not be retrieved from the aerator until the aeration time has been completed.

Rationale
Adequate aeration is essential for patient and employee health and safety for minimizing the risk of occupational exposure.

RECOMMENDED PRACTICE VII
A programme for monitoring occupational exposure to EO must be established.

Interpretative statement 1
The monitoring program must comply with OSHA regulations.

Rationale
Compliance with standards ensures a safe work environment within federally mandated limits.

Interpretative statement 2
Initial baseline monitoring should be performed to determine accurately the airborne concentrations of EO to which personnel are potentially exposed. The specific OSHA regulations should be referenced related to personnel safety related to the use of EO.

Rationale
Monitoring and sampling ensure that environmental EO and concentration limits have not exceeded OSHA action level.

Interpretative statement 3
Qualified personnel trained in air sampling and monitoring techniques should supervise EO monitoring.

Rationale
Monitoring involves many factors. The frequency of EO use, the level and type of monitoring needed, and the availability of instrumentation dictate the need for qualified personnel to perform monitoring.

Interpretative statement 4
Documentation of EO environmental monitoring should be maintained for a period of time as determined by local, state, and/or federal regulations.

Rationale
Documentation establishes a continuous history of the work environment.

Discussion
Personnel health and safety procedures should be developed to ensure that employees are aware of the potential hazards associated with exposure to EO. Upon assignment and at least annually, each worker should be given the current information on the health effects of EO exposure. Additionally, recommended examinations, testing, and physical assessment should be carried out and documented according to current OSHA standards. To be in compliance with OSHA regulations, health care facilities should follow these regulations related to employee exposure.

RECOMMENDED PRACTICE VIII
Low temperature hydrogen peroxide plasma sterilization may be used for moisture stable and moisture-sensitive items.

Interpretative statement 1
Low temperature hydrogen peroxide plasma sterilization should be used and maintained according to the manufacturer’s written instructions.

Rationale
Low temperature hydrogen peroxide plasma sterilization may be used as an alternative to EO and many uses of steam in health care facilities. This type of sterilization system is nontoxic and provides an environmentally sound process. This technology requires neither personnel nor exhaust monitoring.

Discussion
In low temperature plasma technology, the presence of a strong electrified charge accelerates the molecules of hydrogen peroxide. When the electric field is created, electrons are “stripped” from some of the atoms and the charged particles are accelerated. As the stripped electrons recombine with atoms or electrons, return from higher to lower energy produces a visible glow. The free radicals in this plasma are known to be capable of interacting with cell membranes, enzymes, or nucleic acids to disrupt the life functions of micro-organisms.

Interpretative statement 2
Sterilizer function should be monitored with chemical and biological indicators to meet the monitoring standards for low temperature hydrogen peroxide plasma sterilization.

Rationale
The use of indicators provides information to demonstrate that the conditions for sterilization have been met. Biological monitoring for peracetic acid should be done according to the sterilizer manufacturer’s written instructions.

Interpretative statement 3
Items sterilized in an automated system using peracetic acid must be used immediately.

Rationale
Peracetic acid is an effective sterilizing agent that does not leave toxic residues when properly rinsed. Peracetic acid is a toxic chemical that can cause serious injury if not properly handled, neutralized and rinsed. Peracetic acid solutions are corrosive, but newer systems use anticorrosive solutions in the buffers to make the solution acceptable as a method of instrument sterilization.

Interpretative statement 4
Sterilizer function should be monitored with a biological indicator to meet monitoring standards.

Rationale
The use of indicators provides information to demonstrate that the conditions for sterilization have been met. Biological monitoring for peracetic acid should be done according to the sterilizer manufacturer’s written instructions.

Discussion
The manufacturer of the device should provide written instructions based on the packaging and storage requirements when using automated sterilization with peracetic acid.

Interpretative statement 4
Sterilizer function should be monitored with a biological indicator to meet monitoring standards.

Rationale
The use of indicators provides information to demonstrate that the conditions for sterilization have been met. Biological monitoring for peracetic acid should be done according to the sterilizer manufacturer’s written instructions.

Discussion
Differences of opinion exist within the scientific literature as to how the monitoring of liquid peracetic acid should be accomplished at this time. It is the responsibility of the individual practice setting to establish policies and procedures related to the use and implementation of this type of sterilization technology.
Re-use of Sterilization Wrap Cannot be Recommended

The practice of re-using sterilization wrap in order to reduce a hospital’s “non-chargeable” costs cannot be recommended as it may compromise sterile pack integrity by the following mechanisms:

- The efficacy of the steam sterilization process may be impaired through superheating and
- The microbial barrier properties of the sterilization packaging may be reduced.

It must be understood that with the exception of woven materials such as green linen and specially designed re-usable wraps, all types of sterilization packaging are manufactured and tested as single-use, disposable items. There are two fundamental reasons why re-use cannot be recommended:

Re-usable packaging material needs to be processed to maintain the properties required for sterilization. Maintenance of room temperature and moisture content of woven packaging is necessary for steam penetration and prevents superheating during the sterilization process. Superheating occurs when dehydrated fabrics are subjected to steam sterilization. The temperature of the fabric exceeds that of the surrounding steam by 8 to 11°C. The package or product becomes too dry and causes destructive effects on the strength of the cloth fibres.

It is obvious that single use sterilization wrap will not lend itself to being re-processed in the required fashion as this will lead to degradation of the product. In addition if a single use wrap is not re-processed the additional bioburden of the unlaunched wrap will cause additional challenges to the sterilization process.

Manufacturers of Cellulosic and Non-Woven Sterilization Wrap only warrant their products for single use

As all manufacturers of the above types of sterilization wrap design their products as disposable, they will only warrant their products performance with respect to compatibility with the sterilization process and microbial barrier properties for single use. It must be realised that if a hospital chooses to re-process such a single use item, the facility assumes full liability for the product.

References

1. Kennedy, Reichert, Thorsfeldt, “Packaging in the health care facility”, 43; L.Groah, Operating Room Nursing, Perioperative Practice, second ed (Norwalk, Conn: Appleton & Lang, 1990; Association or the Advancement of Medical Instrumentation, “ Good Hospital Practice: Steam Sterilization and sterility assurance,” 131.
2. Atkinson, Fortunato, Berry & Kohn’s Operating Room Technique, eighth ed, 554-556