

Ethylene Oxide Sterilization-Good, Bad or Damaging?

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Objectives:

1. Describe what Ethylene Oxide is.
2. Discuss what pieces of equipment are sterilized by EtO.
3. Discuss the emission standards for EtO.

Ethylene Oxide is a flammable, colorless gas at temperatures above 51.3 degrees F (10.7 C) that smells like ether at toxic levels. EtO is found in the production of solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam and pharmaceuticals. Smaller amounts can be found in fumigants and cosmetics. As all of you already know, EtO is used in our facilities to sterilize certain types of equipment that are considered to be too fragile for sterilization with steam.

EtO was originally used for the sterilization of spices as an insecticide. It wasn't until the early 1950's that Dr. Charles Phillips took the time to investigate the microbicidal potential of ethylene oxide. Because of his work, EtO is now used to sterilize at least 50% by the medical device manufacturers.

The way EtO works is by infiltrating not only the packages but the products themselves. Currently, EtO is the only methodology to sterilize items that

have lengthy ports. For example, it is possible to sterilize GI scopes via EtO. Currently this is the only method that can sterilize GI scopes without doing damage to the lenses, which would happen if the scopes were soaked in Gluteraldehyde. This is done in order to kill any microorganisms that are left during production or packaging processes. Items that contain rubber and plastic are especially susceptible to the uptake of ethylene oxide. As such, it is especially important that these items have the correct time in the aeration cycle in order to prevent potential problems to patients.

One of the most important parts for sterilization by EtO is the preparation of the instruments themselves. EtO has to have a straight shot through any piece of equipment it needs to sterilize. For the CS tech, this means that any piece of equipment that has multiple parts must be taken apart and cleaned thoroughly and then packaged so the OR tech can put all the pieces back together. This also means that all channels must be clear and there be a clear path to allow the gas to penetrate all cavities.

The EtO sterilization process involves at least three stages. These are pre-conditioning,

sterilization and aeration.

The pre-conditioning phase has to do with the load being held under a controlled environment of temperature and humidity. There are two good reasons for this. During the start of the pre-conditioning phase, the items to be sterilized are exposed to the EtO and are allowed to sit in order for the items to absorb as much gas as is possible. Temperature is regulated slowly increasing as the EtO is added in order to prevent excessive usage of the gas. This makes the load cost less of an issue.

The second stage involves the actual sterilization process itself. Most of the EtO sterilizers are built much like a steam sterilizer in that the outer portion of the sterilizer is called a jacket. Steam is actually pumped between the jacket and the innermost wall of the sterilizer. This allows the EtO sterilizer to maintain a consistent temperature for a longer period of time. The EtO is pumped into the chamber along with a certain amount of steam to keep the humidity up in the chamber as well as to make sure the EtO is getting to all parts of the equipment. The sterilization cycle can be as short as 4 hours or as long as 8 hours depending on the size of the sterilizer as well as the age of the unit.



The cycle temperatures are considered to be safer for the more fragile equipment or any piece of equipment that would be harmed by steam sterilization. This includes and is not limited to light cords, plastic instruments, Ophthalmic (eye) instruments, anesthesia or respiratory therapy equipment, electrical equipment and other rubber or silastic products. This makes it easier for the CS tech to do loads without having to heat the chamber each time a load needs to be done. Unless you have an older unit, most of the sterilizers today have an automatic cycle that goes through all the processes without any assistance from the staff.

The aeration cycle is considered to be an important part of the entire cycle. Without the gas being removed from the equipment, the potential for patient harm is great. If the sterilizer is automatic, the aeration cycle will automatically happen. If the sterilizer is older, the aeration cycle has to happen in another chamber. This means that one of the staff members must manually remove the items and put them in the aeration chamber. The temperature of the aeration chamber must be consistent in order to assist the removal of the gas. The cycles for the passive removal of the gas are much longer than the automatic version. This is to ensure that the gas has had a

sufficient time to evacuate from the equipment.

OSHA has designated EtO as a carcinogen (cancer causing). It is also considered to be harmful to an unborn fetus, therefore pregnant women or women considering pregnancy should be extremely aware of the effect of breathing EtO for an extended period of time or frequency. If the gassed items have to be moved from the sterilizer to an aerator, extreme care should be taken in the process. If the sterilizer has a purge cycle, care should be taken so that as soon as the purge cycle is finished, the items are transferred to the aerator. If there is a delay in the transfer, the degassing process will cause the EtO to build up in the chamber and the staff member that opens the door will be exposed to a higher concentration than is warranted. If there is no purge cycle, the sterilizer door should be opened to about 6-8 inches wide and the staff member should immediately leave the area until the room ventilation and exhaust systems remove most of the EtO from the surrounding air. If the staff member has to transfer the items from the sterilizer to the aerator, special precautions should be taken. Staff should wear neoprene gloves to prevent contact with the EtO and at the completion of the transfer, remove the gloves and wash hands well to remove any potential EtO residue.

According to OSHA, exposure should be limited to one part EtO per million parts of air

(1ppm) measured as an 8-hour time weighted average (TWA). There is something called the short-term excursion which is a 15 minute sampling period. The exposure for this must be limited to 5 ppm EtO as an average over any 15 minute period. These are called permissible exposure limits or PELs. These samples must be done on a yearly basis and a report is sent from the sampling company to the facility. These records must be kept for a period of not less than 30 years. The employee medical records must be kept for the duration of the employment plus 30 years. In the event exposures exceed either the PEL or the excursion limit, it is up to the facility to establish and implement a written compliance program to reduce exposures to or below the TWA and exposure limit. Training must also be established in order to insure the staff understand the exposure limits as well as what to do in case of an emergency exposure. The facility is also responsible for providing PPE to any staff member who is expected to come into contact with EtO, provide education as to rationale for PPE and consequences for not using PPE. As a staff member of CS, it is your responsibility to remember the ground rules for handling items needing to be sterilized with EtO and to watch out for your fellow team members and help them to take care.

Ethylene Oxide Sterilization

1. EtO is a flammable, colorless gas that smells like ether at toxic levels.
True False
2. Dr. Sam Phillips investigated the microbial potential of EtO.
True False
3. The preparation of the items to be EtO sterilized is considered to be one of the most important steps
True False
4. The three stages in EtO sterilization are: pre-conditioning, sterilization and distribution.
True False
5. During the pre-conditioning stage, the temperature is regulated, slowly increasing as the EtO is added in order to prevent excess usage of the gas.
True False
6. The cycle temperatures are considered to be safer for the more fragile instruments or equipment such as light cords, eye instruments and respiratory therapy equipment.
True False
7. The aeration cycle is not considered to be important to the sterilization cycle.
True False
8. OSHA has designated EtO as a carcinogen.
True False
9. Pregnant women or women thinking about becoming pregnant should be aware of the potential harmful effects of EtO on an unborn fetus.
True False
10. According to OSHA, it is OK for exposure to be 25 ppm as an average for a 15 minute exposure.
True False

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