Objectives

After completion of this self-study activity, the learner will be able to:
1. Explain the history and characterization of the two most prominent low temperature sterilization modalities used in United States (U.S.) hospitals and clinics.
2. Identify advantages and limitations of the two most prominent low temperature sterilization modalities used in U.S. hospitals and clinics.
3. Develop a working knowledge of the quality control practices and recognize the differences for the two most prominent low temperature sterilization modalities used in U.S. hospitals and clinics.

Test Questions

1. Ethylene oxide (EO) is the most widely utilized low temperature sterilization method in U.S. healthcare facilities and industry today?
   A. True  B. False

2. Both EO and hydrogen peroxide (H2O2) can be formed naturally and found in the environment?
   A. True  B. False

3. Hydrogen peroxide may be regarded as nature's own disinfectant and preservative?
   A. True  B. False

4. EO is currently used today safely on spices and agriculture products?
   A. True  B. False

5. An advantage of vaporized hydrogen peroxide sterilization systems is fast total sterilization cycle times?
   A. True  B. False

6. An advantage of ethylene oxide sterilization is excellent materials compatibility (least likely to damage medical devices) and good penetrability (no lumen restrictions)?
   A. True  B. False

7. Internal chemical indicators are not required for low temperature sterilization monitoring?
   A. True  B. False

8. Routine monitoring with a biological indicator (BI) is recommended at least daily for EO sterilization cycles?
   A. True  B. False

9. An Association for the Advancement of Medical Instrumentation (AAMI) defined BI process challenge device (PCD) is recommended for use in vaporized hydrogen peroxide sterilization systems for routine monitoring?
   A. True  B. False

10. The placement or location of the BI PCD inside the chamber for routine monitoring can be different for EO sterilization systems as compared to vaporized H2O2 systems?
    A. True  B. False
**Introduction**

The most prominent low temperature sterilization methods used today in United States (U.S.) healthcare facilities and industry is ethylene oxide (EO) and hydrogen peroxide (H\textsubscript{2}O\textsubscript{2}). It must be noted that steam sterilization is still by far the most prominent sterilization method used in the U.S. for sterilization of reusable medical devices, greater than 85% of reusable devices are sterilized with steam. With that said, low temperature sterilization methods will continue to be required because many critical reusable medical devices are made of materials and components that cannot withstand the tortuous high temperature and residual moisture prevalent in today’s steam sterilization processes.

EO continues to be the most widely used low temperature sterilization modality in the U.S. with H\textsubscript{2}O\textsubscript{2} the second most prominent low temperature sterilization method. Figure 1 illustrates the high percentage of EO use versus other sterilization modalities. This global data reflects both healthcare facilities and industrial use. The heat section of the pie chart on the left includes saturated steam and filtration sterilization. The pie chart on the right is a breakdown of the 63% chemical sterilization from the pie chart on the right. Radiation sterilization is not included in these charts.\textsuperscript{1,2}

There are many aspects one should have proficient understanding of to successfully employ either EO or H\textsubscript{2}O\textsubscript{2} low temperature sterilization methods routinely. The sterilizer manufacturer’s Operators Manual should be the primary reference for the proper use and function of any sterilizer. In addition, AAMI develops and maintains standard documents with recommended practices for both EO and gaseous H\textsubscript{2}O\textsubscript{2} sterilization. ANSI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness and ANSI/AAMI ST58:2005R Chemical sterilization and high-level disinfection in health care facilities provide valuable guidance to the users of these technologies.\textsuperscript{3,4}

This in-service will focus on U.S. healthcare facility applications of the low temperature sterilization methods of EO and H\textsubscript{2}O\textsubscript{2}. Since there are many important aspects of both sterilization methods, we will focus on a brief history and background, advantages and limitations, and conclude with similarities and differences in Quality Control for both of these methods.

**History and Background of Ethylene Oxide**

“Contemporary sterile processing of medical devices in the healthcare community using gaseous agent ethylene oxide (EO) developed as an outgrowth of its application in the fields of agriculture and industrial fumigation. EO is a chemical compound that reportedly was first discovered by Wurtz in 1859.\textsuperscript{5} EO was first used as a pest control and a fumigant for spices, gums, cereal and some foods in the 1930s.\textsuperscript{6,7} Considerable experimentation took place in the 1940’s and the 1950’s that demonstrated laboratory plastics, medical and biological preparations, hospital bedding, plastic bandages, medical instrumentation, surgical transplants, and many other items could be successfully sterilized using EO.\textsuperscript{6} The increased use of heat and moisture sensitive plastics and polymers in complex and critical medical devices dramatically increased the need for use of EO as a sterilization method. The first EO sterilizers for routine use in healthcare facilities in the U.S. were introduced in the late 1950’s and early 1960’s.

EO, sometimes referred to as oxirane, is the simplest cyclic ether. It is a colorless gas or liquid and has a sweet, etheric odor. EO has a high odor threshold, >250 parts per million (ppm). The structure of an EO molecule is shown in Figure 2.\textsuperscript{8}
“Ethylene Oxide is produced from a few natural sources. In certain plants, ethylene (a natural plant growth regulator) is degraded to ethylene oxide. EO is also a product of ethylene catabolism in certain microorganisms. Ethylene oxide can be generated from water-logged soil, cow manure, and sewage sludge. Quantitative estimates of production from these natural sources are not available, but emissions are expected to be negligible.”

Today, even though EO continues to be the most widely used low temperature sterilization modality in U.S. healthcare facilities and industry, medical use of EO is only a fraction of the use of EO in the U.S. EO is produced and consumed daily for a variety of products. “A versatile and valuable building block of chemistry, ethylene oxide and its derivatives help make many products we use every day, such as plastics, household cleaners, polyurethanes and ointments.”

Figure 3 on the right illustrates the extremely large scope of EO use in the U.S.

**Background and History of Hydrogen Peroxide**

“Hydrogen peroxide was discovered by the French chemist Thénard in 1818 while trying to produce chloride from the reaction of hydrochloric acid on barium dioxide.

He was surprised to find that oxygen was generated in the glass apparatus. After further studies he discovered a new combination of hydrogen and oxygen which he named eau oxygénée. This was first translated into English as ‘oxidized water’ but it is now known as hydrogen peroxide. In 1858 the English physician Richardson noted the ability of this substance to combat bad smells, considered at the time to be the manifestation of infection though there was no proof at that time that microorganisms were the cause of infections. It became a very popular antiseptic for the time, though it was considered to have limited applications due to instability at low concentrations and the peroxidase activity of living tissues. Since 1913 hydrogen peroxide has been used for the preservation of milk, water as well as fruity juices.”

Since it was first commercialized in the 1800’s, hydrogen peroxide production has now grown to over a billion pounds per year (as 100%). In addition to pollution control, hydrogen peroxide is used to bleach textiles and paper products, and to manufacture or process foods, minerals, petrochemicals, and consumer products (detergents). Its use for pollution control parallels those of the movement itself — municipal wastewater applications in the 1970’s; industrial waste/wastewater applications in the 1980’s; and more recently, air applications in the 1990’s. Today, hydrogen peroxide is readily available throughout the U.S. in drum, tote, mini-bulk, and bulk quantities in concentrations of 35% or 50% by weight.”

The typical concentrations for hydrogen peroxide used in a large scope of products is contained in Table 1.

**Table 1. Concentration of H₂O₂ for an array of products and applications**

<table>
<thead>
<tr>
<th>H₂O₂ Concentration</th>
<th>Products and Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;8%</td>
<td>Contact lens sterilizer (2%)</td>
</tr>
<tr>
<td></td>
<td>Over the counter pharmaceutical grade hydrogen peroxide (3%)</td>
</tr>
<tr>
<td></td>
<td>Hair bleach (7.5%)</td>
</tr>
<tr>
<td>8–20%</td>
<td>Pool shock (27%)</td>
</tr>
<tr>
<td>20–52%</td>
<td>Industrial strength – pulp and paper bleaching (20–52%)</td>
</tr>
<tr>
<td>52–91%</td>
<td>STERRAD® Cassettes for STERRAD® Sterilizers (58%)</td>
</tr>
<tr>
<td></td>
<td>VAPROX® HC Sterilant for STERIS® AMSCO®, V-PRO® Sterilizers (59%)</td>
</tr>
<tr>
<td></td>
<td>Rocket propellant (&gt;70%)</td>
</tr>
<tr>
<td></td>
<td>Specialty applications and uses (52-91%)</td>
</tr>
<tr>
<td>&gt;91%</td>
<td>Rocket propellant</td>
</tr>
</tbody>
</table>

Hydrogen peroxide is a clear colorless liquid and some say has a nitrous smell. The chemical formula for H₂O₂ can be represented as H–O–O–H. Development of hydrogen peroxide vapor devices for use in sterilization of reusable medical devices did not occur until the 1990s. Hydrogen peroxide may be regarded as nature’s own disinfectant and preservative. It is naturally present in milk, and in honey which helps to preserve spoilage, and it is an ordinary resident of tissues as a result of normal cell function. Furthermore hydrogen peroxide protects us from infection by invading pathogenic microorganisms. In the mouth, where it is present in the mucous membranes it acts as a powerful oxidant. H₂O₂ is produced by both animal and plant cells.
Hydrogen peroxide has been used safely in clinical settings for many years. The safe use in reprocessing and sterilization of medical devices is widely publicized in clinical documents and industry standards. Table 2 outlines some thoughtful points regarding the history and background of EO and \( \text{H}_2\text{O}_2 \).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>( \text{EO or H}_2\text{O}_2 ) or Both?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which sterilant was first discovered in the 1800’s?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant was first used in U.S. healthcare facilities in the 1950s?</td>
<td>EO</td>
</tr>
<tr>
<td>Which sterilant can be formed naturally &amp; is found in the environment?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant is naturally biodegradable in the environment?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant is used for preservation of milk, water, and fruity juices?</td>
<td>( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant is currently used today safely on spices and agriculture?</td>
<td>EO</td>
</tr>
<tr>
<td>Which sterilant in high concentrations is also used as rocket propellant?</td>
<td>( \text{H}_2\text{O}_2 )</td>
</tr>
</tbody>
</table>

**Advantages and Disadvantages of EO**

There are at least three renowned truths in sterilization:

1. Today there is still no ideal sterilant or sterilization method; there will always be a need for multiple types of sterilization processes.
2. All low temperature sterilants are toxic; after all their function is to kill or inactivate microorganisms.
3. All sterilants must come in direct contact with microorganisms to kill or inactivate them.

EO comes close to dispelling the first truth of sterilization as listed above. EO is known as the “Gold Standard” for low temperature sterilization. EO is the sterilization method for which all other low temperature sterilization methods are compared. There are only a couple aspects where EO may fall short as compared to other low temperature sterilization methods and these shortcomings may play little significance to most U.S. healthcare facility’s individual sterilization needs.

The advantages of ethylene oxide sterilization have been thoroughly researched and documented by many sources throughout the years. The advantages of ethylene oxide sterilization include:

- Superior materials compatibility: EO does not have a reputation of damaging devices.
- There are minimal design or device restrictions in regards to lumen length and lumen diameter. All endoscope types can be safely sterilized.
- Finally EO has a very low cost of operation on a cycle-to-cycle comparison basis to other low temperature sterilization methods used in the U.S. healthcare facilities.

EO sterilization improves patient safety with the capability to sterilize complex and sensitive critical patient care devices which cannot be terminally sterilized in any other method available on the market today. EO allows healthcare facilities to provide the patient with wrapped, terminally sterilized devices for every procedure.

The limitations of EO sterilization have also been thoroughly researched and understood. EO sterilization, including required aeration, necessitates long cycle times from start of the sterilization cycle to the time the operator can open the door after aeration is complete (e.g., an estimated 16-8 hours). In addition, because the toxicity of EO is so well understood there are U.S. Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) requirements that must be met to safely employ EO sterilization.

An important note is that EO is NOT being banned! In the next few months, only 100% EO will be available for use in the U.S. healthcare market. “The primary supplier of mixed EO gas is phasing out its line of Oxyfume® ethylene oxide sterilant blends, primarily used to sterilize hospital and laboratory equipment, by the end of 2013. The phase-out is in response to U.S. Clean Air Act regulations that will ban the sale and use of most HCFC-based products like Oxyfume in the U.S. as of Dec. 31, 2014. Oxyfume ethylene oxide sterilant blends have been widely used by healthcare facilities, laboratories and medical device manufacturers for more than 40 years. It is estimated that more than 70 percent of hospitals in the U.S. have used the product in their sterilization facilities, now only sterilizers utilizing 100% EO sterilants can be used in the U.S. healthcare market.” Access more detailed information about this phase out at: http://www.honeywell-sterilants.com/phaseout-info/.
Advantages and Disadvantages of \( \text{H}_2\text{O}_2 \)

In U.S. healthcare facility use, there are two types of vaporized hydrogen peroxide sterilization systems available on the market today for gaseous sterilization of reusable medical devices. One type of system utilizes hydrogen peroxide and plasma and the other unit merely vaporizes hydrogen peroxide. There is no magic to the plasma on the plasma units, little or no antimicrobial effect is gained from the plasma. The plasma simply helps facilitate off gassing of hydrogen peroxide from the packaging and devices.

The delivered vaporized hydrogen peroxide concentrations for the available systems range from 58% to 94% inside the chamber, on packaging and medical devices.

The advantages of vaporized hydrogen peroxide include:14
- Rapid antimicrobial efficacy, little aeration required, resulting in short cycle times and rapid instrument turnaround
- Non-toxic residuals or byproducts which leaves a perception of no toxicity

The disadvantages and limitations of vaporized hydrogen peroxide are understood as well.14
- Vaporized hydrogen peroxide is very difficult to drive down long narrow lumens of medical devices. Therefore all vaporized hydrogen peroxide sterilization systems have strict limits on the number and types of devices (e.g., endoscopes) that can be processed in the systems based upon material type, lumen length, and lumen inner diameter.
- In addition, vaporized hydrogen peroxide is one of the strongest oxidizers known to man, which results in excessive damage (e.g., cracking, crazing, discoloring and malfunction) of materials, packaging, and devices that are not compatible with vaporized hydrogen peroxide.

Careful consideration must be followed when selecting devices for sterilization in vaporized hydrogen peroxide systems. The sterilizer manufacturer’s Operators Manual should be the primary reference for guidance on devices, materials, and packaging that can be safely processed in the sterilizer. Table 3 below is a snap shot of the advantages and limitations of EO and \( \text{H}_2\text{O}_2 \).

<table>
<thead>
<tr>
<th>Advantages and Limitations</th>
<th>EO or ( \text{H}_2\text{O}_2 ) or Both?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which sterilant is toxic and users must follow the sterilizer manufacturer’s IFUs?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant is least likely to damage medical devices during processing?</td>
<td>EO</td>
</tr>
<tr>
<td>Which sterilant is efficacious on microbes including spores?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant requires aeration and or sterilant removal or off gassing?</td>
<td>Both EO &amp; ( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant has fast turn-around times and quick cycles?</td>
<td>( \text{H}_2\text{O}_2 )</td>
</tr>
<tr>
<td>Which sterilant has minimal to no restrictions on device lumen length &amp; inner diameters?</td>
<td>EO</td>
</tr>
<tr>
<td>Which sterilant is a strong oxidizer?</td>
<td>( \text{H}_2\text{O}_2 )</td>
</tr>
</tbody>
</table>

Table 3. Advantages and limitations of ethylene oxide (EO), hydrogen peroxide (\( \text{H}_2\text{O}_2 \)), or both sterilants?

Quality Control

Quality control of sterilization processes in U.S. healthcare facilities is a compilation of measures that are designed to work as a system. All components of the quality control measurement system must be available, performed, and valid for successful sterilization process monitoring. As described eloquently in ANSI/AAMI ST41:2008:

“An essential element of sterility assurance is sterilization process monitoring, which consists of
- Monitoring of every package and sterilization load (see Table 2 and 10.6)
- Routine monitoring of sterilizer efficacy (see Table 2 and 10.7)
- Sterilizer testing after sterilization process failures (see Table 2 and 10.6.4)
- Qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, and major repairs (see Table 2 and 10.8), and
- Periodic product quality assurance testing (see Table 2, 10.9, and 10.10)”13

*Sterilization process monitoring devices include physical monitors, chemical indicators, and biological indicators. Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance. Physical monitors verify that the parameters of the sterilization cycle have been met. Chemical indicators (CIs) verify that one or more conditions necessary for sterilization have been achieved outside or within the package and/or at a specific location within the load. Biological indicators (BIs) verify that the conditions at a location within the load were adequate to kill a
population of microorganisms resistant to the sterilization process and demonstrate lethality of the sterilization cycle. BIs and CIs are used within a process challenge device (PCD), an item that is designed to constitute a defined resistance to a sterilization process and used to assess the performance of the process. PCDs are commonly known as test packs, challenge packs, or load packs.3

As described in Section 10 of ANSI/AAMI ST41, there are comprehensive methods and tools for monitoring sterility assurance of a sterilization process, yet for low temperature sterilization processes of vaporized hydrogen peroxide and ethylene oxide the tools can be different and today are not yet standardized throughout the industry.

Physical Monitors

Physical monitors are the operator’s first line of defense for detecting sterilization assurance failures. All EO and H2O2 sterilizers currently approved for use in the U.S. healthcare industry have physical measurement sensors and computer controlled processes. Each of these systems has cycle performance parameters with tolerances that are monitored during each cycle and will alert the operator when a malfunction or a sterilization process failure has occurred. In addition, all of these cleared sterilization systems provide a print record of the cycle performance with indications of a successful process or completed process and indications of alarms and faults. At a minimum, the operator should mark the print record with correct date and sterilizer identification at beginning of cycle and read and verify by initializing at end of cycle. If not correct, do not release the load. The sterilizer manufacturer’s Operators Manual should be the primary reference for guidance on reading and interpreting print records of the cycle performance.

Chemical Indicators (CIs)

Chemical indicators, external and internal, to the packaged load items are valuable tools in detecting sterilization process failures and are critical in preventing the misuse of items that were never sterilized or items that never saw sterlant exposure. All EO and H2O2 sterilizers currently approved for use in the U.S. healthcare industry recommend the use of external and internal chemical indicators for every item in the load! It is important to note a difference between EO and vaporized H2O2 systems in regards to CIs.

Currently CIs designed for one type of vaporized H2O2 sterilization system cannot be used in a different vaporized H2O2 sterilization system unless clearly indicated in the sterilizer or CI manufacturer’s IFU. Even though two sterilization systems utilize H2O2 as the sterilant, a chemical indicator for Company A Sterilizer A is not designed or cleared by the FDA for use in Company B Sterilizer B. A majority of these FDA cleared CIs for H2O2 are manufactured by the sterilizer manufacturer.

This is contrary to EO where the majority of the external and internal CIs on the market are designed and labeled for all EO sterilization cycles. The CI manufacturer’s IFUs should be the primary reference for guidance on use, and interpretation of subject CIs.

Biological Indicators Process Challenge Devices (BI PCD)

Another striking difference between low temperature sterilization systems of EO and H2O2 is the BI PCDs recommended. The BI is a critical tool for monitoring the sterility assurance of all sterilization assurance processes. “Using BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs.”(AAMI Section 10.5.3.2)3

The biggest difference between BIs approved for vaporized hydrogen peroxide systems vs. ethylene oxide processes is the species of spores used in the indicators. The spore species are different because scientific evidence has demonstrated that different species of bacterial spores can survive longer or are more resistant to some sterilants as compared to other sterilants. BIs approved for vaporized hydrogen peroxide sterilizers contain the spores from the bacteria species Geobacillus stearothermophilus, the same spores utilized in steam BIs. BIs approved for EO sterilizers contain spores from the bacteria species Bacillus atrophaeus.

An important difference to note on BIs, similar to CIs for vaporized hydrogen peroxide systems, BIs cleared for use in vaporized hydrogen peroxide systems can only be used in that specific brand of sterilization system unless otherwise noted in the BI manufacturer’s IFUs. On the contrary cleared BIs for EO cycles are not cycle specific but are cleared for use with all EO sterilization cycles. The BI manufacturer’s IFUs should be the primary reference for guidance on the application and use of BIs.

Another important difference between biological monitoring for low temperature sterilization cycles between EO and vaporized hydrogen peroxide systems is the PCD (or lack thereof) that are cleared for routine monitoring use in the different systems. As you may recall Section 10.5.4 of ANSI/AAMI ST41 defines a process challenge device:

“A process challenge device is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. This recommended practice defines two types of PCDs:

a) a routine BI test pack (10.7.2) for use in routine biological monitoring of EO sterilization cycles (10.7) and in sterilizer testing after a sterilization process failure, malfunction, or major repair(10.6) and

b) a challenge BI test pack (10.8.2) for use in sterilizer qualification testing after installation, relocation, or major redesign (10.8)3

“A PCD may be a user-assembled test pack or a commercially available, preassembled test pack.”3

For routine efficacy monitoring for EO sterilization cycles there is a clearly defined and rationalized PCD for all EO cycles explicitly illustrated in ANSI/AAMI ST41. The standardized PCD for EO is replicated below from Section 10.7.2.
The PCD (routine BI test pack) should be made up as follows:

a) One BI should be placed in a plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe (Figure 3). The BI should not be removed from the protective covering supplied by the manufacturer. The instructions of the BI manufacturer should be consulted to ensure that the BI selected is appropriate for use in the specific sterilizer being monitored. The correct orientation of the BI in the syringe ensures that any vent in the BI faces toward the needle end of the syringe. (Paper strip BIs may be used in any orientation.) The needle end of the syringe should be open (i.e., the tip guard should be removed).

NOTE — Syringes to be used in patient care or laboratory applications are not customarily sterilized with the plunger inserted in the barrel.

b) The syringe and a CI should be placed in the folds of a clean, freshly laundered, preconditioned surgical towel (woven, 100% cotton huck, 18 inches by 30 inches), which has been folded lengthwise into thirds and then in thirds again to create nine layers (Figure 3).

c) These items should be placed in one peel pouch or one woven or nonwoven wrapper large enough to contain the test pack components and typical of that customarily used in the health care facility (Figure 3).

d) Before assembly, the test pack components should be held at room temperature (18°C to 24°C [65°F to 75°F]) and at a relative humidity of at least 35% for at least 2 hours. If the towel is inadvertently ironed, stored in an area in which the relative humidity is lower than 30%, or otherwise dried out, the minimum temperature and humidity equilibration time should be extended to 24 hours.

NOTE — Although the recommended humidity range for all work areas is 30% to 60%, ideal relative humidity in processing areas is 50% and should not be less than 35% for best results in achieving sterilization.

Rationale: This routine BI PCD presents a validated challenge to an EO process. The plastic syringe acts as an EO absorbent and penetration challenge. The BI represents a microbial challenge to the sterilization process. The towel absorbs heat and moisture. Placing the syringe within the folds of the towel presents the greatest challenge. This PCD (routine BI test pack) is not designed to represent as severe a challenge as the PCD (challenge BI test pack). It is presented as a simplified, alternative test pack that will facilitate more frequent monitoring of sterilization loads.

In the contrary, for vaporized H₂O₂ systems there is no standardized BI PCD described in national or international standards. It must be noted the method for biologically monitoring these systems was cleared for use by the FDA.

Both types of vaporized H₂O₂ systems, with and without plasma, describe their biological monitoring device for routine monitoring as a BI in a peel pouch or the BI for routine monitoring should be packaged in the same manner as the worst-case load items. Examples are pictured below in Figure 4 and Figure 5.

Currently there is no rationale or justification to describe or explain why there is no defined BI PCD or explanation how a peel pouch or routine device packaging entails additional resistance to the BI as clearly defined for EO in ANSI/AAMI ST41. A process challenge device is a device used to assess the “effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.” The concern is whether these biological monitoring devices meet this definition.
It should be noted, current vaporized hydrogen peroxide systems do have FDA cleared ‘Challenge Packs’ or ‘Test Packs’ that are not intended for routine monitoring but are to be used only for qualification testing after installation, relocation, and major repair of the sterilizer.

Another difference in biological monitoring is the frequency of use. For EO sterilization processes, every load monitoring (ELM) is the recommendation in Section 10.5.3.2 of ANSI/AAMI ST41 and in the sterilizers manufactures’ Operators Manuals for these systems in the U.S.³ For vaporized hydrogen peroxide systems there is less assurance with the recommendation per Section 9.5.4.3 of ANSI/AAMI ST58:2005:

“A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle.”³

The sterilizer manufacturer’s Operators Manuals should be consulted for the recommended frequency of biological monitoring but the trend in these manuals includes the following...Frequency of biological testing should be at least once per day or in accordance with your facility’s policy.... for each cycle type that is used in the facility.

For the same assurance of an effective low temperature sterilization process don’t you think every low temperature sterilization process should be tested with a BI PCD?

The last difference to detail is the placement (location in the sterilizer) of the BI for routine monitoring. For EO sterilization, it is clear and concise, place the BI in the worst case location in the sterilizer, which is in the center of the full load as illustrated in Figure 6.

Location of the BI for routine BI monitoring for the vaporized hydrogen peroxide systems is a little more confusing, each system has a different worst case location in the chamber. Placement in the back bottom of the chamber is suggested for some sterilizers, the top center for other sterilizers. It is very important to consult the sterilizer manufacturer’s Operators Manuals for the proper location of the BI PCD for routine BI monitoring in the load for vaporized hydrogen peroxide systems.

Table 4 Outlines some thoughtful points regarding quality control of EO and H₂O₂ sterilization processes.
In summary, ethylene oxide and hydrogen peroxide have a complex and rich history in the scientific and healthcare industries. The history of each sterilant demonstrates why they are both prominent low temperature sterilization modalities used in U.S. healthcare facilities. Both EO and H₂O₂ sterilization processes have distinguishing advantages and limitations. It is important that the potential user understand and weigh the advantages and limitations of each method before purchasing and use. Furthermore, the quality control practices have the same high level requirements as compared to other sterilization modalities but the application details can be quite different. Reading and understanding manufacturer’s IFUs and Operator’s Manuals is the most important practice to follow.

### Table 4. Is this a characteristic universal of ethylene oxide (EO), hydrogen peroxide (H₂O₂), or both sterilants?

<table>
<thead>
<tr>
<th>Quality Control</th>
<th>EO or H₂O₂ or Both?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which process requires users to follow manufacture’s IFUs and sterilizer manufacturer’s Operators Manual?</td>
<td>Both EO &amp; H₂O₂</td>
</tr>
<tr>
<td>Many chemical indicators for this gaseous process are brand and cycle specific?</td>
<td>H₂O₂</td>
</tr>
<tr>
<td>External and internal chemical indicators are required on all items in the load for this process?</td>
<td>Both EO &amp; H₂O₂</td>
</tr>
<tr>
<td>Per ANSI/AAMI ST41:2008, routine BI monitoring is required in a defined PCD for this process?</td>
<td>EO</td>
</tr>
<tr>
<td>BI monitoring is recommended daily or per our facilities policy for this process?</td>
<td>H₂O₂</td>
</tr>
<tr>
<td>A recognized acceptable PCD is documented in AAMI and in FDA consensus standards for this process?</td>
<td>EO</td>
</tr>
<tr>
<td>A BI in a peel pouch might be an acceptable practice for routine biological monitoring for this process?</td>
<td>H₂O₂</td>
</tr>
</tbody>
</table>

### Summary

In summary, ethylene oxide and hydrogen peroxide have a complex and rich history in the scientific and healthcare industries. The history of each sterilant demonstrates why they are both prominent low temperature sterilization modalities used in U.S. healthcare facilities. Both EO and H₂O₂ sterilization processes have distinguishing advantages and limitations. It is important that the potential user understand and weigh the advantages and limitations of each method before purchasing and use. Furthermore, the quality control practices have the same high level requirements as compared to other sterilization modalities but the application details can be quite different. Reading and understanding manufacturer’s IFUs and Operator’s Manuals is the most important practice to follow.
References

<table>
<thead>
<tr>
<th>Answers</th>
<th>Larry Talapa BS, MS, CQE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A</td>
<td>Larry Talapa has over 20 years of experience in the area of sterilization and is currently a Technical Service Specialist in 3M’s Infection Prevention Division. Larry has extensive experience as a Sterilization Microbiologist, responsible for the development, validation and control of ethylene oxide, steam, irradiation and gas plasma sterilization processes. Larry is a voting member of several AAMI working groups and is also a member of MHCSMA and IAHCSMM.</td>
</tr>
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<td>2. A</td>
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<td>3. A</td>
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<td>10. A</td>
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### Sterile Process and Distribution CE Information

<table>
<thead>
<tr>
<th>CE Applicant Name:</th>
<th>City:</th>
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<tbody>
<tr>
<td>Address:</td>
<td>State:</td>
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</tbody>
</table>

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at [www.sterileprocessing.org](http://www.sterileprocessing.org).

IAHCSMM has awarded 1.5 approved contact points for completion of this continuing education lesson toward IAHCSMM recertification.

### Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. Keep a copy for your records.
6. Submit this form and the answer sheet to:
   - 3M Infection Prevention
     - Attn: HC4160
     - RR Donnelly Fulfillment Services
     - 585 Hale Avenue North
     - Oakdale, MN 55128-9935
7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly’s receipt of the application.

### Application  Please print clearly or type.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Daytime phone: ( )</th>
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<tbody>
<tr>
<td>Mailing Address:</td>
<td>Position/Title:</td>
</tr>
<tr>
<td>City:</td>
<td>Social Security or Nursing License Number:</td>
</tr>
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<td>State:</td>
<td>Date application submitted:</td>
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<td>Zip Code:</td>
<td>Signature:</td>
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Offer expires September 2018

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