

Advances in Sterilization

NEWS AND OPINION IN THE ADOPTION OF NEW-GENERATION STERILIZATION TECHNOLOGY

Why Hospitals are Adopting New Sterilization Technologies

In recent years, increasing numbers of hospitals worldwide have adopted new sterilization technologies as replacements for older techniques such as ethylene oxide (EtO), formaldehyde, and other chemical sterilization methods. *Advances in Sterilization* interviewed **Ernest Allen, C.S.P., A.R.M.**, a safety and risk management consultant and District Manager for Ohio Hospital Insurance Company (OHIC), who discussed why hospitals are investing in new sterilization technologies. According to Allen, the inherent health risks of EtO to workers and patients, its flammability, and the need to cut sterilization and instrument costs while accelerating processing and turnaround time of sterile instruments are all key factors influencing hospitals to move away from EtO sterilization.

What's Wrong with EtO?

Although EtO has been relatively successful for low-temperature sterilization since it was introduced in the 1950s, efficacy has not come without significant trade-offs. "EtO is very effective," Allen said. "It's effective because it's deadly."

In 1978, the Environmental Protection Agency (EPA) declared EtO to be mutagenic, and in 1994, the International Agency for Research on Cancer reclassified EtO from a suspected to a recognized carcinogen. Allen noted that, because of these dangers, EtO systems require expensive state and federally mandated abatement and monitoring equipment to protect healthcare workers and patients. Protective garments for workers, industrial hygiene testing of the work area, employee and facility licensing, and proper retention of testing records are other requirements which may significantly affect costs.

Even with these protections, EtO leaks and accidental exposures occur. In his 17 years with OHIC, Allen said he has seen a number of hospitals that have experienced EtO leaks. "Some hospitals have had a leak and have had to evacuate the entire department and call out a team

of hazardous materials specialists," he said. As a result, healthcare workers are deeply concerned about the possibility of exposure. "Many hospital workers aren't comfortable working with ethylene oxide," Allen noted. "They know that EtO is a deadly gas that can cause cancer and other major health problems, so they're always nervous. If someone were to have a miscarriage in the department, the staff might wonder if it was related to the EtO."

In addition to the requirements for abatement and monitoring equipment, Allen noted that the Occupational Safety and Health Administration (OSHA) may require workers using EtO to comply with its Respiratory Protection Standard. "Workers who change the large gas cylinders used in EtO systems need special training, are required to wear respiratory protection equipment, and must undergo periodic pulmonary testing," he said. "If a hospital is not using ethylene oxide properly, OSHA can fine them \$20,000 for a spill, and another \$20,000 because the person who changed the tank didn't have a respirator on." Allen said that costs of OSHA fines have escalated nearly 700% during the past few years. Many hospitals have been cited for infractions regarding the use of respirators and EtO.

Banning CFCs and HCFCs

Fines from OSHA are only one example of rising regulatory costs associated with the use of EtO. In many systems, EtO is mixed with

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Mission Statement

Advances in Sterilization is a quarterly newsletter designed to present news and opinion about unique state-of-the-art sterilization technologies as well as reports of clinical and economic studies about their safety, speed, cost, and efficacy. Reader comments, questions, and suggestions are welcome.

Adopting New Technologies . . .

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chlorofluorocarbon (CFC), a diluent gas used to retard flammability. The creation of the 1987 "Montreal Protocol," a multinational document calling for a worldwide ban of ozone-depleting chemicals, led to a United States phase-out of CFC production. In 1989, the United States imposed a progressively increasing excise tax on CFCs to discourage use (see story below) with all production to cease by the end of 1995.

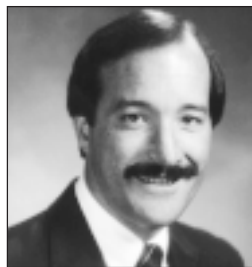
Hydrochlorofluorocarbons (HCFCs) were designed to temporarily replace CFCs in sterilizers that operate on a mixture of 12% ethylene oxide and 88% CFC-12 (Freon®) known as "12/88." A phase-out of HCFC production in the United States is scheduled to begin in 2004 with all production to cease by 2030.

Allen said that using pure EtO is a concern because of its flammability

and explosive properties and that it still requires hospitals to maintain high-cost monitoring and abatement equipment. Similarly, impending regulations and the possibility that excise taxes will soon be placed on HCFC production and use make retrofitting 12/88 systems for HCFC use a temporary and expensive solution. "In either case, worker safety would still be a serious issue," Allen noted.

Sterility Assurance: Disinfection vs. Sterilization

Beyond the equipment, training, and licensing costs associated with the use of EtO-based systems and the fines associated with their misuse are the costs related to the operation and efficiency of the sterilizers themselves. "With ethylene oxide, the sterilization process is complete in two hours,



"[Hospitals] stand to profit in many ways by proceeding with the adoption of new sterilization technology."

Ernest Allen

but you can't take the equipment out of the sterilizer for another 12 hours," Allen said. "You need an aeration cycle to pump out any remaining EtO since it would be hazardous to the hospital staff or the patient if any residue was left on the operating equipment."

According to Allen, such long processing times are not practical for today's hospitals. The increase in same-day surgeries over inpatient operations requires faster sterilization turnaround, or

throughput, to ensure that the proper instruments are available for each procedure. Consequently, some hospitals have resorted to the use of disinfection in lieu of sterilization because disinfection is significantly faster and cheaper. The problem, however, is that disinfection is not equivalent to sterilization. Sterilization is a process designed to kill all life forms, while disinfection is designed to kill vegetative (living) microorganisms—but not bacterial or fungal spores that resist disinfection.

At the 1994 International Symposium on Chemical Germicides in Health Care, participants from the Association for Professionals in Infection Control and Epidemiology noted that continuing problems of nosocomial infections often result from inadequate cleaning, inappropriate or ineffective disinfection, and failure to follow recommended disinfection practices, particularly for endoscopic instruments.

The Promise of New Sterilization Technologies

The issues of risk and expense are causing hospitals to abandon technologies born decades ago in favor of sterilizers based on new principles. Allen said that hospitals he visits are reporting positive experiences with these new systems. "Hospitals now can make sterilized instruments available more rapidly and cost effectively while enhancing worker and patient safety," he said. "They stand to profit in many ways by proceeding with the adoption of new sterilization technology." ❖

European Parliament Calls for Ban on HCFCs by 2003

The worldwide movement to ban hydrochlorofluorocarbons (HCFCs) is accelerating. The European Parliament (EP), a 518-member body elected by popular vote from each of the 12 countries represented in the European Union,* recently called for a production phase-out of HCFCs by 2003. Among other applications, HCFCs are used to retard flammability in many EtO-based sterilization systems. This deadline comes 12 years earlier than the original target date of 2015. The revised European goal is expected to have some impact in the United States, where HCFC production is slated to be phased out by 2030.

HCFCs were developed as a replacement for the chlorofluorocarbons (CFCs) used in many EtO systems. These chemicals are approximately 50 times less damaging to the ozone than CFCs, which are scheduled for a United States production phase-out by the end of 1995.

To curb CFC use prior to this cutoff date, the United States Congress levied a punitive excise tax on CFC use in 1989 that has escalated annually to a high this year of \$5.35 per pound. The trade publication *OR Manager* (August, 1994) reports that, as a result, a typical 300-bed hospital using an estimated 5,280 pounds of CFCs per year can expect to pay \$28,000 in taxes in 1995, compared to \$8,800 for the same level of usage in 1993. If the United States follows the lead of the EP, the date of 2030 for a phase-out of HCFCs mandated by the Clean Air Act may be revised, and healthcare facilities could soon be facing a similar tax for HCFC usage. ❖

* Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the United Kingdom

Hydrogen Peroxide Gas Plasma: Defining a New Technology

A hydrogen peroxide gas plasma sterilization system has been available in Europe since 1992 and has been available for use in American healthcare facilities since 1993. Key benefits over EtO and other low-temperature sterilization technologies include its rapid processing time (about one hour) and use of sterilizing agents that are non-toxic for both healthcare workers and the environment.

Plasma: 'The Fourth State of Matter'

Plasma, which occurs most often in outer space, has been referred to by scientists as the "fourth state of mat-

ter." Neither solid, liquid, nor gas, plasma is a cloud-like mixture of charged ions, electrons, and neutral atomic and molecular species produced by a strong electric or magnetic field. The *aurora borealis* or "northern lights" is an example of a naturally occurring plasma.

Peroxide Plasma Sterilization

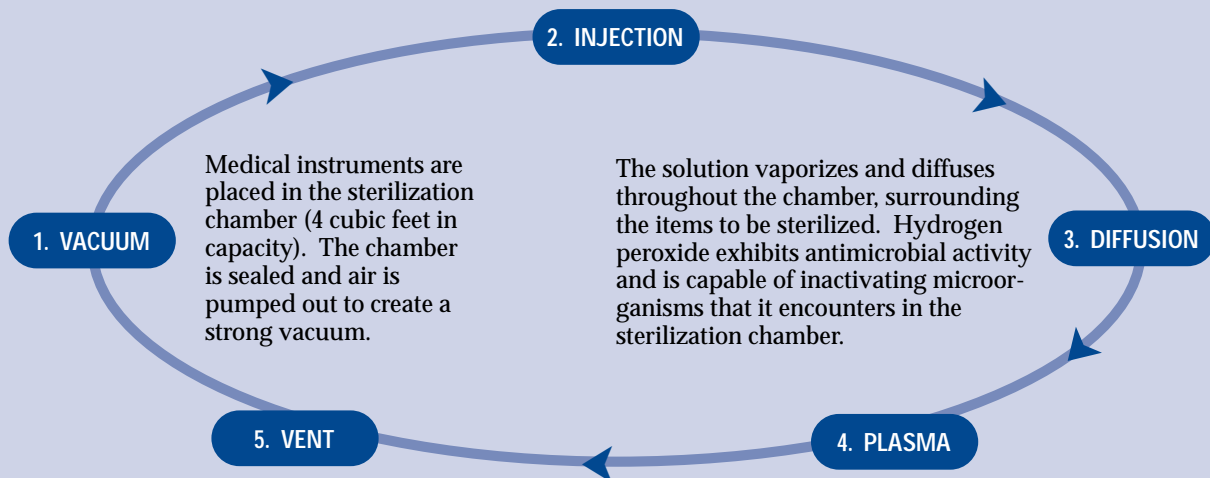
The plasma phenomenon has been adapted to form a key element of the hydrogen peroxide gas plasma sterilization system (see below). Since there are no toxic residues or emissions, sterilized items require no aeration period and can be used immediately after the completion of

the 75-minute process. An adapted 208-volt electrical connection is the only requirement for installation, making the system well-suited for placement wherever it is needed within the healthcare facility, including the surgical suite.

Studies performed by the manufacturer have shown the system to be effective for a majority of medical items traditionally sterilized by ethylene oxide, with the exception of linens and cellulosic materials, which can be easily and economically sterilized with steam. ❖

The Hydrogen Peroxide Gas Plasma Sterilization Process

A solution of 59% hydrogen peroxide and water (from a cassette inserted by the operator at the beginning of every 10 cycles) is automatically injected into the sterilization chamber.



Medical instruments are placed in the sterilization chamber (4 cubic feet in capacity). The chamber is sealed and air is pumped out to create a strong vacuum.

The solution vaporizes and diffuses throughout the chamber, surrounding the items to be sterilized. Hydrogen peroxide exhibits antimicrobial activity and is capable of inactivating microorganisms that it encounters in the sterilization chamber.

The RF energy is turned off, the vacuum is released, and the chamber is filled with filtered air, returning it to normal atmospheric pressure. After 10 sterilization cycles, the cassette self-ejects into an internal receptacle for future disposal.

Radio frequency (RF) energy is applied to create an electrical field, which in turn initiates the generation of the low-temperature plasma, i.e., a cloud of reactive and unstable species. These unstable particles collide with one another to produce a variety of new species, including free radicals, that, like the hydrogen peroxide vapor, are capable of inactivating any microorganisms, viruses, or spores that may be encountered within the sterilization chamber. In the plasma phase, the activated components ultimately lose their high energy and recombine to form primarily oxygen and water vapor. The combination of the diffusion pretreatment and plasma phases acts to sterilize while eliminating harmful residuals.

Case Report: Adapting to a New Sterilization Technology at UCLA Medical Center

After using EtO for 40 years, is it difficult for hospitals to select and adapt to a new sterilization technology? *Advances in Sterilization* asked **Clare Morningstar, R.N., B.S.N.**, Manager of Central Processing and Distribution at the University of California, Los Angeles (UCLA) Medical Center, to discuss her institution's experiences in implementing a new sterilization system.

The 500-bed UCLA Medical Center performs 10,000–12,000 surgical procedures annually according to Morningstar, who supervises a staff of 22 and is responsible for the decontamination, sterile processing, and sterile storage of medical and surgical instruments in the main operating suite at UCLA. Until July 1994, the hospital used "12/88" systems, which operate on a mixture of 12% ethylene oxide and 88% chlorofluorocarbon (CFC) gas, to sterilize the instruments.

In 1993, recognizing that the 1995 deadline for the phase-out of CFC production was fast approaching, UCLA began a search for alternative ways to sterilize heat- and moisture-sensitive items. "Although several new technologies were being developed, we found that only a few were commercially available and would meet our needs," Morningstar said.

UCLA chose a hydrogen peroxide gas plasma sterilization system because of the improvements it offered in worker and patient safety,

Morningstar said. "Because of EtO's flammability, the federal government and many states have stringent regulations governing its use. For example, in California, EtO sterilizers need to be confined and enclosed in a specific room separate from the EtO tanks which also require special storage," she said. "There are also strict EtO emission laws requiring hospitals to install abatement and monitoring equipment. Even so, I know of several hospitals that have had EtO leaks," she added.

Safety is no longer an issue with UCLA's new system, according to Morningstar. "You insert a hydrogen peroxide cassette and press a button to start the cycle," she said. "The peroxide plasma breaks down into water and oxygen, so there is no need for personnel monitoring or aeration of equipment after sterilization is complete."

Morningstar said it wasn't difficult to adapt to the new technology. "The major change involved using trays designed specifically for the new system," she said. "It was a matter of transferring the items that were normally sterilized by the ethylene oxide system to the trays needed for the hydrogen peroxide plasma

system." Installation was similarly easy, she added. "There are no toxic byproducts, so venting is not required. The system can be placed anywhere it is needed—all you need is a modified electrical outlet." UCLA typically runs 4–8 sterilization cycles per day with the new system, Morningstar said. "The cycle time is only an hour and fifteen minutes, very short compared with EtO systems that require approximately 12 hours of aeration per cycle. For hospitals with a limited inventory of instruments, a quick turn-around time can be very advantageous."

UCLA has been able to significantly reduce its use of EtO since installing the new system, Morningstar said. "We were processing two loads of instruments per day with EtO prior to installing the new system. Now we're down to one load, which may consist of only one or two items."

Morningstar said that UCLA uses an EtO system primarily for the few items, such as flexible endoscopes, that cannot yet be sterilized in the hydrogen peroxide plasma system. ❖



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Clare Morningstar

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