

ILLINOIS STATE MEDICAL SOCIETY

**Late Resolution A
(A-19)**

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Subject: Removing Ethylene Oxide as a Medical Sterilant from Healthcare

1 Whereas, on February 15, 2019, at 10:30 PM Michael Hawthorne in the Chicago
2 Tribune reported that “Gov. J.B. Pritzker’s administration on Friday banned [Sterigenics](#)
3 [from using ethylene oxide](#) at its Willowbrook sterilization plant, responding to an
4 intense public outcry about toxic air pollution that left surrounding neighborhoods with
5 some of the highest cancer risks in the nation.” Yet no action was taken with respect to
6 facilities in the Waukegan and Gurnee areas nor attention given to assuring the necessary
7 sterile medical supplies; and

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9 Whereas, ethylene oxide is a known human carcinogen as identified by the
10 International Agency for Research on Cancer (IARC) and USEPA. It is used for
11 sterilization of medical equipment that cannot be sterilized by steam. This process is
12 open to the workplace environment at various points allowing the escape of EtO into the
13 area and community. Safer substitution, therefore, should be considered, as alternatives
14 exist that are equally efficacious with respect to sterilization of non-metal products. [6]
15 While many hospitals have switched away from ethylene oxide due to the toxicities, an
16 estimated 80% of non-metallic medical equipment is still being sterilized with EtO at
17 industrial facilities before delivery [6]; and

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19 Whereas, only 0.05% of the annual production is used for sterilization,
20 sterilization and fumigation is where the highest exposure levels to workers and
21 communities have been measured. [6] Inhaling contaminated air exposes surrounding
22 communities to ethylene oxide when the gas is released from a sterilant facility; and

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24 Whereas, ethylene oxide exposure is associated with irritation of the respiratory
25 tract, eyes, and skin. [6] With direct contact it can cause burns, blistering, and
26 desquamation of the skin. It can also cause conjunctivitis and contact dermatitis. [6, 4]
27 Acute high-level exposure can cause asthma, and sensitization. [6, 4] It can lead to
28 peripheral neuropathy and central neurotoxicity including neuropsychological
29 abnormalities, and seizures. [4] In animals, exposure has been shown to cause
30 spontaneous abortion, preterm births, and reproductive toxicity in both males and
31 females [4][6]; and

1 Whereas, in 1984, the International Agency for Research on Cancer (IARC)
2 included ethylene oxide in its list as a probable carcinogen by 2008 with adequate
3 information available only in animals, microorganisms, and invitro. It has been shown
4 to induce sensitive, persistent dose-related frequency of chromosomal aberrations, sister
5 chromatid exchange in peripheral lymphocytes and micronuclei in bone-marrow cells
6 of exposed workers [4][14]; and

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8 Whereas, epidemiologic studies of humans in 2004, since reviewed by IARC and
9 USEPA, have documented EtO as a Class 1 known human carcinogen. EtO's
10 carcinogenic impact is due to its action as an alkylating agent and specifically has been
11 associated with malignancies of the breast, lymphatic and hematopoietic systems in
12 humans [6][18][19]; and

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14 Whereas, based on this new information, USEPA changed EtO's adult-based
15 inhalation unit risk from 0.0001 per microgram per cubic meter ($\mu\text{g}/\text{m}^3$) to 0.003 per
16 $\mu\text{g}/\text{m}^3$, a 30-fold increase in cancer potency. In Willowbrook, Illinois, this elevated the
17 additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be
18 exposed to EtO emissions from a local industrial sterilizing facility. This cancer risk
19 exceeds U.S. EPA's decision-making cancer risk range of 1.0×10^{-6} to 1.0×10^{-4} , and
20 adds to the lifetime background cancer risk of an average American of 1 in 3 people [24]
21 [25]; and

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23 Whereas, for community exposures no regulations exist save the USEPA's
24 advice with respect to carcinogenic risk and the need for action when the risk exceeds
25 the U.S. EPA's decision-making cancer risk range of 1.0×10^{-6} to 1.0×10^{-4} ; and

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27 Whereas, due to the impossibility of sterilizing these materials in an enclosed
28 system, safer substitution is the most effective means to address this problem of EtO
29 community exposures. As described by the industry consensus standards Association
30 for the Advancement of Medical Instrumentation, these include radiation sterilization,
31 hydrogen peroxide, nitrogen dioxide and hydrogen peroxide-ozone. The Federal Drug
32 Administration noted in 2016 that hydrogen peroxide was an alternative that they were
33 familiar with and invited applications for sterilization process reviews using this
34 chemical [23]; and

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36 Whereas, on February 19, 2019, the Chicago Medical Society adopted policy that
37 supports the substitution of ethylene oxide with less toxic alternatives that are currently
38 available, including hydrogen peroxide, steam, and other safer alternatives, which do
39 not release carcinogens into the workplace or community and allow no residual
40 exposures to the patient; the new policy directs CMS to urge the prevention of emissions
41 or the phase-out of EtO and replacement with other safer methods of sterilization in
42 health care; CMS policy also states that when health care facilities are evaluating

1 surgical and medical devices that require sterilization, in addition to effectiveness of the
2 device for best patient outcomes, that the facilities also be required to prioritize the
3 modes of sterilization for the highest degree of worker and environmental safety;
4 therefore, be it

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6 RESOLVED, that the Illinois State Medical Society (ISMS) adopt as policy and
7 urge, as appropriate, the substitution of ethylene oxide with less toxic alternatives that
8 are currently available, including hydrogen peroxide, steam, and other safer alternatives,
9 which do not release carcinogens into the workplace or community air and allow no
10 residual exposures to the patient, and that ISMS urge the prevention of emissions or the
11 phase-out of EtO and replacement with other safer methods of sterilization in health
12 care; and be it further

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14 RESOLVED, that ISMS adopt as policy and urge that when health care facilities
15 are evaluating surgical and medical devices that require sterilization, in addition to
16 effectiveness of the device for best patient outcomes, that facilities also be required to
17 prioritize the modes of sterilization for the highest degree of worker and environmental
18 safety; and be it further

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20 RESOLVED, that ISMS bring this resolution to the American Medical
21 Association (AMA) for adoption as policy and to urge, as appropriate, the substitution
22 of ethylene oxide with less toxic alternatives that are currently available, including
23 hydrogen peroxide, steam, and other safer alternatives, which do not release carcinogens
24 into the workplace or community air and allow no residual exposures to the patient, and
25 that AMA urge the prevention of emissions or the phase-out of EtO and replacement
26 with other safer methods of sterilization in health care; and be it further

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28 RESOLVED, that ISMS request that AMA adopt as policy and urge that when
29 health care facilities are evaluating surgical and medical devices that require
30 sterilization, in addition to effectiveness of the device for best patient outcomes, that
31 facilities also be required to prioritize the modes of sterilization for the highest degree
32 of worker and environmental safety.

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Ethylene oxide (EtO) is a chemical used to sterilize medical equipment in hospitals, healthcare facilities, and industrial settings. It is also used to fumigate items that cannot be sterilized by steam such as spices, cosmetics, and plastic devices. While over 95 percent of industrial use of EtO is for closed reaction to less volatile, explosive, and toxic derivatives such as ethylene glycol, 0.5% is used in sterilizing processes designed to kill bacterial and other living organisms. It is estimated that over 80% of medical supplies in the US composed of rubber or plastic are sterilized in this manner. Workers,

including those in health care, engaged in these activities and the surrounding communities are exposed on a regular basis.

The World Health Organization's International Agency for Research on Cancer (IARC) concluded in 2008 that ethylene oxide is a known human carcinogen. Data has shown that ETO causes lymphopietic and breast cancers, reproductive toxicity, central and peripheral neurologic damage, and sensitization. In 2016, the US Environmental Protection Agency, after 4 years and 2 external peer reviews, recognized ETO as a known carcinogen and readjusted its toxicity estimate. The FDA recognizes alternatives which are less toxic to accomplish the same sterilization tasks including but not limited to Hydrogen Peroxide. While not compromising patient care, the orderly substitution of less hazardous substances is recommended and the immediate control of releases utilizing best available technologies.

Fiscal Note:

N/A

Existing ISMS policy related to this issue:

ISMS fully supports patient safety initiatives and quality measures designed to improve medical outcomes. (HOD 2011; BOT 2012-FEB; Last BOT Review 2012)

ISMS encourages the development of national environmental contaminant bio-monitoring programs to track harmful chemicals and toxic agents. (HOD 2007; Last BOT Review 2014)

ISMS encourages health care professionals to frequently clean their stethoscopes and handheld devices between patient encounters, and urges that all locations where physicians practice have the appropriate cleaner or disposable options accessible for use to minimize the potential risk of nosocomial infection. (HOD 2015)