

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507
(A-19)

Introduced by: Illinois

Subject: Removing Ethylene Oxide as a Medical Sterilant from Healthcare

Referred to: Reference Committee E
(Leslie H. Secrest, MD, Chair)

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

10 Whereas, Only 0.05% of the annual production is used for sterilization, sterilization and
11 fumigation is where the highest exposure levels to workers and communities have been
12 measured. [6] Inhaling contaminated air exposes surrounding communities to ethylene oxide
13 when the gas is released from a sterilant facility; and
14

15 Whereas, Ethylene oxide exposure is associated with irritation of the respiratory tract, eyes, and
16 skin. [6] With direct contact it can cause burns, blistering, and desquamation of the skin. It can
17 also cause conjunctivitis and contact dermatitis. [6, 4] Acute high-level exposure can cause
18 asthma, and sensitization. [6, 4] It can lead to peripheral neuropathy and central neurotoxicity
19 including neuropsychological abnormalities, and seizures. [4] In animals, exposure has been
20 shown to cause spontaneous abortion, preterm births, and reproductive toxicity in both males
21 and females [4][6]; and
22

23 Whereas, In 1984, the International Agency for Research on Cancer (IARC) included ethylene
24 oxide in its list as a probable carcinogen by 2008 with adequate information available only in
25 animals, microorganisms, and invitro. It has been shown to induce sensitive, persistent dose-
26 related frequency of chromosomal aberrations, sister chromatid exchange in peripheral
27 lymphocytes and micronuclei in bone-marrow cells of exposed workers [4][14]; and
28

29 Whereas, Epidemiologic studies of humans in 2004, since reviewed by IARC and USEPA, have
30 documented EtO as a Class 1 known human carcinogen. EtO's carcinogenic impact is due to its
31 action as an alkylating agent and specifically has been associated with malignancies of the
32 breast, lymphatic and hematopoietic systems in humans [6][18][19]; and
33

34 Whereas, Based on this new information, USEPA changed EtO's adult-based inhalation unit risk
35 from 0.0001 per microgram per cubic meter ($\mu\text{g}/\text{m}^3$) to 0.003 per $\mu\text{g}/\text{m}^3$, a 30-fold increase in
36 cancer potency. In Willowbrook, Illinois, this elevated the additional lifetime risk of 6.4 cancers in
37 a population of 1,000 residents who could be exposed to EtO emissions from a local industrial
38 sterilizing facility. This cancer risk exceeds U.S. EPA's decision-making cancer risk range of 1.0

1 x 10⁻⁶ to 1.0 x 10⁻⁴, and adds to the lifetime background cancer risk of an average American of
2 1 in 3 people [24] [25]; and
3

4 Whereas, For community exposures no regulations exist save the USEPA's advice with respect
5 to carcinogenic risk and the need for action when the risk exceeds the U.S. EPA's decision-
6 making cancer risk range of 1.0 x 10⁻⁶ to 1.0 x 10⁻⁴; and
7

8 Whereas, Due to the impossibility of sterilizing these materials in an enclosed system, safer
9 substitution is the most effective means to address this problem of EtO community exposures.
10 As described by the industry consensus standards Association for the Advancement of Medical
11 Instrumentation, these include radiation sterilization, hydrogen peroxide, nitrogen dioxide and
12 hydrogen peroxide-ozone. The Federal Drug Administration noted in 2016 that hydrogen
13 peroxide was an alternative that they were familiar with and invited applications for sterilization
14 process reviews using this chemical [23]; therefore be it
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16 RESOLVED, That our American Medical Association adopt as policy and urge, as appropriate,
17 the prevention of ethylene oxide emissions and substitution of ethylene oxide with less toxic
18 sterilization alternatives that are currently available, including hydrogen peroxide, steam, and
19 other safer alternatives, which do not release carcinogens into the workplace or community air
20 and allow no residual exposures to the patient (New HOD Policy); and be it further
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22 RESOLVED, That our AMA adopt as policy and urge that when health care facilities are
23 evaluating surgical and medical devices that require sterilization, in addition to effectiveness of
24 the device for best patient outcomes, that facilities also be required to prioritize the modes of
25 sterilization for the highest degree of worker and environmental safety. (New HOD Policy)

Fiscal Note: Not yet determined

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