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

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

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

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

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

Whereas, Based on this new information, USEPA changed EtO’s adult-based inhalation unit risk  
from 0.0001 per microgram per cubic meter (μg/m3) to 0.003 per μg/m3, a 30-fold increase in  
cancer potency. In Willowbrook, Illinois, this elevated the additional lifetime risk of 6.4 cancers in  
a population of 1,000 residents who could be exposed to EtO emissions from a local industrial  
sterilizing facility. This cancer risk exceeds U.S. EPA’s decision-making cancer risk range of 1.0
x 10^{-6} to 1.0 \times 10^{-4}, and adds to the lifetime background cancer risk of an average American of
1 in 3 people [24] [25]; and

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

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

RESOLVED, That our American Medical Association adopt as policy and urge, as appropriate,
the prevention of ethylene oxide emissions and substitution of ethylene oxide with less toxic
sterilization alternatives that are currently available, including hydrogen peroxide, steam, and
other safer alternatives, which do not release carcinogens into the workplace or community air
and allow no residual exposures to the patient (New HOD Policy); and be it further

RESOLVED, That our AMA adopt as policy and urge that when health care facilities are
evaluating surgical and medical devices that require sterilization, in addition to effectiveness of
the device for best patient outcomes, that facilities also be required to prioritize the modes of
sterilization for the highest degree of worker and environmental safety. (New HOD Policy)

Fiscal Note: Not yet determined

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References:

& Environmental Medicine, 5e. New York, NY: McGraw-Hill Education. Retrieved from
Carcinogenic Risks to Humans: Volume 100F. Retrieved Jan 14, 2019 from
Carcinogenic Risks to Humans: Volume 100F. Retrieved Jan 15, 2019 from
2019.
and meta-analysis. PloS one, 9(2), e87347. doi:10.1371/journal.pone.0087347
https://www.cdc.gov/niosh/topics/hierarchy/default.html
22. The Association for the Advancement of Medical Instrumentation. AAMI TIR17:2017 pages 44-98.