

Ethylene Oxide Gas Sterilization

エチレンオキシドガス滅菌

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Outline 概要

- Ethylene oxide sterilization: advantage & limitation
EO滅菌： 利点と注意点
- Microbiocidal mechanism 微生物の殺滅機構
- Toxicity 毒性
- Work Environmental control 作業環境管理

EO Sterilization EO滅菌

Advantages 利点

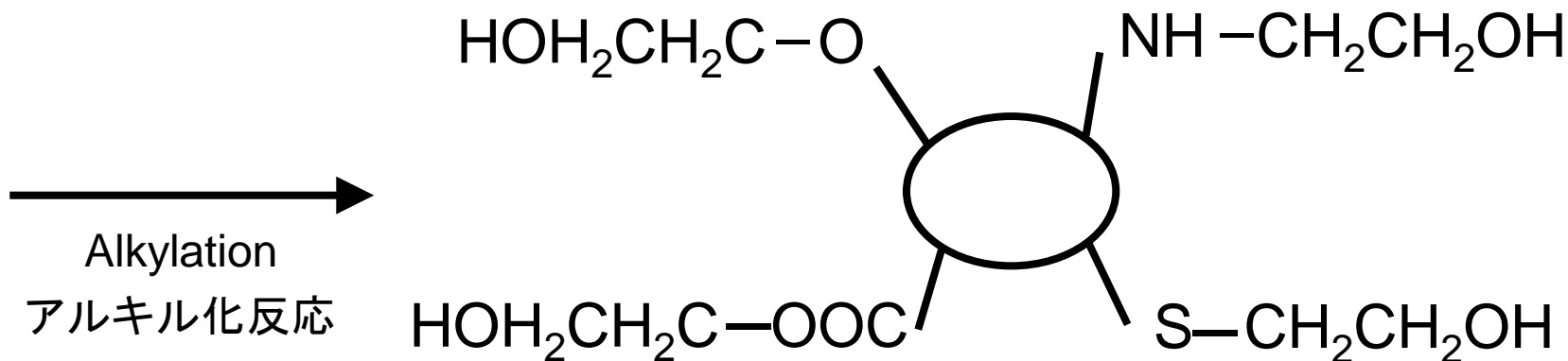
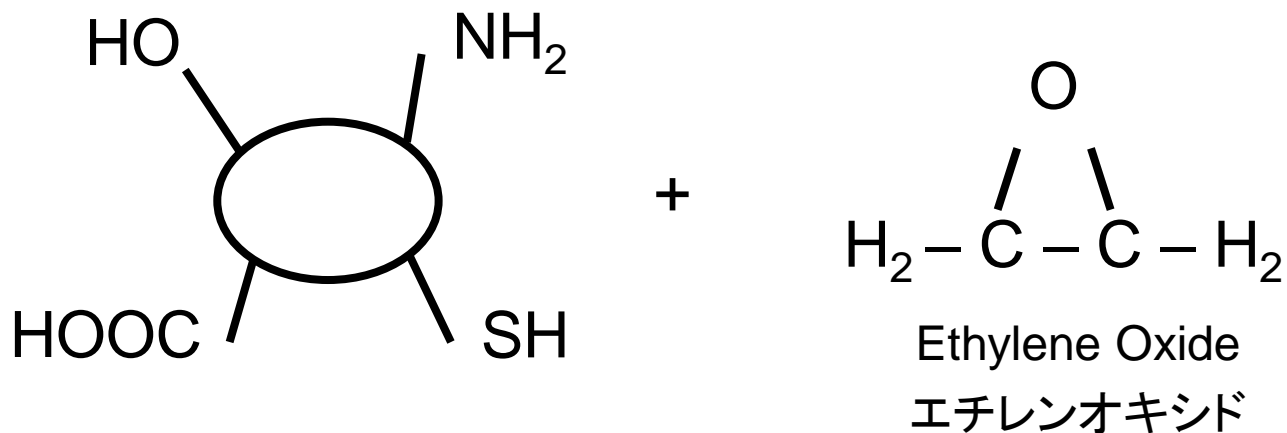
- Penetration 浸透力
 - Device construction 器材の構造
 - Load configuration 積載形態
- Material Compatibility 材質適合性
 - Device & instrument 器材
 - Packaging materials 包装材料
- Well understood & Long history (since 1960's)
1960年代からの豊富な知見と歴史
- Standardized 規格の整備
- Inexpensive 低コスト

Limitation 注意点

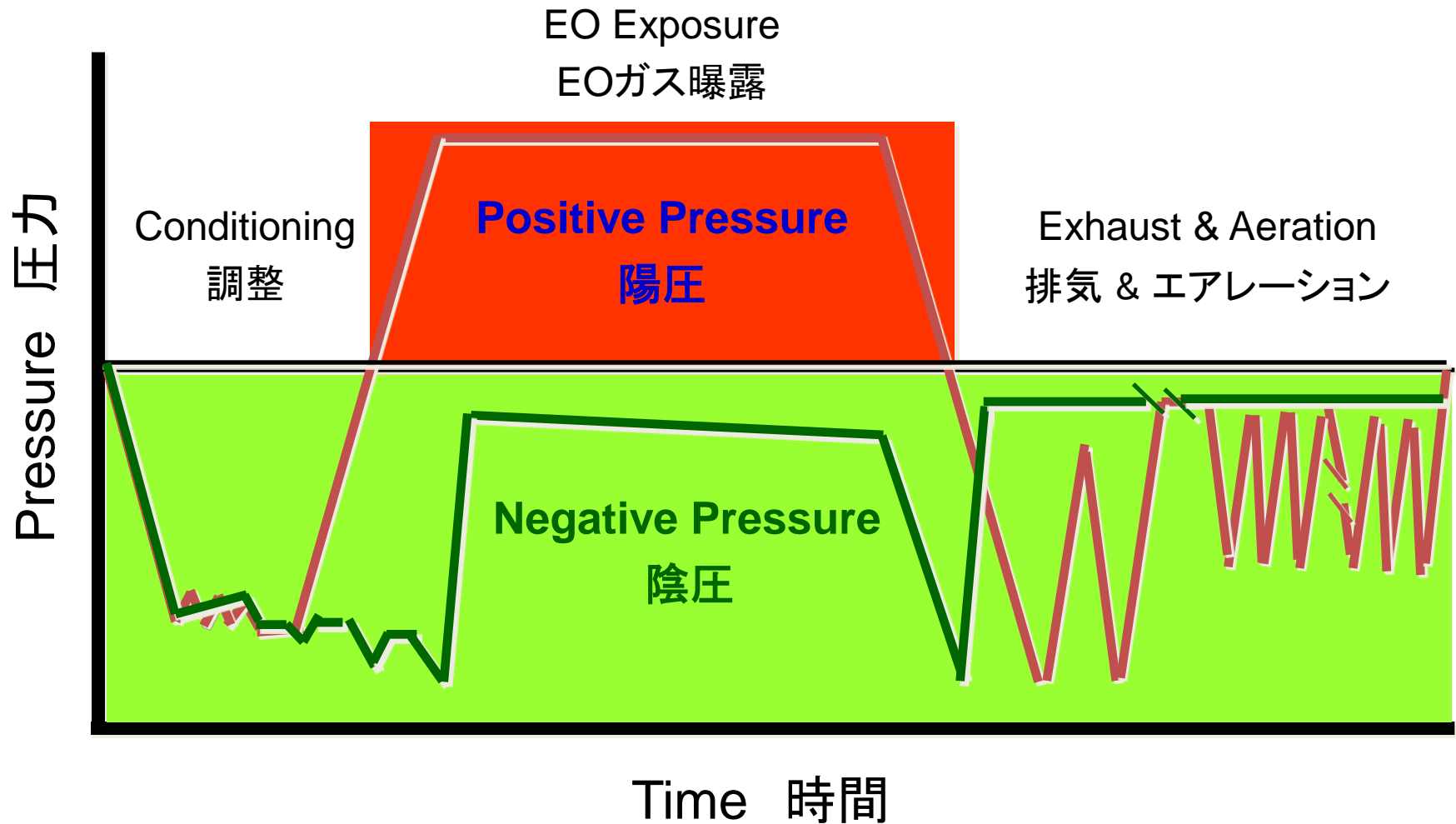
- Toxicity (other sterilants as well)
毒性(他の滅菌剤と同じく)
- Flammability 可燃性
- Longer cycle time for aeration
長いサイクル時間

How to kill microorganisms

EOG滅菌の仕組み



EO Sterilization Processes EO滅菌プロセス



EO toxicity EOの毒性

EO is toxic and well known carcinogen.

EOは毒性があり、発がん性物質として知られている

Does EO have an extraordinary greater toxicity compared to other sterilants?

他の滅菌剤と比べて特別に毒性が強い?

NO !

Sterilant Toxicity 滅菌剤の毒性

Sterilant	US OSHA	US NIOSH
	8hr TWA*	IDLH**
EO	1 ppm	800 ppm
H ₂ O ₂	1 ppm	75 ppm
Formaldehyde	0.75 ppm	30 ppm

OSHA: Occupational Safety and Health Administration

*** TWA: Time Weighted Average**

NIOSH: National Institute for Occupational Safety and Health

**** IDLH: Immediate Danger to Life and Health**

(the lower the value the greater the concern for health and life)

Work Environmental Control 作業環境管理

- US OSHA 米国労働安全衛生局

1984 8 hr TWA 8時間荷重平均限界 1 ppm (0.0001%)

Action Level 実施レベル 0.5 ppm

1988 15 min TWA 15分間荷重平均限界 5 ppm

- JPN Ministry of Health and Labor Welfare 厚生労働省

2001 Control Limit 管理濃度 1 ppm

Recommended aeration conditions

推奨エアレーション条件

- Based on aeration of PVC tubing
塩ビチューブを用いた試験結果に基づく
- Recommended by AORN, AAMI, AHA, JSMI
多くの関連学会/団体からの推奨
 - 60 °C 8 hours
 - 55 °C 10 hours
 - 50 °C 12 hours
 - 38 °C 32 ~ 36 hours

How does the US OSHA TWA work? (US NIOSH study)

New England Journal of Medicine 1991;324;1402-1407



Actual number of deaths among EO workers (app 18,000 personnel)
EOG滅菌従事歴のある人の疾患(実数)



Expected number of deaths in similar segment of general population
一般市民の疾患(人数を緑色と揃えた場合)

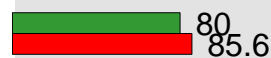
Hematopoietic Cancers 白血病



Brain Cancer 脳腫瘍



Digestive Cancer 消化器系がん



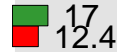
Respiratory Cancer 呼吸器系がん



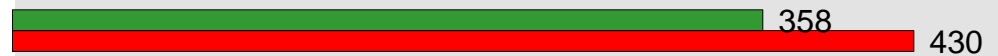
Breast Cancer 乳がん



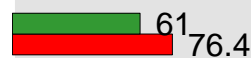
Urinary Cancer 膀胱がん



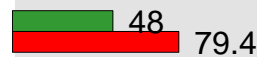
Heart Disease 心臓疾患



Nonmalignant Digestive Disease
消化器系疾患



Nonmalignant Respiratory Disease
呼吸器系疾患



Nonmalignant Genitourinary Disease
泌尿生殖器疾患



US NIOSH study update 2003

Findings of the NIOSH Ethylene Oxide Studies

Summary of the recent NIOSH Ethylene Oxide (EO) Studies

Purpose	To determine if exposure to EO is related to cancer or other diseases.
Subjects	18,235 men and women exposed to EO from 14 sterilizer plants around the country. Most of these workers used EO to sterilize medical supplies and treat spices. These were the largest studies ever conducted on EO exposure and the risk of disease.
Findings	No overall elevated risk for any type of cancer or other diseases as compared to the general U.S. population. However, among those workers with very high EO exposures, (combination of exposure levels and years worked); there was evidence of an elevated risk for blood cancers among men and breast cancers among women.
Conclusions	Persons exposed to very high levels of EO may be at an increased risk of developing blood cancers among men and breast cancers among women. Since 1985, when the new OSHA EO standard went into effect, worker EO exposures have been significantly lowered, which has reduced the risk of disease.

作業者曝露の発生状況 (US FDA MAUDE)

- Adverse events due to EO sterilization

EO滅菌作業に起因する有害事象

- Nov 22, 2009 ~ Nov 22, 2012

2009年11月22日 ~ 2012年11月22日

– “Injury” 健康被害 3 cases 3件

– “Malfunction” 故障 2 cases 2件

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm>

EO sterilization summary まとめ

- Rigid and simple method 確実かつシンプルな滅菌法
- Applicable to most of instruments and wrapping materials
ほとんどの器材と包装材料を使用できる
- Longer aeration times エアレーションに長時間を要する
- Safe operation 安全に使用できる