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**GENERAL PERMIT TO INSTALL FOR
ETHYLENE OXIDE STERILIZERS**

BACKGROUND

On May 28, 1997, the Michigan Department of Environmental Quality (MDEQ), Air Quality Division (AQD), issued a general permit to install for ethylene oxide (EtO) sterilizers. This general permit, issued pursuant to R 336.1201a promulgated pursuant to Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Rule 201a), provides a streamlined permitting alternative for affected facilities which meet the specified applicability criteria and allows facilities more operational flexibility. Prior to approval, the MDEQ held a 30-day public comment period to receive comments on the proposed general permit. A public hearing was not requested and the MDEQ received no written comments during the comment period.

EMISSIONS

EtO sterilizers are commonly used at hospitals to sterilize and fumigate medical equipment. At the end of the sterilizing cycle, the sterilant gas, which is often a mixture of EtO and an inert gas, such as a hydrochlorofluorocarbon (HCFC), is discharged from the sterilizer chamber. All emissions occur intermittently with the worst hourly emissions taking place during the initial evacuation of the sterilizer. Following the initial evacuation, the sterilizer chamber is purged several times to remove all residual gas. The general permit requires all exhaust gases from the sterilization and aeration processes be vented to an acid-water scrubber or catalytic oxidation unit that is guaranteed by the manufacturer to reduce EtO emissions to the atmosphere by at least 99.9%.

The table below shows the emissions that are allowed pursuant to the terms and special conditions of the general permit. The annual limits are based on a 12-month rolling time period as determined at the end of each calendar month.

Pollutant	Hourly Emissions (pounds / hour)	Annual Emissions (tons / year)
VOC	0.006	0.0008 (1.69 pounds/year)
HCFC	62.3	9.0
Individual HAPs		
EtO	0.006	0.0008 (1.69 pounds/year)

VOC = Volatile Organic Compound emissions include EtO

HAPs = Hazardous Air Pollutants

AMBIENT AIR IMPACTS

Operation of EtO sterilizers and aerators under the terms and conditions of the general permit to install will impact the ambient air as summarized in the following table. These impacts were calculated using a maximum emission rate and a worst case dilution factor based on modeling results

of nine different hospitals. The intermittent nature of the emissions was taken into consideration in calculating the maximum predicted ambient impact. Because the general permit limits the EtO usage rate for all sterilization processes at the source, the predicted impacts of EtO were compared to the Secondary Risk Screening Level (SRSL) as defined in R 336.1119(c). The predicted impacts of the inert gas were compared to the Initial Threshold Screening Level (ITSL) for HCFC-124.

Pollutant	Averaging Time	Acceptable Impact	Basis	Predicted Maximum Impact
EtO	Annual	0.3 $\mu\text{g}/\text{m}^3$	Rule 225(2) - SRSL	0.0267 $\mu\text{g}/\text{m}^3$
Inert Gas	24 hour	5000 $\mu\text{g}/\text{m}^3$	Rule 225(1) - ITSL	2772 $\mu\text{g}/\text{m}^3$

$\mu\text{g}/\text{m}^3$ = microgram per cubic meter

REVISIONS

The AQD may revise or update a general permit to install for various reasons, including administrative changes (i.e., addresses, contacts, formatting), clarifying instructions or permit language, or correcting an underlying applicable requirement. These types of minor changes are made without a comment period because they do not affect the applicability criteria or the special conditions of the general permit.

The general permit for ethylene oxide sterilizers has been revised and/or updated as follows:

- July 20, 1999 – added alternative methods of drawing a vacuum and evacuating the sterilizer chamber, if the alternative method prevents any discharge of EtO to a wastewater stream.
- March 20, 2000 - addressed applicability for a source, process or process equipment that may be identified in a consent order or consent judgment. Deleted the Stack or Vent Information form (EQP5728) and moved information to the Process Information form (EQP5730).
- September 29, 2000 - included a new version of the General Information form (EQP5727) and revised General Condition language.
- January 2002 and January 2003 - updated General Conditions and made minor administrative changes (i.e., addresses, formatting, etc.).
- February 12, 2004 – changed format of the Special Conditions and removed the temperature recording requirement for catalytic oxidizers.
- December 2010 – updated General Information and Process Information forms (EQP5727 and EQP5730)

If a change or revision will affect the applicability criteria or special conditions of the general permit, the MDEQ will hold a public comment period to receive comments on the proposed changes. If the applicability criteria or special conditions become less stringent as a result of the change (e.g., a setback requirement relaxed from 1000 feet to 500 feet; a reporting requirement reduced from daily to monthly), sources operating under an existing general permit will be notified of the change and allowed to operate under the revised criteria, which can be downloaded from the internet. A source operating under an existing general permit to install will not be required to meet the new requirements if the applicability criteria or special conditions become more stringent as a result of the change.

The most recent version of the general permit is available on the AQD Permit website at <http://www.deq.state.mi.us/aps/>. All changes to the general permit are summarized in the Background document.