# OREGON DEPARTMENT OF ENVIRONMENTAL QUALITY

# GENERAL AIR CONTAMINANT DISCHARGE PERMIT

# ATTACHMENT

Department of Environmental Quality
Air Quality Division
Air Operations Section
700 NE Multnomah Street, Suite 600
Portland, OR 97232
Telephone: (503) 229-5696

This permit is being issued in accordance with the provisions of ORS 468A.040 and OAR 340-216-0062.

**ISSUED BY THE DEPARTMENT OF ENVIRONMENTAL QUALITY**

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| Signed Copy on File with DEQ | April 16, 2020 |
| Ali Mirzakhalili, Air Quality Division Administrator | Dated |

Hospital ethylene oxide sterilizers subject to 40 C.F.R. part 63 subpart WWWWW, as adopted under OAR chapter 340 division 244.

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# 1.0 ATTACHMENT ASSIGNMENT

## 1.1. Qualifications

The permittee must meet all of the following conditions in order to qualify for assignment to this General Air Contaminant Discharge Permit (ACDP) Attachment:

a. The permittee is a hospital performing sterilization of medical equipment using ethylene oxide as listed on the cover page of this permit;

b. A Simple or Standard ACDP is not required for the source; and

c. The source is not having ongoing, reoccurring or serious compliance problems.

## 1.2. Assignment

DEQ will assign qualifying permittees to this attachment that have and maintain a good record of compliance with DEQ's Air Quality regulations and that DEQ determines would be appropriately regulated by a General ACDP. DEQ may rescind assignment if the permittee no longer meets the qualifications in Condition 1.1 above, conditions of OAR 340-216-0060, or the Conditions of this attachment.

## 1.3. Permitted Activities

Until this permit expires, is modified, or is revoked, the permittee is allowed to discharge air contaminants from processes and activities directly related to or associated with the air contaminant source(s) listed on the first page of this attachment in addition to any categorically insignificant activities, as defined in OAR 340-200-0020, at the source. Discharge of air contaminants from any other equipment or activity not identified herein is not authorized by this attachment.

# 2.0 NESHAP 5W APPLICABILITY

## 2.1. 40 C.F.R. Part 63 Subpart WWWWW – Emission Standards for Hospital Ethylene Oxide Sterilizers

The permittee must comply with all applicable provisions of 40 C.F.R. 63.10382 – 63.11048 for all affected emissions to which this subpart applies by the applicable date in 63.10384. The permittee must also comply with all applicable provisions of 40 C.F.R. Part 63, Subpart A – NESHAP General Provisions. For a full text of the federal standard, please refer to 40 C.F.R. Part 63, Subpart WWWWW.

NESHAP Subpart WWWWW is adopted and incorporated by reference in OAR chapter 340 division 244.

# 3.0 SPECIFIC PERFORMANCE AND EMISSION STANDARDS

## 3.1. Ethylene Oxide Sterilizers

The permittee must sterilize full load of items having a common aeration time, except under medically necessary circumstances. Medically necessary means circumstances that a central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

### 3.2. Control Devices

The permittee must install and operate an air pollution control device for all ethylene oxide sterilizers prior to using more than 50 pounds of ethylene oxide in any 12 consecutive calendar month period. Air pollution control devices must be certified by the manufacturer to at least 99% control efficiency.

The permittee must:

a. Operate and maintain the control device(s) in accordance with the manufacturer's recommended operation and maintenance procedures;

b. Repair any control device malfunction or defect within 30 calendar days of detection.

   i. If the permittee cannot return the control device to normal operation within 30 days, the permittee must retain documentation explaining the reason for the delay (e.g. emails or phone logs with service providers establishing timelines and schedules, work orders, service receipts, etc.).

   ii. The permittee must retain documentation demonstrating the date repair or replacement was completed.

## 4.0 COMPLIANCE DEMONSTRATION

### 4.1. Initial Compliance Demonstration

A new permittee must demonstrate initial compliance upon startup of the sterilization unit by submitting an Initial Notification of Compliance Status in accordance with Condition 6.1.

### 4.2. Continuous Compliance Demonstration

The permittee must demonstrate continuous compliance by operating and maintaining the air pollution control device at all possible times.

For permittees without an air pollution control device and for any sterilization cycles completed while a control device is not operational, the permittee must:

a. Record the date and time of each sterilization cycle; and

b. Record whether each sterilization cycle contains a full load of items. For any sterilization cycles conducted without a full load of items, the permittee must acquire and retain a statement from a hospital central services staff, a hospital administrator, or a physician that concludes conducting a sterilization cycle without a full load was medically necessary.

## 5.0 RECORDKEEPING REQUIREMENTS

### 5.1. Operation and Maintenance

The permittee must keep the following records:

a. A copy of the Initial Notification of Compliance Status;

b. The total amount of ethylene oxide gas, in pounds, used per month;

c. The total number of sterilization cycles per month and the number of sterilization cycles per month conducted without an air pollution control device in operation;

d. For each sterilization unit and air pollution control device, the permittee must retain the manufacturer's recommended operation and maintenance procedures for as long as ethylene oxide is used at the source.
   i. The permittee must retain documentation demonstrating that the manufacturer's recommended maintenance procedures have been followed and completed as recommended.

e. For permittees without an air pollution control device and for any sterilization cycles completed while a control device is not operational, documentation demonstrating compliance with Condition 4.2.

### 5.2. Retention of Records

Unless otherwise specified the permittee must retain all records for a period of at least five (5) years from the date of each report or record and make them available to DEQ upon request. The permittee must maintain at least the two (2) most recent years of records onsite or otherwise readily available electronically for expeditious review during an on-site inspection.

## 6.0 REPORTING REQUIREMENTS

### 6.1. Initial Notification of Compliance Status

A new permittee must submit an Initial Notification of Compliance Status within 180 days of startup. A form for this purpose is available from DEQ. The notification must comply with NESHAP WWWWW (40 C.F.R. §63.10430). The notification must be sent to DEQ and the U.S. EPA.

| Hard Copy Required | Hard Copy or Email Required |
|---|---|
| Oregon DEQ<br>ATTN: Air Operations<br>700 NE Multnomah St. Suite 600<br>Portland, OR 97232 | Hard Copy:<br>U.S. EPA, Sector Policies and Programs Division<br>Coatings and Chemicals Group (E143–01)<br>ATTN: Hospital Sterilizers Project Leader<br>Research Triangle Park, NC 27711<br><br>Email:<br>CCG-ONG@epa.gov |

### 6.2. Annual Report

The permittee must submit to DEQ by **February 15** of each year this permit is in effect, two (2) copies of the following information for the previous calendar year:

a. The number of sterilization cycles conducted during each calendar month;
   i. Identification of how many sterilization cycles were conducted without an air pollution control device in operation;

b. The total amount of ethylene oxide, in pounds, used during the previous calendar year;

c. The height of the stack exit point for ethylene oxide emissions;

d. A statement certifying that all air pollution control devices, if installed, were operated and maintained according to manufacturer's recommended procedures;

e. A description, or negative declaration, of any permit deviations or malfunctions that had potential to cause an increase in emissions;

f. List of changes made in plant processes, production levels, equipment changes, materials used, and pollution control equipment. Identify which changes affected air contaminant emissions; and

g. List major maintenance performed on pollution control equipment.

### 6.3. Initial Startup Notice

The permittee must notify DEQ in writing of the date a newly permitted source is first brought into normal operation. The notification must be submitted no later than seven (7) days after the initial startup.

### 6.4. Where to Send Reports and Notices

Reports, with the permit number prominently displayed, must be sent to the DEQ Permit Coordinator for the region where the source is located unless otherwise specified.

Once DEQ's online portal Environmental Data Management System, 'Your DEQ Online' is available for this permit, the permittee will be directed to submit any reports, notices, applications, or fees required by this permit within the online system or through the addresses and information provided at that time. Until the online portal is available for this permit, the permittee must use the established Permit Coordinator contact information.

## 7.0 ADMINISTRATIVE REQUIREMENTS

### 7.1. Reassignment to the General ACDP Attachment

A permittee that wishes to continue assignment to this General ACDP attachment must submit to DEQ an application for reassignment as follows:

a. The application must be received by DEQ within 30 days prior to the expiration date listed on the permit;

b. The application must be sent to the appropriate regional office; and

c. The permittee may submit an application for a Simple or Standard ACDP at any time, but the permittee must continue to comply with the General ACDP Attachment until DEQ takes final action on the Simple or Standard ACDP application.

## 8.0 FEES

### 8.1. Annual Compliance Fee

The annual fees specified in OAR 340-216-8020, Table 2, are due on or by **December 1** of each year this attachment is in effect. Invoices indicating the amount, as determined by DEQ regulations, will be mailed prior to the above date. **Late fees in accordance with Part 5 of the table will be assessed as appropriate.**

## 9.0 GENERAL CONDITIONS AND DISCLAIMERS

### 9.1. Conflicting Conditions

In any instance in which there is an apparent conflict relative to conditions in this permit, the most stringent conditions apply.

### 9.2. Attachment Availability

The permittee must have a copy of the attachment available at the facility at all times.

# 10.0 ABBREVIATIONS, ACRONYMS, AND DEFINITIONS

| | | | |
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| ACDP | Air Contaminant Discharge Permit | NESHAP | National Emissions Standards for Hazardous Air Pollutants |
| AQMA | Air Quality Maintenance Area | NSPS | New Source Performance Standard |
| calendar year | The 12-month period beginning January 1st and ending December 31st | OAR | Oregon Administrative Rules |
| CAO | Cleaner Air Oregon | ORS | Oregon Revised Statutes |
| C.F.R. | Code of Federal Regulations | O&M | operation and maintenance |
| DEQ | Oregon Department of Environmental Quality | PSEL | Plant Site Emission Limit |
| ECO | Employee Commute Options program | SIC | Standard Industrial Code |
| EPA | US Environmental Protection Agency | Special Control Area | as defined in OAR 340-204-0070 |
| FCAA | Federal Clean Air Act | VOC | volatile organic compound |
| HAP | Hazardous Air Pollutant as defined by OAR 340-244-0040 | year | A period consisting of any 12- consecutive calendar months |
| NA | not applicable | | |

| Term | Definition |
|---|---|
| Air Pollution Control Device | means a catalytic oxidizer, acid-water scrubber, or any other air pollution control equipment that reduces the quantity of ethylene oxide in the effluent gas stream from sterilization and aeration processes. |
| Full load | means the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation in the sterilization unit. |
| Hospital | means a facility that provides medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis. |
| Hospital central services staff | means a healthcare professional, including manager and technician, who is either directly involved in or responsible for sterile processing at a hospital. |