



**OREGON DEPARTMENT OF ENVIRONMENTAL QUALITY**

**GENERAL**

**AIR CONTAMINANT DISCHARGE PERMIT**

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 340-216-0060.

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**ISSUED BY THE DEPARTMENT OF ENVIRONMENTAL QUALITY**

Signed Copy of File with DEQ  
Ali Mirzakhali, Air Quality Division Administrator

April 16, 2020  
Dated

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

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## **1.0 PERMIT 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):

- 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 permit 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 permit.

### **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 permit 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 permit.

### **1.4. Relation to Local Land Use Laws**

This permit is not valid in Lane County, or at any location where the operation of the permittee's processes, activities, or insignificant activities would be in violation of any local land use or zoning laws. For operation in Lane County, contact Lane Regional Air Protection Agency for any necessary permits at (541) 736-1056. It is the permittee's responsibility to obtain local land use approvals as, or where, applicable before operating this facility at any location.

## **2.0 GENERAL EMISSION STANDARDS AND LIMITS**

### **2.1. Visible Emissions**

The permittee must comply with the following visible emission limits:

- a. Visible emissions must not equal or exceed an average of 20 percent opacity;
- b. The visible emission limitation in this condition is based upon a six-minute block average of 24 consecutive observations recorded at 15-second intervals as specified in OAR 340-208-0110(2); and
- c. The visible emission standard in this condition does not apply to fugitive emissions from the source.

### **2.2. Fugitive Emissions**

The permittee must comply with the following: [OAR 340-208-0210]

- a. The permittee must take reasonable precautions to prevent particulate matter, including fugitive dust, from becoming airborne from all site operations from which it may be generated;
- b. The permittee must not allow visible fugitive particulate emissions to leave the permittee's property for a period or periods totaling more than 18 seconds in a six-minute period;
- c. Compliance with the fugitive emissions standard in Condition 2.2.b is determined by EPA Method 22 at the downwind property boundary; and

- d. If requested by DEQ, the permittee must develop and implement a fugitive emission control plan to prevent any visible emissions from leaving the property of a source for more than 18 seconds in a six-minute period as determined by EPA Method 22.

### **2.3. Particulate Matter Fallout**

The permittee must not cause or permit the emission of any particulate matter larger than 250 microns in size at sufficient duration or quantity, as to create an observable deposition upon the real property of another person.

### **2.4. Nuisance and Odors**

The permittee must comply with the following nuisance and nuisance odor requirements, as applicable:

- a. The permittee must not cause or allow air contaminants from any source to cause a nuisance. Nuisance conditions will be verified by DEQ personnel. [OAR 340-208-0300]
- b. When operating in Clackamas, Columbia, Multnomah, and Washington Counties, control apparatus and equipment, using the highest and best practicable treatment currently available, must be installed and operated to reduce to a minimum odor-bearing gases or odor-bearing particulate matter emitted into the atmosphere. [OAR 340-208-0550]

## **3.0 NESHAP 5W APPLICABILITY**

### **3.1. 40 C.F.R. Part 63 Subpart WWWW – 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 WWWW.

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

## **4.0 SPECIFIC PERFORMANCE AND EMISSION STANDARDS**

### **4.1. Ethylene Oxide Sterilizing and Full Loads**

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.

### **4.2. 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; and

- 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.

## **5.0 COMPLIANCE DEMONSTRATION**

### **5.1. 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 7.1.

### **5.2. 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.

## **6.0 RECORDKEEPING REQUIREMENTS**

### **6.1. 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 5.2.

**6.2. Compliant Log**

The permittee must maintain a log of all complaints received that specifically refer to air pollution, odor, or nuisance concerns associated with the permitted facility. The permittee must investigate the condition within 24 hours, if possible.

The log must include at least the following for each complaint or concern received:

- a. The date the complaint was received;
- b. The date and time the complaint states the condition was present;
- c. A description of the complaint;
- d. The location of the complainant or receptor relative to the plant site;
- e. The status of plant operations and activities during the complaint’s stated time of pollution or odor condition;
- f. A description of the permittee’s actions to investigate the validity of the complaint; and
- g. A description of any actions taken in response to the complaint investigation.

**6.3. 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.

**7.0 REPORTING REQUIREMENTS**

**7.1. 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 WWWW (40 C.F.R. §63.10430). The notification must be sent to the appropriate DEQ office as listed in Condition 8.3 and the U.S. EPA.

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

**7.2. 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. Summary of complaints relating to air quality received by the permittee during the year;
- f. A description, or negative declaration, of any permit deviations or malfunctions that had potential to cause an increase in emissions;
- g. 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
- h. List major maintenance performed on pollution control equipment.

**7.3. Notice of Change of Ownership or Company Name**

The permittee must notify DEQ in writing using a DEQ "Transfer Application Form" within 60 days after any of the following:

- a. Legal change of the name of the company as registered with the Corporations Division of the State of Oregon; or
- b. Sale or exchange of the activity or facility.

**7.4. Construction or Modification Notices**

The permittee must notify DEQ in writing using a DEQ "Notice of Intent to Construct Form," or other permit application form, and obtain approval in accordance with OAR 340-210-0205 through 340-210-0250 before:

- a. Constructing, installing, or establishing a new stationary source that will cause an increase in any regulated pollutant emissions;
- b. Making any physical change or change in operation of an existing stationary source that will cause an increase, on an hourly basis at full production, in any regulated pollutant emissions; or
- c. Constructing or modifying any air pollution control equipment.

**7.5. 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.

**7.6. Where to Send Reports and Notices**

Reports, with the permit number prominently displayed, must be sent to the Permit Coordinator for the region where the source is located as identified in Condition 8.3 unless otherwise specified.

## 8.0 ADMINISTRATIVE REQUIREMENTS

### 8.1. Employee Commute Options Program

Sources located inside the Portland Air Quality Maintenance Area (AQMA) with more than 100 employees at a work site must comply with the Employee Commute Options Program requirements located in OAR 340-242-0020 through 340-242-0390.

For forms (Fact Sheet, Registration, or Survey Guidance documents) or questions regarding ECO, please contact the ECO program directly at 503-229-6154 or [ECO@deq.state.or.us](mailto:ECO@deq.state.or.us).

Additional information is available from DEQ's website for the ECO program located here:

<https://www.oregon.gov/deq/aq/programs/Pages/ECO.aspx>

### 8.2. Reassignment to the General ACDP

A permittee that wishes to continue assignment to this General ACDP 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 this permit;
- b. The application must be sent to the appropriate regional office identified in Condition 8.3; and
- c. The permittee may submit an application for either a Simple or Standard ACDP at any time, but the permittee must continue to comply with the General ACDP until DEQ takes final action on the Simple or Standard ACDP application.

### 8.3. Permit Coordinator Addresses

All reports, notices, and applications must be directed to the Permit Coordinator for the area where the source is located. The Permit Coordinator addresses are as follows:

Counties	Permit Coordinator Address and Telephone
Statewide	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 addresses and information identified below.
Clackamas, Clatsop, Columbia, Multnomah, Tillamook, and Washington	Department of Environmental Quality Northwest Region 700 NE Multnomah St., Suite 600 Portland, OR 97232-4100 Telephone: (503) 229-5582 <a href="mailto:NWRaqPermits@deq.state.or.us">NWRaqPermits@deq.state.or.us</a>
Benton, Coos, Curry, Douglas, Jackson, Josephine, Lincoln, Linn, Marion, Polk, and Yamhill	Department of Environmental Quality Western Region 4026 Fairview Industrial Drive Salem, OR 97302 Telephone: (503) 378-8240 ext. 225 <a href="mailto:WRaqPermits@deq.state.or.us">WRaqPermits@deq.state.or.us</a>

Baker, Crook, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Klamath, Lake, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, Wheeler	Department of Environmental Quality Eastern Region 475 NE Bellevue, Suite 110 Bend, OR 97701 Telephone: (541) 388-6146 ext. 223 <a href="mailto:ERaqPermits@deq.state.or.us">ERaqPermits@deq.state.or.us</a>
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#### 8.4. DEQ Contacts

Information about air quality permits and DEQ's regulations may be obtained from DEQ's web page at <http://www.oregon.gov/DEQ/>. All inquiries about this permit should be directed to the regional office for the area where the source is located. DEQ's regional offices are as follows:

Counties	Office Address and Telephone
Clackamas, Clatsop, Columbia, Multnomah, Tillamook, and Washington	Department of Environmental Quality Northwest Region 700 NE Multnomah St., Suite 600 Portland, OR 97232-4100 Telephone: (503) 229-5263
Benton, Lincoln, Linn, Marion, Polk, and Yamhill	Department of Environmental Quality Salem Office 4026 Fairview Industrial Drive Salem, OR 97302 Telephone: (503) 378-8240
Coos, Curry, and Western Douglas	Department of Environmental Quality Coos Bay Office 381 N Second Street Coos Bay, OR 97420 Telephone: (541) 269-2721
Eastern Douglas, Jackson, and Josephine	Department of Environmental Quality Medford Office 221 Stewart Avenue, Suite 201 Medford, OR 97501 Telephone: (541) 776-6010
Crook, Deschutes, Harney, Hood River, Jefferson, Sherman, Wasco, and Wheeler	Department of Environmental Quality Bend Office 475 NE Bellevue, Suite 110 Bend, OR 97701 Telephone: (541) 388-6146
Baker, Gilliam, Grant, Malheur, Morrow, Umatilla, Union, and Wallowa	Department of Environmental Quality Pendleton Office 800 SE Emigrant Avenue, Suite 330 Pendleton, OR 97801 Telephone: (541) 276-4063
Klamath and Lake	Department of Environmental Quality Klamath Falls Office 317 South 7 <sup>th</sup> Street, Suite 231 Klamath Falls, OR 97601 Telephone: (541) 273-7002



## **9.0 FEES**

### **9.1. 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 permit 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.**

### **9.2. Change of Ownership or Company Name Fee**

The Non-Technical Permit Modification specific activity fee specified in OAR 340-216-8020, Table 2, Part 4 is due with an application for changing the ownership or the name of the company of a source assigned to this permit. Forms that require fees must be sent together to the address in Condition 9.3.

### **9.3. Where to Submit Fees**

Fees, with a permit number prominently displayed, must be submitted to:

Department of Environmental Quality  
Financial Services – Revenue Section  
700 NE Multnomah St. Suite 600  
Portland, OR 97232-4100

## **10.0 GENERAL CONDITIONS AND DISCLAIMERS**

### **10.1. Other Regulations**

In addition to the specific requirements listed in this permit, the permittee must comply with all other applicable legal requirements enforceable by DEQ.

### **10.2. Conflicting Conditions**

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

### **10.3. Masking of Emissions**

The permittee must not cause or permit the installation of any device or use any means designed to mask the emissions of an air contaminant that causes or is likely to cause detriment to health, safety, or welfare of any person or otherwise violate any other regulation or requirement.

### **10.4. DEQ Access**

The permittee must allow DEQ's representatives access to the plant site and pertinent records at all reasonable times for the purposes of performing inspections, surveys, collecting samples, obtaining data, reviewing and copying air contaminant emissions discharge records and conducting all necessary functions related to this permit in accordance with ORS 468.095.

### **10.5. Permit Availability**

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

### **10.6. Open Burning**

The permittee may not conduct any open burning except as allowed by OAR 340, division 264.

### **10.7. Asbestos**

The permittee must comply with the asbestos abatement requirements in OAR 340, division 248 for all activities involving asbestos-containing materials, including, but not limit to, demolition, renovation, repair, construction, and maintenance.

**10.8. Property Rights**

The issuance of this permit does not convey any property rights in either real or personal property, or any exclusive privileges, nor does it authorize any injury to private property or any invasion of personal rights, nor any infringement of federal, state, or local laws or regulations.

**10.9. Termination, Revocation, Rescission, or Modification**

DEQ may modify or revoke this permit as authorized under OAR chapter 340 division 216.

**11.0 ABBREVIATIONS, ACRONYMS, AND DEFINITIONS**

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

<b>Term</b>	<b>Definition per 40 C.F.R. part 63 subpart WWWW</b>
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.

gce: 12/21/09; drd: 1/14/20

AQGP-020, hospital sterilizers