GENERAL

AIR CONTAMINANT DISCHARGE PERMIT

ATTACHMENT

Department of Environmental Quality
Air Quality Division
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Portland, OR 97204-1390
Telephone: (503) 229-5359

This attachment is issued on March 1, 2010 in accordance with the provisions of ORS 468A.040 and OAR 340-216-0062 for the following source category:

Hospital ethylene oxide sterilizers subject to 40 CFR part 63 subpart WWWW, as adopted under OAR 340-244-0220. NAICS 622110, 622310.

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1.0 ATTACHMENT ASSIGNMENT

1.1. Qualifications All of the following conditions must be met 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.

c. The source is not having ongoing, recurring 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 of the permittee no longer meets the requirements of this attachment.

1.3. Permitted Activities The permittee is allowed to discharge air contaminants from processes and activities related to the air contaminant source(s) listed on the first page of this attachment until the attachment expires, is modified, revoked or rescinded, as long as the permittee complies with the conditions of this attachment. If there are other emissions activities occurring at the site besides those listed on the cover page of this attachment, the permittee may be required to obtain a Standard or Simple ACDP or additional General ACDP Attachment(s), if applicable.

2.0 SPECIFIC PERFORMANCE AND EMISSION STANDARDS

2.1. 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.

3.0 COMPLIANCE DEMONSTRATION

3.1. Initial Compliance The permittee must demonstrate initial compliance as follows:
Demonstration

a. Demonstrate compliance with the management practice standard in Condition 2.1 by submitting an Initial Notification of Compliance Status (see Condition 5.1) certifying that the permittee is sterilizing full loads of items having a common aeration time, except under medically necessary circumstances.

b. If operating a sterilization unit(s) with an air pollution control device, the permittee may demonstrate compliance with Condition 2.1 by submitting an Initial Notification of Compliance Status (see Condition 5.1) certifying that ethylene oxide emissions from each sterilization unit is being vented to an add-on air pollution control device. The permittee must also certify that the air pollution control device is operating in accordance with the manufacturer’s recommended procedures.

3.2. Continuous Compliance Demonstration

For each sterilization unit not equipped with an air pollution control device, the permittee must demonstrate continuous compliance with the management practice standard in Condition 2.1 by recording the information in Condition 4.1.

4.0 RECORDKEEPING REQUIREMENTS

4.1. Operation and Maintenance

The permittee must keep the following records:

a. A copy of the Initial Notification of Compliance Status that was submitted to comply with Conditions 3.1 and 5.1.

b. For each sterilization unit not equipped with an air pollution control device:

i. Daily record of the date and time of each sterilization cycle.

ii. For each sterilization cycle, document that the cycle contained a full load of items.

iii. For each sterilization cycle that does not include a full load of items; record the following:

   (a) Date and time;

   (b) A statement from a hospital central services staff, a hospital administrator, or a physician why it was medically necessary to conduct a sterilization cycle without a full load of items.

4.2. Retention of

Unless otherwise specified, all records must be maintained for a period of 5 years. The permittee must hold the records on site for
Records a period of two (2) years and make them available to DEQ upon request.

5.0 REPORTING REQUIREMENTS

5.1. Initial Notification of Compliance Status

The permittee must submit an Initial Notification of Compliance Status upon assignment to this permit. A form for this purpose is available from DEQ. The notification must be sent to the appropriate DEQ office. In addition, the permittee must submit a copy of the Initial Notification of Compliance Status to EPA’s Office of Air Quality Planning and Standards via e-mail to cccong@epa.gov or via U.S. mail or other mail delivery service to U.S. EPA, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Attn: Hospital Sterilizers Project Leader, Research Triangle Park, NC 27711.

5.2. Annual Report

The permittee must submit an annual report by February 15 of each year that includes the following information:

a. The number of sterilization cycles conducted during the previous calendar year.

b. The number of sterilization cycle conducted during the previous calendar year that did not include a full load.

c. Reasons listed in the previous calendar year for not conducting full loads.

6.0 ADMINISTRATIVE REQUIREMENTS

6.1. Reattachment

A complete application for reattachment is due within 60 days after the attachment is reissued. DEQ will notify the permittee when the attachment is reissued. The application must be sent to the appropriate regional office.

a. If DEQ is delinquent in renewing the attachment, the existing attachment will remain in effect and the permittee must comply with the conditions of the attachment until such time that the attachment is reissued and reattached to the permit.

b. 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 attachment until DEQ takes final action on the application.

c. If a complete application for reattachment or Simple or Standard ACDP is filed with DEQ in a timely manner, the
attachment will not be deemed to expire until final action has been taken on the application.

### 7.0 FEES

7.1. **Annual Compliance Fee**

   The Annual Compliance Determination Fee for a General ACDP Attachment is due on **December 1** of each year this attachment is in effect. An invoice indicating the amount, as determined by DEQ regulations, will be mailed prior to the above date.

### 8.0 GENERAL CONDITIONS AND DISCLAIMERS

8.1. **Conflicting Conditions**

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

8.2. **Attachment Availability**

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