Safety Standards for Ethylene Oxide

Chapter 296-855 WAC

May 2014 Edition
Chapter 296-855 WAC
Safety Standards for Ethylene Oxide
(Form Number 414-132-000)

LAST UPDATED 05/01/2014


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• Industry and Task-Specific Rules
• Proposed Rules and Hearings
• Newly Adopted Rules and New Rule Information
• WISHA Regional Directives (WRDs)
• WISHA Interim Operations and Interpretive Memoranda (WHM)
• Memoranda of Understanding (MOU)
### Chapter 296-855 WAC
### ETHYLENE OXIDE

**LAST UPDATED 05/01/14**

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WAC 296-855-100  Scope. This chapter applies to all occupational exposure to ethylene oxide.

Definitions:

- **Ethylene oxide** (EtO) is an organic chemical represented by the Chemical Abstract Service (CAS) registry number 75-21-8. It is a flammable colorless gas that is commonly used to sterilize medical equipment and as a fumigant for certain agricultural products. It is also used as an intermediary in the production of various chemicals such as ethylene glycol, automotive antifreeze, and polyethylene.

- **Exposure** is the contact an employee has with EtO, whether or not protection is provided by respirators or other personal protective equipment (PPE). Exposure can occur through various routes of entry such as inhalation, ingestion, or skin and eye contact.

Some of the requirements in this chapter may not apply to every workplace with an occupational exposure to EtO. The following steps will show which requirements apply to your workplace based on employee exposure monitoring results.

**Step 1:** Follow requirements in the basic rules section, WAC 296-855-20010 through 296-855-20090.

**Step 2:** Use employee exposure monitoring results from the exposure evaluations required by Exposure evaluations, WAC 296-855-20050, and follow Table 1 to find out which additional sections of this chapter apply to your workplace.

**Step 3:** You need only follow Exposure records, WAC 296-855-20070 and Medical records, WAC 296-855-30080 if you have documentation conclusively demonstrating that employee exposure for ethylene oxide and the operation where it is used, cannot exceed the AL or STEL during any conditions reasonably anticipated.

- Such documentation can be based on observations, data, calculations, and previous air monitoring results
Table 1  Sections That Apply to Your Workplace

<table>
<thead>
<tr>
<th>If:</th>
<th>Then continue to follow the basic rules, and the additional requirements in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee exposure monitoring results are below the AL and STEL</td>
<td>No additional requirements if exposures remain stable</td>
</tr>
<tr>
<td>Employee exposure monitoring results are above the PELs</td>
<td>• Exposure and medical monitoring, WAC 296-855-30010 through 296-855-30080; AND</td>
</tr>
<tr>
<td>Note: PEL refers to both the STEL and TWA</td>
<td>• Exposure control, WAC 296-855-40005 through 296-855-40045</td>
</tr>
<tr>
<td>Employee exposure monitoring results are above the AL; AND Below the STEL</td>
<td>Exposure and medical monitoring, WAC 296-855-30010 through 296-855-30080</td>
</tr>
<tr>
<td>When there is a possibility of an emergency release of EtO</td>
<td>Establish a written emergency response plan and a means of alerting potentially exposed employees as found in Exposure control plan, WAC 296-855-40005</td>
</tr>
</tbody>
</table>

[Statutory Authority:  RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-100, filed 08/23/05, effective 01/01/06].

WAC 296-855-200  Basic rules.

Summary:

Your responsibility:

To evaluate employee exposure and protect employee from ethylene oxide.

IMPORTANT:

- The requirements in basic rules apply to all employers covered by the scope of this chapter, WAC 296-855-100. Additional sections may apply to you, based on employee exposure monitoring results. Turn to the Scope, WAC 296-855-100, and follow Table 1.

[Statutory Authority:  RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-200, filed 08/23/05, effective 01/01/06].

WAC 296-855-20010  Preventive practices.

You must:

- Make sure that all containers of EtO whose contents are capable of causing employee exposure above the action level or above the STEL are labeled, tagged, or marked with this warning.

AND

Prior to June 1, 2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in WAC 296-855-420:
WAC 296-855-20010 (Cont.)

DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD

AND

A warning stating that breathing airborne concentrations of EtO is hazardous.

- Keep container labels free of statements that contradict or detract from the labels' hazard warning.

Note:

- EtO is highly flammable and should be kept in a tightly covered container, and in a cool, well-ventilated area away from any type of ignition source.

You must:

- Make sure warning labels remain on containers of EtO when these containers are transported.

Exemption:

- Reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers and do not require labeling.

- Labeling requirements do not apply when EtO:
  
  - Is used as a pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticides Act (7 U.S.C. 136 et seq.);
  
  AND
  
  - Meets the Environmental Protection Agency labeling requirements for pesticides.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 14-07-086 (Order 13-08), § 296-855-20010, filed 03/18/14, effective 05/01/14.  Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20010, filed 08/23/05, effective 01/01/06].

WAC 296-855-20020 Exposure control areas.

You must:

- Establish temporary or permanent exposure control areas where airborne concentrations of ethylene oxide (EtO) exceed or could exceed the permissible exposure limits (PELs) by doing all the following:
  
  - Clearly identify the boundaries of exposure control areas in any way that minimizes employee access.
  
  - Post signs at access points to exposure control areas that:
    
    - Are easy to read (for example, they are kept clean and well lit).
    
    AND
    
    - Include this warning:

DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY
Prior to June 1, 2016, employers may use the following legend in lieu of that specified in this section:

<table>
<thead>
<tr>
<th>DANGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLENE OXIDE</td>
</tr>
<tr>
<td>CANCER HAZARD AND REPRODUCTIVE HAZARD</td>
</tr>
<tr>
<td>AUTHORIZED PERSONNEL ONLY</td>
</tr>
<tr>
<td>RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA</td>
</tr>
</tbody>
</table>

Keep signs and areas near them free of statements that contradict or detract from their message.

Note:

This requirement does not prevent you from posting other signs.

You must:

Allow only authorized personnel to enter exposure control areas.

Note:

When identifying the boundaries of exposure control areas you should consider factors such as:

- The level and duration of airborne exposure.
- Whether the area is permanent or temporary.
- The number of employees in adjacent areas.

You may use permanent or temporary enclosures, caution tape, ropes, painted lines on surfaces, or other materials to visibly distinguish exposure control areas or separate them from the rest of the workplace.

You must:

Make sure employees entering exposure control areas have appropriate respirators available for use.

Prevent all of the following activities from occurring in exposure control areas:

- Eating food.
- Drinking beverages.
- Smoking.
- Chewing tobacco or gum.
- Applying cosmetics.
- Storing food, beverages, or cosmetics.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 14-07-086 (Order 13-08), § 296-855-20020, filed 03/18/14, effective 05/01/14. Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20020, filed 08/23/05, effective 01/01/06.]
WAC 296-855-20040 Personal protective equipment (PPE).

You must:

- Make sure employees wear appropriate PPE as protection from skin or eye contact with ethylene oxide (EtO), liquid EtO, or EtO solutions.
- Provide appropriate PPE at no cost to employees.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20040, filed 08/23/05, effective 01/01/06].

WAC 296-855-20050 Exposure evaluations.

IMPORTANT:

This section applies when there is a potential for airborne exposure to ethylene oxide (EtO) in your workplace.

When you conduct an exposure evaluation in a workplace where an employee uses a respirator, the protection provided by the respirator is not considered.

Following this section will also meet the requirements to identify and evaluate respiratory hazards found in chapter 296-841 WAC, Airborne contaminants.

You must:

- Conduct an employee exposure evaluation to accurately determine airborne concentrations of EtO by completing Steps one through seven of the exposure evaluation process, each time any of the following apply:
  - No evaluation has been conducted.
  - Changes have occurred in any of the following areas that may result in new or increased employee exposures:
    - Production.
    - Processes.
    - Personnel.
    - Exposure controls such as ventilation systems or work practices.
  - You have any reason to suspect new or increased employee exposure may occur.
- Provide affected employees and their designated representatives an opportunity to observe any exposure monitoring during Step six of the exposure evaluation process.
- Make sure observers entering areas with EtO exposure:
  - Are provided with and use the same protective clothing, respirators, and other personal protective equipment (PPE) that employees working in the area are required to use;
    AND
  - Follow all safety and health requirements that apply.
Exposure evaluation process

Step 1: Identify all employees who have potential exposure to airborne ethylene oxide (EtO) in your workplace.

Step 2: Identify operations where employee exposures could exceed EtO's 15-minute short-term exposure limit (STEL) of 5 parts per million (ppm).

Step 3: Select employees from those working in the operations you identified in Step 2 who will have their STEL exposures measured.

Step 4: Select employees from those identified in Step 1 who will have their 8-hour exposures monitored.
   - Make sure the exposures of the employees selected represent 8-hour exposures for all employees identified in Step 1 including each job classification, work area, and shift.
   - If you expect all employee exposures to be below the action level (AL), you can choose to limit your selection to those employees reasonably believed to have the highest exposures. If you find these employees' exposure to be above the AL, then you will need to repeat Step 4 to represent all employees identified in Step 1.

Note: You can use Steps 3 through 6 of this process to create a written description of the procedure used for obtaining representative employee exposure monitoring results, which is a requirement in Exposure records, WAC 296-855-20070.

Exemption:
   - You can skip Steps 4 through 7 if you have documentation conclusively demonstrating that employee exposure for a particular material and the operation where it is used, cannot exceed the AL or STEL during any conditions reasonably anticipated.
   - Such documentation can be based on observations, data, calculations, and previous air monitoring results. Previous air monitoring results:
     - Must meet the accuracy required by Step 5.
     - May be from outside sources, such as industry or labor studies.
     - Must be based on data that represents conditions being evaluated in your workplace.

Step 5: Determine how you will obtain accurate employee exposure monitoring results. Select and use an air monitoring method with a confidence level of 95 percent, that is accurate to:
   - ±25 percent when concentrations are potentially above the AL or 8-hour time-weighted average of one part per million (ppm).
   - ±35 percent when concentrations are potentially above the AL of 0.5 ppm or the STEL of 5 ppm.

Note: Here are examples of air monitoring methods that meet this accuracy requirement:
   - NIOSH Method 3800 found by going to: http://www.cdc.gov/niosh/homepage.html and linking to the NIOSH Manual of analytical methods.
Step 6: Obtain employee monitoring results by collecting air samples representing employees identified in Steps 3 and 4.

- Collect STEL samples for employees and operations selected in Step 3.
- Collect samples representing the 8-hour exposure, for at least one shift, for each employee selected in Step 4.
- Make sure samples are collected from each selected employee's breathing zone.

Note:

- You may use any sampling method that meets the accuracy specified in Step 5. Examples of these methods include:
  - Real-time monitors that provide immediate exposure monitoring results.
  - Equipment that collects samples that are sent to a laboratory for analysis.
- The following are examples of methods for collecting samples representative of 8-hour exposures.
  - Collect one or more continuous samples, such as a single 8-hour sample or 4 2-hour samples.
  - Take a minimum of 5 brief samples, such as five 15-minute samples, during a work shift at randomly selected times.
- For work shifts longer than 8 hours, monitor the continuous 8-hour portion of the shift expected to have the highest average exposure concentration.

Step 7: Have the samples you collected analyzed to obtain monitoring results for 8-hour and STEL exposures.

- Determine if employee exposure monitoring results are above or below the following values:
  - 8-hour time-weighted average (TWA₈) of one ppm.
  - 15-minute short-term exposure limit (STEL) of 5 ppm.
  - 8-hour action level (AL) of 0.5 ppm.

Note:

- You may contact your local WISHA consultant for help:
  - Interpreting data or other information.
  - Determining eight-hour or 15-minute employee exposure monitoring results.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 07-05-062, 07-060-005 (Order 06-38), § 296-855-20050, filed 02/20/07, effective 04/01/07. Statutory Authority: RCW 49.17.010, .040, .050, and .060. 06-17-068 (Order 05-01), § 296-855-20050, filed 08/23/05, effective 01/01/06].
WAC 296-855-20060 Notification.

You must:

• Provide written notification of exposure monitoring results to employees represented by your exposure evaluation, within 5 business days after monitoring results become known to you.
• In addition, when employee exposure monitoring results are above either the TWA₈ or STEL permissible exposure limit (PEL), provide written notification of all the following within 15 business days after the results become known to you:
  – Corrective actions being taken and a schedule for completion;
  AND
  – Any reason why exposures can not be lowered to below the PELs.

Note:

• You can either notify employees individually or post the notifications in areas readily accessible to affected employees.
• Posted notification may need specific information that allows affected employees to determine which monitoring results apply to them.
• Notification may be:
  – In any written form, such as hand-written or e-mail.
  – Limited to the required information, such as exposure monitoring results.
• When notifying employees about corrective actions, your notification may refer them to a separate document that is available and provides the required information.

WAC 296-855-20070 Exposure records.

You must:

• Establish and keep complete and accurate records for all exposure monitoring evaluations conducted under this chapter. Make sure the record includes, at least:
  – The name, unique identifier, and job classification of:
    • The employee sampled;
    AND
    • All other employees represented by the sampled employee.
  – A description of the methods used to obtain exposure monitoring results and evidence of the methods' accuracy.
  – The operation being monitored for employee exposure to EtO.
  – A description of the procedure used to obtain representative employee exposure monitoring results.
  – The date, number, duration, location, and the result of each sample taken.
  – Any environmental conditions that could affect exposure concentration measurements.
WAC 296-855-20070 (Cont.)

– Any personal protective equipment (PPE) worn by the employee including the type of respirator.

Note:

• You can use Steps 3 through 6 of the exposure evaluation process in Exposure evaluations, WAC 296-855-20050, to create a description of the procedure you used for obtaining representative employee exposure monitoring results.

You must:

• Keep exposure monitoring records for at least 30 years.

Reference:

• To see additional requirements for employee exposure records including access, and transfer requirements, go to another chapter, Employee medical and exposure records, chapter 296-802 WAC.

• Exposure monitoring records need to be kept longer than 30 years for employees participating in medical monitoring, go to Medical records, WAC 296-849-12080.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20070, filed 08/23/05, effective 01/01/06.]

WAC 296-855-20080 Documentation records.

You must:

• Keep documentation you develop, of the processing, use, or handling of products made from or containing EtO, that conclusively demonstrates that the action level or STEL for EtO cannot be exceeded under any foreseeable conditions of use.

• Include the following in the documentation record:

  – The product that is the subject of the documentation;
  – The source of the data;
  – Any testing protocol, results of testing, and/or analysis of the product for the release of EtO;
  – A description of the operation where the product is used and how the data support your conclusion; and
  – Other data relevant to the operations, materials, processing, or employee exposures covered by your conclusion.

• Maintain the documentation record for as long as you rely on your conclusion that the action level and STEL cannot be exceeded.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20080, filed 08/23/05, effective 01/01/06.]
Chapter 296-855 WAC
Safety and Health Core Rules

Ethylene Oxide

WAC 296-855-20090 Training.

You must:

- Train employees who are potentially exposed above the:
  - Action level (AL) 0.5 parts per million (ppm);
  - OR
  - 15-minute short-term exposure limit (STEL) of 5 ppm.

- Provide training:
  - At the time of initial assignment;
  - AND
  - Then at least every 12 months.

- Make sure training and information includes all of the following:
  - The requirements of this chapter.
  - The location and availability of this chapter.
  - The purpose of medical evaluations and a description of your medical evaluation program required in Medical evaluations, WAC 296-855-30030 in this chapter.
  - Monitoring procedures and observations to detect the presence or release of EtO.
  - The physical and health hazards of EtO.
  - Actions employees can take to protect themselves from EtO exposure such as work practices, emergency procedures, and PPE.
  - The details of your hazard communication program required by another chapter, Hazard communication, WAC 296-901-140.
  - Operations in employee work areas where EtO is present.
  - The following information found in the General occupational health standards, chapter 296-62 WAC:
    - The Substance safety data sheet, WAC 296-62-07383 Appendix A.
    - The Substance technical guidelines, WAC 296-62-07385 Appendix B.
    - Medical surveillance guidelines, WAC 296-62-07387 Appendix C.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 14-07-086 (Order 13-08), § 296-855-20090, filed 03/18/14, effective 05/01/14. Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-20090, filed 08/23/05, effective 01/01/06].
WAC 296-855-300  Exposure and medical monitoring.

Summary:

Your responsibility:

To monitor employee health and workplace exposures to ethylene oxide (EtO).

IMPORTANT:

- These sections apply when employee exposure monitoring results are either above the:
  - Action level (AL) of 0.5 parts per million (ppm);
  OR
  - Short-term exposure limit (STEL) of 5 ppm.

[Statutory Authority:  RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-300, filed 08/23/05, effective 01/01/06]
WAC 296-855-30010  Periodic exposure monitoring.

Exemption: Periodic employee exposure monitoring is not required if exposure monitoring results conducted to fulfill requirements in Exposure evaluation, WAC 296-855-20050, are below the action level (AL).

You must:

- Obtain employee exposure monitoring results according to the frequency specified in Table 2, Periodic Exposure Evaluation Frequencies.

Note:

- If you documented that one work shift consistently has higher exposure monitoring results than another for a particular operation, then you may limit sample collection to the work shift with higher exposures and use those results to represent all employees performing the operation on other shifts.

### Table 2 Periodic Exposure Evaluation Frequencies

<table>
<thead>
<tr>
<th>If employee exposure monitoring results:</th>
<th>Then:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are between the:</td>
<td>Conduct additional exposure monitoring</td>
</tr>
<tr>
<td>• Action level (AL) of 0.5 parts per million (ppm); AND</td>
<td>at least every 6 months.</td>
</tr>
<tr>
<td>• TWA₈ of 1 ppm</td>
<td></td>
</tr>
<tr>
<td>Are above the TWA₈;</td>
<td>Conduct additional exposure monitoring</td>
</tr>
<tr>
<td>OR</td>
<td>at least every 3 months.</td>
</tr>
<tr>
<td>Above the STEL</td>
<td></td>
</tr>
<tr>
<td>Have been obtained at least every 3 months;</td>
<td>You may decrease your evaluation frequency</td>
</tr>
<tr>
<td>AND</td>
<td>for the TWA₈ to every 6 months.</td>
</tr>
<tr>
<td>Have 2 consecutive monitoring results, taken at</td>
<td></td>
</tr>
<tr>
<td>least 7 days apart, showing 8-hour employee</td>
<td></td>
</tr>
<tr>
<td>exposure monitoring results that have dropped</td>
<td></td>
</tr>
<tr>
<td>below the TWA₈, but remain at or above the AL</td>
<td></td>
</tr>
<tr>
<td>Have 2 consecutive evaluations, taken at least 7</td>
<td>You may stop periodic exposure</td>
</tr>
<tr>
<td>days apart, showing 8-hour employee exposure</td>
<td>evaluations.</td>
</tr>
<tr>
<td>monitoring results that have dropped below the</td>
<td></td>
</tr>
<tr>
<td>AL and STEL</td>
<td></td>
</tr>
</tbody>
</table>

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-30010, filed 08/23/05, effective 01/01/06.]
Chapter 296-855 WAC  
Safety and Health Core Rules  

**WAC 296-855-30030 Medical evaluations.**

**IMPORTANT:**

Medical evaluations meeting all requirements of this section will fulfill the medical evaluation requirement found in another chapter, Respirators, chapter 296-842 WAC.

Employees who wear respirators need to be medically evaluated to make sure the respirator will not harm them, before they are assigned work in areas requiring respirators.

**You must:**

- Make medical evaluations available to current employees:
  - Who have been, are, or may be exposed above the action level (AL) for at least 30 days in any 12-month period.
  - Exposed to EtO during an emergency situation.
  - Wanting medical advice on EtO exposure and reproductive health.
  - Whenever the employee develops signs and symptoms commonly associated with ethylene oxide.
  - At no cost including travel costs and wages associated with any time spent obtaining the medical evaluation.
  - At reasonable times and places.

- Complete Steps 1 through 4 of the medical evaluation process at the following times:
  - Initially, when employees are assigned to work in an area where exposure monitoring results are, or will likely be, above the action level (AL) for at least 30 days in a 12-month period.
  - Every 12 months for employees exposed above the AL for at least 30 days in the preceding year unless the examining physician determines that they should be provided more frequently.
  - When employment with exposure ends, if the employee has not had an evaluation within the 6-month period before exposure ends.

**Note:**

- Employees who decline to receive medical examination and testing to monitor for health effects caused by EtO are not excluded from receiving a separate medical evaluation for respirator use.
- If employers discourage participation in medical monitoring for health effects caused by EtO, or in any way interfere with an employee’s decision to continue with this program, this interference may represent unlawful discrimination under RCW 49.17.160, Discrimination against employee filing complaint, instituting proceedings, or testifying prohibited--Procedure--Remedy.

**Helpful tool:**  Declination form for nonemergency related medical evaluations

You may use this optional form to document employee decisions to decline participation in the medical evaluation process for exposure to ethylene oxide (EtO). To see this form, go to the resources section within this chapter.
Medical evaluation process

Step 1: Select an appropriate licensed health care professional (LHCP) who will conduct or supervise examinations and procedures.

- If the LHCP is not a licensed physician, make sure individuals who conduct pulmonary function tests have completed a training course in spirometry sponsored by an appropriate governmental, academic, or professional institution.

Step 2: Make sure the LHCP receives all of the following information before the medical evaluation is performed:

- A copy of:
  - This chapter.
  - The following information found in the General occupational health standards, chapter 296-62 WAC:
    - The Substance safety data sheet, WAC 296-62-07383(1) Appendix A.
    - The Substance technical guidelines, WAC 296-62-07385(2) Appendix B.
    - Medical surveillance guidelines, WAC 296-62-07387(3) Appendix C.
  - A description of the duties of the employee being evaluated and how these duties relate to EtO exposure.
  - The anticipated or representative exposure monitoring results for the employee being evaluated.
  - A description of the personal protective equipment (PPE) and respirators each employee being evaluated uses or will use.
  - Information from previous employment-related examinations when this information is not available to the examining LHCP.
  - Instructions that the written opinions the LHCP provides you be limited to the following information:
    - Whether or not medical conditions were found that would increase the employee's risk for impairment from exposure to EtO.
    - Any recommended limitations for EtO exposure and use of respirators or other PPE.
    - A statement that the employee has been informed of medical results and medical conditions caused by EtO exposure requiring further examination or treatment.

Step 3: Make medical evaluations available to the employee. Make sure they include the content listed in Table 3, Content of Medical Evaluations.
Step 4: Obtain the LHCP's written opinion for the employee's medical evaluation and make sure the employee receives a copy within 5 business days after you receive the written opinion.

- Make sure the written opinion is limited to the information specified for written opinions in Step 2.

Note:
- If the written opinion contains specific findings or diagnoses unrelated to occupational exposure, send it back and obtain a revised version without the additional information.

<table>
<thead>
<tr>
<th>Table 3 Content of Medical Evaluations</th>
<th>When conducting:</th>
<th>Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>An initial and annual evaluation</td>
<td>• A work history and medical history that includes emphasis on:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Pulmonary, hematological, neurological, reproductive systems;</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>– The eyes and skin.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A physical examination that includes emphasis on:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Pulmonary, hematological, neurological, and reproductive systems;</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>– The skin and eyes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A complete blood count including a:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– White cell count with differential</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Red cell count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Hematocrit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Hemoglobin.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Additional examinations the licensed health care professional (LHCP) believes appropriate based on the employee's exposure to ethylene oxide (EtO) or respirator use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Additional testing:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Pregnancy test, and laboratory evaluation for fertility if requested by employee and approved by evaluating LHCP.</td>
<td></td>
</tr>
<tr>
<td>Evaluations due to termination of employment</td>
<td>• The same content as specified for initial and annual evaluations.</td>
<td></td>
</tr>
<tr>
<td>Evaluations due to reassignment to an area where EtO exposure is below the AL</td>
<td>• The same content as specified for initial and annual evaluations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• As determined by the LHCP.</td>
<td></td>
</tr>
</tbody>
</table>
Table 3  Content of Medical Evaluations (Cont.)

<table>
<thead>
<tr>
<th>When conducting:</th>
<th>Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluations due to exposure during an</td>
<td>• The same content as specified for initial and annual evaluations.</td>
</tr>
<tr>
<td>emergency</td>
<td></td>
</tr>
<tr>
<td>Evaluations triggered by employee signs</td>
<td>• The content of medical examinations and consultations will be determined by the examining LHCP.</td>
</tr>
<tr>
<td>and symptoms commonly associated with</td>
<td></td>
</tr>
<tr>
<td>overexposure to EtO or a request for</td>
<td>– Pregnancy test, and laboratory evaluation for fertility if requested by</td>
</tr>
<tr>
<td>reproductive advice</td>
<td>employee and approved by evaluating LHCP.</td>
</tr>
<tr>
<td>Evaluations determined necessary by LHCP</td>
<td>• The content of medical examinations and consultations will be determined by the examining LHCP.</td>
</tr>
<tr>
<td>for exposed employees</td>
<td></td>
</tr>
</tbody>
</table>

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-30030, filed 08/23/05, effective 01/01/06].

WAC 296-855-30080  Medical records.

IMPORTANT:

This section applies when a medical evaluation is performed, or any time a medical record is created for an employee exposed to ethylene oxide (EtO).

You must:

• Establish and maintain complete and accurate medical records for each employee receiving a medical evaluation for EtO and make sure the records include all the following:
  – The employee's name and unique identifier.
  – Any employee medical complaints related to EtO.
  – A description of the employee's duties.
  – A copy of the licensed health care professional's (LHCP's) written opinions.
  – The anticipated or representative employee exposure monitoring results provided to the LHCP for the employee.
  – A copy of the information required in Step two of the medical evaluation process, found in WAC 296-855-30030, except the copy of this chapter and the appendices.

• Maintain medical records for the duration of employment plus 30 years.

Note:

• Your medical provider may keep these records for you. Other medical records, such as the employee's medical history or X rays, need to be kept as confidential records by the medical provider.

Reference: For additional requirements that apply to employee exposure records including access and transfer requirements, go to, Employee medical and exposure records, chapter 296-802 WAC.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-30080, filed 08/23/05, effective 01/01/06].
WAC 296-855-400 Exposure control.

Summary:

Your responsibility:

To protect employees from exposure to ethylene oxide (EtO) by using feasible exposure controls and appropriate respirators.

IMPORTANT:

- These sections apply when employee exposure monitoring results are above either of the following permissible exposure limits (PELs):
  - The 8-hour time-weighted average (TWA8) of one part per million (ppm);
  - The 15-minute short-term exposure limit (STEL) of 5 ppm.

[Statutory Authority: RCW 49.17.010, .040, .050, and .060. 05-17-068 (Order 05-01), § 296-855-400, filed 08/23/05, effective 01/01/06.]

WAC 296-855-40010 Exposure control plan.

You must:

- Establish and implement a written exposure control plan to reduce employee exposure to EtO below both TWA8 and the STEL by the use of feasible exposure controls. Include at least the following in your plan:
  - A schedule for periodic leak detection surveys.
  - Make sure employee rotation is not included as a method to control employee exposure.
- Establish a written plan for emergency situations for each work area where there is a possibility of an emergency from a release of EtO. The plan must include, at a minimum:
  - Emergency escape:
    - Procedures.
    - Route assignments.
  - Emergency evacuation plans and procedures to account for all employees after emergency evacuation has been completed.
  - Procedures to be followed by employees who remain to operate critical plant operations before they evacuate.
  - Requirements for the use of respiratory protection as required in WAC 296-855-40045.
  - Rescue and medical duties for those employees who will perform them.
  - The preferred means of reporting fires and other emergencies.
  - Names or regular job titles of persons or departments who can be contacted for further information or explanation of duties under the plan.
• Establish an employee alarm system that meets the requirements of Employee alarm systems, WAC 296-800-31070 in the safety and health core rules.
  – The employee alarm system must be distinctive and recognizable as a signal to perform actions designated under the emergency response plan.

• Review your exposure control plan at least every 12 months and update as needed to reflect your current workplace conditions.

• Provide a copy of your exposure control plan to affected employees and their designated representatives, when they ask to review or copy it.

WAC 296-855-40030  Exposure controls.

IMPORTANT:

The use of an employee rotation schedule to control employee exposure to ethylene oxide (EtO) is prohibited.

Respirators and other personal protective equipment (PPE) are not exposure controls.

You must:

• Use feasible exposure controls to:
  – Reduce exposure to, or below, the permissible exposure limit (PELs);
  OR
  – To reduce exposure to the lowest achievable level above the PELs.

WAC 296-855-40040  Respirators.

IMPORTANT:

The requirements in this section are in addition to the requirements found in another chapter, Respirators, chapter 296-842 WAC.

Medical evaluations meeting all requirements of WAC 296-855-30030, will fulfill the medical evaluation requirement found in another chapter, Respirators, chapter 296-842 WAC.

You must:

• Provide each employee with an appropriate respirator that complies with the requirements of this section, and require that employees use them in circumstances where exposure is above either PEL, such as when:
  – Feasible exposure controls are being put in place.
  – Employees conduct work operations such as maintenance and repair activities or vessel cleaning for which exposure controls are not feasible.
  – Feasible exposure controls do not reduce exposures to or below the PELs.
  – Employees are responding to emergencies.
WAC 296-855-40040 (Cont.)

- Ensure all respirator use is accompanied by eye protection either through the use of full-facepiece respirators, hoods, or chemical goggles.
- Develop, implement, and maintain a respirator program that meets the requirements of another chapter, Respirators, chapter 296-842 WAC, which covers each employee required by this chapter to use a respirator.
  - Select and provide to employees appropriate respirators according to this section and WAC 296-842-13005 in the respirator rule.
  - Limit selection and use of respirators, including escape respirators, to those with a full-facepiece or another type of respirator providing eye protection. This is necessary to prevent eye irritation or injury from EtO exposure.
  - Equip full-facepiece air-purifying respirators, including escape respirators, with a front- or back-mounted canister certified for protection against ethylene oxide.

WAC 296-855-420 Communication of Hazards.

Hazard Communication-General.

- Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS), WAC 296-901-140 for EtO.
- In classifying the hazards of EtO at least the following hazards are to be addressed: Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.
- Employers shall include EtO in the hazard communication program established to comply with the HCS, WAC 296-901-140. Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS and WAC 296-855-20090.

WAC 296-855-500 Definitions.

Action level: An airborne concentration of ethylene oxide (EtO) of 0.5 parts per million, calculated as an 8-hour time-weighted average.

Authorized personnel: Individuals specifically permitted by the employer to enter the exposure control area to perform necessary duties, or to observe employee exposure evaluations.

Breathing zone: The space around and in front of an employee's nose and mouth, forming a hemisphere with a 6- to 9-inch radius.

CAS (Chemical Abstract Service) number: CAS numbers are internationally recognized and used on safety data sheets (SDSs) and other documents to identify substances. For more information see http://www.cas.org/about.
Container: Any container, except for pipes or piping systems that contains ethylene oxide. It can be any of the following:

- Barrel.
- Bottle.
- Can.
- Cylinder.
- Drum.
- Reaction vessel.
- Storage tank.

Day: Any part of a calendar day.

Director: The director means the director of the department of labor and industries or their designee.

Emergency: Any event that could or does result in the unexpected significant release of ethylene oxide. Examples of emergencies include equipment failure, container rupture, or control equipment failure.

Ethylene oxide (EtO): Is an organic chemical represented by the CAS registry number 75-21-8. EtO is a flammable colorless gas and is commonly used to sterilize medical equipment and as a fumigant for certain agricultural products. It is also used as an intermediary in the production of various chemicals such as ethylene glycol, automotive antifreeze, and polyurethane.

Exposure: The contact an employee has with ethylene oxide, whether or not protection is provided by respirators or other personal protective equipment (PPE). Exposure can occur through various routes of entry such as inhalation, ingestion, skin contact, or skin absorption.

Licensed health care professional (LHCP): An individual whose legally permitted scope of practice allows him or her to provide some or all of the health care services required for medical evaluations.

Permissible exposure limits (PELs): PELs are employee exposures to toxic substances or harmful physical agents that must not be exceeded. PELs are specified in applicable WISHA rules. The PELs for ethylene oxide (EtO) are:

- 8-hour time-weighted average (TWA₈) of one part per million (ppm);
- 15-minute short-term exposure limit (STEL) of 5 ppm.

Short term exposure limit (STEL): An exposure limit averaged over a short time period (usually 15 minutes) that must not be exceeded during any part of an employee's workday.

Time-weighted average (TWA₈): An exposure limit averaged over an 8-hour period that must not be exceeded during an employee's workday.
### ETHYLENE OXIDE RESOURCES

**HELPFUL TOOLS**

<table>
<thead>
<tr>
<th>Sample Medical Evaluation Declination Form</th>
<th>R-1</th>
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</thead>
</table>

Page R-i
SAMPLE MEDICAL EVALUATION DECLINATION FORM
OPTIONAL

Employer ______________________________________________________________________

I understand that because of my occupational exposure to ethylene oxide, I may be at risk for serious health effects including:

______________________________________________________________________________

You have given me the opportunity to receive medical examination and testing for the potential health effects from ethylene oxide exposures, at no cost to me. However, I decline to receive this medical examination and testing at this time.

I understand that by declining this medical examination and testing, I continue to be at risk for

______________________________________________________________________________

and other health effects related to ethylene oxide exposure.

I understand that I must have a medical evaluation to wear a respirator and without such an evaluation, I cannot wear a respirator as part of my job. I also understand that declining to receive medical examination and testing for health effects from ethylene oxide exposure does NOT exclude me from receiving a separate medical evaluation for respirator use.

If, in the future, I continue to have occupational exposure to ethylene oxide and decide to receive medical examination and testing, I will be given the opportunity to receive them at no cost to me.

__________________________
(Employee’s Name (Print))

__________________________
Employee’s Signature

__________________________
Date