

Rule Summary:
Final Area Source NESHAP for Hospital Ethylene Oxide Sterilizers

Rule: **40 CFR Part 63, Subpart WWWW (5W)**
Docket: **EPA-HQ-OAR-2005-0171**
FR Date: **December 28, 2007, pp. 73611-73625**

Submission of Comments:

The final rule has been published in the Federal Register; comments are no longer being accepted.

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Applicability

The NESHAP applies to any new or existing hospital ethylene oxide sterilization facility that as an area source of HAP. The primary NAICS codes are 622110 and 622310.

Existing sources are defined as those that commenced construction or reconstruction on or before November 6, 2006. Likewise, new sources are defined as those that commenced construction or reconstruction after November 6, 2006.

Target HAP: Ethylene Oxide

Compliance Dates:

1. Existing affected sources must comply with the requirements by no later than December 29, 2008.
2. If you start up a new source on or before December 28, 2007, you must comply with the applicable requirements by December 28, 2007.
3. If you start up a new affected source after December 28, 2007, you must comply with the applicable requirements by December 28, 2007.

Standards:

The standards and requirements of the rule are the same for new and existing sources; only the compliance dates differ. You must sterilize full loads of items having a common aeration time, except under medical necessity.

Certification of Initial Compliance

1. You must demonstrate initial compliance with the management practice standard in §63.10390 by submitting an Initial Notification of Compliance Status certifying that you are sterilizing full loads of items having a common aeration times, except under medically necessary conditions.
2. If you operate your sterilization unit(s) with an air pollution control device pursuant to a state or local regulation, you may demonstrate initial compliance with §63.10390 by submitting an Initial Notification of Compliance status by certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device.

Records:

The following records demonstrating compliance must be maintained for five years and must be kept on site for at least two years:

1. A copy of the Initial Notification of Compliance Status that you submitted to comply with this subpart.
2. Records required by §63.10420 for each sterilization unit not equipped with a pollution control device.