FACT SHEET for Hospital Sterilizers

Background

- On December 20, 2007, the Environmental Protection Agency (EPA) issued standards to reduce emissions of ethylene oxide (EO) from hospital sterilizers.

- The hospital sterilizers use ethylene oxide to sterilize medical equipment. EPA’s action covers all facilities nationwide.

- The Clean Air Act defines two types of stationary sources that emit air toxics: major sources and area sources. This rule regulates hospital sterilizers as area sources.

- Area sources are smaller commercial and industrial operations that release lesser quantities of toxic pollutants into the air. Area sources emit less than 10 tons per year of a single air toxic, or less than 25 tons per year of a combination of air toxics. Sources that emit more than these amounts are characterized as “major” sources.

- This final action requires hospitals and other healthcare and dental facilities to implement a management practice to reduce ethylene oxide emissions by sterilizing full loads to the extent practicable. Facilities, which route ethylene oxide to a control device, are in compliance with the rule requirements.

RULE REQUIREMENTS

What is the Compliance Date?

- December 29, 2008 is the compliance date for an existing source (Constructed or reconstructed before November 6, 2006).

- New Sources (any others) must comply upon initial start-up.

Compliance Methods

There are two ways for a source to achieve compliance with this area source rule – Management practices or by use of an air pollution control device.

1. Management practice; requires sterilizing full loads except under medically necessary circumstances to protect human health. Hospital staff can decide the medically necessary circumstance based on generally accepted medical practices.

2. Air Pollution Control Device, used to reduce routed Ethylene Oxide emissions.

Testing

Testing is not required
Initial Notification - Due Date

- June 25, 2009 is the initial notification due date for an existing source (Constructed or reconstructed before November 6, 2006).

- 180 days after initial start-up, which is the compliance date for a new source.

Each facility that produces ethylene oxide emissions is required to provide an initial notification to Tennessee’s Air Pollution Control Agency (APC). You may submit the information to APC via your own letter and certification statement or the sample notification document developed by the Small Business Assistance Program (SBEAP). Also provided below is contact information.

Keeping Records and Reporting Requirements

- Keep Records for 5 years, with 2 most recent years maintained onsite.

- Records must show date, time of each sterilization cycle, weather the cycle was run full or not, and if not what was the facilities reason for not running a full load during sterilization.

- Only an initial report is required and your report should be sent to Tennessee’s Division of Air Pollution Control (APC) and the Environmental Protection Agency (EPA).

Contact Information

- You may contact the Small Business Environmental Assistance Program (SBEAP) for compliance assistance at 1- 800-734-3619 or at 615-532-8013 or by e-mail at: BGSBEAP@tn.gov or visit our website at http://www.tn.gov/environment/section/sbeap-small-business-environmental-assistance.

- Tennessee Department of Environment and Conservation
  Division of Air Pollution Control (APC)
  William R. Snodgrass Tennessee Tower
  312 Rosa L. Parks Avenue, 15th Floor
  Nashville, TN 37243
  Attention: APC Hospital Sterilizer Point of Contact

- U.S. Environmental Protection Agency (EPA) or Email: CCG-NG@EPA.GOV
  Sectors Policies and Programs Divisions
  Attn: Mr. David Markwordt,
  Hospital Sterilizers Project Leader
  Research Triangle Park, NC 27711

- Interested parties can download the notice from EPA's website on the Internet under recently signed rules at the following address: www.epa.gov/ttn/oarpg/new.html. For additional information, visit the EPA’s website at: www.epa.gov/ttn/atw/, or contact David Markwordt of the EPA’s Office of Air Quality Planning and Standards at (919) 541-0837 or by e-mail at markwordt.david@epa.gov.