

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

REGION 2  
290 BROADWAY  
NEW YORK, NY 10007-1866

JUN 30 2008

**COPY**

Mr. Fitzroy Jennings  
Sr. Associate Director  
Network Central Sterile Supply  
Lincoln Medical and Mental Health Center  
149<sup>th</sup> Street  
Bronx, NY 10451

Dear Mr. Jennings:

This letter is in response to your April 10, 2008 request for a determination of the applicability of the National Emission Standard for Hazardous Air Pollutants for Hospital Ethylene Oxide Sterilizers, 40 CFR Subpart WWWW, to the ethylene oxide (EO) gas sterilizers at your facility.

The EO gas sterilization system you described uses 100% EO gas cartridges and plastic sterilization bags. Items to be sterilized are placed in individual plastic bags and placed inside a sterilization cabinet. EO gas cartridges, specific to the size of the bag, are manually activated through the wall of each sealed sterilization bag.

Subpart WWWW applies to an EO sterilization facility at a hospital that is an area source of hazardous air pollutant emissions. Sterilization facility is defined as "the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing." Sterilization unit is defined as "any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing."

We believe the individual sterilization bags utilized in the system you described meet the definition of "sterilization unit", in that the sterilization bags are an "enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing."

To comply with Subpart WWWW, the facility must meet the following management practice standard in Section 63.10390:

You must sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in §63.10448.

The management practice in 63.10390 is considered met if the individual sterilization bags described above are fully loaded during the sterilization process except under medically necessary circumstances, as provided in the rule.

If the sterilization unit is operated with an air pollution control device, the facility may meet the following requirements in section 63.10400(b) and (c), in lieu of the management practice in section 63.10390:

63.10400(b)- 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 certifying that you are operating the sterilization unit in accordance with your State or local regulation and following control device manufacturer's recommended procedures.

63.10400(c)- If you operate your sterilization unit(s) with an air pollution control device but are not subject to any State or local regulation, you may demonstrate initial compliance with §63.10390 by submitting an Initial Notification of Compliance Status certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device. You must certify that you are operating the control device during all sterilization processes and in accordance with manufacturer's recommended procedures.

If you have any additional questions, please contact Mozafar Ghaffari of my staff at 212-637-3925.

Sincerely,



Kenneth Eng, Chief  
Air Compliance Branch

CC: Scott Throwe, OECA