National Association of Clean Air Agencies

January 4, 2006

National Emission Standards for
Hospital Ethylene Oxide Sterilizers
Docket No. EPA-HQ-OAR-2005-0171
Environmental Protection Agency
EPA Docket Center, Mailcode 6102T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Sir/Madam:

On behalf of the National Association of Clean Air Agencies (formerly known as STAPPA and ALAPCO), thank you for this opportunity to comment on the proposed National Emission Standards for Hospital Ethylene Oxide Sterilizers, which were published in the *Federal Register* on November 6, 2006 (71 *Federal Register* 64907). The National Association of Clean Air Agencies (NACAA) is the national association of air pollution control agencies in 54 states and territories and over 165 metropolitan areas across the country.

NACAA believes the proposed standard for area source hospital ethylene oxide (EtO) sterilizers is inadequate and should be strengthened, particularly in light of the significant health risks associated with exposure to ethylene oxide (EtO). Not only have the International Agency on Cancer and the National Toxicology Program determined that EtO is a human carcinogen, but the U.S. Environmental Protection Agency (EPA) also described it as such in its draft "Evaluation of the Carcinogenicity of Ethylene Oxide." Besides being carcinogenic, EtO presents mutagenic, genotoxic, reproductive, neurological and sensitization hazards to those who work with it. It is a mucous membrane, eye, skin and respiratory irritant that is absorbed via the lungs or skin. Further, EPA has designated EtO as one of the 33 hazardous air pollutants presenting the greatest threat to public health in urban areas.

Since EtO presents such significant adverse health effects, emissions from hospital EtO sterilizers should be very well controlled. Many hospital sterilizers in the country have installed effective controls and used them for many years, so those controls have been proven to be practical and feasible. NACAA strongly recommends that EPA require such controls as part of this area source rule.

EPA presents two regulatory alternatives in the proposal, neither of which is sufficiently protective. The first alternative calls for facilities to sterilize only full loads except for emergency situations (first option) or to sterilize only full loads "to the extent practical" (second option). It seems that sterilizing full loads is only common sense, when the cost of operating the sterilizer and the length of time it takes to sterilize and aerate a load are considered. The second option is particularly meaningless, as what would be considered "practical" is very arbitrary.

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Sterilizing full loads should be merely standard practice and is not sufficient control in and of itself.

The second "alternative" merely states that "there are no generally available control technologies or management practices within the meaning of section 112(d)(5) for this category of sources." EPA claims that the costs of control and recordkeeping would be high and the control strategies therefore not cost effective.

Neither of these alternatives is sufficient, nor do they reflect what many sterilizers have achieved and are capable of achieving cost effectively. Proven control technology is readily available to easily and effectively control EtO emissions from hospital sterilizers. As the preamble indicates, both acid-water scrubbers and catalytic oxidation units are very effective technologies (providing reductions of approximately 99 percent). In fact, these control technologies, along with prudent venting and discharge practices, have been required by some state programs for many years. The proposal itself indicates that over half of all hospitals that use ethylene oxide sterilizers use emission controls. If so many are already using controls, it seems very unlikely that such measures are too costly, as the proposal claims. Controlling emissions from these sources should be required by the regulation.

Many of the control measures that hospital EtO sterilizers have taken are the result of state and local programs to limit EtO emissions from sterilizers. EPA, in the proposal, recognizes the contributions of the state and local programs and would rely upon them to ensure adequate controls: "[a]s for hospitals with controlled sterilizers, we propose that these hospitals be required to certify that the control devices are operating and will continue to operate in accordance with applicable State and/or local law…" (page 64909). EPA further argues:

> Hospitals that are currently controlling their ethylene oxide sterilizers generally are doing so to comply with existing State or local requirements. More than half of the hospital sterilizers have add-on controls. Due to this widespread use of controls on hospital sterilizers, the MACT floor level of control would be add-on controls if we were to develop this area source rule based on CAA section 112(d)(2) (page 64910).

If more than half of the sources have add-on controls, it suggests that those controls are practical and feasible. However, it also means that the rest are not controlled to the same level, even though they could be. Those people living, working and visiting the vicinity of the uncontrolled sources are not afforded the same level of protection as those near controlled sterilizers.

While many existing state and local programs are very effective, NACAA believes EPA's proposal to rely upon them, in lieu of federal requirements, is unwise and inappropriate. The Clean Air Act obligates EPA to establish standards to regulate area sources of hazardous air pollutants. The existence of state and local regulations does not relieve the agency of its duty to set emission control requirements under Section 112. Many state and local agencies are not able to be more stringent than federal requirements. If this rule is adopted, it is conceivable that some agencies could be required to change their regulations, making them consistent with those of the federal government. If the actual requirements for these sources to be controlled are not

contained in the federal rule itself, those existing non-federal rules could be relaxed. Furthermore, whether or not a state or local agency is allowed to be more stringent than federal rules, state and local regulations can change in the future for other reasons. In the absence of federal requirements, there would be nothing to prevent backsliding by the sources if a state or local rule is relaxed or eliminated.

EPA's proposal seeks comment on whether the requirements on hospital EtO sterilizers should apply only to those facilities in urban areas. NACAA believes the requirements should apply nationwide, rather than just in urban areas. The impacts of EtO emissions are localized and would be similar for most urban and rural areas. Hospitals are typically located in residential areas, whether they are in an urban area or not. Accordingly, there would likely be exposed populations residing nearby. Further, hospitals clearly serve more sensitive populations who could be more susceptible to impacts from exposure to EtO and parking areas are typically close to the hospital, so improper control and venting could be hazardous to visitors and employees. The cost of controlling a sterilizer would also be the same for rural and urban hospitals. Because the costs and environmental impacts are the same, there does not appear to be any rationale for treating rural and urban hospitals differently. NACAA recommends that good controls, practices and recordkeeping be required for hospital sterilizers in urban and rural areas alike.

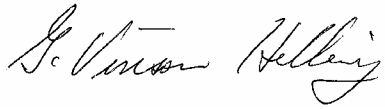
With respect to recordkeeping, EPA claims that recordkeeping would be costly and burdensome. However, some state programs have required that records be kept for many years. Some hospitals accomplish this through computerized recordkeeping systems, while others use handwritten records. These requirements are not likely to be overly burdensome or costly to the facilities.

Finally, one important note about the controls themselves: some sterilizers only operate their catalytic control devices during the initial purge of EtO and not during the entire aeration cycle. The control devices should be used for all discharges, not just the initial purge.

In summary, NACAA recommends that EPA examine the strategies in use by the well-controlled hospital EtO sterilizers around the country and develop federal control requirements that will call for that level of control, applicable to hospital EtO sterilizers nationwide. Additionally, EPA should call for effective recordkeeping.

Thank you for this opportunity to comment on the proposal. Please contact us if we can provide additional information.

Sincerely,



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