ENVIRONMENTAL

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Hundreds of Hospitals Subject to New EPA Rule Governing Air Emissions From Ethylene Oxide Sterilizers

The U.S. Environmental Protection Agency (EPA) issued a new rule on December 28, 2007, which applies to hospitals with ethylene oxide sterilization facilities. 72 FR 73611. Under the federal Clean Air Act, ethylene oxide is considered a "hazardous air pollutant" (HAP).

EPA estimates that approximately 1,600 to 1,900 of the nation's 5,800 hospitals use ethylene oxide gas to sterilize medical items. EPA's new HAP rule requires these hospitals to comply with a management practice standard, to submit an initial notification, and to maintain certain records.

Hospitals with existing sterilization facilities must comply with the rule by December 28, 2008. Hospitals installing new sterilization facilities must comply with the rule immediately upon startup of the new facility.

As described briefly below, the management practice standard should not be particularly costly or burdensome. Affected hospitals should take care, however, to ensure that they are in timely compliance with the new rule, especially with the notification and recordkeeping requirements. EPA has often initiated enforcement against facilities subject to HAP rules for failure to comply with notification and recordkeeping requirements, even when a facility's operations might otherwise generally comply with the rule's substantive requirements. Failure to comply with HAP rules may lead to civil as well as criminal sanctions.

The management practice standard requires hospitals to sterilize full loads of items having a common aeration time, except when medical necessity dictates the use of less than a full load to protect human health. The determination that sterilizing less than a full load is medically necessary may be made by a hospital central services staff, a hospital administrator, or a physician. Such personnel are not required to consider whether there are viable alternatives to running a partial load such as purchasing additional sterilizer equipment or medical devices before invoking the medical necessity exception. EPA recognizes that it may be medically necessary to sterilize devices under research and development without a full load.

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All covered sources must submit an Initial Notification of Compliance Status to EPA, and, in certain states, to the state air pollution control authority. The notification must provide specified information about the source, and must include a certification that the source is operating in compliance with the management practice standard. In lieu of certifying compliance with the management practice standard, operators of sterilization units equipped with air pollution control devices may certify compliance by stating that the unit is being operated in accordance with applicable state and/or local regulations or, if there are no such regulations, with the manufacturer's specifications. For new sources, the initial notification must be submitted 180 calendar days after initial startup. For existing sources, the initial notification must be submitted 180 calendar days after the compliance date (December 28, 2008).

Recordkeeping requirements apply to all sterilization units that are not equipped with an air pollution control device. Records must be maintained of the date and time of each sterilization cycle, whether the cycle contained a full load and, if not, a statement that it was medically necessary to run less than a full load. Records must be maintained for five years, and at least the most recent two years must be maintained onsite.

The rule defines "hospital" as any "facility that provides medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day." 72 FR at 73624 (40 CFR 60.10448). The definition includes diagnostic and major surgery facilities but excludes doctor's offices, clinics, and other facilities primarily providing outpatient care.

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