

## Environmental Protection Agency

## § 63.10430

28, 2007, you must comply with applicable requirements in this subpart by December 28, 2007.

(c) *New source.* If you start up a new affected source after December 28, 2007, you must comply with applicable requirements in this subpart upon start-up of your affected source.

### STANDARDS

#### § 63.10390 What management practice standard must I meet?

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.

### INITIAL COMPLIANCE REQUIREMENTS

#### § 63.10400 How do I demonstrate initial compliance?

(a) Except as provided in paragraphs (b) and (c) of this section, 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 time except under medically necessary circumstances.

(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.

(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.

#### § 63.10402 By what date must I demonstrate initial compliance?

You must demonstrate initial compliance with § 63.10390 upon startup or no later than 180 calendar days after your compliance date, whichever is later.

### MONITORING—CONTINUOUS COMPLIANCE REQUIREMENTS

#### § 63.10420 How do I demonstrate continuous compliance with the management practice requirements?

For each sterilization unit not equipped with an air pollution control device, you must demonstrate continuous compliance with the management practice standard in § 63.10390 by recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.

### NOTIFICATIONS, REPORTS, AND RECORDS

#### § 63.10430 What notifications must I submit and by when?

(a) You must submit an Initial Notification of Compliance Status that includes the information required in paragraphs (a)(1) through (5) of this section and the applicable certification in § 63.10400.

(1) The name and address of the owner or operator.

(2) The address (i.e., physical location) of the affected source.

(3) An identification of the standard and other applicable requirements in this subpart that serve as the basis of the notification and the source's compliance date.

(4) A brief description of the sterilization facility, including the number of ethylene oxide sterilizers, the size (volume) of each, the number of aeration units, if any, the amount of annual ethylene oxide usage at the facility, the control technique used for each sterilizer, and typical number of sterilization cycles per year.

(5) A statement that the affected source is an area source.

(b) You must submit the Initial Notification of Compliance Status to the

appropriate authority(ies) specified in § 63.9(a)(4). In addition, you must submit a copy of the Initial Notification of Compliance Status to EPA's Office of Air Quality Planning and Standards. Send your notification via e-mail to *CCG-ONG@EPA.GOV* or via U.S. mail or other mail delivery service to U.S. EPA, Sector Policies and Programs Division, Coatings and Chemicals Group (E143-01), Attn: Hospital Sterilizers Project Leader, Research Triangle Park, NC 27711.

(c) You must submit the Initial Notification of Compliance Status no later than 180 calendar days after your compliance date, consistent with § 63.10402.

**§ 63.10432 What records must I keep?**

You must keep the records specified in paragraphs (a) and (b) of this section.

(a) A copy of the Initial Notification of Compliance Status that you submitted to comply with this subpart.

(b) Records required by § 63.10420 for each sterilization unit not equipped with an air pollution control device.

**§ 63.10434 In what form and for how long must I keep my records?**

(a) Your records must be in a form suitable and readily available for expeditious review.

(b) You must keep each record for 5 years following the date of each record.

(c) You must keep each record onsite for at least 2 years after the date of each record. You may keep the records offsite for the remaining 3 years.

**OTHER REQUIREMENTS AND INFORMATION**

**§ 63.10440 What parts of the General Provisions apply to me?**

Table 1 to this subpart shows which parts of the General Provisions in 40 CFR 63.1 through 63.16 apply to you.

**§ 63.10442 Who implements and enforces this subpart?**

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your State, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your State, local, or tribal agency, then that agency has the authority to implement and enforce this

subpart. You should contact your U.S. EPA Regional Office to find out if this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by the Administrator of the U.S. EPA and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies include approval of alternatives to the applicability requirements under 40 CFR 63.10382, the compliance date requirements in 40 CFR 63.10384, and the management practice standards as defined in 40 CFR 63.10390.

**§ 63.10446 Do title V permitting requirements apply to area sources subject to this subpart?**

You are exempt from the obligation to obtain a permit under 40 CFR part 70 or 40 CFR part 71, provided you are not otherwise required by law to obtain a permit under 40 CFR 70.3(a) or 40 CFR 71.3(a). Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart.

**§ 63.10448 What definitions apply to this subpart?**

Terms used in this subpart are defined in the Clean Air Act (CAA), in 40 CFR 63.2, and in this section as follows:

*Aeration process* means any time when ethylene oxide is removed from the aeration unit through the aeration unit vent or from the combination sterilization unit through the sterilization unit vent, while aeration or off-gassing is occurring.

*Aeration unit* means any vessel that is used to facilitate off-gassing of ethylene oxide.

*Air pollution control device* means a catalytic oxidizer, acid-water scrubber, or any other air pollution control equipment that reduces the quantity of ethylene oxide in the effluent gas stream from sterilization and aeration processes.

*Combination sterilization unit* means any enclosed vessel in which both the sterilization process and the aeration