

**§ 63.10390**

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.

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**§ 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