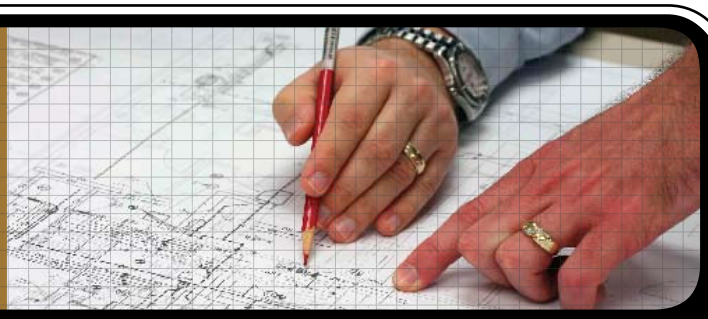
Compliance News



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New EPA Rule on Ethylene Oxide Sterilizers Will Affect Many Hospitals

By Dean Samet, CHSP - DSamet@ssr-inc.com

"The Clean Air Act considers ethylene oxide as a hazardous air pollutant . . ."

The Environmental Protection Agency (EPA) issued a new rule (see 40 CFR Part 63) effective December 28, 2007 which applies to new and existing hospitals with ethylene oxide sterilization facilities used to sterilize medical devices. The Clean Air Act considers ethylene oxide (ETO) as a hazardous air pollutant (HAP) so hospitals will now be required to sterilize full loads of items in their ETO sterilizers in order to reduce hazardous emissions. There are some exceptions permitting less than a full load if "medically necessary" as determined by central services staff, a hospital administrator, or physician on duty or when the sterilizer(s) has an acceptable air pollution control device.

Per Federal Register/Vol.72,No.248/Friday, Dec.28, 2007/Rules and Regulations P.73611, the EPA has issued national emissions standards for new and existing hospital sterilizers that emit hazardous air pollutants and are area sources within the meaning of Clean Air Act section 112(a)(2). The final rule is based on EPA's determination as to what constitutes the general available control technology or management practices for the hospital sterilization area source category. This action is being finalized as part of EPA's obligation to regulate area sources listed for regulation pursuant to Clean Air Act section 112(c)(3).

To determine whether your facility is regulated by this action, you should examine the applicability criteria in 40 CFR 63.10382 of subpart WWWWW (National Emissions Standards for Hospital Ethylene Oxide Sterilizers) as follows.

Applicability and Compliance Dates

§ 63.10382_Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate an ethylene oxide sterilization facility at a hospital that is an area source of hazardous air pollutant (HAP) emissions.

(b) The affected source subject to this subpart is each new or existing sterilization facility.

(1) An affected source is existing if you commenced construction or reconstruction of the affected source before November 2006.

(2) An affected source is new if you commenced construction or reconstruction of the affected source on or after November 6, 2006.

§ 63.10384_What are my compliance dates?

(a) Existing source. If you have an existing source, you must comply with applicable requirements in this subpart no later than December 29, 2008.

(b) New source. If you start up a new affected source on or before December 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 startup of your affected source.

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 *(continued on page 3)*

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TJC Sentinel Event Alert #38 - Preventing Accidents and Injuries in the MRI Suite

By Dean Samet, CHSP - DSamet@ssr-inc.com

The Joint Commission released its 38th Sentinel Event Alert on February 14, 2008 which warns us about the potential safety hazards associated with the magnetic resonance imaging (MRI) scanning process. While the capabilities of the MRI scanner have been well recognized for over 30 years, there are some inherent dangers in its use. The following types of injuries can and have occurred during the MRI scanning process:

- *"Missile effect" or "projectile" injury in which ferromagnetic objects (those having magnetic properties) such as ink pens, wheelchairs, and oxygen canisters are pulled into the MRI scanner at rapid velocity.*
- *Injury related to dislodged ferromagnetic implants such as aneurysm clips, pins in joints, and drug infusion devices.*
- *Burns from objects that may heat during the MRI process, such as wires (including lead wires for both implants and external devices) and surgical staples, or from the patient's body touching the inside walls (the bore) of the MRI scanner during the scan.*
- *Injury or complication related to equipment or device malfunction or failure caused by the magnetic field. For example, battery-powered devices (laryngoscopes, micro infusion pumps, monitors, and so forth) can suddenly fail to operate; some programmable infusion pumps may perform erratically; and pacemakers and implantable defibrillators may not perform as programmed.*
- *Injury or complication due to failure to attend to patient support systems during the MRI. This is especially true for patient sedation or anesthesia in MRI arenas. For example, oxygen canisters or infusion pumps run out and staff must either leave the MRI area to retrieve a replacement or move the patient to an area where a replacement can be found.*
- *Acoustic injury from the loud knocking noise that the MRI scanner makes.*
- *Adverse events related to the administration of MRI contrast agents.*
- *Adverse events related to cryogen handling, storage, or inadvertent release in superconducting MR imaging system sites.*

The Joint Commission's Sentinel Event Alert newsletter recommends that health care organizations take the following steps to reduce the risk for MRI injuries to patients:

- *Restrict access to all MRI sites by creating safe zones recommended by the American College of Radiology (ACR);*
- *Use trained screeners to perform double checks of patients for items such as metal objects, implanted or other devices, drug delivery patches and tattoos;*
- *Ensure that the MRI technologist has the patient's complete and accurate medical history to ensure that the patient can be safely scanned;*
- *Have a specially trained staff person accompany any patients, visitors and staff into the MRI suite at all times;*
- *Annually educate all medical and ancillary staff who may accompany patients into the MRI suite about the risk of accidents;*
- *Take precautions to prevent patient burns during scanning;*
- *Only use fire extinguishers, oxygen tanks and other equipment that have been tested and approved for use during MRI scans (equipment that will not be attracted to the magnet);*
- *Manage critically ill patients who require monitoring and life-sustaining drugs to assure that their care needs are continuously met while in the MRI suite;*
- *Provide all MRI patients with ear plugs to diminish the loud "knocking" noise emanating from the equipment; and*
- *Never run a cardio-pulmonary arrest code or resuscitate a patient in the MRI room.*

While millions of MRI scans are performed each year and while most cause no harm, the inherent dangers of the process need to be better known. The most common types of injuries are burns, while many accidents are caused by common objects that become missiles when brought into the MRI scanner's magnetic field. Hopefully, by implementing the recommendations listed above, risks of injury can be significantly reduced.

New EPA Rule on Ethylene Oxide Sterilizers Will Affect Many Hospitals

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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 § 63.1039 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 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 staff, a hospital administrator, or a physician that it was medically necessary.

Note: If your hospital uses ethylene oxide sterilizers, you are highly encouraged to read the entire Environmental Protection Agency 40 CFR Part 63 to ensure that you are in or will be in compliance by the dates noted above. For further information, you may contact Mr. David Markwordt, Office of Air Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group, Environmental Protection Agency, Research Triangle Park, NC 27711. E-mail address: markwordt.david@epa.gov

Concealed Sprinklers

By Robert Trotter - RTrotter@ssr-inc.com

Concealed sprinklers, as part of a fire sprinkler system, feature a flat cover plate designed as an architectural feature to conceal the sprinkler head. Whether installed in a suspended ceiling or monolithic ceiling, they must be installed and maintained in compliance with the manufacturer listing and the applicable standards of the National Fire Protection Association. Absence of the cover plate assembly may delay sprinkler operation in a fire situation. When properly installed, there is a manufacturer preset (nominal 3/32-inch) air gap between the lip of the cover plate and the ceiling. This air gap is necessary for proper operation of the sprinkler. If the ceiling is to be repainted after the installation of the sprinkler, care must be exercised to ensure that caulking and the new paint DOES NOT seal off any of the air gap. Factory painted cover plates MUST NOT be repainted. They should be replaced, if necessary, by factory painted units.

To learn more about commissioning and LEED, please see the SSRCx news here . . .

PUBLICATIONS & SEMINARS

Look for these articles in publication

"Power Players - Finding emergency power system vulnerabilities," *Health Facilities Management*, February 2008

Speaking Engagements/Seminars in 2008

April 15-18	TAHFM Interlink 2008, Dallas, TX, "Life Safety Code Statement of Conditions and The Joint Commission Survey Focus for 2008"
May 8	HCPro BHS Symposium, Las Vegas, NV, "Environment of Care Survey Focus"
May 8-9	Arkansas Association for Healthcare Engineering Annual Meeting, Hot Springs, AR, "Building Commissioning for LEED & Non-LEED Projects," "Environment of Care Survey Focus," and "Operating Safer Hospitals, A Review of NFPA 99"
May 14-16	Alabama Society for Healthcare Engineering Spring Meeting, Pensacola Beach, FL, "TJC 2008 Emergency Management Standards"
May 15	Oregon Society for Healthcare Engineers Spring Conference, Bend, OR, "TJC EC Update and Survey Focus 2008"
June 2-5	NFPA World Safety Conference & Exposition, Las Vegas, NV, "Rx for Emergency Power Reliability"
June 4-6	Mississippi Hospital Association Society for Healthcare Engineers, Bay St. Louis, MS, "Planning for Power Failures & Sentinel Event Alert 37," and "EOC Survey Focus 2008"
June 4-6	Georgia Society for Hospital Engineers Annual Meeting, Savannah, GA, "2008 Emergency Management Standards"
June 18	Nebraska Hospital Association Webinar, "Planning for Power Failures"
July 20-23	ASHE 45th Annual Conference & Technical Exhibition, Washington, DC, "Taking Care of Business - How Power Shutdowns Can Facilitate Emergency Management" and "NFPA 110 Update - Paying More Attention to the Business of Emergency Power Reliability"
October 7-10	New England Healthcare Engineers Society Fall Conference, New Haven, CT, "EOC Survey Focus 2008-2009"
October 27-29	Florida Healthcare Engineers Association Annual Meeting, Orlando, FL, "Emergency Power Challenges in 2009 and Beyond"
November 5-7	Midwest Healthcare Engineering Conference, Indianapolis, IN, ""TJC's New 2008 Emergency Management Standards: What's New? What's Not?" and "Filling the Rx for Reliable Power in 2009 and Beyond"
November 20	Colorado Association of Hospital Engineers & Directors, Denver, CO, "TJC Newly Expanded 2008 Emergency Management Standards"

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Compliance News

A newsletter dedicated to accreditation, regulatory compliance and facility management issues for healthcare executives and facility managers.