Tentative Interim Amendment

NFPA 560

Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation

2007 Edition

Reference: Chapter 3 and Section 11.5
TIA 07-1
(SC 07-6-4/TIA Log #873)

Pursuant to Section 5 of the NFPA Regulations Governing Committee Projects, the National Fire Protection Association has issued the following Tentative Interim Amendment to NFPA 560, *Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation,* 2007 edition. The TIA was processed by the Technical Committee on Industrial and Medical Gases, and was issued by the Standards Council on June 4, 2007, with an effective date of June 24, 2007.

A Tentative Interim Amendment is tentative because it has not been processed through the entire standards-making procedures. It is interim because it is effective only between editions of the standard. A TIA automatically becomes a proposal of the proponent for the next edition of the standard; as such, it then is subject to all of the procedures of the standards-making process.

1. Add a new definition to Chapter 3 as follows:

3.3.3 Back-Vent System. An exhaust vent system designed to transport residual vapors from a sterilization chamber to a designated point of termination outside of the building.

2. Revise Section 11.5 as follows:

11.5* Oxidizing Emission Control Devices.
11.5.1 General.
~~*11.5.1*~~ **11.5.1.1** All interlocks and safeguards shall be in place before sterilization begins.
~~**11.5.2**~~ **11.5.1.2** Sterilization products that sit idle in the sterilization or aeration room shall be periodically washed or vented.
~~**11.5.3** Ethylene oxide concentration in the sterilizer before the back vents shall be monitored to avoid venting high ethylene oxide concentrations to the oxidizing emission control device.~~
~~**11.5.4**~~ **11.5.1.3** Confined spaces shall be vented to the outside after power loss.
~~**11.5.5** Ethylene oxide lines shall not be purged to an oxidizing emission control device.~~
~~**11.5.6**~~ **11.5.1.4** Regular preventive maintenance shall be performed.
11.5.2 Sterilizers Equipped with Back-Vent Systems Connected to Emission Control Devices.
11.5.2.1 Sterilizers equipped with a back-vent system connected to an oxidizing emission control device shall be in accordance with 11.5.2.1.
11.5.2.1.1* Engineering controls shall be provided to ensure that residual ethylene oxide concentration at the entrance to the oxidizing emission control device does not exceed 25% of the lower flammable limit (0.75% by volume) as follows:
(1) The sterilization chamber shall be equipped with gas detection to monitor the concentration of ethylene oxide within the sterilization chamber.
(2) A safety interlock shall be provided to prevent the back-vent system from opening if the concentration of ethylene oxide in the sterilization chamber exceeds the predetermined limits required by the operating procedures specified in 8.1.1.

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(3)* Exhaust duct systems used to convey ethylene oxide vapors shall be in accordance with the mechanical code.
11.5.3 Piping used to convey ethylene oxide to the sterilization process shall not be purged to an oxidizing emission control device.

3. Add Annex notes to Annex A as follows:

A.11.5 Oxidizing emission control devices can include catalytic converters, flares or other active sources of ignition.
A.11.5.2.1.1 Engineering controls can include computer and/or programmable logic controllers and associated software and hardware that control the sterilization process, safety interlocks, purge systems, gas detection, and monitoring systems. The controls provided are to ensure that the concentration of ethylene oxide at the point where it is released to the emission control device is reduced below 25% of its lower flammable limit.
A.11.5.2.1.1(3) The mechanical code in use by the jurisdiction in which the installation is located is used to establish design requirements of the exhaust duct system. Requirements for the duct system can vary depending on the mechanical code in use as well as with the maximum concentration of ethylene oxide to be released to the duct system for any specific process.

4. Add an informational reference to Annex C.1.1 as follows:

NFPA 86, *Standard for Ovens and Furnaces*, 2007 edition.

5. Add an informational reference to Annex C.2 as follows:

NIOSH Alert: *Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities*. The report is available to the public through www.cdc.gov/niosh/homepage.html.

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