

**15A NCAC 02D .0538 CONTROL OF ETHYLENE OXIDE EMISSIONS**

(a) For purposes of this Rule, "medical devices" means instruments, apparatus, implements, machines, implants, in vitro reagents, contrivances, or other similar or related articles including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or intended to affect the structure or any function of the body of man or other animals.

(b) This Rule applies to emissions of ethylene oxide resulting from use as a sterilant in:

- (1) the production and subsequent storage of medical devices; or
- (2) the packaging and subsequent storage of medical devices for sale;

at facilities for which construction began after August 31, 1992.

(c) This Rule does not apply to hospital or medical facilities.

(d) Facilities subject to this Rule shall comply with the following standards:

- (1) For sterilization chamber evacuation, a closed loop liquid ring vacuum pump, or equipment demonstrated to be as effective at reducing emissions of ethylene oxide shall be used;
- (2) For sterilizer exhaust, a reduction in the weight of uncontrolled emissions of ethylene oxide of at least 99.8 percent by weight shall be achieved;
- (3) For sterilizer unload and backdraft valve exhaust, a reduction:
  - (A) in uncontrolled emissions of ethylene oxide of at least 99 percent by weight shall be achieved; or
  - (B) to no more than one part per million by volume of ethylene oxide shall be achieved;
- (4) Sterilized product ethylene oxide residual shall be reduced by:
  - (A) a heated degassing room to aerate the products after removal from the sterilization chamber; the temperature of the degassing room shall be maintained at a minimum of 95 degrees Fahrenheit during the degassing cycle, and product hold time in the aeration room shall be at least 24 hours; or
  - (B) a process demonstrated to be as effective as Part (d)(4)(A) of this Rule.
- (5) Emissions of ethylene oxide from the degassing area (or equivalent process) shall be vented to a control device capable of reducing uncontrolled ethylene oxide emissions by at least 99 percent by weight or to no more than one part per million by volume of ethylene oxide.. The product aeration room and the product transfer area shall be maintained under a negative pressure.

(e) Before installation of the controls required by Paragraph (d) of this Rule, and annually thereafter, a written description of waste reduction, elimination, or recycling plan shall be submitted [as specified in G.S. 143-215.108(g)] to determine if ethylene oxide use can be reduced or eliminated through alternative sterilization methods or process modifications.

(f) The owner or operator of the facility shall conduct a performance test to verify initial efficiency of the control devices. The owner or operator shall maintain temperature records to demonstrate proper operation of the degassing room. Such records shall be retained for a period of at least two calendar years and shall be made available for inspection by Division personnel.

(g) If the owner or operator of a facility subject to the Rule demonstrates, using the procedures in Rule .1106 of this Section, that the emissions of ethylene oxide from all sources at the facility do not cause the acceptable ambient level of ethylene oxide in Rule .1104 of this Section to be exceeded, then the requirements of Paragraphs (d) through (e) of this Rule shall not apply. This demonstration shall be at the option of the owner or operator of the facility. If this option is chosen, the Director shall write the facility's permit to satisfy the requirements of Rule .1104(a) of this Section.

*History Note:* Authority G.S. 143-215.3(a)(1); 143-215.107(a)(4),(5); 143-215.108(c);  
Eff. September 1, 1992;  
Amended Eff. June 1, 2004; August 1, 2002.