TITLE 26 DEPARTMENT OF THE ENVIRONMENT

SUBTITLE 11 AIR QUALITY

CHAPTER 19 CONTROL OF VOLATILE ORGANIC COMPOUNDS FROM SPECIFIC PROCESSES

.31 Control of Volatile Organic Compounds from Medical Device Manufacturing.

[SIP effective date: February 12, 2007]

A. Definitions. In this regulation, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Biopassive coating" means a coating applied to a product to reduce blood coagulation.

(2) "Fixed needle syringe process" means insulin syringe assembly process with silicone and glue application, barrel printing, and drying.

(3) "Hypodermic needle process" means a standard syringe assembly process with silicone and glue application, barrel printing, and drying.

(4) "Medical device" means a device intended for use:

(a) In the diagnosis of disease or other conditions; or

(b) In the cure, mitigation, treatment, or prevention of disease.

(5) "Medical device manufacturing installation" means a process or operation that causes VOC emissions during the manufacture of medical devices.

C. Applicability.

(1) This regulation applies to a person who owns or operates a medical device manufacturing installation at a premises that emits, or has the potential to emit, 100 pounds or more per day of VOC emissions from all medical device manufacturing installations.

(2) Except as provided in §C(3) of this regulation, a person that owns or operates an installation subject to the requirements of this chapter is not, for that installation, subject to any other provisions of this chapter.

(3) A person subject to the requirements of this regulation also is subject to Regulations .01, .02, and .16 of this chapter.

D. VOC Control Requirements. A person who is subject to this regulation shall:

(1) Do all of the following:

(a) Provide and maintain appropriately designed VOC impermeable covers on dip pots used for manual bonding operations when not in use;

(b) Upon request of the Department, participate in the evaluation of new or innovative designs or VOC material substitutions to minimize the use of solvent bonds for medical device manufacturing;

(c) Use an enclosed system to apply biopassive coating to fully assembled medical devices;

(d) Apply biopassive coating to individual medical device components only when it is not feasible to coat medical devices in assembled form, and

(e) Use a solvent chiller system to chill solvent to 50F or less prior to use in steel cannula coating to minimize VOC emissions on the following:

(i) Fixed needle syringe processes; and

(ii) Hypodermic needle processes; or

(2) Use a Department approved alternative method of compliance or alternative control technology that achieves an equivalent or better level of VOC control.

E. Before coating individual components under §D(1)(d) of this regulation, a person subject to this regulation shall submit to the Department for review and approval, a report documenting the technical and economic justification for coating components individually.

F. Before using an alternative method of compliance or control technology a person subject to this regulation shall submit a proposal to use such alternative method of compliance or control technology to the Department for review and approval.