

Amendments to 310 CMR 7.00: Massachusetts Air Pollution Control Regulation

310 CMR 7.00 – Definitions

BIOTECHNOLOGY means the use of cellular and molecular processes from living systems to make or assist in making products.

310 CMR 7.02(2) Exemptions from Plan Approval

(b) Exemptions

33. Biotechnology Laboratory. A laboratory used solely for research, development or support for medical device, drug, or biologic products derived in whole or in part from biotechnology, and such products are either undergoing preclinical research in preparation for, or are the subject of, one of the following U.S. Food and Drug Administration (FDA) regulatory applications or notices: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, premarket approval application, premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) and any other product exempted by FDA from the 510(k) premarket notification requirement.

310 CMR 7.03 Plan Approval Exemption: Construction Requirements

(25) Biotechnology Surface Disinfection Processes

- (a) Construction, substantial reconstruction, or alteration of any surface disinfection process used in making any of the following medical device, drug, or biologic products:
1. a product derived in whole or in part from biotechnology, and
 2. one of the following applications or notices has been filed with U.S. Food and Drug Administration (FDA) for such product: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, a premarket approval application, or a premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement).
- (b) Surface disinfection processes shall comply with the following criteria:
1. The total facility-wide actual emissions, including new or modified surface disinfection processes, shall not exceed 15 tons of volatile organic compounds (VOC) per 12-month rolling period. This VOC emission limitation includes all process operations at the facility. In addition, facility-wide actual emissions of VOC shall not exceed 2.5 tons per calendar month.

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2. The total facility-wide actual emissions, shall not exceed 9 tons of any single Hazardous Air Pollutants (HAP as defined at 40 CFR Part 63) per 12-month rolling period, and shall not exceed 15 tons of any combination of (total) HAP per 12-month rolling period. In addition, facility-wide actual emissions of any individual HAP shall not exceed 2 tons per calendar month, and any combination of (total) HAP shall not exceed 3 tons per calendar month.
3. Processes that emit or will emit VOCs or HAPs in exceedance of limitations for VOCs and HAPs established in Subsections (b)1 or (b)2 above, are subject to 310 CMR 7.02(5) Comprehensive Plan Approval (CPA), and a person shall obtain written Department plan approval prior to commencement of construction, installation and operation of said processes.
4. Combustion processes that support processes subject to 310 CMR 7.03(25) are subject to regulatory standards found at 310 CMR 7.02 Plan Approval and Emission Limitations, 310 CMR 7.03 Plan Approval Exemption: Construction Requirements, or 310 CMR 7.26 Industry Performance Standards.
5. Cleaning, sterilization, disinfection, and other operations:
 - a. Cleaning, sterilization, disinfection, and other solutions which contain VOC shall be kept in tightly closed containers when not in active use and during transport and storage, and
 - b. The spent cleaning cloths and/or wipes used in conjunction with the cleaning and sterilization solutions shall be placed, after use, in tightly closed containers and collected for proper recycling or disposal.
6. Any person subject to this regulatory standard shall maintain records sufficient to demonstrate compliance with 310 CMR 7.03(25) for each calendar month. Records kept to demonstrate compliance with 310 CMR 7.03(25) shall be maintained on-site for five years and shall be made available to representatives of the Department upon request. For each process and operation, such records shall include, but not be limited to:
 - a. Gallons of VOC used;
 - b. Pounds of VOC used;
 - c. Gallons of individual and total HAP used; and
 - d. Pounds of individual and total HAP used.