



Industrial Waste Program Biotechnology Industry Sector Permitting Guidelines

Applicability

These permitting guidelines apply to the discharge of process wastewater from biotechnology industry sector facilities into sewerage facilities tributary to the King County sewer system. These guidelines apply to biotechnology industry sector facilities engaged in bench scale, pilot scale, and full-scale operations. Typical activities expected to be present at these facilities include, but are not limited to, research & development, fermentation, cell culture, biological extraction, and chemical synthesis.

Definitions

- (a) The term *biotechnology industry sector* includes commercial and noncommercial organizations that use living organisms, biological research and pure organic chemical research to develop medical, environmental, and agricultural pharmaceutical products.
- (b) The term *King County sewer system* means all or any part of the sewerage facilities acquired, constructed or used by King County.
- (c) The term *process wastewater* means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product.
- (d) *Bench scale operations* (laboratory scale) are biotechnology industry sector operations primarily engaged in research and development of biotech products.
- (e) *Pilot scale operations* are biotechnology industry sector operations engaged in the manufacturing of biotech products for phases, I, II, and III clinical trials and testing.
- (f) *Full scale operations* are U.S. Food and Drug Administration (FDA) licensed biotechnology industry sector operations engaged in the manufacturing of products for commercial sale.

Permitting Guidelines

1. Discharge requirements applicable to all biotechnology industry sector operations
All biotechnology industry sector operations discharging into the King County sewer system must comply with the discharge restrictions and limitations detailed in King County Code 28.84.060 and King County Industrial Waste local discharge limits. In addition, these operations should follow the process wastewater treatment and discharge guidelines and best management practices detailed in the Laboratory Waste Management Guide published by the Local Hazardous Waste Management Program in King County.
2. Bench scale operations discharging process wastewater at a rate of less than 25,000 gallons per day – These operations are not required to apply for and obtain individual waste discharge approvals from the King County Industrial Waste Program. In accordance with King County Code 28.84.060, the King County Industrial Waste Program hereby approves the discharge of process wastewater generated by these operations provided that they comply with the conditions set forth in Item 1 of this policy.

3. Bench scale operations discharging process wastewater at a rate greater than 25,000 gallons per day, pilot scale operations, and full-scale operations – In addition to complying with the conditions set forth in Item 1 of this policy, these operations need to apply for and obtain individual waste discharge approvals.

The Industrial Waste Program issues several types of discharge approvals including letters of authorization, discharge authorizations, and waste discharge permits. The type of discharge approval issued to each individual operation will depend on the following factors:

- a. Daily industrial waste discharge volume
- b. Categorical vs. non-categorical status (see 40 CFR – Part 439)
- c. Wastewater characteristics
- d. Compliance history with King County discharge limits, when applicable
- e. Need to install and/or operate pretreatment system
- f. Apparent risk to sewerage facilities

Compliance Deadline

Affected operations must comply with these guidelines by October 15, 2006.

For documents and information relevant to these permitting guidelines go to:
www.kingcounty.gov/industrialwaste

The Industrial Waste Program Internet pages contain:

- Types of discharge approvals issued by the King County Industrial Waste Program
- The King County Industrial Waste Program Wastewater Discharge Permit Application

King County Internet pages also contain links to:

- King County Code 28.84.060
- King County Public Rules and Regulations
- King County Industrial Waste Local Discharge Limits

For the Laboratory Waste Management Guide published by the Local Hazardous Waste Management Program in King County go to:

www.lhwmp.org/home/publications/publications_detail.aspx?DocID=o5fpDUrc%2f%2bc%3d

For the Code of Federal Regulations (CFR) – 40 CFR Part 439 Pharmaceutical Manufacturing Point Source Category go to: www.access.gpo.gov/nara/cfr/waisidx_99/40cfr439_99.html