

increase in the concentrations of nitrites and nitrates.

(j) *Non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(k) *Pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(l) *POTW* means publicly owned treatment works (40 CFR 403.3).

(m) *Process wastewater*, as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active antimicrobial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(n) *Non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor "toxic" pollutants (40 CFR 401.15).

(o) *Surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A of this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(p) *Xylenes* means a combination of the three isomers: o-xylene, m-xylene, and p-xylene.

3. Section 439.2 is revised to read as follows:

§ 439.2 General monitoring requirements.

(a) Permit compliance monitoring is required for each regulated pollutant

generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part, a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with a recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and measurement of a non-detect value for each regulated pollutant or its surrogate. Permits must specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

(b) Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged.

4. Section 439.4 is revised to read as follows:

§ 439.4 General limitation or standard for pH.

The pH must remain within the range 6.0 to 9.0 in any discharge subject to BPT, BCT or NSPS limitations or standards in this part.

5. Revise the heading of subpart A to read as follows:

Subpart A—Fermentation Products

6. Section 439.11 is revised to read as follows:

§ 439.11 Special definitions.

For the purpose of this subpart:

(a) *Fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.

(b) *Product* means pharmaceutical products derived from fermentation processes.

7. Section 439.12 is amended by revising paragraphs (a) introductory text, and (b) through (e) to read as follows:

§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

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(a) The maximum monthly average limitation for BOD₅, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

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(b) The maximum monthly average limitation for TSS, expressed as mass loading (lbs., kg) per day, must be calculated as 1.7 times the BOD₅ limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the limitations for COD are as follows:

EFFLUENT LIMITATIONS (BPT)

| Regulated parameter | Maximum daily ¹ | Maximum monthly average ¹ |
|---------------------|----------------------------|--------------------------------------|
| COD | 1675 | 856 |

¹mg/L (ppm).

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the monthly average limitation for COD corresponding to the lower concentration value must be applied.

(e) The effluent limitations for cyanide are as follows:

EFFLUENT LIMITATIONS (BPT)

| Regulated parameter | Maximum daily ¹ | Maximum monthly average ¹ |
|---------------------|----------------------------|--------------------------------------|
| Cyanide (T) | 33.5 | 9.4 |

¹mg/L (ppm).

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8. Section 439.14 is revised to read as follows:

§ 439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: