

(2) For purposes of this part, the following waters and wastewaters are excluded from the definition of process wastewater: noncontact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other water generated on site that are not process wastewaters.

The discharge of such waters and wastewaters must be regulated separately.

Process wastewater collection system—A piece of equipment, structure, or transport mechanism used in conveying or storing a process wastewater stream. Examples of process wastewater collection system equipment include individual drain systems, wastewater tanks, surface impoundments, and containers.

Process wastewater stream—When used in connection with CAA obligations, any HAP-containing liquid that results from either direct or indirect contact of water with organic compounds.

Process water—Water used to dilute, wash, or carry raw materials or any other materials used in pharmaceutical manufacturing processes.

PSES—Pretreatment standards for existing sources of indirect discharges, under section 307(b) of the CWA.

PSNS—Pretreatment standards for new sources of indirect discharges, under sections 307(c) of the CWA.

RCRA—Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901, *et seq.*).

Research—Bench-scale activities or operations used in research and/or product development of a pharmaceutical product. The Research operations define subcategory E (40 CFR 439, Subpart E).

SIC—Standard Industrial Classification. A numerical categorization system used by the U.S. Department of Commerce to denote segments of industry. An SIC code refers to the principal product, or group of products, produced or distributed, or to services rendered by an operating establishment. SIC codes are used to group establishments by the primary activity in which they are engaged.

Source Category—A category of major or area sources of hazardous air pollutants.

Source Reduction—The reduction or elimination of waste generation at the source, usually within a process. A source reduction practice is any practice that (1) Reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the

environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.

Stationary source—Any building, structure, facility, or installation that emits or may emit any air pollutant. See CAA section 111(a)(3).

Support Document(s)—see section II for titles.

TDD—Technical Development Document

TEQ—Toxic Equivalent.

TSCA—Toxic Substances Control Act (15 U.S.C. 2601, *et seq.*).

TSS—Total Suspended Solids.

Toxic pollutants—the pollutants designated by EPA as toxic in 40 CFR 401.15.

Variability factor—The daily variability factor is the ratio of the estimated 99th percentile of the distribution of daily values divided by the expected value, or mean, of the distribution of the daily data. The monthly variability factor is the estimated 95th percentile of the monthly averages of the data divided by the expected value of the monthly averages.

VOC—Volatile Organic Compound—means any organic compound, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions other than those that the Administrator designates as having negligible photochemical reactivity. The Administrator has designated the following organic compounds as negligibly reactive: methane; ethane; methylene chloride; methyl chloroform; CFC-113; CFC-111; CFC-12; CFC-22; CFC-23; CFC-114; CFC-115; HCFC-123; HFC-134a; HCFC-141b; HCFC-142b; HCFC-124; HFC-125; HFC-134; HFC-143a; HFC-152a; and perfluorocarbon compounds which fall into these classes: (i) Cyclic, branched, or linear, completely fluorinated alkanes; (ii) cyclic, branched, or linear, completely fluorinated ethers with no unsaturations; cyclic, branched, or linear, completely fluorinated tertiary amines with no unsaturations; and (iv) sulfur containing perfluorocarbons with no unsaturations and with sulfur bonds only to carbon and fluorine. 40 CFR 51.100(s)(1).

Waters of the United States—the same meaning set forth in 40 CFR 122.2.

Zero discharge (ZD)—No discharge of wastewater to waters of the United States or to a POTW.

II. Background Documents

The rule proposed today is supported by several major documents: (1) EPA's technical conclusions concerning the wastewater regulations are detailed in the "Development Document for Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category," hereafter referred to as the Technical Development Document (TDD) (EPA 821-R-95-019), (2) the Agency's economic analysis is found in the "Economic Impact and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Economic Impact Analysis (EPA 821-R-95-018), (3) the regulatory impact analysis (including the Agency's assessment of environmental benefits) is detailed in the "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Regulatory Impact Assessment (EPA 821-R-95-017), (4) an analysis of the incremental costs and pollutant removals for the proposed effluent limitations guidelines and standards is presented in "Cost-effectiveness Analysis of Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry," (EPA 821-R-95-015), (5) analytical methods used in the development of the proposed effluent limitations guidelines and standards are found in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater," a compendium of analytical methods (EPA 821-R-95-014), and (6) the statistical (EPA 821-R-95-016) support for today's proposed effluent limitations guidelines and standards is found in "Statistical Support Document for the Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry."

III. Legal Authority

This regulation is being proposed under the authority of sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act, 33 U.S.C. 1311, 1314, 1316, 1317, 1318, and 1361.

IV. Summary and Scope of the Proposed Rule

In today's notice, EPA proposes effluent limitations guidelines and standards for process wastewater generated by the pharmaceutical manufacturing industry. Section IX of this notice discusses the rationale for