

IU—Industrial User. Synonym for “Indirect Discharger.”

Junction box—A manhole access point to a wastewater sewer system or a lift station.

LTA—Long-term average. For purposes of proposed effluent limitations guidelines and standards, average pollutant levels achieved over a period of time by a plant, subcategory, or technology option. LTAs were used in developing the limitations and standards in today’s proposed regulation.

MACT—Maximum Achievable Control Technology. Technology basis for the national emission standards for hazardous air pollutants.

Major source—As defined in section 112(a) of the Clean Air Act, major source is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.

Maximum daily discharge limitation—The highest allowable daily discharge of a pollutant measured during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

Mg—Megagram. One million (10<sup>6</sup>) grams, or one metric ton.

Metric ton—One thousand (10<sup>3</sup>) kilograms (abbreviated as kkg), or one megagram. A metric ton is equal to 2,204.5 pounds.

Minimum level—The level at which an analytical system gives recognizable signals and an acceptable calibration point.

Mixing/Compounding/Formulating—Processes through which pharmaceutically active ingredients are put in dosage forms. Processes involving mixing/compounding/formulating define subcategory D (40 CFR 439, subpart D).

Modification—As defined in section 112(a) of the Clean Air Act, modification is any physical change in, or change in the method of operation of, a major source which increases the actual emissions of any hazardous air pollutant emitted by such source by more than a de minimis amount or which results in the emission of any hazardous air pollutant not previously emitted by more than a de minimis amount.

NESHAP—National Emission Standard for Hazardous Air Pollutants. Emission standard promulgated that has been or will be promulgated under section 112(d) of the Clean Air Act for

hazardous air pollutants listed in section 112(b) of the Clean Air Act.

New Source—As defined in 40 CFR 122.2, 122.29, and 403.3(k), a new source is any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced (1) For purposes of compliance with New Source Performance Standards, after the promulgation of such standards being proposed today under CWA section 306; or (2) for the purposes of compliance with Pretreatment Standards for New Sources, after the publication of proposed standards under CWA section 307(c), if such standards are thereafter promulgated in accordance with that section.

Nonconventional pollutants—Pollutants that are neither conventional pollutants nor toxic pollutants.

Non-detect value—A concentration-based measurement reported below the minimum level that can reliably be measured by the analytical method for the pollutant.

Non-water quality environmental impact—An environmental impact of a control or treatment technology, other than to surface waters.

NPDES—The National Pollutant Discharge Elimination System authorized under section 402 of the CWA. The Clean Water Act requires NPDES permits for discharge of pollutants from any point source into waters of the United States.

NRDC—Natural Resources Defense Council.

NSPS—New Source Performance Standards. As used in this notice, this term refers to standards for new sources under section 306 of the CWA.

OMB—Office of Management and Budget.

Outfall—The mouth of conduit drains and other conduits from which a plant discharges effluent into receiving waters.

Pharmaceutically active ingredient—Any substance considered to be an active ingredient by Food and Drug Administration regulations (21 CFR 210.3(6)(7)).

Pilot-scale operation—The trial operation of processing equipment, which is the intermediate stage between laboratory experimentation and full-scale operation in the development of a new process or product.

Point of Generation—The location where the process wastewater stream exits the pharmaceutical process equipment.

Point source category—A category of sources of water pollutants that are included within the definition of “point

source” in section 502(14) of the Clean Water Act.

Pollutant (to water)—Dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, certain radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water. See CWA section 502(6); 40 CFR 122.2.

POTW or POTWs—Publicly owned treatment works, as defined at 40 CFR 403.3(o).

Pretreatment standard—A regulation specifying industrial wastewater effluent quality required for discharge to a POTW.

Primary fuel—The fuel that provides the principal heat input to a combustion device. To be considered primary, the fuel must be able to sustain operation of the combustion device without the addition of other fuels.

Priority pollutants—The toxic pollutants listed in 40 CFR part 403, Appendix A (printed immediately following 40 CFR 423.17).

Process changes—Alterations in process operating conditions, equipment, or chemical use that reduce the formation of chemical compounds that are pollutants and/or pollutant precursors.

Process emission point—A gas stream that contains hazardous air pollutants discharged during operation of process equipment. Process emission points include gas streams that are discharged directly to the atmosphere, discharged to the atmosphere via vents or open process equipment, or discharged after diversion through a product recovery device.

Process unit—A piece of equipment, such as a chemical reactor or fermentation tank, associated with pharmaceutical manufacturing operations.

Process wastewater—Any water that, 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. Process wastewater includes surface runoff from the immediate process area that has the potential to become contaminated.

(1) For purposes of this part, the following materials are excluded from the definition of process wastewater:

1. Trimethyl silanol;
2. Any active anti-microbial materials;
3. Wastewater from imperfect fermentation batches; and
4. Process area spills.