

can have a dramatic effect on the monitoring results for that facility. Therefore, it may be necessary to require internal monitoring points in order to assure compliance. Authority to address internal waste streams is provided in 40 CFR 122.44(i)(1)(iii) and 122.45(h). In some instances, today's proposed rule establishes internal monitoring points to ensure compliance with the effluent limitations guidelines and standards. Permit writers may establish additional internal monitoring points to the extent consistent with EPA's regulations.

#### 5. Best Management Practices

EPA is not proposing in today's notice best management practices (BMPs) pursuant to Section 304(e) of the Clean Water Act. BMPs established under Section 304(e) may be different from effluent limitations guidelines and standards principally because BMPs are specific requirements for conduct, not performance standards. When EPA sets technology-based effluent limits, those limits may be achieved by any technology a discharger chooses. However, when EPA establishes BMPs under Section 304(e) of the CWA, and those BMPs are incorporated into a dischargers permit, the discharger must perform those specific BMPs. The fact that a discharger had met all its technology-based effluent limits would not be a defense, if the discharger were charged with a permit violation for failing to perform its BMPs.

BMPs for the pharmaceutical manufacturing industry, which might include spill prevention, control provisions, and other aspects to prevent the release of raw materials, solvents, and process chemicals to wastewaters, would control the release of constituents listed in sections 307(a) and 311(e) of the CWA, such as methylene chloride, toluene, chloroform, and chloromethane (methyl chloride).

The EPA believes these BMPs are important because: discharges of raw materials, process chemicals and other materials are not recognized process wastewaters and contribute to significant portions of untreated wastewater loadings and to final effluent discharge loadings of oxygen demanding substances and priority and nonconventional pollutants. Prevention and control of discharges of materials used in pharmaceutical manufacturing processes will result in less demand for make-up chemicals; energy efficiency through recovery of process materials; more effective and less costly wastewater treatment system operations; reduced formation of wastewater treatment sludges; and reduced

atmospheric emissions of hazardous air pollutants (HAPs) and other volatile organic pollutants.

EPA is soliciting comment on whether BMPs are applicable to pharmaceutical manufacturing facilities in any or all subcategories for which effluent limitations guidelines and standards are being proposed. The principal focus of the BMPs are prevention and control of losses of raw materials, process chemicals and other process materials from spills and equipment leaks. More information related to the BMPs is outlined in Section XIV regarding solicitation of comments and data (see specific solicitation number 31.0). Appendix B of the Technical Development Document presents details on the specifics of BMPs that may be appropriate.

#### 6. Analytical Methods

Section 304(h) of the Clean Water Act (CWA) directs the EPA to promulgate guidelines establishing test procedures (methods) for the analysis of pollutants. These methods are used to determine the presence and concentration of pollutants in wastewater, and for compliance monitoring. Dischargers seeking NPDES permits must supply information on the characteristics of their effluent, analyzed in accordance with approved test procedures, as part of their permit applications. 40 CFR 122.21(g)(7). Similarly, holders of NPDES permits are required to conduct monitoring in accordance with such test procedures. 40 CFR 122.41(j)(4). Information and analysis performed in accordance with these methods are also required under the pretreatment program, 40 CFR 403.12(d)(5)(vi), and as a condition for receiving a conditional removal credit under 40 CFR 403.7(d).

EPA has promulgated analytical methods for monitoring discharges to surface water at 40 CFR part 136, and has promulgated methods for parameters specific to a given industrial category and for other purposes at parts 400-480 of the CFR. In today's notice, EPA also proposes to establish appropriate analytical methods at 40 CFR part 439 to support regulation of discharges in the pharmaceutical manufacturing industrial point source category. Those methods are presented in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Industry Wastewater," a compendium of analytical methods and are incorporated herein by reference. See Section XIV, solicitation number 33.

Methods 1624 and 1625 are two of the previously promulgated methods applicable to the determination of volatile and semivolatile organic

pollutants in water and wastewater for the proposed effluent guidelines. They employ gas chromatography coupled to a mass spectrometer (GC/MS) to separate and quantify volatile and semivolatile organic pollutants. Detected pollutants are quantified by isotope dilution. For volatile organic pollutants, samples of water or solids suspended in water are purged by a stream of inert gas into the gaseous phase where they are concentrated into a trap. Subsequent heating of the trap introduces the concentrated volatile organics into a GC/MS for separation and quantification. The sensitivity of these methods are sufficient to detect and quantify volatile and semivolatile organics at parts per billion (ppb) levels in environmental samples. EPA also solicits comment on whether it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. See Section XIV, solicitation number 38.3.

Many of the non-conventional pollutants that may be released from the pharmaceutical manufacturing industry are not included in methods previously promulgated for monitoring effluents from other industries. For this reason it has been necessary to develop methods for these pollutants. Some are amenable to extraction from aqueous solution and can be analyzed by GC/MS after extraction and concentration. Method 1665 has been developed for these analytes. Others may be concentrated by purging from aqueous solution and trapping in a column containing sorbent material. For these substances, purge-and-trap followed by GC/MS analysis as described in Method 1666 was developed. Some highly water soluble analytes, however, could not be extracted from aqueous solution and could not be efficiently purged from water. For this reason, it was necessary to develop a direct aqueous injection technique for GC/MS analysis by Method 1666. A subset of these highly water soluble substances, all containing nitrogen, were found not to chromatograph well on the column used. For this reason, a third technique, Method 1668, was developed using a different GC column and detection by electrolytic conductivity. Formaldehyde is not extractable from water and can not be readily analyzed by either purge-and-trap GC/MS or direct aqueous injection. For this reason a fourth approach, Method 1667, was developed for formaldehyde and the other aldehydes included in the analyte list. A complete description of these