Where to Get Additional Help

- EPA Headquarters
- EPA Regional Contacts

Information Relating to the Pharmaceutical Rule

- Documents Supporting the 1998 Promulgated Rule
- General Information About Permits and NPDES Program
- Databases
- Websites

Other Sources and Contacts

- EPA Headquarters Information Resource Center
- National Technical Information Service (NTIS)

Appendix A Glossary

10. Where to Get Additional Help

This section presents additional sources of information, as well as EPA contacts, that may help permit writers and control authorities obtain additional information related to implementation of the final pharmaceutical effluent limitations guidelines and standards for subparts A, B, C, D, and E. Specifically, this section presents a list of selected documents, databases, and websites either relating generally to the pharmaceutical industry, or specifically to the September 21, 1998 Promulgated Rule. These lists also include information on how to reach EPA program personnel and how to access these information sources.

Questions specifically related to the effluent limitations guidelines and standards for the pharmaceutical industry should be directed to:

Headquarters:

Meghan Hessenauer
Engineering and Analysis Division
Office of Water
U.S. EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460
Email: hessenauer.meghan@epa.gov

Regional Contacts:

Region 1
Justin Pimpare
1 Congress Street, Suite 1100
Boston, MA 02114-2023
Email: pimpare.justin@epa.gov

Region II
Jacqueline Rios
290 Broadway
New York, NY 10007-1866
Email: rios.jacqueline@epa.gov

Region IV
Dee Stewart
61 Forsyth Street, S.W.
Atlanta, GA 30303-8960
Email: stewart.dee@epa.gov

Region V
Matthew Gluckman
77 West Jackson Boulevard
Chicago, IL 60604-3507
Email: gluckman.matthew@epa.gov

Region IX
Keith Silva
75 Hawthorne Street
San Francisco, CA 94105
Email: silva.keith@epa.gov

10.1 Information Relating to the Pharmaceutical Rule

This manual is one element in a broad spectrum of materials that are available related to the regulations promulgated September 21, 1998 for pharmaceutical manufacturing facilities with operations in subparts A, B, C, D, and E. Figure 10-1 illustrates some of the information resources currently available.

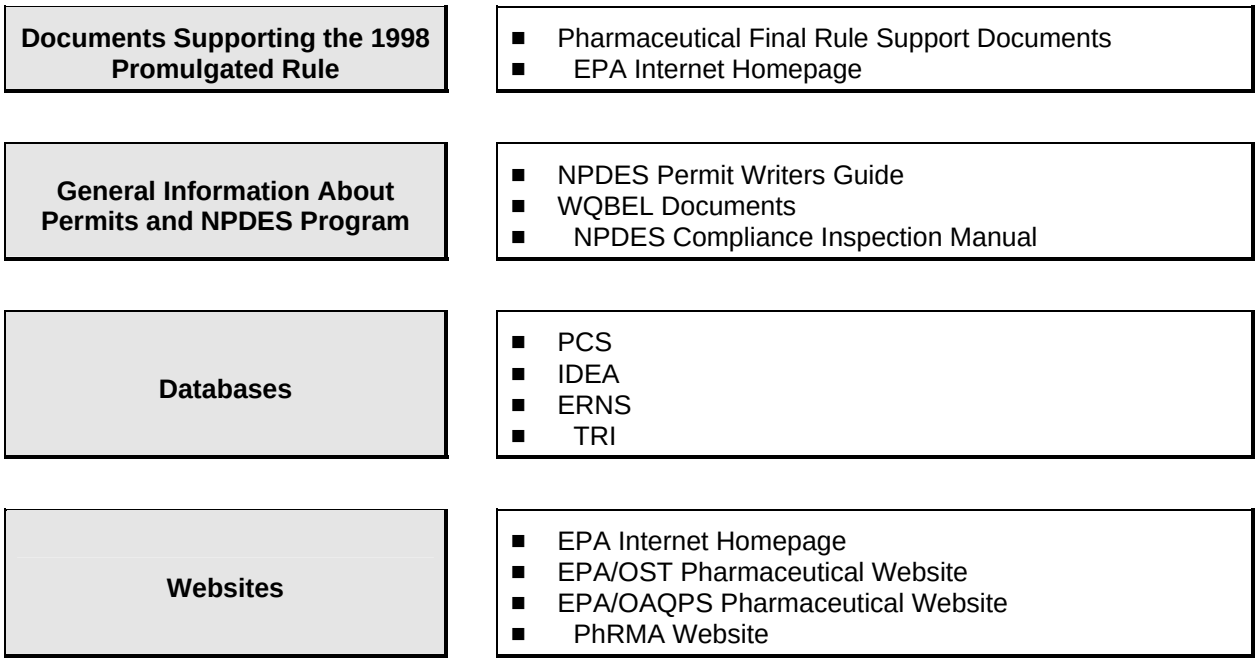

Figure 10-1: Information Resources Map

10.1.1 Documents Supporting the 1998 Promulgated Rule

- *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*, EPA-821-R-98-005, July 1998.
- *Environmental Assessment of the Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry*, EPA 821-B-98-008, July 1998.
- *Statistical Support Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry*, EPA 821-B-98-007, July 1998.
- *National Emission Standards for Hazardous Air Pollutants for the Pharmaceutical Manufacturing Industry; Summary of Public Comments and Responses*, EPA 450-R-98-002, July 1998.

10.1.2 General Information About Permits and NPDES Program

- *NPDES Permit Writer's Manual*, EPA-833-B-96-003. This 1996 EPA manual was prepared to provide the basic regulatory framework and technical considerations that support the development of wastewater discharge permits as required under the NPDES program.

- *NPDES Compliance Inspection Manual*, EPA 305-X-03-004, July 2004. This EPA manual was developed to support personnel that conduct NPDES inspections of wastewater treatment plants, industrial storm water and construction site dischargers, pretreatment facilities, biosolids handling and treatment facilities, Concentrated Animal Feeding Operations, municipal wastewater collection systems, as well as pollution prevention and multimedia concerns. The manual presents standard procedures for inspections and specific technical information necessary to conduct the full range of NPDES compliance inspection activities. This document is available from EPA's Web site at: **http://www.epa.gov/compliance/resources/publications/monitoring/inspections/npdesinspect/index.html**

- *Guidance for Water Quality-Based Decisions: The TMDL Process*, EPA-440-4-91. This document is intended to define and clarify the requirements under Section 303(d) of the Clean Water Act. Its purpose is to aid state water-quality program managers in understanding the application of total maximum daily loads within the water quality-based approach to establish pollution control limits for waters not meeting water quality standards.

- *Technical Support Document for Water Quality-Based Toxics Control*, EPA/505/2-90-001. This document was prepared as technical guidance for assessing and regulating the discharge of toxic substances to waters of the United States.

- *Industrial User Permitting Guidance*, EPA#833R89001, September 1989.

10.1.3 Databases

- **PCS.** The Permit Compliance System (PCS) is a national information system that automates entry, updating and retrieval of NPDES data and tracks permit issuance, permit limits, and monitoring data for NPDES facilities. Public access is available by obtaining a mainframe account on EPA's National Computer Center. See **http://www.epa.gov/compliance/data/systems/index.html** for further details.

- **IDEA.** The Integrated Data for Enforcement Analysis System (IDEA) is an interactive data retrieval and integration system developed by EPA's Office of Enforcement and Compliance Assurance. Users can retrieve data for performing multimedia analyses of regulated facilities, produce compliance histories of individual facilities, identify a group of facilities that meet user-defined criteria, and produce aggregated data on selected industries. Public access is available by obtaining a mainframe account on EPA's National Computer Center. See **http://www.epa.gov/compliance/data/systems/index.html** for further details.

- **ERNS.** Through The Emergency Response Notification System, EPA maintains a database of reported spills of oil and other materials. See **http://www.epa.gov/compliance/data/systems/waste/index.html** for further details.

- **TRI Data.** The Toxics Release Inventory (TRI) provides the public with information on toxic chemicals being used, manufactured, transported, or released into the environment.

See **http://www.epa.gov/opptintr/tri** for access to numerous TRI topics, including; "What is TRI", "Accessing and Using TRI Data", "Tri Forms and Reporting Requirements", "TRI chemicals", "TRI Program Development", "TRI National and International Programs", "TRI Contacts", and "What's New with TRI". See **http://www.epa.gov/opptintr/tri/ttpubacc.htm** to learn more about TRI information found on CD-ROM, the Right-to-Know Network (RTK NET), Envirofacts, TOXNET (user fee), and TRI User Support (TRI-US).

10.1.4 Websites

- **EPA on the World Wide Web.** EPA's webserver is the primary public access mechanism on the Internet for EPA. The webserver provides a range of EPA-generated information in electronic format, and also offers access to EPA's Online Library Service (OLS), the national online catalog of the EPA library network. It includes the catalogs of the Headquarters Information Resource Center and all the Regional libraries.

  Via Internet:
  EPA's homepage on the World Wide Web: **http://www.epa.gov**
  EPA's pharmaceutical rulemaking actions homepages on the World Wide Web:
  http://www.epa.gov/ost/guide/pharm (water documents)
  http://www.epa.gov/ttn/oarpg (air documents)

10.2 Other Sources and Contacts

10.2.1 EPA Headquarters Information Resource Center

The EPA Headquarters Information Resource Center provides information support services to EPA staff and maintains a varied collection of environmental resources, including CD-ROMs, an online catalog, and other program-specific services. The library provides services to the general public and develops several publications, including newsletters and brochures. Library hours are 8:00 a.m. to 5:00 p.m. ET, Monday through Friday. EPA's Online Library Service (OLS) is available through Telnet: "epaibm.rtpnc.epa.gov."

10.2.2 National Technical Information Service (NTIS)

Located in the U.S. Department of Commerce, the National Technical Information Service (NTIS) is the central source for the public sale of U.S. Government-sponsored research, development, and engineering reports. It is also a central source of federally generated machine processible data files. It contains reports on air pollution, acid rain, water pollution, marine pollution, marine ecosystems, land use planning, fisheries management, solar energy, offshore oil drilling, solid wastes, traffic noise, and radiation monitoring.

For more information, contact:
Chief, Order Processing Branch
National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161
Tel: (703) 487-4650
Fax: (703) 321-8547

Appendix A Glossary

Biochemical oxygen demand (BOD_5) - Five-Day Biochemical Oxygen Demand. A measure of biochemical decomposition of organic matter in a water sample. It is determined by measuring the dissolved oxygen consumed by microorganisms to oxidize the organic contaminants in a water sample under standard laboratory conditions of five days at 20°C. BOD_5 is not related to the oxygen requirements in chemical combustion.

Chemical oxygen demand (COD) - A bulk parameter that measures the oxygen-consuming capacity of organic and inorganic matter present in water or wastewater. It is expressed as the amount of oxygen consumed from a chemical oxidant in a specific test.

Continuous discharge - Discharge that occurs without interruption throughout the operating hours of the facility.

Conventional pollutants - The pollutants identified in sec. 304(a)(4) of the CWA and the regulations thereunder (biochemical oxygen demand (BOD_5), total suspended solids (TSS), oil and grease, fecal coliform, and pH).

Daily discharge - The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day. For pollutants with limitations expressed as mass, the daily discharge is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the average measurement of the pollutant over the day.

Direct discharger - A facility that discharges or may discharge treated or untreated process wastewaters, non-contact cooling waters, or non-process wastewaters (including stormwater runoff) into waters of the United States.

Effluent limitation - Any restriction, including schedules of compliance, established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean.

End of the pipe - The point at which final facility effluent is discharged to waters of the United States or introduced to a POTW.

Final effluent - Facility wastewater discharges to receiving waters including streams, lakes, and other waters of the U.S.

Indirect discharger - A facility that discharges or may discharge wastewaters into a publicly owned treatment works or a treatment works not owned by the discharging facility.

Influent - Facility wastes, water, and other liquids, which can be raw or partially treated, flowing into a treatment plant, reservoir, basin, or holding pond.

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.

Minimum level (ML) - The level at which the analytical system gives recognizable signals and an acceptable calibration point.

Non-continuous discharge - Discharge that occurs only during specific periods of time (seasons, or operating shift variations). Does not apply to treatment plant or process upset conditions; periods of no discharge are at least 24 hours in duration.
Nonconventional pollutants - Pollutants that are neither conventional pollutants nor toxic pollutants (see 40 CFR Sections 401.15, 401.16 and Part 423, Appendix A).

NPDES - National Pollutant Discharge Elimination System. The NPDES program is authorized by the Clean Water Act and requires permits for the discharge of pollutants from any point source into waters of the United States.

POTW - Publicly-owned treatment works as defined at 40 CFR 403.3(o).

Pretreatment standard - A regulation addressing industrial wastewater effluent quality required for discharge to a POTW.

Process water - Water used to dilute, wash, or carry raw materials and any other materials used in the manufacturing process.

Toxic pollutants - Pollutants designated as toxic pursuant to Section 307(a)(1) of the Act and listed in 40 CFR Section 401.15.

Wastewater - Water carrying waste materials from a facility. It is a mixture of water, and dissolved and suspended pollutants.

Waters of the United States - As defined in 40 CFR 122.2. This definition includes all waters that are currently used, may be used in the future, or were used in the past, in interstate or foreign commerce (including all waters subject to the ebb and flow of the tide) and adjacent wetlands.