

Sunshine Act Meetings

Federal Register

Vol. 56, No. 159

Friday, August 16, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Wednesday, August 21, 1991.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposal to modify and clarify the Federal Reserve Board's risk-based capital guidelines. (Proposed earlier for public comment; Docket No. R-0709.)

2. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's

Freedom of Information Office, and copies may be ordered for \$5 per cassette by calling (202) 452-3684 or by writing to:

Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, (202) 452-3204.

Dated: August 14, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-19747 Filed 8-14-91; 12:41 pm]

BILLING CODE 6210-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM:

TIME AND DATE: Approximately 10:30 a.m., Wednesday, August 21, 1991, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street

entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: August 13, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-19748 Filed 8-14-91; 12:41 pm]

BILLING CODE 6210-01-M

Corrections

Federal Register

Vol. 56, No. 159

Friday, August 16, 1991

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP91-2562-000, et al.]

Northwest Pipeline Corp., et al.; Natural Gas Certificate Filings

Correction

In notice document 91-18935 beginning on page 37905 in the issue of Friday, August 9, 1991, make the following corrections:

On page 37907, in the second column, the fifth and sixth lines should read "[Docket Nos. CP91-2618-000, CP91-2619-000, CP91-2620-000, CP91-2621-000]".

BILLING CODE 1505-01-D

GENERAL SERVICES ADMINISTRATION

41 CFR Part 302-1

[FTR Amendment 17]

RIN 3090-AE36

Federal Travel Regulation; Pre-employment Interview Travel Expenses and Relocation Expenses of New Appointees

Correction

In rule document 91-12252 beginning on page 23653 in the issue of Thursday, May 23, 1991, make the following correction:

§ 302-1.3 [Corrected]

On page 23656, in the second column, in amendatory instruction 30 for § 302-1.3, in the last line line "§ 302-1.102" should read "§ 301-1.102".

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-29497; File No. SR-CBOE-91-25]

Self-Regulatory Organizations; Chicago Board Options Exchange; Notice of Filing of Proposed Change Relating to Minor Rule Violation Fine Plan

Correction

In notice document 91-17584 beginning on page 37376 in the issue of Tuesday, August 6, 1991, the Release number

should have appeared as set forth above.

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 161

[CGD 90-020]

RIN 2115-AD56

National Vessel Traffic Services Regulations

Correction

In proposed rule document 91-17984 beginning on page 36910 in the issue of Thursday, August 1, 1991, make the following corrections:

§ 161.904 [Corrected]

On page 36918, in the first column, in § 161.904, in the table:

1. In the second column, remove "Gros" from the first entry; the second entry in that column should read "Gros Cap Reefs Light."; and in the third column, the first "Report" should be moved down opposite the second entry.

2. In the second column, the second and last entries from the bottom should read "Munuscong Lake Junction Lighted Buoy.." and "De Tour Reef Light." respectively.

BILLING CODE 1505-01-D

federal register

**Friday
August 16, 1991**

Part II

Environmental Protection Agency

40 CFR Part 122

**NPDES General Permits and Reporting
Requirements for Storm Water
Discharges Associated With Industrial
Activity; Proposed Rule**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 122

[FRL 3756-1]

RIN 2040-AA79

National Pollutant Discharge Elimination System General Permits and Reporting Requirements for Storm Water Discharges Associated With Industrial Activity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and Notice of draft general NPDES permits for Storm Water Discharges Associated with Industrial Activity.

SUMMARY: Section 405 of the Water Quality Act of 1987 (WQA) added section 402(p) of the Clean Water Act (CWA) which requires the Environmental Protection Agency (EPA) to develop a phased approach to regulating storm water discharges under the National Pollutant Discharge Elimination System (NPDES) program. EPA published a final regulation on November 16, 1990, (55 FR 47990) establishing permit application requirements for storm water discharges associated with industrial activity and for discharges from municipal separate storm sewer systems serving a population of 100,000 or more. In the permit application regulations, EPA defined the term "storm water discharge associated with industrial activity" in a comprehensive manner to cover a wide variety of facilities. This definition greatly expanded the number of industrial facilities subject to the NPDES program.

This notice requests comments on a National NPDES permitting strategy to address the large number of storm water discharges associated with industrial activity. To assist in implementing the strategy, this notice requests comments on proposed regulatory changes to existing minimum requirements for NPDES permits with regard to annual monitoring reports and minimum requirements for filing notices of intent to be authorized to discharge under NPDES general permits.

This notice also requests comments on separate general permits for the majority of storm water discharges associated with industrial activity in 12 States (MA, ME, NH, FL, LA, TX, OK, NM, SD, AZ, AK, ID), and 6 Territories (District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the

Trust Territory of the Pacific Islands) without authorized NPDES State programs; on Indian lands in AL, CA, GA, KY, MI, MN, MS, MT, NC, ND, NY, NV, SC, TN, UT, WI, and WY; located within Federal facilities and Indian lands in CO and WA; and located within Federal facilities in Delaware. Separate general permits are being noticed for each State.

DATES: Comments on this proposed rule and permits must be received on or before October 15, 1991. See Supplementary Information for information on hearings.

ADDRESSES: The public should also send an original and two copies of their comments addressing any aspect of this notice to Kevin Weiss, Permits Division (EN-336), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Comments addressing factors or issues which are specific to one or several general permits (e.g., specific requirements for the general permit authorizing storm water discharges associated with industrial activity in MA), should clearly indicate the applicability of the comment to a particular State. The public record is located at EPA Headquarters, EPA Public Information Reference Unit, room 2402, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For further information on the proposed rule and draft general permits contact the NPDES Storm Water Hotline at (703) 821-4823 or: Kevin Weiss, Office of Wastewater Enforcement and Compliance (EN-336), United States Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202)-475-9518. The Fact Sheet accompanying this rule provides additional contacts for information regarding the issuance of general permits in specific States.

SUPPLEMENTARY INFORMATION:

Hearings

Public hearings to discuss general permits for the State in which the hearing is held are scheduled as follows:

(1) September 23, 1991, question and answer session from 3 p.m. to 5 p.m. and hearing from 7 p.m. to 10 p.m., Reunion Ballroom, Hyatt Regency Hotel, 300 Reunion Blvd., Dallas, TX 75207.

(2) September 20, 1991, question and answer session from 3 p.m. to 5 p.m. and hearing from 7 p.m. to 10 p.m., Lincoln Plaza Hotel, Gold Crown Room, 4445 North Lincoln Boulevard, Oklahoma City, OK 73105.

(3) September 24, 1991, question and answer session from 3 p.m. to 5 p.m. and

hearing from 7 p.m. to 10 p.m., Ramada Hotel, 1480 Nicholson Drive, Baton Rouge, LA.

(4) September 25, 1991, question and answer session from 3 p.m. to 5 p.m. and hearing from 7 p.m. to 10 p.m., Hyatt Regency, Grand Pavilion Ballroom, 330 Tijeras NW., Albuquerque, NM 87102.

(5) September 26, 1991, 1 p.m. to 4 p.m., Parkplace Building, 1200 Sixth Avenue, 12A (12th Floor), Seattle, WA 98101.

(6) September 16, 1991, 1 p.m. to 4 p.m., Holiday Inn Convention Center, 3300 Vista Avenue, Boise, ID 83705.

(7) September 19, 1991, 1 p.m. to 4 p.m., Centennial Hall (Sheffield Ballroom #2), 101 Egan Drive, Juneau, AK 99801.

(8) September 30, 1991, 1 p.m. to 6 p.m., Best Western, Kings Inn, 220 South Pierre Street, Pierre, SD 58501. (Note: This hearing will address the general permit for SD as well as the general permit for Indian lands in MT, ND, UT and WY, and the general permit for Indian lands and Federal facilities in CO).

(9) September 18, 1991, two hearings will be held at the following times 10 a.m. to 12 noon, 1:30 p.m. to 5 p.m., a third hearing will start at 7 p.m. and continue as necessary, Phoenix Civic Plaza, Flagstaff Room, 225 East Adams Street, Phoenix, AZ 85004.

(10) September 10, 1991, public meeting from 1 p.m. to 4 p.m., public hearing from 7 p.m. to 10 p.m., Civic Convention Center, 9800 International Drive, Orlando, FL 32819.

(11) September 12, 1991, public meeting from 1 p.m. to 4 p.m., public hearing from 7 p.m. to 10 p.m., Tallahassee Leon County Civic Center, 505 West Pensacola, Tallahassee, FL.

(12) September 25, 1991, 1 p.m. to 4 p.m., University of Maine at Augusta, Jewett Hall Auditorium, University Heights, Augusta, ME, 04330.

(13) September 24, 1991, 1 p.m. to 4 p.m., Federal Reserve Bank, Ground Floor Auditorium, 600 Atlantic Avenue, Boston, MA 02106.

(14) September 26, 1991, 7 p.m. to 10 p.m., Holiday Inn, Ballroom Area, 700 Elm Street, Manchester, NH 03101.

Persons wishing to make an oral presentation must restrict them to 15 minutes and are encouraged to have written copies of their complete comments for inclusion in the official record.

I. Background

A. NRDC v. Costle

B. Water Quality Act of 1987

II. Framework of NPDES System

A. State Programs

B. Requirements in NPDES Permits

- III. Prior Storm Water Permitting Efforts
- IV. November 16, 1990 Permit Application Regulations
- V. Burdens on Permitting Agencies
- VI. Today's Notice
- A. Long-Term Permitting Strategy
- B. Proposed Changes to Annual Monitoring Reporting Requirements
- C. Application Requirements for General Permits
- D. Fact Sheet for Draft General Permit
- VII. Economic Impact
- VIII. Executive Order 12291
- IX. Paperwork Reduction Act
- X. Regulatory Flexibility Act

I. Background

The 1972 amendments to the Federal Water Pollution Control Act (FWPCA, also referred to as the Clean Water Act or CWA), prohibited the discharge of any pollutant to navigable waters from a point source unless the discharge is authorized by a NPDES permit. Efforts to improve water quality under the NPDES program have focused traditionally on reducing pollutants in discharges of industrial process waste water and from municipal sewage treatment plants. This program emphasis has developed for a number of reasons. At the onset of the program in 1972, many sources of industrial process waste water and municipal sewage were not controlled adequately, and represented pressing environmental problems. In addition, sewage outfalls and industrial process discharges were easily identified as responsible for poor, often drastically degraded water quality conditions. However, as pollution control measures were developed initially for these discharges, it became evident that more diffuse sources (occurring over a wide area) of water pollution, such as agricultural and urban runoff, were also major causes of water quality problems. Some diffuse sources of water pollution, such as agricultural storm water discharges and irrigation return flows, are exempted statutorily from the NPDES program. Controls for other diffuse sources have been slow to develop under the NPDES program.

Several National assessments have been conducted to evaluate impacts on receiving water quality. For the purpose of these assessments, urban runoff was considered to be a diffuse source or nonpoint source pollution, although legally, most urban runoff is discharged through conveyances such as separate storm sewers or other conveyances which are point sources under the CWA and subject to the NPDES program. The "National Water Quality Inventory, 1988 Report to Congress" provides a general assessment of water quality based on biennial reports submitted by the States under section 305(b) of the CWA. In

preparing section 305(b) reports, the States were asked to indicate the fraction of the States' waters that were assessed, as well as the fraction of the States' waters that were fully supporting, partly supporting, or not supporting designated uses. The report indicates that of the rivers, lakes, and estuaries that were assessed by States (approximately one-fifth of stream miles, one-third of lake acres and one-half of estuarine waters), roughly 70 percent to 75 percent are supporting the uses for which they are designated. For waters with use impairments, States were asked to determine impacts due to diffuse sources (agricultural and urban runoff and other categories of diffuse sources), municipal sewage, industrial (process) wastewaters, combined sewer overflows, and natural sources, then combine impacts to arrive at estimates of the relative percentage of State waters affected by each source. In this manner, the relative importance of the various sources of pollution causing use impairments was assessed and weighted national averages were calculated. Based on 37 States that provided information on sources of pollution, industrial process wastewaters were cited as the cause of use impairment for 7 percent of rivers and streams, 10 percent of lakes, 8 percent of estuaries, 41 percent of the Great Lakes shoreline and 6 percent of coastal waters. Municipal sewage was the cause of use impairment for 13 percent of rivers and streams, 5 percent of lakes, 48 percent of estuaries, 41 percent of the Great Lakes shoreline and 11 percent of coastal waters.

The Assessment also concluded that pollution from diffuse sources such as runoff from agricultural, urban areas, construction sites, land disposal activities, and resource extraction activities is cited by the States as the leading cause of water quality impairment.¹ Diffuse sources appear to be increasingly important contributors of use impairment as discharges of industrial process wastewaters and municipal sewage plants come under control and intensified data collection efforts provide additional information. Some examples where use impairments are cited as being caused by diffuse sources include: rivers and streams, where 9 percent are caused by separate storm sewers, 4 percent are caused by construction and 11 percent are caused by resource extraction; lakes where 8

percent are caused by separate storm sewers and 7 percent are caused by land disposal; the Great Lakes shoreline, where 35 percent are caused by separate storm sewers, 46 percent are caused by resource extraction, and 19 percent are caused by land disposal; for estuaries where, 41 percent are caused by separate storm sewers; and for coastal areas, where 20 percent are caused by separate storm sewers and 29 percent are caused by land disposal.

The States conducted a more comprehensive study of diffuse pollution sources under the sponsorship of the Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) and EPA. The study resulted in the report "America's Clean Water—The States' Nonpoint Source Assessment, 1985" which indicated that 38 States reported urban runoff as a major cause of beneficial use impairment. In addition, 21 States reported construction site runoff as a major cause of use impairment.

Studies conducted by the National Oceanic and Atmospheric Administration (NOAA)² indicate that urban runoff is a major pollutant source which adversely affects shellfish growing waters. The NOAA studies identified urban runoff as affecting over 578,000 acres of shellfish growing waters on the East Coast (39 percent of harvest-limited area); 2,000,000 acres of shellfish growing waters in the Gulf of Mexico (59% of the harvest-limited area); and 130,000 acres of shellfish growing waters on the West Coast (52% of harvest-limited areas).

A. NRDC v. COSTLE³

The appropriate means of regulating storm water point sources within the National Pollutant Discharge Elimination System (NPDES) program has been a matter of serious concern since implementing the NPDES program in 1972. In 1973, EPA promulgated its first storm water regulations exempting from permit requirements those point source conveyances carrying storm water runoff uncontaminated by industrial or commercial activity unless the particular storm water discharger had been identified by the NPDES Director as a significant contributor of pollution (38 FR 13530 (May 22, 1973)). The Agency maintained that, while these sources fell within the definition of

¹ Major classes of diffuse sources that include, in part, storm water point source discharges are: urban runoff conveyances, construction sites, agriculture (feedlots), resource extraction sites, and land disposal facilities.

² See "The Quality of Shellfish Growing Waters on the East Coast of the United States", NOAA, 1989; "The Quality of Shellfish Growing Waters in the Gulf of Mexico", NOAA, 1988; and "The Quality of Shellfish Growing Waters on the West Coast of the United States", NOAA, 1990.

³ 568 F.2d 1369 (D.C. Cir. 1977).

a point source, they were nonetheless ill-suited to the traditional, end-of-pipe controls that are the basis of the NPDES program for process discharges and discharges from Publicly Owned Treatment Works⁴ (POTWs). The Agency also justified its decision by noting that issuing individual NPDES permits for the hundreds of thousands of storm water point sources in the United States would create an overwhelming administrative burden and would divert resources away from control of industrial process waste water and municipal sewage, which at the time, were more pressing and identifiable environmental problems.

In a series of challenges to the storm water regulations, the Natural Resources Defense Council (NRDC) brought suit in the U.S. District Court for the District of Columbia, challenging the Agency's authority to exempt selectively categories of point sources from permit requirements, *NRDC v. Train*, 396 F. Supp. 1393 (D.D.C. 1975), *aff'd*, *NRDC v. Costle*, 568 F.2d 1369 (D.C. Cir. 1977). The District Court held that EPA could not exempt discharges identified as point sources from regulation under the NPDES permit program. The District Court was convinced that the permit program would be manageable even without the exemptions sought by EPA. The court recognized two alternatives for reducing the permit workload:

- (1) Discretion to define what constitutes a point source; and
- (2) Discretion to use certain administrative devices, such as general permits, to help manage the workload.

With respect to the appropriate administrative mechanisms, the Court recognized that EPA has wide latitude to rank categories and subcategories of point sources of different importance and treat them differently within a permit program. On review, the Court of Appeals stated that technological or administrative infeasibility was a reason for adjusting Court mandates to realize the general objectives of the Act and may result in adjustments in the permit program (568 F.2d 1369, 1679 (1977)). The Court of Appeals recognized that section 402 of the CWA gives EPA considerable flexibility in framing the permit to achieve a desired reduction in pollutant discharges. One area of flexibility is that permits may regulate industry practices to lessen point source pollution problems. The Court of

Appeals noted that in certain cases, it may be appropriate for EPA to require a permittee simply to monitor and report effluent levels.

The Court of Appeals encouraged EPA to use its interpretation authority to mitigate burdens in establishing a practical regulatory scheme. Section 402 provides the Agency with flexibility in determining the appropriate scope and form of an NPDES permit. As a result, the Court suggested using area or general permits.

B. Water Quality Act of 1987

The Water Quality Act (WQA) of 1987 added section 402(p) to the CWA to provide a comprehensive framework for EPA to address storm water discharges. Section 402(p)(1) provides that EPA or NPDES States cannot require a permit for certain storm water discharges until October 1, 1992, except for storm water discharges listed under section 402(p)(2). Section 402(p)(2) lists five types of storm water discharges which are required to obtain a permit before October 1, 1992:

(A) A discharge with respect to which a permit has been issued prior to February 4, 1987;

(B) A discharge associated with industrial activity;

(C) A discharge from a municipal separate storm sewer system serving a population of 250,000 or more;

(D) A discharge from a municipal separate storm sewer system serving a population of 100,000 or more, but less than 250,000; or

(E) A discharge for which the Administrator or the State, as the case may be, determines that the storm water discharge contributes to a violation of a water quality standard or is a significant contributor of pollutants to the waters of the United States.

Section 402(p)(4) establishes deadlines to implement the permit program for: Storm water discharges associated with industrial activity; discharges from large municipal separate storm sewer systems (systems serving a population of 250,000 or more); and discharges from medium municipal separate storm sewer systems (systems serving a population of 100,000 or more but less than 250,000). This section of the Act specifies deadlines for EPA to promulgate permit application requirements, applicants to submit permit applications, EPA and authorized NPDES States to issue NPDES permits, and for permit compliance for the identified storm water discharges.

NPDES permits for all other storm water discharges cannot be required until October 1, 1992, unless a permit for the discharge was issued prior to the date of enactment of the WQA (i.e.,

February 4, 1987), or the discharge is determined to be a significant contributor of pollutants to waters of the United States or is contributing to a violation of water quality standards.

The WQA clarified and amended the requirements for permits for storm water discharges in the new CWA section 402(p)(3). The Act clarified that permits for discharges associated with industrial activity must meet all of the applicable provisions of section 402 and section 301 including BAT/BCT technology-based requirements and that permits for discharges from municipal separate storm sewer must meet a new statutory standard requiring controls to reduce the discharge of pollutants to the maximum extent practicable (MEP). As with all point source discharges under the CWA, storm water discharges are subject to applicable water quality-based standards.

EPA, in consultation with the States, is required to conduct two studies on storm water discharges that are in the class of discharges for which EPA and NPDES States cannot require permits prior to October 1, 1992. The first study will identify those storm water discharges or classes of storm water discharges for which permits are not required prior to October 1, 1992 and determine, to the maximum extent practicable, the nature and extent of pollutants in such discharges. The second study is for the purpose of establishing procedures and methods to control storm water discharges to the extent necessary to mitigate impacts on water quality. Based on the two studies, EPA in consultation with State and local officials, is required to issue regulations by no later than October 1, 1992, which designate additional storm water discharges to be regulated to protect water quality and establish a comprehensive program to regulate such designated sources. This program must establish, at a minimum, (A) priorities, (B) requirements for State storm water management programs, and (C) expeditious deadlines. The program may include performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate.

II. Framework of NPDES System

Congress established the NPDES program with the 1972 Amendments to the FWPCA. Section 402 of the Act requires EPA to administer a national permit program to regulate point source discharges of pollutants to waters of the United States and sets out the basic elements of the program.

⁴ Note that since 1975 the scope of NPDES permitting efforts, particularly for POTWs, has expanded significantly to address program-oriented pollution control approaches. Examples of program-oriented requirements in permits for POTWs are initiatives for pretreatment, sludge, and combined sewer overflows.

A. State Programs

The Act allows States to request EPA authorization to administer the NPDES program instead of EPA. Under section 402(b), EPA must approve a State's request to operate the permit program once it determines that the State has adequate legal authorities, procedures, and the ability to administer the program.

EPA is also directed by section 304(i) of the FWPCA to adopt procedural and programmatic requirements for State NPDES programs, including guidelines on monitoring, reporting, enforcement, personnel and funding, and to develop uniform national forms for use by both EPA and approved States. At all times following authorization, State NPDES programs must be consistent with minimum Federal requirements, although they may always be more stringent.

Upon authorization of a State program, the State is primarily responsible for issuing permits and administering the NPDES program in that State. At the same time, EPA suspends the issuance of Federal permits for those activities subject to the approved State program.

State NPDES authority is divided into four parts: the core program (POTW and industrial permitting), Federal facilities, pretreatment, and general permitting. At this point in time, 39 States or Territories are authorized to, at a minimum, issue NPDES permits for municipal and industrial sources. Of these 39 States, 23 are currently authorized by EPA to issue NPDES general permits. In the 12 States (MA, ME, NH, FL, LA, TX, OK, NM, SD, AZ, AK, and ID) and 6 territories (District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands) without NPDES authorized programs, EPA issues all NPDES permits. In 5 of the 39 States that are authorized to issue NPDES permits for municipal and industrial sources, EPA retains authority to issue permits for discharges from Federal facilities.

B. Requirements in NPDES Permits

The CWA establishes two types of standards for conditions in NPDES permits, technology-based standards and water quality-based standards. These standards are used to develop effluent limitations, special conditions, and monitoring requirements in NPDES permits. Numeric effluent limitations that establish pollutant concentration or mass limits for effluents at the point of discharge (end-of-pipe conditions) are

generally at the heart of permits for discharges from POTWs and industrial process discharges. More recent permitting efforts have also addressed limiting the toxicity of effluents through specific toxicity limitations included in permits. Section 402(a)(1) authorizes the inclusion of other types of conditions that are determined to be necessary, known as special conditions, in NPDES permits. Special conditions include requirements for best management practices (BMPs).

1. Technology-Based Standards

Technology-based requirements under section 301(b) of the Act represent the minimum level of control that must be imposed in a permit issued under section 402 of the Act. Two technology-based requirements are appropriate for existing storm water discharges associated with industrial activity:

(1) Best conventional pollutant control technology (BCT); and

(2) Best available technology economically achievable (BAT). The BCT standard applies to the control of conventional pollutants, while the BAT standard applies to the control of all toxic pollutants and for all pollutants which are neither toxic nor conventional pollutants. Section 306 of the CWA provides for EPA to establish new source performance standards for new sources.

Technology-based requirements may be established through one of two methods:

(1) Application of national BAT/BCT effluent limitations guidelines promulgated by EPA under section 304 of the CWA and new source performance standards promulgated under section 306 of the CWA applicable to dischargers by category or subcategory; and

(2) On a case-by-case basis under section 402(a)(1) of the Act, using best professional judgement (BPP), for pollutants or classes of discharges for which EPA has not promulgated national effluent limitations guidelines.

(Note: EPA only establishes new source performance standards under section 306 of the CWA when developing national effluent limitations guidelines, and not when establishing permit conditions on a case-by-case basis).

2. Water Quality-Based Standards for Controls

In addition to technology-based controls, section 301(b) of the CWA also requires that NPDES permits must include any conditions more stringent than technology-based controls necessary to meet State water quality standards. Water quality-based

requirements are established under this provision on a case-by-case basis.

III. Prior Storm Water Permitting Efforts

Between 1976 and 1984, EPA regulations required that permit applications be submitted for a wide range of storm water discharges. Many facilities that were required to submit applications for storm water discharges did not apply. In addition, many of the permit applications received by EPA and authorized NPDES States were never acted upon for a number of reasons, including: Lack of resources for permitting, lack of technical understanding of the causes and controls for pollutants in storm water, reluctance of industrial dischargers to accept requirements for best management practices (BMPs) in NPDES permits, and a general perception that storm water discharges, when considered one at a time, were of low priority. In 1984, EPA again promulgated permit application requirements and deadlines for storm water discharges. However, these regulations were never implemented. The regulations were in litigation when Congress enacted the Water Quality Act (WQA) on February 4, 1987, which directly specified a new national strategy for storm water control.

Despite the lack of a comprehensive permitting program for all storm water discharges prior to the passage of the WQA of 1987, permitting efforts nonetheless proceeded in some areas. Between 1974 and 1982, EPA promulgated effluent limitations guidelines for storm water discharges from ten categories of industrial discharges:

- Cement Manufacturing.
- Feedlots.
- Fertilizer Manufacturing.
- Petroleum Refining.
- Phosphate Manufacturing.
- Steam Electric.
- Coal Mining.
- Ore Mining and Dressing.
- Mineral Mining and Processing.
- Asphalt Emulsion.

Permitting efforts for storm water discharges have focussed on industrial facilities subject to these effluent limitations guidelines. In addition, some EPA Regions and States with authorized State NPDES programs have, to varying degrees, written permits for storm water discharges from other industrial facilities. For example, in some States and Regions, storm water discharges from industrial facilities are often addressed when NPDES permits for process wastewaters of a facility are reissued.

IV. November 16, 1990 Permit Application Regulations

On November 16, 1990, (55 FR 47990), EPA published NPDES permit application requirements for: Storm water discharges associated with industrial activity; and discharges from municipal separate storm sewer systems serving a population of 100,000 or more. The rulemaking accomplished three major tasks:

- (1) The rule defined the initial scope of the NPDES storm water program;
- (2) The rule established a permitting scheme with respect to storm water discharges associated with industrial activity through municipal separate storm sewer systems; and
- (3) The rule established permit application requirements for those storm water discharges which are initially subject to the program.

A. Scope of NPDES Storm Water Program

The initial scope of the NPDES storm water program is defined by two key regulatory definitions, "storm water discharges associated with industrial activity" and "large and medium municipal separate storm sewer systems". The term "storm water discharge associated with industrial activity" is defined at 40 CFR 122.26(b)(14) and addresses point source discharges of storm water from eleven major categories of facilities. (This definition is reprinted in the definition section of the draft general permits published in the appendix to today's notice).

The terms "large and medium municipal separate storm sewer systems" (systems serving a population of 100,000 or more) are defined at 40 CFR 122.26(b) (4) and (7) to include municipal separate storm sewers located in: 173 incorporated places (cities) with a population of 100,000 or more; unincorporated portions of 47 counties identified as having large populations in unincorporated, urbanized portions of the county; and other municipal storm sewers which are designated by the Director on a case-by-case basis.

The definitions of "storm water discharge associated with industrial activity" and "large and medium municipal separate storm sewer system" only address point source discharges. Section 502(14) of the CWA defines the term "point source" broadly to include "any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, * * *

from which pollutants are or may be discharged."

In most court cases, the term "point source" has been interpreted broadly. For example, the holding in *Sierra Club v. Abston Construction Co., Inc.*, 620 F.2d 41 (5th Cir., 1980) indicates that changing the surface of land or establishing grading patterns on land will result in a point source where the runoff from the site ultimately is discharged to waters of the United States:

Simple erosion over the material surface, resulting in the discharge of water and other materials into navigable waters, does not constitute a point source discharge, absent some effort to *change the surface*, to *direct the water flow* or otherwise impede its progress * * * Gravity flow, resulting in a discharge into a navigable body of water, may be part of a point source discharge if the (discharge) at least initially collected or channeled the water and other materials. A point source of pollution may also be present where (dischargers) design spoil piles from discarded overburden such that, during periods of precipitation, erosion of spoil pile walls results in discharges into a navigable body of water by means of ditches, gullies and similar conveyances, even if the (dischargers) have done nothing beyond the mere collection of rock and other materials * * * Nothing in the Act relieves (discharges) from liability simply because the operators did not actually construct those conveyances, so long as they are reasonably likely to be the means by which pollutants are ultimately deposited into a navigable body of water. Conveyances of pollution formed either as a result of natural erosion or by material means, and which constitute a component of a * * * drainage system, may fit the statutory definition and thereby subject the operators to liability under the Act. (emphasis added) 620 F.2d 41, 45 (1980).

Under this approach, point source discharges of storm water result from structures that increase the imperviousness of the ground that acts to collect runoff, with runoff being conveyed along the resulting drainage or grading patterns.

The Agency will embrace the broadest possible definition of point source consistent with the legislative intent of the CWA and court interpretations to include any identifiable conveyance from which pollutants might enter the waters of the United States.

B. Industrial Storm Water Discharges Through Municipal Separate Storm Sewer Systems

The November 16, 1990 notice clarifies that storm water discharges associated with industrial activity to waters of the United States, including those through municipal separate storm sewers to waters of the United States, must obtain

NPDES permit coverage. However, storm water discharges associated with industrial activity to municipal sanitary sewer systems (i.e. those systems which are part of a POTW collection system), including combined sewer systems, generally do not need to obtain NPDES permit coverage, although they may be subject to pretreatment requirements. (Note that municipalities which operate combined sewer overflows (CSOs) need NPDES permit coverage for the CSO discharge).

C. Permit Application Requirements

The November 16, 1990 rule established individual (40 CFR 122.26(c)(1)) and group (40 CFR 122.26(c)(2)) application requirements for storm water discharges associated with industrial activity. The requirements associated with individual application requirements for storm water discharges associated with industrial activity are incorporated into Forms 1 and 2F, which are generally to be submitted to the Director by November 18, 1991. In addition, operators of storm water discharges associated with industrial activity through large and medium municipal separate storm sewer systems are required to submit a notification of their discharge to the operator of the municipal separate storm sewer system receiving the discharge by no later than May 15, 1991 or 180 days prior to commencing such discharge (40 CFR 122.26(a)(4)).

The rule also established permit application requirements for discharges from large and medium municipal separate storm sewer systems at 40 CFR 122.26(d).

V. Burdens on Permitting Agencies

The focal issue in developing appropriate requirements for the NPDES storm water program continues to be addressing the resource burdens of implementing an effective regulatory program for the extremely large number of storm water discharges. Understanding the burdens of the program on permitting Agencies is a first step towards developing a workable regulatory program.

Implementing the NPDES permitting program is a complex process. Major steps to issue a permit include:

- *Training of Permit Writers.* Permit writers must acquire the appropriate expertise necessary for writing permits.
- *Permit Application Review.* Permit applications (or notices of intent to be covered under a general permit) that are received initially must be screened and reviewed for completeness. When this

review indicates that necessary information is not provided, the applicant must be notified and an explanation of the deficiency provided. Applications that are complete must be assigned to a permit writer and filed.

- *Preparing a Draft Permit.* Preparing a draft permit and fact sheet involves a technical evaluation of the discharge based on a review of the permit application or other appropriate information. The appropriate factors associated with technology-based or water quality-based standards must be evaluated. Appropriate effluent limitations, monitoring requirements, and any special conditions need to be developed.

- *Public Notice of the Draft Permit.* Draft permits must undergo appropriate public notice. In some cases public hearings must be held.

- *Permit Issuance.* Public comments must be received, evaluated, and responded to in developing a final permit. Any request for an evidentiary hearing must be addressed.

- *Compliance Monitoring/Enforcement.* A number of compliance monitoring activities can be conducted including reviewing discharge monitoring reports, conducting site inspections, and evaluating other information. Enforcement actions include assessing penalties and issuing administrative orders. In some cases, enforcement actions lead to litigation.

In addition to these steps, a number of administrative functions, such as responding to public inquiries, can create burdens for permit issuing agencies. The number of such inquiries can be particularly high when a new regulation is involved.

As discussed earlier in this notice, efforts to permit point source discharges under the CWA have focussed primarily on industrial process discharges and discharges from POTWs. EPA and authorized NPDES States have issued more than 48,600 NPDES permits for industrial process discharges, 15,600 NPDES permits for POTWs, and approximately 59 general permits have been issued covering at least 7,200 facilities. The Agency estimates that over 100,000 facilities (not including oil and gas exploration and production operations) discharge storm water associated with industrial activity. Most of the facilities that discharge storm water associated with industrial activity have not been addressed under the NPDES program in the past. Today's notice incorporates several elements of EPA's initial attempts to establish a workable NPDES program that reflects the realities of these administrative burdens.

VI. Today's Notice

Today's notice requests public comment on four major areas:

- (1) EPA's long-term permitting strategy for storm water discharges associated with industrial activity;
- (2) Proposed changes to 40 CFR 122.44(i)(2) addressing annual monitoring and reporting requirements;
- (3) Proposed changes to 40 CFR 122.28(b)(2) addressing notice of intent requirements for general permits; and
- (4) Proposed baseline general permits for storm water discharges associated with industrial activity in 12 States (MA, ME, NH, FL, LA, TX, OK, NM, SD, AZ, AK, ID), and 6 Territories (District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands) without authorized NPDES State programs; on Indian lands in AL, CA, GA, KY, MI, MN, MS, MT, NC, ND, NY, NV, SC, TN, UT, WI, and WY; located within Federal facilities and Indian lands in CO and WA; and located within Federal facilities in Delaware.

A. Long-Term Permitting Strategy

Many of the comments received during the storm water NPDES permit application rulemaking focussed on the difficulties that EPA Regions and authorized NPDES States, with their finite resources, will have in implementing an effective permitting program for the large number of storm water discharges associated with industrial activity. Many commenters noted that problems with implementing a permit program are caused not only by the large number of industrial facilities subject to the program, but by the difficulties associated with identifying and assessing appropriate technologies and other measures for controlling storm water at various sites and the differences in the nature and extent of storm water discharges from different types of industrial facilities. The Agency recognizes these concerns, and is developing an approach to serve as a foundation for future program development.

Based on a consideration of comments from authorized NPDES States, municipalities, industrial facilities and environmental groups on the permitting framework and permit application requirements for storm water discharges associated with industrial activity, EPA is developing a strategy for permitting storm water discharges associated with industrial activity. In developing this strategy, the Agency recognizes that the CWA provides flexibility in the manner

in which NPDES permits are issued.⁵ The Agency intends to use this flexibility in designing a workable and reasonable permitting system. In accordance with these considerations, in today's notice the Agency is publishing and requesting comments on a discussion of its draft strategy for implementing the NPDES storm water program. The Strategy establishes two major components, a framework for developing permitting priorities and a framework for the development of State Storm Water Permitting Plans.

1. Permitting Priorities

The Agency believes that most permitting activities can be described in terms of the following four classes of activities:

- *Tier I—Baseline Permitting:* One or more general permits will be developed to initially cover the majority of storm water discharges associated with industrial activity;
- *Tier II—Watershed Permitting:* Facilities within watersheds shown to be adversely impacted by storm water discharges associated with industrial activity will be targeted for individual or watershed-specific general permits.
- *Tier III—Industry-Specific Permitting:* Specific industry categories will be targeted for individual or industry-specific general permits; and
- *Tier IV—Facility-Specific Permitting:* A variety of factors will be used to target specific facilities for individual permits.

These four classes of activities will be implemented over time and will reflect priorities within given States. In most States, Tier I activities, issuance of baseline permits, will be the initial starting point. As priorities and risks within the State are evaluated, classes of storm water discharges or individual storm water discharges will be identified for Tier II, III or IV permitting activities. Usually a storm water discharge or a class of discharges will not go through a sequence that involves all four of the Tiers associated with the strategy, but may for example, go from initial coverage under a Tier I baseline

⁵ As discussed earlier in this notice, the Court in *NRDC v. Train*, 396 F.Supp. 1393 (D.D.C. 1975) *aff'd*, *NRDC v. Costle*, 566 F.2d 1389 (D.C.Cir. 1977), has acknowledged the administrative burden placed on the Agency by requiring individual permits for a large number of storm water discharges. These courts have recognized EPA's discretion to use certain administrative devices, such as area permits or general permits to help manage its workload. In addition, the courts have recognized flexibility in the type of permit conditions that are established, including requirements for best management practices.

permit to coverage under a Tier III industry specific general permit.

a. *Tier I—Baseline permitting.* The Agency intends to issue general permits that initially cover the majority of storm water discharges associated with industrial activity in States without authorized NPDES programs. These permits also will serve as models for States with authorized NPDES programs.

Consolidating many sources under one permit will greatly reduce the administrative burden of permitting storm water discharges associated with industrial activity. This approach will allow:

- Pollution prevention and control requirements to be established for discharges covered by the permit;
- Facilities whose discharges are covered by the permit to be certain of their legal responsibilities and have an opportunity to comply with the CWA;
- EPA and authorized NPDES States will begin to collect and review data on storm water discharges from priority industries, thereby supporting subsequent permitting activities;
- The public, including municipal operators of municipal separate storm sewers which may receive storm water discharges associated with industrial activity, to have access under section 308(b) of the CWA to monitoring data and certain other information developed by the permittee;
- Applicable requirements of municipal storm water management programs established in permits for discharges from municipal separate storm sewer systems to be enforceable directly against noncomplying industrial facilities that generate the discharges where the permit for the storm water discharge includes a condition requiring compliance with the municipal storm water management program;
- The public to have the opportunity to review data and reports developed by industrial permittees and to be given an opportunity to comment on permitting activities;
- The baseline permits will provide a basis for bringing selected enforcement actions by eliminating many issues which might otherwise arise in an enforcement proceeding; and
- The baseline permit, along with the State storm water permitting plans (discussed below), will provide a focus for public comment on subsequent phases of the permitting strategy for storm water discharges.

Initially, the coverage of the baseline permits will be broad. However, the coverage will shrink as other permits are issued for storm water discharges

associated with industrial activity pursuant to Tier II through Tier IV activities. The Agency believes that Tier I permits can establish the appropriate balance between monitoring requirements and implementable controls that will initiate facility-specific controls and provide sufficient data for compliance monitoring and future program development. Baseline general permits are flexible enough to allow the introduction of Tier II, III or IV types of activities, such as industry specific monitoring or control conditions. (See the draft general permits in this notice for examples of how this balance may be achieved). The Agency requests comments on the appropriate role of sampling requirements and on facility-specific controls in Tier I permits.

b. *Tier II—Watershed permitting.* Facilities within watersheds shown to be adversely impacted by storm water discharges associated with industrial activity will be targeted for individual and general permitting activities. This process can be initiated by identifying receiving waters (or segments of receiving waters) where storm water discharges associated with industrial activity have been identified as a source of use impairment or are suspected to be contributing to use impairment. Information developed under sections 304(l), 305(b), and 319(a) of the CWA, along with information from other sources (including information developed under the baseline general permits for storm water discharges), can be used in evaluating impacts on receiving waters. This information may identify classes of storm water discharges that are of particular concern and portions of watersheds where the sources of concern are located. Appropriate classes of storm water discharges in these locations can be targeted for additional permit conditions which may provide additional information to characterize the discharge (e.g., additional monitoring and reporting requirements) or where appropriate for more stringent controls.

Information gathered under initial permits for storm water discharges as well as information from other sources can be used to upgrade lists of impacted receiving waters and reassess water quality-based controls. As discussed in more detail below, State storm water permitting strategies are expected to have a major role in this process.

c. *Tier III—Industry-Specific Permitting.* Specific industry categories will be targeted for individual or industry-specific general permits. These permits will allow permitting authorities to focus attention and resources on industry categories of particular concern

and/or industry categories where tailored requirements are appropriate. The Agency will work with the States to develop model permits for selected classes of industrial storm water discharges. EPA is also working to identify priority industrial categories in the two Reports to Congress required under section 402(p)(5) of the CWA. In addition, the group application process adopted in the final regulation published on November 18, 1990, (55 FR 47990) will provide an additional mechanism for developing industry-specific general permits. Group applications that are received can be used to develop model permits for the appropriate industries.

d. *Tier IV—Facility-specific permitting.* Individual permits will be appropriate for some storm water discharges in addition to those identified under Tier II and Tier III activities. Individual permits should be issued where warranted by: The pollution potential of the discharge, the need for individual control mechanisms, and where reduced administrative burdens exist. For example, individual NPDES permits for facilities with process discharges should be expanded during the normal process of permit reissuance to cover storm water discharges from the facility. This provides an opportunity to develop individual controls where the incremental administrative burden is not greatly increased.

2. Relationship of Strategy to Permit Application Requirements

The long-term permitting Strategy described above identifies several permit approaches that the Agency anticipates will be used in addressing storm water discharges associated with industrial activity. One issue that arises with this Strategy is determining the appropriate information needed to develop and issue permits for these discharges. The NPDES regulatory scheme provides three potential routes for applying for permit coverage for storm water discharges associated with industrial activity:

- (1) Individual permit applications;
- (2) Group applications; and
- (3) Case-by-case requirements developed for general permit coverage.

Individual Permit Application Requirements

Individual permit application requirements are applicable to all storm water discharges associated with industrial activity except where the operator of the discharge is participating in a group application, or a general permit is issued to cover the discharge

and the general permit provides alternative means to obtain permit coverage.

The requirements for an individual permit application are reflected in Form 1 and Form 2F. These forms require the development and submission of relatively detailed site-specific information, including: A drainage site map, an estimate of the area of impervious surfaces and the total area drained by each outfall, a narrative description of specified features that may impact the pollution potential of a discharge, a list of significant spills and leaks of toxic or hazardous pollutants that occurred at the facility after the effective date of the permit, a certification that the discharge has been tested for the presence of non-storm water discharges, and sampling data from a representative storm event. This information is intended to be used to develop the site-specific conditions generally associated with individual permits.

Individual permit applications will play an important role in all tiers of the Strategy, even where general permits are used. Although general permits may provide for notification requirements that operate instead of the requirement to submit individual permit applications, the individual permit applications may be needed under several circumstances. Examples include: general permits requiring the submission of a permit application as the notice of intent to be covered by the permit; where the owner or operator of a discharge authorized by a general permit requesting to be excluded from the coverage of the general permit by applying for a permit (see 40 CFR 122.28(b)(2)(iii) for EPA-issued general permits); and a Director requiring an owner or operator of a discharge authorized by a general permit to apply for an individual permit (see 40 CFR 122.29(b)(2)(ii) for EPA-issued general permits).

Group Applications

On November 16, 1990, (55 FR 47990), EPA promulgated requirements for group applications for storm water discharges associated with industrial activity. These applications provide participants of groups with sufficiently similar storm water discharges an alternative mechanism for applying for permit coverage.

The group application requirements provide information for developing industry-specific general permits. (Group applications can also be used to issue individual permits in authorized NPDES States without general permit authority or where otherwise appropriate). As such, group application

requirements correlate with the Tier III permitting activities identified in the long-term permitting Strategy.

Requirements in General Permits

40 CFR 122.21(a) excludes persons covered by general permits from requirements to submit individual permit applications. In section VI.C of this preamble, the Agency is proposing minimum requirements for filing notices of intent (NOI) to be authorized to discharge under general permits. NOI requirements established in general permits operate instead of individual permit application requirements for the discharges covered by the general permit. (NOI requirements are discussed in more detail below).

3. State Storm Water Permitting Plans

The CWA provides a framework for the long-term development of the NPDES program to address storm water discharges. Section 402(p)(2) of the CWA identifies those storm water discharges, including storm water discharges associated with industrial activity, which are the initial priorities for permitting. Section 402(p)(5) of the CWA requires the Agency to study other storm water discharges. Section 402(p)(6) of the CWA requires EPA, in consultation with State and local officials, to issue regulations by no later than October 1, 1992 which designate additional storm water discharges to be regulated to protect water quality and establish a comprehensive program to regulate such designated sources. The Act provides that this regulatory program include requirements for State Storm Water Management Programs.

Although section 402(p)(6) contemplates that State Storm Water Management Programs address Phase II storm water discharges identified in section 402(p)(5) studies (e.g., a subset of storm water discharges other than storm water discharges associated with industrial activity, and discharges from large and medium municipal separate storm sewer systems), the Agency believes that permitting activities for storm water discharges associated with industrial activity and for discharges from large and medium municipal separate storm sewer systems under Phase I should also be considered and evaluated when developing the scope of comprehensive State Storm Water Management Programs.

As EPA and NPDES authorized States implement efforts to permit storm water discharges, it is necessary to ensure adequate public input, evaluate program activities and provide for program oversight. The Agency believes that State Storm Water Management

Programs can provide an appropriate basis for these activities, particularly during the earlier stages of program development. EPA has outlined below a number of the components and elements of a State Storm Water Permitting Plan which it believes are essential to assure successful implementation of the storm water initiative called for in section 402(p) of the CWA, and which can serve as a foundation for subsequent development of State Storm Water Management Programs. These plans will provide an effective coordination and tracking mechanism for evaluating the initial permitting activities for storm water discharges required under section 402(p) of the CWA. In addition, these plans will facilitate the technology transfer among the States.

State Storm Water Permitting Plans should include a description of a strategy to issue NPDES permits for discharges from large and medium municipal separate storm sewer systems; storm water discharges associated with industrial activity; and case-by-case designations of storm water discharges needing a permit. Plans should be developed for each State. EPA will request that the Director of the NPDES program provide a copy of the draft State Storm Water Permitting Plan to the Office of Wastewater Enforcement and Compliance within 12 months after the date of publication of this final regulation. EPA anticipates that States will update these plans on a regular basis. EPA intends to continue to review these plans while evaluating the manner in which Phase II storm water discharges are addressed in State Storm Water Management Programs developed under section 402(p)(6) of the CWA. These plans will assist EPA in technology transfer activities, evaluating the progress of States in implementing storm water permitting activities, and identifying problems with program implementation.

EPA believes that at a minimum, the initial State Storm Water Permitting Plans should address permitting of large and medium municipal separate storm sewer systems; storm water discharges associated with industrial activity; and case-by-case designations of storm water discharges needing a permit. Much of the information in the first phase of the plan will be generated from storm water applications required by the November 16, 1990 application rule and the industry specific analysis required by the rule. The basic framework for the Plan should address on a State-wide basis:

Municipal Separate Storm Sewer Systems

- A list of municipal separate storm sewer systems serving a population of 100,000 or more within the State;
- For systems identified, a summary of the estimated pollutant loadings as provided in the permit application for such discharges, or as otherwise updated; and
- The status of permitting activities for discharges from municipal separate storm sewer systems serving a population of 100,000 or more, including any NPDES permit number for such discharges.

Storm Water Discharges Associated with Industrial Activity

- A description of the status and objectives of activities to issue and implement a baseline general permit, including a copy of any final general permit for storm water discharges associated with industrial activity;⁶
- A list of categories of industrial facilities that have storm water discharges associated with industrial activity that are being considered for industry-specific general permits for their storm water discharges associated with industrial activity;
- A description of procedures, including activities conducted under any general permit (such as inspections, review of notices of intent or review of monitoring reports) to identify specific storm water discharges associated with industrial activity that are appropriate for individual permits;
- A description of how permits for discharges from municipal separate storm sewer systems require the development of municipal storm water management programs addressing the control of pollutants in storm water discharges associated with industrial activity.

Impacted Waters

- A description of procedures to identify receiving waters where discharges from municipal separate storm sewers, storm water discharges associated with industrial activity, or any other class of storm water discharges are, or have the potential to, cause or contribute to a violation of a water quality standard, including a list of waters identified by these procedures.

⁶ EPA is not requesting permits in as part of these Plans for the purpose of commenting on the adequacy of the permit. Rather the Agency is requesting the copies of the permit to coordinate technology transfer regarding permitting approaches and classes of storm water discharges addressed, and to provide a general evaluation of the status of National permitting activities.

Case-by-Case Designations

- A description of procedures to identify storm water discharges (other than those currently subject to requirements for obtaining a permit) that contribute to a violation of a water quality standard or significantly contribute pollutants to the waters of the United States.
- A list of storm water discharges considered for designation or designated under section 402(p)(2)(E) as needing a permit.

EPA strongly encourages public participation and comment at the State level during the development of these plans.

These initial State storm water permitting components will ensure that permitting efforts are implemented adequately for storm water discharges associated with industrial activity and other priority storm water discharges by creating a framework for planning State storm water permitting activities, and providing EPA information for technology transfer purposes and evaluating State permit issuance efforts. The State Storm Water Permitting Plans will provide a framework for implementing the tiered long-term strategy for permitting storm water discharges associated with industrial activity. Provisions for State Storm Water Management Programs will be expanded in the future to address other storm water discharges in accordance with section 402(p)(6) of the CWA. EPA requests comments on the appropriate scope and content of State Storm Water Permitting Plans. The Agency also requests comments on whether the guidelines for Plans should be made requirements that are incorporated into EPA regulations, or remain non-binding recommendations for States. EPA notes that it may require preparation of such Plans pursuant to sections 304(i)(2) and 402(p)(6) of the CWA.

4. States without NPDES General Permit Authority

As noted, the issuance of general permits is a very important component in the recommended permit issuing strategy. Presently 38 States (and 1 territory) have been authorized to implement the NPDES permit program. However, only 23 of these States have been authorized to issue general permits. If NPDES authority is not obtained for any of the remaining 15 States, storm water controls will have to be implementation based on the submission of individual or group permit applications, and the development of individual permits. Under the CWA, EPA cannot issue general permits in

States that have been authorized to administer the NPDES program.

EPA strongly recommends that States with authorized State NPDES programs, but without general permit authority, consider obtaining general permit authority as soon as possible. EPA is currently working with States to expedite the authorization process.

B. Proposed Changes To Annual Monitoring and Reporting Requirements

Section 308 of the CWA authorizes EPA to require information, monitoring, and recordkeeping to carry out the objectives of the Act including but not limited to: (1) Characterization of discharges to assist in the development of permit conditions and controls; and (2) compliance monitoring to determine whether a discharger is in violation of a permit condition. The authority to collect information under section 308 is broad and can include requirements for record keeping, making reports, effluent monitoring, and other information reasonably required. EPA and authorized NPDES States implement this authority in a number of ways, including permit application requirements, permit monitoring and reporting requirements, and specific information requests under section 308 (section 308 letters). In addition, section 402(a)(2) of the CWA provides that NPDES permits shall prescribe requirements to assure compliance with permit conditions, including requirements on data and information collection, reporting, and such other requirements deemed appropriate.

Monitoring data serves a number of functions under the NPDES program. Discharge monitoring data can be used to assist in the evaluation of the risk of the discharge by indicating the types and the concentrations of pollutant parameters in the discharge. Monitoring of storm water from an industrial site can assist in evaluating sources of pollutants. Discharge monitoring data can be used in evaluating the potential of the discharge to cause or contribute to water quality impacts and water quality standards violations.

Discharge monitoring data can also be used to evaluate the effectiveness of controls on reducing pollutants in discharges. This function of monitoring can be important in evaluating the effectiveness of source control or pollution prevention measures as well as evaluating the operation of end-of-pipe treatment units. Where numeric or toxicity effluent limits are incorporated into permits, discharge monitoring data plays a critical role by providing EPA and authorized NPDES States with data

to evaluate compliance with effluent limits. The use of discharge monitoring data to determine permit compliance greatly enhances the ability of EPA and authorized NPDES States to enforce permit conditions.

As part of efforts to obtain sufficient information to run the program effectively, the existing regulations at 40 CFR 122.44(i) specify factors to consider in developing monitoring requirements in permits. These regulations indicate that permit monitoring requirements are to be established on a case-by-case basis to ensure, as noted above, compliance with permit limitations. In addition, 40 CFR 122.44(i)(2) provides that requirements to report monitoring results to the permitting authority shall in no case be less than once a year.

To date, the minimum requirement that permittees submit an annual discharge monitoring report (DMR) has proved to be a valuable baseline for NPDES permitting efforts for POTWs and industrial process discharges. Among the most important functions of DMRs is to assess compliance with numeric effluent limits contained in permits. However, some important administrative, technical, and policy concerns regarding DMRs arise as the Agency begins to fully implement permit requirements for storm water discharges. The Agency is considering the following factors in addressing this issue:

Administrative Burdens on Permitting Agencies. Requiring annual DMRs from each facility that discharges storm water associated with industrial activity would result in an enormous increase in the number of DMRs received by EPA Regions and authorized NPDES States. The Agency estimates that nationwide, over 100,000 facilities (not including oil and gas exploration and production operations) discharge storm water associated with industrial activity. Receiving annual DMRs containing complex technical information from each of these facilities would demand a large amount of permitting resources dedicated to reviewing and filing these reports. The Agency believes that such an increase in information would overwhelm permitting agencies who would have limited opportunities to review or otherwise analyze the information.

Difficulties in Sample Collection. Where storm water is not collected in a retention pond, the collection of storm water samples may pose a number of difficulties. These difficulties include determining when a discharge will occur, safety considerations, the potential for a large number of discharge points at a given facility, the limited

duration of the event, the limited number of events that occur in some parts of the country, and variability in flow rates.

Variability of Data. The types and concentrations of pollutants in storm water discharges associated with industrial activity depend on a number of factors, including the nature of industrial activities occurring at the site, the nature of the precipitation event generating the discharge, and the time period from the last storm. Variations in these parameters at a site may result in variation from event to event in the concentrations and types of pollutants in a given discharge.

Types of Permit Conditions. Permits for industrial process discharges and discharges from POTWs traditionally have incorporated numeric and/or toxicity effluent limitations as conditions. Monitoring reports for these discharges provide a direct indication whether the discharge complies with permit conditions. However, it is anticipated that permits for storm water discharges will contain a variety of types of controls. While numeric or toxicity limitations are expected to be appropriate for some storm water discharges, permits for other storm water discharges are expected to contain requirements to implement best management or pollution prevention practices. In these cases, monitoring information may not provide as direct a link to compliance with permit conditions. However, monitoring data can still play an important role in identifying priority facilities, providing information on sources and types of pollutants which can be evaluated when designing or modifying best management or pollution prevention practices, and evaluating the effectiveness of best management practices and pollutant prevention measures.

Focused Permitting Efforts

The long-term permitting strategy discussed earlier in today's notice provides for a flexible system for conducting permit issuance and reissuance activities. Flexibility has been incorporated into the strategy to facilitate EPA and authorized NPDES States permit issuance activities which reflect Regional and State prioritization of storm water impacts on particular watersheds and specific receiving waters, and on specific classes of facilities. In most States, the issuance of baseline permits (Tier I activities), will be the initial starting point. As priorities and risks within a State are evaluated, classes of facilities will be identified for more specific permit issuance activities

(Tiers II, III and IV of the strategy). Storm water discharge monitoring data will have an important role, along with other information, in identifying facilities or classes of facilities where Tier II, III and IV permit issuance activities are appropriate. In addition, monitoring data will play an important role in developing appropriate permit conditions.

1. Options for Regulatory Modifications

EPA requests comments on five options (plus a no change option) for modifying the existing regulatory provision that NPDES permits at a minimum require the submittal of DMRs annually for permits for storm water discharges associated with industrial activity. It should be clarified that these options only address *minimum* requirements for discharge monitoring in NPDES permits. All options for modifying these regulations would retain authority to require more stringent monitoring requirements where appropriate. The six options⁷ are as follows:

No Change Option: Case-by-case monitoring conditions in permits for storm water discharges, with a minimum requirement to report monitoring results at least annually.

Under this approach, EPA would not change its existing regulations which provide that monitoring conditions in NPDES permits be established on a case-by-case basis, but at a minimum, must contain requirements to report monitoring results at least annually.

Option 1: Case-by-case monitoring conditions in permits for storm water discharges with a minimum requirement to report monitoring results at least twice per permit term.

This option would change the minimum requirement for reporting monitoring results at least annually to reporting monitoring at a different frequency, such as twice during a five year period (during the term of a permit). This approach would provide permit writers with additional flexibility to develop monitoring requirements in

⁷ EPA will consider developing a final regulation which combines aspects of several of the options articulated below. For example, the Agency may determine that it is appropriate to issue a final regulation which provides that, at a minimum, NPDES permits will require annual monitoring (without reporting) for all storm water discharges associated with industrial activity except for permits for targeted storm water discharges associated with industrial activity located in the watershed of receiving waters that are sensitive to or impacted by storm water discharges which at a minimum would be required to sample quarterly and be required to report information to the permitting authority.

permits that were less burdensome to the permittee. Reducing monitoring and reporting requirements would also be less burdensome to the entity that reviewed the monitoring report.

The Agency also requests comments on providing permit writers with flexibility to establish requirements for conducting biological surveys of receiving waters as part of efforts to comply with minimum monitoring requirements. Under this approach, permittees could be required to conduct a survey of the biological health of the receiving water, to provide information on existing conditions. (See, "Biological Criteria, National Program Guidance for Surface Waters," Office of Water Regulations and Standards (WH-585), EPA-440/5-90-004 and "A Survey of the Status of Biomonitoring in State NPDES and Nonpoint Source Monitoring Programs," 1989, Office of Policy, Planning and Evaluation, U.S. EPA, RTO/7839/02-03F).

Data from a biological survey can be used by a permitting authority when assessing biological criteria to evaluate surface water quality. In this manner, the biological survey data can identify locations where water quality impacts are thought to be occurring. Where such impacts occur, additional monitoring or control requirements could be pursued.

Chemical specific monitoring, toxicity monitoring and biosurveys have unique as well as overlapping attributes, sensitivities, and program applications. No single approach for detecting impact should be considered uniformly superior to any other approach. EPA is encouraging States to implement and integrate all three approaches into their water quality programs, while applying them in combination or independently as site-specific conditions and assessment objectives dictate (See draft Final "Policy on the Use of Biological Assessments and Criteria in the Water Quality Program", EPA, January 1990).

Option 2: Case-by-case monitoring conditions in permits for storm water discharges with a minimum requirement that facilities conduct annual sampling. Facilities would not be required to report monitoring information unless the information was requested in a permit or by the Director, but would be required to retain information.

Under this approach, permits for storm water discharges associated with industrial activity will, at a minimum, require the discharger to sample storm water discharges at least annually. However, permits would not have to require dischargers to submit monitoring reports. Facilities could use this data to review the effectiveness of BMPs or storm water pollution prevention

practices conducted at the site. Monitoring data would be available to the Director or the public upon request. In addition, dischargers could be required to submit a summary of their monitoring results they had collected during the previous permit term every five years when they resubmit permit applications or notices of intent to be covered under a general permit.

This approach could provide additional flexibility to permit writers for developing reasonable and workable permit conditions which can limit the administrative burdens associated with receiving and reviewing monitoring results from a large number of facilities. Facilities would still be required to conduct discharge monitoring at least annually even where permits require the development of pollution prevention or best management practices instead of numeric or toxicity effluent limits. The permittee would evaluate discharge monitoring data as part of efforts to identify pollutant sources, evaluate risks, and evaluate the effectiveness of its pollution prevention/best management practices program. In addition, requiring monitoring data would ensure that the permitting authority would be able to request information from the facility either during the term of the permit, or when the discharger is reapplying for permit coverage. This would allow the permit writer to identify pollutant sources, evaluate priorities based on the nature of pollutants in the discharge and the potential for the discharge to contribute to a water quality standard violation, and to evaluate the effectiveness of controls at the facility.

The Agency remains concerned about the ability of permitting authorities to adequately review annual monitoring reports from all facilities that discharge storm water associated with industrial activity. EPA requests comments on whether providing permit writers with the flexibility to require permittees to retain monitoring information until the information is requested or until a permit is reissued is an adequate and appropriate manner in which to address this problem.

Option 2 could be modified to provide minimum requirements to establish reporting of monitoring results in permits in specified situations. One approach would be to provide that permits for storm water discharges associated with industrial activity to receiving waters that are sensitive to or impacted by storm water discharges must require dischargers to report monitoring results at least annually (or at a higher minimum frequency). This approach would assist permitting

agencies in evaluating causes of water quality impairment. The discussion accompanying *Option 4* describes how receiving waters that are sensitive to or impacted by storm water discharges may be identified.

The second approach would be to provide that permits for storm water discharges associated with industrial activity must require dischargers to report monitoring results where pollutants are detected above specified threshold concentrations. Maximum pollutant threshold concentrations which would trigger reporting requirements could be established by regulation. These concentrations would apply to all storm water discharges associated with industrial activity nationally. (For example, values which could be established at the high end of the range of pollutant concentrations typically found in urban runoff. The NURP data base indicates that high values within the typical range for urban runoff may include concentrations such as 50 mg/l five-day biochemical oxygen demand, 30 mg/l oil and grease, 400 mg/l total suspended solids. Alternatively, for parameters with water quality standards, EPA could require that concentrations in excess of the numeric water quality criteria be reported). Alternatively, pollutant threshold concentrations could be established on a State-by-State basis, with different sets of pollutant threshold concentrations for different classes of receiving waters. The Agency requests comments on appropriate pollutant threshold concentrations under this approach. As stated above, dischargers could be required to submit summaries of all of the monitoring information that they collected during the previous permit term when they resubmit applications or notices of intent for permit coverage.

Option 3: Case-by-case monitoring conditions in permits for storm water discharges with a minimum requirement that facilities (other than those from oil and gas exploration or production operations and inactive mining operations where a past or present mine operator cannot be identified) conduct annual sampling. Facilities would not be required to report information unless the information was requested in a permit or by the Director, but would be required to retain information. For contaminated storm water discharges from oil and gas exploration or production operations or from inactive mining operations where a past or present mine operator cannot be identified, either case-by-case monitoring conditions in permits for

storm water discharges with a minimum requirement of annual sampling (without reporting) or, instead of sampling, a Professional Engineer's certification attesting that good engineering practices were being employed to meet appropriate permit conditions.

This option is identical to Option 2 for storm water discharges associated with industrial activity from facilities other than: oil and gas exploration or production operations; and inactive mining operations where a past or present mine operator cannot be identified. However, for contaminated storm water discharges associated with industrial activity from oil and gas exploration or production operations (e.g. drilling or well operations) or from inactive mining operations where a past or present mine operator cannot be identified, this option would provide permit writers with flexibility to require, at a minimum, either annual monitoring or, instead of monitoring, a certification by a Professional Engineer (PE) attesting that good engineering practices were being employed to meet appropriate permit conditions.

Under this approach, permit writers would be provided with two options for developing minimum monitoring requirements for storm water discharges from oil and gas exploration and production operations. The first option satisfying the minimum requirement would be to require owners or operators of storm water discharges from oil and gas exploration and production operations to conduct annual monitoring of representative storm water discharges. Where dischargers are not required to report monitoring results to the Director, permits must require that monitoring results be retained by the discharger for at least the term of the permit and be made available to the Director upon request. In such cases, results of any monitoring conducted during the term of the permit should be submitted as part of a permit application or NOI requirement prior to permit reissuance.

A second option for minimum requirements for permits for storm water discharges from oil and gas exploration and production operations or from inactive mine sites where a past or present mine operator cannot be identified would be available where a permit requires the facility owner or operator to develop and implement a storm water pollution prevention plan or a storm water best management practices plan. In such a case, the permit writer could require the discharger to obtain a Registered Professional Engineer's certification that the plan had

been prepared and is being implemented in accordance with good engineering practices. Such certification would be obtained at a minimum of once every three years. The Agency believes that a minimum requirement of once every three years is necessary to evaluate changing site conditions and practices. Of course permit writers would retain discretion to, where appropriate, establish monitoring and certification requirements in excess of these minimum requirements.

EPA is proposing this option to address some of the specific concerns associated with storm water from oil and gas operations and from inactive mining operations where a past or present operator cannot be identified.

Information from sources such as nonpoint source assessments developed pursuant to section 319(a) of the CWA indicate that significant water quality impacts can be caused by wet-weather failure of on-site waste disposal systems at oil and gas exploration and production operations (such as storm induced overflows of reserve pits used to hold spent drilling muds and cuttings). Periodic sampling of discharges may not be sufficient to identify or predict these events. Rather, a PE certification may provide a more appropriate link for evaluating the potential for and preventing these types of events. Further, many oil and gas exploration and production with contaminated storm water discharges are already required to obtain similar PE certifications for Spill Prevention Control and Countermeasure (SPCC) Plans for discharges of oil under 40 CFR part 112. The Agency believes that developing an approach under the NPDES program for storm water discharges from oil and gas operations that is consistent with existing regulatory programs (e.g. the SPCC program) will potentially reduce industry burdens and provide for a greater degree of industry compliance. EPA is also considering other factors in evaluating requirements for oil and gas exploration and production operations, including the potentially large number *

* The American Petroleum Institute (API) estimates that there are about 850,000 active oil and gas wells, 219,000 tank batteries and 150,000 injection wells in the United States. API also estimates that SPCC plans have been developed for about 130,000 of these facilities. The Agency anticipates that many sites are composed of multiple components (e.g. active wells, a tank battery, and injection wells). The Agency also anticipates that not all sites discharge 'contaminated' runoff. EPA requests comments on the number of sites with oil and gas exploration and production operations that discharge contaminated storm water to waters of the United States, and hence would be subject to NPDES storm water requirements.

of facilities subject to the program and that such facilities are typically found at remote locations and may have a limited operating staff.

Monitoring contaminated storm water discharges associated with industrial activity from inactive mining operations where a past or present mine operator cannot be identified can pose unique problems, particularly on Federal lands which have many thousands of inactive mines without identifiable mine operators. The Agency will be developing draft general permits in several States for inactive mining operations on Federal lands where a past or present mine operator cannot be identified and where EPA retains NPDES permit issuance responsibilities (these discharges are excluded from the draft general permits noticed elsewhere in today's Federal Register). The Agency believes that requiring the appropriate Federal land manager to monitor discharges from every one of the thousands of inactive mines on their lands is not appropriate. Rather, the Agency is evaluating the appropriate combination of discharge monitoring requirements for selected inactive mining operations and requirements to assess water quality impacts, such as biosurveys, instream sampling and sediment sampling. Further, the Agency recognizes that many of the methods used to control pollutant discharges and reclaim inactive mining operations can be evaluated from site inspections, and that unique resource problems may arise where a past or present operator cannot be identified. (Note that SMCRA regulations applicable to coal mining operations incorporate PE certifications (see 30 CFR 816.133(d)(5) and 30 CFR 817.133(d)(5).)

EPA requests comments on whether providing that NPDES permits for contaminated storm water discharges associated with industrial activity from oil and gas exploration and production operations and from inactive mining operations where a past or present mine operator cannot be identified, a PE certification instead of annual monitoring is an effective mechanism to ensure compliance with permit conditions.

EPA requests comments on other classes of industries where a PE certification may be an appropriate alternative to discharge sampling (e.g. construction activities where conditions change dramatically and frequently; portions of active mining operations which are not subject to effluent limitations guidelines, inactive industrial operations where an operator is not identifiable and which are not expected

to undergo extensive changes; and small businesses⁹ which may not have the expertise to monitor). In addition, the Agency requests comment on portions of industrial facilities, such as haul roads, where a PE certification may be an appropriate alternative to discharge sampling.

EPA also requests comments on the costs of obtaining Professional Engineer's certification for two scenarios: (1) Where the engineer is a company employee and (2) where the company does not have an appropriate Professional Engineer on staff and must hire a consultant. In addition, EPA requests comments on the appropriate minimum frequency for obtaining such a certification.

The proposed changes to the language of 40 CFR 122.44(i) found in the back of today's notice reflects this option.

Option 4: Case-by-case monitoring conditions in permits for storm water discharges with a minimum requirement that monitoring reports be submitted at least annually for targeted classes of storm water discharges associated with industrial activity located in the watershed of receiving waters that are sensitive to or impacted by storm water discharges.

Option 4 differs from the other options presented in this notice in that it establishes a minimum requirement for DMRs in NPDES permits for storm water discharges associated with industrial activity based on receiving water concerns. This approach would focus permitting resources and controls on discharges to receiving waters that are sensitive to or impacted by storm water discharges. This option would establish a minimum requirement that facilities report monitoring results at least annually for those storm water discharges associated with industrial activity that are located within the watershed of any receiving water (or receiving water segment) that is determined by an NPDES State or EPA to be impacted by or sensitive to storm water discharges. Monitoring requirements in permits for storm water discharges associated with industrial activity which are not located within such watersheds would be established on a case-by-case basis. These storm

water discharges would not be subject to a minimum requirement to submit or otherwise collect discharge monitoring information, although monitoring and reporting requirements could still be established in permits on a case-by-case basis.

A key aspect of this approach would be developing a list of waters that are either impacted by or sensitive to storm water discharges associated with industrial activity. All States would be required to submit lists for their State for the review and approval or disapproval by EPA. EPA would develop the list of waters for States that fail to develop approved lists.

The Agency anticipates that such lists could be based on existing and readily available data. The CWA provides a number of mechanisms for identifying impacted surface waters which could be useful in developing lists of waters impacted by or sensitive to storm water discharges, including the identification of lists of receiving waters under Sections 304(l),¹⁰ 305(b),¹¹ 314(a),¹²

319(a),¹³ and 320.¹⁴ Additional sources of information which may be appropriate for identifying impacted or sensitive surface waters include the waters identified by the International Joint Commission,¹⁵ the Chesapeake Bay program, and other EPA and State programs.

Several of the lists of receiving waters developed under the CWA also identify sources of water quality impairment and classes of pollutants associated with the water quality impairment. For example, the general classes of sources of water quality impairment addressed in section 305(b) reports which would be of particular interest when addressing storm water discharges associated with industrial activity, include separate storm sewers/urban runoff, construction, waste disposal, and resource extraction.¹⁶ Sources of pollutants identified in section 305(b) reports include nutrients, organic enrichment, pathogens, siltation, and metals.¹⁷ Under this option, these

¹⁰ Section 304(l) of the CWA requires States to develop three lists of waters in the State. Section 304(l)(1)(A)(i) requires the development of a list of all waters which after the application of effluent limitations required under the CWA cannot reasonably be anticipated to attain or maintain newly adopted numeric water quality standards due to toxic pollutants. Section 304(l)(1)(A)(ii) requires the development of a list of all waters which, after the application of effluent limitations required under the CWA, cannot reasonably be anticipated to attain or maintain water quality that assures protection of public health, public water supplies, agricultural and industrial uses, and the protection and propagation of a balanced population of shellfish, fish and wildlife, and allow recreational activities in and on the water. Section 304(l)(1)(B) requires the development of a list of all waters for which the State does not expect the applicable standard under section 303 of the CWA will be achieved after the requirements of sections 301(b), 306, and 307(b) are met, due entirely or substantially to discharges from point sources or any toxic pollutants listed pursuant to section 307(a) of the CWA.

¹¹ Section 305(b) of the CWA provides that every two years States shall submit to the EPA a report describing the water quality of all navigable waters in a State during the preceding year. The report shall also include, among other things, an analysis of the extent to which those waters protect and support shellfish, fish and wildlife and allow recreational use, the basis for the assessment (evaluated or monitored), and causes of nonsupport of designated uses.

¹² Section 314(a) requires States to submit biennial reports that identify and classify publicly owned lakes according to their eutrophic condition. In addition, Section 314(a) reports should describe those publicly owned lakes for which uses are known to be impaired; procedures, processes, and methods to control sources of pollutants on such lakes; and methods and procedures to restore the quality of such lakes.

¹³ Section 319(a) of the CWA provides for States to submit to EPA a report that identifies those navigable waters which, without additional action to control nonpoint sources of pollution, cannot reasonably be expected to attain or maintain applicable water quality standards or the goals and requirements of the CWA, and to identify those categories and subcategories of nonpoint sources that add significant pollution to each portion of the navigable waters identified.

¹⁴ Section 320 of the CWA provides for EPA to designate estuaries of national significance based on a nomination of the Governor of any State in which the estuary lies in whole or in part and convene a management conference to develop a comprehensive management plan for the estuary.

¹⁵ The International Joint Commission has identified areas of concern in the Great Lakes.

¹⁶ EPA has issued a number of guidance materials to assist States in the section 305(b) process to identify sources of pollution that impact water quality. "The Water Body System User's Guide" provides a detailed list of subcategories of sources to develop section 305(b) reports. The list includes: separate storm sewers; discharges from separate storm sewers; construction; resource extraction; Runoff and process fluids from mining, petroleum drilling, and mine tailing sites; and land disposal; Runoff and leachate from landfills, septic tanks, and hazardous waste disposal sites.

¹⁷ The "National Water Quality Inventory, 1988 Report to Congress" provides a general assessment of water quality based on biennial reports submitted by the States under section 305(b) of the CWA. The National Water Quality Inventory summarizes sources of water quality impairment identified under section 305(b) in terms of the following classes: industrial, POTWs, combined sewer overflows, separate storm sewers/urban runoff, agriculture, silviculture, construction, resource extraction, land disposal, and hydro modification/habitat modification. The Agency believes the classes of separate storm sewers/urban runoff, construction, resource extraction, and land disposal correlate well with certain classes of storm water discharges associated with industrial activity.

⁹ For the purposes of developing permit application requirements, EPA defines small businesses at 40 CFR 122.21(g)(8) as coal mines with a probable total annual production of less than 100,000 tons per year, and for all other applicants, businesses with gross total annual sales averaging less than \$100,000 per year (in second quarter 1980 dollars or approximately \$150,000 in 1990 dollars). This provision exempts small businesses from permit application monitoring requirements for certain organic chemicals.

additional parameters could be used to develop minimum monitoring requirements for those general classes of storm water discharges associated with industrial activity that are specifically identified as causing water quality impairment.

The Agency is concerned that Option 4 would place large burdens on permitting Agencies and the regulated community during the initial phases of developing the storm water program. The Agency is also concerned that significant storm water discharges would not be addressed by this option because the discharge is to waters which were not assessed or to waters that were impacted by storm water but not identified for the purpose of this regulation. The Agency also recognizes that as storm water permitting programs develop, they must focus on controlling pollutant discharges located with watersheds of impacted and sensitive waters. The Agency is requesting comments on addressing these concerns by modifying the DMR regulation such that minimum DMR requirements would not be established for the initial set of permits to be issued under the new storm water permitting initiative (e.g., the minimum DMR requirements for storm water discharges in impacted or sensitive watershed would not be effective until three years after the date of promulgation of this regulation). However, after a specified time, at a minimum, annual DMRs for storm water discharges associated with industrial activity in watersheds that are impaired by or sensitive to storm water discharges would be required.

This approach would provide permit issuing agencies with an opportunity to initiate storm water permitting efforts and to identify those watersheds impacted by storm water discharges. In addition, this approach would also ensure that storm water discharges in watersheds of sensitive or impacted waters were appropriately evaluated and addressed.

Option 5: Case-by-case monitoring conditions in permits for storm water discharges with no minimum requirement to report monitoring results.

Under this approach, the existing regulations at 40 CFR 122.44(i)(2) would be modified to allow permit writers to require discharge monitoring and reporting on a case-by-case basis. However, under this option, there would be no minimum requirement to submit or otherwise collect discharge monitoring information for most storm water discharges, except for certain facilities, such as those with effluent limitation guidelines for storm water discharges. The existing regulations would be

modified to provide minimum requirements for annual monitoring only for certain facilities, such as those with storm water discharges that are subject to national effluent limitation guidelines, those within specified industrial categories, or those that have a storm water discharge that is subject to a numeric or toxicity limitation in a permit that has been established on a case-by-case basis.

Under this option, some facilities may not be required to sample their storm water discharges associated with industrial activity. However, the broad authorities of sections 308 and 402(a)(2) provide other means, such as information collection and reporting, that can ensure compliance with permit conditions. Even under this approach, monitoring programs would play an important role for some facilities in determining compliance with numeric limitations and/or the effectiveness of requirements in a storm water pollution prevention plan that the facility is required to develop under a NPDES permit. However, in other cases, limited storm water sampling data may not provide adequate information regarding the effectiveness of the controls in the storm water pollution prevention plan. (For example, the primary focus of a storm water pollution prevention plan at a facility may be directed towards preventing a catastrophic event like a spill. Where no spill has occurred at the facility, sampling of the storm water discharge would convey little information regarding the effectiveness of the spill controls.)

Option 5 would provide permit writers with the discretion to require the submission of DMRs while limiting burdens on permittees and permit issuing agencies. This option would provide permit writers with the maximum flexibility to adopt a wide range of permit monitoring strategies (including strategies consistent with other options addressed in this notice) on a case-by-case basis. The flexibility in establishing monitoring requirements in permits could significantly reduce the burden that monitoring samples annually would place on permittees.

The Agency also requests comments on whether a minimum regulatory monitoring reporting requirement should be established for storm water discharges from industrial categories that have a high pollutant potential (such as landfills, wood preserving facilities, airports, facilities subject to SARA title III, primary metal manufactures, etc.). Conversely, the Agency requests comments on whether minimum annual monitoring requirements should be developed for

all but specified industry groups or for small businesses, and the appropriate basis for excluding such groups from minimum monitoring requirements. For example, small businesses may lack the expertise to conduct sampling or sampling costs may be too high.

Option 6: Case-by-case monitoring conditions in permits for storm water discharges, with a minimum requirement for the first permit for the discharge that monitoring results be reported at least once a year. After a facility has submitted five years of data, monitoring conditions for storm water would be established on a case-by-case basis with no minimum requirement to conduct annual sampling.

Under this approach, the minimum monitoring requirement for permits for storm water discharges associated with industrial activity would change with time. This approach would allow permit writers to evaluate a minimum of five years of storm water monitoring data. This data would assist permit writers in determining appropriate monitoring conditions when reissuing permits. In addition, data collection activities required under the first set of NPDES permits for storm water discharges associated with industrial activity can be used to develop priorities for implementing Tiers II through IV of the long term permitting strategy for storm water discharges.

C. Application Requirements for General Permits

As discussed above, EPA intends to increase its use of general permits to address the expansion of the scope of the NPDES program to address storm water discharges associated with industrial activity as well as other classes of discharges other than storm water, and encourages States with general permit authority to do so as well. The Agency intends to increase the use of general permits to address other sources as well. General permits are an important tool for assuring adequate environmental safeguards for large numbers of similar facilities without the administrative and resource burdens involved in individual permit issuance. In order to improve administration and operation of the general permits program, the Agency is proposing to facilitate and clarify general permit requirements and procedures.

EPA wants to emphasize that, except for the procedural differences set out at § 122.28 in the NPDES regulations, general permits are analogous to individual permits in every respect. General permits are still subject to the same reporting and monitoring

requirements, limitations, enforcement provisions, penalties, and other substantive requirements as individual permits. General permits should be viewed as an administrative tool enabling the issuance of one permit to authorize a group of dischargers.

Although the general permit program has been available to authorized NPDES States since its inception in 1979, some States have been reluctant to seek and use general permit authority. This has created an administrative dilemma. Even in circumstances where a general permit is appropriate, EPA is unable to issue a general permit in an authorized NPDES State. Of the 39 States with NPDES authorization, 23 have been authorized to issue general permits. In the other 16 authorized NPDES States neither EPA nor the State has the authority to issue general permits.

As discussed above in the storm water context, full individual permit applications (e.g., Form 2C for process discharges or Form 2F for storm water discharges associated with industrial activity) containing a significant amount of site-specific information from each discharger may not be necessary for developing general permits. 40 CFR 122.21(a) excludes persons covered by general permits from requirements to submit individual permit applications. Existing general permit regulations at 40 CFR 122.28, however, do not address the issue of how a potential permittee is to apply to be covered under a general permit. Rather, conditions for filing an application to be covered by a general permit (typically called a Notice of Intent (NOI)) are established on a case-by-case basis.

Under existing practice, general permit coverage is by two methods. First, as applied under federal law and where authorized under State law, the Director may issue a general permit covering a particular class of dischargers (or treatment works treating domestic sewage) informing potential permittees of their coverage by public notice. Second, the Director may issue a general permit where eligible dischargers (or treatment works treating domestic sewage) are not authorized to discharge under the permit until they have submitted a NOI to be covered by the general permit. The public notice for a general permit specifies whether an NOI is required prior to coverage. In almost all cases, general permits require the submittal of NOIs containing basic information such as the name and address of the facility and a brief description of the discharge and receiving water.

NOIs serve a number of functions. NOI requirements in general permits can

establish a clear accounting of the number of permittees covered by the general permit, the nature of operations at the facility generating the discharge, and their identity and location. NOIs can be used to develop a data base of facility-specific information. NOIs can be used as a screening tool to identify discharges where individual permits are appropriate. For example, the identification of discharges to impacted receiving waters can be used in the development of water quality-based permit conditions. Also, the NOI can be used to identify classes of discharges appropriate for more specific general permits covering a more limited set of discharges. The NOI can provide information needed by the Director to notify dischargers that a more specific general permit was issued. The NOI also can identify the permittee to provide a basis to develop and implement enforcement and compliance monitoring strategies and priorities. In addition, the administrative burdens on the permitting issuing agency and the costs to dischargers can be reduced by replacing more complicated permit application requirements with simplified requirements.

To encourage the use of general permits, to provide for more consistent NOI requirements, and to ensure that dischargers covered by general permits provide appropriate information, the Agency is proposing to modify the regulatory framework for general permits to provide minimum requirements for NOIs. (These proposed changes would apply to a number of other classes of general permits for non-storm water discharges as well as storm water discharges.)

Proposed § 122.28(b)(2) would require that, at a minimum, NOIs include the legal name and address of the owner or operator, the facility name and address, the number and type of facilities or discharges, the receiving stream(s), and other information necessary to ascertain whether the discharger should be included under the terms of the general permit as specified in the final general permit. This provision would be a minimum requirement. Permits may require additional information where appropriate.

The proposal also provides guidelines for deadlines to submit NOIs. The guidelines recommend that general permits be written to require dischargers to submit NOIs 60 days before the date of intended permit coverage. Under the proposal, the Director may specify different time periods in the general permit for these submissions.

Under the proposal, unless otherwise provided in the permit, dischargers

would automatically be authorized to discharge under the general permit by submitting an NOI in accordance with the terms of the permit. This provision would still allow general permits to specify that the permittee must receive notification of coverage under the general permit from the Director before discharges would be authorized.

The proposal provides for two situations where an NOI would not have to be submitted to authorize discharges under a general permit. The first situation is where the Director notifies the discharger that its discharge is covered by the permit. The second situation is where the Director decides that an NOI is inappropriate for a general permit. To make the latter decision, the Director would consider the type of discharge, the expected nature of the discharge, the potential for toxic and conventional pollutants in the discharges, the expected volume of the discharges, other means of identifying discharges covered by the permit, and the estimated number of discharges to be covered by the permit. Also, if this approach is pursued, the Director would be required to describe the reasons for not requiring an NOI in the fact sheet of the general permit. This notice proposes that such a finding could only be made for discharges other than discharges from POTWs, combined sewer overflows (CSOs), primary industrial facilities, contaminated runoff from mining operations or oil and gas operations and other storm water discharges associated with industrial activity. The Agency believes that, given the potential environmental significance and NPDES program priorities associated with discharges from POTWs, CSOs, primary industrial facilities, contaminated runoff from mining operations or oil and gas operations and other storm water discharges associated with industrial activity, it is appropriate to require NOIs in all general permits for these discharges. However, the Agency requests comments on whether general permits without NOI requirements are appropriate for the large number of storm water discharges associated with industrial activity from oil and gas exploration or production operations. Oil and gas exploration or production operations that discharge storm water associated with industrial activity are typically subject to Spill Prevention Control and Countermeasure (SPCC) program requirements at 40 CFR part 112, which may provide an alternative means for tracking these facilities.

Public accessibility to this information would be enhanced by proposed

§ 122.28(d), which provides that such lists would be available to the public.

D. Fact Sheet for Draft General Permit

The following portion of this notice provides notice for draft NPDES general permits and accompanying fact sheets for storm water discharges associated with industrial activity in AK, AZ, FL, ID, LA, MA, ME, NH, NM, OK, SD, TX, District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands; on Indian lands in AL, CA, GA, KY, MI, MN, MS, MT, NC, ND, NY, NV, SC, TN, UT, WI and WY; located within Federal facilities and Indian lands in CO and WA; and located within Federal facilities in Delaware. Separate general permits are being noticed for each State. These draft general permits are intended to cover storm water discharges associated with industrial activity to waters of the United States, including discharges through large and medium municipal separate storm sewer systems, and through other municipal separate storm sewer systems. Publication of this draft general permit and fact sheet is designed to comply with the requirements of 40 CFR 124.10 simultaneously for all 35 draft general permits being noticed today. Public hearings on selected permits will be held as indicated at the beginning of this notice.

The language of the draft general permits is provided as an appendix to the preamble of this notice. In general, most conditions of the draft general permits are intended to apply to all of the general permits indicated above. Where conditions in different permits vary, these differences are indicated in the draft general permit in the appendix.

1. Background

In 1972, the Federal Water Pollution Control Act (also referred to as the Clean Water Act (CWA)) was amended to provide that the discharge of any pollutants to waters of the United States from any point source is unlawful, except if the discharge is in compliance with an National Pollutant Discharge Elimination System (NPDES) permit.

For a number of reasons, EPA and authorized NPDES States have failed to issue NPDES permits for the majority of point source discharges of storm water. Recognizing this, Congress added section 402(p) to the CWA in 1987 to establish a comprehensive framework for addressing storm water discharges under the NPDES program. Section 402(p)(4) of the CWA clarifies the requirements for EPA to issue NPDES

permits for storm water discharges associated with industrial activity. On November 16, 1990 (55 FR 47990), EPA published final regulations which define the term "storm water discharge associated with industrial activity". The final regulations also establish requirements for submitting individual permit applications and group applications.

EPA estimates that about 100,000 facilities nationwide discharge storm water associated with industrial activity (not including oil and gas exploration and production operations). The large number of facilities addressed by the regulatory definition of "storm water discharge associated with industrial activity" will place correspondingly large administrative burdens on EPA and States with authorized NPDES programs to issue and administer permits for these discharges.

To provide a reasonable and rational approach to addressing this permitting task, the Agency is developing a Strategy for issuing permits for storm water discharges associated with industrial activity. In developing this Strategy, the Agency recognizes that the CWA provides flexibility in the manner in which NPDES permits are issued,¹⁸ and will use this flexibility to design a workable permitting system. In accordance with these considerations, the draft permitting Strategy (described in more detail earlier in today's notice) describes a four-tier set of priorities for issuing permits for these discharges. The four-tier set of priorities for issuing permits under the policy are:

- **Tier I—Baseline Permitting:** One or more general permits will be developed to initially cover the majority of storm water discharges associated with industrial activity;
- **Tier II—Watershed Permitting:** Facilities within watersheds shown to be adversely impacted by storm water discharges associated with industrial activity will be targeted for individual or watershed-specific general permits.
- **Tier III—Industry-Specific Permitting:** Specific industry categories will be targeted for individual or industry-specific general permits; and
- **Tier IV—Facility-Specific Permitting:** A variety of factors will be

used to target specific facilities for individual permits.

The draft general permits accompanying this fact sheet will initiate Tier I activities for storm water discharges associated with industrial activity in Alaska, Arizona, Idaho, Louisiana, Massachusetts, Maine, New Hampshire, New Mexico, Oklahoma, South Dakota, Texas, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands; for Federal facilities and Indian lands in Colorado and Washington, and for Indian lands in Alabama, California, Georgia, Kentucky, Michigan, Minnesota, Mississippi, Montana, New York, Nevada, North Carolina, North Dakota, New York, Nevada, South Carolina, Tennessee, Utah, Wisconsin, and Wyoming, and for Federal facilities in Delaware¹⁹ by proposing baseline general permits for the majority of storm water discharges in these States.

In addition to establishing baseline requirements for the majority of storm water discharges associated with industrial activity in these States, the draft general permits have some of the features of Tier III permitting activities in that they establish requirements for specific industries.

Consolidation of many sources under one permit will greatly reduce the otherwise overwhelming administrative burden associated with storm water discharges associated with industrial activity. This approach has a number of additional advantages:

- General requirements will be established for discharges covered by the permit;
- Facilities whose discharges are covered by the permit will have an opportunity to comply with the CWA;
- The Agency will have the opportunity to collect and review data on storm water discharges for priority industries;
- The public will have the opportunity to review data and reports and to comment on permitting activities;
- Applicable requirements of municipal storm water management programs established in permits for

¹⁸ The court in *NRDC v. Train*, 396 F.Supp. 1393 (D.D.C. 1975) *aff'd*, *NRDC v. Costle*, 568 F.2d 1369 (D.C.Cir. 1977), has acknowledged the administrative burden placed on the Agency by requiring permits for a large number of storm water discharges. The courts have recognized EPA's discretion to use certain administrative devices, such as area permits or general permits, to help manage its workload. In addition, the courts have recognized flexibility in the type of permit conditions that can be established, including the use of requirements for best management practices.

¹⁹ In 6 of the 39 States that are authorized to issue NPDES permits for municipal and industrial sources, EPA issues permits for discharges from Federal facilities. State programs do not generally address permitting of discharges from Indian lands, as EPA retains this responsibility. However, this fact sheet only addresses general permits as indicated above. Where EPA is the permit issuing authority for other storm water discharges, either individual permits or a different general permit will be issued.

discharges from municipal separate storm sewer systems will be enforceable directly against noncomplying industrial facilities that generate the discharge;

- The baseline permits will provide a basis for bringing selected enforcement actions by eliminating many issues which might otherwise arise in an enforcement proceeding (e.g., clarifying requirement to obtain NPDES permit coverage); and

- Finally, the baseline permit will provide a focus for public comment on developing subsequent phases of the permitting strategy for storm water discharges, including the priorities for State storm water management programs developed under section 402(p)(6) of the CWA.

Initially, the coverage of the baseline permits will be broad, but will decrease as other permits are issued for storm water discharges associated with industrial activities pursuant to Tier II through IV activities.

2. Types of Discharges Covered

On November 16, 1990, (55 FR 47990), EPA promulgated the regulatory definition of "storm water discharges associated with industrial activity" which addresses point source discharges of storm water from eleven major categories of facilities. (This definition is reprinted in the definition section of the draft general permits found in the Appendix of today's notice).

The draft general permits do not cover storm water discharges associated with industrial activity from inactive mining or inactive oil and gas operations occurring on Federal lands where an operator cannot be identified. Given the long history of mining activity on the extensive tracts of Federal lands, and the relationship of the Federal land management Agencies to prior operators of these sites, the Agency believes that a distinct set of permits are generally

appropriate to control pollutants in storm water discharges from these sites. EPA is currently working with a number of Federal land management Agencies, including the Bureau of Land Management and the Forest Service, to develop permits to address the unique circumstances associated with these sites in an appropriate manner.

3. Description of Discharges Covered

The volume and quality of storm water discharges associated with industrial activity will depend on a number of factors, including the industrial activities occurring at the facility, the nature of precipitation, and the degree of surface imperviousness. Rain water may pick up pollutants from structures and other surfaces as it drains from the land. In addition, sources of pollutants other than storm water, such as illicit connections,²⁰ spills, and other improperly dumped materials may increase the pollutant loads discharged from separate storm sewers. The sources which contribute pollutants to storm water discharges differ with the type of industry operation and facility-specific features. For example, air emissions may be a significant source of pollutants at some facilities, material storage operations may be important at different operations, while other facilities may discharge storm water associated with industrial activity with relatively low levels of pollutants.

The most extensively studied storm water discharges have been those from residential and commercial areas (urban runoff). Evaluating these discharges will provide a starting point for understanding the pollutants that can be expected in storm water discharges associated with industrial activity.

²⁰ Illicit connections are point source discharges of pollutants that are not composed entirely of storm water, that are not covered by an existing NPDES permit, and which are discharged through separate storm sewers to waters of the United States.

Many storm water discharges are expected to contain the pollutants typically associated with urban runoff, along with additional pollutants that result from the specific industrial operations of the facility.

From 1978 through 1983, EPA provided funding and guidance to the Nationwide Urban Runoff Program (NURP) to study the nature of runoff from commercial and residential areas. The NURP program included 28 projects across the Nation, conducted separately at the local level but centrally reviewed, coordinated, and guided.

One focus of the NURP program was to characterize the water quality of discharges from separate storm sewers which drain residential, commercial, and light industrial (industrial parks) sites. The majority of samples collected in the NURP study were analyzed for seven conventional pollutants and three metals. Table 1 summarizes the pollutant concentrations from the NURP data base is presented in Table 1 for these 10 constituents and fecal coliform. Data collected in NURP indicated that on an annual loading basis, suspended solids in discharges from separate storm sewers draining runoff from residential, commercial and light industrial areas are around an order of magnitude or more greater than effluent from sewage treatment plants receiving secondary treatment. The study also indicated that annual loadings of chemical oxygen demand (COD) are comparable to effluent from sewage treatment plants receiving secondary treatment. When analyzing annual loadings associated with urban runoff, it is important to recognize that discharges of urban runoff are highly intermittent, and that the short-term loadings associated with individual events will be high and may have shock loading effects on receiving water such as sag in dissolved oxygen levels.

TABLE 1.—QUALITY CHARACTERISTICS OF RUNOFF FROM RESIDENTIAL AND COMMERCIAL AREAS

Constituent	Average residential or commercial site concentration	Weighted mean residential or commercial site concentration	NURP recommendations for load estimates
TSS	239 mg/l	180 mg/l	180-548 mg/l
BOD	12 mg/l	12 mg/l	12-19 mg/l
COD	94 mg/l	82 mg/l	82-178 mg/l
Total phosphorus	0.5 mg/l	0.42 mg/l	0.42-0.88 mg/l
Soluble phosphorus	0.15 mg/l	0.15 mg/l	0.15-0.28 mg/l
Total Kjeldahl nitrogen	2.3 mg/l	1.90 mg/l	1.90-4.18 mg/l
Nitrate-nitrite	1.37 mg/l	0.86 mg/l	0.86-2.21 mg/l
Total copper	53 µg/l	43 µg/l	43-118 µg/l
Total lead	238 µg/l	182 µg/l	182-443 µg/l
Total zinc	353 µg/l	202 µg/l	202-633 µg/l
Fecal coliform:			
Warm weather	50,240 counts/100 ml	27,605 counts/100 ml	
Cold weather	22,918 counts/100 ml	7,057 counts/100 ml	

Source: Developed from *Results of the Nationwide Urban Runoff Program, Vol. 1—Final Report*, EPA 1983.

The NURP program also involved monitoring 120 priority pollutants. Seventy-seven priority pollutants were detected in samples of storm water discharges from residential, commercial, and light industrial lands taken during the NURP study, including 14 inorganic and 63 organic pollutants. Table 2 shows the priority pollutants that were detected in at least ten percent of the discharge samples that were sampled for priority pollutants. The NURP data also showed a significant number of these samples exceeded various freshwater water quality criteria.

Although NURP did not evaluate oil and grease, other studies have demonstrated that urban runoff is an extremely important source of oil pollution to receiving waters, with hydrocarbon levels in urban runoff typically being reported at a range of 2 mg/l to 10 mg/l. These hydrocarbons tend to accumulate in bottom sediments where they may persist for long periods of time, and exert adverse impacts on benthic organisms.

TABLE 2.—PRIORITY POLLUTANTS DETECTED IN AT LEAST 10% OF NURP SAMPLES

	Frequency of detection (percent)
Metals and inorganics:	
Antimony.....	13
Arsenic.....	52
Beryllium.....	12
Cadmium.....	48
Chromium.....	58
Copper.....	91
Cyanides.....	23
Lead.....	94
Nickel.....	43
Selenium.....	11
Zinc.....	94
Pesticides:	
Alpha-hexachlorocyclohexane.....	20
Alpha-endosulfan.....	19
Chlordane.....	17
Lindane.....	15
Halogenated aliphatics: Methane, dichloro.....	11
Phenols and cresols:	
Phenol.....	14
Phenol, pentachloro.....	19
Phenol, 4-nitro.....	10
Phthalate esters: Phthalate, bis(2-ethylhexyl).....	22
Polycyclic aromatic hydrocarbons:	
Chrysene.....	10
Fluoranthene.....	16
Phenanthrene.....	12
Pyrene.....	15

Other studies have shown that many storm sewers contain illicit discharges of non-storm water, and that large amounts of wastes are disposed improperly in storm sewers. Removal of

these discharges present opportunities for dramatic improvements in the quality of storm water discharges. Storm water discharges from industrial facilities may contain, in addition to illicit connections and improperly disposed wastes, toxics and conventional pollutants when material management practices allow exposure to storm water.

In some municipalities, illicit connections of sanitary, commercial, and industrial discharges to storm sewer systems have had a significant impact on the water quality of receiving waters. Although the NURP study did not characterize illicit connections to storm sewers other than to ensure that monitoring sites used in the study were free from sanitary sewage contamination, the study concluded that illicit connections can result in high bacterial counts and dangers to public health.

Studies have shown that illicit connections to storm sewers can create severe, widespread contamination problems. For example, the Huron River Pollution Abatement Program inspected 660 businesses, homes, and other buildings located in Washtenaw County, Michigan. The program identified that 14 percent of the buildings had improper storm drain connections. Illicit discharges were detected at a higher rate of 60 percent for automobile-related businesses, including service stations, automobile dealerships, car washes, body shops, and light industrial facilities. While some of the problems discovered in this study were due to improper plumbing or illegal connections, a majority were approved connections at the time they were built, but have since become unlawful discharges.

Intensive construction activities may result in severe localized impacts on water quality because of high unit loads of pollutants, primarily sediments. Construction sites can also generate other pollutants such as phosphorus and nitrogen from fertilizer, pesticides, petroleum products, construction chemicals, and solid wastes. These materials can be toxic to aquatic organisms and degrade water for drinking and water-contact recreation. Sediment runoff rates from construction sites are typically 10 to 20 times that of agricultural lands, with runoff rates as high as 100 times that of agricultural lands, and typically 1,000 to 2,000 times that of forest lands. Even a small amount of construction may have a significant negative impact on water

quality in localized areas. Over a short period of time, construction sites can contribute more sediment to streams than was deposited previously over several decades.

The NURP study and other studies of urban runoff provide insight on what can be considered background levels of pollutants for urban runoff, as these studies have focused primarily on monitoring runoff from residential, commercial, and light industrial areas. However, NURP concluded that the quality of urban runoff can be impacted adversely by several sources of pollutants that were not evaluated directly in the study and which are generally not reflected in the NURP data, such as illicit connections, construction site runoff, industrial site runoff and illegal dumping.

For some industrial facilities, the types and concentrations of pollutants in storm water discharges will be similar to the types and concentrations of pollutants generally found in storm water discharges from residential and commercial areas. However, storm water discharges from other industrial facilities will have a significant potential for higher pollutant levels. In addition, pollutant loadings per unit area from some industrial facilities may be high because of a high degree of imperviousness.

Six activities can be identified as major potential sources of pollutants in storm water discharges associated with industrial activity: (1) Loading or unloading of dry bulk materials or liquids; (2) outdoor storage of raw materials or products; (3) outdoor process activities; (4) dust or particulate generating processes; (5) illicit connections or management practices; and (6) waste disposal practices. The potential for pollution from many of these activities may be influenced by the use and presence of toxic chemicals. These activities are discussed in more detail below.

(1) Loading and unloading operations typically are performed along facility access roads, railways, and at loading/unloading docks and terminals. These operations include pumping of liquids or gases from truck or rail car to a storage facility or vice versa, pneumatic transfer of dry chemicals to or from the loading or unloading vehicle, transfer by mechanical conveyor systems, and transfer of bags, boxes, drums, or other containers from vehicle by forklift trucks or other materials handling equipment. Material spills or losses in areas can

discharge directly to the storm drainage systems, or may accumulate in soils or on surfaces, and be washed away during a storm event or facility washdowns.

(2) Outdoor storage activities include the storage of fuels, raw materials, byproducts, intermediates, final products, and process residuals. Storage can be accomplished in various ways, for example, using storage containers (e.g., drums or tanks), platforms or pads, bins, silos, boxes, or piles. Materials, containers, and material storage areas that are exposed to rainfall and/or runoff can contribute pollutants to storm water when solid materials wash off or materials dissolve into solution.

(3) Other outdoor activities include certain types of manufacturing and commercial operations and land-disturbing operations. Although many manufacturing activities are performed indoors, some activities, such as timber processing, rock crushing, and concrete mixing, typically occur outdoors. Processing operations can result in liquid spillage and losses of material solids to the drainage system or surrounding surfaces, or creation of dusts or aerosols, which can be deposited locally. Some outdoor industrial activities cause substantial physical disturbance of land surfaces that result in soil erosion by storm water.

Examples where disturbed land occurs include construction and mining. Disturbed land can result in soil losses and other pollutant loadings associated with increased runoff rates. Facilities whose major process activities are conducted indoors may still apply chemicals such as herbicides, pesticides, and fertilizer outdoors for a variety of purposes.

(4) Dust or particulate generating processes include industrial activities with stack emissions or process dusts that settle on plant surfaces. Localized atmospheric deposition is a particular concern with heavy manufacturing industries. For example, monitoring of areas surrounding smelting industries has shown much higher levels of metals at sites nearest the smelter (Bearington 1977). Other industrial sites, such as mines, cement manufacturing, and

refractories, will generate significant levels of dusts.

(5) Illicit connections or inappropriate management practices result in improper non-storm water discharges to storm sewer systems. The likelihood of illicit discharges to storm water collection systems is expected to increase for older facilities as well as for those facilities that use high volumes of process water or that dispose of significant amounts of liquid wastes, including process waste waters, cooling waters, and rinse waters.

Pollutants from non-storm water discharges to the storm sewer system of individual facilities are caused typically by a combination of improper connections, spills, improper dumping, and a belief that the absence of visible solids in a discharge is equivalent to the absence of pollution. Illicit connections are often associated with floor drains that are connected to separate storm sewers. Rinse waters used to clean or cool objects discharge to floor drains that may be connected to separate storm sewers. Large amounts of rinse waters may originate from industries that use regular wash down procedures; for example, bottling plants use rinse waters for removing waste products, debris, and labels. Rinse waters can be used to cool materials by dipping, washing, or spraying objects with cool water, for example, rinse water is sometimes sprayed over the final products of a metal plating facility for cooling purposes. Condensate return lines of heat exchangers often discharge to floor drains. Heat exchangers, particularly those used under stressed conditions such as in the metal finishing and electroplating industry, typically develop pin-hole leaks, which may result in contamination of condensate by process wastes. These and other non-storm water discharges to a storm sewer may be intentional, based on the belief that the discharge (condensate in the example previously discussed), does not contain pollutants, or it may be inadvertent, as the operator may be unaware that a floor drain is connected to the storm sewer.

(6) Waste management practices include operating landfills, waste piles, and land application sites that involve land disposal. Outdoor waste treatment

operations also include waste water and solid waste treatment and disposal processes, such as waste pumping, additions of treatment chemicals, mixing, aeration, clarification, and solids dewatering. Facilities often conduct some waste management on site.

Coal pile runoff. The following description of coal pile runoff is summarized from the "Final Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category", (EPA-440/1-82/029), EPA, November 1982. A more complete description of coal pile runoff can be found in the Development Document.

The pollutants in coal pile runoff can be classified into specific types according to chemical characteristics. The type relates to pH of the coal pile drainage. The pH tends to be of an acidic nature, primarily as a result of the oxidation of iron sulfide in the presence of oxygen and water. The potential influence of pH on the behavior of toxic and heavy metals is of particular concern. Many of the metals are amphoteric with regard to their solubility behavior. The factors affecting acidity, pH and the subsequent leaching of trace metals are:

- Concentration and form of pyritic sulfur in coal;
- Size of the coal pile;
- Method of coal preparation and clearing prior to storage;
- Climatic conditions, including rainfall and temperature;
- Concentrations of CaCO₃ and other neutralizing substances in the coal;
- Concentration and form of trace metals in the coal; and
- The residence time in the coal pile.

Table 3 shows data of selected pollutants in coal pile runoff at two steam electric plants. Both facilities generated runoff with low pH values, with the acid values being quite variable in both cases. The suspended solids levels observed went up to 2,500 mg/l. The metals present in the greatest concentrations were copper, iron, aluminum, nickel and zinc. Others present in trace amounts include chromium, cadmium, mercury, arsenic, selenium, and beryllium.

TABLE 3.—POLLUTANTS IN COAL PILE RUNOFF

Plant	pH	Acidity (mg/l CaCO ₃)	Sulfate (mg/l)	Dissolved solids (mg/l)	Total suspended solids (mg/l)	Mn (mg/l)
1 Range.....	2.3-3.1	300-7100	1800-9600	2500-16000	8-2300	8.9-45
Mean.....	2.8	3400	5160	7900	470	28.7
N.....	19	18	18	18	18	19

TABLE 3.—POLLUTANTS IN COAL PILE RUNOFF—Continued

Plant	pH	Acidity (mg/l CaCO ₃)	Sulfate (mg/l)	Dissolved solids (mg/l)	Total suspended solids (mg/l)	Mn (mg/l)
2 Range.....	2.5-3.1	860-2100	1900-4000	2900-5000	38-270	2.4-10
Mean.....	2.7	1360	2780	3600	190	4.1
N.....	6	6	6	6	6	6
2 ¹ Range.....	2.5-2.7	300-1400	870-5500	1200-7500	69-2500	0.9-5.4
Mean.....	2.6	710	2300	2700	650	2.3
N.....	14	14	14	14	14	14
	Cu (mg/l)	Zn (mg/l)	Al (mg/l)	Ni (mg/l)	Fe (mg/l)	As (mg/l)
1 Range.....	0.43-1.4	2.3-16	66-440	0.74-04.5	240-1800	.005-0.6
Mean.....	0.86	6.68	260	2.59	940	0.17
N.....	19	19	19	19	19	19
2 Range.....	0.01-0.46	1.1-3.7	22-60	0.24-0.46	280-480	.0006-0.046
Mean.....	0.23	2.18	43.3	0.33	380	0.02
N.....	6	6	6	6	6	4
	Cr (mg/l)	Hg (mg/l)	Sa (mg/l)	Be (mg/l)	Cd (mg/l)	
1 Range.....	<0.005-.011	<.0002-.0025	<.001-.03	<.001-.03	<.001	
Mean.....	.007	.0004	0.006	0.044	<.001	
N.....	17	20	18	18	19	
ND.....	11	12	4	0	19	
2 Range.....	<0.005-.011	<.001-.001	<.01-.03	<.001-.003	<0.001-.003	
Mean.....	0.007	0.001	0.014	0.002	0.002	
N.....	6	4	4	6	6	
ND.....	3	3	3	2	2	

N=Number of samples.

ND=Below detection levels.

Source: Final Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category, (EPA-440/1-82/029), EPA, November 1982.

¹ Discrete Storm.

4. Summary of Options for Controlling Pollutants

Options for controlling pollutants in storm water discharges associated with industrial activities (other than from construction activities) will be discussed in terms of two major pollutant sources: (1) Materials discharged to separate storm sewers via illicit connections, improper dumping, and spills; and (2) pollutants associated with runoff collected by separate storm sewers. Options for controlling pollutants in storm water discharges associated with industrial activities from construction activities are addressed separately.

a. *Non-storm water discharges to separate storm sewers.* As discussed earlier, in some cases, a substantial portion of the pollutant load from separate storm sewers which discharge storm water associated with industrial activity is associated with non-storm water discharges. Non-storm water discharges to separate storm sewers include a wide variety of sources, including illicit connections, improper dumping, spills, or leakage from storage tanks and transfer areas. Measures to control spills and visible leakage can be incorporated into storm water pollution prevention plans (see below).

In many cases, operators of industrial facilities may be unaware of illicit discharges or leakage from underground storage tanks or other non-visible systems. In some cases, illicit connections to storm sewers were installed before their legal prohibition, and forgotten about. For example, illicit connections are often associated with floor drains that are connected to separate storm sewers. Rinse waters used to clean or cool objects, and other process wastewaters may be discharged to the separate storm sewer by an improperly connected floor drain. These non-storm water discharges to a storm sewer may be inadvertent with the operator unaware that the floor drain is connected to the storm sewer. In this case, the key to controlling these discharges is to identify them.

Methods to identify non-storm water discharges to separate storm sewers. Several methods for identifying the presence of non-storm water discharges are discussed below.^{21 22} A comprehensive evaluation of the storm sewers at a facility may incorporate several methods.

^{21 22} A more complete discussion of methods to identify illicit connections can be found in the draft "Manual of Practice: Identification of Illicit Connections", U.S. EPA, Sept. 1990.

- *Schematics.* Where they exist, accurate piping schematics can be inspected as a first step in evaluating the integrity of the separate storm sewer system. The use of schematics is limited because schematics usually reflect the design of the piping system and may not reflect the actual configuration constructed. Schematics should be updated or corrected based on additional information found during inspections.

- *Evaluation of drainage map and inspections.* Drainage maps should identify the key features of the drainage system: each of the inlet and discharge structures, the drainage area of each inlet structure, and units such as storage or disposal units or material loading areas, which may be the source of an illicit discharge or improper dumping. In addition, floor drains and other water disposal inlets that are thought to be connected to the sanitary sewer can be identified. A site inspection can be used to augment and verify map development. These inspections, along with the use of the drainage map, can be coordinated with other best management practices discussed below.

- *End-of-pipe screening.* Discharge points or other access points such as manhole covers can be inspected for the

presence of dry weather discharges and other signs of non-storm water discharges. Dry weather flows can be screened by a variety of methods. Inexpensive onsite tests include measuring pH; observing for oil sheens, scums and discoloration of pipes and other structures; as well as colormetric detection tests for chlorine, detergents, metals and other parameters. In some cases, it may be appropriate to collect samples for more expensive analysis in a laboratory for fecal coliform, fecal streptococcus, conventional pollutants, volatile organic carbon, or other appropriate parameters.

- **Water balance.** Many sewage treatment plants require that industrial discharges measure the volume of effluent discharged to the sanitary sewer system. Similarly, the volume of water supplied to a facility is generally measured. A significantly higher volume of water supplied to the facility relative to that discharged to the sanitary sewer and other consumptive uses may be an indication of illicit connections. This method is limited by the accuracy of the flow meters used.

- **Dry weather testing.** Where storm sewers do not discharge during dry weather conditions, water can be introduced into floor drains, toilets and other points where non-storm water discharges are collected. Storm drain outlets are then observed for possible discharges.

- **Dye testing.** Dry weather discharges from storm sewers can occur for a number of legitimate reasons including ground water infiltration or the presence of a continuous discharge subject to an NPDES permit. Where storm sewers do have a discharge during dry weather conditions, dye testing for illicit connections can be used. Dye testing involves introducing fluorometric or other types of dyes into floor drains, toilets and other points where non-storm water discharges are collected. Storm drain outlets are then observed for possible discharges.

- **Manhole and Internal TV Inspection.** Physical inspection of manholes and internal inspection of storm sewers either physically or by television are used to identify potential entry points for illicit connections. Dry weather flows, material deposits, and stains are often indicators of illicit connections. TV inspections are relatively expensive and generally should be used only after a storm sewer has been identified as having illicit connections.

- **Options for preventing pollutants in storm water.** The following five categories describe options for reducing

pollutants in storm water discharges from industrial plants:

- (i) Providing end-of-pipe treatment;
- (ii) Implementing Best Management Practices to prevent pollution;
- (iii) Diverting storm water discharge to municipal sewage treatment plants;
- (iv) Using traditional storm water management practices; and
- (v) Eliminating pollution sources.

A comprehensive storm water management program for a given plant may include controls from each of these categories. Development of comprehensive control strategies should be based on a consideration of plant characteristics.

- i. **End-of-pipe treatment.** End-of-pipe treatment requirements are typically imposed through numeric effluent limitations, which provide the discharger with flexibility to design the most cost effective type of treatment for the given facility.

At many types of industrial facilities, it may be appropriate to collect and treat the runoff from targeted areas of the facility. This approach was taken with 10 industrial categories with national effluent guideline limitations for storm water discharges. There are several basic similarities among the national effluent guideline limitations for storm water discharges:

- To meet the numeric effluent limitation, most, if not all, facilities must collect and temporarily store onsite runoff from targeted areas of the plant;

- The effluent guideline limitations do not apply to discharges whenever rainfall events, either chronic or catastrophic, cause an overflow of storage devices designed, constructed, and operated to contain a design storm. The 10-year, 24-hour storm, or the 25-year, 24-hour storm commonly are used as the design storm in the effluent guideline limitations; and

- Most technology-based treatment standards are based on relatively simple technologies such as settling of solids, neutralization, and drum filtration. Potential ground water impacts should also be considered by operators when designing storage devices.

- ii. **Best management practices.** The term best management practices (BMPs) can describe a wide range of management procedures, schedules of activities, prohibitions on practices, and other management practices to prevent or reduce the pollution of waters of the United States. BMPs also include operating procedures, treatment requirements and practices to control plant site runoff, drainage from raw materials storage, spills or leaks. BMPs can be established in two ways: BMP

plans and site or pollutant-specific BMPs.

BMP plans. EPA has worked with industry to identify the generic BMPs which most well-operated facilities use for pollution control, fire prevention, occupational safety and health, or product loss prevention. EPA often establishes NPDES permit conditions that require generic BMPs to be identified and implemented through BMP plans. Many of the BMPs in a typical BMP plan involve planning, reporting, training, preventive maintenance, and good housekeeping.

Many industrial facilities currently employ BMPs as part of normal plant operation. For example, preventive maintenance and good housekeeping are routinely used in the chemical and related industries to reduce equipment downtime and to promote a safe work environment for employees. Good housekeeping BMPs generally are aimed at preventing spills and similar environmental incidents by stressing the importance of proper management and employee awareness. Experience has shown that many spills of hazardous chemicals can be attributed, in one way or another, to human error. Improper procedures, lack of training, and poor engineering are among the major causes of spills. Experience has shown that BMPs can be used appropriately and BMP plans can effectively reduce pollutant discharges in a cost-effective manner. BMP plans should reflect requirements for Spill Prevention Control and Countermeasure (SPCC) plans required under section 311 of the CWA, and many incorporate any part of the SPCC plan into the BMP plan by reference. BMP plans should also ensure that solid and hazardous waste is managed in accordance with requirements established under the Resource Conservation and Recovery Act (RCRA). Management practices required under RCRA should be expressly incorporated into the BMP plan.

In addition, each of the following nine specific requirements should be addressed in the BMP plan to reduce pollutants in runoff from the plant:

- Statement of policy;
- Spill Control Committee;
- Material inventory;
- Material compatibility;
- Employee training;
- Visual inspections;
- Preventive maintenance;
- Reporting and notification procedures;
- Housekeeping;
- Security.

Additional technical information on BMPs and the elements of a BMP plan is contained in the publication entitled "NPDES Best Management Practices Guidance Document," U.S. EPA, June 1981.

Site or pollutant-specific best management practices. In addition to

the requirements of BMP plans discussed above, more advance site or pollutant-specific BMP requirements can be developed. The following four categories described these site or pollutant-specific BMPs:

- Prevention;
- Containment;

- Mitigation;
- Ultimate Disposition.

Table 4 lists BMPs associated with each category. Requirements for SPCC plans for oil pollution prevention (see 40 CFR part 112) illustrate how pollutant-specific BMPs can be implemented.

TABLE 4.—ADVANCED BMP ALTERNATIVES

Prevention	Containment	Mitigation		Waste disposal
		Cleanup	Treatment	
Monitoring.....	Secondary containment.....	Physical.....	Liquid-solids separation.....	Landfill.
Nondestructive.....	Flow diversion to secondary containment.	Mechanical.....	Volatilization.....	Land treatment.
Labeling.....	Vapor control.....	Chemical.....	Coagulation/precipitation.....	Reclamation.
Covering.....	Dust control.....		Neutralization.....	Discharge to surface water.
Pneumatic and vacuum conveying.	Sealing.....		Ion exchange.....	Deep well injection.
Vehicle positioning.....			Chemical oxidation.....	Discharge to POTW.
Dry cleanup.....			Biological treatment.....	Offsite disposal.
			Thermal oxidation.....	

iii. *Diversion of discharge to sewage treatment plant.* Where storm water discharges contain significant amounts of pollutants that can be removed by a sewage treatment plant, the storm water discharge can be discharged to the sanitary sewage system. Such diversions must be coordinated with the operators of the sewage treatment plant and the collection system to avoid worsening problems with either combined sewer overflows (CSOs), basement flooding or wet weather operation of the treatment plant. Where CSO discharges, flooding or plant operation problems can result, onsite storage followed by a controlled release during dry weather conditions may be considered.

iv. *Traditional storm water management practices.* In some situations, traditional storm water management practices such as grass swales, catch basin design and maintenance, infiltration devices, unlined retention or detention basins, water reuse, and oil and grit separators can be applied to an industrial setting. However, care must be taken to evaluate the potential of many of these traditional devices for ground water contamination. In some cases, it is appropriate to limit traditional storm water management practices to those areas of the drainage system that generate storm water with relatively low levels of pollutants (e.g., many rooftops, parking lots, etc.). At facilities located in northern areas of the country, snow removal activities may play an important role in a storm water

management program. In addition, other types of controls such as spill prevention measures can be considered to prevent catastrophic events that can lead to surface or ground water contamination.

v. *Elimination of pollution sources.* In some cases, the elimination of pollution source may be the most cost-effective way to control pollutants in storm water discharges associated with industrial activity. Options for eliminating pollution sources include reducing onsite air emissions affecting runoff quality, changing chemicals used at the facility, and modification of material management practices such as moving storage areas into buildings.

c. *Options for Controlling Pollutants in Storm Water Discharges Associated With Industrial Activity From Construction Activities.*

Most controls for construction activities can be broken into two groups: (1) Sediment and erosion controls; and (2) storm water controls. Sediment and erosion controls are generally those controls which address pollutants in storm water generated from the site during the time when construction activities are occurring. Storm water controls are generally those controls which are installed during the construction process, but primarily result in reductions of pollutants in storm water discharged from the site after the construction has been completed. Additional measures can be classified as housekeeping best management practices.

(i) *Sediment and erosion controls.*

Erosion controls provide the first line of defense in preventing off-site sediment movement and are designed to prevent erosion by protecting soils. Sediment controls are designed to remove sediment from runoff before the runoff is discharged from the site. Sediment and erosion controls can be further divided into two major classes of controls: vegetative practices and structural practices. Major types of sediment and erosion practices are summarized below. A more complete description of these practices is described in "Draft—Sediment and Erosion Control, An Inventory of Current Practices", U.S. EPA, OWEC, April 20, 1990.

(A) *Sediment and erosion controls: vegetative practices.* Vegetation, as discussed here, refers to covering or maintaining an existing cover over soils. The cover may be grass, trees, vines, shrubs, bark, mulch or straw. The establishment and maintenance of vegetation are one of the most important factors in minimizing erosion while construction activities are occurring. A vegetation cover reduces the erosion potential of a site by: Absorbing the kinetic energy of raindrops which would otherwise impact soil; intercepting water so it can infiltrate into the ground instead of running off carrying surface soils; and by slowing the velocity of runoff promoting deposition of sediment in the runoff. Vegetative controls are often the most important measures taken to prevent off-site sediment movement, and can provide a six-fold

reduction in discharge suspended sediment levels.²³

Temporary seeding. Temporary seeding provides for temporary stabilization by establishing vegetation of areas of the site which will be disturbed at some time during the construction operation, and where work (other than the initial disturbance) is not conducted until some time later in the project. Soils at these areas may be exposed to precipitation for an extended time period, even though work is not occurring on these areas. In most climates, temporary seeding is typically appropriate for areas exposed by grading or clearing for more than seven to fourteen days. Temporary seeding practices have been found to be up to 95% effective in reducing erosion.²⁴

Permanent seeding. Permanent seeding involves establishing a sustainable ground cover at a site. Permanent seeding stabilizes the soil to reduce sediment in runoff from the site. Permanent seeding is typically required at most sites for aesthetic reasons.

Mulching. Mulching is typically conducted as part of permanent and temporary seeding practices. Where temporary and permanent seeding is not feasible, exposed soils can be stabilized by applying plant residues or other suitable materials to the soil surface. Although generally not as effective as seeding practices, mulching, by itself, does provide some erosion control. Mulching in conjunction with seeding practices provides erosion protection prior to the onset of vegetation growth. In addition, mulching protects seeding practices, providing a higher likelihood of their success. To maintain optimum effectiveness, mulches must be anchored to resist wind displacement.

Sod stabilization. Sod stabilization involves establishing long-term stands of grass with sod in sediment producing areas. When installed and maintained properly, sodding can be 99% effective in reducing erosion,²⁵ making it the most effective vegetation practice available. The higher cost of sod stabilization relative to other vegetative controls typically limits its use to exposed soils where a quick vegetative cover is desired and on sites which can be maintained with ground equipment. In addition, sod is sensitive to climate and

may require intensive watering and fertilizing.

Vegetative buffer strips. Vegetative buffer strips are preserved or planted strips of vegetation at the top and bottom of a slope, outlining property boundaries, or adjacent to receiving waters such as streams or wetlands. Vegetative buffer strips can slow runoff flows at critical areas, decreasing erosion and allowing sediment deposition.

Protection of trees. This practice involves preserving and protecting selected trees that were on the site prior to development. Mature trees have extensive canopy and root systems which help to hold soil in place. Shade trees also keep soil from drying rapidly and becoming susceptible to erosion. Measures taken to protect trees can vary significantly, from simple measures such as installing tree fencing around the drip line and installing tree armoring, to more complex measures such as building retaining walls and tree wells.

(B) Sediment and erosion controls: structural practices. Structural practices involve the installation of devices to divert flow, store flow or limit runoff. Structural practices can have several objectives. First, structural practices can be designed to prevent water from crossing disturbed areas where sediment may be removed. This involves diverting runoff from undisturbed upslopes areas by use of earth dikes, temporary swales, perimeter dike/swales, or diversions that outlet in stable areas. A second objective of structural practices can be to remove sediment from site runoff before the runoff leaves the site. Several approaches to removing sediment from site runoff include diverting flows to a trapping or storage device, or filtering diffuse flow through straw bale dikes, silt fences, or brush barriers before it leaves the site. All structural practices require proper maintenance (removal of sediment) to remain functional.

Earth dike. Earth dikes are temporary berms or ridges of compacted soil which channel water to a desired location. Earth dikes should be stabilized with vegetation.

Straw bale dikes. Straw bales are temporary barriers of straw or similar material used to intercept sediment in runoff from small drainage areas of disturbed soil. When installed and maintained properly, straw bale dikes can remove approximately 67% of the sediment in runoff.²⁶ This optimum

efficiency can only be achieved through careful maintenance with special attention to replacing rotted or broken bales.

Silt fence. Silt fences are a barrier of geotextile fabric (filter cloth) used to intercept sediment in diffuse runoff. Care must be taken in maintaining silt fences with an emphasis on maintaining the structural stability of the silt fence and removal of excessive sedimentation.

Brush barriers. Brush barriers are sediment barriers composed of tree limbs, weeds, vines, root mat, soil, rock and other cleared materials placed at the toe of a slope.

Drainage swales. A drainage swale is a drainage way with a lining of grass, riprap, asphalt, concrete, or other materials. Drainage swales are installed to convey runoff without causing erosion.

Check dams. Check dams are small temporary dams constructed across a swale or drainage ditch to reduce the velocity of runoff flows, thereby reducing erosion of the swale or ditch. Check dams should not be used in a live stream. Check dams reduce the need for more stringent erosion control practices in the swale due to the decreased velocity and energy of runoff. Materials which can be used to install a check dam include rock, logs and covered straw bales.

Level spreader. Level spreaders are outlets for dikes and diversions consisting of an excavated depression constructed at zero grade across a slope. Level spreaders convert concentrated runoff into diffuse runoff and release it onto areas stabilized by existing vegetation.

Subsurface drain. Subsurface drains transport water to an area where it can be managed effectively. Drains can be made of tile, pipe or tubing.

Pipe slope drain. A pipe slope drain is a temporary structure placed from the top of a slope to the bottom of a slope to convey surface runoff down slopes without causing erosion.

Temporary storm drain diversion. Temporary storm drain diversions are used to re-direct flow in a storm drain to discharge into a sediment trapping device.

Storm drain inlet protection. Storm drain inlet protection can be provided by a sediment filter or an excavated impounding area around a storm drain inlet. These devices prevent sediment from entering storm drainage systems prior to permanent stabilization of the disturbed area.

Rock outlet protection. Rock protection placed at the outlet end of culverts or channels can reduce the

²³ "Performance of Current Sediment Control Measures at Maryland Construction Sites", January 1990, Metropolitan Washington Council of Governments.

²⁴ "Guides for Erosion and Sediment Control in California", USDA—Soil Conservation Service, Davis CA, Revised 1985.

²⁵ "Guides for Erosion and Sediment Control in California", USDA—Soil Conservation Service, Davis, CA, Revised 1985.

²⁶ "Draft—Sediment and Erosion Control, An Inventory of Current Practices", U.S. EPA, OWEC, April 20, 1990.

depth, velocity and energy of water such that the flow will not erode the receiving downstream reach.

Sediment traps. Sediment traps can be installed in a drainageway, at a storm drain inlet, or other points of discharge from a disturbed area.

Other controls. Other controls include temporary sediment basins, sump pits, entrance stabilization measures, waterway crossings, and wind breaks.

(ii) **Storm water management controls.** Storm water controls are generally those controls which are installed during the construction process, but primarily result in reductions of pollutants in storm water discharged from the site after the construction has been completed. Construction activities often result in a significant change in land use. These changes in land use typically involve an increase in the overall imperviousness of the site, which can result in dramatic changes to the runoff patterns of a site. As the amount of runoff from a site increases, the amount of pollutants carried by the runoff increases. In addition, activities such as automobile travel on roads can result in higher pollutant concentrations in runoff than preconstruction levels. Traditional storm water management controls do not influence the change in land use associated with construction. Rather, traditional storm water management controls attempt to limit the increases in the amount of runoff and the amount of pollutants discharged from a site associated with the change in land use.

Major classes of storm water management controls include: Infiltration of runoff onsite; flow attenuation by vegetation or natural depressions; outfall velocity dissipation devices; storm water retention structures and artificial wetlands; and storm water detention structures. For many sites, a combination of these controls may be appropriate. A summary of storm water management controls is provided below. A more complete description of storm water management controls is found in "Draft—Construction Site Storm Water Discharge Control—An Inventory of Practices", EPA, OWEC, 1991.

(A) **Infiltration of runoff onsite.** A variety of infiltration technologies can be used to reduce the volume and pollutant loadings of storm water discharges from a site, including infiltration trenches and infiltration basins. Infiltration devices tend to mitigate changes to pre-development hydrologic conditions. Properly designed and installed infiltration devices can reduce peak discharges, provide groundwater recharge, augment low flow conditions of receiving streams, reduce storm water discharge volumes

and pollutant loads, and protect downstream channels from erosion. Infiltration devices are a feasible option where soils are permeable and the water table and bedrock are well below the surface. Infiltration basins can also be used as sediment basins during construction.²⁷ Infiltration trenches can be more easily placed into under utilized areas of a development, and can be used for small sites and infill developments. However trenches may require regular maintenance to prevent clogs, particularly where grass inlets or other pollutant removing inlets are not used. In some situations, such as low density areas of parking lots, porous pavement can provide for infiltration.

(B) **Flow attenuation by vegetation or natural depressions.** Flow attenuation provided by vegetation or natural depressions can provide pollutant removal, infiltration, and lower the erosive potential of flows.²⁸ In addition, these practices can enhance habitat values and the appearance of a site. Vegetative flow attenuation devices include grass swales and filter strips as well as trees that are either preserved or planted during construction.

Typically the costs of vegetative controls are small relative to other storm water practices. The use of check dams incorporated into flow paths can provide additional infiltration and flow attenuation.²⁹ Given the limited capacity to accept large volumes of runoff, and potential erosion problems associated with large concentrated flows, vegetative controls should typically be used in combination with other storm water devices.

Grass swales are typically used in low or medium residential development and highway medians as an alternative to curb and gutter drainage systems.³⁰

(C) **Outfall velocity dissipation devices.** Outfall velocity dissipation devices include riprap and stone or concrete flow spreaders. Outfall velocity dissipation devices slow the flow of water discharged from a site to lessen the amount of erosion caused by the discharge.

(D) **Storm water retention structures.** Properly designed and maintained storm water retention structures, also referred to as wet ponds, can achieve a high

removal rate of sediment, BOD, organic nutrients and metals. Retention basins are most cost-effective in larger, more intensively developed sites. Retention ponds can also create wildlife habitat, recreation, and landscape amenities, and corresponding higher property values.

(E) **Retention structures/artificial wetlands.** Retention structures include ponds and artificial wetlands that are designed to maintain a permanent pool of water. Property installed and maintained retention structures (also known as wet ponds) and artificial wetlands^{31, 32} can achieve a high removal rate of sediment, BOD, organic nutrients and metals, and are most cost-effective when used to control runoff from larger, intensively developed sites.³³ These devices rely on settling and biological processes to remove pollutants.

(F) **Water quality detention structures.** Storm water detention structures include extended detention ponds, which control the rate at which the pond drains after a storm event. Extended detention ponds are usually designed to completely drain in about 24 to 40 hours, and will remain dry at other times. They can provide pollutant removal efficiencies that are similar to those of retention ponds.³⁴ Extended detention systems are typically designed to provide both water quality and water quantity (flood control) benefits.³⁵

iii. **Housekeeping BMPs.** Pollutants that may enter water from construction sites due to poor housekeeping include oils, grease, paints, gasoline, concrete truck washdown, concrete raw materials used in the manufacture of concrete, including sand, aggregate, and cement, solvents, litter, debris and sanitary wastes. Construction site management plans can address the following to prevent the discharge of these pollutants:

- Designate areas for equipment maintenance and repair;
- Provide waste receptacles at convenient locations and provide regular collection of wastes;

²⁷ "Controlling Urban Runoff: A Practical Manual for Planning and Designing Urban BMPs", Maryland Sediment and Stormwater Division, 1987.

²⁸ "The Value of Wetlands for Nonpoint Source Control—Literature Summary", Strecker, E., et al., 1990.

²⁹ "Controlling Urban Runoff, A Practical Manual for Planning and Designing Urban BMPs", Metropolitan Washington Council of Governments, 1987.

³⁰ "Urban Targeting and BMP Selection", United States EPA, Region V, November 1990.

³¹ "Urban Surface Water Management", Welsh, S.G., Wiley, 1989.

³² "Controlling Urban Runoff: A Practical Manual for Planning and Designing Urban BMPs", July, 1987, Metropolitan Washington Council of Governments.

³³ "Urban Targeting and BMP Selection", United States EPA, Region V, November 1990.

³⁴ "Standards and Specifications for Infiltration Practices", 1984, Maryland Water Resources Administration

³⁵ "Controlling Urban Runoff: A Practical Manual for Planning and Designing Urban BMPs", Metropolitan Washington Council of Governments, July 1987.

- Locate equipment washdown areas on site, and provide appropriate control of washwaters;

- Provide protected storage areas for chemicals, paints, solvents, fertilizers and other potentially toxic materials; and

- Provide adequately maintained sanitary facilities.

d. *Coal pile runoff treatment technology.* The primary technology options for treating coal pile runoff considered in the final "Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category", (EPA-440/182/029), November 1982, EPA, were:

- (1) Equalization, pH adjustment, settling; and

- (2) Equalization, chemical precipitation treatment, settling, pH adjustment.

Metals may be removed from wastewater by raising the pH of the wastewater to precipitate them out as hydroxides. Typically, wastewater pH's of 9 to 12 are required to achieve the desired precipitation levels. Lime is frequently used for pH adjustment. Wastewaters which have a pH greater than 9 after lime addition will require acid addition to reduce the pH before final discharge. Polymer addition may be required to enhance the settling characteristics of the metal hydroxide precipitate. Typical polymer feed concentrations in the wastewater are 1 to 4 ppm. The metal hydroxide precipitate is separated from the wastewater in a clarifier or a gravity thickener. Unlike settling ponds, these units continually collect and remove the sludge formed. Filters are typically used for effluent polishing and can reduce suspended solids levels below 10 mg/l. Sand or coal are the most common filter media. Vacuum filtration is a common technique for dewatering sludge to produce a cake that has good handling properties and minimum volume.

The major equipment requirements for such a system include a lime feed system, mix tank polymer feed system, flocculator/clarifier, deep bed filter, and acid feed system. For wastewaters which have a pH of less than 6, mixers and mixing tanks are made of special materials of construction (stainless steel or lined-carbon steel). For wastewaters with pH's greater than 6, concrete tanks are typically used. The underflow from the clarifier may require additional treatment with a gravity thickener and a vacuum filter to provide sludge which can be transported economically for landfill disposal.

5. The Federal/Municipal Partnership: The Role of Municipal Operators of Large and Medium Municipal Separate Storm Sewer Systems

A key issue in developing a workable regulatory program for controlling pollutants in storm water discharges associated with industrial activity is the proper use and coordination of limited regulatory resources. This is especially important when addressing the appropriate role of municipal operators of large and medium municipal separate storm sewer systems in the control of pollutants in storm water associated with industrial activity which discharge through municipal separate storm sewer systems.

Several key policy factors arise when considering the appropriate strategy for regulating storm water discharges associated with industrial activity through municipal separate storm sewer systems. These factors include the following:

- The role and responsibilities of municipalities to control pollutants from nonmunicipal facilities which are discharged through a storm sewer owned or operated by the municipality;

- The large number of storm water discharges through municipal systems (the Agency anticipates that the majority of storm water discharges associated with industrial activity from many industrial classes discharge through municipal separate storm sewer systems);

- The ability of municipalities to recognize and represent local concerns and considerations;

- The ability of municipal operators to assist EPA and authorized NPDES States in identifying local priorities for controlling storm water discharges associated with industrial activity through specific municipal systems;

- The ability of municipal operators to assist EPA and authorized NPDES States to oversee effectively the development of appropriate site-specific controls for storm water discharges associated with industrial activity through municipal systems and to effectively require compliance with such controls;

- The authorities provided by the CWA (including those provided to the public) to review information developed under the NPDES program and to enforce NPDES permits; and

- The requirements of the CWA to develop and implement the NPDES permit program.

On November 16, 1990 (55 FR 47990), EPA promulgated a permitting scheme where controls for storm water discharges associated with industrial

activity through large and medium municipal separate storm sewer systems may be addressed by two permits issued in a coordinated manner. This complementary permit approach envisions cooperative efforts by the permit issuing agency and municipal operators of large and medium municipal separate storm sewer systems to develop programs that will result in controls on pollutants in storm water discharges associated with industrial activity which discharge through municipal systems.

Under the complementary permit approach, storm water discharges associated with industrial activity which discharge through large and medium municipal separate storm sewer systems are required to obtain permit coverage. Permits for these discharges will establish requirements (such as controls or monitoring) for industrial operators of the discharge into the municipal system. In addition, these permits provide a basis for enforcement actions directly against the owner or operator of storm water discharges associated with industrial activity.

A second permit, issued to the operator of the large or medium municipal separate storm sewer, establishes the responsibilities of the municipal operators in controlling pollutants from storm water associated with industrial activity which discharges through their system. The framework for permits for discharges from large and medium municipal separate storm sewer systems has been developed to establish the responsibilities of the municipal operator to control pollutants discharged through these municipal systems. At the heart of the permit program for discharges from municipal separate storm sewer systems serving a population of 100,000 or more are requirements that municipal applicants develop and implement municipal storm water management programs. The municipal storm water management programs that will be incorporated into NPDES permits for discharges from municipal separate storm sewer systems will generally address (in addition to other possible requirements) the following three major components:

- Reducing pollutants in storm water discharges from municipal landfills; hazardous waste treatment, storage and disposal facilities; facilities subject to SARA Title III, Section 313; and other priority industrial facilities through municipal separate storm sewers;

- Reducing pollutants in construction site runoff through municipal separate storm sewers; and

- Identifying and controlling non-storm water discharges to municipal separate storm sewer systems.

These components of a municipal program can initiate the role of the municipality in assisting EPA and authorized NPDES States in implementing controls to reduce pollutants in storm water discharges associated with industrial activity which discharge into large and medium municipal separate storm sewer systems. Municipal programs to reduce pollutants in industrial site runoff and construction site runoff through municipal separate storm sewer systems specifically will address municipal responsibilities in controlling pollutants from industrial facilities. In addition, programs to identify and control non-storm water discharges to municipal separate storm sewer systems will in many cases focus on industrial areas because these areas often have a high potential for illicit connections, spills or improper dumping.

Consistent with the final permit applications regulations published on November 16, 1990 (55 FR 47990), the general permits accompanying this fact sheet have been developed to assist in establishing a cooperative approach between EPA and municipal operators of large and medium municipal separate storm sewer systems for controlling pollutants from storm water discharges associated with industrial activity which discharge through large and medium municipal separate storm sewer systems. These requirements will be coordinated with requirements in permits for discharges from large and medium municipal separate storm sewer systems. Major features of the draft general permits which establish the framework for this cooperative approach include:

- Operators of storm water discharges associated with industrial activity which discharge through a large or medium municipal separate storm sewer system may be required to submit a copy of the notice of intent to the municipal operators of large or medium municipal system receiving the discharge;

- Requirements to monitor and reduce pollutants in discharges will be established for storm water discharges associated with industrial activity which discharge through large and medium municipal separate storm sewer systems (as well as other storm water discharges associated with industrial activity). Any records, reports, or information obtained by the Director as part of the permit implementation process, including site-specific storm water pollution prevention programs that are developed

pursuant to the draft general permit, are available to municipalities under section 308(b) of the CWA. This will assist municipalities in reviewing the adequacy of such requirements and developing priorities among industrial storm water sources; and

- Industrial permittees with discharges through large and medium municipal systems may be required to submit discharge monitoring reports to municipal operators of these systems (as well as to the permitting issuing agency) or other monitoring results as required by the operator of the municipal separate storm sewer to assist the municipal operator in identifying priorities.

These permit conditions, along with appropriate conditions in permits for discharges from large and medium municipal separate storm sewer systems, will allow municipal operators of these systems to:

- Assist EPA in identifying priority storm water discharges associated with industrial activity to their system;
- Assist EPA in reviewing and evaluating storm water pollution prevention plans that industrial facilities are required to develop under the draft general permit; and
- Assist EPA in compliance efforts regarding storm water discharges associated with industrial activity to their municipal systems.

6. Notification Requirements

EPA's regulations at 40 CFR 122.21(a) exclude persons covered by general permits from requirements to submit individual permit applications. Under these existing regulations, conditions for NOIs to be covered by the general permit are established in the permits on a case-by-case basis. Elsewhere in today's notice, EPA is proposing to amend the general permit regulations at 40 CFR 122.28 to establish minimum requirements for NOIs in general permits.

The draft general permits associated with this fact sheet would establish limited NOI requirements that would operate instead of individual permit application requirements and that are consistent with the minimum regulatory requirements for NOIs proposed in this notice.

These draft general permits have the following NOI requirements for discharges covered by each permit:

- Name, mailing address, and location of the facility for which the notification is submitted;
- Up to four 4-digit Standard Industrial Classification (SIC) codes that best represent the principal products or activities provided by the facility;

- The operator's name, address, telephone number, ownership status and status as Federal, State, private, public, or other entity;

- The latitude and longitude of the approximate center of the facility to the nearest 15 seconds, or the nearest quarter section (if the section, township, or range is provided) that the facility is located in;

- The name of the receiving water(s), or if the discharge is to a municipal separate storm sewer, the name of the municipal operator of the storm sewer and the ultimate receiving water(s); and

- Existing quantitative data describing the concentration of pollutants in discharges.

The permits in AZ, Guam and American Samoa will, in addition to the information described above, require that an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage are (e.g. low under 40%), medium (40% to 65%) or high (above 65%)) be provided. This information will be used to estimate the volume of storm water discharged from the facility, which will assist in evaluating pollutant loads.

The proposed NOI requirements for storm water discharges associated with industrial activity from a construction site include, in addition to the information required above, a brief description of the project, estimated timetable for major activities, and estimates of the number of acres of the site that will be disturbed.

The NOI requirements of the draft general permits are intended to establish a mechanism that will provide a clear accounting of the number of permittees covered by the general permit, the nature of operations at the facility generating the discharge, their identity and location. In addition, the NOI can identify the permittee to provide a basis for enforcement and compliance monitoring strategies. The NOI can be used as an initial screening tool to determine discharges where individual permits are appropriate. Also, the NOI can be used to identify classes of discharges appropriate for general permits with more specific requirements, as well as provide information needed to notify such dischargers of the issuance of a more specific general permit.

The NOI requirements in the draft general permit have been designated to provide much of the information needed for these purposes, and will be supplemented by other information obtained through processes such as section 308 information requests.

EPA is considering developing a central address for receiving all NOIs required under these general permits. This would assist the Regional Offices in handling and filing NOIs. EPA is also considering developing a form for NOIs that can be read by automatic data processing equipment. Operations of storm water discharges associated with industrial activity which discharge through a large or medium municipal separate storm sewer system must, in addition to submitting an NOI to the Director, submit a copy of the NOI to the municipal operator of the system receiving the discharge. This additional notice will assist municipal operators in developing inventories of industrial facilities which discharge to their municipal separate storm sewer systems. This will be an initial step in implementing municipal storm water management programs to reduce pollutants from runoff from industrial facilities. This also will assist municipal operators in overseeing the implementation of permit conditions.

Individuals who intend to obtain coverage under the general permit must notify their intent within 180 days of the effective date of this general permit or at least 30 days prior to the commencement of construction of a new storm water discharge associated with industrial activity.

The deadlines for submitting NOIs under the draft general permit differ from the deadlines for submitting individual permit applications under 40 CFR 122.26(e) in several respects. First, the deadline for submitting NOIs for existing storm water discharges associated with industrial activity is 180 days from issuance of the general permits rather than the November 18, 1991, deadline for submitting individual permit applications.³⁶ The Agency believes that it is appropriate to base the NOI submittal date on the issuance date of the final general permit establishing the NOI requirement. The Agency also believes that 180 days provides the discharger with adequate opportunity to prepare and submit an NOI, particularly because dischargers are not required to conduct sampling activities to submit a complete NOI. Second, the draft permits provide that NOIs be submitted at least 30 days before construction of a new storm water discharge associated with industrial activity begins. This time is less than the 60 days prior to commencement of construction that 40 CFR 122.26(e) provides for submitting

permit applications for individual permits for new storm water discharges associated with industrial activity. The Agency believes that under these general permits, less time is necessary to review NOIs than to review individual permit applications and to issue permits for new storm water discharges associated with industrial activity. In addition, reducing the minimum time to a 30 day period to submit NOIs before beginning construction will assist discharges in complying with the permit.

7. Description of Draft Permit Conditions

The conditions of these draft permits have been designed to comply with the technology-based standards of the CWA (BAT/BCT). Based on a consideration of the appropriate factors for BAT and BCT requirements, and a consideration of the factors and options discussed in this fact sheet for controlling pollutants in storm water discharges associated with industrial activity, the draft general permits proposes two prohibitions, a set of tailored requirements for developing and implementing storm water pollution prevention plans, and for selected discharges, two effluent limitations.³⁷

Part 4 of this fact sheet summarizes the options for controlling pollutants in storm water discharges associated with industrial activity. The draft general permit proposes numeric effluent limitations for two classes of discharges, coal pile runoff, and runoff that comes into contact with certain chemical storage or handling facilities at SARA title III, section 313 facilities.

For other discharges covered by the permit, the draft permit conditions reflect EPA's decision to select a number of best management practices and traditional storm water management practices which prevent pollution in storm water discharges as the BAT/BCT level of control for the majority of storm water discharges covered by these permits. The draft permit conditions applicable to these discharges are not numeric effluent limitations, but rather are flexible requirements for developing and

implementing site specific plans to minimize and control pollutants in storm water discharges associated with industrial activity.

EPA is authorized under 40 CFR 122.44(k)(2) to impose BMPs in lieu of numeric effluent limitations in NPDES permits when the Agency finds numeric effluent limitations to be infeasible. EPA may also impose BMPs which are "reasonably necessary * * * to carry out the purposes of the Act" under 40 CFR 122.44(k)(3). Both of these standards for imposing BMPs were recognized in *NRDC v. Costle*, 568 F.2d 1369, 1380 (D.C. Cir. 1977). The conditions in the draft general permits are proposed under the authority of both of these regulatory provisions. The pollution prevention or BMP requirements in these permits operate as limitations on effluent discharges that reflect the application of BAT/BCT. This is because the BMPs identified require the use of source control technologies which, in the context of these general permits, are the best available of the technologies economically achievable (or the equivalent BCT finding). See, e.g. *NRDC v. EPA*, 822 F.2d 104, 122-23 (D.C. Cir. 1987) (EPA has substantial discretion to impose non-quantitative permit requirements pursuant to section 402(a)(1)).

a. *Prohibitions.* The draft general permits prohibit non-storm water discharges as a component of discharges authorized by this permit. This permit is intended to authorize discharges composed entirely of storm water associated with industrial activity. The prohibition on non-storm water discharges in these permits ensures that non-storm water discharges are not inadvertently authorized by these permits. Where a storm water discharge is mixed with process wastewaters or other sources of non-storm water prior to discharge, and the discharge is currently not authorized by an NPDES permit, the discharger should submit the appropriate application forms to obtain permit coverage. The Agency believes that these mixed discharges are addressed more appropriately through individual NPDES permits or other general permits will allow development of more tailored and specific permit conditions appropriate for such discharges.

The draft general permits also prohibit discharges that contain a hazardous substance in excess of reporting quantities established at 40 CFR 117.3 or 40 CFR 302.4, and clarifies that where such a discharge occurs, the permit does not relieve the permittee of the reporting

³⁶ EPA has proposed to extend this deadline to May 18, 1992. (56 FR 12101, March 21, 1991).

³⁷ Part I.C.2 of the draft general permits provide that facilities with storm water discharges associated with industrial activity which, based on an evaluation of site specific conditions, believe that the appropriate conditions of these permits do not adequately represent BAT and BCT requirements for the facility may request to be excluded from the coverage of the general permit by either submitting to the Director an individual application (Form 1 and Form 2F) with a detailed explanation of the reasons supporting the request, including any supporting documentation showing that certain permit conditions are not appropriate, or participating in a group application (see 40 CFR 112.26(c)).

requirements of 40 CFR part 117 and 40 CFR part 302. The Agency believes that the vast majority of discharges that contain a hazardous substance in excess of reporting quantities will be associated with non-storm water sources (e.g. chemical spill events). Where a discharge composed entirely of storm water associated with industrial activity containing a hazardous substance in excess of reporting quantities occurs or is expected to occur, the Agency believes that the potential risks associated with the discharge are such that it is more appropriate to address the discharge with an individual permit which contains more specific permit conditions based on industry specific or site specific factors and a consideration of receiving water characteristics. Since discharges containing a hazardous substance in excess of reporting quantities are not authorized by these permits, such releases are not exempted from reporting requirements by 40 CFR 117.12(a)(1), and hence the permits do not relieve the permittee of the reporting requirements of 40 CFR part 117 and 40 CFR part 302.

EPA anticipates that storm water discharges that contain oil in excess of reporting quantities established under 40 CFR 110.6 (e.g. exhibit an oil sheen) will be more common. For example, many storm water discharges from parking lots or roads, as well as from industrial facilities, contain an oil sheen. Although discharges composed entirely of storm water associated with industrial activity are authorized by these permits where the discharge complies with the other applicable requirements of the permit and 40 CFR part 110, it should be noted that where a discharge of oil in excess of reporting quantities is caused by a nonstorm water discharge (e.g. a spill of oil into a separate storm sewer), the spill is not authorized by this permit, and the discharger is not relieved of their obligation to report the spill under 40 CFR part 110. In this regard, the requirements of section 311 of the CWA and otherwise applicable provisions of sections 301 and 402 of the CWA continue to apply.

b. Tailored pollution prevention plan requirements. All facilities covered by the storm water general permits must prepare, retain and implement a storm water pollution prevention plan. The storm water permits address tiered sets of pollution prevention plan requirements for a number of categories of industries: Construction activities; baseline requirements for all industries except construction activities; special requirements for certain facilities

subject to SARA title III, section 313; special requirements for storm water discharges associated with industrial activity to large and medium municipal separate storm sewer systems; and special requirements for facilities with outdoor salt storage piles. These tailored requirements have been developed to allow the implementation of site-specific measures that address features, activities, or priorities for control associated with the identified storm water discharges.

The Agency is using the term "pollution prevention" in the context of these plans because the term emphasizes that requirements in the plans provide a flexible basis for developing site-specific measures to minimize and control the amounts of pollutants that would otherwise enter storm water. The term 'pollution prevention' distinguishes this source reduction approach from traditional pollution control measures that typically rely on end-of-pipe treatment to remove pollutants in the discharges. The plan requirements are based primarily on traditional storm water management, pollution prevention and BMP concepts which have been tailored to pollutants in storm water discharges associated with industrial activity.

The pollution prevention approach adopted in the storm water pollution prevention plans in the draft general permits focuses on two major objectives:

- (1) To identify sources of pollution potentially affecting the quality of storm water discharges associated with industrial activity from the facility; and
- (2) Describe and ensure that practices are implemented to minimize and control pollutants in storm water discharges associated with industrial activity from the facility and to ensure compliance with the terms and conditions of this permit.

The Agency believes that it is not appropriate, at this time, to require a single set of effluent guidelines or a single design or operational standard for all facilities which discharge storm water associated with industrial activity. Rather, this permit establishes a framework for the development and implementation of site-specific storm water pollution prevention plans. This framework provides the necessary flexibility to address the variable risk for pollutants in storm water discharges associated with the different types of industrial activity that are addressed by these permits, while ensuring procedures to prevent storm water pollution at a given facility are appropriate given the processes employed, engineering aspects,

functions, costs of controls, location, and age of facility (as contemplated by 40 CFR 125.3). The approach taken allows flexibility to establish controls which can appropriately address different sources of pollutants at different facilities.

i. Plan requirements for construction activities. The requirements for storm water pollution prevention plans for operations that discharge storm water associated with industrial activity from construction activities differ from the requirements for other types of facilities.

In developing these draft permits, the Agency has reviewed a significant number of existing State and local requirements for sediment and erosion controls, and storm water management controls for construction activities/new development addressing a wide range of climates and types of construction activities.

(A) Source Identification. Storm water pollution prevention plans must be based on an accurate understanding of the pollution potential of the site. The first part of the plan requires an evaluation of the sources of pollution at a specific construction site. The source identification components for pollution prevention plans for construction activities proposed in these permits include, at a minimum, a description of the following:

- A description of the nature of the construction activity;
- Estimates of total area of the site and the area of the site that is expected to undergo excavation or grading;
- An estimate of the runoff coefficient of the site and existing data describing the soil or the quality of any discharge from the site. Estimates of the runoff coefficient can be based on estimates of the site size, the increase in impervious area after the construction is completed, and the location of structures that will be built on the site;
- A site map indicating, at a minimum, drainage patterns and approximate slopes anticipated after major grading activities, areas used for the storage of soils or wastes, the location of major control structures identified in the plan, and surface waters; and
- The name of the receiving water(s), or if the discharge is to a municipal separate storm sewer, and the ultimate receiving water(s).

EPA requests comments on whether the permits should require information describing other major features which may provide a better understanding of site runoff or other major pollutant sources, such as identification of areas

intended to be used for the storage of soils or wastes, be included in plans.

(B) Controls to reduce pollutants.

Many municipalities and States have developed sediment and erosion control requirements for construction activities. A significant number of municipalities and States have also developed storm water management controls. This permit requires that facilities which discharge storm water associated with industrial activity from construction activities must reflect in their storm water pollution prevention plan procedures and requirements specified in applicable sediment and erosion site plans or storm water management plans approved by State or local officials. Applicable requirements specified in sediment and erosion plans or storm water management plans approved by State or local officials are, upon submittal of an NOI to be authorized to discharge under this permit, incorporated by reference and are enforceable under this permit even if they are not specifically included in a storm water pollution prevention plan required under this permit.³⁸

The sediment and erosion controls for construction activities proposed in this permit have three goals: 1) to divert upslope water around disturbed areas of the site; 2) to limit the exposure of disturbed areas to the shortest duration possible; and 3) to remove sediment from storm water before it leaves the site.

Each construction operation covered by the permit is required to develop a description of three classes of controls appropriate for inclusion in the facility's plan, and implement controls identified in the plan in accordance with the plan. The description of controls must address erosion and sediment controls, storm water management and a specified set of other controls.

Erosion and sediment controls include both vegetative practices and structural practices. Vegetative practices are the first line of defense for preventing erosion. These controls are to be based on a consideration of temporary seeding, permanent seeding, mulching, sod stabilization, vegetative buffer strips, and protection of trees. Temporary seeding practices are often cited as the single most important factor

in reducing erosion at construction sites.³⁹

Since vegetative practices play such an important role in preventing erosion, it is critical that they are rapidly employed in appropriate areas. The draft permits provide that the operator shall initiate appropriate vegetative practices on all disturbed areas within 7 calendar days of the last activity at that area. Appropriate vegetative practices may include temporary seeding, permanent seeding, mulching or sod stabilization procedures, or equivalent measures that protect exposed soils. EPA requests comments on the application of this criterion or other appropriate criteria (such as criterion that would only be applicable during specified seasons) for initiating appropriate vegetative practices in arid areas (areas with less than 10 inches average annual rainfall) and semi-arid areas (areas with between 10 and 20 inches average annual rainfall) with well defined seasonal rainfall patterns. For example, it may be appropriate to only apply the requirement to initiate appropriate vegetative practices within 7 days of the last activity in a given area during seasons or months which have a reasonable probability of a rain event occurring. However, EPA has concerns about its ability to define appropriate dry weather periods, and requests comments on this approach.

Structural controls provide a second line of defense by capturing pollutants before they leave the site. Structural controls are necessary because vegetative controls cannot be employed at areas of the site which are continually disturbed and because a finite time period is required before vegetative practices are fully effective. Structural practices selected for incorporation into a plan are to be based on a consideration of the attainability at a given site of implementing particular controls. Options for such controls include straw bale dikes, silt fences, earth dikes, brush barriers, drainage swales, check dams, subsurface drain, pipe slope drain, level spreaders storm drain inlet protection, rock outlet protection, sediment traps, and temporary sediment basins. For sites with more than 10 disturbed acres at one time which are served by a common drainage location, a detention basin providing storage for runoff from disturbed areas from a 24 hour, 10 year storm or equivalent controls (such as suitably sized dry wells or infiltration structures), shall be provided where

sufficient space and other factors allow these controls to be attained. For drainage locations with more than 10 disturbed acres at one time which are served by a common drainage location where a detention basin providing storage or equivalent controls for runoff from disturbed areas from a 10 year, 24-hour storm is not attainable, silt fences, straw bale dikes, or equivalent sediment controls are required for all sideslope and downslope boundaries of the construction area.

For drainage locations serving 10 or less acres, at a minimum, silt fences, straw bale dikes, or equivalent sediment controls are required for all sideslope and downslope boundaries of the construction area or a detention basin providing storage for runoff from disturbed areas.

EPA requests comment on the use of the 10 acre limit and the 24 hour, 10 year storm for this requirement.⁴⁰ Although sediment basins are generally viewed as being more effective than other structural controls, flexibility has been added to the proposed requirements for drainage locations serving 10 or less acres since these smaller sites may have more difficulty finding an appropriate location for a basin.

"Storm water management" controls⁴¹ are to include a description of measures or controls to minimize pollutants in storm water discharges that will be installed during construction, but that will continue to control pollutants in storm water discharges after the construction operations have been completed. Options for "storm water management" controls that are to be evaluated in the development of plans include: infiltration of runoff onsite; flow attenuation by use of open vegetated swales and natural depressions; storm water retention structures and storm water detention structures. Often it is appropriate to incorporate several of these measures at a site.

Developing land often significantly increases peak discharge volumes and velocities. These increased discharge velocities can greatly accelerate erosion near the outlet of on-site structural controls. To mitigate these effects, the

³⁸ Facilities with storm water discharges associated with industrial activity related to construction activities which, based on an evaluation of site specific conditions, believe that State and local plans do not adequately represent BAT and BCT requirements for the facility may request to be excluded from the coverage of the general permit by submitting to the Director an individual application with a detailed explanation of the reasons supporting the request, including any supporting documentation showing that certain permit conditions are not appropriate.

³⁹ "New York Guidelines for Urban Erosion and Sediment Control". USDA—Soil Conservation Service, March, 1988.

⁴⁰ This control is a BCT control, and hence the design storm differs from design storms used elsewhere in this permit as BAT controls. (See "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991).)

⁴¹ For the purpose of the special requirements for construction activities, the term "storm water management controls" refers to controls that will primarily reduce the discharge of pollutants in storm water from sites after construction activities have been completed.

draft permits require velocity dissipation devices to be placed at the outfall of detention or retention structures and along the length of outfall channels to provide a non-erosive velocity flow from the structure to a water course needed to ensure that erosion is prevented or minimized.

These permits do not establish specific standards for "storm water management" (e.g. controls to reduce pollutants in storm water discharges from a site after construction is completed) (other than requirements in approved State and local storm water site plans and requirements for velocity dissipation devices). However, the permittee must evaluate the appropriateness of various options for storm water measures at the site when developing their plan and provide a summary of the evaluation and justification for not selecting a given practice. The Agency requests comment on the appropriateness of establishing performance standards,⁴² or design standards.⁴³ While the Agency recognizes that such requirements will often be appropriate in individual permits or in other permit issuing efforts, the Agency has concerns about the extensive use of such standards in this Tier I general permit. The Agency will continue to evaluate appropriate standards for storm water management applicable to new developments along with the need to provide flexibility in allowing for site-specific modifications of the standard based on project constraints, local conditions and the location of the discharge within the watershed.

Other controls to be addressed in storm water pollution prevention plans for construction activities require that no non-storm water wastes, including building material wastes shall be discharged at the site, unless the facility is licensed for such disposal.

The draft permit proposes that off-site vehicle tracking of sediments shall be minimized. This can be accomplished by measures such as providing gravel or paving at access entrance and exit drives, parking areas, and unpaved roads on the site carrying significant amounts of traffic (e.g. more than 25

vehicles per day). These measures, along with other appropriate measures, can limit erosion and the transport of sediment offsite from these areas.

In addition, the plan shall ensure and demonstrate compliance with applicable State or local sanitary sewer, septic⁴⁴ system and waste disposal regulations.

Erosion and sediment controls can become ineffective if they are inappropriately disturbed or otherwise damaged. Maintenance of controls has been identified as a major part of effective erosion and sediment programs. Plans are required to provide a description of procedures to maintain in good and effective condition and promptly repair or restore all grade surfaces, walls, dams and structures, vegetation, erosion and sediment control measures and other protective measures identified in the site plan. At a minimum, procedures in a plan must provide that all erosion controls on the site are inspected at a minimum of once every seven calendar days and at other suitable times (e.g. within 24 hours after any storm event of greater than 0.5 inches of rain per 24 hour period). Diligent inspections are necessary to assure adequate implementation of onsite sediment and erosion controls, particularly in the later stages of construction when the volume of runoff is greatest and the storage capacity of the sediment basins has been reduced.⁴⁵

ii. Plan requirements for facilities other than construction activities. In 1979, EPA completed a technical survey of industry best management practices (BMPs) which was based on a review of practices used by industry to control the non-routine discharge of pollutants from non-continuous sources including runoff, drainage from raw material storage area, spills, leaks, and sludge or waste disposal. This review included analysis and assessment of published articles

⁴⁴ In rural and suburban areas that are served by septic systems, malfunctioning septic systems can contribute pollutants to storm water discharges. Malfunctioning septic tanks may be a more significant surface runoff pollution problem than a ground water problem. This is because a malfunctioning septic system is less likely to cause ground water contamination where a bacterial mat in the soil retards the downward movement of wastewater. Surface malfunctions are caused by clogged or impermeable soils, or when stopped up or collapsed pipes forces untreated wastewater to the surface. Surface malfunctions can vary in degree from occasional damp patches on the surface to constant pooling or runoff of wastewater. These discharges have high bacteria, nitrate and nutrient levels and can contain a variety of household chemicals. This permit does not establish new criteria for septic systems, but rather addresses existing State or local criteria.

⁴⁵ "Performance of Current Sediment Control Measures at Maryland Construction Sites", January, 1990, Metropolitan Washington Council of Governments.

and reports, technical bulletins, and discussions with industry representatives through telephone contacts, written questionnaires and site visits.

The review identified two classes of pollution control measures. The first class of controls are those management practices which are generally considered to be essential to a good BMP program, low in cost, and applicable to broad categories of industry and types of substances. These practices are independent of the type of industry, ancillary sources, specific chemicals, group of chemicals, or plant-site locations. The survey concluded that these controls were broadly applicable to all industry types and activities, and should be viewed as minimum requirements in any effective BMP program. The second class of controls are management practices controls which provide a second line of defense against the release of pollutants and included prevention measures, containment measures, mitigation and cleanup measures, and treatment methods.⁴⁶

Since that time, EPA has, on a case-by-case basis, imposed BMP requirements in NPDES permits. The Agency has also continued to review and evaluate case studies involving the use of BMPs⁴⁷ and the use of pollution prevention measures associated with spill prevention and containment measures for oil.⁴⁸ During the development of NPDES permit application requirements for storm water discharges associated with industrial activity, the Agency evaluated appropriate means for identifying and evaluating the potential risk of pollutants in storm water from industrial sites. Public comments received during the rulemaking provided additional insight regarding storm water risk assessment, as well as appropriate

⁴⁶ For a complete description of the BMP survey, see "NPDES Best Management Practices Guidance Document", U.S. EPA, December 1979, EPA-600/9-79-045. See also the 1981 document of the same name, "NPDES Best Management Practices Guidance Document" which provides a more complete discussion of baseline BMPs.

⁴⁷ For example, see: "Best Management Practices: Useful Tools for Cleaning Up", Thron, H., Rogoshewski, P., 1982, Proceedings of the 1982 Hazardous Material Spills Conference; "The Chemical Industries' Approach to Spill Prevention" Thompson, C., Goodier, J., 1980, Proceedings of the 1980 National Conference on Control of Hazardous Material Spills; and a series of EPA memorandum entitled "Best Management Practices in NPDES Permits—Information Memorandum", 1983, 1985, 1986, 1987, 1988.

⁴⁸ See Oil Pollution Prevention requirements, including Spill Prevention, Control, and Countermeasure Plan requirements, at 40 CFR part 112.

⁴² One approach to performance standards commonly adopted in State or local controls is to require no increase in the rate and volume of runoff from predevelopment conditions. Another common approach is to require on-site control for a specified storm event (e.g. the first inch of runoff from a site).

⁴³ Design standards are commonly used by State and local governments as part of the plan approval process. Such requirements can address a wide range of requirements, such as providing infiltration for runoff from roofs or paved areas exceeding a specified area, or requiring that residential driveways slope toward adjacent landscaped areas.

pollution prevention and control measures and strategies. During this time, the Agency again reviewed storm water control practices and measures.⁴⁹ These experiences have shown the Agency that pollution prevention measures such as BMPs can be appropriately used and that permits containing BMP requirements can effectively reduce pollutant discharges in a cost-effective manner. EPA again indicates that BMP requirements are being imposed in this general permit in lieu of numeric effluent limitations pursuant to 40 CFR 122.44(k)(2).

(A) *Source identification.* Storm water pollution prevention plans must be based on an accurate understanding of the pollution potential of the site. The first part of the plan requires an evaluation of the sources of pollution at a specific industrial site. The permit proposes that the source identification components of the plan identify all activities and significant materials which may potentially be significant pollutant sources. Plans shall include:

- A drainage site map and a topographic map;
- A list of significant spills and leaks of toxic or hazardous pollutants that occurred at the facility after the effective date of the permit;
- A narrative description of significant materials that have been treated, stored or disposed in a manner to allow exposure to storm water between the time of three years prior to the date of the issuance of this permit and the present; method of on-site storage or disposal; materials management practices employed to minimize contact of these materials with precipitation and storm water runoff between the time of three years prior to the date of the issuance of this permit and the present; materials loading and access areas; the location and a description of existing structural and non-structural control measures to reduce pollutants in storm water runoff; and a description of any treatment the storm water receives;
- For each area of the plant that generates storm water discharges associated with industrial activity with a reasonable potential for containing significant amounts of pollutants, a prediction of the direction of flow, and an estimate of the types of pollutants that are likely to be present in storm water discharges associated with industrial activity; and

• A summary of existing sampling data describing pollutants in storm water discharges.

Activities associated with (1) loading and unloading of dry bulk materials or liquids, (2) outdoor storage of raw materials, intermediary products or products, (3) outdoor process activities, (4) dust or particulate generating processes, (5) illicit connections or management practices, and (6) waste disposal practices should be evaluated to see if they are likely to be significant sources of pollutants to storm water discharges.

The prediction of the direction of flow and the rate of flow will typically be based on an evaluation of the area of impervious surfaces and total area drained by each outfall, along with estimates of appropriate representative rainfall events, or actual measurements of discharge volumes. Impervious surfaces include paved areas and buildings within the drainage area of each discharge point.

Estimates of the total quantity of pollutants that are likely to be present in storm water discharges associated with industrial activity should be made from assessments of sampling data, and other information describing significant materials that are used or otherwise found at the site, and that, because of potential exposure to storm water may be significant pollutant sources. Although the monitoring requirements of this permit are limited to conventional pollutants for most discharges, the estimates of the types of pollutants that may be present in storm water required as part of the source identification information should address all types of pollutants (conventional and toxic) that may be present. Examples of information that should be evaluated when estimating pollutants in storm water discharges include information describing of significant materials that have been treated, stored or disposed in a manner to allow exposure to storm water between the time of three years prior to the date of the issuance of this permit and the present; method of on-site storage or disposal; materials management practices employed to minimize contact of these materials with storm water runoff between the time of three years prior to the date of the issuance of this permit and the present; materials loading and access areas; the location and a description of existing structural and non-structural control measures to reduce pollutants in storm water runoff; and a description of any treatment the storm water receives. Other information to consider, if applicable, include the manner and

frequency in which pesticides, herbicides, fertilizers or soil enhancers are applied at the site and an evaluation of significant spills or leaks of conventional, toxic and hazardous pollutants based on a description of the materials released, an estimate of the volume of the release, the location of the release, and any remediation or cleanup measures taken. Information and data used for these predictions and estimates must be clearly identified in the storm water pollution prevention plan.

The Agency requests comments on what other types of information may be appropriate for source identification purposes.

(B) *Practices and program elements to control pollutants.* The second major section of the storm water pollution prevention plan addresses practices and program elements to reduce pollutants in areas identified as being potential pollutant sources for storm water discharges associated with industrial activity. In developing these requirements, the Agency has selected those practices identified in studies of BMPs which are widely used by industrial facilities with storm water discharges associated with industrial activity which it believes to be best available technology for the purpose of this permit.⁵⁰ In addition, the Agency has also addressed widely-used pollution prevention measures for storm water discharges (traditional storm water management and sediment and erosion prevention) and a requirement for facilities to certify that storm water discharges have been tested for the presence of non-storm water pollution sources.⁵¹

- (1) pollution prevention committee;
- (2) risk identification and assessment/material inventory;
- (3) preventive maintenance;
- (4) good housekeeping;
- (5) spill prevention and response procedures;
- (6) traditional storm water management;
- (7) sediment and erosion prevention;
- (8) employee training;
- (9) visual inspections; and

⁴⁹ See "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991).

⁵⁰ The certification requirement that storm water discharges associated with industrial activity have been tested for the presence of non-storm water pollution sources is similar to the certification requirement in the Form 2F application for storm water discharges associated with industrial activity (see November 16, 1990 (55 FR 47990)). EPA is including this certification provision in these general permits since dischargers may obtain coverage under these permits without the submittal of Form 2F.

⁴⁹ "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991).

(10) recordkeeping and internal reporting procedures; and

(11) certification that storm water discharges have been tested for the presence of non-storm water pollution sources.

These permits establish the framework and the basic elements for storm water pollution prevention measures. However, the plan requirements provide flexibility to allow the development of site-specific measures. At a given site, specific measures incorporated into the pollution prevention plan will reflect the sources of pollutants that have been identified at the site. For example, a facility that has identified dust and particulate generating processes as potential sources of storm water pollution will incorporate appropriate good housekeeping and traditional storm water management practices to address these sources. However, a facility without dust and particulate generating processes would not have to incorporate measures to address dust and particulate generating processes into their plan.

Pollution Prevention Committee. The Storm Water Pollution Prevention Committee identifies specific individuals within the plant organization who are responsible for developing the storm water pollution prevention plan and assisting the plant manager in its implementation, maintenance, and revision. The activities and responsibilities of the committee should address all aspects of the facility's storm water pollution prevention plan. However, EPA prefers that plant management, not the committee, have overall responsibility and accountability for the quality of the storm water pollution prevention plan, to ensure adequate implementation of the plan.

Risk identification and assessment/material inventory. The storm water pollution prevention plan is to assess the potential of various sources at the plant to contribute pollutants to storm water discharges associated with industrial activity. These activities should assist in assessing the pollution potential of runoff from specific areas of the plant. The plan must contain an inventory the types of materials handled, the location of material management activities, and types of material management activities. Facilities subject to SARA title III, section 313 must include in the plan a description of releases to land or water of SARA title III water priority chemicals that have occurred at any time after the date of three years prior to the issuance of this permit.

The layout and activities at the plant identified as high-priority areas with a significant potential for contributing pollutants to the drainage system must be assessed. Factors to consider when evaluating the reasonable pollution potential of runoff from various portions of an industrial plant include:

- Loading and unloading operations;
- Outdoor storage activities;
- Outdoor manufacturing or processing activities;
- Significant dust or particulate generating processes; and
- On-site waste management and disposal practices.

Other factors that are to be considered include the toxicity of chemicals; quantity of chemicals used, produced, or discharged; the likelihood of these materials coming into contact with storm water, and the history of significant leaks or spills of toxic or hazardous pollutants.

Chemicals should be compatible with the materials used in storage and process equipment, including the piping, valves and pumps. Incompatibility of materials can cause equipment failure resulting from corrosion, fire, or explosion. Equipment failure can be prevented by ensuring that the materials of construction for containers handling hazardous substances or toxic pollutants are compatible with the container's contents and surrounding environment.

Preventive maintenance. A preventive maintenance program involves inspection and maintenance of storm water management devices (cleaning oil/water separators, catch basins) as well as inspecting and testing plant equipment and systems to uncover conditions that could cause breakdowns or failures resulting in discharges of pollutants to surface waters. A good preventive maintenance program includes identifying equipment or systems used in the program; periodically inspecting or testing equipment and systems; adjusting, repairing, or replacing items; and maintaining complete records on the equipment and systems.

Good housekeeping. Good housekeeping requires the maintenance of a clean, orderly facility. Good housekeeping includes establishing housekeeping protocols to reduce the possibility of mishandling chemicals or equipment and training of employees in housekeeping techniques. These measures also ensure that discharges of wash waters to separate storm sewers are avoided.

Spill prevention and response procedures. Areas where potential spills

can occur, and their accompanying drainage points should be identified clearly in the storm water pollution prevention plan. Where appropriate, specifying material handling procedures and storage requirements in the plan should be considered. Procedures for cleaning up spills should be identified in the plan and made available to the appropriate personnel. The necessary equipment to implement a clean up should be available to personnel. Spill response procedures should avoid discharging to separate storm sewers unless necessary because of immediate safety considerations.

Appropriate storm water management. Based on an assessment of the potential of various sources at the plant to contribute pollutants to storm water discharges associated with industrial activity, the plan shall provide that traditional storm water management measures determined to be reasonable and appropriate shall be implemented and maintained.

For the purposes of these permits, traditional storm water management practices are measures which reduce pollutant discharges by reducing the volume of storm water discharges associated with industrial activity, such as directing storm water to vegetative swales, or preventing storm water to run onto areas of the site which conduct industrial activity. Low-cost measures that can be applied to an industrial setting may include diverting rooftop or other drainage across grass swales, cleaning catch basins, and installing and maintaining oil and grit separators. Other measures that may be appropriate include infiltration devices and unlined retention and detention basins. Traditional storm water management practices can include water reuse activities, such as the collection of storm water for later uses such as irrigation or dust control. Appropriate snow removal activities may be considered, such as selecting a site for removed snow and selecting and using deicing chemicals. The Agency requests comment on whether a facility that reuses substantially all of its storm water (for example, a facility that provides for storage and reuse of storm water from a 24 hour, 25 year storm) should be exempt from certain other storm water pollution prevention plan requirements. Such facilities would have already minimized their discharge in manner that may provide equivalent pollution removal benefits to other measures in a storm water pollution prevention plan.

However, care must be taken to evaluate whether these traditional devices cause ground water

contamination. In some cases, it is appropriate to limit traditional storm water management practices to those areas of the drainage system that generate storm water with relatively low levels of pollutants (e.g., many rooftops, parking lots, etc.).

Sediment and erosion prevention. The plan shall identify areas which, due to topography, activities, or other factors, have a high potential for soil erosion, and identify and ensure the implementation of measures to limit erosion.

Employee training. Employee training programs are necessary to inform personnel at all levels of responsibility of the components and goals of the storm water pollution prevention plan. Training should address topics such as spill response, good housekeeping and material management practices. A pollution prevention plan should identify periodic dates for such training.

Visual inspection and records. Qualified plant personnel should be identified to inspect designated equipment and plant areas. Typical inspections should include examination of pipes, pumps, tanks, supports, foundations, dikes, and drainage ditches. Material handling areas should be inspected for evidence of, or the potential for, pollutants entering the drainage system. A tracking or followup procedure must be used to ensure that appropriate and adequate response and corrective actions have been taken. Records of inspections are required to be maintained.

Recordkeeping and reporting procedures. A recordkeeping system ensures adequate implementation of the storm water pollution prevention plan. Incidents such as spills, leaks and improper dumping, along with other information describing the quality and quantity of storm water discharges should be included in the records. Inspections and maintenance activities such as cleaning oil and grit separators or catch basins should be documented and recorded.

Records of releases of a hazardous substance in excess of reporting quantities established at 40 CFR 117.3 or 40 CFR 302.4 describing each release that has occurred at any time after the date of three years prior to the issuance of this permit, measures taken in response to the release, and measures taken to prevent recurrence must be included in plans.

Non-storm discharges. Plans shall include a certification that the discharge has been tested for the presence of non-storm water discharges. The certification shall include a description of the results of any test for the presence

of non-storm water discharges, the method used, the date of any testing, and the on-site drainage points that were directly observed during the test. Such certification may not be feasible if the facility operating the storm water discharge associated with industrial activity does not have access to an outfall, manhole, or other point of access to the ultimate conduit which receives the discharge. In such cases, the source identification section of the storm water pollution plan shall indicate why the certification required by this part was not feasible.

iii. **Special requirements for storm water discharges associated with industrial activity from facilities subject to SARA title III, section 313 requirements.** The Superfund Amendments and Reauthorization Act (SARA) of 1986 resulted in the enactment of title III of SARA, the Emergency Planning and Community-Right-to-Know Act. Section 313 of title III of SARA requires operators of certain facilities that manufacture, import, process, or otherwise use listed toxic chemicals to report annually their releases of those chemicals to any environmental media. Listed toxic chemicals include 329 chemicals listed at 40 CFR part 372.

Facilities that meet all of the following criterion for a calendar year are subject to title III reporting requirements for that calendar year and must report under 40 CFR 372.30:

- The facility has 10 or more full-time employees;
- The facility is a multi-establishment complex where all establishments have a primary SIC code of 20 through 39;
- The facility is a multi-establishment complex in which one of the following is true:

—The sum of the value of products shipped and/or produced from those establishments that have a primary SIC code of 20 through 39 is greater than 50 percent of the total value of all products shipped and/or produced from all establishments at the facility;

—One establishment has a primary SIC code of 20 through 39 and contributes more in terms of value of products shipped and/or produced than any other establishment within the facility;

- The facility manufactured (including imported), processed, or otherwise used a toxic chemical in excess of an applicable threshold quantity of that chemical set forth in 40 CFR 372.25.

After 1989, the threshold quantity of listed chemicals that the facility must manufacture, import or process in order to be required to submit a release report

is 25,000 pounds per year. The threshold for a use other than manufacturing, importing or processing of listed toxic chemicals is 10,000 pounds per year. EPA estimates that 22,000 facilities nationwide will be subject to SARA title III reporting requirements after 1990. EPA promulgated a final regulation clarifying these reporting requirements on February 16, 1988 (53 FR 4500). EPA believes that the information received through reporting is a "front end" of the toxics program to which EPA is already committed and ultimately will assist in better controls for routine toxics releases and improved industrial practices to prevent and respond to accidents involving toxics.

Of the 329 toxic chemicals listed at 40 CFR 372 which are used to define the scope of SARA title III, section 313 requirements, the Agency has identified approximately 175 chemicals which it is classifying, for the purposes of this general permit, as 'section 313 water priority chemicals'. For the purposes of this general permit, "section 313 water priority chemicals" are defined as chemicals or chemical categories which also:

- (1) Are listed at 40 CFR 372.65 pursuant to SARA title, section 313;
- (2) Are present at or above threshold levels at a facility subject to SARA title III, section 313 reporting requirements; and
- (3) That meet at least one of the following criteria:
 - (i) Are listed in appendix D of 40 CFR part 122 on either table II (organic priority pollutants), table III (certain metals, cyanides, and phenols) or table V (certain toxic pollutants and hazardous substances);
 - (ii) Are listed as a hazardous substance pursuant to section 311(b)(2)(A) of the CWA at 40 CFR 116.4; or
 - (iii) Are pollutants for which EPA has published an acute or a chronic toxicity criteria.

The Agency estimates that about 9,000 facilities with storm water discharges associated with industrial activity nationwide have section 313 water priority chemicals in threshold amounts.

The large amounts of toxic chemicals at facilities with section 313 water priority chemicals raises concerns regarding the potential of material handling and storage operations to add pollutants to storm water discharges associated with industrial activity. As discussed earlier in this fact sheet, the material management practices associated with the storage and use of toxic chemicals is a major potential source of pollutants in storm water

discharges associated with industrial activity. The Agency believes that the threshold criteria established in SARA title III, section 313, along with the regulatory definition of storm water discharge associated with industrial activity, which for many facilities in SIC codes 20-39, only includes storm water from areas where material handling equipment or activities, materials or industrial machinery are exposed to storm water (see 40 CFR 122.26(b)(14)), identify potential risks in a manner that is appropriate for use in developing priorities for establishing the applicability of specialized monitoring and pollution prevention measures for facilities which use and manage toxic chemicals.

In evaluating risks and establishing regulatory priorities for facilities with storm water discharges associated with industrial activity, the Agency believes that the large amounts of toxic chemicals found at facilities with section 313 water priority chemicals pose sufficient risk to warrant special permit conditions for these facilities. The Agency is requesting comments on two primary options for developing special permit conditions for these facilities.

Under Option A, the permit would provide for:

- (1) In addition to baseline requirements for storm water pollution prevention plans, special pollution prevention measures, including spill prevention and containment requirements for areas of the facility used for material management of these chemicals;

- (2) An acute WET limit for storm water associated with industrial activity that comes into contact with any equipment, tank, container, or other vessel used for section 313 water priority chemicals; and for truck and rail car loading and unloading areas for liquid section 313 water priority chemicals; and

- (3) Biannual (twice a year) monitoring and reporting requirements for a number of parameters including acute whole effluent toxicity.

Under Option B, the general permits would provide for:

- (1) An acute WET limit for storm water associated with industrial activity that comes into contact with any equipment, tank, container, or other vessel used for section 313 water priority chemicals; and for truck and rail car loading and unloading areas for liquid section 313 water priority chemicals; and

- (2) Monitoring and reporting requirements at a higher frequency⁵² than biannual (twice a year) monitoring for acute whole effluent toxicity for discharges of storm water that comes into contact with any equipment, tank, container, or other vessel used for section 313 water priority chemicals. Under Option B, the Agency is considering and requests comment on a range of monitoring options for the WET limitation, including monitoring biannually, quarterly, or every discharge event. Under Option B, facilities would remain subject to the baseline requirements for storm water pollution prevention plans, but would not be subject to the technology-based spill prevention and containment requirements outlined in Option A.

Option B would provide dischargers with more flexibility than Option A for complying with the permit. By providing additional flexibility by not requiring spill prevention and containment requirements, Option B may reduce compliance costs at facilities whose storm water discharges are not toxic. In addition, by not prescribing the specific method for controlling toxic storm water discharges, facilities can better take into account local factors in designing an appropriate cost-effective approach for meeting the WET test performance standard. Establishing a performance standard also encourages the development of new innovative and more cost-effective approaches for controlling toxic storm water discharges.

EPA requests comments on whether the criteria used for identifying priority facilities subject to specialized containment provisions and the WET effluent limitation are appropriate or whether these requirements should address a smaller or larger set of facilities including whether any set of facilities should be subject to the provisions of Option A or B.

⁵² Under Option A, the draft permit proposes biannual monitoring for storm water discharges from containment areas. The Agency believes that if the final permit follows Option B (e.g. provides for an effluent limitation but does not require containment), then a higher frequency of monitoring may be appropriate for a number of reasons. First, where containment is required, such controls may provide the operator with a better opportunity to evaluate and correct periodic releases of chemicals which may influence the toxicity of the discharge prior to discharge. Second, facilities with containment systems are expected to discharge storm water less frequently than facilities without containment systems, thereby reducing the variability of system discharges. Third, discharges from containment systems may exhibit less variability due to mixing occurring in the containment unit, thereby requiring less frequent monitoring to characterize the discharge. EPA requests comment on the appropriate monitoring frequency for these discharges if the permit does not require containment.

One alternative on which EPA specifically requests comments would be to impose the requirements of Options A or B only on facilities (including facilities that are not subject to SARA title III, section 313) that have had a discharge of a hazardous substance in excess of reporting quantities established at 40 CFR 117.3 or 40 CFR 302.4 at any time after the date of three years prior to the issuance of these general permits which either discharge through a separate storm sewer systems or that otherwise comes into contact with storm water.

The Agency also requests comment on alternative approaches, including either alternative design standards or performance standards,⁵³ to establishing permit requirements which target containment requirements for chemical storage and handling activities where aquatically toxic chemicals are likely to be exposed to, or otherwise come into contact with, storm water. Comments addressing alternative approaches should also provide a description of the alternative performance standards or design standards. The Agency requests comments on the advantages and disadvantages of using design standards or performance standards for controlling storm water discharges associated with industrial activity. Comments can also address other regulatory or market incentives that can assure sufficient spill control and material managing practices that would make the imposition of containment requirements unnecessary.

Under Option A, the general permit would provide that storm water pollution prevention plans for facilities with section 313 water priority chemicals must, in addition to the requirements associated with the baseline pollution prevention plans, provide for spill prevention and containment-oriented controls.⁵⁴

⁵³ The most commonly used performance standards under the CWA are numeric effluent limitations and whole effluent toxicity limitations.

⁵⁴ The spill prevention and containment provisions for hazardous substances were analyzed in the 1979 survey of BMPs (see "NPDES Best Management Practice Guidance Document", U.S. EPA, December 1979, EPA-600/9-79-045); and the draft "Analysis of Implementing Permitting Activities for Storm Water Discharges Associated With Industrial Activity", EPA, 1991. EPA has also analyzed similar pollution prevention requirements for oil in the Spill Prevention, Control, and Countermeasure (SPCC) plan requirements at 40 CFR part 112, (see "The Oil Spill Prevention, Control, and Countermeasures Program Task Force Report", EPA, May 1988).

Containment involves the use of physical structures or collection/drainage equipment used to confine a release of material after it escapes from its physical location or containment. Dikes, berms, retaining walls, impounding basins, diversion ponds, and retention ponds surrounding material storage tanks are the most common examples of containment. Containment systems must be sufficiently impervious to contain spilled Section 313 water priority chemicals. The spill prevention and containment provision of these general permits are designed to mitigate the discharge of toxic chemicals to waters of the United States from both significant spill events and from more routine material management practices and leaks.

Under Option A, the spill prevention and containment control requirements would only apply to priority areas of facilities with section 313 water priority chemicals (e.g. portions of the facility where section 313 water priority chemicals are stored or managed and which generate storm water discharges associated with industrial activity).⁵⁵ Secondary containment requirements would only be required for liquid storage areas where storm water comes into contact with equipment, tank, container, or other vessel used for section 313 water priority chemicals; and truck and rail car loading and unloading areas for liquid section 313 water priority chemicals. In developing the containment-oriented provisions of Option A, the Agency has provided flexibility to allow facilities to use or modify appropriate existing containment approaches that facilities currently employ.

EPA believes that where, economically achievable, containment structures for storm water associated with industrial activity that comes into contact with any equipment, tank,

container, or other vessel used for section 313 water priority chemicals; and for truck and rail car loading and unloading areas for liquid section 313 water priority chemicals can prevent discharges of toxic chemicals after releases associated with spills, chronic leaks, and other material management practices occur.

Option B can also result in the implementation of measures to prevent discharges of toxic chemicals associated with spills, chronic leaks, and other material management practices.

Option A provides that if the installation of secondary containment structures or equipment is not economically achievable at a given facility, the facility operator must develop and implement a spill contingency and integrity testing plan which provides, as an alternative to secondary containment, a description of measures to ensure that discharges of toxic amounts of section 313 water priority chemicals do not occur. In these situations, a spill contingency and integrity plan must include:

- A detailed description which demonstrates that secondary containment requirements are not economically achievable based on the appropriate factors described at 40 CFR 125.3(d)(3);
- A spill contingency plan must include, at a minimum; a description of response plans, personnel needs, and methods of mechanical containment (such as the use of sorbents, booms, collection devices, etc.); steps to be taken for removal of spilled section 313 water priority chemicals; access to and availability of sorbents and other equipment; and such other information as required by the Director;
- The testing component of the plan must provide for conducting integrity testing of storage tanks at least once every five years, and conducting integrity and leak testing of valves and piping a minimum of at least once every year; and
- A written and actual commitment of manpower, equipment and materials required to comply with the permit and to expeditiously control and remove any quantity of section 313 water priority chemicals that may result in a toxic discharge.

Spill contingency and integrity plans can prevent discharges of toxic chemicals by minimizing the potential for spills or leaks of toxic chemicals to occur or for material management practices to release toxic chemicals. In addition, where such releases occur, this approach can minimize the potential for contact of storm water with toxic

chemicals. Option A requires secondary containment where achievable because of the degree of certainty that such containment will prevent toxic discharges. Nonetheless, where effectively implemented, a spill contingency and integrity testing plan may result in a level of control similar to that of installing containment structures, (e.g. the prevention of discharges of toxic amounts of section 313 water priority chemicals). Thus, spill contingency and integrity plans constitute an acceptable alternative set of requirements for some facilities based on the appropriate factors at 40 CFR 125.3(d)(3) (iii) and (v). Option B would also result in actions which would prevent toxic discharges.

EPA requests comment on the frequency and cost of integrity testing for tanks, valves, or pipes and whether integrity testing is an appropriate alternative to containment provisions where secondary containment is not economically achievable.

The Agency also notes that under both Options A and B, facilities with storm water discharges associated with industrial activity which, based on an evaluation of site specific conditions, believe that the appropriate conditions of these permits do not adequately represent BAT and BCT requirements for the facility may request an individual permit by submitting to the Director an individual application (Form 1 and Form 2F). Under Option A, the storm water pollution prevention plans at facilities with section 313 water priority chemicals and with storm water discharges associated with industrial activity must be reviewed and certified by a Registered Professional Engineer. With the certification, the Engineer must attest that the storm water pollution prevention plan has been prepared in accordance with good engineering practice. Such certifications will in no way relieve the owner or operator of a facility covered by the plan of their duty to prepare and fully implement such a plan.

The spill prevention and containment provision of Option A are designed to mitigate the discharge of toxic chemicals to waters of the United States from both significant spill events and from more routine material management practices and leaks. The Agency requests comment on a number of other approaches to meet these objectives. EPA requests comments on providing permittees with the option of Professional Engineer's certification that material management practices and controls provide equivalent control as the design specifications in the draft

⁵⁵ It should be noted that many facilities which are subject to SARA title III, section 313 reporting requirements because they manage section 313 water priority chemicals do not generate storm water discharges associated with industrial activity. The regulatory definition of "storm water associated with industrial activity" (40 CFR 122.26(b)(14)) addresses facilities in all Standard Industrial Classification (SIC) codes between 20 and 39 (as well as additional classes of facilities). However, facilities under SIC codes 20, 21, 22, 23, 2424, 25, 265, 267, 27, 283, 285, 30, 31 (except 311), 323, 34 (except 3441), 35, 36, 37 (except 373), 38, 39 which are not otherwise addressed in other parts of the regulatory definition only generate storm water associated with industrial activity where material handling equipment or activities, raw materials, intermediate products, final products, waste materials, by-products, or industrial machinery are exposed to storm water. Such facilities which do not generate storm water discharges associated with industrial activity are not subject to these permits (see (40 CFR 122.26(b)(14)(xi))).

permit. The Agency requests comment on what level of assurance is appropriate to determine that material management practices and controls are sufficient to provide equivalent control as the design specifications in the draft permit.

Storm water collected in containment areas can pick up significant levels of pollutants where material management practices result in leaks, spills or other exposure to chemicals. Rather than attempt to establish specific numeric limits of each type of pollutant subject to section 313, the Agency believes that it is more appropriate to establish acute whole-effluent toxicity limits for these discharges. For this reason, under both Options A and B, the general permit would establish an acute whole-effluent toxicity effluent limitation applied as a technology-based performance standard for discharges of storm water that comes into contact with any equipment, tank, container, or other vessel used for section 313 water priority chemicals, and for storm water discharged from truck and rail car loading and unloading areas for liquid section 313 water priority chemicals.

Toxicity monitoring and WET limits have been used in the NPDES program to address a wide range of discharges, including intermittent discharges. Applying numeric or toxicity limits on a technology-basis to intermittent discharges such as storm water protects against periodic releases of high levels of pollutants. Establishing limits for intermittent discharges is consistent with the approach taken in the NPDES program which does not allow for periodic exceedances of limits by continuous discharges.

For the purpose of this permit, EPA is defining toxicity for use as a technology-based limit as not being lethal to 20% or more of the more sensitive of either appropriate fish or invertebrate test organisms. EPA is requesting comment as whether this is the appropriate definition of the toxicity parameter as a technology-based limit for the purposes of this permit.

Since these discharges are generated from limited-sized, specific storage and material handling areas, a wide range of technologies are available to reduce the toxicity of the limited volume of storm water that is subject to the WET effluent limitation. The Agency anticipates that most storm water discharges from these areas at well-maintained facilities with good housekeeping practices will not exhibit acute toxicity. For the majority of storm water discharges that do exhibit acute toxicity, the toxicity can be reduced by improving storage or material handling procedures, practices

or equipment. Other classes of discharges may require various types of end-of-pipe treatment or various offsite disposal options such as discharging to a POTW.⁵⁶

EPA requests comments on possible alternatives to the WET effluent limitation for storm water discharges that come into contact with any equipment, tank, container, or other vessel used for section 313 water priority chemicals, or from truck and rail car loading and unloading areas for liquid section 313 water priority chemicals, including: (1) Establishing an effluent limitation that provides for zero discharge (compliance determinations based on the level of detection) for the specific Section 313 water priority chemicals used at the site, along with the containment provisions of the draft general permits. (Any untreated overflow from containment facilities properly designed, constructed and operated to treat the volume of runoff associated with a 25 year, 24 hour rainfall event would not be subject to the effluent limitation). This approach would be based on the showing that the best available technology for these facilities would include containment requirements and material management practices and other measures that ensured that storm water did not come into contact with SARA title III, section 313 chemicals; (2) establishing a zero discharge effluent limitation (compliance determinations based on the level of detection) without the containment provision of the draft general permit, and requiring discharge sampling at a higher frequency (such as quarterly or at every storm event) to ensure permit compliance. This approach is similar to approach 1, but would not rely on containment provisions to ensure and assist in meeting the zero discharge effluent limitation; (3) modifying approach 1 and 2 by establishing a non-zero effluent limitation for specific section 313 water priority chemicals based on BAT/BCT criteria (the Agency requests comment on which chemicals this approach would be appropriate for); (4) using an alternative indicator parameter other than toxicity for establishing limitations (the Agency requests comments on what indicator parameters would be appropriate for this purpose); and (5) instead of the WET effluent limitation, require facilities that detect a statistical difference in acute toxicity between the control and 100% effluent to submit a toxicity reduction evaluation (TRE) to

the Director within one year.⁵⁷ Under this last approach, a TRE could be used in issuing an individual permit containing technology or water quality-based requirements based on an evaluation of site-specific conditions.

The Agency believes that the increased use of toxicity testing in the NPDES program has resulted in the development of adequate laboratory capacity to conduct the toxicity testing required by these permits. The Agency requests comment on any anticipated problems with inadequate laboratory capacity to conduct toxicity testing in the States addressed by these permits.

The draft general permits provide that any untreated overflow from containment facilities properly designed, constructed and operated to treat the volume of runoff associated with a 24 hour, 25 year rainfall event is not subject to the WET limitation. The 24 hour, 25 year rainfall event is the most commonly used design storm for BAT national effluent limitations guidelines which address storm water. The 24 hour, 25 year rainfall event provides a reasonable margin of safety when sizing secondary containment units.⁵⁸ EPA requests comments on the use of alternative storm events to a 25 year, 24 hour rainfall event in association with both the WET effluent limitation and containment provisions of the general permits.

iv. *Special requirements for storm water discharges associated with industrial activity from salt storage facilities.* The draft permits provide that storm water pollution prevention plans for facilities with storage piles of salt used for deicing or other commercial or industrial purposes must, in addition to the requirements associated with the baseline pollution prevention plans, enclose or cover their salt storage to prevent exposure to precipitation.⁵⁹

v. *Special requirements for storm water discharges associated with industrial activity through large and medium municipal separate storm sewer systems.* Facilities covered by these

⁵⁷ EPA has developed the following guidance documents which describe methods and procedures for conducting TREs and Toxicity Identification Evaluations: (1) "Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations" (EPA/600/2-88/070); (2) "Methods for Aquatic Toxicity Identification Evaluations: Phase 1 Toxicity Characterization Procedures (EPA/600/3-88/034), Phase 2 Toxicity Identification Procedures (EPA/600/3-88/035), Phase 3 Toxicity Confirmation Procedures (EPA/600/3-88/036).

⁵⁸ "NPDES Best Management Practices Guidance Document", EPA, 1979, (EPA-600/9-79-045).

⁵⁹ See "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991).

⁵⁶ See "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" EPA, 1991.

permits must comply with applicable requirements in municipal storm water management programs developed under NPDES permits issued for the discharge of the municipal separate storm sewer system that receives the facility's discharge, provided the discharger has been notified of such conditions. Part 5 of this fact sheet discusses how permits for discharges from large and medium municipal separate storm sewer systems will typically require municipal permittees to develop storm water management programs which address storm water associated with industrial activity which discharges through their system.

vi. Special requirements for storm water discharges associated with industrial activity composed of coal pile runoff.

The draft general permits establish effluent limitations of 50 mg/l total suspended solids (TSS) and a pH range of 6 to 9 for storm water discharges associated with industrial activity.⁶⁰ This effluent limitation is similar to the effluent guideline limitation for coal pile runoff from facilities in the steam electric power generating point source category (see 40 CFR 423.12(b)(9)).

The limitation does not apply to any untreated overflow from facilities properly designed, constructed and operated to treat the volume of coal pile runoff which is associated with a 25 year, 24 hour rainfall event. Providing a limit to effluent guidelines for events that exceed a specified storm event provides operators with a basis for installing and operating a treatment system, as the design of the system, particularly the collection devices, will depend on the design storm chosen. The 25 year, 24 hour storm is most commonly used in the BAT national effluent limitations guideline that have been developed by EPA.⁶¹ The effluent guideline limitation for coal pile runoff from facilities in the steam electric power generating point source category at 40 CFR 423.12(b)(9) incorporates a 10 year, 24 hour design storm into a best practicable control technology currently available (BPT) limit. BCT and BAT effluent limitation guidelines for coal pile runoff are currently reserved. The Agency believes that the appropriate design storm for coal pile runoff addressed by these permits is the more stringent 25 year, 24 hour design storm

as these permits establish BAT/BCT limits (which are typically more stringent than BPT limits), and the 25 year, 24 hour storm is more commonly used in effluent guideline limitations based on the BAT or BCT standards. The Agency requests comments on the appropriate design storm (e.g. the 25 year, 24 hour, or the 10 year, 24 hour) for this limitation.

vii. Public Availability. The draft general permits clarify that all storm water pollution prevention plans required under the permit are considered reports that shall be available to the public under section 308(b) of the CWA. However, the permittee may claim any portion of a storm water pollution plan as confidential in accordance with 40 CFR part 2.

8. Monitoring and Reporting Requirements

a. Monitoring requirements. The draft permits have been developed to provide different monitoring requirements for certain classes of discharges. Monitoring and reporting requirements are established for storm water discharges associated with industrial activity from six classes of industries: SARA title III, section 313 facilities with water priority chemicals; primary metal facilities; land disposal units; wood treatment facilities (wood preservers) using chlorophenolic/creosote formulations; wood treatment facilities (wood preservers) using arsenic/chromium preservatives; and coal pile runoff. These categories and the associated monitoring and reporting requirements are discussed in more detail below. These categories of industrial facilities have been selected as priority sites in terms of monitoring requirements based on an evaluation of activities at these types of facilities which have the potential for contributing toxic pollutants to storm water discharges. EPA believes that requiring these facilities to submit monitoring reports will allow the Agency to continue to assess the nature of pollutants in storm water discharges from these types of facilities. EPA requests comments on the appropriateness of categories specific monitoring and reporting requirements for other categories of industrial facilities.

The draft general permit provides that operators of storm water discharges associated with industrial activity from oil and gas operations have the option of either monitoring their storm water discharges associated with industrial activity annually or, in lieu of the monitoring, a facility may have a

Registered Professional Engineer certify that a storm water pollution plan has been prepared and is being implemented in accordance with the requirements of the permit.

Operators of other storm water discharges associated with industrial activity covered by the draft general permits which are not addressed by one of the industry-specific monitoring requirements are required to conduct annual monitoring of a set of specified parameters. Facilities subject to these 'baseline' monitoring requirements are subject to record keeping requirements, but generally do not have reporting requirements. Although EPA is proposing to not require the reporting of monitoring data for facilities without industry-specific monitoring requirements, the Agency believes that monitoring requirements remain appropriate as they will assist operators of storm water discharges in identifying sources of pollutants and in evaluating the effectiveness of the implementation of their storm water pollution prevention plans. In addition, EPA may review monitoring data during the term of the permit or during the permit reissuance process for the purposes of evaluating the effectiveness of a facility's storm water pollution prevention plan and for determining priorities for future permit issuance or modification.

i. Monitoring requirements—Baseline monitoring requirements. The following eight parameters have been identified as baseline parameters that generally form the foundation for different monitoring requirements in the permit: Oil and grease, pH, five-day biochemical oxygen demand (BOD5), chemical oxygen demand (COD), total suspended solids (TSS), total phosphorus, total Kjeldahl nitrogen (TKN), and nitrate plus nitrite nitrogen.

Oil and grease is a common industrial pollutant which can be indicative of material management, housekeeping and transportation activities. TSS is a common pollutant found in storm water discharges that reflects surface disturbances and material management practices, and can have significant impacts on receiving waters. Oxygen demand (COD and BOD5) will help the permitting authority evaluate the oxygen depletion potential of the discharge. BOD5 is the most commonly used indicator of oxygen demand. COD is considered a more inclusive indicator of oxygen demand, especially where metals interfere with the BOD5 test, and generally is better suited for comparing the oxygen demand of a storm water discharge with that of other discharges. The pH will provide important

⁶⁰ See "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991).

⁶¹ BAT effluent limitations guidelines that incorporate a 25-year, 24-hour storm event include animal feedlots (40 CFR part 412), fertilizer manufacturing (40 CFR part 418), and phosphate manufacturing (40 CFR part 422).

information on the potential availability of metals to the receiving flora, fauna, and sediment. In some cases it will provide information regarding material management. Total phosphorus, TKN, nitrate plus nitrite nitrogen are measures of nutrients that can impact water quality. In addition, most of the monitoring requirements contain a requirement to monitor pollutants subject to effluent limitation guidelines. Effluent limitation guidelines can identify industry-specific pollutants which may be of concern.

SARA title III, section 313 Facilities. The large amounts of toxic chemicals stored and utilized at SARA title III, section 313 facilities with section 313 water priority chemicals raises concerns regarding the potential of material handling and storage operations to add pollutants to storm water discharges associated with industrial activity. Storm water discharges associated with industrial activity that comes into contact with any equipment, tank, container, or other vessel used for title III, section 313 water priority chemicals; and for truck and rail car loading and unloading areas for liquid title III, section 313 water priority chemicals must be monitored semiannually (2 times per year) for: Oil and grease; biochemical oxygen demand (BOD₅), chemical oxygen demand (COD), total suspended solids, total Kjeldahl nitrogen (TKN), total phosphorus, pH, nitrate plus nitrite nitrogen, acute whole effluent toxicity, and any chemical constituent for which the operator is subject to reporting requirements under section 313 of the Emergency Planning and Community Right to Know Act of 1986 for chemicals which are classified as "section 313 water priority chemicals".

The monitoring requirements for storm water discharges associated with industrial activity that comes into contact with any equipment, tank, container, or other vessel used for title III, section 313 water priority chemicals; and for truck and rail car loading and unloading areas for liquid title III, section 313 water priority chemicals modify the baseline parameters for other storm water discharges by adding the requirement to test for any chemical constituent for which the operator is subject to reporting requirements under section 313 and acute whole effluent toxicity. Acute whole effluent toxicity monitoring requirements are being established for two reasons: (1) Acute whole effluent toxicity is a non-chemical specific parameter suitable for characterizing the potential impacts of the wide range of chemicals and chemical formulations expected to be

found at the wide variety of section 313 facilities; and (2) To support the acute whole effluent toxicity limitation proposed in the draft general permits. Requirements to test chronic toxicity have not been included in this permit because discharges from the containment areas are expected to be generally less frequent than other storm water discharges (e.g. containment system discharges are typically not expected to occur with each event) and relatively low volume where the area generating the storm water discharges associated with industrial activity subject to the containment requirements described in the pollution prevention plans developed under this permit is relatively small. Monitoring requirements for storm water discharges from containment areas are not applicable where there is not a discharge to a waters of the United States (including discharges through municipal separate storm sewer systems to waters of the United States), such as where the discharge is to a POTW.

Storm water discharges associated with industrial activity from other portions of SARA title III section 313 facilities (e.g. those storm water discharges associated with industrial activity that are not composed of storm water that comes into contact with any equipment, tank, container, or other vessel used for title III, section 313 water priority chemicals, or from truck and rail car loading and unloading areas for liquid title III, section 313 water priority chemicals) are subject to baseline monitoring requirements of the permit.

Primary Metal Facilities. Facilities classified as Standard Industrial Classification (SIC) 33 (Primary Metal Industry) include steel works, blast furnaces, rolling and finishing mills, iron and steel foundries, primary and secondary smelting and refining of nonferrous metals, rolling, drawing and extruding of nonferrous metals, and nonferrous foundries. These facilities typically have significant dust or particulate generating processes, as well as other activities, which can contribute a wide range of pollutants, including metals, to storm water discharges associated with industrial activity.

Under the draft general permits facilities classified as SIC 33 must monitor semiannually (2 times per year) all storm water discharges associated with industrial activity that are discharged from the facility for: oil and grease, pH, BOD₅, COD, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, any pollutant limited in an effluent guideline

to which the facility is subject, acute whole effluent toxicity, total lead, total cadmium, total copper, total arsenic, and total chromium.

The monitoring requirements for storm water discharges associated with industrial activity from primary metal facilities modify the baseline monitoring requirements by adding requirements to monitor acute whole effluent toxicity, and five metals. The five metals selected are typically the most common toxic metals generally expected in storm water from primary metal facilities. However, dust or particulate generating processes or material management activities at primary metal facilities can result in a number of other metals and pollutants in storm water discharges associated with industrial activity from primary metal facilities. Acute whole effluent toxicity is a non-chemical specific parameter suitable for characterizing the potential impacts of these additional pollutants.

Land Disposal Units. Land disposal units with storm water discharges associated with industrial activity may receive a diverse range of industrial wastes. EPA has summarized case studies documenting surface water impacts and ground water contamination incidents of land disposal units (see August 30, 1988 (53 FR 33372)). Evaluation of 163 case studies revealed surface water impacts at 73 facilities. Elevated levels of organics, including pesticides, and metals have been found in ground water and/or surface water at many sites.

Facilities that discharge storm water associated with industrial activity from any active or inactive landfill, land application site, or open dump that received any industrial wastes are required to monitor semiannually (2 times per year) for: ammonia, bicarbonate, calcium, chloride, total iron, magnesium (total), magnesium (dissolved), nitrate plus nitrite nitrogen, potassium, sodium, sulfate, chemical oxygen demand (COD), total dissolved solids (TDS), total organic carbon (TOC), pH, total arsenic, total barium, total cadmium, total chromium, total cyanide, total lead, total mercury, total selenium, total silver, volatile organic carbon (VOC) acute whole effluent toxicity.

The parameters addressed by the monitoring requirements for storm water discharges associated with industrial activity from land disposal units is similar to the parameters addressed by proposed ground water monitoring requirements for municipal solid waste landfills established under subtitle D of RCRA (see August 30, 1988 (53 FR

33372)). The Agency believes that the pollutants identified for the purpose of evaluating ground water quality at land disposal units should also be considered when evaluating storm water discharges. Given the wide range of materials that may be disposed at land disposal units, many other pollutants may potentially be found in storm water discharges from land disposal units. For this reason, the draft permits require sampling of acute whole effluent toxicity. The toxicity parameter is particularly relevant in situation, since the evaluation of the toxicity parameter does not require specific chemical identification.

Wood Treatment (chlorophenolic/creosote formulations). Pollutants in storm water runoff from treated material storage yards at wood-preserving facilities were studied by EPA in 1981 in support of effluent guidelines development, and in support of a proposed hazardous waste listing in 1988 (December 30, 1988 (53 FR 53287)). Several organic pollutants were found at significant concentrations, including pentachlorophenol, fluoranthene, benzo(a)anthracene, chrysene, phenanthrene, and pyrene.

All storm water discharges associated with industrial activity from areas that are used for wood treatment, wood surface application or storage of treated or surface protected wood at any wood preserving or wood surface facilities that currently use chlorophenolic formulations and/or creosote formulation shall be monitored semiannually (2 times per year) for: oil and grease, pH, BOD5, COD, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, acute whole effluent toxicity, and pentachlorophenol.

The monitoring requirements for storm water discharges associated with industrial activity from wood treatment facilities modify the baseline monitoring requirements by adding requirements to monitor pentachlorophenol, acute whole effluent toxicity. Pentachlorophenol is a major constituent of preservatives used at these facilities, and acute whole effluent toxicity testing will assist in assessing the presence of other toxics in these discharges.

Wood Treatment (arsenic/chromium preservatives). Arsenic/chromium preservatives consist of mixtures of bivalent copper, pentavalent arsenic, hexavalent chromium or fluorides. The three most widely used compounds for commercial wood treatment include chromatic copper arsenate (CCA); ammoniacal copper arsenate (ACA); and fluorochrome-arsenate phenol (FCAP). Pollutants in storm water runoff from treated material storage yards at

wood-preserving facilities were studied by EPA in 1981 in support of effluent guidelines development, and in support of a proposed hazardous waste listing in 1988. Certain metals, including chromium, copper, and arsenic, were found at high levels in storm water from wood-preserving facilities using inorganic arsenical preservatives.

All storm water discharges associated with industrial activity from areas that are used for wood treatment or storage of treated wood at any wood preserving facilities that currently use inorganic preservatives containing arsenic or chromium shall be monitored semiannually (2 times per year) for: Oil and grease, pH, BOD5, COD, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, total arsenic, total chromium, and total copper.

The monitoring requirements for storm water discharges associated with industrial activity from wood treatment or storage of treated wood at any wood preserving facilities that currently use inorganic preservatives containing arsenic or chromium modify the baseline monitoring requirements by adding requirements to monitor arsenic, chromium and copper, three major toxic constituents found in the preservatives used by these facilities.

Coal Pile Runoff. Coal pile runoff has been shown to contain significant levels of suspended solids, copper, iron, aluminum, nickel, zinc and other trace metals. (See "Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category", (EPA-440/182/029)).

All storm water discharges associated with industrial activity from coal piles shall be monitored semiannually (2 times per year) for: Oil and grease, pH, TSS, total copper, total nickel and total zinc.

The monitoring requirements for storm water discharges associated with industrial activity from coal piles support the effluent limitations for pH and TSS in these permits. The three metals, total copper, total nickel, and total zinc have been shown to be at concentrations of concern in coal pile runoff (see Table 3 above). Oil and grease is a common industrial pollutant which can be indicative of material management, housekeeping and transportation activities.

Oil and gas exploration or production operations. Operators of storm water discharges associated with industrial activity from oil and gas exploration or production operations have the option of either monitoring their storm water discharges associated with industrial

activity annually or, in lieu of the monitoring, a facility may have a Registered Professional Engineer certify that a storm water pollution plan has been prepared and is being implemented in accordance with the requirements of the permit.

Oil and Gas Exploration or Production Operations (Sampling Option). Operators of storm water discharges associated with industrial activity from oil and gas exploration and production operations which elect to conduct monitoring rather than obtain a Professional Engineer's certification are required to analyze samples annually (once a year) for the following parameters: Oil and grease, pH, BOD5, COD, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, and any pollutant limited in an effluent guideline to which the facility is subject. The rationale for selecting these baseline parameters is discussed above.

Oil and Gas Exploration or Production Operations (Certification Option). Operators of storm water discharges associated with industrial activity from oil and gas exploration or production operations have the option of obtaining a Professional Engineer's certification that a storm water pollution plan has been prepared by the facility and is being implemented in accordance with the requirements of the permit. Dischargers pursuing this option are required to obtain recertification of the plan every three years. By means of certification, the Engineer shall attest that: The Engineer has visited and examined the facility and is familiar with the provisions of this part; the Plan has been prepared in accordance with good engineering practice; reserve pits used to hold spent drilling muds or cuttings have been designed and built to prevent storm induced overflows; and the Plan is adequate for the facility. Such certifications will in no way relieve the owner or operator of a facility covered by the plan of their duty to prepare and fully implement such plan.

Information from sources such as non-point source assessments developed pursuant to section 319(a) of the CWA indicate that significant water quality impacts can be caused by wet-weather failure of on-site waste disposal systems at oil and gas exploration and production operations (such as storm induced overflows of reserve pits used to hold spent drilling muds and cuttings). Periodic sampling of discharges may not be sufficient to identify or predict these events. Rather, a PE certification may provide a more appropriate link for evaluating the

potential for and preventing these types of events.

Allowing this class of dischargers the option of obtaining Professional Engineer's certifications addresses a number of concerns. First, Professional Engineering certifications will provide a direct link to the implementation of the central provision of the general permits, the requirement to develop and implement storm water pollution prevention plans. Second, providing dischargers with the option of either conducting annual sampling or obtaining a Professional Engineer's certification will provide the discharger with flexibility to select the most cost-effective manner to comply with the draft permits. Third, this approach will reduce the administrative burdens on EPA while not limiting its ability to ensure permit compliance.

Storm Water Discharges Not Otherwise Addressed. Operators of storm water discharges covered by the draft general permits which are not subject to an industry specific monitoring requirement under the permits shall monitor their storm water discharges associated with industrial activity annually (once a year) for the following baseline parameters: oil and grease, pH, BOD₅, COD, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, and any pollutant limited in an effluent guideline to which the facility is subject. The rationale for selecting these baseline parameters is discussed above.

ii. *Volume estimates.* The draft general permits take two approaches for estimating volumes associated with storm water discharges. The first approach, which is applicable to two classes of facilities, discharges from SARA title III section 313 containment areas for chemicals which are classified as 'Section 313 water priority chemicals', and discharges from land disposal units, requires that an estimate of the total volume of the discharge monitored be provided. This approach is taken for these types of facilities because it is anticipated that some degree of retention will be provided for the storm water discharges associated with industrial activity from these facilities⁶² and that providing volume estimates will be more practicable.

Other classes of storm water discharges covered by the general permits (wood preserving facilities,

primary metal facilities, and other discharges without industry specific requirements) are required to provide an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)). This information assists in characterizing the magnitude of the volume of discharges that will occur for different magnitude storm events. In addition, this information will generally be easier for dischargers to provide.

iii. *Sampling waiver.* The draft general permits have an "adverse climatic conditions" provision allowing a discharger to submit a description of why samples could not be collected in lieu of sampling data when the discharger is unable to collect samples due to climatic conditions which prohibit the collection of samples including weather conditions that create dangerous conditions for personnel (such as local flooding, high winds, hurricane, tornadoes, electrical storms, etc.) or otherwise make the collection of a sample impracticable (drought, extended frozen conditions, etc.).

iv. *Sample type.* The requirements for the type of samples taken vary depending on the nature of the discharge. A minimum of one grab sample may be taken for discharges from holding ponds or other impoundments with a retention period greater than 24 hours. For all other discharges, data shall be reported for both a grab sample and a composite sample. All such samples shall be collected from the discharge resulting from a storm event that is greater than 0.1 inches and at least 72 hours from the previously measurable (greater than 0.1 inch rainfall) storm event. The grab sample shall be taken during the first thirty minutes of the discharge (or as soon thereafter as practicable). The composite sample shall either be flow-weighted or time-weighted. Composite samples may be taken with a continuous sampler or as a combination of a minimum of three sample aliquots taken in each hour of discharge for the entire discharge or for the first three hours of the discharge, with each aliquot being separated by a minimum period of fifteen minutes. Only grab samples must be used for pH, cyanide, and oil and grease.

v. *Reporting requirements.* Dischargers addressed by the sampling requirements for the six classes of storm water discharges associated with industrial activity (SARA Title III, land disposal units, primary metal, wood preserving (chlorophenolic/creosote

formulations), wood preserving (arsenic/chromium preservatives), and coal pile runoff) are required to submit signed discharge monitoring reports (DMRs) to the appropriate EPA Regional Office biannually.

Dischargers with at least one storm water discharge associated with industrial activity through a large or medium municipal separate storm sewer system (systems serving a population of 100,000 or more) in addition to filing copies of the DMR to the Regional Office, must submit signed copies to the operator of the municipal separate storm sewer system biannually.

Operators of storm water discharges associated with industrial activity from oil and gas exploration or production operations and that conduct sampling requirements rather than obtaining a Professional Engineer's certification, as well as operators of other storm water discharges that are not subject to industry specific monitoring requirements, are not required to submit monitoring reports unless specifically requested by the Director. These dischargers must maintain sampling data collected during the term of the permit. Upon reissuance of a new general permit, the permittee will be required to notify the Director of their intent to be covered by the new general permit. The Agency intends that NOI provisions for the reissued permits will require dischargers to summarize the quantitative data they had collected during the previous permit term. This approach will reduce the administrative burdens associated with reviewing annual DMRs for these discharges, while providing for an opportunity for Agency review at least every five years. Further, reviewing discharger data during the permit reissuance process will assist in efforts to implement the permitting strategy to address industry specific or individual permitting. The Agency requests comment as to whether facilities covered by these permits should be required to submit an annual certification that a pollution prevention plan has been developed for the site and is being implemented.

vi. *Relationship between permit requirements and proposed rule change.* These monitoring requirements of the draft general permits are consistent with the proposed regulatory modifications to 40 CFR 122.28(b)(2)(ii), discussed earlier in today's notice. The final permits will be consistent with the regulatory requirements regarding this provision that are in existence at the time of

⁶² For example, EPA has proposed requirements for run-off control systems from the active portion of the municipal solid waste landfills to collect and control at the water volume resulting from a 24-hour, 25-year storm (see August 30, 1988 (53 FR 33408)).

permit issuance.⁶³ If EPA promulgates less stringent regulations specifying minimum monitoring requirements, the monitoring requirements in these permits may be limited to priority facilities. The Agency believes that classes of industrial facilities that may be considered priority facilities for monitoring include the classes of facilities for which industrial specific monitoring requirements are proposed in these draft permits, deicing activities at airports, steam electric facilities, pulp and paper facilities, and organic chemical facilities with storm water discharges associated with industrial activity. EPA requests comment on classes of facilities that should be considered a priority for retaining monitoring requirements in these permits.

B. *Other reporting requirements.* The draft general permits provide that any facility that is unable to provide the certification that separate storm sewer outfalls have been tested for illicit connections must notify the Director within 180 days of the effective date of the permit. Such notification shall describe: The procedure of any test conducted for the presence of non-storm water discharges, the results of such test or other relevant observations, potential sources of non-storm water discharges

to the storm sewer, and why adequate tests for such storm sewers were not feasible.

C. *Retention of records.* The permittee is required to retain records of all monitoring information, copies of all reports required by this permit, and records of all data used to complete the Notice of Intent to be covered by the permit, for a period of at least three years from the date of the measurement, report, or application. This period may be extended by request of the Director.

9. Cost estimates

a. *Pollution prevention plan implementation.* Storm water pollution prevention plans for the majority of facilities will address relatively low cost baseline controls for the majority of industrial facilities. EPA's analysis of storm water pollution prevention plans indicates that the cost of developing and implementing the costs of these plans is variable and will depend on a number of factors, including: The size of the facility, chemicals stored or used at a facility, the nature of the plant operations and plant designs and the housekeeping measures employed. Table 5 provides estimates of the range of costs of preparing and implementing a storm water pollution prevention plan. It is expected that the low cost estimates provided in Table 5 is appropriate for the majority of smaller facilities. High cost estimates are also provided.

Additional information regarding the estimates of the costs required to comply with the conditions proposed in this permit are provided in "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity"

(EPA, 1991). The Agency requests comments on these cost estimates.

b. *SARA Title III Facilities.* Table 6 provides estimates of the range of costs of preparing and implementing a storm water pollution prevention plan for facilities which are subject to the special requirements for facilities subject to SARA title III section 313 reporting requirements for chemicals which are classified as "section 313 water priority chemicals". EPA anticipates that the majority of facilities are expected to have existing containment systems that will meet the majority of the requirements of these permits. High cost estimates correspond to facilities that are expected to be required to undertake some actions to upgrade existing containment systems to meet the requirements of these permits. Costs associated with meeting the toxicity limitation in this permit only apply to facilities whose discharges exhibit toxicity, and are based on an assumption that the toxicity of discharge can be reduced by: Modifying material handling practices; by modifying existing storage equipment to eliminate leaks and other sources of chemical exposure; or by discharging waters collected by a containment system to a POTW. Costs of treatment where the facility does not have existing treatment capacity or off site disposal is typically expected to be higher.

Additional information regarding the estimates of the costs required to comply with the conditions proposed in this permit are provided in "Staff Analysis of Implementing Permitting Activities for Storm Water Discharges Associated with Industrial Activity" (EPA, 1991). The Agency requests comments on these cost estimates.

TABLE 5.—SUMMARY OF ESTIMATED COSTS FOR COMPLIANCE WITH STORM WATER POLLUTION PREVENTION PLANS WITH BASELINE REQUIREMENTS

Control measure	Costs in 1988 dollars			
	Low costs		High costs	
	Capital costs (annualized)	Annual O & M Costs	Capital costs (annualized)	Annual O & M costs
Plan Preparation.....	2,000		75,000	19,650
Plan Revisions.....	200		7,500	1,955
Material Inventory/Risk Assessment.....		90		640
Spill prevention/response Procedures.....		90		700
Employee Training.....		100		1,115
Visual Inspections.....		100		1,025
Preventive Maintenance/Housekeeping.....				4,160
Storm Water Management.....			5,000	500
Sediment and Erosion Prevention.....		100	500	1,000
Recordkeeping.....		50	100	100
Non-storm water certification.....	200		14,000	
Total Fixed cost ¹	2,400		102,100	

TABLE 5.—SUMMARY OF ESTIMATED COSTS FOR COMPLIANCE WITH STORM WATER POLLUTION PREVENTION PLANS WITH BASELINE REQUIREMENTS—Continued

Control measure	Costs in 1988 dollars			
	Low costs		High costs	
	Capital costs (annualized)	Annual O & M Costs	Capital costs (annualized)	Annual O & M costs
Total Annual costs.....		530		30,855

This table identifies estimated low and high costs to develop and implement storm water pollution prevention plans.

Low costs of implementing program components are zero where existing programs, procedures or security is assumed adequate.

Annualized costs are based upon a 5 year permit and 10% discount

¹ Total costs only address situation where storm water pollution plan needs to be developed and not the lower cost situation where a plan is existing and needs revision.

TABLE 6.—SUMMARY OF ESTIMATED COSTS FOR COMPLIANCE WITH STORM WATER POLLUTION PREVENTION PLANS PER APPLICABLE UNIT OPERATION FOR FACILITIES SUBJECT TO SECTION 313 OF SARA TITLE III WITH WATER PRIORITY CHEMICALS

Control measure	Low costs		High costs	
	Capital costs (annualized)	Annual O & M Costs	Capital costs (annualized)	Annual O & M costs
Liquid Storage Curbing.....	0		1,120	
Raw Material Storage Tarpaulin.....	0	0	400	160
Runon Diversion Trench.....	0	0	1,100	250
Collection System.....	0	0	15,000	3,000
Toxicity Reduction Evaluation/Remediation.....	0	0	25,000	500
Total Fixed Costs.....	0		42,620	
Total Annual Costs.....		0		3,910

This table identifies estimated additional low and high costs to develop and implement storm water pollution prevention plans for SARA Title III, Section 313 facilities subject to special conditions.

Low costs of implementing program components are zero where existing programs, procedures or security is assumed adequate.

Annualized costs are based upon a 5 year permit and 10% discount rate.

c. *Construction sites.* The two major costs associated with pollution prevention plans for construction activities include the costs of sediment and erosion controls (see Table 7), and the costs of storm water management controls (see Table 8). The draft general permits provide flexibility in developing controls for construction activities. Typically, most construction sites will employ several types of sediment and erosion controls and storm water management controls, but not all of the controls listed in Tables 7 and 8. In general, sites which disturb a larger area will incur higher pollution prevention costs.

TABLE 7.—SEDIMENT AND EROSION CONTROL COSTS

Vegetative practices	
Temporary seeding.....	\$1.00 per square yard.
Permanent seeding.....	\$1.00 per square yard.
Mulching.....	\$1.25 per square yard.
Sod stabilization.....	\$4.00 per square yard.
Vegetative buffer strips.....	\$1.00 per square yard.
Protection of trees.....	\$30.00 to \$200 per tree set.
Earth dikes.....	\$5.50 per linear foot.
Straw bale dikes.....	\$5.00 per linear foot.
Silt fences.....	\$6.00 per linear foot.

TABLE 7.—SEDIMENT AND EROSION CONTROL COSTS—Continued

Vegetative practices	
Brush barriers.....	
Drainage swales—grass.....	\$3.00 per square yard.
Drainage swales—sod.....	\$4.00 per square yard.
Drainage swales—riprap.....	\$45.00 per square yard.
Drainage swales—asphalt.....	\$35.00 per square yard.
Drainage swales—concrete.....	\$65.00 per square yard.
Check dams—rock.....	\$100 per dam.
Check dams—covered straw bales.....	\$50 per dam.
Level spreader—earthen.....	\$4.00 per square yard.
Level spreader—concrete.....	\$65.00 per square yard.
Subsurface drain.....	\$2.25 per linear foot.
Pipe slope drain.....	\$5.00 per linear foot.
Temporary storm drain diversion.....	Variable.
Storm drain inlet protection.....	\$300 per inlet.
Rock outlet protection.....	\$45 per square yard.
Sediment traps.....	\$500 to \$7,000 per trap.
Temporary sediment basins.....	\$5,000 to \$50,000 per basin.
Sump pit.....	\$500 to \$7,000.
Entrance stabilization.....	\$1,500 to \$5,000 per entrance.
Entrance wash rack.....	\$2,000 per rack.
Temporary waterway crossing.....	\$500 to \$1,500.
Wind breaks.....	\$2.50 per linear foot.

Practices such as sod stabilization and tree protection increase property values and satisfy consumer aesthetic needs.

TABLE 8.—COSTS OF STORM WATER MANAGEMENT FOR CONSTRUCTION SITES

	Cost for 5 acre developed area	Cost for 20 acre developed area
Wet ponds.....	\$5,770	\$16,300
Dry ponds.....	12,000	29,330
Dry ponds with extended detention.....	5,950	15,500
Infiltration trenches.....	8,500	34,100

Estimates based on methodology presented in "Cost of Urban Runoff Quality Controls", Wiegand, C., Schueler, T., Chittenden, W., and Jellick, D., Urban Runoff Quality-Impact and Quality Enhancement Technology, Proceedings of an Engineering Foundation Conference, ASCE, 1986, edited by B. Urbonas and L.A. Roesner.

d. *Oil and gas production or exploration operations.* Facilities with contaminated storm water discharges associated with industrial activity, in addition to the baseline requirements for storm water pollution prevention plans, are required to obtain professional engineer certifications or monitor their discharges. The estimated cost of a professional engineer certification is

\$200. Some oil and gas exploration or production facilities are expected to monitor their storm water discharges instead of obtaining professional engineer certifications. This additional cost is not applicable to such facilities.

e. Salt storage facilities. Salt pile covers or tarpaulins are anticipated to have a fixed cost of \$400 and an annual cost of \$160 for medium sized piles, and a fixed cost of \$4,000 and an annual cost of \$2,000 for very large piles. Structures such as salt domes are generally expected to have a fixed cost of between \$30,000 for small piles (\$70 to \$80 per cubic yard) and \$100,000 for larger piles (\$18 per cubic yard) with costs depending on their size and other construction parameters.

f. Coal pile runoff. The effluent limitations for coal pile runoff in the draft permits can be achieved by two primary methods: by limiting exposure to coal by use of covers or tarpaulins; and by collecting and treating the runoff. In some cases, coal pile runoff may be in compliance with the effluent limitations without covering the pile or collecting or treating the runoff. In these cases, the operator of the discharge would not have a control cost.

The use of covers or tarpaulins to prevent or minimize exposure of the coal pile to storm water is generally expected to be practical only for relatively small piles. Coal pile covers or tarpaulins are anticipated to have a fixed cost of \$400 and annual cost of \$160.

Table 9 provides estimates of the cost of treating coal pile runoff.^{64 65} These costs are based on a consideration of a treatment train requiring equalization, pH adjustment and settling, including the costs for impoundment (for equalization), a lime feed system and mixing tanks for pH adjustment, and a clarifier for settling. The costs for the impoundment area include diking and containment around each coal pile and associated sumps and pumps and piping from runoff areas to impoundment area. The costs for land are not included. The lime feed system employed for pH adjustment includes a storage silo, shaker, feeder, and lime slurry storage tank, instrumentation, electrical connections, piping and controls.

^{64 65} The type and degree of treatment required to meet the effluent limitations of these permits will vary depending upon factors such as the amount of sulfur in the coal. This section describes a model treatment scheme for the purposes estimating costs for compliance with the proposed effluent limitations. Dischargers may implement other less expensive treatment approaches to enable them to discharge in accordance with these limits where appropriate.

Additional costs may be incurred if a polymer system is needed. In such a case, costs would include impoundment for equalization, a lime feed system, mixing tank, and polymer feed system for chemical precipitation, a clarifier for settling and an acid feeder and mixing tank to readjust the pH within the range of 6 to 9. The equipment and system design, with the exception of the polymer feeder, acid feeder and final mixing tank, is essentially the same as shown in Table 9. Two tanks are required for a treatment train with a polymer system, one for precipitation and another for final pH adjustment with acid. The cost of mixing is therefore twice that shown in Table 9. The polymer feed system includes storage hoppers, chemical feeder, solution tanks, solution pumps, interconnecting piping, electrical connections and instrumentation. The costs of clarification is identical to that of Table 9. A treatment train with a polymer system requires the use of an acid additional system to readjust the pH within the range of 6 to 9. The components of this system include a lined acid storage tank, two feed pumps, an acid pH control loop, and associated piping, electrical connections and instrumentation.

Additional information regarding the cost of these technologies can be found in: "Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category", (EPA-440/182/029), November 1982, EPA).

TABLE 9.—SUMMARY OF ESTIMATED COSTS FOR TREATMENT OF COAL PIPE RUNOFF

	30,000 cubic meter coal pile	1,200,000 cubic meter coal pile
Impoundment:		
Installed Capital Cost (dollars).	6,300.....	12,500.
Operation and Maintenance (dollars/year).	negligible.....	negligible.
Lime feed system:		
Installed Capital Cost (dollars).	127,000.....	361,200.
Operation and Maintenance (dollars/year).	5,300.....	16,100.
Energy Requirements (kwh/yr).	3.6 × 10**4.	3.6 × 10**4.
Land Requirements (ft**2).	5,000.....	5,000.
Mixing Equipment:		
Installed Capital Cost (dollars).	60,500.....	107,500.
Operation and	2,100.....	2,400.

TABLE 9.—SUMMARY OF ESTIMATED COSTS FOR TREATMENT OF COAL PIPE RUNOFF—Continued

	30,000 cubic meter coal pile	1,200,000 cubic meter coal pile
Maintenance (dollars/year).		
Energy Requirements (kwh/yr).	1.3 × 10**3.	1.3 × 10**3.
Land Requirements (ft**2).	2,000.....	2,000.
Clarification:		
Installed Capital Cost (dollars).	168,000.....	260,500.
Operation and Maintenance (dollars/year).	3,000.....	3,800.
Energy Requirements (kwh/yr).	1.3 × 10**3.	1.3 × 10**3.
Land Requirements (ft**2).	3,000.....	7,000.

Source: "Development Document for Effluent Limitations Guidelines and Standards and Pretreatment Standards for the Steam Electric Point Source Category", (EPA-440/182/029), November 1982, EPA). Costs estimates have been revised to account for inflation.

10. *Effective date requirements.* This permit shall be effective upon issuance.

11. *EPA contacts.*

MA, ME, NH

United States EPA, Region I, Water Management Division, (WCP-2109), John F. Kennedy Federal Building, Room 2209, Boston, MA 02203. Contact: Veronica Harrington, (617) 565-3525.

NY (Indian lands), Puerto Rico

United States EPA, Region II, Water Management Division, (WM-WPC), Jacob K. Javitz Federal Building, 26 Federal Plaza, New York, NY 10278. Contact: Jose Rivera (WM-WPC), (212) 264-1859.

District of Columbia, DE (Federal facilities)

United States EPA, Region III, Water Management Division, (3WM55), 841 Chestnut Building, Philadelphia, PA 19107. Contact: Kevin Magerr, (215) 597-1651.

AL (Indian lands), FL, GA (Indian lands), KY (Indian lands), MS (Indian lands), NC (Indian lands), SC (Indian lands), TN (Indian lands)

United States EPA, Region IV, Water Management Division, (FPB-3), 345 Courtland Street, NE, Atlanta, GA 30365. Contact: Chris Thomas, (404) 347-3021.

MI (Indian lands), MN (Indian lands), WI (Indian lands)

United States EPA, Region V, Water Quality Branch (5WQP), 230 South Dearborn Street, Chicago, IL 60604. Contact: Irving Dzikowski, (312) 355-2105.

LA, MN, OK, TX

United States EPA, Region VI, Water Management Division, (6W-PM), First Interstate Bank Tower at Fountain Place, 1445 Ross Avenue, 12th Floor, Suite 1200, Dallas, TX 75202. Contact: Craig Weeks, (214) 655-7180.

SD, CO (Federal facilities and Indian lands), MT (Indian lands), ND (Indian lands), UT (Indian lands), WY (Indian lands)

United States EPA, Region VIII, Water Management Division, Compliance Branch (8WM-C), 999 18th Street, Suite 500, Denver, CO 80202-2405. Contact: Vern Berry, (303) 293-1260.

AZ, CA (Indian lands), NV (Indian lands), Guam, American Samoa

United States EPA, Region IX, Water Management Division, (W-5-1), 75 Hawthorne Street, San Francisco, CA 94105. Contact: Eugene Bromley, (415) 744-1906.

AK, ID, WA (Federal facilities and Indian lands)

United States EPA, Region X, Water Management Division, (WD-134), 1200 Sixth Street, Seattle, WA 98101, Andrea Lindsay, (206) 553-8399.

12. Proposed schedule for general permits issuance.

Draft Permits Transmitted to State requesting section 401 certification: August 16, 1991.

Notice of Draft Permits in Federal Register: August 16, 1991.

Comment Period Closed: October 15, 1991.

Notice of Final Permit Expected in Federal Register: 12/91

VII. Economic Impact

EPA has prepared an Information Collection Request (ICR) for the purpose of estimating the information collection burden imposed on Federal, State and local governments and industry by proposed revisions to requirements to submit annual monitoring reports, minimum notice of intent (NOI) requirements for NPDES general permits, and for States to submit State Storm Water Permitting Plans. (A summary of the costs of compliance with the general permit notice herein is provided in the fact sheet presented earlier in today's notice).

The ICR evaluates five options for modifying the existing regulatory requirement that NPDES permits for storm water discharges associated with industrial activity must, at a minimum, require dischargers to report monitoring data annually. All options considered would lower the burdens on the Federal government, State governments and industry. The burden savings to the Federal and State governments range from a savings of 6,743 hours per year (\$105,724 per year) for Option 4 to a

savings of 14,848 hours per year (\$232,817 per year) for Options 2, 3 and 5. Option 3 is currently favored by EPA. The burden savings to industry range from a savings of 66,300 hours per year (2.2 million per year) for Option 2 to a savings of 795,600 hours per year (\$26 million per year) for Option 5. The option currently favored by EPA (Option 3) would result in a burden savings to industry of 231,300 hours/year (\$7.5 million/year).

EPA believes that the regulatory modifications to the notice of intent requirements for general permits will codify existing practices. Therefore, this regulatory change, while ensuring national consistency, will not increase the burdens to the Federal government, State governments or industry.

The reporting burden for State Storm Water Permitting Plans is estimated to range from 340 hours (\$5,350) per response to 1,500 hours (\$23,500) per response. The national total burden for the 57 States (including 7 Territories), averaged over a three year period, is 14,794 hours per year or \$231,965 per year. The Agency also estimates that the costs to the Federal Government 20 hours (\$315) to review each State Storm Water Permitting Plan. The total burden of reviewing these plans, averaged over a three year period is 380 hours per year or \$5,958 per year.

VIII. Executive Order 12291

EPA has submitted this notice to the Office of Management and Budget for review under Executive Order 12291.

IX. Paperwork Reduction Act

The information collection requirements associated with the proposed regulatory changes have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0229.05) and a copy may be obtained from: Florice Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM-2234); Washington, DC or by calling (202) 382-2740.

The ICR document estimates the information collection burdens imposed on the Federal Government, State governments and industry associated with the proposed revisions to requirements to: submit annual monitoring reports for storm water discharges under 40 CFR 122.44; establish minimum notice of intent requirements for general permits under 40 CFR 122.28. In addition, the ICR estimates the information collection burdens imposed on the Federal government and the States to submit

State Storm Water permitting plans and the burden imposed on the Federal government to review these plans.

The ICR estimates that the reporting burdens on industry for collecting information associated with discharge monitoring reports (DMRs) typically ranges from 6 hours to 10.5 hours per response. The ICR estimates that the EPA or NPDES States will require 0.2 hours to review each DMR submitted.

The ICR estimates that the reporting burdens on industry for collecting information associated with a notice of intent (NOI) is one hour per response. The ICR estimates that the EPA or NPDES States will require 0.25 hours to review each NOI submitted.

The reporting burden for State Storm Water Management Programs is estimated to range from 340 hours per response for small States to 1,500 hours per response for large States. Estimates of reporting burden include reviewing guidance, planning activities, analyzing existing data, analyzing other data, developing the strategy, public review and comment and reviewing the strategy. The Agency also estimates the Federal Government will require 20 hours to review each State Storm Water Permitting Strategy.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223Y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20490; and to the Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to OMB or public comments on the information collection requirements contained in this proposal.

X. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 USC 601 *et seq.*, EPA is required to prepare a Regulatory Flexibility Analysis to assess the impact of rules on small entities. No Regulatory Flexibility Analysis is required, however, where the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Today's proposed amendments to the regulations would generally make the NPDES regulations more flexible and less burdensome for permittees. Accordingly, I hereby certify, pursuant to 5 U.S.C. 605(b), that these amendments, if promulgated, and that these general permits, when issued, will not have a significant impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 122

Administrative practice and procedure, Environmental protection, Reporting and record keeping requirements, Water pollution control.

Dated: July 31, 1991.

William K. Reilly,
Administrator.

For the reasons stated in the preamble, part 122 of title 40 of the Code of Regulations is proposed to be amended as follows:

**PART 122—EPA ADMINISTERED
PERMIT PROGRAMS; THE NATIONAL
POLLUTANT DISCHARGE
ELIMINATION SYSTEM**

1. The authority citation for part 122 is revised to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart C—Permit Conditions

2. Section 122.28 is amended by redesignating current paragraph (b)(2) as (b)(3) and by adding a new paragraph (b)(2) to read as follows:

§ 122.28 General permits (applicable to State NPDES programs, see § 123.25).

* * *

(b) * * *

(2) *Authorization to discharge, or to engage in sludge use and disposal practices.* (i) Except as provided in paragraphs (b)(2)(v) and (b)(2)(vi) of this section, dischargers (or treatment works treating domestic sewage) seeking coverage under a general permit shall submit to the Director a written notice of intent to be covered by the general permit. A discharger (or treatment works treating domestic sewage) who fails to submit a notice of intent in accordance with the terms of the permit is not authorized to discharge, or in the case of a sludge disposal permit, to engage in a sludge use or disposal practice, under the terms of the general permit unless the general permit, in accordance with paragraph (b)(2)(v) of this section, contains a provision that a notice of intent is not required or the Director notifies a discharger (or treatment works treating domestic sewage) that it is covered by a general permit in accordance with paragraph (b)(2)(vi) of this section. A complete and timely notice of intent to be covered constitutes a permit application for purposes of §§ 122.6, 122.21 and 122.26.

(ii) The notice of intent shall include, at a minimum, the legal name and address of the owner or operator, the facility name and address, type of facilities or discharges, the receiving stream(s), and such other information as

is reasonably necessary to ascertain whether the discharger (or treatment works treating domestic sewage) should be included under the terms of the general permit as specified in the final general permit. General permits for storm water discharges associated with industrial activity from inactive mining or inactive oil and gas operations occurring on Federal lands where an operator cannot be identified may contain alternative notice of intent requirements.

(iii) Unless the general permit specifies different time periods, the notice of intent to be covered (including notices of intent to be covered for new discharges) shall be submitted within 60 days before the date of intended coverage.

(iv) After a discharger (or treatment works treating domestic sewage) has filed its notice of intent to be covered, the discharger (or treatment works treating domestic sewage) shall be deemed covered on the date specified in the permit and may discharge or, in the case of a sludge disposal permit, engage in a sludge use or disposal practice under the general permit, unless the Director notifies the discharger (or treatment works treating domestic sewage) that it is not covered by the general permit and instead must obtain coverage under an individual permit or an alternative general permit. The Director may specify in the general permit that this paragraph shall not apply and that dischargers (or treatment works treating domestic sewage) submitting a notice of intent to be covered by the permit will not be authorized to discharge or, in the case of a sludge disposal permit, to engage in a sludge use or disposal practice until notified of their inclusion under the permit by the Director.

(v) Discharges other than discharges from publicly owned treatment works, combined sewer overflows, primary industrial facilities, contaminated runoff from mining operations or oil and gas operations and other storm water discharges associated with industrial activity, may, at the discretion of the Director, be authorized to discharge under a general permit without submitting a notice of intent where the Director finds that a notice of intent requirement would be inappropriate. In making such a finding, the Director shall consider: The type of discharge; the expected nature of the discharge; the potential for toxic and conventional pollutants in the discharges; the expected volume of the discharges; other means of identifying discharges covered by the permit; and the estimated number of discharges to be

covered by the permit. The Director shall provide in the public notice of the general permit the reasons for not requiring a notice of intent.

(vi) The Director may notify a discharger (or treatment works treating domestic sewage) that it is covered by a general permit, even if the discharger (or treatment works treating domestic sewage) has not submitted a notice of intent to be covered. A discharger (or treatment works treating domestic sewage) so notified may request an individual permit under paragraph (b)(3)(iii) of this section.

* * *

3. Section 122.44 is amended by revising paragraph (i)(2) and adding paragraphs (i)(3) through (i)(6) to read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * *

(i) * * *

(2) Except as provided in paragraphs (i)(4) and (i)(5) of this section, requirements to report monitoring results with a frequency dependent on the nature and effect of the discharge, but in no case less than once a year. For sewage sludge use or disposal practices, requirements to monitor and report results with a frequency dependent on the nature and effect of the sewage sludge use or disposal practice; minimally this shall be as specified in 40 CFR part 503 (where applicable), but in no case less than once a year.

(3) Requirements to report monitoring results for storm water discharges associated with industrial activity which are subject to an effluent limitation guideline shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge, but in no case less than once a year.

(4) Requirements to monitor storm water discharges associated with industrial activity (other than those addressed in paragraphs (i)(3) and (i)(5) of this section) shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge, however, at a minimum, a permit for such a discharge must require annual monitoring of representative storm water discharges associated with industrial activity. Where dischargers are not required to report monitoring results to the Director, permits must require that the results of monitoring be retained for at least the term of the permit and be made available to the Director upon request. In such cases,

results of any monitoring conducted during the term of the permit shall be submitted as part of a permit application or notice of intent requirement prior to permit reissuance.

(5) Requirements to monitor contaminated storm water discharges associated with industrial activity from oil and gas exploration or production operations or from inactive mining operations where a past or present mine operator cannot be identified shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge. However, at a minimum, a permit for such a discharge must require either:

(i) Annual monitoring of representative contaminated storm water discharges associated with industrial activity from oil and gas exploration or production operations or inactive mines where a past or present mine operator cannot be identified. Where dischargers are not required to report monitoring results to the Director, permits must require that the results of monitoring be retained for at least the term of the permit and be made available to the Director upon request. In such cases, results of any monitoring conducted during the term of the permit shall be submitted as part of a permit application or notice of intent requirement prior to permit reissuance; or

(ii) the facility owner or operator to develop and implement a storm water pollution prevention plan or a storm water best management plan which includes a Registered Professional Engineer's certification that the plan has been prepared and is being implemented in accordance with good engineering practices, with such certification being obtained at a minimum frequency of at least once every three years. Such certification shall in no way relieve the owner or operator of a storm water discharge associated with industrial activity of their duty to prepare and fully implement such plan in accordance with the requirements of their permit. Where dischargers are not required to report results of such certification to the Director, permits must require that the certification be retained for at least the term of the permit and be made available to the Director upon request. In such cases, an indication of whether the certification was received should be submitted as part of a permit application or notice of intent requirement prior to permit reissuance.

(6) Permits which do not require the submittal of monitoring result reports at least annually shall require that the permittee report all instances of noncompliance not reported under

paragraphs 122.41(l)(1), (4), (5), and (6) at least annually.

* * * * *

Appendix—Draft General Permits

Note: The following Appendix will not appear in the Code of Federal Regulations.

Draft General Permits

Table of Contents.

Part I. Coverage Under this Permit.

- A. Permit Area.
- B. Eligibility.
- C. Requiring an individual permit or an alternative general permit.
- D. Authorization.

Part II. Notice of Intent Requirements.

- A. Deadlines for Notification.
- B. Failure to Notify.
- C. Contents of Notice of Intent.
- D. Where to Submit.
- E. Additional Notification.
- F. Renotification.

Part III. Special Conditions, Management Practices, and Other Non-Numeric Limitations

- A. Prohibition on non-storm water discharges.
- B. Releases in excess of Reportable Quantities.
- C. Storm water pollution prevention plans.

Part IV. Numeric Effluent Limitations

- A. Acute Whole Effluent Toxicity.
- B. Alternative Requirements.

Part V. Monitoring and Reporting Requirements

- A. Failure to Certify.
- B. Monitoring Requirements.
- C. Toxicity testing.
- D. Reporting: Where to Submit.
- E. Retention of Records.

Part VI. Standard Permit Conditions

- A. Duty to Comply.
- B. Continuation of the Expired General Permit.
- C. Need to halt or reduce activity not a defense.
- D. Duty to Mitigate.
- E. Duty to Provide Information.
- F. Other Information.
- G. Signatory Requirements.
- H. Certification.
- I. Penalties for Falsification of Reports.
- J. Penalties for Falsification of Monitoring Systems.
- K. Oil and Hazardous Substance Liability.
- L. Property Rights.
- M. Severability.
- N. Transfers.
- O. State Laws.
- P. Proper Operation and Maintenance.
- Q. Monitoring and records.
- R. Bypass of Treatment Facilities.
- S. Upset Conditions.
- T. Inspection and Entry.
- U. Permit Actions.

Part VII. Reopener Clause

Part VIII. Definitions

Part I. Coverage Under this Permit

A. Permit Area. The permit covers all areas of the State of _____.¹

B. Eligibility.

1. Except for storm water discharges identified under paragraph I.B.2, this permit may cover all new and existing discharges composed entirely of storm water discharges associated with industrial activity.

2. **Limitations on Coverage.** The following storm water discharges associated with industrial activity are not covered by this permit:

a. Storm water discharges associated with industrial activity from facilities with existing effluent guideline limitations for storm water;²

b. Storm water discharges associated with industrial activity from facilities with an existing NPDES individual or general permit for the storm water discharges or which are issued a permit in accordance with paragraph I.C of this permit;

c. Storm water discharges associated with industrial activity that the Director has shown to be or may reasonably be expected to be contributing to a violation of a water quality standard; and

d. Storm water discharges associated with industrial activity from inactive mining or inactive oil and gas operations occurring on Federal lands where an operator cannot be identified.

C. Requiring an individual permit or an alternative general permit.

1. The Director may require any person authorized by this permit to apply for and obtain either an individual NPDES permit or an alternative NPDES general permit. Any interested person may petition the Director to take action under this paragraph. The Director may require any owner or operator authorized to discharge under this permit to apply for an individual NPDES

¹ Note that the Agency is noticing distinct draft general permits in Alaska, Arizona, Florida, Idaho, Louisiana, Massachusetts, Maine, New Hampshire, New Mexico, Oklahoma, South Dakota, Texas, District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands; on Indian lands in AL, CA, GA, KY, MI, MN, MS, MT, NC, ND, NY, NV, SC, TN, UT, WI, and WY; from Federal facilities and Indian lands in CO and WA; and from Federal facilities in Delaware.

² For the purpose of this permit, the following effluent guideline limitations address storm water: cement manufacturing (40 CFR part 411); feedlots (40 CFR part 412); fertilizer manufacturing (40 CFR part 418); petroleum refining (40 CFR part 419); phosphate manufacturing (40 CFR part 422); steam electric (40 CFR part 423); coal mining (40 CFR part 434); mineral mining and processing (40 CFR part 436); ore mining and dressing (40 CFR part 440); and asphalt emulsion (40 CFR part 443).

permit only if the owner or operator has been notified in writing that a permit application is required. This notice shall include a brief statement of the reasons for this decision, an application form, a statement setting a deadline for the owner or operator to file the application, and a statement that on the effective date of the individual NPDES permit or the alternative general permit as it applies to the individual permittee, coverage under this general permit shall automatically terminate. The Director may grant additional time to submit the application upon request of the applicant. If an owner or operator fails to submit in a timely manner an individual NPDES permit application required by the Director under this paragraph, then the applicability of this permit to the individual NPDES permittee is automatically terminated at the end of the day specified for application submittal.

2. Any owner or operator authorized by this permit may request to be excluded from the coverage of this permit by applying for an individual permit or participating in an applicable group application. The owner or operator shall submit an individual application (Form 1 and Form 2F) with reasons supporting the request, or participate in a group application in accordance with the requirements of 40 CFR 122.26, to the Director. The request shall be granted by issuing of any individual permit or an alternative general permit if the reasons cited by the owner or operator are adequate to support the request.

3. When an individual NPDES permit is issued to an owner or operator otherwise subject to this permit, or the owner or operator is approved for coverage under an alternative NPDES general permit, the applicability of this permit to the individual NPDES permittee is automatically terminated on the effective date of the individual permit or the date of approval for coverage under the alternative general permit, whichever the case may be. When an individual NPDES permit is denied to an owner or operator otherwise subject to this permit, or the owner or operator is denied for coverage under an alternative NPDES general permit, the applicability of this permit to the individual NPDES permittee is automatically terminated on the date of such denial, unless otherwise specified by the Director.

D. *Authorization.* Owners or operators of storm water discharges associated with industrial activity must submit a Notice of Intent (NOI) in accordance with the requirements of part II of this

permit to be authorized to discharge under this general permit. Unless notified by the Director to the contrary, owners or operators who submit such notification are authorized to discharge storm water associated with industrial activity under the terms and conditions of this permit. Upon review of the NOI, the Director may deny coverage under this permit and require submittal of an application for an individual NPDES permit.

Part II. Notice of Intent Requirements

A. *Deadlines for notification.* Individuals who intend to obtain coverage for an existing storm water discharge associated with industrial activity under this general permit shall submit a Notice of Intent (NOI) in accordance with the requirements of this part within 180 days of the date of issuance of this general permit or at least 30 days prior to the commencement of construction of a new storm water discharge associated with industrial activity.

B. *Failure to notify.* Owners (or operators when owners do not operate the facility), who fail to notify the Director of their intent to be covered, and discharge pollutants to waters of the United States without an NPDES permit, are in violation of the Clean Water Act.

C. *Contents of notice of intent.* The Notice of Intent shall include the following information:

1. Name, mailing address, and location of the facility for which the notification is submitted;
2. Up to four 4-digit SIC codes that best represent the principal products or activities provided by the facility;
3. The operator's name, address, telephone number, ownership status and status as Federal, State, private, public or other entity;
4. The latitude and longitude of the approximate center of the facility to the nearest 15 seconds, or the nearest quarter section (if the section, township and range is provided) that the facility is located in;
5. The name of the receiving water(s), or if the discharge is through a municipal separate storm sewer, the name of the municipal operator of the storm sewer and the ultimate receiving water(s); and
6. Existing quantitative data describing the concentration of pollutants in storm water discharges.

7. *Additional requirements for construction activities.* The Notice of Intent for a storm water discharges associated with industrial activity from a construction site shall, in addition to the information required above, include a brief description of the project,

estimated timetable for major activities, estimates of the number of acres of the site on which soil will be disturbed, and a certification that the storm water pollution prevention plan for the facility provides compliance with approved State or local sediment and erosion plans or storm water management plans in accordance with part III.C.5.b.(3) of this permit.

D. *Where to Submit.* Facilities which discharge storm water associated with industrial activity must submit signed copies of the Notice of Intent to the Director of the NPDES program at the following address:

Address of Central Receiving Office to be determined later

E. Additional Notification.

1. Except for facilities subject to part II.E.2, facilities which discharge storm water associated with industrial activity to a large or medium municipal separate storm sewer system (systems serving a population of 100,000 or more) must, in addition to filing copies of the Notice of Intent in accordance with paragraph II.D, shall submit signed copies of the Notice of Intent to the operator of the municipal separate storm sewer to which they discharge.

2. Facilities which discharge storm water associated with industrial activity from construction activities and are operating under approved State or local sediment and erosion or storm water management plans, in addition to filing copies of the Notice of Intent in accordance with paragraph II.D, shall submit signed copies of the Notice of Intent to the State or local agency approving such plans.

F. *Renotification.* Upon reissuance of a new general permit, the permittee is required to notify the Director of his intent to be covered by the new general permit.

Part III. Special conditions, management practices, and other non-numeric limitations

A. *Prohibition on non-storm water discharges.* All discharges covered by this permit shall be composed entirely of storm water. Discharges of material other than storm water must be in compliance with a NPDES permit (other than this permit) issued for the discharge.

B. *Releases in excess of Reportable Quantities.* This permit does not relieve the permittee of the reporting requirements of 40 CFR part 117 and 40 CFR part 302. The discharge of hazardous substances in the storm water discharge(s) from a facility shall be minimized in accordance with the applicable storm water pollution

prevention plan for the facility, and in no case, during any 24-hour period, shall the discharge(s) contain a hazardous substance equal to or in excess of reporting quantities.

C. *Storm water pollution prevention plans.* A storm water pollution prevention plan shall be developed for each facility covered by this permit. Storm water pollution prevention plans shall be prepared in accordance with good engineering practices. The plan shall identify potential sources of pollution which may reasonably be expected to affect the quality of storm water discharges associated with industrial activity from the facility. In addition, the plan shall describe and ensure the implementation of practices which are to be used to reduce the pollutants in storm water discharges associated with industrial activity at the facility and to assure compliance with the terms and conditions of this permit.

1. The plan shall be signed in accordance with part VI.G, and be retained on site in accordance with part V.A of this permit. It shall be completed within 180 days of the effective date of this permit (and updated as appropriate), or, in the case of new facilities, prior to submitting a NOI to be covered under this permit. Plans shall provide for compliance with the terms of the plan within 365 days of the effective date of this permit, or, in the case of new facilities, prior to submitting a NOI to be covered under this permit. The owner or operator of a facility with storm water discharges covered by this permit shall make plans available upon request to the Director, or authorized representative, or in the case of a storm water discharge associated with industrial activity which discharges through a municipal separate storm sewer system with an NPDES permit, to the municipal operator of the system.

2. If the plan is reviewed by the Director, or authorized representative, the Director, or authorized representative, may notify the permittee at any time that the plan does not meet one or more of the minimum requirements of this Part. After such notification from the Director, or authorized representative, the permittee shall make changes to the plan and shall submit to the Director a written certification that the requested changes have been made. Unless otherwise provided by the Director, the permittee shall have 30 days after such notification to make the changes necessary.

3. The permittee shall amend the plan whenever there is a change in design, construction, operation, or maintenance, which has a significant effect on the

potential for the discharge of pollutants to the waters of the United States or if the storm water pollution prevention plan proves to be ineffective in achieving the general objectives of controlling pollutants in storm water discharges associated with industrial activity. Amendments to the plan may be reviewed by EPA in the same manner as part III.C.2 above.

4. Except for storm water discharges associated with industrial activity from construction activities, which are subject to the requirements of paragraph III.C.5, the plan shall include, at a minimum, the following items:

a. *Description of Potential Pollutant Sources.* Each plan shall provide a description of potential sources which may be reasonably expected to add significant amounts of pollutants to storm water discharges or which may result in the discharge of pollutants during dry weather from separate storm sewers draining the facility. Each plan shall identify all activities and significant materials which may potentially be significant pollutant sources. Each plan shall include:

(1). A site map indicating, an outline of the drainage area of each storm water outfall; each existing structural control measure to reduce pollutants in storm water runoff; and surface water bodies;

(2). A topographic map (or other map if a topographic map is unavailable), extending one-quarter of a mile beyond the property boundaries of the facility. The requirements of this paragraph may be included in the site map required under part III.C.4.a.(1) if appropriate.

(3). A narrative description of significant materials that have been treated, stored or disposed in a manner to allow exposure to storm water between the time of three years prior to the date of the issuance of this permit and the present; method of on-site storage or disposal; materials management practices employed to minimize contact of these materials with storm water runoff between the time of three years prior to the date of the issuance of this permit and the present; materials loading and access areas; the location and a description of existing structural and nonstructural control measures to reduce pollutants in storm water runoff; and a description of any treatment the storm water receives;

(4). A list of significant spills and significant leaks of toxic or hazardous pollutants that occurred at the facility after the effective date of this permit.

(5). For each area of the plant that generates storm water discharges associated with industrial activity with a reasonable potential for containing significant amounts of pollutants, a

prediction of the direction of flow, and an estimate of the types of pollutants which are likely to be present in storm water discharges associated with industrial activity; and

(6). A summary of existing sampling data describing pollutants in storm water discharges.

b. *Storm Water Management Controls.* Each facility covered by this permit shall develop a description of storm water management controls appropriate for the facility, and implement such controls. The appropriateness and priorities of controls in a plan shall reflect identified potential sources of pollutants at the facility. The description of storm water management controls shall address the following minimum components, including a schedule for implementing such controls:

(1). *Pollution Prevention Committee.* The description of the storm water Pollution Prevention Committee shall identify specific individuals within the plant organization who are responsible for developing the storm water pollution prevention plan and assisting the plant manager in its implementation, maintenance, and revision. The activities and responsibilities of the committee should address all aspects of the facility's storm water pollution prevention plan.

(2). *Risk Identification and Assessment/Material Inventory.* The storm water pollution prevention plan shall assess the potential of various sources at the plant to contribute pollutants to storm water discharges associated with industrial activity. The plan shall include an inventory of the types of materials handled. Facilities subject to SARA title III, section 313 shall include in the plan a description of releases to land or water of SARA Title III water priority chemicals that have occurred at any time after the date of three years prior to the issuance of this permit. Each of the following shall be evaluated for the reasonable potential for contributing pollutants to runoff: loading and unloading operations; outdoor storage activities; outdoor manufacturing or processing activities; significant dust or particulate generating processes; and on-site waste disposal practices. Factors to consider include the toxicity of chemicals; quantity of chemicals used, produced, or discharged; the likelihood of contact with storm water; and history of significant leaks or spills of toxic or hazardous pollutants.

(3). *Preventive Maintenance.* A preventive maintenance program shall involve inspection and maintenance of

storm water management devices (cleaning oil/water separators, catch basins) as well as inspecting and testing plant equipment and systems to uncover conditions that could cause breakdowns or failures resulting in discharges of pollutants to surface waters.

(4). *Good Housekeeping.* Good housekeeping requires the maintenance of a clean, orderly facility.

(5). *Spill Prevention and Response Procedures.* Areas where potential spills can occur, and their accompanying drainage points shall be identified clearly in the storm water pollution prevention plan. Where appropriate, specifying material handling procedures and storage requirements in the plan should be considered. Procedures for cleaning up spills shall be identified in the plan and made available to the appropriate personnel. The necessary equipment to implement a clean up should be available to personnel.

(6). *Storm Water Management.* The plan shall contain a narrative consideration of the appropriateness of traditional storm water management practices (practices other than those which control the source of pollutants). Based on an assessment of the potential of various sources at the plant to contribute pollutants to storm water discharges associated with industrial activity (see Part III.C.4.b.(2) of this permit), the plan shall provide that measures determined to be reasonable and appropriate shall be implemented and maintained.

(7). *Sediment and Erosion Prevention.* The plan shall identify areas which, due to topography, activities, or other factors, have a high potential for significant soil erosion, and identify measures to limit erosion.

(8). *Employee Training.* Employee training programs shall inform personnel at all levels of responsibility of the components and goals of the storm water pollution prevention plan. Training should address topics such as spill response, good housekeeping and material management practices. A pollution prevention plan shall identify periodic dates for such training.

(9). *Visual Inspections.* Qualified plant personnel shall be identified to inspect designated equipment and plant areas. Material handling areas shall be inspected for evidence of, or the potential for, pollutants entering the drainage system. A tracking or followup procedure shall be used to ensure that appropriate response has been taken in response to the inspection. Records of inspections shall be maintained.

(10). *Recordkeeping and Internal Reporting Procedures.* Incidents such as spills, or other discharges, along with

other information describing the quality and quantity of storm water discharges shall be included in the records. Inspections and maintenance activities shall be documented and recorded.

(11). *Non-Storm Discharges.* A certification that the discharge has been tested for the presence of non-storm water discharges. The certification shall include a description of the results of any test for the presence of non-storm water discharges, the method used, the date of any testing, and the on-site drainage points that were directly observed during the test. Such certification may not be feasible if the facility operating the storm water discharge associated with industrial activity does not have access to an outfall, manhole, or other point of access to the ultimate conduit which receives the discharge. In such cases, the source identification section of the storm water pollution plan shall indicate why the certification required by this part was not feasible. A discharge that is unable to provide the certification required by this paragraph must notify in accordance with part V.A of this permit.

c. *Site inspection.* A site inspection shall be conducted annually by appropriate personnel named in the storm water pollution prevention plan to verify that the description of potential pollutant sources required under part III.C.4.a is accurate, the drainage map has been updated or otherwise modified to reflect current conditions; and the controls to reduce pollutants in storm water discharges associated with industrial activity identified in the storm water pollution prevention plan are being implemented and are adequate. Records documenting significant observation made during the site inspection shall be retained as part of the storm water pollution prevention plan for three years.

d. *Special requirements for storm water discharges associated with industrial activity through municipal separate storm sewer systems serving a population of 100,000 or more.* Facilities covered by this permit must comply with applicable requirements in municipal storm water management programs developed under NPDES permits issued for the discharge of the municipal separate storm sewer system that receives the facility's discharge, provided the discharger has been notified of such conditions.

e. *Consistency with other plans.* Storm water management programs may reflect requirements for Spill Prevention Control and Countermeasure (SPCC) plans under section 311 of the CWA or Best Management Practices (BMP) Programs otherwise required by an

NPDES permit and may incorporate any part of such plans into the storm water pollution prevention plan by reference.

f. *Special requirements for storm water discharges associated with industrial activity from facilities subject to SARA title III, section 313 requirements.* (Option A would include part III.C.4.f. as shown below. See section 7.B of the Fact Sheet for a discussion of Option A and Option B.) Storm water pollution prevention plans for facilities subject to reporting requirements under SARA title III, section 313 for chemicals which are classified as ("Section 313 water priority chemicals") in accordance with the definition in Part VII of this permit are required to include, in addition to the information listed above, a discussion of the facility's conformance with the appropriate guidelines listed:

(1). In areas where Section 313 water priority chemicals are stored, processed or otherwise handled, appropriate containment, drainage control and/or diversionary structures shall be provided. At a minimum, one of the following preventive systems or its equivalent shall be used:

(a) Curbing, culverting, gutters, sewers or other forms of drainage control to prevent or minimize the potential for storm water run-on to come into contact with significant sources of pollutants; or

(b) Roofs, covers or other forms of appropriate protection to prevent storage piles from exposure to storm water, and wind blowing.

(2) If the installation of structures or equipment listed in parts III.C.4.f.(3).(a).(ii), or III.C.4.f.(3).(c) of this permit is not economically achievable at a given facility, the facility operator shall develop and implement a spill contingency and integrity testing plan which provides a description of measures that ensure spills or other releases of toxic amounts of Section 313 water priority chemicals do not occur as an alternative to the requirements of parts III.C.4.f.(3).(a).(ii), or III.C.4.f.(3).(c) of this permit. A spill contingency and integrity plan developed under this paragraph shall comply with the minimum requirements listed in parts III.C.4.f.(2). (a) through (d).

(a) The plan shall include a detailed description which demonstrates that the requirements of Parts III.C.4.f.(3).(a).(ii) and III.C.4.f.(3).(c) of this permit are not economically achievable;

(b) A spill contingency plan must include, at a minimum; a description of response plans, personnel needs, and methods of mechanical containment; steps to be taken for removal of spilled Section 313 water priority chemicals;

access to and availability of sorbents and other equipment; and such other information as required by the Director;

(c) The testing component of the alternative plan must provide for conducting integrity testing of storage tanks at least once every five years, and conducting integrity and leak testing of valves and piping a minimum every year; and

(d) A written and actual commitment of manpower, equipment and materials required to comply with the provisions of Part III.C.4.f.(2). (b) and (c) of this permit and to expeditiously control and remove quantity of Section 313 water priority chemicals that may result in a toxic discharge.

(3) In addition to the minimum standards listed under Part III.C.4.f.(1) of this permit, the storm water pollution prevention plan shall include a complete discussion of measures taken to conform with the following applicable guidelines, other effective storm water pollution prevention procedures, and applicable State rules, regulations and guidelines:

(a) *Liquid storage areas where storm water comes into contact with any equipment, tank, container, or other vessel used for Section 313 water priority chemicals.*

(i) No tank or container shall be used for the storage of a Section 313 water priority chemical unless its material and construction are compatible with the material stored and conditions of storage such as pressure and temperature, etc.

(ii) Secondary containment, sufficient to contain the capacity of the largest single container or tank in a drainage system where section 313 water priority chemicals are stored shall be provided. If the secondary containment area and its upstream drainage system are subject to precipitation, an allowance for drainage from a 25-year, 24-hour precipitation event shall be provided over and above the volume necessary to contain the largest single tank or container. Secondary containment systems shall be sufficiently impervious to contain spilled section 313 water priority chemicals until they can be removed or treated. The plant treatment system may be used to provide secondary containment, provided it has sufficient excess holding capacity always available to hold the contents of the largest container in the drainage area plus an allowance for drainage from a 25-year, 24-hour precipitation event.

(b) *Material storage areas for section 313 water priority chemicals other than liquids.* Material storage areas for section 313 water priority chemicals other than liquids which are subject to

runoff, leaching, or wind blowing shall incorporate drainage or other control features which will minimize the discharge of section 313 water priority chemicals. Drainage control shall minimize storm water contact with section 313 water priority chemicals.

(c) *Truck and rail car loading and unloading areas for liquid section 313 water priority chemicals* shall contain sufficient secondary containment or treatment capacity to hold or treat the largest tank truck or rail car or the largest compartment of a tank truck or rail car if the tanks are compartmented, which is loaded or unloaded at the facility. If secondary containment is provided in the treatment system, it must be designed so that adequate hydraulic capacity always exists to contain a spill of the largest container from the loading and unloading areas, including an allowance for drainage from a 25-year, 24-hour precipitation event.

(d) *In plant areas where section 313 water priority chemicals are transferred, processed or otherwise handled,* piping, processing equipment and materials handling equipment shall be designed and operated so as to prevent discharges of section 313 chemicals. Materials used in piping and equipment shall be compatible with the substances handled. Drainage from process and materials handling areas shall be designed as described in paragraphs (a), (b) and (c) of this section. Additional protection such as covers or guards to prevent wind blowing, spraying or releases from pressure relief vents from causing a discharge of Section 313 water priority chemicals to the drainage system shall be provided as appropriate.

(e) *Discharges from areas covered by paragraphs (a), (b), (c) or (d).*

(i) Drainage from areas covered by paragraphs (a), (b), (c) or (d) of this part shall be restrained by valves or other positive means to prevent a spill or other excessive leakage of section 313 water priority chemicals into the drainage system. Containment areas may be emptied by pumps or ejectors; however, these shall be manually activated.

(ii) Flapper-type drain valves shall not be used to drain containment areas. Valves used for the drainage of containment areas shall, as far as is practical, be of manual, open-and-closed design.

(iii) If plant drainage is not engineered as above, the final discharge of all in-plant storm sewers should be equipped to be equivalent with a diversion system that could, in the event of an uncontrolled spill of section 313 water

priority chemicals, return the spilled material to the facility.

(iv) Records shall be kept of the frequency and estimated volume (in gallons) of discharges from containment areas.

(f) *Plant site runoff other than from areas covered by (a), (b), (c) or (d).* Other areas of the facility (those not addressed in paragraphs (a), (b), (c) or (d)), from which runoff which may contain section 313 water priority chemicals or spills of section 313 water priority chemicals could cause a discharge shall incorporate the necessary drainage or other control features to prevent discharge of spilled or improperly disposed material and ensure the mitigation of pollutants in runoff or leachate.

(g) *Preventive maintenance and housekeeping.* All areas of the facility shall be inspected at specific intervals for leaks or conditions that could lead to discharges of section 313 water priority chemicals or direct contact of storm water with raw materials, intermediate materials, waste materials or products. In particular, plant piping, pumps, storage tanks and bins, pressure vessels, process and material handling equipment, and material bulk storage area shall be examined for any conditions or failures which could cause a discharge. Inspection shall include examination for leaks, wind blowing, corrosion, support or foundation failure, or other forms of deterioration or noncontainment. Inspection intervals shall be specified in the plan and shall be based on design and operational experience. Different areas may require different inspection intervals. Where a leak or other condition is discovered which may result in significant releases of section 313 water priority chemicals to the drainage system, corrective action shall be immediately taken or the unit or process shut down until corrective action can be taken. When a leak or noncontainment of a section 313 water priority chemical has occurred, contaminated soil, debris, or other material must be promptly removed and disposed in accordance with Federal, State, and local requirements and as described in the plan.

(h) *Facility security.* Facilities shall have the necessary security systems to prevent accidental or intentional entry which could cause a discharge. Security systems described in the plan shall address fencing, lighting, vehicular traffic control, and securing of equipment and buildings.

(i) *Training.* Facility employees and contractor personnel using the facility shall be trained in and informed of

preventive measures at the facility. Employee training shall be conducted at intervals specified in the plan, but not less than once per year, in matters of pollution control laws and regulations, and in the storm water pollution prevention plan and the particular features of the facility and its operation which are designed to minimize discharges of section 313 water priority chemicals. The plan shall designate a person who is accountable for spill prevention at the facility and who will set up the necessary spill emergency procedures and reporting requirements so that spills and emergency releases of section 313 water priority chemicals can be isolated and contained before a discharge of a section 313 water priority chemical can occur. Contractor or temporary personnel shall be informed of plant operation and design features in order to prevent discharges or spills from occurring.

(j) *Engineering Certification.* No storm water pollution prevention plan for facilities subject to SARA title III, section 313 requirements for chemicals which are classified as "Section 313 water priority chemicals" shall be effective to satisfy the requirements of part III.C.4.g of this permit unless it has been reviewed by a Registered Professional Engineer and certified to by such Professional Engineer. A Registered Professional Engineer shall recertify the plan every three years thereafter. By means of these certifications the engineer, having examined the facility and being familiar with the provisions of this part, shall attest that the storm water pollution prevention plan has been prepared in accordance with good engineering practices. Such certifications shall in no way relieve the owner or operator of a facility covered by the plan of their duty to prepare and fully implement such plan.

(Option B—Under option B, facilities subject to SARA title III, section 313 would not be subject to the requirements of part III.C.4.f. Such facilities would remain subject to other applicable requirements of parts III (baseline plan requirements) and IV (effluent limitations). In addition, under Option B, the monitoring frequencies for such facilities could be raised from biannually (2 times per year) (see part V.B.1 of this permit) to monitoring of discharges at a higher frequency (e.g. quarterly).)

g. *Salt storage.* Storage piles of salt used for deicing or other commercial or industrial purposes shall be enclosed or covered to prevent exposure to precipitation.

5. *Alternative requirements for construction activities.* Operations that discharge storm water associated with industrial activity from construction activities are not subject to the requirements of part III.C.4 of this permit, but are instead subject to the following requirements. The storm water pollution prevention plan shall include the following items:

a. *Site description.* Each plan shall provide a description of the following:

(1). A description of the nature of the construction activity;

(2). Estimates of the total area of the site and the area of the site that is expected to undergo excavation or grading;

(3). An estimate of the runoff coefficient of the site and existing data describing the soil or the quality of any discharge from the site;

(4). A site map indicating drainage patterns and approximate slopes anticipated after major grading activities, the location of major control structures identified in the plan, and surface waters; and

(5). The name of the receiving water(s) and the ultimate receiving water(s).

b. *Controls.* Each construction operation covered by this permit shall develop a description of controls appropriate for the facility, and implement such controls. The description of controls shall address the following minimum components:

(1). *Erosion and sediment controls.*

(a). *Vegetative practices.* A description of vegetative practices designed to preserve existing vegetation where attainable and revegetate open areas as soon as practicable after grading or construction. Such practices may include: temporary seeding, permanent seeding, mulching, sod stabilization, vegetative buffer strips, and protection of trees. The operator shall initiate appropriate vegetative practices on all disturbed areas within 7 calendar days of the last activity at that area.

(b). *Structural practices.* A description of structural practices to the degree attainable divert flows from exposed soils, store flows or otherwise limit runoff from exposed areas of the site. Such practices may include straw bale dikes, silt fences, earth dikes, brush barriers, drainage swales, check dams, subsurface drain, pipe slope drain, level spreaders, storm drain inlet protection, rock outlet protection, sediment traps, and temporary sediment basins.

(i) For sites with more than 10 disturbed acres at one time which are served by a common drainage location, a detention basin providing storage or

equivalent controls for runoff from disturbed areas from a 10 year, 24-hour storm, shall be provided where attainable. For drainage locations with more than 10 disturbed acres at one time which are served by a common drainage location where a detention basin providing storage or equivalent controls for runoff from disturbed areas from a 10 year, 24-hour storm is not attainable, silt fences, straw bale dikes, or equivalent sediment controls are required for all sideslope and downslope boundaries of the construction area.

(ii) For drainage locations serving 10 or less acres, silt fences, straw bale dikes, or equivalent sediment controls are required for all sideslope and downslope boundaries of the construction area or a detention basin providing storage for runoff from disturbed areas from a 10 year, 24-hour storm shall be provided.

(2). *Storm water management.* A description of measures to control pollutants in storm water discharges that will occur after construction operations have been completed. Such practices may include: infiltration of runoff onsite; flow attenuation by use of open vegetated swales and natural depressions; storm water retention structures and storm water detention structures. Where such controls are needed to prevent or minimize erosion, velocity dissipation devices shall be placed at the outfall of all detention or retention structures and along the length of any outfall channel as necessary to provide a non-erosive velocity flow from the structure to a water course. Justification shall be provided by the permittee for rejecting each practice based on site conditions.

(3). *Other controls.*

(a). *Waste disposal.* No solid waste, including building materials, shall be discharged.

(b) Off-site vehicle tracking of sediments shall be minimized.

(c). The plan shall ensure and demonstrate compliance with applicable State or local waste disposal, sanitary sewer or septic system regulations.

(4). *Approved state or local plans.* Facilities which discharge storm water associated with industrial activity from construction activities must include in their storm water pollution prevention plan procedures and requirements specified in applicable sediment and erosion site plans or storm water management plans approved by State or local officials. Applicable requirements specified in sediment and erosion plans or storm water management plans approved by State or local officials are, upon submittal of an NOI to be

authorized to discharge under this permit, incorporated by reference and are enforceable under this permit even if they are not specifically included in a storm water pollution prevention plan required under this permit. Operators of facilities seeking alternative permit requirements shall submit an individual permit application in accordance with part I.C.2 of the permit, along with a description of why requirements in approved State or local plans should not be applicable as a condition of an NPDES permit.

(5). *Maintenance.* A description of procedures to maintain in good and effective operating condition vegetation, erosion and sediment control measures and other protective measures identified in the site plan. Procedures in a plan shall provide that all erosion controls on the site are inspected at least once every seven calendar days.

(6). All storm water pollution prevention plans required under this permit are considered reports that shall be available to the public under section 308(b) of the CWA. The owner or operator of a facility with storm water discharges covered by this permit shall make plans available to members of the public upon request by the public. However, the permittee may claim any portion of a storm water pollution plan as confidential in accordance with 40 CFR part 2.

(7). No condition of this permit shall release the permittee from any responsibility or requirements under other environmental statutes or regulations.

Part IV. Numeric Effluent Limitations

A. SARA title III, section 313 Facilities. The effluent (100%) composed in part or in whole of storm water associated with industrial activity from facilities subject to reporting requirements pursuant to SARA title III, section 313 for chemicals which are classified as "section 313 water priority chemicals" that comes into contact with any equipment, tank, container or other vessel used for storage of a section 313 chemical, or located at a truck or rail car loading or unloading area, shall not be lethal to 20% or more of the more sensitive of either appropriate fish or invertebrate test organisms (96 hour static replacement toxicity tests (96-hr. LC20 > 100% effluent) for fish test organisms and 48 hour static replacement toxicity tests (48-hr. LC20 > 100% effluent) for invertebrate test organisms). Failure to demonstrate compliance with the acute whole effluent toxicity requirement after the compliance date of three years after the date of issuance of this permit will

constitute a violation of this permit (see part V.D of this permit). Any untreated overflow from facilities designed, constructed and operated to treat the volume of runoff from areas identified above which is associated with a 25 year, 24 hour rainfall event shall not be subject to the limitations of this part.

B. Coal pile runoff. Subject to the provisions of part IV.D, any composed in part or in whole of coal pile runoff shall not exceed a maximum concentration for any time of 50 mg/1 total suspended solids. The pH of such discharges shall be within the range of 6.0-9.0. Any untreated overflow from facilities designed, constructed and operated to treat the volume of coal pile runoff which is associated with a 25 year, 24 hour rainfall event shall not be subject to the limitations of this part.

Part V. Monitoring and Reporting Requirements

A. Failure to Certify. Any facility that is unable to provide the certification required under paragraph III.C.4.b.(11) (testing for illicit connections), must notify the Director within 180 days of the effective date of this permit. Such notification shall describe: the procedure of any test conducted for the presence of non-storm water discharges; the results of such test or other relevant observations; potential sources of non-storm water discharges to the storm sewer; and why adequate tests for such storm sewers were not feasible.

B. Monitoring Requirements:

1. Section 313 of SARA title III facilities. During the period beginning on the effective date and lasting through the expiration date of this permit, facilities subject to requirements to report releases into the environment under section 313 of SARA title III for chemicals which are classified as "section 313 water priority chemicals" are subject to the following monitoring requirements for storm water discharges associated with industrial activity that are discharged from any containment area:

a. Parameters. The parameters to be measured include: Oil and Grease (mg/L); Five Day Biochemical Oxygen Demand (BOD5) (mg/L); Chemical Oxygen Demand (COD) (mg/L); Total Suspended Solids (mg/L); Total Kjeldahl Nitrogen (TKN) (mg/L); Total Phosphorus (mg/L); pH; acute whole effluent toxicity; and any Section 313 water priority chemical for which the facility is subject to reporting requirements under section 313 of the Emergency Planning and Community Right to Know Act of 1986. In addition: the date and duration (in hours) of the

storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the total volume (in gallons) of the discharge sampled shall be provided;

b. Frequency of Monitoring. Sampling shall be conducted at least semi-annually (2 times per year) except as provided by paragraph V.B.10, V.B.11 or V.C.1;

2. Primary metal industries. During the period beginning on the effective date and lasting through the expiration date of this permit, facilities classified as Standard Industrial Classification (SIC) 33 (Primary Metal Industry) are subject to the following monitoring requirements for storm water discharges associated with industrial activity that are discharged from the facility:

a. Parameters. The parameters to be measured include: oil and grease (mg/L); five day biochemical oxygen demand (BOD5) (mg/L); chemical oxygen demand (COD) (mg/L); total suspended solids (mg/L); total Kjeldahl nitrogen (TKN) (mg/L); nitrate plus nitrite nitrogen (mg/L); total phosphorus (mg/L); pH; acute whole effluent toxicity; total lead (mg/L); total cadmium (mg/L); total copper (mg/L); total arsenic (mg/L); and total chromium (mg/L). In addition: the date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. Frequency of monitoring. Sampling shall be conducted at least semi-annually (2 times per year) except as provided by paragraph V.B.10, V.B.11 or V.C.1;

3. Land disposal units. During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity from any active or inactive landfill, land application site, or open dump that received any industrial wastes are subject to the following monitoring requirements:

a. Parameters. The parameters to be measured include: Ammonia (mg/L),

Bicarbonate (mg/L), Calcium (mg/L), Chloride (mg/L), Total Iron (mg/L), Magnesium (total) (mg/L), Magnesium (dissolved) (mg/L), nitrate plus nitrite nitrogen (mg/L), Potassium (mg/L), Sodium (mg/L), Sulfate (mg/L), Chemical Oxygen Demand (COD) (mg/L), Total Dissolved Solids (TDS) (mg/L), Total Organic Carbon (TOC) (mg/L), oil and grease (mg/L), pH, Total Arsenic (mg/L), Total Barium (mg/L), Total Cadmium (mg/L), Total Chromium (mg/L), Total Cyanide (mg/L), Total Lead (mg/L), Total Mercury (mg/L), Total Selenium (mg/L), Total Silver (mg/L), acute whole effluent toxicity. In addition: the date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the total volume (in gallons) of the discharge sampled shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least semi-annually (2 times per year) except as provided by paragraph V.B.10, V.B.11 or V.C.1;

4. *Wood treatment (chlorophenolic/creosote formulations).* During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity from areas that are used for wood treatment, wood surface application or storage of treated or surface protected wood at any wood preserving or wood surface facilities that currently use chlorophenolic formulations and/or creosote formulations are subject to the following monitoring requirements:

a. *Parameters.* The parameters to be measured include: oil and grease (mg/L), pH, BOD5 (mg/L), COD (mg/L), TSS (mg/L), total phosphorus (mg/L), total Kjeldahl nitrogen (mg/L), nitrate plus nitrite nitrogen (mg/L), acute whole effluent toxicity, and pentachlorophenol (mg/L). In addition: the date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least semi-

annually (2 times per year) except as provided by paragraph V.B.10, V.B.11 or V.C.1;

5. *Wood treatment (arsenic or chromium preservatives).* During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity from areas that are used for wood treatment or storage of treated wood at any wood preserving facilities that currently use inorganic preservatives containing arsenic or chromium are subject to the following monitoring requirements:

a. *Parameters.* The parameters to be measured include: oil and grease (mg/L), pH, BOD5 (mg/L), COD (mg/L), TSS (mg/L), total phosphorus (mg/L), total Kjeldahl nitrogen (mg/L), nitrate plus nitrite nitrogen (mg/L), total arsenic (mg/L), total chromium (mg/L), and total copper (mg/L). In addition: the date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least semi-annually (2 times per year) except as provided by paragraph V.B.10 or V.B.11;

6. *Coal pile runoff.* During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity from coal pile runoff are subject to the following monitoring requirements:

a. *Parameters.* The parameters to be measured include: oil and grease (mg/L), pH, TSS (mg/L), copper, nickel and zinc. In addition: the date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least semi-annually (2 times per year) except as provided by paragraph V.B.10 or V.B.11;

7. *Oil and gas exploration or production operations.* During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity from oil and gas exploration or production operations are, except as provided in part V.B.7.c, subject to the following monitoring requirements:

a. *Parameters.* The parameters to be measured include: oil and grease (mg/L), pH, BOD5 (mg/L), COD (mg/L), TSS (mg/L), total phosphorus (mg/L), total Kjeldahl nitrogen (mg/L), nitrate plus nitrite nitrogen (mg/L), and any pollutant limited in an effluent guideline to which the facility is subject. In addition: The date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least annually (1 time per year) except as provided by paragraph V.B.10 or V.B.11;

c. *Engineering certification.* In lieu of the monitoring requirements specified in parts V.B.7.a and b, a facility may have a Registered Professional Engineer certify that a storm water pollution plan has been prepared and is being implemented in accordance with the requirements of part III.C. A Registered Professional Engineer shall recertify the plan every three years. By means of these certifications the engineer, having examined the facility and being familiar with the provisions of this part, shall attest that the storm water pollution prevention plan has been prepared in accordance with good engineering practices. Such certifications shall in no way relieve the owner or operator of a facility covered by the plan of their duty to prepare and fully implement such plan.

8. *Other facilities.* During the period beginning on the effective date and lasting through the expiration date of this permit, storm water discharges associated with industrial activity which are covered by this permit, but are not subject to sampling requirements under parts V.B.1 through V.B.7 are subject to the following monitoring requirements:

a. *Parameters.* The parameters to be measured include: oil and grease (mg/L),

pH, BOD₅ (mg/L), COD (mg/L), TSS (mg/L), total phosphorus (mg/L), total Kjeldahl nitrogen (mg/L), nitrate plus nitrite nitrogen (mg/L), and any pollutant limited in an effluent guideline to which the facility is subject. In addition: The date and duration (in hours) of the storm event(s) sampled; rainfall measurements or estimates (in inches) of the storm event which generated the sampled runoff; the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event; and an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided;

b. *Frequency of monitoring.* Sampling shall be conducted at least annually (1 time per year) except as provided by paragraph V.B.10 or V.B.11.

9. *Sample type.* For discharges from holding ponds or other impoundments with a retention period greater than 24 hours (estimated by dividing the volume of the detention pond by the estimated volume of water discharged during the 24 hours previous to the time that the sample is collected), a minimum of one grab sample may be taken. For all other discharges, data shall be reported for both a grab sample and a composite sample. All such samples shall be collected from the discharge resulting from a storm event that is greater than 0.1 inches in magnitude and that occurs at least 72 hours from the previously measurable (greater than 0.1 inch rainfall) storm event. The grab sample shall be taken during the first thirty minutes of the discharge. If the collection of a grab sample during the first thirty minutes is impracticable, a grab sample can be taken during the first hour of the discharge, and the discharger shall submit with the monitoring report a description of why a grab sample during the first thirty minutes was impracticable. The composite sample shall either be flow-weighted or time-weighted. Composite samples may be taken with a continuous sampler or as a combination of a minimum of three sample aliquots taken in each hour of discharge for the entire discharge or for the first three hours of the discharge, with each aliquot being separated by a minimum period of fifteen minutes. Only grab samples must be collected and analyzed for the determination of pH, cyanide, and oil and grease.

10. *Sampling waiver.* When a discharger is unable to collect samples due to adverse climatic conditions, the

discharger must submit in lieu of sampling data a description of why samples could not be collected, including available documentation of the event. Adverse climatic conditions which may prohibit the collection of samples includes weather conditions that create dangerous conditions for personnel (such as local flooding, high winds, hurricane, tornadoes, electrical storms, etc.) or otherwise make the collection of a sample impracticable (drought, extended frozen conditions, etc.).

11. *Representative discharge.* When a facility has two or more outfalls that, based on a consideration of features and activities within the area drained by the outfall, the permittee reasonably believes discharge substantially identical effluents, the permittee may test the effluent of one of such outfalls and report that the quantitative data also applies to the substantially identical outfalls. In addition, for each outfall that the permittee believes is representative, an estimate of the size of the drainage area (in square feet) and an estimate of the runoff coefficient of the drainage area (e.g. low (under 40%), medium (40% to 65%) or high (above 65%)) shall be provided.

C. *Toxicity testing.* In accordance with Parts IV and V of this permit, permittees that are required to monitor for acute whole effluent toxicity shall initiate the series of tests described below within 180 days after the issuance of this permit or within 30 days after the commencement of a new discharge.

1. The permittee shall conduct an acute 48 hour static replacement toxicity test on an appropriate invertebrate test species (EPA/600/4-85/013, Table 1) and an acute 96 hour static replacement toxicity test using an appropriate fish test species (EPA/600/4-85/013, Table 1). (Recommendation: A *Daphnia* species, and the fathead minnow (*Pimephales promelas*)). All test organisms, procedures and quality assurance criteria used shall be in accordance with Methods for Measuring the Acute Toxicity of Effluent to Freshwater and Marine Organisms, EPA-600/4-85/013 (Rev. March 1985). EPA has proposed to establish regulations regarding these test methods (December 4, 1989, (53 FR 50216)). Tests shall be conducted semiannually. Such tests shall be conducted on a grab sample of the discharge at 100% strength (no dilution). Compliance with the acute whole effluent toxicity limit of no significant difference from the control at the 95% confidence interval will be determined using the "t-test" statistical method described in Appendix H of

Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms (Second Edition, EPA/600/4-89/001, March 1989 and subsequent editions). Results of all tests conducted with any species shall be reported according to EPA/600/4-85/013, Section 13, Report Preparation and Data Utilization, or its latest revision, and shall be submitted to EPA with the quarterly discharge monitoring report. The permittee's monthly Discharge Monitoring Reports (DMR's) will report "0" if there is no statistical difference between the control mortality and the effluent mortality.³

2. If acute whole effluent toxicity is found in storm water discharges subject to the effluent limitation of Part IV.A in any samples collected after the compliance date of two years after the date of issuance of this permit, it will constitute a violation of this permit. The permittee will then be subject to the enforcement provisions of the Clean Water Act. In the event a violation of toxicity limits results in an enforcement action, any different or more stringent monitoring requirements imposed in that enforcement action shall apply in lieu of the requirements of this permit condition for whatever period of time is specified by EPA in the enforcement action.

3. If acute whole effluent toxicity is detected in storm water discharges subject to the effluent limitation of part IV.A before the compliance date of two years after the date of issuance of this permit, and it is determined by the permit issuing authority that a toxicity reduction evaluation (TRE) is necessary, the permittee shall be so notified and shall initiate a TRE immediately thereafter. The purpose of the TRE will be to establish the cause of the toxicity.

³ In order to provide consistency with other permits written in Region VIII, the permits for discharges in CO, WY, MT, ND and UT would substitute the following language for Part V.C.1: "The permittee shall conduct an acute 48-hour static replacement toxicity test using *Ceriodaphnia* sp. and an acute 96-hour static replacement toxicity test using fathead minnows. The replacement static toxicity tests shall be conducted in general accordance with the procedures set out in the latest revision of "Methods for Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms", EPA-600/4-85-013 (Rev. March 1985) and the "Region VIII EPA NPDES Acute Test Conditions—Static Renewal Whole Effluent Toxicity Tests". Tests shall be conducted semiannually. Such tests shall be conducted on a grab sample of the discharge at 100% strength (no dilution). After four (4) sets of tests of two (2) species, the permittee may limit subsequent testing to the most sensitive of the two (2) species, based on the results of the previous tests. Results of all tests shall be reported in a format consistent with the latest revision of the "Region VIII Guidance for Acute Whole Effluent Reporting", and shall include all chemical and physical data as specified.

locate the source(s) of the toxicity, and control or provide treatment for the toxicity priority to the compliance date of two years after the date of issuance of this permit.

D. Noncompliance reporting:

1. *Anticipated noncompliance.* The permittee shall give advance notice, if possible, at least ten days before the date of any planned changes in the permitted facility or activity which may result in any bypass, upset, or other noncompliance with permit requirements.

2. *Unanticipated bypass or upset.* The permittee shall submit notice of an unanticipated bypass or upset. Any information regarding the unanticipated bypass or upset shall be provided orally within 24 hours from the time the permittee became aware of the circumstances. A written submission shall also be provided within 5 days of the time the permittee became aware of the circumstances. The written submission shall contain a description of the bypass or upset and its cause; the period of the bypass or upset, including exact dates and times, and if the bypass or upset has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the bypass or upset.

E. Reporting: where to submit:

1. a. Permittees which are required to conduct sampling pursuant to parts V.B.1, V.B.2, and V.B.3 must submit monitoring results obtained during the previous 6 months on Discharge Monitoring Report Form(s) postmarked no later than the 28th day of the month following the completed reporting period. The reports are due on the 28th day of January and July. The first report may include less than the 6 months of information.

b. Permittees which are required to conduct sampling pursuant to parts V.B.4, V.B.5, and V.B.6 must submit monitoring results obtained during the previous 6 months on Discharge Monitoring Report Form(s) postmarked no later than the 28th day of the month following the completed reporting period. The reports are due on the 28th day of April and October. The first report may include less than the 6 months of information.

c. Signed copies of discharge monitoring reports required under parts V.E.1.a and V.E.1.b, and all other reports required herein, shall be submitted to the Director of the NPDES program at the following address:

Regional Office

2. Except as provided in part V.E.1 of this permit, for discharges subject to

sampling requirements pursuant to parts V.B.7 and V.B.8, permittees are not required to submit monitoring results pursuant to part V.E.1. However, such permittees must retain monitoring results in accordance with part V.F.

3. *Additional Notification.* Facilities with at least one storm water discharge associated with industrial activity through a large or medium municipal separate storm sewer system (systems serving a population of 100,000 or more) in addition to filing copies of discharge monitoring reports in accordance with paragraph V.E.1, must submit signed copies to the operator of the municipal separate storm sewer system of monitoring results obtained during the previous 6 months on Discharge Monitoring Report Form(s) postmarked no later than the 28th day of the month following the completed reporting period. For permittees which are required to conduct sampling pursuant to parts V.B.1, V.B.2, and V.B.3 the reports are due on the 28th day of January and July. For permittees which are required to conduct sampling pursuant to parts V.B.4, V.B.5, and V.B.6 the reports are due on the 28th day of April and October. The first report may include less than the 6 months of information.

F. Retention of records:

1. The permittee shall retain records of all monitoring information, copies of all reports required by this permit, and records of all data used to complete the Notice of Intent to be covered by this permit, for a period of at least three years from the date of the measurement, report, or application. This period may be explicitly modified by alternative provisions of this permit (see Part V.F.2 of this permit) or extended by request of the Director at any time.

2. For discharges subject to sampling requirements pursuant to part V.B., in addition to the requirements of part V.F.1, permittees are required to retain for a three-year period from the date of sample collection or for the term of this permit, whichever is greater, records of all monitoring information collected during the term of this permit. Permittees must submit such monitoring results to the Director upon the request of the Director, and submit a summary of such result as part of renotification requirements in accordance with part II.F.

Part VI. Standard Permit Conditions

A. Duty to Comply. The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of CWA and is grounds for enforcement action; for permit termination, revocation and

reissuance, or modification; or for denial of a permit renewal application.

1. *Toxic pollutants.* The permittee shall comply with effluent standards or prohibitions established under section 307(a) of the CWA for toxic pollutants within the time provided in the regulations that establish these standards or prohibitions, even if the permit has not yet been modified to incorporate the requirement.

2. *Penalties for violations of permit conditions.* Section 309 of the CWA provides significant penalties for any person who violates a permit condition implementing sections 301, 302, 306, 307, 308, 318, or 405 of the CWA, or any permit condition or limitation implementing any such sections in a permit issued under section 402. Any person who violates any permit condition of this permit is subject to a civil penalty not to exceed \$25,000 per day of such violation, as well as any other appropriate sanction provided by section 309 of the CWA.

B. Continuation of the expired general permit. An expired general permit continues in force and effect until a new general permit is issued. Only those facilities authorized to discharge under the expiring general permit are covered by the continued permit.

C. Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

D. Duty to mitigate. The permittee shall take all reasonable steps to minimize or prevent any discharge in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

E. Duty to provide information. The permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine compliance with this permit. The permittee shall also furnish to the Director upon request copies of records required to be kept by this permit.

F. Other information. When the permittee becomes aware that he or she failed to submit any relevant facts or submitted incorrect information in the Notice of Intent or in any other report to the Director, he or she shall promptly submit such facts or information.

G. Signatory requirements. All Notices of Intent, storm water pollution prevention plans, reports, certifications or information either submitted to the Director or the operator of a large or

medium municipal separate storm sewer system, or that this permit requires be maintained by the permittee, shall be signed.

1. All Notices of Intent shall be signed as follows:

a. For a corporation: By a responsible corporate officer. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation; or

(2) The manager of one or more manufacturing, production or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding \$25,000,000 (in second-quarter 1980 dollars) if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures;

b. For a partnership or sole proprietorship: By a general partner or the proprietor, respectively; or

c. For a municipality: State, Federal, or other public agency: by either a principal executive officer or ranking elected official. For purposes of this section, a principal executive officer of a Federal agency includes (1) the chief executive officer of the agency, or (2) a senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g. Regional Administrators of EPA).

2. All reports required by the permit and other information requested by the Director shall be signed by a person described above or by a duly authorized representative of that person. A person is a duly authorized representative only if:

a. The authorization is made in writing by a person described above and submitted to the Director.

b. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity, such as the position of manager, operator, superintendent, or position of equivalent responsibility or an individual or position having overall responsibility for environmental matters for the company. (A duly authorized representative may thus be either a named individual or any individual occupying a named position).

c. *Changes to authorization.* If an authorization under paragraph IV.D.2. is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of paragraph I.D.2 must be

submitted to the Director prior to or together with any reports, information, or applications to be signed by an authorized representative.

H. *Certification.* Any person signing documents under this section shall make the following certification:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

I. *Penalties for falsification of reports.* Section 309(c)(4) of the Clean Water Act provides that any person who knowingly makes any false material statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including reports of compliance or noncompliance shall, upon conviction, be punished by a fine of not more than \$10,000, or by imprisonment for not more than 2 years, or by both.

J. *Penalties for falsification of monitoring systems.* The CWA provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by fines and imprisonment described in section 309 of the CWA.

K. *Oil and hazardous substance liability.* Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject under section 311 of the CWA.

L. *Property rights.* The issuance of this permit does not convey any property rights of any sort, nor any exclusive privileges, nor does it authorize any injury to private property nor any invasion of personal rights, nor any infringement of Federal, State or local laws or regulations.

M. *Severability.* The provisions of this permit are severable, and if any provision of this permit, or the application of any provision of this permit to any circumstance, is held invalid, the application of such provision to other circumstances, and the remainder of this permit shall not be affected thereby.

N. *Transfers.* This permit is not transferable to any person except after notice to the Director. The Director may require the operator to apply for and obtain an individual NPDES permit as stated in part I.C.

O. *State laws.* Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable State law or regulation under authority preserved by section 510 of the Act.

P. *Proper operation and maintenance.* The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit and with the requirements of storm water pollution prevention plans. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. Proper operation and maintenance requires the operation of backup or auxiliary facilities or similar systems, installed by a permittee only when necessary to achieve compliance with the conditions of the permit.

Q. *Monitoring and records:*

1. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

2. The permittee shall retain records of all monitoring information including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of the reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement, report or application. This period may be extended by request of the Director at any time.

3. *Records contents.* Records of monitoring information shall include:

a. The date, exact place, and time of sampling or measurements;

b. The initials or name(s) of the individual(s) who performed the sampling or measurements;

c. The date(s) analyses were performed;

d. The time(s) analyses were initiated;

e. The initials or name(s) of the individual(s) who performed the analyses;

f. References and written procedures, when available, for the analytical techniques or methods used; and

g. The results of such analyses, including the bench sheets, instrument

readouts, computer disks or tapes, etc., used to determine these results.

4. Monitoring must be conducted according to test procedures approved under 40 CFR part 136, unless other test procedures have been specified in this permit.

5. The Clean Water Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than 2 years per violation, or by both.

R. Bypass of treatment facilities:

1. Notice:

a. Anticipated bypass. If the permittee knows in advance of the need for a bypass, he or she shall submit prior notice, if possible, at least ten days before the date of the bypass; including an evaluation of the anticipated quality and effect of the bypass.

b. Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass. Any information regarding the unanticipated bypass shall be provided orally within 24 hours from the time the permittee became aware of the circumstances. A written submission shall also be provided within 5 days of the time the permittee become aware of the circumstances. The written submission shall contain a description of the bypass and its cause; the period of the bypass, including exact dates and times, and if the bypass has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the bypass.

2. Prohibition of bypass:

a. Bypass is prohibited and the Director may take enforcement action against a permittee for a bypass. Unless:

- (1). The bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;
- (2). There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if the permittee should, in the exercise of reasonable engineering judgement, have installed adequate backup equipment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and
- (3). The permittee submitted notices as required under Part R.1 of this section.

b. The Director may approve an anticipated bypass after considering its adverse effects, if the Director

determines that it will meet the three conditions listed in part VIR.2.a. of this section.

S. Upset conditions.

1. An upset constitutes an affirmative defense to an action brought for noncompliance with technology-based permit limitations if the requirements of paragraph 2 below are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, if final administrative action subject to judicial review.

2. A permittee who wishes to establish the affirmative defense of an upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence, that:

- a. An upset occurred and that the permittee can identify the specific cause(s) of the upset;
- b. The permitted facility was at the time being properly operated;
- c. The permittee submitted notice of the upset as required under Part V; and
- d. The permittee complied with any remedial measures required under III.F.

3. In any enforcement proceeding the permittee seeking to establish the occurrence of an upset has the burden of proof.

T. Inspection and entry. The permittee shall allow the Director or an authorized representative of EPA, the State, or, in the case of a facility which discharges through a municipal separate storm sewer, an authorized representative of the municipal operator or the separate storm sewer receiving the discharge, upon the presentation of credentials and other documents as may be required by law, to:

1. Enter upon the permittee's premises where a regulated facility or activity is located or conducted or where records must be kept under the conditions of this permit;
2. Have access to and copy at reasonable times, any records that must be kept under the conditions of this permit; and
3. Inspect at reasonable times any facilities or equipment (including monitoring and control equipment).

U. Permit actions. This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.

Part VII. Reopener Clause

A. If there is evidence indicating potential or realized impacts on water quality due to any storm water discharge associated with industrial activity covered by this permit, the owner or operator of such discharge may be required to obtain individual permit or an alternative general permit in accordance with part I.C of this permit or the permit may be modified to include different limitations and/or requirements.

B. Permit modification or revocation will be conducted according to 40 CFR 122.62, 122.63, 122.64 and 124.5.

Part VII. Definitions

Best Management Practices (BMPs) means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of waters of the United States. BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage.

Bypass means the intentional diversion of waste streams from any portion of a treatment facility

Coal pile runoff means the rainfall runoff from or through any coal storage pile

CWA means Clean Water Act or the Federal Water Pollution Control Act.

Director means the Regional Administrator or an authorized representative.

Flow-weighted composite sample means a composite sample consisting of a mixture of aliquots collected at a constant time interval, where the volume of each aliquot is proportional to the flow rate of the discharge.

Landfill means an area of land or an excavation in which wastes are placed for permanent disposal, and which is not a land application unit, surface impoundment, injection well, or waste pile.

Land application unit means an area where wastes are applied onto or incorporated into the soil surface (excluding manure spreading operations) for treatment or disposal.

Large and Medium municipal separate storm sewer system means all municipal separate storm sewers that are either:

- (i) Located in an incorporated place with a population of 100,000 or more as determined by the latest Decennial Census by the Bureau of Census; or

(ii) Located in the counties with unincorporated urbanized populations of 100,000 or more, except municipal separate storm sewers that are located in the incorporated places, townships or towns within such counties; or

(iii) Owned or operated by a municipality other than those described in paragraph (i) or (ii) and that are designated by the Director as part of the large or medium municipal separate storm sewer system.

NOI means notice of intent to be covered by this permit (see part II of this permit.)

Runoff coefficient means the fraction of total rainfall that will appear at the conveyance as runoff.

Section 313 water priority chemical means a chemical or chemical categories which are:

(1) Are listed at 40 CFR 372.65 pursuant to section 313 of Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986, also titled the Emergency Planning and Community Right-to-Know Act of 1986;

(2) Are present at or above threshold levels at a facility subject to SARA title III, section 313 reporting requirements; and

(3) That meet at least one of the following criteria:

(i) Are listed in appendix D of 40 CFR part 122 on either Table II (organic priority pollutants), Table III (certain metals, cyanides, and phenols) or Table V (certain toxic pollutants and hazardous substances);

(ii) Are listed as a hazardous substance pursuant to section 311(b)(2)(A) of the CWA at 40 CFR 116.4; or

(iii) Are pollutants for which EPA has published acute or chronic water quality criteria.

Severe Property Damage means substantial physical damage to property, damage to treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

Significant materials includes, but is not limited to: Raw materials; fuels; materials such as solvents, detergents, and plastic pellets; finished materials such as metallic products; raw materials used in food processing or production; hazardous substances designated under section 101(14) of CERCLA; any chemical the facility is required to report pursuant to section 313 of title III of SARA; fertilizers; pesticides; and waste products such as ashes, slag and sludge

that have the potential to be released with storm water discharges.

Significant spills includes, but is not limited to: releases of oil or hazardous substances in excess of reportable quantities under section 311 of the Clean Water Act (see 40 CFR 110.10 and CFR 117.21) or section 102 of CERCLA (see 40 CFR 302.4).

Storm Water means storm water runoff, snow melt runoff, and surface runoff and drainage.

Storm Water Associated with Industrial Activity means the discharge from any conveyance which is used for collecting and conveying storm water and which is directly related to manufacturing, processing or raw materials storage areas at an industrial plant. The term does not include discharges from facilities or activities excluded from the NPDES program. For the categories of industries identified in subparagraphs (i) through (x) of this subsection, the term includes, but is not limited to, storm water discharges from industrial plant yards; immediate access roads and rail lines used or traveled by carriers of raw materials, manufactured products, waste material, or by-products used or created by the facility; material handling sites; refuse sites; sites used for the application or disposal of process waste waters (as defined at 40 CFR part 401); sites used for the storage and maintenance of material handling equipment; sites used for residual treatment, storage, or disposal; shipping and receiving areas; manufacturing buildings; storage areas (including tank farms) for raw materials, and intermediate and finished products; and areas where industrial activity has taken place in the past and significant materials remain and are exposed to storm water. For the categories of industries identified in subparagraph (xi), the term includes only storm water discharges from all areas listed in the previous sentence (except access roads) where material handling equipment or activities, raw materials, intermediate products, final products, waste materials, by-products, or industrial machinery are exposed to storm water. For the purposes of this paragraph, material handling activities include the: storage, loading and unloading, transportation, or conveyance of any raw material, intermediate product, finished product, by-product or waste product. The term excludes areas located on plant lands separate from the plant's industrial activities, such as office buildings and accompanying parking lots as long as the drainage from the excluded areas is not mixed with storm water drained from the above described areas. Industrial facilities

(including industrial facilities that are Federally or municipally owned or operated that meet the description of the facilities listed in this paragraph (i)-(xi)) include those facilities designated under 122.26(a)(1)(v). The following categories of facilities are considered to be engaging in "industrial activity" for purposes of this subsection:

(i) Facilities subject to storm water effluent limitations guidelines, new source performance standards, or toxic pollutant effluent standards under 40 CFR Subchapter N (except facilities with toxic pollutant effluent standards which are exempted under category (xi) of this paragraph);

(ii) Facilities classified as Standard Industrial Classifications 24 (except 2434), 26 (except 265 and 267), 28, 29, 30, 311, 32, 33, 3441, 373;

(iii) Facilities classified as Standard Industrial Classifications 10 through 14 (mineral industry) including active or inactive mining operations (except for areas of coal mining operations meeting the definition of a reclamation area under 40 CFR 434.11(1)) and oil and gas exploration, production, processing, or treatment operations, or transmission facilities that discharge storm water contaminated by contact with or that has come into contact with, any overburden, raw material, intermediate products, finished products, byproducts or waste products located on the site of such operations; inactive mining operations are mining sites that are not being actively mined, but which have an identifiable owner/operator;

(iv) Hazardous waste treatment, storage, or disposal facilities, including those that are operating under interim status or a permit under Subtitle C of RCRA;

(v) Landfills, land application sites, and open dumps that have received any industrial wastes (waste that is received from any of the facilities described under this subsection) including those that are subject to regulation under Subtitle D of RCRA;

(vi) Facilities involved in the recycling of materials, including metal scrapyards, battery reclaimers, salvage yards, and automobile junkyards, including but limited to those classified as Standard Industrial Classification 5015 and 5093;

(vii) Steam electric power generating facilities, including coal handling sites;

(viii) Transportation facilities classified as Standard Industrial Classifications 40, 41, 42, 44, and 45 which have vehicle maintenance shops, equipment cleaning operations, or airport deicing operations. Only those portions of the facility that are either involved in vehicle maintenance

(including vehicle rehabilitation, mechanical repairs, painting, fueling, and lubrication), equipment cleaning operations, airport deicing operations, or which are otherwise identified under paragraphs (i)-(vii) or (ix)-(xi) of this subsection are associated with industrial activity;

(ix) Treatment works treating domestic sewage or any other sewage sludge or wastewater treatment device or system, used in the storage treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated to the disposal of sewage sludge that are located within the confines of the facility, with a design flow of 1.0 mgd or more, or required to have an approved pretreatment program under 40 CFR part 403. Not included are farm lands, domestic gardens or lands

used for sludge management where sludge is beneficially reused and which are not physically located in the confines of the facility, or areas that are in compliance with 40 CFR part 503;

(x) Construction activity including clearing, grading and excavation activities except: operations that result in the disturbance of less than five acres of total land area which are not part of a larger common plan of development or sale;

(xi) Facilities under Standard Industrial Classifications 20, 21, 22, 23, 2434, 25, 265, 267, 27, 283, 31 (except 311), 34 (except 3441), 35, 36, 37 (except 373), 38, 39, 4221-25, (and which are not otherwise included within categories (i)-(x));

Time-weighted composite means a composite sample consisting of a

mixture of equal volume aliquots collected at a constant time interval.

Waste pile means any noncontainerized accumulation of solid, nonflowing waste that is used for treatment or storage.

25-year, 24-hour precipitation event means the maximum 24-hour precipitation event with a probable reoccurrence interval of once in 25 years. This information is available in "Weather Bureau Technical Paper No. 40," May 1961 and "NOAA Atlas 2," 1973 for the 11 Western States, and may be obtained from the National Climatic Center of the Environmental Data Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

[FR Doc. 91-18825 Filed 8-15-91; 8:45 am]

BILLING CODE 6560-50-M

Federal Register

Friday
August 16, 1991

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 333

Topical Acne Drug Products for Over- the-Counter Human Use; Final Monograph; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 333**

[Docket No. 81N-0114]

RIN 0905-AA06

Topical Acne Drug Products for Over-the-Counter Human Use; Final Monograph**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) topical acne drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC topical acne drug products that have come to the agency's attention. This final rule does not include final agency action on the OTC topical acne active ingredient benzoyl peroxide. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 16, 1992.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 23, 1982 (47 FR 12430), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical acne drug products, together with the recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products (Antimicrobial II Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 21, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by July 21, 1982.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm.

4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC topical acne drug products was published in the Federal Register of January 15, 1985 (50 FR 2172). Interested persons were invited to file by May 15, 1985 written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by May 15, 1985. New data could have been submitted until January 15, 1986, and comments on the new data until March 17, 1986.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulation for OTC topical acne drug products (50 FR 2172), the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the Federal Register. Therefore, on or after August 16, 1992, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered

for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC topical acne drug products, eight consumers, one drug manufacturers association, one cosmetic manufacturers association, and four drug manufacturers submitted comments. A request for oral hearing before the Commissioner was also received on one issue. Copies of the comments and the hearing request received are on public display in the Dockets Management Branch (address above). Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

The Antimicrobial II Panel in its advance notice of proposed rulemaking (47 FR 12430 at 12475) and the agency in its tentative final monograph (50 FR 2172 at 2181) proposed monograph status for the ingredient benzoyl peroxide for OTC topical use in the treatment of acne. However, following this proposal the agency became aware of a study by Slaga, et al. (Ref. 1) that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a study by Kurokawa, et al. (Ref. 2) that reported benzoyl peroxide to have tumor initiation potential. Neither of these studies was discussed by the Panel or by the agency in the Federal Register publications identified above.

Subsequently, a drug manufacturers association submitted data and information in support of the safety of benzoyl peroxide (Refs. 3 through 6). FDA has evaluated these data and information and determined that the studies show that benzoyl peroxide is a skin tumor promoter in more than one strain of mice as well as in other laboratory animals tested. To date, topical studies (which have shown only tumor promotion) have been of short duration (about 52 weeks), which the agency considers insufficient to rule out the potential for carcinogenicity. Although extensive animal data and human epidemiology data are available, the agency is unable to state that benzoyl peroxide is generally recognized as safe at this time. In the Federal Register of August 7, 1991 (56 FR 37622), the agency published an amended tentative final monograph for OTC topical acne drug products in which it reclassified benzoyl peroxide from Category I (as proposed in the Federal Register of January 15, 1985) to Category III. Opportunities for public

comment and the submission of new data in response to this reclassification are discussed in that amended tentative final monograph.

This reclassification of benzoyl peroxide does not relate directly to the establishment of other acceptable ingredients, labeling, and other conditions for OTC topical acne drug products. Accordingly, in order to establish a final monograph for these other conditions without undue delay, at this time the agency is issuing a final monograph that addresses all other conditions. Final agency action on all aspects of the OTC topical acne drug product rulemaking except issues related to benzoyl peroxide occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC topical acne drug products.

In proceeding with this final monograph, the agency has considered all objections, the request for oral hearing, and the changes in the procedural regulations. Based on the discussion in comment 15 below, the agency considers the request for a hearing to be moot.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the *Federal Register* of December 16, 1972 (37 FR 26842) or to additional information that has come to the agency's attention since publication of the notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

References

- (1) Slaga, T. J., et al., Skin-Tumor Activity of Benzoyl Peroxide, A Widely Used Free Radical-Generating Compound, *Science*, 213:1023-1025, 1981.
- (2) Kurokawa, Y., et al., Studies on the Promoting and Complete Carcinogenic Activities of Some Oxidizing Chemicals in Skin Carcinogenesis, *Cancer Letters*, 24:299-304, 1984.
- (3) Comment No. RPT, Docket No. 81N-0114, Dockets Management Branch.
- (4) Comment No. RPT00002, Docket No. 81N-0114, Dockets Management Branch.
- (5) Comment No. SUP00002, Docket No. 81N-0114, Dockets Management Branch.
- (6) Comment No. SUP00003, Docket No. 81N-0114, Dockets Management Branch.

I. The Agency's Conclusions on the Comments

A. General Comments on OTC Topical Acne Drug Products

1. One comment stated its continuing position that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted

earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the *Federal Register* of May 11, 1972 (37 FR 9464 at 9471 to 9472); in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the *Federal Register* of November 12, 1973 (38 FR 31260); and in paragraph 1 of the preamble to the tentative final monograph in the present proceeding (50 FR 2172 at 2173). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696-698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers v. FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. Several comments agreed with the agency's proposed rulemaking for OTC topical acne drug products. In particular, support was noted for (1) the proposed labeling in § 333.350, in which the agency consolidated the numerous claims recommended by the Panel into a few concise statements in order to improve clarity and reduce repetition; (2) the categorization of active ingredients in § 333.310, which would require each OTC acne drug product to contain one of the approved ingredients or the specific combination of sulfur and resorcinol included under permitted combinations in § 333.320; and (3) the proposed warning in § 333.350(c)(1)(ii) regarding the use of more than one topical acne medication at the same time, which the agency believed necessary in order to alert consumers using more than one acne product about the increased potential for dryness and irritation because all of the Category I acne ingredients are keratolytic and tend to dry out the skin. Another comment specifically stated its support for the agency's proposed Category I classification of the combination of 8 percent sulfur and 2 percent resorcinol. The comment pointed out that this combination has a long history of safe and effective use as an OTC topical acne drug product.

3. One comment disagreed with the Panel's decision not to classify adjunctive treatment products (i.e., wash-off medicated cleansers, soaps, and washes) in its review of topical acne drug products. The comment maintained that these adjunctive therapies are effective for their antiseborrheic and keratolytic

properties in the self-treatment of acne. The comment stated that the usefulness of these cleansers has been widely accepted by dermatologists, and washing the skin with medicated acne cleansers or soap as an adjunct to other acne treatment has been highly recommended. The comment requested that these products be recognized as adjuncts to acne treatment for the purpose of "promoting drying and peeling," "alleviating oiliness," and "removing/reducing sebum."

Although the Panel discussed adjunct therapies in its review of ingredients for the treatment of acne (Ref. 1), it did not classify adjunct therapies for the treatment of acne because of the lack of specific information regarding such treatments (e.g., abrasive scrubs, cleansers, and soaps). The Panel did not consider an ingredient unless it actually treated acne, i.e., actually reduced lesion count. The Panel noted that some consumers may prefer acne products that are formulated as abrasive scrubs. For this reason, the Panel included a short discussion of abrasive scrubs (physical abrasives) in its report (47 FR 12430 at 12441). The Panel did state its belief that it is unlikely that superficial epidermabrasion will remove the tightly adherent comedo. The Panel discussed a study by Mills and Kligman (Ref. 2) in which the authors concluded there was no evidence showing that abrasives could effectively remove comedones.

The agency has not received any submissions of data regarding adjunct therapies in treating acne in response to either the Panel's report or the tentative final monograph for OTC topical acne drug products. The comment did not submit any data on the safety and efficacy of these therapies. Therefore, the agency has no basis upon which to grant the comment's request. Data on the safety and effectiveness of these products, from controlled clinical studies, are needed before such therapies can be considered generally recognized as safe and effective as an adjunct in the treatment of acne. In addition, the agency points out that products that contain only claims for cleansing of the skin or removing oil are considered cosmetic products and are not subject to this OTC drug monograph. For the above reasons, the agency is not including in this final monograph either adjunctive therapies or the labeling claims suggested by the comment.

References

- (1) Minutes of the 49th Meeting of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products, March 21 and 22, 1980, pp. 46-56.

(2) Mills, O. H., Jr., and A. M. Kligman, *Evaluation of Abrasives in Acne Therapy, CUTIS: Cutaneous Medicine for the Practitioner*, 23:704-705, 1979.

B. Comments on OTC Topical Acne Ingredients

4. One comment contended that the agency's proposed classifications of various active drug ingredients do not establish requirements for the cosmetic uses of those ingredients. The comment gave several examples of ingredients that the Panel and agency have found lack effectiveness as active anti-acne drug ingredients, but which have other uses in cosmetic products (e.g., preservative, emulsifier, stabilizer, viscosifier, fragrance, and antioxidant) and could be used for these purposes in acne drug products. The comment requested that the agency include a statement in this final rule similar to statements that appeared in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6822 to 6823). These statements were that this monograph "covers only the drug use of the active ingredients listed therein," and "the concentration range, limitations, warnings, and directions established for these ingredients in the monograph do not apply to the use of the same ingredients in products intended solely as cosmetics."

As noted by the comment, the agency discussed this subject in the tentative final monograph for OTC skin protectant drug products. The same principles are applicable in this final monograph. Because this final rule covers only the drug use of the active ingredients listed herein, the concentration range, limitations, warnings, and directions established for these ingredients in the monograph do not apply to the use of the same ingredients for non-drug effects in products intended solely as cosmetics. Those products intended for both drug and cosmetic use must conform to the requirements of the final monograph, the cosmetic labeling requirements of section 602 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 362), and the provisions of 21 CFR part 701, especially 21 CFR 701.3(d) regarding label declarations where a cosmetic product is also a drug.

5. One comment objected to the agency's placement of borates (boric acid and sodium borate) in Category II in products used for the treatment of acne. The comment noted that it did not know the actual concentrations or functions of borates in the acne preparations evaluated because it did not have access to the proprietary formulations submitted to the

rulemaking for OTC acne drug products. However, the comment maintained that because the ingredients were referred to as "active," their inclusion in the products must serve an efficacious purpose. The comment stated its belief that borax and/or boric acid were acting as pH control agents, preservative additives, or astringent and/or surface tension reducing additives, and that the concentration used in these products is relatively low—probably at a maximum of 5 percent by weight. The comment argued that, considering these functions, a Category II classification of borates based on efficacy was questionable.

Regarding safety, the comment maintained that the data bases used in evaluating borates were an inadequate series of literature reviews and did not include an evaluation of the only controlled clinical study on humans or long-term chronic animal studies. The comment stated that borax and boric acid have a long history of safe use in cosmetics, cleaning products, bath preparations, and pharmaceuticals. The comment added that a report by the Cosmetic Ingredient Review (CIR) Panel indicated that a level of borates up to 5 percent in cosmetics was safe for topical use. The comment included a summary of acute as well as chronic toxicity data, which had been generated over a period of years, to support the safety of borates. The comment stated that a closer examination of the criteria for classifying borates as Category II ingredients was justified considering the data cited as well as the long history of safety associated with borax and boric acid.

The Antimicrobial II Panel reviewed borates for safety and effectiveness in topical acne and topical antifungal drug products. The Panel concluded that borate preparations with a concentration of 5 percent or less were safe for topical application. However, there were very little data available for the Panel to evaluate the effectiveness of borates for the treatment of acne. There were no reports of clinical trials that showed definitive activity of borates in treating acne. The Panel found only one study that addressed borates as single ingredients in the treatment of acne. The study included 22 individuals treated with 50 percent sodium borate (present as small abrasive particles) in a vehicle of soapless cleansers. The rationale for the preparation's use was oil removal (the soapless cleansers) and gentle abrasion of the skin (the abrasive particles). The Panel noted that the study was neither controlled nor double-blind, lesion counts were not used as the method of evaluation, and concomitant therapy

was administered. The Panel concluded that borates had not been conclusively shown to be effective in treating acne.

Regarding the comment's belief that borates were acting as pH control agents, preservative additives, or astringent and/or surface-tension reducing additives in topical acne drug products, the comment did not submit any data to support this position. If the borate were functioning as a pH control agent, preservative additive, or surface tension reducing additive, it would be an inactive ingredient as defined in 21 CFR 220.3(b)(7) and (8). Borates as active/inactive ingredients in OTC astringent drug products were discussed in an amendment of the notice of proposed rulemaking for OTC skin protectant drug products (54 FR 13490 at 13491 to 13492). The acceptability of boric acid as a buffering agent or stabilizer in OTC drug products was discussed there. However, neither the data submitted to the Panel, nor the information provided by the comment, are sufficient to alter the nonmonograph classification of borates as active ingredients for the treatment of acne.

C. Comments on Labeling of OTC Topical Acne Drug Products

6. One comment noted its continuing opposition to the agency's exclusivity policy. The comment contended that FDA should not prescribe exclusive lists of terms from which indications for use for OTC drugs must be drawn, thereby prohibiting alternative OTC drug labeling terminology which is truthful, not misleading, and intelligible to the consumer. The comment subsequently requested clarification whether the proposed modifications in FDA's exclusivity policy (published in the *Federal Register* of April 22, 1985; 50 FR 15810) were intended to supersede the labeling policy on indications proposed in the tentative final monograph for OTC topical acne drug products (published in the *Federal Register* of January 15, 1985; 50 FR 2172 at 2177).

The general labeling policy proposed in the tentative final monograph for OTC topical acne drug products has been superseded. In the *Federal Register* of May 1, 1986 (51 FR 16258), the agency published a rule finalizing the April 22, 1985 proposal and changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated

APPROVED USES; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated APPROVED USES; or (3) the approved monograph language on indications, which may appear within a boxed area designated APPROVED USES, plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). The indications (§ 333.350(b)) in this final monograph for OTC acne drug products specifically refer to the general labeling policy stated in 21 CFR 330.1(c)(2).

7. Three comments disagreed with the agency's not including an antibacterial labeling claim for any topical acne ingredient in the tentative final monograph (50 FR 2172 at 2177 to 2178). The comments requested that the agency place an antibacterial claim in Category I in the final monograph for OTC topical acne drug products. Two of the comments specifically requested that products containing either benzoyl peroxide or the combination of 8 percent sulfur and 2 percent resorcinol be allowed to use the antibacterial claim in their labeling. These comments stated that the agency was in error regarding the statement in the tentative final monograph that no in vivo data were submitted in support of an "antibacterial" claim following publication of the Panel's report. The comments mentioned the presentations (and submissions) of data and literature (Ref. 1) addressing the antibacterial effectiveness of benzoyl peroxide and the combination of sulfur and resorcinol that had been made to the Panel. The comments contended that because the Panel had classified the antibacterial claim in Category I at its final meeting and included the claim as an indication in the labeling in its recommended monograph (47 FR 12430 at 12474 to 12476), there appeared to be no need for additional data submissions following publication of the Panel's report. One comment urged the agency to require an active acne ingredient to meet the in vivo testing criteria of both the free fatty acid reduction, as well as the *Propionibacterium acnes* log-reduction tests, in order to use the antibacterial

indication on the product labeling. The comment also suggested that the definitional testing methodologies be subject to modification or substitution by suitably equivalent test procedures.

One comment (Ref. 2) included two studies and selected literature previously presented to the Panel in support of the antibacterial effectiveness of benzoyl peroxide against the *P. acnes* organisms commonly associated with acne. Another comment (Ref. 3) included two studies that utilized the Panel's recommended *P. acnes* reduction technique and an optional free fatty acid reduction assay to determine in vivo antimicrobial activity of benzoyl peroxide. The comment also included an antibacterial study on *P. acnes* and fatty acid reduction previously provided to the Panel for the combination of 8 percent sulfur and 2 percent resorcinol (Ref. 1). The third comment (Ref. 4) included three clinical studies that assessed the effectiveness of benzoyl peroxide in reducing *P. acnes* and free fatty acids. The comment also resubmitted four presentations that had been made to the Panel on *P. acnes* and free fatty acid reduction by the combination of 8 percent sulfur and 2 percent resorcinol as well as several concentrations of benzoyl peroxide.

The agency has reviewed these studies and determined that no single study satisfies the Panel's in vivo testing criteria recommended in § 333.340 of its monograph (47 FR 12430 at 12475). One study (Ref. 5) was a 30-day, double-blind, half-face comparison of a 5-percent benzoyl peroxide wash with its vehicle in 20 subjects with facial acne. Nonblinded arms of the study consisted of Ivory soap washes compared with the 5-percent benzoyl peroxide wash or its vehicle in 40 subjects. During the first 15 days, subjects washed only with tap water. During the next 15 days, twice-daily washings of contralateral sides of the face were done by ancillary personnel using 2 of 3 treatments (5-percent benzoyl peroxide wash, the vehicle, or Ivory soap) in each subject to one or the other side of the face. Quantitative *P. acnes* cultures were performed using a modified Williamson scrub technique at baseline and on days 15, 22, and 29. Twenty subjects in the benzoyl peroxide-placebo group demonstrated a reduction in *P. acnes* counts of 16 percent on the benzoyl peroxide side and 2 percent on the placebo side ($p < 0.01$). In the total of 40 subjects treated with benzoyl peroxide, there was a reduction in *P. acnes* counts of greater than 0.75 log ($p < 0.01$) on the side of the face washed with benzoyl

peroxide. Although the only apparent deviation in this study from the Panel's recommended guidelines (47 FR 12430 at 12473 to 12474) was the determination of a single (instead of the preferred three separate) *P. acnes* baseline count, insufficient information was provided regarding microbiological techniques, sample sites utilized, and individual *P. acnes* counts. The study satisfies a majority of the in vivo testing criteria set forth by the Panel in its recommended monograph; however, as presented, it does not support the antibacterial claim. The data that were provided could not be appropriately, statistically analyzed because the original data were not included with the submission.

In another study (Ref. 6), 15 subjects with a high facial density of *P. acnes* were treated with a 5-percent benzoyl peroxide lotion and assessed for the suppression of *P. acnes* over a 24-hour period. The test lotion was applied 3 times over a 12-hour period. A modified Williamson and Kligman procedure was used for test site preparation, sample collection, and culturing. Samples for quantitative cultures of *P. acnes* were taken from each subject at baseline and 12 and 24 hours after the last treatment. A statistically significant ($p = 0.001$) reduction in *P. acnes* counts was reported at both 12 and 24 hours after treatment (34 percent and 22 percent, respectively). There was a greater than 0.75 log reduction in the *P. acnes* counts at both time periods. The agency finds that this study deviated from the Panel's recommended in vivo criteria for antibacterial activity in two key ways: The uncontrolled design and the very short duration of the study. In addition, appropriate statistical analysis was not possible because the original data were not provided with the submission.

In another study (Ref. 7), 20 subjects with Pillsbury Grades II and III acne were enrolled in this single blind, randomized, parallel group comparison of 10 percent benzoyl peroxide lotion (applied to the face twice daily) with oral tetracycline hydrochloride (250 milligrams (mg) three times per day) for 8 weeks. The Williamson and Kligman scrub technique was used to quantify the skin-surface bacteria at baseline, at 8 weeks at the end of treatment, and 4 weeks after treatment ended. Ten subjects in the test-lotion group and 7 subjects in the tetracycline group completed the treatment period. *P. acnes* Type I and Type II reductions occurred in 78 percent ($p = 0.001$) and 100 percent ($p = 0.12$), respectively, of the benzoyl peroxide subjects and in 43 percent and 83 percent, respectively, of the tetracycline subjects.

In another study (Ref. 8), 8 subjects with acne were involved in a double-blind, half-face comparison of a 10-percent benzoyl peroxide cream with 5 and 10 percent benzoyl peroxide lotions. Each subject received 2 applications per day of the cream to one side of the face, and the 5- or 10-percent lotion to the opposite side of the face, 6 days a week for 2 weeks. Beginning at day 1, a significant ($p < 0.1$) reduction from baseline of *P. acnes* Type I and Type II counts was seen in both the cream and lotion groups. The median reduction in *P. acnes* Type I and Type II counts at day 11 was 99.8 and 93.3 percent, respectively, in the cream group.

The two studies (Refs. 7 and 8) differ significantly from the Panel's recommended *in vivo* criteria for antibacterial activity. Neither study included a vehicle control or the recommended number of subjects for a half-face (minimum of 30 subjects) or a full-face (minimum of 15 subjects) study design. It was not clear in either study whether the same skin site (in each subject) was sampled at each of the different time points. In addition, while the two baseline bacteria counts reported in one study (Ref. 8) appeared adequate, the other study (Ref. 7) reported only a single baseline count.

Finally, the preferred baseline *P. acnes* density (1×10^5 to 1×10^6 organisms per square centimeter) was not satisfied by all the subjects in one study (Ref. 7), and only the mean counts for the subjects in the other study (Ref. 8) were reported.

The agency notes that, although a dramatic reduction in organisms was reported in three of the four studies discussed above, these studies all have flaws. Although the results of these studies make it difficult to rule out the possibility of antimicrobial activity for benzoyl peroxide, these studies, because of their flaws, cannot be used to support general recognition of an antibacterial claim for topical acne drug products containing benzoyl peroxide.

Three clinical studies (Ref. 4) published after the Panel ceased its deliberations assessed the effectiveness of benzoyl peroxide in reducing *P. acnes* and free fatty acids. A study by Leyden et al. (Ref. 9) was a controlled, parallel-group comparison of gel and lotion formulations of benzoyl peroxide (2.5 percent, 5 percent, and 10 percent concentrations). A reduction in *P. acnes* counts of approximately 1.5 log was reported with all benzoyl peroxide formulations (with no significant difference between the formulations). An 8-week, double-blind study by Cunliffe and Holland (Ref. 10) compared 5-percent benzoyl peroxide gel and

lotion in 48 subjects (paired according to sex, grade of acne, and lesion count). A reduction in both *P. acnes* counts and free fatty acids was shown throughout the treatment period. Nacht et al. (Ref. 11) compared a 3-percent hexachlorophene suspension with a 5-percent benzoyl peroxide lotion in a half-face study in 9 subjects with high-density *P. acnes* baseline counts. A reduction in mean *P. acnes* counts of 98 percent (1.6 log) and a 52-percent reduction in free fatty acid/triglyceride ratios was reported for benzoyl-peroxide treated areas.

The agency has determined that further information on the design and conduct of the Leyden et al. study (Ref. 9) would be needed to reach a definite conclusion regarding antibacterial activity. The details provided for the Cunliffe and Holland study (Ref. 10) and the Nacht et al. study (Ref. 11) were insufficient for appropriate evaluation; further, neither of these studies included vehicle control groups. Therefore, neither of these studies (Refs. 10 and 11) are adequate to establish general recognition of an antibacterial claim for OTC topical acne products containing benzoyl peroxide.

The agency has determined that all of the studies described above either differ significantly from the guidelines recommended by the Panel or do not provide sufficient detail of the study design, conduct, or data to allow for an appropriate evaluation. One critical deviation, in almost every study, was the lack of a vehicle control. The agency considers the vehicle control group essential in order to rule out any activity which might be attributable to the vehicle. In addition, inclusion of a vehicle control is necessary because the antimicrobial effectiveness of the acne drug product may be contingent upon the contact time permitted by the vehicle. Further, with one exception, it is impossible to determine whether the active ingredient produced the recommended minimum reduction of 0.75 log in *P. acnes* count from the baseline measurement, because the original data were not provided in the submissions.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (address above) (Ref. 12).

The submitted data do not support inclusion in this final monograph of the antibacterial labeling that the Panel proposed in § 333.350(b)(3). Therefore, the Panel's recommended testing criteria under § 333.340 of its proposed monograph, which support use of the antibacterial labeling proposed in § 333.350(b)(3), are not being included in

this final monograph. However, the agency believes that an OTC topical acne ingredient should meet specific testing criteria in order to be allowed to make an antibacterial claim.

The Panel recommended an optional *in vivo* test in § 333.340(e)(2) of its monograph using a reduction in free fatty acids on the skin surface to confirm antibacterial activity (47 FR 12430 at 12475). Although one comment urged the agency to require an active acne ingredient to meet this test to use the antibacterial indication in labeling, the agency concludes that such a test should continue to be optional if, based on the studies submitted and other information, the following modification is made to the criterion for *in vivo* testing for antibacterial activity that was recommended by the Panel in § 333.340(e)(1):

* * * A reduction of *P. acnes* counts of 0.75 log by the active ingredient must be demonstrated using an appropriate statistical test at an alpha error of less than or equal to 0.05. The *P. acnes* count in the active drug post treatment specimens must be at least 0.75 log lower than the corresponding baseline specimens and must be at least 0.75 log lower than the lesser of the vehicle baseline or vehicle post treatment *P. acnes* counts.

Regarding one comment's suggestion that the definitional testing methods be subject to modification or substitution by suitably equivalent test procedures, the agency notes that alternate methods would be acceptable so long as they have been evaluated and accepted by the agency. Such methods should be submitted to the agency for review. If found acceptable, they could be included in the monograph in the future as an alternate method. However, adequate data need to be submitted to the agency to support the testing procedures that would support antibacterial labeling for OTC acne drug products.

References

- (1) OTC Volumes 070234, 070235, and 070236.
- (2) Comment No. C00025, Docket No. 81N-0114, Dockets Management Branch.
- (3) Comment No. C00021, Docket No. 81N-0114, Dockets Management Branch.
- (4) Comment No. C00026, Docket No. 81N-0114, Dockets Management Branch.
- (5) Unpublished Study, The Effect of Oxy Wash 5% on the Cutaneous Population of Propionibacterium Acnes, Report No. NTI-004, Comment No. C00025, Docket No. 81N-0114, Dockets Management Branch.
- (6) Unpublished Study, Quantitative Determination of Suppression of Propionibacterium Acnes Over a 24 Hour Period by 5% Benzoyl Peroxide (Oxy 5), Report No. MA-00112, Comment No. C00025.

Docket No. 81N-0114, Dockets Management Branch.

(7) Unpublished protocol, IR Number 61-77, Comment No. C00021, Docket No. 81N-0114, Dockets Management Branch.

(8) Unpublished Protocol, IR Number 90-79, Comment No. C00021, Docket No. 81N-0114, Dockets Management Branch.

(9) Leyden, J., et al., Topical Antibiotics and Topical Antimicrobial Agents in Acne Therapy, *Acta Dermatovener*, Supplement 89:75-82, 1980.

(10) Cunliffe, W. J., and K. T. Holland, The Effect of Benzoyl Peroxide on Acne, *Acta Dermatovener*, 61(3):267-269, 1981.

(11) Nacht, S., et al., Comparative Activity of Benzoyl Peroxide and Hexachlorophene, *Archives of Dermatology*, 119:577-579, 1983.

(12) Letter from W. E. Gilbertson, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, coded LET11, Docket No. 81N-0114, Dockets Management Branch.

8. One comment contended that the proposed definition of acne in § 333.303(a) [i.e., "An inflammatory skin disease involving the oil glands and hair follicles of the skin"] is incomplete because it fails to recognize the noninflammatory lesions that are also characteristic of acne. The comment cited three references (Refs. 1, 2, and 3) to support its position. The comment stated that mild acne can be caused by either noninflammatory or inflammatory lesions and recommended that the definition of acne be expanded as follows: "A skin disease, involving the oil glands and hair follicles of the skin. This disease includes noninflammatory lesions (comedones, whiteheads, and blackheads) as well as inflammatory lesions, also called pimples (papules and pustules)."

A standard medical dictionary defines acne as "an inflammatory disease of the pilosebaceous unit" (Ref. 4). However, other authors define acne based on the clinical manifestations of the disease. Moschella, Pillsbury, and Hurley (Ref. 3) note that the interaction of many factors leads to the production of clinical lesions which are either noninflammatory (i.e., open and closed comedones) or inflammatory. The closed comedones (whiteheads) are the first visible lesions of acne and suffer one of two fates, either they rupture and incite an inflammatory lesion or they transform into open comedones (blackheads) (Ref. 2). Although many clinicians regard blackheads as the hallmark of acne, their absence by no means negates the diagnosis, because many acne sufferers have few or no blackheads (Ref. 1). Hurwitz (Ref. 5) noted that acne usually appears as a variety of lesions with the comedones being characteristic of the disease. Gossell (Ref. 6) also described comedones as being the typical lesions

of acne. In its mildest form, acne consists of open (blackheads) and closed (whiteheads) comedones. Tunnessen (Ref. 7) noted that while there exists great variation in the number and type of lesions in each person, comedones are usually the predominant lesions present in early adolescence. The comedones have been referred to as the noninflammatory lesions of acne (Refs. 8 and 9). Acne consisting primarily of blackheads and whiteheads has been designated as mild or noninflammatory acne (Refs. 10 through 13). Although individuals usually have a combination of noninflammatory and inflammatory lesions, one or the other type may predominate (Ref. 8).

The Panel designated the comedo the primary lesion of acne (47 FR 12430 at 12435). The comedo has been considered by many (as noted above) to be a sign or symptom on which a diagnosis of acne can be made. Because the comedo may be the predominant lesion of acne in some individuals, the agency agrees with the comment and concludes that it would be appropriate to include the noninflammatory lesions of acne in the monograph definition of acne. However, the definition section of the monograph only includes those terms that are necessary for the information that appears in the monograph. The agency does not believe that consumers differentiate between inflammatory or noninflammatory lesions, or use the terms inflammatory or noninflammatory to describe their lesions. Likewise, consumers do not use the terms comedo or comedones to describe their blackheads or whiteheads. Therefore, the agency is not including the terms inflammatory, noninflammatory, or comedones in the monograph definition of acne. Consumers do use the terms "blackheads," "whiteheads," "pimples," and "blemishes" to describe their acne. The terms "blackheads," "pimples," and "blemishes" were proposed in the tentative final monograph to appear in the indications for OTC acne drug products. These terms plus the term "whiteheads" describe the inflammatory and noninflammatory appearances of acne in consumer terms. (See discussion of definitions for these terms in comment 9 below.) Accordingly, the agency is revising the definition of acne in § 333.303(a) of this final monograph to read as follows: "Acne. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes."

References

- (1) Cunliffe, W. J., and J. A. Cotterill, The Acnes "Clinical Features, Pathogenesis and Treatment", in *Major Problems in Dermatology*, Volume VI, edited by A. Rook, W. B. Saunders Co. Ltd., London, pp. 19-21, 1975.
- (2) Plewig, G., and A. M. Kligman, Acne. Morphogenesis and Treatment, Springer-Verlag, New York, pp. 58-60, 1975.
- (3) Tolman, L. E., Acne and Acneiform Dermatoses, in *Dermatology*, Volume II, edited by S. L. Moschella, D. M. Pillsbury, and H. J. Hurley, Jr., W. B. Saunders Co., Philadelphia, p. 1130, 1975.
- (4) Dorlands' Illustrated Medical Dictionary 27th Ed., W. B. Saunders Co., Philadelphia, 1988, s.v. acne.
- (5) Hurwitz, S., Acne Vulgaris, *American Journal of Diseases of Children*, 133:538-544, 1979.
- (6) Gossell, T. A., Acne: Myths, Facts and the Role of Benzoyl Peroxide, *U.S. Pharmacist*, 12:22-32, 1986.
- (7) Tunnessen, W. W., Acne: An approach to Therapy for the Pediatrician, *Current Problems in Pediatrics*, 14:1-36, 1984.
- (8) Spector, R., The Topical and Systemic Treatment of Acne Vulgaris, *Iowa Medicine*, 76:280-283, 1986.
- (9) Strauss, J. S., Update on Acne, *Primary Care*, 4:167-176, 1987.
- (10) Billows, J. A., Acne Products, in *Handbook of Nonprescription Drugs*, 8th Ed., American Pharmaceutical Association, Washington, pp. 533-591, 1988.
- (11) Quan, M. and R. A. Strick, Management of Acne Vulgaris, *American Family Physician*, 38:207-218, 1988.
- (12) Commens, C., Management of Acne, *Australian Family Physician*, 15:893-894, 1986.
- (13) Stubborn and Vexing, That's Acne, *FDA Consumer*, 14:14-17, 1980.

9. One comment requested that the following definitions, some of which the Panel adopted in the advance notice of proposed rulemaking (47 FR 12430 at 12435), be included in the final monograph for OTC acne drug products:

Comedo. The primary lesion of non-inflammatory acne.

Whitehead. A noninflammatory acne lesion, also called a closed comedo, characterized by a small, whitish, firm nodule.

Blackhead. A noninflammatory acne lesion, also called open comedo, characterized by a black tip.

Pimples. A small prominent inflamed elevation of the skin, including papules and pustules.

Papules. A small inflammatory lesion that appears red and raised.

Pustules. A small, raised inflammatory lesion that is filled with pus and arises from a papule.

The comment maintained that the terms, as defined above, should be included in the definition section of the monograph because they would provide clarity and consistency in referring to

the lesions that characterize acne. In addition, the comment disagreed with the agency's deleting the terms "follicle" and "lesion" from the definition section of the proposed monograph. The comment stated that the definition section will frequently be used by professionals involved with OTC acne drug products. The comment requested the agency to reinstate the terms "follicle" and "lesion" in the final rule, because they are correct medical terms. Two comments urged the agency to allow the use of such terms as "comedones," "whiteheads," "papules," and "pustules" in addition to the proposed terms of "blackheads," "acne pimples," and "acne blemishes" in § 333.350(b)(2) "other allowable indications" for OTC topical acne drug products. One comment stated that the different types of acne lesions are often defined and/or discussed in articles and books written for the general public; thus, the public is well-advised and continually exposed to the meanings of these terms. Both comments believed that including these terms in the monograph would provide more accurate and meaningful descriptions of the various types of acne lesions and thus would be appropriate for use in the indications section and other parts of the labeling.

The Panel's definitions relating to the use of acne drug products included "comedo," "whitehead," "papule," and "pustule" (47 FR 12430 at 12435). However, the Panel did not include these terms in the definitions in § 333.350(b) of its recommended monograph (47 FR 12475). Further, in the tentative final monograph the agency did not propose any of these terms for use in the labeling of OTC acne drug products.

The Panel proposed the terms "blackhead," "pimple," and "lesion" in § 333.350(b) of its recommended monograph (47 FR 12475) because it considered these terms to be more meaningful to consumers. However, the Panel defined a lesion generally (i.e., a characteristic area of a skin condition), and stated that lesions in acne include blackheads and pimples. The agency considers the terms "blackheads" and "pimples" appropriate for the labeling of OTC acne drug products, but does not consider the terms "comedo," "papule," "pustule," "lesion," and "follicle" as being widely used or understood by the majority of consumers who use OTC acne drug products. As discussed in comment 8 above, none of these terms has been included in the definition of acne that appears in this final monograph. The agency agrees with the

comment that allowing the term "whiteheads" in the indications for use is appropriate, because a whitehead is both the initial, and a primary, lesion of acne (see comment 8 above). In addition, the agency believes that consumers understand the meaning of the term and commonly use it to describe their acne lesions. However, the agency does not believe that many consumers use the terms "comedo" or "comedones" to refer to "whiteheads" or "blackheads" (closed and open comedones, respectively). Thus, the agency concludes that the terms "comedo" or "comedones" in the labeling of OTC acne drug products would be confusing to consumers.

Although a standard medical dictionary (Ref. 1) defines a pimple as a papule or pustule most often due to acne vulgaris, the agency does not believe that the terms "papule" or "pustule" are widely understood by consumers. The agency considers the term "acne pimples" to be more informative and less confusing to consumers. The terms "blackhead" and "pimple" were defined in the tentative final monograph. The term "acne blemish," which appeared in the labeling proposed in § 333.350(b)(2), was not. Therefore, the agency is clarifying the definition of the word "pimple" that was proposed in § 333.303(d) of the tentative final monograph by adding the word "acne" before "pimple" and by adding the words "resulting from acne" at the end of the definition. The agency is also adding a definition for "acne blemish" that reads: "A flaw in the skin resulting from acne." The agency is revising the definition for "blackhead" to read: "A condition of the skin that occurs in acne and is characterized by a black tip." Finally, the agency is adding a definition for "whitehead," which reads: "A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin." The agency is not using the term "nodule" in defining a whitehead, as suggested by the comment, because this type of acne lesion is usually macular or papular but rarely nodular. The Panel defined a "nodule" as a deep-seated lesion that develops from the rupture of closed comedones (whiteheads) (47 FR 12430 at 12435). Nodular lesions are more characteristic of acne conglobata, while the whiteheads in acne vulgaris are a more superficial type lesion (i.e., papular) (Ref. 2).

The above changes and addenda to the definitions require some editing of the definition section proposed in the tentative final monograph. Also, based on the amended definitions appearing in

this final monograph, the indications section of this final monograph (§ 333.350(b)) now includes the terms "acne blemishes," "acne pimples," "blackheads," and "whiteheads."

References

- (1) Dorlands' Illustrated Medical Dictionary 27th Ed., W. B. Saunders Co., Philadelphia, 1988, s.v. pimple.
- (2) Dorlands' Illustrated Medical Dictionary 27th Ed., W. B. Saunders Co., Philadelphia, 1988, s.v. papule.

10. One comment contended that the statement of identity (i.e., "acne medication") proposed in § 333.350(a), although accurate, was limiting as it did not distinguish between types of topical acne products. As an example, the comment cited a lack of distinction made between products intended to remain on the skin and those which are rinsed off after being applied. The comment suggested the agency allow other statements of identity which it felt would be appropriate for acne drug products, such as "acne treatment," "medicated acne cleanser," and "antibacterial acne medication (or cleanser or treatment)." The comment also asked that the product form, e.g., lotion, cream, gel, foam, etc., be allowed to be added, where appropriate, to more fully inform consumers.

The agency agrees with the comment that the term "acne treatment" would be an appropriate alternative statement of identity for OTC acne drug products because this term is as informative to consumers as the proposed statement of identity "acne medication." The agency also concurs with the comment's request to allow the dosage form to be added, following the product's statement of identity. Such information could be helpful to consumers in comparing and selecting topical acne drug products. The United States Pharmacopeia (U.S.P.) lists a number of dosage forms that might be used for OTC topical drug products, e.g., aerosol, cream, emulsion, gel, lotion, ointment, solution, or suspension (Ref. 1). The agency notes however that a foam, which the comment cited as an example, is not defined as a pharmaceutical dosage form in the U.S.P. (Ref. 1). In addition, although an aerosol is a defined pharmaceutical dosage form in the U.S.P., the agency determined from a marketplace survey of topical acne drug products (Refs. 2, 3, and 4) and from reviewing the submissions made to the Panel that there are only two aerosol drug products promoted as a "foam." However, neither product contains monograph ingredients. The agency is not aware of any topical acne

ingredients included in this final monograph having been marketed in an aerosol or foam dosage form. Therefore, the agency is not including "aerosol" or "foam" in the monograph as a part of the statement of identity.

The dosage forms listed in the monograph are examples only and are not intended to be all inclusive. Section 333.301(a) of the monograph states that an OTC acne drug product is in a form "suitable" for topical administration. The agency's marketplace survey shows that the most widely used dosage forms for OTC topical acne drug products are lotions, creams, and gels. Therefore, the agency is selecting these dosage forms to appear as examples in the statements of identity in § 333.350(a) of this final monograph as follows: "acne treatment," "acne medication," "acne treatment" (insert dosage form, e.g., "cream," "gel," or "lotion"), and "acne medication" (insert dosage form, e.g., "cream," "gel," or "lotion"). Other dosage forms would also be acceptable for OTC topical acne drug products based on their previous marketing history for this type of product. Examples include pads and ointments.

The agency believes that the other terms suggested by the comment, which included "antibacterial acne medication (or cleanser or treatment)" and "medicated acne cleanser," are not appropriate terms for the labeling of OTC acne drug products. Regarding the term "antibacterial," although several submissions were made in support of reinstating the "antibacterial claim" to Category I status, the agency has determined that the studies were not adequate; therefore, the term "antibacterial" is nonmonograph in this final rule (see comment 7 above). The agency considers the term "medicated" to be unnecessary because all OTC topical acne drug products contain medication. In addition, the agency notes that while "medicated acne cleanser" may be a term associated with adjunctive acne therapies, the agency is not including such products in this final monograph (see comment 3 above). Accordingly, the agency is not including these other terms in this final monograph.

References

- (1) The United States Pharmacopeia XXII—The National Formulary XVII, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1688–1697, 1989.
- (2) Physicians Desk Reference for Nonprescription Drugs, 10th Ed., Medical Economics Co., Inc., Oradell, NJ, p. 209, 1989.
- (3) Billows, J. A., Acne Products, in Handbook of Nonprescription Drugs, 8th Ed., American Pharmaceutical Association, Washington, pp. 583–591, 1988.

(4) Acne Products, in Facts and Comparisons, J. B. Lippincott Co., New York, pp. 544a–545a, 1989.

11. Two comments requested that the agency reinstate to Category I status the following labeling claims that had been recommended by the Panel: "loosens blackheads," "helps remove blackheads," and "unclogs (or unplugs) pores to help clear acne." The comments stated that the agency did not include these claims in the tentative final monograph because it believed that they were not clear or would be misleading to the consumer. The comments stated that Category I acne ingredients cause exfoliation of the stratum corneum, which causes an increased rate of turnover of the cells lining the duct walls of the comedo (blackhead). The comments added that peeling agents can also reduce the cohesiveness of these cells lining the duct. The comments stated that "the net effect of this topical treatment reduces the tendency of forming new comedones and loosens the structure of the formed comedones to help their extrusion" (Refs. 1, 2, and 3). The comments concluded that based on these mechanisms of action, the above claims are accurate, meaningful, and truthful statements that should be permitted in the monograph.

The agency does not agree with the comments that these statements should be included in the final monograph. In the tentative final monograph for OTC topical acne drug products (50 FR 2172 at 2179), the agency stated its belief that the Panel's recommended phrases "loosens blackheads," "helps remove blackheads," and "unclogs (or unplugs) pores to help clear acne," do not meaningfully or accurately describe the action of topical acne drug products. The agency has reviewed the three references cited by the comments and determined that they primarily describe the effectiveness of acne ingredients in terms of sebum removal and a mild peeling action. The agency notes that one of these references (Ref. 1) attributes some of the activities, as discussed by the comments, to topical acne ingredients which cause mild irritation and desquamation. However, a number of other sources in the literature (Refs. 4 through 9) present a different viewpoint. Accordingly, the agency concludes that there is insufficient basis to make the requested changes.

The agency considers the claims requested by the comments as accurately describing the action of comedolytic agents (i.e., agents which cause the unseating and expelling of comedones) (Refs. 4 and 10). A comedo (or blackhead, which is the term used in

the labeling claims requested by the comment) is a plug of keratin and sebum within the dilated orifice of a hair follicle (Ref. 11). A comedolytic agent acts by preventing infundibulum horny cells from sticking together and by causing an increased turnover of epithelial cells lining the pilosebaceous canal. This rapid turnover of loose horny cells causes the unseating and expulsion of existing comedones (Refs. 7, 8, and 9). The agency notes that benzoyl peroxide is the only OTC ingredient for the treatment of acne which has known comedolytic activity (Refs. 4 through 7). However, as discussed above, this final rule does not include final agency action on benzoyl peroxide.

As pointed out by the comments, certain Category I ingredients (i.e., sulfur and resorcinol) have exfoliating activity (i.e., agents which evoke a superficial peeling) (Refs. 4 and 10). The agency notes, however, that exfoliating agents do not necessarily function as a comedolytic. A comedolytic can be described as an exfoliant of the follicular infundibulum. However, an exfoliating agent, in general, is not specific for pilosebaceous epithelium. In addition, an exfoliating agent does not attack fibrous proteins (keratin) or cause loss of horny substance, does not dissolve comedones, and acts primarily on the epidermis (Refs. 4 and 5). Because most pustular acne lesions are quite superficial, an exfoliating agent (through its surface peeling action) can unroof these lesions and produce spontaneous drainage (Ref. 7). However, most of the agents that induce exfoliation, e.g., sulfur and resorcinol, are not a comedolytic. Although salicylic acid at concentrations of 5 to 10 percent is an effective comedolytic, the concentrations included in this final monograph (i.e., 0.5 to 2 percent) work primarily as a peeling agent, produce desquamation by hydrolyzing the intracellular substances of surface squames (exfoliants), and have less comedolytic activity (Refs. 7, 8, and 9). None of the active ingredients included in this portion of the final monograph are effective as a comedolytic agent at OTC concentrations (Refs. 4 and 5).

Accordingly, the agency concludes that the claims requested by the comments do not apply to the primary activity of the current monograph ingredients. The agency is not including these claims in the final monograph at this time.

References

- (1) Hopponen, R. E., Acne Products, in "Handbook of Nonprescription Drugs," 5th

Ed., American Pharmaceutical Association, Washington, pp. 316-323, 1977.

(2) Montagna, W., and P. F. Parakkal, *The Structure and Function of Skin*, 3rd Ed., Academic Press, Inc., New York, pp. 321-331, 1974.

(3) Tolman, E. L., *Acne and Acneiform Dermatoses*, in *Dermatology*, Volume II, edited by S. L. Moschella, D. M. Pillsbury, and H. J. Hurley, Jr., W. B. Saunders Co., Philadelphia, pp. 1132-1133, 1975.

(4) Schachner, L., *The Treatment of Acne: A Contemporary Review*, *The Pediatric Clinics of North America*, 30:501-510, 1983.

(5) Plewig, G., and A. M. Kligman, *Acne. Morphogenesis and Treatment*, Springer-Verlag, New York, pp. 277-311, 1975.

(6) Gossell, T. A., *Acne: Myths, Facts and the Role of Benzoyl Peroxide*, *U.S. Pharmacist*, 12:22-32, 1986.

(7) Reisner, R. M., *Acne Vulgaris*, in *Current Dermatologic Therapy*, W. B. Saunders Co., Philadelphia, pp. 3-8, 1982.

(8) Olsen, T. G., *Therapy of Acne*, *The Medical Clinics of North America*, 66:851-871, 1982.

(9) Quan, M., and R. A. Strick, *Management of Acne Vulgaris*, *American Family Physician*, 38:207-218, 1988.

(10) Melski, J. W., and K. A. Arndt, *Current Concepts: Topical Therapy for Acne*, *New England Journal of Medicine*, 302:503-506, 1980.

(11) *Dorlands' Illustrated Medical Dictionary*, 27th Ed., W. B. Saunders Co., Philadelphia, 1988, s.v. comedo.

12. One comment recommended that the agency delete the term "entire" from the proposed directions for using topical acne drug products in § 333.350(d)(1), which read: "Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily * * *."

Believing that the term "entire" in these directions might encourage overuse of topical acne drug products, the comment provided an example how the directions could be misread by consumers. A person with pimples speckling the back or shoulders might cover the whole back or shoulder area with an acne medication one to three times daily. The comment maintained that such application could result in overdrying of large areas of the skin. Therefore, the comment recommended that the directions simply read "Apply to the affected area."

In the advance notice of proposed rulemaking for OTC topical acne drug products, the Panel stated that the aim of acne therapy is not only to clear up existing acne lesions but also to prevent the formation of new acne lesions (47 FR 12430 at 12438). Studies reviewed by the Panel used a conservative estimate of 4 weeks as the natural resolution time of acne pimples. A person who has not been treated for acne will have a natural cyclical rise and fall in the number of

acne lesions over this time period. Using this estimate, the Panel concluded that any acne therapy that significantly reduced lesion counts over the first 4 weeks was effective in treating existing lesions. Also, any ingredient shown to be effective by reducing lesion counts beyond 4 weeks was also effective in preventing the development of new acne lesions.

The Panel discussed the fact that if individuals are instructed to cover the whole area where they have acne (i.e., the general area where they have the disease, rather than spot treatment), the medication will treat the existing acne lesions as well as prevent the development of new lesions (Refs. 1 and 2). Treating only the existing lesions will not provide successful long-term management of the disease due to its cyclical nature. Tunnessen (Ref. 3) emphasized the importance of covering all of the skin with the acne medication, not just the active lesions, to prevent new pimples from beginning. Quan and Strick (Ref. 4) recommended that patients using topical preparations be specifically instructed to apply the medication to all the affected areas (not just the individual lesions).

The agency believes, as did the Panel, that the purpose of acne therapy is to clear existing lesions and prevent the formation of new ones. In order to be as effective as possible, acne medications must be left on the skin for a finite period of time to penetrate into the follicle and dermis. Accordingly, they should be applied directly to areas of the skin with active lesions as well as to surrounding areas which have the potential for developing lesions. The directions to cover the entire affected area are intended to inform the user to apply the acne medication to all areas of the skin where existing lesions are visible as well as the surrounding areas where new acne lesions are likely to occur. Accordingly, the agency does not agree with the comment's recommendation that the term "entire" be deleted from the directions for use of topical acne drug products in § 333.350(d)(1).

References

(1) Minutes of the 41st Meeting of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products, April 27 and 28, 1979, pp. 165-168.

(2) Minutes of the 51st Meeting of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products, June 6 and 7, 1980 p. 74-75.

(3) Tunnessen, W. W., "Acne: An Approach to Therapy for the Pediatrician," *Current Problems in Pediatrics*, 14(5):1-36, 1984.

(4) Quan, M., and R. A. Strick, *Management of Acne Vulgaris*, *American Family Physician*, 38(2):207-218, 1988.

13. One comment objected to the proposed elimination of the term "caution(s)" in the labeling of OTC drug products. The comment asserted that while the terms "warning" and "caution" are both usually used to call attention to potential danger, there is a distinction between the terms that is important, especially when products contain long lists of warnings. The comment contended that the word "warning" is significantly harsher than "caution." A warning precludes the use of a product under certain conditions, e.g., "Warning: For external use only. Avoid contact with the eyes." The word "caution" on the other hand, does not preclude the use of the product but may alert the user to a potential problem, e.g., "Caution: If irritation develops discontinue use and consult a physician." Because the same phrases may be warnings with regard to one class of products and merely cautions with regard to another, the comment maintained that the flexibility of both terms is essential in order to prepare accurate and comprehensible labeling.

Section 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)(2)) states, in part, that a drug must bear in its labeling " * * * such adequate warnings * * * as are necessary for the protection of users." Section 330.10(a)(4)(v) of the OTC drug regulations provides that labeling of OTC drug products should include " * * * warnings against unsafe use, side effects, and adverse reactions * * *."

The agency notes that historically there has not been consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in §§ 369.20 and 369.21 (21 CFR 369.20 and 369.21), which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances, either of these signal words is used to convey the same or similar precautionary information.

FDA has considered which of these signal words would be most likely to attract consumers' attention to that information describing conditions under which the drug product should not be used or its use should be discontinued. The agency concludes that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. The agency considers the word "warning" alone to be the simplest, clearest signal to consumers. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC

drug labeling that is intended to alert consumers to potential safety problems.

14. One comment contended that the labeling statements included in a final monograph for OTC acne drug products can create no inferences for cosmetics or for the cosmetic aspects of acne drug products intended for both drug and cosmetic use. The comment stated that in other OTC drug rulemaking proceedings, such as in the tentative final monograph for OTC skin bleaching drug products (47 FR 39108 at 39115), the agency acknowledged that OTC drug monographs apply only to the active ingredients that fall within the statutory definition of "drugs." Maintaining that this same principle applies to OTC topical acne drug products, the comment requested that the agency include in the preamble to the final monograph the following statement: "The agency emphasizes that OTC drug monographs contain appropriate drug labeling claims to be used on OTC drug products and do not preclude the use of acceptable cosmetic claims if the product is both a drug and a cosmetic."

The agency agrees with the ideas expressed in this statement. While this monograph does not include any cosmetic labeling, such labeling may also appear on appropriate products along with the required drug labeling. (See comment 15 below for a discussion of where cosmetic labeling may appear.) Products labeled for both drug and cosmetic use must conform to the pertinent final OTC drug monograph(s), the cosmetic labeling requirements of section 602 of the act (21 U.S.C. 362), and 21 CFR 701.

15. One comment disagreed with the agency's position of prohibiting cosmetic claims from appearing in any portion of the labeling that is required by the monograph. The comment stated that so long as the labeling is truthful and not misleading, information about both the cosmetic and drug properties of a product should be permitted anywhere on the labeling. The comment contended that although acne is a medical condition treated with drug products, it is also a "cosmetic" problem because it "afflicts" the appearance. Therefore, the goal of therapy is a cosmetic one (i.e., to achieve a better appearance). Pointing out that the agency included the instructions "Cleansse the skin thoroughly before applying medication" in the directions proposed in § 333.350(d)(1), the comment argued that because the directions require an acne medication to be applied after the skin has been cleansed (a cosmetic claim), the agency should permit an acne product to bear unified, truthful

cosmetic/drug claims. The comment requested that the agency reconsider its position regarding segregating cosmetic labeling information from monograph information, and requested a hearing on this policy before the Commissioner.

The agency does not agree with the comment that the directions for use for OTC topical acne drug products contain a cosmetic claim. The consumer is instructed to cleanse the skin before applying the topical acne drug product. The act of cleansing is not done with the topical acne drug product, and this cleansing is intended to enhance the effectiveness of the topical acne drug product. The agency also does not agree with the comment that a statement about cleansing in the directions of these products supports an integrated drug-cosmetic labeling approach.

A final OTC drug monograph covers only the drug use of the active ingredients listed therein. The concentration range limitations, statements of identity, indications, warnings, and directions established for these ingredients in the monograph do not apply to the use of the same ingredients in products intended solely as cosmetics. However, if a product is intended for both drug and cosmetic use, it must conform to the requirements of the final OTC drug monograph. In addition, such products may also bear appropriate labeling for cosmetic uses provided the labeling complies with section 602 of the act (21 U.S.C. 362) and the provisions of 21 CFR part 701.

The labeling requirements for products covered by OTC drug monographs were being revised at the time of publication of the OTC topical acne tentative final monograph. The revised regulations in § 330.1(c)(2) set out three alternatives for stating an OTC drug product's indications for use in OTC drug labeling, as discussed in comment 6 above. If the labeling uses the APPROVED USES and boxed area designations provided in the regulations, cosmetic labeling may not appear within the boxed area. Such terminology is not reviewed and approved by FDA and, therefore, cannot appropriately be included in the APPROVED USES boxed area. However, cosmetic claims may appear elsewhere in the labeling (but not in the box), should manufacturers choose the labeling alternative provided in § 330.1(c)(2) (i) or (iii). If the APPROVED USES and boxed area options are not used, drug and cosmetic labeling may be commingled. However, the drug labeling must contain the information set out in the monograph and be presented in such a manner that consumers will readily be able to

differentiate the drug aspects from the cosmetic aspects of such labeling. Otherwise, commingled drug and cosmetic labeling claims may be confusing or misleading and thereby subject the product to regulatory action under the act.

Because drug and cosmetic labeling may appear together, in the circumstances described above, the request for a hearing on this issue is moot.

16. One comment stated that manufacturers should be allowed to use one or more of the three alternatives included in § 330.1(c)(2), provided that each labeling is complete and in compliance with all other labeling requirements. As an example, the comment stated that a manufacturer might wish to use the first alternative by listing APPROVED USES or FDA APPROVED USES in a boxed area on the outer container and also use the third alternative by presenting the same FDA approved indications under APPROVED USES or FDA APPROVED USES together with alternative truthful and nonmisleading terminology outside the boxed area on the immediate container. The comment requested that the final rule provide this labeling flexibility.

This comment was submitted before FDA issued a final rule in the *Federal Register* of May 1, 1986 (51 FR 16258) in which it changed its policy to allow such labeling. (See § 330.1(c)(2)(iv).) The indications (§ 333.350(b)) in this final rule contain a cross-reference to the labeling provisions in § 330.1(c)(2).

17. One comment recommended allowing manufacturers the option to include in the labeling under § 333.350(d) "Directions," an appropriate "directions for sensitivity test" to determine possible consumer sensitivity to the active ingredient(s) in topical acne drug products. The comment maintained that instructions on sensitivity testing would be informative as well as helpful in minimizing possible reactions for new users of acne medications. The comment proposed the following example for sensitivity test labeling:

SENSITIVITY TEST FOR NEW USER

1. Apply cream sparingly with finger-tips to one or two small affected areas during the first three days. If no discomfort occurs, apply up to two times daily, wherever pimples are a problem.

2. If bothersome dryness or peeling occurs, reduce dosage to one application per day or every other day.

The Panel, in its review of topical acne drug products, discussed whether

or not to include in the monograph labeling for a "sensitivity test" (Ref. 1). The directions for this test would advise individuals, especially those with unusually dry or sensitive skin, to pretest an acne medication on a small area of the skin before applying the product over a large area. The Panel believed that while it is common for mild irritation to occur with the use of OTC topical acne drug products, in particular products containing benzoyl peroxide, a greater degree of irritation is usually associated with excess use or improper application of the acne medication. The Panel considered the warning it recommended in § 333.350(c)(2), which advises consumers that there exists potential for irritation with the use of benzoyl peroxide, along with the directions for general use of topical acne drug products it recommended in § 333.350(d)(1), as including the information which would be conveyed to consumers in directions for a "sensitivity test." Although, the Panel did not propose to require such labeling in the monograph, the Panel had no objections to including a sensitivity test as optional labeling.

The agency notes that benzoyl peroxide is reported to be the most potentially irritating of OTC acne ingredients. However, as discussed above, benzoyl peroxide and labeling for products containing benzoyl peroxide are not included in this final rule. The active ingredients included in this final monograph act primarily as exfoliating agents (i.e., agents which evoke a superficial peeling) (Refs. 2 and 3) and thus their potential to cause irritation is greatly reduced. However, there are some individuals with sensitive skin who may benefit from labeling for a sensitivity test. Therefore, as requested by the comment, in this final monograph the agency is including "directions for a sensitivity test" as optional labeling. Manufacturers who believe this information is necessary can convey it to consumers in the labeling of their products. Section 333.350(d) is revised to include a new paragraph (3) to read as follows:

Optional directions. In addition to the required directions in paragraphs (d) (1) and (2) above, the product may contain the following optional labeling: *'Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions stated' (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')

The agency has determined that the second sentence of the sensitivity test suggested by the comment should be included as part of the regular directions for all OTC acne drug products.

Accordingly, the directions in § 333.350(d)(1) are being revised to read as follows: "Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day."

References

(1) Minutes of the 51st Meeting of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products, June 6 and 7, 1980, pp. 93-96.

(2) Melski, J. W., and K. A. Arndt, Current Concepts: Topical Therapy for Acne, New England Journal of Medicine, 302:503-506, 1980.

(3) Schachner, L., The Treatment of Acne: A Contemporary Review, The Pediatric Clinics of North America, 30:501-510, 1983.

II. Summary of Significant Changes to the Proposed Rule

1. The definition of acne proposed in § 333.303(a) is being revised by adding the terms "blackheads," "whiteheads," "acne pimples," and "acne blemishes." These terms are commonly used by consumers in describing acne. In addition, the agency is deleting the term "inflammatory" because it believes that consumers do not differentiate between the "inflammatory" and "noninflammatory" types of lesions that occur in acne. Also, consumers do not use these terms to describe their lesions. Accordingly, the agency is including the following definition of acne in § 333.303(a): "Acne. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes." Likewise, the agency is revising the definition of "acne drug product" in § 333.303(b) (redesignated § 333.303(c)) to delete the term "lesions" at the end of the definition and replace it with the terms "acne blemishes," "acne pimples," "blackheads," and "whiteheads," as follows: "Acne drug product. A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads." (See comment 8 above.)

2. Based on these definitions of acne and acne drug product, the agency is adding the term "whiteheads" to the proposed terms "blackheads," "acne pimples," and "acne blemishes" in the

indications for use in § 333.350(b)(2). The agency believes that consumers understand these terms and commonly use them to describe their acne lesions. (See comment 9 above.)

3. The agency is including a definition of the term "whitehead" in § 333.303(f) as follows: "A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin." (See comment 9 above.)

4. The agency is revising the definition of "blackhead" proposed in § 333.303(c) (redesignated § 333.303(e)) as follows: "A condition of the skin that occurs in acne and is characterized by a black tip." (See comment 9 above.)

5. The agency is clarifying the definition of the word "pimple" proposed in § 333.303(d) by adding the word "acne" before "pimple" and by adding the words "resulting from acne" at the end of the definition as follows: "Acne pimple. A small, prominent, inflamed elevation of the skin resulting from acne." (See comment 9 above.)

6. The term "acne blemish" which appeared in the labeling proposed in § 333.350(b)(2) was not defined in the tentative final monograph. Therefore, the agency is adding a definition for "acne blemish" in § 333.303(b) of this final monograph as follows: "Acne blemish. A flaw in the skin resulting from acne." (See comment 9 above.)

7. The agency is adding the term "acne treatment" as an alternate statement of identity in § 333.350(a). The agency is also including several representative examples of dosage forms that may appear in the statement of identity as follows: "acne treatment" (insert dosage form, e.g., "cream," "gel," "lotion," or "ointment") and "acne medication" (insert dosage form, e.g., "cream," "gel," "lotion," or "ointment"). (See comment 10 above.)

8. The agency is expanding the directions for use of all OTC acne drug products in § 333.350(d)(1) by adding an additional sentence at the end of the directions as follows: "Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day." (See comment 17 above.)

9. The agency is including "directions for a sensitivity test" as optional labeling. A new paragraph (3) in § 333.350(d) provides as follows: *Optional directions.* In addition to the

required directions in paragraphs (d) (1) and (2) above, the product may contain the following optional labeling: 'Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions stated' (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')

10. Although the in vivo testing criterion for antibacterial activity (as recommended by the Panel in § 333.340(e)(1)) is not being included in this final monograph, the agency believes that the following standards should apply:

A reduction of *P. acnes* counts of 0.75 log by the active ingredient must be demonstrated using an appropriate statistical test at an alpha error of less than or equal to 0.05. The *P. acnes* count in the active drug post treatment specimens must be a least 0.75 log lower than the corresponding baseline specimens and must be at least 0.75 log lower than the lesser of the vehicle baseline or vehicle post treatment *P. acnes* counts. (See comment 7 above.)

III. The Agency's Final Conclusions on OTC Topical Acne Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC topical acne drug products are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only ingredients that meet monograph conditions are salicylic acid, sulfur, and resorcinol and resorcinol monoacetate (in combination products). With the exception of benzoyl peroxide (see amended tentative final monograph for OTC topical acne drug products published in the *Federal Register* of August 7, 1991 (56 FR 37622), all other ingredients considered in this rulemaking have been determined to be nonmonograph conditions for use in a topical acne drug product. These ingredients are: alcloxa, alkyl isoquinolinium bromide, aluminum chlorohydrate, aluminum hydroxide, benzocaine, benzoic acid, boric acid, calcium polysulfide, calcium thiosulfate, camphor, chlorhydroxyquinoline, chloroxylonol, coal tar, dibenzothioephene, estrone, magnesium aluminum silicate, magnesium sulfate, phenol, phenolate sodium, phenyl salicylate, povidone-iodine, pyrillamine maleate, resorcinol (as single ingredient), resorcinol monoacetate (as single ingredient), salicylic acid (over 2 up to 5 percent), sodium borate, sodium thiosulfate, tetracaine hydrochloride,

thymol, vitamin E, zinc oxide, zinc stearate, and zinc sulfide. In the *Federal Register* of November 7, 1990 (55 FR 46914), the agency published a final rule in 21 CFR part 310 establishing that certain active ingredients that had been under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective. That final rule included in § 310.545(a)(1) all of the OTC topical acne ingredients listed above and was effective on May 7, 1991. This final rule does not result in the addition of any other ingredients to those already listed in § 310.545(a)(1). Accordingly, any drug product labeled, represented, or promoted for use as an OTC topical acne drug product that contains any of the ingredients listed in § 310.545(a)(1) or that is not in conformance with the monograph (21 CFR part 333), except for benzoyl peroxide as discussed above, may be considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352) and may not be marketed for this use unless it is the subject of an approved application under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314). An appropriate citizen petition to amend the monograph may also be submitted under 21 CFR 10.30 in lieu of an application. Any OTC topical acne drug product initially introduced or initially delivered for introduction into interstate commerce after the effective date of the final rule mentioned above or this final rule that is not in compliance with the regulation or the amended tentative final monograph for OTC topical acne drug products (56 FR 37622) is subject to regulatory action.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (50 FR 2172 at 2180 to 2181). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the *Federal Register* of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC topical acne drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC topical acne drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined that under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs, Topical acne drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 333 of Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Subpart C is added and reserved, and Subpart D consisting of §§ 333.301 to 333.350 is added to read as follows:

Subpart C—[Reserved]

Subpart D—Topical Acne Drug Products

Sec.

- 333.301 Scope.
- 333.303 Definitions.
- 333.310 Acne active ingredients.
- 333.320 Permitted combinations of active ingredients.
- 333.350 Labeling of acne drug products.

Subpart D—Topical Acne Drug Products

§ 333.301 Scope.

(a) An over-the-counter acne drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this

subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.303 Definitions.

As used in this subpart:

(a) *Acne*. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes.

(b) *Acne blemish*. A flaw in the skin resulting from acne.

(c) *Acne drug product*. A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

(d) *Acne pimple*. A small, prominent, inflamed elevation of the skin resulting from acne.

(e) *Blackhead*. A condition of the skin that occurs in acne and is characterized by a black tip.

(f) *Whitehead*. A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin.

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following when labeled according to § 333.350.

(a) Resorcinol 2 percent when combined in accordance with § 333.320(a).

(b) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b).

(c) Salicylic acid 0.5 to 2 percent.

(d) Sulfur 3 to 10 percent.

(e) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(a) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(b) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

§ 333.350 Labeling of acne drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "acne medication," "acne treatment," "acne medication" (insert dosage form, e.g., "cream," "gel,"

"lotion," or "ointment"), or "acne treatment" (insert dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(b) *Indications*. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the" (select one of the following: "management" or "treatment") "of acne."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any one or more of the following statements:

(i) (Select one of the following: "Clears," "Clears up," "Clears up most," "Dries," "Dries up," "Dries and clears," "Helps clear," "Helps clear up," "Reduces the number of," or "Reduces the severity of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "and allows skin to heal."

(ii) "Penetrates pores to" (select one of the following: "eliminate most," "control," "clear most," or "reduce the number of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iii) "Helps keep skin clear of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iv) "Helps prevent new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "from forming."

(v) "Helps prevent the development of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(c) *Warnings*. The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 333.310*. (i) "For external use only."

(ii) "Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor."

(2) *For products containing sulfur identified in §§ 333.310 (d) and (e)*. "Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor."

(3) *For products containing any combination identified in § 333.320*. "Apply to affected areas only. Do not use on broken skin or apply to large areas of the body."

(d) *Directions*. The labeling of the product contains the following information under the heading "Directions":

(1) "Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day."

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions*. In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: "*Sensitivity Test for a New User*. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

Dated: June 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-19304 Filed 8-15-91; 8:45 am]

BILLING CODE 4180-01-M