manure off-site. EPA's goal is to track the majority of the manure that is transferred to third parties. This information kept by the large operations is sufficient for EPA needs.

EPA decided not to include a small quantity exemption for off-site transfer of manure in the final rule. The reason for the proposed exemption was to provide record keeping relief to small operators. However, EPA determined that effective implementation of the small-quantity exemption would itself have required considerable recordkeeping by the operator. Practically, then, including this exemption would not have significantly reduced the record keeping burden to small operators.

The annual report, which includes seven elements that are readily available to the CAFO owner/operator in the nutrient management plan, is being required in today's rule rather than the proposed PNP written notification, cover sheet and executive summary. The annual report gives the permitting authority information on the number of overflows occurring in a year (in order to verify compliance with the production area design requirements), the amount of manure generated, the amount of manure transferred off-site, and the number of acres available for land application. The annual report also provides information, such as the degree to which CAFOs are expanding and accounting for increased manure production, which is important to evaluate changes that might be needed to comply with permitting requirements. The final rule requires the permittee to indicate whether its plan was either written or reviewed by a certified CNMP planner. EPA is not requiring that a certified planner be used to develop or review the plan required under this rule. However, EPA believes that certified planners provide a valuable service in plan development such as consistency and improved plan quality. Knowledge of which plans were developed by a certified planner will help EPA focus its compliance assistance efforts and help States determine level of permit review needed for each facility. EPA has concluded that the annual report is a more effective method for ensuring permitting authorities and EPA have basic information documenting CAFO performance relative to permit

requirements. EPA disagrees with the public comments suggesting that the monitoring and reporting requirements do not provide any benefit to water quality. Monitoring and reporting provide the basis for CAFO operators

and permitting authorities to evaluate compliance with the requirements of today's rule and the associated environmental implications. Monitoring provides valuable benchmark information and subsequent data that a permittee can use to adjust its activities, better comply with the requirements of the permit, and thereby better control its runoff or potential runoff. Monitoring also provides documentation of the operation's activities, which is essential to determine whether regulatory requirements are being implemented effectively and the success of those activities in protecting water quality. Monitoring allows the permittee and the permitting authority to know what, if any, contribution the permittee is making to the degradation of water quality. Such information is also helpful in determining the improvements in water quality as a result of permit compliance activities.

In this final rule, EPA has made great efforts to reduce burden beyond what is noted above. EPA has eliminated all certifications that were proposed, which include middle category certification that a facility is not a CAFO, certification of off-site manure recipients, and the use of certified CNMP planners. In addition, EPA is not including a national requirement for operators to document that there is no direct hydrological connection from groundwater beneath their production area to surface waters (or add controls where there is such a connection).

V. States' Roles and Responsibilities

A. What Are the Key Roles of the States?

State regulatory agencies with authorized NPDES programs are principally responsible for implementing and enforcing today's rule. This final rule obligates NPDES permit authorities to revise their NPDES programs expeditiously and to issue new or revised NPDES permits to include the revised effluent guidelines and other permit requirements adopted today. In authorized States, their role would also include determinations for no potential to discharge (see section IV.B.2 of this preamble) and CAFO designation (see section IV.A.7 of this preamble) of AFOs as CAFOs.

Various State organizations, such as environmental agencies, agricultural agencies, conservation districts, play a central role in implementing voluntary and other programs (e.g., technical assistance, funding, public involvement, legal access to information, and setting protocols) that support the goal of protecting water quality through proper management of animal manure. EPA

fully expects and promotes effective cooperation between voluntary and regulatory programs to achieve this goal. In designing this final rule, EPA has placed the principal emphasis on Large CAFOs which are part of the base NPDES program. With this in mind, EPA is promoting and encouraging States to use the full range of voluntary and regulatory tools to address medium and small operations.

B. Who Will Implement These New Regulations?

The requirements of today's rule will be implemented by issuing NPDES permits. Today's rule will be implemented by States with authorized NPDES permit programs for CAFOs. As of the date of this final rule, there are 45 States and 1 Territory with authorized NPDES permit programs for CAFOs. In States without an authorized NPDES program for CAFOs and in Indian Country, EPA will implement the rule.

C. When and How Must a State Revise Its NPDES Permit Program?

NPDES regulations require State NPDES permitting programs to be revised to reflect today's changes within one year of the date of promulgation of final changes to the Federal CAFO regulations (see 40 CFR 123.62(e)). In cases where a State must amend or enact a statute to conform with the revised CAFO requirements, such revisions must take place within two years of promulgation of today's regulations. States that do not have an existing authorized NPDES permitting program but who seek NPDES authorization after these CAFO regulatory provisions are promulgated must have authorities that meet or exceed the revised federal CAFO regulations at the time authorization is requested.

Today's regulation requires States to have technical standards for nutrient management consistent with 40 CFR 412.4(c)(3). If the State already has nutrient management standards in place, it is sufficient to provide those to EPA along with the State's submission of regulatory revisions to conform to today's changes. If the State has not already established technical standards for nutrient management, the Director shall establish such standards by the date specified in § 123.62(e) and provide those to EPA along with the State's submission of regulatory revisions.

The NPDES program modification process is described at 40 CFR 123.62. Opportunities for public input into the process of review and approval of State program revisions and approvals is

described in section V.C of this preamble.

D. When Must States Issue New CAFO NPDES Permits?

EPA does not typically establish requirements for when States must develop and issue NPDES permits. However, today's regulations require CAFOs to seek NPDES permit coverage under general permits within certain time frames, and CAFOs may not discharge any pollutants to waters of the United States without a permit. Thus, it is in States' interests to issue new or revised NPDES permits in a timely manner. It is EPA's expectation that new general permits will be available no later than the date on which CAFOs have a duty to apply for an NPDES permit. See section IV.B.3 for a full description of when CAFOs must seek permit coverage.

E. What Types of NPDES Permits Are Appropriate for CAFOs?

The NPDES regulations provide the permitting authority with the discretion to determine the most appropriate type of permit for a CAFO. The two basic types of NPDES permits are individual and general permits. An individual permit is a permit specifically tailored for a specific facility, while a general permit is developed and issued by a permitting authority to cover multiple facilities with similar characteristics.

EPA recognizes that most CAFOs will likely be covered by NPDES general permits; however, there are some circumstances where an individual permit might be appropriate (e.g., exceptionally large facilities, facilities that have a history of noncompliance, or facilities applying for approval to use an alternative performance standard in lieu of baseline technology-based effluent guidelines). The decision whether to issue a general or individual permit lies with the NPDES permitting authority. Section VI of the preamble discusses opportunity for public involvement in the NPDES permitting process.

As permit authorities explore innovative permitting approaches, the use of "watershed-based NPDES permits" might become more prevalent. For example, a watershed-based permit could be issued to CAFOs within a specific watershed. EPA is currently promoting pilot projects to help evaluate the benefits of watershed-based permitting and encourages States to use such a flexible tool to address the varied needs of specific watersheds.

F. What Flexibility Exists for States To Use Other Programs To Support the Achievement of the Goals of This Regulation?

In designing this final rule, EPA has striven to maximize the flexibility for States to implement appropriate and effective programs to protect water quality and public health by ensuring proper management of manure and related wastewater. This rule establishes binding legal requirements for Large CAFOs and maintains substantial flexibility for States to set other sitespecific requirements for CAFOs as needed to achieve State program objectives. EPA encourages States to maximize use of voluntary and other non-NPDES programs to support efforts by medium and small operations to implement appropriate measures and correct problems that might otherwise cause them to be defined or designated as a CAFO. EPA encourages States to use the flexibility available under the rule so that their State non-NPDES programs complement the required regulatory program. The following examples can illustrate opportunities for this State flexibility:

- States are encouraged to work with State agriculture agencies, conservation districts, USDA and other stakeholders to create proactive programs to fix the problems of small and medium operations in advance of compelling the facilities to apply for NPDES permits.
- Where a small or medium facility has been covered by an NPDES permit, the permitting authority may allow the facility to exit the permit program at the end of the 5-year permit term if the problems that caused the facility to be defined or designated as a CAFO have been corrected to the satisfaction of the permitting authority.
- A small or medium AFO might be taking early voluntary action in good faith to develop and implement a comprehensive nutrient management plan, yet might have an unexpected situation that could be the basis for the facility's being defined or designated as a CAFO. EPA encourages the permitting authority to provide an opportunity to address the cause of the discharge before defining or designating the operation a CAFO.

These examples are intended to illustrate the flexibility that EPA is promoting with regard to medium and small operations. They are not applicable to Large CAFOs.

What did EPA propose? EPA's proposed rule included an option to expand substantially the criteria for when medium and small AFOs could be defined or designated as CAFOs. The

effect of these proposed changes to the structure and definition of a CAFO was to require a substantially larger number of medium and small operations to be brought into the NPDES regulatory program. EPA estimated that as many as 30,000 medium and small AFOs could be brought into the regulatory program under this option. Another option presented in the proposal was to structure the permitting requirements to build in inherent flexibility for the medium facilities. In addition, the proposal and the subsequent 2001 Notice introduced a variety of more specific options for State flexibility, including one under which a State with an effective non-NPDES program could request to operate under a simplified permitting structure.

What were the key comments? The proposed expansion of the NPDES program for medium and small operations caused great concern, particularly among the States. Many comments from both States and facility operators centered on the desire that EPA recognize the effectiveness of existing State CAFO programs. More specifically, many States wanted EPA to allow effective State non-NPDES programs to operate in lieu of a Staterun NPDES program, particularly in the event that EPA in the final rule expanded the criteria for defining medium facilities as CAFOs.

In general, comments from environmental groups expressed opposition to most types of flexibility because of concerns regarding potential loss of accountability at facilities and reduced public participation. Industry commenters generally supported State flexibility as necessary to address factors such as soil, climate, and site and regional characteristics that vary within and among States. Commenters maintained that State flexibility promotes those program elements States have found to be most effective and allows States and industry to achieve workable solutions to water quality issues. States also supported maintaining a high degree of flexibility both to accommodate State-specific characteristics and priorities and to preserve their investment in existing good quality programs. Some State and industry commenters asserted that EPA's options for flexibility were too limited.

Rationale. EPA recognizes that EPA's proposed expansion of the criteria for when medium and small AFOs would be defined or designated as CAFOs would have had the effect of eliminating the flexibility for States to use voluntary and other programs. EPA is also aware that many of the States authorized to

implement the NPDES program supplement their NPDES CAFO requirements with additional State requirements. Some States currently regulate or manage CAFOs predominantly under State non-NPDES programs, or in conjunction with other water quality protection programs through participation in the CWA section 401 certification process (for permits) as well as through other means (e.g., development of water quality standards, development of TMDLs, and coordination with EPA). Several States have effective alternative or voluntary programs that are intended to help small and medium operations fix potential problems that could cause them to be defined or designated as a CAFO.

EPA is encouraging States to use their non-NPDES programs to help small and medium AFOs to reduce water quality impacts and to ensure that they do not become point sources under this regulation. To the extent the voluntary program eliminates the practice that results in the AFO's being defined or designated a CAFO, the AFO may not be required to obtain NPDES permit coverage. Given that EPA has not expanded the criteria for when AFOs would be defined as CAFOs, the Agency believes that States will have the flexibility necessary to leverage effective non-NPDES programs for medium and small AFOs. EPA has also offered specific examples of flexibility that permitting authorities can exercise.

Once a facility is determined to be a CAFO, however, coverage under a permit issued by a non-NPDES program will not satisfy the NPDES permit requirement. EPA is committed to work with States to modify existing non-NPDES State programs that currently regulate CAFOs to gain EPA's approval as NPDES-authorized programs. Such a change would require a formal modification of the State's authorized NPDES program, and the State would have to demonstrate that its program meets all of the minimum criteria specified in 40 CFR part 123, Subpart B, for substantive and procedural regulations. Among other things, these criteria include the restriction that permit terms may not exceed five years, procedures for public participation, and provisions for enforcement, including third party lawsuits and federal enforceability.

VI. Public Role and Involvement

The public has an important role in the entire implementation of the NPDES Program, including the implementation of NPDES permitting of CAFOs. The NPDES regulations in 40 CFR parts 122, 123, and 124 establish public participation in EPA and State permit issuance, in enforcement, and in the approval and modification of State NPDES Programs. The purpose of this section is to provide a brief review of the key areas where the public has opportunities for substantial involvement. These opportunities for public involvement are long-standing elements of the NPDES Program. Nothing in today's final rule is intended to inhibit public involvement in the NPDES Program.

A. How Can the Public Get Involved in the Revision and Approval of State NPDES Programs?

Sections 123.61 and 123.62 of the NPDES regulations specify procedures for review and approval of State NPDES Programs. In the case of State authorization or a substantial program modification, EPA is required to issue a public notice, provide an opportunity for public comment, and provide for a public hearing if there is deemed to be significant public interest. To the extent that these final regulations require a substantial modification to a State's existing NPDES Program authorization, the public will have an opportunity to comment on the proposed modifications.

B. How Can the Public Get Involved if a State Fails To Implement Its CAFO NPDES Permit Program?

Section 123.64 of the NPDES regulations provides that any individual or organization having an interest may petition EPA to withdraw a State NPDES Program for alleged failure of the State to implement the NPDES permit program, including failure to implement the CAFO permit program.

C. How Can the Public Get Involved in NPDES Permitting of CAFOs?

Section 124.10 establishes public notice requirements for NPDES permits, including those issued to CAFOs. Under these existing regulations, the public may submit comments on draft individual and general permits and may request a public hearing on such a permit. Various sections of part 122 and § 124.52 allow the Director to determine on a case-by-case basis that certain operations may be required to obtain an individual permit rather than coverage under a general permit. Section 124.52 specifically lists CAFOs as an example point source where such a decision may be made. Furthermore, § 122.28(b)(3) authorizes any interested person to petition the Director to require an entity authorized by a general permit to apply for and obtain an individual permit. Section 122.28(b)(3) also provides

example cases where an individual permit may be required, including where the discharge is a significant contributor of pollutants. See § 122.23(f)(3) for opportunities for public involvement in the process for making a "no potential to discharge" determination (refer to section IV.B.2 of this preamble for further discussion). Nothing in today's final rule is intended to change these provisions.

D. What Information About CAFOs Is Available to the Public?

Today's rule requires that all CAFOs, Large, Medium, and Small, and whether covered by a general or an individual permit, report annually to the permitting authority the following information:

- The number and type of animals, whether in open confinement or housed under roof:
- The estimated amount of total manure, litter and process wastewater generated by the CAFO in the previous 12 months:
- The estimated amount of total manure, litter and process wastewater transferred to other person by the CAFO in the previous 12 months;
- The total number of acres for land application covered by the nutrient management plan;
- The total number of acres under control of the CAFO that were used for land application of manure, litter and process wastewater in the previous 12 months;
- A summary of all manure, litter and process wastewater discharges from the production area that have occurred in the previous 12 months, including date, time, and approximate volume; and
- A statement indicating whether the current version of the CAFO's nutrient management plan was developed or approved by a certified nutrient management planner.

EPA expects that the permitting authority will make this information available to the public upon request. This should foster public confidence that CAFOs are complying with the requirements of the rule. In particular, the information in the annual report will confirm that CAFOs have obtained coverage under an NPDES permit, are appropriately controlling discharges from the production area, and have developed and are implementing a nutrient management plan. The annual report will also provide summary information on discharges from the production area and the extent of manure production and available land application area. This will help foster public confidence that the manure is being land applied at rates that ensure