

**EVALUATION OF EPA OFFICE OF SCIENCE AND TECHNOLOGY'S  
ANALYTICAL METHODS PROGRAM**

**Office of Planning, Analysis, and Accountability  
U.S. Environmental Protection Agency**

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### **APPENDICES**

Appendix A: Interview Guides

Appendix B: Analysis of Methodological Issues

## LIST OF ACRONYMS

A2LA -	American Association of Laboratory Accreditation
ACIL -	American Council of Independent Laboratories
ASTM -	American Society for Testing and Materials
ATP -	Alternate Test Procedures
CFR -	<i>Code of Federal Regulations</i>
CSO -	Combined sewer overflow
CWA -	Clean Water Act
EAD -	Engineering and Analysis Division (EPA/OW/OST)
EPA -	U.S. Environmental Protection Agency
ETV -	EPA Environmental Technology Verification Program
FEM -	EPA Forum on Environmental Measurement
FTE -	Full-time equivalent
HECD -	Health and Ecological Criteria Division (EPA/OW/OST)
NELAP -	National Environmental Laboratory Accreditation Program
NPDES -	National Pollutant Discharge Elimination System
OCFO -	EPA Office of the Chief Financial Officer
OMB -	U.S. Office of Management and Budget
OPAA -	Office of Planning, Analysis, and Accountability (EPA/OCFO)
OPEI -	EPA Office of Policy, Economics, and Innovation
ORD -	EPA Office of Research and Development
OST -	Office and Science and Technology (EPA/OW)
OW -	EPA Office of Water
OWM -	Office of Wastewater Management (EPA/OW)
PBMS -	Performance-based measurement system
QA -	Quality assurance
SASB -	Statistics and Analytical Support Branch (EPA/OW/OST/EAD)
SSO -	Sanitary sewer overflow
USGS -	U.S. Geological Survey
WEF -	Water Environment Federation
WET -	Whole Effluent Toxicity

## EXECUTIVE SUMMARY

Monitoring is a fundamental component of national clean water policy implementation. It is used to assess the condition of the Nation's waters, ensure compliance with pollutant discharge regulations, and support development of standards, regulations, and policy. The effectiveness of monitoring depends critically on the quality of analytical methods ("test procedures") and the consequent reliability and defensibility of the analytical data produced.

The Clean Water Act (CWA) requires EPA to promulgate guidelines establishing test procedures for the analysis of pollutants. Prior to 1996, responsibility for this requirement was shared by the EPA Office of Water's (OW's) Office of Science and Technology (OST) and the EPA Office of Research and Development (ORD). In 1996, OST took full responsibility for this requirement under the auspices of the Analytical Methods Program, expanding its responsibilities to include analytical methods validation, alternate test procedure (ATP) review, and promulgation of new methods, updated methods, and ATPs in the Code of Federal Regulations (CFR).

In 2003, EPA's Office of the Chief Financial Officer (OCFO), Office of Planning, Analysis, and Accountability (OPAA), working with the program staff, developed a plan to evaluate the effectiveness of the Analytical Methods Program in carrying out its responsibilities and to recommend program improvements. In April and May, 2004, an independent evaluation team conducted 34 open-ended interviews with program personnel and key stakeholders. Interview and other data were summarized and, along with subsequent analyses, are presented in this report.

The results of the evaluation represent a "snapshot" in time, particularly as they relate to activities that were ongoing or planned at the time that the interviews were conducted. However, the recommendations presented herein focus on long-term improvements and remain relevant despite this limited evaluation window.

### EVALUATION CONTEXT

The Analytical Methods Program provides analytical methods services along two distinct orientations, each involving a different set of stakeholders:

- Regulatory and strategic support to EPA's Office of Water, and
- Support for implementation of EPA's analytical methods program for ambient recreational water, drinking water, wastewater, biosolids, and other water-related matrices.

The Analytical Methods Program is responsible for providing analytical methods support to OW program offices in support of EPA's implementation of the Clean Water Act. A principal role of the Program is to validate analytical methods in support of water quality criteria and effluent limitations guidelines. Program staff provide technical advisory support as members of workgroups formed by other OW offices for regulatory and policy development and administer a laboratory services contract for methods evaluation and validation. Methods validation studies provide documentation needed to support rulemaking (e.g., new methods, effluent limitations guidelines, water quality standards), water quality criteria, and associated litigation. Program staff provide technical assistance to Effluent Guidelines Program staff and other EPA staff regarding the collection and review of environmental

data. This includes issuance of laboratory services contracts for analyses of pollutants in effluents and other water-related matrices in support of effluent guidelines development and special projects.

The Analytical Methods Program also oversees implementation of the provisions of the CWA that require promulgation of test procedures for the analysis of pollutants. Program staff review applications from analytical laboratories and laboratory equipment technologists for nationwide approval of alternatives to EPA-approved methods, provide technical assistance to EPA Regions for review of limited-use alternatives, support promulgation of improved and new analytical methods in the CFR, and provide technical assistance to those involved in the application of analytical methods for wastewater and other water matrices. In addition, the Program works with the American Society of Testing and Materials (ASTM), AOAC International (formerly known as the Association of Official Analytical Chemists) and other consensus standards organizations to update and revise methods.

The Analytical Methods Program currently consists of a staff of three and is overseen by OST's Statistics and Analytical Support Branch (SASB) Branch Chief.

The Analytical Methods Program affects both internal and external stakeholders. Key internal stakeholders include, OW's Standards and Health Protection Division, Health and Ecological Criteria Division (HECD), and Water Permits Division. Key external stakeholders include EPA Regions, state environmental programs, analytical laboratories, laboratory equipment vendors, consensus standards organizations, and industries and municipalities regulated under the CWA.

## **EVALUATION FINDINGS**

The Analytical Methods Program has devoted most of its resources in recent years to providing support to the Effluent Guidelines Program to help meet the requirements of court-orders. It has met this challenge. The Program has been critical to the success of the National Pollutant Discharge Elimination System (NPDES) permit program. It has helped ensure the availability of reliable analytical methods, and these methods have enabled EPA to collect credible data to support the regulations governing permits. In addition, these methods are included in NPDES permits and have been critical for gathering credible data for compliance. The Analytical Methods Program has provided effective support for development of water quality standards and criteria, and has fulfilled a critical function by providing expert consultation and review of environmental data issues.

Nonetheless, the Program has lacked visibility at the strategic level and, over time, its funding has evolved to align with the tactical capabilities of individual programs rather than the strategic objectives of the Agency. The Program's lack of resources has delayed actions that would help OW more effectively achieve its strategic objectives of protecting human health and improving water quality.

In addition, the lack of focus on the Program's implementation responsibilities (i.e., review and promulgation of improved and new methods) has slowed the potential for market-driven innovation in the wastewater analytical methods field. This has created burdens on Regional and state regulatory resources, slowed the adoption of more efficient technologies by analytical laboratories, and led to higher-than-necessary compliance costs. It has created inconsistencies that could

eventually affect EPA's ability to compare with confidence data collected from different Regions and states.

## RECOMMENDATIONS

EPA expects that support for court-orders will require far less effort from the Analytical Methods Program in the foreseeable future. In addition, the Agency is moving toward a more outcome-oriented approach to budgeting, as reflected in the *2003-2008 EPA Strategic Plan* (EPA 2003b). These events provide an opportunity to refocus the Analytical Methods Program, address its current deficiencies, and create a program that supports EPA's strategic goals of "Clean and Safe Water" and "Healthy Communities and Ecosystems." The following actions are recommended to capture this opportunity:

1. *Directly fund the analytical methods validation services of the Analytical Methods Program* - the services provided by the Analytical Methods Program are clearly aligned with the EPA's strategic goals, and direct funding of the Program would help OST and OW better communicate relationships among budget requests, expenditures, accomplishments, and environmental outcomes.
2. *Assign the Analytical Methods Program a more strategic role in coordinating analytical methods resources* - greater responsibility for coordinating wastewater analytical methods requirements would help ensure that EPA's strategic objectives relative to analytical methods are met. Components of this recommendation include:
  - A. Establish a formal, systematic approach to collecting and discussing analytical methods requirements and evaluating priorities and resources among other program offices.
  - B. Develop and communicate an analytical methods validation strategy for wastewater and other non-drinking water matrices.
  - C. Identify and coordinate interrelationships among the EPA offices with analytical methods development and validation responsibilities.
3. *Invest in a sustainable, market-oriented system for methods review and approval* - EPA may be able to lower the resources required for implementation of the Analytical Methods Program and create a more sustainable, less costly program by taking advantage of competition in the analytical methods marketplace. Components of this recommendation include:
  - A. Pursue cooperative partnerships with other organizations for review of analytical methods.
  - B. Regularly update improved and new methods in the CFR.
  - C. Develop an effective means for communicating with external customers about the status of approved modified methods and ATPs and for forecasting nationwide-use ATP and new methods approvals.
  - D. Develop and sustain a common understanding of responsibilities for review and approval of analytical methods.
  - E. Update the ATP and new method application protocols for organic and inorganic analytes in wastewater and drinking water.

## CONCLUSION

The Analytical Methods Program has helped ensure the availability of reliable analytical methods and has underpinned the success of the NPDES permit program. However, the lack of resources available for activities other than support for court-orders has delayed actions that would help OW more effectively achieve its strategic objectives and has slowed the potential for market-driven innovation in the wastewater analytical methods field.

The recommendations presented herein are intended to help EPA develop an effective approach to help the Agency obtain the funding necessary to create an Analytical Methods Program that will “Enhance Science” at EPA and advance its objectives of “Clean and Safe Water” and “Healthy Communities and Ecosystems.” They are also intended to encourage innovation in the analytical methods marketplace for the development and introduction of more efficient, innovative technologies and techniques, reduce analytical costs, and facilitate the evolution of analytical methods in response to changes in application (e.g., different types of wastewater) and performance requirements (e.g., sensitivity, specificity). This evolution, in turn, would strengthen the analytical methods used by EPA to support the development of its standards and criteria and other core clean water programs.



## **SECTION I: INTRODUCTION**

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### **PROGRAM BACKGROUND**

Monitoring is a fundamental component of national clean water policy implementation. It is used to assess the condition of the Nation's waters, ensure compliance with pollutant discharge regulations, and support development of standards, regulations, and policy. The effectiveness of monitoring depends critically on the quality of analytical methods and the consequent reliability and defensibility of the analytical data produced.

Section 304(h) of the Clean Water Act requires EPA to promulgate guidelines establishing test procedures for the analysis of pollutants. EPA uses these test procedures to support the development of effluent limitations guidelines, to establish compliance with NPDES permits, for implementation of pretreatment standards, and for section 401 certifications (EPA 1997b). EPA-approved analytical methods for the analysis of wastewater and requirements for application and approval of new and improved methods are outlined at 40 CFR 136, *Guidelines Establishing Test Procedures for the Analysis of Pollutants*.

Prior to 1996, many of the provisions of CWA Section 304(h) were the responsibility of EPA's ORD. In 1996, OST took full responsibility for these provisions, expanding its activities to include analytical methods validation, ATP review, and promulgation of new methods, updated methods, and ATPs in the CFR. The Statistics and Analytical Support Branch (SASB) of OST's Engineering and Analysis Division (EAD) oversees OST's Analytical Methods Program.

### **EVALUATION OBJECTIVES**

In the *2003-2008 EPA Strategic Plan*, EPA proposed an evaluation of the Analytical Methods Program in support of Goal 2, "Clean and Safe Water" (EPA 2003b). Support for the evaluation was provided through an internal EPA competition jointly sponsored by EPA's Office of the Chief Financial Officer (OCFO) and the Office of Policy, Economics, and Innovation (OPEI). OCFO's Office of Planning, Analysis, and Accountability (OPAA), working with the program staff, developed the scope of the evaluation. Two consulting firms, SRA International, Inc., and Industrial Economics, Inc., led the third-party objective evaluation effort under contract with OCFO.

The following specific research questions were posed to the evaluation team:

1. How effective has the program office been in the review of ATPs for use by the regulated community to comply with monitoring requirements?
2. How effective has the program office been in updating or revising existing analytical methods or in approving improved or new analytical methods in the *Code of Federal Regulations* (CFR)?
3. Has OST met the needs of the Regions and States regarding the review of ATPs and method approvals?
4. What deficiencies exist and what short-term and long-term improvements should be made to the analytical methods review and approval program to ensure that the program addresses the

needs of all stakeholders, including NPDES permittees, commercial vendors and analytical laboratories, EPA Regions, and States?

5. What are the consequences of not approving improved and new methods in the CFR?

## **EVALUATION METHODOLOGY**

The evaluation effort consisted of review of Program-related documentation and 34 open-ended interviews with program personnel and key stakeholders. Interview protocols were developed and mapped to the five research questions to ensure efficient and effective data collection and analysis. Interview and other data were summarized and, along with subsequent analyses, are presented in this report. The interview frame, interview protocols, and approach for summarizing and analyzing the evaluation data are described below.

### **Interview Frame**

The Analytical Methods Program provides analytical methods services along two distinct orientations, each involving a different set of stakeholders. The interview frame was designed to capture information from each of these stakeholder groups, as well as personnel who overlap both orientations (i.e., program staff and management).

The Analytical Methods Program provides regulatory and strategic support to EPA OW. EPA stakeholders most familiar with this support include people in the other divisions and branches within OW who rely on the Analytical Methods Program's expertise and services. To evaluate this aspect of the Program, the evaluation team interviewed personnel from the Office of Wastewater Management's (OWM's) Water Permits Division and OST's HECD. The Water Permits Division leads the Agency's development and implementation of the NPDES permit program. HECD provides risk assessment support for the CWA and develops water quality criteria.

In addition, the Analytical Methods Program provides support for implementation of EPA's analytical methods program for wastewater. This second orientation focuses primarily on stakeholders external to EPA OW, including EPA Regions and state environmental programs. To evaluate this aspect of the Program, the team interviewed personnel from the 10 EPA Regions, state environmental agencies, commercial analytical laboratories, laboratory equipment vendors, consensus standards organizations (e.g., the American Society for Testing and Materials, ASTM), and regulated entities (e.g., NPDES permittees).

To help define the evaluation context and obtain program staff and management perspectives, the evaluation team interviewed current and former members of the program staff, the SASB Branch Chief, who is responsible for overseeing the Program, and the Office Director for OST. Table 1 summarizes the interview frame for the evaluation.

<b>Table 1</b>
<b>Summary of Interviewee Affiliations and Positions</b>
<b>Analytical Methods Program and Management Interviews (Overlapping Orientations)</b>
OW/OST, Director
OW/OST, Engineering and Analysis Division, Statistics and Analytical Support Branch, Branch Chief
Analytical Methods Program staff (current and former)
<b>Internal Orientation (OW Support)</b>
OW/OST, Health and Ecological Criteria Division, Microbial Program Manager
OW/OWM, Water Permits Division: <ul style="list-style-type: none"> <li>• Municipal Branch, Branch Chief</li> <li>• State and Regional Branch, Branch Chief and staff</li> </ul>
<b>External Orientation (Program Implementation)</b>
EPA Regions 1 through 10: <ul style="list-style-type: none"> <li>• ATP contacts, Regions 1 through 10</li> <li>• Environmental Services Branch Chief, Region 6</li> <li>• Water Division, Region 9</li> </ul>
State environmental agencies: <ul style="list-style-type: none"> <li>• Massachusetts Department of Environmental Protection, Laboratory Certification Office</li> <li>• Louisiana Department of Environmental Quality, Laboratory Accreditation Program</li> <li>• Texas Commission on Environmental Quality, Laboratory Inspections/Certifications</li> <li>• California Environmental Protection Agency, Laboratory Accreditation Program</li> <li>• Nevada Division of Environmental Protection, Laboratory Certification Program</li> </ul>
Analytical laboratories: <ul style="list-style-type: none"> <li>• One small, regional commercial laboratory</li> <li>• One large, national commercial network laboratory</li> <li>• American Council of Independent Laboratories (ACIL)</li> </ul>
Laboratory equipment vendors (3 vendors), covering: <ul style="list-style-type: none"> <li>• Measurement technologies</li> <li>• Laboratory automation equipment</li> </ul>
Consensus standards organizations: <ul style="list-style-type: none"> <li>• American Society for Testing and Materials (ASTM)</li> <li>• AOAC International</li> </ul>
Regulated entities (2 entities), covering: <ul style="list-style-type: none"> <li>• Pulp and paper industry</li> <li>• Automotive manufacturing industry</li> </ul>

## **Interview Protocols**

The evaluation team used open-ended protocols for interviews with the program staff, SASB Branch Chief, and OST Office Director. The protocols for the program staff focused primarily on obtaining information about the services provided by the Program to help define the program context and develop the remainder of the protocols. The protocol for the SASB Branch Chief focused on both program services and context and short-term and long-term program goals. The protocol for the OST Office Director focused primarily on EPA's future needs in the area of analytical methods for wastewater and related matrices.

The remainder of the interviews involved recipients of program services and were structured around eight core, open-ended interview questions. The first question collected information regarding the context of the interviews to enable the evaluation team to categorize and interpret responses. The eighth question was designed to identify sources of quantitative information to be used in the evaluation. Questions 2 through 7 collected information that was used directly to answer the five research questions.

The eight core questions differed depending on stakeholder orientation (i.e., internal or external) and perspective. The questions associated with each of the primary orientations are summarized in Table 2. Text boxes included at the beginning of different sections of the report identify the interview questions that were used to gather information for that section and illustrate the relationships between the interview questions and the five research questions.

The eight core questions were shared with interviewees prior to the interviews. Additional, more detailed questions were developed for use as interviewer guides to ensure a consistent approach to collecting information at a sufficient level of detail to inform the evaluation.

Using the interview guides, the evaluation team conducted 34 open-ended interviews with program staff and management and program stakeholders during April and May 2004. Interview data were compiled for each stakeholder group, combined across stakeholder groups, and used, in conjunction with program-related documentation, to answer the five research questions. Interview guides, including the core and more detailed questions are included in Appendix A. Methodological issues encountered during the evaluation, mitigating approaches, and analysis of the potential effect on the evaluation results are described in Appendix B.

The results of the evaluation represent a "snapshot" in time, particularly as they relate to activities that were ongoing or planned at the time that the interviews were conducted. However, the recommendations presented in this report focus on long-term improvements and remain relevant despite this limited evaluation window.

**Table 2**  
**Summary of Core Interview Questions**

No.	EPA Headquarters Interviews (Internal Orientation)	EPA Regions, States, and Other External Stakeholders
1	What is your role relative to EPA OST's Analytical Methods Program?	What is your role relative to EPA OST's Analytical Methods Program, which includes ATP review?
2	Please describe the services provided by the Analytical Methods Program to your office.	Please describe the services provided by the Analytical Methods Program to your organization.
3	How is the Analytical Methods Program important to the success of your office?	How is the Analytical Methods Program important to the success of your organization?
4	How effective is the Analytical Methods Program in meeting your office's needs?	How effective is the Analytical Methods Program in meeting your organizations's needs?
5	If resources were not an issue, how could the Analytical Methods Program better help your office accomplish its goals?	How could the Analytical Methods Program better help your organization accomplish its goals?
6	What do you think is preventing the Program from getting the resources it needs?	How has the Analytical Methods Program's current level of service effected your organization?
7	How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?	How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?
8	We are attempting to gather quantitative information regarding the number of rulemakings the AMR program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your program?	We are attempting to gather quantitative information regarding the number of rulemakings the AMR program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your organizations?

## **ORGANIZATION OF THE REPORT**

The following sections present the context for the evaluation, evaluation findings, and recommendations for Analytical Methods Program improvements.

Section II develops the context and presents an evaluation of the effectiveness of the Analytical Methods Program relative to its internal orientation. The section describes key program services, resources, and stakeholders and addresses research question 2 (effectiveness of the Program in promulgating new and improved analytical methods in the CFR) relative to this orientation.

Section III develops the context and presents an evaluation of the effectiveness of the Analytical Methods Program relative to its external orientation. The section describes key program services, resources, partners, and other stakeholders and addresses research questions 1 through 3 (effectiveness of ATP and new methods approval activities, effectiveness in meeting EPA Region and state needs) relative to Program's implementation responsibilities.

Section IV of the report presents recommendations for addressing the deficiencies identified in Sections II and III and for short-term and long-term improvements to the Analytical Methods Program. It addresses research questions 4 (deficiencies and recommendations) and 5 (consequences of not approving improved and new methods in the CFR).

## SECTION II: EVALUATION OF REGULATORY AND STRATEGIC SUPPORT FOR EPA OFFICE OF WATER

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This section presents the evaluation of the effectiveness of the Analytical Methods Program relative to its support for OW regulatory and strategic activities (“internal orientation”). The section summarizes information collected by the evaluation team regarding the services provided by the Analytical Methods Program and addresses the following research question:

- How effective has the program office been in updating or revising existing analytical methods or in approving improved or new analytical methods in the *Code of Federal Regulations* (CFR)?

The following discussions reflect responses provided by interviewees and supplemental information collected from EPA documents, as necessary, to help interpret interview data and put it in the proper context.

### A. PROGRAM CONTEXT (INTERNAL ORIENTATION)

The following section provides the context for evaluation of the Analytical Methods Program relative to its support of OW regulatory and strategic activities. It describes the services provided by the Program, program resources, and key stakeholders. Sources of information used to develop this context are listed in the box to the right.

**Primary information sources for this section:**

- Program Interviews:
  - Analytical Methods Program personnel
  - SASB Branch Chief
  - OST Office Director
- Stakeholder Interviews (Question 2): *Please describe the services provided by the Analytical Methods Program to your office.*
- Program documents

#### Description of Services

The Analytical Methods Program is responsible for providing analytical methods support to OW program offices in support of EPA’s implementation of the Clean Water Act. The Program provides technical assistance, administrative record development, and contracts management for analytical methods validation and laboratory analytical services in support of policy development and rulemaking. Analytical methods support covers chemical (e.g., metals and organics), whole effluent toxicity (WET), and microbiological methods.

A principal role of the Analytical Methods Program is to validate and promulgate analytical methods in support of water quality criteria and effluent limitations guidelines. When new parameters (e.g., chemical substances, pathogens) or matrices (e.g., source water, sewage sludge) are identified by the other OW program offices as priorities for monitoring or standard-setting, the Analytical Methods Program will scope analytical methods needs and provide methods validation support.

When the Effluent Guidelines Program or another office makes a new request, program staff review approved analytical methods to determine their applicability, or, if no approved method is applicable, program staff research other sources of analytical methods. The Analytical Methods Program does not generally develop new methods. Its main role is to identify and evaluate potential analytical

methods for a specific measurement requirement. If no available method is identified, the Program may work with ORD or another methods development organization to investigate whether additional research is necessary to develop an appropriate method.

Program staff provide technical advisory support as members of workgroups formed by other OW offices for regulatory and policy development. During development periods, program staff participate in workgroup meetings and technical discussions at frequencies ranging from once a month to several times a week. Program staff assess analytical methods requirements, research options, and provide estimates of laboratory analysis and methods validation costs to assist in planning.

The Analytical Methods Program administers laboratory services contracts for methods validation and for environmental data collection. The Program develops method validation plans, coordinates laboratory resources available through the contract, and conducts, compiles, and reports the findings of the validation studies. Studies for validated methods provide documentation needed to support rulemaking (e.g., new methods, effluent limitations guidelines, water quality standards), water quality criteria, and associated litigation.

Support also involves response to challenges brought under EPA's information quality guidelines (EPA 2002). These guidelines allow internal EPA work, such as guidance, to be challenged and have placed a greater emphasis and focused more program resources on peer review.

In addition to regulatory and policy development support, the Analytical Methods Program provides technical assistance in support of existing program implementation. The NPDES permit program receives frequent questions from EPA Regions and states regarding analytical methods, which often reflect questions from permit holders regarding compliance with permit requirements. Many of these questions are forwarded to the Program. Other program offices rely on the Analytical Methods Program's expertise to provide this support. On average, program staff field about 15 technical assistance-related calls and emails per day.

In addition to providing support to other offices, the Analytical Methods Program has taken lead responsibility for analytical methods-focused initiatives. During the 1990s, the Analytical Methods Program supported a 9-year effort to establish a performance-based approach for analytical methods. The initiative attempted to balance flexibility with accountability and culminated in a Notice of Intent to implement a Performance Based Measurement System (PBMS) (EPA 1997c). The performance-based approach was not adopted by EPA, though this initiative did lead some states to adopt a PBMS approach. EPA's Forum on Environmental Measurement (FEM) has established an Action Team to take another look at this issue.

## **Program Resources**

Historically, the Analytical Methods Program has been supported by a staff of three to four, with a high of five staff members. The Program has lost two staff members over the past year and has had difficulty replacing staff, due to the overall downsizing of the Engineering and Analysis Division. The Program is currently authorized to hire one additional staff person. In recent years, the contract funding for analytical methods support has been declining.



Program staff also have responsibilities outside of the Analytical Methods Program. Two of the current staff are not dedicated solely to the Analytical Methods Program but, rather, support QA and other functions demanding approximately 15% of their total hours. The third staff member is completely dedicated to program activities.

Program staff estimate that at present, about 15-20% of their time is devoted to support for methods validation. This level of effort is lower than it has been in the past. About 15-20% of staff time is devoted to external, program implementation activities (see Section III), and the remainder is devoted to providing technical assistance and regulatory support.

Internal contract resources are devoted primarily to providing technical assistance. About two thirds of the contract resources are devoted to providing regulatory and strategic support to OW (internal orientation). The Analytical Methods Program receives contract funding from other program offices for analytical methods-related activities (e.g., rulemaking, methods validation).

The Program is not directly responsible for drinking water methods; however, it does provide some contractor support to the drinking water program, for example, in the evaluation of laboratories and review of ATPs for drinking water methods. The Program also provides contract support for validation of microbiological methods for drinking water analysis, drinking water laboratory certification, and method rulemakings.

## **Key Stakeholders**

Key stakeholders relative to the Analytical Methods Program's support for OW regulatory and strategic activities include the OW program offices that rely on the Program's expertise. These include the Office of Science and Technology's Health and Ecological Criteria Division and Standards and Health Protection Division; Office of Wastewater Management's Water Permits Division; Office of Wetlands, Oceans, and Watersheds; and Office of Ground Water and Drinking Water.

## **B. PROGRAM EVALUATION (INTERNAL ORIENTATION)**

The following section addresses the second research question posed to the evaluation team as it pertains to the Analytical Methods Program's support or OW regulatory and strategic activities. The evaluation relies primarily on information collected from key stakeholders interpreted within the context outlined in the previous section (see box to the right).

### **Primary information sources for this section:**

Stakeholder Interviews:

- Question 3: *How is the Analytical Methods Program important to the success of your office?*
- Question 4: *How effective is the Analytical Methods Program in meeting your office's needs?*

***Research Question 2: How effective has the program office been in updating or revising existing analytical methods or in approving improved or new analytical methods in the Code of Federal Regulations (CFR)?***

Program Successes

All of the internal EPA stakeholders interviewed for this evaluation agreed that given available resources, the Analytical Methods Program has been very effective in updating and revising existing analytical methods and approving analytical methods in the CFR in support of OW regulatory and strategic activities. The Analytical Methods Program provides effective technical support as a participant in EPA workgroups, effectively identifying analytical methods needs, assessing requirements, and establishing realistic duration and cost estimates for methods validation and laboratory analytical services. The Program consistently meets its budget and schedule commitments for validation work and provides effective rulemaking support.

The Program's principal function since its inception has been to help meet the requirements of court-orders. It has met this challenge. The Program has been critical to the success of the NPDES permit program. It has helped ensure the availability of reliable analytical methods, and these methods have enabled EPA to collect credible data to support the regulations governing permits. In addition, these methods are included in NPDES permits and have been critical for gathering credible data for compliance.

In addition to support for the NPDES permits program, participants in the internal stakeholder interviews noted that the Analytical Methods Program has provided effective support for implementation guidelines for ambient water quality for bacteria in recreational waters; analytical methods development for pathogens in biosolids; and whole effluent toxicity test methods.

Through its technical assistance, the Program has fulfilled a critical function by providing expert consultation and review of environmental data issues. EPA has been frequently challenged regarding analytical methods in a variety of contexts, and the Program has provided critical expertise in support of regulators in the EPA Regions and states.

Internal EPA stakeholders also agreed that the transfer of complete responsibility for the analytical methods program to OST has been effective. As part of OST, the Analytical Methods Program is well aligned with the needs of OW programs. Program priorities have been driven by the needs of OW programs and have not had to compete directly with other research needs of the Agency. Program personnel are accessible, cognizant of the practical challenges of OW's programs, and responsive.

Areas for Improvement

All of the internal EPA stakeholders interviewed for this evaluation also agreed that the Analytical Methods Program could more effectively support OW's strategic objectives if given adequate resources. The Program requires that other program offices provide funding for methods validation work and rulemaking support. If funding were not an obstacle, other program offices would request Analytical Methods Program support more often, the pace of development of new standards and

criteria would be accelerated, and the Agency would be more responsive to concerns about existing standards and criteria.

Other OW program offices are allocated budgets for implementation of existing programs and have found it difficult to budget for and set-aside funding to meet their analytical methods needs. The lack of dedicated resources for analytical methods review and validation has, therefore, forced program offices to delay action on certain standards or criteria. As a result, the relative pace of development of standards and criteria may reflect tactical decisions at the program level rather than strategic decisions at the OW level.

More than one internal EPA stakeholder indicated that this situation has limited EPA's ability to address emerging concerns about pathogens in the Nation's waters. The lack of validated analytical methods for pathogens (e.g., bacteria, protozoa, and viruses) in effluent matrices has limited EPA's ability to evaluate health impacts and implement water quality-based standards for pathogen-contaminated discharges (e.g., municipal wastewater, combined sewer overflows (CSOs), sanitary sewer overflows (SSOs), and stormwater). Without validated methods, it has been difficult for EPA to demonstrate the effectiveness of technology-based standards in addressing these pathogens.

The following situations were described as specific examples of the impacts of inadequate resources to support methods validation in this area:

- EPA received thousands of comments on its proposed Blending Policy (EPA 2003c), many concerning pathogens in blended discharges during wet weather conditions. The lack of validated analytical methods for *E. coli*, enterococci, *giardia*, and *cryptosporidium* in effluent matrices at the time the policy was proposed limited EPA's ability to respond to these comments. As a result of public comment, EPA has initiated validation studies for these pathogens.
- OWM would like to proceed with validation of analytical methods for pathogens for discharges associated CSOs, SSOs, and storm sewers as soon as possible.<sup>1</sup> However, because of lack of adequate funding, OWM plans to focus its methods development resources on validating methods for pathogens in CSO discharges first and delay methods validation associated with other effluent matrices to a later date.

## C. CONCLUSION

Based on interviews with internal EPA stakeholders, the Analytical Methods Program has been very effective in updating and revising existing analytical methods and approving analytical methods in the CFR in support of OW regulatory and strategic activities. However, the lack of resources available for analytical methods validation has forced other OW program offices to delay action on assessments or regulations that would help achieve OW's strategic objectives of protecting human health and improving water quality.

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<sup>1</sup> EPA's *National Water Program Guidance for FY 2005* (EPA 2004b) identifies the reduction of pathogens in recreational waters as a key national strategy. The guidance identifies CSOs, SSOs, and storm sewers as key sources of pathogens in the Nation's waters.

## SECTION III: EVALUATION OF ANALYTICAL METHODS PROGRAM IMPLEMENTATION

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This section presents the evaluation of the effectiveness of the Analytical Methods Program relative to its support for the implementation of EPA's analytical methods program for wastewater and related matrices. The section summarizes information collected by the evaluation team regarding the services provided by the Analytical Methods Program and addresses the following research questions:

- How effective has the program office been in the review of ATPs for use by the regulated community to comply with monitoring requirements?
- How effective has the program office been in updating or revising existing analytical methods or in approving improved or new analytical methods in the *Code of Federal Regulations* (CFR)?
- Has OST met the needs of the Regions and states regarding the review of ATPs and method approvals?

The following discussions reflect responses provided by interviewees and supplemental information collected from EPA documents, as necessary, to help interpret interview data and put it in the proper context.

### A. PROGRAM CONTEXT (EXTERNAL ORIENTATION)

The following section provides the context for evaluation of the Analytical Methods Program relative to its implementation of EPA's analytical methods program for wastewater and related matrices. It describes the services provided by the Program, program resources, and key stakeholders. Sources of information used to develop this context are listed in the box to the right.

#### Primary information sources for this section:

- Program Interviews:
  - Analytical Methods Program personnel
  - SASB Branch Chief
  - OST Office Director
- Stakeholder Interviews (Question 2): *Please describe the services provided by the Analytical Methods Program to your office.*
- Program documents

### Description of Services

The Analytical Methods Program oversees implementation of the provisions of 40 CFR 136. The Analytical Methods Program reviews nationwide-use ATPs and new methods applications, provides technical assistance for Regional review of limited-use ATPs, promulgates improved and new analytical methods in the CFR, and provides other support, such as general technical assistance, for those involved in the application of analytical methods for wastewater. The ATP application and review process is defined at 40 CFR 136.4 and 136.5, which outline the procedures, formal roles of States, EPA Regions, and Analytical Methods Program Director, and timetables for EPA response to and approval of ATP applications.

The analytical methods published at 40 CFR 136 have been developed by EPA, consensus standards organizations, and others. Under the ATP program, persons may request approval to modify steps in a reference method or approval to use a new method. The person that submits the ATP application is responsible for validating the new or modified method. Agency staff review the ATP validation package, and successful nationwide-use ATP and new methods applications undergo formal rulemaking. Rulemaking is required before a new or modified method is officially approved for use under Clean Water Act compliance monitoring programs and is added to the list of approved methods in the CFR.

The ATP program, as designed, is intended to provide analysts with the opportunity to use best professional judgement to enhance compliance monitoring and to encourage use of innovative technologies. EPA defines an ATP as “a modification of an approved method or a procedure that uses the same determinative technique and measures the same analyte(s) of interest as the approved method.” The ATP process can also be used to extend the scope of approved analytical methods to the determination of other analytes. Approval for an ATP may be sought when the alternate procedure achieves better method sensitivity or selectivity, reduces analytical costs, overcomes matrix interference problems, improves laboratory productivity, or reduces the amount of hazardous materials used and/or produced in the laboratory (EPA 1999a, EPA 1999b).

EPA has defined three tiers of ATPs, depending on the intended use. Tier 1 ATPs are intended for use by a single laboratory for wastewater, Tier 2 ATPs are intended for nationwide use and a single matrix, and Tier 3 ATPs are intended for nationwide use for multiple matrices. The different tiers require different levels of method validation and involve different application and approval processes.

The Analytical Methods Program is responsible for review of nationwide-use ATP applications (i.e., Tier 2 and 3) and promulgation of approved ATPs in the CFR. The Analytical Methods Program also supports EPA Regions in the review of limited-use ATP applications, including technical review and recommendations regarding approval or rejection. The Program provides technical assistance to EPA Regions in relation to ATP application review and to analytical laboratories, equipments vendors, and others regarding application requirements.

The Program has occasionally issued “interim approval” letters to Regions for priority methods that have been validated and are widely accepted as providing reliable data but have yet to be approved in the CFR. This has been done to facilitate Regional processing of applications to use these methods. The Program also issues letters approving “minor modifications” to approved methods.

In addition, the Program works with ASTM and other consensus standards organizations, such as AOAC International, to update methods. The Program is currently involved in two international efforts in support of consensus standards development. Program staff also participate in conferences and serve as representatives to external organizations, such as the Water Environment Federation (WEF).

In addition to these activities, the Program provides direct laboratory services to other EPA offices, other federal agencies, such as the U.S. Geological Survey (USGS), and states through its analytical

methods contract. Examples of this support include the National Fish Tissue Study, sewage sludge (biosolids) studies, and studies in the Delaware River and Niagara River basins.

## **Program Resources**

Program resources are described in detail in Section II. Program staff estimate that at present, about 15-20% of their time is devoted to external, program implementation activities.

## **Key Partnerships**

The EPA Regions and state environmental organizations are key partners in the implementation of the Analytical Methods Program's ATP and new methods review activities.

### EPA Regions

EPA Regions are a key partner in the implementation of the analytical methods program. Each EPA Region has assigned an ATP Coordinator to address and coordinate ATP applications. In several Regions this responsibility has been assigned to the Regional QA Manager. EPA Regions provide guidance to states, laboratories, and other stakeholders regarding the ATP and new methods review process, review limited-use ATP applications, and coordinate nationwide-use ATP and new method applications within their Regions.

Based on interviews with EPA Regional personnel, the estimated number of ATPs reviewed by the Regions in recent years has varied from 1 to 35 per year. All personnel in the ATP Coordinator role had other main responsibilities and spent anywhere from less than ¼ to ½ FTE performing ATP coordination tasks. Most Regional staff indicated that although they have the job title of ATP Coordinator, this role was not recognized as part of their annual employee performance review.

Two out of the ten ATP Coordinators had gotten few ATP requests since taking over the role of ATP Coordinator and had little knowledge of their responsibilities under the Program.

Half of the Regional coordinators attempt to address requests for minor modifications without involving program staff. The remainder forward all methods-related requests to program staff, including minor modifications. The Regions that review minor modifications employ different processes. Some confer with Regional or state laboratories. One coordinator addresses most requests with little input from others and occasional guidance from program contacts. Some Regions maintain detailed records regarding minor modification approvals to facilitate review.

The Regional coordinators implement the interim approval process differently. Some have given state-wide interim approval for methodologies that have been validated but not approved in the CFR, while others grant interim approvals on a case-by-case, limited-use basis. The majority of Regions are concerned that the use of "interim approvals" is not allowed under Federal regulations, and two Regions have decided not to use the interim approval process.

### State Regulators

States are also key partners in the implementation of the analytical methods program. The ATP and new methods approval process is designed such that states with approved permit programs accept requests for ATP review and new methods applications and coordinate ATP review with EPA Regions, though this is not often the practice. In states with laboratory accreditation programs, states audit laboratories for compliance with approved methods. States have the authority to review and validate analytical methods in the absence of comparable EPA-approved methods. Some Regions have delegated the authority to grant interim approvals of analytical methods to the states.

The procedures, level of communication between the state and Regional ATP Coordinator, and level of understanding regarding the ATP program varied greatly among the five states interviewed for the evaluation. In addition, all of the states interviewed monitored their labs in different ways. For example, one state representative mentioned that laboratories are allowed to incorporate minor modifications to methods without explicit approval from the state. Others said that they enforce the method directly as written and will not allow minor modifications unless they have documented approval from EPA.

## **Other Key Stakeholders**

### Analytical Laboratories

EPA sponsors the National Environmental Laboratory Accreditation Program (NELAP) in 11 states. The program requires that commercial laboratories attain accreditation by the NELAP state authority to work in a particular state. Accreditation is valid for a specified time period and specified tests. Non-NELAP states may certify laboratories through their own state accreditation programs or through other, larger nationwide accrediting organizations, such as the American Association of Laboratory Accreditation (A2LA). Audits are an integral part of accreditation programs; they evaluate the effectiveness of the laboratory in complying with the laboratory's own quality system as well as the requirements for its accreditation.

Analytical laboratories provide services to NPDES permit holders in support of their monitoring requirements. The analytical laboratory services market is competitive, and laboratories are constantly in search of approaches to lower costs and gain competitive advantage. Analytical laboratories also must respond to trends in more stringent permit requirements that necessitate, for example, greater sensitivity.

To meet these challenges, laboratories primarily seek services from the EPA Regions ranging from limited technical guidance on methods implementation to review of limited-use ATPs. Laboratories also request approval of "minor modifications" either from the EPA Regions or state accreditors for audit purposes, though this requirement varies from state to state. Smaller-scale laboratories primarily interact with state accreditors, rather than EPA Regions.

### Laboratory Equipment Vendors

Analytical laboratory equipment vendors respond to the demand for more cost-effective and/or more reliable analytical methods. Equipment vendors produce technologies to help automate laboratory analyses. They also develop technologies to improve sample preparation and measurement

processes. Equipment vendors most often seek nationwide-use ATP or new method approval for their technologies from the Analytical Methods Program at EPA Headquarters. In recent years, some vendors have chosen to seek approval of their technologies Region-by-Region in recognition of the backlog of ATPs at EPA Headquarters.

### Consensus Standards Organizations

Voluntary consensus standards organizations such as ASTM and AOAC International offer services parallel to EPA in terms of review and approval of new methods. These organizations provide a vehicle for communication between their members and EPA, including the Analytical Methods Review program. They convene organizations interested in analytical methods, including EPA, to develop consensus on analytical methods for different uses. Over the past 2 to 3 years, consensus standards organizations, have also been researching and identifying analytical methods development priorities within EPA. Methods developed by consensus standards organizations and periodic updates to these methods are included in EPA updates to approved methods in the CFR.

### Regulated Industries and Municipalities

Regulated industries and municipalities must meet the monitoring requirements of their NPDES permits. In general, industries and municipalities rely on analytical laboratories to produce reliable and defensible compliance monitoring data, and, although they are directly affected (e.g., in terms of monitoring costs), they generally have very limited interaction with the Analytical Methods Program.

## **B. PROGRAM EVALUATION (EXTERNAL ORIENTATION)**

The following section addresses research questions 1 through 3 as they pertain to the Analytical Methods Program's implementation responsibilities. The evaluation relies primarily on information collected from key partners and other stakeholders, interpreted within the context outlined in the previous section (see box to the right).

### ***Research Question 1: How effective has the program office been in the review of ATPs for use by the regulated community to comply with monitoring requirements?***

The Analytical Methods Program is not meeting the regulatory commitments of the Agency for ATP review. The Program has consistently not responded to ATP review applications within 90 days of receipt. Until recently, the backlog of ATP

#### **Primary information sources for this section:**

Stakeholder Interviews:

- Question 3: *How is the Analytical Methods Program important to the success of your organization?*
- Question 4: *How effective is the Analytical Methods Program in meeting your office's needs?*
- Question 6: *How has the Analytical Methods Program's current level of service effected your organization?*

#### **Methodological Note:**

In general, the evaluation team noted a lack of consistency in understanding and use of the terms "new methods" and "ATPs" among program stakeholders. To the extent possible, the evaluation team has used the interview context to disaggregate data for research questions 1 (ATPs) and 2 (new methods). However, because of the lack of precise understanding, some interview comments were interpreted as applying to both research



applications exceeded 50, and knowledge of this has limited the willingness of laboratories and vendors to submit new applications.

### EPA Regions

All ten of the EPA Regions were dissatisfied with the level of service provided by the Analytical Methods Program for ATP review. Of the eight Regional coordinators with sufficient operational experience with the Program to respond, some were more satisfied than others regarding the level of technical guidance provided by the Program. All of the Regional coordinators stated that they did not have the funding or the technically skilled people needed to adequately review true limited-use ATPs but, instead, depended on program staff to provide technical assistance.

### State Regulators

Although all five state representatives interviewed were very complimentary of the support provided by the EPA Regions, four of the five state representatives commented on the Analytical Methods Program's perceived lack of ability to provide technical guidance or to get innovative methods updated and promulgated in the CFR.

Four of the five representatives mentioned that they are not aware when ATPs or new methods have been approved in their states. This creates problems during audits and undermines the state auditors when they are "blind sided" by an EPA-approved methodology change.

One of the state representatives indicated that she was pleased with the timely answer received from Headquarters regarding the use of EPA Method 300.8 for wastewater analysis. This was the representative's only experience with the Program.

### Other Stakeholders

Based on interviews with analytical laboratories, vendors, and regulated industries, the ATP review process has not met their needs. Many external stakeholders, such as small laboratories and municipalities, are unaware of the existence and procedures of the ATP review process. Those stakeholders that are aware of the process are unwilling to apply for ATP approval as they do not expect that their application will be reviewed in a timely manner. Other stakeholders have decided to pursue limited-use approval of ATPs through multiple Regions in light of the backlog of nationwide-use ATP applications. Specific comments are summarized below.

#### *Analytical Laboratories*

Based on interviews with analytical laboratories, Regions, and states, the lack of an effective ATP program has hampered laboratories' ability to modify analytical methods to meet changing technical requirements and implement productivity-enhancing techniques and technologies.

Laboratories are hesitant to deviate from approved methods without documented approval from EPA or the state regulatory agency. Otherwise, they could be cited in an audit. The lack of effective communication among the Analytical Methods Program, EPA Regions, and states exacerbates this

situation. Laboratories are hesitant to seek ATP approval from EPA Regions as they are concerned that state auditors may not concur with Regional approval. For network laboratories, the decision to pursue limited-use ATP approval in multiple Regions in lieu of nationwide-use ATP approval, has resulted in inefficient use of laboratory resources.

With regard to the PBMS approach, laboratories noted that auditors charge a higher fee for PBMS audits, which, given the highly competitive market, creates a disincentive for using this approach. Larger laboratories that adopt the PBMS approach do so for their clients where the combination of analyte/detection limit is difficult to achieve with EPA-approved methods. Each state has its own level of acceptance of the PBMS approach.

### *Equipment Vendors*

Based on interview data, the lack of an effective ATP and new methods review program has hampered vendors' ability to introduce new technologies and has hindered technological innovation in the wastewater analysis market. Laboratories and vendors indicated that laboratories were hesitant to invest in new technologies that did not comply with EPA-approved methods. The vendors interviewed for this evaluation indicated that the effect of deficiencies in the Analytical Methods Program on their market ranged from minimal to very significant.

Equipment vendors recounted situations where they had submitted applications for AMR review but had to wait over a year before they were informed that the Program did not have adequate resources to review the submission. Vendors seek approval from EPA or consensus standards organizations, and both processes take approximately 2 to 5 years before a method is approved. ASTM concurred that its review and consensus process typically takes 2 years or more.

In general, vendors do not wait for promulgation of approved methods in the CFR before they begin approaching customers. Often, vendors will market their equipment and methods to the Analytical Methods Program, EPA Regions, state regulators, and laboratories simultaneously and will build the cost of marketing into the cost of their product.

Vendors shared their perception that a few, select vendors who have had methods approved in the past and are familiar with the Analytical Methods Program's expectations may be "winning favor" with program staff. They suggested that the complexity of the application requirements have created a barrier to market entry for newer vendors.

### *Consensus Standards Organizations*

The consensus standards organizations interviewed for this evaluation were not critical of the Analytical Methods Program. One organization indicated that it maintains an open dialogue with EPA on areas of common interest and is aware of EPA's water concerns. The other indicated that it has yet to establish this relationship with EPA's Analytical Methods Program. One organization noted that the frequency of promulgation is not as much of a concern as it was 8 or 9 years ago, because water chemistry is a mature area. Both organizations noted their capacity to bring EPA, states, and other key stakeholders together to create consensus and facilitate the methods review

process. Both also expressed their desire to work cooperatively with EPA to address issues associated with ATP and new methods review.

### *Regulated Industries and Municipalities*

The industry representatives interviewed for this evaluation indicated that the approved EPA methods are outdated and cumbersome and that the concept of ATPs offers a more efficient approach. Interviewees recounted that in their experience, the use of ATPs in lieu of approved methods does not alter data quality. Industry representatives indicated that in addition to the disincentives created by the length of time for approval of nationwide-use ATPs, the lack of consistent acceptance by states within a Region of a Region-approved ATP was a deterrent to submitting limited-use ATPs. Interviewees noted that requirements for ATP submissions were more stringent than those for new methods. Other stakeholders echoed this perception. Industry representatives also voiced their belief that the Analytical Methods Program as it exists is a disincentive for technological innovation in the wastewater analytical methods field.

### ***Research Question 2: How effective has the program office been in updating or revising existing analytical methods or in approving improved or new analytical methods in the Code of Federal Regulations (CFR)?***

#### EPA Regions

Of the eight Regional coordinators with sufficient operational experience with the Program to respond, all were dissatisfied with the process for review and approval of new methods and nationwide-use ATPs in the CFR. Regional coordinators consistently stated that the slow review and approval of nationwide-use ATPs increased the number of limited-use ATP requests processed by the Regions, increasing the pressure on Regional resources.

In addition, the EPA Regions and other Headquarters personnel familiar with the external orientation of the Program agreed that the increased number of limited-use approvals has created significant inconsistencies in the analytical methods being used in different states and Regions. Inconsistencies in the process and approval of ATP applications creates a problem for EPA's external stakeholders. Several Regional coordinators stated their concern that these inconsistencies have affected or could affect EPA's ability to compare with confidence data collected from different Regions and states. Three of the Regional coordinators stated that they were concerned that their limited-use approvals would be used at multiple sites including those outside the Region.

#### State Regulators

All five state representatives interviewed commented that they did not understand why more analytical methods were not being approved on a national level. They thought that the current methods are antiquated, are not "good science," and are not providing the quality of data needed to ensure clean water. Although all five state representatives interviewed were very complimentary of the support provided by the EPA Regions, four of the five state representatives commented on the Analytical Methods Program's perceived lack of ability to provide technical guidance or to promulgate updated and innovative methods.

## Other Stakeholders

As noted above, most of the other stakeholders interviewed for this evaluation did not distinguish between ATPs and new methods. Given this lack of precision in understanding and terminology, the comments summarized above regarding the effectiveness of the ATP review and approval process have been interpreted as applying also to the Program's effectiveness in promulgating approved nationwide-use ATPs and new methods in the CFR.

### ***Research Question 3: Has OST met the needs of the Regions and states regarding the review of ATPs and method approvals?***

Based on data collected through Regional and state interviews, the Program has not met the needs of the Regions and states regarding the review of ATPs and method approvals. The Program has not articulated clear roles and responsibilities for Regions and states relative to ATP and new method review and approval. Due to limited resources, the Program has been unable to provide the technical assistance and coordination necessary to meet the needs of these potential program partners. The effects of these shortcomings on other stakeholders have been mitigated to an extent in those Regions where the Regional ATP Coordinators have taken an active role in managing the analytical methods process.

Regional interviewees indicated that the Program has not established an effective mechanism for communication among Regions regarding implementation of the ATP process and approvals, ATP and new methods guidance, and decisions regarding interim approvals and minor modifications. Lack of understanding regarding roles and responsibilities and lack of communication among Regions has led to inconsistencies in implementation of the ATP program at the Regional level. The Program has also not taken advantage of the potential for the dissemination of information from those Regions who have developed an effective ATP review process.

Lack of consistency at the Regional level has led to lack of consistency in understanding and coordination of ATP and new methods review at the state level. Whereas some states understand and effectively communicate the ATP and new methods processes to analytical laboratories and dischargers/permittees, others are unaware of the process, creating barriers to effective implementation.

Based on the interviews with ATP Regional Coordinators, the program staff's ability to respond to requests for technical assistance from the Regions has been limited by the limited resources available to the Program. These limitations translate to limitations by the Regions to provide technical assistance to state agencies and laboratories. Some Regions have overcome this by applying Regional resources to establish effective lines of communication for technical assistance to state agencies.

Based on these findings, the Analytical Methods Program has not taken full advantage of Regional and state partnerships in implementation of the Program. In turn, this has further undermined the effectiveness of the Program in meeting other stakeholder needs.

## C. CONCLUSIONS

Based on interviews with EPA Regions, state regulators, and other stakeholders, the Analytical Methods Program has not been effective in its implementation of the national analytical methods program for wastewater. The Program has not met regulatory requirements for review of ATP requests and has not effectively promulgated approved ATPs and improved and new methods in the CFR. The Program has not met the needs of EPA Regions and states and has not effectively leveraged the resources of these potential partners in program implementation.

The Analytical Methods Program has made significant efforts to address the deficiencies in the ATP and new methods review and approval processes, despite the limited resources devoted to this aspect of its responsibilities. In March 1997, EPA proposed to streamline the process for EPA approval of modified analytical methods under the CWA as an initial step in the Agency's pursuit of a performance-based approach to environmental measurement. The process could have significantly reduced the need for Agency review of ATPs and made it easier for the analyst to select analytical methods that are most suited to specific regulatory measurement needs (EPA 1997a) This proposed rule was never finalized due to concerns within the Agency regarding the effects of such a process on enforcement.

In addition, the Analytical Methods Program has developed ATP and new method application protocols (EPA 1999a, EPA 1999b) and recently proposed a new protocol for microbiological monitoring methods (EPA 2004a). Many laboratories and vendors interviewed stated that the 1999 ATP protocols were not easy to understand and, therefore, were not an effective guidance tool. EPA requested comments on microbiological ATP protocol in April 2004.

Despite these efforts, deficiencies in the ATP and new methods review and approval processes have slowed the potential for market-driven innovation in the wastewater analytical methods field. They have also resulted in the inefficient use of Regional and state regulatory resources and have slowed adoption of more efficient technologies by analytical laboratories, creating a resource burden on regulated industries and municipalities.

Inconsistencies in the process and approval of ATP and new methods applications and in decisions regarding interim approvals and minor modifications create problems for EPA's external stakeholders that could become a problem for EPA. Finally, the lack of precision in the understanding and terminology relative to ATPs, new methods, interim approvals, and minor modifications have undermined effective communication among the Program, its partners, and other stakeholders.

All of these issues have led to a widely-held perception of a program that is "broken," a perception that will need to be overcome in order for the Program to reach its potential relative to its implementation-focused orientation.

## SECTION IV: RECOMMENDATIONS AND CONCLUSION

The following section addresses the fourth and fifth research questions, regarding recommendations for program improvements and related potential consequences. The recommendations address the deficiencies noted in the previous section and rely on information collected from interviews and Program documents (see box to the right).

### A. RECOMMENDATIONS

***Research Question 4: What deficiencies exist and what short-term and long-term improvements should be made to the analytical methods review and approval program to ensure that the program addresses the needs of all stakeholders, including NPDES permittees, commercial vendors and analytical laboratories, EPA Regions, and states?***

The Analytical Methods Program has devoted most of its resources in recent years to addressing issues associated with past actions by meeting the requirements of court-orders. In the words of one interviewee, the Program has been in “court receivership” since the start. The Program has met these challenges but has done so at the expense of other critical functions of the Agency.

The Analytical Methods Program has helped ensure the availability of reliable analytical methods and has underpinned the success of the NPDES permit program. The Program, however, has lacked visibility at the strategic level and, over time, its funding has evolved to align with the tactical capabilities of individual programs rather than the strategic objectives of the Agency. Although the Program has successfully supported some of the strategic objectives of OST’s standards and criteria program, its lack of resources has delayed actions that would help OW more effectively achieve its strategic objectives of protecting human health and improving water quality.

In addition, the lack of focus on the Program’s implementation responsibilities (i.e., ATP and new methods review and approval) has slowed the potential for market-driven innovation in the wastewater analytical methods field. This has created burdens on Regional and state regulatory resources, slowed the adoption of more efficient technologies by analytical laboratories, and led to higher-than-necessary compliance costs. It has also created inconsistencies that could eventually affect EPA’s ability to compare with confidence data collected from different Regions and states.

EPA expects that support for court-orders will require far less effort from the Analytical Methods Program in the foreseeable future. In addition, the Agency is moving toward a more outcome-

#### Primary information sources for this section:

- Program Interviews:
  - Analytical Methods Program personnel
  - SASB Branch Chief
  - OST Office Director
- Stakeholder Interviews
  - Question 5: *How could the Analytical Methods Program better help your office or organization accomplish its goals?*
  - Question 6: *What do you think is preventing the Program from getting the resources it needs; or how has the Analytical Methods Program’s current level of service effected your organization?*
  - Question 7: *How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?*
- Program documents

oriented approach to budgeting, as reflected in the *2003-2008 EPA Strategic Plan* (EPA 2003b). The confluence of these events provides an opportunity to refocus the Analytical Methods Program on the future, move out of “court receivership,” and create a program of EPA’s own design. The desirability for this change, in terms of stakeholder needs and the strategic objectives of the Agency, is clearly reflected in the comments of everyone interviewed for this evaluation.

In light of this opportunity, it is recommended that OW directly fund the analytical methods validation services of the Analytical Methods Program, rather than through other program offices, assign the Program a more strategic role in coordinating analytical methods resources, and invest in a sustainable, market-oriented system for ATP and new methods review and approval. Specific recommendations are presented below.

***Recommendation 1: Directly fund the analytical methods validation services of the Analytical Methods Program.***

The services provided by the Analytical Methods Program are clearly aligned with the EPA’s strategic goals, and direct funding of the Program would help OST and OW better communicate relationships among budget requests, expenditures, accomplishments, and environmental outcomes. The *2003-2008 EPA Strategic Plan* identifies “Enhancing Science” as a key Cross-Goal Strategy for achieving EPA’s five strategic goals, including Goal 2, “Clean and Safe Water,” and Goal 4, “Healthy Communities and Ecosystems” (EPA 2003b). The *2003-2008 EPA Strategic Plan* states,

**EPA DEPENDS ON SCIENCE, TECHNOLOGY, AND SCIENTIFICALLY DEFENSIBLE DATA AND MODELS TO EVALUATE RISK, DEVELOP AND DEFEND PROTECTIVE STANDARDS, ANTICIPATE FUTURE HEALTH AND ENVIRONMENTAL THREATS, AND IDENTIFY THEIR SOLUTIONS.**

This Cross-Goal Strategy is reflected under Objectives 2.3 and 4.4, both entitled “Enhance Science and Research.” Under Sub-objective 2.3.1, EPA states the objective:

By 2008, **APPLY THE BEST AVAILABLE SCIENCE (E.G., TOOLS, TECHNOLOGIES, AND SCIENTIFIC INFORMATION) TO SUPPORT AGENCY REGULATIONS AND DECISION-MAKING FOR CURRENT AND FUTURE ENVIRONMENTAL AND HUMAN HEALTH HAZARDS RELATED TO REDUCING EXPOSURE TO CONTAMINANTS IN DRINKING WATER, FISH AND SHELLFISH,**

**AND RECREATIONAL WATERS, AND  
PROTECTING AQUATIC ECOSYSTEMS.**

**UNDER SUB-OBJECTIVE 2.3.2, EPA STATES  
THE OBJECTIVE:**

By 2008, conduct leading-edge, sound scientific research to support the protection of human health through the reduction of human exposure to contaminants in drinking water, fish and shellfish, and recreational waters and to support the protection of aquatic ecosystems—specifically, the quality of rivers, lakes and streams, and coastal and ocean waters.

**THE DEVELOPMENT OF “ANALYTIC TEST METHODS TO SUPPORT PROGRAMS’ SCIENTIFIC INTEGRITY” IS IDENTIFIED AS A KEY MEANS FOR ACHIEVING THIS SUB-OBJECTIVE 2.3.1. THE DEVELOPMENT OF “TOOLS TO DIAGNOSE AND ASSESS IMPAIRMENT AND RESTORE AND PROTECT AQUATIC SYSTEMS” WITH PARTICULAR ATTENTION TO, AMONG OTHER PRIORITIES, “PATHOGENS AND PATHOGEN INDICATORS” IS A KEY MEANS FOR ACHIEVING SUB-OBJECTIVE 2.3.2.**

Under Sub-objective 4.4.1, EPA states the objective:

By 2008, identify and synthesize the best available scientific information, models, methods and analyses to support Agency guidance and policy decisions related to the health of people, communities, and ecosystems.

The promotion of “acceptable performance standards for the inspection and operation of environmental laboratories ... to ensure that decisions are made from a sound technical, scientific, and statistical basis and that laboratories deliver quality data” is identified as a key means to this end.

**BOTH THE PROGRAM’S INTERNAL AND EXTERNAL ORIENTATIONS CLEARLY ALIGN WITH THESE OBJECTIVES. FOR EXAMPLE, THE PROGRAM’S** methods validation and technical assistance services clearly and directly align Sub-objective 2.3.1. The Program’s responsibilities to ensure consistent application of approved, validated methods clearly align with the goal of ensuring that laboratories deliver quality data, under Sub-objective 4.4.1. The Program’s methods validation support and



potential to encourage innovation in the wastewater analytical methods field align with Sub-objective 2.3.2.

The relationships between the Analytical Methods Program and EPA's strategic goals are further reinforced in the *National Water Program Guidance for FY 2005* (EPA 2004b) and OST's 2003 *Water Quality Standards and Criteria Strategy* (EPA . The documents identify less direct, though equally important linkages between analytical methods support and other objectives, such as "Making Waters Safe for Swimming," identified in EPA's 5-year strategic plan.

In addition to helping OST and OW better communicate accomplishments and justify budget requests, direct funding of the Analytical Methods Program will more fully engage in strategic planning and budgetary decisions those most familiar with the technical, cost, and schedule implications of methods requirements. This should help ensure that the implications of analytical methods requirements in terms of funding and critical path are more fully embodied in EPA's annual budget requests and commitments. This issue was identified by several interviewees as critical to successful implementation of the Analytical Methods Program.

***Recommendation 2: Assign the Analytical Methods Program a more strategic role in coordinating analytical methods resources.***

Although direct funding of the Program would facilitate EPA's ability to connect budget requests, expenditures, accomplishments, and environmental outcomes, it would not guarantee that EPA's strategic objectives relative to analytical methods are met. Rather, the Analytical Methods Program would need to assume greater responsibility for coordinating wastewater analytical methods requirements among all of the OW offices.

Based on interviews with the EPA managers associated with the Program and internal EPA stakeholders, it is recommended that this role include the following elements:

- ***Recommendation 2A: Establish a formal, systematic approach to collecting and discussing analytical methods requirements and evaluating priorities and resources among other program offices.***

A formal, systematic approach for collecting internal OW priorities, estimating requirements, and providing input to other program planning activities will help ensure that methods resources are available to meet regulatory and guidance commitments. The SASB Branch Chief has initiated this activity on an informal basis and has distributed an initial list of priorities to OW Division Directors. The approach should tap the expertise of those dealing most directly with developments in health and ecological assessment and analytical methods. It should also include a component whereby funding decision-makers convene, discuss, and agree on a common set of priorities for analytical methods validation funding.

- ***Recommendation 2B: Develop and communicate an analytical methods validation strategy for wastewater and other non-drinking water matrices.***

An annual analytical methods validation strategy would help organize the Analytical Methods Program's resources, ensure alignment between program activities and EPA's strategic objectives, and communicate validation priorities and commitments. Primary input for the strategy would come from the formal, internal network established under Recommendation 2A. EPA can anticipate most critical needs for analytical methods development, and it is expected that annual updates with a 3 to 5-year planning horizon would provide an effective strategy. The strategy should include clear performance goals and should connect these goals to OST, OW, and EPA strategic performance objectives.

It is recommended that the Analytical Methods Program conduct outreach with consensus standards organizations, analytical laboratory organizations, and equipment vendor organizations. This activity would help collect information regarding technological developments that could be useful in formulating the strategy. It would also help communicate EPA's analytical methods plans to provide a signal to the market for analytical technologies and help guide innovation (see, also, Recommendation 3).

- **Recommendation 2C:** *Identify and coordinate interrelationships among the EPA offices with analytical methods validation and development responsibilities.*

Regular interaction with EPA's program offices and Regional laboratories with responsibility for analytical methods development and validation would help the Analytical Methods Program leverage other Agency resources and more effectively target OW analytical methods funds. These interactions would help ensure that the Analytical Methods Program stays abreast of research activities in other parts of the Agency, better informs others of the methods-related priorities within OW, and helps sustain a knowledge-sharing network among methods experts across the Agency and elsewhere in the environmental monitoring community.

ORD's Forum on Environmental Measurement (FEM) could be a key partner in the future of the Analytical Methods Program. Close ties with FEM could help identify alternative sources of funding for specific methods development or validation needs (e.g., through ORD programs), ensure effective use of the National Environmental Monitoring Conference as an outreach tool, and anticipate future PBMS developments. Other potential partners could include the Technical Support Center (e.g., relative to source water methods), and Environmental Technology Verification (ETV) program (e.g., relative to rapid toxicity testing systems).

**Recommendation 3:** *Invest in a sustainable, market-oriented system for ATP and new methods review and approval.*

The market for analytical laboratory services to monitor water quality in accordance with EPA and state laws and regulations is a competitive market. External stakeholders interviewed for this evaluation consistently agreed that this competition creates incentives to innovate. As long as such innovation maintains the reliability of the data produced, it is aligned with EPA objectives.

During periods of general stasis in monitoring requirements (e.g., when permits require the same general level of sensitivity for a set of methods), innovation is driven by the demand for lower costs. Laboratories will be able to gain a competitive advantage by offering analytical services at lower cost. If standards development and permitting trends indicate that higher sensitivity will be required, innovation will be driven by demand for better quality. Laboratories will gain competitive advantage by offering more reliable services and data.

EPA may be able to lower the resources required for implementation of the analytical methods program (“external orientation) and, thereby, create a more sustainable and less costly program if the process for ATP and new methods review and approval can take advantage of these competitive markets forces. To be successful, such an approach would need to:

- Lower the costs of implementation for EPA and, therefore, be less susceptible to budget fluctuations;
- Maintain requisite standards of data reliability;
- Maintain an equitable marketplace (i.e., not create barriers to entry); and
- Facilitate participation of EPA Regions and state accreditation authorities.

Using this as a framework and based on interviews with EPA managers and internal EPA stakeholders, it is recommended that EPA consider the following actions, in total or separately, to create a more sustainable approach for ATP and new methods review and approval:

- Recommendation 3A: *Pursue cooperative partnerships with other organizations for review of analytical methods.*

The Analytical Methods Program should maintain responsibility for final approval of ATP and new method applications. However, the burden of administering the methods review program could be reduced by working with other organizations to streamline program administration and preliminary application review.

The program could contract with or create memoranda of understanding with other organizations that would delegate responsibility for interactions with applicants to ensure that applications meet all documentation requirements and information is presented in a format to facilitate review by program staff. These organization would charge a fee-for-service commensurate with (and less than or equal to) the benefits received by the applicant. In the event that the fee structure would not cover operational costs of these administrative and review services, Program funds would make up the difference. The program could also delegate responsibility for tracking and communicating the status of approved modified methods and ATPs and forecasting nationwide-use ATP and new methods approvals (see Recommendation 3B).

It is recommended that EPA pursue such partnerships via competitive contracting with an appropriate organization—a consensus standards organization, accreditation organization, academic institution, or other qualified, non-conflicted organization—for administration and preliminary review of ATP and new methods applications. It is also recommended that EPA

consider how this process could be further streamlined by including Regional laboratories or other EPA resources in the methods review process.

The intent of this arrangement would be to enable the Analytical Methods Program to meet its obligations for methods review while minimizing the burden on program resources. This would be accomplished by reducing the time required of program staff for methods review and approval and by lowering the overall program implementation costs (i.e., by collecting offsetting funds from those who benefit directly from program services). This more sustainable approach would, in turn, facilitate analytical methods innovation.

- Recommendation 3B: *Regularly update improved and new methods in the CFR.*

The collection of fees for service could create market barriers for smaller analytical laboratories hoping to incorporate ATPs or new methods. This potential could be contained by calibrating the fee structure to reflect differences in the value of limited-use versus nationwide-use ATPs and by ensuring that approved nationwide-use ATPs and new methods are approved in the CFR on a regular basis. Once approved in the CFR, nationwide-use ATPs and new methods are available to be used by all laboratories.

Regardless of whether the Recommendation 3A is adopted, based on recommendations received from multiple stakeholders, it is recommended that the CFR be updated annually to include approved ATPs and new methods. It is also recommended that the signature authority for amendments to approved methods at 40 CFR 136 be delegated to the Assistant Administrator for OW to facilitate timely rulemaking.

Regular updates in the CFR would reduce the burdens on EPA Regions and states for review of redundant limited-use ATP requests, facilitate analytical methods innovation and lower the cost of CWA compliance over time, enable the market to more readily adapt to changing permit requirements, eliminate the need for “interim approvals,” and help address inconsistencies among Regions and states.

- Recommendation 3C: *Develop an effective means for communicating with external customers about the status of approved modified methods and ATPs and for forecasting nationwide-use ATP and new methods approvals.*

Program staff and management, EPA Regions, states, and other external stakeholders all agreed that it would be useful to create a Website and/or other accessible means of widespread communication (e.g., Listserv) to communicate information regarding modified methods, ATP, and new methods approvals. The Website could be used to document the status of national-use ATP and new method reviews, limited-use ATPs and minor modifications that have been approved on a Regional basis, and other information, such as announcements and guidance.

- Recommendation 3D: *Develop and sustain a common understanding of responsibilities for review and approval of analytical methods.*

EPA Regions and states write permits and routinely interact with analytical laboratories and permit holders. They represent the best conduit for information regarding Analytical Methods Program processes and decisions. A common understanding of roles and responsibilities of the Analytical Methods Program, EPA Regions, and states will help address current inconsistencies in program implementation and create common ground for cooperation in the future. The effectiveness of changes in program implementation will depend critically on this cooperation.

It is recommended that EPA Headquarters convene a meeting of EPA Regional ATP Coordinators, state accreditation officials, and Regional and state permit writers to discuss the current state and future of the ATP and new methods review and approval process and agree on a common set of roles and responsibilities. It is further recommended that the Program conduct regular outreach and training with EPA Regions, state auditors, permit writers, and laboratory organizations to communicate the availability and operation of the ATP and new methods review process.

**Recommendation 3E:** *Update the ATP and new method application protocols for organic and inorganic analytes in wastewater and drinking water.*

Many laboratories and vendors interviewed for this evaluation stated that the 1999 ATP and new method application protocols were not easy to understand and were not an effective guidance tool. It is recommended that the protocols be updated to address issues that have been raised since they were initially published. It is also recommended that the protocols reflect any changes to the process introduced by implementation of the Recommendations 3A and 3D, above. Clearer guidance should help address the barriers to entry perceived by equipment manufacturers with less experience with the methods review and approval process.

## **B. CONCLUSION**

### **Research Question 5:** *What are the consequences of not approving improved and new methods in the CFR?*

The Analytical Methods Program has helped ensure the availability of reliable analytical methods and has underpinned the success of the NPDES permit program; however, the lack of resources available for activities other than support for court-orders has delayed actions that would help OW more effectively achieve its strategic objectives and has slowed the potential for market-driven innovation in the wastewater analytical methods field.

The consequences of not addressing these issues and not improving the process by which improved and new methods are approved in the CFR will result in a continuation of existing deficiencies. Decisions regarding funding for analytical methods validation will continue to align with the tactical capabilities of individual programs rather than the strategic objectives of the Agency, Regional and state regulatory resources will be unnecessarily burdened, and the pace of analytical methods innovation will continue to be hampered. Eventually, the inconsistencies that have arisen among Regions and states may affect EPA's ability to compare with confidence data collected from different Regions and states.

The recommendations presented herein are intended to help EPA develop an effective approach to help the Agency obtain the funding necessary to create an Analytical Methods Program that will “Enhance Science” at EPA and advance its objectives of “Clean and Safe Water” and “Healthy Communities and Ecosystems.”

They are also intended encourage innovation in the analytical methods marketplace to encourage the development and introduction of more efficient, innovative technologies and techniques, reduce analytical costs, and facilitate the evolution of analytical methods in response to changes in application (e.g., different types of wastewater) and performance requirements (e.g., sensitivity, specificity). This evolution, in turn, would strengthen the analytical methods used by EPA to support the development of its standards and criteria and other core clean water programs.

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**APPENDIX A**  
**INTERVIEW GUIDES**

EPA Regions, ATP Coordinators (QA Managers). . . . . A-2

EPA Headquarters, Non-Program Staff. . . . . A-6

EPA Headquarters, Management. . . . . A-8

Program Customers. . . . . A-10



**Interviewer's Guide**  
**EPA Regions, ATP Coordinators (QA Managers)**  
**Evaluation of OST's Analytical Methods Review and Approval Program**

4/12/04

<i>1a. What is your role relative to EPA OST's Analytical Methods Program?</i>	
	Briefly, what are your general responsibilities within the Regional office (i.e., not specific to the analytical methods program)?
	What is your role relative to ATP review and/or other activities that are directly related to the analytical methods program (e.g., limited-use new methods review and validation, technical assistance)?
	How long have you been involved in ATP review and/or other activities directly related to the analytical methods program?
	How much time do you devote to ATP review and/or other activities directly related to the analytical methods program (per day, per month, per year)?
	With whom do you interact in this capacity—in OST, the Region, states, and other entities (e.g., regulated community, laboratories, vendors)?
<i>1b. What is the role of the Region relative to wastewater-related analytical methods support, in general?</i>	
	From whom and how do you receive ATP requests?
	Do you track requests received and actions taken?
	How many ATP requests have been received? In what time frame?
	How many ATP requests have been approved or rejected? In what time frame?
	How has the number of ATP review requests received by the Region changed over time, most importantly, since 1996?
	How has the nature of ATP review requests received by the Region changed over time (e.g., more or less complex)?
	If there have been changes to the number and/or nature of ATP review requests, what do you think are the reasons for these changes?
	Does the Region provide support other than ATP review that is directly related to the objectives of the analytical methods program (e.g., limited-use new methods review and validation, technical assistance)?
	To whom you provide this non-ATP support?
	How has the level of effort or nature of this non-ATP support changed over time?
	Which of the following stakeholders rely most on the analytical methods services of the Region: states; local governments; regulated entities; vendors (e.g., of laboratory instrumentation); or commercial laboratories?
	What types of services do each of these stakeholders listed in question B5.a. request of the Region?
	Please describe any other key stakeholders not mentioned in question B5.a.
	What level of Regional resources (e.g., number of FTEs/month) are dedicated to review of ATPs?

	What level of Regional resources (e.g., number of FTEs/month) are dedicated to other analytical methods support (e.g., limited-use new methods review and validation, technical assistance)?
	How and by whom are requests for analytical methods support prioritized?
	How has the overall level of resources dedicated to the program and/or the focus of program resources changed over time, most importantly, since 1996?
	Briefly, what do you think are the principal reasons for any changes in the level of resources dedicated to the program and/or the focus of program?
	What are the key distinctions between Regional and Headquarters roles and responsibilities for providing analytical methods support to stakeholders?
	Do you think that these Regional and Headquarters roles and responsibilities are clearly understood by: 1) Regional personnel; 2) EPA Headquarters; and 3) key stakeholders (e.g., states, laboratories, vendors)?
	Is it always clear whether ATP or other analytical methods requests made of the Region should be handled by the Region or should be referred to Headquarters?
	How do the Region and Headquarters collaborate on decisions regarding who should handle ATP or other analytical methods requests made of the Region?
	How have the Regional and Headquarters roles and responsibilities for analytical methods support changed over time? Why?
<i>2. Please describe the services provided by the Analytical Methods Program to your office.</i>	
	What types of support does the Region require from the OST analytical methods program (e.g., technical assistance, guidance)?
	How often does the Region require this support from the OST analytical methods program?
	How have the Region's requirements for support from the OST program—in terms of type of support and frequency—changed over time? Why have these requirements changed?
	How often does the Region communicate with OST regarding analytical methods review?
	Does Headquarters make changes to the operation of the program based on Regional recommendations?
<i>3. How is the Analytical Methods Program important to the success of your office?</i>	
	What is your understanding of the primary objectives of the analytical methods program?
	Do you believe that there is a greater or lesser need for analytical methods support than there was 5 or 6 years ago? Please explain.
	How does the success of Regional activities depend on the support of the analytical methods program?
	Does the Region have adequate resources to satisfy the demands placed on the Regions for ATP review and other analytical methods support? Please explain.
	Does the Region have adequate resources to satisfy all requests for ATP review and other services within required time frames?
	Are there analytical methods review priorities that the Region is not meeting?
	What analytical methods review needs go unmet?

	How do delays in providing ATP review and/or other analytical methods support affect the other parties involved?
	Do you receive support for analytical methods review from anyone else other than the OST analytical methods program? If so, please describe.
	How can the analytical methods program help the Region meet its objectives?
	How can the analytical methods program help States enforce the requirements of the CWA?
	How can the analytical methods program help the regulated community comply with the requirements of the CWA?
	How can the analytical methods program encourage technological innovation in this area?
<i>4. How effective is the Analytical Methods Program in meeting your office's needs?</i>	
	Is OST meeting the Region's expectations of the type and quality of analytical methods support provided?
	How time-sensitive are your needs for support from the analytical methods program?
	Do you ever encounter delays in receiving the necessary support?
	How do or would delays affect your program?
	Have you noticed any change over time in the speed with which support is provided? If so, what do you think accounts for this?
	How effective is the existing guidance regarding who should handle ATP or other analytical methods requests made of the Region?
	Is the current distribution of responsibility for ATP and other analytical methods support between HQ and the Regions effective? Why or why not?
	Is the ATP application guidance effective? Why or why not?
	Do you think that given resource constraints, the Headquarters program has been as effective as could be reasonably expected? Please explain.
<i>5. If resources were not an issue, how could the Analytical Methods Program better help your office accomplish its goals?</i>	
	If the Headquarters program had adequate resources to accomplish its objectives, how would you define an "effective program," in terms of the types services provided?
	If the Headquarters program had adequate resources to accomplish its objectives, how would you define an "effective program," in terms of the quantity of services provided?
	If the Headquarters program had adequate resources to accomplish its objectives, how would you define an "effective program," in terms of Review and approval times?
	If the Headquarters program had adequate resources to accomplish its objectives, how would you define an "effective program," in terms of anything else not mentioned above?
	What would be the benefits and/or consequences if the obstacles to an effective analytical methods program could be overcome?

	In your opinion, would the resources spent to overcome the obstacles to an effective analytical methods program be an effective use of EPA's limited resources? Please explain.
	What are the sources of monetary costs and benefits associated with newer, cheaper, and better technologies that are approved (e.g., specific pollutant/method combinations on a per analysis basis)?
6. <i>What do you think is preventing the Analytical Methods Program from getting the resources it needs?</i>	
	What are the two or three key obstacles to the ability of the analytical methods program to achieve its objectives effectively?
	How can these obstacles best be overcome?
7. <i>How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?</i>	
	How can the analytical methods program be more effective in meeting the needs of its stakeholders (i.e., program offices, Regions, States, regulated communities, laboratories, and technologists), within existing resource constraints?
	<p>Please provide recommendations for how the analytical methods program could be improved in the following specific areas:</p> <ul style="list-style-type: none"> <li>• Procedures for ATPs</li> <li>• Procedures for new or modified methods review and validation?</li> <li>• Procedures for method updates?</li> <li>• Procedures for publication of updated methods in the CFR?</li> <li>• ATP application procedures and guidance?</li> <li>• Development of new types of services?</li> <li>• Allocation of responsibilities between EPA HQ and EPA Regions?</li> <li>• Priority-setting</li> <li>• Any other areas</li> </ul>
8. <i>We are attempting to gather quantitative information regarding the number of rulemakings the Analytical Methods Program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your program?</i>	
	Are there other data sources (e.g., records, reports) that would be useful?
	Is there someone else that you would recommend we speak with?

EPA Headquarters, *Non-Analytical Methods Program Staff*

Evaluation of OST's Analytical Methods Review and Approval Program

1. <i>What is your role relative to EPA OST's Analytical Methods Program?</i>	
	Briefly, what are your general responsibilities within the office (i.e., not specific to the analytical methods program)?
	How often do you interact with the analytical methods program staff?
	For how long have you been in this role relative to the analytical methods program?
2. <i>Please describe the services provided by the Analytical Methods Program to your office.</i>	
	What kinds of support do you request of the analytical methods staff?
	What types services does your office require from the OST analytical methods review and approval program?
	How often does your office require services from the OST analytical methods review and approval program?
	Have your office's requirements for the types or frequency for analytical method review and approval services changed over time? If so, why?
	What is the current relative distribution among the different types of services required of the analytical methods review and approval program (i.e., are most of your requests for ATPs, new method review/validation, or technical guidance)?
	How do you request support from the analytical methods review and approval program?
	What information is required of your office to support the analytical methods review and approval (or what role does your office play in the process)?
	How often does your office consult with the analytical methods program during review?
	Has the type and quantity of information required or your office's role in analytical methods review and approval changed over time? Please explain.
3. <i>How is the Analytical Methods Program important to the success of your program?</i>	
	What is your understanding of the primary objectives of the analytical methods program?
	How does the success of your program depend on the services provided by the Analytical Methods program?
4. <i>How effective is the Analytical Methods Program in meeting your office's needs?</i>	
	Is OST meeting your office's expectations of what analytical methods support should be provided and the quality of that support?
	How time sensitive are your needs relative to analytical methods review and approval?
	Do you ever encounter delays in analytical methods review or approval? If so, what part of the review and approval process is the usual source of the delay?
	How do or would delays affect your program?

	Have you noticed any change over time in the speed with which approvals (of different types and complexity) are accomplished? If so, what do you think accounts for this?
	Is collaboration between your office and the analytical methods program effective? Why or why not?
5. <i>If resources were not an issue, how could the Analytical Methods Program better help your office accomplish its goals?</i>	
	What would be the benefits and/or consequences if the obstacles to an effective analytical methods program could be overcome?
	In your opinion, would the resources spent to overcome the obstacles to an effective analytical methods program be an effective use of EPA's limited resources? Please explain.
	What are the sources of monetary costs and benefits associated with newer, cheaper, and better technologies that are approved (e.g., specific pollutant/method combinations on a per analysis basis)?
6. <i>What do you think is preventing the Program from getting the resources it needs?</i>	
	What are the two or three key obstacles to the ability of the analytical methods program to achieve its objectives effectively?
	How can these obstacles best be overcome?
7. <i>How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?</i>	
	How can the analytical methods program be more effective in meeting the needs of its stakeholders (i.e., program offices, Regions, States, regulated communities, laboratories, and technologists), within existing resource constraints?
	<p>Please provide recommendations for how the analytical methods program could be improved in the following areas:</p> <ul style="list-style-type: none"> <li>• Procedures for new methods review and validation?</li> <li>• ATPs</li> <li>• Application procedures and guidance</li> <li>• Development of new types of services</li> <li>• Allocation of resources among the analytical methods program and other OW programs</li> <li>• Priority-setting</li> <li>• Any other areas</li> </ul>
8. <i>We are attempting to gather quantitative information regarding the number of rulemakings the Analytical Methods program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your program?</i>	
	Are there other data sources (e.g., records, reports) that would be useful?
	Is there someone else that you would recommend we speak with?

**Interviewer's Guide**  
**EPA Headquarters, Management**  
**Evaluation of OST's Analytical Methods Review and Approval Program**

4/8/04

1. <i>What is your role relative to EPA OST's Analytical Methods Program?</i>	
	Briefly, what are your general responsibilities within the office (i.e., not specific to the analytical methods program)?
	What is your role relative to the analytical methods review and approval program?
	How much time do you devote to this role (per day, per month, per year)?
2. <i>Please describe the services provided by the Analytical Methods Program to your office.</i>	
	Which office(s) rely most on the analytical methods program?
3. <i>How is the Analytical Methods Program important to the success of the programs that you oversee?</i>	
	What is your understanding of the primary objectives of EAD's analytical methods program?
	How do these objectives support the overall objectives of the Office of Water?
	How can the analytical methods program help other program offices meet their objectives?
	How can the analytical methods program help EPA Regional offices meet their objectives?
	How can the analytical methods program help States enforce the requirements of the CWA?
	How can the analytical methods program help the regulated community comply with the requirements of the CWA?
	How can the analytical methods program encourage technological innovation in this area?
4. <i>How effective is the Analytical Methods Program in meeting your office's needs?</i>	
	Is OST meeting its customers' expectations of what analytical methods support should be provided and the quality of that support?
	Do you think that given its resource constraints, the program has been as effective as could be reasonably expected? Please explain.
	What are the most effective aspects of the analytical methods program?
5. <i>If resources were not an issue, how could the Analytical Methods Program better help your office accomplish its goals?</i>	
	How do you think the lack of adequate resources has affected other program offices, EPA Regions, states, and the regulated community?
	How do you think the lack of adequate resources has affected technological innovation in the development of new analytical methods?
	Assuming no resource constraints, what is your vision of what would constitute an effective analytical methods program?

	What would be the benefits and/or consequences if the obstacles to an effective analytical methods program could be overcome?
	In your opinion, would the resources spent to overcome the obstacles to an effective analytical methods program be an effective use of EPA's limited resources? Please explain.
	What are the sources of monetary costs and benefits associated with newer, cheaper, and better technologies that are approved (e.g., specific pollutant/method combinations on a per analysis basis)?
	What are the top priorities of the Office of Water related to analytical methods development, validation, and approval for the next 5 years.
6. <i>What do you think is preventing the Program from getting the resources it needs?</i>	
	How are resources prioritized among the analytical methods program and other Office of Water needs?
	Do you think that the analytical methods program receives the resources that it needs to accomplish its objectives?
	How has the relative allocation of resources to the analytical methods program changed over time? Why?
	How do you think the relative allocation of resources to the analytical methods program might change in the future?
	How have you fulfilled (or how do you intend to fulfill) the GAO's 2001 recommendation that the EPA Administrator "direct the Office of Water to track the results of its review and approval of these applications over the course of the coming year" and "compare these results to those of recent years to determine the impact of fiscal year 2001 funding reductions on the timeliness of its reviews"?
	What are the two or three key obstacles to the ability of the analytical methods program to achieve its objectives effectively?
	How can these obstacles best be overcome?
7. <i>How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?</i>	
	How can the analytical methods program be more effective in meeting the needs of its stakeholders (i.e., program offices, Regions, States, regulated communities, laboratories, and technologists), within existing resource constraints?
8. <i>We are attempting to gather quantitative information regarding the number of rulemakings the Analytical Methods program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your program?</i>	
	Are there other data sources (e.g., records, reports) that would be useful?
	Is there someone else that you would recommend we speak with?



***Program Customers***

**Evaluation of OST's Analytical Methods Review and Approval Program**

<i>1a. What is your role relative to EPA OST's Analytical Methods Program?</i>	
	What is your position/job title?
	What are your general responsibilities relative to analytical methods modification and/or development (including validation)?
	How much time do you devote to analytical methods modification and/or development?
	How important is this role to your overall job function?
	For how long have you been in this role relative to the EPA analytical methods program?
<i>1b. How does your organization interact with the Analytical Methods Program?</i>	
	Do you interact directly with the EPA Region, EPA Headquarters, or both?
	How often do you interact with the analytical methods staff at: (1) EPA Regions? (2) EPA Headquarters?
<i>2. Please describe the services provided by the Analytical Methods Program to your organization.</i>	
	What kinds of analytical methods services do you request of: (1) EPA Regions; (2) EPA Headquarters?
	How often does your organization require services from: (1) The EPA Region; (2) EPA Headquarters?
	Have your organization's requirements for the types or frequency for analytical method review and approval services changed over time? If so, why?
	Has the complexity of your requests changed over time? Please describe.
	How do you request analytical methods support from EPA?
	If you work with both EPA Regions and EPA HQ, how do you decide whether to approach the Region or Headquarters for review and approval of: (1) an ATP; (2) a new or modified method?
	What information is required of your organization to support analytical methods review and approval (or what role does your organization play in the process)?
	How often does your organization consult with EPA during review?
	Has the type and quantity of information required or your organization's role in analytical methods review and approval changed over time? Please explain.
	What is the current relative distribution among the different types of services required of the analytical methods review and approval program (i.e., are most of your requests for ATP or new method review)?
	Have you decided not to submit applications for EPA review and approval in the following areas and, if so, why and for how long has this situation persisted? (1) ATPs; (2) New or modified methods.

	What is your understanding of the types of services provided by EPA’s analytical methods review and approval program, including: a. Updates to standard methods; b. Approval of improved analytical methods; c. Development and validation of new or modified methods; d. Review of alternative test procedures; and e. Technical assistance?
<i>3. How is the Analytical Methods Program important to the success of your organization?</i>	
	What is your understanding of the primary objectives of EPA’s analytical methods review and approval program?
	How does the success of your organization depend on review and approval of: (1) Minor methods modifications; (2) Limited-use ATPs; (3) Nationwide-use ATPs?; and (4) Modified or new methods?
	How does the success of your organization depend on publication in the <i>Federal Register</i> and CFR of: (1) Method updates? (2) Updated standard analytical methods?
	How does the success of your organization depend on technical guidance (e.g., application protocols)?
	How does the success of your organization depend on general technical assistance from EPA?
	How can the analytical methods program help EPA meet the objectives of the CWA?
	How can the analytical methods program help States enforce the requirements of the CWA?
	How can the analytical methods program help the regulated community comply with the requirements of the CWA?
	How can the analytical methods program encourage technological innovation in this area?
<i>4. How effective is the Analytical Methods Program in meeting your organization’s needs?</i>	
	Is EPA meeting your organization’s expectations of what analytical methods support should be provided and the quality of that support? Please explain.
	How effective is the EPA guidance for the following applications (please explain): (1) ATPs; (2) new or modified methods?
	Is collaboration between your organization and EPA effective? Why or why not?
	Do you get better support from Regions or from HQ? Please explain.
	If the EPA had adequate resources to accomplish its objectives, how would you define an “effective program,” in terms of... a. the types services provided; b. the quantity of services provided; review and approval times; d. anything else?
	Do you think that given resource constraints, EPA has been as effective as could be reasonably expected? Please explain.
<i>5. How could the Analytical Methods Program better help your organization accomplish its goals?</i>	
	Please provide recommendations for how the analytical methods program could better meet the needs of your organization.
	What do you perceive as the two or three key obstacles to the ability of the analytical methods program to achieve its objectives effectively?
	How do you think these obstacles can best be overcome?
	What would be the benefits and/or consequences if these obstacles could be overcome?

	In your opinion, do you think that this would be an effective use of EPA's limited resources? Please explain.
	What are the sources of monetary costs and benefits associated with newer, cheaper, and better technologies that are approved (e.g., specific pollutant/method combinations on a per analysis basis)?
	How could your organization help contribute to improvements in EPA's analytical methods program?
6. <i>How has the Analytical Methods Program's current level of service effected your organization?</i>	
	How time sensitive are your needs relative to analytical methods review and approval?
	Do you ever encounter delays in analytical methods review or approval? If so, what part of the review and approval process is the usual source of the delay?
	How do or would delays affect your organization?
	Have you noticed any change over time in the speed with which approvals (of different types and complexity) are accomplished? If so, what do you think accounts for this?
7. <i>How could the Program be more effective given its existing resources (i.e., absent any significant, sustained increase in resources)?</i>	
	How can EPA's analytical methods program be more effective in meeting your organization's needs, within existing resource constraints?
8. <i>We are attempting to gather quantitative information regarding the number of rulemakings the Analytical Methods program supports, magnitude of technical assistance provided, etc. How do you suggest we collect this type of quantitative information relative to your organization?</i>	
	Are there other data sources (e.g., records, reports) that would be useful?
	Is there someone else that you would recommend we speak with?

## **APPENDIX B**

### **ANALYSIS OF METHODOLOGICAL ISSUES**

The interview guides were developed for interviewer use only, so as not to unduly influence the interview process. However, at one point, the interview guides were mistakenly shared with EPA Regional interviewees, which subsequently led to discussions among some interviewees prior to their interviews. The evaluation team readily became aware of this and added questions at the outset of the Regional interviews to assess the nature and extent of these discussions. It was determined that specific questions were not discussed among the interviewees and that this incident has not biased the evaluation results.