



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

EPA's Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater Met Requirements But Controls Need to Be Strengthened

Report No. 13-P-0317

July 11, 2013



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Abbreviations

ADP	Action Development Process
ATP	Alternate Test Procedure
CFR	Code of Federal Regulations
CWA	Clean Water Act
EASB	Engineering and Analytical Support Branch
EPA	U.S. Environmental Protection Agency
MUR	Methods Update Rule
NODA	Notice of Data Availability
NPDES	National Pollutant Discharge Elimination System
NTTAA	National Technology Transfer and Advancement Act
OIG	Office of Inspector General
OMB	Office of Management and Budget
OST	Office of Science and Technology
OW	Office of Water
VCSB	Voluntary Consensus Standards Body

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At a Glance

Why We Did This Review

We received a hotline complaint regarding the U.S. Environmental Protection Agency's (EPA's) handling of a proposed alternative method for measuring oil and grease in wastewater, known as ASTM D7575. Our objective was to evaluate whether EPA, in reviewing ASTM D7575, adhered to applicable laws, regulations, policies, procedures, and guidance.

The Clean Water Act requires EPA to establish and approve methods to measure pollutants in water and wastewater. Oil and grease is a regulated pollutant cited in hundreds of thousands of permits. Regulators determine compliance by using test methods approved by EPA. Oil and grease differs from many other pollutants in that it is a "method-defined analyte" – a pollutant defined solely by the method used to measure it.

This report addresses the following EPA Goals or Cross-Cutting Strategies:

- *Advancing science, research, and technological innovation.*
- *Protecting America's waters.*

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2013/20130711-13-P-0317.pdf

EPA's Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater Met Requirements But Controls Need to Be Strengthened

What We Found

EPA's handling of the proposed alternative method for measuring oil and grease in wastewater (ASTM D7575) adhered to applicable laws, regulations, policies, procedures, and guidance.

However, during the course of our review, we identified management control weaknesses that need to be addressed. Because requests to consider alternative methods for method-defined analytes have been rare, EPA did not have established procedures for reviewing such methods. As such, the Agency faced unique challenges in reviewing ASTM D7575. The challenges pertained mainly to assessing comparability between ASTM D7575 and EPA's current method for measuring oil and grease without established Agency procedures. Although we found that EPA took appropriate steps to make an informed decision on ASTM D7575, management control weaknesses contributed to confusion and delays, and fostered concerns among some stakeholders about fairness, transparency, and preferential treatment for the developer of ASTM D7575. Specific EPA management control weaknesses we identified include:

- EPA lacked a formal procedure for reviewing proposed methods like ASTM D7575, which delayed the review process due to differing views regarding data and statistical analyses needs.
- EPA lacked a clearly defined "cut-off" date for method submissions for the methods update rule, which fostered concerns about transparency, fairness, and preferential treatment.
- EPA's communications with the method developer about pathways for method approval and other key matters were unclear, which led to confusion and misunderstandings about whether EPA was going to approve the method.

If not addressed, these management control weaknesses have the potential to affect the timeliness of future EPA method reviews and perceptions of EPA's fairness and transparency.

Recommendations and Planned Corrective Actions

We recommend that the Assistant Administrator for Water (1) establish a formal procedure for reviewing proposed methods for method-defined analytes, (2) establish procedures for designating official cut-off dates for future proposed methods update rules, and (3) clarify on the Agency's website the different routes for method review and approval. The Agency generally agreed with our report and provided corrective actions and estimated completion dates that meet the intent of our recommendations. Also, the Office of Water issued a memorandum on June 6, 2013, establishing the procedures in recommendation 2; thus, we are closing this recommendation upon issuance of the final report.




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

July 11, 2013

MEMORANDUM

SUBJECT: EPA's Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater Met Requirements But Controls Need to Be Strengthened
Report No. 13-P-0317

FROM: Arthur A. Elkins Jr. 

TO: Nancy Stoner, Acting Assistant Administrator
Office of Water

This is our report on the subject evaluation conducted by the Office of the Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report describes issues the OIG identified and makes recommendations to address these issues. The report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

You are not required to provide a written response to this final report, because you agreed to all recommendations and provided corrective actions and planned completion dates that meet the intent of our recommendations. Recommendations 1 and 3 remain open with corrective actions ongoing. Please update the EPA's Management Audit Tracking System as you complete the planned corrective actions for recommendations 1 and 3. Since the Office of Water already completed actions that meet the intent of recommendation 2, we are closing recommendation 2 upon issuance of this final report. Please notify my staff if there is a significant change in the agreed-to corrective actions.

We have no objections to the further release of this report to the public. We will post this report on our website at <http://www.epa.gov/oig>.

If you or your staff have any questions regarding this report, please contact Assistant Inspector General for Program Evaluation Carolyn Copper at (202) 566-0829 or copper.carolyn@epa.gov, or Director for Air and Research Evaluations Rick Beusse at (919) 541-5747 or beusse.rick@epa.gov.

Table of Contents

Chapters

1	Introduction	1
	Purpose	1
	Background	1
	Scope and Methodology	4
2	EPA Adhered to Applicable Laws and Regulations But Needs a Framework and Procedures for Conducting Reviews of Methods Like ASTM D7575	6
	EPA's Review of ASTM D7575 Adhered to Applicable Laws, Regulations, Policies, Procedures, and Guidance	6
	ASTM D7575 Posed Unique Challenges, and EPA Took Appropriate Steps to Make an Informed Decision	8
	OW Lacked Procedures for Reviewing Proposed Methods for Method-Defined Analytes	12
	OW's Method Review Process Lacked Other Important Management Controls	13
	Conclusions	15
	Recommendations	15
	Agency Comments and OIG Evaluation	16
	Status of Recommendations and Potential Monetary Benefits	17

Appendices

A	EPA's Adherence to Applicable Laws, Regulations, Policies, and Guidance	18
B	Agency Comments on Draft Report	20
C	Distribution	22

Chapter 1

Introduction

Purpose

The U.S. Environmental Protection Agency (EPA) Office of Inspector General (OIG) received a hotline complaint concerning EPA’s handling of “ASTM D7575,” a proposed alternative method for measuring oil and grease in wastewater. In response to the allegations, we assessed whether EPA adhered to applicable laws, regulations, policies, procedures, and guidance in reviewing ASTM D7575 as an alternative method¹ for measuring oil and grease, and in issuing the proposed Methods Update Rule (MUR) and subsequent Notice of Data Availability (NODA).

Background

The Clean Water Act (CWA) requires EPA to establish and promulgate test procedures (i.e., methods) to measure pollutants regulated by CWA programs. This includes establishing methods for measuring pollutants in wastewater under the National Pollutant Discharge Elimination System (NPDES) program. Under this program, point source² discharges must meet the discharge limits for regulated pollutants as identified in their NPDES permits. To determine compliance, regulated pollutants must be measured using available methods approved by EPA.

Oil and grease³ is a regulated wastewater pollutant that is included in hundreds of thousands of NPDES permits. However, oil and grease differs from many other wastewater pollutants in that oil and grease is a method-defined analyte. A method-defined analyte is an analyte (e.g., pollutant) that is defined solely by the method used to measure the amount of the analyte. In the case of oil and grease, measurement for regulatory purposes is dependent on the use of EPA Method 1664A. This method uses n-hexane as an extracting solvent for determining the amount of oil and grease in a wastewater sample. As such, the measurement of oil and grease depends on the use of n-hexane to extract oil and grease from the sample.

¹ We use the term “alternative method” to mean a method that could be used in lieu of, or as a replacement for, the existing approved method for oil and grease.

² CWA Section 502(14) generally defines a point source as “any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.”

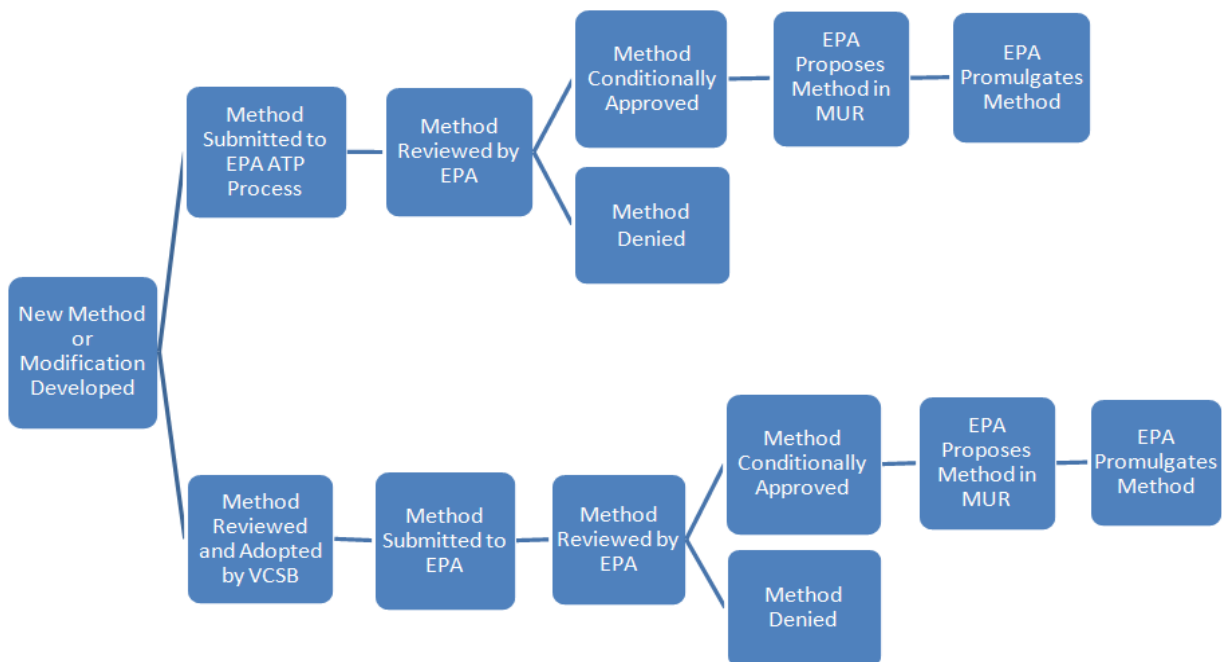
³ “Oil and grease” is a singular category of pollutant that is regulated by the CWA. Although they may be different substances, oil and grease are regulated as one singular pollutant.

Two Routes for Nationwide Approval of New Methods and Method Modifications

The Office of Science and Technology (OST) within EPA’s Office of Water (OW) is responsible for reviewing and promulgating methods for measuring pollutants for CWA applications, including alternatives to existing methods. Specifically, OST’s Engineering and Analytical Support Branch (EASB) reviews proposed new methods and modifications to existing methods that are submitted for approval. If EASB finds that a method or modification meets certain criteria, it conditionally approves the method or modification. Methods that EASB conditionally approves must then be proposed and promulgated through the formal rulemaking process. Because promulgating individual methods separately would be very resource-intensive, EASB periodically⁴ combines numerous proposed methods and modifications into a proposed MUR. Once these rules are finalized, the approved methods are codified per the Code of Federal Regulations (CFR) at 40 CFR Part 136 and can be used nationwide to determine compliance with NPDES permits.

As shown in figure 1, there are two distinct routes through which a proposed new method or modification may be reviewed and approved by EPA in 40 CFR Part 136.

Figure 1: Routes of method review and approval



Source: OIG analysis.

VCSB - Voluntary Consensus Standards Body

⁴ According to EASB, methods update rules are promulgated approximately every 4 years.

The first route is EPA’s Alternate Test Procedure (ATP) program. Under this program, method developers submit an application for a proposed new method or modification directly to EASB for nationwide use. The ATP program has established formal protocols for reviewing new methods and modifications submitted through this route. These protocols lay out specific requirements, such as validation studies that must be conducted for the method to be proposed by EPA in a MUR.

The second route involves methods that are adopted by a voluntary consensus standards body (VCSB)⁵ such as ASTM International⁶ and Standard Methods.⁷ VCSBs may submit methods and modifications they have adopted to EPA under the provisions of the National Technology Transfer and Advancement Act (NTTAA) of 1995. The NTTAA requires EPA to adopt methods approved by VCSBs unless doing so would be inconsistent with applicable laws or otherwise impractical. Methods submitted to EPA via either route (ATP or NTTAA) must be reviewed by EASB and, if appropriate, proposed and ultimately promulgated in a MUR.

EPA’s Rulemaking and Review of Proposed Methods Are Governed by Multiple Statutes, Regulations, Policies, and Guidance

Regardless of the route of approval used, there are several laws, regulations, and guidance – generally referred to as criteria – that govern EPA’s methods update rulemakings and review of proposed methods. These include the following:

Table 1: Criteria governing EPA’s rulemaking process and review of proposed methods

Criteria document	Brief description
Administrative Procedure Act	This act lays out the general requirements for rulemakings for all federal agencies. This includes the publication of proposed rules in the Federal Register.
Clean Water Act	Section 304 (h) of the CWA requires EPA to promulgate guidelines establishing test procedures for the measurement of pollutants under the NPDES program.
40 CFR Part 136	40 CFR Part 136 describes EPA’s general guidelines for establishing test procedures for analysis and measurement of pollutants regulated under the NPDES program. It also lays out the application process to be followed by method developers when submitting an application to EPA under the CWA ATP program.
EPA’s Action Development Process (ADP): Guidance for EPA Staff on Developing Quality Actions (revised March 2011)	The ADP is a comprehensive framework to ensure that EPA develops quality actions, including rulemakings. Its intent is to ensure the use of quality information and an open process to support Agency actions.

Source: OIG analysis.

⁵ A VCSB is a domestic or international organization that plans, develops, establishes, or coordinates voluntary consensus standards using agreed-upon procedures.

⁶ ASTM International, formerly known as the American Society for Testing and Materials, was established in 1898, and provides a global forum for the development and publication of international voluntary consensus standards. ASTM has over 30,000 members from 150 countries.

⁷ Standard Methods, like ASTM International, is a voluntary consensus standard body that regularly submits methods to OW for approval.

In addition, the NTTAA and Office of Management and Budget (OMB) Circular A-119 apply specifically to methods developed by VCSBs. These are summarized below.

Table 2: Criteria applicable to methods developed by VCSBs

Criteria document	Brief description
NTTAA	Section 12(d) states that federal agencies shall use technical standards developed or adopted by VCSBs, unless doing so would be inconsistent with applicable law or otherwise impractical. EPA has interpreted technical standards to include test methods.
OMB Circular A-119 (revised February 1998)	This circular establishes policies for federal agencies in implementing the NTTAA. The circular states that agencies have discretion to decline to use a standard developed by a VCSB, if the agency determines that such standards are inconsistent with applicable law or otherwise impractical.

Source: OIG analysis.

EPA Reviewed Proposed Alternative Method ASTM D7575 During Its Most Recent Methods Update Rulemaking

EPA reviewed ASTM D7575⁸ as part of its most recent methods update rulemaking as an alternative method for oil and grease. EPA issued a proposed MUR in September 2010 that included numerous new methods and method modifications. In the proposed MUR, EPA stated that it was not planning to approve ASTM D7575 because it does not use n-hexane to extract oil and grease. However, after the proposed MUR was issued, EPA received additional information on ASTM D7575 and conducted additional review of the method. Subsequently, in December 2011, EPA issued a NODA to reconsider ASTM D7575 as an alternative method for oil and grease, and requested public comment on the method. EPA’s review and handling of ASTM D7575 is discussed in greater detail in chapter 2.

Scope and Methodology

We conducted our review from April 2012 to March 2013. We conducted this performance review in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the review to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our review objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our review objective.

To address our objective, we reviewed the proposed MUR, the NODA to reconsider ASTM D7575, the final MUR, and relevant information in the rulemaking docket. We also reviewed the analyses and studies conducted by the method developer and ASTM, as well as documents pertaining to EPA’s review

⁸ We use the term “ASTM D7575” in this report to refer to the alternative method for oil and grease from its initial development through its adoption by ASTM. However, the method did not obtain the designation of ASTM D7575 until it was adopted by ASTM in January 2010.

of the method. We reviewed applicable statutes, regulations, policies, procedures, and guidance, including the following:

- Clean Water Act (CWA)
- National Technology Transfer and Advancement Act (NTTAA)
- Administrative Procedure Act
- 40 CFR Part 136 – Guidelines Establishing Test Procedures for the Analysis of Pollutants
- EPA’s Action Development Process (ADP) Guidance (revised March 2011)
- Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water (OW, March 1999)
- Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water (OW, March 1999)

We interviewed EPA OW personnel, including EASB staff and managers, Office of Groundwater and Drinking Water staff, OW’s senior regulatory manager, and OW’s Deputy Assistant Administrator. We also interviewed EPA’s standards executive (the Agency’s NTTAA expert), and staff and managers from EPA’s Office of General Counsel, Office of Congressional and Intergovernmental Relations, and Office of Policy. We also interviewed the complainant and reviewed documents, emails, and other materials provided.

Chapter 2

EPA Adhered to Applicable Laws and Regulations But Needs a Framework and Procedures for Conducting Reviews of Methods Like ASTM D7575

EPA's review of ASTM D7575 and issuance of the proposed MUR and subsequent NODA adhered to applicable laws, regulations, policies, procedures, and guidance. However, during our review, we found management control weaknesses that need to be addressed. Specifically, EPA lacked a framework and procedures for reviewing alternative methods for method-defined analytes, such as ASTM D7575, which led to challenges in reviewing the method. The primary challenge EPA faced was in assessing the comparability of ASTM D7575 to the existing method for measuring oil and grease. EPA's lack of established procedures stemmed from the fact that it generally had not considered approving proposed alternative methods for method-defined parameters in the past, and requests to do so had been very rare. Because of its inexperience in reviewing such methods, OW had to devise the review process for ASTM D7575 as it went along. We found that OW took appropriate steps to review ASTM D7575 and make an informed decision, despite the challenges it faced and its lack of procedures for reviewing such alternative methods. However, the lack of an established review framework, and other management control weaknesses, contributed to confusion and delays in the review process, and contributed to concerns from stakeholders regarding preferential treatment of ASTM D7575. If not addressed, these weaknesses have the potential to affect the timeliness of future EPA method reviews and perceptions of EPA's fairness and transparency.

EPA's Review of ASTM D7575 Adhered to Applicable Laws, Regulations, Policies, Procedures, and Guidance

EPA adhered to applicable statutes, regulations, policies, procedures, and guidance during its review of ASTM D7575. Specifically, we found that EPA adhered to the following in its review of ASTM D7575:

- The Administrative Procedure Act
- The CWA
- 40 CFR Part 136
- EPA's ADP: Guidance for EPA Staff on Developing Quality Actions (revised March 2011)
- The NTTAA
- OMB Circular A-119 (revised February 1998)

Appendix A provides details on EPA's adherence to each of the above criteria during its review of ASTM D7575.

Two key documents governing EPA's actions in the MUR rulemaking and review of ASTM D7575 are the EPA's ADP guidance and the NTTAA. EPA's actions to adhere to the requirements of these two documents are discussed in detail below.

Action Development Process Guidance

The ADP provides guidance for properly categorizing the type and significance of EPA's actions. This process is known as "tiering" the Agency action. The ADP also provides guidance for assembling workgroups and selecting the appropriate action for the desired outcome. In reviewing ASTM D7575, OW followed the ADP guidance related to these three areas.

EPA tiered the MUR as a Tier 3 action, which we believe is an appropriate tier level for this action. Per the ADP, significant actions such as rulemakings are tiered according to multiple factors. These factors include the complexity of the action, the need for cross-agency input and senior leadership involvement, and potential impacts. Actions are designated as Tier 1, Tier 2, or Tier 3. Tier 1 actions are the most complex and have the greatest need for cross-agency input and senior leadership involvement, and the greatest potential impacts. According to the Director of the Regulatory Management Division in EPA's Office of Policy, almost all MURs across the Agency are Tier 3 actions. Further, the Director said that NODAs are typically tiered the same as the adjoining rulemaking. Thus, it was acceptable for OW to tier the NODA for ASTM D7575 as a Tier 3 action because this was consistent with the tiering of the associated MUR.

For Tier 3 rules, a workgroup is not required. However, it is required for actions tiered at higher levels (i.e., Tier 1 and Tier 2). Although not required by EPA's ADP guidance, OW assembled an intra-agency workgroup to review both the MUR and NODA. The workgroup chair shared drafts of the proposed MUR, the NODA, and the final MUR with workgroup members for review and comment.

Also, the decision to issue the NODA involved senior EPA leadership. The OW Deputy Assistant Administrator reviewed a couple of options pertaining to ASTM D7575 and selected the option he determined to be most appropriate. This is consistent with EPA's ADP guidance.

National Technology Transfer and Advancement Act

The NTTAA requires EPA to use test methods adopted by VCSBs, such as ASTM D7575, unless the Agency determines that the method does not meet Agency requirements. EPA considered ASTM D7575 in accordance with the NTTAA. After ASTM approved the method, EPA staff reviewed the data from the ASTM studies. In particular, EPA focused on the assessments of comparability between ASTM D7575 and Method 1664A. Further, EPA spent

considerable time and effort reviewing the method to determine whether it was practical and appropriate to approve the method.

ASTM D7575 Posed Unique Challenges, and EPA Took Appropriate Steps to Make an Informed Decision

The proposal of ASTM D7575 as an alternative method for oil and grease posed unique challenges to EPA because oil and grease, unlike most other pollutants, is a method-defined analyte. The measurement of oil and grease is dependent on the use of n-hexane to extract oil and grease from a sample. This is outlined in EPA Method 1664A. ASTM D7575, in contrast, does not use n-hexane. Instead, it uses an extracting membrane. Further, Method 1664A uses gravimetric measurement, whereas ASTM D7575 uses infrared absorption measurement to measure a sample. Thus, the two methods use different determinative techniques.⁹ Because of these differences, the main challenge for EPA was to assess whether using ASTM D7575 to measure oil and grease in a sample would yield results comparable to using EPA Method 1664A.

While EPA has a protocol¹⁰ for assessing comparability between methods for non-method-defined analytes, it does not have an established process to assess comparability for method-defined analytes. Prior to ASTM D7575, EPA's informal practice had been generally to deny proposals for new or alternative methods for method-defined analytes based on different determinative techniques. Further, such requests were very rare. The only time that EPA had approved a new method for measuring oil and grease in wastewater was when the Agency had to change its former method because it used Freon as the extracting solvent. EPA had to discontinue using Freon under the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer. After conducting several comparability studies, EPA approved Method 1664A in 1999 for measuring oil and grease in wastewater. This changed the extracting solvent from Freon to n-hexane.

However, ASTM D7575 appeared to have some advantages over EPA Method 1664A that, in combination with additional data received after the proposed MUR, led EPA to reconsider its informal practice to deny such methods. For example, ASTM D7575 does not use n-hexane, which poses potential health risks, particularly at higher levels. Also, ASTM D7575 had potential to lower analytical costs to users. ASTM International also approved ASTM D7575. Under the provisions of the NTTAA, EPA is required to adopt methods approved by VCSBs like ASTM International, unless doing so would be inconsistent with applicable laws or otherwise impractical. As such, after reviewing additional data, EPA decided to review ASTM D7575 to determine its viability as an alternative to EPA Method 1664A. Its viability hinged primarily on its comparability to Method

⁹ A determinative technique is defined as the way in which an analyte is identified and quantified.

¹⁰ *Protocol for EPA Approval of Alternate Test Procedures Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water* (EPA 821-B-98-002, March 1999).

1664A – specifically, whether it would produce measurement results comparable to Method 1664A. Details concerning EPA’s review and assessment of ASTM D7575 are described below.

EPA’s Review of ASTM D7575 Prior to Issuance of the Proposed MUR

In April 2009, the company that initiated development of ASTM D7575 (hereinafter, “the method developer”) sent an early version of the method to the ATP coordinator in EASB and asked him to review the method. The method developer did not submit an ATP application for formal evaluation under the ATP program. In an email response to the method developer, the ATP coordinator outlined several concerns with the draft method. He also stated that “multi-matrix, multi-lab full validation” would be required before EPA would consider approving the method.

After this communication, the method developer began working with ASTM International to get the method adopted by the organization. In September 2009, the method developer submitted to EPA a summary report of its multi-laboratory validation study for D7575. The study was conducted for ASTM as part of the ASTM approval process. Soon after, the ATP coordinator asked to see all of the raw data from the study. Later that month, EPA requested that its independent contractor review the information provided on D7575 and the validation study. The contractor had concerns with the data, including that there was no raw data from the labs. The contractor agreed with the need for further testing of ASTM D7575. In January 2010, ASTM adopted D7575.¹¹

In March 2010, the EPA MUR workgroup was asked to review and comment on ASTM D7575. In response, several EPA regional staff expressed concerns. In particular, there were concerns with the comparability of ASTM D7575 to EPA Method 1664A. There were also concerns because oil and grease is an analyte defined by Method 1664A. EPA did not recommend ASTM D7575 for approval in the September 2010 proposed MUR because it does not use n-hexane as the extracting solvent. ASTM D7575 used a different extraction technique than EPA Method 1664A.

EPA’s Review of ASTM D7575 After Issuance of the Proposed MUR

Upon learning that ASTM D7575 was not going to be recommended for approval in the proposed MUR, the method developer contacted its senator’s office. According to documentation provided to EPA by the method developer, the method developer had been under the impression that EPA was going to recommend ASTM D7575 for approval in the proposed MUR. Staff from the senator’s office contacted EPA about its decision. A congressional liaison specialist in EPA’s Office of Congressional and Intergovernmental Relations told us that it is quite common for senators to contact

¹¹ ASTM sent a letter to EPA on September 21, 2010, formally requesting that the Agency consider ASTM D7575 as an alternative method for determining oil and grease in wastewater.

EPA on behalf of the interests of their constituents. He estimated that his office receives calls from members of Congress almost daily. Although a senator's involvement on a specific issue may bring additional attention to that issue, it does not mean that preferential treatment occurred, according to the congressional liaison specialist. He said the senator's staff were primarily concerned with whether method ASTM D7575 received a fair and thorough review by EPA.

After the senator's office contacted EPA, Agency managers and staff attended several meetings with the method developer, ASTM, and staff from the senator's office. At these meetings, EPA staff discussed concerns they had with ASTM D7575, specifically with its comparability to Method 1664A. Some EPA staff, particularly the ATP coordinator, had concerns about whether the data from the ASTM studies showed that ASTM D7575 was comparable to Method 1664A. EPA requested that the method developer and ASTM provide more data on ASTM D7575, particularly assessments of comparability between ASTM D7575 and Method 1664A. In October 2010, the method developer provided the following data to EASB:

- Raw data from the single- and multi-lab studies conducted for ASTM approval
- An expanded validation report
- Comparability statistics from the single lab validation
- Answers to EPA's most recent questions

An EPA contractor reviewed the method developer's data and concluded that ASTM D7575 was not statistically comparable to EPA Method 1664A in most scenarios. EPA statisticians also reviewed the data and reached similar conclusions.

In addition, EPA received and reviewed numerous public comments to the proposed MUR that pertained to ASTM D7575. One commenter submitted an analysis conducted by a statistician which concluded that ASTM D7575 "is statistically equivalent" to Method 1664A. Another commenter submitted a report documenting the health risks posed by n-hexane, the solvent used in EPA Method 1664A. Also, the method developer submitted over 80 documents in its comments on the proposed rule. Most of these documents did not provide new data on ASTM D7575 beyond what was provided to EASB via email in October 2010.

In June 2011, ASTM provided written responses to several EPA questions pertaining to technical issues and the statistical analyses conducted by the method developer and ASTM. In its written responses, ASTM made it clear that its intention was for D7575 to be an alternative method to EPA Method 1664A, with the same regulatory standing as Method 1664A. ASTM also stated that it disagreed with the EPA contractor's statistical assessment.

Despite the new information provided by the method developer and ASTM, EASB staff continued to have concerns about comparability of ASTM D7575 with EPA Method 1664A. In particular, they were concerned with the breadth of matrices (types of wastewater samples) that had been tested. Thus, in June 2011, EASB requested that ASTM test ASTM D7575 in three additional matrices selected by EASB staff. According to the EASB branch chief, EPA told ASTM that EPA would consider issuing a NODA for ASTM D7575 if ASTM tested these additional matrices, pending positive results. ASTM subsequently tested the three additional matrices¹² and issued a report to EPA in November 2011.¹³ In that report, ASTM concluded that the results for the new matrices demonstrated comparability between ASTM D7575 and Method 1664A.

OW looked at the new matrices tested along with all other data submitted by the method developer and ASTM after the proposed MUR. Based on this information, OW determined that it was worthwhile to issue a NODA to reconsider ASTM D7575 and obtain public comment on the information obtained to date.

EPA Issued NODA to Reconsider ASTM D7575

On December 14, 2011, EPA published a NODA to reconsider ASTM D7575 as an alternative to Method 1664A. The NODA was based primarily on the new information from the method developer and ASTM. In the NODA, EPA did not state whether they would be approving ASTM D7575 as an alternative to Method 1664A (i.e., with the same regulatory standing). Rather, EPA stated that ASTM D7575 was a good “stand alone method.” EPA provided the following three reasons for reconsidering ASTM D7575:

1. EPA’s analysis demonstrates ASTM D7575 is an acceptable stand-alone method for the measurement of oil and grease in wastewater, producing results “generally very close” to those obtained using EPA Method 1664A for the matrices tested.
2. ASTM D7575 has advantages over 1664A, including that its membrane is a green technology (e.g., it uses a solventless extraction, there is no solvent waste, and no analyst exposure to solvent).
3. ASTM D7575 may offer other advantages such as ease of analysis, reduced analysis time, and lower analytical costs.

In the NODA, EPA solicited public comment on several topics. These included whether EPA should reconsider promulgating ASTM D7575 as an additional method for oil and grease, and provisions pertaining to side-by-side comparisons for permitting purposes.

¹² The three additional matrices that ASTM tested were from the following categories: a large refinery, a large food and restaurant complex, and a large chemical manufacturer.

¹³ *Study Report from the Testing of Additional Industrial Wastewater Matrices in Support of ASTM Standard D7575 for USEPA’s Reconsideration of this Method in the Forthcoming Method Update Rule* (ASTM D19.06 Subcommittee, November 2011).

EPA Issued Final Decision to Not Approve ASTM D7575 on a Nationwide Basis

On March 6, 2013, EPA issued a notice of final decision in the Federal Register, stating that it is not approving ASTM D7575 as an alternative method for oil and grease on a nationwide basis. According to the notice, this decision was based primarily on the fact that oil and grease is a method-defined analyte and comparability between ASTM D7575 and Method 1664A had not been established on a wide-scale basis. However, EPA stated that permittees could apply for limited use approval through the regional ATP coordinators to use ASTM D7575 for limited, specific uses. Such approval would require demonstrating comparability between ASTM D7575 and 1664A for the intended use by the permittee. Additionally, OW developed and provided guidance to the regional ATP coordinators for evaluating the comparability of ASTM D7575 to EPA Method 1664 for limited use approvals. This guidance was issued to the regions at the time the final decision was published in March 2013.

OW Lacked Procedures for Reviewing Proposed Methods for Method-Defined Analytes

The challenges posed by ASTM D7575 stemmed from the fact that EPA had not considered a new, VCSB-approved method for oil and grease in the past, and did not have a procedure in place for reviewing proposed methods for method-defined analytes. As such, EPA had no clearly defined data requirements or criteria to assess the comparability of ASTM D7575 and EPA Method 1664A. This resulted in confusion between the method developer and EPA. It also led to numerous formal and informal exchanges regarding data requirements and next steps. In the end, OW used the comparison studies done when EPA replaced Freon in 1999 as a general framework for reviewing ASTM D7575. However, an OW manager told us it is uncertain whether that is the best approach to use.

OW managers told us they are uncertain about a one-size-fits-all approach to approving proposed methods for method-defined analytes. At the same time, they want to provide flexibility to method developers to foster technological advancements in measurement methods. OW managers realize that new methods may be improvements over existing methods. They also anticipate that EPA will get more requests of this nature in the future, particularly now that they have considered an alternative method for oil and grease that does not use n-hexane.

OW's protocol¹⁴ for reviewing new methods (for non-method-defined analytes) under the ATP program sets the expectation that the ATP and rulemaking processes can take a year or more to promulgate a major modification or a new technology. However, the Agency's review of ASTM D7575 took more than

¹⁴*Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water* (EPA 821-B-98-003, March 1999).

3 years to complete. Much of this delay was due to the lack of a formal procedure for reviewing new methods for method-defined analytes, and the resulting confusion about what data and statistical analyses are required to assess comparability. An established framework and procedures for method-defined analytes that is communicated up front to the method developer and/or VCSB would better explain EPA's expectations for data quality. It would also reduce the confusion around EPA's data requirements.

OW's Method Review Process Lacked Other Important Management Controls

In addition to the lack of procedures for reviewing alternative methods for method-defined analytes, we found that EPA's method review process lacked other important management controls. Specifically, regarding EPA's review of ASTM D7575:

- EPA lacked a firm "cut-off" date for method submissions for the MUR, resulting in Agency staff and external stakeholders having different interpretations of a July 2009 "pens down" memorandum.
- EPA did not clearly and consistently communicate with the method developer and ASTM regarding potential pathways for approval and other key matters.

Ambiguous "Cut-off" Date for Methods Submissions

In the most recent MUR rulemaking, OW provided notice to methods developers as to when it would no longer accept additional proposed methods for consideration in the rulemaking. This notification to stakeholders is known as the pens down memorandum. On July 20, 2009, the ATP coordinator sent a pens down memo, written by the former EASB branch chief, via email to a limited number of external stakeholders. The memo stated that:

...Because all of us want these valuable revisions out for internal Agency review and subsequent public review, we are drafting the proposed rule with the methods and suggestions collected so far.

"Pens Down" Memorandum

We have received many helpful suggestions, insights, and products from Part 136 community members including ASTM International, the Standard Methods Committee, laboratory auditors, and method developers. We are now moving forward to incorporate the many improvements and revisions. Our scientists are assembling and writing the documentation required to publish proposed changes to the regulations at 40 CFR Part 136. Publication in the Federal Register, and responding to public comment are part of the critical path to allow the 136 community to use these tools for compliance monitoring.

Because all of us want these valuable revisions out for internal Agency review and subsequent public review, we are drafting the proposed rule with the methods and suggestions collected so far. Thus, you have no need to begin or rush development of a new laboratory study, or ongoing method-testing project. Meanwhile if you have a new method, you may ask to put it into the queue of methods in the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) alternate test procedure (ATP) programs. We remind developers that the flexibility at 40 CFR Part 136.6 to modify and use a Part 136 method has eliminated the previous need for EPA to review, under the ATP program, most modifications. In addition, the 1996 SDWA amendments allow use of methods for drinking water compliance monitoring without conducting the rulemaking required for CWA methods.

Thus, you have no need to begin or rush development of a new laboratory study, or ongoing method-testing project. Meanwhile if you have a new method, you may ask to put it into the queue of methods in the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) alternate test procedure (ATP) programs....

OW's memo did not clearly state whether a method must be fully approved by the date of the memo or whether the method could still be in review (i.e., not finalized). This resulted in ambiguity and differing perceptions of the meaning of the memo. The ATP coordinator said his interpretation was that the method submission process must have been completed by the memo date. However, the current EASB branch chief said that the memo meant if a method developer has not submitted a new method or started the approval process they should not bother doing so now. In her view, the memo did not mean that all data for a specific method had to be submitted by that date.

The ATP coordinator and another method developer interpreted the pens down memo as an approval cut-off date. Thus, when Method D7575, which was adopted by ASTM almost 6 months after the cut-off date, was included in the proposed MUR, these stakeholders perceived this as preferential treatment. For example, the other method developer wrote to EPA stating that EPA should have also considered its method after the cut-off date, as EPA had done with ASTM D7575.¹⁵ The company said that EPA was not providing its proposed method with a "level playing field in comparison with other methods." Further, the ATP coordinator stated that EPA continued to review ASTM D7575 past the pens down deadline but did not consider other methods.

Processes for Communications With Stakeholders Need Improvement

OW did not clearly and consistently communicate with the method developer and ASTM during its review of ASTM D7575. When the method developer first approached OW staff in April 2009, the Agency did not clearly explain that there were two distinct approval pathways: through EPA's ATP process or through a VCSB. Further, this information had not been communicated on EPA's public website. According to the EASB branch chief, EPA recognizes this issue and has recently clarified with ASTM International the two distinct pathways for obtaining approval.

Following the method developer's decision to seek approval through ASTM, EPA did not clearly explain to the method developer that communications from that point forward should be between EPA and ASTM, not between EPA and the method developer. EASB staff continued to communicate directly with the method developer throughout and following ASTM's review of D7575. For

¹⁵ The method submitted by this other method developer was not reviewed and conditionally approved by EPA until late June 2010, less than 3 months before the proposed MUR was published, whereas ASTM D7575 was adopted by ASTM in January 2010.

example, the method developer continued to submit materials for EPA review after submitting them to ASTM. The method developer also believed that EASB staff had approved its validation study plans, which EASB staff have denied. EPA's continued correspondence with the method developer led to confusion as to whether EPA was planning to recommend ASTM D7575 for approval. Based on our review of written communications between the method developer and EPA, EPA did not state that it was planning to recommend ASTM D7575 for approval. However, we identified one email the former EASB branch chief sent to the method developer that was open to interpretation. The method developer viewed this email as evidence that ASTM D7575 would be recommended in the proposed MUR.

EPA's ongoing communication with the method developer also contributed to the perception from some stakeholders that the method developer received preferential treatment. In our view, OW's lack of controls governing its communications with external stakeholders contributed to this perception.

Conclusions

EPA's review of ASTM D7575 adhered to applicable laws, regulations, policies, procedures, and guidance. Further, EPA took appropriate steps to address the challenges posed by ASTM D7575 and to make an informed decision, despite the lack of an established procedure for reviewing proposed new or alternative methods for method-defined analytes. Improved management controls are needed to ensure that EPA's method reviews avoid perceptions of partiality and unfairness. Such controls would also ensure that reviews are completed in a more transparent, timely manner. The lack of a formal procedure for reviewing new methods for method-defined parameters, the lack of a clearly defined "cut-off" date for method submissions, and the failure to clearly communicate the two approval pathways played substantial roles in the issues observed. In our view, these management control weaknesses also have the potential to impact future EPA method reviews if not addressed.

Recommendations

We recommend that the Assistant Administrator for Water:

1. Establish a procedure for reviewing proposed methods for method-defined analytes. This procedure should provide a general framework for review and address, at a minimum, the following issues:
 - Data to be submitted by the method developer or VCSB.
 - Statistical tests or analyses to be conducted to determine comparability between the new proposed method and the existing approved method.

2. Establish procedures for designating official cut-off dates for future proposed MURs, and include these procedures on OW's website
3. Clarify on EPA's website OW's procedures and communications policies regarding the two distinct routes through which new methods may be approved by EPA.

Agency Comments and OIG Evaluation

OW generally agreed with our recommendations and provided a corrective action plan with milestone dates to address recommendations 1 and 3. OW's proposed corrective actions and planned completion dates for recommendations 1 and 3 meet the intent of our recommendations. These recommendations will remain open pending completion of the proposed corrective actions.

For recommendation 2, OW issued a memorandum on June 6, 2013, that outlines procedures for establishing cut-off dates for future MUR rulemakings, including posting the cut-off dates on OW's website at least 6 months before proposing a MUR. According to the memorandum, OW will also post an explanation on its website as to what the cut-off dates mean. This action meets the intent of recommendation 2. Therefore, we are closing recommendation 2 upon issuance of this report.

No further EPA response to this report is required. Appendix B contains the Agency's response to our draft report, including its planned actions for each recommendation. The Agency also provided technical comments on the draft report, which we have incorporated into our report as appropriate.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in \$000s)	
Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	15	Establish a procedure for reviewing proposed methods for method-defined analytes. This procedure should provide a general framework for review and address, at a minimum, the following issues: <ul style="list-style-type: none"> • Data to be submitted by the method developer or VCSB. • Statistical tests or analyses to be conducted to determine comparability between the new proposed method and the existing approved method. 	O	Assistant Administrator for Water	12/31/13		
2	16	Establish procedures for designating official cut-off dates for future proposed MURs, and include these procedures on OW's website.	C	Assistant Administrator for Water	6/6/13		
3	16	Clarify on EPA's website OW's procedures and communications policies regarding the two distinct routes through which new methods may be approved by EPA.	O	Assistant Administrator for Water	9/30/13		

¹ O = recommendation is open with agreed-to corrective actions pending
 C = recommendation is closed with all agreed-to actions completed
 U = recommendation is unresolved with resolution efforts in progress

EPA's Adherence to Applicable Laws, Regulations, Policies, and Guidance

Table A-1 below lists the statutes, regulations, policies, and guidance (i.e., criteria documents) that are applicable to EPA's review and handling of ASTM D7575. The table provides a brief description of the applicable requirements for each criteria document and a description of the actions EPA took regarding those requirements.

Table A-1: Summary of EPA actions taken to meet applicable requirements

Key criteria	Description of applicable criteria or requirements	Description of actions regarding applicable requirements
Administrative Procedure Act	This act discusses the general requirements federal agencies must follow for rulemakings. It states that agencies must provide notice of proposed rulemakings in the Federal Register. After this notice, the agency must provide the opportunity for public comment on the proposal.	EPA published its September 2010 proposed MUR and December 2011 NODA in the Federal Register. EPA provided periods of public comment for both.
Clean Water Act	Section 304(h) requires EPA to promulgate guidelines establishing test procedures for the measurement of pollutants regulated under the NPDES program (i.e., Section 402).	EPA developed these guidelines, which are codified in 40 CFR Part 136.
40 CFR Part 136	<p>40 CFR Part 136 establishes guidelines for test procedures (methods) to be used in wastewater programs, specifically the NPDES program and its related applications, permits, and reports. It lists all the methods that have been approved and promulgated by EPA for use.</p> <p>Part 136 describes the application and approval process to be followed for methods submitted to the ATP program. The guidelines require comparability data to be submitted which show how the proposed method performs in comparison to an already-approved method. After the ATP coordinator reviews the proposed method, he or she is to recommend to the Administrator whether to accept or reject the method. Methods recommended for approval are to be published in the Federal Register for public comment, and subsequently a final decision on approval is to be made in the Federal Register.</p> <p>Part 136 does not discuss the review and approval of methods submitted to EPA via the NTTAA.</p>	<p>Although D7575 was submitted under the NTTAA, not the ATP program, EPA required the method developer and ASTM to submit comparability data as required by 40 CFR Part 136. EPA used those data to assess how ASTM D7575 performs in comparison to EPA Method 1664A.</p> <p>Further, EPA published the NODA in the Federal Register to obtain public comment on whether to reconsider ASTM D7575.</p>

Key criteria	Description of applicable criteria or requirements	Description of actions regarding applicable requirements
<p>EPA's Action Development Process (ADP): Guidance for EPA Staff on Developing Quality Actions (revised March 2011)</p>	<p>Under the ADP, each new regulatory action is assigned a tier level that appropriately corresponds to the level of complexity, needed cross-Agency input, controversy/visibility, and need for involvement by top-level managers. Actions are assigned as Tier 1, Tier 2, or Tier 3 actions. Tier 1 actions are the most complex, require the most cross-agency collaboration, and have the highest need for involvement by top-level managers.</p> <p>The ADP contains many specific requirements for actions that are tiered at more elevated levels (i.e., Tier 1 and Tier 2). These include forming intra-agency workgroups and developing options selections to present to senior officials in EPA. However, these are voluntary for Tier 3 actions.</p>	<p>EPA tiered the MUR as a Tier 3 action. The NODA is also a Tier 3 action since it is an outgrowth of the MUR.</p> <p>EPA convened a workgroup for the MUR rulemaking, although this is not required for Tier 3 actions.</p>
<p>National Technology Transfer and Advancement Act</p>	<p>Per section 12(d) of the NTTAA, federal agencies shall use technical standards developed or adopted by VCSBs, unless doing so would be inconsistent with applicable law or otherwise impractical.</p>	<p>EPA assessed the viability of ASTM D7575 per the requirements of the NTTAA. It spent considerable effort in attempting to determine whether approving ASTM D7575 as an alternative for EPA Method 1664A would be practical, specifically by assessing comparability between the two methods.</p>
<p>OMB Circular A-119 (revised February 1998)</p>	<p>OMB Circular A-119 is OMB's implementing guidance for the NTTAA for federal agencies. It states that agencies "must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical. In all cases, your agency has the discretion to decline to use existing voluntary consensus standards if your agency determines that such standards are inconsistent with applicable law or otherwise impractical."</p>	<p>EPA spent considerable effort in trying to determine whether approving the use of ASTM D7575 would be practical, specifically considering its comparability to EPA Method 1664A. Note that the OMB circular provides EPA discretion in declining the use of ASTM D7575 if it determines it is impractical.</p>

Source: OIG analysis.

Agency Comments on Draft Report

May 15, 2013

MEMORANDUM

SUBJECT: Response to Office of Inspector General Draft Report No. OPE-FY12-0013 “Results of Hotline Complaint Review Concerning EPA’s Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater,” dated March 28, 2013

FROM: Nancy K. Stoner
Acting Assistant Administrator

TO: Arthur A. Elkins, Jr.
Inspector General

Thank you for the opportunity to respond to the issues and recommendations in the subject report. Following is a summary of the Agency’s overall position, along with its position on each of the report recommendations. For those report recommendations with which the Agency agrees, we have provided either high-level intended corrective actions and estimated completion dates to the extent we can or reasons why we are unable to provide high-level intended corrective actions and estimated completion dates at this time. For your consideration, we have included a version of the report with our suggested edits and comments as an attachment to supplement this response.

AGENCY’S OVERALL POSITION

The Office of Water generally agrees with the draft report. We note that the objective as stated in the draft report was to “evaluate whether the EPA, in reviewing ASTM D7575, adhered to applicable laws, regulations, policies, procedures, and guidance,” and that the investigation concludes that the EPA did, in fact, adhere to applicable laws, regulations, policies, procedures, and guidance in handling the proposed alternative oil and grease method, ASTM D7575.

AGENCY’S RESPONSE TO REPORT RECOMMENDATIONS

Agreements

No.	Recommendation	High Level Intended Correction Action	Estimated Completion by Quarter and FY
1	Establish a procedure for reviewing proposed methods for method-defined analytes.	1.1 The OW will establish a procedure for reviewing proposed methods for method-	The EPA expects to have a draft procedure by December 2013.

		defined analytes for CWA use	
2	Establish procedures for designating official cut-off dates for future proposed MURs, and include these procedures on the OW's website	<p>1.1 When the EPA initiates a methods update rulemaking (MUR), it will designate cut-off dates for consideration of a method for the MUR</p> <p>1.2 The OW will post these dates on its website</p> <p>1.3 If the MUR is delayed and the EPA determines it is appropriate to extend these dates, OW will post revisions to its website</p>	The OW will make such determinations and post the information on its website within a sufficient amount of time prior to proposing a MUR, generally at least 6 months. ^[16]
3	Clarify on the EPA's website OW's procedures and communications policies regarding the two distinct routes through which new methods may be approved by the EPA	The OW will clarify on its website its procedures and communications policies regarding the two distinct routes through which new methods may be approved by the EPA in 40 CFR Part 136	The OW plans to post this information to its website in 3rd Quarter FY 2013. ^[17]

Thank you for the opportunity to review the draft report. The Office of Water generally agrees with the draft recommendations. Please contact Jan Matuszko at 202-566-1035 if you have any questions or need additional information.

Attachment

cc: EPA IG Liaison Team

¹⁶ Subsequent to this action plan, OW clarified its response to Recommendation 2. On June 6, 2013, OW issued a memorandum to staff that outlines OW's procedures for establishing cut-off dates for future MUR rulemakings, including posting the cut-off dates on OW's website at least 6 months before proposing a MUR. According to the memorandum, OW will also post an explanation on its website as to what the cut-off dates mean.

¹⁷ On July 2, 2013, the Director of OW's Engineering and Analysis Division requested that the planned completion date for the corrective action for recommendation 3 be changed to September 30, 2013. We agreed with this change.

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