SUPPORTING STATEMENT

Application for Reference and Equivalent Method Determination

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) **Title**: Application for Reference and Equivalent Method Determination;
OMB Control Number 2080-0005, EPA ICR No. 0559.10 (Final Rule).

1(b) **Short Characterization (Abstract)**

Under the ambient air monitoring regulations in 40 CFR Part 58, certain state and local air monitoring agencies are required to operate and maintain ambient air monitoring networks to determine attainment or non-attainment with the National Ambient Air Quality Standards (NAAQS) in 40 CFR 50. To help ensure the accuracy and quality of the air monitoring data obtained in these monitoring networks, the regulations require that the pollutant measurement methods used be designated by the EPA as either reference or equivalent methods. Regulatory requirements for designation of air monitoring methods by the EPA as reference or equivalent methods are set forth in 40 CFR Part 53. The principle requirement is testing of the method according to prescribed test procedures to demonstrate that the method meets indicated design and performance specifications, is quantitatively comparable (provides equivalent pollutant measurements) to a reference method, or both (depending on the type of method). Respondents (applicants) who seek to have an ambient air pollutant measurement method designated by the EPA as a reference or equivalent method must conduct the required tests of the candidate method and submit the test results and associated information to the EPA in an application for reference or equivalent method determination. Usually, the applicant is a manufacturer or vendor of an instrumental air analyzer (called an automated method) or an air sampler (manual method) who wishes to have its method (product) designated by the EPA so that state and local air monitoring agencies can purchase the analyzer or sampler for use in their air monitoring networks under 40 CFR Part 58. Only about 5 major and 14 minor applications (19 total responses) are expected annually, but recent revisions to the NAAQS regulations increased that to an estimated average of 6.33 major and 15.67 minor applications (22 total responses) per year. This Final Rule revising NAAQS regulations was published in the Federal Register on Oct. 17, 2006 (71 FR 61236).

Accordingly, the primary type of collection is an application for EPA-designation of a method used for ambient air pollutant measurement. The information is collected by the Process Modeling Research Branch, Human Exposure and Atmospheric Sciences Division, National Exposure Research Laboratory (NERL) of EPA's Office of Research and Development, which receives and processes the applications. The information being collected via the application is a detailed description of the nature of the method and measurement principle employed by the method, the operational instructions and calibration procedure associated with the method,

method test results, descriptions of the test apparatus and test procedures used, and other related information required by 40 CFR Part 53. This information is used by the Process Modeling Research Branch to determine whether the method is qualified to be designated by the EPA as a reference or equivalent method. Such designation of the method allows it to be used by state and local air monitoring agencies in their required air surveillance networks. The information is submitted in the form of text, data tables, diagrams, copies of strip chart or data acquisition system records, instruction or operation manuals, or other items as appropriate. The information is usually stored as submitted, but some information may be microfilmed or stored electronically.

Subsequent to designation of a method as a reference or equivalent method, a manufacturer or user of the method may submit a request for approval of a modification to the method (minor application). The information submitted in such a request is similar in nature to that in an application, but is usually of a greatly reduced scope, since it deals only with the specific aspects of the changes to the method. Usually, the frequency of submission of requests for approval of modifications is higher than that for applications.

Vendors of designated methods must maintain a list of the names and addresses of all ultimate purchasers of such methods so that they can be notified in the event that the designation has been canceled or that the method must be modified or adjusted to maintain designated status.

Consistent with the final revisions to the NAAQS for particulate matter (PM), the amendments added new requirements for both coarse PM ($PM_{10-2.5}$) and $PM_{2.5}$ to the application requirements. The final amendments also added a new category of monitoring methods for which reference or equivalent method applications would be accepted and would likely increase the annualized number of applications received by the EPA. The new category is continuous (or semi-continuous) Class III equivalent methods (analyzers) for $PM_{2.5}$ and $PM_{10-2.5}$.

2. NEED FOR AND USE OF THE COLLECTION

2(a) **Need/Authority for the Collection**

The information submitted under this request for information collection is needed to determine whether specific methods intended for use in measuring the quantitative concentrations of certain atmospheric pollutants are adequate for purposes of pollutant monitoring to determine attainment or non-attainment with the NAAQS set forth in 40 CFR 50. These methods are primarily commercial instrumental air analyzers used for continuous atmospheric monitoring or commercial air samplers used to collect integrated air samples for laboratory analyses, but they may also include noncommercial manual methods used for noncontinuous air monitoring. Under the provisions of 40 CFR 53, an applicant conducts prescribed performance tests of a monitoring method and submits the test results, a detailed description of the method, and other associated information to EPA. If EPA determines, on the basis of the submitted information and test results, that the method meets the design, performance, and/or comparability requirements specified in 40 CFR 53, the method is designated as either a reference or equivalent method, as appropriate. Under 40 CFR 58 Appendix B, EPA requires state and local air monitoring and control agencies to use either reference or equivalent methods in their federally required air monitoring networks to help

ensure the accuracy and quality of the air monitoring data they collect for determining attainment or non-attainment.

The authority to collect this information is Section 301(a) of the Clean Air Act [42 U.S.C. sec. 1857g(a)], as amended by sec. 15(c)(2) of Public Law 91-604, 84 Stat. 1713. The information is collected according to the provisions set forth in 40 CFR Part 53.

2(b) **Practical Utility/Users of the Data**

Upon receipt by the Process Modeling Research Branch, an application is logged and an acknowledgment of receipt is sent to the applicant, as required by the regulation. The application is then technically reviewed by the Branch, and any additional tests or information needed to complete the technical review or to make the reference or equivalent method determination is formally requested from the applicant in accordance with the provisions of the regulation. If the technical evaluation of the application indicates that all requirements are satisfied and that the method fully qualifies for designation as a reference or equivalent method, a notice of designation for the method is prepared and sent through the Laboratory Director of ORD's National Exposure Research Laboratory for publication in the *Federal Register*. If not, a request for additional tests or information may be sent to the applicant, the applicant may be notified that additional tests will be conducted by EPA before a determination can be made, or the applicant may be notified that the application is rejected.

Following approval of a designation by the NERL Laboratory Director and publication of the notice of designation, notification of the designation is sent to the applicant, and the method is added to the List of Designated Reference and Equivalent Methods maintained by the Process Modeling Research Branch. This list identifies all methods that have been designated as reference or equivalent methods and is posted at http://www.epa.gov/ttn/amtic/criteria.html, where it is available to the EPA Regional Offices, state and local air monitoring agencies, and other interested users of air monitoring methods. Based on applications received under this program, EPA has designated 155 reference and equivalent methods as of August 2005. Many of these methods are currently in service in ambient air monitoring networks in all 50 states, obtaining air quality data used by EPA to determine attainment or non-attainment of the NAAQS in all regions of the United States.

There is also an associated recordkeeping requirement such that an applicant who offers designated reference or equivalent methods for sale must maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such methods. For a period of seven years after publication of a reference or equivalent method designation, the applicant must notify all ultimate purchasers of the method within 30 days if the designation is canceled or if adjustment of the method is determined by EPA to be necessary to avoid cancellation of the method designation. This purchaser name and address information is not required to be reported to EPA.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) **Nonduplication**

A computer search of the Federal Information Locator System indicated that, with the exception of the existing rule, there are no similar information requests being carried out by the Federal government. A similar search of EPA's ongoing ICR's revealed no duplication of information-gathering efforts.

Since the purpose and nature of the information requested, as specified in the regulation, is highly specialized, it is very unlikely that any other agency collects or is planning to collect such information. The regulatory requirements for the information are very explicit in describing the tests that must be conducted, how they are to be conducted, and the way that the test results are to be submitted and interpreted. It is therefore difficult or impossible to use similar data not obtained in accordance with the regulation requirements. However, if information necessary for a specific application is duplicative of information contained in a previously submitted application or otherwise already in the EPA's possession, the previously submitted information may be cited and need not be resubmitted. Also, where possible, method test or performance information obtained by or for other testing or regulatory organizations, including foreign organizations, may be used to support or corroborate submitted test information or to obviate the need for special or supplemental test results which may otherwise be required.

3(b) **Public Notice Required Prior to ICR Submission to OMB**

This section is not applicable because this is a rule-related ICR.

3(c) **Consultations**

Process Modeling Research Branch personnel frequently have discussed method performance and testing issues with representatives of many of the air monitoring manufacturers during application processing, during preliminary consultations, during EPA testing campaigns, at technical meetings, and during occasional visits by such representatives to the Branch Office. Some of the most recent consultations are listed here:

Larry Hackworth, Zedek Corporation, Durham, NC
Bill Roe, Grimm Technologies, Inc., Douglasville, GA
Tom Merrifield, BGI Incorporated, Waltham, MA
David Gobeli, MetOne Instruments, Grants Pass, OR
Kevin J. Goohs, Thermo Environmental Corp., Franklin, MA
Peter Phaedonos, Ecotech Pty. Ltd., Blackburn, Victoria, Australia
Lucien Lonigro, SERES, Provence, France

In addition, many comments and consultations were received from members of the Ambient Air Monitoring and Methods Subcommittee of EPA's Clean Air Scientific Advisory Committee. The members of that subcommittee are listed in Appendix A.

3(d) **Effects of Less Frequent Collection**

Since the information is collected only once for each application, less frequent collection is not possible. Modest recordkeeping is required, but the information in these records is not required to be reported.

3(e) **General Guidelines**

Record retention over 7 years. Section 53.9 of 40 CFR 53 requires applicants who offer analyzers or samplers for sale as reference or equivalent methods to maintain records of the names and current mailing addresses of all ultimate purchasers of such analyzers or samplers for a period of seven years from the date of designation of the method as a reference or equivalent method. This recordkeeping requirement is necessary because the regulation further requires such an applicant to notify all purchasers of the designated analyzer or sampler during that seven year period if the reference or equivalent method designation is canceled or if adjustment or modification of the designated analyzer or sampler is required to maintain its designated status. Seven years is representative of the estimated average useful life of such instruments. This recordkeeping requirement is quite modest, and there are no periodic reporting requirements associated with the recordkeeping.

Submission of confidential information. Submission of information that is claimed by the applicant to be confidential business information may be necessary to make a reference or equivalent method determination. This information collection adheres to all of the other general guidelines.

3(f) **Confidentiality and Sensitive Questions**

Confidentiality. The Process Modeling Research Branch has instituted procedures to protect the confidentiality of any submitted information identified as such, in full accordance with 40 CFR 53.15 and all applicable provisions of 40 CFR Part 2.

Sensitive Questions. No information concerning sexual behavior or attitudes, religious beliefs, or other information of a similarly sensitive nature is collected.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) **Respondents/NAICS Codes**

Since the collection of this information is voluntary and related to application for a benefit, the information is collected only from entities for which the benefit is sufficient to justify the costs of the required testing and submission of an application. The largest category of applicants is manufacturers or vendors (NAIC #334513) of air monitoring instruments suitable for use by state and local air monitoring agencies in their federally required air surveillance monitoring networks, and agents acting for instrument manufacturers or vendors. Other potential applicants include state or local air monitoring agencies (NAIC #924110), analytical laboratories (NAIC #541380), and the EPA (NAIC #924110).

4(b) **Information Requested**

(i) *Data Items, Including Recordkeeping Requirements*

The type or nature of the information requested for the new categories of applications would be generally the same as that required for other categories of applications, and particularly for applications for $PM_{2.5}$ methods, as set forth in the current regulation. That information is summarized below.

Information requested:

1. A clear identification of the candidate method, which will distinguish it from all other methods such that the method may be referred to unambiguously. This identification must consist of a unique series of descriptors such as title, identification number, analyte, measurement principle, manufacturer, brand, model, etc., as necessary to distinguish the method from all other methods or method variations, both within and outside the applicant's organization. [§53.4(b)(1)]
2. A detailed description of the candidate method, including but not limited to the following: The measurement principle, manufacturer, name, model number and other forms of identification, a list of the significant components, schematic diagrams, design drawings, and a detailed description of the apparatus and measurement procedures. Drawings and descriptions pertaining to candidate methods or samplers for $PM_{2.5}$ or $PM_{10-2.5}$ must meet all applicable requirements in Reference 1 of Appendix A of Part 53 subpart A, using appropriate graphical, nomenclature, and mathematical conventions such as those specified in References 3 and 4 of Appendix A of Part 53 subpart A. [§53.4(b)(2)]
3. A copy of a comprehensive operation or instruction manual providing a complete and detailed description of the operational, maintenance, and calibration procedures prescribed for field use of the candidate method and all instruments utilized as part of that method [§53.4(b)(3)].

(i) As a minimum this manual shall include:

(A) Description of the method and associated instruments.

(B) Explanation of all indicators, information displays, and controls.

(C) Complete setup and installation instructions, including any additional materials or supplies required.

(D) Details of all initial or startup checks or acceptance tests and any auxiliary equipment required.

(E) Complete operational instructions.

(F) Calibration procedures and a description of the required or recommended calibration equipment and standards.

(G) Instructions for verification of correct or proper operation.

(H) Trouble-shooting guidance and suggested corrective actions for abnormal operation.

(I) Required or recommended routine, periodic, and preventative maintenance and maintenance schedules.

(J) Any calculations required to derive final concentration measurements.

(K) Appropriate references to the applicable Appendix of Part 50, Reference 6 of Appendix A of Part 53 subpart A, and any other pertinent EPA guidelines.

(ii) The manual shall also include adequate warning of potential safety hazards that may result from normal use and/or malfunction of the method and a description of necessary safety precautions. [See also §53.9(b).] For samplers and automated methods, the manual shall include a clear description of all procedures pertaining to installation, operation, preventive maintenance, and troubleshooting and shall also include parts identification diagrams. [§53.4(b)(3)]

4. Statements that the candidate method has been tested in accordance with the procedures described in subparts B, C, D, E, and/or F of 40 CFR 53 (as applicable), and that the method, analyzer, or sampler tested is representative of the candidate method described in the application. [§53.4(b)(4) and (6)]

5. Descriptions of test facilities and test configurations, test data, records, calculations, and test results as specified in subparts B, C, D, E, and/or F of 40 CFR Part 53, as applicable. Salient requirements from these references include the following:

(i) The applicant shall maintain and include records of all relevant measuring equipment, including the make, type, and serial number or other identification, and most recent calibration with identification of the measurement standard or standards used and their National Institute of Standards and Technology (NIST) traceability.

(ii) Test data shall be collected according to the standards of good practice and by qualified personnel. Calculations or data manipulations shall be explained in detail so they can be verified. Test anomalies or irregularities shall be documented and explained or justified. [§53.4(b)(5)]

6. For candidate automated methods and candidate manual methods for PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$, the application shall (or would be required to) also contain the following [§53.4(c)]:

(i) A detailed description of the quality system that will be utilized in production of the method, if the candidate method is designated as a reference or equivalent method.

(ii) A description of the durability characteristics of such analyzers or samplers. [See also §53.9(c).]

7. For candidate reference and equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$, the applicant must (or would be required to) submit documentation verifying that the reference or equivalent method samplers will be manufactured in an ISO-9001-registered and maintained facility. [§53.51(b)(1)]

8. For candidate reference and equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$, the applicant must (or would be required to) submit information related to designation testing and product manufacturing, confirmed by an ISO-certified auditor. [§53.51(f)]

9. Also for candidate reference or equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$, the applicant shall (or would be required to) provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under §53.5(f), and such tests may include special tests not described in this part. Arrangements for, and the cost of, return shipment are the responsibility of the applicant. [§53.4(d)]

10. Identification of confidential or proprietary information (if applicable). [§53.15]

Maintain records on:

1. Section 53.9(f) of 40 CFR 53 requires applicants who offer analyzers or samplers for sale as reference or equivalent methods to maintain records of the names and current mailing addresses of all ultimate purchasers of such analyzers or samplers for a period of seven years from the date of designation of the method as a reference or equivalent method. This recordkeeping requirement is necessary because that Section of the regulation further requires such an applicant to notify all purchasers of the analyzer or sampler if the reference or equivalent method designation is canceled or if adjustment or modification of the analyzer or sampler is required to maintain its designated status. This recordkeeping requirement is quite modest, and there are no periodic reporting requirements associated with the recordkeeping. [53.9(f)]

2. For $PM_{2.5}$ or $PM_{10-2.5}$ methods, quality control and quality assurance records and documentation must (or would be required to) be maintained as required by ISO 9001 facility registration or equivalent standards [§53.51(b), §53.9(h), and §53.9(i)].

(ii) *Respondent Activities*

Typical or representative respondent activities are as follows:

1. Obtain a copy of the 40 CFR 50 and 40 CFR 53 regulations.

2. Study the application requirements and become familiar with the specific test procedures; obtain assistance from the Branch, if needed.

3. Plan the required tests and determine requirements for test equipment, instruments, facilities, standards, materials, personnel, and any contractual services needed.

4. Obtain required test equipment, instruments, facilities, standards, and materials and arrange for required personnel. Arrange for contractual services, if needed.

5. Train personnel.

6. Assemble the test equipment, set up the test apparatus and facilities, and run practice tests as may be needed.

7. Carry out all required tests and obtain required test results.

8. Compile all test results, test parameters, instrument readings, measurement data, and other pertinent test documentation.

9. Prepare descriptions, tables, diagrams, illustrations, strip chart records, calculations, statements, and other documents as necessary.

10. Assemble final application and submit it to EPA.

11. Respond to any requests from EPA for additional tests or information that may be determined to be necessary to make the final reference or equivalent method determination.

12. Maintain records of ultimate purchasers of designated analyzers or samplers.

13. Obtain or maintain ISO 9001 registration for the test and manufacturing facility (for $PM_{2.5}$ and $PM_{10-2.5}$ method designation only).

14. Calibrate and maintain testing instruments.

(Because of their specific nature, none of these items may be considered "customary and usual business practice," although somewhat similar types of tests and facilities may be used during product design, development, and production quality control.)

5. THE INFORMATION COLLECTED – AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) **Agency Activities**

1. Make available copies of the 40 CFR 53 regulation and other helpful material, establish specific interpretation of regulatory requirements if necessary, and provide guidance or technical assistance to applicants.

2. Receive applications, file applications and associated information, send acknowledgment of receipt to applicant, maintain confidentiality of application material identified as confidential business information.

3. Carry out comprehensive technical review of application information; identify any inadequacies and request additional tests or information as determined to be required. If necessary, arrange for special auxiliary tests, as may be determined to be required.

4. Upon determination of designation, prepare and publish a notice of designation in the *Federal Register* and notify the applicant of designation.

5. Maintain a List of Designated Reference and Equivalent Methods and make the list available on the Internet (www.epa.gov/ttn/amtic/criteria.html).

6. Technically evaluate and approve requests (or take other action, as appropriate) for modifications to designated reference or equivalent methods from applicants, manufacturers, and users.

7. Provide program support, including management, program planning, computer software and data calculation systems, regulation development and maintenance, administrative support, and quality assurance guidance.

5(b) **Collection Methodology and Management**

The nature of this information collection does not lend itself readily to use of high technology and automation. The number of applications submitted per year is few, and the information contained in each application is extensive, diverse, varies for different types of methods, and is highly specific to the subject method. Where possible, applicants are allowed to submit test results or measurement data obtained with automated digital data acquisition systems, analog or digital chart recorders, or other automated or semi-automated devices. Entire test sequences may by automated, if feasible, at the applicant's discretion. Optional data entry forms (hard copy) are suggested to help define the test readings required, to facilitate calculations, and to present summarized results. Use of electronic spreadsheets is encouraged for compilation and submission of test data.

Similarly, there is no need to store the information in machine-readable form because the information submitted is normally used only once, it is not compiled with information from other applications, no composite statistical analysis or report of the information is generated, and no rapid retrieval of selected data is needed. For the occasional need to retrieve the archived information after the initial analysis, paper or microfilm files serve acceptably. The cost of a rapid data or record retrieval system is not justified.

The information in each application is evaluated for accuracy, completeness, appropriateness, and credibility by a technical analyst. To the extent possible, techniques used are evaluated, calculations are verified, measurements are confirmed, test results are corroborated, and supporting information is substantiated. Electronic spreadsheet templates may be used to calculate test results accurately and uniformly. Additional technical analysts may evaluate portions of the application or the entire application when results appear to be inadequate or marginal. If the information provided by the applicant is insufficient or inconclusive, additional information, explanations, or tests may be requested to clarify data or resolve issues to complete the evaluation of the application. If necessary, the Process Modeling Research Branch may conduct its own tests of the method, or carry out supplemental testing that may be determined to be needed because of unique technical issues not resolved by the formally specified tests. Finally, monitoring data quality is assessed continually as the method is used in state and local monitoring networks, and follow up tests can be conducted if any performance questions arise.

The submitted information is accessible to the public by inspection and copying of Process Modeling Research Branch files; modest requests for copies of specific information to be mailed or faxed are generally fulfilled by branch personnel. Information identified as Confidential Business Information is available only to the extent allowed under the Freedom of Information Act in accordance with 40 CFR Part 2.

5(c) **Small Entity Flexibility**

The amendments impose no enforceable duty on small businesses. Although the applicable regulations contain no special provisions for small entities, the information collection burden for small entities is minimized in several ways. These include providing additional, specialized assistance such as augmented and customized guidance, instructions, and suggestions for conducting tests; carefully defining the minimum information requirements for specific applications; furnishing certain hard-to-obtain or special reagents or other materials, standards, or calibration equipment; making available special test sites, facilities or equipment; identifying applicable information already on file that need not be duplicated; offering recommendations for compiling the application information; providing suggested language for instruction or operation manuals; and accepting handwritten or similarly informal but acceptable information submission.

5(d) **Collection Schedule**

For the most part, applications are voluntary and are accepted whenever they are received from applicants, rather than on any required schedule. Following receipt of an application, the regulation requires EPA to respond to the applicant within 120 calendar days with one of the following actions: (1) designation of the method as a reference or equivalent method, (2) rejection of the method, (3) notification and specification of additional information required, (4) notification and specification of additional tests required, or (5) notification and specification of additional tests to be conducted by EPA, before a determination can be made [§53.5]. Response to requests for approval of modifications to designated methods must be within 30 days [§53.14(c)], although this limit was increased in the final Rule to 90 days for modifications other than minor ones. The Final Rule also added the requirement that EPA publish Federal Register notices upon receipt of application and 15-day requirement for publication of a notice after a determination.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a, b) **Estimating Respondent Burden and Cost**

In attempting to estimate respondent burden, it is important to recognize that *each application is unique*. The actual number of burden hours and cost required to submit a specific application will vary widely, depending on many factors. These factors include the pollutant for which the method is applicable, whether the method qualifies as a reference method or an equivalent method, the measurement principle utilized, the design and configuration of the analyzer or sampler, the test facilities available to the applicant, availability and location of suitable field testing sites, weather and other conditions at field testing sites, the level of training or experience of the personnel involved, problems encountered during the tests, and other special or unique situations related to the testing of the method.

To obtain information for use in estimating costs for the base ICR, nine vendors of monitoring devices who have submitted applications for designation in the past were contacted (see Section 3(c)). The information obtained in this informal survey was compiled in

conjunction with Process Modeling Research Branch estimates to produce a composite estimate of costs for application submittal. Descriptions of the various application categories and the weighting factors used to derive the composite weighted burden hours are given in Appendix B. Average total burdens for various categories of applications could range from 150 hours for PM_{10} monitors to possibly 1800 hours or more for $PM_{2.5}$ Class II equivalent samplers. It is estimated that 5 applications will be received per year. Respondent burdens for submitting requests for approval of modifications to designated reference or equivalent methods are usually (although not necessarily) much lower; however, they vary even more widely. Estimates for such burdens range from 2 hours to perhaps 200 hours, with most less than 50 hours. It is estimated that an average of 14 modification requests will be received per year, with an average burden of 30 hours each.

The Final Rule created two new categories of applications. One new category was reference methods for $PM_{10-2.5}$. The qualification tests for designation of $PM_{10-2.5}$ reference methods would be the same as those for reference methods for $PM_{2.5}$. Methods that have been designated as reference methods for $PM_{2.5}$ could be also designated as reference methods for $PM_{10-2.5}$ with no additional testing. Therefore, the cost burden for this new category would be negligible and would be covered by the current burden estimates for $PM_{2.5}$. The other new category would be for Class III equivalent methods for either $PM_{2.5}$ or $PM_{10-2.5}$. The tests for this category of applications may include some laboratory tests, but are primarily field tests. As with the other categories of applications, the burdens for actual applications could vary widely, depending on the nature and design complexity of the method, the availability and location of suitable field testing sites, the test facilities available to the applicant, the variability of the weather and other conditions at the field test sites, problems encountered during the tests, and other special or unique situations related to the nature of the candidate method. The burdens estimated for a presumed "typical" application in this category were based on the estimates from other categories, primarily $PM_{2.5}$ Class II equivalent samplers and PM_{10} monitors, because the type of testing for these categories are the closest to the type of testing for the new Class III equivalent method category. These estimates are given in Table R-1, which shows an estimated average total burden of 2047.8 hours per application. It is further estimated that an average of 1.33 applications in this category would be received per year by the EPA over the three year period following promulgation of the regulation amendments.

Modifications to designated methods in either of the new categories would be expected to be generally similar in nature to modifications to other reference and equivalent methods, and respondent requests for approval of such modifications would be expected to be similar also. Accordingly, the burden estimates for modification requests for $PM_{10-2.5}$ reference methods or Class III equivalent methods is the same as that for other reference and equivalent methods, as given in Table R-2 of the base ICR (30 hours each). It is estimated that an average of 1.67 requests for modification of designated methods in the new categories would be received by the EPA over the three year period following promulgation of the regulation amendments.

Table R-1. Estimated respondent burden hours and costs for a full Class III application.

Activity	Management		Professional/ Technical		Clerical		Total Labor		Contractor O&M cost	In-house O&M	Total O&M	Capital/ Startup ($)	O&M + Startup	Total $
Average fully loaded hourly rate ($/hr.)		**$123.31**		**$72.05**		**$37.11**								
	hr/yr	**$/yr**	**hr/yr**	**$/yr**	**hr/yr**	**$/yr**	**hr/yr**	**$/yr**	**$/yr**	**$/yr**	**$/yr**	**$/yr**	**$/yr**	$/yr
1. Obtaining Regulations & Other Relevant Materials from EPA; Searching Data Sources	11.5	$1,418	25.0	$1,801	4.0	$148	40.5	$3,368	$0	$0	$0	$0	$0	$3,368
2. Becoming Familiar with Test Procedures and Application Requirements	9.0	$1,110	54.0	$3,891	3.0	$111	66.0	$5,112	$0	$0	$0	$0	$0	$5,112
3. Planning Tests, Determining Requirements for Test Equipment, Supplies, Personnel	6.0	$740	35.0	$2,522	0.0	$0	41.0	$3,262	$0	$0	$0	$0	$0	$3,262
4. Obtaining Required Equipment, Instruments, Facilities, Materials; Arranging for Personnel	2.0	$247	40.0	$2,882	0.0	$0	42.0	$3,129	$0	$0	$0	$2,713	$2,713	$5,842
5. Training Personnel	0.0	$0	4.0	$288	0.0	$0	4.0	$288	$0	$0	$0	$0	$0	$288
6. Assembling Test Equipment; Setting Up Test Apparatus & Facilities; Running Practice Tests	0.0	$0	84.0	$6,052	0.0	$0	84.0	$6,052	$0	$583	$583	$0	$583	$6,635
7. Carrying Out Tests & Obtaining Test Results	0.0	$0	362.0	$26,082	0.0	$0	362.0	$26,082	$7,250	$0	$7,250	$0	$7,250	$33,332
8. Compiling Test Results, Parameters, Instrument Readings, & Other Test Documentation	0.0	$0	44.0	$3,170	5.0	$186	49.0	$3,356	$0	$0	$0	$0	$0	$3,356
9. Preparing Text, Data, Calculations, Diagrams, Tables, & Other Test Documents	0.0	$0	421.0	$30,333	0.0	$0	421.0	$30,333	$0	$0	$0	$0	$0	$30,333
10. Assembling Final Application and Submitting Application to EPA	0.0	$0	48.0	$3,458	0.0	$0	48.0	$3,458	$0	$0	$0	$0	$0	$3,458
11. Responding to EPA Requests for Additional Tests or Information	0.0	$0	13.5	$973	0.0	$0	13.5	$973	$0	$0	$0	$0	$0	$973
12. Recordkeeping Including Lists of Customers, Notifications for Recall, Etc.	0.0	$0	0.0	$0	12.0	$445	12.0	$445	$0	$0	$0	$0	$0	$445
13. ISO 9001 Registration or Equivalent:														
a. *Startup Cost for Establishing ISO 9001*	45.6	$5,623	25.2	$1,816	0.0	$0	70.8	$7,439	$5,185		$5,185	$0	$5,185	$12,624
b. *ISO 9001 Maintenance Cost*	76.0	$9,372	256.0	$18,445	362.0	$13,434	694.0	$41,250	$4,815	$0	$4,815		$4,815	$46,065
14. Calibrating, Maintaining, & Recertifying Equipment	0.0	$0	100.0	$7,205	0.0	$0	100.0	$7,205	$1,149	$0	$1,149	$0	$1,149	$8,354
15. Additional Costs: (Please Describe)	0.0	$0	0.0	$0	0.0	$0	0.0	$0	$0	$1,300	$1,300	$0	$1,300	$1,300
Totals	150.1	$18,509	1511.7	$108,918	386.0	$14,324	**2047.8**	**$141,751**	$18,399	$1,883	**$20,282**	$2,713	**$22,995**	**$164,746**

As summarized in Table R-2, the total additional burden estimate for Class III (major) applications from Table R-1, 2047.8 hours, was multiplied by the expected number of applications per year (1.33) yielding 2724 total labor hours for applications. The estimated average burden for (minor) applications for approval of modifications of existing methods (30 hours) was multiplied by the average number of additional Class III modification applications expected per year (1.67) resulting in 50 additional burden hours. The total increased hours burden is thus 2724 + 50 = 2774. When added to the current OMB inventory of 4718 hours, the grand total estimated increased labor burden is thus 7492 hours, for a total of 19 original + 3 new = 22 responses. The current OMB inventory for ICR 2080-0005 lists 4718 hours (line 13d), and the difference is thus 2774 hours. This difference is all due to the recent revisions to the NAAQS.

Table R-2. Summary of estimated additional annual respondent burden hours and cost.

	Labor hours	Labor cost	O & M	Capital & startup	Total non-labor	Total cost
Class III application	2047.8	$141,751	$20,282	$2,713	$22,995	$164,746
Number of respondents	1.33	1.33	1.33	1.33	1.33	1.33
Subtotal	**2,724**	**$188,529**	**$26,975**	**$3,608**	**$30,583**	**$219,112**
Composite modification request	30	$2,033	$477	$134	$611	$2,644
Number of respondents	1.67	1.67	1.67	1.67	1.67	1.67
Subtotal	**50.1**	**$3,395**	**$797**	**$224**	**$1,020**	**$4,415**
Total increase, all responses	**2,774**	**$191,924**	**$27,772**	**$3,832**	**$31,604**	**$223,528**
Current ICR	4,718	$325,907	$81,408	$19,651	$101,064	$426,966
Combined grand totals	**7,492**	**$517,831**	**$109,180**	**$23,483**	**$132,668**	**$650,494**

Estimated increases in respondent labor costs associated with the burden hours breakdown discussed above are also shown in Table R-1 for the new Class III application category, using fully loaded hourly labor rates of $123.31 for managerial staff, $72.05 for professional/technical staff, and $37.11 for clerical staff (these are the same rates used in the currently approved base ICR). These rates were derived for the base ICR from cost estimates provided in direct consultation with manufacturers who have previously submitted applications for reference or equivalent method designations. Since these cost estimates had been provided

about 6 years prior, they have been adjusted by factors of 1.280, 1.264, and 1.237, respectively, which represent the 6-year, non-seasonally-adjusted change in the Employment Cost Index for these labor categories in private industry, obtained from Bureau of Labor Statistics (BLS) data. Although use of seasonally-adjusted ECI data are recommended for this adjustment, such seasonally adjusted data for these labor categories were not available from the BLS. Since the time period of adjustment is an integral number of years, seasonal adjustments should have no significant effect.

Test equipment capital costs and associated operating and maintenance costs related to this information collection are very difficult to estimate. There is no specifically prescribed equipment or apparatus that must be used, and in some cases there are a number of alternatives. Many applicants are also the developers of the candidate analyzers or samplers and, accordingly, have some of the test equipment needed as part of their normal equipment inventory. A few tests, such as those for particulate matter inlet performance, require a highly specialized wind tunnel test facility, but the applicant may elect to avoid these tests by using a previously tested inlet. Some applicants may lack some of the required equipment and have to acquire it directly, but they may also consider borrowing, renting, or otherwise gaining access to suitable equipment without purchasing it. Finally, some applicants choose to contract out a portion of or the entire testing and application process.

Similarly, costs for supplies consumed during testing and application preparation vary with the particular test situation. To some extent, these costs can be significantly different, depending on which of several alternative approaches to some of the test procedures is selected by the applicant.

These estimates were derived primarily from an informal survey of nine manufacturers of instruments previously designated as reference or equivalent methods. Our experience based on conducting these tests or similar tests in our own laboratory and preparing equivalent or similar test reports also influenced the estimates.

Survey results covered manufacturers of several types of instruments. The survey results were compiled and summarized to estimate costs for general categories of instruments (*i.e.*, gas analyzers, PM_{10} monitors). The category descriptions and weighting factors used are given in Appendix B to this supporting statement. Since these cost estimates were provided about 6 years previously, the non-labor costs (except capital/startup costs) have been adjusted by a factor of 1.064, which was derived as a weighted average of the 1997-to-2003 change in the Producer Price Index for "measuring and controlling instruments" (1.064, 40%), "engineering and scientific instruments" (1.061, 50%), and "total manufacturing industries" (1.075, 10%) obtained from Bureau of Labor Statistics data. Projected future application plans from the instrument manufacturers and Process Modeling Research Branch records of past applications were used to estimate the number of expected applications and the likely distribution of the total number of applications among each of the application categories. These distribution estimates were used with the category cost estimates to arrive at a weighted composite cost estimate for a "typical" or model reference or equivalent method application, as presented in Table R-1 of the base ICR. Note that these burden hours and cost estimates include those for recordkeeping. Increases due to the program change were similarly estimated, as noted previously, based on similar types of

costs given for other application categories and on projections by the Process Modeling Research Branch.

As summarized in Table R-2, the estimated total increased annualized capital and startup cost for applications (Table R-1), multiplied by the estimated 1.33 applications per year, results in a total estimated increased annualized capital and startup cost of $3,608. The corresponding cost for the estimated 1.67 modification applications is $224. The total increased annualized capital and startup cost for all respondents, $3,832, is added to the current OMB-approved costs of $19,651, resulting in a total annualized capital and startup cost of $23,483, which is reported as $23.5 (thousand) on line 14a of form OMB 83-I. Similarly, the estimated increased operating and maintenance cost for a Class III application from Table R-1 ($20,282), multiplied by the estimated 1.33 additional (major) applications per year, gives an estimated total annualized O&M cost increase of $26,975, and the corresponding O & M estimated cost increase for the 1.67 estimated additional modification (minor) applications from Table R-2 is $797. The total increased O & M cost for all respondents is $27,772. Added to the currently approved ICR O & M cost of $81,408, the revised total O & M cost is $109,180, which is reported as $109.2 (thousand) on line 14b of for OMB 83-I. The total estimated annualized non-labor cost, including the $101, 064 amount from the currently approved ICR, is thus $132,668 (Table R-2), which is reported as $132.7 (thousand) on line 14c of form OMB 83-I. The current OMB inventory for ICR 2080-0005 is listed as $101.1 (thousand) on line 14d, and the difference, $132.7 − $101.1 = $31.6 (thousand), is reported on line 14e. This difference is due entirely to the program change and is thus reported as such on line 14f1, and thus Line 14f2 is zero.

6(c) **Estimating Agency Burden and Cost**

The increase in agency burden and cost estimates due to the changes in the program are given in Table R-3. They are based on the estimates in the base ICR and on our experience in collecting this information and operating the Reference and Equivalent Method Program for many years and include processing of both full applications and modification requests. The costs are based on technical staff labor at the GS-12/13 level, at $36/hr., using the locally applicable hourly salary table for 2005 for the locality pay area of “Rest of U.S.” This rate was raised to $57.60 per hour to include a 1.6 multiplier for overhead. Similarly determined clerical costs were based on a loaded labor rate of $26/hr. As indicated previously, there is no way to predict the exact number of applications that will be received in a given year, so actual cost could deviate from these estimates.

Table R-3. Representative Increased Annual Agency Burden and Cost

Collection Activities		Burden Hours and Costs per Year		Total Hours and Costs
		Tech. Staff ($57.60/hr)*	Clerical ($26/hr)*	
Provide copies of regulation and assistance materials; regulation interpretation; technical assistance	Hours	25	7	32
	Costs	$1,440	$182	$1,622
Receive applications; administrative activities	Hours	7	3	10
	Costs	$403	$78	$481
Technical review and evaluation	Hours	85	8	93
	Costs	$4,896	$208	$5,104
Designation activities	Hours	3	1	4
	Costs	$173	$26	$199
Maintain & distribute List of Designated Methods	Hours	24	8	32
	Costs	$1,382	$208	$1,590
Review and process modification requests	Hours	28	2	30
	Costs	$1,613	$52	$1,665
Program support	Hours	19	3	22
	Costs	$1,094	$78	$1,172
Totals	Hours	191	32	**223**
	Costs	$11,002	$832	**$11,834**
Base ICR	Hours	718	126	844
	Costs	$40,208	$3,150	$43,358
Grand total, base ICR + increase	Hours	909	158	1067
	Costs	$51,210	$3,982	$55,192

* Burdened labor rates (salary 1.6).

6(d) **Estimating the Respondent Universe and Total Burden and Cost**

Based on historical data for application submittals and other information available to the Process Modeling Research Branch, it is estimated that an average of 1.3 additional applications for reference or equivalent method determinations, and an average of 1.6 additional minor applications for approval of modifications, will be received annually during the 3 year time period following promulgation of the final regulation changes. Labor and other costs for a typical designation application are described in Section 6(a, b). Total annual burden and cost for the Information Collection are summarized in Table R-4.

6(e) **Bottom-Line Burden Hours and Costs**

The total annual increase and grand total burden for respondents and the agency is shown in Table R-4.

Table R-4. Total Annual Increased Burden and Cost Summary

	Increase		Base ICR		Total, Base + Increase	
	Hours	Cost	Hours	Cost	Hours	Cost
Total respondent burden and cost (including recordkeeping) (from Table 2)	2774	$223,528	4718	$426,966	7492	$650,494
Total Agency in-house burden and cost (Table 3)	223	$11,834	844	$43,358	1067	$55,192
Total Agency contract cost	0	$45,000	0	$100,000	0	$145,000
Totals	2997	$280,362	5562	$570,324	8559	$850,686

6(f) **Reasons for Change in Burden**

(i) *Respondent burden*

The increase in the burden estimates due to the new categories of reference and equivalent method applications which were created and a resulting increase in the number of applications submitted due to changes to 40 CFR Part 53 which were promulgated.

As noted previously, the actual respondent cost varies widely, depending on the type and nature of the application submitted. A simple request for approval of a minor modification to a currently designated method may cost only a few dollars. At the other extreme, the full cost for conducting the complete complement of tests and submission of a complete application for designation for a new Class III $PM_{2.5}$ analyzer, for example, could cost $200,000 or more, depending on the exact circumstances and facilities available to the applicant. New applications are often related to previously designated instruments that have been redesigned to incorporate

new technology and features. Many monitoring instrument manufacturers redesign and update their air monitoring instruments to incorporate advances in electronics and in digital and microprocessor circuitry, adding many new data processing and user-programmable capabilities. Manufacturers must reapply to have these redesigned analyzers designated (or re-designated) as reference or equivalent methods, either via approval of modifications or, more likely, via a complete reference or equivalent method application. Such redesign may extend to a manufacturer's entire line of designated pollutant analyzers. Burdens may or may not be somewhat lower for these types of applications. On the other hand, air monitoring instrument manufacturers occasionally produce new or unconventional types of instruments for which they seek reference or equivalent method designation; and burdens may be somewhat higher for these applications. Since each application is unique, there are many variables associated with each situation that substantially affect the cost of a particular application or submission.

(ii) *Agency burden*

The agency's cost to process the information depends on the number and type of applications or requests received. The agency burden will also be similarly increased from the current estimate, reflecting the increase in the number and type of applications received due to Program changes which were promulgated. Based on the projections by the Process Modeling Research Branch of the increase in number and type of applications in the 3 years following promulgation of the regulatory program change, the annual increase in the agency burden is estimated to be about $11,834, with an additional $45,000 for contract support.

6(g) **Burden Statement**

The average annual respondent burden per facility is estimated to be 331 hours. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR Part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-ORD-2005-0530 which is available for online viewing at www.regulations.gov, or in person viewing at the Office of Research and Development Docket in the EPA Docket

Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Office of Research and Development Docket is (202) 566-1752. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-ORD-2005-0530 and OMB control number 2080-0005 in any correspondence.

Appendix A

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Appendix B

Assumptions and Notes: Determination of Burden Hours and Cost Estimates for Applications for Reference and Equivalent Methods

Based on information provided by an informal survey of nine previous applicants, representative burden hours and cost estimates for the base ICR were prepared for five categories of applications: Gas Analyzers, Open Path Analyzers, PM_{10} Monitors, $PM_{2.5}$ Reference and Class I Equivalent Samplers, and $PM_{2.5}$ Class II Equivalent Samplers. The new category is $PM_{10-2.5}$ and $PM_{2.5}$ Class III analyzers. These average category estimates are not included here but are available in the associated Excel spreadsheet file, *ICR0559-2005Suppl Tables - PMc.xls*, as Tables E-1 through E-6. These category estimates were derived as described below.

1) Gas Analyzers: These numbers represent mean values received from survey respondents for gas analyzer designation application burden and costs.

2) Open Path Analyzers: No useful cost figures for open path analyzers were received from survey respondents. It was assumed that the cost for preparing an open path analyzer designation application is roughly three times that for a standard gas analyzer. However, a typical open path analyzer would likely be submitted for designation for three or more pollutants at little additional cost per pollutant. Consequently, the cost per designation application for open path analyzers was assumed to be the same as that for a typical gas analyzer.

3) PM_{10} Monitors: These numbers represent mean values received from survey respondents for PM_{10} monitor designation application costs and include both PM_{10} samplers and analyzers.

4) $PM_{2.5}$ Reference and Class I Equivalent Samplers: These numbers represent mean values received from survey respondents for $PM_{2.5}$ Reference and Class I Equivalent Method Sampler designation application costs.

5) $PM_{2.5}$ Class II Equivalent Samplers: No useful cost figures for $PM_{2.5}$ Class II Equivalent Samplers were received from survey respondents. It was estimated that the costs for $PM_{2.5}$ Class II Equivalent samplers are approximately 1.35 times higher than for Reference/Class I samplers.

6) $PM_{10-2.5}$ and $PM_{2.5}$ Class III analyzers: Estimates for this new category were derived from similar activity profiles from the other categories and from Process Modeling Research Branch projections.

Weighted average, composite burden and cost estimates for a typical designation application for the base ICR were developed by summing up the estimates for all the different analyzer categories, after multiplying each by a factor based on the expected fraction of total applications expected over the next 3 years for each analyzer category. The fractions used for this purpose are as follows:

20% Gas Analyzers
5% Open Path Analyzers
30% PM_{10} Monitors
40% $PM_{2.5}$ Reference/Class I Equivalent Samplers
5% $PM_{2.5}$ Class II Equivalent Samplers

7) ISO 9001: No useful cost figures were received from respondents. Instead, data provided to EPA by four ISO-9001 consultants were reviewed and used to develop ISO 9001 cost estimates as detailed below:

Contractor's Startup Cost for Establishing ISO 9001 includes (1) a pre-assessment meeting; (2) preliminary evaluations; (3) registration assessment; (4) $PM_{2.5}$ checklist including evaluation and registration; and (5) training costs. These costs are one-time fees and can range from a combined total of $15,250 to $34,500 depending on the size of the facility. The average cost is therefore about $24,900. Annualizing this cost over a three-year period results in approximately $8,300 per year. Assuming that 40 percent of the companies already have ISO 9001 programs in place, the annual cost is $4,980. Assuming further that these costs will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual cost of approximately $2,241.

Contractor's ISO 9001 Maintenance Cost includes (1) continuous assessment; (2) ISO file maintenance fee; and (3) continuous checks for $PM_{2.5}$ checklist. These costs are annual fees and can range from a combined total of $2,375 to $6,875 depending on the size of the facility. The average cost is therefore $4,625 per year. Assuming that these costs will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual cost of approximately $2,081.

In-House Startup Cost for Establishing ISO 9001 includes labor cost for management, technical/professional, and clerical staff.

1. Management Startup Cost for Establishing ISO 9001: Management labor hours range from 32 hours per year to 120 hours per year depending on the size of the facility. These hours are used for management reviews. The average management labor hours is therefore 76 hours per year. Assuming that 40 percent of the companies already have ISO 9001 programs in place, the annual burden is 45.6 hours, and assuming further that these hours will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual burden of 20.5 hours.

2. Technical/Professional Startup Cost for Establishing ISO 9001: Technical/professional labor hours include training internal ISO coordinators and auditors. It is assumed that 2 to 5 technical/professional staff are involved at 24 to 40 hours per staff, resulting in 48 to 200 hours depending on the size of the facility. The average technical/professional labor hours are therefore 124 hours per year. Annualizing this cost over a three-year period results in approximately 42 hours per year. Assuming that 40 percent of the companies already have ISO 9001 programs in place, gives a burden of 25.2 hours per year, and assuming further that these hours will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual burden of 11.3 hours.

3. Clerical Startup Cost for Establishing ISO 9001: None identified

In-House Maintenance Cost for Establishing ISO 9001 includes labor cost for management, technical, and clerical staff.

1. Management ISO 9001 Maintenance Cost: Management labor hours range from 32 hours per year to 120 hours per year depending on the size of the facility. These hours are used for management reviews. The average management labor hours is therefore 76 hours per year. Assuming that these hours will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual burden of 34.2 hours.

2. Technical/Professional ISO Maintenance Cost: Technical/professional labor hours include reviewing, recommending revisions, and approving internal audits. It is assumed that 2 to 20 technical/professional staff are involved at 16 to 24 hours per staff, resulting in 32 to 480 hours per year depending on the size of the facility. The average technical/professional labor hours is therefore 256 hours per year. Assuming that these hours will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual burden of 115.2 hours.

3. Clerical ISO Maintenance Cost: Clerical labor hours include drafting new or revising existing SOPs, and training SOP writers. It is assumed that 48 to 675 clerical hours are needed for these tasks depending on the size of the facility. The average clerical labor is therefore 362 hours per year. Assuming that these hours will be incurred only by companies applying for $PM_{2.5}$ methods results in an annual burden of 162.9 hours.