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 (Renewal); OMB Control Number 2080-0005, EPA ICR No. 0559.12.

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. Approximately 6.33 major and 16.67 minor applications (22 total responses) are expected annually.

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 non-continuous 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 (Office of Research and Development) 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 170 reference and equivalent methods as of March 2008. 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. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) **Non duplication**

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 ICR was posted for public comment on July 1, 2014 under EPA-HQ-ORD-2005-0530. The comment period closed on September 2, 2014 and received no public comments.

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) Review of Anticipated Burden Changes as a Function of Pollutant or Sub-Pollutant

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 for submitting a specific application will vary widely, depending on many factors. Particularly salient factors include the specific pollutant (or sub-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.

Changes to the previously established base ICR burden estimates are likely if any of the regulations associated with reference and equivalent method applications (40 CFR Parts 50 and 53, respectively) are amended, or new regulations are promulgated, such that the nature, number, or type of applications in this collection is affected. The regulatory rule-making process is typically quite lengthy, and it is therefore often difficult to predict with accuracy the effect such regulatory changes will have on the information collection or when in the ICR approval period such changes will take effect, at least until late in the rule-making process. Also, there is usually a lag in time between the promulgation of a regulatory change and the time when EPA starts receiving the first applications based on or affected by the change. To help in the process of determining the adjustment in burden estimates that would be due to such changes, a review of potential regulatory changes for each of the major pollutant or sub-pollutant categories follows. The review puts particular emphasis on those categories that may be potentially impacted by new regulations that have either been recently promulgated or are likely to be promulgated within the next period of approval for this ICR.

TSP. Applications for measurement methods specifically for total suspended particulate matter (TSP) are not included in the reference and equivalent method program, and therefore are not included in this ICR. However, methods for TSP are described in an appendix to Part 50

(Appendix B), and TSP sampling methods are typically included as part of methods for measuring lead (Pb) in the atmosphere (see next paragraph). No changes in the regulations associated with TSP are currently planned nor are any likely to occur within this ICR approval period.

Lead. An older, established Pb reference method in Appendix G of Part 50 has now been joined by a new, second reference method for Pb in Appendix Q, promulgated in November of 2008. The older reference method specifies a TSP sampler, described in Appendix B of Part 50; the new reference method specifies a PM_{10c} sampler as described in Appendix O of Part 50. These reference methods are manual methods, which are generally fully described in the respective Part 50 appendixes and don't require a reference method application (hence no collection burden). However, the PM_{10c} sampler specified for the new Pb reference method does require an application, which is typically submitted and approved as part of an application for a coarse particulate matter ($PM_{10-2.5}$) reference method sampler.

Burden estimates associated with applications for equivalent methods for Pb and for the PM_{10c} sampler are already incorporated into the base ICR estimates. Although a NAAQS review for Pb by the Office of Air Quality Planning and Standards (OAQPS) is scheduled to take place during this ICR approval period, no associated changes in any of the regulations (nor any new regulations) associated with monitoring methods for Pb are currently planned or are likely to occur within this ICR approval period. Therefore, no changes in the burden estimates associated with applications for equivalent methods for Pb are expected.

PM_{10}. Although some changes in the form of the NAAQSs for PM_{10} may be likely by OAQPS, no changes in the regulations associated with reference or equivalent methods for PM_{10} are currently under consideration or are likely to occur within this ICR approval period. Burden estimates associated with applications for reference and equivalent methods for PM_{10} are already incorporated into the base ICR estimates.

$PM_{2.5}$ Reference Methods and Class I Equivalent Methods. No changes in the regulations associated with reference or Class I equivalent methods for $PM_{2.5}$ are currently under consideration, nor are any such changes likely to occur within this ICR approval period. Burden estimates associated with applications for these types of methods for $PM_{2.5}$ are already incorporated into the base ICR estimates.

$PM_{2.5}$ Class II Equivalent Methods. No changes in the regulations associated with Class II equivalent methods for $PM_{2.5}$ are currently under consideration nor are any such likely to occur within this ICR approval period. Burden estimates associated with applications for this type of method for $PM_{2.5}$ are already incorporated into the base ICR estimates.

$PM_{2.5}$ Class III Equivalent Methods. No changes in the regulations associated with Class III equivalent methods for $PM_{2.5}$ are currently under consideration nor are likely to occur within this ICR approval period. Burden estimates associated with applications for this type of method for $PM_{2.5}$ are already incorporated into the base ICR estimates.

$PM_{2.5}$ Monitoring Methods for a Possible Secondary NAAQS for Visibility. $PM_{2.5}$ monitoring methods of this type are not currently addressed in the monitoring methods regulations or in the reference and equivalent methods application program. A possible future secondary NAAQS for $PM_{2.5}$ in regard to degradation of ambient visibility is under consideration

by EPA. Any such new NAAQS would require promulgation of a new reference method for $PM_{2.5}$ specifically for this application. EPA has not yet established a consensus regarding either a new NAAQS or a particular type of monitoring method for this application. Therefore, it is unlikely that any new regulations for monitoring this particular pollutant indicator or for applications for approval of either reference or equivalent methods for it will be promulgated within the approval period for this ICR.

$PM_{10-2.5}$. No changes in the regulations associated with $PM_{10-2.5}$ reference or equivalent methods are currently under consideration nor are any regulatory changes likely to occur within this ICR approval period. Burden estimates associated with applications for methods for $PM_{10-2.5}$ are already incorporated into the base ICR estimates.

SO_2. A new (second) SO_2 reference method was promulgated on June 22, 2010, along with some associated changes to Part 53, Subpart B that were applicable to candidate SO_2 reference and equivalent methods. The very minimal effects that these regulatory changes had on the burden estimates associated with applications for SO_2 reference and equivalent methods has already been considered in the existing estimates; therefore, no changes in the burden estimates for the ICR renewal period are necessary.

O_3. A new (second) O_3 reference method, possible minor modification of the existing reference method, and some associated changes to some of the performance requirements of Part 53, Subpart B that would be applicable to candidate reference and equivalent methods for O_3 are currently under consideration by EPA. These regulatory changes are (tentatively) scheduled to be promulgated in November, 2015, which is within the renewal period of this ICR. However, the effect that these new or modified regulations would have on the ICR burden estimates of O_3 method applications would be very minimal. The new O_3 reference method specifies an automated chemiluminescence method that is quite similar to the existing chemiluminescence reference method, and two analyzers utilizing this tentative new reference method have already been designated by EPA as equivalent methods. The existing O_3 chemiluminescence reference method would be left in place to make sure that all the existing O_3 equivalent methods would retain their equivalent method designation without interruption. The tentative new performance requirements for designation of new reference and equivalent method analyzers are more stringent than the existing requirements for both reference and equivalent method analyzers. However, it is very likely that any new chemiluminescence analyzers designed for routine ambient monitoring would meet the new requirements.

Optional new (tentative) test requirements with even more stringent performance requirements would be added to Part 53, Subpart B and would be applicable to any candidate O_3 reference or equivalent method for which the applicant elects to have one or more lower, more sensitive measurement ranges approved (in addition to the standard range) under its reference or equivalent method designation. Testing and designation of lower ranges has always been permitted, but the new testing requirements would be more formal, and the performance requirements for such lower ranges would be more stringent. Although this additional testing is voluntary, there is some market for low-range O_3 analyzers, and it seems likely that many, if not most, applicants would want to have at least one lower range approved. These more stringent requirements and the additional testing would add a very modest additional burden for the applicant. The magnitude of these minor, potential ICR burden variations are deemed quite

inconsequential relative to the considerable uncertainties in the assumptions of the number of O_3 reference and equivalent method applications that EPA will receive in the next ICR approval period and in the burden for preparing a typical (composite) application. These small changes in the burden estimates are almost certainly well within the inevitable margin of uncertainty already inherent in the burden estimates of the base ICR.

CO. Changes to the Part 53 requirements for reference and equivalent methods for CO were promulgated on August 31, 2011. The relatively minor effect that these regulatory changes had on the burden estimates associated with applications for CO reference and equivalent methods has already been considered in the existing estimates; therefore, no changes in the burden estimates for this ICR approval period are necessary.

NO_2. Potential changes to the regulatory requirements for reference and equivalent methods for NO_2 that might affect the burden estimates are under consideration by EPA. However, any such changes are tentatively scheduled for promulgation in June, 2017 (at the very earliest, more likely somewhat later) and would likely take effect a month or more after that. Therefore those changes (if any) would occur too late in the current ICR approval period (through 10/31/2017) to have any significant effect on the associated burden estimates. Moreover, any such changes are expected to be similar to, but less extensive than, those described above for O_3 methods (*e.g.*, no substantive changes are expected to the reference method description for NO_2 in Part 50). Accordingly, such changes would have minimal effect on estimated burdens. Thus, no changes to the current burden estimates are needed for this renewal period.

Open-Path analyzers. Open-path analyzers, by nature, are typically capable of monitoring multiple gaseous pollutants simultaneously. No changes in the regulations associated specifically with open-path equivalent methods are currently under consideration nor are any changes likely to occur within this ICR approval period. Open-path analyzers would be subject to the pending changes in the O_3 equivalent method application requirements (to the extent that they are candidate methods for that pollutant). However, as noted previously, any changes in the burden estimates associated with applications for designation of O_3 methods are deemed insignificant. Further, applications for open-path candidate methods are received very infrequently. The burden estimates associated with applications for open-path methods are already adequately incorporated into the base ICR estimates.

Methods for dry deposition of SO_x and NO_x.

No secondary NAAQS for dry deposition for SO_2 and NO_x are anticipated during this ICR's period of performance. Therefore, it is estimated that no substantive changes in existing applicant or Agency labor and/or cost burden would be associated with the new secondary NAAQS for dry deposition currently under consideration.

6(b) Summary

The previous section provided a comprehensive review of any potential regulatory changes for each of the major pollutant or sub-pollutant categories. Emphasis was placed on those categories that may be potentially impacted by regulations which have either been recently promulgated or are likely to be promulgated within the period of approval for this ICR (i.e. through10/31/2017). In all cases except for methods for O_3, no changes in the NAAQS regulations are anticipated that would materially affect the estimates for either respondent or

agency burdens for the approval period of this ICR. For methods for O_3, some regulatory changes are anticipated, but any changes in burden estimates are expected to be inconsequential relative to the magnitude of existing burdens. Collectively, therefore, there are no estimated changes in respondent and/or Agency burdens associated with pollutants or subpollutants during this ICR's period of performance.

6(b) Estimated Respondent Burden Hours and Costs

As summarized in the previous section, no overall changes in respondent burdens (either labor or cost) are estimated for this ICR's period of performance based on a review of regulatory revisions. As Table 1 indicates, no changes in subcategories of labor hours, labor costs, O&M costs, or capital and startup costs are expected.

Table 1. Summary of Estimated Annual Respondent Burden Hours and Costs for Annual Reporting and Recordkeeping

	Labor hours	Labor cost	O & M	Capital & startup	Total non-labor	Total cost
Total increase, all responses	**0**	**$0**	**$0**	**$0**	**$0**	**$0**
Current ICR	**7,492**	**$517,831**	**$109,185**	**$23,483**	**$132,668**	**$650,494**
Combined grand totals	**7,492**	**$517,831**	**$109,185**	**$23,483**	**$132,668**	**$650,494**

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

As is the case of respondent burden discussed in the previous section, no changes in Agency burdens (either labor or cost) are estimated for this ICR's period of performance based on a review of programmatic regulatory revisions. As Table 2 indicates, no changes in administrative activities, application technical reviews and evaluations, or programmatic support are estimated.

Table 2. Representative Annual Agency Burden and Cost

Collection Activities	**Hours**	**Cost**
Provide copies of regulation and assistance materials; regulation interpretation; technical assistance	32	$1,717
Receive applications; administrative activities	10	$510
Technical review and evaluation	93	$5,393
Designation activities	4	$211
Maintain & distribute List of Designated Methods	32	$1,590
Review and process modification requests	30	$1,759
Program support	22	$1,240
In-house Agency Subtotal	**1,067**	**$55,871**
Agency Contract Support Subtotal	**-**	**$177,631**
Grand total, base ICR + increase	**1,067**	**$233,502**

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

Based on OMB's current inventory for ICR 2080-0005, and a review of respondent and Agency burdens for this ICR's period of performance, the grand total burden for respondents and the agency is shown in Table 3.

Table 3. Total Respondent and Agency Burden and Cost

	New		**Base ICR**		**New Total**	
	Hours	Cost	Hours	Cost	Hours	Cost
Total Respondent	0	$0	7,492	$650,494	7,492	$650,494
Total Agency in-house	0	$0	1,067	$55,871	1,067	$55,871
Total Agency contract	0	$0	0	$177,631	0	$177,631
Totals	0	$0	8,559	$883,996	8,559	$883,996

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

There is no anticipated change in burden. The instrument manufacturers were contacted in reference to this ICR and responded that salaries had been relatively flat over the last few years. For that reason, the respondent burden salaries are remaining the same as the previous ICR package. When the next ICR is due for renewal, the respondents will be contacted again to check on any changes to salary levels.

6(f) **Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 341 hours per response. 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 and 48 CFR chapter 15.

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 Number 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 Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-ORD-2005-0530 and OMB control number 2080-0005 in any correspondence.

Appendix A

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